



Document Title

**Summary of the fate and behaviour in the environment for Iodosulfuron-methyl-sodium**

Data Requirements

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

Document MCA

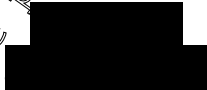
**Section 7: Fate and behaviour in the environment**

According to the guidance document SANCO 10181/2013, for preparing dossiers for the approval of a chemical active substance

Date

**2015-05-27**

Author(s)



**Bayer CropScience**



M-482070-02-4

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### Version history

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

<sup>1</sup> It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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### Table of Contents

	Page
CA 7	FATE AND BEHAVIOUR IN THE ENVIRONMENT ..... 5
CA 7.1	Fate and behaviour in soil ..... 12
CA 7.1.1	Route of degradation in soil ..... 2
CA 7.1.1.1	Aerobic degradation ..... 14
CA 7.1.1.2	Anaerobic degradation ..... 39
CA 7.1.1.3	Soil photolysis ..... 40
CA 7.1.2	Rate of degradation in soil ..... 40
CA 7.1.2.1	Laboratory studies ..... 50
CA 7.1.2.1.1	Aerobic degradation of the active substance ..... 50
CA 7.1.2.1.2	Aerobic degradation of metabolites breakdown and reaction products ..... 65
CA 7.1.2.1.3	Anaerobic degradation of the active substance ..... 72
CA 7.1.2.1.4	Anaerobic degradation of metabolites breakdown and reaction products ..... 72
CA 7.1.2.2	Field studies ..... 73
CA 7.1.2.2.1	Soil dissipation studies ..... 75
CA 7.1.2.2.2	Soil accumulation studies ..... 98
CA 7.1.3	Adsorption and desorption in soil ..... 98
CA 7.1.3.1	Adsorption and desorption ..... 98
CA 7.1.3.1.1	Adsorption and desorption of the active substance ..... 99
CA 7.1.3.1.2	Adsorption and desorption of metabolites, breakdown and reaction products ..... 105
CA 7.1.3.2	Aged sorption ..... 136
CA 7.1.4	Mobility in soil ..... 136
CA 7.1.4.1	Column leaching studies ..... 139
CA 7.1.4.1.1	Column leaching of the active substance ..... 139
CA 7.1.4.1.2	Column leaching of metabolites, breakdown and reaction products ..... 139
CA 7.1.4.2	Lysimeter studies ..... 139
CA 7.1.4.3	Field leaching studies ..... 140
CA 7.2	Fate and behaviour in water and sediment ..... 141
CA 7.2.1	Route and rate of degradation in aquatic systems (chemical and photochemical degradation) ..... 143
CA 7.2.1.1	Hydrolytic degradation ..... 144
CA 7.2.1.2	Direct photochemical degradation ..... 144
CA 7.2.1.3	Indirect photochemical degradation ..... 144
CA 7.2.2	Route and rate of biological degradation in aquatic systems ..... 144
CA 7.2.2.1	"Ready biodegradability" ..... 151
CA 7.2.2.2	Aerobic mineralisation in surface water ..... 152
CA 7.2.2.3	Water/sediment study ..... 159
CA 7.2.2.4	Irradiated water/sediment study ..... 169
CA 7.2.3	Degradation in the saturated zone ..... 177
CA 7.3	Fate and behaviour in air ..... 178
CA 7.3.1	Route and rate of degradation on air ..... 178
CA 7.3.2	Transport via air ..... 178
CA 7.3.3	Local and global effects ..... 178
CA 7.4	Definition of the residue ..... 179
CA 7.4.1	Definition of the residue for risk assessment ..... 179
CA 7.4.2	Definition of the residue for monitoring ..... 179
CA 7.4.3	Monitoring data ..... 179

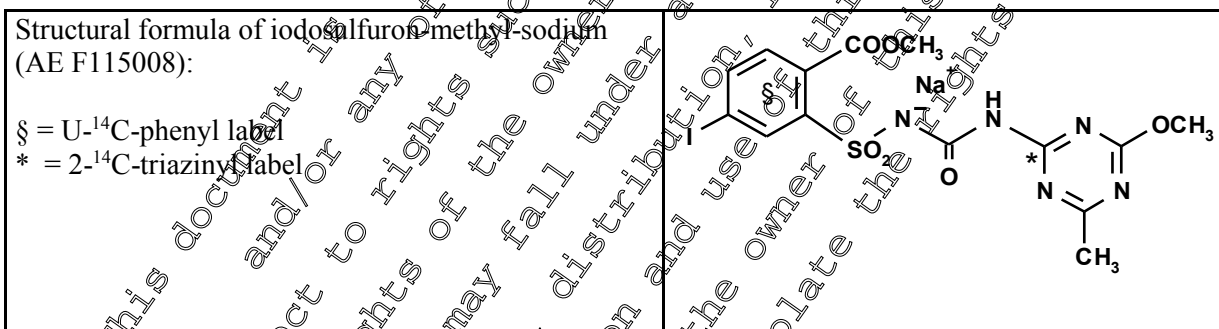
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**CA 7 FATE AND BEHAVIOUR IN THE ENVIRONMENT**

Data on the fate and behaviour of iodosulfuron-methyl-sodium (AE F115008) in soil, water and air were submitted and evaluated within the original EU Dossier which resulted in the Annex I inclusion in 2003. The evaluation of the studies evaluated at that time was published in the form of a Monograph and its amendments. These studies are presented in this document in grey boxes. Copies of the study reports are included in the electronic dossier (Baseline Dossier). The numbering and the headlines correspond to latest EU requirements. No detailed summary of these data are presented in this update. In the Supplemental Dossier for Annex I Renewal presented here only those environmental fate studies are described in sections 7.1 to 7.5, which were not submitted within the baseline dossier.

However, for a better understanding of the behaviour of iodosulfuron-methyl-sodium in soil, water and sediment, short summaries including the results of all the environmental fate studies are given in sections CA 7.1, CA 7.1.3.1 and CA 7.2.

The studies concerning the fate and behaviour of iodosulfuron-methyl-sodium in the environment were conducted using two different radiolabel positions, [phenyl-<sup>14</sup>C] and [triazinyl-<sup>14</sup>C] as well as unlabelled iodosulfuron-methyl-sodium. These radiolabel positions are sufficient to define the route of degradation of iodosulfuron-methyl-sodium. The structure of iodosulfuron-methyl-sodium and the positions of the different radiolabels are as follows:



The proposed degradation pathways in soil and water and sediment are given in Figure 7.1.1- 1 and Figure 7.2- 1, respectively.

The table below gives identity information about the metabolites and/or degradates of iodosulfuron-methyl-sodium observed in the various studies performed on the fate and behaviour in the environment.

In all sections, the metabolites are primarily identified by their company code numbers (AE-codes / BCS-codes). In certain study reports, further names have been used.

**Iodosulfuron-methyl-sodium / Active ingredient and metabolites detected in environmental compartments**

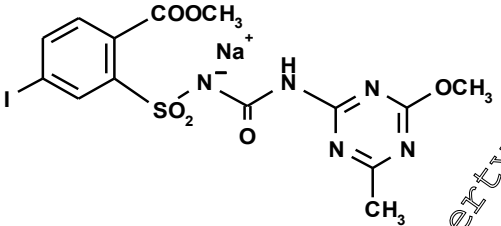
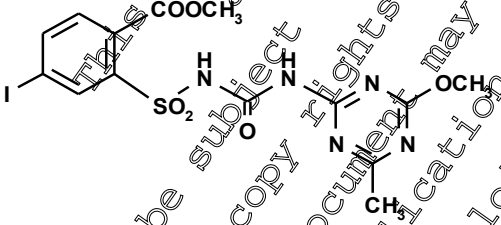
In original reports study authors may have used different names or codes for degradation products of iodosulfuron-methyl-sodium. A full list containing structural formula, various names, short forms, codes and occurrences of degradation products is provided as Document N.



**Nomenclature version information:**

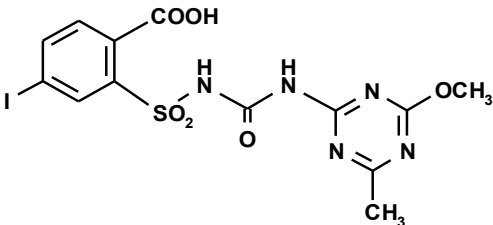
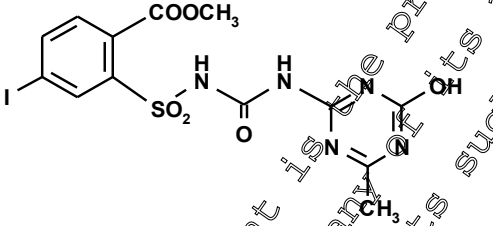
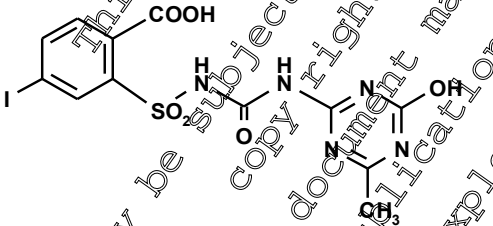
CAS index names: according to the Chemical Abstracts Services 9th Collective Index (9CI)

IUPAC names: generated using ACD/Name Batch software, version 9.02  
(Advanced Chemistry Development Inc.)

Company Code Numbers Chemical Structures Chemical Formulas / Molecular Weights	CAS# / CA index name IUPAC nomenclature Other names / codes	Occurrence
<p><b>AE F115008</b></p>  <p>Stoichiometric formula: C<sub>14</sub> H<sub>13</sub> I N<sub>5</sub> Na O<sub>6</sub> S Molecular weight: 529.3</p>	<p>CAS-No.: 144550-06-7</p> <p>Benzoic acid, 4-iodo-2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-, methyl ester, monosodium salt (CAS, 9CI)</p> <p>methyl 4-iodo-2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)carbamoyl]amino]sulfonyl]benzoate, sodium salt (IUPAC)</p> <p>Iodosulfuron-methyl sodium Hoe-015008 BCS-BB66887</p>	<p>Used as active substance in all reports</p>
<p><b>AE F114844</b></p>  <p>Stoichiometric formula: C<sub>14</sub> H<sub>14</sub> I N<sub>5</sub> O<sub>6</sub> S Molecular weight: 507.3</p>	<p>CAS-No.: 144530-06-1</p> <p>Benzoic acid, 4-iodo-2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-, methyl ester (CAS, 9CI)</p> <p>methyl 4-iodo-2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)carbamoyl]amino]sulfonyl]benzoate (IUPAC)</p> <p>BCS-AF78414</p>	<p>(Non-salt form of the active substance)</p>

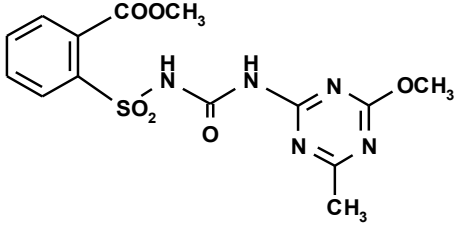
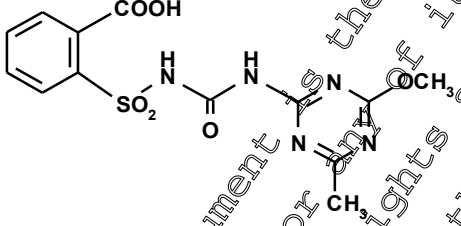
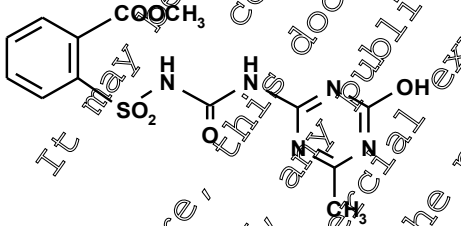
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Company Code Numbers Chemical Structures Chemical Formulas / Molecular Weights	CAS# / CA index name IUPAC nomenclature Other names / codes	Occurrence
<p><b>AE F145740</b></p>  <p>Stoichiometric formula: C<sub>13</sub> H<sub>12</sub> I N<sub>5</sub> O<sub>6</sub> S Molecular weight: 493.2</p>	<p>CAS-No.: 185119-76-0</p> <p>Benzoic acid, 4-iodo-2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]- (CAS, 9CI)</p> <p>4-iodo-2-({[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)carbamoyl]amino} sulfonyl)benzoic acid (IUPAC)</p> <p>BCSAU71533</p>	<p>Aerobic Soil Anaerobic Soil Hydrolysis Water/Sed. Rat Dog</p>
<p><b>AE F145741</b></p>  <p>Stoichiometric formula: C<sub>13</sub> H<sub>12</sub> I N<sub>5</sub> O<sub>6</sub> S Molecular weight: 493.2</p>	<p>CAS-No.: 887751-16-0</p> <p>methyl-({[(4-hydroxy-6-methyl-1,3,5-triazin-2-yl)carbamoyl]amino} sulfonyl)-4-iodobenzoate (IUPAC)</p> <p>BCSAU71532</p>	<p>Aerobic Soil Anaerobic Soil Hydrolysis Water/Sed. Rat Dog Wheat</p>
<p><b>AE 0014967</b></p>  <p>Stoichiometric formula: C<sub>12</sub> H<sub>10</sub> I N<sub>5</sub> O<sub>6</sub> S Molecular weight: 479.2</p>	<p>CAS-No.: 887751-21-8</p> <p>2-({[(4-hydroxy-6-methyl-1,3,5-triazin-2-yl)carbamoyl]amino} sulfonyl)-4-iodobenzoic acid (IUPAC)</p> <p>BCSAW41741</p>	<p>(Hydrolysis)</p>

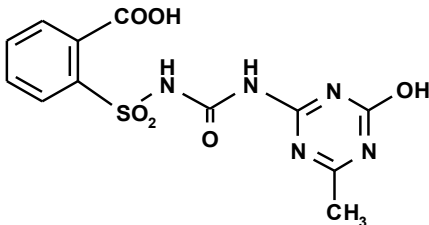
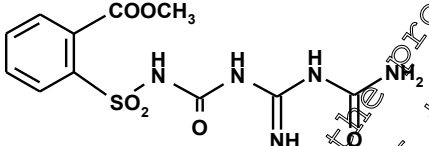
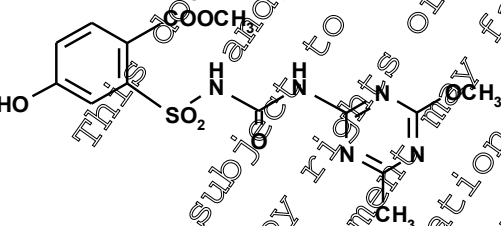
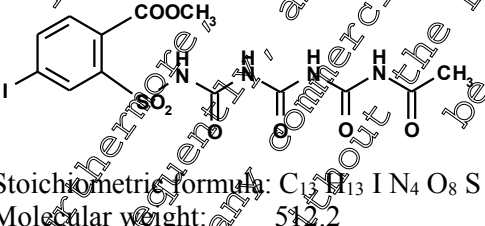
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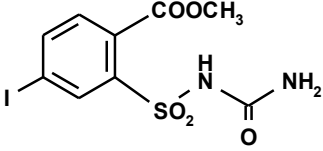
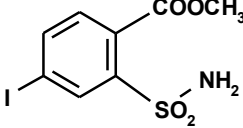
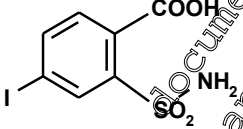
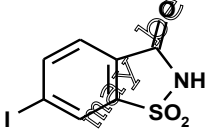
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<p>AE F075736</p>  <p>Stoichiometric formula: C<sub>14</sub> H<sub>15</sub> N<sub>5</sub> O<sub>6</sub> S Molecular weight: 381.4</p>	<p>CAS-No.: 74223-64-6</p> <p><i>Benzoic acid, 2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-, methyl ester (CAS, 9CI)</i></p> <p>methyl 2-({[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)carbamoyl]amino} sulfonyl)benzoate (IUPAC)</p> <p>Metsulfuron-methyl</p> <p>BCS-AE12305</p>	<p>Aerobic Soil Anaerobic Soil Water/Sed. Bat Dog Wheat</p>
<p>AE 0014966</p>  <p>Stoichiometric formula: C<sub>13</sub> H<sub>13</sub> N<sub>5</sub> O<sub>6</sub> S Molecular weight: 367.3</p>	<p>CAS-No.: 79500-48-8</p> <p><i>Benzoic acid, 2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]- (CAS, 9CI)</i></p> <p>2-({[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)carbamoyl]amino} sulfonyl) benzoic acid (IUPAC)</p> <p>Metsulfuron</p> <p>BGS AI21563</p>	<p>Anaerobic Soil Water/Sed.</p>
<p>AE F161778</p>  <p>Stoichiometric formula: C<sub>14</sub> H<sub>13</sub> N<sub>5</sub> O<sub>6</sub> S Molecular weight: 367.3</p>	<p>CAS No.: 126312-31-0</p> <p><i>Benzoic acid, 2-[[[(1,4-dihydro-6-methyl-4-oxo-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-, methyl ester (CAS, 9CI)</i></p> <p>methyl 2-({[(4-hydroxy-6-methyl-1,3,5-triazin-2-yl)carbamoyl]amino} sulfonyl)benzoate (IUPAC)</p> <p>BCS-AU85549</p>	<p>Aerobic Soil Anaerobic Soil Water/Sed. Rat</p>





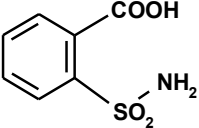
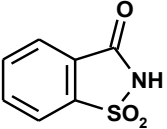
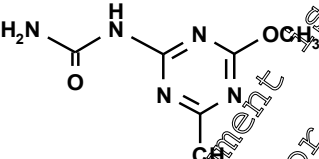
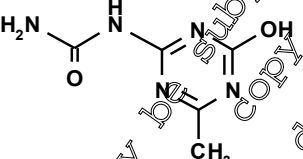
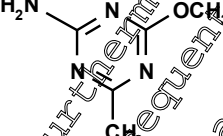
Company Code Numbers Chemical Structures Chemical Formulas / Molecular Weights	CAS# / CA index name IUPAC nomenclature Other names / codes	Occurrence
<p>AE 0014965</p>  <p>Stoichiometric formula: C<sub>12</sub> H<sub>11</sub> N<sub>5</sub> O<sub>6</sub> S Molecular weight: 353.3</p>	<p>CAS# and name not available (compound not indexed in CAS)</p> <p>2-(((4-hydroxy-6-methyl-1,3,5-triazin-2-yl)carbamoyl)amino)sulfonyl benzoic acid (IUPAC)</p> <p>BCS-AW41740</p>	<p>Water Sed.</p>
<p>BCS-CW81253</p>  <p>Stoichiometric formula: C<sub>11</sub> H<sub>13</sub> N<sub>5</sub> O<sub>6</sub> S Molecular weight: 343.32</p>	<p>CAS-No.: 223907-38-8</p> <p>methyl 2-(((N-carbamoylcarbamimidoyl)carbamoyl)sulfonyl)amino (IUPAC)</p> <p>BCS-CW81253</p> <p>Des-iodo-carbamoyl-guanidine</p>	<p>Soil</p>
<p>AE 0002166</p>  <p>Stoichiometric formula: C<sub>16</sub> H<sub>15</sub> N<sub>5</sub> O<sub>7</sub> S Molecular weight: 397.4</p>	<p>CAS-No.: 102394-83-5</p> <p>methyl 4-hydroxy-2-(((4-methoxy-6-methyl-1,3,5-triazin-2-yl)carbamoyl)amino)sulfonylbenzoate (IUPAC)</p> <p>BCS-AW35524</p>	<p>Soil Photolysis Aqueous Photolysis</p>
<p>AE F149760</p>  <p>Stoichiometric formula: C<sub>13</sub> H<sub>13</sub> I N<sub>4</sub> O<sub>8</sub> S Molecular weight: 512.2</p>	<p>CAS-No.: 857047-89-3</p> <p>methyl 2-(((acetamidocarbonyl)carbamoyl)carbamoyl)amino sulfonyl]-4-iodobenzoate (IUPAC)</p> <p>BCS-AU75582</p>	<p>Hydrolysis</p>



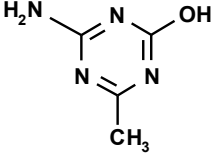
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<p><b>AE F143628</b></p>  <p>Stoichiometric formula: C<sub>9</sub> H<sub>9</sub> I N<sub>2</sub> O<sub>5</sub> S Molecular weight: 384.2</p>	<p>CAS# and name not available (compound not indexed in CAS)</p> <p>methyl 2-[(carbamoylamino)sulfonyl]-4-iodobenzoate (IUPAC)</p> <p>AE C627337 BCS-AU70201</p>	<p>Hydrolysis Rat Dog</p>
<p><b>AE F114368</b></p>  <p>Stoichiometric formula: C<sub>8</sub> H<sub>8</sub> I N<sub>2</sub> O<sub>4</sub> S Molecular weight: 341.1</p>	<p>CAS No.: 14550-70-8</p> <p>Benzoic acid, 2-(aminosulfonyl)-4-iodo-, methyl ester (CAS, 9CI)</p> <p>methyl 2-(aminosulfonyl)-4-iodobenzoate (IUPAC)</p> <p>BCS-AF78424</p>	<p>Hydrolysis Rat Dog</p>
<p><b>AE 0031850</b></p>  <p>Stoichiometric formula: C<sub>7</sub> H<sub>6</sub> I N<sub>2</sub> O<sub>4</sub> S Molecular weight: 327.0</p>	<p>CAS# and name not available (compound not indexed in CAS)</p> <p>2-(aminosulfonyl)-4-iodobenzoic acid (IUPAC)</p> <p>BCS-AW48847</p>	<p>Rat Dog Water/Sed.</p>
<p><b>AE F143133</b></p>  <p>Stoichiometric formula: C<sub>7</sub> H<sub>4</sub> I N<sub>2</sub> O<sub>3</sub> S Molecular weight: 309.1</p>	<p>CAS No.: 14591-34-3</p> <p>6-iodo-1,2-benzisothiazol-3(2H)-one, 1,1-dioxide (CAS, 9CI)</p> <p>6-iodo-1,2-benzisothiazol-3(2H)-one 1,1-dioxide (IUPAC)</p> <p>BCS-AU69256</p>	<p>Hydrolysis Rat Dog</p>

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Company Code Numbers Chemical Structures Chemical Formulas / Molecular Weights	CAS# / CA index name IUPAC nomenclature Other names / codes	Occurrence
<p>AE 1234964</p>  <p>Stoichiometric formula: C<sub>7</sub> H<sub>7</sub> N O<sub>4</sub> S Molecular weight: 201.2</p>	<p>CAS-No.: 632-24-6</p> <p>2-sulfamoylbenzoic acid (IUPAC)</p> <p>BCS-AB34589</p>	<p>Water/Sed.</p>
<p>AE F159737</p>  <p>Stoichiometric formula: C<sub>7</sub> H<sub>5</sub> N O<sub>3</sub> S Molecular weight: 183.2</p>	<p>CAS-No.: 81-07-2</p> <p>1,2-benzisothiazol-3(2H)-one, 1,1-dioxide (IUPAC)</p> <p>BCS-AB34762</p>	<p>Water/Sed. Hydrolysis Rat Dog</p>
<p>AE 0000119</p>  <p>Stoichiometric formula: C<sub>6</sub> H<sub>8</sub> N<sub>5</sub> O<sub>2</sub> Molecular weight: 185.2</p>	<p>CAS-No.: 208252-67-9</p> <p>Urea, 1-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)- (CAS, 9CI)</p> <p>1-(4-methoxy-6-methyl-1,3,5-triazin-2-yl)urea (IUPAC)</p> <p>BCS-AB56501</p>	<p>Aerobic Soil (Aqueous Photolysis) Water/Sed.</p>
<p>AE 0034855</p>  <p>Stoichiometric formula: C<sub>5</sub> H<sub>7</sub> N<sub>5</sub> O<sub>3</sub> Molecular weight: 169.1</p>	<p>CAS-No.: 405915-98-8</p> <p>Urea, 1-(4-hydroxy-6-methyl-1,3,5-triazin-2-yl)- (CAS, 9CI)</p> <p>1-(4-hydroxy-6-methyl-1,3,5-triazin-2-yl)urea (IUPAC)</p> <p>BCS-AW52268</p>	<p>Water/Sed.</p>
<p>AE F059411</p>  <p>Stoichiometric formula: C<sub>5</sub> H<sub>8</sub> N<sub>4</sub> O Molecular weight: 140.2</p>	<p>CAS-No.: 1668-54-8</p> <p>1,3,5-Triazin-2-amine, 4-methoxy-6-methyl- (CAS, 9CI)</p> <p>4-methoxy-6-methyl-1,3,5-triazin-2-amine (IUPAC)</p> <p>BCS-AA40997</p>	<p>Aerobic Soil Anaerobic Soil Water/Sed. Rat Wheat</p>



Company Code Numbers Chemical Structures Chemical Formulas / Molecular Weights	CAS# / CA index name IUPAC nomenclature Other names / codes	Occurrence
<p>AE F154781</p>  <p>Stoichiometric formula: C<sub>4</sub> H<sub>6</sub> N<sub>4</sub> O Molecular weight: 126.1</p>	<p>CAS-No.: 16352-06-0</p> <p>1,3,5-Triazin-2(1H)-one, 4-amino-6-methyl- (CAS, 9CI)</p> <p>4-amino-6-methyl-1,3,5-triazin-2-ol (IUPAC)</p> <p>BCSAU80568</p>	<p>Aerobic mineralization in surface water</p>

**CA 7.1 Fate and behaviour in soil**

**CA 7.1.1 Route of degradation in soil**

The metabolic pathway of iodosulfuron-methyl-sodium in soil is summarised in figure 7.1.1.-1.

Route of degradation of iodosulfuron-methyl-sodium in soil, aerobic conditions:

The dominant initial metabolic step in soil is a reductive loss of iodine at the phenyl ring, leading to high amounts of AE F075736 (metsulfuron-methyl). Parallel or sequential further metabolic steps are hydrolysis of the methyl ester at the phenyl ring, ether demethylation at the triazine ring, and cleavage of the sulfonylurea bridge and the triazine ring itself. The products resulting from methyl loss at the phenyl and at the triazine ring before iodine loss are AE F145740 and AE F145741, respectively, and after iodine loss are AE 0614966 (intermediate not observed in aerobic soil) and AE F161778, respectively. Subsequent cleavage of the sulfonylurea bridge leads to AE 0000119 and the terminal product AE F059411, both derived from the triazine moiety. On the other hand the cleavage of the triazine ring leads to the des-iodo-carbamoyl-guanidine of Iodosulfuron (BCS-CW81253). The absolute abundance of the individual metabolites showed significant soil-to-soil variation in the ten soil tested, however, predominant products reaching major levels were AE F075736 (up to 88.5 %), AE F145740 (up to 8.7%), AE F145741 (up to 6.9% at 10 °C only), AE F161778 (up to 13.7 % at 20°C; up to 14.5% at 10°C), BCS-CW81253 (up to 35.1 %), AE 0000119 (up to 19.9 %), and AE F059411 (up to 40.9 %). All degradates are transient intermediates, being either transformed to their respective metabolic downstream products, mineralized to carbon dioxide (up to 22.2 %), or integrated into the soil matrix as non-extractable residues (up to 39.3 %).

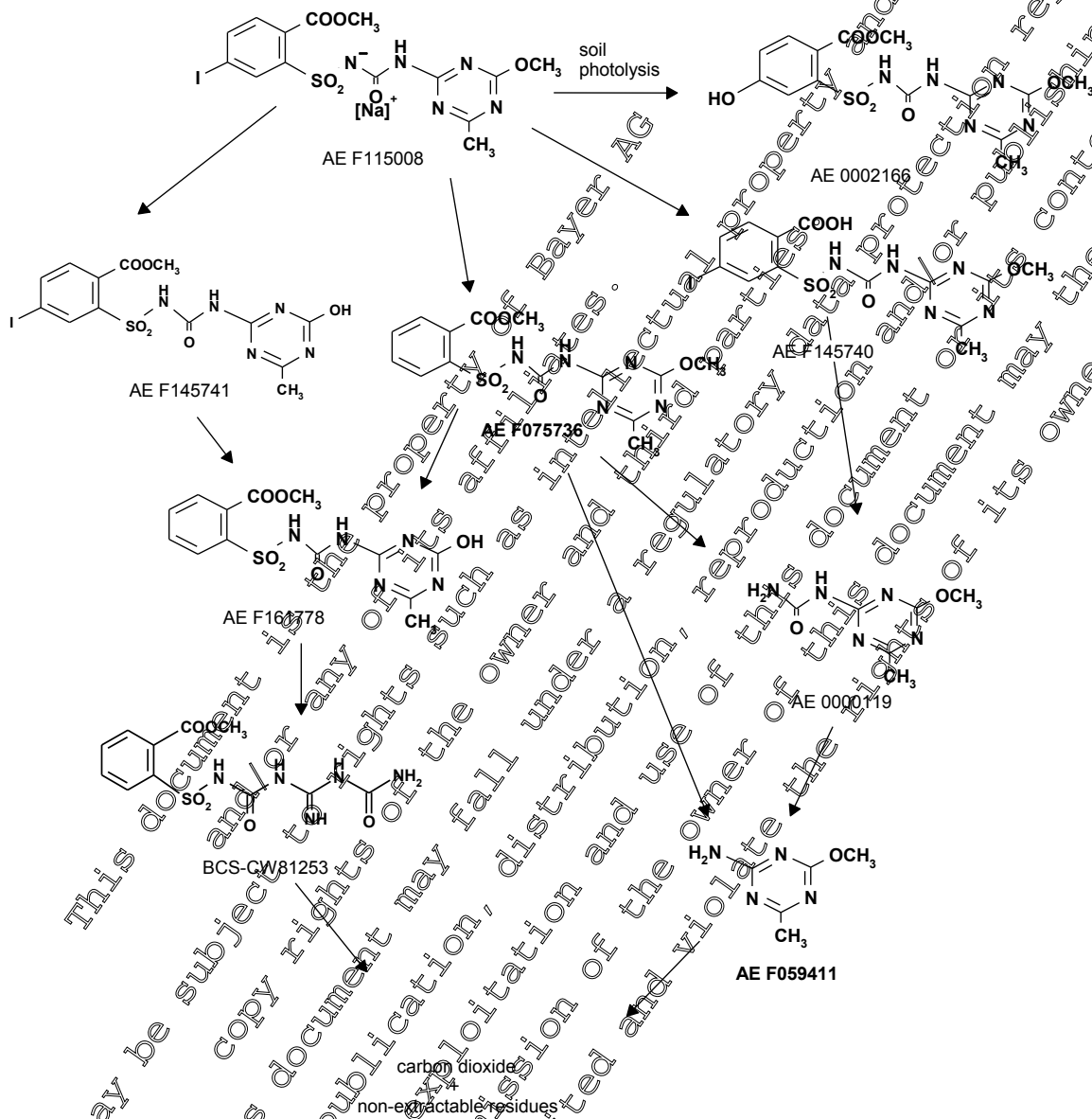
Route of degradation of iodosulfuron-methyl-sodium in soil, anaerobic conditions:

Degradation in soil under anaerobic conditions follows basically the same pathways as under aerobic conditions, with generally lower levels of downstream metabolites formed after AE F075736.

Route of degradation of iodosulfuron-methyl-sodium in soil, photolysis:

Iodosulfuron-methyl-sodium is susceptible for photodegradation on soil surface, which predominantly leads to oxidative loss of iodine at the phenyl ring: AE 0002166 (max. 20.0 %) and in addition to AE F059411 (max. 23.6%).

Figure 7.1.1- 1: Proposed degradation pathway of iodosulfuron-methyl-sodium in soil



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CA 7.1.1.1 Aerobic degradation

The route of degradation of iodosulfuron-methyl-sodium in soil under aerobic conditions in the data in the laboratory was evaluated during the Annex I inclusion using two radiolabel positions, [phenyl-<sup>14</sup>C] and [triazinyl-2-<sup>14</sup>C], and was accepted by the European Commission (SANCO/10166/2003-Final, 3 July 2003). The following studies are included in the baseline dossier and

<b>Report:</b>	[redacted];1998;M-180556-01
<b>Title:</b>	Degradation in four agricultural soils at room temperature under aerobic conditions in the laboratory AE F115008-triazinyl-2-14C
<b>Report No:</b>	C000375
<b>Document No:</b>	M-180556-01-1
<b>Guidelines:</b>	BBA: IV, 4-1; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted];1998;M-181517-01
<b>Title:</b>	Degradation in two loam soils under standard conditions in the laboratory AE F115008-triazinyl-2-14C
<b>Report No:</b>	C000947
<b>Document No:</b>	M-181517-01-1
<b>Guidelines:</b>	BBA: IV, 4-1; USEPA (=EPA): N162-1; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted];1998;M-180558-01
<b>Title:</b>	Degradation in a loamy sand soil at room temperature under non-sterile and sterile aerobic conditions in the laboratory AE F115008-phenyl-u-14C
<b>Report No:</b>	C000375
<b>Document No:</b>	M-180558-01-1
<b>Guidelines:</b>	BBA: IV, 4-1; USEPA (=EPA): N162-1; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted];1998;M-181173-01
<b>Title:</b>	Degradation in a light loam soil at different temperature and soil moisture under aerobic conditions in the laboratory AE F115008-triazinyl-2-14C
<b>Report No:</b>	C000744
<b>Document No:</b>	M-181173-01-1
<b>Guidelines:</b>	BBA: IV, 4-1; USEPA (=EPA): N162-1; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted];1998;M-181732-01
<b>Title:</b>	Degradation in two soils at room temperature and two moisture conditions under aerobic conditions in the laboratory AE F115008-triazinyl-2-14C
<b>Report No:</b>	C001065
<b>Document No:</b>	M-181732-01-1
<b>Guidelines:</b>	SETAC: 1, 1; Deviation not specified
<b>GLP/GEP:</b>	yes

In order to elucidate the structure of formerly not identified metabolites occurred in the [redacted] and [redacted] studies, a modified soil degradation has been performed and is submitted within this supplemental dossier for the iodosulfuron-methyl-sodium Annex I Renewal.

Formerly not assigned regions of interest were now assigned as BCS-CW81253 (des-iodo-carbamoyl-guanidine) or could be reassigned as AE F059411 and/or as AE 0000119. Based on the results of the



metabolite elucidation study the regions of interest were in part reassigned in the [redacted] and [redacted] studies.

<b>Report:</b>	[redacted];2013;M-458024-01
<b>Title:</b>	[Triazinyl-2-14C]iodosulfuron-methyl-sodium: Retrospective identification of metabolites from aerobic soil metabolism study no. CB94/049 (1998)
<b>Report No:</b>	EnSa-13-0267
<b>Document No:</b>	M-458024-01-1
<b>Guidelines:</b>	<b>OECD Test Guideline No. 307, 2007</b> <b>Commission Directive 95/36/EC amending Council Directive 91/414, 1995</b> <b>Regulation (EC) No.1107/2009, 2009;not specified</b>
<b>GLP/GEP:</b>	yes

**Executive Summary**

The objective of the study was to retrospectively identify unknown major degradation products reported in the aerobic soil metabolism studies CB94/049 (KCA 7.1.1.2/01), CB96/051 (KCA 7.1.1.2/02), CB96/146 (KCA 7.1.1.2/05), and AGR08 (KCA 7.1.1.2/08), performed in 1998-2009. In these studies, major degradation products were identified but other major degradation products U1, U2, M2 (study CB94/049), U4 (CB96/051, CB96/146) and M4 (AGR08) were characterized by their formation in soil and their chromatographic retention behaviour, only. The study CB94/049 was taken as starting point because this study had been performed first and relative retention times and related chromatograms of the unknown metabolites (U1, U2, M2) of four soils were reported. The other major degradation products detected in other studies characterized as U4 (CB96/051, CB96/146) and M4 (AGR08) were identified by comparison of the chromatographic profile.

A simplified aerobic soil metabolism experiment using four different soils was performed. A test concentration of  $\mu\text{g}$  per 100 g soil dry weight was applied in order to obtain the same test item concentration as was used in the previous study. This concentration is equivalent to the 1.5 fold amount of the maximum field application rate of 0.01 kg iodosulfuron-methyl-sodium / ha. Additional samples were applied with the 10-fold application rate in order to produce higher amounts of degradation products (MID samples).

The occurrence of the test item and its degradation products in soil extracts was investigated by HPLC/radiodetection using two HPLC methods (method 1 and 2) that were based on methods used in the previous study. One sample showing a representative pattern of degradation products was used for the identification of the unknown degradation products. This sample was collected at DAT-13 from soil [redacted] (sandy loam) and it was applied with the 10-fold amount of test item. The unknown degradation products U2 and M2 were identified by HPLC-MS(/MS) and HPLC co-chromatography with reference items. Further degradation products were identified by HPLC-MS(/MS), HPLC co-chromatography and/or profile comparison using non-radiolabeled reference items.

The unknown degradation product M2 showed a sharp peak overlapping a broad peak with fronting and tailing of the also unknown degradation product U2 (HPLC method I) in the previous aerobic soil degradation study CB94/049. Within the present study, the same peak profile was observed. For identification purposes, the main peak as well as its fronting and tailing were isolated by HPLC/radiodetection and each fraction was further characterized by HPLC-MS(/MS). In both, the



fronting and tailing, AE F059411 (Aminotriazine) was identified. In the central main peak (M2), BCS-CW81253 (des-iodo-carbamoyl-guanidine) was identified as the major compound. The identity of BCS-CW81253 in the extracts was further confirmed by HPLC-MS(/MS) analysis using a peak fraction isolated with method 2. The identity of AE F059411 was further confirmed by HPLC chromatography.

The resulting chromatograms of method 1 reveal that the retention time of the broad AE F059411 peak changes by the addition of the non-radiolabeled reference item. This shift is possibly caused by a change in the pH value which affects the protonation of AE F059411 and its interactions with the HPLC column. Based on this observation, it is considered that the unknown degradation product M1 (RRT of about 0.37 – 0.46) is AE F059411. The assumption is based on the fact that U1 was only observed in those soils in which U2 was not detected and that it shows a similar formation pattern.

In the previous study CB94/049, the degradation product named M1 was not correctly assigned. AE F059411 shows a shift of retention times from 40 min. observed with method 1 to 20 min. using method 2 while the retention times of the other degradation products remain more or less stable. Therefore, the order of the peaks changes in method 1 and method 2. In the old study, the first peak was mistakenly always assigned as M1. But this peak M1 has to be assigned as AE 0000119 (method 1) or AE F059411 (method 2).

In the other previous studies CB96/051, CB96/146 and AGR08 degradation products were identified by comparison of the chromatographic profiles (HPLC method 2). The unknown metabolite named U4 (CB96/0513 and CB96/146) or M4 (AGR08) is now identified as BCS-CW81253 based on the retention behaviour.

## 1 MATERIALS AND METHODS

### A. MATERIALS

#### 1. Test Item

[Triazinyl-2-<sup>14</sup>C]Iodosulfuron-methyl-sodium  
Sample ID: KMF 9137  
Specific Radioactivity: 3.8 MBq/mg  
Radiochemical Purity: 98% (HPLC) 99% (TLC)  
Chemical Purity: 98% (HPLC UV)

#### 2. Test Soils

Four different soils were used in the study. The soils were taken from agricultural use areas representing different geographical origins and different soil properties as required by the guidelines. No plant protection products were used for the previous 5 years. The soils were sampled freshly from the fields (upper horizon of 0 to 20 cm) and sieved to a particle size of  $\leq 2$  mm.





Table CA 7.1.1.1- 1: Physico-chemical properties of test soils

Soil	AXXa	4a	II	
Geographic Location (City / State / Country)	/ NRW / Germany	NRW / Germany	NRW / Germany	/ NRW / Germany
GPS coordinates				
Soil Taxonomic Classification (USDA)	Sandy, mixed, mesic Typic Cambudoll	Loamy mixed, mesic Typic Argudalf	Fine loamy, mixed, active, rigid Typic Eutrudept	Loamy mixed, mesic Typic Argudalf
Pesticide use history	No pesticide use for previous 5 years			
Collection procedures	Sample taken with shovel and placed into plastic bag/bucket			
Sampling depth	0-20 cm			
Storage conditions	Stored after sieving at 20 °C			
Storage length	17 days (from sampling until application)			
Soil preparation	Soil was passed through a 2 mm sieve			
Texture Class (USDA)	Loamy sand	Silt loam	Loam	Sandy loam
Sand [50 µm - 2 mm] (%)	14	25	39	55
Silt [2 µm - 50 µm] (%)	7	13	36	38
Clay [< 2 µm] (%)	7	13	25	17
pH in Water	6.4	6.4	7.4	5.4
pH in CaCl <sub>2</sub> (0.01 M)	5.9	6.2	7.2	5.2
pH in KCl (1 M)	5.7	6.0	7.1	4.9
Organic Matter <sup>A</sup> (%)	3.1	3.8	8.8	3.3
Organic Carbon (%)	1.8	2.2	5.1	1.9
CEC (meq/100 g)	9.4	11.1	20.0	10.1
MWHC (g/100 g)	53.9	53.3	81.0	58.2
Moisture at 1/10 bar = pF (%)	13.9	29.9	42.6	20.1
Bulk density (g/cm <sup>3</sup> )	1.23	1.05	0.95	1.09
Microbial biomass (10 <sup>6</sup> C <sub>biomass</sub> /100-g dry vital soil)	not determined			

<sup>A</sup> % organic matter = % organic carbon x 1.724

**B. STUDY DESIGN**

**1. Experimental Conditions**

Samples of 100 g dry weight of soil each were filled into Erlenmeyer glass flasks (e.g. 300 mL) and moisture was adjusted to 55 ± 5% maximum water holding capacity (MWHC) for the individual test systems by addition of de-ionized water, taken into account the water content of the application solution. The flasks were then fitted with trap attachments filled with soda lime and a polyurethane foam plug. The system was open to air. The untreated test systems were equilibrated to study conditions by placement in a temperature-controlled walk-in climatic chamber at 20 ± 2 °C in the dark for 2 days prior to application.

A nominal test concentration of 2 µg per 100 g soil dry weight was applied in order to obtain the same test item concentration as was used in the previous study CB94/049. This concentration is equivalent to the 1.5-fold amount of the maximum field application rate of 0.01 kg iodosulfuron-methyl-sodium / ha. Additional samples were applied with the 10-fold application rate in order to produce higher amounts of degradation products (MID samples). For application, the targeted amount of test item was dissolved in methanol/water 1/1 (v/v) and applied dropwise directly to the soil surface using a pipette.



The actual dose applied per test vessel was 2.4 µg of iodosulfuron-methyl-sodium for all soils. After application, the vessels (except DAT-0 samples) were fitted with trap attachments and placed into a temperature-controlled walk-in climatic chamber for incubation at 20 ± 2 °C in the dark for up to 28 days at a moisture content of 55% MWHC).

## 2. Sampling

Four sampling intervals were distributed over an incubation period of 28 days. Samples applied with the 1-fold application rate were taken at days 0, 6, 13 and 28. MID samples were taken at days 13 and 28. The extracts were analyzed by LSC and HPLC within 2 days after sampling. Samples were stored deep-frozen until analysis for identification purposes.

## 3. Analytical Procedures

The entire soil sample in each test vessel was extracted three times at ambient conditions using a mechanical shaker followed by one accelerated extraction using a microwave with a magnetic stirrer. 80 mL of acetonitrile/water 4/1 (v/v) were used as extraction solvent for all steps. After each extraction step, extract and soil were separated by centrifugation and decantation. The volumes of the combined ambient extracts and the microwave extract were determined and the radioactivity content of these extracts was measured by liquid scintillation counting (LSC). The soda lime and the PU-foam plug in the trap attachments were subjected to further processing or analysis.

Aliquots of the soil extracts (DAT-0) or concentrates thereof were characterized by means of reversed phase (RP) HPLC/radiodetection using an ODS Hypersil column and 0.01 M H<sub>2</sub>PO<sub>4</sub> and acetonitrile as solvents. This method is equivalent to method condition I in study CB94/049 and was also used to analyse several reference items. The LOD and LOQ of the HPLC method were not determined since the purpose of this study was the identification of degradation products.

A second HPLC method was used to analyse one concentrate of a MID sample of soil [REDACTED] as well as solutions of the reference items. This method uses a ODS Hypersil column and 0.1 M ammonium acetate (adjusted to pH 4 with formic acid) and acetonitrile as solvents and is equivalent to the method condition IV used in study CB94/049 as well as to the first chromatographic methods used in studies CB96/051, B96/146 and AGR08. Identification of degradation products was performed by HPLC-MS(/MS) as well as by HPLC co-chromatography and comparison of the HPLC profiles.

## II. RESULTS AND DISCUSSION

The test systems were incubated under aerobic conditions in the dark at 20.0±2 °C for 28 days. The test was performed at a soil moisture of 55% of the maximum water holding capacity. Due to the short duration of the study, the soil moisture was not monitored.

### A. DATA

The aim of the study was the identification of the unknown major degradation products found in previous studies. Therefore, material balances were not established for the test systems. The amounts of the individual degradation products in the investigated soil extracts were evaluated as “regions of interest” but, due to the aim of the study, the amounts of the degradation products were not expressed



in % AR. Both chromatographic methods were developed in order to reproduce methods used in previous studies. By comparison of relative retention times as well as by the comparison of HPLC profiles it was shown that comparable distributions of radioactivity were obtained.

## B. IDENTIFICATION OF DEGRADATION PRODUCTS

### Substances to be identified from Study CB49/049

The unknown degradation product M2 was observed at a relative retention time (RRT) of about 0.57-0.59 in the previous aerobic soil degradation study CB94/049. The sharp peak of M2 was overlapped with the broad peak with fronting and tailing of the also unknown degradation product U2 (HPLC condition I). Within the present study, the same peak profile was observed (HPLC method 1). For identification purposes, the main peak as well as its fronting and tailing were isolated by HPLC/radiodetection and each fraction was further characterized by HPLC-MS/MS. In both, the fronting and tailing, AE F059411 (Aminoflazine) was identified. In the central main peak (M2), BCS-CW81253 (des-iodo-carbamoyl-guanidine) was identified as the major compound. The identity of BCS-CW81253 (des-iodo-carbamoyl-guanidine) in the extracts was further confirmed by HPLC-MS/MS analysis using a peak fraction isolated with method 1. The identity of AE F059411 was further confirmed by HPLC co-chromatography. The resulting chromatograms of method 1 reveal that the retention time of the broad AE F059411 peak changes by the addition of the respective non-radiolabeled reference item. This shift is possibly caused by a change in the pH value which affects the protonation of AE F059411 and its interactions with the HPLC column. Based on this observation, it is considered that the unknown degradation product U1 (RRT of about 0.57 – 0.46) is AE F059411. The assumption is based on the fact, that U1 was only observed in those soils in which U2 was not detected and that it shows a similar formation pattern.

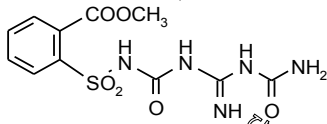
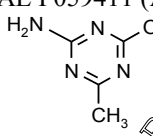
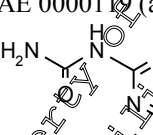
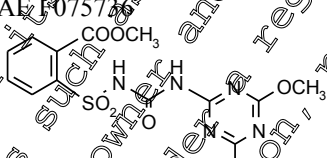

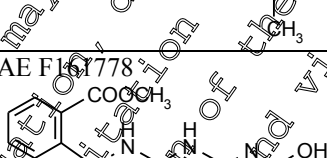
In the previous study CB94/049 the degradation product named M1 was not correctly assigned. AE F059411 shows a shift of retention times from 40 min. observed with method 1 to 20 min. using method 2 while the retention times of the other degradation products remain more or less stable. Therefore, the order of the peaks changes in method 1 and method 2. In the old study, the first peak was mistakenly always assigned as M1. But this peak M1 has to be assigned as AE 0000119 (method 1) or AE F059411 (method 2).

For the other previous studies CB96/051, CB96/146 and AGR08 degradation products were identified by comparison of the chromatographic profiles with HPLC method 2 observed in the different studies. The unknown metabolite named U4 (CB96/051 and CB96/146) or M4 (AGR08) is identified as BCS-CW81253 (des-iodo-carbamoyl-guanidine) based on the retention behaviour.

Besides the newly identified degradation products, the known degradation products AE 161778, AE F075736 and AE F145741 were detected in the extracts and used for chromatographic comparison. A summary of the degradation products identified in the course of the study is presented in Table CA 7.1.1-2.



Table CA 7.1.1.1- 2: Summary of degradation products identified in the course of this study

New identified degradation products:	
ID in previous studies	Company Code and Chemical Structure
M2 (study CB94/049) U4 (study CB96/051 and study CB96/146) M4 (study AGR08)	BCS-CW81253 (Des iodo-carbamoyl-guanidine) 
U1 and U2 (study CB 94/049)  M2 (studies CB96/051 and CB96/146)	AE F059411 (Aminotriazine, also called Amine) 
M1 (study CB94/049*) M3 (studies CB96/051 and CB96/146)	AE 0000119 (also called Ursa) 
Known degradation products used for comparison of chromatographic methods:	
M4 (study CB94/049) M8 (studies CB96/051 and CB96/146) AEF075736 in study AGR08	AE F075736 
M7 (studies CB96/051 and CB96/146)	AE F145741 
M3 (study CB94/049) M5 (study CB96/146) AEF161778 in study AGR08	AE F161778 

\* In study CB94/049 M1 was mistakenly assigned to AE F059411 while it was clearly identified as AE 0000119 within the present study.

### III. CONCLUSIONS

The compounds called M2 and U2 in the previous study CB94/049 were identified as BCS-CW81253 (des-iodo-carbamoyl-guanidine) and AE F059411 (Aminotriazine), respectively. Based on the observation that the retention time of AE F059411 changes in dependence on the concentration/pH value as well as on the formation pattern, U1 was also identified as AE F059411.

The compound called M1 in the previous study was assigned to AE 0000119 within the present study, the assignment of M1 made in the previous study is considered as wrong.



The unidentified degradation products U4 (studies CB96/051 and CB96/146) and M4 (study AGR08) were identified as BCS-CW81253 (des-iodo-carbamoyl-guanidine) based on their chromatographic behaviour.

New assignment of the not further evaluated regions of interest in the aerobic soil degradation studies of [redacted] 1998

<b>Report:</b>	[redacted]; [redacted]; 2013; M-471682-01
<b>Title:</b>	Statement - Iodosulfuron-methyl: Re-evaluation of aerobic soil degradation studies following the identification of formerly unidentified soil metabolites in degradation studies of [redacted] 1998: M-180556-01-1, M-181175-01-1, M-181517-01-1 and M-181732-01-1
<b>Report No:</b>	EnSa-13-1050
<b>Document No:</b>	M-471682-01-1
<b>Guidelines:</b>	not specified; not specified
<b>GLP/GEP:</b>	n.a.

Following the retrospective identification of unknown metabolites ([redacted] 2013; M-458024-01-1, KCA 7.1.1.1 /06) and the consequent reassignment of the metabolites AE F059411 and AE 0000119 in studies M-180556-01-1 (KCA 7.1.1.1 /01), M-181517-01-1 (KCA 7.1.1.1 /02), M-181175-01-1 (KCA 7.1.1.1 /04), and M-181732-01-1 (KCA 7.1.1.1 /05), a re-evaluation of the [redacted] studies (KCA 7.1.1.1 /01, 02, 04, 05) has been performed.

No new assignments were necessary in M-180558-01 (KCA 7.1.1.1 /03), this study did not require new evaluation and original evaluation is still valid.

