



Document Title

Summary of the fate and behaviour in the environment
Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl
OD 42 (2+10+30 g/L)

Data Requirements

EU Regulation 1107/2009 & EU Regulation 284/2013

Document MCB

Section 9: Fate and behaviour in the environment

According to the guidance document, SANCO 10781/2013, for preparing dossiers for the approval of a chemical active substance

Date

2014-06-20

1st update: 2015-02-27

2nd update: 2015-04-23

Author(s)

[Redacted]

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M-489169-03-5

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Version history

| Date | Data points containing amendments or additions ¹ and brief description | Document identifier and version number |
|------------|---|--|
| Feb. 2015 | Document update in response to ANSES request for additional information, received via email Lea RIFFAUT(Anses) to Geraldine Thevenon-Emeric (BCS) of 15 th December 2014 (17:48). Document modifications are marked yellow. | |
| April 2015 | Document update in response to ANSES request for additional information, received via email Lea RIFFAUT (ANSES) to Geraldine Thevenon-Emeric (BCS) of 14 th April 2015 (18:41). Document modifications are marked green. | |
| | | |

¹ 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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Covers the point required in SANCO 10181/2013 format shown below

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In agreement with the Rapporteur Member State, the product dossier is submitted following the dRR format. All points required under the SANCO 10181/2013 are covered, although their naming might differ slightly.

IIIA 9 FATE AND BEHAVIOUR IN THE ENVIRONMENT

This document reviews predicted environmental concentrations for the plant protection product IMS MSM + MPR OD 42 which contains the active substances iodosulfuron-methyl-sodium (IMS) and mesosulfuron-methyl (MSM), and the crop safener mefenpyr-diethyl (MPR).

This product is the representative formulation for the renewal of approval of mesosulfuron-methyl at European level. In its function as Document MCP for the EU review process, the assessment will focus only on the active substance mesosulfuron-methyl. A complete assessment to cover all active substances of the formulation will be provided at a later stage, as part of the post-AIRO process for renewal of authorisations at member state level, once mesosulfuron-methyl is re-approved under Regulation (EU) 1107/2009.

In general, formulants (inactive ingredients) present in a product do not influence to a relevant extent the behaviour of the active substances in the environment. An exemption is for slow release formulations but this is not the case for the present product. Therefore, data derived from tests with the individual active substances are considered representative for the behaviour of these substances in product IMS+MSM+MPR OD 42. Detailed information on these active substance studies is found reported in Document MCA, only brief overview summaries on fundamental results are given in the present document.

Intended application pattern

The formulation is intended for use as a post-emergent herbicide to control weeds in winter and spring cereals. The critical use pattern for this formulation is summarised as follows. A detailed use pattern can be found in Appendix 2 of this document.

Table 9- 1: Intended application pattern for the representative uses of mesosulfuron-methyl in product IMS+MSM+MPR OD 42

| Crop | Timing of application | Number of applications | Application interval [days] | Maximum label rate [L/ha] | Maximum application rate, individual treatment [g a.s./ha] | |
|--------------|--|------------------------|-----------------------------|---------------------------|--|---------------------|
| | | | | | iodosulfuron-methyl-sodium | mesosulfuron-methyl |
| Winter wheat | BBCH 20-32 end of winter, beginning of vegetation | | - | 1.5 | 3 | 15 |
| Winter rye | BBCH 20-32 end of winter, beginning of vegetation | 1 | - | 0.6 | 1.2 | 6 |



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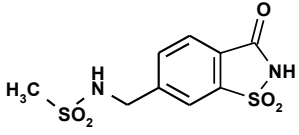
Table 9- 2: Active substance and metabolites addressed in this document: mesosulfuron-methyl

| Compound / Codes | Chemical Structure | Explanation for Consideration | Considered for |
|----------------------------------|--------------------|---|--|
| Mesosulfuron-methyl / AE F130060 | | active substance | PEC _{soil} PEC _{gw} PEC _{sw} & PEC _{sed} |
| AE F154851 | | aerobic soil: >10% anaerobic soil: < 5% soil photolysis: n.d. water/sediment: <5% hydrolysis: <5% aqu. photolysis: n.d. | PEC _{soil} PEC _{gw} PEC _{sw} & PEC _{sed} |
| AE F160459 | | aerobic soil: <5% anaerobic soil: >10% soil photolysis: n.d. water/sediment: >10% hydrolysis: n.d. aqu. photolysis: n.d. | PEC _{soil} PEC _{gw} PEC _{sw} & PEC _{sed} |
| AE F099095 | | aerobic soil: >10% anaerobic soil: <5% soil photolysis: n.d. water/sediment: <5% hydrolysis: n.d. aqu. photolysis: n.d. | PEC _{soil} PEC _{gw} PEC _{sw} & PEC _{sed} |
| AE F092944 | | aerobic soil: >10% anaerobic soil: <5% soil photolysis: n.d. water/sediment: <5% hydrolysis: >10% aqu. photolysis: n.d. | PEC _{soil} PEC _{gw} PEC _{sw} & PEC _{sed} |
| AE F160460 | | aerobic soil: >5% anaerobic soil: >5% soil photolysis: n.d. water/sediment: >5% hydrolysis: n.d. aqu. photolysis: n.d. | PEC _{soil} PEC _{gw} PEC _{sw} & PEC _{sed} |
| AE F140584 | | aerobic soil: >5% anaerobic soil: <5% soil photolysis: n.d. water/sediment: <5% hydrolysis: >10% aqu. photolysis: n.d. | PEC _{soil} PEC _{gw} PEC _{sw} & PEC _{sed} |



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

| Compound / Codes | Chemical Structure | Explanation for Consideration | Considered for |
|------------------|---|---|--|
| AE F147447 |  | <p>aerobic soil: >5% anaerobic soil: >5% soil photolysis: n.d. water/sediment: >10% hydrolysis: >10% aqu. photolysis: n.d.</p> | <p>PEC_{soil} PEC_{gw} PEC_{sw} & PEC_{sd}</p> |

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III A 9.1 Rate of Degradation in Soil

III A 9.1.1 Aerobic degradation of the preparation in soil

Aerobic soil metabolism: In laboratory studies using ^{14}C -radiolabels positioned in the pyrimidyl and phenyl moieties, two initial degradation routes were observed for mesosulfuron-methyl in aerobic soil: Cleavage of the methyl ester at the phenyl ring to result in AE F154851, and ether demethylation at the pyrimidine ring to yield AE F160459. As common successor product of both intermediates, AE F160460 may be formed via metabolic loss of the respective second methyl group. Moreover, breakdown of the molecule backbone occurs via chemically or microbially induced cleavage of the sulfonylurea bridge, which leads to the fragments AE F099095 and AE F092944 derived from the pyrimidine moiety, and AE F140584 and AE F140447 derived from the phenyl moiety. Of all above soil metabolites, however, only AE F154851 (max. 16.2 %), AE F099095 (max. 29.2 %), and AE F092944 (max. 10.1 %) reached major abundances in some, but not all, soils. Terminal bioconversion of the residues led to formation of significant amounts of ^{14}C -carbon dioxide (max. 49 % or 18 % for pyrimidyl- and phenyl-label, respectively) and non-extractable soil-bound residues (max. 64 % or 58 % for pyrimidyl- and phenyl-label, respectively) by the end of the incubation period.

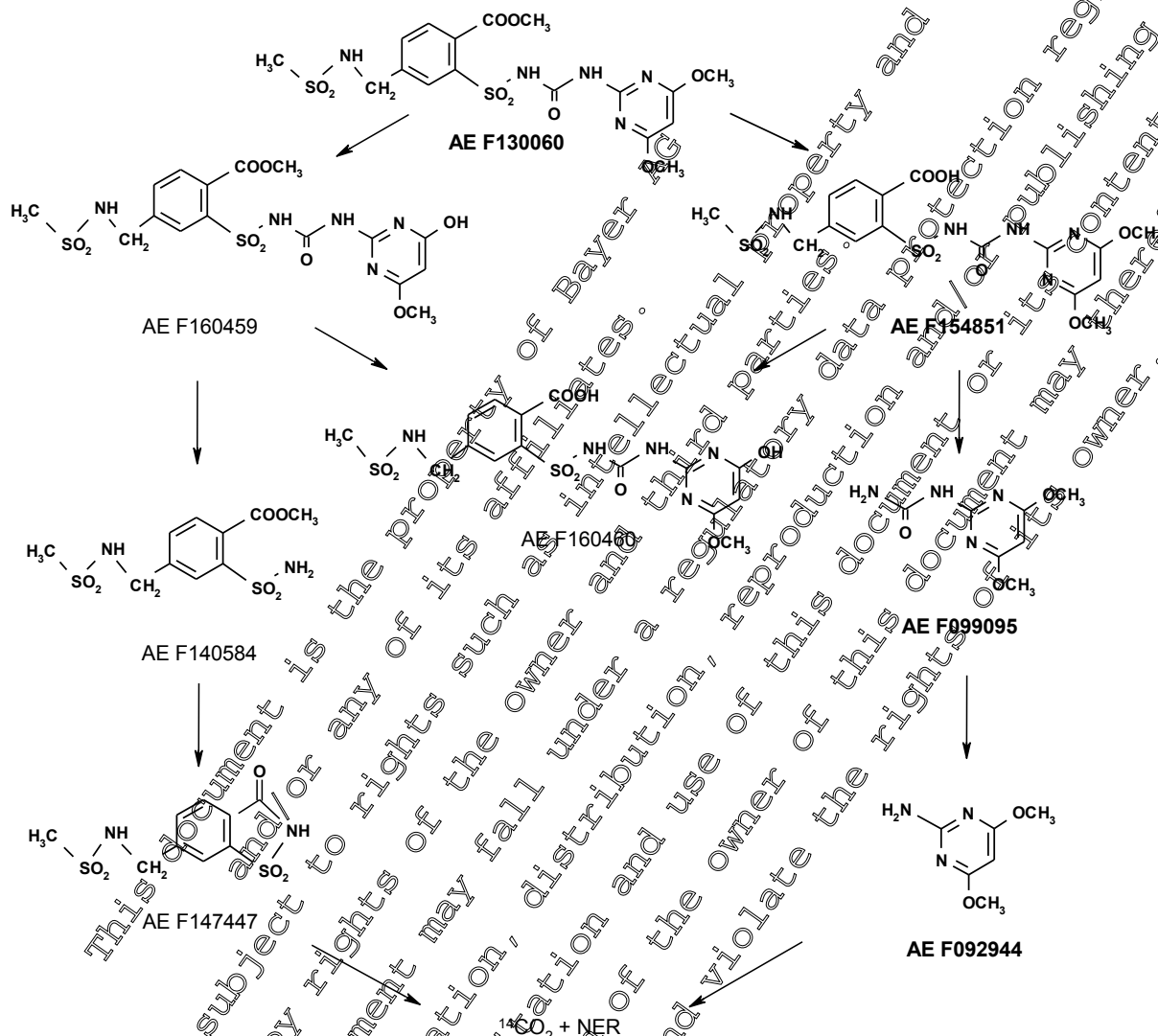
Indirect photolysis on soil surface: Mesosulfuron-methyl is not photodegraded to significant extent at wavelengths >290 nm on soil surfaces. Soil photolysis will therefore not contribute notably to elimination from the terrestrial environment, and will not lead to the generation of relevant degradates.

The proposed biotransformation pathway for mesosulfuron-methyl in aerobic soil is shown in Figure 9.1.1-1. The identical scheme is proposed to apply as well for the degradation of mesosulfuron-methyl in aerobic water/sediment systems.

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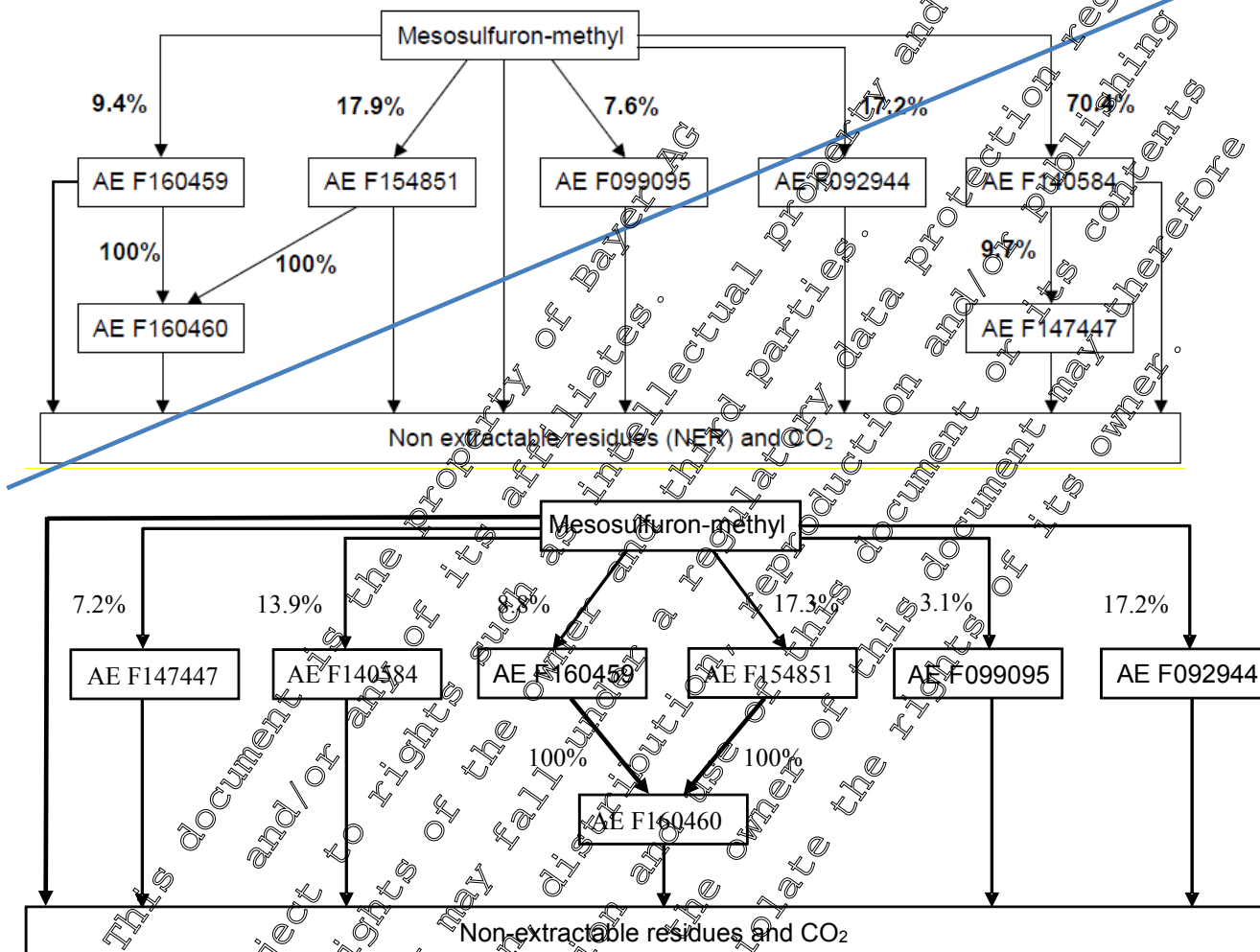
Figure 9.1.1- 1: Proposed transformation scheme for mesosulfuron-methyl in the environment (soil and water/sediment)



To enable a kinetic description suitable for environmental exposure simulation purposes, an optimized compartmental model representation of the transformation scheme was developed, shown in Figure 9.1.1-1. The evaluation was based on experimental data from a total of 11 tests on 8 soils for the parent active substance, and an additional 8 tests on 4 soils dosed directly with two of the metabolites. A numeric summary of the resulting half-life information suitable for exposure simulations of the components relevant for assessment is given in Table 9.1.1-1.

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Figure 9.1.1-2: Compartmental model for evaluation of the degradation of mesosulfuron-methyl in soil under aerobic conditions; the numbers attached to the arrows are the formation fractions for the respective metabolite



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Table 9.1.1-1: Normalised DT50 values for mesosulfuron-methyl and its metabolites in aerobic soil.

Values obtained from the same batches of soil LS2.2 were averaged before calculating mean values.

| Soil | DT50 [days] | | | | | | | | |
|---------------------------|------------------------------------|---------------------|----------------|----------------|----------------|--------------------------|--------------------|----------------|--------------------|
| | Model used for Mesosulfuron-methyl | Mesosulfuron-methyl | AE-F154851 | AE-F160459 | AE-F099095 | AE-F092944 | AE-F140460 | AE-F140524 | AE-F147447 |
| SLI | SFO | 12.2 | 13.8 | 33.9 | 76.1 | 77 | 17.5 | n.d. | n.d. |
| SLV | SFO | 54.3 | 30.1 | n.d. | 1 ² | 1 ² | n.d. | n.d. | n.d. |
| CHL | DFOP | 109.7 ¹⁾ | 1 ² | 1 ² | 1 ² | 29.6 ³⁾ | n.d. | n.d. | n.d. |
| SLS | SFO | 7.7 | 1 ² | 1 ² | 47.7 | 1 ² | 1 ² | n.d. | n.d. |
| SCL | SFO | 2.2 | 1 ² | 1 ² | 14.1 | 1 ² | 1 ² | n.d. | n.d. |
| FF | SFO | 33.4 | 64.3 | 73.8 | 234 | 1 ² | 31.6 | n.d. | n.d. |
| CLF | SFO | 15.4 | 44.8 | 37.3 | 77 | 1 ² | 60.4 | n.d. | n.d. |
| LS 2.2 (pyr. label 20°C) | DFOP | 155.1 | 63.9 | 1 ² | 79.5 | 1 ² | 44.2 ³⁾ | n.d. | n.d. |
| LS 2.2 (pyr. label, 10°C) | SFO | 64.4 | 1 ² | 1 ² | 1 ² | 1 ² | 1 ² | n.d. | n.d. |
| Geom. LS 2.2 pyrimidyl | - | 99.0 | - | - | - | - | - | - | - |
| LS 2.2 (ph. label 20°C) | SFO | 35.0 | 37.5 | 72.4 | n.d. | n.d. | 16.9 | 1 ² | 647 |
| LS 2.2 (ph. label, 10°C) | SFO | 13.5 | 32.2 | 35.8 | n.d. | n.d. | 1 ² | 5.9 | 176 |
| Geom. LS 2.2 phenyl | - | 37.5 | 24.7 | 53.0 | - | - | - | - | 337 |
| -AIIIa (metabolite appl.) | - | - | - | - | - | - | - | 4.0 | 60.6 |
| -XXXa (metabolite appl.) | - | - | - | - | - | - | - | 7.1 | 78.5 |
| 4a (metabolite appl.) | - | - | - | - | - | - | - | 2.4 | 75.3 |
| -H (metabolite appl.) | - | - | - | - | - | - | - | 1.5 | 73.7 ¹⁾ |
| Geometric Mean | - | 31.9 | 37.0 | 40.1 | 87.9 | 60.4⁴⁾ | 25.6 | 3.6 | 97.7 |

¹⁾ DT50 calculated slow degradation rate of DFOP model.

²⁾ Value statistically not acceptable (p(t-test) or Chi² error too large) and not considered for calculation of mean.

³⁾ Derived from decline fit.

⁴⁾ Maximum of two values used instead of geometric mean.

n.d. = not determined

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| Soil | DT ₅₀ [days] | | | | | | | | |
|-------------------------------|-------------------------------|---------------------|----------------|----------------|-------------------|-------------------------|----------------|----------------|--------------------|
| | Model used for test substance | Mesosulfuron-methyl | AE F154851 | AE F160459 | AE F099095 | AE F092944 | AE F160460 | AE F140584 | AE F147447 |
| SLI | SFO | 10.3 | 11.5 | 79.3 | 64.9 | n.d. | 14.9 | n.d. | n.d. |
| SLV | SFO | 39.8 | 22.2 | n.d. | n.d. | n.d. | n.d. | n.d. | n.d. |
| CHL | DFOP | 80.5 ¹ | n.d. | n.d. | n.d. | 11.9 | n.d. | n.d. | n.d. |
| SLS | SFO | 6.7 | - ² | - ² | 43.4 ³ | - ² | - ² | n.d. | n.d. |
| SCL | SFO | 57.8 | - ² | - ² | 6.3 | - ² | - ² | n.d. | n.d. |
| FF | SFO | 29.5 | 27.4 | 116.3 | 234 | - ² | 29.1 | n.d. | n.d. |
| CLF | SFO | 11.9 | 34.6 | 28.8 | 59.8 | 46.7 | - ² | n.d. | n.d. |
| LS 2.2 pyrimidyl | DFOP | 155 | 64.6 | n.d. | 80.4 | n.d. | - ² | n.d. | n.d. |
| LS 2.2 phenyl | FQMC | 30.8 ¹ | 29.8 | 61.9 | n.d. | n.d. | 14.1 | - ² | - ² |
| ■ AIIIa (metabolite appl.) | SFO/ HS ⁵ | - | - | - | - | - | - | 4.0 | 82.7 ¹ |
| ■ AXXa (metabolite appl.) | SFO/ HS ⁵ | - | - | - | - | - | - | 7.0 | 111.4 ¹ |
| ■ 4a (metabolite appl.) | SFO/ HS ⁵ | - | - | - | - | - | - | 2.4 | 203.0 ¹ |
| ■ II (metabolite appl.) | SFO/ DFOP ⁵ | - | - | - | - | - | - | 1.5 | 73.3 ¹ |
| Geometric Mean | | 30.3 | 31.5 | 63.6 | 72.9 | 46.7⁴ | 18.3 | 3.2 | 108.2 |

¹) DT₅₀ calculated slow degradation rate of DFOP or HS model or from DT₉₀ value of FQMC model.
²) Value statistically not acceptable (t-test or Chi² error too large) and not considered for calculation of mean.
³) Derived from decline fit.
⁴) Maximum of two values used instead of geometric mean.
⁵) SFO for AE F140584; bi-basic for AE F147447.

III A 9.1.2 Anaerobic degradation of the preparation in soil

Mesosulfuron-methyl was found degradable in flooded anaerobic soil, with a half-life comparable to that observed under aerobic conditions (geometric mean DT₅₀ = 30.3 days at 20 °C). The biotransformation led to the same components as observed in aerobic soils, except for the only negligible formation of CO₂ (1% AR), inherent to anaerobic condition. The proposed metabolic route therefore is equivalent to that proposed for aerobic conditions (see Figure 9.1.1-1).



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Table 9.1.2- 1: DT₅₀ values of mesosulfuron-methyl in anaerobic soil.

| Soil | Model used for Mesosulfuron-methyl | Mesosulfuron-methyl DT ₅₀ [days] |
|----------------|------------------------------------|---|
| SLI | SFO | 30.1 |
| SLV | SFO | 30.5 |
| Geometric mean | - | 30.3 |

IIIA 9.2 Field Studies**IIIA 9.2.1 Soil dissipation testing on a range of representative soils**

The degradation of mesosulfuron-methyl after a single, exaggerated rate application of 1050 g/ha was investigated in Northern Europe (Germany, France, Great Britain) on two plots per trial, for spring or autumn use on bare soil, and in Southern Europe (France and Spain) on one plot per trial, for a spring application situation. The regions and the methods of cultivation were typical for cereal crops. Analytical monitoring in the studies focused on the parent substance, degradates were not traced.

The experimental data was kinetically evaluated according to FOOCUS guidance, including a referencing to standard conditions for soil temperature (20°C) and soil moisture (field capacity) via the time-step normalisation approach. For the temperature normalisation a Q₁₀ value of 2.58 was used.

Normalised single first-order DT₅₀ values for mesosulfuron-methyl ranged from 16.1 to 54.0 days, the overall geometric mean value was 34.6 days, including both the spring and the autumn applied studies. This data is consistent with the degradation behaviour observed for mesosulfuron-methyl in the set of laboratory studies, considering experimental variation in biological systems and the by factor 7× exaggerated use rate tested in field. As a Tier 1 approach, all environmental exposure simulations for the present product will therefore be based solely on the broad and representative set of laboratory half-life information, being founded on a kinetic model description of the entire metabolic pathway scheme.

No significant downward movement of mesosulfuron-methyl in the soil profile was observed, for both application timings and all locations tested. The active substance was only sporadically detected in soil layers deeper than 10 cm, and residues were low despite of the exaggerated application rate.

IIIA 9.2.2 Soil residue testing

Soil residues relevant for succeeding crops can be predicted from soil dissipation data provided in IIIA 9.1.1 and 9.2.1 (see also IIIA 9.4). Therefore, no further soil residue testing with the preparation is required.

IIIA 9.2.3 Soil accumulation testing

No additional studies have been performed. Concluded from PEC_{plateau} calculation presented in IIIA 9.6, mesosulfuron-methyl would not be expected to have relevant accumulation potential in soil.



IIIA 9.2.4 Aquatic (sediment) field dissipation

This is not an EC data requirement / not required by Directive 91/414/EEC.

IIIA 9.2.5 Forestry field dissipation

This is not an EC data requirement / not required by Directive 91/414/EEC

IIIA 9.3 Mobility of the Plant Protection Product in Soil

The mobility in soil of mesosulfuron-methyl and its metabolites relevant for assessment was studied by batch equilibrium tests on a variety of different soils. An overview of the data is presented in the tables below. These data did not indicate a correlation of soil adsorption with soil pH for any component.

For the only transient and short-lived degrade ADP F140584 no experimental study was performed, a worst-case default parameterisation for adsorption ($K_{oc} = 0$) and concentration dependency ($1/n = 1$) will therefore be used in exposure simulations for this component.

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Document MCP: Section 9 Fate and behaviour in the environment

Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.3-1: Soil adsorption data of mesosulfuron-methyl and its metabolites relevant for assessment

| Component / Soil | Kf [mL/g] | Koc [mL/g] | Kom [mL/g] | Freundlich exponent 1/n |
|----------------------------|--------------|---------------|---------------|----------------------------|
| Mesosulfuron-methyl | | | | |
| [REDACTED] | 1.69 | 345 | 200.1 | 0.85 |
| [REDACTED] | 3.71 | 137 | 79.5 | 0.93 |
| [REDACTED] | 0.41 | 37 | 21.5 | 0.93 |
| [REDACTED] | 0.71 | 31 | 18.0 | 0.91 |
| [REDACTED] | 2.28 | 86 | 49.9 | 0.90 |
| [REDACTED] | 0.24 | 26 | 15.1 | 0.92 |
| [REDACTED] | 0.60 | 36 | 20.9 | 0.93 |
| [REDACTED] | 1.22 | 85 | 49.3 | 0.93 |
| [REDACTED] | 0.56 | 48 | 27.8 | 0.93 |
| Median | | 48.0 | 27.8 | 0.92 |
| Arithmetic mean | | 92.7 | 57.6 | 0.91 |
| Geometric mean | | 63.9 | 37.1 | 0.94 |
| AE F154851 | | | | |
| A – USA | 3.1 | 98 | 66.8 | 0.92 |
| B – Germany | 0.79 | 31 | 35.4 | 0.94 |
| C - Germany | 0.75 | 46 | 26.7 | 0.95 |
| Arithmetic mean | | 68.3 | 39.6 | 0.94 |
| Geometric mean | | 65.0 | 37.7 | 0.94 |
| AE F160459 | | | | |
| [REDACTED] | 0.978 | 11.2 | 7.5 | 0.93 |
| [REDACTED] | 3.3797 | 15.9 | 9.1 | 0.94 |
| II | 0.7639 | 16.2 | 9.4 | 0.93 |
| [REDACTED] | 0.1475 | 21.1 | 12.2 | 0.98 |
| [REDACTED] | 0.7590 | 44.6 | 25.9 | 0.93 |
| Arithmetic mean | | 21.8 | 12.6 | 0.94 |
| Geometric mean | | 19.3 | 11.2 | 0.94 |
| AE F099095 | | | | |
| A – USA | 42.8 | 660 | 788.9 | 0.83 |
| B – Germany | 2.64 | 226 | 131.1 | 0.84 |
| C - Germany | 1.33 | 141 | 81.8 | 0.86 |
| Arithmetic mean | | 576 | 334 | 0.84 |
| Geometric mean | | 351 | 204 | 0.84 |
| AE F092944 | | | | |
| S 2.1 | 2.47 | 211 | 122.4 | 0.69 |
| LS 2.2 | 2.5 | 89 | 51.6 | 0.86 |
| SL 2.3 | 8.25 | 625 | 362.5 | 0.65 |
| Arizona A | 1.05 a) | 663 a) | 384.6 a) | 0.52 a) |
| Arizona B | 1.82 a) | 696 a) | 403.7 a) | 0.63 a) |
| SL V | 4.11 | 395 | 229.1 | 0.78 |
| SL 2 | 81.3 b) | 11289 b) | 6548.1 b) | 0.58 b) |
| Kanada | 16.5 | 917 | 531.9 | 0.62 |
| Arithmetic mean | | 447 | 260 | 0.72 |
| Geometric mean | | 336 | 195 | 0.71 |



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

| Component / Soil | Kf [mL/g] | Koc [mL/g] | Kom [mL/g] | Freundlich, exponent 1/n |
|--------------------------------------|--------------|---------------|---------------|-----------------------------|
| AE F160460 | | | | |
| [redacted] | 0.2069 | 11.5 | 6.6 | 0.9745 |
| [redacted] | 0.2258 | 9.4 | 9.5 | 0.8692 |
| [redacted] II | 0.3488 | 7.6 | 4.4 | 0.8387 |
| [redacted] | 0.0743 | 10.6 | 6.1 | 0.9524 |
| [redacted] | 0.5329 | 31.3 | 18.2 | 0.8628 |
| Arithmetic mean | | 14.1 | 8.2 | 0.90 |
| Geometric mean | | 12.2 | 7.1 | 0.90 |
| AE F140584 | | | | |
| <i>generic worst case parameters</i> | 0 | 0 | 0 | 1.00 |
| AE F147447 | | | | |
| [redacted] AXXa | 0.097 | 4.6 | 2.7 | - |
| [redacted] | 0.096 | 3.8 | 2.2 | - |
| [redacted] Alla | 0.036 | 6.6 | 3.7 | - |
| [redacted] | 0.096 | 7.0 | 4.1 | - |
| [redacted] II | 0.181 | 4.4 | 2.4 | - |
| Arithmetic mean | | 5.2 | 3.0 | 1.00 |
| Geometric mean | | 5.1 | 2.9 | 1.00 |

a) value excluded, not considered in the evaluation (EU-DAR 2003, addendum)

b) variation not understood, not considered in the evaluation (EU-DAR 2003, addendum)

IIIA 9.3.1 Column leaching

The potential mobility of mesosulfuron-methyl and its metabolites can be characterised based the adsorption/desorption studies, described under point 9.3 and environmental modelling simulations based hereon. No column leaching studies were therefore performed.

IIIA 9.3.2 Lysimeter studies

The fate and mobility of ¹²⁻¹⁴C (pyrimidyl)-labelled mesosulfuron-methyl was investigated outdoors under actual use conditions in two lysimeter studies with undisturbed monoliths of sandy soils (depth 1.0 m, surface area 0.5 m²). Applications were made to winter wheat at a rate of 15 g/ha, twice in consecutive years. The treatment was timed either in spring (first study) or in autumn (second study).

Both studies confirmed that mesosulfuron-methyl is short-lived and not mobile to relevant extent in field soils; neither the active substance nor any metabolite identified in the route of degradation studies leached at concentrations reaching or exceeding 0.1 µg/L in annual average.

Polar material detected in leachate samples in slight excess of the trigger level could not be identified with the technology available at the time of lysimeter study conduct. A bioassay revealed no growth inhibition potential to the most sensitive aquatic plant species, *Lemna gibba*. Only later, a dedicated supportive experiment allowed via state-of-the art spectroscopy a retrospective assignment of the chemical structure of BCS-CV14885. The component was synthesized and assessed for groundwater relevance according SANCO 221/2000 guidance. In these tests, BCS-CV14885 was found clearly non-relevant, i.e. devoid of herbicidal activity, and of no genotoxic potential.



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

| Compound / Codes | Chemical Structure | Explanation for Consideration | Considered for |
|------------------|--------------------|-------------------------------|---|
| BCS-CV14885 | | Detect in lysimeter leachate. | specific risk-envelope assessment for ground- and surface water, cf. Document MCA |

Owing to the fact that BCS-CV14885 was not formed at quantities triggering identification in any of the standard soil metabolism studies and could only be addressed via special test design, the component could not be included in the regular environmental modelling pathway scheme for standard exposure assessments for products. Specific simulations to extrapolate the experimental findings of the lysimeter tests to other representative regions of European agriculture were made in Document MCA, estimating worst case PEC_{gw} and PEC_{sw} of BCS-CV14885 for spring and autumn uses of mesosulfuron-methyl in cereals at its maximum rate of 1.0 g a.s./ha once per season. The subsequent risk assessments for ground and surface water allowed for the conclusion of safe use for a risk envelope covering all anticipated uses of mesosulfuron-methyl within products; degrade BCS-CV14885 was therefore considered not to qualify for regular assessment at product level, and in consequence was not included in the residue definition.

IIIA 9.3.3 Field leaching studies

Field leaching studies have not been conducted for mesosulfuron-methyl, as sufficient information can be derived from the existing studies.

IIIA 9.3.4 Volatility – laboratory study

No volatility studies on the preparation have been performed. Details of the volatility of the active substance(s) are given in Section 1. The vapour pressures are also reported in Section 9.9.

IIIA 9.3.5 Volatility – field study

Field volatility studies have not been performed and are not required.

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IIIA 9.4 Predicted Environmental Concentrations in Soil (PECs) for the Active Substance

Endpoints for PEC_{soil}

Table 9.4- 1: Comparison of EU endpoints and modelling input parameters for mesosulfuron-methyl

| End-Point | Active substance: mesosulfuron-methyl | |
|-------------------------|---------------------------------------|--------------------------|
| | Proposed EU endpoints [Document N2] | Value used for modelling |
| DT ₅₀ [days] | 109.7 | 109.7 |

PEC_{soil} modelling approach

Calculations were based on a simple first tier approach (Microsoft Excel spreadsheet) considering even distribution of the compound in upper 0-5 cm soil layer. A standard soil density of 1.5 g/cm³ was assumed. Crop interception will reduce the amount of a compound reaching the soil and is taken into account depending on the growth stage at application. The interception rates follow the recommendations for cereals given in the FOCUS groundwater guidance paper (FOCUS 2002).

Metabolites were addressed via a model approach equivalent to that of parent substance, assuming virtual application of the metabolite at a rate derived from its maximum abundance observed in soil, and corrected for molecular weight difference to parent.

If not specified otherwise, the time-course of PEC_{soil} and subsequently TWA_{soil} was derived based on simple first order kinetics, using worst case soil half life as the input parameter.

| | |
|---------------------|--|
| Report: | [REDACTED]; 2014; M 481618-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites; PEC _{soil} EUR - Use in winter cereals in Europe |
| Report No: | EnSA-14-0226 |
| Document No: | M 481618-01-1 |
| Guidelines: | not applicable; not applicable |
| GLP/GEP: | no |

Methods and Materials

The predicted environmental concentrations in soil (PEC_{soil}) of mesosulfuron-methyl were estimated based on a first tier approach using a Microsoft Excel spreadsheet. A bulk density of 1.5 kg/L and a soil mixing depth of 5 cm were used as recommended by FOCUS (1997) and EU Commission (1995, 2000). Crop interception was taken into account according to the BBCH growth stage, as recommended by FOCUS (2002). Detailed application data used for simulation of PEC_{soil} were compiled in Table 9.4- 2.



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.4- 2: Application pattern used for PEC_{soil} calculations of mesosulfuron-methyl

| Individual crop | FOCUS crop used for interception | Application | | | | Amount reaching soil per season application [g a.s./ha] |
|-------------------------------|----------------------------------|------------------------------|-----------------|------------------------|------------|---|
| | | Rate per season [g a.s. /ha] | Interval [days] | Plant interception [%] | BBCH Stage | |
| Winter wheat GAP & Simulation | winter cereals | 1 × 15 | - | 50 | 20-32 | 1 × 3.0 |
| Winter rye GAP & Simulation | winter cereals | 1 × 6 | - | 50 | 20-32 | 3.0 |

Substance Specific Parameters:

PEC_{soil} calculations were based on the maximum DT₅₀ of laboratory studies (109.7 days) at standard temperature and moisture, according to FOCUS (2000). Further compound specific input parameters are summarized below.