The new evaluated biotransformation tables are shown below:

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M-180556-01-1 ( [REDACTED] 1998, KCA 7.1.1.1 /01):

Table CA 7.1.1.1-3 Application of [2-triazinyl-<sup>14</sup>C]AE F115008 to Soil I (SL V) and aerobic incubation at ca. 20 °C (data are given in % of applied radioactivity; mean of duplicate samples)

	Sampling Times [days]									
	0	2	4	7	11	14	28	42	63	86
AE F115008	100.8	41.6	24.0	10.8	4.7	2.8	1.1	1.1	-	-
AE F075736	-	53.8	70.1	79.6	78.6	75.1	44.7	37.2	25.1	11.2
AE F161778	-	-	-	-	1.2	2.8	2.9	1.1	-	-
Formerly AE F059411 (AMT) Now assigned as urea (AE 0000119)	-	-	-	-	5.3	6.8	12.7	10.7	19.4	19.9
M2 assigned as BCS-CW81253 (des-iodo-carbamoyl-guanidine)	-	-	-	-	-	5.3	3.3	13.7	18.6	13.3
U1 (unidentified)	-	-	-	-	-	-	-	-	-	-
U2 assigned as Aminotriazine (AMT, AE F059411)	-	-	-	-	-	-	-	-	-	11.1
Total extractable	100.8	95.4	94.1	90.4	89.9	89.1	78.6	63.4	63.5	55.5
<sup>14</sup> CO <sub>2</sub> a)	<0.1	0.1	<0.1	<0.1	<0.1	0.1	0.6	0.9	2.0	3.3
Non-extractable	1.5	2.9	4.4	6.1	7.4	7.9	17.4	25.0	31.7	36.7
Total recovery	100.2	98.4	98.5	96.5	97.3	97.1	96.6	99.4	97.2	95.4

a) Other volatiles accounted for < 0.1 % of total applied radioactivity

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Table CA 7.1.1.1-4 Application of [2-triazinyl-<sup>14</sup>C]AE F115008 to Soil II (LS 2.2) and aerobic incubation at ca. 20 °C (data are given in % of applied radioactivity; mean of duplicate samples)

	Sampling Times [days]									
	0	2	4	7	11	14	28	42	63	86
AE F115008	97.0	38.8	15.4	5.5	3.0	2.1	-	-	-	-
AE F075736	2.5	54.8	78.2	82.0	75.2	71.2	45.8	27.2	12.3	6.3
AE F161778	-	-	3.2	5.0	7.4	7.8	7.4	3.6	-	-
Formerly AE F059411 (AMT) now assigned as urea (AE 0000119)	-	-	-	3.8	6.8	7.8	9.1	7.4	4.8	8
M2 assigned as BCS-CW81253 (des-iodo-carbamoyl-guanidine)	-	-	-	-	1.0	4.5	16.0	20.0	5.1	20.5
U1 (unidentified)	-	-	-	-	-	-	-	-	-	-
U2 assigned as Aminotriazine (AE F059411)	-	-	-	-	-	-	-	13.8	7.8	23.5
Total extractable	99.5	93.6	96.9	96.6	92.1	93.5	79.0	75.7	59.6	53.1
<sup>14</sup> CO <sub>2</sub> a)	n.a.	0.1	0.1	0.1	0.1	0.8	2.5	6.8	6.8	11.6
Non-extractable	2.4	5.6	8.5	5.8	6.4	8.6	20.7	20.3	32.4	32.9
Total recovery	101.6	96.3	100.4	100.4	99.6	102.8	101.9	99.1	98.8	97.6

a) Other volatiles accounted for 0.1 % of total applied radioactivity

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Table CA 7.1.1.1-5 Application of [2-triazinyl-<sup>14</sup>C]AE F115008 to Soil III (S 2.1) and aerobic incubation at ca. 20 °C (data are given in % of applied radioactivity; mean of duplicate samples)

	Sampling Times [days]									
	0	2	4	7	11	15	28	42	63	90
AE F115008	96.8	57.9	38.1	22.6	8.2	3.5	1.6	3.0	1.6	1.1
AE F075736	-	36.1	54.3	69.0	82.6	83.1	75.4	64.7	51.5	43.5
AE F161778	-	-	-	-	-	-	3.4	4.1	2.2	2.2
Formerly AE F059411 (AMT) now assigned as urea (AE 0000119)	-	-	-	-	-	-	1.6	2.6	5.8	8
M2 assigned as BCS-CW81253 (des-iodo-carbamoyl-guanidine)	-	-	-	-	-	-	-	7.7	8.7	8.7
U1 assigned as Aminotriazine (AE F059411)	-	-	-	-	-	-	-	10.0	12.3	12.3
U2	-	-	-	-	-	-	-	-	-	-
Total extractable	96.8	94.0	92.4	91.1	90.8	86.7	82.0	79.2	78.7	72.7
<sup>14</sup> CO <sub>2</sub> a)	n.a.	<0.1	<0.1	<0.1	<0.1	<0.1	0.7	1.3	1.3	2.1
Non-extractable	2.4	2.7	5.9	6.5	8.3	17.5	12.8	17.4	19.3	28.0
Total recovery	99.2	97.5	98.2	98.2	99.1	98.2	95.1	97.4	99.3	102.8

a) Other volatiles accounted for <0.1 % of total applied radioactivity

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Table CA 7.1.1.1-6 Application of [2-triazinyl-<sup>14</sup>C]AE F115008 to Soil IV (SL 2) and aerobic incubation at ca. 20 °C (data are given in % of applied radioactivity; mean of duplicate samples)

	Sampling Times [days]									
	0	2	4	7	11	15	28	42	63	90
AE F115008	96.5	15.6	3.1	-	-	-	-	-	-	-
AE F075736	-	75.8	88.5	87.5	87.0	80.5	71.2	60.9	51.8	37.2
AE F161778	-	-	-	-	-	-	2.9	2.3	2.4	3.0
Formerly AE F059411 (AMT) now assigned as urea (AE 0000119)	-	-	-	-	-	5.5	7.6	8.4	11.6	14.0
M2 assigned as BCS-CW81253 (des-iodo-carbamoyl-guanidine)	-	-	-	-	-	-	-	-	4.4	5.4
U1 assigned as Aminotriazine (AE F059411)	-	-	-	-	-	-	-	-	-	18.3
U2	-	-	-	-	-	-	-	-	-	-
Total extractable	96.5	91.4	91.6	87.7	87.0	83.1	81.6	73.5	70.2	78.2
<sup>14</sup> CO <sub>2</sub> a)	n.a.	<0.1	<0.1	<0.1	<0.1	0.1	0.7	1.6	1.2	2.1
Non-extractable	2.3	2.3	9.0	9.6	13.0	15.7	17.6	19.7	26.4	32.4
Total recovery	98.7	98.7	100.0	97.4	100.0	98.9	99.5	93.7	97.9	112.6

a) Other volatiles accounted for 0.1 % of total applied radioactivity

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M-181175-01-1 ( ) 1998, KCA 7.1.1.1 /04):

Table CA 7.1.1.1-7 Application of [2-triazinyl-14C]AE F115008 to Soil FF and aerobic incubation at 20 °C 40 % MWHC (data are given in % of applied radioactivity; mean of duplicate analysis)

	Sampling Times [days]										
	0	2	4	7	11	14	28	42	63	91	120
AE F115008	97.8	69.7	50.6	34.2	26.5	19.0	8.9	4.9	3.9	2.6	2.2
AE F075736	-	20.4	35.6	45.1	46.6	47	44.0	34.2	24.5	13.5	10.9
AE F145740	-	-	0.8	1.1	1.3	1.3	1.3	1.4	1.1	1.1	0.7
AE F145741	-	2.8	3.2	4.6	4.1	4.9	3.5	3.5	3.2	2.7	2.2
AE F161778	-	-	1.5	3.2	5.4	8.1	12.0	13.7	13.5	11.4	9.1
AE 0000119	-	-	1.2	1.5	1.1	1.9	2.9	3.4	3.1	4.1	5.4
AE F059411	-	1.4	1.4	1.7	1.4	3.1	4.1	5.1	2.1	17.6	18.8
U1 (unidentified)	-	-	-	-	-	-	-	-	-	1.5	7.5
U4 assigned as BCS-CW81253 (des-iodo-carbamoyl-guanidine)	-	-	-	-	-	1	5.8	8.3	8.9	8.9	8.6
Total extractable	97.8	94.2	94.2	91.5	86.5	88.2	82.9	76.9	77.1	62.8	58.6
<sup>14</sup> CO <sub>2</sub> a)	n.a.	0.3	0.4	0.5	0.5	0	1.1	1.7	1.2	5.7	8.1
Non-extractable	1.2	3.8	5.8	7.0	9.9	10.1	16.2	20.8	26.2	30.6	33.8
Total recovery	99.0	98.3	91.2	99.0	94.9	98.9	99.3	98.5	99.6	99.0	100.6

a) Other volatiles accounted for < 0.1% of total applied radioactivity

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**Table CA 7.1.1.1-8 Application of [2-triazinyl-14C]AE F115008 to Soil FF and aerobic incubation at 20 °C / 30 % MWHC (data are given in % of applied radioactivity; mean of duplicate analysis)**

	Sampling Times [days]										
	0	2	4	7	11	14	28	42	63	91	120
AE F115008	95.4	76.0	60.1	41.1	31.8	28.1	15.7	8.4	6.2	4.2	3.2
AE F075736	-	16.3	26.6	39.0	44.1	47.7	45.9	42.7	36.2	27.4	22.8
AE F145740	-	-	1.0	1.2	1.3	1.5	1.1	1.1	1.4	1.1	1.2
AE F145741	-	1.5	2.6	3.1	3.6	3.2	3.1	3.2	2.9	3.2	3.5
AE F161778	-	-	0.8	2.1	3.4	3.4	-	8.8	9.8	9.7	8.2
AE 0000119	-	-	-	1.0	2.2	1.4	2.1	3.0	2.9	3.3	3.8
AE F059411	-	1.0	0.7	1.4	1.6	1.8	5.7	8.3	10.8	11.3	16.0
U1 (unidentified)	-	-	-	-	-	-	-	-	-	-	0.8
U4 assigned as BCS-CW81253 (des-iodo-carbamoyl-guanidine)	-	-	-	-	0.4	0.1	1.1	2.3	3.1	4.1	4.7
Total extractable	95.4	94.7	91.8	88.9	87.0	87.1	82.9	77.9	72.9	63.3	63.4
<sup>14</sup> CO <sub>2</sub> a)	n.a.	0.3	0.4	0.6	0.5	0.5	0.9	1.2	2.0	3.3	4.8
Non-extractable	1.1	4.5	7.0	7.4	8.1	11.3	15.9	19.4	22.5	25.7	29.2
Total recovery	96.6	99.5	99.2	96.6	95.6	99.1	98.9	98.6	97.3	99.3	97.5

a) Other volatiles accounted for < 0.1 % of total applied radioactivity

**Table CA 7.1.1.1-9 Application of [2-triazinyl-14C]AE F115008 to Soil FF and aerobic incubation at 10 °C / 40 % MWHC (data are given in % of applied radioactivity; mean of duplicate analysis)**

	Sampling Times [days]										
	0	2	4	7	11	14	28	42	63	91	120
AE F115008	96.4	87.7	74.7	66.4	54.0	47.6	30.0	21.8	16.0	11.5	9.4
AE F075736	-	7.6	15.9	24.1	29.7	34.1	40.3	42.4	39.6	38.0	29.3
AE F145740	-	-	0.8	0.8	1.0	1.1	1.7	1.4	1.4	1.4	1.3
AE F145741	-	1.1	2.6	3.5	3.4	5.0	5.6	6.5	6.9	5.2	6.1
AE F161778	-	-	-	-	1.1	2.6	7.3	7.7	10.8	11.8	14.5
AE 0000119	-	-	-	-	0.8	1.0	2.1	2.1	2.6	2.4	2.9
AE F059411	-	1.1	1.2	-	0.7	1.5	2.1	3.7	5.8	8.0	10.1
U1 (unidentified)	-	-	-	-	-	-	-	-	-	-	-
U4 assigned as BCS-CW81253 (des-iodo-carbamoyl-guanidine)	-	-	-	-	-	-	0.5	1.4	1.9	3.6	5.5
Total extractable	96.4	95.9	96.1	94.7	90.8	92.8	89.6	87.2	84.9	81.8	79.1
<sup>14</sup> CO <sub>2</sub> a)	n.d.	0.2	0.3	0.3	0.4	0.4	0.6	0.8	0.9	1.4	2.0
Non-extractable	1.1	2.6	3.9	3.9	4.4	5.8	7.9	10.6	12.1	14.7	18.0
Total recovery	97.6	98.7	100.3	99.0	95.6	99.0	98.1	98.5	97.9	97.9	99.1

a) Other volatiles accounted for < 0.1 % of total applied radioactivity



M-181517-01-1 ( [REDACTED] 1998, KCA 7.1.1.1 /02):

Table CA 7.1.1.1-10 Application of [2-triazinyl-14C]AE F115008 to Soil SL S and aerobic incubation at ca. 20 °C (data are given in % of applied radioactivity; mean of duplicate analysis)

	Sampling Times [days]										
	0	2	4	7	11	14	28	38	63	91	120
AE F115008	96.6	60.7	38.0	20.3	12.4	6.9	2.0	1.6	1.4	1.0	0.6
AE F075736	-	30.3	44.4	54.9	52.7	51.9	33.6	22.0	8.7	3.8	1.5
AE F145740	-	-	1.4	2.7	3.2	1.9	1.6	1.6	3.3	2.2	1.3
AE F145741	-	2.5	3.2	3.2	2.2	2.6	4.5	0.8	-	-	-
AE F161778	-	-	1.4	4.1	6.3	9.2	12.2	11.9	10.2	5.6	3.7
AE 0000119	-	-	1.6	2.6	2.6	3.2	4.2	3.1	3.6	3.5	4.1
AE F059411	-	-	1.5	2.7	2.4	7.1	15.9	18.3	24.1	24.5	20.0
U4 assigned as BCS-CW81253 (des-iodo-carbamoyl-guanidine)	-	-	-	-	-	2.7	4.0	5.0	5.7	3.3	3.3
Total extractable	96.6	93.5	90.8	90.6	86.8	85.6	77.6	68.2	57.1	45.4	36.4
<sup>14</sup> CO <sub>2</sub> a)	n.a.	0.4	0.5	0.5	0.8	1.0	2.5	4.4	10.2	16.5	22.2
Non-extractable	1.3	5.0	6.1	9.2	9.7	11.9	19.2	25.2	31.5	36.5	39.3
Total recovery	97.9	99.0	97.3	100.4	95.3	98.5	97.7	97.7	98.8	98.4	97.9

a) Other volatiles accounted for < 0.1 % of total applied radioactivity

Table CA 7.1.1.1-11 Application of [2-triazinyl-14C]AE F115008 to Soil CL L and aerobic incubation at ca. 20 °C (data are given in % of applied radioactivity; mean of duplicate analysis)

	Sampling Times [days]										
	0	2	4	7	11	14	28	38	63	91	120
AE F115008	97.8	47.6	41.3	25.4	12.2	10.7	3.6	2.8	2.0	4.3	0.9
AE F075736	-	25.9	38.5	47.0	55.3	48.8	32.2	22.6	8.7	4.7	2.9
AE F145740	-	-	0.8	2.0	2.4	2.2	2.4	1.9	1.2	1.7	-
AE F145741	-	-	2.9	2.8	2.3	1.8	0.9	-	-	-	1.6
AE F161778	-	-	1.4	3.0	5.0	4.8	5.5	4.9	4.6	2.5	2.0
AE 0000119	-	-	1.4	1.1	2.4	2.8	2.6	1.9	-	-	-
AE F059411	-	-	2.3	4.6	6.5	12.6	27.2	30.9	40.9	39.8	40.3
U4 assigned as BCS-CW81253 (des-iodo-carbamoyl-guanidine)	-	-	-	-	0.7	1.0	1.4	-	-	-	-
Total extractable	97.8	93.5	89.7	87.1	86.1	84.4	76.3	67.8	59.5	53.0	48.8
<sup>14</sup> CO <sub>2</sub> a)	n.a.	0.2	0.4	0.6	0.6	0.9	2.4	4.1	11.2	16.6	20.3
Non-extractable	1.3	4.7	7.3	10.3	10.7	12.8	19.2	23.2	26.3	28.9	30.5
Total recovery	99.1	98.4	97.4	98.0	97.4	98.0	97.8	95.1	97.1	98.5	99.6

a) Other volatiles accounted for < 0.1 % of total applied radioactivity



M-181732-01-1 ( ) 1998, KCA 7.1.1.1 /05):

Table CA 7.1.1.1-12 Application of [2-triazinyl-14C]AE F115008 to Soil C T and aerobic incubation at ca. 20 °C / 25 % MWHC (data are given in % of applied radioactivity; mean of duplicate analysis)

	Sampling Times [days]										
	0	2	4	7	11	14	28	42	64	91	120
AE F115008 (a.s.)	98.2	78.5	69.2	64.6	56.9	49.6	38.0	31.3	24.7	18.4	12.7
AE F075736 (M4)	-	8.8	13.4	15.1	17.7	17.9	22.0	25.6	26.4	24.6	21.5
AE F145740 (M6)	-	-	0.7	1.2	1.1	1.6	2.0	2.3	2.6	2.9	2.9
AE F145741 (M7)	-	2.8	2.2	2.4	3.0	3.6	3.7	3.6	4.0	3.8	3.8
AE F161778 (M3)	-	-	-	-	1.0	1.1	2.0	2.8	2.8	2.2	4.7
AE 0000119 (M5)	-	-	-	-	2.8	2.6	4.1	4.3	1.5	1.3	1.9
AE F059411 (M1)	-	2.6	2.7	3.7	4.4	6.2	8.6	9.6	12.0	12.0	11.2
U1 ( not identified)	-	-	-	-	-	-	-	-	-	-	-
U4 assigned as BCS-CW81253 (des-iodo-carbamoyl-guanidine)	-	-	-	-	-	-	-	-	-	0.6	0.9
Total extractable	98.2	92.7	88.3	87.1	85.0	80.9	78.5	75.5	76.0	67.9	66.2
14CO2 a)	n.a.	0.3	0.4	0.5	0.5	0.6	0.7	0.9	1.2	1.6	2.2
Non-extractable	1.4	5.6	8.9	9.4	11.2	13.0	16.9	19.1	18.4	26.5	29.3
Total recovery	99.5	98.6	96.5	96.9	96.8	94.5	96.9	95.4	95.6	96.0	97.7

a) Other volatiles accounted for 0.1 % of total applied radioactivity

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Table CA 7.1.1.1-13 Application of [2-triazinyl-14C]AE F115008 to Soil C T and aerobic incubation at ca. 20 °C / 50% MWHC (data are given in % of applied radioactivity; mean of duplicate analysis)

	Sampling Times [days]										
	0	2	4	7	11	14	28	42	64	91	135
AE F115008	98.3	54.1	34.4	24.9	18.7	14.0	9.9	6.1	5.2	4.0	2.2
AE F075736	-	33.4	47.2	51.4	53.9	46.7	43.3	37.5	29.9	23.8	15.5
AE F145740	-	0.8	0.8	0.8	0.7	1.2	0.7	0.8	0.6	0.5	0.5
AE F145741	-	1.9	1.7	1.3	1.4	1.9	1.4	1.1	1.1	0.9	1.1
AE F161778	-	0.9	1.5	2.9	4	5.8	7.5	6.5	7.2	5.0	5.2
AE 0000119	-	-	1.3	1.6	1.9	2.4	2.9	3.6	4.1	3.3	3.9
AE F059411	-	1.6	2.6	3.6	3.8	5.1	5.7	5.7	3.8	15.2	17.5
U1 (not identified)	-	-	-	-	-	-	-	-	-	-	-
U4 assigned as BCS-CW81253 (des-iodo-carbamoyl-guanidine)	-	-	-	-	-	0.6	2	5	8	11	9.8
Total extractable	98.3	92.1	89.5	86.5	82.2	79.4	66.0	62.9	69.3	60.6	55.5
<sup>14</sup> CO <sub>2</sub> a)	n.a.	0.4	0.5	0.6	0.6	0.6	1.1	1.7	2.6	3.9	5.3
Non-extractable	1.1	4.5	7.3	12.0	11.4	14.0	18.9	27.3	34.0	31.6	35.7
Total recovery	99.4	97.4	97.2	99.3	98.2	94.0	96.0	96.9	95.9	96.2	96.5

a) Other volatiles accounted for < 0.1% of total applied radioactivity

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Table CA 7.1.1.1-14 Application of [2-triazinyl-14C]AE F115008 to Soil CL B and aerobic incubation at ca. 20 °C / 25 % MWHC (data are given in % of applied radioactivity; mean of duplicate analysis)

	Sampling Times [days]										
	0	2	4	7	11	14	28	42	64	91	120
AE F115008	98.0	81.1	69.2	57.8	44.0	35.9	20.0	11.8	8.0	5.0	2.6
AE F075736	-	8.5	18.5	26.8	37.2	37.3	43.9	42.2	35.0	28.0	18.4
AE F145740	-	0.6	1.5	2.0	2.7	2.9	3.6	3.9	4.4	3.9	3.0
AE F145741	-	0.4	0.7	1.1	1.2	1.1	1.0	1.0	1.0	0.8	1.0
AE F161778	-	-	-	0.6	0.8	0.9	0.9	1.6	2.1	1.7	2.3
AE 0000119	-	-	-	0.8	0.9	1.0	1.7	1.5	1.1	1.4	1.4
AE F059411	-	0.7	-	1.4	1.9	3.0	3.6	1.8	2.5	2.0	3.4
U1 (unidentified)	-	-	-	-	-	-	-	-	-	0.6	-
U4 assigned as BCS-CW81253 (des-iodo-carbamoyl-guanidine)	-	-	-	-	-	-	-	0	-	-	0.5
Total extractable	98.0	91.3	89.0	90.0	88.0	89.0	89.9	87.2	74.9	70.3	63.7
<sup>14</sup> CO <sub>2</sub> a)	n.a.	0.3	0.3	0.3	0.5	0.5	0.8	1.1	1.6	2.7	4.3
Non-extractable	0.7	3.9	6.3	8.2	8.8	11.1	15.1	20.1	24.8	23.6	29.0
Total recovery	98.7	95.4	96.4	98.3	97.6	99.9	97.6	98.4	98.3	96.7	96.9

a) Other volatiles accounted for 0.1 % of total applied radioactivity

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Table CA 7.1.1.1-15 Application of [2-triazinyl-14C]AE F115008 to Soil CL B and aerobic incubation at ca. 20 °C / 50 % MWHC (data are given in % of applied radioactivity; mean of duplicate analysis)

Table with columns for Sampling Times [days] (0, 2, 4, 7, 11, 14, 28, 42, 64, 91, 120) and rows for various AE F115008 metabolites and recovery percentages.

a) Other volatiles accounted for 0.1 % of total applied radioactivity

Conclusion

Due to the reassignment of the regions of interest in the aerobic soil degradation studies of iodosulfuron-methyl of [redacted] from 1998 (KCA 7.1.1.1 /01, 02, 04, 05) the assignment of the peak AE F059411 now was assigned as AE 0000119, and the peaks U1 and U2 now were assigned as AE F059411 in study M-180556-01-1 ([redacted] 1998, KCA 7.1.1.1 /01). The unidentified degradation products called M2 (KCA 7.1.1.1 /01) and U4 (KCA 7.1.1.1 /02, 04, 05) were identified as BCS-CW81253 (des-iodo-carbamoyl-guanidine) based on their chromatographic behaviour.

Table with 2 columns: Report information (Report, Title, Report No, Document No) and Guidelines (GLP/GEP).

Another soil degradation study has been performed but was not finalised in time to be included in the last dossier.

Executive Summary

The degradation of AE F115008 was investigated under aerobic conditions at 20 ± 2 °C and a soil moisture of about 40% of MWHC in one European soil by incubation in the dark for 141 days. The





test substance was applied at a nominal test concentration of 30 µg AE F115008/kg soil (dry matter), equivalent to the 1.5-fold amount derived from the single maximum recommended field use rate of 10 g/ha (assuming incorporation into the top 5 cm of soil and a bulk density of 1.5 g/mL).

The mean material balance was 95.0% of applied radioactivity [% AR] (range from 86.53 – 97.76% AR). Material balance values < 90% were caused by non-quantified <sup>14</sup>C<sub>2</sub>O<sub>2</sub> work-up losses.

The maximum amount of carbon dioxide detected was 37.9% AR at day 99 after treatment (DAT). Formation of volatile organic compounds was insignificant as demonstrated by values of < 0.05% AR at all sampling intervals.

Extractable residues decreased from 101.04 and 105.82 at study start (DAT-0) to 23.3% AR towards study end (DAT-141). Non-extractable radioactivity was increasing for about 40 days. After that period the share remained constant within a range of 24.9% to 32.5% of the applied activity.

The amount of AE F115008 in the soil extracts decreased from DAT-0 to DAT-20 from 103.4 to 1.9% AR and was not detectable at study end (DAT-141).

Degradation products in the organic extracts were characterised by their relative retention time (RRT) and, if possible, identified by HPLC co-chromatography after addition of a mixture containing different reference substances.

Four major degradation products were detected with the following maximum amounts: AE F075736 with a maximum amount of 54.5% at DAT-3, AE F145740 with up to 5.2% AR at DAT-7, M4 (relative retention time (RRT): 0.47-0.48 min.) with a maximum of 16.5% at DAT-99 and M5 (RRT: 0.53 – 0.54 min.) with a maximum of 6.1% AR at DAT-50. It was not possible to identify M4 during the course of the study.

In addition, 9 minor degradation products were observed with the following maximum amounts: M1 (RRT: 0.04 – 0.05 min.) with up to 2.9% AR, M2 (RRT: 0.41 min.) with up to 1.2% AR, M3 (RRT: 0.43-0.44 min.) with up to 7.4% AR, AE F161778 with up to 6.3% AR, M6 (RRT: 0.56 – 0.63 min.) with up to 3.5% AR, M7 (RRT: 0.63 min.) with up to 5.1% AR, AE F145741 with up to 3.6% AR, M8 (RRT: 0.7 min.) with up to 1.9% AR and M9 (RRT: 0.74 min.) with up to 3.3% AR.

Assuming single first order kinetics the half-life of AE F115008 under aerobic conditions was 1.8 days and the DT<sub>90</sub> value was determined to be 5.8 days.

## I. MATERIALS AND METHODS

### A. MATERIALS

#### 1. Test Item

AE F115008-[phenyl-U-<sup>14</sup>C]

Batch: Z 29004-0

Specific Activity: 4134 KBq/mg

Radiochemical Purity: > 97%



Chemical Purity: not reported

## 2. Test Soil

One soil originating from [REDACTED] ( [REDACTED] France) was used (see [Table CA 7.1.1.1-16](#)). One week before start of the test the soil was sieved through a 2 mm sieve.

**Table CA 7.1.1.1-16: Physico-chemical properties of test soil**

Parameter	Results/Units
Soil	[REDACTED]
Geographic Location (City / State / Country)	[REDACTED] ( [REDACTED] ) France
Sampling Depth	0-10 cm
Soil Preparation	Sieved through a 2 mm sieve, air dried
Storage	Undisturbed soil cores were stored at 2 ± 4 °C. Two weeks prior to study initiation the soil cores were stored at room temperature and daylight. One week before application soil from the upper 10 cm of the soil cores was sieved soil and further stored in a plastic bag at room temperature
Texture Class <sup>A</sup>	Loamy Silt
Sand <sup>A</sup>	4.8%
Silt <sup>A</sup>	79.8%
Clay <sup>A</sup>	15.4%
pH (CaCl <sub>2</sub> )	6.2
pH (Water)	5.7
Organic Matter	1.57%
Organic Carbon	0.91%
Microbial Biomass (after application)	167.5 mg C <sub>mic</sub> /kg dry soil

<sup>A</sup> according to US classification

## B. STUDY DESIGN

### 1. Experimental Conditions

The test system consisted of 300 mL Erlenmeyer flasks which were closed with a trap attachment filled with soda lime and paraffin coated quartz wool. The trap attachment allows gas exchange but adsorbs <sup>14</sup>C<sup>14</sup>CO<sub>2</sub> and other volatile compounds.

The soil received a nominal test concentration of 30 µg/kg soil corresponding to the 2.3-fold amount derived from the single maximum recommended field use rate of 10 g/ha (assuming incorporation into the top 5 cm of soil and a bulk density of 1.5 g/mL).

The test substance was dissolved in acetone before dropwise application solution to 10 g soil aliquots (dry weight). After evaporation of the solvent, 90 g aliquots of soil were added to the Erlenmeyer flasks and the flasks were shaken to distribute the chemical in the entire soil sample. Soil moisture was adjusted to 40% of the maximum water holding capacity (MWHC). Afterwards, the flasks were closed with the trap attachments and incubated in the dark at 20 ± 2 °C for up to 141 days.

Microbial activity of the test soil was determined after application.



## 2. Sampling

Duplicate samples were collected and processed at DAT-0 and single samples were collected and processed after 1, 3, 7, 10, 15, 20, 27, 34, 41, 48, 58, 66, 78, 90, 99, 120 and 141 days of incubation. In addition, single samples were collected and stored at  $\leq -18^{\circ}\text{C}$  (repetition b).

## 3. Analytical Procedures

At the time of work-up,  $^{14}\text{CO}_2$  and other radioactive volatile compounds that might have formed in the incubation vessels were swept into the trap attachment with a stream of nitrogen while vigorously shaking the vessel. Carbon dioxide absorbed by soda lime was liberated with 6 N hydrochloric acid and trapped in a scintillation cocktail selective for binding of carbon dioxide using an air-tight assembly. The radioactivity content was determined by liquid scintillation counting (LSC).

The quartz wool with the paraffin oil dissolved in hexane was extracted with acetone to desorb volatile organic compounds. The radioactivity content was determined by LSC.

The entire soil sample in each test vessel was processed by a stepwise extraction procedure. The soil was extracted three times with 150 mL acetonitrile/water (4:1 v/v) for 60 min, each followed by centrifugation. The extracts were combined and analyzed for volume and radioactivity. The extracts were concentrated prior to analysis with HPLC/radiodetection and HPLC/UV-detection. Possible metabolites of the test substance occurring in the organic extracts were characterised via HPLC-co-chromatography after addition of a mixture containing different reference substances.

The determination of non-extractable residues (NER) was performed by combustion/LSC of aliquots of the air-dried and homogenized extracted soil.

The degradation kinetics of AEI15008 was determined assuming single-exponential first-order kinetics. For the calculation an Excel spread-sheet was used.

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II. RESULTS AND DISCUSSION

A. DATA

The results of the aerobic biotransformation of AE F115008-[phenyl-U-<sup>14</sup>C] in one European soil are summarized in Table CA 7.1.1.1-17.

Table CA 7.1.1.1-17: Degradation of AE F115008 in a loamy silt soil under aerobic conditions

Compound	Residues (% AR) on the following days after treatment (DAT)									
	0/a <sup>1</sup>	0/b <sup>1</sup>	1	3	7	10	15	20	27	34
AE F115008	103.43		65.80	28.33	10.83	6.82	5.49	2.61	3.14	2.55
M1										2.64
M2										
M3				2.76	7.11					
M4					6.29	8.87	9.08	11.00	11.56	12.67
AE F161778 <sup>4</sup>				2.01	6.28					
M5 <sup>4</sup>						6.15	5.49	5.04	4.85	3.55
M6 <sup>5</sup>				1.74	3.19					
AE F145740 <sup>5</sup>				5.08	4.19	2.31	3.73	1.36	3.35	2.16
M7 <sup>5</sup>						5.07	4.61	2.77	4.67	2.87
AE F145741				2.62	3.56					
M8										
M9						0.27		0.66		
AE F075736			2.00	4.47	12.14	50.76	43.88	44.86	27.40	23.97
Total extractable residues	107.04	105.82	93.80	97.10	91.19	83.22	72.27	65.22	57.87	49.37
<sup>14</sup> CO <sub>2</sub> <sup>2</sup>	0.07	0.05	0.07	0.23	2.07	0.36	0.81 <sup>3</sup>	0.12	18.51	3.66 <sup>3</sup>
Non-extractable residues	1.12	0.98	2.56	5.97	9.07	11.76	15.13	19.82	22.27	25.99
<b>Total % recovery</b>	<b>102.23</b>	<b>106.85</b>	<b>96.42</b>	<b>102.35</b>	<b>102.53</b>	<b>95.34</b>	<b>88.20</b>	<b>102.16</b>	<b>98.66</b>	<b>79.02<sup>3</sup></b>

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Table CA 7.1.1.1-17 (continued)

Compound	Residues (% AR) on the following days after treatment (DAT)								
	41	48	58	66	78	90	99	120	141
AE F115008	2.83	2.22	2.32	2.27	1.05	2.04	1.15	1.86	
M1									
M2									2.42
M3	2.14		1.55					2.44	2.06
M4	13.27	14.51	14.29	15.27	15.22	16.40	16.69	14.11	16.10
AE F161778 <sup>4</sup>	2.90	3.21	1.76		9.60				
M5 <sup>4</sup>									
M6 <sup>5</sup>	1.11		1.33	1.01					
AE F145740 <sup>5</sup>	3.26	3.20	2.99	3.92	3.21	3.98	2.88	1.38	
M7 <sup>5</sup>									
AE F145741									
M8						1.86			
M9									
AE F075736	19.15	16.15	17.39	19.17	9.61	5.59	5.94	4.39	2.21
Total extractable residues	44.65	39.28	36.52	33.63	29.70	27.86	26.68	24.18	22.32
<sup>14</sup> CO <sub>2</sub> <sup>2</sup>	27.57	30.37	25.51 <sup>3</sup>	35.43	35.49	29.91 <sup>3</sup>	37.77	37.11 <sup>3</sup>	34.20 <sup>3</sup>
Non-extractable residues	25.54	27.11	24.85	26.38	30.51	21.59	32.54	30.49	30.01
<b>Total % recovery</b>	<b>97.76</b>	<b>96.82</b>	<b>86.89<sup>3</sup></b>	<b>93.43</b>	<b>95.96</b>	<b>88.77<sup>3</sup></b>	<b>96.97</b>	<b>87.78</b>	<b>86.53<sup>3</sup></b>

<sup>1</sup> 1-2 h after application.

<sup>2</sup> Including volatile metabolites. The fraction assigned for less than 0.05% of the applied radioactivity throughout the entire study.

<sup>3</sup> Material balance <90% due to non-quantified <sup>14</sup>CO<sub>2</sub> work up losses.

<sup>4</sup> due to new chromatographic evaluation the amounts of AE F161778 and M5 were added up and assigned to the metabolite AE F161778 (see KCA 7.1.1.1/09)

<sup>5</sup> due to new chromatographic evaluation the amounts of AE F145740, M6 and M7 were added up and assigned to metabolite AE F145740 (see KCA 7.1.1.1/09)

**B. MATERIAL BALANCE**

The mean material balance was 94.96% of applied radioactivity (% AR) with a range from 86.53 – 97.76% AR. Material balance values < 90% were caused by non-quantified <sup>14</sup>CO<sub>2</sub> work-up losses.

**C. EXTRACTABLE AND NON-EXTRACTABLE RESIDUES**

Extractable residues decreased from 101.64 and 105.82 at study start (DAT-0) to 22.3% AR towards study end (DAT-141). Non-extractable radioactivity was increasing for about 40 days. After that period the share remained constant within a range of 24.9 to 32.5% of the applied activity.

**D. VOLATILES**

The maximum amount of <sup>14</sup>CO<sub>2</sub> detected was 37.77% of AR at DAT-99. At the end of the study values of <sup>14</sup>CO<sub>2</sub> were slightly lower due to losses during work up. No significant amounts of volatile organic compounds were detected in any soil (values being < 0.05% AR at all sampling intervals).

**E. DEGRADATION OF PARENT COMPOUND**

The amount of AE F115008 decreased from DAT-0 to DAT-20 from 103.43 to 2.61% AR and remained constant with values between 1 and 3% AR until DAT-120. At study end (DAT-141) AE F115008 was not detectable in the soil extract.

Four major degradation products were detected with the following maximum amounts: AE F075736 with a maximum amount of 54.5% at DAT-3, AE F145740 with up to 5.2% AR at DAT-7, M4 (relative retention time (RRT): 0.47-0.48 min.) with a maximum of 16.7% at DAT-99 and M5 (RRT:



0.53 – 0.54 min) with a maximum of 6.1% AR at DAT-10. It was not possible to identify M4 during the course of the study.

In addition, 9 minor degradation products were observed with the following maximum amounts: M1 (RRT: 0.04 – 0.05 min.) with up to 2.9% AR, M2 (RRT: 0.41 min) with up to 1.2% AR, M3 (RRT: 0.43 0.44 min.) with up to 7.4% AR, but found at one time point only, AE F161778 with up to 6.3% AR, M6 (RRT: 0.56 – 0.63 min) with up to 3.5% AR, M7 (RRT: 0.63 min.) with up to 5.9% AR, AE F145741 with up to 3.6% AR, M8 (RRT: 0.7 min.) with up to 1.9% AR, and M9 (RRT: 0.74 min.) with up to 3.3% AR.

Assuming single first order kinetics the DT<sub>50</sub> and DT<sub>90</sub> values for AE F115008 were calculated to be 1.8 days and 5.8 days, respectively (see Table CA 7.1.1.1-18)

Table CA 7.1.1.1-18: Degradation kinetics of AE F115008 in soil under aerobic conditions

Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]	R
SFO	1.8	5.8	0.9907

<sup>1</sup> SFO: single first order

### III- CONCLUSIONS

AE F115008 was rapidly degraded in soil under aerobic conditions in the dark in the laboratory with a calculated half-life of 1.8 days. Based on the study results the route of aerobic degradation of AE F115008 in soil is characterised by the formation of carbon dioxide and non-extractable residues as well as by the formation of four major degradation products in the extracts: AE F075736, AE F145740 and the unidentified products named M4 and M5. In addition, 9 minor degradation products were detected, of which two were identified as AE F161778 and AE F145741.

New assignment of the not further evaluated regions of interest in the soil degradation study of Iodosulfuron-methyl from [redacted] 2000: AGR08 (M-198118-01-1, KCA 7.1.1.1/ 08))

<b>Report:</b>	[redacted] 2012; M-438147-01
<b>Title:</b>	Statement - Iodosulfuron-methyl: Additional information to the not identified regions of interest in study AGR08 (M-198118-01-1): Degradation and metabolism of AE F115008 in one soil under standard conditions
<b>Report No:</b>	EnSA-12-0517
<b>Document No:</b>	M-438147-01-1
<b>Guidelines:</b>	not applicable
<b>GLP/GEP:</b>	not applicable

In the soil degradation study different peaks in the radio-HPLC chromatograms were assigned to different regions of interest and further identified via co-chromatography to different known metabolites. With the identification of new metabolites of iodosulfuron-methyl in new conducted e-fate study (KCA 7.1.1.1/06) the formerly unknown metabolite M4 could be assigned and identified as BCS-CW81253 (des-iodo-carbamoyl-guanidine) using HPLC-MS(/MS) and co-chromatography. A re-evaluation of the chromatograms resulted in a re-assignment of some regions of interest: the formerly so called region of interest M5 has been assigned to the metabolite AE F161778 and the



regions M6 and M7 has been assigned to the metabolite AE F145740. In Table CA 7.1.1.1-19 the amounts of the different regions of interest are expressed as percent of applied radioactivity (% of AR):

Table CA 7.1.1.1-19: Degradation of AE F115008 in a loamy silt soil under aerobic conditions

Compound	M4= BCS-CW81253 (des-iodo-carbamoyl-guanidine)	AE F161778 + M5	AE F145740 + M6 + M7	AE F145741	AE F075736	AE F115008
RRT	0.47 - 0.48	0.51 - 0.54	0.56 - 0.63	0.68 - 0.69	0.96 - 0.97	
Sampling Date						
0						103.43
1					28.00	65.89
3		2.01	6.82	2.62	54.44	28.95
7	2.29	6.28	8.73	3.56	52.14	10.83
10	8.87	6.13	7.57		50.76	6.82
15	9.08	4.49	8.34		43.88	5.49
20	11.00	4.04	4.08		44.86	2.61
27	11.56	4.85	8.02		27.40	3.14
34	12.62	2.55	7.03		23.97	2.55
41	13.27	2.90	4.37		19.17	2.83
48	14.51	3.21	3.29		16.5	2.22
58	14.29	1.76	4.32		12.29	2.32
66	15.27		4.93		11.17	2.27
78	15.22	0.60	3.24		9.61	1.05
90	16.40		3.98		3.59	2.04
99	16.69		2.88		5.94	1.15
120	14.11		1.38		4.39	1.86
141	16.10				2.73	

RRT: Relative retention time

Other regions of interest detected (M1, M2, M3, M8, M9) exceed not 3.27 % of AR besides at one sampling date M3 occurred in amounts of 7.38 % of AR

### Conclusions

Due to the reassignment of the regions of interest in the aerobic soil degradation study of iodosulfuron-methyl (AGR08, MCA 7.1.1.1-08) the amounts of some formerly identified metabolites have changed. In addition a formerly not identified metabolite of iodosulfuron-methyl could be identified as BCS-CW81253 (des-iodo-carbamoyl-guanidine).

Four degradation products remain to be considered as major, BCS-CW81253, AE F161778, AE F145740 and AE F075736.

### CA 7.1.2 Anaerobic degradation

The route of degradation of iodosulfuron-methyl in soil under anaerobic conditions in the dark in the laboratory was evaluated during the Annex I inclusion using one radiolabel position, [triazinyl-2-<sup>14</sup>C], and was accepted by the European Commission (SANCO/10166/2003-Final, 3 July 2003). It was concluded that degradation in soil under anaerobic conditions follows basically the same pathways as



under aerobic conditions, with generally lower levels of downstream metabolites formed after AE F075736.

The following study is included in the baseline dossier. No additional studies are submitted within this supplemental dossier for the iodosulfuron-methyl Annex I Renewal.

<b>Report:</b>	[redacted];1998;M-182261-01
<b>Title:</b>	Degradation in two soils under anaerobic conditions in the laboratory Co. AE F115008-triazinyl-2-14C
<b>Report No:</b>	C001285
<b>Document No:</b>	M-182261-01-1
<b>Guidelines:</b>	SETAC: 1, 1.2; Deviation not specified
<b>GLP/GEP:</b>	yes

### CA 7.1.1.3 Soil photolysis

The route of degradation of iodosulfuron-methyl-sodium on soil under photolytic conditions in the laboratory was evaluated during the Annex I inclusion using one radiolabel position, [phenyl-<sup>14</sup>C], and was accepted by the European Commission (SANCO/19166/2003-Final, 3 July 2003). The following study is included in the baseline dossier.

<b>Report:</b>	[redacted];1998;M-180263-01; Amended: 1998-07-01
<b>Title:</b>	The photodegradation of AE F115008 on soil surfaces
<b>Report No:</b>	C000105
<b>Document No(s):</b>	M-180263-02-1
<b>Guidelines:</b>	USEPA (=EPA): N 1-3, 6, 18, 18.2; Deviation not specified
<b>GLP/GEP:</b>	yes

An additional study has been performed for iodosulfuron-methyl-sodium and is submitted within this supplemental dossier for the iodosulfuron-methyl-sodium Annex I Renewal using another radiolabel position, triazinyl-2-<sup>14</sup>C.

<b>Report:</b>	[redacted];2014;M-474581-01
<b>Title:</b>	[triazinyl-2- <sup>14</sup> C]iodosulfuron-methyl-sodium phototransformation on soil
<b>Report No:</b>	ENSA/13-0490
<b>Document No(s):</b>	M-474581-01-1
<b>Guidelines:</b>	EC SANCO/11844/2010 Rev. 00; SANCO/11844/2010 Rev. 00; OECD Draft Test Guideline: Phototransformation of Chemicals on Soil Surfaces Fate, Transport and Transformation Test Guidelines, OPPTS 835.2410: Photodegradation on Soil, October 2008; not applicable
<b>GLP/GEP:</b>	yes

### Executive Summary

The photolytic route and rate of degradation of [triazinyl-2-<sup>14</sup>C]iodosulfuron-methyl-sodium (iodosulfuron-methyl-sodium) were studied on one soil under exposure to simulated sunlight and aerobic conditions in the laboratory for 14 days at 20 ± 2 °C and a soil moisture of about 50% of the maximum water holding capacity in comparison to samples incubated in the dark.





Soil	Source	Soil type	pH*	OC [%]
[REDACTED]	[REDACTED], Germany	silt loam	6.4	1.6

\* pH value was derived from aqueous 0.01 M CaCl<sub>2</sub> suspension

A nominal test concentration of 3.0 µg per test system (surface area of test system: 10.2 cm<sup>2</sup>, equivalent to 3.0 mg/kg soil dry weight) was applied based on a field use rate of iodosulfuron-methyl-sodium of 30 g/ha.

14 days of continuous irradiation corresponded to 39.0 solar summer days at [REDACTED], Arizona, USA. For comparison, additional samples were incubated in the dark for up to 34 days.

Mean material balances were 97.3% AR (range of 95.9 to 99.7% AR) for irradiated samples and 97.4% AR (range of 91.1 to 99.7% AR) for dark samples.

Formation of carbon dioxide and volatile organic compounds (VOC) was insignificant as demonstrated by values of ≤ 0.1% AR at all sampling intervals for irradiated samples. The formation of volatiles was not investigated for dark samples.

Extractable residues decreased from DAT-0 to DAT-14 from 97.9 to 91.9 and 94.6% AR in irradiated and dark samples, respectively. In the course of the additional incubation period for dark samples, extractable residues decreased further to 82.5% AR.

Non-extractable residues (NER) increased from 0.1% AR at DAT-0 to 5.9 and 4.1% AR at DAT-14 in irradiated and dark samples, respectively. NER increased further to 12.1% AR towards the additional sampling interval at DAT-34.

The amount of iodosulfuron-methyl-sodium decreased from 95.9% AR at DAT-0 to 58.9 and 19.4% AR at DAT-14 in irradiated and dark samples, respectively. At the additional dark sampling day (DAT-34) the amount of iodosulfuron-methyl-sodium accounted for 1.9% AR. Differences in the degradation could be explained by lower microbial activity in irradiated samples due to exposition.

Degradation of iodosulfuron-methyl-sodium in irradiated samples was accompanied by the formation of two major metabolites<sup>1</sup>: AE 0002166 (R1) with up to 5.8% AR (DAT-10 and 14) and AE F059411 (R2) with up to 23.6% AR (DAT-10). In addition, six minor degradation products were detected of which two were identified as AE 0000149 (R3) with up to 2.1% AR and AE F075736 (M1) with up to 4.3% AR (DAT-14).

In the dark samples, two major degradation products were detected during 14 days of incubation: AE F059411 (R2) with up to 9.5% AR (DAT-8) and AE F075736 (M1) with up to 52.4% AR (DAT-14). Furthermore, 9 minor degradation products were detected from which three were identified as AE 0000149 (R3) with up to 1.8% AR (DAT-14), BCS-CW81253 (ME) with up to 1.4% AR (DAT-14) and AE 002166 (R1) with up to 3.2% AR (DAT-8).

<sup>1</sup> Definition of major: > 10%, 2 x > 5% sequentially or > 5% and increasing at end of study



The total unidentified residues amounted to a maximum of 1.6% AR in irradiated samples and 11.1% AR in dark samples. No single component exceeded 0.8% AR and 4.5% AR in irradiated and dark samples, respectively, at any sampling interval.

During the additional incubation of dark samples until DAT-34, degradation products AE F059411 (R2), AE 0000119 (R3) and BCS-CW81253 (ME) increased to 23.9, 4.6 and 7.7% AR, respectively, while degradation products AE 0002166 (R1) and AE F075736 (M1) decreased to 0.5 and 30.3% AR, respectively. The total unidentified residues amounted to a maximum of 21.2% AR and no single component exceeded 5.9% AR.

The experimental DT50 and DT90 values of iodosulfuron-methyl-sodium in irradiated and dark samples were calculated using single first order (SFO) kinetics. The experimental half-lives for iodosulfuron-methyl-sodium were 18.1 and 7.1 days in the irradiated and dark samples, respectively. Due to the different microbial activity in irradiated and dark samples the net experimental photodegradation rate constant (difference between irradiated and dark samples) could not be determined. Based on the experimental DT50 value of 18.1 days for irradiated samples the DT50 of iodosulfuron-methyl-sodium under environmental conditions is calculated to be e.g. 50.4 solar summer days at [redacted] Arizona, USA, or 78.1 solar summer days at [redacted] Greece.

Because of the higher DT50 for iodosulfuron-methyl-sodium in presence of light compared to in the dark, it is concluded that the degradation of iodosulfuron-methyl-sodium is driven by microbial degradation under typical conditions in the environment and photodegradation plays no role in the overall fate of iodosulfuron-methyl-sodium.

### 1. MATERIALS AND METHODS

#### A. MATERIALS

##### 1. Test Item

[Triazinyl-2-<sup>14</sup>C]Iodosulfuron-methyl-sodium  
Sample ID: KML 912  
Specific Activity: 95 MBq/mg (106.87 Ci/mg)  
Radiochemical Purity: > 98%  
Chemical Purity: > 98%

##### 2. Test Soil

One soil was used (see Table CA 7.1.1.3.1), which was sampled freshly from the field and sieved to a particle size of < 2 mm. The soil is representative for agricultural use areas.

Table CA 7.1.1.3- 1 Physico-chemical properties of test soil

Parameter	Results / Units
Soil Designation	[redacted] 4a
Geographic Location	
City	[redacted]
State	North [redacted]-Westphalia
Country	Germany



Parameter	Results / Units
Soil Designation	██████████ 4a
Soil Taxonomic Classification (USDA)	loamy, mixed, mesic, Typic Argudalf
Soil Series	no information available
Textural Class (USDA)	silt loam
Sand [50 µm – 2 mm]	19%
Silt [2 µm – 50 µm]	64%
Clay [< 2 µm]	17%
pH (0.01 M CaCl <sub>2</sub> , 1/2)	6.4
pH (Water, 1/1)	6.6
pH (Saturated Paste)	6.7
pH (1 N KCl, 1/1)	6.1
Organic Carbon	4.6%
Organic Matter <sup>1</sup>	2.8%
Cation Exchange Capacity [meq/100 g]	11
Water Holding Capacity maximum (MWHC) at 0.1 bar (pF 2.0)	55.0% H <sub>2</sub> O ad 100 g DW 35.2%
Bulk Density (disturbed) [g cm <sup>3</sup> ]	1.14
Microbial Biomass (start of test)	481 mg microbial carbon per g soil DW

<sup>1</sup> % organic matter = % organic carbon x 1.724

DW: dry weight

USDA: United States Department of Agriculture

## B. STUDY DESIGN

### 1. Experimental Conditions

The test system for photolytic degradation on soil consisted of quartz glass vessels (36 mm inner diameter, 35 mm height, inner surface area 10.2 cm<sup>2</sup>). The upper edge of a vessel is beaded and provided with a ground joint and a glass neck with ground joint (NS 10) is attached to the side of the wall. Each vessel was closed with round quartz glass covers being 3 mm thick (sealed with metallic clips). Additionally, the glass neck of each irradiated test system was closed with a trap attachment (permeable for oxygen), containing soda lime for absorption of carbon dioxide and a polyurethane (PU) foam plug for adsorption of volatile organic compounds. The glass necks of the dark test systems were closed with a glass plug.

For preparation of the test systems, 3 g dry weight equivalents of the sieved soil were weighed into each test vessel. Soil moisture was adjusted to 50 ± 5% of the maximum water holding capacity (MWHC) for the individual test systems by addition of de-ionized water. The test vessels were then closed with covers and fitted with trap attachments (irradiated samples) or gas plugs (dark samples).

A nominal test concentration of 3.0 µg per test system (surface area of test system: 10.2 cm<sup>2</sup>; equivalent to 3.0 mg/kg soil dry weight) was applied. The test item was applied dropwise onto the soil surface of the vessels in 50 µL methanol using a pipette.

The irradiated test systems were placed in a Suntest® unit containing a xenon lamp simulating natural sunlight. The light emission was filtered with a 290 nm cut-off UV-filter which eliminated all



wavelengths < 290 nm. The temperature inside the Suntest® unit was maintained by a cooling plate connected to a refrigerated circulating chiller. The intensity of the xenon lamp was determined at the beginning and the end of the overall test period using an irradiance monitor and calculated as 999 W/m<sup>2</sup> for 300 to 2450 nm. The radiation intensity and exposure time under experimental conditions can be related to natural solar radiation at e.g. ██████████ (Arizona, USA), representing extraordinary conditions. At this light intensity, it takes 8.6 hours in the Suntest® unit to equal one solar summer day at ██████████. Therefore, the equivalent of 30 solar days is achieved by this design using continuous irradiation for 258 hours or about 10.8 days.

The dark test systems were incubated in a walk-in climatic chamber in the dark for 34 days at 20 ± 2°C and a soil moisture of 50% of the maximum water holding capacity.

## 2. Sampling

Seven sampling intervals were distributed over the entire incubation period of 14 days. Duplicate samples were processed and analyzed 0, 1, 3, 6, 8, 10 and 14 days after treatment (DAT) for both irradiated and dark samples. To obtain further information on the degradation pathway, duplicate dark samples were additionally analyzed at DAT-34. Microbial soil biomass was determined once for the test batch at the beginning of the study.

## 3. Analytical Procedures

Carbon dioxide absorbed by soda lime was liberated with 18% aqueous hydrochloric acid and trapped in a scintillation cocktail selective for binding of carbon dioxide using an air-tight assembly. The radioactivity content was determined by liquid scintillation counting (LSC).

The PU foam plugs were extracted with ethyl acetate in an ultrasonic bath to desorb volatile organic compounds. The radioactivity content was determined by LSC.

The entire soil of each test system was extracted three times at ambient temperature using a mechanical shaker followed by one accelerated extraction using a microwave at 70 °C with a magnetic stirrer. The extraction solvent for all steps was acetonitrile/water 4/1 (v/v). After each extraction step, extract and soil were separated by centrifugation (4550 × g) and decantation. The radioactivity content of the combined ambient soil extracts and the microwave soil extract was determined by LSC. Aliquots of the soil extracts were combined. Aliquots thereof were concentrated and analysed by reversed phase HPLC radiodetection. The limit of detection and limit of quantitation for HPLC radiodetection analysis of the combined soil extracts were about 0.3 and 0.9% AR, respectively.

The exhaustive extracted soils were air-dried and non-extractable residues were determined by combustion/LSC.

Test item identity in stock solution was confirmed by HPLC-MS(/MS) and <sup>1</sup>H-NMR. Degradation products in soil extracts were identified by HPLC co-chromatography with reference items, profile comparison and HPLC-MS(/MS) including accurate mass determination.



The data for the test item were evaluated according to the FOCUS guidance document on degradation kinetics<sup>2</sup> using the software KinGUI 2. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. For the evaluation of the data three different kinetic models (SFO, FOMC and DFOP) were tested in order to determine the best-fit kinetic model. The best-fit kinetic model was selected on the basis of the chi<sup>2</sup> scaled-error criterion and on the basis of a visual assessment of the goodness of the fits (diagrams of measured and calculated values vs. time, diagrams of residuals vs. time). The initial total recovery (material balance) at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit, the value was allowed to be estimated by the models. DT<sub>50</sub> and DT<sub>90</sub> values were calculated from the resulting kinetic parameters.

## II. RESULT AND DISCUSSION

Results indicated that the anticipated standardized conditions were maintained over the duration of the laboratory study.

### A. DATA

Table CA 7.1.1.3- 2: Photodegradation of Iodosulfuron-methyl-sodium on soil [redacted] and [redacted] 4a in irradiated samples (values expressed as % AR)

Compound	Replicate No.	DAT						
		0	1	3	6	8	10	14
Iodosulfuron-methyl-sodium	A	96.9	88.6	85.0	83.5	66.8	56.3	58.2
	B	96.8	79.9	76.2	74.4	58.9	55.7	59.6
	Mean	95.9	74.9	80.6	61.5	62.8	56.0	58.9
B	A	n.d.	n.d.	n.d.	0.9	n.d.	0.6	0.8
	B	n.d.	n.d.	n.d.	n.d.	0.7	0.7	0.9
	Mean				0.5	0.4	0.6	0.8
R2 (AE F059411)	A	n.d.	20.0	6.0	35.4	20.0	22.0	19.0
	B	n.d.	15.5	14.5	9.9	25.9	25.3	17.8
	Mean		14.7	10.3	22.3	23.0	23.6	18.4
R3 (AE 0000119)	A	n.d.	n.d.	n.d.	0.9	1.4	1.5	2.1
	B	n.d.	n.d.	n.d.	0.8	1.0	1.2	2.0
	Mean				0.8	1.2	1.4	2.1
H	A	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	B	n.d.	n.d.	n.d.	n.d.	0.8	n.d.	n.d.
	Mean					0.4		
R1 (AE 002166)	A	1.0	1.9	3.1	4.1	4.4	5.9	5.8
	B	1.7	2.0	3.0	4.3	4.6	5.6	5.8
	Mean	0.9	3.4	3.1	4.2	4.5	5.8	5.8
K	A	n.d.	1.6	n.d.	n.d.	n.d.	n.d.	n.d.
	B	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	Mean		0.8					
M1 (AE F058736)	A	0.7	n.d.	2.4	1.9	3.7	3.6	3.7
	B	0.6	1.7	2.1	3.2	2.6	3.2	4.8
	Mean	0.6	0.8	2.3	2.6	3.2	3.4	4.3
L	A	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	B	n.d.	n.d.	n.d.	0.6	n.d.	n.d.	n.d.
	Mean				0.3			

<sup>2</sup> FOCUS (2006). Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. Report of the FOCUS work group on degradation kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp.



Compound	Replicate No.	DAT						
		0	1	3	6	8	10	14
Diffuse Residues	A	n.d.	0.6	n.d.	0.4	0.2	0.5	0.2
	B	n.d.	0.3	0.5	0.2	n.d.	0.2	0.3
	<b>Mean</b>	<b>n.d.</b>	<b>0.5</b>	<b>0.3</b>	<b>0.3</b>	<b>0.1</b>	<b>0.4</b>	<b>0.7</b>
Sum of Unid./Diff. Residues	A	< LOD	2.2	< LOD	1.3	0	1.1	1.0
	B	< LOD	0.3	0.5	0.7	0.6	0.9	2.2
	<b>Mean</b>	<b>&lt; LOD</b>	<b>1.2</b>	<b>0.3</b>	<b>1.0</b>	<b>0.9</b>	<b>1.0</b>	<b>1.6</b>
Total Extractable Residues <sup>1</sup>	A	96.7	95.6	96.5	92.1	96.6	90.5	89.9
	B	98.2	93.3	96.3	92.8	94.5	92.0	92.2
	<b>Mean</b>	<b>97.5</b>	<b>94.5</b>	<b>96.4</b>	<b>92.2</b>	<b>95.6</b>	<b>91.2</b>	<b>91.0</b>
Carbon Dioxide <sup>1</sup>	A	n.a.	<0.1	<0.1	0.1	<0.1	<0.1	0.1
	B	n.a.	n.d.	<0.1	n.d.	<0.1	<0.1	0.1
	<b>Mean</b>							
Volatile Organic Compounds <sup>1</sup>	A	n.a.	0.1	<0.1	0.1	0.1	0.1	0.1
	B	n.a.	<0.1	<0.1	0.1	0.1	0.1	0.1
	<b>Mean</b>							
Non-Extractable Residues <sup>1</sup>	A	0.1	1.2	0.9	3.8	3.4	5.6	6.2
	B	0.1	2.5	2.5	3.7	4.7	5.5	6.2
	<b>Mean</b>	<b>0.1</b>	<b>1.6</b>	<b>2.2</b>	<b>3.4</b>	<b>4.1</b>	<b>5.5</b>	<b>5.9</b>
Total Recovery <sup>1</sup>	A	96.7	97.1	98.4	95.9	100	99.9	96.1
	B	98.3	95.6	98.9	95.9	99.3	97.5	97.8
	<b>Mean</b>	<b>97.5</b>	<b>96.1</b>	<b>98.6</b>	<b>95.9</b>	<b>99.7</b>	<b>96.7</b>	<b>97.0</b>

n.d.: not detected, n.a.: not analyzed, DAT: days after treatment

<sup>1</sup> Values taken from Material Balance Table in Report

The degradation products ME (BCS-GW81253), I, F and G were not detected in irradiated samples

Table CA 7.1.1.3- 3: Degradation of Iodosulfuron-methyl-sodium on soil [redacted] am [redacted] 4a in dark samples (values expressed as % OR)

Compound	Repl. No.	DAT								
		0	1	3	6	8	10	14	34	
Iodosulfuron-methyl-sodium	A	94.9	79.9	78.3	62	43.6	36.9	16.2	2.2	
	B	96.8	81.1	76.3	57.5	36.6	38.1	22.6	1.6	
	<b>Mean</b>	<b>95.9</b>	<b>80.5</b>	<b>77.3</b>	<b>60.6</b>	<b>40.1</b>	<b>37.5</b>	<b>19.4</b>	<b>1.9</b>	
B	A	n.d.	n.d.	n.d.	1.4	n.d.	n.d.	n.d.	2.0	
	B	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	1.9	
	<b>Mean</b>				<b>0.7</b>				<b>2.0</b>	
R2 (AE F05946)	A	n.d.	4.3	3.5	2.4	8.3	7.3	9.0	24.1	
	B	n.d.	4.9	4.0	5.3	10.7	6.9	6.9	23.7	
	<b>Mean</b>		<b>4.1</b>	<b>3.7</b>	<b>3.9</b>	<b>9.5</b>	<b>7.1</b>	<b>8.0</b>	<b>23.9</b>	
R3 (AE 000119)	A	n.d.	n.d.	n.d.	n.d.	0.6	0.8	2.2	4.8	
	B	n.d.	n.d.	n.d.	n.d.	0.8	0.9	1.3	4.4	
	<b>Mean</b>					<b>0.7</b>	<b>0.8</b>	<b>1.8</b>	<b>4.6</b>	
BCS-GW81253 (ME, des-iodo-carbamoyl-guanidine)	A	n.d.	n.d.	n.d.	n.d.	0.3	0.5	2.0	7.5	
	B	n.d.	n.d.	n.d.	n.d.	0.4	0.6	0.9	7.9	
	<b>Mean</b>					<b>0.4</b>	<b>0.5</b>	<b>1.4</b>	<b>7.7</b>	
F	A	n.d.	n.d.	n.d.	n.d.	0.4	n.d.	n.d.	0.9	
	B	n.d.	n.d.	n.d.	n.d.	0.6	n.d.	n.d.	0.6	
	<b>Mean</b>					<b>0.5</b>			<b>0.8</b>	
G	A	n.d.	n.d.	n.d.	n.d.	1.5	1.0	2.6	2.4	
	B	n.d.	n.d.	n.d.	n.d.	1.8	0.9	1.2	2.4	
	<b>Mean</b>					<b>1.7</b>	<b>1.0</b>	<b>1.9</b>	<b>2.4</b>	
H	A	n.d.	n.d.	n.d.	n.d.	1.3	1.3	4.0	5.8	
	B	n.d.	n.d.	n.d.	0.6	1.2	1.1	1.8	5.9	
	<b>Mean</b>				<b>0.3</b>	<b>1.2</b>	<b>1.2</b>	<b>2.9</b>	<b>5.9</b>	
I	A	n.d.	n.d.	n.d.	n.d.	1.0	n.d.	0.6	n.d.	
	B	n.d.	n.d.	n.d.	n.d.	1.3	n.d.	n.d.	0.4	
	<b>Mean</b>					<b>1.1</b>		<b>0.3</b>	<b>0.2</b>	
R1 (AE 002166)	A	1.0	3.2	1.6	2.4	3.2	2.3	1.9	0.5	



Compound	Repl. No.	DAT							
		0	1	3	6	8	10	14	34
	B	0.7	2.7	2.1	2.7	3.3	2.1	1.9	0.4
	Mean	0.9	3.0	1.8	2.5	3.2	2.2	1.9	0.5
	A	n.d.	n.d.	1.1	2.7	3.3	3.8	4.2	2.2
K	B	n.d.	n.d.	1.6	3.3	3.2	3.7	4.9	2.4
	Mean			1.3	3.0	3.2	3.7	4.5	2.3
	A	0.7	2.8	12.7	25.7	35.4	40.3	50.6	30.2
M1 (AE F075736)	B	0.6	2.9	14.1	26.8	35.1	41.7	44.3	30.5
	Mean	0.6	2.9	13.4	26.3	35.2	41.0	52.4	30.3
	A	< LOD	0.1	0.7	0.3	LOD	< LOD	< LOD	< LOD
Diffuse Residues	B	< LOD	< LOD	0.6	0.2	0.1	< LOD	< LOD	0.2
	Mean	< LOD	< LOD	0.7	0.3	< LOD	< LOD	< LOD	LOD
	A	< LOD	0.1	1.7	4.5	8.8	6.5	13.3	20.8
Sum of Unid./Diff. Residues	B	< LOD	< LOD	2.3	4.1	8.5	6.2	8.9	21.6
	Mean	< LOD	< LOD	2.0	4.3	8.1	6.0	11.1	21.2
	A	96.7	90.4	97.8	97.7	98.8	97.2	93.3	82.8
Total Extractable Residues <sup>1</sup>	B	98.2	90.6	98.0	97.3	95.0	96.0	95.9	82.4
	Mean	97.5	90.5	98.2	97.5	96.9	95.1	94.6	82.5
	A	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Carbon Dioxide <sup>1</sup>	B	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
	Mean								
	A	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Volatile Organic Compounds <sup>1</sup>	B	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
	Mean								
	A	0.1	0.6	1.5	2.8	3.1	4.5	12.0	
Non-Extractable Residues <sup>1</sup>	B	0.1	0.6	1.5	2.1	2.8	3.3	3.7	12.2
	Mean	0.1	0.6	1.5	2.1	2.8	3.2	4.1	12.1
	A	96.7	91.0	99.2	99.9	101.6	99.3	97.9	94.7
Total Recovery <sup>1</sup>	B	98.3	91.2	100.2	99.5	97.7	99.3	99.6	94.3
	Mean	97.5	91.1	99.7	99.7	99.7	98.3	98.7	94.5

n.d.: not detected, n.a.: not analyzed, DAT = days after treatment

<sup>1</sup> Values taken from Material Balance Table in Report

The degradation product L was not detected in dark samples

**B. MATERIAL BALANCE**

Mean material balances were 97.3% AR (range of 95.9 to 99.7% AR) for irradiated samples and 97.4% AR (range of 91.1 to 99.7% AR) for dark samples.