Table 9.4- 3: Input parameters of mesosulfuron-methyl for PEC_{soil} (from Table CA 7.1.2.1.1-1)

| Compound | DT ₅₀ [days] | Max. occur. in soil [%] | Molar mass [g/mol] |
|---------------------|-------------------------|-------------------------|--------------------|
| mesosulfuron-methyl | 109.7 | 100 | 503.5 |

Findings:

The maximum PEC_{soil} values for mesosulfuron-methyl are summarised in the Table 9.4- 4. The maximum, short-term and long-term PEC_{soil} values and the time weighted average values (TWAC_{soil}) are provided thereafter (Table 9.4- 5).

Table 9.4- 4: Maximum PEC_{soil} of mesosulfuron-methyl for the uses assessed

| Use pattern | Winter cereals | Winter cereals |
|---------------------|------------------------------------|-----------------------------------|
| | 1 × 15 g a.s./ha, 50% interception | 1 × 6 g a.s./ha, 50% interception |
| | [mg/kg] | [mg/kg] |
| mesosulfuron-methyl | 0.010 | 0.004 |



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.4- 5: PEC_{soil} (actual) and TWAC_{soil} of mesosulfuron-methyl

| | Time [days] | Mesosulfuron-methyl | | | |
|------------|-------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 50% interception | | Winter cereals 1 × 6 g a.s./ha, 50% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | 0 | 0.010 | - | 0.004 | - |
| Short term | 1 | 0.010 | 0.010 | 0.004 | 0.004 |
| | 2 | 0.010 | 0.010 | 0.004 | 0.004 |
| | 4 | 0.010 | 0.010 | 0.004 | 0.004 |
| Long term | 7 | 0.010 | 0.010 | 0.004 | 0.004 |
| | 14 | 0.009 | 0.010 | 0.004 | 0.004 |
| | 21 | 0.009 | 0.009 | 0.004 | 0.004 |
| | 28 | 0.008 | 0.009 | 0.003 | 0.004 |
| | 42 | 0.008 | 0.009 | 0.003 | 0.004 |
| | 50 | 0.007 | 0.009 | 0.003 | 0.003 |
| | 100 | 0.006 | 0.007 | 0.002 | 0.003 |

Potential accumulation in soil:

The accumulation potential after long term use for mesosulfuron-methyl was also assessed. The results for a standard mixing depth of 5 cm are presented in Table 9.4- 6.

Table 9.4- 6: PEC_{soil} of mesosulfuron-methyl for the uses assessed, taking the effect of accumulation into account (standard mixing depth of 5 cm)

| Use Pattern | PEC _{soil} | Mesosulfuron-methyl [mg/kg] |
|--|---------------------|--------------------------------|
| Winter cereals 1 × 15 g a.s./ha, 50% interception | plateau | 0.001 |
| | total* | 0.011 |
| Winter cereals 1 × 6 g a.s./ha, 50% interception | plateau | <0.001 |
| | total* | 0.004 |

* total = plateau (background concentration after multi-year use) + max. PEC_{soil} (see Table 9.4- 4)

Alternative PEC_{soil} simulation using RMS requested modelling parameters:

| | |
|---------------|--|
| Report: | [redacted]; 2015-M-517446-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{soil} EUR - Use in winter cereals in Europe |
| Report No.: | EnSa15-0310 |
| Document No.: | M-517446-01-1 |
| Guidelines: | not applicable; not applicable |
| GLP/GEP: | no |

The document reports an alternative calculation of predicted environmental concentrations in soil following the methodology presented under KIIIA 9.4/01, but based on a set of kinetic input parameters selected by the RMS.

Methods and Materials: reference is made to KIIIA 9.4/01, see summary before.



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Table 9.4- 7: Application pattern used for PEC_{soil} calculations of mesosulfuron-methyl

| Individual crop | FOCUS crop used for interception | Application | | | | Amount reaching soil per season application [g a.s./ha] |
|-------------------------------|----------------------------------|-----------------------------|-----------------|------------------------|------------|---|
| | | Rate per season [g a.s./ha] | Interval [days] | Plant interception [%] | BBCH Stage | |
| Winter wheat GAP & Simulation | winter cereals | 1 × 15 | 1 | 20 | 20-32 | 1 × 150 |
| Winter rye GAP & Simulation | winter cereals | 1 × 6 | 1 | 20 | 20-32 | 1 × 48 |

Substance Specific Parameters:

Table 9.4- 8: Input parameters of mesosulfuron-methyl for PEC_{soil}

| Compound | DT ₅₀ [days] | Max. occur. in soil [%] | Molar mass [g/mol] |
|---------------------|-------------------------|-------------------------|--------------------|
| mesosulfuron-methyl | 15 | 100 | 503.5 |

Findings:

Table 9.4- 9: Maximum PEC_{soil} of mesosulfuron-methyl for the uses assessed

| Use pattern | Winter cereals | Winter cereals |
|---------------------|------------------------------------|-----------------------------------|
| | 1 × 15 g a.s./ha, 20% interception | 1 × 6 g a.s./ha, 20% interception |
| mesosulfuron-methyl | 0.016 [mg/kg] | 0.006 [mg/kg] |

Table 9.4- 10: PEC_{soil} (actual) and FWAC_{soil} of mesosulfuron-methyl

| | Time [days] | Mesosulfuron-methyl | | | |
|------------|-------------|--|------------------------------|---|------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | | PEC _{soil} [mg/kg] | FWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | FWAC _{soil} [mg/kg] |
| Initial | | 0.016 | 0.016 | 0.006 | 0.006 |
| Short term | 1 | 0.016 | 0.016 | 0.006 | 0.006 |
| | 2 | 0.016 | 0.016 | 0.006 | 0.006 |
| | 7 | 0.016 | 0.016 | 0.006 | 0.006 |
| Long term | 14 | 0.016 | 0.016 | 0.006 | 0.006 |
| | 21 | 0.015 | 0.015 | 0.006 | 0.006 |
| | 28 | 0.014 | 0.015 | 0.006 | 0.006 |
| | 42 | 0.013 | 0.015 | 0.005 | 0.006 |
| | 50 | 0.013 | 0.014 | 0.005 | 0.006 |
| | 100 | 0.010 | 0.013 | 0.004 | 0.005 |



Potential accumulation in soil:

Table 9.4- 11: PEC_{soil} of mesosulfuron-methyl for the uses assessed, taking the effect of accumulation into account (standard mixing depth of 5 cm)

| Use Pattern | PEC _{soil} | Mesosulfuron-methyl [mg/kg] |
|--|---------------------|-----------------------------|
| Winter cereals 1 × 15 g a.s./ha, 20% interception | plateau | 0.004 |
| | total* | 0.020 |
| Winter cereals 1 × 6 g a.s./ha, 20% interception | plateau | 0.002 |
| | total* | 0.006 |

* total = plateau (background concentration after multi-year use) + max. PEC_{soil}

IIIA 9.4.1 Initial PECs values

Please refer to point IIIA 9.4.

IIIA 9.4.2 Short-term PECs values (1-4 days after last application)

Please refer to point IIIA 9.4.

IIIA 9.4.3 Long-term PECs values (from 7-100 days after last application)

Please refer to point IIIA 9.4.

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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

IIIA 9.5 Predicted Environmental Concentrations in Soil (PECs) for Relevant Metabolites

Endpoints for PEC_{soil}

Table 9.5- 1: Comparison of EU proposed endpoints and modelling input parameters for mesosulfuron-methyl metabolites

| End-Point | Active substance: mesosulfuron-methyl | |
|----------------------------------|--|--------------------------|
| | Proposed EU endpoints [Document N2] | Value used for modelling |
| AE F154851 | | |
| DT ₅₀ soil [days]* | 64.3 | 64.3 |
| Maximum occurrence in soil [%]** | 16.2 | 16.2 |
| AE F160459 | | |
| DT ₅₀ soil [days]* | 130 | 80 |
| Maximum occurrence in soil [%]** | 8.9 | 8.9 |
| AE F099095 | | |
| DT ₅₀ soil [days]* | 34 | 24 |
| Maximum occurrence in soil [%]** | 29.2 | 9.2 |
| AE F092944 | | |
| DT ₅₀ soil [days]* | 60.4 | 60.4 |
| Maximum occurrence in soil [%]** | 10.1 | 10.1 |
| AE F160460 | | |
| DT ₅₀ soil [days]* | 44.2 | 44.2 |
| Maximum occurrence in soil [%]** | 8.6 | 8.6 |
| AE F140584 | | |
| DT ₅₀ soil [days]* | 7.1 | 7.1 |
| Maximum occurrence in soil [%]** | 7.1 | 7.1 |
| AE F147447 | | |
| DT ₅₀ soil [days]* | 337 | 337 |
| Maximum occurrence in soil [%]** | 6.5 | 6.5 |

* Table CA-7.1.2.1.1-1

** Table CA-7.1.1.1-1

According to the definition of residues relevant for soil risk assessment, the following degradates were considered for PEC_{soil} calculation: AE F154851, AE F160459, AE F099095, AE F092944, AE F160460, AE F140584 and AE F147447.

| | |
|---------------------|--|
| Report: | EnSa-14-0226; 2014CM-481618-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{soil} EUR - Use in winter cereals in Europe |
| Report No: | EnSa-14-0226 |
| Document No: | M-481618-01 |
| Guidelines: | not applicable; not applicable |
| GLP/GEP: | no |

Methods and Materials: PEC_{soil} for the metabolites were calculated using the approach, scenarios and application rates described for the calculations for the parent compound in Point 9.4. Compound specific parameters are summarised in Table 9.5- 2.



Document MCP: Section 9 Fate and behaviour in the environment

Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.5- 2: Input parameters for PEC_{soil} for metabolites of mesosulfuron-methyl

| Compound | DT ₅₀ [days] | Max. occur. in soil* [%] | Molar mass [g/mol] | Molar mass correction factor | Amount reaching soil per season application | |
|------------|----------------------------|--------------------------------|-----------------------|------------------------------------|--|-------------|
| | | | | | 15 g a.s./ha | 6 g a.s./ha |
| AE F154851 | 64.3 | 16.2 | 489.5 | 0.9722 | 1.18 | 0.47 |
| AE F160459 | 130 | 8.9 | 489.5 | 0.9722 | 0.65 | 0.26 |
| AE F099095 | 234 | 29.2 | 198.2 | 0.3936 | 0.86 | 0.34 |
| AE F092944 | 60.4 | 10.1 | 155.2 | 0.3082 | 0.23 | 0.09 |
| AE F160460 | 44.2 | 8.6 | 475.5 | 0.9444 | 0.61 | 0.24 |
| AE F140584 | 7.1 | 7.1 | 322.4 | 0.6403 | 0.34 | 0.14 |
| AE F147447 | 337 | 6.5 | 290.3 | 0.7666 | 0.28 | 0.11 |

Findings: The maximum PEC_{soil} values for mesosulfuron-methyl metabolites are summarised in Table 9.5- 3. The maximum, short-term and long-term PEC_{soil} values and the time weighted average values (TWAC_{soil}) are provided thereafter.

Table 9.5- 3: Maximum PEC_{soil} of metabolites of mesosulfuron-methyl for the uses assessed

| Use pattern | Winter cereals 1 × 15 g a.s./ha, 50% interception | Winter cereals 6 g a.s./ha, 50% interception |
|-------------|--|---|
| | [mg/kg] | [mg/kg] |
| AE F154851 | 0.002 | <0.001 |
| AE F160459 | <0.001 | <0.001 |
| AE F099095 | <0.001 | <0.001 |
| AE F092944 | <0.001 | <0.001 |
| AE F160460 | <0.001 | <0.001 |
| AE F140584 | <0.001 | <0.001 |
| AE F147447 | <0.001 | <0.001 |

Table 9.5- 4: PEC_{soil} (actual) and TWAC_{soil} of mesosulfuron-methyl metabolite AE F154851

| | Time [days] | AE F154851 | | | |
|------------|----------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 50% interception | | Winter cereals 1 × 6 g a.s./ha, 50% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | | 0.002 | <0.001 | <0.001 | - |
| Short term | 1 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 2 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 7 | 0.002 | 0.002 | <0.001 | <0.001 |
| Long term | 14 | 0.001 | 0.001 | <0.001 | <0.001 |
| | 21 | 0.001 | 0.001 | <0.001 | <0.001 |
| | 28 | 0.001 | 0.001 | <0.001 | <0.001 |
| | 42 | 0.001 | 0.001 | <0.001 | <0.001 |
| | 50 | <0.001 | 0.001 | <0.001 | <0.001 |
| | 100 | <0.001 | <0.001 | <0.001 | <0.001 |



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.5- 5: PEC_{soil} (actual) and TWAC_{soil} of of mesosulfuron-methyl metabolite AE F160459

| | Time [days] | AE F160459 | | | |
|------------|-------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 50% interception | | Winter cereals 1 × 6 g a.s./ha, 50% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | 0 | <0.001 | - | <0.001 | - |
| Short term | 1 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 2 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 4 | <0.001 | <0.001 | <0.001 | <0.001 |
| Long term | 7 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 14 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 21 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 28 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 42 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 50 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 100 | <0.001 | <0.001 | <0.001 | <0.001 |

Table 9.5- 6: PEC_{soil} (actual) and TWAC_{soil} of of mesosulfuron-methyl metabolite AE F099095

| | Time [days] | AE F099095 | | | |
|------------|-------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 50% interception | | Winter cereals 1 × 6 g a.s./ha, 50% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | 0 | <0.001 | - | <0.001 | - |
| Short term | 1 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 2 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 4 | <0.001 | <0.001 | <0.001 | <0.001 |
| Long term | 7 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 14 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 21 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 28 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 42 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 50 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 100 | <0.001 | <0.001 | <0.001 | <0.001 |

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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl +Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.5- 7: PEC_{soil} (actual) and TWAC_{soil} of of mesosulfuron-methyl metabolite AE F092944

| | Time [days] | AE F092944 | | | |
|------------|-------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 50% interception | | Winter cereals 1 × 6 g a.s./ha, 50% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | 0 | <0.001 | - | <0.001 | - |
| Short term | 1 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 2 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 4 | <0.001 | <0.001 | <0.001 | <0.001 |
| Long term | 7 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 14 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 21 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 28 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 42 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 50 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 100 | <0.001 | <0.001 | <0.001 | <0.001 |

Table 9.5- 8: PEC_{soil} (actual) and TWAC_{soil} of of mesosulfuron-methyl metabolite AE F160460

| | Time [days] | AE F160460 | | | |
|------------|-------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 50% interception | | Winter cereals 1 × 6 g a.s./ha, 50% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | 0 | <0.001 | - | <0.001 | - |
| Short term | 1 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 2 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 4 | <0.001 | <0.001 | <0.001 | <0.001 |
| Long term | 7 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 14 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 21 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 28 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 42 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 50 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 100 | <0.001 | <0.001 | <0.001 | <0.001 |

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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.5- 9: PEC_{soil} (actual) and TWAC_{soil} of of mesosulfuron-methyl metabolite AE F140584

| | Time [days] | AE F140584 | | | |
|------------|-------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 50% interception | | Winter cereals 1 × 6 g a.s./ha, 50% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | 0 | <0.001 | - | <0.001 | - |
| Short term | 1 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 2 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 4 | <0.001 | <0.001 | <0.001 | <0.001 |
| Long term | 7 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 14 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 21 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 28 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 42 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 50 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 100 | <0.001 | <0.001 | <0.001 | <0.001 |

Table 9.5- 10: PEC_{soil} (actual) and TWAC_{soil} of of mesosulfuron-methyl metabolite AE F147447

| | Time [days] | AE F147447 | | | |
|------------|-------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 50% interception | | Winter cereals 1 × 6 g a.s./ha, 50% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | 0 | <0.001 | - | <0.001 | - |
| Short term | 1 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 2 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 4 | <0.001 | <0.001 | <0.001 | <0.001 |
| Long term | 7 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 14 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 21 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 28 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 42 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 50 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 100 | <0.001 | <0.001 | <0.001 | <0.001 |

Potential accumulation in soil:

The accumulation potential after long term use was also assessed for mesosulfuron-methyl metabolites having the longest maximum DT₅₀: AE F160459, AE F099095 and AE F147447. The results for a standard mixing depth of 5 cm are presented in Table 9.5- 11.

Table 9.5- 11: PEC_{soil} of mesosulfuron-methyl metabolites for the uses assessed, taking the effect of accumulation into account (standard mixing depth of 5 cm)

| Use Pattern | PEC _{soil} | AE F160459 | AE F099095 | AE F147447 |
|--|---------------------|------------|------------|------------|
| | | [mg/kg] | [mg/kg] | [mg/kg] |
| Winter cereals 1 × 15 g a.s./ha, 50% interception | plateau | <0.001 | <0.001 | <0.001 |
| | total* | 0.001 | 0.002 | 0.001 |
| Winter cereals 1 × 6 g a.s./ha, 50% interception | plateau | <0.001 | <0.001 | <0.001 |
| | total* | <0.001 | <0.001 | <0.001 |

* total = plateau (background concentration after multi-year use) + max. PEC_{soil} (see Table 9.5- 3)



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Alternative PECsoil simulation using RMS requested modelling parameters:

| | |
|--------------|--|
| Report: | ü: 2015;M-517446-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PECsoil EUR Use in winter cereals in Europe |
| Report No: | EnSa-15-0310 |
| Document No: | M-517446-01-1 |
| Guidelines: | not applicable;not applicable |
| GLP/GEP: | no |

The document reports an alternative calculation of predicted environmental concentrations in soil following the methodology presented under KIIIA 9.5/01 before, but applying a set of modelling parameters requested by the RMS.

Methods and Materials: reference is made to KIIIA 9.5/01, see summary before

Substance Specific Parameters:

Table 9.5- 12: Input parameters for PEC_{soil} for metabolites of mesosulfuron-methyl

| Compound | DT ₅₀ [days] | Max. occur. in soil [%] | Molar mass [g/mol] | Molar mass correction factor | Amount reaching soil per season application | |
|------------|----------------------------|-------------------------------|-----------------------|------------------------------------|--|-------------|
| | | | | | 15 g a.s./ha | 6 g a.s./ha |
| AE F154851 | 207.4 | 16.2 | 489.5 | 0.9722 | 1.89 | 0.76 |
| AE F160459 | 144.8 | 8.9 | 489.5 | 0.9722 | 1.04 | 0.42 |
| AE F099095 | 261.2 | 29 | 199.2 | 0.3936 | 1.38 | 0.55 |
| AE F092944 | 82.7 | 10.1 | 155.2 | 0.5082 | 0.37 | 0.15 |
| AE F160460 | 44.2 | 8.6 | 475.5 | 0.9444 | 0.97 | 0.39 |
| AE F140584 | 15.1 | 7.1 | 322.3 | 0.6403 | 0.55 | 0.22 |
| AE F147447 | 833.1 | 5.5 | 290.3 | 0.5766 | 0.45 | 0.18 |

Findings:

Table 9.5- 13: Maximum PEC_{soil} of metabolites of mesosulfuron-methyl for the uses assessed

| Use pattern | Winter Cereals 1 × 15 g a.s./ha, 20% interception | Winter cereals 1 × 6 g a.s./ha, 20% interception |
|-------------|--|---|
| | [mg/kg] | [mg/kg] |
| AE F154851 | 0.003 | 0.001 |
| AE F160459 | 0.001 | <0.001 |
| AE F099095 | 0.002 | <0.001 |
| AE F092944 | <0.001 | <0.001 |
| AE F160460 | 0.001 | <0.001 |
| AE F140584 | <0.001 | <0.001 |
| AE F147447 | <0.001 | <0.001 |



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Table 9.5- 14: PEC_{soil} (actual) and TWAC_{soil} of mesosulfuron-methyl metabolite AE F154851

| | Time [days] | AE F154851 | | | |
|------------|-------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | 0 | 0.003 | 0.003 | <0.001 | <0.001 |
| Short term | 1 | 0.003 | 0.003 | 0.001 | <0.001 |
| | 2 | 0.003 | 0.003 | 0.001 | <0.001 |
| | 4 | 0.002 | 0.003 | <0.001 | 0.001 |
| Long term | 7 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 14 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 21 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 28 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 42 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 50 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 100 | 0.002 | 0.002 | <0.001 | <0.001 |

Table 9.5- 15: PEC_{soil} (actual) and TWAC_{soil} of mesosulfuron-methyl metabolite AE F160459

| | Time [days] | AE F160459 | | | |
|------------|-------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | 0 | 0.001 | 0.001 | <0.001 | <0.001 |
| Short term | 1 | 0.001 | 0.001 | <0.001 | <0.001 |
| | 2 | 0.001 | 0.001 | <0.001 | <0.001 |
| | 4 | 0.001 | 0.001 | <0.001 | <0.001 |
| Long term | 7 | 0.001 | 0.001 | <0.001 | <0.001 |
| | 14 | 0.001 | 0.001 | <0.001 | <0.001 |
| | 21 | 0.001 | 0.001 | <0.001 | <0.001 |
| | 28 | 0.001 | 0.001 | <0.001 | <0.001 |
| | 42 | 0.001 | 0.001 | <0.001 | <0.001 |
| | 50 | 0.001 | 0.001 | <0.001 | <0.001 |
| | 100 | <0.001 | 0.001 | <0.001 | <0.001 |

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Table 9.5- 16: PEC_{soil} (actual) and TWAC_{soil} of of mesosulfuron-methyl metabolite AE F099095

| | Time [days] | AE F099095 | | | |
|------------|-------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | 0 | 0.002 | 0.002 | <0.001 | <0.001 |
| Short term | 1 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 2 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 4 | 0.002 | 0.002 | <0.001 | <0.001 |
| Long term | 7 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 14 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 21 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 28 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 42 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 50 | 0.002 | 0.002 | <0.001 | <0.001 |
| | 100 | 0.001 | 0.002 | <0.001 | <0.001 |

Table 9.5- 17: PEC_{soil} (actual) and TWAC_{soil} of of mesosulfuron-methyl metabolite AE F092944

| | Time [days] | AE F092944 | | | |
|------------|-------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | 0 | <0.001 | <0.001 | <0.001 | <0.001 |
| Short term | 1 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 2 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 4 | <0.001 | <0.001 | <0.001 | <0.001 |
| Long term | 7 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 14 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 21 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 28 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 42 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 50 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 100 | <0.001 | <0.001 | <0.001 | <0.001 |

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Table 9.5- 18: PEC_{soil} (actual) and TWAC_{soil} of of mesosulfuron-methyl metabolite AE F160460

| | Time [days] | AE F160460 | | | |
|------------|-------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | 0 | 0.001 | 0.001 | 0.001 | 0.001 |
| Short term | 1 | 0.001 | 0.001 | <0.001 | 0.001 |
| | 2 | 0.001 | 0.001 | <0.001 | 0.001 |
| | 4 | 0.001 | 0.001 | <0.001 | 0.001 |
| Long term | 7 | 0.001 | 0.001 | <0.001 | 0.001 |
| | 14 | 0.001 | 0.001 | <0.001 | 0.001 |
| | 21 | <0.001 | 0.001 | <0.001 | 0.001 |
| | 28 | <0.001 | 0.001 | <0.001 | 0.001 |
| | 42 | <0.001 | <0.001 | <0.001 | 0.001 |
| | 50 | <0.001 | 0.001 | <0.001 | 0.001 |
| | 100 | <0.001 | 0.001 | <0.001 | 0.001 |

Table 9.5- 19: PEC_{soil} (actual) and TWAC_{soil} of of mesosulfuron-methyl metabolite AE F140584

| | Time [days] | AE F140584 | | | |
|------------|-------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | 0 | 0.001 | 0.001 | <0.001 | 0.001 |
| Short term | 1 | 0.001 | 0.001 | <0.001 | 0.001 |
| | 2 | <0.001 | 0.001 | <0.001 | 0.001 |
| | 4 | <0.001 | 0.001 | <0.001 | 0.001 |
| Long term | 7 | <0.001 | 0.001 | <0.001 | 0.001 |
| | 14 | <0.001 | 0.001 | <0.001 | 0.001 |
| | 21 | <0.001 | 0.001 | <0.001 | 0.001 |
| | 28 | <0.001 | 0.001 | <0.001 | 0.001 |
| | 42 | <0.001 | 0.001 | <0.001 | 0.001 |
| | 50 | <0.001 | 0.001 | <0.001 | 0.001 |
| | 100 | <0.001 | 0.001 | <0.001 | 0.001 |

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Table 9.5- 20: PEC_{soil} (actual) and TWAC_{soil} of mesosulfuron-methyl metabolite AE F147447

| | Time [days] | AE F147447 | | | |
|------------|-------------|--|---------------------------------|---|---------------------------------|
| | | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] | PEC _{soil} [mg/kg] | TWAC _{soil} [mg/kg] |
| Initial | 0 | <0.001 | <0.001 | <0.001 | <0.001 |
| Short term | 1 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 2 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 4 | <0.001 | <0.001 | <0.001 | <0.001 |
| Long term | 7 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 14 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 21 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 28 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 42 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 50 | <0.001 | <0.001 | <0.001 | <0.001 |
| | 100 | <0.001 | <0.001 | <0.001 | <0.001 |

Potential accumulation in soil:

Triggered by the RMS selection of kinetic input data to PEC_{soil} calculation, the potential for accumulation in soil is assessed for components AE F154851, AE F160459, AE F099095, and AE F147447.

Table 9.5- 21: PEC_{soil} of mesosulfuron-methyl metabolites for the uses assessed, taking the effect of accumulation into account (standard mixing depth of 5 cm)

| Use Pattern | PEC _{soil} | AE F154851 | AE F160459 | AE F099095 | AE F147447 |
|--|---------------------|------------|------------|------------|------------|
| | | [mg/kg] | [mg/kg] | [mg/kg] | [mg/kg] |
| Winter cereals 1 × 15 g a.s./ha 20% interception | plateau | 0.001 | <0.001 | 0.001 | 0.002 |
| | total* | 0.004 | 0.002 | 0.003 | 0.002 |
| Winter cereals 1 × 6 g a.s./ha 20% interception | plateau | <0.001 | <0.001 | <0.001 | <0.001 |
| | total* | 0.001 | <0.001 | 0.001 | <0.001 |

* total = plateau (background concentration after multi-year use) + max. PEC_{soil}

IIIA 9.5.1 Initial PECs values

See under IIIA 9.4.

IIIA 9.5.2 Short-term PECs values (1-4 days after last application)

See under IIIA 9.4.

IIIA 9.5.3 Long-term PECs values (from 7-100 days after last application)

See under IIIA 9.4.



Document MCP: Section 9 Fate and behaviour in the environment

Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

IIIA 9.6 Predicted Environmental Concentrations in Ground Water (PEC_{gw})EU endpoints for PEC_{gw}

Table 9.6- 1: Comparison of proposed EU endpoints and modelling input parameters for mesosulfuron-methyl and its metabolites

| End-point | Active substance: mesosulfuron-methyl | |
|--|--|--------------------------|
| | Proposed EU endpoints [Document N2] | Value used for modelling |
| Mesosulfuron-methyl | | |
| Aqueous solubility [mg/L] | 483 | 483 |
| Vapour pressure [Pa] | 5×10^{-12} | 50×10^{-12} |
| DT ₅₀ soil [days] (geomean, lab) | 31.9 | 31.9 |
| K _{oc} / K _{om} [L/kg] (median) | 48 / 27.8 | 48 / 27.8 |
| 1/n (arith. mean) | 0.910 | 0.910 |
| Plant uptake factor | 0 | 0 |
| AE F154851 | | |
| Aqueous solubility [mg/L] | 200000 | 200000 |
| Vapour pressure [Pa] | 7×10^{-8} | 7×10^{-8} |
| DT ₅₀ soil [days] (geomean, lab) | 37.1 | 37.1 |
| K _{oc} / K _{om} [L/kg] (arith. mean) | 68.3 / 39.6 | 68.3 / 39.6 |
| 1/n (arith. mean) | 0.940 | 0.940 |
| Plant uptake factor | 0 | 0 |
| Formation fraction (arith. mean) | 0.179 | 0.179 |
| AE F160459 | | |
| Aqueous solubility [mg/L] | 10000 | 10000 |
| Vapour pressure [Pa] | 8×10^{-8} | 6.8×10^{-8} |
| DT ₅₀ soil [days] (geomean, lab) | 70.1 | 70.1 |
| K _{oc} / K _{om} [L/kg] (arith. mean) | 21.8 / 12.6 | 21.8 / 12.6 |
| 1/n (arith. mean) | 0.940 | 0.940 |
| Plant uptake factor | 0 | 0 |
| Formation fraction (arith. mean) | 0.094 | 0.094 |
| AE F099095 | | |
| Aqueous solubility [mg/L] | 190 | 190 |
| Vapour pressure [Pa] | 1.9×10^{-5} | 1.9×10^{-5} |
| DT ₅₀ soil [days] (geomean, lab) | 87.9 | 87.9 |
| K _{oc} / K _{om} [L/kg] (arith. mean) | 576 / 334 | 576 / 334 |
| 1/n (arith. mean) | 0.840 | 0.840 |
| Plant uptake factor | 0 | 0 |
| Formation fraction (arith. mean) | 0.076 | 0.076 |
| AE F092044 | | |
| Aqueous solubility [mg/L] | 5200 | 5200 |
| Vapour pressure [Pa] | 2.6×10^{-2} | 2.6×10^{-2} |
| DT ₅₀ soil [days] (geomean, lab) | 60.4 | 60.4 |
| K _{oc} / K _{om} [L/kg] (arith. mean) | 447 / 260 | 447 / 260 |
| 1/n (arith. mean) | 0.72 | 0.72 |
| Plant uptake factor | 0 | 0 |
| Formation fraction (arith. mean) | 0.172 | 0.172 |
| AE F160460 | | |
| Aqueous solubility [mg/L] | 100000 | 100000 |
| Vapour pressure [Pa] | 5.6×10^{-7} | 5.6×10^{-7} |
| DT ₅₀ soil [days] (geomean, lab) | 25.6 | 25.6 |
| K _{oc} / K _{om} [L/kg] (arith. mean) | 14.1 / 8.2 | 14.1 / 8.2 |
| 1/n (arith. mean) | 0.900 | 0.900 |
| Plant uptake factor | 0 | 0 |



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

| End-point | Active substance: mesosulfuron-methyl | |
|--|--|--|
| | Proposed EU endpoints [Document N2] | Value used for modelling |
| Formation fraction (arith. mean) | 1.000 (from AE F154851) 1.000 (from AE F160459) | 1.000 (from AE F154851) 1.000 (from AE F160459) |
| AE F140584 | | |
| Aqueous solubility [mg/L] | 100 | 100 |
| Vapour pressure [Pa] | 1.3×10^{-6} | 1.3×10^{-6} |
| DT ₅₀ soil [days] (geomean, lab) | 3.6 | 3.6 |
| K _{oc} / K _{om} [L/kg] (default value) | 0.0 / 0.0 | 0.0 / 0.0 |
| 1/n (default value) | 1.000 | 1.000 |
| Plant uptake factor | 0 | 0 |
| Formation fraction (maximum) | 0.704 | 0.704 |
| AE F147447 | | |
| Aqueous solubility [mg/L] | 150000 | 150000 |
| Vapour pressure [Pa] | 1.9×10^{-6} | 1.9×10^{-6} |
| DT ₅₀ soil [days] (geomean, lab) | 97.7 | 97.7 |
| K _{oc} / K _{om} [L/kg] (arith. mean) | 5.2 / 3.0 | 5.2 / 3.0 |
| 1/n (default value) | 1.000 | 1.000 |
| Plant uptake factor | 0 | 0 |
| Formation fraction (maximum) | 0.097 (from AE F140584) | 0.097 (from AE F140584) |

PEC_{gw} modelling approach - FOCUS scenario simulation

The predicted environmental concentrations in groundwater (PEC_{gw}) for the active substances were calculated using the simulation models PEARL and PELMO following the recommendations of the FOCUS working group on groundwater scenarios.

The leaching calculations were run over 26 years, as proposed for pesticides which may be applied every year. The first six years are a 'warm up' period; only the last 20 years were considered for the assessment of the leaching potential. The 80th percentile of the average annual groundwater concentrations in the percolate at 1 m depth under a treated plantation were evaluated and were taken as the relevant PEC_{gw} values. In respect to the assessment of a potential groundwater contamination this shallow depth reflects a worst case. The effective long-term groundwater concentrations will be even lower due to dilution in the groundwater layer.

According to FOCUS, the calculations were conducted based on geomean soil half-lives, referenced to standard temperature and moisture conditions. Crop interception will reduce the amount of a compound reaching the soil and therefore this has been taken into account depending on the growth stage at application. The interception rates follow the FOCUS recommendations.

IIIA 9.6.1 Active substance

For the implementation of the complex soil degradation pathway of mesosulfuron-methyl in the groundwater exposure model PEARL and PELMO, a set of separate simulation runs had to be performed in order to overcome technical limitations of the models¹. The overall groundwater assessment consists of the following three calculations, which are reported in separate documents:

¹ Kinetic evaluation of the soil degradation of mesosulfuron-methyl leads to situation where the sum of formation fractions of all metabolites formed directly from parent is larger than one. This is typical for degradation studies with substances



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

1. FOCUS PEARL with parent and all metabolites, corresponding calculations are presented in KIIIA 9.6.1/01.
2. FOCUS PELMO (pathway 1) with parent and metabolites AE F154831, AE F160459, AE F099095, AE F092944, and AE F160460 (in order to keep sum of formation fractions for metabolites generated from the parent below 1), corresponding calculations are presented in KIIIA 9.6.1/02.
3. FOCUS PELMO (pathway 2) with parent and metabolites AE F140584 and AE F147447 (in order to address the remaining part of the soil degradation pathway) corresponding calculations are presented in KIIIA 9.6.1/03.

| | |
|---------------------|---|
| Report: | 3; 2014;M-481632-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites PECgw FOCUS PEARL EUR (combination) - Use in winter cereals in Europe |
| Report No: | EnSa-14-0363 |
| Document No: | M-481632-01-1 |
| Guidelines: | not applicable/not applicable |
| GLP/GEP: | no |

undergoing cleavage since the (re) distribution of the applied radioactivity (flow of molar equivalents) in time and not the mass flow is observed and kinetically evaluated.

In PELMO, reaction-specific DT50 (i.e., for the respective parent-metabolite pair) are calculated based on the DT50 of the parent and formation fraction of the respective metabolite. The process is as follows:

- calculate parent rate constant from $k(\text{par}) = \ln(2) / \text{DT50}(\text{par})$
- calculate pathway rate constant using the formation fraction of the respective metabolite from $k(\text{par-met}) = k(\text{par}) * ff(\text{met})$
- repeat previous step for all metabolites formed from parent

It is apparent that if sum of all formation fractions is $(1+x)$ (let's denote it $(1+x)$) then the sum of parent rate constants $k(\text{sum}) = k(\text{par-met1}) + k(\text{par-met2}) + \dots = k(\text{par}) * (ff(\text{met1}) + ff(\text{met2}) + \dots) = k(\text{par}) * (1+x)$

This leads to the situation where the rate constant of the parent $k(\text{sum})$ as defined in the simulation is larger than the rate constant of the parent which was obtained from the kinetic evaluations. As a consequence, since $k = \ln(2)/\text{DT50}$, the DT50 of the parent substance will be shorter than intended.

In order to overcome this problem, we splitted the calculation so that the sum of the formation fractions in the individual run does not exceed 1. The remaining flow is directed into the sink compartment in order to ensure the correct parent DT50. As a result, there are 2 PELMO PECgw calculations concerning parent (concentrations of parent are the same in both simulations which serves as a consistency check) and individual parts of the degradation scheme which are calculated using correct and consistent degradation parameters.

In PEARL this effect is accounted for automatically by the model and therefore, all metabolites can be addressed in a single model run. In case that the sum of the formation fractions is greater than 1, the model just warns the user that "this seldom occurs". This does not influence the calculations in any way and leads to correct and consistent results for all of the substances.

For technical reasons, the results are split into 3 separate reports which are to be seen as individual building blocks of the overall PECgw assessment.



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

| | |
|---------------------|---|
| Report: | [REDACTED];2014;M-481633-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{gw} FOCUS PELMO EUR (pathway 1, combination) - Use in winter cereals in Europe |
| Report No: | EnSa-14-0364 |
| Document No: | M-481633-01-1 |
| Guidelines: | not applicable;not applicable |
| GLP/GEP: | no |

| | |
|---------------------|--|
| Report: | [REDACTED];2014;M-481624-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{gw} FOCUS PELMO EUR (pathway 2) - Use in winter cereals in Europe |
| Report No: | EnSa-14-0229 |
| Document No: | M-481624-01-1 |
| Guidelines: | not applicable;not applicable |
| GLP/GEP: | no |

Materials and Methods:

The predicted environmental concentrations in groundwater (PEC_{gw}) for mesosulfuron-methyl were calculated using the simulation model FOCUS PEARL (version 4.4.4) and FOCUS PELMO (version 5.5.3). Detailed application data used for simulation of PEC_{gw} were compiled in Table 9.6.1-1.