**C. EXTRACTABLE AND NON-EXTRACTABLE RESIDUES**

Extractable residues decreased from DAT-0 to DAT-14 from 97.5 to 91.0 and 94.6% AR in irradiated and dark samples, respectively. In the course of the additional incubation of dark samples extractable residues decreased further to 82.5% AR at DAT-34.

Non-extractable residues (NER) increased from 0.1% AR at DAT-0 to 5.9 and 4.1% AR at DAT-14 in irradiated and dark samples, respectively. NER in dark samples increased to further to 12.1% AR until DAT-34.

**D. VOLATILES**

Formation of carbon dioxide and volatile organic compounds (VOC) was insignificant as demonstrated by values of ≤ 0.1% AR at all sampling intervals for irradiated samples. For the dark samples the formation of volatiles was not determined.

**E. DEGRADATION OF PARENT COMPOUND**



The amount of iodosulfuron-methyl-sodium decreased from 95.9% AR at DAT-0 to 58.9 and 19.4% AR at DAT-14 in irradiated and dark samples, respectively. At the additional dark sampling day (DAT-34) the amount of iodosulfuron-methyl-sodium accounted for 1.9% AR. Differences in the rate of degradation could be explained by minor microbial activity in irradiated samples due to exposition. However, the route of degradation of iodosulfuron-methyl-sodium differed only slightly between irradiated and dark samples.

Degradation of iodosulfuron-methyl-sodium in irradiated samples was accompanied by the formation of two major metabolites<sup>1</sup>: AE 0002166 (R1) with up to 5.8% AR (DAT-10 and DAT-14) and AE F059411 (R2) with up to 23.6% AR (DAT-10). In addition, six minor degradation products were detected of which two were identified as AE 0000119 (R3) with up to 2.1% AR and AE F075736 (M1) with up to 4.3% AR (DAT-14).

In the dark samples, two major degradation products were detected during 14 days of incubation: AE F059411 (R2) with up to 9.5% AR (DAT-8) and AE F075736 (M1) with up to 52.4% AR (DAT-14). Furthermore, 9 minor degradation products were detected from which three were identified as AE 0000119 (R3) with up to 1.8% AR (DAT-14), BCS-CW81253 (des-iodo-carbamoyl-guanidine, ME) with up to 1.4% AR (DAT-14) and AE 0002166 (R1) with up to 3.2% AR (DAT-8).

The total unidentified residues amounted to a maximum of 1.6% AR in irradiated samples and 11.1% AR in dark samples. No single component exceeded 0.8% AR and 4.3% AR in irradiated and dark samples, respectively, at any sampling interval.

During the additional incubation of dark samples until DAT-34, degradation products AE F059411 (R2), AE 0000119 (R3) and BCS-CW81253 (des-iodo-carbamoyl-guanidine, ME) increased to 23.9, 4.6 and 7.7% AR, respectively, while degradation products AE 0002166 (R1) and AE F075736 (M1) decreased to 0.5 and 30.3% AR, respectively. The total unidentified residues amounted to a maximum of 21.2% AR and no single component exceeded 5.9% AR.

The best-fit DT<sub>50</sub> values of iodosulfuron-methyl-sodium in irradiated and dark samples were obtained using the SFO kinetic model (see Table CA 7.1.1.3.4).

Table CA 7.1.1.3- 4: Photodegradation kinetics of Iodosulfuron-methyl-sodium on soil [redacted] am [redacted] 4a

Test System	SFO					
	DT <sub>50</sub> (exp.) [days]	DT <sub>90</sub> (exp.) [days]	Chi <sup>2</sup> Error [%]	Rate Constant [days <sup>-1</sup> ]	DT <sub>50</sub> under natural conditions in [redacted], USA [days]	Net Photodegradation Rate Constant <sup>1</sup> / DT <sub>50</sub> [days <sup>-1</sup> / days]
Irradiated	18.1	60.2	8.0	0.04	50.4 ([redacted], USA) 78.1 ([redacted], Greece)	Degradation under dark conditions was faster than under irradiated conditions
Dark	7.1	23.6	5.6	0.10	no conversion	

<sup>1</sup> net rate constant = rate constant of irradiated samples – rate constant of dark samples





### III. CONCLUSIONS

Iodosulfuron-methyl-sodium was well degraded on soil under exposure to simulated sunlight and rapidly degraded in the dark under aerobic conditions in the laboratory. The experimental half-lives for iodosulfuron-methyl-sodium were 18.1 and 7.1 days in the irradiated and dark samples, respectively. Due to the different microbial activity in irradiated and dark samples, the net experimental photodegradation rate constant (difference between irradiated and dark samples) could not be determined. Based on the experimental DT<sub>50</sub> value of 18.1 days for irradiated samples, the DT<sub>50</sub> of Iodosulfuron-methyl-sodium under environmental conditions is calculated to be e.g. 50 solar summer days at ██████████, Arizona, USA, or 78.1 solar summer days at ██████████, Greece. The route of degradation in irradiated and dark samples differed slightly with regard to maximum amounts of degradation products.

Three major metabolites were identified in irradiated and dark samples, respectively, with the following maximum amounts: AE 0002166 with 5.8% AR in irradiated samples and 3.2% AR in dark samples, AE F075736 with 4.3% AR in irradiated samples and 52.4% in dark samples, AE F059411 with 23.6% AR in irradiated samples and 9.5% AR in dark samples. Degradation product BCS-CW81253 was found in dark samples only with 1.4% AR at DAT-14 and 7.7% AR at additional sampling day DAT-34.

These results show that photodegradation processes play no role in the degradation of iodosulfuron-methyl-sodium on soil. Faster degradation in dark samples could be explained by decreased microbial activity and water content in irradiated samples due to light exposition.

#### CA 7.1.2 Rate of degradation in soil

Iodosulfuron-methyl-sodium was rapidly degraded in soil under aerobic and anaerobic conditions in the laboratory as well as under field conditions. The DT<sub>50</sub> and formation fractions of iodosulfuron-methyl-sodium and its major degradation products under aerobic conditions in the laboratory are listed in Tables CA 7.1.2.1 and -2.

Table CA 7.1.2.1: Overall summary of DT<sub>50</sub> values for degradation of iodosulfuron-methyl and its major degradation products (laboratory studies, normalised)

Compound	Laboratory Aerobic Conditions		
	DT <sub>50</sub> [days]		
	geomean	min.	max.
AE F115008	2.1**	0.6	12.2***
AE F075736	25.1**	10.6	66.7
AE F45740	51.3	37.1	81.4***
AE F145741	11.1	2.2	43.0***
AE F161978	9.2	1.8	17.5***
BCS-CW81253	32.1	9.5	115.8
AE 000119	10.7	2.5	91.0
AE F059411	172.5	139.4	242.3***
AE 0002166*	7.5	4.7	10.1

\*: not normalised      \*\*: median  
 \*\*\*: geometric mean of several testing result generated with one soil

**Table CA 7.1.2- 2: Overall summary of formation fractions derived from the different data sets from laboratory studies**

	IMS → AE F075736	IMS → AE F145741	IMS → AE F145740	AE F075736 → AE F161778	AE F075736 → AE F000119	AE F075736 AE F059411	AE F161778 → BCS-CW81253	AE F145740 → AE F000119
Minimum	0.68	0.03	0.02	0.27	0.01	0.01	0.30	1.00
Maximum	1.00	0.68	0.08	1.00	0.38	0.74	1.00	1.00
Arithmetic mean	0.83	0.06	0.04	0.50	0.27	0.40	0.81	0.60

To derive more realistic DT<sub>50</sub>-values of iodosulfuron-methyl-sodium and a more realistic formation fraction for its main metabolite AE F075736 field studies in Europe and North America has been performed. Results are listed in Tables CA 7.1.2- 3 and - 4.

**Table CA 7.1.2- 3: Overall summary of DT<sub>50</sub> values for degradation of iodosulfuron-methyl and its main metabolite AE F075736 (field studies, normalised)**

Compound	Normalised to 20°C and field capacity		
	geomean/median	min.	max.
AE F115008	3.3*	0.6	10.3
AE F075736	14.2*	5.0	35.6

\*: geomean    \*\*: median

**Table CA 7.1.2- 4: Overall summary of formation fractions from AE F115008 to AE F075736 derived from different field studies**

	IMS → AE F075736
Minimum	0.31
Maximum	1.00
Arithmetic mean	0.61

More details are given in sections CA 7.1.2.1 and CA 7.1.2.2.

**CA 7.1.2.1 Laboratory studies**

**CA 7.1.2.1.1 Aerobic degradation of the active substance**

The rates of degradation of iodosulfuron-methyl-sodium and its metabolites in soil under aerobic conditions in the dark in the laboratory were evaluated during the Annex I inclusion using two radiolabel positions, [phenyl-UL-<sup>14</sup>C] and [triazinyl-2-<sup>14</sup>C], and was accepted by the European



Commission (SANCO/10166/2003-Final, 3 July 2003). The following studies are included in the baseline dossier:

<b>Report:</b>	[redacted];1998;M-180556-01
<b>Title:</b>	Degradation in four agricultural soils at room temperature under aerobic conditions in the laboratory AE F115008-triazinyl-2-14C
<b>Report No:</b>	C000375
<b>Document No:</b>	M-180556-01-1
<b>Guidelines:</b>	BBA: IV, 4-1; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted];1998;M-181517-01
<b>Title:</b>	Degradation in two loam soils under standard conditions in the laboratory AE F115008-triazinyl-2-14C
<b>Report No:</b>	C000947
<b>Document No:</b>	M-181517-01-1
<b>Guidelines:</b>	BBA: IV, 4-1; USEPA (=EP): N 162-1; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted];1998;M-180558-01
<b>Title:</b>	Degradation of a loamy sand soil at room temperature under non-sterile and sterile aerobic conditions in the laboratory AE F115008-triazinyl-2-14C
<b>Report No:</b>	C000375
<b>Document No:</b>	M-180558-01-1
<b>Guidelines:</b>	BBA: IV, 4-1; USEPA (=EP): 161-1; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted];1998;M-181175-01
<b>Title:</b>	Degradation in a silty loam soil at different temperature and soil moisture under aerobic conditions in the laboratory AE F115008-triazinyl-2-14C
<b>Report No:</b>	C000744
<b>Document No:</b>	M-181175-01-1
<b>Guidelines:</b>	BBA: IV, 4-1; USEPA (=EP): N 162-1; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted];1998;M-181732-01
<b>Title:</b>	Degradation in two soils at room temperature and two moisture conditions under aerobic conditions in the laboratory AE F115008-triazinyl-2-14C
<b>Report No:</b>	C001065
<b>Document No:</b>	M-181732-01-1
<b>Guidelines:</b>	SETAC, 1.1; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted];1998;M-181415-01
<b>Title:</b>	Kinetic evaluation of the aerobic soil metabolism of AE F115008 in four standard soils using TopFit 2.0 (addendum) Code: AE F115008
<b>Report No:</b>	C000888
<b>Document No:</b>	M-181415-01-1
<b>Guidelines:</b>	Deviation not specified
<b>GLP/GEP:</b>	no

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<b>Report:</b>	[redacted];1998;M-181639-01
Title:	Kinetic evaluation of the aerobic soil metabolism of AE F115008 in two different soils using TopFit 2.0 (addendum) Code: AE F115008
Report No:	C001014
Document No:	M-181639-01-1
<b>Guidelines:</b>	Deviation not specified
<b>GLP/GEP:</b>	no

<b>Report:</b>	[redacted];1998;M-181413-01
Title:	Kinetic evaluation of the aerobic soil metabolism of AE F115008 in loamy and sandy soils (LS S) using TopFit 2.0 (addendum) Code: AE F115008
Report No:	C000887
Document No:	M-181413-01-1
<b>Guidelines:</b>	Deviation not specified
<b>GLP/GEP:</b>	no

<b>Report:</b>	[redacted];1998;M-181637-01
Title:	Kinetic evaluation of the aerobic soil metabolism of AE F115008 in a silt loam soil using TopFit 2.0 (addendum) Code: AE F115008
Report No:	C001013
Document No:	M-181637-01-1
<b>Guidelines:</b>	Deviation not specified
<b>GLP/GEP:</b>	no

<b>Report:</b>	[redacted];1998;M-181641-01
Title:	Kinetic evaluation of the aerobic soil metabolism of AE F115008 in different soils using TopFit 2.0 (addendum) Code: AE F115008
Report No:	C001014
Document No:	M-181641-01-1
<b>Guidelines:</b>	Deviation not specified
<b>GLP/GEP:</b>	no

An additional study (M-198118-01-1, [redacted] 2000, see MCA 7.1.1.1) has been performed for iodosulfuron-methyl-sodium and is submitted within this supplemental dossier for the iodosulfuron-methyl-sodium Annex I Renewal.

<b>Report:</b>	[redacted];2000;M-198118-01
Title:	Degradation and metabolism of AE F115008 in one soil under standard conditions
Report No:	C009125
Document No(s):	M-198118-01-1
<b>Guidelines:</b>	BBA: IC 4-1; USEPA (EPA): N § 161-1; Deviation not specified
<b>GLP/GEP:</b>	yes

Assuming single first order kinetics the DT<sub>50</sub> and DT<sub>90</sub> values for AE F115008 were calculated to be 1.8 days and 8 days, respectively.

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<b>Report:</b>	██████████;2013;M-447102-03; Amended: 2015-04-14
<b>Title:</b>	Kinetic evaluation of laboratory aerobic soil degradation of iodosulfuron-methyl-sodium and its metabolites according to FOCUS kinetics
<b>Report No:</b>	EnSa-13-0100
<b>Document No:</b>	M-447102-03-1
<b>Guidelines:</b>	<b>FOCUS kinetics (2006)</b>
<b>GLP/GEP:</b>	<b>no</b>

<b>Report:</b>	██████████;2014;M-491200-01
<b>Title:</b>	Supplementary information for the kinetic evaluation of laboratory aerobic soil degradation of iodosulfuron-methyl-sodium and its metabolites
<b>Report No:</b>	EnSa-14-0811
<b>Document No(s):</b>	M-491200-01-1
<b>Guidelines:</b>	<b>not applicable;not applicable</b>
<b>GLP/GEP:</b>	<b>no</b>

A kinetic evaluation of the degradation behaviour of iodosulfuron-methyl-sodium and its major metabolites in soil under aerobic conditions in the laboratory has been performed according to FOCUS kinetics (2006) to derive kinetic parameters suitable for modelling purpose and environmental risk assessment using the ██████████ Study (M-198118-01-1 (KCA 7.1.2.1.1/08) and its additional metabolite assignment information (M-426147-01-1 (KCA 7.1.2.1.1/09)), the baseline dossier submitted studies (KCA 7.1.2.1.1/1 to 5) together with additional informations on metabolite new assignment (M-471682-01-1 (KCA 7.1.2.1.1/07)).

**Executive Summary**

The kinetic analysis of soil residue data from the aerobic soil degradation studies as described above, was performed with the software KinGUI 2 according to FOCUS kinetics (2006) to derive

- half-lives for iodosulfuron-methyl-sodium and its degradation products AE F075736, AE F145741, AE F161778, des-iodo-carbamoyl-guanidine (BCS-CW81253), AE 0000119, AE F059411 and AE F145740
- formation fractions for degradation products which are suitable for modelling purpose.

The most appropriate kinetic model for modelling purpose for the degradation of iodosulfuron-methyl-sodium was single first order in soils S 2.2, LS 2.2, SL V, SL 2, LS S, CL L, SL S and CL B (20 °C, 50% MWHC), first order multi compartment for soils SL FF, CT (20 °C, 50% MWHC), CL B (20 °C, 25% MWHC) and ██████████ and dual first order in parallel for soil CT (20 °C, 25% MWHC), respectively, under aerobic conditions in the dark in the laboratory at different temperatures (20 and 10 °C), soil moistures (25, 30, 40 and 50% of the maximum water holding capacity) and test concentrations (20.0 µg/kg for soils SL V, LS 2.2, S 2.1, SL 2 und LS S and 30.0 µg/kg for soils SL S, CL L, FF, C T and CL B). Single first order was used for modelling purpose for the degradation of all degradation products.

Prior to calculating the overall geometric mean of the normalised DT50 values, identical soils types with originally different study conditions (as SL FF, C T and CL B) were averaged.



For iodosulfuron methyl sodium and AE F075736 more than ten DT50 values are available. In these cases median normalised half-lives of 2.1 days for iodosulfuron methyl sodium and 25.1 days for AE F075736 were derived. For the remaining metabolites the evaluation resulted in geometric mean half-lives of 11.1 days for AE F145741, 32.1 days for BCS-CW81253 (des-iodo-carbamoyl-guanidine), 9.2 days for AE F161778, 10.7 days for AE 0000119, 172.5 days for AE F059411 and 51.3 days for AE F145740.

Table CA 7.1.2.1.1- 1: Overall compilation of normalised DT50 –values for iodosulfuron-methyl-sodium and its metabolites derived from the different data sets

Table with 10 columns: Soil, Model used for parent, IMS, AE F145741, AE F075736, AE F161778, BCS-GW 81253, AE 0000119, AE F059411, AE F145740. Rows include various soil types (LS, S, SL, CL, CT) and conditions (FF, B, CT) with their respective DT50 values and model types (SFO, FOMC, DEOP).

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Table CA 7.1.2.1.1- 2: Overall compilation of formation fractions derived from the different data sets from laboratory studies

Soil	IMS → AE F075736	IMS → AE F145741	IMS → AE F145740	AE F075736 → AE F161778	AE F075736 → AE 0000119	AE F075736 → AE F059411	AE F161778 → BCS-CW81253	AE F145740 → AE 0000119
LS 2.2	1.00			0.51	0.34		1.00	
S 2.1	0.99			0.27	) <sup>a</sup>			
SL 2	0.97			0.28	) <sup>a</sup>		1.00	
SL V	0.98			) <sup>a</sup>	0.33			
LS S	0.83	0.06	) <sup>a</sup>	0.6				
SL FF (10°C; 40% MWHC)	0.74	0.10	) <sup>a</sup>	0.72	0.35	0.01	1.00	1.00
SL FF (20°C; 30% MWHC)	0.76	0.05	) <sup>a</sup>	0.64	0.00	0.36	0.51	1.00
SL FF (20°C; 40% MWHC)	0.76	0.07	0.02	0.64		0.94	0.94	) <sup>a</sup>
SL FF average	0.75	0.07	0.02	0.67	0.18	0.21	0.82	1.00
CL L	0.85	0.05	0.03	0.22	0.26	0.5	1.00	) <sup>a</sup>
SL S	0.80	0.05	) <sup>a</sup>	0.2	) <sup>a</sup>	0.37	1.00	) <sup>a</sup>
CL B (20°C, 25% MWHC)	0.74	) <sup>a</sup>	0.05	0.12	) <sup>a</sup>	0.4	) <sup>a</sup>	) <sup>a</sup>
CL B (20°C, 50% MWHC)	0.82	0.07	0.02	0.36	) <sup>a</sup>	0.49	) <sup>a</sup>	) <sup>a</sup>
CL B average	0.78	0.03	0.04	0.24	) <sup>a</sup>	0.62	) <sup>a</sup>	
CT (20°C, 25% MWHC)	0.68	0.09	0.04	0.44	0.38	0.55	) <sup>a</sup>	1.00
CT (20°C, 50% MWHC)	0.75	) <sup>a</sup>	) <sup>a</sup>	0.5	0.71	0.40	0.58	1.00
CT average	0.72	0.09	0.04	0.52	0.20	0.48	0.58	1.00
Arithmetic mean ) <sup>b</sup>	0.83	0.06	0.04	0.50	0.27	0.44	0.81	1.00

)<sup>a</sup> No reliable formation fraction can be determined from available data  
 )<sup>b</sup> Mean values were calculated considering the averages for soils with more than one testing result.

**1. METHODS**

Soil residue data from the aerobic soil degradation studies KCA 7.1.2.1.1 /01 (M-180556-01-1), KCA 7.1.2.1.1 /02 (M-181517-01-1), KCA 7.1.2.1.1 /03 (M-180558-01-1), KCA 7.1.2.1.1 /04 (M-181175-01-1), KCA 7.1.2.1.1 /05 (M-181732-01-1), KCA 7.1.2.1.1 /08 (M-198118-01-1), KCA 7.1.1.1 /07 (M-471682-01-1) and KCA 7.1.1.1 /09 (M-438147-01-1) were used. In these studies, the degradation of iodosulfuron-methyl-sodium was studied in soils S 2.1 (sand), LS 2.2 (loamy sand), SL V (sandy loam), SL 2 (silt loam), LS S (loamy sand), (SL FF, loam), (SL S, silt loam), (CL L, clay loam), (C T, clay), (CL B, clay loam) and (LS H, loam silt) under aerobic conditions in the dark in the laboratory for up to 141 days at different temperatures (20 and 10°C, soil moisture (25, 30, 40 and 50% of the maximum water holding capacity) and test concentrations (20.0 µg/kg for soils SL V, LS 2.2, S 2.1, SL 2 und LS S and 30.0 µg/kg for soils SL S, CL L, C T and CL B).



The kinetic analysis was performed according to FOCUS kinetics (2006) using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. In some cases a metabolite (AE F145741) was already detected at time zero. In these cases the respective percentages were added to the parent values and the values for the metabolite were set to zero. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits,  $\chi^2$  scaled-error criterion, t-test significance, correlation analysis and standard deviation. The  $DT_{50}$  value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model. The resulting  $DT_{50}$  value from the first order multi compartment model was calculated as  $DT_{50} = 3.32$  as recommended by FOCUS. This procedure produces the worst case  $DT_{50}$  for the parent compound, which, however, does not describe the worst case scenario for the subsequent degradation products. The  $DT_{50}$  value taken for modelling is based on the iteratively calculated value from KinGUI 2.

## II. RESULTS

The most appropriate kinetic model for modelling purpose for the degradation of iodosulfuron-methyl-sodium was single first order (SFO) in soils S 2.1, LS 2.2, SL V, SC 2, LS S, CL L, SL S and CL B (20 °C, 50% MWHC), first order multi compartment (FQMC) for soils SL FR CT (20 °C, 50% MWHC), CL B (20 °C, 25% MWHC) and [REDACTED] and dual first order in parallel (DFOP) for soil CT (20 °C, 25% MWHC), respectively. Single first order (SFO) was used for modelling purpose for the degradation of all degradation products (see [Table CA 71.2.1.14](#)).

In cases where it turned out that the degradation of the parent compound iodosulfuron-methyl-sodium could not acceptably be fitted with SFO kinetics, the best fitting kinetic model was determined by fitting only the parent data separately to alternative models. Then this model was implemented in the model for the whole degradation scheme which was then fitted to the full data set.

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Table CA 7.1.2.1.1- 3: DT<sub>50</sub> values for the degradation of iodosulfuron-methyl-sodium in soils under aerobic conditions for modelling purpose (normalised) according to FOCUS

Temp. [°C]	Soil	Texture (USDA)	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]
20	S 2.1	sand	SFO	2.9
	LS 2.2	loamy sand	SFO	1.0
	SL V	sandy loam	SFO	1.3
	SL 2	silt loam	SFO	0.6
	LS S	loamy sand	SFO	
	SL FF (10°C; 40% MWHC)	loam	FOMC	8.9
	SL FF (20°C; 30% MWHC)	loam	FOMC	7.6
	SL FF (20°C; 40% MWHC)	loam	FOMC	7.8
	SL FF (geometric mean)			7.3
	CL L	clay loam	SFO	2.4
	SL S	silt loam	SFO	2.0
	CT (20°C, 25% MWHC)	clay	DFOP	20.8
	CT (20°C, 50% MWHC)	clay	FOMC	7.2
	CT (geometric mean)			12.2
	CL B (20°C, 25% MWHC)	clay loam	FOMC	7.0
	CL B (20°C, 50% MWHC)	clay loam	SFO	2.7
CL B (geometric mean)			4.6	
		loamy silt	FOMC	1.9
			<b>Median<sup>2</sup></b>	<b>2.1</b>

<sup>1</sup> SFO: single first order, FOMC: first order multi compartment, DFOP: double first order in parallel

<sup>2</sup> Mean values were calculated considering the averages for soils with more than one testing result.

Table CA 7.1.2.1.1- 4: Kinetic parameters for the degradation of iodosulfuron-methyl in aerobic soils for trigger evaluation (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Kinetic Model <sup>1</sup>	DT <sub>50</sub> <sup>2,3</sup> [days]	DT <sub>90</sub> [days]	Chi <sup>2</sup> Error [%]	t-test
20	S 2.1	sand	SFO	3.1	10.2	7.1	< 0.0001
	LS 2.2	loamy sand	SFO	1.5	5.1	5.3	< 0.0001
	SL V	sandy loam	SFO	1.8	6.0	10.3	< 0.0001
	SL 2	silt loam	SFO	0.8	2.6	1.1	< 0.0001
	LS S	loamy sand	SFO	2.7	9.1	11.3	< 0.0001
10	SL FF (10°C; 40% MWHC)	loam	FOMC	31.6	105.0	1.3	n.a.
20	SL FF (20°C; 30% MWHC)	loam	FOMC	12.9	42.8	3.9	n.a.
	SL FF (20°C; 40% MWHC)	loam	FOMC	8.0	26.7	2.9	n.a.
	CL L	clay loam	SFO	3.7	12.3	8.7	< 0.0001
	SL S	silt loam	SFO	2.9	9.5	8.6	< 0.0001
	CT (20°C, 25% MWHC)	clay	DFOP	37.2	111.0	6.5	K1, k2: < 0.0001
	CT (20°C, 50% MWHC)	clay	FOMC	7.3	24.4	3.6	n.a.
	CL B (20°C, 25% MWHC)	clay loam	FOMC	15.4	51.0	1.7	n.a.
	CL B (20°C, 50% MWHC)	clay loam	SFO	3.1	10.5	6.0	< 0.0001
			loamy silt	FOMC	2.4	8.0	9.8

n.a.: not applicable

<sup>1</sup> SFO: single first order, FOMC: first order multi compartment, DFOP: double first order in parallel

<sup>2</sup> for FOMC: calculated from DT<sub>90</sub>: DT<sub>50</sub> = DT<sub>90</sub> / 3.32

<sup>3</sup> for DFOP: calculated from k-rate from slow phase



Table CA 7.1.2.1.1- 5: DT<sub>50</sub> values for degradation of AE F075736 in aerobic soils for modelling purpose (normalised) according to FOCUS

Temp. [°C]	Soil	Texture (USDA)	Formation Fraction <sup>1</sup>	Kinetic Model <sup>2</sup>	DT <sub>50</sub> [days]
20	S 2.1	sand	0.99	SFO	66.2
	LS 2.2	loamy sand	1.00	SFO	14.2
	SL V	sandy loam	0.98	SFO	21.1
	SL 2	silt loam	0.97	SFO	51.0
	LS S	loamy sand	0.83	SFO	52.7
	SL FF (10°C; 40% MWHC)	loam	0.74	SFO	23.4
	SL FF (20°C; 30% MWHC)	loam	0.76	SFO	32.9
	SL FF (20°C; 40% MWHC)	loam	0.76	SFO	24.1
	SL FF (geometric mean)		0.75	SFO	26.5
	CL L	clay loam	0.85	SFO	10.6
	SL S	silt loam	0.80	SFO	12.8
	CT (20°C, 25% MWHC)	clay	0.68	SFO	33.7
	CT (20°C, 50% MWHC)	clay	0.75	SFO	42.4
	CT (geometric mean)		0.72	SFO	43.0
	CL B (20°C, 25% MWHC)	clay loam	0.74	SFO	27.0
	CL B (20°C, 50% MWHC)	clay loam	0.82	SFO	23.4
CL B (geometric mean)		0.82	SFO	25.1	
		loamy silt	0.77	SFO	15.3
	<b>Mean value<sup>3</sup></b>			<b>0.83<sup>4</sup></b>	<b>25.1<sup>5</sup></b>

<sup>1</sup> iodosulfuron-methyl-sodium → AE F075736

<sup>2</sup> SFO: single first order

<sup>3</sup> Mean values were calculated considering the averages for soils with more than one testing result.

<sup>4</sup> arithmetic mean <sup>5</sup> median

Table CA 7.1.2.1.1-6: Kinetic parameters for the degradation of AE F075736 in aerobic soils for trigger evaluation (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]	Chi <sup>2</sup> Error [%]	t-test
20	S 2.1	sand	SFO	77.6	238.0	2.41	< 0.0001
	LS 2.2	loamy sand	SFO	21.5	71.6	2.5	< 0.0001
	SL V	sandy loam	SFO	29.3	97.4	2.6	< 0.0001
	SL 2	silt loam	SFO	69.0	229.2	1.3	< 0.0001
	LS S	loamy sand	SFO	69.9	232.1	1.9	< 0.0001
10	SL FF (10°C; 40% MWHC)	loam	SFO	83.3	276.9	3.1	< 0.0001
20	SL FF (20°C; 30% MWHC)	loam	SFO	55.4	184.2	3.7	< 0.0001
	SL FF (20°C; 40% MWHC)	loam	SFO	33.3	110.6	3.3	< 0.0001
	CL L	clay loam	SFO	16.5	54.9	5.2	< 0.0001
	SL S	silt loam	SFO	18.7	62.1	2.7	< 0.0001
	CT (20°C, 25% MWHC)	clay	SFO	78.0	252.3	1.6	< 0.0001
	CT (20°C, 50% MWHC)	clay	SFO	43.5	144.6	6.0	< 0.0001
	CL B (20°C, 25% MWHC)	clay loam	SFO	52.0	106.2	4.1	< 0.0001
	CL B (20°C, 50% MWHC)	clay loam	SFO	27.8	92.2	4.8	< 0.0001
		loamy silt	SFO	19.7	7.8	9.8	< 0.0001

<sup>1</sup> SFO: single first order



Table CA 7.1.2.1.1- 7: DT50 values for degradation of AE F145740 in aerobic soils for modelling purpose (normalised) according to FOCUS

Temp. [°C]	Soil	Texture (USDA)	Formation Fraction <sup>1</sup>	Kinetic Model <sup>2</sup>	DT <sub>50</sub> [days]
20	LS S	loamy sand	- <sup>3</sup>	SFO	- <sup>4</sup>
	SL FF (10°C; 40% MWHC)	loam	- <sup>3</sup>	SFO	- <sup>4</sup>
	SL FF (20°C; 30% MWHC)	loam	- <sup>3</sup>	SFO	- <sup>4</sup>
	SL FF (20°C; 40% MWHC)	loam	0.02	SFO	55.8
	SL FF (geometric mean)		0.02	SFO	55.8
	CL L	clay loam	0.03	SFO	7.1
	SL S	silt loam		SFO	- <sup>4</sup>
	CT (20°C, 25% MWHC)	clay	0.04	SFO	- <sup>4</sup>
	CT (20°C, 50% MWHC)	clay	<sup>3</sup>	SFO	<sup>4</sup>
	CT (geometric mean)		0.04	SFO	
	CL B (20°C, 25% MWHC)	clay loam	0.05	SFO	123.7
	CL B (20°C, 50% MWHC)	clay loam	0.6	SFO	2.6
	CL B (geometric mean)		0.04	SFO	1.4
			loamy silt	0.08	SFO
<b>Mean value <sup>5</sup></b>			<b>0.04 <sup>6</sup></b>		<b>51.3</b>

<sup>1</sup> iodosulfuron-methyl-sodium → AE F145740

<sup>2</sup> SFO: single first order

<sup>3</sup> No reliable formation fraction can be determined from available data

<sup>4</sup> No reliable half-lives determinable

<sup>5</sup> Mean values were calculated considering the averages for soils with more than one testing result.

<sup>6</sup> arithmetic mean geometric mean

Table CA 7.1.2.1.1- 8: Kinetic parameters for the degradation of AE F145740 in aerobic soils for trigger evaluation (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]	Chi <sup>2</sup> Error [%]	t-test
20	LS S	loamy sand	SFO	- <sup>2</sup>			
10	SL FF (10°C; 40% MWHC)	loam	SFO				
20	SL FF (20°C; 30% MWHC)	loam	SFO	- <sup>2</sup>			
	SL FF (20°C; 40% MWHC)	loam	SFO	76.9	255.5	8.1	< 0.0001
	CL L	clay loam	SFO	57.8	192.0	17.5	0.0002
	SL S	silt loam	SFO	- <sup>2</sup>			
	CT (20°C, 25% MWHC)	clay	SFO	- <sup>2</sup>			
	CT (20°C, 50% MWHC)	clay	SFO	- <sup>2</sup>			
	CL B (20°C, 25% MWHC)	clay loam	SFO	238.3	791.7	4.9	< 0.0001
	CL B (20°C, 50% MWHC)	clay loam	SFO	63.6	211.1	17.5	0.0002
		loamy silt	SFO	53.2	176.7	16.2	< 0.0001

<sup>1</sup> SFO: single first order

<sup>2</sup> No reliable half-lives determinable



Table CA 7.1.2.1.1- 9: DT<sub>50</sub> values for degradation of AE F145741 in aerobic soils for modelling purpose (normalised) according to FOCUS

Temp. [°C]	Soil	Texture (USDA)	Formation Fraction <sup>1</sup>	Kinetic Model <sup>2</sup>	DT <sub>50</sub> [days]
20	LS S	loamy sand	0.06	SFO	2.2
	SL FF (10°C; 40% MWHC)	loam	0.10	SFO	41.8
	SL FF (20°C; 30% MWHC)	loam	0.05	SFO	35.6
	SL FF (20°C; 40% MWHC)	loam	0.07	SFO	41.7
	SL FF (geometric mean)		0.07	SFO	43.0
	CL L	clay loam	0.05	SFO	5.1
	SL S	silt loam	0.05	SFO	7.1
	CT (20°C, 25% MWHC)	clay	0.09	SFO	37.7
	CT (20°C, 50% MWHC)	clay	- <sup>3</sup>	SFO	-
	CT (geometric mean)		0.09	SFO	37.7
	CL B (20°C, 25% MWHC)	clay loam	- <sup>4</sup>	SFO	-
	CL B (20°C, 50% MWHC)	clay loam	0.03	SFO	14.5
	CL B (geometric mean)		0.03	SFO	14.5
		loamy silt	- <sup>3</sup>	SFO	-
<b>Mean value</b>			<b>0.06</b>		<b>11.1</b> <sup>7</sup>

<sup>1</sup> Iodosulfuron-methyl-sodium → AE F145741

<sup>2</sup> SFO: single first order

<sup>3</sup> No reliable formation fraction can be determined from available data

<sup>4</sup> No reliable half-lives determinable

<sup>5</sup> Mean values were calculated considering the averages for soils with more than one testing result.

<sup>6</sup> arithmetic mean geometric mean

Table CA 7.1.2.1.1- 10: Kinetic parameters for the degradation of AE F145741 in aerobic soils for trigger evaluation (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]	Chi <sup>2</sup> Error [%]	t-test
20	LS S	loamy sand	SFO	2.2	11.3	31.0	0.02974
10	SL FF (10°C; 40% MWHC)	loam	SFO	48.5	493.3	9.0	0.0002
20	SL FF (20°C; 30% MWHC)	loam	SFO	76.8	255.2	10.1	< 0.0001
	SL FF (20°C; 40% MWHC)	loam	SFO	57.5	191.0	12.2	< 0.0001
	CL L	clay loam	SFO	7.9	26.4	36.5	0.023
	SL S	silt loam	SFO	10.3	34.1	16.3	0.0002
	CT (20°C, 25% MWHC)	clay	SFO	67.4	217.2	12.2	< 0.0001
	CT (20°C, 50% MWHC)	clay	SFO	- <sup>2</sup>			
	CL B (20°C, 25% MWHC)	clay loam	SFO	- <sup>2</sup>			
	CL B (20°C, 50% MWHC)	clay loam	SFO	17.2	57.0	24.7	0.007
			loamy silt	SFO	- <sup>2</sup>		

<sup>1</sup> SFO: single first order

<sup>2</sup> No reliable half-lives determinable



Table CA 7.1.2.1.1- 11: DT<sub>50</sub> values for degradation of AE F161778 in aerobic soils for modelling purpose (normalised) according to FOCUS

Temp. [°C]	Soil	Texture (USDA)	Formation Fraction <sup>1</sup>	Kinetic Model <sup>2</sup>	DT <sub>50</sub> [days]
20	S 2.1	sand	0.27	SFO	12.2
	LS 2.2	loamy sand	0.51	SFO	3.4
	SL V	sandy loam	- <sup>3</sup>	SFO	- <sup>4</sup>
	SL 2	silt loam	- <sup>3</sup>	SFO	- <sup>4</sup>
	LS S	loamy sand	0.64	SFO	4.9
	SL FF (10°C; 40% MWHC)	loam	0.70	SFO	17.5
	SL FF (20°C; 30% MWHC)	loam	0.64	SFO	25.4
	SL FF (20°C; 40% MWHC)	loam	0.64	SFO	19.5
	SL FF (geometric mean)		0.67	SFO	17.5
	CL L	clay loam	0.22	SFO	10.5
	SL S	silt loam	0.42	SFO	15.0
	CT (20°C, 25% MWHC)	clay	0.44	SFO	19.5
	CT (20°C, 50% MWHC)	clay	0.59	SFO	14.8
	CT (geometric mean)		0.52	SFO	17.1
	CL B (20°C, 25% MWHC)	clay loam	0.12	SFO	16.6
	CL B (20°C, 50% MWHC)	clay loam	0.36	SFO	15.9
	CL B (geometric mean)		0.24	SFO	16.2
	loamy silt	1.00	SFO	1.8	
	<b>Mean value<sup>5</sup></b>		<b>0.50<sup>6</sup></b>		<b>9.2<sup>7</sup></b>

<sup>1</sup> AE F075736 → AE F161778

<sup>2</sup> SFO: single first order

<sup>3</sup> No reliable formation fraction can be determined from available data

<sup>4</sup> No reliable half-lives determinable

<sup>5</sup> Mean values were calculated considering the averages for soils with more than one testing result.

<sup>6</sup> arithmetic mean

<sup>7</sup> geometric mean

Table CA 7.1.2.1.1- 12: Kinetic parameters for the degradation of AE F161778 in aerobic soils for trigger evaluation (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]	Chi <sup>2</sup> Error [%]	t-test
20	S 2.1	sand	SFO	13.2	43.7	27.2	0.003
	LS 2.2	loamy sand	SFO	5.2	17.1	14.9	< 0.0001
	SL V	sandy loam	SFO	- <sup>2</sup>			
	SL 2	silt loam	SFO	- <sup>2</sup>			
	LS S	loamy sand	SFO	10.5	35.0	16.7	0.00050
10	SL FF (10°C; 40% MWHC)	loam	SFO	62.8	208.5	13.5	0.001
	SL FF (20°C; 30% MWHC)	loam	SFO	25.9	86.0	6.5	0.0004
20	SL FF (20°C; 40% MWHC)	loam	SFO	26.9	89.2	8.7	< 0.0001
	CL L	clay loam	SFO	16.3	54.2	23.2	0.0002
	SL S	silt loam	SFO	22.0	73.0	8.8	< 0.0001
	CT (20°C, 25% MWHC)	clay	SFO	35.0	> 1000	21.0	0.040
	CT (20°C, 50% MWHC)	clay	SFO	15.2	50.6	17.0	< 0.0001
	CL B (20°C, 25% MWHC)	clay loam	SFO	32.0	106.2	20.3	0.0001
	CL B (20°C, 50% MWHC)	clay loam	SFO	18.8	62.4	20.5	0.00027
		loamy silt	SFO	2.3	7.8	16.2	< 0.0001

<sup>1</sup> SFO: single first order

<sup>2</sup> No reliable half-lives determinable



Table CA 7.1.2.1.1- 13: DT<sub>50</sub> values for degradation of BCS-CW81253 in aerobic soils for modelling purpose (normalised) according to FOCUS

Temp. [°C]	Soil	Texture (USDA)	Formation Fraction <sup>1</sup>	Kinetic Model <sup>2</sup>	DT <sub>50</sub> [days]
20	S 2.1	sand	- <sup>3</sup>	SFO	- <sup>4</sup>
	LS 2.2	loamy sand	1.00	SFO	36.6
	SL V	sandy loam	- <sup>3</sup>	SFO	- <sup>4</sup>
	SL 2	silt loam	1.00	SFO	-
	SL FF (10°C; 40% MWHC)	loam	1.00	SFO	-
	SL FF (20°C; 30% MWHC)	loam	0.94	SFO	8.2
	SL FF (20°C; 40% MWHC)	loam	0.94	SFO	16.1
	SL FF (geometric mean)		0.82	SFO	16.1
	CL L	clay loam	1.00	SFO	- <sup>4</sup>
	SL S	silt loam	1.00	SFO	9.5
	CT (20°C, 50% MWHC)	clay	0.58	SFO	52.7
	CT (geometric mean)		0.58	SFO	52.7
	CL B (20°C, 25% MWHC)	clay loam	- <sup>3</sup>	SFO	- <sup>4</sup>
	CL B (20°C, 50% MWHC)	clay loam	- <sup>3</sup>	SFO	- <sup>4</sup>
	CL B (geometric mean)			SFO	
<b>Mean value <sup>5</sup></b>			<b>0.81</b>		<b>32.1<sup>7</sup></b>

<sup>1</sup> AE F161778 → BCS-CW81253

<sup>2</sup> SFO: single first order

<sup>3</sup> No reliable formation fraction can be determined from available data

<sup>4</sup> No reliable half-lives determinable

<sup>5</sup> Mean values were calculated considering the averages for soils with more than one testing result.

<sup>6</sup> arithmetic mean

<sup>7</sup> geometric mean

Table CA 7.1.2.1.1- 14: Kinetic parameters for the degradation of BCS-CW81253 in aerobic soils for trigger evaluation (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Kinetic Model	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]	Chi <sup>2</sup> Error [%]	t-test
20	S 2.1	sand	SFO	- <sup>2</sup>			
	LS 2.2	loamy sand	SFO	55.6	184.7	22.2	0.006
	SL V	sandy loam	SFO	- <sup>2</sup>			
	SL 2	silt loam	SFO	- <sup>2</sup>			
10	SL FF (10°C; 40% MWHC)	loam	SFO	50.9	169.0	10.0	0.068
20	SL FF (20°C; 30% MWHC)	loam	SFO	27.3	90.7	12.1	0.003
	SL FF (20°C; 40% MWHC)	loam	SFO	22.3	74.0	5.2	< 0.0001
	CL L	clay loam	SFO	- <sup>2</sup>			
	SL S	silt loam	SFO	13.8	46.0	9.0	< 0.0001
	CT (20°C, 25% MWHC)	clay	SFO	-			
	CT (20°C, 50% MWHC)	clay	SFO	54.2	180.0	9.1	0.002
	CL B (20°C, 25% MWHC)	clay loam	SFO	- <sup>2</sup>			
	CL B (20°C, 50% MWHC)	clay loam	SFO	- <sup>2</sup>			
		loamy silt	SFO	149.4	496.4	14.4	0.0027

<sup>1</sup> SFO: single first order

<sup>2</sup> No reliable half-lives determinable



Table CA 7.1.2.1.1- 15: DT<sub>50</sub> values for degradation of AE 0000119 in aerobic soils for modelling purpose (normalised) according to FOCUS

Temp. [°C]	Soil	Texture (USDA)	Formation Fraction <sup>1</sup>	Formation Fraction <sup>2</sup>	Kinetic Model <sup>3</sup>	DT <sub>50</sub> [days]
20	S 2.1	sand	- <sup>4</sup>		SFO	-
	LS 2.2	loamy sand	0.34		SFO	7.8
	SL V	sandy loam	0.33		SFO	91.0
	SL 2	silt loam	0.28		SFO	-
	SL FF (10°C; 40% MWHC)	loam	0.35	1.00	SFO	-
	SL FF (20°C; 30% MWHC)	loam	0.00	1.00	SFO	- <sup>5</sup>
	SL FF (20°C; 40% MWHC)	loam	- <sup>4</sup>	- <sup>4</sup>	SFO	- <sup>5</sup>
	SL FF (geometric mean)		0.18	1.00	SFO	-
	CL L	clay loam	0.26	- <sup>4</sup>	SFO	2.5
	SL S	silt loam	- <sup>4</sup>	- <sup>4</sup>	SFO	- <sup>5</sup>
	CT (20°C, 25% MWHC)	clay	0.38	1.00	SFO	7.5
	CT (20°C, 50% MWHC)	clay	0.00	0.00	SFO	- <sup>5</sup>
	CT (geometric mean)		0.20	1.00	SFO	7.5
	CL B (20°C, 25% MWHC)	clay loam	- <sup>4</sup>	-	SFO	- <sup>5</sup>
	CL B (20°C, 50% MWHC)	clay loam	- <sup>4</sup>	-	SFO	-
CL B (geometric mean)			1.00	SFO	-	
<b>Mean value</b>			<b>0.27</b>	<b>1.00</b>		<b>10.7<sup>8</sup></b>

<sup>1</sup> AE F075736 → AE 0000119

<sup>2</sup> AE F145740 → AE 0000119 (worst case assumption)

<sup>3</sup> SFO: single first order

<sup>4</sup> No reliable formation fraction can be determined from available data

<sup>5</sup> No reliable half-lives determinable

<sup>6</sup> Mean values were calculated considering the averages for soils with more than one testing result.

<sup>7</sup> arithmetic mean      geometric mean

Table CA 7.1.2.1.1- 16: Kinetic parameters for the degradation of AE 0000119 in aerobic soils for trigger evaluation (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Kinetic Model	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]	Chi <sup>2</sup> Error [%]	t-test
20	S 2.1	sand	SFO	- <sup>2</sup>			
	LS 2.2	loamy sand	SFO	11.9	39.4	9.7	< 0.0001
	SL V	sandy loam	SFO	126.4	420.0	10.3	< 0.0001
	SL 2	silt loam	SFO	- <sup>2</sup>			
10	SL FF (10°C; 40% MWHC)	loam	SFO	- <sup>2</sup>			
20	SL FF (20°C; 30% MWHC)	loam	SFO	- <sup>2</sup>			
	SL FF (20°C; 40% MWHC)	loam	SFO	- <sup>2</sup>			
	CL L	clay loam	SFO	3.9	13.1	15.2	0.021
	SL S	silt loam	SFO	- <sup>2</sup>			
	CT (20°C, 25% MWHC)	clay	SFO	13.4	> 1000	17.0	0.0002
	CT (20°C, 50% MWHC)	clay	SFO	- <sup>2</sup>			
	CL B (20°C, 25% MWHC)	clay loam	SFO	- <sup>2</sup>			
	CL B (20°C, 50% MWHC)	clay loam	SFO	- <sup>2</sup>			

<sup>1</sup> SFO: single first order

<sup>2</sup> No reliable half-lives determinable



Table CA 7.1.2.1.1- 17: DT<sub>50</sub> values for degradation of AE F059411 in aerobic soils for modelling purpose (normalised) according to FOCUS

Temp. [°C]	Soil	Texture (USDA)	Formation Fraction <sup>1</sup>	Kinetic Model <sup>2</sup>	DT <sub>50</sub> [days]
20	SL FF (10°C; 40% MWHC)	loam	0.01	SFO	- <sup>3</sup>
	SL FF (20°C; 30% MWHC)	loam	0.36	SFO	-
	SL FF (20°C; 40% MWHC)	loam	0.27	SFO	- <sup>3</sup>
	SL FF (geometric mean)		0.21	SFO	
	CL L	clay loam	0.53	SFO	-
	SL S	silt loam	0.37	SFO	122.0
	CT (20°C, 25% MWHC)	clay	0.55	SFO	- <sup>3</sup>
	CT (20°C, 50% MWHC)	clay	0.40	SFO	139.4
	CT (geometric mean)		0.48	SFO	139.4
	CL B (20°C, 25% MWHC)	clay loam	0.44	SFO	190.2
	CL B (20°C, 50% MWHC)	clay loam	0.49	SFO	308.2
	CL B (geometric mean)		0.52	SFO	242.5
<b>Mean value <sup>4</sup></b>			<b>0.44 <sup>5</sup></b>		<b>172.5 <sup>6</sup></b>

<sup>1</sup> AE F075736 → AE F059411

<sup>2</sup> SFO: single first order

<sup>3</sup> No reliable half-lives determinable

<sup>4</sup> Mean values were calculated considering the averages for soils with more than one testing result.

<sup>5</sup> arithmetic mean

<sup>6</sup> geometric mean

Table CA 7.1.2.1.1- 18: Kinetic parameters for the degradation of AE F059411 in aerobic soils for trigger evaluation (non-normalised)

Temp. [°C]	Soil	Texture (USDA)	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]	Chi <sup>2</sup> Error [%]	t-test
10	SL FF (10°C; 40% MWHC)	loam	SFO				
20	SL FF (20°C; 30% MWHC)	loam	SFO	- <sup>2</sup>			
	SL FF (20°C; 40% MWHC)	loam	SFO	- <sup>2</sup>			
	CL L	clay loam	SFO	- <sup>2</sup>			
	SL S	silt loam	SFO	222.2	737.9	7.4	0.001
	CT (20°C, 25% MWHC)	clay	SFO	- <sup>2</sup>			
	CT (20°C, 50% MWHC)	clay	SFO	143.1	475.3	13.4	0.034
	CL B (20°C, 25% MWHC)	clay loam	SFO	367.1	> 1000	2.1	0.0003
	CL B (20°C, 50% MWHC)	clay loam	SFO	365.2	> 1000	4.1	0.003

<sup>1</sup> SFO: single first order

<sup>2</sup> No reliable half-lives determinable

### III. CONCLUSIONS

The calculated half-lives for modelling purpose (normalised) for the degradation of idosulfuron-methyl-sodium and its degradation products in soil under aerobic conditions in the dark in the laboratory were between 0.6 and 20.8 days (mean: 2.1 days) for idosulfuron-methyl-sodium, between 10.6 and 66.7 days (mean: 25.1 days) for AE F075736, between 37.1 and 123.7 days (mean: 51.3 days) for AE F145740, between 2.2 and 45.6 days (mean: 11.1 days) for AE F145741, between 1.8 and 19.6 days (mean: 7.2 days) for AE F161778, between 9.5 and 115.8 days (mean: 32.1 days) for BCS-W81253 (des-iodo-carbamoyl-guanidine), between 2.5 and 91.0 days (mean: 10.7 days) for AE 0000119 and between 139.4 and 308.2 days (mean: 172.5 days) for AE F059411 in the tested soils.





The calculated half-lives for trigger evaluation for the degradation of iodosulfuron-methyl-sodium and its degradation products in soil under aerobic conditions in the dark in the laboratory were between 0.8 and 37.2 days for iodosulfuron-methyl-sodium, between 16.5 and 83.3 days for AE F075736, between 53.2 and 238.3 days for AE F145740, between 2.9 and 148.5 days for AE F145741, between 2.9 and 62.8 days for AE F161778, between 13.8 and 149.4 days for BCS-CW81253 (des-iodo-carbamoyl-guanidine), between 3.9 and 126.4 days for AE 0000119 and between 143.1 and 367.1 days for AE F059411 in the tested soils.

Additional data requested by the RMS during the review

<b>Report:</b>	KCA 7.1.2.1.1/14 [REDACTED] 2014;M-491240-01
<b>Title:</b>	pH dependency of adsorption and degradation processes of iodosulfuron-methyl and its metabolites
<b>Report No:</b>	EnSa-14-0870
<b>Document No:</b>	M-491240-01-1
<b>Guidelines:</b>	<b>not applicable;not applicable</b>
<b>GLP/GEP:</b>	<b>n.a.</b>

**Summary**

On request of the RMS the data of all laboratory degradation studies of iodosulfuron-methyl and its soil metabolites were evaluated in order to investigate a potential pH-dependency of degradation kinetics. A linear regression of the (normalized) DT50 values and soil pH values of each compound was made – respective figures are presented in the report.

The regression analyses revealed that no significant pH-dependency could be observed for iodosulfuron-methyl and its metabolites. The R<sup>2</sup> values are all below 0.5 except for the metabolite AE 0002166. The low R<sup>2</sup> values indicate that there is no significant pH-dependency of iodosulfuron-methyl or its metabolites in the conducted aerobic soil degradation studies.

For metabolite AE 0002166 the visual fit of the linear regression and the R<sup>2</sup> value of 0.7744 of linear regression might imply that degradation is pH dependent. However, only four data points are available for the compound in a very narrow range of +/- 2.7 days (DT<sub>50</sub> values for AE 0002166: 4.7 – 10.1 d). Also the pH-values of the soils are close together (pH 6.1 – 7.1). The implied correlation is triggered by only one data point (4.7 d / pH 7.1), while the other data points build a homogenous cloud. Taking into account the uncertainty of the analytical measurement and the variation in experimental systems with biologically active soil, the pH dependence is seen as non-significant. In conclusion, no significant correlation between the DT<sub>50</sub> of AE 0002166 and the pH values of the corresponding soils is considered.

Overall, degradation of iodosulfuron-methyl-sodium and its soil metabolites is not considered pH dependent.