Table 9.6.1- 1: Application pattern used for PEC_{gw} calculations

| Individual crop | FOCUS crop used for interception | Application | | | | Amount reaching soil per season application [g a.s./ha] |
|-------------------------------|----------------------------------|-----------------------------|-----------------|------------------------|------------|---|
| | | Rate per season [g a.s./ha] | Interval [days] | Plant interception [%] | BBCH Stage | |
| Winter wheat GAP & Simulation | winter cereals | 1 × 15.0 | - | 50 | 20-32 | 1 × 7.5 |
| Winter rye GAP & Simulation | winter cereals | 1 × 6.0 | - | 50 | 20-32 | 1 × 3.0 |

Application timing: The spring application in winter cereals according to GAP is done at the end of winter, at the beginning of the vegetation period (*i.e.* when the temperature is high enough to expect crop and weed growth) onto well-developed crop. No pre-defined event dates are implemented in the FOCUS model that would directly translate this cropping situation into discrete calendar dates for each groundwater scenario setting. Therefore, the following approach was used to define suitable scenario-adapted application dates: the simulated treatment was referenced relative to the tabulated crop emergence date of the earliest emerging spring crop (*i.e.* not necessarily cereals) that was defined by FOCUS for the respective scenario. An application day 14 days before that date was then selected, which is considered an adequate representation for the start of the vegetation period in the respective scenario environment. An overview of the date selections is found compiled in the table below.

Table 9.6.1- 2: Application dates per scenario as used for the simulation runs

| Scenario | Reference date: FOCUS listed emergence of earliest spring crop per scenario | Winter cereals, spring application at the end of winter, at the beginning of the vegetation period | |
|------------|--|--|------------|
| | | Application date selected | Julian day |
| [REDACTED] | spring cereals: 10 Mar | 24 Feb | 55 |
| [REDACTED] | carrots: 10 Mar | 24 Feb | 55 |
| [REDACTED] | spring cereals: 18 May | 04 May | 124 |



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

| Scenario | Reference date: FOCUS listed emergence of earliest spring crop per scenario | Winter cereals, spring application at the end of winter, at the beginning of the vegetation period | |
|----------|--|--|------------|
| | | Application date selected | Julian day |
| | carrots: 10 Mar | 24 Feb | 55 |
| | field beans: 15 Mar | 01 Mar | 60 |
| | sugar beet: 20 Mar | 06 Mar | 65 |
| | carrots: 28 Feb | 14 Feb | 45 |
| | cabbage: 01 Mar | 25 Feb | 46 |
| | potatoes: 01 Mar | 15 Feb | 45 |

Substance specific and model related input parameters for the different PEC_w calculations are summarised in the following tables.

1. Calculation 1: FOCUS PEARL with parent and all metabolites (Table 9.6.1- 3).
2. Calculation 2: FOCUS PELMO with parent and metabolites AE F154851, AE F160449, AE F099095, AE F092944, and AE F160460 (Table 9.6.1- 4).
3. Table 9.6.1- 4).
4. Calculation 3: FOCUS PELMO with parent and metabolites AE F140584 and AE F147447 (Table 9.6.1- 5).
5. Table 9.6.1- 5).

Soil degradation of mesosulfuron-methyl and its metabolites was based on geometric mean DT₅₀ as derived from laboratory studies, normalized to 20°C and 100% field capacity according to FOCUS (2000). The modelled degradation pathway scheme was identical to that of the underlying kinetic evaluation; arithmetic mean or maximum formation fractions were considered for the metabolites. Soil adsorption was described by median K_{oc} / K_{om} for the parent active substance, or arithmetic mean values for all other components with experimental data from batch equilibrium studies available. For metabolite AE F140584, a worst case default value of zero soil adsorption was used in the absence of experimental data. For concentration dependency arithmetic mean Freundlich exponents were used, or a default value of 1.0 in the absence of experimental information.

Ignoring the systemic action of mesosulfuron-methyl, a worst case default for plant uptake (PUF = 0) was assumed for parent active substance and all metabolites in this first tier calculation.

² As supportive information for comparison purposes, requested by RMS France (ANSES), a second set of simulation runs was made based on alternative formation fractions. These were derived strictly formally, considering in the averaged results only formation fractions where they are associated with a statistically significant DT₅₀ value of the next generation metabolite. This will reduce the number of individual values contributing to metabolites AE F154851, AE F099095, and AE F092944; rejecting a total of 5 values.

In effect, this would lead to only small changes as follows:

| | Notifier recommended approach | Strictly formal approach |
|---------------------|-------------------------------|--------------------------|
| parent → AE F154851 | 0.179 (n=8) | 0.203 (n=7) |
| parent → AE F099095 | 0.076 (n=8) | 0.092 (n=5) |
| parent → AE F092944 | 0.172 (n=3) | 0.238 (n=2) |

The results of these supportive calculations are provided in the Appendices sections to reports KIIIA 9.6.1/01 and KIIIA 9.6.1/02. (not applicable for report KIIIA 9.6.1/03 due to the selection of metabolites covered herein)



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.6.1- 3: Substance specific and model related input parameter for PEARL PEC_{gw} calculation of mesosulfuron-methyl and its metabolites (model parameters not listed are kept as default) – Calculation 1

| Parameter | Unit | Mesosulfuron-methyl | AE F154851 | AE F160459 | AE F099095 |
|---|----------|---|------------|------------|------------|
| Molar Mass | [g/mol] | 503.5 | 489.5 | 489.5 | 198.2 |
| Solubility (20 °C) | [mg/L] | 483 | 20000 | 10000 | 190 |
| Vapour Pressure (20 °C) | [Pa] | 3.50E-12 | 1.70E-08 | 6.80E-08 | 1.90E-05 |
| Freundlich Exponent | | 0.910 | 0.940 | 0.940 | 0.840 |
| Plant Uptake Factor | | 0.0 | 0.0 | 0.0 | 0.0 |
| Walker Exponent | | 0.7 | 0.7 | 0.7 | 0.0 |
| PEARL Parameters | | | | | |
| Substance Code | | MSM | M851 | M459 | M095 |
| DT ₅₀ | [days] | 31.9 | 37.0 | 70.1 | 87.9 |
| Molar Activ. Energy | [kJ/mol] | 65.4 | 65.4 | 65.4 | 65.4 |
| K _{om} | [mL/g] | 27.8 | 9.6 | 12.6 | 34.0 |
| Parameter | Unit | AE F092944 | AE F160460 | AE F140584 | AE F147497 |
| Molar Mass | [g/mol] | 455.2 | 472.5 | 22.4 | 290 |
| Solubility (20 °C) | [mg/L] | 5200 | 10000 | 100 | 15000 |
| Vapour Pressure (20 °C) | [Pa] | 2.60E-02 | 6.0E-07 | 1.30E-06 | 1.00E-08 |
| Freundlich Exponent | | 0.720 | 0.900 | 1.000 | 1.000 |
| Plant Uptake Factor | | 0.0 | 0.0 | 0.0 | 0.0 |
| Walker Exponent | | 0.7 | 0.7 | 0.7 | 0.7 |
| PEARL Parameters | | | | | |
| Substance Code | | M944 | M460 | M584 | M447 |
| DT ₅₀ | [days] | 60.4 | 25.6 | 3.6 | 97.7 |
| Molar Activ. Energy | [kJ/mol] | 65.4 | 65.4 | 65.4 | 65.4 |
| K _{om} | [mL/g] | 260.0 | 8.2 | 0.0 | 3.0 |
| Degradation fraction from → to (FOCUS PEARL) ³ | | 0.179 MSM → M851 0.094 MSM → M459 0.076 MSM → M095 0.172 MSM → M944 0.704 MSM → M584 1 M851 → M460 1 M459 → M460 0.097 M584 → M447 | | | |

³ Alternative set of formation fractions, for supportive calculation requested by RMS France (ANSES) – see also footnote 2:

| | |
|--|---|
| Degradation fraction from → to (FOCUS PEARL) | 0.203 MSM → M851 0.094 MSM → M459 0.092 MSM → M095 0.238 MSM → M944 0.704 MSM → M584 1 M851 → M460 1 M459 → M460 0.097 M584 → M447 |
|--|---|

Other model input parameters used for the ANSES calculations are summarized in Table 9.6.1- 3.



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.6.1- 4: Substance specific and model related input parameter for PELMO (pathway 1) PEC_{gw} calculation of mesosulfuron-methyl and its metabolites (model parameters not listed are kept as default) – Calculation 2

| Parameter | Unit | Mesosulfuron-methyl | AE F154851 | AE F160459 |
|---|---------|--|------------|------------|
| Molar Mass | [g/mol] | 503.5 | 489.5 | 489.5 |
| Solubility (20 °C) | [mg/L] | 483 | - | - |
| Vapour Pressure (20 °C) | [Pa] | 3.50E-12 | - | - |
| Freundlich Exponent | | 0.910 | 0.940 | 0.940 |
| Plant Uptake Factor | | 0.0 | 0.0 | 0.0 |
| Walker Exponent | | 0.7 | 0.7 | 0.7 |
| PELMO Parameters | | | | |
| Substance Code | | AS | A1 | B1 |
| Rate Constant | [1/day] | 0.02073 | 0.01968 | 0.02089 |
| Q ₁₀ | | 2.58 | 2.58 | 2.58 |
| K _{oc} | [mL/g] | 48.0 | 68.3 | 21.8 |
| Parameter | Unit | AE F092995 | AE F092944 | AE F160460 |
| Molar Mass | [g/mol] | 198.2 | 15.2 | 45.5 |
| Solubility (20 °C) | [mg/L] | - | - | - |
| Vapour Pressure (20 °C) | [Pa] | - | - | - |
| Freundlich Exponent | | 0.840 | 0.730 | 0.990 |
| Plant Uptake Factor | | 0.0 | 0.0 | 0.0 |
| Walker Exponent | | 0.7 | 0.7 | 0.7 |
| PELMO Parameters | | | | |
| Substance Code | | C1 | D1 | B2 |
| Rate Constant | [1/day] | 0.02789 | 0.01148 | 0.02708 |
| Q ₁₀ | | 2.58 | 2.58 | 2.58 |
| K _{oc} | [mL/g] | 576.0 | 447.0 | 14.1 |
| Degradation fraction from → to (FOCUS PELMO) ⁴ | | 0.0038900 AS → A1 0.0020400 AS → B1 0.0016500 AS → C1 0.0037400 AS → D1 0.0104100 AS → <BR/CO ₂ > 0.0186800 A1 → B2 0.0098900 B1 → B2 0.0078900 C1 → <BR/CO ₂ > 0.0114800 D1 → <BR/CO ₂ > 0.0270800 B2 → <BR/CO ₂ > | | |

⁴ Alternative set of formation fractions for supportive calculation requested by RMS France (ANSES) – see also footnote 2:.

| | |
|--|--|
| Degradation fraction from → to (FOCUS PELMO) | 0.0044100 AS → A1 0.0020400 AS → B1 0.0020000 AS → C1 0.0051700 AS → D1 0.0081000 AS → <BR/CO ₂ > 0.0186800 A1 → B2 0.0098900 B1 → B2 0.0078900 C1 → <BR/CO ₂ > 0.0114800 D1 → <BR/CO ₂ > 0.0270800 B2 → <BR/CO ₂ > |
|--|--|

Other model input parameters used for the ANSES calculations are summarized in Table 9.6.1- 4.



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.6.1- 5: Substance specific and model related input parameter for PELMO (pathway 2) PEC_{gw} calculation of mesosulfuron-methyl and its metabolites (model parameters not listed are kept as default) – Calculation 3

| Parameter | Unit | Mesosulfuron-methyl | AE F140584 | AE F147447 |
|--|---------|--|------------|------------|
| Molar Mass | [g/mol] | 503.5 | 322.4 | 290.3 |
| Solubility (20 °C) | [mg/L] | 483 | - | - |
| Vapour Pressure (20 °C) | [Pa] | 3.50E-12 | - | - |
| Freundlich Exponent | | 0.910 | 1.000 | 1.000 |
| Plant Uptake Factor | | 0.0 | 0.0 | 0.0 |
| Walker Exponent | | 0.7 | 0.7 | 0.7 |
| PELMO Parameters | | | | |
| Substance Code | | AS | A1 | A2 |
| Rate Constant | [1/day] | 0.0273 | 0.1954 | 0.0709 |
| Q ₁₀ | | 2.58 | 2.58 | 2.58 |
| K _{oc} | [mL/g] | 48.0 | 0.0 | 5.2 |
| Degradation fraction from → to (FOCUS PELMO) | | 0.0153000 AS → A1 0.0064300 AS → BR/CO ₂ 0.0186800 A1 → A2 0.173600 A1 → BR/CO ₂ 0.0070900 A2 → BR/CO ₂ | | |

Findings:

PEC_{gw} were evaluated as the 80th percentile of the mean annual leachate concentration at 1 m soil depth. All PEC_{gw} values (Calculations 1-3) for mesosulfuron-methyl are given in Table 9.6.1- 6.

Table 9.6.1- 6: PEC_{gw} (PEARL & PELMO) of mesosulfuron-methyl in winter cereals

| FOCUS Scenario | Mesosulfuron-methyl | | | |
|----------------|--|-----------------------------|---|-----------------------------|
| | Winter cereals 1 × 15 g a.s./ha, 50% interception | | Winter cereals 1 × 6 g a.s./ha, 50% interception | |
| | PEARL | PELMO | PEARL | PELMO |
| | Calculation 1* | Calculation 2&3* | Calculation 1* | Calculation 2&3* |
| | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] |
| | 0.002 | 0.002 | <0.001 | 0.001 |
| | 0.023 | 0.023 | 0.007 | 0.007 |
| | 0.007 | 0.008 | 0.002 | 0.003 |
| | 0.015 | 0.018 | 0.004 | 0.005 |
| | 0.038 | 0.042 | 0.009 | 0.010 |
| | 0.009 | 0.011 | 0.003 | 0.003 |
| | 0.011 | 0.017 | 0.003 | 0.005 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |

* Calculation 1, 2 and 3 - for compound specific input parameters see Table 9.6.1- 3,

Table 9.6.1- 4 and

Table 9.6.1-

Conclusion:

PEC_{gw} does not reach or exceed the parametric limit value of 0.1 µg/L in any of the simulation scenarios. There are no concerns for groundwater from the use of mesosulfuron-methyl in accordance with the use pattern for the representative formulation.



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Alternative PEC_{gw} simulation using RMS requested modelling parameters:

| | |
|---------------------|---|
| Report: | [redacted]; 2015;M-517436-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{gw} FOCUS PEARL EUR(combination) - Use in winter cereals in Europe |
| Report No: | EnSa-15-0312 |
| Document No: | M-517436-01-1 |
| Guidelines: | not applicable;not applicable |
| GLP/GEP: | no |

| | |
|---------------------|---|
| Report: | [redacted]; 2015;M-517440-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{gw} FOCUS PELMO EUR (pathway 1, combination) - Use in winter cereals in Europe |
| Report No: | EnSa-15-0313 |
| Document No: | M-517440-01-1 |
| Guidelines: | not applicable;not applicable |
| GLP/GEP: | no |

| | |
|---------------------|--|
| Report: | [redacted]; 2015;M-517442-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{gw} FOCUS PELMO EUR (pathway 2) - Use in winter cereals in Europe |
| Report No: | EnSa-15-0314 |
| Document No: | M-517442-01-1 |
| Guidelines: | not applicable;not applicable |
| GLP/GEP: | no |

The documents report an alternative calculation of predicted environmental concentrations in groundwater, following the methodology presented under KIIIA 9.6.1/01 to /03 before, but applying a set of modelling parameters requested by the RMS.

Materials and Methods: reference is made to KIIIA 9.6.1/01 to /03. See summary before.

Table 9.6.1- 7: Application pattern used for PEC_{gw} Calculations

| Individual crop | FOCUS crop used for interception | Application | | | | Amount reaching soil per season application [g a.s./ha] |
|-------------------------------|----------------------------------|-----------------------------|-----------------|------------------------|------------|---|
| | | Rate per season [g a.s./ha] | Interval [days] | Plant interception [%] | BBCI Stage | |
| Winter wheat GAP & Simulation | winter cereals | 1 × 15.0 | ! | 20 | 20-32 | 1 × 12.0 |
| Winter rye GAP & Simulation | winter cereals | 1 × 6.0 | ! | 20 | 20-32 | 1 × 4.8 |

Application timing: reference is made to KIIIA 9.6.1/01 to /03, see summary before.

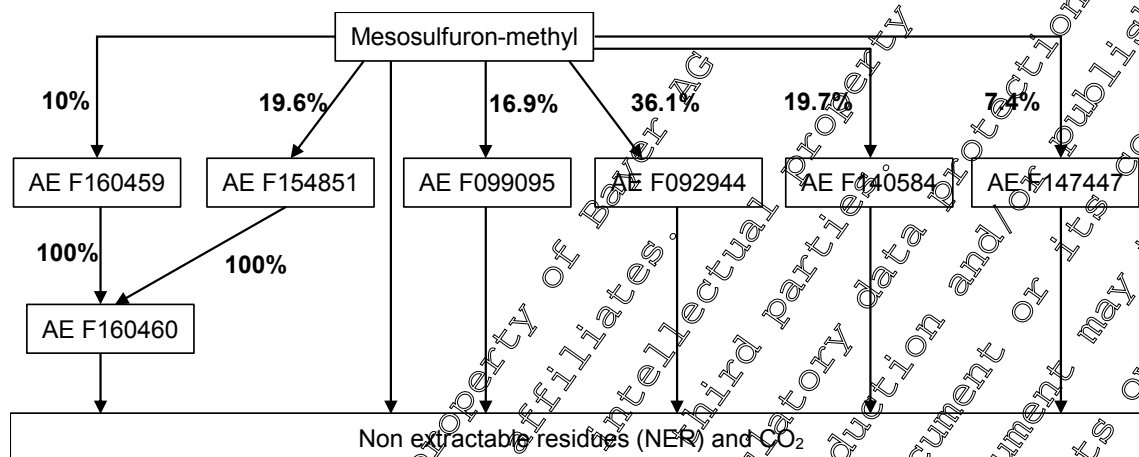
Substance-specific and model-related input parameters for the different PEC_{gw} calculations are summarised in the following tables.

1. Calculation 1: FOCUS PEARL with parent and all metabolites (Table 9.6.1-8).
2. Calculation 2: FOCUS PELMO with parent and metabolites AE F154851, AE F160459, AE F099095, AE F092944, and AE F160460 (Table 9.6.1-9).
3. Calculation 3: FOCUS PELMO with parent and metabolites AE F140584 and AE F147447 (Table 9.6.1-10).



Document MCP: Section 9 Fate and behaviour in the environment
Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Soil degradation of mesosulfuron-methyl and its metabolites is described based on a set of kinetic parameters requested by the RMS. The degradation pathway scheme used for modelling is shown below, including the formations fractions considered for the metabolites.



As requested, soil adsorption was described by the geometric mean K_{oc} and K_{om} values for all components, except metabolite AE F140584, for which a worst case default value of zero was used in the absence of experimental data. For concentration dependency, arithmetic mean Freundlich exponents were used, or a default value of 1.0 in the absence of experimental information.

Ignoring the systemic action of mesosulfuron-methyl, a worst case default for plant uptake ($PUF = 0$) was assumed for parent active substance and all metabolites in this first tier calculation.

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Document MCP: Section 9 Fate and behaviour in the environment
Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.6.1- 8: Substance specific and model related input parameter for PEARL PEC_{gw} calculation of mesosulfuron-methyl and its metabolites (model parameters not listed are kept as default) – Calculation 1

| Parameter | Unit | Mesosulfuron-methyl | AE F154851 | AE F160459 | AE F099095 |
|--|----------|--|------------|------------|------------|
| Molar Mass | [g/mol] | 503.5 | 489.5 | 489.5 | 198.2 |
| Solubility (20 °C) | [mg/L] | 483 | 20000 | 10000 | 190 |
| Vapour Pressure (20 °C) | [Pa] | 3.50E-12 | 1.70E-08 | 6.80E-08 | 1.90E-05 |
| Freundlich Exponent | | 0.910 | 0.940 | 0.940 | 0.840 |
| Plant Uptake Factor | | 0.0 | 0.0 | 0.0 | 0.0 |
| Walker Exponent | | 0.7 | 0.7 | 0.7 | 0.7 |
| PEARL Parameters | | | | | |
| Substance Code | | MSM | M851 | M459 | M095 |
| DT ₅₀ | [days] | 42.4 | 52.4 | 44.9 | 104.6 |
| Molar Activ. Energy | [kJ/mol] | 65.4 | 65.4 | 65.4 | 65.4 |
| K _{om} | [mL/g] | 37.1 | 37.7 | 11.2 | 204.0 |
| Parameter | Unit | AE F092944 | AE F160460 | AE F140584 | AE F147497 |
| Molar Mass | [g/mol] | 155.2 | 475.5 | 322.4 | 290.0 |
| Solubility (20 °C) | [mg/L] | 5200 | 100000 | 100 | 150000 |
| Vapour Pressure (20 °C) | [Pa] | 2.60E-02 | 6.0E-07 | 1.30E-06 | 1.00E-08 |
| Freundlich Exponent | | 0.720 | 0.900 | 1.000 | 1.000 |
| Plant Uptake Factor | | 0.0 | 0.0 | 0.0 | 0.0 |
| Walker Exponent | | 0.7 | 0.7 | 0.7 | 0.7 |
| PEARL Parameters | | | | | |
| Substance Code | | M944 | M460 | M584 | M447 |
| DT ₅₀ | [days] | 39.8 | 29.3 | 4.3 | 162.8 |
| Molar Activ. Energy | [kJ/mol] | 65.4 | 65.4 | 65.4 | 65.4 |
| K _{om} | [mL/g] | 195.0 | 7.1 | 0.0 | 2.9 |
| Degradation fraction from → to (FOCUS PEARL) | | 0.190 MSM → M851 0.100 MSM → M459 0.169 MSM → M095 0.361 MSM → M944 0.197 MSM → M584 0.074 MSM → M447 1 M851 → M460 1 M459 → M460 | | | |

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Document MCP: Section 9 Fate and behaviour in the environment
Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.6.1- 9: Substance specific and model related input parameter for PELMO (pathway 1) PEC_{gw} calculation of mesosulfuron-methyl and its metabolites (model parameters not listed are kept as default) – Calculation 2

| Parameter | Unit | Mesosulfuron-methyl | AE F154851 | AE F160459 |
|--|-------------|--|-------------------|-------------------|
| Molar Mass | [g/mol] | 503.5 | 489.5 | 489.5 |
| Solubility (20 °C) | [mg/L] | 483 | | |
| Vapour Pressure (20 °C) | [Pa] | 3.50E-12 | | |
| Freundlich Exponent | | 0.910 | 0.940 | 0.940 |
| Plant Uptake Factor | | 0.0 | 0.0 | 0.0 |
| Walker Exponent | | 0.7 | 0.7 | 0.7 |
| PELMO Parameters | | | | |
| Substance Code | | AS | A1 | B1 |
| Rate Constant | [1/day] | 0.00633 | 0.00913 | 0.00816 |
| Q ₁₀ | | 2.58 | 2.58 | 2.58 |
| K _{oc} | [mL/g] | 64.0 | 65.0 | 19.3 |
| Parameter | Unit | AE F092095 | AE F092944 | AE F160460 |
| Molar Mass | [g/mol] | 192.2 | 15.2 | 45.5 |
| Solubility (20 °C) | [mg/L] | | | |
| Vapour Pressure (20 °C) | [Pa] | | | |
| Freundlich Exponent | | 0.840 | 0.720 | 0.990 |
| Plant Uptake Factor | | 0.0 | 0.0 | 0.0 |
| Walker Exponent | | 0.7 | 0.7 | 0.7 |
| PELMO Parameters | | | | |
| Substance Code | | C1 | D1 | B2 |
| Rate Constant | [1/day] | 0.00789 | 0.0148 | 0.02366 |
| Q ₁₀ | | 2.58 | 2.58 | 2.58 |
| K _{oc} | [mL/g] | 35.1 | 336 | 12.2 |
| Degradation rate from → to (FOCUS PELMO) | | 0.0032000 Active Substance -> A1 0.0016300 Active Substance -> B1 0.0027600 Active Substance -> C1 0.0039000 Active Substance -> D1 0.0284000 Active Substance -> <BR/CO2 0.0131280 A1 -> B2 0.0081640 B1 -> B2 0.0078900 C1 -> <BR/CO2 0.0114800 D1 -> <BR/CO2 0.0236670 B2 -> <BR/CO2 | | |

Table 9.6.1- 10: Substance specific and model related input parameter for PELMO (pathway 2) PEC_{gw} calculation of mesosulfuron-methyl and its metabolites (model parameters not listed are kept as default) – Calculation 3

| Parameter | Unit | Mesosulfuron-methyl | AE F140584 | AE F147447 |
|--|---------|---|------------|------------|
| Molar Mass | [g/mol] | 503.5 | 322.4 | 290.3 |
| Solubility (20 °C) | [mg/L] | 483 | | |
| Vapour Pressure (20 °C) | [Pa] | 3.50E-12 | | |
| Freundlich Exponent | | 0.910 | 1.000 | 1.000 |
| Plant Uptake Factor | | 0.0 | 0.0 | 0.0 |
| Walker Exponent | | 0.7 | 0.7 | 0.7 |
| PELMO Parameters | | | | |
| Substance Code | | AS | A1 | A2 |
| Rate Constant | [1/day] | 0.01635 | 0.16045 | 0.00426 |
| Q ₁₀ | | 2.58 | 2.58 | 2.58 |
| K _{oc} | [mL/g] | 64.0 | 0.0 | 5.1 |
| Degradation rate from → to (FOCUS PELMO) | | 0.0032200 Active Substance -> A1 0.0012100 Active Substance -> B1 0.0119200 Active Substance -> <BR/CO2 | | |



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

| | |
|--|-------------------------|
| | 0.1604510 A1 -> <BR/CO2 |
| | 0.0042590 A2 -> <BR/CO2 |

Findings:

Table 9.6.1- 11: PEC_{gw} (PEARL & PELMO) of mesosulfuron-methyl in winter cereals

| FOCUS Scenario | Mesosulfuron-methyl | | | |
|----------------|--|-----------------------------|---|-----------------------------|
| | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 0.6 g a.s./ha, 20% interception | |
| | PEARL | PELMO | PEARL | PELMO |
| | Calculation 1* | Calculation 2&3* | Calculation 1 | Calculation 2&3 |
| | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] |
| | 0.006 | 0.004 | 0.001 | 0.001 |
| | 0.049 | 0.052 | 0.015 | 0.016 |
| | 0.015 | 0.019 | 0.004 | 0.005 |
| | 0.033 | 0.057 | 0.010 | 0.010 |
| | 0.057 | 0.063 | 0.018 | 0.020 |
| | 0.022 | 0.027 | 0.007 | 0.008 |
| | 0.022 | 0.034 | 0.005 | 0.011 |
| | 0.001 | <0.001 | <0.001 | <0.001 |
| | 0.002 | 0.001 | 0.001 | <0.001 |

* Calculation 1, 2 and 3 - for compound specific input parameters see Table 9.6.1-8, Table 9.6.1-9 and Table 9.6.1-10

Conclusion:

PEC_{gw} does not reach or exceed the parametric limit value of 0.1 µg/L in any of the simulation scenarios. There are no concerns for groundwater from the use of mesosulfuron-methyl in accordance with the use pattern for the representative formulation.

IIIA 9.6.2 Relevant metabolites

PEC_{gw} for mesosulfuron-methyl metabolites

According to the definition of residues relevant for groundwater risk assessment, the following degradates were considered for PEC_{gw} calculation: AE F154851, AE F160459, AE F099095, AE F092944, AE F160460, AE F140584 and AE F140447.

| | |
|---------------------|--|
| Report: | 5; ; 2014;M-481632-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{gw} FOCUS PEARL EUR (combination) Use in winter cereals in Europe |
| Report No: | EnS4-0363 |
| Document No: | M-481632-01-1 |
| Guidelines: | not applicable;not applicable |
| GLP/GEP: | no |



Document MCP: Section 9 Fate and behaviour in the environment

Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

| | |
|---------------------|---|
| Report: | [redacted];2014;M-481633-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{gw} FOCUS PELMO EUR (pathway 1, combination) - Use in winter cereals in Europe |
| Report No: | EnSa-14-0364 |
| Document No: | M-481633-01-1 |
| Guidelines: | not applicable;not applicable |
| GLP/GEP: | no |

| | |
|---------------------|--|
| Report: | [redacted];2014;M-481624-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{gw} FOCUS PELMO EUR (pathway 2) - Use in winter cereals in Europe |
| Report No: | EnSa-14-0229 |
| Document No: | M-481624-01-1 |
| Guidelines: | not applicable;not applicable |
| GLP/GEP: | no |

Materials and Methods: The PEC_{gw} for mesosulfuron-methyl metabolites were calculated using the approach, scenarios and application rates described for the parent active substance in section 9.6.1. Compound specific input data are summarized in Table 9.6.1- 3 (Calculation 1, PEARL), in

Table 9.6.1- 4 (Calculation 2, PELMO – pathway 1), and in

Table 9.6.1- 5 (Calculation 3, PELMO – pathway 2)

Findings: The 80th percentile PEC_{gw} values for the metabolites are given in the following tables for the use in winter cereals.

Table 9.6.2- 1: PEC_{gw} (PEARL & PELMO) of mesosulfuron-methyl metabolite AE F154851

| FOCUS Scenario | AE F154851 ⁵ | | | |
|----------------|---|-----------------------------|--|-----------------------------|
| | Winter cereals 10 15 g a.s./ha, 50% interception | | Winter cereals 10 6 g a.s./ha, 50% interception | |
| | PEARL | PELMO | PEARL | PELMO |
| | Calculation 1 | Calculation 2 | Calculation 1 | Calculation 2 |
| | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] |
| [redacted] | 0.003 | 0.002 | <0.001 | 0.001 |
| [redacted] | 0.015 | 0.016 | 0.005 | 0.005 |
| [redacted] | 0.006 | 0.007 | 0.002 | 0.002 |
| [redacted] | 0.011 | 0.012 | 0.004 | 0.004 |
| [redacted] | 0.017 | 0.018 | 0.006 | 0.006 |
| [redacted] | 0.007 | 0.009 | 0.003 | 0.003 |
| [redacted] | 0.009 | 0.010 | 0.002 | 0.004 |
| [redacted] | <0.001 | <0.001 | <0.001 | <0.001 |
| [redacted] | 0.001 | <0.001 | <0.001 | <0.001 |

⁵ Results of supportive calculation using alternative set of formation fractions, as requested by RMS France (ANSES): Only small (max. Δ = 0.009 µg/L) to negligible numeric differences in PEC_{gw} for the concerned metabolites and successor component AE F160460; changes remain without impact of on regulatory conclusions.

- AE F154851: max. 0.019 µg/L (PEARL) / 0.021 µg/L (PELMO)
- AE F160460: max. 0.107 µg/L (PEARL) / 0.112 µg/L (PELMO)
- AE F099095: max. <0.001 µg/L (PEARL) / <0.001 µg/L (PELMO)
- AE F092944: max. <0.001 µg/L (PEARL) / <0.001 µg/L (PELMO)



Document MCP: Section 9 Fate and behaviour in the environment

Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.6.2- 2: PEC_{gw} (PEARL & PELMO) of mesosulfuron-methyl metabolite AE F160459

| FOCUS Scenario | AE F160459 | | | |
|----------------|--|-----------------------------|---|-----------------------------|
| | Winter cereals 1 × 15 g a.s./ha, 50% interception | | Winter cereals 1 × 6 g a.s./ha, 50% interception | |
| | PEARL | PELMO | PEARL | PELMO |
| | Calculation 1 | Calculation 2 | Calculation 1 | Calculation 2 |
| | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] |
| | 0.046 | 0.044 | 0.017 | 0.017 |
| | 0.085 | 0.085 | 0.032 | 0.033 |
| | 0.079 | 0.082 | 0.029 | 0.030 |
| | 0.056 | 0.066 | 0.021 | 0.025 |
| | 0.058 | 0.061 | 0.022 | 0.024 |
| | 0.039 | 0.050 | 0.005 | 0.019 |
| | 0.037 | 0.040 | 0.014 | 0.015 |
| | 0.010 | 0.014 | 0.003 | 0.005 |
| | 0.034 | 0.025 | 0.017 | 0.009 |

Table 9.6.2- 3: PEC_{gw} (PEARL & PELMO) of mesosulfuron-methyl metabolite AE F099095

| FOCUS Scenario | AE F099095 | | | |
|----------------|--|-----------------------------|---|-----------------------------|
| | Winter cereals 1 × 15 g a.s./ha, 50% interception | | Winter cereals 1 × 6 g a.s./ha, 50% interception | |
| | PEARL | PELMO | PEARL | PELMO |
| | Calculation 1 | Calculation 2 | Calculation 1 | Calculation 2 |
| | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |

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Document MCP: Section 9 Fate and behaviour in the environment

Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.6.2- 6: PEC_{gw} (PEARL & PELMO) of mesosulfuron-methyl metabolite AE F140584

| FOCUS Scenario | AE F140584 | | | |
|----------------|--|-----------------------------|---|-----------------------------|
| | Winter cereals 1 × 15 g a.s./ha, 50% interception | | Winter cereals 1 × 6 g a.s./ha, 50% interception | |
| | PEARL | PELMO | PEARL | PELMO |
| | Calculation 1 | Calculation 3 | Calculation 1 | Calculation 3 |
| | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] |
| | 0.001 | 0.001 | 0.001 | 0.001 |
| | 0.014 | 0.045 | 0.005 | 0.006 |
| | 0.027 | 0.041 | 0.010 | 0.016 |
| | 0.004 | 0.006 | 0.001 | 0.002 |
| | 0.008 | 0.012 | 0.003 | 0.004 |
| | 0.003 | 0.005 | <0.001 | 0.002 |
| | 0.005 | 0.012 | 0.002 | 0.004 |
| | <0.001 | 0.001 | <0.001 | 0.001 |
| | <0.001 | 0.001 | <0.001 | <0.001 |

Table 9.6.2- 7: PEC_{gw} (PEARL & PELMO) of mesosulfuron-methyl metabolite AE F147447

| FOCUS Scenario | AE F147447 | | | |
|----------------|--|-----------------------------|---|-----------------------------|
| | Winter cereals 1 × 15 g a.s./ha, 50% interception | | Winter cereals 1 × 6 g a.s./ha, 50% interception | |
| | PEARL | PELMO | PEARL | PELMO |
| | Calculation 1 | Calculation 3 | Calculation 1 | Calculation 3 |
| | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] |
| | 0.085 | 0.073 | 0.034 | 0.029 |
| | 0.106 | 0.091 | 0.042 | 0.036 |
| | 0.163 | 0.122 | 0.065 | 0.049 |
| | 0.059 | 0.070 | 0.024 | 0.028 |
| | 0.057 | 0.056 | 0.023 | 0.022 |
| | 0.052 | 0.069 | 0.021 | 0.027 |
| | 0.052 | 0.048 | 0.020 | 0.019 |
| | 0.033 | 0.032 | 0.013 | 0.013 |
| | 0.077 | 0.051 | 0.030 | 0.020 |

Conclusion: For the product use in winter rye (6 g a.s./ha), PEC_{gw} does not reach or exceed the trigger value of 0.1 µg/L for any of the metabolites in any of the FOCUS groundwater scenarios; thus the risk is acceptable for groundwater with no further assessment required.

For the product use in winter wheat (15 g a.s./ha), PEC_{gw} of metabolites AE F160460 and AE F147447 was predicted to reach or exceed the trigger of 0.1 µg/L for 1/9 or 2/9 of the FOCUS groundwater scenarios, respectively. The maximum predicted concentrations in groundwater recharge were 0.103 µg/L for AE F160460 and 0.163 µg/L for AE F147447.

An assessment of the potential relevance in groundwater for these components is therefore made following the guidance given in SANCO 221/2000. Details hereon are found in Document N4, only a brief summary is provided below:

Screening for herbicidal activity:



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Both components were assayed for herbicidal activity in greenhouse tests (see KCA 3.6/03), and were found not to retain comparable target activity as the parent active substance.

Screening for genotoxicity:

Both components were assayed in a standard battery of genotoxicity and mutagenicity tests *in-vitro*, (see KCA 5.8.1/01 to /06) and were found clearly devoid of mutagenic potential.