**CA 7.1.21.2 Aerobic degradation of metabolites, breakdown and reaction products**

The degradation rate of the major degradation product AE F059411 in soil under aerobic conditions in the dark in the laboratory was evaluated during the Annex I inclusion using the radiolabel position, [triazinyl-<sup>14</sup>C], and was accepted by the European Commission (SANCO/10166/2003-Final, 3 July 2003). The following study is included in the baseline dossier:



<b>Report:</b>	██████████;2001;M-202633-01
<b>Title:</b>	Degradation and metabolism of AE F059411 in one soil under standard conditions
<b>Report No:</b>	C012400
<b>Document No:</b>	M-202633-01-1
<b>Guidelines:</b>	SETAC: 1; 1.1; USEPA (=EPA): 162-1;Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	██████████;2013;M-447102-03; Amended: 2015-04-14
<b>Title:</b>	Kinetic evaluation of laboratory aerobic soil degradation of iodosulfuron-methyl-sodium and its metabolites according to FOCUS kinetics
<b>Report No:</b>	EnSa-13-0100
<b>Document No:</b>	M-447102-03-1
<b>Guidelines:</b>	FOCUS kinetics (2006)
<b>GLP/GEP:</b>	no

<b>Report:</b>	██████████;2014;M-491200-01
<b>Title:</b>	Supplementary information for the kinetic evaluation of laboratory aerobic soil degradation of iodosulfuron-methyl-sodium and its metabolites
<b>Report No:</b>	EnSa-14-0811
<b>Document No(s):</b>	M-491200-01-1
<b>Guidelines:</b>	not applicable;not applicable
<b>GLP/GEP:</b>	no

The evaluation of degradation rates of the degradation products AE F075736, AE F145741, AE F161778, des-iodo-carbamoyl-guanidine (BG-CW81253), AE 0000119, AE F059411 and AE F145740 are summarized together with the degradation rates of iodosulfuron-methyl-sodium in CA 7.1.2.1.1 (KCA 7.1.2.1.1/12)

An additional study (M-294487-01, ██████████ 2007) has been performed for the soil photolysis metabolite AE 0002166 and is submitted within this supplemental dossier for the iodosulfuron-methyl-sodium Annex I Renewal.

<b>Report:</b>	██████████;2007;M-294487-01
<b>Title:</b>	AE 0002166: Aerobic soil degradation in four EU soils
<b>Report No:</b>	MEF-07329
<b>Document No:</b>	M-294487-01-1
<b>Guidelines:</b>	OECD 307; none
<b>GLP/GEP:</b>	yes

**Executive Summary**

The degradation of AE 0002166, a soil photolysis degradation product of iodosulfuron-methyl-sodium, was investigated under aerobic conditions at 20 ± 2 °C and a soil moisture of about 55% of MWHC in four European soils by incubation in the dark for 42 days. The test substance was applied at a nominal test concentration of 40 µg AE 0002166/kg soil (dry matter), equivalent to the 15-fold amount derived from the single maximum recommended field use rate of the parent active ingredient iodosulfuron-methyl-sodium (10 g/ha) and the worst case assumption of 20% maximum formation of AE 0002166 (2.5 cm depth, 1.5 g/cm<sup>3</sup> bulk density).

The recovered mean amount of AE 0002166 directly after soil treatment was 100.9%, 101.2%, 99.4% and 98.2% of the applied for soils ██████████ AIIIa, ██████████ AXXa, ██████████ Am ██████████



4a and II, respectively. During study incubation the amount of AE 0002166 decreased rapidly in all four soils, dropping below 10% of the applied amount 14 to 42 days after application. At study end the residue levels ranged from 1.2 to 6.3% of the applied.

Following FOCUS kinetic guidance, the experimental data could be well described by single first order kinetics with half-lives in the range of 4.7 to 10.1 days. Therefore, the compound will not persist in a viable soil environment, and no significant mobility of AE 0002166 in soil is to be expected.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

unlabelled AE 0002166
Certificate of Analysis: AZ 13861
Batch Code: AE 0002166-PU-01
Chemical Purity: 95% w/w

2. Test Soils

The four soils used in the study were taken from agricultural use areas representing different geographical origins and different soil properties as required by the guidelines (see Table CA 7.1.2.1.2- 1). No plant protection products were used for the previous 5 years. The soils were sampled freshly from the fields (upper horizon of 0 to 20 cm) and sieved to a particle size of <= 2 mm. Soil collection and handling were in accordance to ISO 10381-6.

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Table CA 7.1.2.1.2- 1: Physico-chemical properties of test soils

Soil	Allia	AXXa	Am 4a	II
Geographic Location (City / State / Country)	NRW / Germany	/ Germany	NRW / Germany	NRW / Germany
GPS coordinates				
Pesticide use history	No pesticide use for previous 5 years			
Collection procedures	Sample taken with spade and placed into plastic bags			
Sampling depth	about 0-20 cm			
Storage conditions	2 days at room temperature and 6 days at approx. 4 °C			
Storage length	8 days after sampling before pre-incubation			
Soil preparation	Sieved (2 mm)			
Texture Class (USDA)	Loam	Sandy loam	Silt loam	Clay loam
Sand [50 µm - 2 mm] (%)	45	76	27	55
Silt [2 µm - 50 µm] (%)	34	6	58	32
Clay [< 2 µm] (%)	21	9	15	33
pH in Water	6.4	6.7	6.5	7.2
pH in CaCl <sub>2</sub> (0.01 M)	6.1	6.4	6.3	7.1
pH in KCl (1 M)	5.8	6.3	6.3	6.8
Organic Matter <sup>A</sup> (%)	1.4	4.1	7.2	9.1
Organic Carbon (%)	1.4	2.4	4.2	5.3
CEC (meq/100 g)	9.3	85	13	21.7
MWHC (g/100 g)	43.2	46.8	57.6	82.8
Moisture at 1/3 bar = pF 2.5 (g H <sub>2</sub> O /100 g dry soil)	17.9	13	26.5	35.8
Microbial biomass (µg C <sub>biomass</sub> /100 g dry wtal soil)				
Initial (Day 0)	374/451	550/550	1405/1407	2138/2149
Final, Day 120 (untreated)	431/447	470/424	1180/1207	1898/1672

<sup>A</sup> % organic matter = % organic carbon x 1.724

**B. STUDY DESIGN**

**1. Experimental Conditions**

Samples of 50 g dry weight of soil each were filled into standard borosilicate glass laboratory flasks (250 mL volume) which were closed with punched caps allowing free air exchange and pre-equilibrated for 11 days (darkness, 20 ± 1 °C, moisture content of 55% MWHC). At application, each sample received a dose of AE 0002166 equivalent to a nominal test concentration of 40 µg AE 0002166/kg soil corresponding to the 15-fold amount derived from the single maximum recommended field use rate of the parent active ingredient iodosulfuron-methyl-sodium (10 g/ha) and the worst case assumption of 20% maximum formation of AE 0002166 (2.5 cm depth, 1.5 g/cm<sup>3</sup> bulk density assumed for dose calculation). For application, the targeted amount of test item was dissolved in methanol/water 1/1 (v/v) and applied as small droplets directly to the soil surface using a pipette. The actual dose applied per test vessel was 1.89 µg of AE 0002166 for all soils. After application, each flask was gently shaken to incorporate the chemical into the test soil. All flasks were weighed, closed with punched caps and immediately placed back into the temperature controlled incubation chamber.



Samples were incubated at  $20 \pm 2$  °C and a soil moisture content of 55% MWHC in the dark for 42 days. In addition, samples containing untreated soil were incubated under the same conditions for determination of soil microbial activity at the end of the study.

## 2. Sampling

Duplicate samples were removed for work-up after 0, 1, 3, 8, 14, 21, 29, and 42 days of incubation. Samples for determination of soil microbial biomass were investigated after 0 and 42 days of incubation. The complete samples were immediately processed by extraction and HPLC-MS/MS analysis was usually performed within one day, except for the samples of day 14 which were re-analyzed 9 days after extraction because of a malfunction of the HPLC-MS/MS equipment. The extracts were stored refrigerated while not in use.

## 3. Analytical Procedures

The entire soil sample in each test vessel was extracted with 100 mL of acetonitrile/water 4/1 (v/v) by microwave-accelerated solvent extraction for 10 minutes at 250 W (temperature < 40 °C) under magnetic stirring. The test systems were fortified with an internal stable-labelled standard solution ( $c = 1024 \mu\text{g/L}$  [triazine- $^{15}\text{N}_4$ ]AE 0002166, resulting in an ISD concentration of  $205 \mu\text{g/L}$  corresponding to  $4.10 \mu\text{g/kg}$ ) and stirred for another 5 minutes. Sedimentation of soil particles was allowed before aliquots of 1 mL were ultra-centrifuged for 5 min at  $40000 \times g$ . Aliquots of the clear supernatants were transferred into HPLC vials for quantification by HPLC-MS/MS in the selected reaction monitoring (SRM) mode using internal stable labelled standards. No analysis for possible transformation products was performed.

Concurrent recovery samples were freshly prepared at each sampling interval by fortification of test item to a representative control soil (██████████ AIIIa) at the LOQ level, and the level of application (=20-fold LOQ level) in duplicate. These flasks were extracted and analysed along with the kinetic test systems. The lowest fortification level experimentally tested corresponds to the limit of quantification (LOQ =  $2.0 \mu\text{g/kg}$ ). The limit of detection (LOD) was set to about 1/5 of the LOQ, being  $0.4 \mu\text{g/kg}$ .

The HPLC-MS/MS method was validated with regard to linearity, accuracy and precision. The range of the linearity of the detector used was tested in pure solvent. The test was performed by comparison of the injected amount of AE 0002166 and the response to the internal stable-labelled standard [triazine- $^{15}\text{N}_4$ ]AE 0002166. The concentration of the internal labelled standard mixture was maintained at a similar level ( $2.05 \mu\text{g/L}$  corresponding to  $4.10 \mu\text{g/kg}$ ). The test was performed by injections of standards in solvent at concentrations corresponding to about 1/5 LOQ to 20-times LOQ.

The accuracy of the method was assessed on the basis of determined recovery rates. For this reason control samples were fortified with AE 0002166 at fortification levels of  $2.0 \mu\text{g/kg}$  (LOQ level) and  $40 \mu\text{g/kg}$  (level at application, 20-fold LOQ level). The lowest fortification level experimentally tested corresponds to the limit of quantification (LOQ =  $2.0 \mu\text{g/kg}$ ). As a measure for the precision of the method, the intra-laboratory repeatability was shown. The repeatability was determined for all tested soils running five recoveries at the LOQ level, and the level of application.



The degradation kinetics of the test item was determined according to FOCUS kinetics (2006 using the software KinGUI with three different kinetic models: single first order (SFO), first order multi compartment (FOMC) and double first order in parallel (DFOP). Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The initial recovery at DAT-0 was included in the parameter optimization procedure, but for optimal goodness of fit the value was allowed to be estimated by the model. The best-fit kinetic model was selected on the basis of the chi<sup>2</sup> scaled-error criterion and on the basis of a visual assessment of the goodness of the fit. DT<sub>50</sub> and DT<sub>90</sub> values were calculated from the resulting kinetic parameters.

## II. RESULTS AND DISCUSSION

Results indicated that the anticipated standardized aerobic conditions were maintained and that the soils were microbially active over the duration of the laboratory study.

### A. DATA

The results of the aerobic biotransformation of AE 0002166 after incubation in four European soils are summarized in Table CA 7.1.2.1.2- 2 to Table CA 7.1.2.1.2- 5.

Table CA 7.1.2.1.2- 2: Degradation of AE 0002166 in soil [redacted] Alla under aerobic conditions

Compound	Replicate No	Residues (% Applied) on the following days after treatment (DAT)							
		0	1	3	8	14	21	29	42
AE 0002166	(A)	100.3	95.8	82.1	64.0	41.3	21.6	12.1	5.1
	(B)	101.4	92.4	81.9	63.0	41.0	17.2	12.3	4.6
	Mean	100.9	93.9	83.0	63.8	41.2	19.4	12.2	4.9

Table CA 7.1.2.1.2- 3: Degradation of AE 0002166 in soil [redacted] AXA under aerobic conditions

Compound	Replicate No	Residues (% Applied) on the following days after treatment (DAT)							
		0	1	3	8	14	21	29	42
AE 0002166	(A)	101.3	93.0	85.7	62.0	38.8	15.8	9.7	6.0
	(B)	101.1	96.7	79.4	62.2	38.7	17.8	10.1	6.5
	Mean	101.2	95.2	82.6	62.2	38.8	16.8	9.9	6.3

Table CA 7.1.2.1.2- 4: Degradation of AE 0002166 in soil [redacted] Am [redacted] 4a under aerobic conditions

Compound	Replicate No	Residues (% Applied) on the following days after treatment (DAT)							
		0	1	3	8	14	21	29	42
AE 0002166	(A)	98.7	92.2	83.0	50.5	26.8	9.5	4.8	3.0
	(B)	100.1	90.5	82.8	52.5	20.7	9.1	4.9	2.3
	Mean	99.4	91.4	82.6	51.5	23.8	9.3	4.8	2.7

Table CA 7.1.2.1.2- 5: Degradation of AE 0002166 in soil [redacted] II under aerobic conditions

Compound	Replicate No	Residues (% Applied) on the following days after treatment (DAT)							
		0	1	3	8	14	21	29	42
AE 0002166	(A)	96.2	85.5	72.6	27.2	9.9	3.9	1.6	1.0
	(B)	100.1	88.5	71.0	30.2	9.8	3.6	1.4	1.3
	Mean	98.2	87.0	71.8	28.7	9.8	3.7	1.5	1.2



**B. METHOD VALIDATION**

The HPLC-MS/MS method was successfully validated prior to application of the degradation samples. Excellent linear correlation between the injected amount and detector response was observed within the range of 0.19 to 22.34 µg/L with a correlation coefficient of 0.9998. The individual method validation recovery rates were in the range of 90% to 109% (overall mean 98%, relative standard deviation (RSD) 0.7%, n = 160). The RSD of the repeatability tests for each recovery set ranged from 0.6% to 6.1%, showing excellent repeatability with this method.

The blank values in control samples were far below 30% of the LOQ for AE 0002166 in all soils tested. The recoveries were not corrected for interferences.

In addition to the recovery rates during method validation, recovery rates at the same fortification levels were performed concurrent to each sampling interval. The concurrent recovery rates were in the range of 89% to 106% (overall mean 97%, RSD 3.8%, n = 16).

The combination of the very selective MS/MS detection method used with the preceding HPLC separation leads to a high specificity of the method.

**C. DEGRADATION OF PARENT COMPOUND**

During study incubation the concentration of test item decreased rapidly in all soils, dropping from 100.9, 101.2, 99.4 and 98.2% at day 0 to 4.9, 6.3, 2.7 and 1.2% of the applied amount towards the end of the study (day 42).

The degradation of AE 0002166 followed single first order (SFO) kinetics in all four soils according to the lowest chi error values and the visual assessments. Table CA 7.1.2.1.2- 6 summarizes the best fit results of the DT<sub>50</sub> and DT<sub>90</sub> calculations.

Table CA 7.1.2.1.2- 6: Degradation kinetics of AE 0002166 in soils under aerobic conditions for trigger values according to FOCUS

Soil	Kinetic Model	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]	Chi <sup>2</sup> Error [%]
Allla	<b>SFO</b>	<b>10.1</b>	<b>33.6</b>	<b>4.1</b>
	FOMC	10.1	33.9	4.5
	DFOP	10.1	33.6	4.7
AXXa	<b>SFO</b>	<b>9.5</b>	<b>31.5</b>	<b>4.5</b>
	FOMC	9.4	31.9	4.9
	DFOP	9.5	31.5	5.1
am 4a	<b>SFO</b>	<b>7.2</b>	<b>24.0</b>	<b>5.9</b>
	FOMC	7.2	24.2	6.5
	DFOP	7.2	24.0	6.8
II	<b>SFO</b>	<b>4.7</b>	<b>15.7</b>	<b>6.3</b>
	FOMC	4.7	15.8	6.9
	DFOP	4.7	15.7	7.3

Best fits according to the criteria set are marked in bold.



### III. CONCLUSIONS

AE 0002166, a soil photolysis degradation product of iodosulfuron-methyl-sodium, was found to rapidly dissipate from soils under aerobic laboratory conditions with typical half-lives in the range of 4.7 to 10.1 days. Therefore, the compound will not persist in a viable soil environment, and no significant mobility of AE 0002166 in soil is to be expected.

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

The degradation rate of iodosulfuron-methyl-sodium in soil under anaerobic conditions in the dark in the laboratory was evaluated during the Annex I inclusion using one radiolabel position, [triazinyl-2-<sup>14</sup>C], and was accepted by the European Commission (SANCO/10166/2003-Final, 3 July 2003). The following study is included in the baseline dossier:

<b>Report:</b>	[REDACTED]:1998:M-182261-01
<b>Title:</b>	Degradation in two soils under anaerobic conditions in the laboratory Code: AE F115008-triazinyl-2- <sup>14</sup> C
<b>Report No:</b>	C001285
<b>Document No:</b>	M-182261-001
<b>Guidelines:</b>	SETAC: 1.2; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[REDACTED]:1998:M-182653-01
<b>Title:</b>	Kinetic evaluation of the anaerobic soil metabolism of AE F115008 in two standard soils using Touhit 2.0 (addendum) Code: AE F15008
<b>Report No:</b>	C001449
<b>Document No:</b>	M-182653-01-1
<b>Guidelines:</b>	Deviation not specified
<b>GLP/GEP:</b>	no

Iodosulfuron-methyl-sodium was found to break down moderately rapid also under anaerobic conditions, with half-lives of 14.3 and 28.1 days in the tested two soils, respectively. The results clearly indicated that even in a flooded soil / anaerobic situation there is no risk of soil accumulation for the parent compound.

No additional studies are submitted within this supplemental dossier for the iodosulfuron-methyl-sodium Annex I Renewal.

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

No studies are submitted within this supplemental dossier for the iodosulfuron-methyl-sodium Annex I Renewal.

Iodosulfuron-methyl-sodium is intended for use in cereals where anaerobic conditions in soil do not prevail for extended time periods and usually not on a full field plot scale. Metabolites formed under anaerobic conditions will be degraded when the soil turns back to aerobic conditions after a period of low oxygen content. This will prevent accumulation of metabolites in the soil. For these reasons specific studies on anaerobic degradation of relevant metabolites, degradation and reaction products in soil are not required.





CA 7.1.2.2 Field studies

The dissipation and degradation of iodosulfuron-methyl-sodium in soil under field conditions were evaluated during the Annex I inclusion using unlabelled iodosulfuron-methyl-sodium formulated as WG20, and were accepted by the European Commission (SANCO/10166/2003-Final, 3 July 2003). The following studies are included in the baseline dossier:

<b>Report:</b>	[redacted];1998;M-182730-01
<b>Title:</b>	The degradation of AE F115008 in soil following a single application of AE F115008 02 WG20 B002 at 6 locations in Europe (Northern and Southern Zone), 1998
<b>Report No:</b>	C001478
<b>Document No:</b>	M-182730-01-1
<b>Guidelines:</b>	Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[redacted];1998;M-181584-01
<b>Title:</b>	Stability of AE F115008 and its metabolite AE F075736 in soil during deep freeze storage of 24 months (interim report) Code: AE F115008
<b>Report No:</b>	C000984
<b>Document No(s):</b>	M-181584-01
<b>Guidelines:</b>	Deviation not specified
<b>GLP/GEP:</b>	yes

From the of iodosulfuron-methyl-sodium and its predominant metabolite AE F075736 dissipation and degradation studies originally submitted in 6 European soils, a new kinetic evaluation according to FOCUS Guidance (2006) has been performed (KCA 7.1.2.2/01).

In addition, the dissipation behaviour of iodosulfuron-methyl, its metabolites AE F075736 and AE F059411 has been studied in Canada (4 soils) and US (3 soils). These studies are considered as supplemental information and are summarised in the supplemental dossier under point KCA 7.1.2.2.1.

The overall new data package is also used to produce a new kinetic evaluation according to FOCUS Guidance (2006) (KCA 7.1.2.2/05).

Summary results of all kinetics studies are listed in [Table CA 7.1.2.2- 1](#) and [Table CA 7.1.2.2- 2](#).

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Table CA 7.1.2.2- 1: Overall summary of DT<sub>50</sub> for degradation of iodosulfuron-methyl-sodium in soils for modelling purpose (normalised to 20 °C and field capacity)

Soil (Country)	Texture (USDA)	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]
(Germany)	silt loam	SFO	10.3	34.3
(Germany)	silt loam	SFO	0.8	2.6
(France)	silt	SFO	- <sup>2</sup>	12
(Great Britain)	silt loam	-	- <sup>2</sup>	- <sup>2</sup>
(France)	silt loam	SFO	4.4	14.4
(Spain)	silt loam	SFO	4.8	15.8
(Canada)	loam	SFO	6.6	22
(Canada)	clay loam	-	- <sup>2</sup>	- <sup>2</sup>
(Canada)	clay loam	SFO	6.2	20.6
(Canada)	clay loam	SFO	9.6	31.6
(USA)	sandy loam	FOMC	5.7	18.8
(USA)	sandy loam	FOMC	0.7	2.2
(USA)	silt loam	-	- <sup>2</sup>	- <sup>2</sup>
		median	3.3	

<sup>1</sup> SFO: single first order; FOMC: first order multi compartment

<sup>2</sup> no reliable value could be obtained

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Table CA 7.1.2.2- 2: Overall summary of DT50 values for degradation of AE F075736 in soils for modelling purpose (normalised to 20 °C and field capacity)

Soil (Country)	Texture (USDA)	Formation Fraction	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	DT <sub>50</sub> [days]
(Germany)	silt loam	1.0	SFO	7.9	26.1
(Germany)	silt loam	0.43	SFO	19.0	27.1
(France)	silt	0.56	SFO	6.9	19.8
(Great Britain)	silt loam				
(France)	silt loam	0.31	SFO	13.6	37.1
(Spain)	silt loam	0.31	SFO	34.9	115.9
(Canada)	loam	1.0	SFO	4.0	6.0
(Canada)	clay loam	- <sup>2</sup>		- <sup>2</sup>	- <sup>2</sup>
(Canada)	clay loam		SFO	6.6	118.4
(Canada)	clay loam	0.41		- <sup>2</sup>	- <sup>2</sup>
(USA)	sandy loam	0.88	SFO	1.4	57.9
(USA)	sandy loam	- <sup>2</sup>		- <sup>2</sup>	- <sup>2</sup>
(USA)	silt loam			- <sup>2</sup>	- <sup>2</sup>
	<b>arithmetic mean</b>	<b>0.61</b>	<b>geomean</b>	<b>14.2</b>	

<sup>1</sup> SFO: single first order, FOMC: first order multi compartment

<sup>2</sup> no reliable value could be obtained

From the soil field dissipation studies no reliable degradation rates could be obtained for the metabolite AE F059414

CA 7.1.2.2.1 Soil dissipation studies

New kinetic evaluation according to FOCUS kinetics (2006).

<b>Report:</b>	[redacted]; 2013; M-447334-01-1
<b>Title:</b>	Kinetic evaluation of field dissipation studies with Iodosulfuron-methyl-sodium and its metabolite AE F075736 under European conditions
<b>Report No:</b>	ENSA-133/116
<b>Document No:</b>	M-447334-01-1
<b>Guidelines:</b>	not applicable; not applicable
<b>GLP/GEP:</b>	no

Data from six field dissipation studies by [redacted] (1998) were evaluated in order to determine kinetic parameters for idosulfuron-methyl-sodium and its metabolite AE F075736 that are suitable inputs for environmental fate models.



The evaluations were performed following the guidance given by the FOCUS report on kinetic evaluation (FOCUS, 2006). The evaluation was based on data normalised to standard reference conditions for soil temperature (20°C) and soil moisture (field capacity) using the time-step method. For this daily temperature and soil moisture values were determined for each site by simulations with PEAR3 using site-specific soil properties and weather data. For the temperature normalisation a Q10-value of 2.58 was used.

Based on a visual and statistical quality check, the kinetic parameters derived from all but one field study were deemed to be reliable and appropriate inputs for environmental fate models. For iodosulfuron-methyl-sodium temperature- and moisture-normalised single first-order DT50 values ranged from 0.8 days to 10.3 days with a geometric mean of 3.0 days. For AE F075736 the range was 6.9 days to 34.9 days with geometric mean of 13.7 days. The arithmetic mean formation fraction of AE F075736 was 0.52.

Table CA 7.1.2.2.1- 1: First-order DT50 values of iodosulfuron-methyl-sodium and its metabolite AE F075736 at 20°C and field capacity, derived from field dissipation studies under European conditions.

	Iodosulfuron-methyl sodium		AE F075736		
	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)	formation fraction	DT <sub>50</sub> (days)	DT <sub>90</sub> (days)
█	10.3	34.9	1.0	7.9	26.1
█	0.8	2.6	0.46	9.0	63.1
█	7	12.2	0.56	6.9	19.8
█	*	*	*	*	
█	4	7.9	0.91	13.6	37.9
█	4.8	15.8	0.31	34.9	115.9
<b>Geometric mean</b>	<b>3.0</b>			<b>13.7</b>	
<b>Arithmetic mean</b>			<b>0.52</b>		

\* data did not allow to determine a reliable value

❖ **New field dissipation studies**

One field study in Canada and one field study in USA have been performed for iodosulfuron-methyl-sodium and are submitted within this supplemental dossier for the iodosulfuron-methyl-sodium Annex I Renewal.

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<b>Report:</b>	██████████; 2002;M-394108-01-1
<b>Title:</b>	Field Dissipation of Iodosulfuron-methyl-sodium (AE F115008) Applied to Four Soils in Western Canada, 2000.
<b>Report No:</b>	ACC01-05
<b>Document No:</b>	M-394108-01-1
<b>Guidelines:</b>	PMRA DACO 8.3.2.1
<b>GLP/GEP:</b>	yes

**Executive Summary**

The dissipation of AE F115008 in bare soil was investigated at four test sites located in western Canada: ██████████, Saskatchewan (SK), ██████████, Manitoba (MB), ██████████, Saskatchewan (SK) and ██████████, Alberta (AB). AE F115008 was applied once in June at a nominal rate of 10 g/ha in a product formulated as a 20% water dispersible granular.

At each trial site, a control plot and three test plots were established on level ground and kept bare during the monitoring period. Soil samples from the treated plots were collected down to a depth of 60 cm in two stages (0-15 cm depth with a diameter of 5.6 cm, 15-60 cm with a diameter of 4.4 cm) at the following sampling intervals; one to 7 days prior to application and 0, 2, 6-7, 14-15, 30-34, 56-66 and 90-94 days after treatment (DAT). In addition, samples from an untreated control plot were collected prior to treatment, on day 0 and at day 14-15. All soil cores were frozen on the day of sampling.

The analytical targets were the parent compound AE F115008 and its two metabolites AE F075736 and AE F059411. Extractable residues were removed from the soil matrix using a solution of sodium carbonate/sodium bicarbonate/methanol. AE F115008 and AE F075736 were analyzed using LC-MS to a lower limit of 0.0005 ppm (w/w). AE F059411 was analyzed to a lower limit of 0.0005 ppm (w/w) using GC-MS.

The concentration (oven dry basis) of AE F115008 in soil samples collected immediately following application ranged from 0.0028 to 0.0070 ppm at site ██████████ (SK), from 0.0071 to 0.0103 ppm at site ██████████ (MB), from 0.0025 to 0.0088 at ██████████ (SK) and from 0.0076 to 0.0117 ppm at ██████████ (AB). When converted to a field application rate, the average amounts of AE F115008 extracted from dosimeter pads ranged from 4.3 to 7.3 g/ha across all four locations. On an individual site basis, the residue amounts detected within a plot and among replicate plots were generally consistent, the standard deviation of the mean for all locations ranged from 1.0 to 1.5 g/ha. Trace amounts of AE F075736 were also detected at all four locations (0.02 to 0.6 g/ha).

AE F115008 dissipated rapidly and completely at all four sites following a first-order exponential decay. The calculated DT<sub>50</sub> values for AE F115008 were 2.0 days at site ██████████ (SK), 4.3 days at site ██████████ (AB), 7.4 days at site ██████████ (SK) and 8.7 days at site ██████████ (MB). The corresponding DT<sub>90</sub> values ranged from 6.8 to 28.7 days.

Initially, the soil residue levels of metabolites AE F075736 and AE F059411 increased as AE F115008 levels declined. At all four locations, AE F075736 residues in the 0-7.5 cm depth reached a maximum concentration of 0.0021 to 0.0048 ppm between DAT-6 and DAT-36. AE F075736 residue levels declined to < 0.0005 ppm to 0.0011 ppm by DAT-90 to DAT-94. The time to reach 50% of the





Table CA 7.1.2.2.1- 2: Properties of the test sites

Trial	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
City (Nearest town)	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Province	Saskatchewan (SK)	Manitoba (MB)	Saskatchewan (SK)	Alberta (AB)
Country	Canada	Canada	Canada	Canada
Classification <sup>A</sup>	Dark Brown Chernozemic (Orthic) from the Weyburn Association	Orthic Black Chernozemic from the Neuhorst Association	Orthic Dark Brown Chernozemic soil from the Elstow Association	Grey wooded soil (Peoria-Gage soil series)
Textural class according to USDA classification <sup>B</sup>	Clay Loam	Clay Loam	Clay Loam	Clay Loam
% Sand <sup>B</sup>	38	21.0	28	27
% Silt <sup>B</sup>	36	44.6	43	44
% Clay <sup>B</sup>	26	34.4	29	29
Organic Matter <sup>B</sup> [%]	7.0	7.6	4.7	6.2
Soil pH <sup>B</sup>	6.6	7.0	5.7	6.2
CEC (meq/100 g) <sup>B</sup>	22.5	30	20.6	21.1
Moisture Holding Capacity (1/3 bar) [%] <sup>B</sup>	30.4	31.4	33.4	30.6
Bulk density [kg/m <sup>3</sup> ]	980	929	930	1020
Irrigation	No	No	No	No
AE F15008 Residues	No	No	No	No

<sup>A</sup> according to Canadian System of Soil Classification

<sup>B</sup> data were obtained for the 0 – 7.5 cm depth.

**B. Study design**

**1. Application**

The general plot layout included one treatment replicated 3 times and separated from each other by a buffer no less than 4 meters. The replicate plots were 30 to 31.5 meters long and 3 to 6 meters wide. Each replicate plot was further divided into a minimum of 9 subplots no less than 3 m wide by 2.5 m long. An untreated plot was established no less than 10 meters from the closest treated plot at all four test sites. The untreated plot was no less than 10 m long and contained at least four subplots.

The test substance was applied during the period of June 14 and June 27, 2000, which corresponds to the recommended application timing of the herbicide.

The application equipment for all locations consisted of a small plot tractor with a three point hitch mounted boom sprayer with flat fan nozzles spaced at 50 cm. The delivery system was maintained under CO<sub>2</sub> pressure (approx. 275 kPa). Prior to the application of the test substance, each nozzle was calibrated for output volume and uniformity of spray pattern. The tractor speed was established to deliver a pass time representing a nominal water volume of 110 l/ha over each of the replicate plots. The boom was positioned at approximately 50 cm above the soil surface.

At each site, nine dosimeter pads (3 per replicate plot) were positioned at ground level prior to application. Each pad consisted of 4 small squares of cellulose material with a total area of 1024 cm<sup>2</sup>. For each treated plot, a single dosimeter was placed near the front, middle and back in areas that



would be sprayed but not sampled. After application, the pads were allowed to air dry and stored frozen.

During the course of the study, the test sites were kept weed free using glyphosate.

## 2. Sampling and sample processing

For all treated plots, ten cores were collected prior to application, immediately after the application (DAT-0), followed by days 3, 7, 14, 30, 60 and 90 (nominal). For each sampling event, only one subplot per replicate plot was sampled except for DAT-0 when two subplots per replicate plot were sampled. No subplot was ever sampled twice. The untreated plot was always sampled prior to the treated plots. Five cores were collected prior to the application, immediately after application (DAT-0) and on DAT-14.

At all sites, soil cores were extracted with a hydraulically powered, dual-stage, tractor-mounted probe. The first stage collected a larger diameter (e.g. 5.6 cm) core from the 0 to 15 cm depth followed by a smaller diameter (e.g. 4.4 cm) core from the 15 to 60 cm soil profile depth. Each coring section was thoroughly cleaned of loose soil between cores. Each sampling stage was lined with a clear acetate tube to contain the soil core once removed from the ground.

Immediately following a sampling event, all soil cores were placed in chilled coolers at the field site as soon as possible, and then transferred to separate monitored freezer storage units. Once frozen, the cores were cut into predetermined lengths (0-7.5, 7.5-15, 15-30, 30-45 and 45-60 cm). A single composite sample by depth per replicate plot for each sampling event was prepared by rigorous mixing at the field test facilities. To ensure homogeneity, the core segments were allowed to thaw briefly but remained cool during the mixing process. Two subsamples < 500 g were prepared from the composite sample and returned back to freezer. One of them was retained at the field test facility in case the shipped subsample was compromised. Frozen samples (soil and dosimeters) were shipped with dry ice to ETL (Xenos Division) via air transport. All samples were received in a frozen state by the analytical facility.

## 3. Irrigation and weather data

When compared with Environment Canada's 1961 to 1990 normal for the Prairie Provinces, total precipitation amounts were slightly higher and average monthly temperatures were slightly lower during June and September 2000 across western Canada. However, no extreme or unusual weather events were recorded for all four test sites that would have adversely impacted this field study.

## 4. Description of workup of samples and analytical procedure

Prior to extraction, samples were homogenized by breaking the cores, removing stones and other debris and mixing well. Extractable residues of AE F115008, AE F075736 and AE F059411 were removed from the soil matrix using a solution of sodium carbonate/sodium bicarbonate/methanol. After filtration, the extract was rotary evaporated down to approximately 25 mL. The volume of the extract was adjusted to 50 mL with distilled water and split into two equal portions. One portion of the extract was transferred to a separatory funnel and partitioned with dichloromethane (DCM). The organic extract was separated, dried through sodium sulphate and evaporated to dryness. A clean-up procedure using LC-NH<sub>2</sub> cartridges was introduced. Following clean-up and rotary evaporation, the





solution was reconstituted in diisopropyl ether or hexane and analyzed by GC-MS for AE F059411. The other portion of the extract was acidified to pH 3.0, cleaned up using C<sub>18</sub> and silica SPE column chromatography and evaporated to dryness. The solution was reconstituted in water/acetonitrile (70/30) and analyzed by LC-MS for AE F115008 and AE F075736. The validated limit of quantification (LOQ) for this procedure is 0.0005 ppm for the three analytes of concern. The peak area responses for AE F115008, AE F075736 and AE F059411 were determined from a series of calibration standards. Detector responses were linear. In each analytical set, the calibration data were used to perform a linear regression analysis. Both samples and standards were analyzed under the same HPLC or GC conditions and with the same analytical sequence. Minor contaminants in the control samples having the same retention time as the analyte were subtracted from the corresponding fortified samples as raw peak area, but not from samples.

The analytical method BY/01/99 was validated prior to use for sample analysis using control samples originating from soil [redacted] (SK). Two samples fortified with AE F115008, AE F075736 and AE F059411 at the LOQ (0.0005 ppm) and one sample was fortified at the 10-fold LOQ level were analyzed. Recoveries ranged from 79.8% to 96.4% for AE F115008, from 90.6% to 110% for AE F075736 and from 77.8% to 87.4% for AE F059411. The overall recoveries  $\pm$  standard deviations were  $88.7 \pm 8.36\%$  (AE F115008),  $103 \pm 10.4\%$  (AE F075736) and  $83.5 \pm 5.1\%$  (AE F059411). In addition, two control samples were fortified over a range from 0.0005 to 0.0100 ppm and analyzed concurrently with each analytical set. For site [redacted], the mean recoveries from these laboratory fortified controls were  $92.9 \pm 19.1\%$  (n = 23) for AE F115008,  $89.5 \pm 16.0\%$  (n = 23) for AE F075736 and  $90.2 \pm 15.4\%$  (n = 23) for AE F059411. For site [redacted], the mean recoveries were  $82.2 \pm 14.4\%$  (n = 20) for AE F115008,  $78.4 \pm 8.9\%$  (n = 19) for AE F075736 and  $92.8 \pm 16.9\%$  (n = 18) for AE F059411. For site [redacted], the mean recoveries were  $85.7 \pm 12.8\%$  (n = 21) for AE F115008,  $88.0 \pm 11.4\%$  (n = 21) for AE F075736 and  $91.1 \pm 19.5\%$  (n = 18) for AE F059411. For site [redacted], the mean recoveries were  $87.9 \pm 12.1\%$  (n = 21) for AE F115008,  $81.3 \pm 8.9\%$  (n = 21) for AE F075736 and  $92.7 \pm 22.0\%$  (n = 21) for AE F059411.

From the dosimeters, AE F115008 and AE F075736 were extracted by shaking for at least six hours with a known volume of acetonitrile. A 10 mL aliquot was measured and concentrated to dryness. The solution was reconstituted in acetonitrile/water (30/70) and analyzed by LC-MS for AE F115008 and AE F075736.

No field spikes were used to determine residue stability in this study. Results from a freezer stability study concluded that no declines of AE F115008 and AE F075736 concentrations were detected during a deep freeze interval of 24 months. The duration of frozen storage prior to extraction ranged from 100-300 days and, therefore, it can be assumed that AE F115008 and its metabolites remained stable throughout this study.

### 5. Calculation of Dissipation rates

A first-order rate model was fit to the AE F115008 field degradation data using the software SigmaPlot™ ver. 7.0 for Windows™. The software used least-squares non-linear curve-fitting to fit the equation for first-order decay. The dissipation time to 50 and 90% of initial concentration (DT<sub>50</sub>)

<sup>3</sup> [redacted], A(1998): "Stability of AE F115008 and its metabolite AE F075736 in soil during deep freeze storage of 24 months." C000984, M-181584-01-1; KCA 7.1.2.2/02



and (DT<sub>90</sub>) for AE F115008 was calculated by the rate constants of degradation. Summary statistics including coefficient of determination (R<sup>2</sup>), indicating wellness of curve-fit were also determined by no-linear regression analysis.

To describe the formation and decline of both AE F075736 and AE F059411 residue over time, a least-squares nonlinear peak model (Gaussian) was used. The DT<sub>50</sub> values for the metabolites represent the time required to decline to 50% of its maximum soil concentration.

## II. Results and Discussion

### A. Application verification and recovery

Based on calibrated spray equipment and pass times over each treated plot, the mean application rate (n=3) of AE F115008 was calculated to be 9.99 ± 0.12 g/ha for ██████ (SK), 9.94 ± 0.02 g for ██████ (MB), 9.99 ± 0.01 g/ha for ██████ (SK) and 9.43 ± 0.04 g/ha for ██████ (AB).

The adjusted concentration (oven dry basis) of AE F115008 in soil samples collected immediately following application ranged from 0.0028 to 0.0070 ppm at site ██████ (SK), from 0.0071 to 0.0103 ppm at site ██████ (MB), from 0.0025 to 0.0088 at ██████ (SK) and from 0.0076 to 0.0117 ppm at ██████ (AB).

In addition, the application rate was determined from the analysis of dosimeter pads. When converted to a field application rate, the average amounts of AE F115008 extracted from these pads ranged from 4.3 to 7.3 g/ha across all four locations. On an individual site basis, the residue amounts detected within a plot and among replicate plots were generally consistent, the standard deviation of the mean for all locations ranged from 1.0 to 1.5 g/ha. Trace amounts of AE F075736 were also detected at all four locations (0.02 to 0.6 g/ha after conversion). AE F059411 was not detected.

### B. Dissipation and Behaviour of AE F115008 and its metabolites in Soil

The data for the dissipation of AE F115008 at the four test sites as well as the formation and dissipation of the metabolites AE F075736 and AE F059411 are presented in [Table CA 7.1.2.2.1-3](#) to [Table CA 7.1.2.2.1-6](#).

AE F115008 dissipated rapidly and completely at all four sites following a first-order exponential decay. The calculated DT<sub>50</sub> values for AE F115008 were 2.0 days at ██████ (SK), 4.3 days at ██████ (AB) 7.4 days at ██████ (SK) and 8.7 days at ██████ (MB). The DT<sub>90</sub> values at all sites ranged from 6.8 to 28.7 days (see [Table CA 7.1.2.2.1-7](#) for a summary of all kinetic data).

Initially, the soil residue levels of metabolites AE F075736 and AE F059411 increased as AE F115008 levels declined. At all four locations, AE F075736 residues in the 0-7.5 cm depth reached a maximum concentration of 0.0021 to 0.0048 ppm between DAT-6 and DAT-36. AE F075736 residue levels declined to 0.0005 ppm to 0.0011 ppm by DAT-90 to DAT-94. The time to reach 50% of the maximum soil concentration occurred during the 3 month monitoring period and ranged from 5 to 41 days.



At three of the test sites, trace levels of AE F059411 were detected only in the 0-7.5 cm depth throughout the monitoring period. AE F059411 was not detected above the LOQ at ██████████, Saskatchewan, for all sampling events. AE F059411 reached a maximum concentration of 0.0013 to 0.0014 ppm by DAT-61 to DAT-66 declining slightly to a concentration of 0.0007 to 0.0011 by DAT-90/91. The time to reach 50% of the maximum soil concentration could not be determined for AE F059411 due to its low soil concentration throughout the 3 month monitoring period.

With the exception of one sample from ██████████ (MB) and two samples from ██████████ (SK) no residues above the LOQ were detected below the 0 - 7.5 cm depth. This indicated that residues derived from an application of AE F115008 are not mobile in western Canadian soils.

Table CA 7.1.2.2.1- 3: Residue data for the dissipation of AE F115008 in soil at test site ██████████ (SK) under field conditions as well as residue data for AE F075736 and AE F059411 (ppm, data are adjusted to a moisture free basis)

Depth [cm] – (Replicate)	Days after treatment (DAT)						
	0	3	6	24	32	56	94
<b>AE F115008</b>							
0 - 7.5 (1)	0.0053	0.0009	0.0003	-	-	-	-
0 - 7.5 (2)	0.0070	0.0012	0.0014	-	-	-	-
0 - 7.5 (3)	0.0065	0.0030	0.0012	-	-	-	-
0 - 7.5 (4)	0.0070	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0 - 7.5 (5)	0.0028 <sup>A</sup>	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0 - 7.5 (6)	0.0076	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>AE F075736</b>							
0 - 7.5 (1)	0.0010	0.0029	0.0038	0.0015	-	-	-
0 - 7.5 (2)	0.0007	0.0038	0.0048	0.0016	-	-	-
0 - 7.5 (3)	0.0008	0.0040	0.0043	0.0020	-	-	-
0 - 7.5 (4)	0.0008	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0 - 7.5 (5)	0.0024	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0 - 7.5 (6)	0.0008	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>AE F059411</b>							
0 - 7.5 (1)	-	-	-	-	-	-	-
0 - 7.5 (2)	-	-	-	-	-	-	-
0 - 7.5 (3)	-	-	-	-	-	-	-
0 - 7.5 (4)	-	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0 - 7.5 (5)	-	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0 - 7.5 (6)	-	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a.: Not analyzed

<sup>A</sup> Data value represents a mean of duplicate or multiple analysis

No residues were detected in the 7.5-15 cm or the 15 to 30 cm soil layer.

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Table CA 7.1.2.2.1- 4: Residue data for the dissipation of AE F115008 in soil at test site (MB) under field conditions as well as residue data for AE F075736 and AE F059411 (ppm, data are adjusted to a moisture free basis)

Table with columns: Depth [cm] - (Replicate), Days after treatment (DAT) (0, 3, 7, 15, 30, 66, 90). Rows are grouped by AE F115008, AE F075736, and AE F059411, with sub-rows for different depths (e.g., 0-7.5 cm).

n.a.: Not analyzed

^ Data value represents a mean of duplicate or multiple analysis

o residues of AE F115008 and AE F075736 were detected in the 7.5-15 cm soil layer (all values < LOQ).

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Table CA 7.1.2.2.1- 5: Residue data for the dissipation of AE F115008 in soil at test site (SK) under field conditions as well as residue data for AE F075736 and AE F059411 (ppm, data are adjusted to a moisture free basis)

Depth [cm] – (Replicate)	Days after treatment (DAT)						
	0	2	7	14	34	61	91
<b>AE F115008</b>							
0 - 7.5 (1)	0.0082	0.0051	0.0056	0.0006	< 0.0005	< 0.0005	-
0 - 7.5 (2)	0.0030 <sup>A</sup>	0.0053	0.0047	< 0.0005	< 0.0005	< 0.0005	-
0 - 7.5 (3)	0.0025 <sup>A</sup>	0.0056	0.0021	0.0007	< 0.0005	< 0.0005	-
0 - 7.5 (4)	0.0081	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0 - 7.5 (5)	0.0054	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0 - 7.5 (6)	0.0088	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
7.5 - 15 (1)	-	-	-	-	-	-	-
7.5 - 15 (2)	-	-	-	-	-	-	-
7.5 - 15 (3)	0.0009	-	-	-	-	-	-
7.5 - 15 (4)	-	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
7.5 - 15 (5)	-	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
7.5 - 15 (6)	0.0009	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>AE F075736</b>							
0 - 7.5 (1)	0.0010	0.0009	0.0018	0.0019	0.0008	< 0.0005	-
0 - 7.5 (2)	-	0.0014	0.0009	0.0010	0.0005	0.0009	-
0 - 7.5 (3)	-	0.0009	0.0014	0.0021	0.0014	0.0008	0.0008
0 - 7.5 (4)	0.0010 <sup>A</sup>	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0 - 7.5 (5)	0.0010	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0 - 7.5 (6)	0.0011 <sup>A</sup>	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
<b>AE F059411</b>							
0 - 7.5 (1)	0.0007	0.0009	0.0008	0.0010	0.0010	0.0010	0.0010
0 - 7.5 (2)	0.0006	0.0007	0.0007	0.0009	0.0009	0.0011	0.0009
0 - 7.5 (3)	0.0005	0.0006	0.0006	0.0007	0.0007	0.0014	0.0010
0 - 7.5 (4)	0.0006	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0 - 7.5 (5)	0.0006	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
0 - 7.5 (6)	0.0007	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

n.a.: Not analyzed

<sup>A</sup> Data value represents a mean of duplicate or multiple analysis

No residues of AE F075736 and AE F059411 were detected in the 7.5 - 15 cm soil layer.

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Table CA 7.1.2.2.1- 6: Residue data for the dissipation of AE F115008 in soil at test site (AB) under field conditions as well as residue data for AE F075736 and AE F059411 (ppm, data are adjusted to a moisture free basis)

Table with 8 columns: Depth [cm] - (Replicate), 0, 2, 7, 14, 36, 62, 90. Rows are grouped by substance: AE F115008, AE F075736, and AE F059411, each with 6 depth measurements (0-7.5 cm).

n.a.: Not analyzed

A Data value represents mean of duplicate or multiple analysis

No residues of AE F115008, AE F075736 and AE F059411 were detected in the 0-15 cm soil layer.

Table CA 7.1.2.2.1- 7: Summary of DT50 values, DT90 values and coefficients of determination for AE F115008 and its metabolites AE F075736 and AE F059411 at four locations in western Canada

Table with 5 columns: Location, Substance, DT50 (days), DT90 (days), R2. Rows list substances at four locations: (SK), (AB), (SK), and (AB).

days after reaching its maximum soil concentration

ND indicates that a calculated value could not be determined



### III. Conclusion

This study concluded that AE F115008 will rapidly and completely degrade in the environment. The degradation followed a first order exponential decay with calculated DT<sub>50</sub> values of 2.0, 4.3, 7.4 and 8.7 days at sites ██████ (SK), ██████ (AB), ██████ (SK) and ██████ (MB) respectively. The corresponding DT<sub>90</sub> values ranged from 6.8 to 28.7 days.

A 50% decline of the maximum observed concentration of AE F075736 occurred during the course of the study and DT<sub>50</sub> values were estimated to be in the range of 5 to 41 days for all four locations. A relevant half-life for AE F059411 could not be estimated for the three locations that detected low concentrations of this metabolite.

Soil residues derived from AE F115008 are not expected to leach as no measurable levels of parent or metabolites were found below the top layer (0-15 cm) of soil at all four field locations in western Canada.

<b>Report:</b>	██████████, 2006 M-238505-01
<b>Title:</b>	Dissipation of AE F115008 and AE F130360 in soil following application of AE F115008 WDG and AE F122006 WDG or AE F130060 WDG and AE F107892 WDG to a bare plot at the maximum proposed rates, USA, 1998. AE F115008
<b>Report No:</b>	B00278
<b>Document No:</b>	M-238505-01
<b>Guidelines:</b>	USEPA (=EPA): 04-1; not specified
<b>GLP/GEP:</b>	yes

#### Executive Summary

The dissipation of AE F115008 in bare soil was investigated at three test sites located in the United States of America. AE F115008 was applied once in the time from July to August in a 20% water dispersible granule formulation at a nominal rate of 10 g a.s./ha. A tank mix was prepared by blending AE F115008 WDG 20, the safener AE F122006 WDG 50, an esterified seed oil and a nitrogen fertilizer.

At each trial site, a control plot and a treated test plot were established on nearly level ground and the soil was kept bare during the monitoring period. Soil samples from the treated plots were collected down to a depth of 90 cm during a period of 18 months and analyzed for the following sampling intervals: prior to application, after application as well as 1, 3-4, 7-8, 14, 21-22, 28, 48-56, 62-67 and 282 days after treatment (DAT). In addition, samples from an untreated control plot were collected prior to treatment and at representative sampling intervals. All soil cores were frozen on the day of sampling.

The analytical targets were the parent compound AE F115008 and its two metabolites AE F075736 and AE F059411. Extractable residues were removed from the soil matrix using a solution of sodium carbonate and sodium bicarbonate in aqueous methanol. AE F115008 and AE F075736 were analyzed using HPLC-MS to a lower limit of 0.5 µg/kg. AE F059411 was analyzed to a lower limit of 0.5 µg/kg using GC-NPD (nitrogen phosphorus detection).



The calculated application rates were 9.9, 12.0 and 10.2 g/ha for sites [redacted], [redacted] and [redacted], respectively (verified by the total amount delivered per treated area sprayed). In general, analysis of AE F115008 derived residues on the spray dosimeter pads showed reasonable agreement with the predicted application rates. In [redacted], the dosimeter pads accounted for 100.9% of the target rate. In [redacted] the dosimeter pads accounted for 77.7% of the target rate. Dosimeter pads were not used in [redacted] (due to oversight).

The decline of iodosulfuron-methyl-sodium (AE F115008) was rapid at all sites with first order half lives ranging from 2 to 8 days. The half-life of the soil metabolite AE F075736 ranged from 7 to 41 days. The half-life of the soil metabolite AE F059411 was about 7 days in the [redacted] soil and could not be determined in the [redacted] and [redacted] soils. There were no residues of AE F059411 greater than the limit of quantitation in the [redacted] soil. In general the residue levels of the metabolite AE F059411 in the soil were too low to permit the reliable calculation of decline trends. The half-life of the combined residues (sum of the three analytes) was about 5 days in the [redacted] soil, 32 days in the [redacted] soil and about 10 days in the [redacted] soil.

No evidence for leaching of any compound was observed at any trial location.

**1. Material and Methods**

**A. Materials**

**1. Test Item**

AE F115008 00 WDG 20 (water dispersible granular formulation)  
Batch No.: A107 and A108  
Active Ingredient: AE F115008 (19.9 and 20.4% of AE F115008 by weight, respectively)  
Safener: Isoxadifen-Ethyl (50% per weight, Formulation: AE F122006 00 WDG 50 A203)

**2. Trial Location**

Three test sites located in the United States were used, representing different cultural and climatic conditions. The slope of the soil surface at all field sites was nearly level ( $\leq 1\%$ ) and the soil surface was bare of vegetation prior to test substance application. Detailed site descriptions including soil characterization data for all depths for each of the three sites are presented in the report. The field characteristics summarized in [Table CA 7.1.2.2.1](#) give a general comparison of the sites.

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Table CA 7.1.2.2.1- 8: Properties of the test sites

Trial No.	R02-01	R05-01	R10-01	
State:				
City (Nearest town)				
County				
Country	USA	USA	USA	
EPA Region	III	V		
Soil Type <sup>A</sup>	Sandy Loam	Silt Loam	Sandy Loam	
			Control	Treated Plot
% Sand <sup>A</sup>	56	22	7	7
% Silt <sup>A</sup>	34	54	8	8
% Clay <sup>A</sup>	10	24	4	6
Organic Matter <sup>A</sup> [%]	2.4	3.5	0.4	0.4
Soil pH <sup>A</sup>	6.1	5.5	6	7
CEC (meq) <sup>A</sup>	9.0	21.2	6.6	4.8
Moisture Holding Capacity (at 1/3 bar) <sup>A</sup>	16.8	29.4	7.4	7.8
Bulk density [g/cm <sup>3</sup> ] <sup>A</sup>	1.32	1.12	1.2	1.4
Irrigation	Yes	Yes	Yes	
AE F115008 Residues	No	No	No	

<sup>A</sup> refers to the 0-7.5 cm depth

**B. Study design**

**1. Application**

Prior to the start of experimental work each plot was divided into subplots. Each subplot was sufficiently large to allow five cores to be taken from each. The individual subplots were then numbered and randomized with respect to the sampling time points.

The test substance was applied during the period of July 23 and August 31, 1998. The application equipment for all locations consisted of mounted sprayers with flat fan nozzles. The target application rate for AE F115008 was 10 g a.s./ha. In addition to AE F115008, the tank mix contained the safener AE F122006 WDG50, an esterified seed oil and a nitrogen fertilizer.

Each field location was supplied with six application dosimeter pads (except for site [redacted]). Each dosimeter consisted of four squares of a cellulose, each approximately 15 cm per side. Just prior to each application event three dosimeter pads were placed on previously sampled sub-plots in the treated plot. The pads were placed to receive the same application as the treated plot but not be damaged by the spray equipment. After application, the pads were stored deep frozen. The plots were kept bare for the duration of the trial by the use of pre-approved herbicides. Disturbance of the soil surface was avoided wherever possible.

**2. Sampling and sample processing**

The soil at each location was sampled for characterization prior to the start of the study. At each site, triplicate samples, each of five cores, were taken; prior to treatment and after each application. Samples from the treated plots were collected at the following sampling intervals (nominally): 1, 4, 7, 14, 21, 28 and 45 days, then 2, 4, 6, 9, 12, 15 and 18 months following the application. During winter months, when frozen ground precluded sampling, nominal time points were missed. The plots were sampled as soon as they had thawed and dried sufficiently. This sampling was assigned to the most



recently missed time point. The treated plot was also sampled if a heavy rainfall event, defined as over 50 millimetres in twenty four hours, occurred. The treated plot was sampled as soon as the plot had dried sufficiently. The control plot was sampled less frequently than the treated plot (nominal sampling intervals: Pre-treatment, post application, at days 1 and 28, after 6, 12, and 18 months).

At each time point three subplots were sampled from the treated plot. Five cores were taken from each subplot. The core was taken in two portions to minimize the risk of contamination of the lower horizons. The 0 to 15 cm segment of the core was taken separately. A small excavation to a depth of 15 cm was dug and the 15 cm to 90 cm section of the core taken from the bottom of the excavation.

All cores were collected with a hydraulic corer using "zero contamination" butyl liners. The liner was changed after each core was sampled. The corers were thoroughly washed between each use.

Soil cores were placed in coolers, with ice or ice substitute immediately after collection. They were transferred to frozen storage within two hours of collection and maintained in frozen condition. Frozen cores were sectioned into appropriate horizons at the field sites. Sectioned cores were kept frozen until shipped to the ARC via freezer truck.

3. Irrigation and weather data

Daily weather data was collected at each trial location. The rainfall was monitored, and during periods when the rainfall fell below the average irrigation was applied to make up the shortfall (see Table CA 7.1.2.2.1-9 for irrigation data). The daily weather data collected during the trial was included in the study raw data and archived at the conclusion of the study. At site [redacted], rainfall and temperature were considered to have been normal. At site Illinois there was less rainfall during the study period while the air temperature was normal. At site [redacted] there was less rainfall and air temperature was considered to have been cooler than normal.

Table CA 7.1.2.2.1- 9: Precipitation and irrigation at the test sites

Trial No.	R02-01		R05-01		R10-01	
	Precipitation <sup>A</sup>	Irrigation	Precipitation	Irrigation	Precipitation	Irrigation
June 1998	-	0.0	-	-	-	127 <sup>B</sup>
July 1998	193.6	0.0	-	-	0.0	80.7
August 1998	79.9	9.1	-	7.6 (B), 7.0 (C)	0.0	74.3
September 1998	703.6	0.0	18.5	0.0	3.6	42.9
October 1998	736	0.0	52.3	100.4	9.5	33.0
November 1998	182.1	144.9	55.9	0.0	13.4	0.0
December 1998	78	0.0	27.7	0.0	14.6	0.0
January 1999	92	0.0	110.7	0.0	56.5	6.6
February 1999	14.7	0.0	58.4	0.0	28.2	0.0
March 1999	158	27.9	28.7	0.0	16.3	0.0
April 1999	74.9	0.0	109.2	0.0	28.1	9.9
May 1999	435	0.0	51.8	0.0	0.2	3.3
June 1999	174	0.0	111.0	0.0	0.0	13.2
July 1999	136	76.2	60.7	0.0	0.0	46.2
August 1999	182	0.0	160.0	0.0	0.0	0.0
September 1999	64	16.5	43.9	0.0	0.6	23.1



Trial No.	R02-01		R05-01		R10-01	
State:	[REDACTED]		Illinois		[REDACTED]	
October 1999	155	0.0	50.5	0.0	0.0	49.5
November 1999	60.7	0.0	-	0.0	-	

<sup>A</sup> on-site weather data

<sup>B</sup> Method of irrigation was Flood and source was well.

<sup>C</sup> Method of irrigation was Sprinkler and source was well for all the remaining dates.

#### 4. Description of work-up of samples and analytical procedure

All sample analysis was conducted at the AgrEvo Research Center, [REDACTED], NC. Cores from horizons below 15 cm were subcored. The matching horizons from each core were then composited. The composited horizons were homogenized by coarse sieving and manual mixing. The mixed, composited samples were stored frozen pending analysis.

Soil samples were analyzed for iodosulfuron-methyl-sodium (AE F115008) parent compound and the principal soil metabolites AE F075736 and AE F059411, by a method which allowed the quantification of all three analytes from a single sample:

Iodosulfuron-methyl-sodium (AE F115008) derived residues are extracted from the soil matrix using a solution of sodium carbonate and sodium bicarbonate in aqueous methanol. After filtration through Celite, the extract is evaporated to a reduced volume and divided equally into two portions, one portion for the analysis of AE F115008 and AE F075736, the second portion for the analysis of AE F057411. One portion of the extract is acidified to pH 3.0, then loaded onto a silica gel SPE column. The column eluate and aqueous rinses are then loaded onto a C-18 SPE column. After water removal, the analytes (AE F115008 and AE F075736) are eluted with ethyl acetate acidified with acetic acid. This eluate is taken to dryness, reconstituted in ethyl acetate/hexane and loaded onto a second C-18 SPE column. After rinsing, the analytes are again eluted with ethyl acetate acidified with acetic acid. The final eluate is taken to dryness then reconstituted with acetonitrile/water for analysis of AE F115008 and AE F075736 residues by HPLC-MS. The second portion of the initial extract is partitioned with methylene chloride. The methylene chloride partitions are dried through sodium sulphate, taken to dryness then reconstituted in toluene for analysis of AE F059411 residues by GC-NPD (nitrogen phosphorus detection). The LOQ was the lowest level at which the method was validated, 0.5 µg/kg. The LOD was defined as three times the standard deviation of the procedural recovery, in µg/kg, for all samples fortified at the LOQ of 0.5 µg/kg (range for the three analytes: 0.219 – 0.325 µg/kg)

The efficiency of the analytical method was tested by including one unfortified and at least one fortified control sample with each set of samples analyzed. The fortified control samples were spiked with the analytes of interest just prior to extraction. Any apparent residues in the unfortified control were subtracted from the residues found in the fortified control before the method efficiency was calculated. With the exception of the accountability determination, residues from treated samples have not been corrected for any procedural recoveries. Apparent residues reported in control samples have not been corrected for procedural recovery. Over a calibration range from 0.5 to 10 µg/kg, the recoveries ranged from 58 to 134% for AE F115008 (mean: 86%), 64 to 122% for AE F075736 (mean: 84%) and from 60 to 130% for AE F059411 (mean: 91%).



The stability of iodosulfuron-methyl-sodium, AE F075736 and AE F059411 was investigated in ongoing studies. Three compounds have exhibited satisfactory stability for the respective periods of approximately 8 months, 8 months and 104 days<sup>4</sup>. Hence no correction factor for any possible losses during frozen storage has been indicated by the storage stability study. Therefore, the residue data were not corrected for losses during freezer storage even though treated samples from this study were stored under frozen conditions for as long as 457 days.

**5. Calculation of dissipation rates**

Since the observed iodosulfuron-methyl-sodium (AE F115008) derived residues were located in the surface to 7.5 cm deep horizon the half-life calculations were based on the residues in the top horizon only (mean values). The analyte residues in each sample were added, with consideration for molecular weight, to get a "combined residue" which is presented in units of AE F115008 equivalents. The residues for each analyte and the combined residue were plotted versus days after application. Regression analysis was performed on each set of data to yield the best fit straight line and to calculate the first-order rate constants used to determine the half-lives.

**II. Results and Discussion**

**A. Application verification and recovery**

The calculated application rates were 9.9, 12.0 and 10.2 g/ha for sites [redacted] Illinois and [redacted], respectively (verified by the total amount delivered per treated area sprayed).

In general, analysis of AE F115008 derived residues on the spray dosimeter pads showed reasonable agreement with the predicted application rates. In [redacted], the dosimeter pads accounted for 100.9% of the target rate. In Illinois the dosimeter pads accounted for 77.7% of the target rate. Dosimeter pads were not used in [redacted] (due to oversight).

The mean adjusted concentration (oven dry basis) for the combined residues (expressed as AE F115008 equivalents) in soil samples collected immediately following application were 3.51 µg/kg at site [redacted], 8.85 µg/kg at site Illinois and 11.16 µg/kg at site [redacted].

**B. Dissipation and behaviour of AE F115008 and its metabolites in soil**

The data for the dissipation of AE F115008 at the three test sites as well as the formation and dissipation of the metabolites AE F075736 and AE F05941 are presented in [Table CA 7.1.2.2.1-10](#) to [Table CA 7.1.2.2.1-11](#).

At all three locations the maximum AE F115008 residues were observed either immediately after or one day after the application. AE F115008 derived residues were generally confined to the surface to 7.5 cm horizon. Residues detected at deeper levels were limited to two observations of AE F115008, just above the limit of quantitation, in the Illinois soil on the day of application, which are probably artefacts of sampling. The decline of iodosulfuron-methyl-sodium (AE F115008) was rapid at all sites with first order half-lives ranging from 2 to 8 days. The half-life of the soil metabolite AE F075736

<sup>4</sup> [redacted], A. (1998): "Stability of AE F115008 and its metabolite AE F075736 in soil during deep freeze storage of 24 months." C000984, M-181584-01-1; KCA 7.1.2.2/02



ranged from 7 to 41 days. The half-life of the soil metabolite AE F059411 was about 7 days in the [redacted] soil and could not be determined in the Illinois and [redacted] soils. There were no residues of AE F059411 greater than the limit of quantitation in the [redacted] soil (see Table CA 7.1.2.2.1-9 for a summary of all kinetic data).

Table CA 7.1.2.2.1- 10: Residue data for the dissipation of AE F115008 in soil at test site [redacted] under field conditions as well as residue data for AE F075736 and AE F059411 (ppb, data are adjusted to a moisture free basis)

Table with columns: Depth [cm] - (Replicate), Days after treatment (DAT) 0, 1, 4, 7, 21. Rows are grouped by AE F115008, AE F075736, and AE F059411, showing residue levels (ppb) at various depths and time points.

ND: Not detected
LOQ: 9.5 ppb
Soil layers deeper than 30 cm were not analyzed.

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Table CA 7.1.2.2.1- 11: Residue data for the dissipation of AE F115008 in soil at test site Illinois under field conditions as well as residue data for AE F075736 and AE F059411 (ppb)

Illinois	Days after treatment (DAT)									
	0	1	3	8	14	22	28	56	67	282
<b>AE F115008</b>										
0 - 7.5 (1)	4.87	2.14	2.08	1.92	1.19	0.61	< LOQ	< LOQ	< LOQ	n.a.
0 - 7.5 (2)	4.60	1.80	2.34	3.49	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	n.a.
0 - 7.5 (3)	5.99	2.70	2.65	3.60	0.84	< LOQ	< LOQ	< LOQ	< LOQ	n.a.
7.5 - 15 (1)	ND	ND	ND	ND	ND	ND	< LOQ	ND	ND	n.a.
7.5 - 15 (2)	ND	ND	< LOQ	ND	ND	< LOQ	ND	ND	ND	n.a.
7.5 - 15 (3)	ND	< LOQ	< LOQ	ND	ND	ND	ND	< LOQ	ND	n.a.
15 - 30 (1)	0.58	< LOQ	< LOQ	< LOQ	ND	ND	ND	< LOQ	< LOQ	n.a.
15 - 30 (2)	0.76	ND	< LOQ	< LOQ	< LOQ	< LOQ	ND	ND	ND	n.a.
15 - 30 (3)	< LOQ	ND	< LOQ	< LOQ	< LOQ	ND	ND	ND	ND	n.a.
<b>AE F075736</b>										
0 - 7.5 (1)	1.51	2.20	1.00	0.76	0.91	0.84	< LOQ	0.53	< LOQ	n.a.
0 - 7.5 (2)	1.71	2.02	0.80	0.94	ND	0.87	0.62	< LOQ	< LOQ	n.a.
0 - 7.5 (3)	< LOQ	1.66	0.82	0.78	< LOQ	0.61	< LOQ	0.66	< LOQ	n.a.
7.5 - 15 (1)	ND	< LOQ	ND	< LOQ	ND	< LOQ	< LOQ	< LOQ	ND	n.a.
7.5 - 15 (2)	ND	< LOQ	ND	ND	< LOQ	ND	< LOQ	ND	ND	n.a.
7.5 - 15 (3)	ND	< LOQ	ND	< LOQ	ND	ND	ND	ND	ND	n.a.
15 - 30 (1)	ND	< LOQ	ND	< LOQ	ND	< LOQ	ND	< LOQ	< LOQ	n.a.
15 - 30 (2)	ND	ND	ND	ND	ND	< LOQ	ND	ND	ND	n.a.
15 - 30 (3)	ND	< LOQ	ND	< LOQ	ND	ND	ND	ND	< LOQ	n.a.
<b>AE F059411</b>										
0 - 7.5 (1)	< LOQ	0.70	< LOQ	< LOQ	< LOQ	0.72	< LOQ	0.52	< LOQ	0.57
0 - 7.5 (2)	< LOQ	< LOQ	0.80	0.80	0.62	< LOQ	< LOQ	< LOQ	0.54	0.51
0 - 7.5 (3)	< LOQ	0.51	0.62	0.70	0.66	0.56	< LOQ	0.76	0.51	0.98
7.5 - 15 (1)	< LOQ	< LOQ	ND	ND	ND	ND	ND	ND	ND	ND
7.5 - 15 (2)	ND	< LOQ	ND	ND	ND	ND	ND	ND	ND	ND
7.5 - 15 (3)	ND	< LOQ	ND	ND	ND	ND	ND	ND	ND	< LOQ
15 - 30 (1)	ND	< LOQ	< LOQ	ND	ND	ND	ND	ND	ND	ND
15 - 30 (2)	< LOQ	< LOQ	< LOQ	< LOQ	ND	< LOQ	ND	ND	ND	ND
15 - 30 (3)	ND	ND	ND	< LOQ	ND	ND	ND	ND	ND	ND

n.a.: not analyzed  
 ND: Not detected  
 LOQ: 0.5 ppb  
 Soil Layers deeper than 30 cm were not analyzed

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Table CA 7.1.2.2.1- 12: Residue data for the dissipation of AE F115008 in soil at test site [redacted] under field conditions as well as residue data for AE F075736 and AE F059411 (ppb, data are adjusted to a moisture free basis)

Depth [cm] – (Replicate)	Days after treatment (DAT)								
	0	1	4	7	14	21	28	48	62
<b>AE F115008</b>									
0 - 7.5 (1)	3.36	3.27	1.88	<LOQ	<LOQ	<LOQ	ND	ND	<LOQ
0 - 7.5 (2)	4.19	2.72	0.84	<LOQ	<LOQ	<LOQ	ND	<LOQ	<LOQ
0 - 7.5 (3)	2.97	3.00	1.01	0.77	ND	<LOQ	ND	ND	<LOQ
7.5 - 15 (1)	<LOQ	ND	<LOQ	ND	<LOQ	ND	ND	<LOQ	<LOQ
7.5 - 15 (2)	<LOQ	<LOQ	ND	ND	ND	ND	ND	<LOQ	ND
7.5 - 15 (3)	ND	ND	ND	<LOQ	<LOQ	<LOQ	ND	ND	ND
15 - 30 (1)	<LOQ	ND	ND	ND	<LOQ	ND	ND	ND	ND
15 - 30 (2)	<LOQ	<LOQ	<LOQ	ND	ND	ND	ND	<LOQ	<LOQ
15 - 30 (3)	<LOQ	ND	<LOQ	ND	ND	ND	ND	ND	ND
<b>AE F075736</b>									
0 - 7.5 (1)	<LOQ	0.53	1.07	1.17	1.23	0.52	0.52	<LOQ	<LOQ
0 - 7.5 (2)	<LOQ	0.79	1.33	1.48	1.26	0.71	<LOQ	<LOQ	<LOQ
0 - 7.5 (3)	<LOQ	0.66	0.52	1.78	0.91	0.73	<LOQ	<LOQ	<LOQ
7.5 - 15 (1)	<LOQ	<LOQ	<LOQ	<LOQ	ND	ND	<LOQ	<LOQ	ND
7.5 - 15 (2)	ND	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	ND	<LOQ	ND
7.5 - 15 (3)	ND	ND	ND	ND	ND	ND	ND	<LOQ	ND
15 - 30 (1)	ND	ND	ND	<LOQ	ND	ND	ND	ND	<LOQ
15 - 30 (2)	ND	ND	<LOQ	ND	<LOQ	<LOQ	ND	ND	ND
15 - 30 (3)	ND	<LOQ	ND	ND	ND	ND	ND	ND	<LOQ
<b>AE F059411</b>									
0 - 7.5 (1)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
0 - 7.5 (2)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
0 - 7.5 (3)	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
7.5 - 15 (1)	ND	ND	ND	ND	ND	ND	ND	ND	ND
7.5 - 15 (2)	ND	ND	ND	ND	ND	ND	ND	<LOQ	ND
7.5 - 15 (3)	ND	ND	ND	ND	ND	ND	ND	ND	ND
15 - 30 (1)	ND	ND	ND	<LOQ	ND	ND	ND	ND	ND
15 - 30 (2)	ND	ND	ND	ND	ND	ND	ND	ND	<LOQ
15 - 30 (3)	ND	ND	ND	ND	ND	ND	<LOQ	ND	ND

ND: Not detected

LOQ: 0.5 ppb

Soil Layers deeper than 30 cm were not analyzed.

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Table CA 7.1.2.2.1- 13: Estimated kinetic parameters for the dissipation of AE F115008 and its metabolites AE F075736 and AE F059411 at three locations in the USA

Location	Substance	Calculated Half Life (days)	Visual DT <sub>50</sub> (approx. days)	Visual DT <sub>90</sub> (days)	RSQ
[Redacted]	AE F115008	2.2	3	CNE	0.79
	AE F075736	7.2	5	CNE	0.76
	AE F059411	6.6	5	CNE	0.85
	Combined	4.9	5	CNE	0.95
[Redacted]	AE F115008	7.9	12	CNE	0.67
	AE F075736	41	40	CNE	0.14
	AE F059411	CNE	CNE	CNE	0.02
	Combined	32.4	40	70	0.19
[Redacted]	AE F115008	6	9	9	0.99
	AE F075736	11.6	12	8	0.99
	AE F059411	CNE	CNE	CNE	-
	Combined	10.4	12	> 28	0.98

CNE: Could not be estimated due to low residues and/or no trend

III Conclusion

The decline of iodosulfuron-methyl-sodium (AE F115008) was rapid at all sites with first order half-lives ranging from 2 to 8 days. The half-life of the soil metabolite AE F075736 ranged from 7 to 41 days. The half-life of the soil metabolite AE F059411 was about 7 days in the [Redacted] soil and could not be determined in the Illinois soil. There were no residues of AE F059411 greater than the limit of quantitation in the [Redacted] soil. In general the residue levels of the metabolite AE F059411 in the soil were too low to permit the reliable calculation of decline trends.

No evidence for leaching of any iodosulfuron-methyl-sodium (AE F115008) derived compound was observed at any trial location.

❖ New kinetic evaluation of the newly submitted studies according to FOCUS kinetics (2006)

Report:	[Redacted];2014;M-476836-01
Title:	Iodosulfuron-methyl-sodium (IMS) and metabolites: Kinetic evaluation of field dissipation studies in the USA and Canada according to Focus kinetics
Report No:	EnS4-14-0148
Document No:	M-476836-01-1
Guidelines:	not applicable;not applicable
GLP/GEP:	no

Executive Summary

A kinetic analysis of soil residue data from the field dissipation studies KCA 7.1.2.2.1 /03 and KCA 7.1.2.2.1 /04 (M-394108-01-1 and M-238505-01-1) was performed with the software KinGUI 2 according to FOCUS kinetics (2006, 2011) to derive normalised (20 °C and field capacity) half-lives for iodosulfuron-methyl-sodium and its degradation products AE F075736 and AE F059411 as well as normalised (20 °C and field capacity) formation fractions for AE F075736 and AE F059411, which are suitable for modelling purpose.





Single first order was the most appropriate kinetic model for modelling purpose for the degradation of iodosulfuron-methyl-sodium at the sites [redacted] (Canada), [redacted] (Canada) and [redacted] (Canada), as well as first order multi compartment at sites [redacted] (USA) and [redacted] (USA) under field conditions with an application rate of 10 g/ha and normalised to 20 °C and field capacity. Kinetic parameters derived from two field studies ([redacted] and Illinois) were found to be not suitable as inputs for environmental fate models. The single first order kinetic model was used for modelling purpose to describe the degradation of AE F075736 at sites [redacted] (Canada). The subsequent SFO, SFO and FOMC-SFO pathway fits were used for modelling purpose to describe the degradation of AE F075736 at sites [redacted] (Canada) and [redacted] (USA), respectively. For AE F059411 no valid parameters could be obtained.

The half-lives (geometric means) were 2.1 days for iodosulfuron-methyl-sodium and 15.0 days for AE F075736.

The formation fraction (arithmetic mean) was 0.76 for AE F075736.

## I. METHODS

Soil residue data from the field dissipation studies KCA 7.1.2.2.1 /03 and KCA 7.1.2.2.1 /04 (M-394108-01-1 and M-238595-01-1) were used. In this study, the degradation of iodosulfuron-methyl-sodium was studied at sites [redacted] (Canada), [redacted] (Canada), [redacted] (Canada), [redacted] (Canada), [redacted] (USA), [redacted] (USA) and Illinois (USA) under field conditions for up to 18 months with an application rate of 10 g/ha and normalised to 20 °C and field capacity.

Soil temperature and moisture were simulated with the FOCUS PEARL 4.4.4 model based on daily weather data (precipitation and irrigation, maximum and minimum air temperature, humidity or vapour pressure, wind speed, global solar radiation). These values were used as input values for the time-step normalisation process implemented in a Microsoft Excel® spreadsheet.

The kinetic analysis was performed according to FOCUS kinetics (2006, 2011) using the software KinGUI 2 with four different kinetic models: single first order, first order multi compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The most appropriate kinetic model was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi<sup>2</sup> scaled error criterion, t-test significance, correlation analysis and standard deviation. The DT<sub>50</sub> value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model. The DT<sub>50</sub> value taken for modelling is based on the iteratively calculated values from KinGUI 2.

## II. RESULTS

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of iodosulfuron-methyl-sodium at the sites [redacted] (Canada), [redacted] (Canada) and [redacted]

(Canada), as well as first order multi compartment at sites [redacted] (USA) and [redacted] (USA). The subsequent SFO-SFO and FOMC-SFO pathway fits were used for modelling purpose to describe the degradation of AE F075736 at sites [redacted] (Canada) and [redacted] (USA), respectively. For AE F059411 no valid parameters could be obtained.

Table CA 7.1.2.2.1- 14 and Table CA 7.1.2.2.1- 15 are summarizing the results of the kinetic analysis.

**Table CA 7.1.2.2.1- 14: Kinetic parameters for the degradation of iodosulfuron-methyl-sodium in soil under field conditions for modelling purpose according to FOCUS (normalised to 20 °C and field capacity)**

Site	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	Chi <sup>2</sup> Error [%]	t-test	DT <sub>90</sub> [days]
[redacted] (Canada)	SFO	0.6	17.0	0.0001	2.2
[redacted] (Canada)	- <sup>3</sup>				
[redacted] (Canada)	SFO	6.2	6.2	< 0.0001	20.6
[redacted] (Canada)	SFO	2.9	11.3	0.0031	9.6
[redacted] (USA)	FOMC	5.7	13.4	n.a.	18.7
[redacted] (USA)	FOMC	6.7	4.6	n.a.	22
[redacted] (USA)					
	<b>geomean</b>	<b>2.1</b>			<b>7.1</b>

<sup>1</sup> SFO: single first order, FOMC: first order multi compartment

<sup>3</sup> no reliable value could be obtained

<sup>4</sup> n.a.: not applicable for parameters of FOMC model

**Table CA 7.1.2.2.1- 15: Kinetic parameters for the degradation of AE F075736 in soil under field conditions for modelling purpose according to FOCUS (normalised to 20 °C and field capacity)**

Site	FF	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	Chi <sup>2</sup> Error [%]	t-test	DT <sub>90</sub> [days]
[redacted] (Canada)	1.00	SFO	4	5.2	< 0.0001	18.0
[redacted] (Canada)	- <sup>3</sup>					
[redacted] (Canada)	- <sup>3</sup>	SFO-SFO	35.6	1.8	0.0009	118.4
[redacted] (Canada)	0.41	- <sup>3</sup>				
[redacted] (USA)	0.88	FOMC-SFO	7.4	15.1	< 0.0001	57.9
[redacted] (USA)	- <sup>3</sup>					
[redacted] (USA)	- <sup>3</sup>					
	<b>arithmetic mean</b>	<b>0.76</b>	<b>geomean</b>	<b>15.0</b>		<b>49.8</b>

FF: formation fraction

<sup>1</sup> SFO: single first order, FOMC: first order multi compartment

<sup>3</sup> no reliable value could be obtained

**CA 7.1.2.2.2. Soil accumulation studies**

As shown in various laboratory and field degradation experiments no accumulation of iodosulfuron-methyl-sodium nor its metabolites is expected.

**CA 7.1.3 Adsorption and desorption in soil**

**CA 7.1.3.1 Adsorption and desorption**

The adsorption and desorption behaviour of iodosulfuron-methyl-sodium and its major degradation products in soil was studied using labelled and unlabelled material.



The studies have been performed in a number of soils in batch equilibrium experiments. Adsorption and desorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation. In addition, the Koc values for the metabolites AE 0002166 and AE F145741 are estimated in order to reflect the most conservative approach in the risk assessments.

A mean K<sub>OC</sub>-value of 50.7 mL/g (1/n 0.87) was determined for the parent compound iodosulfuron-methyl-sodium, by batch equilibrium tests with nine different soils.

Concerning metabolites, mean K<sub>OC</sub> values are 12.3 mL/g (1/n 0.92) for AE F075736 (7 soils), 31.4 mL/g (1/n 0.96) for AE F161778 (3 soils), 193 mL/g (1/n 0.92) for AE F145740 (4 soils), 158.6 mL/g (1/n 0.91) AE 0000119 (5 soils), 36.8 mL/g (1/n 0.90) for BCS CW81253 (des-iodo-carbamoyl-guanidine) (4 soils) and 80.1 mL/g (1/n 0.90) for AE F05941109 soils.

The K<sub>OC</sub> values of AE 0002166 and AE F145741 were assumed to be zero to cover any possible risk in the groundwater leaching assessment which is related to the sorption behavior of AE 0002166 and AE F145741.

CA 7.1.3.1.1 Adsorption and desorption of the active substance

The adsorption and desorption behaviour of iodosulfuron-methyl-sodium in soil in batch equilibrium experiments was evaluated during the Annex I inclusion and was accepted by the European Commission (SANCO/10166/2003-Final, 3 July 2003). The following studies are included in the baseline dossier:

Table with 2 columns: Field (Report, Title, Report No., Document No., Guidelines, GLP/GEP) and Value (Report No., Title, M-140745-01-1, OECD: 105, Deviation not specified)

Adsorption parameters according to the Review Report for iodosulfuron-methyl-sodium (SANCO/10166/2003-Final):

Iodosulfuron-methyl-sodium

Table with 4 columns: Soil type, Kf, Koc, 1/n. Rows include Sand 2, Loamy sand 2.2, Sandy loam V, Sandy loam 2, Clay loam M, Silt loam J, Loamy sand.



Iodosulfuron-methyl-sodium

<b>Report:</b>	[redacted];1998;M-182978-01
<b>Title:</b>	Determination of the adsorption/desorption behaviour in the system soil/water in two soil types according to OECD Guideline #106 Code: (14C)-AE F115008 and (14C)-AE F075736
<b>Report No:</b>	C001578
<b>Document No:</b>	M-182978-01-1
<b>Guidelines:</b>	OECD: 106; Deviation not specified
<b>GLP/GEP:</b>	yes

Adsorption parameters according to the Review Report for Iodosulfuron-methyl-sodium (SANCO/10166/2003-Final):

**Iodosulfuron-methyl-sodium**

Soil type	K <sub>f</sub>	K <sub>oc</sub>	1/n
Sandy clay loam FL	0.69	23	0.993
Clay loam FB	0.37	5	0.82

An additional adsorption/desorption study with Iodosulfuron-methyl-sodium had been performed but was not completed before the dossier submission for Annex I inclusion.

<b>Report:</b>	[redacted];2000;M-198449-01
<b>Title:</b>	Adsorption/desorption of AE F115008-(phenyl-U- <sup>14</sup> C) on one soil
<b>Report No:</b>	C010115
<b>Document No:</b>	M-198449-01-1
<b>Guidelines:</b>	OECD: 106 (1981); Deviation not specified
<b>GLP/GEP:</b>	yes

**Executive Summary**

The adsorption/desorption characteristics of AE F115008-[phenyl-U-<sup>14</sup>C] were determined for one soil ([redacted] France) in a concentration range of two orders of magnitude. For the definitive test a soil-to-solution ratio of 1/1 corresponding to 20 g soil and 20 ml solution was chosen. A shaking period of 24 hours was determined to be sufficient for the establishment of adsorption and desorption equilibrium.

The overall values of recoveries in the definitive test for the four concentrations were in the range of 97.2 to 104.2% and thus in an acceptable range.

The coefficient of adsorption according to Freundlich (K<sub>F(ads)</sub>) was 0.4507 mL/g with a corresponding value related to organic carbon (K<sub>OC(ads)</sub>) of 49.5 mL/g. The value for the Freundlich exponent of adsorption 1/n was 0.9182. The coefficient of desorption according to Freundlich (K<sub>F(des)</sub>) was 0.8647 mL/g with a corresponding value related to organic carbon (K<sub>OC(des)</sub>) of 95.0 mL/g. The value for the Freundlich exponent of desorption 1/n was 0.9121.

AE F15008 showed low adsorption on the tested soil.

**I. MATERIALS AND METHODS**



**A. MATERIALS**

**1. Test Item**

AE F115008-[phenyl-U-<sup>14</sup>C]  
 Charge: Z 29045-0  
 Specific Activity: 4253 kBq/mg  
 Radiochemical Purity: > 99.0%  
 Chemical Purity: not reported

**2. Test Soil**

One soil originating from [redacted] (France) was used (see Table CA 7.1.3.1.1-1)

**Table CA 7.1.3.1.1- 1: Physico-chemical properties of test soil**

Parameter	Results/Units
Soil	[redacted]
Geographic Location (City / State / Country)	[redacted] Paris (Basin) France
Sampling Depth	0-10 cm
Soil Preparation	Air-dried and sieved through a 2mm sieve
Storage	In plastic containers at room temperature
Texture Class <sup>A</sup>	Loamy Silt
Sand <sup>A</sup>	4.8%
Silt <sup>A</sup>	79.8%
Clay <sup>A</sup>	15.4%
pH (0.01 M CaCl <sub>2</sub> , 1:1)	5.9
pH (Water, 1:1)	6.7
Organic Substance	1.5%
Organic Carbon	0.91%

<sup>A</sup> according to DIN19682

**B. STUDY DESIGN**

**1. Experimental Conditions**

The test system for adsorption and desorption in batch equilibrium experiments consisted of borosilicate glass centrifuge tubes (volume 42 mL) closed with Teflon<sup>®</sup> lined screw caps. All experiments were performed in duplicate. Samples of 20 g dry weight of soil (<2 mm) were weighed each into centrifuge tube to which 20 mL of the respective application solution were added.

A preliminary test was performed using a mixture of the <sup>14</sup>C-test substance and non-radiolabelled AE F115008 to establish the equilibration time as well as to determine the stability of the test item in presence of soil. In addition, control samples containing no soil were prepared in the same way for determination of the stability of the test item in calcium chloride solution and for testing of adsorption to the walls of the test vessels.

In the definitive test, initial nominal concentrations of the <sup>14</sup>C-test substance in the aqueous phase were 5.0, 1.0, 0.2, and 0.04 mg/L thus covering two orders of magnitude. The desorption phase was performed by supplying pre-adsorbed soil samples with fresh aqueous 0.01 M CaCl<sub>2</sub> solution.



Adsorption and desorption took place in the dark at 20 ± 1 °C for 24 hours each using a rotary shaker at approximately 20 rpm. For work-up the aqueous supernatants were separated from soil by centrifugation (20 min, 5000 rpm) and decantation of the supernatants.

2. Analytical Procedures

The radioactivity contents in the supernatants were analysed by liquid scintillation counting (LSC). For determination of the radioactivity in soil, the soil was mixed with approximately 0.4 g cellulose/g soil, air-dried, homogenized and combusted. The radioactivity was then determined by liquid scintillation counting (LSC). Mass balance was established on all test systems from the definitive tests.

The aqueous supernatants of the preliminary test as well as the supernatants from the highest concentration specimen in the definitive test were analysed by reversed phase HPLC with radiodetection.

The pH was measured in the supernatants of all samples from the definitive adsorption test as well as in one replicate of the highest concentration specimen in the definitive desorption test.

Adsorption and desorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation

II. RESULTS AND DISCUSSION

A. MATERIAL BALANCE AND RESULTS OF PRELIMINARY TESTS

Preliminary tests were performed to determine the stability of the test item as well as the time required to establish the equilibrium between the test item concentration in the solution and the amount adsorbed to the soil. The tests showed that equilibrium was established after 24 h of shaking. Within the time period of 24 to 48 h the concentration of the test item in the supernatant did not change more than 5%. The chromatographic analysis of the clear centrifuged supernatants, taken after the 24, 48, and 72 hours shaking periods, showed more than 98% of the activity could be assigned to be the unchanged test item.

For the definitive tests the overall mass balances (mean values of duplicates) at the four concentration levels ranged from 97.2% to 104.2% of AR (see Table CA 7.1.3.1.1- 2)

Table CA 7.1.3.1.1- 2: Overall material balances for soil [redacted] after adsorption, desorption and combustion, expressed as percentage of applied radioactivity (Mean and difference of the individual values)

Test concentration (mg/L)	Soil Recovery [% AR]
5.07	97.2 ± 0.1
1.01	98.6 ± 0.1
0.20	97.5 ± 0.1
0.04	104.2 ± 3.1
Mean	100.1

Data are calculated based on sum of radioactivity in removed supernatants after adsorption and desorption steps and final soil combustion.



**B. DEGRADATION OF TEST COMPOUND**

The chromatographic analysis of the clear centrifuged supernatants after establishment of the equilibrium in the pre-test showed that more than 98% of the measured radioactivity could be assigned to be the unchanged test item.

**C. FINDINGS**

Within definitive tests, the portion of AE F115008-[phenyl-U-<sup>14</sup>C] adsorbed to soil after 24 hours was found to be 28.3% to 36.8% AR (Table CA 7.1.3.1.1-3). The adsorption behaviour of AE F115008-[phenyl-U-<sup>14</sup>C] could be accurately described by the Freundlich equation within a nominal concentration range of 0.04 mg/L to 5.0 mg/L (Table CA 7.1.3.1.1-5). The adsorption constant  $K_F^{(ads)}$  of the Freundlich isotherm was 0.4507 mL/g with an associated Freundlich exponent  $1/n$  below 1 (0.9182). The correlation coefficient of the adsorption isotherm was 0.9997. When being normalized for organic carbon content of soil the  $K_{OC}^{(ads)}$  was calculated as 49.5 mL/g.

The proportion of AE F115008 being desorbed from soil [redacted] ranged from between 34.8% to 56.7% (Table CA 7.1.3.1.1-4). The desorption constant  $K_F^{(des)}$  according to Freundlich was calculated to be 0.8647 mL/g with a Freundlich exponent  $1/n$  of 0.9121. The corresponding  $K_{OC}^{(des)}$  value was 95.0 mL/g (see Table CA 7.1.3.1.1-5).

The pH value in the supernatants after adsorption ranged from 6.4 to 6.4 and the pH value in the supernatant after desorption determined in one replicate of the highest concentration was 6.3.

Table CA 7.1.3.1.1-3: Definitive test: Concentration of AE F115008-[phenyl-U-<sup>14</sup>C] in aqueous and soil phase at the end of adsorption equilibrium (mean ± difference)

Description	Solution		Soil		Percentage adsorbed
Concentration of a.i.	(µg/20 mL)		(µg/20 mL)		
Soil	[redacted]		[redacted]		
101.3 µg/20 mL	7.63	± 0.03	28.68	± 0.03	28.3 ± 0.0
20.3 µg/20 mL	13.81	± 0.03	6.47	± 0.03	31.9 ± 0.2
4.1 µg/20 mL	2.50	± 0.01	1.47	± 0.01	36.2 ± 0.6
0.8 µg/20 mL	0.51	± 0.00	0.30	± 0.00	36.8 ± 0.6

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Table CA 7.1.3.1.1- 4: Definitive test: Percentages of AE F115008-[phenyl-U-<sup>14</sup>C] desorbed at the end of desorption equilibrium (mean ± difference)

Description			
Concentration of a.i.	Initially adsorbed <sup>A</sup> Percentage	Adsorbed after Desorption Percentage	Percentage desorbed
Soil	██████████		
101.3 µg/20 mL	28.68 ± 0.03	12.43 ± 0.17	56.7 ± 0.6
20.3 µg/20 mL	6.47 ± 0.03	3.09 ± 0.00	52.2 ± 0.6
4.1 µg/20 mL	1.47 ± 0.01	0.72 ± 0.01	51.5 ± 0.6
0.8 µg/20 mL	0.30 ± 0.00	0.19 ± 0.03	34.8 ± 7.7

<sup>A</sup> Reflects differences in AE F115008 in the aqueous solution before and after adsorption.

Table CA 7.1.3.1.1- 5: Adsorption and desorption constants for AE F115008 in soil ██████████ and correlation coefficients

Soil	Soil type	Adsorption			Desorption				
		K <sub>F(ads)</sub> [mL/g]	1/n	R <sup>2</sup>	K <sub>OC(ads)</sub> [mL/g]	K <sub>F(des)</sub> [mL/g]	1/n	R <sup>2</sup>	K <sub>OC(des)</sub> [mL/g]
██████████	loamy silt	0.4507	0.9182	0.9997	49.5	0.8647	0.9121	0.9995	95.0

K<sub>F</sub>: Freundlich coefficients of adsorption (ads) and desorption (des)

1/n : Slope of the Freundlich adsorption/desorption isotherms

K<sub>OC</sub>: Adsorption coefficient per organic carbon (K<sub>F</sub> · 100/% organic carbon)

R<sup>2</sup>: Regression coefficient of Freundlich equation

### III. CONCLUSIONS

AE F115008 showed only low adsorption on soil ██████████. The coefficient of adsorption according to Freundlich (K<sub>F(ads)</sub>) was 0.4507 mL/g with a corresponding value related to organic carbon (K<sub>OC(ads)</sub>) of 49.5 mL/g. The value for the Freundlich exponent of adsorption 1/n was 0.9182.

Additional data requested by the RMS during the review

<b>Report:</b>	CA 7.1.3.1.1/04 ██████████ 2014; MCA91240-01
<b>Title:</b>	pH dependency of adsorption and degradation processes of iodosulfuron-methyl and its metabolites
<b>Report No:</b>	EnSa-14-0870
<b>Document No:</b>	M-491240-01-1
<b>Guidelines:</b>	not applicable; not applicable
<b>GLP/GEP:</b>	n.a.

### Summary

On request of the RMS the data of 12 adsorption studies of iodosulfuron-methyl and its soil metabolites (all submitted experimental studies) were evaluated in order to investigate a potential pH-dependency of adsorption. A linear regression of the K<sub>OC</sub> values and the pH values of each compound were made, respective figures are presented in the report.

The regression analyses revealed that no significant pH-dependence could be observed for iodosulfuron-methyl and its metabolites. The R<sup>2</sup> values are very low for iodosulfuron-methyl, AE F059411 and AE 0000119 (R<sup>2</sup> = 0.004 – 0.046) and low for AE F075736 and BCS CW81253 (R<sup>2</sup> = 0.283 - 0.326). The highest R<sup>2</sup> values were observed for AE 161778 and AE F145740 with 0.6085





and 0.8327, respectively. However, the overall analysis revealed that irrespective of the pH of the test soils all Koc-values were low for AE 161778 (20.4-39.7 mL/g) and AE F145740 (12.5-32.6 mL/g) and all Koc-values are all in a very narrow range of +/- 10 ml/g. Thus, the slope of the regression line, if considered significant - would be very flat. Therefore it can be concluded that even if a pH-dependence for these two metabolites would be assumed the overall impact on the environmental risk assessment would be negligible.

In conclusion, adsorption of iodosulfuron-methyl-sodium and its soil metabolites is not considered pH dependent to an extent which would be relevant for environmental risk assessment.

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

The adsorption and desorption behaviour of major degradation products, AE F075736, AE F059411 and AE F161778 in soil in batch equilibrium experiments were evaluated during the Annex Conclusion and were accepted by the European Commission (SANCO/10166/2003-Final, 3 July 2003). The following studies are included in the baseline dossier:

Table with 2 columns: Report, Title, Report No, Document No, Guidelines, GLP/GEP. Row 1: Report: [redacted], 1998;M-182978-01; Title: Determination of the adsorption/desorption behaviour in the system soil/water in two soil types according to OECD Guideline #106 Code: (14C)-AE F115008 and (14C)-AE F075736; Report No: C007578; Document No: M-182978-01-1; Guidelines: OECD 106; Deviation not specified; GLP/GEP: yes.

Adsorption parameters according to the Review Report for iodosulfuron-methyl-sodium (SANCO/10166/2003-Final):

AE F075736:

Table with 4 columns: Soil type, Kf, Koc, 1/n. Row 1: Sandy clay loam FL, 0.03, 4.3, 0.943; Row 2: Clay loam FB, 0.07, 2.9, 0.885.

Table with 2 columns: Report, Title, Report No, Document No, Guidelines, GLP/GEP. Row 1: Report: [redacted], 1998;M-182943-01; Title: Determination of the adsorption/desorption behaviour in the system soil/water in three soil types according to OECD Guideline #106 Code: (14C)-AE F075736; Report No: C007558; Document No: M-182943-01-1; Guidelines: OECD 106; Deviation not specified; GLP/GEP: yes.

Adsorption parameters according to the Review Report for iodosulfuron-methyl-sodium (SANCO/10166/2003-Final):



AE F075736:

Soil type	Kf	Koc	1/n
Sandy loam S	0.11	5.3	0.855
Loamy sand 2.2	0.15	7.7	0.917
Sandy loam V	0.07	15.1	0.893

<b>Report:</b>	[redacted]; 1998; M-182934-02; Amended: 2001-11-28
<b>Title:</b>	Adsorption/desorption of AE F075736 on two different soils
<b>Report No:</b>	C001554
<b>Document No(s):</b>	M-182934-02-1
<b>Guidelines:</b>	OECD: 106; Deviation not specified
<b>GLP/GEP:</b>	yes

Adsorption parameters according to the Review Report for Iodosulfuron-methyl-sodium (SANCO/10166/2003-Final):

AE F075736:

Soil type	Kf	Koc	1/n
Loamy silt ([redacted])	0.44	26.5	0.963
LUFA 2.2	0.53	24.2	0.978

<b>Report:</b>	[redacted]; 1998; M-182945-01
<b>Title:</b>	Determination of the adsorption/desorption behavior in the system soil/water in three soil types according to OECD Guideline #106 Code: (14C)-AE F059411
<b>Report No:</b>	C001559
<b>Document No:</b>	M-182945-01-1
<b>Guidelines:</b>	OECD: 106; Deviation not specified
<b>GLP/GEP:</b>	yes

Adsorption parameters according to the Review Report for Iodosulfuron-methyl-sodium (SANCO/10166/2003-Final):

AE F059411:

Soil type	Kf	Koc	1/n
Sandy loam S	0.44	21.3	0.873
Loamy sand 2.2	0.30	15.4	0.909
Sandy loam V	0.32	74.4	0.840

<b>Report:</b>	[redacted]; 1998; M-182936-02; Amended: 2001-11-28
<b>Title:</b>	Adsorption/desorption of AE F059411-(2-14C) on one soil
<b>Report No:</b>	C001555
<b>Document No(s):</b>	M-182936-02-1
<b>Guidelines:</b>	OECD: 106; Deviation not specified
<b>GLP/GEP:</b>	yes

Adsorption parameters according to the Review Report for Iodosulfuron-methyl-sodium (SANCO/10166/2003-Final):

AE F059411:



Soil type	Kf	Koc	1/n
█	1.57	172	0.835

<b>Report:</b>	█;1998;M-181615-01
<b>Title:</b>	Distribution coefficient on soil (Koc) by HPLC simulation (evaluation) Code: AE F161778
<b>Report No:</b>	C001001
<b>Document No(s):</b>	M-181615-01-1
<b>Guidelines:</b>	OECD;;Deviation not specified
<b>GLP/GEP:</b>	yes

Adsorption parameters according to the Review Report for iodosulfuron-methyl-sodium (SANCO/10166/2003-Final):

Koc of AE F161778 estimated by HPLC to be ~ 60

Due to new requirements also the adsorption/desorption behaviour of the metabolites AE F145740, AE F145741, AE 0000119 and BCS-CW81253 were evaluated and are submitted within this supplemental dossier for the iodosulfuron-methyl-sodium Annex I Renewal.

<b>Report:</b>	KCA7.1.3.12 /07; █;2013;M-470679-01-1
<b>Title:</b>	Determination of the Adsorption/Desorption Behaviour of BCS-AU71533 (Iodosulfuron-methyl-benzoic-acid, AE F145740) in four Soils
<b>Report No:</b>	S13-03956
<b>Document No:</b>	M-470679-01-1
<b>Guidelines:</b>	OECD Test Guideline No. 106 US EPA OCSBP Test Guideline No. 835.1230
<b>GLP/GEP:</b>	Yes

**Executive Summary**

The adsorption/desorption properties of non-labelled AE F145740 (Iodosulfuron-methyl-benzoic-acid) were determined in four soils of European origin at 20 ± 2 °C in the dark using the batch equilibrium method. The definitive test was performed with an adsorption and desorption time of 24 hours, respectively, and a soil-to-solution ratio of 1/1 (50 g soil and 50 mL solution). The nominal test concentrations cover two orders of magnitude.

The test item was sufficiently stable throughout the study and no adsorption to the surface of the test vessels was observed. The parental mass balance for all soils was in the range of 92.9-109.5% of Applied Amount (AA).

Values for the coefficients of adsorption according to Freundlich (K<sub>F(ads)</sub>) ranged from 0.27 mL/g to 0.95 mL/g with corresponding values related to organic carbon (K<sub>OC(ads)</sub>) to range from 12.5 mL/g to 32.6 mL/g (arithmetic mean: 19.3 mL/g). Values for the Freundlich exponent of adsorption 1/n ranged from 0.90 to 0.95.

Values for the coefficients of desorption according to Freundlich (K<sub>F(des)</sub>) ranged from 0.44 mL/g to 1.22 mL/g with corresponding values related to organic carbon (K<sub>OC(des)</sub>) to range from 19.5 mL/g to



42.0 mL/g (arithmetic mean: 27.6 mL/g). Values for the Freundlich exponent of desorption  $1/n$  ranged from 0.92 to 0.95.

Considering the measured values it can be assumed that AE F145740 has a high mobility in the tested soils.

## I. MATERIALS AND METHODS

### A. MATERIALS

#### 1. Test Item

AE F145740	
Certificate No.:	AZ 18477
Batch No.:	GSE 61082-3-3
Chemical Purity:	97.5%

#### 2. Test Soils

Four test soils of European origin were used, considered representative for agricultural soils and differing in their physico-chemical properties (see Table CA 7.1.3.1.2-9). Soil collection and handling were in accordance to ISO 10381-6:1993(E)<sup>5</sup>.

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<sup>5</sup> International Organization for Standardization (1993): ISO 10381-6:1993 (E): Soil quality – Sampling – Part 6: Guidance on the collection, handling and storage of soil for the assessment of aerobic microbial processes in the laboratory



Table CA 7.1.3.1.2- 1: Physico-chemical properties of test soils

Parameter	Results/Units			
Soil (ID)/ Batch ID	██████ AXXa (AX) 20120703	██████ II (DD) 20120703	██████ 4a (HH) 20120703	██████ (HN) 20120229
Geographic Location (City / State / Country)	██████ am Rhein/ North ██████ Westphalia/ Germany	██████ North ██████ Westphalia/ Germany	██████ North ██████ Westphalia/ Germany	██████ North ██████ Westphalia/ Germany
Pesticide use history	No pesticides used for the previous five years			
Collection procedures	Sample taken with shovel and placed in plastic bag			
Sampling depth	0-20 cm			
Storage conditions	stored at 20 °C			
Storage length	up to one and a half year			
Soil Preparation	passed through a 2 mm sieve, air dried			
Soil Series	N/A	N/A	N/A	N/A
Texture Class <sup>A</sup>	Sandy Loam	Silty Clay Loam	Silt Loam	Sandy Loam
Sand <sup>A</sup>	67%	29%	2%	52%
Silt <sup>A</sup>	19%	45%	61%	29%
Clay <sup>A</sup>	14%	26%	22%	19%
pH (Water, 1:1)	6.8	7.6	6	5.6
pH (Saturated Paste)	6.7	7.5	6.8	5.7
pH (1 N KCl, 1:1)	6.2	7	6.2	5.0
pH (0.01 M CaCl <sub>2</sub> , 1:5)	6.5	7.4	6.5	5.4
Organic Matter <sup>B</sup>	3.4%	3.5%	3.6%	5.0%
Organic Carbon	2.9%	4.9%	2.1%	2.9%
Cation Exchange Capacity (CEC)	8.5 meq/100 g	7.4 meq/100 g	11.5 meq/100 g	9.7 meq/100 g
Maximum Water Holding Capacity (MWHC)	49.6 g H <sub>2</sub> O / 100g DM	51.2 g H <sub>2</sub> O / 100g DM	57.0 g H <sub>2</sub> O / 100g DM	66.1 g H <sub>2</sub> O / 100g DM
Water Holding Capacity at 0.1 bar (pF 2.0)	13.6%	37.2%	29.1 %	41.1%
Water Holding Capacity at 0.33 bar (pF 2.5)	10.2%	30.4%	17.4%	26.2%
Bulk Density	1.22 g/cm <sup>3</sup>	1.00 g/cm <sup>3</sup>	1.12 g/cm <sup>3</sup>	1.06 g/cm <sup>3</sup>
Soil Taxonomic Classification (USDA)	N/A	N/A	N/A	N/A
GPS Coordinates	██████ ██████	██████ ██████	██████ ██████	██████ ██████

<sup>A</sup> according to USDA classification

<sup>B</sup> organic matter = % organic carbon x 1.724

**B. STUDY DESIGN**

**1. Experimental Conditions**

The tests were performed by the serial method in 100 mL glass flasks with PTFE sealed screw caps in duplicate. Known amounts of soil were weighed each into the flasks and a solution of 0.01 M aqueous calcium chloride was added to result in a final volume of 45 mL (considering residue soil moisture).



The slurry was pre-equilibrated for at least 12 hours followed by the addition of 5 mL of the corresponding application solution to result in a final volume of 50 mL.

Preliminary tests were performed prior to the definitive test in order to test the stability of the test item in matrix solution as well as the possible adsorption of the test item to the test vessel. Furthermore, the test conditions were optimized by the determination of the adequate soil-to-solution ratio and the adequate equilibration time for adsorption. Using these optimized conditions, the parental mass balance was determined for each soil. All preliminary tests were performed with the highest test concentration (nominal 1 mg/L) in duplicate with all soils according to the general procedure.

For the definitive test the test systems were prepared with a soil-to-solution ratio of 10 for all soils (50 g soil dry weight and 50 mL solution, including the application aliquot). Adsorption and desorption took place in the dark at  $20 \pm 2$  °C for 24 hours each using a fluted shaker with a frequency of around 130 rpm. The nominal test concentrations were 1.0, 0.3, 0.1, 0.03 and 0.01 mg/L. After the adsorption step, the phases were separated by centrifugation and the supernatant was removed as much as possible and replaced with an equivalent volume of untreated aqueous 0.01 M  $\text{CaCl}_2$  solution. The solid pellet was re-suspended and the samples were continuously agitated again.

## 2. Analytical Procedures

At the respective sampling times the samples were centrifuged for 4 min at  $1295 \times g$ . The supernatants of the preliminary and the definitive tests were diluted with 0.01 M  $\text{CaCl}_2$  and water (1/10 – 1/20, v/v) and analyzed without further preparation by HPLC-MS/MS.

The parental mass balance (PMB) was determined in a preliminary test for all soils using a soil-to-solution ratio of 1 (w/v). The aqueous phase was recovered as much as possible and acetonitrile/water (80/20, v/v) was added to the soil to extract the test item at ambient conditions (three times).

Adsorption and desorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation.

Validation of the HPLC-MS/MS method was performed for all four soils. To check the matrix caused ion suppression effects in the HPLC/MS-MS analysis, samples of test item in pure 0.01 M  $\text{CaCl}_2$  diluted with water (1/10, v/v) and in soil blank matrix diluted with water (1/10, v/v) were measured. Matrix effects > 10% were observed in soil blank matrices/water (1:10, v/v) of soils AX, DD, HH and HN, respectively. Thus, further calibration curves were performed with standards in 0.01 M  $\text{CaCl}_2$  diluted with water (1:10, v/v) and in the respective blank matrix diluted with water (1:10, v/v).

The detector linearity was confirmed over the calibration range of interest by constructing a calibration function of peak area versus concentration with the ranges from 0.02 ng/mL to 100.0 ng/mL, 0.05 ng/mL to 100 ng/mL and 0.1 ng/mL to 100 ng/mL (8 to 10-point-calibration) in 0.01 M  $\text{CaCl}_2$ /water (1:10, v/v) and the respective soil matrix/water (1:10, v/v). Quantitative evaluation was done by comparison of the peak areas of AE F145740 of the test systems with these calibration curves.



To determine the recovery of AE F145740 as well as the accuracy and repeatability of the analytical method, soil blank matrix (450 µL) was fortified with the test item at LOQ and 1100-fold LOQ level, with test item solution, respectively.

The limit of quantification (LOQ) of the method was determined as 0.1 ng/mL (application level 0.001 mg/L) and the limit of detection (LOD) was set to 1/5 LOQ, equal to 0.02 ng/mL. At this level the signal to noise ratio was  $\geq 3$ . The LOD of the method was 50 times lower than the lowest test concentration of the definitive test (0.01 mg/L corresponding to 1 ng/mL).

## II. RESULTS AND DISCUSSION

### A. MATERIAL BALANCE AND RESULTS OF PRELIMINARY TESTS

For the definitive test, a material balance was not established. Preliminary tests performed confirmed that the test item was stable in the respective soil blank matrices for at least 96 hours. Furthermore, no adsorption of the test item to the surface of the test vessel was observed. Based on the results of the soil-to-solution ratio test, a soil-to-solution ratio of 1/1 was chosen for all soils. Furthermore, it was shown that the adsorption equilibrium was reached after 24 hours and the stability of the test item was confirmed by parental mass balances of more than 92.9% of the applied amount of test item (AA) after 96 hours of incubation (see Table CA 7.1.3.1.2- 2).

Table CA 7.1.3.1.2- 2: Parental mass balances after 96 hours of incubation, expressed as % of applied amount of test item [% AA]

Soil ID	AX	DD	HH	HN
Sample 1	97.6	91.8	93.4	109.3
Sample 2	94.8	93.9	96.2	109.7
Mean	96.2	92.9	94.8	109.5

### B. METHOD VALIDATION

Method development and validation were performed successfully within this study prior to soil sample analyses. The detector signal in 0.01 M CaCl<sub>2</sub> diluted with water (1:10, v/v) and in the respective soil matrix solution diluted with water (1:10, v/v) was linear over a range from 0.02 to 100 ng/mL (with  $r = 0.9953$  to  $0.9997$ ).

During method validation, recoveries of AE F145740 in 0.01 M CaCl<sub>2</sub> were between 95.3 – 111.8%, (mean: 104.9% at LOQ level, 98.6% at 1100-fold LOQ level). Recoveries of AE F145740 in soil were between 74.1 – 103.6% in soil AX matrix (mean: 83.7% at LOQ level, 102.6% at 1100-fold LOQ level), between 85.2 – 114.3% in soil DD matrix (mean: 108.4% at LOQ level, 86.8% at 1100-fold LOQ level), between 82.4 – 103.1% in soil HH matrix (mean: 101.6% at LOQ level, 84.0% at 1100-fold LOQ level) and between 75.6 – 109.5% in soil HN (mean: 103.2% at LOQ level, 90.9% at 1100-fold LOQ level). The accuracy and precision of the analytical method were considered acceptable (according to the requirements of SANCO/3029/00) since the mean recoveries at all concentrations were in the range of 70 and 110% of applied amount with relative standard deviations below 20%. Furthermore, the determined values of the blank samples were less than 20% of the assigned LOQ of the test item in all four soils.



C. DEGRADATION OF TEST COMPOUND

The test item was stable for at least 96 hours which was demonstrated in soil blank matrices as well as in the parental mass balance test (see Table CA 7.1.3.1.2- 2).

D. FINDINGS

The adsorption behaviour of AE F145740 could be accurately described by the Freundlich equation for all soils within a nominal concentration range of 0.01 mg/L to 1.0 mg/L (Table CA 7.1.3.1.2- 3). The adsorption constants K<sub>F(ads)</sub> of the Freundlich isotherms ranged from 0.27 to 0.95 mL/g with associated Freundlich exponents 1/n to be below 1 for all soils (0.90 to 0.95). The adsorption behaviour to soil was thus to some extent affected by the concentration of the test item. The corresponding correlation coefficients of the adsorption isotherms ranged from 0.996 to 0.999, therefore indicating a good linear fit to the measured data. When being normalized for organic carbon content of soil, values of K<sub>OC(ads)</sub> varied from 12.5 mL/g (soil II) to 32.6 mL/g (soil I) with a mean value of 19.3 mL/g. Considering the measured values it can be assumed that AE F145740 has a high mobility in the tested soils.

Values for the coefficients of desorption according to Freundlich (K<sub>F(des)</sub>) ranged from 0.44 mL/g to 1.22 mL/g with corresponding values related to organic carbon (K<sub>OC(des)</sub>) to range from 19.5 mL/g to 42.0 mL/g (arithmetic mean: 27.6 mL/g). Values for the Freundlich exponent of desorption 1/n ranged from 0.92 to 0.95.

Table CA 7.1.3.1.2- 3: Adsorption and desorption constants and correlation coefficients of AE F145740 in soils

Table with 11 columns: Soil ID, Soil type, pH, K<sub>F(ads)</sub> [mL/g], 1/n, R<sup>2</sup>, K<sub>OC(ads)</sub> [mL/g], K<sub>F(des)</sub> [mL/g], 1/n, R<sup>2</sup>, K<sub>OC(des)</sub> [mL/g]. Rows include Sandy Loam, Silty clay loam, Silt Loam, Sandy Loam, and a Mean (arithmetic) row.

pH: Value given as determined with 0.01 M calcium chloride solution
K<sub>F</sub>: Freundlich coefficients of adsorption and desorption
1/n : Slope of the Freundlich adsorption/desorption isotherms
K<sub>OC</sub>: Adsorption/ desorption coefficient per organic carbon (K<sub>F</sub> · 100/% organic carbon)
R<sup>2</sup>: Regression coefficient of Freundlich equation

III. CONCLUSIONS

Considering the measured values it can be assumed that AE F145740 has a high mobility in the tested soils. Values for the coefficients of adsorption according to Freundlich (K<sub>F(ads)</sub>) ranged from 0.27 mL/g to 0.95 mL/g with corresponding values related to organic carbon (K<sub>OC(ads)</sub>) to range from 12.5 mL/g to 32.6 mL/g (arithmetic mean: 19.3 mL/g). Values for the Freundlich exponent of adsorption 1/n ranged from 0.90 to 0.95.





<b>Report:</b>	[redacted]; 2013; M-471677-01-1;
Title:	Koc Evaluation of the Soil Photolysis Metabolite of Iodosulfuron-methyl AE 0002166 (BCS-AW35544)
Report No:	EnSa-13-1046
Document No:	M-471677-01-1
<b>Guidelines</b>	<b>not specified</b>
<b>GLP/GEP:</b>	<b>no</b>

The iodosulfuron-methyl metabolite AE 0002166 occurred only in a soil photolysis experiment ([redacted] P.W. & [redacted] M., 1998, KCA 7.1.1.3 /04), in amounts of up to 20% of applied radioactivity.

For the evaluation of the potential of a compound to leach to groundwater the Koc together with the degradation rate in soil are decisive. The lower the Koc the higher the potential to reach groundwater. The maximum concentration of a substance in soil is reached if the whole amount of this substance is dissolved in the soil surrounding water and nothing is "bound" or adsorbed to the soil. This case is reflected in the most conservative way if the adsorption of the substance to the soil is set to zero or in other words the K<sub>d</sub> value is zero or with respect to organic carbon normalization the K<sub>oc</sub> value is zero. Therefore, to cover worst case conditions in environmental exposure assessments, the K<sub>oc</sub> of AE 0002166 is proposed to be set to zero.