Screening for toxicity:

The active substance mesosulfuron-methyl has not been classified as being toxic or very toxic, reproductive toxic or carcinogenic; there is no indication that the metabolites would bear any specific risks for toxicity. No further toxicity assessment is therefore triggered for metabolites.

Metabolites AE F160460 and AE F147447 fulfil the criteria for being considered 'non-relevant for groundwater' at Step 4 of the guidance. For simulated PEC_{gw} below the trigger level of 0.7 µg/L, no quantitative consumer risk assessment is deemed necessary.

In overall conclusion, there are no concerns for groundwater with regard to metabolites from the intended use of mesosulfuron-methyl in the present formulation.

Alternative PEC_{gw} simulation using RMS requested modelling parameters:

| | |
|--------------|--|
| Report: | [REDACTED] S; [REDACTED] 2015;M-517436-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{gw} FOCUS PEARL EUR (combination) - Use in winter cereals in Europe |
| Report No: | EnSa-15-0312 |
| Document No: | M-517436-01-1 |
| Guidelines: | not applicable;not applicable |
| GLP/GEP: | no |
| Report: | [REDACTED] S; [REDACTED] 2015;M-517440-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{gw} FOCUS PELMO EUR (pathway 2) (combination) - Use in winter cereals in Europe |
| Report No: | EnSa-15-0313 |
| Document No: | M-517440-01-1 |
| Guidelines: | not applicable;not applicable |
| GLP/GEP: | no |
| Report: | [REDACTED] S; [REDACTED] 2015;M-517442-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{gw} FOCUS PELMO EUR (pathway 2) - Use in winter cereals in Europe |
| Report No: | EnSa-15-0314 |
| Document No: | M-517442-01-1 |
| Guidelines: | not applicable;not applicable |
| GLP/GEP: | no |

The documents report an alternative calculation of predicted environmental concentrations in groundwater, following the methodology presented under KIIIA 9.6.2/01 to /03 before, but applying a set of modelling parameters requested by the RMS.



Document MCP: Section 9 Fate and behaviour in the environment
Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Materials and Methods: reference is made to KIII A 9.6.2/01 to /03, see summary before.

Findings:

Table 9.6.2- 8: PEC_{gw} (PEARL & PELMO) of mesosulfuron-methyl metabolite AE F154851

| FOCUS Scenario | AE F154851 | | | |
|----------------|--|-----------------------------|---|-----------------------------|
| | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | PEARL | PELMO | PEARL | PELMO |
| | Calculation 1 | Calculation 2 | Calculation 1 | Calculation 2 |
| | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] |
| | 0.019 | 0.015 | 0.006 | 0.005 |
| | 0.062 | 0.065 | 0.029 | 0.023 |
| | 0.033 | 0.039 | 0.011 | 0.013 |
| | 0.044 | 0.052 | 0.016 | 0.018 |
| | 0.060 | 0.062 | 0.024 | 0.023 |
| | 0.032 | 0.038 | 0.014 | 0.016 |
| | 0.030 | 0.036 | 0.010 | 0.013 |
| | <0.001 | 0.001 | <0.001 | <0.001 |
| | 0.010 | 0.005 | 0.003 | 0.002 |

Table 9.6.2- 9: PEC_{gw} (PEARL & PELMO) of mesosulfuron-methyl metabolite AE F160459

| FOCUS Scenario | AE F160459 | | | |
|----------------|--|-----------------------------|---|-----------------------------|
| | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | PEARL | PELMO | PEARL | PELMO |
| | Calculation 1 | Calculation 2 | Calculation 1 | Calculation 2 |
| | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] |
| | 0.122 | 0.117 | 0.046 | 0.044 |
| | 0.203 | 0.206 | 0.077 | 0.079 |
| | 0.216 | 0.201 | 0.080 | 0.076 |
| | 0.158 | 0.162 | 0.049 | 0.059 |
| | 0.227 | 0.129 | 0.049 | 0.050 |
| | 0.094 | 0.123 | 0.036 | 0.047 |
| | 0.097 | 0.090 | 0.035 | 0.035 |
| | 0.040 | 0.048 | 0.015 | 0.018 |
| | 0.115 | 0.074 | 0.043 | 0.028 |

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Table 9.6.2- 10: PEC_{gw} (PEARL & PELMO) of mesosulfuron-methyl metabolite AE F099095

| FOCUS Scenario | AE F099095 | | | |
|----------------|--|-----------------------------|---|-----------------------------|
| | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | PEARL | PELMO | PEARL | PELMO |
| | Calculation 1 | Calculation 2 | Calculation 1 | Calculation 2 |
| | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | 0.063 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | 0.001 | <0.001 | <0.001 |
| | <0.001 | 0.001 | <0.001 | <0.001 |
| | <0.001 | 0.001 | <0.001 | <0.001 |
| | <0.001 | 0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |

Table 9.6.2- 11: PEC_{gw} (PEARL & PELMO) of mesosulfuron-methyl metabolite AE F092944

| FOCUS Scenario | AE F092944 | | | |
|----------------|--|-----------------------------|---|-----------------------------|
| | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | PEARL | PELMO | PEARL | PELMO |
| | Calculation 1 | Calculation 2 | Calculation 1 | Calculation 2 |
| | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | 0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |
| | <0.001 | <0.001 | <0.001 | <0.001 |

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Table 9.6.2- 12: PEC_{gw} (PEARL & PELMO) of mesosulfuron-methyl metabolite AE F160460

| FOCUS Scenario | AE F160460 | | | |
|----------------|--|-----------------------------|---|-----------------------------|
| | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | PEARL | PELMO | PEARL | PELMO |
| | Calculation 1 | Calculation 2 | Calculation 1 | Calculation 2 |
| | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] |
| | 0.130 | 0.124 | 0.047 | 0.045 |
| | 0.248 | 0.266 | 0.092 | 0.099 |
| | 0.241 | 0.255 | 0.085 | 0.092 |
| | 0.150 | 0.174 | 0.057 | 0.065 |
| | 0.159 | 0.164 | 0.060 | 0.062 |
| | 0.109 | 0.093 | 0.041 | 0.053 |
| | 0.109 | 0.121 | 0.040 | 0.046 |
| | 0.032 | 0.044 | 0.012 | 0.015 |
| | 0.098 | 0.067 | 0.035 | 0.024 |

Table 9.6.2- 13: PEC_{gw} (PEARL & PELMO) of mesosulfuron-methyl metabolite AE F140584

| FOCUS Scenario | AE F140584 | | | |
|----------------|--|-----------------------------|---|-----------------------------|
| | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | PEARL | PELMO | PEARL | PELMO |
| | Calculation 1 | Calculation 2 | Calculation 1 | Calculation 3 |
| | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] |
| | 0.001 | 0.001 | <0.001 | <0.001 |
| | 0.011 | 0.011 | 0.004 | 0.006 |
| | 0.020 | 0.028 | 0.008 | 0.016 |
| | 0.003 | 0.004 | 0.001 | 0.002 |
| | 0.006 | 0.008 | 0.002 | 0.004 |
| | 0.002 | 0.004 | <0.001 | 0.002 |
| | 0.004 | 0.008 | 0.002 | 0.004 |
| | <0.001 | 0.001 | <0.001 | <0.001 |
| | 0.001 | 0.001 | <0.001 | <0.001 |

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Table 9.6.2- 14: PEC_{gw} (PEARL & PELMO) of mesosulfuron-methyl metabolite AE F147447

| FOCUS Scenario | AE F147447 | | | |
|----------------|--|-----------------------------|---|-----------------------------|
| | Winter cereals 1 × 15 g a.s./ha, 20% interception | | Winter cereals 1 × 6 g a.s./ha, 20% interception | |
| | PEARL | PELMO | PEARL | PELMO |
| | Calculation 1 | Calculation 3 | Calculation 1 | Calculation 3 |
| | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] | PEC _{gw} [µg/L] |
| | 0.224 | 0.207 | 0.089 | 0.082 |
| | 0.217 | 0.186 | 0.087 | 0.074 |
| | 0.337 | 0.242 | 0.135 | 0.097 |
| | 0.119 | 0.141 | 0.048 | 0.056 |
| | 0.114 | 0.113 | 0.046 | 0.045 |
| | 0.130 | 0.062 | 0.042 | 0.064 |
| | 0.111 | 0.108 | 0.044 | 0.043 |
| | 0.116 | 0.098 | 0.046 | 0.039 |
| | 0.239 | 0.163 | 0.095 | 0.065 |

Conclusion: The maximum predicted concentrations in groundwater recharge of metabolites AE F160459, AE F160460 and AE F147447 reach or exceed the parametric trigger value of 0.1 µg/L for some use and FOCUS groundwater scenario combinations. The overall maximum PEC_{gw} values were 0.216 µg/L for AE F160459, 0.266 µg/L for AE F160460, and 0.337 µg/L for AE F147447.

An assessment of the potential relevance in groundwater for these components is therefore made following the guidance given in SANCO 221/2006. Details hereon are found in Document N4, only a brief summary is provided below.

Screening for herbicidal activity:

All three components were assayed for herbicidal activity in greenhouse tests (see KCA 3.6/03), and were found not to retain comparable target activity as the parent active substance.

Screening for genotoxicity:

AE F160460 and AE F147447 were assayed in a standard battery of genotoxicity and mutagenicity tests *in-vitro* (see KCA 3.8.1/01 to /06), and were found clearly devoid of mutagenic potential.

AE F160459 is characterised by a close chemical similarity with the parent compound mesosulfuron-methyl, and with metabolite AE F160460, the only structural difference between the molecules being the presence or absence of methyl substituents. As all the *in vitro* genotoxicity studies with mesosulfuron-methyl, as well as with metabolite AE F160460, were clearly negative when tested both with and without the metabolic activation mix S9, it can be concluded that also AE F160459 is devoid of mutagenic potential. Moreover, AE F160459 is a rat metabolite of mesosulfuron-methyl, and as such has been indirectly tested in the *in vitro* genotoxicity studies in presence of metabolic activation mix S9, which is added *in vitro* to mimic the metabolism of test substance that would occur *in vivo* in mammals. AE F160459 was also present in all apical rat studies, including the chronic toxicity and carcinogenicity and reproduction toxicity studies on mesosulfuron-methyl.



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Screening for toxicity:

The active substance mesosulfuron-methyl has not been classified as being toxic or very toxic, reproductive toxic or carcinogenic; there is no indication that the metabolites would bear any specific risks for toxicity. No further toxicity assessment is therefore triggered for metabolites.

Metabolites AE F160459, AE F160460, and AE F147447 fulfil the criteria for being considered 'non-relevant for groundwater' at Step 4 of the guidance. For simulated PEC_{gw} below the trigger level of 0.75 µg/L, no quantitative consumer risk assessment is deemed necessary.

In overall conclusion, there are no concerns for groundwater with regard to metabolites from the intended use of mesosulfuron-methyl in the present formulation.

IIIA 9.6.3 Additional field testing

No additional field testing was required.

IIIA 9.6.4 Information on impact on water treatment procedures

No impact of mesosulfuron-methyl on sewage treatment processes was concluded in the EU review, based on results of an inhibition test of activated sludge respiration, and on cell multiplication of *Pseudomonas putida*, a representative bacteria of fresh water.

The possibility of impact of mesosulfuron-methyl residues on drinking water treatment was analysed in a statement summarised below:

| | |
|---------------------|---|
| Report: | 2015;M-510337-01 |
| Title: | Concentrations of mesosulfuron-methyl and its metabolites in drinking water - Statement |
| Report No: | M-510337-01-1 |
| Document No: | M-510337-01-1 |
| Guidelines: | not specified;not specified |
| GLP/GEP: | n.a. |

Based on the predicted environmental concentrations for representative uses of mesosulfuron-methyl, an estimate was made for the concentrations of parent active substance and metabolites to be expected at ground- and surface water abstraction points for the production of drinking water.

From this assessment it was concluded that the substance concentrations potentially entering processes for drinking water treatment would only be minimal, i.e. by far less than 0.1 µg/L, and would therefore be highly unlikely to result in the formation of significant levels of by-products that would require human or animal health risk assessment.

Therefore, it was concluded that further information on the effect of water treatment processes on the nature of residues present in surface water and groundwater are not required.



IIIA 9.7 Predicted Environmental Concentrations in Surface Water (PEC_{sw}) for the Active Substance

Summary of fate and behaviour of mesosulfuron-methyl in water

Abiotic hydrolysis: Mesosulfuron-methyl is only slowly hydrolysed in sterile buffer solutions at neutral to alkaline pH (DT₅₀ = 253 d at pH 7, 25 °C, and 318 d at pH 9, 25 °C), but degrades more rapidly in an acidic environment (DT₅₀ = 3.5 d at pH 4, 25 °C). The hydrolytic pathway involves cleavage of the sulfonylurea bridge to form AE F092944 (all pH), and AE F140584 (acidic environment) or AE F147447 (neutral and alkaline environment). As a minor pathway under alkaline conditions, additionally hydrolysis of the methyl ester function may occur, to result in small amounts of AE F154851.

Aqueous photolysis: Mesosulfuron-methyl is not photodegraded to significant extent at wavelengths >290 nm in sterile buffer solution. Direct photolysis will therefore not contribute notably to elimination from the aquatic environment, and will not lead to the generation of relevant degradates.

Water/sediment: Mesosulfuron-methyl was found microbially degraded in two tested aerobic sediment/water systems. The proposed route of degradation is consistent with the route of degradation in aerobic soil, all components shown in Figure 9.1.1-1 were also identified in the water / sediment study. The products of predominant abundance were AE F160459, AE F147447, and AE F160460, which reached maximum abundances of 21.6%AR, 10.9%AR, and 8.4%AR in the total systems, respectively (Table CA 7.2-1). All further degradates remained below 1%AR until sampling day 140. Terminal bioconversion led into the formation of non-extractable residues, and ¹⁴C-carbon dioxide.

The study was kinetically evaluated according FOCUS (2006), an overview of this information provided in the table below:

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Table 9.7- 1: Total system DT₅₀ values and maximum abundances of mesosulfuron-methyl and its metabolites in aerobic water/sediment

| Test system | Mesosulfuron-methyl (days) | AE F154851 (days) | AE F160459 (days) | AE F099095 (days) | AE F092944 (days) | AE F160460 (days) | AE F140584 (days) | AE F141407 (days) |
|------------------------------|-------------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| █ (phenyl label) | 81.2 | 255 | 14 | n.d. | 25.9 | 47.1 | n.d. | 205 |
| █ (pyrimidyl label) | 70.3 | 98.5 | 64.8 | n.d. | 25.9 | 22.9 | n.d. | - b) |
| █ (phenyl label) | 33.1 | 10.8 | 40.4 | n.d. | n.d. | 16.2 | n.d. | n.d. |
| █ (pyrimidyl label) | 23.3 | 8.2 | 16.8 | n.d. | n.d. | 14 | n.d. | - b) |
| Endpoint^{a)} | 45.8 | 38.6 | 47.3 | (1000) | 25.9 | 38.3 | (1000) | 205 |
| Max. abundance [%AR] | (100) | 4.9 | 21.6 | 0.9 | 3.2 | 8.4 | 1.9 | 10.9 |

a) geometric mean for more than 1 value, worst case default of 1000 days where no reliable DT₅₀ derived
b) component not traced by radiolabel position
n.d.: no reliable value determinable

Endpoints for PEC

Table 9.7- 2: Comparison of proposed EU endpoints and modelling input parameters for mesosulfuron-methyl

| End-point | Active substance: mesosulfuron-methyl | |
|---|---------------------------------------|---------------------------------|
| | Proposed EU endpoint [Document N2] | Value used for modelling |
| Mesosulfuron-methyl | | |
| Aqueous solubility [mg/L] | 483 | 483 |
| Vapour pressure [Pa] | 3×10^{-12} | 3.5×10^{-12} |
| DT ₅₀ soil [days] (geomean, lab) | 31.9 | 31.9 |
| K _{oc} [L/kg] (median) | 48 | 48 |
| K _{om} [L/kg] (median) | 27.8 | 27.8 |
| 1/n (arith. mean) | 0.910 | 0.910 |
| Plant uptake factor | 0 | 0 |
| DT ₅₀ water/sed. total system [days] | 45.8 | 45.8 |
| DT ₅₀ water [days] | 45.8 | 45.8 |
| DT ₅₀ sediment [days] | 45.8 (Step 1&2) / 1000 (Step 3) | 45.8 (Step 1&2) / 1000 (Step 3) |

PEC_{sw} modelling approach: FOCUS_{sw} Scenario Calculation

The calculation according FOCUS methodology is a tiered approach with up to four steps. Generally, different potential entry routes of a substance into surface water like spray drift, run-off, erosion and drainage are considered, and in each step PEC values in water and in sediment are calculated.



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Step 1: In this, the most conservative step, all inputs are considered as a single generic loading to a static worst case water body, distributed between water and sediment within 1 day, and a worst-case PECsw and PECsed is calculated.

Step 2: A refinement is made to the Step 1 approach, whereby individual loadings into the water body from different entry routes are considered. Two scenarios are introduced to represent Northern and Southern Europe, but no specific crop scenarios are defined.

Step 1 & Step 2 simulations are run with the FOCUS Steps 1-2 Calculator tool.

Step 3: A more detailed exposure assessment based on 10 realistic worst-case scenarios is made. The scenarios are divided into six scenarios where drainage is the relevant entry route and four where run-off is relevant; spray drift is considered for all scenarios. Three water bodies of differing size and hydrology have been defined, stream, pond and ditch. The scenario settings are each representative of certain agricultural conditions in Europe with respect to weather, soil, crop and water bodies, so that an appropriate subset of scenarios relevant to a specific country and crop can be defined.

The simulations are done using the models PRZM (for entries due to run-off and erosion), MAGRO (for inputs due to drainage) and TOXSWA (for simulation of the behaviour in the water body). The FOCUS SWASH tool is a utility which enables an automatic input of relevant data into the three simulation models.

Step 4: A higher-tier refinement to the Step 3 PEC results is made on a case-by-case basis, e.g. via considering specific mitigation measures, or implementing certain scenario modifications specifically applicable to the respective product use.

PECsw calculations for mesosulfuron-methyl

Table with 2 columns: Field Name and Value. Fields include Report, Title, Report No, Document No, Guidelines, and GLP/GEP.

Materials and Methods:

Predicted environmental concentrations in surface water and sediment (PECsw and PECsed) of mesosulfuron-methyl have been calculated for the use in winter cereals in Europe, via the tiered FOCUSsw approach.