**Conclusion**

The K<sub>oc</sub> value of AE 0002166 was assumed to be zero to cover any possible risk in the groundwater leaching assessment which is related to the sorption behavior of AE 0002166.

<b>Report:</b>	[redacted]; 2013; M-471680-01-1;
Title:	Koc Evaluation of Aerobic Soil Metabolite of Iodosulfuron-methyl, AE F145741 (BCS-AU71539)
Report No:	EnSa-13-1046
Document No:	M-471680-01-1
<b>Guidelines</b>	<b>not specified</b>
<b>GLP/GEP:</b>	<b>no</b>

In aerobic soil degradation studies the iodosulfuron-methyl metabolite AE F145741 in general occurred in amounts of 1-4% of applied radioactivity when standard conditions were used: 20°C temperature and 40-60% of maximum water holding capacity ([redacted] from 1998 (KCA 7.1.1.1 /01, 02, 04/05); [redacted] 2000 (KCA 7.1.1.1 /08)).

Only in the study ([redacted] 1998, M-11175-01-1, KCA 7.1.1.1 /04) in which different temperatures of 10 and 20°C were established the metabolite AE F145741 occurred in amounts of up to 7% of applied radioactivity at 10°C.

For the evaluation of the potential of a compound to leach to groundwater the Koc together with the degradation rate in soil are decisive. The lower the Koc the higher is the potential to reach groundwater.

The maximum concentration of a substance in soil is reached if the whole amount of this substance is dissolved in the soil surrounding water and nothing is "bound" or adsorbed to the soil. This case is reflected in the most conservative way if the adsorption of the substance to the soil is set to zero or in other words the K<sub>d</sub> value is zero or with respect to organic carbon normalization the K<sub>oc</sub> value is zero.



Therefore, to cover worst case conditions in environmental exposure assessments, the K<sub>OC</sub> of AE F145741 is proposed to be set to zero.

**Conclusion**

The K<sub>OC</sub> value of AE F145741 was assumed to be zero to cover any possible risk in the groundwater leaching assessment which is related to the sorption behaviour of AE F145741.

<b>Report:</b>		2013-M-460112-01
<b>Title:</b>	Determination of the adsorption/desorption behaviour of BCS CW81253 in four soils	
<b>Report No:</b>	S13-00814	
<b>Document No:</b>	M-460112-01-1	
<b>Guidelines:</b>	OECD Test Guideline No. 106 US EPA OCSP Test Guideline No. 835.0230; not specified	
<b>GLP/GEP:</b>	yes	

**Executive Summary**

The adsorption/desorption properties of non-labelled BCS CW81253 (des-iodo-carbamoyl-guanidine) were determined in four soils of European origin at 20 ± 2°C in the dark using the batch equilibrium method. The soils cover different pH values and organic carbon contents. The definitive test was performed with an adsorption and desorption time of 24 hours, respectively, and a soil-to-solution ratio of 1/1 (50 g soil and 50 mL solution). The nominal test concentrations cover two orders of magnitude.

The test item was sufficiently stable throughout the study and no adsorption to the surface of the test vessels was observed. The parental mass balance for all soils was in the range of 90.9-110.0% of the applied amount (AA).

Values for the coefficients of adsorption according to Freundlich (K<sub>F(ads)</sub>) ranged from 0.73 mL/g to 1.06 mL/g with corresponding values related to organic carbon (K<sub>OC(ads)</sub>) to range from 19.9 mL/g to 45.4 mL/g (arithmetic mean: 36.8 mL/g). Values for the Freundlich exponent of adsorption 1/n ranged from 0.891 to 0.908.

Values for the coefficients of desorption according to Freundlich (K<sub>F(des)</sub>) ranged from 0.79 mL/g to 1.21 mL/g with corresponding values related to organic carbon (K<sub>OC(des)</sub>) to range from 24.1 mL/g to 49.6 mL/g (arithmetic mean: 35.3 mL/g). Values for the Freundlich exponent of desorption 1/n ranged from 0.84 to 0.89.

Considering the measured values it can be assumed that BCS CW81253 has a high mobility in the tested soils.

**I. MATERIALS AND METHODS**

**A. MATERIALS**

**1. Test Item**

BCS CW81253 (Iodosulfuron-methyl-des-iodo-carbamoyl-guanidine)  
Certificate No.: AZ 18602  
Batch No.: BCS-CW81253-PU-01



Chemical Purity: 99.0%

2. Test Soils

Four test soils of European origin were used, considered representative for agricultural soils and differing in their physico-chemical properties (see Table CA 7.1.3.1.2-4). Soil collection and handling were in accordance to ISO 10381-6:1993(E).

Table CA 7.1.3.1.2- 4: Physico-chemical properties of test soils

Parameter	Results/Units			
	AXXa	II (DD)	4a (HH)	(HN)
Soil (ID)/ Batch ID	(AX) 20120228	(DD) 20120228	(HH) 20120228	(HN) 20120229
Geographic Location (City / State / Country)	North Westphalia/ Germany	North Westphalia/ Germany	North Westphalia/ Germany	North Westphalia/ Germany
Pesticide use history	No pesticides used for the previous five years			
Collection procedures	Sample taken with shovel and placed in plastic bag			
Sampling depth	0-20 cm			
Storage conditions	stored at 20°C			
Storage length	up to one and a half year			
Soil Preparation	passed through a 2 mm sieve, air dried			
Soil Series	N/A	N/A	N/A	N/A
Texture Class <sup>A</sup>	Loamy Sand	Clay Loam	Silt Loam	Sandy Loam
Sand <sup>A</sup>	8%	38%	22%	52%
Silt <sup>A</sup>	9%	32%	59%	29%
Clay <sup>A</sup>	9%	9%	19%	19%
pH (0.01 M CaCl <sub>2</sub> , 1:2)	6.7	7.2	6.3	5.4
pH (Water, 1:1)	6.7	7.3	6.6	5.6
pH (Saturated Paste)	6.7	7.3	6.6	5.7
pH (1 N KCl, 1:1)	6.2	7.0	6.0	5.0
Organic Matter	2.8%	8.6%	2.9%	5.0%
Organic Carbon	1.6%	5.9%	1.7%	2.9%
Cation Exchange Capacity (CEC)	8.5 meq/100 g	20.0 meq/100 g	10.9 meq/100 g	9.7 meq/100 g
Maximum Water Holding Capacity (MWHC)	46.8 g H <sub>2</sub> O / 100g DM	91.4 g H <sub>2</sub> O / 100g DM	54.2 g H <sub>2</sub> O / 100g DM	66.1 g H <sub>2</sub> O / 100g DM
Water Holding capacity at 0.1 bar (pF 2.0)	13.4%	38.0%	33.1 %	41.1%
Water Holding Capacity at 0.33 bar (pF 2.5)	11.6%	33.8%	19.3%	26.2%
Bulk Density	1.21 g/cm <sup>3</sup>	0.97 g/cm <sup>3</sup>	1.13 g/cm <sup>3</sup>	1.06 g/cm <sup>3</sup>
Soil Taxonomic Classification (USDA)	N/A	N/A	N/A	N/A
GPS Coordinates				

<sup>A</sup> according to USDA classification



## B. STUDY DESIGN

### 1. Experimental Conditions

The tests were performed by the serial method in 100 mL glass flasks with PTFE sealed screw caps in duplicate. Known amounts of soil were weighed each into the flasks and a solution of 0.01 M aqueous calcium chloride was added to result in a final volume of 45 mL. The slurry was pre-equilibrated for at least 12 hours followed by the addition of 5 mL of the corresponding application solution to result in a final volume of 50 mL.

Preliminary tests were performed prior to the definitive test in order to test the stability of the test item in matrix solution as well as the possible adsorption of the test item to the test vessel. Furthermore, the test conditions were optimized by the determination of the adequate soil-to-solution ratio and the adequate equilibration time for adsorption. Using these optimized conditions, the parental mass balance was determined for each soil. All preliminary tests were performed with the highest test concentration (nominal 1 mg/L) in duplicate, with all soils according to the general procedure.

For the definitive test the test systems were prepared with a soil-to-solution ratio of 1/1 for all soils (50 g soil dry weight and 50 mL solution, including the application aliquot). Adsorption and desorption took place in the dark at  $20 \pm 2$  °C for 24 hours each using a flatbed shaker with a frequency of around 130 rpm. The nominal test concentrations were 1.0, 0.3, 0.1, 0.03 and 0.01 mg/L. After the adsorption step, the phases were separated by centrifugation and the supernatant was removed as much as possible and replaced with an equivalent volume of untreated aqueous 0.01 M  $\text{CaCl}_2$  solution. The solid pellet was re-suspended and the samples were continuously agitated again.

### 2. Analytical Procedures

At the respective sampling times the samples were centrifuged for 4 min at 1295 x g. The supernatants of the preliminary and the definitive tests were diluted with 0.01 M  $\text{CaCl}_2$  and water (1/5 – 1/20, v/v) and analyzed without further preparation by HPLC-MS/MS. The pH value of the supernatant was determined for the definitive adsorption test.

The parental mass balance (PMB) was determined in a preliminary test for all soils using a soil-to-solution ratio of 1/1 (w/w). The aqueous phase was recovered as much as possible and acetonitrile/water (80/20, v/v) was added to the soil to extract the test item at ambient conditions (three times).

Adsorption and desorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation.

Validation of the HPLC-MS/MS method was performed for all four soils. To check the matrix caused ion suppression effects in the HPLC/MS-MS analysis, samples of test item in pure 0.01 M  $\text{CaCl}_2$  diluted with water (1/10, v/v) (1/5, v/v) and in soil blank matrix diluted with water (1/10, v/v) were measured. Matrix effects of < 10% were observed in 0.01 M  $\text{CaCl}_2$  diluted 1/5 with water and in soil blank matrices of soils AX, DD, HH and HN, respectively. Thus, further calibration curves were performed with standards in pure 0.01 M  $\text{CaCl}_2$  diluted with water (1:10, v/v).



The detector linearity was confirmed over the calibration range of interest by constructing a calibration function of peak area versus concentration with the ranges from 0.05 ng/mL to 100.0 ng/mL, 0.1 ng/mL to 100 ng/mL, 0.5 ng/mL to 25 ng/mL and 5 ng/mL to 100 ng/mL (5 to 10-point-calibration) in 0.01 M CaCl<sub>2</sub>/water (1:10, v/v). Quantitative evaluation was done by comparison of the peak areas of BCS-CW81253 of the test systems with this calibration curve.

To determine the recovery of BCS CW81253 as well as the accuracy and repeatability of the analytical method, soil blank matrix (450 µL) was fortified with the test item at LOQ, 4-fold LOQ and 440-fold LOQ level with test item solution, respectively.

The limit of quantification (LOQ) of the method was determined as 0.5 ng/mL (application level 0.0025 mg/L) and the limit of detection (LOD) was set to 1/10 LOQ, equal to 0.05 ng/mL. At this level the signal to noise ratio was ≥ 3. The LOD of the method was one order of magnitude lower than the lowest test concentration of the definitive test (0.01 mg/L = 2 ng/mL).

## II. RESULTS AND DISCUSSION

### A. MATERIAL BALANCE AND RESULTS OF PRELIMINARY TESTS

For the definitive test, a material balance was not established. Preliminary tests performed confirmed that the test item was stable in the respective soil blank matrices for at least 96 hours. Furthermore, no adsorption of the test item to the surface of the test vessel was observed. Based on the results of the soil-to-solution ratio test, a soil-to-solution ratio of 1:1 was chosen for all soils. Furthermore, it was shown that the adsorption equilibrium was reached after 24 hours and the stability of the test item was confirmed by parental mass balances of more than 90% of the applied amount of test item (AA) after 96 hours of incubation (see Table CA 7.1.3.1.2- 5).

Table CA 7.1.3.1.2- 5: Parental mass balances after 96 hours of incubation, expressed as % of applied amount of test item [% AA]

Soil ID	■	■	■	■
Sample 1	96.9	91.1	90.9	109.2
Sample 2	96.6	91.1	97.5	110.0
Mean	101.9	91.4	94.2	109.6

### B. METHOD VALIDATION

Method development and validation were performed successfully within this study prior to soil sample analyses. The detector signal in 0.01 M CaCl<sub>2</sub> diluted with water (1:10, v/v) was linear over a range from 0.05 to 100 ng/mL (with r = 0.9959 to 0.9997).

During method validation recoveries of BCS-CW81253 in 0.01 M CaCl<sub>2</sub> were between 97.4 – 116.0%, with mean values of 108.6% at LOQ level (0.0025 mg/L), 105.1% at 4-fold LOQ level (0.01 mg/L) and 102.2% at 440-fold LOQ level (1.1 mg/L). The accuracy and precision of the analytical method were considered acceptable (according to the requirements of SANCO/3029/00) since the mean recoveries at all concentrations were in the range of 70 and 110% of applied amount with relative standard deviations below 20%. Furthermore, the determined values of the blank samples were less than 20% of the assigned LOQ of the test item in all four soils.



C. DEGRADATION OF PARENT COMPOUND

The test item was stable for at least 96 hours which was demonstrated in soil blank matrices as well as in the parental mass balance test (see Table CA 7.1.3.1.2- 5).

D. FINDINGS

The adsorption behaviour of BCS CW81253 could be accurately described by the Freundlich equation for all soils within a nominal concentration range of 0.01 mg/L to 1.0 mg/L (Table CA 7.1.3.1.2- 6). The adsorption constants  $K_{F(ads)}$  of the Freundlich isotherms ranged from 0.73 to 1.06 mL/g with associated Freundlich exponents  $1/n$  to be below 1 for all soils (0.886 to 0.908). The adsorption behaviour to soil was thus to some extent affected by the concentration of the test item. The corresponding correlation coefficients of the adsorption isotherms ranged from 0.996 to 0.998, therefore indicating a good linear fit to the measured data. When being normalized for organic carbon content of soil, values of  $K_{OC(ads)}$  varied from 19.9 mL/g (soil [redacted] II) to 45.4 mL/g (soil [redacted] AXXa) with a mean value of 36.8 mL/g. Considering the measured values it can be assumed that BCS-CW81253 has a high mobility in the tested soils.

Desorption constants  $K_{F(des)}$  values according to Freundlich ranged from 0.79 mL/g to 1.21 mL/g. The corresponding values for  $K_{OC(des)}$  ranged from 24.1 mL/g (soil [redacted] II) to 49.6 mL/g (soil [redacted] AXXa).

Table CA 7.1.3.1.2- 6: Adsorption and desorption constants and correlation coefficients of BCS-CW81253 in soils

Soil ID	Soil type	pH	Adsorption			Desorption				
			$K_{F(ads)}$ [mL/g]	$1/n$	$R^2$	$K_{OC(ads)}$ [mL/g]	$K_{F(des)}$ [mL/g]	$1/n$	$R^2$	$K_{OC(des)}$ [mL/g]
[redacted]	Loamy Sand	6.4	0.73	0.908	0.996	45.4	0.79	0.89	0.993	49.6
[redacted]	Clay Loam	7.2	0.99	0.886	0.997	19.9	1.21	0.86	0.992	24.1
[redacted]	Silt Loam	6.3	0.77	0.904	0.996	45.2	0.79	0.88	0.994	46.7
[redacted]	Sandy Loam	7.4	1.06	0.891	0.998	36.5	1.06	0.84	0.994	36.6
Mean (arithmetic)			0.89	0.897	0.997	36.8	0.96	0.87	0.993	39.3

pH: Value given as determined with 0.01 M calcium chloride solution  
 $K_F$ : Freundlich coefficient of adsorption (ads) and after desorption (des)  
 $1/n$ : Slope of the Freundlich adsorption/desorption isotherms  
 $K_{oc}$ : Adsorption coefficient per organic carbon ( $K \times 100\%$  organic carbon)  
 $R^2$ : Regression coefficient of Freundlich equation

III. CONCLUSIONS

Low adsorption of BCS-CW81252 was measured for all soils and all test concentrations. Considering the measured values it can be assumed that BCS-CW81252 has a high mobility in the tested soils. Values for the coefficients of adsorption according to Freundlich ( $K_{F(ads)}$ ) ranged from 0.73 mL/g to 1.06 mL/g with corresponding values related to organic carbon ( $K_{OC(ads)}$ ) to range from 19.9 mL/g to 45.4 mL/g (arithmetic mean: 36.8 mL/g). Values for the Freundlich exponent of adsorption  $1/n$  ranged from 0.891 to 0.908.



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<b>Report No:</b>	AS140
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<b>GLP/GEP:</b>	yes

**Executive Summary**

The adsorption/desorption characteristics of radiolabelled [AE 0000119] [triazine-2-<sup>14</sup>C]BCS-AB56501) were determined for five soils in a concentration range of two orders of magnitude. The adsorption phase of the study (definitive test) was carried out in the dark at 20 ± 2 °C for 12 hours using pre-equilibrated air-dried soil. The equilibrium solution used was 0.01 M aqueous CaCl<sub>2</sub> solution with soil to solution ratios of 1:1 for the soil [REDACTED], 1:2 for the soils [REDACTED] and [REDACTED] and 1:4 for soils [REDACTED] II and [REDACTED]. The desorption phase of the study was carried out by supplying pre-adsorbed soil specimens with fresh 0.01 M aqueous CaCl<sub>2</sub> solution for one desorption cycle.

In the definitive test the overall values of recoveries for all concentrations were in the range of 94.7 to 103.1% (mean: 99.4%) and thus in an acceptable range. Values for the coefficients of adsorption according to Freundlich ( $K_{F(ads)}$ ) ranged from 1.10 mL/g to 5.98 mL/g with corresponding values related to organic carbon ( $K_{OC(ads)}$ ) to range from 55.8 mL/g to 352 mL/g (arithmetic mean: 158.6 mL/g). Values for the Freundlich exponent of adsorption 1/n ranged from 0.8925 to 0.9330.

Values for the coefficients of desorption according to Freundlich ( $K_{F(des)}$ ) ranged from 1.23 mL/g to 6.62 mL/g with corresponding values related to organic carbon ( $K_{OC(des)}$ ) to range from 68.4 mL/g to 389.7 mL/g (arithmetic mean 182.9 mL/g). Values for the Freundlich exponent of desorption 1/n ranged from 0.8991 to 0.9372.

According to Briggs<sup>6</sup> the mobility of [triazine-2-<sup>14</sup>C]BCS-AB56501 (AE 0000119) can be classified as intermediate mobile to low mobile in the tested soils.

**I. MATERIALS AND METHODS**

**A. MATERIALS**

**1. Test Item**

- [triazine-2-<sup>14</sup>C]BCS-AB56501
- Sample ID: KATH 6368
- Specific Activity: 3.97 MBq/mg (107.33 µCi/mg)
- Radiochemical Purity: > 98% by HPLC, > 99% by TLC
- Chemical Purity: > 98% by HPLC

<sup>6</sup> BRIGGS, G.G.: A simple relationship between soil adsorption of organic chemicals and their octanol/water partition coefficients. Proc. 7th British Insecticide and Fungicide Conference, Nottingham/UK, 83-86 (1973).



2. Test Soils

Three soils originating from Germany and two soils originating from the USA were used for the test. The soils were taken from agricultural use areas representing different geographical origins and different soil properties (see Table CA 7.1.3.1.2- 7).

Table CA 7.1.3.1.2- 7: Physico-chemical properties of test soils

Parameter	Results / Units				
Soil Designation	(soil I)	(soil II)	(soil III)	(soil IV)	(soil V)
Geographic Location:					
City					
State	North Westphalia	North Westphalia	North Westphalia		Nebraska
Country	Germany	Germany	Germany	USA	USA
GPS Coordinates					
Pesticide use history	None used			Last use in 2007 (different pesticides)	Last application in 2004
Collection procedures	Packed in plastic bags			shovel, 5 gallon bucket	
Sampling depth	0-20 cm			0-6 inches (0-15.2 cm)	6-8 inches (15.2 – 20.3 cm)
Storage conditions	In closed plastic containers at room temperature				
Storage length	202 days after receipt			180 days after receipt	
Soil Preparation	Air dried and sieved (2 mm)				
Soil Taxonomic Classification (USDA)	no information available				
Soil Series	no information available				
Textural Class (USDA)	Loam	Silt loam	Clay loam	Sandy loam	Silt loam
Sand [50 µm – 2 mm]	51%	27%	61%	56%	12.7%
Silt [2 µm – 50 µm]	68%	54%	38%	32.6%	60.8%
Clay [2 µm]	21%	19%	31%	11.4%	26.5%
pH CaCl <sub>2</sub>	5.3	6.6	7.3	6.7	6.6
pH water	5.5	6.8	7.4	6.8	7.2
Organic Carbon	1.8%	2.4%	4.6%	0.7%	1.7%
Organic Matter	3.0%	4.1%	7.93%	1.1%	2.9%
Cation Exchange Capacity [meq/100 g]	10.8	13.9	21.9	16.1	16.1

<sup>1</sup> % organic matter = % organic carbon x 1.724

GPS: global positioning system

USDA: United States Department of Agriculture





## B. STUDY DESIGN

### 1. Experimental Conditions

The test system for adsorption and desorption in batch equilibrium experiments consisted of borosilicate glass centrifuge tubes (volume 42 mL or 83 mL) and Teflon® lined screw caps. The experiments were performed in duplicate.

In preliminary tests, the solubility and stability of the test item in CaCl<sub>2</sub> solution, the adsorption of the test item to the test system surface, the optimal soil-to-solution ratio, the appropriate adsorption and desorption equilibration times and the stability of the test item in presence of soil were determined.

In the definitive test, the adsorption phase was carried out using air-dried soils equilibrated in aqueous 0.01 M CaCl<sub>2</sub> solution for at least 16 hours. The soil-to-solution ratios were 0/1 (soils [REDACTED]), 1/2 (soils [REDACTED] and [REDACTED]) and 1/4 (Soils [REDACTED] and [REDACTED]). The test item was applied at nominal concentrations of 1.0, 0.3, 0.1, 0.03 and 0.01 mg/L in aqueous 0.01 M CaCl<sub>2</sub> solution. One desorption cycle was performed by supplying pre-adsorbed soil samples with fresh aqueous 0.01 M CaCl<sub>2</sub> solution. Adsorption and desorption took place for 12 hours and 2 hours, respectively.

The test systems were shaken by an overhead shaker in the dark at 20±2 °C in a temperature controlled chamber.

### 2. Analytical Procedures

The suspensions were centrifuged (4200 xg) and the radioactivity contents in the supernatants were analysed by liquid scintillation counting (LSC). In the definitive test, the pH value was measured in all supernatants. The partition of the test item in the adsorption and desorption batch equilibrium experiment was determined based on the radioactivity content in the supernatant only. After the desorption step, the soil was air-dried and the radioactivity content determined by combustion/LSC to establish the material balance. Prior to combustion soil specimens were mixed with approximately 0.4 g cellulose/g soil air dried and homogenised.

In the preliminary parental mass balance test, the soil was extracted up to six times with 40 mL acetonitrile / water (9/1; v/v) for 30 min (using ultrasonic bath). The aqueous supernatants and the combined and concentrated soil extracts were analysed by reversed phase HPLC/radiodetection to determine the stability of the test item and to establish the parental mass balance. Radioactivity remaining in the soil was quantified after combustion in a sample oxidiser. In HPLC analysis, all signals higher than 50 cpm and with a minimum area of 100 area units were integrated. The background was calculated at the cpm-mean value (e.g. 8.23 cpm) of HPLC-runs performed without radioactivity.

Adsorption and desorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation.



## II. RESULTS AND DISCUSSION

### A. MATERIAL BALANCE AND RESULTS OF PRELIMINARY TESTS

In preliminary tests it was shown, that the test item did not show significant adsorption to the inner surfaces of the test vessels. No breakdown of the test item in pure CaCl<sub>2</sub>-solutions was determined in HPLC-analysis. Furthermore, the optimal soil-to-solution ratios were determined as well as the appropriate adsorption equilibration time and the stability of the test item. Parental Mass Balances were >90 % for soils [redacted], [redacted], [redacted] and [redacted] after 24 h equilibration time calculated as recovery of the test item in supernatants and soil extracts. For soil [redacted] II a parental mass balance of 88.4 % was determined after 24 hours (see Table CA 7.1.3.1.2- 8).

Table CA 7.1.3.1.2- 8: Parental mass balance after incubation for 24 hours, respectively, calculated as percentage of applied radioactivity in solution and soil extract.

Soil No./ Matrices	I	II	III	IV	V
Test item in supernatant [% AR]	23.0	33.4	38.9	34.1	2.1
Test item in solid phase [% AR]	68.1	58.6	49.1	57.4	65.3
Test item recovery [% AR]	91.1	92.0	88.4	91.4	92.5

In the definitive test, mean material balances were 100.2, 99.1, 100.0, 101.0 and 96.8% of applied radioactivity [% AR] for soils [redacted], [redacted], [redacted], [redacted] and [redacted], respectively (see Table CA 7.1.3.1.2- 9). The complete material balances found for all soils and concentrations demonstrated that no significant amounts of radioactivity dissipated from the test systems or were lost during sample processing.

Table CA 7.1.3.1.2- 9: Overall material balance for the five test soils after adsorption, desorption and combustion, expressed as percentage of applied radioactivity

Test concentration (mg/L)	Soil No. / Soil	Recovery	Recovery	Recovery	Recovery	Recovery
		Repl. [% AR]	Recovery [% AR]	Recovery [% AR]	Recovery [% AR]	Recovery [% AR]
0.27	a	101.6	97.7	99.1	99.3	94.7
	b	97.9	97.7	98.4	97.8	94.9
0.29	a	98.0	99.1	99.8	99.7	95.9
	b	100.2	98.2	100.2	100.7	95.4
0.10	a	97.8	97.5	101.0	100.9	97.2
	b	102.3	100.1	99.8	101.9	97.5
0.03	a	99.4	100.4	100.7	101.9	98.2
	b	101.8	99.5	101.2	103.1	97.6
0.1	a	102.3	100.8	99.2	102.9	97.0
	b	100.6	99.6	100.8	101.3	99.3
Mean (Arithmetic)		100.2	99.1	100.0	101.0	96.8

Data are calculated based on sum of radioactivity in removed supernatants after adsorption and desorption steps and final soil combustion.



## B. DEGRADATION OF PARENT COMPOUND

The stability of the test substance under test conditions was confirmed by HPLC. Parental mass balances were  $\geq 88.4\%$  AR after 24 hours of shaking.

## C. FINDINGS

Based on the results of the preliminary test for the adequate soil-to-solution ratio, the definitive tests were performed at ratios of 1:1 (soil [REDACTED]), 1/2 (soils [REDACTED] and [REDACTED]) and 1/4 (soils [REDACTED] II and [REDACTED]). The equilibration time for adsorption was 12 hours and the equilibration time for desorption was 2 hours for all soils.

The adsorption behaviour of [triazine-2-<sup>14</sup>C]BCS-AB56501 (AE 0000119) could be accurately described within a nominal concentration range of 0.01 mg/L to 1.0 mg/L by the Freundlich equation for all soils (Table CA 7.1.3.1.2- 10). The adsorption constants  $K_{F(ads)}$  of the Freundlich isotherms ranged from 1.10 to 5.98 mL/g with associated Freundlich exponents  $1/n$  to be below 1 for all soils (0.8925 to 0.9330). The adsorption behaviour to soil was thus to some extent affected by the concentration of the test item. The corresponding correlation coefficients of the adsorption isotherms ranged from 0.9998 to 1.0000, therefore indicating a good linear fit to the measured data.

When being normalized for organic carbon content of soil, values of  $K_{OC(ads)}$  varied from 55.8 mL/g (soil [REDACTED] II) to 352 mL/g (soil [REDACTED]) with an arithmetic mean of 158.6 mL/g.

Using the Briggs<sup>6</sup> classifications for the estimation of the mobility of crop protection agents in soil, [triazine-2-<sup>14</sup>C]BCS-AB56501 (AE 0000119) can be classified as intermediate to low mobile for adsorption and for desorption in the soils.

Desorption constants  $K_{F(des)}$  according to Freundlich ranged from 1.24 mL/g (soil [REDACTED]) to 6.62 mL/g (soil [REDACTED]). The corresponding values for  $K_{OC(des)}$  ranged from 68.4 mL/g (soil [REDACTED] II) to 389.7 mL/g (soil [REDACTED]) to result in an arithmetic mean of 182.9 mL/g.  $K_{OC(des)}$  values were thus slightly higher than the corresponding values of  $K_{OC(ads)}$ , indicating a strengthening of binding of [triazine-2-<sup>14</sup>C]BCS-AB56501 (AE 0000119) once adsorbed to soil particles.

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Table CA 7.1.3.1.2- 10: Adsorption and desorption constants and correlation coefficients of BCS-AB56501 (AE 0000119) in soils

Soil	Soil type	Adsorption					Desorption			
		pH	K <sub>F(ads)</sub> [mL/g]	1/n	R <sup>2</sup>	K <sub>OC(ads)</sub> [mL/g]	K <sub>F(des)</sub> [mL/g]	1/n	R <sup>2</sup>	K <sub>OC(des)</sub> [mL/g]
█	Loam	5.3	1.1032	0.9330	0.9999	61.3	1.2358	0.9372	0.9999	62.0
█	Silt loam	6.6	1.7017	0.9063	0.9999	70.9	1.9692	0.9158	0.9993	82.0
█ II	Clay loam	7.3	2.5663	0.8983	1.0000	55.8	1.4448	0.9157	0.9999	68.4
█	Sandy loam	6.7	1.7723	0.9246	1.0000	253.2	2.1387	0.9368	0.9999	305.5
█	Silt loam	6.6	5.9847	0.8925	0.9998	352.0	6.6241	0.8991	0.9997	389.7
Mean (arithmetic)			2.6257	0.9109	0.9999	158.6	3.0225	0.9209	0.9997	182.6

pH: Value given as determined with 0.01 M calcium chloride solution  
K<sub>F</sub>: Freundlich coefficients of adsorption (ads) and after desorption (des)  
1/n : Slope of the Freundlich adsorption/desorption isotherms  
K<sub>OC</sub>: Adsorption coefficient per organic carbon (K<sub>F</sub> × 100/% organic carbon)  
R<sup>2</sup>: Regression coefficient of Freundlich equation

### III. CONCLUSIONS

Based on the soil sorption parameters measured in this study and classification of soil mobility potential according to BRIGGS<sup>8</sup>, the mobility of [triazinyl-2-<sup>14</sup>C]BCS-AB56501 (AE 0000119) can be classified as intermediate to low mobile for adsorption and for desorption in the soils. Values for the coefficients of adsorption according to Freundlich (K<sub>F(ads)</sub>) ranged from 1.10 mL/g to 5.98 mL/g with corresponding values related to organic carbon (K<sub>OC(ads)</sub>) to range from 55.8 mL/g to 352 mL/g (arithmetic mean: 158.6 mL/g). Values for the Freundlich exponent of adsorption 1/n ranged from 0.8925 to 0.9330.

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<b>GLP/GEP:</b>	yes

### Executive Summary

The adsorption characteristics of AE F161778 [triazinyl-2-<sup>14</sup>C] were determined in three European soils using the batch equilibrium method and a concentration range of two orders of magnitude. The test was performed at 20 ± 0.5 °C in the dark for 24 hours at a soil to solution ratio of 1:1 for all soils.

The overall mean recoveries after the adsorption step (radioactivity in supernatants and combusted soil) ranged from 96.98 to 98.00% of applied radioactivity and were thus in an acceptable range.

The adsorption constants K<sub>F(ads)</sub> of the Freundlich isotherms ranged from 0.75 to 0.94 mL/g with associated Freundlich exponents 1/n to be below 1 for all soils (0.9438 to 0.9824). The adsorption behaviour to soil was thus to some extent affected by the concentration of the test item. The



corresponding correlation coefficients of the adsorption isotherms ranged from 0.9990 to 0.9999, therefore indicating a good linear fit to the measured data.

When being normalized for organic carbon content of soil, values of  $K_{OC(ads)}$  varied from 20.4 mL/g to 39.7 mL/g with an arithmetic mean of 31.4 mL/g.

Using the classification according to Hollis<sup>7</sup> AE F161778 can be classified as a mobile compound.

## I. MATERIALS AND METHODS

### A. MATERIALS

#### 1. Test Item

AE F161778-[triazinyl-2-<sup>14</sup>C]  
Batch No.: Z 28065-0  
Specific Activity: 5.351 MBq/mg  
Radiochemical Purity:  $\geq 96.7\%$  by HPLC and TLC  
Chemical Purity: not reported

#### 2. Test Soils

One soil originating from Germany and two soils originating from the United Kingdom were used (see [Table CA 7.1.3.1.2- 11](#)). The soils were taken from agricultural use areas representing different geographical origins and different soil properties.

<sup>7</sup> Hollis, J.M. (1991): Mapping the vulnerability of aquifers and surface water to pesticide contamination at the national/regional scale. Pesticides in Soils and Water: Current Perspectives (A Walker Ed.), BCPC Monograph 47, pp 165-174.



Table CA 7.1.3.1.2- 11: Physico-chemical properties of test soils

Parameter	Results / Units		
	Soil A	Soil B	Soil C
Soil Designation			
Geographic Location			
City	██████████	██████████	██████████
State	Hesse	Lincolnshire	Rutland
Country	Germany	United Kingdom	United Kingdom
Sampling depth	not given	15-35 cm	15-30 cm
Storage conditions	in the dark at 4 ± 4 °C in closed plastic containers		
Storage length	no reported		
Soil Preparation	air dried, homogenized and passed through a 2 mm sieve		
Soil Type (UK/USDA)	silt loam	sandy loam	clay loam
Particle size distribution (DIN)			
Sand [63 µm – 2 mm]	12%	19%	31%
Silt [2 µm – 63 µm]	58%	10%	41%
Clay [< 2 µm]	21%	11%	1%
pH CaCl <sub>2</sub>	6.4	7.3	7.4
Organic Carbon	1.9%	2.2%	4.6%
Organic Matter	3.2%	3.7%	7.8%

USDA: United States Department of Agriculture

**B. STUDY DESIGN**

**1. Experimental Conditions**

The test system for adsorption in batch equilibrium experiments consisted of FEP (fluorinated ethylene propylene) centrifuge tubes. A 0.01 M CaCl<sub>2</sub> was used as aqueous phase. The pH value of the 0.01 M CaCl<sub>2</sub> solution was adjusted to pH 7.0 (chosen as basis for the adsorption vicinity) and pH 9.0 (for preparing the stock and dose solution, respectively). A previous performed stability screening study came to the conclusion to perform an adsorption study using a CaCl<sub>2</sub> solution with pH values equal or higher than 7.0 to guarantee stability and basic adsorption conditions for the test compound AE F161778.

In preliminary tests, the solubility of the test item in 0.01 M CaCl<sub>2</sub> solution adjusted to pH 7, its adsorption to the test system surface and its stability in CaCl<sub>2</sub> solution and soil matrix were determined.

The adsorption phase of the definitive test was carried in duplicate out using air-dried soils equilibrated in 20 mL aqueous 0.01 M CaCl<sub>2</sub> solution for ≥ 18 hours with a soil-to-solution ratio of 1/1 for all soils. Then, the supernatant was replaced by CaCl<sub>2</sub> solution. Aliquots of the dose solutions were applied directly to the surface of the 0.01 M CaCl<sub>2</sub> solutions to obtain a total volume of 20 mL. The test item was applied at nominal concentrations of 2.0, 1.0, 0.2 and 0.02 mg/L in aqueous 0.01 M CaCl<sub>2</sub> solution adjusted to pH 9. No desorption step was performed.

Following application the samples were shaken continuously in the dark, at 20 °C ± 2 °C for 24 hours on an orbital shaker set at a speed which was sufficient to ensure that the soil material remained in suspension.



## 2. Analytical Procedures

After the adsorption phase, the samples were centrifuged (10 min, 3600 rpm). The aqueous phases were removed and transferred to pre-weighed vessels. Duplicate aliquot samples were analysed for radioactivity by liquid scintillation counting (LSC). Additionally, the pH value of each supernatant was determined.

The remaining soil residues were treated with acetone (20 mL) to ease the air drying process prior to combustion. Triplicate subsamples of the air-dried soils were combusted and the radioactivity of the combusted products was determined by LSC. The radioactivity mass balance for each sample was determined by the addition of the radioactivity present in the CaCl<sub>2</sub> supernatant after adsorption, with the radioactivity of both the 'acetone soil washing fraction' and an 'acetonitrile container washing fraction' and finally the combusted soil residues.

The stability of the test item in CaCl<sub>2</sub> solution and in the aqueous supernatants after adsorption was determined by HPLC with UV- and radiodetection (in preliminary tests and in the definitive test). Non-radiolabelled AE F161778 was co-chromatographed as an authentic standard. The radiochemical purity of the test item in the dose solution (2 mg/L) was additionally determined by TLC with radiodetection.

The partition of the test item in the adsorption and desorption batch equilibrium experiment was determined based on the radioactivity content in the supernatant. Adsorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation.

## II. RESULTS AND DISCUSSION

### A. MATERIAL BALANCE AND RESULTS OF PRELIMINARY TESTS

In preliminary tests, it was shown that the test item was soluble in pure 0.01 M CaCl<sub>2</sub> solution (at pH 7) over the selected concentration range and that adsorption onto container walls was in an acceptable range. Furthermore, the stability of the test item in aqueous CaCl<sub>2</sub> solution as well as in the aqueous supernatants of each soil type was confirmed in a preliminary test (see [Table CA 7.1.3.1.2- 12](#) for stability in presence of soil) as well as in the main study.



Table CA 7.1.3.1.2- 12: HPLC analyses of 0.01 M CaCl<sub>2</sub> supernatants containing [triazinyl-2-<sup>14</sup>C]AE F161778 at a nominal concentration of 2.0 µg/mL after 24 hours of incubation with soil matrix (expressed as % applied radioactivity)

Soil	Replicate	[ <sup>14</sup> C]-AE F161778	Total unknowns	% Run (total)
Soil A	A	98.88	0.79	99.67
	B	99.34	0.59	99.93
	<b>Mean</b>	<b>99.11</b>	<b>0.69</b>	<b>99.80</b>
Soil B	A	99.52	0.27	99.79
	B	99.05	0.95	100.00
	<b>Mean</b>	<b>99.29</b>	<b>0.61</b>	<b>99.90</b>
Soil C	A	97.84	1.26	99.11
	B	97.40	2.34	99.79
	<b>Mean</b>	<b>97.62</b>	<b>1.80</b>	<b>99.43</b>

In the definitive test, mean material balances were 98.00, 95.98 and 96.71% of applied radioactivity (% AR) for soils A, B and C, respectively (see Table CA 7.1.3.1.2- 13). The complete material balances found for all soils and concentrations demonstrated that no significant amounts of radioactivity dissipated from the test systems or were lost during sample processing.

Table CA 7.1.3.1.2- 13: Overall material balance for soils after adsorption and soil combustion expressed as percentage of applied radioactivity

Test concentration (mg/L)	Soil Repl.	Recovery		
		A [% AR]	B [% AR]	C [% AR]
0.02	a	98.08	94.74	99.26
	b	98.65	95.31	96.27
0.2	a	96.77	95.12	95.42
	b	97.26	96.23	97.56
2.0	a	97.54	95.63	96.61
	b	98.17	96.95	95.50
2.0	a	97.98	95.41	96.32
	b	96.97	96.43	96.71
<b>Mean (arithmetic)</b>		<b>98.00</b>	<b>95.98</b>	<b>96.71</b>

Data are calculated based on the sum of radioactivity in removed supernatants after adsorption and soil combustion (including acetone wash of soil and acetonitrile wash of container).

## B. DEGRADATION OF PARENT COMPOUND

The stability of the test substance in aqueous CaCl<sub>2</sub> solution as well as in presence of soil matrix was confirmed by HPLC analysis in preliminary experiments as well as in the main test. It was confirmed, that the radioactivity was exclusively present as AE F161778 with negligible amounts of unidentified compounds. 3.08% of applied radioactivity were assigned to “total unknowns” in the main test).

## C. FINDINGS

The definitive test was performed with a soil to solution ratio of 1:1 for all soils. The equilibration time for adsorption was set at 24 hours.

The portion of AE F161778 adsorbed to soil after 24 hours was found to be 60.5 to 63.9% AR, 60.6 to 63.6% AR and 43.6 to 51.8% AR for soils A, B, and C, respectively (see Table CA 7.1.3.1.2- 14).





The adsorption behaviour of [triazinyl-2-<sup>14</sup>C]AE F161778 could be accurately described within a nominal concentration range of 0.02 mg/L to 2.0 mg/L by the Freundlich equation for all three soils (Table CA 7.1.3.1.2- 15). The adsorption constants  $K_{F(ads)}$  of the Freundlich isotherms ranged from 0.75 to 0.94 mL/g with associated Freundlich exponents  $1/n$  to be below 1 for all soils (0.9438 to 0.9824). The adsorption behaviour to soil was thus to some extent affected by the concentration of the test item. The corresponding correlation coefficients of the adsorption isotherms ranged from 0.9990 to 0.9999, indicating a good linear fit to the measured data.

After normalization for organic carbon content of soil the adsorption coefficients ( $K_{OC(ads)}$ ) varied from 20.4 mL/g to 39.7 mL/g with an arithmetic mean of 31.4 mL/g.

Table CA 7.1.3.1.2- 14: Definitive test: Concentration of [triazinyl-2-<sup>14</sup>C]AE F161778 in aqueous and soil phase at the end of adsorption equilibrium (mean ± s.d.)

Description	Soil* (mg/kg)	Solution (mg/L)	Percentage adsorbed*
<b>Soil</b>		<b>A</b>	
0.0208 mg/L	0.00817	0.01233	60.5 ± 0.0
0.19675 mg/L	0.06685	0.12391	63.0 ± 0.3
0.98256 mg/L	0.3322	0.6283	63.9 ± 0.9
1.963 mg/L	0.6644	1.2439	63.4 ± 1.0
<b>Soil</b>		<b>B</b>	
0.0208 mg/L	0.00710	0.01260	60.6 ± 0.5
0.19675 mg/L	0.06558	0.12402	63.1 ± 0.1
0.98256 mg/L	0.3340	0.6307	62.2 ± 0.1
1.963 mg/L	0.6306	1.2494	63.6 ± 0.3
<b>Soil</b>		<b>C</b>	
0.0208 mg/L	0.01073	0.00907	43.6 ± 0.3
0.19675 mg/L	0.08831	0.10120	51.4 ± 3.7
0.98256 mg/L	0.4668	0.4758	48.4 ± 0.8
1.963 mg/L	0.8754	1.0167	51.8 ± 1.0

\* The percentage of test item adsorbed to the soil was calculated by relating the amount of test item found in solution to the actual applied amount (determined using the concentration of a.i.).  
s.d. = standard deviation

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Table CA 7.1.3.1.2- 15: Adsorption constants of [triazinyl-2-14C]AE F161778 in soils and correlation coefficients

Soil	Soil type (DIN)	Adsorption				
		pH	K <sub>F(ads)</sub> [mL/g]	1/n	R <sup>2</sup>	K <sub>OC(ads)</sub> [mL/g]
Soil A	Silty loam	6.4	0.7538	0.9567	0.9998	39.7
Soil B	Loamy sand	7.3	0.7526	0.9824	0.9999	34.4
Soil C	Sandy clayey loam	7.4	0.9399	0.9438	0.9990	20.4
<b>Mean (arithmetic)</b>			0.8154	0.9610	0.9996	31.4

pH: Value given as determined with calcium chloride solution

K<sub>F(ads)</sub>: Freundlich coefficient of adsorption

1/n: Slope of the Freundlich adsorption/desorption isotherms

R<sup>2</sup>: Regression coefficient of Freundlich equation

K<sub>OC(ads)</sub>: Adsorption coefficient per organic carbon (K<sub>F</sub> x 100 / % organic carbon, in the report K<sub>oc</sub> value has been calculated differently using the K<sub>d</sub> values)

### III. CONCLUSIONS

Based on the soil sorption parameters measured in this study and classification of soil mobility potential according to Hollis, AE F161778 can be classified as a mobile compound.

The adsorption constants K<sub>F(ads)</sub> of the Freundlich isotherms ranged from 0.75 to 0.94 mL/g with associated Freundlich exponents, 1/n to be below 1 for all soils (0.9438 to 0.9824). When being normalized for organic carbon content of soil, values of K<sub>OC(ads)</sub> varied from 20.4 mL/g to 39.7 mL/g with an arithmetic mean of 31.4 mL/g.

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<b>Report No:</b>	MEF-09/41
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<b>GLP/GEP:</b>	yes

### Executive Summary

The adsorption / desorption characteristics of AE F059411 were determined in five soils in a concentration range of two orders of magnitude. The adsorption phase of the study was carried out using air-dried soils pre-equilibrated in aqueous 0.01 M CaCl<sub>2</sub> solution with soil-to-solution ratios of 1/1 for soils ██████████ Am ██████████ 4a, ██████████ and ██████████ as well as 1/2 for soils ██████████ and ██████████. AE F059411 was applied at nominal concentrations of 1.0, 0.3, 0.1, 0.03 and 0.01 mg/L in aqueous 0.01 M CaCl<sub>2</sub> solution. Adsorption and the first desorption cycle took place for 24 hours each in the dark at 19.4 ± 0.2°C. For the highest concentration, two additional desorption cycles were performed with 24 hours equilibration time each.

In the definitive test the overall mean values of recoveries for the five test soils were in the range of 94.5 to 96.4% of applied radioactivity (% AR) and thus in an acceptable range.



Values for the coefficients of adsorption according to Freundlich (K<sub>F(ads)</sub>) ranged from 0.481 to 3.147 mL/g with corresponding values related to organic carbon (K<sub>OC(ads)</sub>) to range from 20.0 to 185.1 mL/g (arithmetic mean: 87.5 mL/g). Values for the Freundlich exponent of adsorption 1/n ranged from 0.9021 to 0.9755. The coefficients of desorption according to Freundlich (K<sub>F(des)</sub>) were in the range of 2.575 to 7.239 mL/g with corresponding values related to organic carbon (K<sub>OC(des)</sub>) to range from 160.2 to 425.8 mL/g. Values for the Freundlich exponent of desorption 1/n ranged from 0.9069 to 1.0069.

The desorption K<sub>F(des)</sub> and the normalized K<sub>OC(des)</sub> values were significantly higher (2.3 to 8.0 times higher) than those obtained for the adsorption phase indicating that the test item once adsorbed to soil is not readily desorbed. There is no significant correlation between pH and adsorption for the investigated soils.

According to Briggs<sup>6</sup>, the mobility of AE E05941 in the tested soils can be classified as low mobile to mobile for adsorption and low mobile for desorption.

### I. MATERIALS AND METHODS

#### A. MATERIALS

##### 1. Test Item

[Triazine-2-<sup>14</sup>C]BCS-CN85650  
Sample ID: KATH 6353  
Specific Activity: 4.85 MBq/mg (131.09 µCi/mg)  
Radiochemical Purity: > 98%  
Chemical Purity: > 98%

##### 2. Test Soils

Five soils originating from Germany, France and the USA were used (see Table CA 7.1.3.1.2- 16). The soils were taken from agricultural use areas representing different geographical origins and different soil properties as required by the guidelines. The selected soils are well-known from different metabolism and sorption studies.

Table CA 7.1.3.1.2- 16 Physico-chemical properties of test soils

Parameter	Results / Units				
Soil Designation	[Redacted]	[Redacted]	(LC)	(GL)	(SP)
Geographic Location	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
City	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]
State	North-Westphalia	North-Westphalia	Du Gres	[Redacted]	Nebraska
Country	Germany	Germany	France	USA	USA
GPS Coordinates	[Redacted]	[Redacted]	[Redacted]	[Redacted]	[Redacted]



Parameter	Results / Units				
Soil Designation	(WW)	(HH)	am 4a (LC)	(GL)	(SP)
Soil Taxonomic Classification (USDA)	Loamy, mixed, mesic, Typic Argudalfs	Loamy, mixed, mesic, Typic Argudalfs	no information available		Fine silty, mixed, superactive, mesic Typic Hapludolls
Soil Series	no information available			Camarillo	Marshall
Pesticide use history	no pesticide use > 5 years			Several Pesticides used	no pesticide use > 5 years
Collection procedures	Soil sample taken with shovel/spade and placed into plastic bags.			Sample taken with shovel and placed into 5 gallon bucket	
Sampling depth	0 – 20 cm				
Storage conditions	Ambient, after sieving storage in walk-in refrigerator			walk-in refrigerator	
Storage length	< 7 months after sieving		8 month after sieving		7 months after sieving
Soil preparation	Passed through a 2 mm sieve, air-dried				
Textural Class (USDA)	Loam	Silt loam	Clay loam	Sandy loam	Silt loam
Sand [50 µm – 2 mm]	51%	27%	24%	56%	12.7%
Silt [2 µm – 50 µm]	38%	54%	45%	33.6%	60.8%
Clay [< 2 µm]	21%	19%	31%	11.4%	26.5%
pH CaCl <sub>2</sub>	5.3	6.6	7.6	6.7	6.6
pH water	5.5	6.8	8.0	6.8	7.2
Organic Carbon	1.8%	2.4%	0.9%	0.7%	1.7%
Organic Matter	3.0%	4.1%	1.6%	1.2%	2.9%
Cation Exchange Capacity [meq/100 g]	10.8	13.2	11.4	16.1	16.1

<sup>1</sup> % organic matter = % organic carbon x 1.724

GPS: global positioning system

USDA: United States Department of Agriculture

## B. STUDY DESIGN

### 1. Experimental conditions

The test system for adsorption and desorption in batch equilibrium experiments consisted of Teflon<sup>®</sup> centrifuge tubes (volume 20 mL) closed with screw caps. All experiments were performed in duplicate. In general, dry weight aliquots of soil (< 2 mm) were weighed each into each centrifuge tube to which 0.01 M CaCl<sub>2</sub> solution was added to obtain a final volume of 20 mL after the addition of the application solution (corrected for soil moisture).

In preliminary tests, the adsorption of the test item to the test system surface, the optimal soil-to-solution ratio, the appropriate adsorption and desorption equilibration times and the stability of the test item were determined.



The adsorption phase in the definitive test was carried out using air-dried soils pre-equilibrated in aqueous 0.01 M CaCl<sub>2</sub> solution for three days. The test was performed with soil-to-solution ratios of 1/1 (soils [redacted] am [redacted] 4a, [redacted] and [redacted]) and 1/2 (soils [redacted] and [redacted]). After pre-equilibration, the test item was applied at nominal concentrations of 1.0, 0.3, 0.1, 0.03 and 0.01 mg/L in aqueous 0.01 M CaCl<sub>2</sub> solution. One desorption step was performed by supplying pre-adsorbed soil samples with fresh aqueous 0.01 M CaCl<sub>2</sub> solution. Adsorption and desorption took place for 24 hours equilibration time each (total of 48 hours). For the highest concentration only, two additional desorption steps were performed (agitation time 24 hours each).

The test systems were shaken by a mechanical overhead shaker in the dark at 19.4 ± 0.2 °C in a walk-in climatic chamber.

## 2. Analytical Procedures

The suspensions were centrifuged (1140 x g) and the radioactivity contents in the supernatants were analysed by liquid scintillation counting (LSC).

In the preliminary parental mass balance test, the soil was additionally extracted twice with 20 mL acetonitrile/water (1/1; v/v) and once with 20 mL acetonitrile/water (7/3; v/v) at ambient temperature by shaking for 30 minutes each, followed by two microwave extractions at 50°C with 15 mL acetonitrile/water (7/3; v/v) for 10 minutes each. The samples were centrifuged after each extraction step, the supernatants decanted and the supernatants of the ambient extracts combined. Each extract was analysed by LSC. To determine the amounts of AE P059411, the aqueous supernatant and the concentrated soil extracts were analysed by phenyl-hexyl-phase HPLC/radiodetection to determine the stability of the test item and to establish the parental mass balance. The limit of detection (LOD) was set to 0.3% of applied radioactivity, the limit of quantification (LOQ) to three times the LOD, i.e. approximately 0.9% of the applied radioactivity.

The partition of the test item in the adsorption and desorption batch equilibrium experiment was determined based on the radioactivity content in the supernatant only. After the desorption step, the soil was air-dried and the radioactivity content determined by combustion/LSC to establish the material balance.

Adsorption and desorption isotherms were calculated by linear regression analysis of the adsorption or desorption data according to the Freundlich equation.

## II. RESULTS AND DISCUSSION

### A. MATERIAL BALANCE AND RESULTS OF PRELIMINARY TESTS

Preliminary tests were performed to determine the stability of the test item as well as the time required to establish the equilibrium between the test item concentration in the solution and the amount adsorbed to the soil. The tests showed that equilibrium was established after 24 h of shaking for all soils. The test item was stable in control samples without soil. After incubation for 96 hours only one minor degradation product was detected in aqueous solution with < 2 % of the injected radioactivity. In the same test, the test substance did not adsorb to the surface of the test vessels.



The parental mass balance of AE F059411 was in the range of 91.8 to 95.9 % (mean: 93.7 %) of the applied radioactivity for all soils (see Table CA 7.1.3.1.2- 17). The stability was adequate to determine the distribution based on LSC of supernatant only in adsorption and desorption experiments.

Table CA 7.1.3.1.2- 17: Parental mass balance after incubation for 96 hours calculated as percentage of applied radioactivity in solution and soil extracts (mean values of duplicates)

Matrices	Soil 1	Soil 2	Soil 3	Soil 4	Soil 5
Soil ID	WW	HH	LC	GH	SP
Supernatant [% AR]	40.3	33.2	33.7	30.7	22.7
a.i. in supernatant [Area %] *	98.6	99.0	98.3	99.7	99.2
<b>Recovery a.i. item in supernatant [% AR]</b>	<b>39.7</b>	<b>32.9</b>	<b>33.4</b>	<b>30.6</b>	<b>22.5</b>
Solid phase (organic extract) [% AR]	46.2	58.4	52.2	58.1	60.1
a.i. in solid phase (organic extract) [Area %] *	100.0	99.4	99.0	99.5	99.4
<b>Recovery a.i. in solid phase [% AR]</b>	<b>46.2</b>	<b>58.0</b>	<b>50.6</b>	<b>57.8</b>	<b>59.8</b>
Solid phase (microwave extract) [% AR]	4.2	3.3	3.7	3.6	5.3
a.i. in solid phase (microwave extract) [Area %] *	99.0	97.0	97.0	96.4	98.8
<b>Recovery a.i. in solid phase (microwave extract) [% AR]</b>	<b>4.1</b>	<b>3.2</b>	<b>3.6</b>	<b>3.5</b>	<b>5.2</b>
Solid phase (microwave extract 2) [% AR]	4.4	1.9	4.0	2.3	4.4
a.i. in solid phase (microwave extract 2) [Area %] *	94.5	91.7	95.2	98.6	98.6
<b>Recovery a.i. in solid phase (microwave extract 2) [% AR]</b>	<b>4.0</b>	<b>1.7</b>	<b>3.8</b>	<b>2.3</b>	<b>4.3</b>
Non-extractable residues	N/A	N/A	N/A	N/A	N/A
<b>Total recovery [% AR]</b>	<b>95.2</b>	<b>96.8</b>	<b>93.5</b>	<b>94.8</b>	<b>92.5</b>
<b>Total recovery of a.i. [% AR]</b>	<b>94.3</b>	<b>95.9</b>	<b>92.1</b>	<b>94.2</b>	<b>91.8</b>

Mean for all soils: 93.7 %

\* % of Regions of Interest from HPLC

For the definitive tests the overall mass balances (mean values of duplicates) were 96.4, 94.8, 96.2, 96.3 and 94.5% of AR for soils [redacted], [redacted] am [redacted] 4a, [redacted], [redacted] and [redacted], respectively (see Table CA 7.1.3.1.2- 18). The complete material balances found for all soils and concentrations demonstrated that there was no significant loss of radioactivity dissipated from the test systems or during sample processing.

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Table CA 7.1.3.1.2- 18: Overall material balances for soils after adsorption, desorption and combustion, expressed as percentage of applied radioactivity (one replicate).

Soil	Recovery [% AR]	Recovery [% AR]	Recovery [% AR]	Recovery [% AR]	Recovery [% AR]
1.08	97.1	95.0	96.7	97.3	95.4
0.32	94.5	94.6	94.9	96.5	95.8
0.11	96.2	94.1	94.3	95.8	94.3
0.033	96.4	95.4	94.7	95.7	94.6
0.011	97.6	95.0	95.2	96.2	93.3
Mean	96.4	94.8	95.2	96.3	94.5
SD	± 1.1	± 0.5	± 0.8	± 0.6	± 1.0

Data are calculated based on sum of radioactivity in removed supernatants after adsorption and desorption steps and final soil combustion.

B. DEGRADATION OF PARENT COMPOUND

AE F059411 was sufficiently stable throughout the study as was demonstrated for aqueous solution as well as in the parental mass balance test.

C. FINDINGS

The adsorption behaviour of AE F059411 could be accurately described by the Freundlich equation within a nominal concentration range of 0.011 mg/L to 1.08 mg/L (Table CA 7.1.3.1.2- 19). The adsorption constants K<sub>F(ads)</sub> of the Freundlich isotherms ranged from 0.481 mL/g soil (soil am ) to 3.147 mL/g (soil ) with an associated Freundlich exponents 1/n to be below 1 for all soils (0.9021 to 0.9755). The adsorption behaviour to soil was thus to some extent affected by the concentration of the test item. The corresponding correlation coefficients of the adsorption isotherms ranged from 0.9963 to 0.9995, therefore indicating a good linear fit to the measured data. When being normalized for organic carbon content of soil, values of K<sub>OC(ads)</sub> varied from 20.0 mL/g (soil am 4a) to 185.1 mL/g in maximum (soil ).

Desorption constants K<sub>F(des)</sub> values according to Freundlich ranged from 2.575 mL/g (soil ) to 7.239 mL/g (soil ). The corresponding values for K<sub>OC(des)</sub> ranged from 160.2 mL/g (soil am 4a) to 425.8 mL/g (soil ). K<sub>OC(des)</sub> values were significantly higher (2.0 to 8.0 times higher) than the K<sub>OC(ads)</sub> indicating a strengthened binding of the test item once adsorbed to the soil.

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Table CA 7.1.3.1.2- 19: Adsorption and desorption constants and correlation coefficients of AE F059411 in soils

Soil	Adsorption				Desorption			
	K <sub>F(ads)</sub> [mL/g]	1/n	R <sup>2</sup>	K <sub>OC(ads)</sub> [mL/g]	K <sub>F(des)</sub> [mL/g]	1/n	R <sup>2</sup>	K <sub>OC(des)</sub> [mL/g]
	1.321	0.9183	0.9965	73.4	5.239	0.9069	0.9927	291.6
am 4a	0.481	0.9755	0.9992	20.0	3.845	0.9805	0.9971	160.2
	0.561	0.9170	0.9994	62.3	2.692	0.9777	0.9905	399.1
	0.675	0.9498	0.9995	96.5	2.575	0.9613	0.9976	367.8
	3.147	0.9021	0.9991	185.1	4.239	0.9069	0.9984	425.8
<b>Mean</b>	<b>1.237</b>	<b>0.9325</b>	<b>0.9987</b>	<b>87.5</b>	<b>4.318</b>	<b>0.9667</b>	<b>0.9953</b>	<b>308.8</b>

K<sub>F</sub>: Freundlich coefficients of adsorption/desorption

1/n: Slope of the Freundlich adsorption/desorption isotherms

R<sup>2</sup>: Regression coefficient of Freundlich equation

K<sub>oc</sub>: Adsorption coefficient per organic carbon (K<sub>F</sub> x 100% organic carbon)

### III. CONCLUSIONS

Using the Briggs<sup>6</sup> classifications for the estimation of the mobility of crop protection agents in soil based on K<sub>F(ads)</sub> and/or K<sub>OC(ads)</sub>-values, AE F059411 can be classified as low mobile to mobile for adsorption and low mobile for desorption.

#### CA 7.1.3.2 Aged sorption

Studies are not required under Commission Regulation (EU) No 283/2013 in accordance with Regulation (EC) No 107/2009.

#### CA 7.1.4 Mobility in soil

<b>Report:</b>	<a href="#">KCA 7.1.4.01</a> ; <a href="#">2013.M-473641-02</a>
<b>Title:</b>	Determination of the plant uptake factor of AE F075736 in wheat
<b>Report No:</b>	InSa-101033
<b>Document No:</b>	M-473641-02-1
<b>Guidelines:</b>	n.a.
<b>GLP/GEP:</b>	Yes

#### Executive Summary

The plant uptake factor (PUF) of AE F075736, a degradation product of iodosulfuron-methyl-sodium, was determined in wheat for 8 days in a greenhouse climatic chamber under controlled temperature (approx. 20 °C), light (day/night cycle of 14 h/10 h) and humidity (60%) conditions.

The volumes taken up by the wheat plants ranged from 130 mL to 210 mL per test (treated test systems). The mean initial concentration in the test solutions amounted to 96 µg/L.

The plant uptake factor was calculated from the amount of test item in the test solution and the volume of test solution at DAT-0 and DAT-8. The PUF for AE F075736 was determined as 0.50 (mean value) at DAT-8.

The plant uptake of AE F075736 was lower than the water uptake of the wheat plants, likely due to the impermeability of the cell walls for polar compounds.





## I. MATERIALS AND METHODS

### A. MATERIALS

#### 1. Test Item

AE F075736  
Batch Code: AE F075736 00 1B98 0002  
Certificate: AZ 16744  
Chemical Purity: 98.6% (w/w)

#### 2. Test Crop

Wheat plants (variety: Thasos) were pre-grown in [redacted] 4" soil (sandy loam) under greenhouse conditions. At growth stage BBCH 14, the pre-grown plants were removed from the soil and their root system was cleaned with a gentle flush of water. Afterwards, the plants were stored for a short time in nutrient solution until transfer to the test vessels.

#### 3. Test Solution

A stock solution of the test item was prepared in methanol. An aliquot of the stock solution was mixed with buffer solution (0.01 M 2-morpholino-ethanesulfonic acid (MES), 0.00M CaCl<sub>2</sub>; adjusted with sodium hydroxide solution to pH 7) to obtain a nominal test item concentration of 100 µg/L.

### B. STUDY DESIGN

#### 1. Experimental Conditions

The test system for the determination of the plant uptake factor (PUF) consisted of a bunch of five pre-grown wheat plants (BBCH code 14) in a brown glass bottle (volume 1 L) filled with 800 mL test solution. The wheat plants were fixed with polyurethane (PU) in the bottle and the bottle was sealed with aluminium foil to avoid test solution losses due to evaporation. The test was performed in quintuplicates. The water uptake behaviour of the wheat plants was tested using two additional controls without test item. The stability of the test item was investigated in two additional test systems without plants.

During the experimental phase, the plants were cultivated in a greenhouse with controlled temperature (approx. 20 °C), humidity (60%) and light (at least 35 klx between 6 am and 8 pm, day/night cycle) conditions.

#### 2. Analytical Procedures

At DAT-0, three application controls were analyzed in duplicate. During the course of the study, five individual treated test systems were removed from the greenhouse climatic chamber at DAT-2, -5 and -8, respectively, and duplicate aliquots taken from the solutions of each test system were analysed. The amount of test item in solution was determined by reversed phase high performance liquid chromatography hyphenated to tandem mass spectrometry (HPLC MS/MS).

Method validation was performed successfully within the study prior to application of the PUF test systems. For quantitation, an external multi-point calibration curve was established using standard solutions in nutrient solution (matrix matched) with concentrations ranging from 1% of the nominal applied concentration in combined solutions for HPLC-MS/MS analysis (nACA) to 150% of the nACA. The resulting linear functions showed excellent correlations between the injected test item



concentration (0.8 µg/L ± 1% of the nACA to 120.0 µg/L ± 150% of the nACA) and the detector response with a correlation coefficient (R<sup>2</sup>) of 0.9999. The accuracy and precision of the instrumental method was assessed at LOQ level (4.0 µg/L ± 5% of the nACA) and at application rate level (800 µg/L ± 100% of the nACA), by 3 and 5 injections, respectively. The relative standard deviations at LOQ level and application rate level were < 20%, demonstrating a sufficient repeatability of the instrumental method. Background abundance of the test item in nutrient solution was far below 30% of the LOQ and no interference by other matrix components occurred, demonstrating the selectivity of the instrumental method. Thus, the detector response was not corrected for interferences. The LOD of this method was set to 1/5 LOQ (0.8 µg/L ± 1% of the nACA).

## II. RESULTS AND DISCUSSION

### A. DEGRADATION OF PARENT COMPOUNDS

The mean test item amount in the stability controls was 92.7% of the applied amount at DAT-8. This demonstrated that the test item was stable during the whole test period of 8 days.

### B. FINDINGS

The transpiration volume of the treated plants ranged from 139 to 219 mL at DAT-8 which was comparable to the transpiration volume of the plant controls ranging from 190 to 215 mL at DAT-8.

The plant uptake factor was calculated from the amount of test item in the test solution and the volume of test solution at DAT-0 and DAT-8. The PUF for AE F05736 was determined as 0.50 (mean value) at DAT-8.

Table CA 7.1.4-1 Calculation of the Plant Uptake Factor

Replicate	V <sub>DAT-0</sub> [mL]	C <sub>DAT-0</sub> [µg/L]	m <sub>DAT-0</sub> [µg]	V <sub>DAT-8</sub> [mL]	C <sub>DAT-8</sub> [µg/L]	m <sub>DAT-8</sub> [µg]	PUF
1	800	100	76.8	670	84.6	68.5	0.42
2	800	100	76.8	645	80.7	67.8	0.58
3 <sup>1</sup>	800	100	76.8	500	91.4	72.2	0.20
4	800	100	76.8	670	80.3	69.9	0.53
5	800	100	76.8	630	82.9	68.8	0.46
					<b>Mean</b>		<b>0.50</b>

V<sub>DAT-0/DAT-8</sub>: initial/final volume of the nutrient solution in the test vessel [mL]

C<sub>DAT-0/DAT-8</sub>: initial/final concentration of the test item in the nutrient solution [µg/L]

m<sub>DAT-0/DAT-8</sub>: (calculated) initial/final mass of the test item in the nutrient solution [µg]

<sup>1</sup> Result of replicate #3 is not considered for evaluation, due to a high deviation from the other replicates.

The plant uptake of AE F05736 was lower than the water uptake of the wheat plants, likely due to the impermeability of the cell walls for polar compounds.

## III. CONCLUSIONS



The plant uptake of AE F075736 in wheat plants was determined as 0.50 (mean value) at DAT-8. The plant uptake of AE F075736 was lower than the water uptake of the wheat plants, likely due to the impermeability of the cell walls for polar compounds.

CA 7.1.4.1 Column leaching studies

Column leaching studies with the parent compound iodosulfuron-methyl-sodium were not performed. Instead, the mobility in soil is assessed by environmental modelling, using data on the degradation under aerobic conditions in the laboratory and the field (CA 7.1.1 / CA 7.1.2), and on adsorption to soil as determined from batch equilibrium experiments (CA 7.1.3). In addition two lysimeter studies have been conducted with radiolabelled iodosulfuron-methyl-sodium (CA 7.1.4.2) and were evaluated during the Annex I inclusion using one radiolabel positions, [triazinyl-2-14C], and were accepted by the European Commission (SANCO/10166/2003-Final, 3 July 2003). A column leaching study with parent compound or its degradates is therefore regarded as not necessary.

CA 7.1.4.1.1 Column leaching of the active substance

No soil column leaching study with iodosulfuron-methyl-sodium has been performed.

CA 7.1.4.1.2 Column leaching of metabolites, breakdown and reaction products

No soil column leaching studies with metabolites of iodosulfuron-methyl-sodium have been performed.

CA 7.1.4.2 Lysimeter studies

The leaching behaviours of iodosulfuron-methyl-sodium and its degradation products in soil in lysimeters were evaluated during the Annex I inclusion using one radiolabel positions, [triazinyl-2-14C], and were accepted by the European Commission (SANCO/10166/2003-Final, 3 July 2003). The following studies are included in the baseline dossier:

Table with 2 columns: Field, Report details. Row 1: Report: [redacted]; 1998;M-181320-01. Title: Leaching in two outdoor lysimeters following spring application: (14C)-triazine labelled AE F115008 Code: AE F115008 - triazinyl-2-14C. Report No: C00083. Document No(s): M-181320-01-1. Guidelines: BBA: IV 4-3, 1990; Deviation not specified. GLP/GEP: yes.

Table with 2 columns: Field, Report details. Row 1: Report: [redacted]; 1998;M-181322-01. Title: Leaching in an outdoor lysimeter following spring application: (14C)-triazine labelled AE F115008 Code: AE F115008-triazinyl-2-14C. Report No: C00085. Document No(s): M-181322-01-1. Guidelines: BBA: IV 4-3, 1990; Deviation not specified. GLP/GEP: yes.



Even under realistic worst-case conditions for leaching, in one study an atypical leaching event has been established, and a factor 1.5 exaggerated maximum application rate, neither AE F115008 nor its main soil metabolite Metsulfuron-methyl, or any other metabolite, leached at concentrations that pose a risk to ground water.

### CA 7.1.4.3 Field leaching studies

A field leaching study is not regarded as necessary: An extensive set of laboratory and field data is available on rate and route of degradation in soil which indicates that residues of AE F115008 are degradable including mineralization, i.e. non-persistent. Lysimeter study results experimentally demonstrated no leaching of relevant components to groundwater. A comprehensive set of laboratory data on adsorption of parent a.s. and major metabolites to soil allow for an assessment of the mobility of all significant residues under various environmental conditions by the use of computer simulations as given, for example, by the FOCUS scenario approach. Such transfer calculation is more flexible and allows for adaptation to crop, site or country specific climate and soil conditions, such overcoming the limitations of a field leaching experiment.

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## CA 7.2 Fate and behaviour in water and sediment

### Route of biodegradation of idosulfuron-methyl-sodium in water, aerobic conditions (Figure 7.2-1):

The dominant initial metabolic step in water is a reductive loss of iodine at the phenyl ring, leading to high amounts of AE F075736 (Metsulfuron-methyl). Parallel or sequential further metabolic steps are hydrolysis of the methyl ester at the phenyl ring, ether demethylation at the triazine ring, and cleavage of the sulfonyleurea bridge and the triazine ring itself. The products resulting from methyl loss at the phenyl and at the triazine ring before iodine loss are AE F145740 and AE F145741, respectively, and after iodine loss are AE 0014966. Subsequent cleavage of the sulfonyleurea bridge leads to AE 0000119 and AE 0034855, AE F059411 and the terminal product AE F154781, derived from the triazine moiety. Using the phenyl label of idosulfuron-methyl-sodium the cleavage of the sulfonyleurea bridge after iodine loss leads to AE F1234964 and AE F159737.

### The absolute abundances of the individual metabolites are:

AE F075736 (up to 67.8 %), AE F145740 (up to 12.6%), AE F145741 (up to 8.7%), AE 0014966 (up to 13.7 %), AE 0034855 (up to 15.5 %), AE 0000119 (up to 24.9 %), AE 0034855 (up to 24.2 %), AE F059411 (up to 27.5 %), AE F154781 (up to 5.7 %), AE F1234964 (up to 7.4 %) and AE F159737 (up to 7.8 %).

All degradates are transient intermediates, being either transformed to their respective metabolic downstream products or mineralized to carbon dioxide.

### Route of degradation of idosulfuron-methyl-sodium in water, anaerobic conditions:

Degradation in water under anaerobic conditions follows basically the same pathways as under aerobic conditions, with generally lower levels of downstream metabolites formed after AE F075736. In difference to aerobic conditions, minor amounts of the intermediate AE 0014966 could be detected in the water/sediment system tested.

### Route of degradation of idosulfuron-methyl-sodium in water, photolysis (Figure 7.2-1):

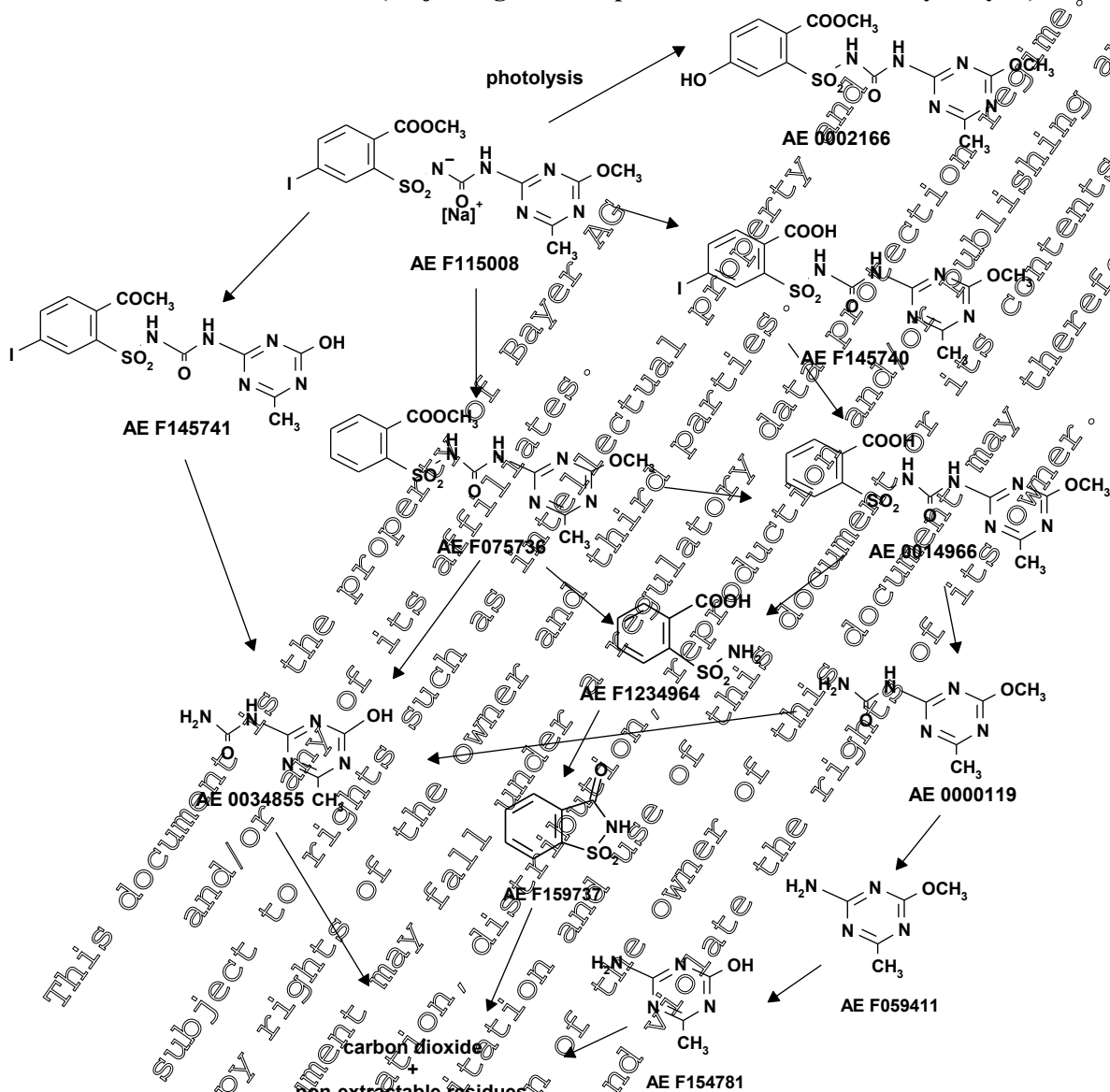
Iodosulfuron-methyl-sodium is only moderately photodegraded at wavelengths >290 nm in sterile buffer solution, with a half-life of about 50 days calculated for typical light intensity at 52° northern latitude. Photodegradation leads to AE 0002166 as the only major product (max. 21.7 %), via oxidative loss of iodine at the phenyl ring. AE 0002166 is transient, with an estimated half-life of ca. 20 days.

Photolysis was also studied in unfiltered natural surface water, with comparable results as in the buffer experiment. Only the amounts of the metabolite AE 0002166 were slightly higher (25.1 % of AR).

### Route of degradation of idosulfuron-methyl-sodium in water, abiotic hydrolysis (Figure 7.2-2):

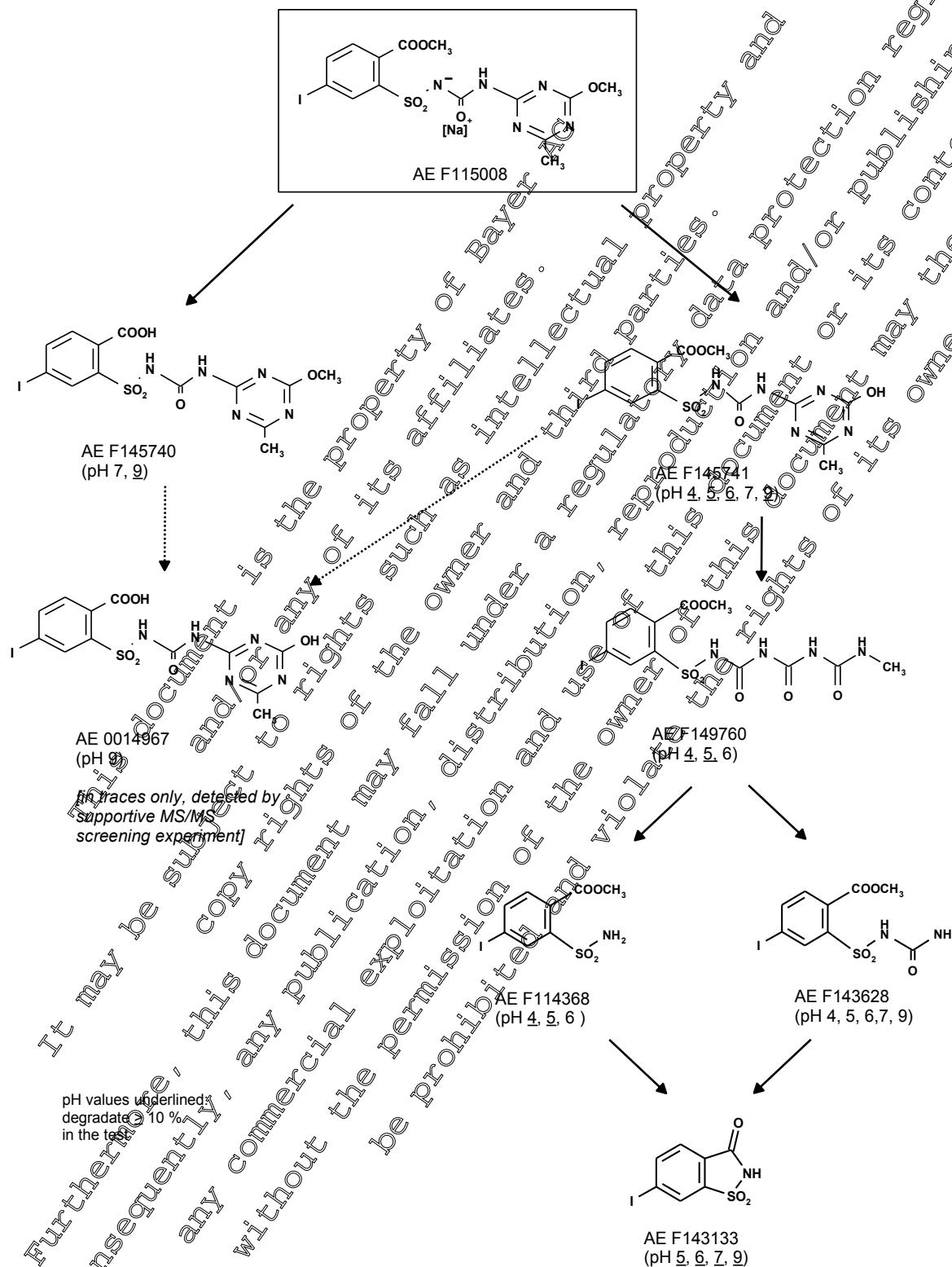
Iodosulfuron-methyl-sodium is relatively stable at neutral to alkaline pH (DT50 ≥ 1 year at pH 7 and pH 9, 20 °C) but is more rapidly hydrolysed in acidic environment (DT50 = 4 d at pH 4, 31 d at pH 5, 20 °C). The main hydrolytic pathway involves demethylation at the triazine ring to yield AE F145741, followed by ring opening (AE F149760) and sulfonyleurea cleavage (AE F114368, which can cyclize to the saccharine component AE F143133 at pH ≥ 5). Under alkaline conditions, additionally hydrolysis of the methyl ester function may occur as a minor second pathway, leading to AE F145740.

Figure 7.2- 1: Proposed degradation pathway of Iodosulfuron-methyl-sodium in water and sediment (major degradation products without abiotic hydrolysis)



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Figure 7.2- 2: Abiotic hydrolysis of Iodosulfuron-methyl-sodium





photochemical degradation)

CA 7.2.1.1 Hydrolytic degradation

The hydrolytic route and rate of degradation of Iodosulfuron-methyl-sodium in buffers under sterile conditions in the dark in the laboratory were evaluated during the Annex I, and were accepted by the European Commission (SANCO/10166/2003-Final, 3 July 2003). The following studies are included in the baseline dossier:

Table with 2 columns: Report/Title, and details. Title: Abiotic hydrolysis as a function of pH pure substance Code: Hoe 5008 ZB90001

Table with 2 columns: Report/Title, and details. Title: Abiotic hydrolysis as a function of pH (adendum) AE F15008 pure substance Code: AE F115008 00397 001

CA 7.2.1.2 Direct photochemical degradation

The photolytic route and rate of degradation of iodosulfuron-methyl-sodium in buffer in the laboratory was evaluated during the Annex I inclusion, and were accepted by the European Commission (SANCO/10166/2003-Final, 3 July 2003). The following study is included in the baseline dossier:

Table with 2 columns: Report/Title, and details. Title: Aqueous photolysis under laboratory conditions phenyl-14C-AE F115008

CA 7.2.1.3 Indirect photochemical degradation

An indirect photochemical degradation in air of iodosulfuron-methyl-sodium report was evaluated during the Annex I inclusion and were accepted by the European Commission (SANCO/10166/2003-Final, 3 July 2003). The following study is included in the baseline dossier:

Table with 2 columns: Report/Title, and details. Title: Calculation of the indirect photolysis reaction using the incremental method of Atkinson and the program AOPWIN, Version 1.80 Active ingredient AE F115008





Photolysis was also studied in unfiltered natural surface water, with comparable results as in the buffer experiment. One major metabolite was identified as AE 0002166 with max. occurrence of 25.1% of AR. Half lives of iodosulfuron-methyl and AE 0002166 were calculated as 29.1 and 13.7 environmental days under solar conditions at [redacted] (Japan), respectively

<b>Report:</b>	[redacted]; [redacted]; 2003;M-223476-01
<b>Title:</b>	Photolysis of iodosulfuron in natural water
<b>Report No:</b>	C037759
<b>Document No:</b>	M-223476-01-1
<b>Guidelines:</b>	MAFF: 12 Nousan 8147, 2000; SETAC: 1995; ISEPA (=EPA): 161-21982; Deviation not specified
<b>GLP/GEP:</b>	yes

**Executive Summary**

The phototransformation of iodosulfuron-methyl was studied in sterile, unfiltered natural water

The test was conducted with [phenyl-<sup>14</sup>C]iodosulfuron-methyl at a concentration of about 1.0 mg/L. The solutions were continuously irradiated in quartz glass vessels in a Suntest® unit with a Xenon lamp for a maximum testing period of 76 hours. The temperature of the test solutions was maintained at 25 ± 2 °C. Duplicate samples were taken for analysis 0, 4, 7, 24, 30, 48 and 76 hours post-treatment and were investigated by liquid scintillation counting (LSC) and thin layer chromatography (TLC) as evaluation method. Additionally, samples were analyzed by a second method using high performance liquid chromatography (HPLC, confirmation method). Dark controls were investigated in the same way after 76 hours of incubation at 25 °C

Material balances were established at each sampling interval. The balances of the test vessels (mean of duplicates) were within a range of 98.2% and 101.7% (mean 99.7%) of applied radioactivity.

Iodosulfuron-methyl was degraded throughout the course of the experiment. After 76 hours of irradiation 45.38% (mean) of the applied radioactivity was recovered as unchanged parent compound.

One major metabolite (10% of applied radioactivity) was formed in the course of the irradiation. This metabolite was identified as AE 0002166. Under exposure to light the amount increased continuously and was maximum 25.1% after 48 hours of irradiation and decreased then to 22.1% after 76 hours.

Furthermore, up to 14 minor metabolites have been observed in the course of the study. The maximum concentration of a radioactive zone representing a minor metabolite was 6.6% of the applied radioactivity after 76 hours irradiation. Iodosulfuron-methyl was stable in the dark samples. At termination of the study only the parent compound (97.5% of applied radioactivity) and a small amount of AE 0002166 (0.9% of AR) were detected in dark samples.

The photolytic half-life of iodosulfuron in natural water was calculated as 29.1 environmental days under solar conditions at [redacted] (Japan), or 14.1 environmental days at [redacted] (Arizona, USA). Therefore, it is concluded that solar radiation contributes to the degradation of the test substance in aquatic systems.



The photolytic half-life of the degradate AE 0002166 was calculated as 13.7 environmental days at [redacted] (Japan) or 6.6 environmental days at [redacted] (Arizona, USA). The half-life of the metabolite is about half of the DT50 of the parent indicating that this metabolite will not be formed in higher amounts.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

[phenyl-UL-14C]Iodosulfuron-methyl
Sample ID: BECH 0779
Specific Activity: 4.44 MBq/mg
Radiochemical Purity: > 98%

2. Test Water

Freshly collected [redacted] River water was used in this study without further filtration. Before application the water was sterilized by steam pressure sterilization to avoid biotic degradation of the test substance.

Table CA 7.2.1.3- 1: Characterisation of natural water sample used to investigate degradation of AE F115008

Table with 2 columns: Characteristics and [redacted] River Water. Rows include Origin, pH, Suspended solid, Total evaporation residue, O2 saturation, Conductivity, TOC, DOC, Hardness, Total nitrate, and Total phosphorus.

B. STUDY DESIGN

1. Experimental Conditions

The test system for photolytic degradation in natural water consisted of flat quartz glass vessels (maximum capacity of about 2 mL). Each vessel was closed with a trap attachment (permeable for oxygen), containing soda lime for absorption of carbon dioxide and a polyurethane (PU) foam plug for adsorption of volatile organic compounds.

The water and all glass ware used for preparation of solutions and the sampling procedure were sterilized by steam pressure sterilization before use (1 hour at 110 °C).



In order to maintain sterile conditions, application and the distribution into the test vessels was performed using a clean bench.

An aliquot of 250 µL of the application solution was added to 100 mL sterilized [redacted] River water in an Erlenmeyer flask. The solution was ultrasonicated for about 10 minutes. Then, [redacted] River water was added to a final volume of 250 mL, resulting in a final test concentration of 1.0 mg/L. Each 10 mL of this solution were distributed into the quartz test vessels. The test vessels were then closed with trap attachments and dark control samples were wrapped with aluminium foil.

The irradiated test systems were placed in a Suntest unit containing a xenon lamp simulating natural sunlight. The light emission was filtered with a 290 nm cut-off UV-filter which eliminated all wavelengths < 290 nm. In order to control the temperature of the samples, the vessels were kept in the Suntest unit on a cooling platform made of metal and connected to a cryostat (heat exchanger as circulation refrigerator unit). A thin layer of silicone oil was placed on the surface of the platform to improve heat transfer between the vessels and the heat exchanger. The temperature in the test system was monitored by a temperature sensor in a separate vessel filled with water. The temperature in the test vessel was recorded continuously using a thermocouple thermometer connected to a data logger. The temperature of the dark control samples, which were stored in a climatic chamber in the dark, was recorded using thermometer and additionally by a thermocouple thermometer connected to a data logger. Dark control samples served for examination of possible dark reactions. The intensity (photon flux) was measured by a radiometer equipped with 300-800 nm global sensor, and determined to be 10 times that of typical natural intensity in April at [redacted] (latitude 35.11° N) or 4.9 times that in June of [redacted], AZ, USA (33.26° N). The experimental irradiation period therefore corresponded to about 32 environmental days in [redacted], or 15 days in [redacted].

## 2. Sampling

In case of the irradiated samples the sampling intervals were 0, 4, 7, 24, 30, 48 and 76 hours after application. The dark controls (two samples) were sampled at the end of the study, i.e. 76 hours after application.

pH measurements and sterility checks were performed with each sample. The oxygen concentration was measured at day 0 and at study termination. For sterility checks, 100 µL aliquots were applied onto a mixed culture medium and incubated at room temperature for about 2 months.

## 3. Analytical Procedures

Carbon dioxide absorbed by soda lime was liberated with 18% aqueous hydrochloric acid and trapped in a scintillation cocktail selective for the binding of carbon dioxide using an air-tight assembly. The radioactivity content was determined by liquid scintillation counting (LSC).

The PU foam plugs were extracted with acetonitrile to desorb volatile organic compounds. The radioactivity content was determined by LSC.

The radioactivity in the solutions was determined by LSC using three 100 µL aliquots, each. The samples were processed and analysed immediately after sampling. All samples were directly investigated by TLC and HPLC without any concentration or extraction. The limit of quantitation for



TLC and HPLC/radiodetection analysis of the water samples were about 0.1 and 1% of applied radioactivity, respectively.

Test item identity in test solution was confirmed by HPLC-MS(/MS). The identity of the test item and a degradation product was confirmed in the course of the study by HPLC and TLC co-chromatography with the respective non-labelled reference substances.

Non-irradiated dark control samples served for examination of possible dark reactions. Half-life calculations for parent compound and degradate AE 0002166 were performed using first order kinetics with the evaluation program ©ModelManager.

## II. RESULT AND DISCUSSION

Results indicated that the anticipated standardized conditions (sterility, pH oxygen saturation and temperature) were maintained over the duration of the laboratory study.

The sterility tests demonstrated that sterile conditions were maintained throughout the test period. No contamination was observed in the test solutions.

The oxygen content of the test solutions was measured at 0 hours and after 76 hours irradiation. The saturation of oxygen was minimum 94.7%.

The pH of the test solution was measured before incubation and at each sampling interval. The pH level remained constant during the irradiation time in the range from pH 7.46 to pH 8.24.

The temperature of the irradiated and dark sample was maintained constant at  $25 \pm 2$  °C throughout the study.

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A. DATA

Table CA 7.2.1.3- 2: Photodegradation of Iodosulfuron-methyl in natural water (values expressed as % AR)

Compound	Replicate	Sampling Time (hours)								
		irradiated								dark control
		0	4	7	24	30	48	76	76	
Iodosulfuron-methyl	A	100.0	90.7	92.0	82.8	70.2	59.2	49.4	98.1	
	B	98.8	92.5	90.4	80.0	66.6	64.8	41.3	96.9	
	Mean	99.4	91.6	91.2	81.4	68.4	62.0	45.4	97.5	
AE 0002166	A	0.9	8.2	7.9	13.6	23.6	26.8	20.3	2.4	
	B	0.9	6.7	7.9	15.6	25.6	23.6	21.8	3.4	
	Mean	0.9	7.4	7.6	14.6	24.6	25.1	22.1	2.9	
Z 1	A	n.d.	n.d.	n.d.	0.2	0.9	2.5	6.0	n.d.	
	B	n.d.	n.d.	n.d.	0.6	0.9	2.0	0.4	n.d.	
	Mean				0.4	0.9	2.3	3.6		
Z 10	A	n.d.	n.d.	n.d.	n.d.	0.4	0.5	2.0	n.d.	
	B	n.d.	n.d.	n.d.	n.d.	0.7	1.0	0.9	n.d.	
	Mean					0.5	0.8	3.4		
Z 14	A	n.d.	n.d.	n.d.	n.d.	0.8	2.7	4.0	n.d.	
	B	n.d.	n.d.	n.d.	n.d.	1.1	1.0	8.5	n.d.	
	Mean					1.0	2.3	6.6		
Aqueous solution <sup>1</sup>	A	100.5	100.1	99.9	99.3	99.7	98.4	96.0	102.0	
	B	100.1	100.0	100.0	99.7	99.2	98.4	98.0	101.4	
	Mean	100.3	100.2	99.9	99.5	99.5	98.4	97.0	101.7	
Carbon Dioxide <sup>1</sup>	A	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	1.3	0.0	
	B	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	1.0	0.0	
	Mean							1.2	0.0	
Volatile Organic Compounds <sup>1</sup>	A	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.d.	0.1	
	B	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.d.	0.0	
	Mean								0.1	
Total Recovery <sup>1</sup>	A	100.5	100.1	99.7	99.3	99.7	98.4	97.3	102.1	
	B	100.1	100.0	100.0	99.7	99.2	98.4	99.1	101.4	
	Mean	100.3	100.2	99.8	99.5	99.4	98.4	98.2	101.7	

n.d.: not detected, n.a.: not analyzed

A number of further minor degradation products were observed (Z2 to Z10, Z11 to Z13, Z15 and Z16), but accounted for 0.9 % of the applied throughout the test.

<sup>1</sup> Values taken from Material Balance Table in Report

B. MATERIAL BALANCE

Mean material balances were 99.4% of applied radioactivity (range of 98.2 to 100.3% AR) for irradiated samples and 101.7% of applied radioactivity (range of 101.4 to 102.1% AR) for dark samples.

C. VOLATILES

Very small amounts of <sup>14</sup>CO<sub>2</sub> were formed during the irradiation of [phenyl-UL-<sup>14</sup>C]iodosulfuron-methyl in natural water. At termination of the experiment (76 hours) about 1.2% of the applied



radioactivity was measured as <sup>14</sup>CO<sub>2</sub>. Volatile organic compounds were not detected (< 0.1% of applied radioactivity).

Neither <sup>14</sup>CO<sub>2</sub>, nor organic volatile compounds were detected in the dark samples (<0.1% of applied radioactivity).

**D. DEGRADATION OF PARENT COMPOUND**

Iodosulfuron-methyl was degraded throughout the course of the experiment. After 76 hours of irradiation 45.4% (mean) of the applied radioactivity was recovered as unchanged parent compound.

One major metabolite (> 10% of applied radioactivity) was formed in the course of the irradiation. This metabolite was identified as AE 0002166. Under exposure to light the amount increased continuously and was maximum 25.1% after 48 hours of irradiation and decreased then to 22.1% after 76 hours.

Furthermore, up to 14 minor metabolites have been observed in the course of the study. The maximum concentration of a radioactive zone representing a minor metabolite was 6.6% of the applied radioactivity after 76 hours irradiation (Z 14).

Iodosulfuron-methyl was stable in the dark samples. At termination of the study only parent compound (97.5% of applied radioactivity) and a small amount of AE 0002166 (2.9% of applied radioactivity) were detected.

The experimental half-life of the direct photodegradation of iodosulfuron-methyl was calculated to be 69.6 hours of continuous irradiation, following first order kinetics.

It was calculated that 76 hours of continuous irradiation in the experiment equals 31.8 and 15.4 days under solar conditions in [redacted], Japan and [redacted], USA, respectively. Therefore, the half-life under experimental conditions of 69.6 hours (DT<sub>50</sub>) is calculated to be DT<sub>50</sub> = 29.1 and 14.1 days under solar conditions at [redacted] and [redacted], respectively.

Table CA 7.2.F.3- 3: Photodegradation kinetics of Iodosulfuron-methyl in natural water.

Test System	First order kinetics				
	DT <sub>50</sub> (exp.) [hours]	DT <sub>50</sub> (exp.) [days]	r <sup>2</sup>	Rate Constant [days <sup>-1</sup> ]	DT <sub>50</sub> under natural conditions [days]
Irradiated	69.6	Not calculated	0.979	0.0096	29.1 ([redacted], Japan) 14.1 ([redacted], USA)

In addition, the half-life of the main metabolite AE 0002166 can be estimated from the degradation behaviour. The DT<sub>50</sub> was about 32.7 hours under experimental conditions and was calculated to be 13.7 days under solar conditions in [redacted], Japan and 6.6 days under extraordinary solar conditions at [redacted], USA.



### III. CONCLUSIONS

Under the experimental conditions used, [phenyl-UL-<sup>14</sup>C]iodosulfuron-methyl degraded in sterile natural water under light exposure with an experimental half-life of 69.6 hours. This corresponds to a calculated environmental half-life of 29.1 days under the solar conditions at █████, Japan or 14.1 days at █████, AZ (USA).

The mean recovery of radioactivity was 99.7% of the applied radioactivity indicating that no radioactivity was lost in the course of the study.

Iodosulfuron-methyl was degraded throughout in the course of the irradiation. After 76 hours irradiation 45.38% of the applied radioactivity was recovered as unchanged parent.

One major metabolite was formed and increased directly from the beginning of the irradiation and was identified as AE 0002166 (iodosulfuron-hydroxy). The maximum amount was 25.1% of AR after 48 hours of irradiation. The amount decreased then to 22.1% of AR after 76 hours. The DT<sub>50</sub> under experimental conditions was 32.7 hours. The half-life of the metabolite is about half of the DT<sub>50</sub> of the parent indicating that this metabolite will not be formed in higher amounts and will not further increase.

Furthermore, 14 minor metabolites were formed. The maximum amount of an individual metabolite, i.e. Z 14 was 6.6% of the AR.

In the dark samples iodosulfuron-methyl was stable. After 76 hours a small amount (2.9% of AR) of AE 0002166 was formed.

The results of this experiment show that the half-life of photolytic degradation of iodosulfuron-methyl was about four weeks (█████, Japan) and two weeks (extraordinary conditions at █████, Arizona, USA) in natural water. Therefore, it is concluded that solar radiation contributes to the degradation of the test substance in aquatic systems.

These results are in good agreement with the results of a previous photolysis study conducted in pure aqueous buffer solution. Potential photosensitizers present in natural surface water therefore do not exert a very pronounced influence on the photolytic degradation of iodosulfuron-methyl.

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

AE F115008 is degradable in aquatic systems, resulting in a complex metabolic pattern. A total of ten major metabolites could be identified. The following maximum amounts were detected in the water phase, the sediment and the entire system, respectively: AE F075736 with up to 19.5, 57.0 and 67.8% AR, AE F145740 with up to 9.1, 3.5 and 12.6% AR, AE F145741 with up to 7.0, 1.9 and 8.7% AR, AE 0014966 with up to 1.8, 10.3 and 15.5% AR, AE F159737 with up to 6.1, 1.7 and 7.8% AR, AE 1234964 with up to 6.8, 0.6 and 7.4% AR, AE 0000119 with up to 14.8, 19.3 and 27.5% AR, AE F059411 with up to 8.3, 16.7 and 27.5% AR, and AE 0034855 with up to 10.7, 16.7 and 24.2% AR. In addition the metabolite AE F154781 was detected at the low dose experiment in the aerobic mineralization in surface water study in amounts of 8.7% at the last sampling interval only.



A significant formation of <sup>14</sup>CO<sub>2</sub> indicated potential for ultimate breakdown of the molecule. Only moderate formation of non-extractable residues occurred.

In aquatic systems therefore it has been demonstrated that AE F115008 and its degradates are not persistent, and hence no accumulation in natural surface waters is to be expected.

**CA 7.2.2.1 "Ready biodegradability"**

According to its molecular structure, iodosulfuron-methyl-sodium was regarded not to be readily biodegradable. Therefore, a study was not conducted.

**CA 7.2.2.2 Aerobic mineralisation in surface water**

<b>Report:</b>	KCA 7.2.2.2 /01; [REDACTED] 2013; M-458191-01-1
<b>Title:</b>	[triazinyl-2- <sup>14</sup> C]Iodosulfuron-methyl-sodium - Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test
<b>Report No:</b>	20120137
<b>Document No:</b>	M-458191-01-1
<b>Guidelines:</b>	OECD Test Guideline No. 309 DG Sanco 11802/2010/rev.1
<b>GLP/GEP:</b>	Yes

**Executive Summary**

The route and rate of degradation of [triazinyl-2-<sup>14</sup>C]Iodosulfuron-methyl-sodium were studied in surface water under aerobic conditions in the dark in the laboratory for 62 days at 21.1 °C.

The test item was applied at nominal concentrations of 0.1 and 0.02 mg/L (high dose and low dose experiments). In addition, a high concentration experiment was performed under sterile conditions in order to gain information about abiotic degradability of the test item (single samples).

Mean material balances were 104.8% of applied radioactivity [% AR] (range from 101.2 to 108.2% AR) for the high concentration, 106.8% AR (range from 104.7 to 111.1% AR) for the low concentration and 106.9% AR (range from 99.7 to 112.3% AR) for the sterile samples.

Formation of radioactive carbon dioxide was negligible, never exceeding mean amounts of 0.3% AR (low concentration, day 41) in any system. Volatile products other than <sup>14</sup>CO<sub>2</sub> were constantly below 0.1% AR in all test systems, except for days 1 and 7 in the low dose experiment in which amounts up to 0.3% AR were formed.

The concentration of Iodosulfuron-methyl-sodium decreased very slowly in all systems. At the first sampling interval (time 0) the test item represented 104.0%, 106.1% and 108.5% AR in the high dose, low dose and sterile systems, respectively. The reference substance benzoic acid degraded from initially 108.5% to 2.5% AR within 14 days of incubation indicating a high microbial activity in the test water.

Besides the test item and radioactive carbon dioxide, two major<sup>1</sup> metabolites were detected in the test systems. Metabolite AE 0000119 (4-hydroxy-6-methyl-1,3,5-triazin-2-yl)urea was observed under all





conditions. It reached a maximum amount of 8.9% AR on day 62 in the sterile experiment. Metabolite AE F154781 (4-amino-2-hydroxy-6-methyl-1,3,5-triazine) was mainly observed in amounts ≤ 3.4% reaching a mean amount of 8.7% AR only at the last interval of the low dose experiment. In addition, four minor metabolites were observed, none of them exceeding a mean amount of 3.0% AR at any time throughout the study.

The experimental DT<sub>50</sub> and DT<sub>90</sub> values of iodosulfuron-methyl-sodium were calculated using single first order kinetics. The half-lives for iodosulfuron-methyl-sodium were 263.5, 500.1 and 179.8 days for the high dose, the low dose and the sterile experiment, respectively.

In conclusion, iodosulfuron-methyl-sodium degraded very slowly in natural surface water systems independent of the concentration used.

### I. MATERIALS AND METHODS

#### A. MATERIALS

##### 1. Test Item

[triazinyl-2- <sup>14</sup> C]-Iodosulfuron-methyl-sodium	
Sample ID:	KML 9434
Specific Activity:	95 MBq/mg (406.87 µCi/mg)
Radiochemical Purity:	> 99% > 97% as determined by HPLC before use.
Chemical Purity:	not reported

##### 2. Test Water

Natural water from a pond system was used. The sampling location was not in an area that received effluent discharges and located far from human activity (see Table CA 7.2.2- 1). The water was sampled freshly from the pond (depth of approx. 15 cm) and passed through a 0.2 mm screen prior to use.

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Table CA 7.2.2.2- 1: Physico-chemical properties of test water

Parameter	Results / Units
Water Designation	[REDACTED]
Origin	[REDACTED], France
GPS Coordinates	[REDACTED]
Storage	at about 4°C in the dark
Sampling Depth [cm]	0 to 5
Temperature [°C] <sup>1</sup>	19.3
pH <sup>1</sup>	7.8
Redox Potential E <sub>H</sub> [mV] <sup>1,2</sup>	9.30
Oxygen Content [mg/L] <sup>1</sup>	9.80
Colour	greenish
Turbidity	visibility through water layer down to about 15 to 20 cm
DOC [mg C/L]	3.48
TOC [mg C/L]	7.05
Total Nitrogen [mg/L]	1.75
Total Phosphorous [mg/L]	0.52
Total Nitrate [mg/L]	1.23
Total Nitrite [mg/L]	< 0.25

<sup>1</sup> measured at sampling site

<sup>2</sup> Redox potential was measured with platinum/silver chloride electrode (not corrected for pH). In order to obtain the redox potential of the hydrogen electrode, +271 mV has to be added to the measured values.

DOC: dissolved organic carbon

GPS: global positioning system

TOC: total organic carbon

## B. STUDY DESIGN

### 1. Experimental Conditions

Each system consisted of an open gas flow-system with 350 mL conical Erlenmeyer flasks. For preparation of the test systems, 100 mL of the natural water were transferred into each flask and equilibrated at 20 °C.

Application rates of 0.1 and 0.6 mg/L were applied for the low and the high concentration sample, respectively. In addition, an experiment was performed under sterile conditions at the high concentration. The test item was applied dropwise onto the water surface of the respective test systems in 1000 µL water using a syringe. Sterile water was used for the preparation of the stock solutions and the application solution of the high dose experiments.

After treatment samples were connected to a trapping system equipped with a total of two absorption traps, one containing ethylene glycol and the other one 2N NaOH (in this sequence) to trap organic volatiles and <sup>14</sup>C<sub>2</sub>O<sub>2</sub>, respectively. Samples were incubated at a controlled temperature of 21.1 ± 0.1 °C, in the dark under aerobic conditions. Each flask was aerated with moistened air. The samples were continuously and gently stirred to maintain particles and micro-organisms in suspension. Agitation also facilitated oxygen transfer from headspace to liquid, in a way that aerobic conditions were maintained.



In order to test the microbial activity of the test water, the degradation of [ $^{14}\text{C}(\text{UL})$ ]benzoic acid was monitored using the same experimental set-up

## 2. Sampling

Seven sampling intervals were distributed over the entire incubation period of 62 days. Duplicate samples from the high and low experiments and single samples from the sterile experiment were processed and analysed 0, 1, 7, 14, 28, 41 and 62 days after treatment.

Two replicates of the samples treated with benzoic acid were removed from the flasks and analysed immediately after treatment and after 7 and 14 days.

## 3. Analytical Procedures

Entire samples were taken at each sampling interval. The volume of the water phase was recorded and the radioactivity present determined by liquid scintillation counting (LSC). An aliquot (20 mL) of the unprocessed water phase was removed and basified with soda lime in order to determine dissolved  $^{14}\text{CO}_2$ . The amount of  $^{14}\text{CO}_2$  bound to soda lime was then liberated using 18% hydrochloric acid, trapped in a scintillation cocktail and measured by LSC. Radioactivity present in the trapping solutions was monitored by liquid scintillation counting and solutions were exchanged after each sampling or at weekly intervals. Prior to measuring the radioactivity the volume of liquid in each ethylene glycol and sodium hydroxide trap was recorded.

After the LSC measurements, aliquots of the water phase were concentrated under reduced pressure and submitted to HPLC analysis using radio- and UV detection. The LOD and LOQ of the HPLC method were, 0.7 and 0.4 ng/L, respectively, corresponding to 0.7 and 0.4% of applied radioactivity (AR). Selected samples were additionally analysed by TLC (UV and radiodetection) in order to confirm the results obtained by HPLC. Non-radio-labelled reference items were used to characterize the degradation products.

Additionally, pH value and oxygen content of water was measured at each sampling interval in the respective treated samples and in two untreated control samples.

Samples treated with benzoic acid were analysed for radioactivity in water layer, dissolved radioactive carbon dioxide, volatile radioactivity in trapping solutions and remaining concentration of benzoic acid as described above.

The degradation rate of the test item in soil was calculated according to FOCUS Kinetics Guidance (2006)<sup>2</sup> on estimating persistence and degradation kinetics from Environmental Fate Studies.

Degradation could be described by single first-order (SFO) kinetics using the CAKE software (version 1.4)<sup>8</sup>.  $\text{DT}_{50}$  and  $\text{DT}_{90}$  values were calculated directly from the software.

<sup>8</sup> CAKE developed by TessellaPlc, Abingdon, Oxfordshire, UK



II. RESULTS AND DISCUSSION

Results indicated that the anticipated standardized conditions were maintained and that the water was microbially active.

The pH in the water ranged from 7.80 to 8.42 for all test systems treated with Iodosulfuron-methyl-sodium. Oxygen contents (range from 6.4 to 10.3 mg/L) indicated aerobic conditions in the water for all experiments. Similar values were determined in untreated control samples which demonstrate that the test item had no significant effects on the physico-chemical parameters of the test system.

A. DATA

Table CA 7.2.2.2- 2: Degradation of Iodosulfuron-methyl-sodium in natural pond water under aerobic conditions (high concentration, single and mean values expressed as % AR)

Compound	Replicate	Residues (% AR) on the following days after treatment (DAT)						
		0	1	7	14	28	41	62
Iodosulfuron-methyl-sodium	(A)	104.0	106.7	102.8	102.9	102.1	92.8	88.5
	(B)	104.1	107.0	100.5	101.9	103.0	11.3	90.6
	Mean	104.0	106.8	101.6	102.4	102.5	92.1	89.5
Roi 1	(A)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	1.1
	(B)	n.d.	n.d.	n.d.	n.d.	n.d.	1.4	0.8
	Mean	n.d.	n.d.	n.d.	n.d.	n.d.	0.7	0.9
Roi 2	(A)	n.d.	n.d.	n.d.	n.d.	n.d.	1.2	1.6
	(B)	n.d.	n.d.	n.d.	n.d.	n.d.	*	1.5
	Mean	n.d.	n.d.	n.d.	n.d.	n.d.	0.6	1.6
AE 0000119	(A)	n.d.	n.d.	1.8	2.0	0.8	5.5	7.3
	(B)	n.d.	n.d.	2.1	3.6	n.d.	3.8	4.2
	Mean	n.d.	n.d.	1.9	2.8	0.4	4.7	5.7
Roi 7	(A)	n.d.	n.d.	1.2	n.d.	1.9	1.8	2.9
	(B)	n.d.	n.d.	1.2	1.1	1.7	3.3	3.1
	Mean	n.d.	n.d.	1.2	0.5	1.8	2.5	3.0
AE F154781	(A)	n.d.	n.d.	n.d.	n.d.	3.7	n.d.	1.4
	(B)	n.d.	n.d.	n.d.	n.d.	3.2	1.0	2.2
	Mean	n.d.	n.d.	n.d.	n.d.	3.4	0.5	1.8
Total water phase	(A)	104.0	106.7	105.8	104.9	108.5	101.3	102.7
	(B)	104.1	107.0	103.8	106.6	107.9	100.8	102.4
	Mean	104.0	106.8	104.8	105.7	108.2	101.0	102.5
<sup>14</sup> CO <sub>2</sub>	(A)	<0.1	<0.1	0.1	0.1	0.1	0.1	0.1
	(B)	<0.1	<0.1	<0.1	0.1	<0.1	0.1	0.1
	Mean	<0.1	0.1	<0.1	0.1	0.1	0.1	0.1
Other	(A)	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
	(B)	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
	Mean	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Total % Recovered	(A)	104.0	106.7	105.9	104.9	108.6	101.4	102.8
	(B)	104.1	107.0	103.8	106.6	107.9	101.0	102.5
	Mean	104.0	106.8	104.9	105.8	108.2	101.2	102.6

n.d.: not detected  
Roi: Region of interest



**Table CA 7.2.2.2- 3: Degradation of Iodosulfuron-methyl-sodium in natural pond water under aerobic conditions (low concentration, single and mean values expressed as % AR)**

Compound	Replicate	Residues (% AR) on the following days after treatment (DAT)						
		0	1	7	14	28	41	62
Iodosulfuron-methyl-sodium	(A)	104.5	105.7	106.8	106.9	103.8	103.6	96.8
	(B)	107.7	105.4	104.7	109.3	114.2	105.1	92.6
	Mean	106.1	105.5	105.8	108.1	109.0	104.4	94.7
AE 0000119	(A)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
	(B)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	3.6
	Mean	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	1.8
AE F154781	(A)	n.d.	n.d.	n.d.	n.d.	3.7	n.d.	2.3
	(B)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	8.1
	Mean	n.d.	n.d.	n.d.	n.d.	1.9	n.d.	8.7
Total water phase	(A)	104.5	105.7	106.8	106.9	107.6	103.6	106.1
	(B)	107.7	105.4	104.7	109.3	114.2	105.1	104.2
	Mean	106.1	105.5	105.8	108.1	110.9	104.4	105.2
<sup>14</sup> CO <sub>2</sub> #	(A)	<0.1	<0.1	<0.1	0.1	0.3	0.2	0
	(B)	<0.1	0.1	<0.1	0.2	0.1	0.4	0.1
	Mean	<0.1	0.1	<0.1	0.1	0.2	0.3	0.2
Other Volatiles	(A)	<0.1	<0.1	0.1	0.1	<0.1	0.1	<0.1
	(B)	<0.1	0.5	0.2	0.1	<0.1	<0.1	<0.1
	Mean	<0.1	0.3	0.2	<0.1	0.1	<0.1	<0.1
Total % Recovery*	(A)	104.5	105.7	106.9	107.6	107.9	103.8	106.6
	(B)	107.7	105.4	104.9	109.5	114.2	105.6	104.3
Mean		106.1	105.9	105.9	108.3	110.1	104.7	105.4

n.d.: not detected

**Table CA 7.2.2.2- 4: Degradation of Iodosulfuron-methyl-sodium in natural pond water under aerobic conditions (sterile, high concentration, single and mean values expressed as % AR)**

Compound	Replicate	Residues (% AR) on the following days after treatment (DAT)						
		0	1	7	14	28	41	62
Iodosulfuron-methyl-sodium	(A)	108.5	109.3	107.6	108.5	104.4	92.6	85.1
Roi 2	(A)	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	2.0
AE 0000119	(A)	n.d.	n.d.	2.8	3.4	2.7	5.0	8.9
M7	(A)	n.d.	n.d.	n.d.	1.4	2.1	2.2	2.7
AE F154781	(A)	n.d.	n.d.	n.d.	n.d.	1.0	n.d.	1.7
Roi 10	(A)	n.d.	n.d.	n.d.	n.d.	2.1	n.d.	n.d.
Total water phase	(A)	108.5	109.3	109.4	108.5	112.3	99.7	100.2
<sup>14</sup> CO <sub>2</sub>	(A)	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Other Volatiles	(A)	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Total Recovery %	(A)	108.5	109.3	109.4	108.5	112.3	99.7	100.2

n.d.: not detected

Roi: Region of interest



**B. MATERIAL BALANCE**

Mean material balances were 104.8% of applied radioactivity [% AR] (range from 101.2 to 108.2% AR) for the high concentration, 106.8% AR (range from 104.7 to 111.1% AR) for the low concentration and 106.9% AR (range from 99.7 to 112.3% AR) for the additional experiment under sterile conditions. The complete material balances found at all sampling intervals demonstrated that there was no significant loss of radioactivity which dissipated from the test systems or was lost during sample processing.

**C. VOLATILES**

The maximum amount of carbon dioxide in treated test system was 0.3 % AR (low concentration, day 41). Volatile products other than <sup>14</sup>CO<sub>2</sub> were constantly below 0.1% AR in all test systems, except for days 1 and 7 in the low dose experiment in which the amounts reached up to 0.3% AR.

**D. DEGRADATION OF PARENT COMPOUND**

The concentration of iodosulfuron-methyl-sodium decreased very slowly in all systems. At the first sampling interval (time 0), the test item represented 104.0%, 106.4% and 108.5% AR in the high dose, low dose and sterile systems, respectively. After 62 days of incubation, the test item concentration decreased to 89.5%, 94.7% and 85.1% for the respective systems.

The reference substance benzoic acid degraded from initially 108.5% to 2.5% AR within 14 days of incubation indicating a high microbial activity in the test water.

Besides the test item and radioactive carbon dioxide, two major metabolites were detected in the test systems. AE 0000199 (4-hydroxy-6-methyl-1,3,5-triazin-2-yl)urea was observed under all conditions. It reached a maximum amount of 8.9% AR on day 62 in the sterile experiment. AE F154781 (4-amino-2-hydroxy-6-methyl-1,3,5-triazine) was mainly observed in amounts ≤ 3.4% reaching a mean amount of 0.7% AR only at the last interval of the low dose experiment. In addition, four minor metabolites were observed, none of them exceeding a mean amount of 3.0% AR at any time throughout the study (see Table CA 7.2.2.2-2 to Table CA 7.2.2.2-4).

The experimental DT<sub>50</sub> and DT<sub>90</sub> values of iodosulfuron-methyl-sodium were calculated using single first order (SFO) kinetics (see Table CA 7.2.2.2-5).

**Table CA 7.2.2.2-5: Degradation kinetics of Iodosulfuron-methyl-sodium in natural pond water under aerobic conditions according to FOCUS**

Test System	SFO <sup>1</sup>		
	DT <sub>50</sub> [days]	DT <sub>90</sub> [days]	Chi <sup>2</sup> Error [%]
High dose	263.5	875.2	1.8
Low dose <sup>2</sup>	500.1	1661	2.3
High dose, sterile	179.8	597.2	1.8

<sup>1</sup> SFO: single first order

<sup>2</sup> not enough intervals with decreasing amount of test item present to generate an accurate fit. Therefore, the longer half-life is not due to the lower application rate of the test item.



### III. CONCLUSIONS

In conclusion, iodosulfuron-methyl-sodium degraded very slowly in natural surface water systems independent of the concentration used. The half-lives calculated according to single first order kinetics were 263.5, 500.1 and 179.8 days for the high dose, the low dose and sterile experiment, respectively.

Besides the test item and radioactive carbon dioxide, two major<sup>1</sup> metabolites were detected in the test systems. AE 0000119 (4-hydroxy-6-methyl-1,3,5-triazin-6-yl)urea was observed under all conditions. It reached a maximum amount of 8.9% AR on day 62 in the sterile experiment. AE 0154731 (4-amino-2-hydroxy-6-methyl-1,3,5-triazine) was mainly observed in amounts ≤ 3.4% reaching a mean amount of 8.7% AR only at the last interval of the low dose experiment. Formation of radioactive carbon dioxide was negligible.

#### CA 7.2.2.3 Water/sediment study

The route and rate of degradation of iodosulfuron-methyl in water/sediment systems under aerobic conditions were evaluated during the Annex I inclusion using one radiolabel position (triazinyl-2-<sup>14</sup>C), and was accepted by the European Commission (SANCO/10166/2003-Final, 3 July 2003). The following studies are included in the baseline dossier:

<b>Report:</b>	[REDACTED]; 1998;M-147858-01
<b>Title:</b>	Aerobic aquatic degradation in two water/sediment systems at 20 degrees C (2-triazinyl- <sup>14</sup> C) - AE F11008
<b>Report No:</b>	A6747
<b>Document No:</b>	M-147858-01-1
<b>Guidelines:</b>	BBA: IV.3.1; EU (=EEC: 95/1/EC, Annex I, CA 7.2.1.3.2 ; USEPA (=EPA): 162-4; Deviation not specified
<b>GLP/GEP:</b>	yes

<b>Report:</b>	[REDACTED]; 1998;M-183086-01
<b>Title:</b>	Calculation of half-life times in two aerobic water/sediment systems Code: AE F11008
<b>Report No:</b>	C901645
<b>Document No:</b>	M-183086-01-1
<b>Guidelines:</b>	Deviation not specified
<b>GLP/GEP:</b>	no

An additional study has been performed for iodosulfuron-methyl and is submitted within this supplemental dossier for the iodosulfuron-methyl Annex I Renewal using another radiolabel position, [phenyl-UL-<sup>14</sup>C].

<b>Report:</b>	[REDACTED]; 2012;M-429594-01
<b>Title:</b>	[Phenyl-UL- <sup>14</sup> C]Iodosulfuron-methyl sodium: Aerobic aquatic metabolism
<b>Report No:</b>	MEIM030
<b>Document No:</b>	M-429594-01-1
<b>Guidelines:</b>	USEPA OPPTS Guideline No. 835.4300 Canada PMRA DACO Number 8.2.3.5.6 OECD Guideline for Testing of Chemicals, Guideline 308;not specified
<b>GLP/GEP:</b>	yes



Executive Summary

The aerobic aquatic metabolism of [phenyl-UL-14C]iodosulfuron-methyl sodium was investigated in a pond water-sediment system from [redacted], North Carolina, USA, at 20 ± 2 °C in the dark for 100 days.

The total recovery of radioactivity in the individual test vessels ranged from 95.4% of AR to 102.9% (mean: 100.0%; SD: 2.5%) and therefore, a full material balance was established for all samples.

The radioactivity in the water layer decreased from 93.2% of applied radioactivity (AR) at day 0 to 68.1 % AR at study termination (day 100). Extractable 14C sediment residues increased from 2.0% AR at day 0 to 19.6% AR at day 46 and declined slightly to 17.2% towards study termination. The maximum of non-extractable 14C residues (mean values of duplicates) in the sediment was 13.7% at day 79. At termination of the study, 14CO2 accounted for 3.1% AR (mean value of duplicates). The formation of other volatile components was insignificant (0.1% AR in all samples).

In the water phase, the amount of Iodosulfuron-methyl decreased from 93.2% AR at DAT-0 to 8.3% at DAT-100. In the sediment phase the amount of Iodosulfuron-methyl increased from 2.9% AR at DAT-0 to a maximum amount of 8.7% AR at DAT-46 and declined then to 7.8% AR towards study termination. In the entire systems, Iodosulfuron-methyl decreased from 95.2% AR at DAT-0 to 12% AR at DAT-100.

In total, six major metabolites were detected: AE F075736, AE F145740, AE F145741, AE 0014966, AE F159737 and AE 1234964 with the following maximum amounts detected in the water phase, the sediment and the entire system, respectively: AE F075736 with up to 0.5, 3.0 and 22.2% AR, AE F145740 with up to 9.1, 3.3 and 12.6% AR, AE F145741 with up to 7.0, 1.9 and 8.7% AR, AE 0014966 with up to 1.8, 3.3 and 13.7% AR, AE F159737 with up to 6.4, 1.7 and 7.8% AR and AE 1234964 with up to 0.8, 0.6 and 7.4% AR. In addition, some minor metabolites did not exceed the trigger values for identification.

The dissipation half-lives of Iodosulfuron-methyl sodium from water and entire system could be best described with simple first order kinetic model and were estimated to be 29.0 and 34.6 days, respectively. The corresponding DT50 values are 96.2 and 115 days.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test Item

[phenyl-UL-14C]Iodosulfuron-methyl-sodium
Sample ID: C-1149
Specific Activity: 6.751 µCi/µMol (266500 dpm/µg)
Radiochemical Purity: 100%
Chemical Purity: not reported

2. Test System

The study was carried out using one water/sediment system originating from a pond in an agricultural area in [redacted] (Wayne County), North Carolina, USA. Water and sediment were collected from the





same area. Water and sediment were collected from the top 0 to 6 inches (0 -15.2 cm) and from 2 - 4 inches (5.1-10.2 cm) depth, respectively, and stored refrigerated (sediment stored with a water layer on top) for less than 15 days. Before set-up of samples, the wet sediment was passed through a 2 mm sieve. The characteristics of the sediment and the associated water layer are summarised in [Table CA 7.2.2.3-1](#) and [Table CA 7.2.2.3-2](#).

**Table CA 7.2.2.3-1: Physico-chemical characteristics of sediment**

Properties of Sediment			
Parameter			
Geographic Location	[REDACTED] (Wayne County) North Carolina USA		
Soil Taxonomic Classification (USDA)	Silt Loam		
Sand (2000 – 50 µm) [%]	28.9		
Silt (< 50 – 2 µm) [%]	71.0		
Clay (< µm) [%]	0.1		
pH	5.4 (CaCl <sub>2</sub> ), 5.5 (H <sub>2</sub> O)		
Organic Matter [%]	0.76		
Organic Carbon [%] <sup>1</sup>	0.44		
Microbial Count	Actinomycetes	Fungi	Bacteria
	(CFU/g dry wt)		
Post Handling	2600	116	73700
Start of the Test	8700	35	70100
Cation Exchange Capacity [meq/100 g]	9.9		
Moisture Capacity at 0.33 bar	9.7		
Moisture Capacity at 15 bar	1.3		
Bulk density [g/cm <sup>3</sup> ]	1.46		

<sup>1</sup>calculated by OM% /1.724

**Table CA 7.2.2.3-2: Physico-chemical characteristics of water**

Properties of Waters	
Parameter	
pH	7.1
Hardness in mg equivalent CaCO <sub>3</sub> /L	19
Oxygen Concentration [mg/L]	6.3 (initial), 7.1 (final)
Dissolved Organic Carbon [ppm]	8.2
Total Organic Carbon [ppm]	10.3 (start), 50.4 (end)
Electrical conductivity [µmhos/cm]	0.17
Redox Potential E <sub>h</sub> [mV]	398.8 (initial), 485.3 (final)

**B. STUDY DESIGN**

**1. Experimental conditions**

The test system consisted of sediment and overlying pond water prepared in 500-mL glass flasks that were 21 cm tall with a 7.2 cm internal diameter. Each flask contained 115 g sediment (dry weight) and 345 mL pond water corresponding to a target ratio of sediment to water of 1:3 (v/v). Prior to treatment



of the test systems, a preincubation period of 9 days was used to establish aerobic conditions.

Duplicate replicates per interval were prepared.

Test systems were continuously flushed with humidified air (flow-through system). The air exiting each flask then passed sequentially through an ethylene glycol trap used for trapping organic volatiles followed by two 2 M KOH traps used for trapping of  $^{14}\text{CO}_2$  and one 1M sulphuric acid trap for trapping any amines.

The nominal application rate of 17.55  $\mu\text{g}/\text{batch}$  corresponds to about 50.9  $\mu\text{g}/\text{L}$  water and the 50-fold amount calculated based on the maximum field application rate of 10 g/ha. The 50-fold amount was used to obtain sufficient analytical sensitivity. Each sample was dosed by applying an aqueous solution of [phenyl-UL- $^{14}\text{C}$ ]Iodosulfuron-methyl sodium uniformly to the surface of the water using a syringe to mimic the introduction of the active ingredient to a pond via direct overspray.

Untreated test systems were used as controls for determining biomass at the beginning and end of the study. In addition, test systems applied with the 5-fold application rate were incubated as metabolite identification samples (MID).

The treated samples were then transferred into the incubation chamber and attached to the flow-through system. The test systems were maintained in the dark in an environmental chamber at  $20 \pm 2^\circ\text{C}$  (mean daily temperature) under an aeration atmosphere for the duration of the study. The test systems were wrapped in foil to prevent any light exposure.

## 2. Sampling

Test systems were sampled at ten intervals over period of 100 days at 0, 3, 4, 7, 14, 30, 46, 60, 79, and 100 days post-treatment. Except for day 0, ethylene glycol traps, potassium hydroxide traps and sulphuric acid traps were analyzed at each interval. The water was separated from the sediment by decanting and centrifuging.

## 3. Analytical procedures

At each sampling interval, the pH and dissolved oxygen content were measured in the water phase. In addition, the redox potential was determined in the water phase and the sediment. Water and sediment were separated by decantation which was followed by the extraction of the sediment at the same day. Sediment was extracted exhaustively with aqueous acetonitrile under ambient and aggravated conditions (3 x 100 mL acetonitrile/water (4/1, v/v) extractions at ambient temperature and 1 x 80 mL acetonitrile/water (4/1, v/v) at  $70^\circ\text{C}$  in microwave). Water samples were analysed by LSC and, after a concentration step, by reversed phase HPLC. The ambient sediment extracts were combined and analysed for radioactivity by LSC. After a concentration step, aliquots were subjected to HPLC analysis. The extract from microwave-accelerated extraction was analyzed by LSC only. For three sampling intervals (day 60, 79 and 100) aliquots of the ambient and aggressive soil extracts were combined, concentrated and analyzed by HPLC, too.

Extracted sediment was air-dried prior to homogenization and quantification of radioactivity via combustion and LSC. The amount of radioactivity in the volatile traps was determined by liquid scintillation counting (LSC) of triplicate aliquots.

Chromatographic investigations were performed by reversed phase HPLC with <sup>14</sup>C-flow-through detection as the primary analytical method for quantification. Non-radiolabelled reference compounds were detected using the HPLC UV-detector. Identification of transformation products was carried out by co-elution with authentic reference material and/or mass spectrometry (LC-MS). The identity of the <sup>14</sup>C-test material was also confirmed by HPLC co-chromatography and LC-MS.

The LOQ for the HPLC method with radiodetection was less than 0.7% of the applied radioactivity while the corresponding LOD was 0.5 to 0.7% of the applied radioactivity.

**C. Determination of degradation kinetics**

Dissipation rates from the water phase and rates of degradation for the total system were calculated using the software KinGUI, version 1.1. The kinetic evaluation included the fitting of the kinetic models SFO, FOMC and DFOP to the experimental data and their assessment by visual inspection and an error criterion based on a chi-square ( $\chi^2$ ) significance test. In addition to these, a coefficient of determination ( $r^2$ ) was also used as a secondary measure of goodness of fit. Only parent iodosulfuron-methyl-sodium was considered in the kinetic modelling analysis. The total radioactivity from the day 0 interval was used as the day 0 value for both, the water phase and the entire systems. All data points were weighed equally. The initial values of iodosulfuron-methyl-sodium and the dissipation rate constants were estimated.

**II. Results and Discussion**

**A. Findings**

Results indicated that the anticipated standardized aerobic conditions were maintained and that the soils were microbially active over the duration of the laboratory study. The measured amounts of dissolved oxygen, pH values and redox potentials are presented in [Table CA 7.2.2.3-3](#).

**Table CA 7.2.2.3-3: Dissolved oxygen, pH and redox (E<sub>h</sub>) measurements of the aerobic test systems throughout the study period.**

Sampling interval (day)	Water			Sediment
	Dissolved Oxygen (mg/L)	pH	Redox (E <sub>h</sub> ) (mV)	Redox (E <sub>h</sub> ) (mV)
0	6.3		398.8	263.8
2	5.4	6.3	404.6	440.3
4	5.8	6.0	421.4	421.3
7	5.0	6.0	422.4	335.9
14	3.7	5.5	407.9	433.5
30	5	5.0	436.0	348.3
46	6.0	5.2	424.6	527.0
50	8.0	5.5	431.1	443.5
79	7.1	5.3	456.7	508.8
100	7.1	5.1	485.3	463.8

E<sub>h</sub>= Redox potential referred to the hydrogen scale

**A. Data**

A summary of key data on total recovery and the distribution of radioactivity into the various components formed in water and sediment is given in [Table CA 7.2.2.3-4](#).



Table CA 7.2.2.3-4: Biotransformation of [phenyl-UL-<sup>14</sup>C]Iodosulfuron-methyl sodium in water/sediment system

Component/Matrix		Repl. No.	Sampling interval (day)									
			0	2	4	7	14	30	46	60	79	100
Iodosulfuron-methyl	Water Layer	1	93.4	94.3	89.4	84.1	74.9	56.9	30.8	20.0	12.4	7.2
		2	93.1	93.9	91.4	81.7	74.8	51.8	32.2	19.6	10.2	5.3
		Mean	93.2	94.1	90.4	82.9	74.9	54.3	31.7	19.8	11.3	6.3
	Sediment	1	1.8	5.2	7.0	7.5	6.5	5.6	8.9	6.5	4.0	3.3
		2	2.2	4.7	5.5	9.2	6.0	6.2	8.4	5.9	5.9	4.4
		Mean	2.0	5.0	6.3	8.4	6.3	5.9	8.7	6.2	5.0	3.8
	Entire System	1	95.2	99.5	96.4	91.6	81.4	62.4	39.7	26.4	16.4	10.5
		2	95.3	98.6	96.9	90.9	80.9	58.0	41.1	25.4	16.1	13.6
		Mean	95.2	99.1	96.7	91.3	81.1	60.2	40.4	25.9	16.3	12.1
Unknown	Water Layer	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Sediment	1	0.0	0.1	0.0	0.0	0.0	0.9	0.0	0.0	0.0	0.0
		2	0.0	0.0	0.0	0.0	0.0	1.4	0.0	0.0	0.0	0.0
		Mean	0.0	0.0	0.0	0.0	0.0	0.9	0.1	0.0	0.0	0.0
	Entire System	1	0.0	0.1	0.0	0.0	0.0	0.9	0.0	0.0	0.0	0.0
		2	0.0	0.0	0.0	0.0	0.0	1.7	0.0	0.0	0.0	0.0
		Mean	0.0	0.1	0.0	0.0	0.0	0.9	0.0	0.0	0.0	0.0
AE F075736	Water Layer	1	0.0	0.4	0.8	0.0	0.0	0.0	11.3	17.7	20.3	16.0
		2	0.0	0.0	2.3	4.2	8.2	14.5	13.6	18.5	18.8	15.9
		Mean	0.0	0.7	2.6	3.6	6.6	12.5	12.5	18.1	19.5	16.0
	Sediment	1	0.0	0.2	0.0	0.8	0.7	0.8	2.2	2.0	2.4	2.7
		2	0.0	0.3	0.5	0.9	0.9	0.8	2.2	3.0	3.0	2.6
		Mean	0.0	0.2	0.5	0.9	0.8	0.8	2.2	3.0	2.7	2.7
	Entire System	1	0.0	1.6	3.4	3.8	5.6	10.8	13.5	20.7	22.7	18.7
		2	0.0	0.7	2.8	5.1	9.1	15.3	15.8	21.5	21.7	18.5
		Mean	0.0	0.9	2.1	4.5	7.4	13.1	14.7	21.1	22.2	18.6
Unknown	Water Layer	1	0.0	0.0	0.0	0.0	0.0	0.0	3.5	0.0	0.0	0.0
		2	0.0	0.0	0.0	0.0	0.0	0.0	1.8	2.7	0.0	0.0
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	2.6	1.4	0.0	0.0
	Sediment	1	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.3	0.0	0.0
		2	0.0	0.0	0.0	0.0	0.0	0.0	0.8	0.5	0.0	0.0
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	0.7	0.4	0.0	0.0
	Entire System	1	0.0	0.0	0.0	0.0	0.0	0.0	4.1	0.3	0.0	0.0
		2	0.0	0.0	0.0	0.0	0.0	0.0	2.5	3.2	0.0	0.0
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	3.3	1.7	0.0	0.0
AE F145741	Water Layer	1	0.0	0.0	0.0	0.9	2.7	5.1	6.9	6.7	3.5	4.3
		2	0.0	0.0	0.0	4.4	1.8	3.3	7.2	5.0	5.6	5.5
		Mean	0.0	0.0	0.0	1.2	2.3	4.2	7.0	5.9	4.6	4.9
	Sediment	1	0.0	0.1	0.5	0.0	0.3	0.6	1.8	1.7	1.5	1.8
		2	0.0	0.0	0.0	0.0	0.2	0.6	1.5	1.4	2.3	2.0
		Mean	0.0	0.0	0.0	0.0	0.3	0.6	1.7	1.5	1.9	1.9
	Entire System	1	0.0	0.9	0.5	0.9	3.0	5.8	8.6	8.4	5.0	6.0
		2	0.0	0.2	0.5	1.4	2.0	4.0	8.8	6.3	7.9	7.5
		Mean	0.0	0.5	0.5	1.2	2.5	4.9	8.7	7.4	6.5	6.8

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Table CA 7.2.2.3-4 (continued)

Component/Matrix		Repl. No.	Sampling interval (day)									
			0	2	4	7	14	30	46	60	79	100
AE F145740	Water Layer	1	0.0	0.0	0.0	1.2	3.8	7.6	8.6	9.5	9.1	7.4
		2	0.0	0.0	0.0	1.1	3.0	8.0	8.6	8.7	9.2	7.7
		Mean	0.0	0.0	0.0	1.1	3.4	7.8	8.6	9.1	9.1	7.5
	Sediment	1	0.0	0.0	0.0	1.1	1.8	2.0	3.4	3.7	2.9	2.9
		2	0.0	0.0	0.0	1.2	1.9	2.0	3.4	3.3	4.1	3.5
		Mean	0.0	0.0	0.0	1.1	1.8	2.0	3.4	3.3	3.5	3.2
	Entire System	1	0.0	0.0	0.0	2.2	5.6	9.0	12.0	12.0	10.0	10.2
		2	0.0	0.0	0.0	2.3	4.9	8.0	12.1	12.0	13.2	11.2
		Mean	0.0	0.0	0.0	2.3	5.2	8.5	12.0	12.0	12.6	10.7
Unknown	Water Layer	1	0.0	0.0	0.0	0.0	0.0	0.0	1.1	0.0	0.0	0.0
		2	0.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	0.8	0.2	0.0	0.0
	Sediment	1	0.0	0.0	0.0	0.0	0.2	0.5	0.2	0.1	0.0	0.0
		2	0.0	0.0	0.0	0.0	0.3	0.5	0.1	0.0	0.0	0.0
		Mean	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.0	0.0
	Entire System	1	0.0	0.0	0.0	0.2	0.5	1.4	0.5	0.0	0.0	0.0
		2	0.0	0.0	0.0	0.0	0.3	0.5	0.6	0.1	0.0	0.0
		Mean	0.0	0.0	0.0	0.0	0.3	0.4	1.0	0.0	0.0	0.0
Unknown	Water Layer	1	0.0	0.0	0.0	0.0	0.0	0.0	3.8	3.5	2.2	3.5
		2	0.0	0.0	0.0	0.0	0.0	0.0	2.4	3.3	3.4	1.1
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	2.6	2.9	2.8	2.3
	Sediment	1	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.3	0.0	0.4
		2	0.0	0.0	0.0	0.0	0.0	0.4	0.3	0.3	0.0	0.3
		Mean	0.0	0.0	0.0	0.0	0.0	0.4	0.3	0.3	0.0	0.3
	Entire System	1	0.0	0.0	0.0	0.0	0.0	0.5	3.2	2.8	2.2	3.9
		2	0.0	0.0	0.0	0.0	0.0	0.4	2.9	3.6	3.4	1.4
		Mean	0.0	0.0	0.0	0.0	0.0	0.4	2.9	3.2	2.8	2.7
AE 0031850	Water Layer	1	0.0	0.0	0.0	0.0	0.0	0.0	3.6	4.0	5.6	5.9
		2	0.0	0.0	0.0	0.0	0.0	0.0	3.4	4.5	5.0	3.0
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	3.5	4.2	5.3	4.5
	Sediment	1	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.8	0.0	0.9
		2	0.0	0.0	0.0	0.0	0.0	0.0	0.2	0.6	0.0	1.4
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	0.3	0.7	0.0	1.1
	Entire System	1	0.0	0.0	0.0	0.0	0.0	0.0	3.9	4.8	5.6	6.9
		2	0.0	0.0	0.0	0.0	0.0	0.0	3.6	5.1	5.0	4.4
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	3.8	4.9	5.3	5.6
AE 0014666	Water Layer	1	0.0	0.0	0.0	0.0	1.1	3.0	5.1	7.9	9.8	8.5
		2	0.0	0.0	0.0	0.0	0.9	4.7	5.6	5.6	9.6	15.0
		Mean	0.0	0.0	0.0	0.0	1.0	3.8	5.3	6.7	9.7	11.8
	Sediment	1	0.0	0.0	0.1	0.4	0.9	0.9	1.6	1.8	3.6	2.0
		2	0.0	0.0	0.2	0.4	0.9	1.0	0.7	1.9	2.9	1.8
		Mean	0.0	0.0	0.1	0.4	0.9	0.9	1.2	1.8	3.3	1.9
	Entire System	1	0.0	0.0	0.1	0.4	1.9	3.9	6.6	9.7	13.3	10.5
		2	0.0	0.0	0.2	0.4	1.8	5.6	6.3	7.4	12.6	16.9
		Mean	0.0	0.0	0.2	0.4	1.9	4.8	6.5	8.6	12.9	13.7
AE F169737	Water Layer	1	0.0	0.0	0.0	0.0	0.0	0.0	1.5	2.8	3.9	6.2
		2	0.0	0.0	0.0	0.0	0.0	0.0	1.1	2.7	4.5	6.0
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	1.3	2.7	4.2	6.1
	Sediment	1	0.0	0.0	0.0	0.0	0.0	0.0	0.4	1.0	1.4	2.3
		2	0.0	0.0	0.0	0.0	0.0	0.0	0.5	1.3	1.3	1.0
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	0.5	1.2	1.4	1.7
	Entire System	1	0.0	0.0	0.0	0.0	0.0	0.0	1.9	3.8	5.3	8.6
		2	0.0	0.0	0.0	0.0	0.0	0.0	1.7	4.0	5.8	7.0
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	1.8	3.9	5.5	7.8

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Table CA 7.2.2.3-4 (continued)

Component/Matrix		Repl. No.	Sampling interval (day)										
			0	2	4	7	14	30	46	60	79	200	
AE 1234964	Water Layer	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.3	1.7	7.0
		2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.6	2.3	6.8
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.4	2.0	6.8
	Sediment	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4
		2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.8
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.6
	Entire System	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4
		2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.6	2.3	7.4
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.5	1.4	2.0	7.4
Unidentified Radioactivity	Water Layer	1	0.0	0.0	0.0	0.0	0.0	0.0	7.4	2.0	2.2	3.3	
		2	0.0	0.0	0.0	0.0	0.0	0.0	4.7	0.0	0.4	1.1	
		Mean	0.0	0.0	0.0	0.0	0.0	0.0	6.1	4.5	2.8	2.3	
	Sediment	1	0.0	0.1	0.0	0.0	0.2	1.8	1.2	0.6	0.0	0.0	
		2	0.0	0.0	0.0	0.0	0.3	1.9	1.4	0.0	0.0	0.4	
		Mean	0.0	0.0	0.0	0.0	0.3	1.9	1.4	0.8	0.0	0.3	
	Entire System	1	0.0	0.0	0.0	0.2	1.8	3.6	3.6	2.2	3.9		
		2	0.0	0.0	0.0	0.0	0.3	1.9	6.0	6.9	3.4	1.4	
		Mean	0.0	0.1	0.0	0.0	0.3	1.9	7.7	5.9	2.9	2.7	
Total Extractable Radioactivity	Water Layer	1	93.2	96.4	92.3	89.1	88.7	87.6	74.2	71.8	68.5	66.0	
		2	93.1	95.7	92.5	88.5	88.8	82.4	66.9	72.1	68.4	70.2	
		Mean	93.2	95.2	93.0	88.8	88.1	82.5	76.1	72.4	68.5	68.1	
	Sediment	1	1.8	5.9	8.6	10.5	11.6	14.6	19.8	19.2	15.8	16.7	
		2	2.3	5.5	7.7	12.5	11.6	14.8	19.4	18.1	19.4	17.6	
		Mean	2.0	5.8	8.2	11.5	11.6	14.6	19.6	18.6	17.6	17.2	
	Entire System	1	93.2	102.4	100.9	99.6	99.0	97.0	94.9	91.9	84.3	82.8	
		2	95.3	99.3	100.8	101.0	100.4	97.0	96.3	90.2	87.9	87.8	
		Mean	95.0	100.8	100.8	100.3	99.7	97.1	95.6	91.1	86.1	85.3	
CO <sub>2</sub>	1	0.0	0.1	0.1	0.1	0.2	0.7	0.5	2.2	2.9	3.5		
	2	0.0	0.1	0.0	0.1	0.2	0.0	0.7	1.7	1.8	2.8		
	Mean	0.0	0.1	0.1	0.1	0.2	0.4	0.6	1.9	2.4	3.1		
Volatile Organics	1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
	2	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
	Mean	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0		
Total Volatiles	1	0.0	0.2	0.1	0.1	0.2	0.7	0.5	2.2	2.9	3.5		
	2	0.0	0.1	0.0	0.1	0.2	0.0	0.7	1.7	1.8	2.8		
	Mean	0.0	0.1	0.1	0.1	0.2	0.4	0.6	1.9	2.4	3.1		
Bound Residues	1	1.4	0.2	0.3	0.8	0.8	2.1	4.1	8.9	14.0	7.0		
	2	0.1	0.1	0.2	0.9	0.8	1.9	3.8	1.09	13.5	6.9		
	Mean	0.8	0.2	0.3	0.9	0.8	2.0	3.9	9.9	13.7	7.0		
Total % Recovery	1	95.6	102.7	101.3	100.5	100.0	99.7	99.5	103.0	101.2	93.2		
	2	95.4	99.6	101.0	102.1	101.4	99.1	100.8	102.8	103.2	97.5		
	Mean	96.0	101.2	101.2	101.3	100.7	99.4	100.2	102.9	102.2	95.4		

Entire system = water + sediment

**B. Material balance**

The total recovery of radioactivity in the individual test vessels ranged from 95.4% to 102.9% AR (mean: 100.0%, SD: 2.5%). The balances of radioactivity were therefore in an acceptable range for all sampling intervals indicating that no significant losses of radioactivity during incubation and processing of samples occurred.



**C. Residues in water, bound and extractable residues in sediment:**

The radioactivity in the water layer decreased from 93.2% AR at day 0 to 68.1% AR at study termination (day 100). Extractable <sup>14</sup>C sediment residues increased from 2.0% AR at day 0 to 19.6% AR at day 46 and declined slightly to 17.2% towards study termination. The maximum of non-extractable <sup>14</sup>C residues (mean values of duplicates) in the sediment was 13.7% at day 79.

In the water phase, the amount of iodosulfuron-methyl decreased from 93.2% AR at day 0 to 8.3% at day 100. In the sediment phase the amount of iodosulfuron-methyl increased from 2.0% AR at day 0 to a maximum amount of 8.7% AR at day 46 and declined then to 3.8% AR towards study termination. In the entire systems, iodosulfuron-methyl decreased from 95.2% AR at day 0 to 12% AR at day 100.

**D. Volatilisation**

At termination of the study, <sup>14</sup>CO<sub>2</sub> accounted for 30% AR (mean value of duplicates). The formation of other volatile components was insignificant by accounting for ≤ 0.1% AR at all sampling intervals.

**E. Transformation of parent compound**

In total, seven metabolites were detected at identification level, AE F075736, AE F045740, AE F145741, AE 0014966, AE F159737, AE 1234964, and AE 0031850.

The test item underwent a cleavage of the ether bond resulting in formation of the AE F145741 (maximum: 8.7% on day 46). The hydrolysis of the methyl ester of the test item resulted in the formation of AE F145740 (maximum: 12.6% on day 60 and 79). Rapid hydrolysis of the methyl ester and the sulfonylurea moiety led to AE 0031850 (maximum: 5.6% on day 100 in total system). In the individual compartment sediment AE 0031850 in amounts up to 1.1% of AR. In water AE 0031850 occurred once on amounts of 3.3% of AR.

The loss of iodine was a rapid process, resulting in AE F075736 detected as the predominant metabolite reaching its peak at 22.2% on day 79. The cleavage of the methyl ester in AE F075736 resulted in the formation of the free acid, AE 0014966 (maximum: 13.7% on day 100). The further hydrolysis of the less stable urea bridge was observed with the formation of AE 1234964 (maximum: 7.4% on day 100) and AE F159737 (maximum: 7.5% on day 100).

The maximum amounts of degradates found in the water and sediment layer as well as in the entire system are summarized in [Table CA 7.2.2.35](#).

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Table CA 7.2.2.3-5: Major metabolites of [phenyl-UL-14C]Iodosulfuron-methyl sodium formed under conditions of water/sediment testing; maximum values

Component	Maximum occurrence (% AR)			Day (maximum in total system)
	Water	Sediment	Total	
AE F075736	19.5	3.0	22.2	79
AE F145741	7.0	1.9	8.9	46
AE F145740	9.1	3.5	12.6	66 and 79
AE 0014966	11.8	3.3	15.1	100
AE F159737	6.1	1.7	7.8	100
AE 1234964	6.8	0.6	7.4	100

In addition, some minor metabolites were detected which did not exceed the trigger value for identification either in the water phase or in the total system.

F. Degradation kinetics

The evaluation of degradation kinetics in the water phase and the total water/sediment systems was performed using the software KinGUI (version 1.1). The results of the kinetic evaluation are provided in Table CA 7.2.2.3-6.

The degradation of Iodosulfuron-methyl sodium in the water phase and in the total water/sediment system could be best described using the single first order kinetic model. The dissipation half-life from water was estimated to 29.0 days with a corresponding DT90 value of 96.2 days. For the degradation in the total system a half-life of 34.6 days was estimated with a corresponding DT90 value of 115 days.

Table CA 7.2.2.3-6: Best-fit kinetics for the dissipation of [phenyl-UL-14C]Iodosulfuron-methyl sodium from water and degradation in total water/sediment systems after incubation at 20°C

System	Matrix	Kinetic model	DT50 (days)	DT90 (days)	Chi² Err (%)
[redacted]	Water phase	<b>SFO</b>	<b>29.0</b>	<b>96.2</b>	<b>4.3</b>
		FOMC	28.8	96.9	4.7
		DFOP	29.0	96.2	4.8
	Total system	<b>SFO</b>	<b>34.6</b>	<b>115</b>	<b>4.3</b>
		FOMC	34.5	116	4.6
		DFOP	34.6	115	4.8

Best fits according to the criteria set are marked bold.

III. Conclusions

Once applied to water surfaces Iodosulfuron-methyl sodium is eliminated from the water phase via sorption processes to the sediment as well as by degradation to result in the formation of the major metabolites AE F075736, AE 0014966 and AE F145740, AE F145741, AE F159737, and AE 1234964.





The dissipation half-life from water was estimated to be 29.0 days with a corresponding DT<sub>90</sub> value of 96.2 days. For the degradation in total systems a half-life of 34.6 days was estimated with a corresponding DT<sub>90</sub> value of 115 days.

A new kinetic evaluation of the new and formerly performed studies has been done according to FOCUS (2006).

<b>Report:</b>	[REDACTED]; 2014; M-474907-01
<b>Title:</b>	Iodosulfuron-methyl-sodium (IMS) and metabolites: Kinetic evaluation of aerobic aquatic metabolism in water-sediment systems according to FOCUS kinetics
<b>Report No:</b>	ENSA-13-0306
<b>Document No:</b>	M-474907-01-1
<b>Guidelines:</b>	not applicable
<b>GLP/GEP:</b>	no

**Executive Summary**

A kinetic analysis of residue data from the two aerobic water/sediment degradation studies KCA 7.2.2.3 /01 (M-147858-01-1) and KCA 7.2.2.3 /03 (M-429594-01-1) was performed with the software KinGUI 2 according to FOCUS kinetics (2006) to derive half-lives for iodosulfuron-methyl sodium and its degradation products metsulfuron-methyl (AE F075736), AE 0000119, AE F059411, AE 0014966, AE 0034855, AE F145740, AE F145741, AE F150737, and AE 1234964, which are suitable for modelling purpose.

Single first order was the most appropriate kinetic model for modelling purpose for the degradation of iodosulfuron-methyl-sodium in the water and total system of water/sediment systems [REDACTED], [REDACTED] and [REDACTED] under aerobic conditions in the dark in the laboratory at 20 °C and test concentrations of 50.7 mg/L water for water/sediment systems [REDACTED] and [REDACTED] and 25.0 µg/L water for water sediment system [REDACTED]. For the sediment first order multi compartment was the most appropriate kinetic model for water/sediment systems [REDACTED] and [REDACTED] and single first order for water/sediment system [REDACTED]. The single first order kinetic model was used for modelling purpose to describe the degradation of all degradation products.

The calculated half-life for modelling purpose (geometric mean) for the degradation of iodosulfuron-methyl-sodium in water/sediment systems under aerobic conditions in the dark in the laboratory was 17.9 days in the water, 8.6 days in the sediment and 19.8 days in the total system. The half-life of AE F075736 for modelling purpose (geometric mean) was 63.8 days in the water, 63.1 days in the sediment and 64.1 days in the total system. The half-life of AE F145740 for modelling purpose (geometric mean) was 45.4 days in the total system and could not be determined in water and sediment. The half-life of AE F145741 for modelling purpose (geometric mean) was 73.4 days in the total system and could not be determined in water and sediment. The half-life of AE 0000119 for modelling purpose (geometric mean) was 84.6 days in the water, 28.4 days in the total system and could not be determined in sediment. The half-life of AE F059411 for modelling purpose (geometric mean) was 9.9 days in the total system and could not be determined in water and sediment. The half-life of AE 0014966 for modelling purpose (geometric mean) was 43.9 days in the total system and could not be determined in water and sediment. The half-life of AE 0034855 for modelling purpose



(geometric mean) was 107 days in the sediment and could not be determined in the water and total system. The half-life of AE F150737 and AE 1234964 could not be determined in the water, sediment and total system.

### I. METHODS

Residue data from the two aerobic water/sediment degradation studies KCA 7.2.2.3 /01 (M-147858-01-1) and KCA 7.2.2.3 /03 (M-429594-01-1) were used. In these studies, the degradation of iodosulfuron-methyl sodium was studied in water/sediment systems [redacted], [redacted] and [redacted] under aerobic conditions in the dark in the laboratory for up to 365 days at 20 °C, and test concentrations of 50.7 µg/mL water for water/sediment systems [redacted] and [redacted] and 2.0 µg/L water for water/sediment system [redacted].

The kinetic analysis was performed according to FOCUS Kinetics (2006) using the software KinGUI 2 with four different kinetic models: single first order, first order multi-compartment, hockey-stick (double first order sequential) and double first order in parallel. Model input datasets were the residual amounts found in each replicate test system at each sampling interval. The most appropriate kinetic model for modelling purpose and trigger evaluation was selected on the basis of a detailed statistical analysis including visual assessment of the goodness of the fits, chi<sup>2</sup> scaled-error criterion, t-test significance, correlation analysis and standard deviation. The DT<sub>50</sub> value was calculated from the resulting kinetic parameters. The degradation of degradation products was described with the single first order model for modelling purpose.

### II. RESULTS

Single first order (SFO) was the most appropriate kinetic model for modelling purpose for the degradation of iodosulfuron-methyl-sodium in total system and water in water/sediment systems [redacted], [redacted] and [redacted] and in sediment in water/sediment system [redacted]. For the degradation of iodosulfuron-methyl sodium in sediment of water/sediment systems [redacted] and [redacted] first order multi compartment (FOMC) was the most appropriate kinetic model for modelling purpose. The SFO kinetic model was used for modelling purpose to describe the degradation of AE F075736, AE 0000119, AE F059411, AE 0014966, AE 0024855, AE F145740, AE 145741, AE F150737 and AE 1234964. Tables CA 7.2.2.3.7 to 16 are summarizing the results of the kinetic analysis for modelling purpose.

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Table CA 7.2.2.3-7: Kinetic parameters for the degradation of iodosulfuron-methyl sodium in water/sediment system under aerobic conditions for modelling purpose according to FOCUS

Water/Sediment System	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	Chi <sup>2</sup> Error [%]	t-test	DT <sub>90</sub> [days]
<b>Total System</b>					
	SFO	20.4	3.0	< 0.0001	67.9
	SFO	11.3	6.8	< 0.0001	77.6
	SFO	33.9	4.84	< 0.0001	112
	<b>geomean</b>	<b>19.8</b>			<b>66.0</b>
<b>Water</b>					
	SFO	19.0	2.9	< 0.0001	63
	SFO	40.5	5	< 0.0001	37.8
	SFO	28.4	4.5	< 0.0001	94.4
	<b>geomean</b>	<b>17.9</b>			<b>59.2</b>
<b>Sediment</b>					
	FOMC	20.4	40.1	n.a.	67.8
	FOMC	3.6 <sup>3</sup>	4.5	n.a.	12.0
	SFO	n.d.	15.9	0.0109	n.d.
	<b>geomean</b>	<b>8.6</b>			<b>28.5</b>

n.a.: not applicable for parameters of FOMC model  
n.d.: not determined (visual and/or statistical fit not acceptable)  
<sup>1</sup> SFO: single first order, FOMC: first order multi compartment  
<sup>3</sup> pseudo-SFO DT<sub>50</sub> calculated from DT<sub>90</sub>/3.32

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Table CA 7.2.2.3- 8: Kinetic parameters for the degradation of AE F075736 in water/sediment system under aerobic conditions for modelling purpose according to FOCUS

Water/Sediment System	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	Chi <sup>2</sup> Error [%]	t-test	DT <sub>90</sub> [days]
<b>Total System</b>					
	SFO	68.4	14.7	< 0.0001	227.4
	SFO	39.3	27.1	0.0002	130.4
	SFO	97.8	10.6	< 0.0001	324.9
	<b>geomean</b>	<b>64.1</b>			<b>212.8</b>

<b>Water</b>					
	SFO	169.5	7.1	0.0001	562.9
	SFO	24.0	10.6	0.0021	79.7
	SFO	n.d.			n.d.
	<b>geomean</b>	<b>63.8</b>			<b>211.8</b>

<b>Sediment</b>					
	SFO	134.9	11.2	0.0020	448.8
	SFO	26.5	22.1	0.0021	87.8
	SFO	n.d.			n.d.
	<b>geomean</b>	<b>63.1</b>			<b>209.4</b>

n.d.: data did not allow to determine a reliable value (1-2 measured residues were available)

<sup>1</sup> SFO: single first order

Table CA 7.2.2.3- 9: Kinetic parameters for the degradation of AE F145740 in water/sediment system under aerobic conditions for modelling purpose according to FOCUS

Water/Sediment System	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	Chi <sup>2</sup> Error [%]	t-test	DT <sub>90</sub> [days]
<b>Total System</b>					
	SFO	45.4	10.4	< 0.0001	150.9
	<b>geomean</b>	<b>45.4</b>			<b>150.9</b>

<b>Water</b>					
	SFO	n.d.			n.d. <sup>3</sup>
	<b>geomean</b>	<b>n.d. <sup>3</sup></b>			<b>n.d. <sup>3</sup></b>

<b>Sediment</b>					
	SFO	n.d. <sup>4</sup>			n.d. <sup>4</sup>
	<b>geomean</b>	<b>n.d. <sup>4</sup></b>			<b>n.d. <sup>4</sup></b>

<sup>1</sup> SFO: single first order

<sup>3</sup> not determined (visual and/or statistical fit not acceptable)

<sup>4</sup> data did not allow to determine a reliable value (1-2 measured residues were available)



Table CA 7.2.2.3- 10: Kinetic parameters for the degradation of AE F145741 in water/sediment system under aerobic conditions for modelling purpose according to FOCUS

Water/Sediment System	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	Chi <sup>2</sup> Error [%]	t-test	DT <sub>90</sub> [days]
<b>Total System</b>					
	SFO	73.4	15.5	0.0033	243.7
	<b>geomean</b>	<b>73.4</b>			<b>243.7</b>
<b>Water</b>					
	SFO	n.d. <sup>3</sup>			n.d. <sup>3</sup>
	<b>geomean</b>	<b>n.d. <sup>3</sup></b>			<b>n.d. <sup>3</sup></b>
<b>Sediment</b>					
	SFO	n.d. <sup>3</sup>			n.d. <sup>3</sup>
	<b>geomean</b>	<b>n.d. <sup>3</sup></b>			<b>n.d. <sup>4</sup></b>

<sup>1</sup> SFO: single first order

<sup>3</sup> not determined (visual and/or statistical fit not acceptable)

<sup>4</sup> data did not allow to determine a reliable value (1-2 measured residues were available)

Table CA 7.2.2.3- 11: Kinetic parameters for the degradation of AE 0000119 in water/sediment system under aerobic conditions for modelling purpose according to FOCUS

Water/Sediment System	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	Chi <sup>2</sup> Error [%]	t-test	DT <sub>90</sub> [days]
<b>Total System</b>					
	SFO	27.7	18.0	0.0006	90.2
	SFO	29.8	16.3	< 0.0001	98.9
	<b>geomean</b>	<b>28.4</b>			<b>94.4</b>
<b>Water</b>					
	SFO	n.d. <sup>3</sup>	2.5	0.0004	n.d. <sup>3</sup>
	SFO	84.6	4.0	0.0047	281.0
	<b>geomean</b>	<b>84.6</b>			<b>281.0</b>
<b>Sediment</b>					
	SFO	n.d. <sup>3</sup>			n.d. <sup>4</sup>
	SFO	n.d. <sup>4</sup>			n.d. <sup>4</sup>
	<b>geomean</b>	<b>n.d. <sup>4</sup></b>			<b>n.d. <sup>4</sup></b>

<sup>1</sup> SFO: single first order

<sup>3</sup> not determined (visual and/or statistical fit not acceptable)

<sup>4</sup> data did not allow to determine a reliable value (1-2 measured residues were available)

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Table CA 7.2.2.3- 12: Kinetic parameters for the degradation of AE F059411 in water/sediment system under aerobic conditions for modelling purpose according to FOCUS

Water/Sediment System	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	Chi <sup>2</sup> Error [%]	t-test	DT <sub>90</sub> [days]
<b>Total System</b>					
	SFO	9.9	6.0	< 0.0001	32.8
	SFO	n.d. <sup>4</sup>			n.d. <sup>4</sup>
	<b>geomean</b>	<b>9.9</b>			<b>32.8</b>
<b>Water</b>					
	SFO	n.d. <sup>3</sup>			n.d. <sup>3</sup>
	SFO	n.d. <sup>3</sup>			n.d. <sup>3</sup>
	<b>geomean</b>	<b>n.d. <sup>3</sup></b>			<b>n.d. <sup>3</sup></b>
<b>Sediment</b>					
		n.d. <sup>3</sup>			n.d. <sup>3</sup>
		n.d. <sup>3</sup>			n.d. <sup>3</sup>
	<b>geomean</b>	<b>n.d. <sup>3</sup></b>			<b>n.d. <sup>3</sup></b>

<sup>1</sup> SFO: single first order

<sup>3</sup> data did not allow to determine a reliable value (1-2 measured residues were available)

<sup>4</sup> not determined (visual and/or statistical fit not acceptable)

Table CA 7.2.2.3- 13: Kinetic parameters for the degradation of AE 0014966 in water/sediment system under aerobic conditions for modelling purpose according to FOCUS

Water/Sediment System	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	Chi <sup>2</sup> Error [%]	t-test	DT <sub>90</sub> [days]
<b>Total System</b>					
	SFO	n.d. <sup>3</sup>	57.5	0.0095	n.d. <sup>3</sup>
	SFO	43.9	15.9	0.0059	145.7
	<b>geomean</b>	<b>43.9</b>			<b>145.7</b>
<b>Water</b>					
		n.d. <sup>3</sup>			n.d. <sup>3</sup>
		n.d. <sup>3</sup>			n.d. <sup>3</sup>
	<b>geomean</b>	<b>n.d. <sup>3</sup></b>			<b>n.d. <sup>3</sup></b>
<b>Sediment</b>					
	SFO	n.d. <sup>3</sup>			n.d. <sup>4</sup>
		n.d. <sup>3</sup>			n.d. <sup>3</sup>
	<b>geomean</b>	<b>n.d. <sup>3,4</sup></b>			<b>n.d. <sup>3,4</sup></b>

<sup>1</sup> SFO: single first order

<sup>3</sup> data did not allow to determine a reliable value (1-2 measured residues were available)

<sup>4</sup> not determined (visual and/or statistical fit not acceptable)



Table CA 7.2.2.3- 14: Kinetic parameters for the degradation of AE 0034855 in water/sediment system under aerobic conditions for modelling purpose according to FOCUS

Water/Sediment System	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	Chi <sup>2</sup> Error [%]	t-test	DT <sub>90</sub> [days]
<b>Total System</b>					
	SFO	n.d. <sup>4</sup>			n.d. <sup>4</sup>
	<b>geomean</b>	<b>n.d.</b>			<b>n.d.</b>
<b>Water</b>					
		n.d. <sup>3</sup>			n.d. <sup>3</sup>
	<b>geomean</b>	<b>n.d. <sup>3</sup></b>			<b>n.d.</b>
<b>Sediment</b>					
	SFO	107	77.3	0.0886	355.5
	<b>geomean</b>	<b>107</b>			<b>355.5</b>

<sup>1</sup> SFO: single first order

<sup>3</sup> data did not allow to determine a reliable value (1-2 measured residues were available)

<sup>4</sup> not determined (visual and/or statistical fit not acceptable)

Table CA 7.2.2.3- 15: Kinetic parameters for the degradation of AE F150737 in water/sediment system under aerobic conditions for modelling purpose according to FOCUS

Water/Sediment System	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	Chi <sup>2</sup> Error [%]	t-test	DT <sub>90</sub> [days]
<b>Total System</b>					
	SFO	n.d. <sup>4</sup>			n.d. <sup>4</sup>
	<b>geomean</b>	<b>n.d. <sup>4</sup></b>			<b>n.d. <sup>4</sup></b>
<b>Water</b>					
		n.d. <sup>3</sup>			n.d. <sup>3</sup>
	<b>geomean</b>	<b>n.d. <sup>3</sup></b>			<b>n.d. <sup>3</sup></b>
<b>Sediment</b>					
		n.d. <sup>3</sup>			n.d. <sup>3</sup>
	<b>geomean</b>	<b>n.d.</b>			<b>n.d. <sup>3</sup></b>

<sup>1</sup> SFO: single first order

<sup>3</sup> data did not allow to determine a reliable value (1-2 measured residues were available)

<sup>4</sup> not determined (visual and/or statistical fit not acceptable)

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Table CA 7.2.2.3- 16: Kinetic parameters for the degradation of AE 1234964 in water/sediment system under aerobic conditions for modelling purpose according to FOCUS

Water/Sediment System	Kinetic Model <sup>1</sup>	DT <sub>50</sub> [days]	Chi <sup>2</sup> Error [%]	t-test	DT <sub>90</sub> [days]
<b>Total System</b>					
	SFO	n.d. <sup>4</sup>			n.d. <sup>4</sup>
	geomean	n.d. <sup>4</sup>			n.d. <sup>4</sup>
<b>Water</b>					
		n.d. <sup>3</sup>			n.d. <sup>3</sup>
	geomean	n.d. <sup>3</sup>			n.d. <sup>3</sup>
<b>Sediment</b>					
		n.d. <sup>3</sup>			n.d. <sup>3</sup>
	geomean	n.d. <sup>3</sup>			n.d. <sup>3</sup>

<sup>1</sup> SFO: single first order

<sup>3</sup> data did not allow to determine a reliable value (1-2 measured residues were available)

<sup>4</sup> not determined (visual and/or statistical fit not acceptable)

### III. CONCLUSIONS

The calculated half-life for modelling purpose (geometric mean) for the degradation of Iodosulfuron-methyl-sodium in water/sediment systems under aerobic conditions in the dark in the laboratory was 17.9 days in the water, 8.6 days in the sediment and 10.8 days in the total system. The half-life of AE F075736 for modelling purpose (geometric mean) was 63.8 days in the water, 63.1 days in the sediment and 64.1 days in the total system. The half-life of AE F145740 for modelling purpose (geometric mean) was 45.4 days in the total system and could not be determined in the water and sediment. The half-life of AE F145741 for modelling purpose (geometric mean) was 73.4 days in the total system and could not be determined in the water and sediment. The half-life of AE 0000119 for modelling purpose (geometric mean) was 84.6 days in the water, 284 days in the total system and could not be determined in the sediment. The half-life of AE F059411 for modelling purpose (geometric mean) was 9.9 days in the total system and could not be determined in the water and sediment. The half-life of AE 004966 for modelling purpose (geometric mean) was 43.9 days in the total system and could not be determined in the water and sediment. The half-life of AE 0034855 for modelling purpose (geometric mean) was 107 days in the sediment and could not be determined in the water and total system. The half-life of AE F150737 and AE 1234964 could not be determined in the water, sediment and total system.

#### CA 7.2.2.4 Irradiated water/sediment study

The route and rate of degradation of Iodosulfuron-methyl-sodium in water and sediment were comprehensively studied in sections CA 7.2.1.1 to CA 7.2.1.3 and CA 7.2.2.1 to CA 7.2.2.3.

Therefore, the route and rate of degradation of Iodosulfuron-methyl-sodium in irradiated water/sediment systems were not separately studied.





### CA 7.2.3 Degradation in the saturated zone

The degradation of iodosulfuron-methyl-sodium in the saturated zone was not studied since iodosulfuron-methyl-sodium is not expected to reach the saturated zone after its use according to good agricultural practices.

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CA 7.3 Fate and behaviour in air

CA 7.3.1 Route and rate of degradation in air

The degradation rate of iodosulfuron-methyl-sodium in air was evaluated during the Annex I inclusion using the Atkinson method, and was accepted by the European Commission (SANCO/10166/2003-Final, 3 July 2003). The following study is included in the baseline dossier:

Report:	[REDACTED];1998;M-180250-01
Title:	Calculation of the indirect photolysis reaction using the incremental method of Atkinson and the program AOPWIN, Version 1.80, active ingredient AE F 75008
Report No:	C000091
Document No:	M-180250-01-1
Guidelines:	Deviation not specified
GLP/GEP:	no

CA 7.3.2 Transport via air

The transport via air of iodosulfuron-methyl-sodium was not studied since its vapour pressure is far below the trigger value of 10<sup>-5</sup> Pa. Being a salt and ionized in solution under environmental conditions, iodosulfuron-methyl-sodium as well as its biologically active metabolite AE F 75736 have a negligible vapour pressure of approximately 10<sup>-9</sup> Pa and 10<sup>-7</sup> Pa at 20°C, respectively. The components are virtually non-volatile. A transfer into the gas phase leading to atmospheric contamination can therefore be excluded.

CA 7.3.3 Local and global effects

Local and global effects of iodosulfuron-methyl-sodium were not estimated since no significant exposure of iodosulfuron-methyl-sodium is expected.

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CA 7.4 Definition of the residue

CA 7.4.1 Definition of the residue for risk assessment

The residue definitions relevant for risk assessment for each compartment are the following:

Compartment	Residue Definition	Major Metabolite in
Soil, Groundwater	Iodosulfuron-methyl-sodium	
	AE F075736	Aerobic soil, anaerobic Soil
	AE F145741	Aerobic soil, anaerobic Soil
	AE F145740	Aerobic soil, anaerobic soil
	AE F161778	Aerobic soil, anaerobic Soil
	AE 0000119	Aerobic soil
	AE F059411	Aerobic soil, anaerobic Soil
	AE 0002166	Soil photolysis
	BCS-CW81253	Aerobic soil
Surface Water	Iodosulfuron-methyl-sodium	
	AE F075736	Aerobic water/sediment, aerobic soil, anaerobic soil
	AE F145740	Aerobic water/sediment, aerobic soil, anaerobic soil
	AE F145740	Aerobic water/sediment, aerobic soil, anaerobic soil
	AE 0014966	Aerobic water/sediment
	AE 0000119	Aerobic water/sediment, aerobic mineralization in surface water, aerobic soil
	AE F059411	Aerobic water/sediment, aerobic soil, anaerobic soil
	AE F154781	Aerobic mineralization in surface water
	AE F234964	Aerobic water/sediment
	AE F159737	Aerobic water/sediment
	AE 0094855	Aerobic mineralization in surface water
	AE 0002166	Aqueous photolysis, soil photolysis
	BCS-CW81253	Aerobic soil
	AE F161778	Aerobic soil, anaerobic soil
Air	Iodosulfuron-methyl-sodium	

CA 7.4.2 Definition of the residue for monitoring

The residue definition for monitoring is iodosulfuron-methyl and AE F075736 for compartments soil and water and iodosulfuron-methyl only for compartment air.

CA 7.5 Monitoring data

Laboratory, lysimeter, and field data demonstrated the degradability of AE F115008 and its residues in the various compartments of the environment, with no indications for persistence or accumulation.



Under recommended use conditions, no unacceptable leaching of parent compound or of any relevant degradates to groundwater is to be expected.

Therefore monitoring studies under outdoor conditions were considered to be not required. No respective data of third party monitoring activities on Iodosulfuron-methyl-sodium is known to the applicant.

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