Detailed application data used for simulation of PECsw were compiled in Table 9.7Table 9.7-.



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Table 9.7- 3: Application pattern used for PEC_{C_{sw, sed}} calculations (FOCUS Step 1&2)

| Individual crop | FOCUS crop used for interception | Application | | | | Amount reaching soil per season application [g a.s./ha] |
|-------------------------------|----------------------------------|------------------------------|-----------------|--------------------------|------------|---|
| | | Rate per season [g a.s. /ha] | Interval [days] | Plant interception [%] | BBCH Stage | |
| Winter wheat GAP & Simulation | cereals, winter (arable crops) | 1 × 15 | - | average crop cover (50%) | 20-32 | 1 × 3.0 |
| Winter rye GAP & Simulation | cereals, winter (arable crops) | 1 × 6 | - | average crop cover (50%) | 20-32 | 3.0 |

Application timing: The spring application in winter cereals according to GAP is done at the end of winter, at the beginning of the vegetation period (i.e. when the temperature is high enough to expect crop and weed growth), onto well-developed crop.

At FOCUS Step 2 the application period in the model was set to “October to February” which will also represent the worst case of the available timing periods.

At FOCUS Step 3 actual application dates are generally determined by the PAT (pesticide application timer) included within SWASH, which selects an appropriate actual application date to ensure at least 10 mm of rainfall in the first 14 days after application, and at the same time less than 2 mm of rain per day in a five day period around the date of application. However, no predefined event dates are implemented in the FOCUS model that would directly translate the above-described cropping situation into discrete PAT windows for each surface water scenario setting. Therefore, the following approach was used to define suitable scenario-adapted application dates: The simulated treatment was referenced relative to the tabulated crop emergence date of the earliest emerging spring crop (i.e. not necessarily cereals) that was defined by FOCUS for the respective scenario. Start of the PAT window was then set to 14 days before that date, which is considered an adequate representation for the start of the vegetation period in the respective scenario environment. An overview of the resulting date selections used in Step 3 is found compiled in the tables below.

Table 9.7- 4: Spring emergence dates of earliest crops in the FOCUS_{sw} scenarios

| Scenario | Location | Crop | Emergence date | Julian date |
|----------|------------|------------------------------|----------------------|----------------------|
| D1 | [REDACTED] | spring cereals | 05-May | 21-Apr |
| D2 | [REDACTED] | spring cereals ^{a)} | 15-Mar ^{a)} | 01-Mar ^{a)} |
| D3 | [REDACTED] | spring cereals | 01-Apr | 18-Mar |
| D4 | [REDACTED] | field beans | 15-Apr | 01-Apr |
| D5 | [REDACTED] | spring cereals | 15-Mar | 01-Mar |
| D6 | [REDACTED] | root vegetables | 25-Feb | 11-Feb |
| R1 | [REDACTED] | field beans | 10-Apr | 27-Mar |
| R2 | [REDACTED] | bulb vegetables | 28-Feb | 14-Feb |
| R3 | [REDACTED] | root vegetables | 26-Feb | 12-Feb |
| R4 | [REDACTED] | root vegetables | 26-Feb | 12-Feb |

^{a)} no crop with emergence in spring defined; D5 data used instead



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Table 9.7- 5: Application dates of mesosulfuron-methyl for the FOCUS Step 3 calculations

| Parameter | Winter cereals (1 × 15 g a.s./ha) | | Winter cereals (1 × 6 g a.s./ha) | |
|---------------------------------|-----------------------------------|------------|----------------------------------|------------|
| PAT start date rel./absolute | Absolute | | Absolute | |
| Appl. method (appl. type) | ground spray (CAM 2) | | ground spray (CAM 2) | |
| No of appl. | 1 | | 1 | |
| PAT window range | 30 | | 30 | |
| Appl. interval | 1 | | 1 | |
| Application Details | PAT Start Date (Julian Day) | Appl. Date | PAT Start Date (Julian Day) | Appl. Date |
| D1 | 21-Apr (111) | 25-Apr | 21-Apr (111) | 25-Apr |
| D2 | 01-Mar (60) | 12-Mar | 01-Mar (60) | 12-Mar |
| D3 | 18-Mar (77) | 17-Mar | 18-Mar (77) | 17-Mar |
| D4 | 01-Apr (91) | 08-Apr | 01-Apr (91) | 08-Apr |
| D5 | 01-Mar (60) | 07-Mar | 01-Mar (60) | 07-Mar |
| D6 | 11-Feb (42) | 27-Feb | 11-Feb (42) | 27-Feb |
| R1 | 29-Mar (86) | 26-Apr | 27-Mar (86) | 26-Apr |
| R3 | 12-Feb (43) | 19-Feb | 12-Feb (43) | 19-Feb |
| R4 | 02-Feb (43) | 02-Mar | 12-Feb (43) | 02-Mar |

Application type: For both uses, application type CAM 2 was selected: crop canopy, default soil incorporation depth DEF for non foliar intercepted chemical is 4 cm; distribution: linearly decreasing with depth.

Substance specific input parameters for the FOCUS Step 1-3 calculations are listed in Table 9.7- .

Soil degradation of mesosulfuron-methyl and its metabolites was based on geometric mean DT₅₀ as derived from laboratory studies, normalized to 20°C and 100 % field capacity according to FOCUS (2000).

Soil adsorption was described by median K_{oc}/K_{om} for the parent active substance, or arithmetic mean values for all other components with experimental data from batch equilibrium studies available. For metabolite AE F40584 a worst case default value of zero soil adsorption was used in the absence of experimental data. For concentration dependency, arithmetic mean Freundlich coefficients were used, or a default value of 1.0 in the absence of experimental information.

For description of substance degradation in the water/sediment, according to FOCUS (2003) the total system degradation DT₅₀ is used for Step 1-2 calculations. In Step 3 calculations, total system degradation DT₅₀ is used for the water phase and default DT₅₀ of 1000 days for the sediment phase.

A default half-life of 1000 days is assumed as well for components where the experimental data did not allow for the derivation statistically reliable kinetic parameters.



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Ignoring the systemic action of mesosulfuron-methyl, a worst case default for plant uptake ($PUF = 0$) was assumed for parent active substance and all metabolites in this first tier calculation.

Table 9.7- 6: Substance parameters used for mesosulfuron-methyl at FOCUS Steps 1-3

| Parameter | Unit | Mesosulfuron-methyl |
|--------------------------------|-------|-----------------------------------|
| General | | |
| Molar Mass | g/mol | 503.1 |
| Water Solubility (pH 7, 20 °C) | mg/L | 483 |
| Vapour Pressure (20 °C) | Pa | 3.5E-12 |
| Plant Uptake Factor | - | 0.0 |
| Wash-Off Factor PRZM | l/cm | 0.3 |
| Wash-Off Factor MACRO | l/mm | 0.25 |
| Sorption | | |
| K_{oc} | ml/g | 48 |
| Freundlich Exponent | - | 0.9 |
| Degradation | | |
| Soil | day | 1.9 |
| Total System | days | 45.8 |
| Water | days | 45.8 |
| Sediment | days | 45.8 (Step 1 & 2) / 1000 (Step 3) |
| Walker Exponent | - | 0.7 |
| Max Occurrence | | |
| Water / Sediment | % | 100 |
| Soil | % | 100 |
| Effect of Temperature | | |
| Activation Energy | J/mol | 65400 |
| Exponent | 1/K | 0.095 |
| Q_{10} | - | 2.58 |

Findings:

Steps 1 and 2: The maximum PEC_{sw} and PEC_{sed} values for mesosulfuron-methyl at Steps 1 and 2 are given in Table 9.7- 6.

Table 9.7- 7: Maximum PEC_{sw} and PEC_{sed} values for mesosulfuron-methyl at Steps 1&2

| Use pattern | FOCUS scenario | Mesosulfuron-methyl | |
|------------------------------------|----------------------------|----------------------|------------------------|
| | | PEC_{sw} [µg/L] | PEC_{sed} [µg/kg] |
| Winter cereals 4 × 15 g a.s./ha | Step 1 | 4.837 | 2.256 |
| | Step 2 | | |
| | N-EU Single S-EU Single | 1.202 0.986 | 0.567 0.465 |
| Winter cereals 1 × 6 g a.s./ha | Step 1 | 1.935 | 0.902 |
| | Step 2 | | |
| | N-EU Single S-EU Single | 0.481 0.395 | 0.227 0.186 |

Step 3: The maximum PEC_{sw} and PEC_{sed} values for relevant FOCUS Step 3 scenarios are given in Table 9.7- 7.



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Table 9.7- 8: Maximum PEC_{sw} and PEC_{sed} of mesosulfuron-methyl for all scenarios at Step 3 after application to winter cereals

| Use pattern | Mesosulfuron-methyl | | | | | |
|----------------|----------------------------------|--------------------------|----------------------------|---------------------------------|--------------------------|----------------------------|
| | Winter cereals, 1 × 15 g a.s./ha | | | Winter cereals, 1 × 6 g a.s./ha | | |
| FOCUS scenario | Entry route* | PEC _{sw} [µg/L] | PEC _{sed} [µg/kg] | Entry route* | PEC _{sw} [µg/L] | PEC _{sed} [µg/kg] |
| D1 (ditch) | S | 0.161 | 0.261 | S | 0.063 | 0.06 |
| D1 (stream) | S | 0.118 | 0.153 | S | 0.047 | 0.062 |
| D2 (ditch) | D | 1.601 | 0.904 | D | 0.576 | 0.363 |
| D2 (stream) | D | 1.010 | 0.522 | D | 0.366 | 0.270 |
| D3 (ditch) | S | 0.096 | 0.019 | S | 0.038 | 0.008 |
| D4 (pond) | D | 0.024 | 0.058 | D | 0.008 | 0.022 |
| D4 (stream) | S | 0.079 | 0.024 | S | 0.031 | 0.009 |
| D5 (pond) | S | 0.011 | 0.024 | S | 0.004 | 0.010 |
| D5 (stream) | S | 0.078 | 0.010 | S | 0.031 | 0.004 |
| D6 (ditch) | S | 0.102 | 0.025 | S | 0.041 | 0.010 |
| R1 (pond) | R | 0.066 | 0.009 | R | 0.002 | 0.004 |
| R1 (stream) | R | 0.170 | 0.016 | R | 0.043 | 0.007 |
| R3 (stream) | R | 0.325 | 0.046 | R | 0.130 | 0.019 |
| R4 (stream) | R | 0.246 | 0.046 | R | 0.100 | 0.020 |

* Entry route: letters S, D, and R correspond to the dominant entry path – spray drift, drainage and runoff

| | |
|----------------------|---|
| Report: | [redacted]; 2015-M-508737-04 |
| Title: | Mesosulfuron-methyl (MSM): Graphical outputs of predicted environmental concentrations in surface water - Use in winter cereals in Europe |
| Report No.: | EnSa-15-0033 |
| Document No.: | M-508737-01-1 |
| Guidelines: | not applicable, not applicable |
| GLP/GEP: | no |

Predicted environmental concentrations of the active substance mesosulfuron-methyl and its metabolites for the use in winter cereals in Europe were calculated and reported in the document EnSa-14-0230 (BCS document number M-481626-01-1, **KHJA 9.7 /01**).

The present report supplements the original document and provides graphical presentation of time resolution of PEC_{sw} concentrations calculated according to the FOCUS Surface Water (SW) approach (FOCUS 2003) at Step3 level. For each of the scenarios, 2 graphic files are provided. The overall time evolution of the respective concentration over the whole course of the TOXSWA simulation and a detailed view at the period around the observed maximum (1 week before the maximum and 8 weeks after the maximum) are shown. These information may support ecotoxicological risk assessments, where timecourse information is considered of importance in addition to the maximum concentrations listed above.

Alternative PEC_{sw} simulation using RMS requested modelling parameters:



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| | |
|----------------------|---|
| Report: | 4; :2015;M-517481-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{sw, sed} FOCUS EUR - Use in winter cereals in Europe |
| Report No.: | EnSa-15-0311 |
| Document No.: | M-517481-01-1 |
| Guidelines: | not applicable; not applicable |
| GLP/GEP: | no |

The document reports an alternative calculation of predicted environmental concentrations in surface water, following the methodology presented under KIIIA 9.7/01 and /02 before, but applying a set of modelling parameters requested by the RMS.

Materials and Methods: reference is made to KIIIA 9.7./01, see summary before.

Table 9.7- 9: Application pattern used for PEC_{sw, sed} calculations (FOCUS Step 1 & 2)

| Individual crop | FOCUS crop used for interception | Application | | | BBCH Stage | Amount reaching soil per season application [g a.s./ha] |
|-------------------------------|----------------------------------|-----------------------------|-----------------|--------------------------|------------|---|
| | | Rate per season [g a.s./ha] | Interval [days] | Plant interception [%] | | |
| Winter wheat GAP & Simulation | cereals, winter (arable crops) | 1 × 15 | 1 | average crop cover (20%) | 20-32 | 1 × 12.0 |
| Winter rye GAP & Simulation | cereals, winter (arable crops) | 1 × 6 | 1 | average crop cover (20%) | 20-32 | 1 × 4.8 |

Application timing

For FOCUS Step 2, reference is made to KIIIA 9.7./01, see summary before

For FOCUS Step 3 the procedure used was identical to that of the previous simulation KIIIA 9.7./01, nevertheless more extensive description is provided here below for better clarity:

Agronomically and in-line with the GAP, the spring application in winter cereals is done at the end of winter, at the beginning of the vegetation period (i.e. when the temperature is high enough to expect crop and weed growth), on a well developed crop. However, in the FOCUS model no pre-defined event dates are implemented for winter cereals that would directly translate the above described cropping situation into discrete PAT windows for each surface water scenario setting. Therefore, the following approach was used to define scenario-adapted application dates: the simulated treatment was referenced relative to the tabulated crop emergence date of the earliest emerging spring crop that is defined by FOCUS for the respective scenario. Start of the PAT window was then set to 14 days before that FOCUS event date date, which is considered an adequate representation for the start of the vegetation period in the respective scenario environment.

For technical reason, this relative timing can only be implemented in the model in form of manually entered 'absolute' PAT start dates, since the used auxiliary for referencing ('earliest emerging spring crop') is not identical to the simulated crop winter cereals, and also may vary between scenarios.

An overview of the date selections resulting is found compiled in the tables below:



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Table 9.7- 10: Spring emergence dates of earliest crops per scenario used as reference for application timing definition in the FOCUSsw scenarios

| Scenario | Location | Crop | Emergence date | Julian date |
|----------|----------|------------------------------|----------------|----------------------|
| D1 | | spring cereals | 05-May | 21-Apr |
| D2 | | spring cereals ^{a)} | 15-Mar | 01-Mar ^{a)} |
| D3 | | spring cereals | 01-Apr | 18-Mar |
| D4 | | field beans | 15-Apr | 01-Apr |
| D5 | | spring cereals | 15-Mar | 01-Mar |
| D6 | | root vegetables | 25-Feb | 12-Feb |
| R1 | | field beans | 10-Apr | 27-Mar |
| R2 | | bulb vegetables | 28-Feb | 14-Feb |
| R3 | | root vegetables | 26-Feb | 12-Feb |
| R4 | | root vegetables | 26-Feb | 12-Feb |

^{a)} no crop with emergence in spring defined; D5 data used instead

Table 9.7- 11: Application dates of mesosulfuron-methyl derived for use in FOCUS Step 3 calculations

| Parameter | Winter Cereals (1 × 15 g a.s./ha) | | Winter cereals (1 × 6 g a.s./ha) | |
|---------------------------------|--|------------|--|------------|
| PAT start date rel./absolute | relative: -14 days to emergence date of earliest spring crop per scenario. (entered as 'absolute' dates for technical reason) | | relative: -14 days to emergence date of earliest spring crop per scenario. (entered as 'absolute' dates for technical reason) | |
| Appl. method (appl. type) | ground spray (CAM 2) | | ground spray (CAM 2) | |
| No of appl. | 1 | | 1 | |
| PAT window range | 30 | | 30 | |
| Appl. interval | 1 | | 1 | |
| Application Details | PAT Start Date (Julian Day) | Appl. Date | PAT Start Date (Julian Day) | Appl. Date |
| D1 | 21-Apr (111) | 25-Apr | 21-Apr (111) | 25-Apr |
| D2 | 01-Mar (60) | 12-Mar | 01-Mar (60) | 12-Mar |
| D3 | 18-Mar (77) | 17-Mar | 18-Mar (77) | 17-Mar |
| D4 | 01-Apr (91) | 18-Apr | 01-Apr (91) | 18-Apr |
| D5 | 01-Mar (60) | 07-Mar | 01-Mar (60) | 07-Mar |
| D6 | 11-Feb (42) | 27-Feb | 11-Feb (42) | 27-Feb |
| R1 | 27-Mar (86) | 26-Apr | 27-Mar (86) | 26-Apr |
| R2 | 12-Feb (43) | 19-Feb | 12-Feb (43) | 19-Feb |
| R4 | 12-Feb (43) | 02-Mar | 12-Feb (43) | 02-Mar |

In a pre-submission meeting between experts BAYER-ANSES of Jan. 30th, 2014, that approach for application timing definition in the FOCUS models environment was presented and extensively discussed between modelling experts. The proposed scenario-specific application dates for the AIR process were set to 2 weeks before the emergence of the first crop at end-of winter in the respective scenario.



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Application type: reference is made to KIIIA 9.7./01, see summary before

Substance specific input parameters:

Table 9.7- 12: Substance parameters used for mesosulfuron-methyl at FOCUS Steps 1-3

| Parameter | Unit | Mesosulfuron-methyl |
|-----------------------------------|--------|---------------------------------|
| General | | |
| Molar Mass | g/mol | 503.3 |
| Water Solubility (pH 7, 20 °C) | mg/L | 4.8 |
| Vapour Pressure (20 °C) | Pa | 3.5E-12 |
| Plant Uptake Factor | | 0.0 |
| Wash-Off Factor PRZM | l/cm | 0.5 |
| Wash-Off Factor MACRO | l/mm | 0.05 |
| Sorption | | |
| K _{oc} / K _{OM} | ml/g | 64 / 37.1 |
| Freundlich Exponent | | 0.94 |
| Degradation | | |
| Soil | days | 42.4 |
| Total System | days | 45.7 |
| Water | days | 45.7 |
| Sediment | days | 15.7 (Step 1&2) / 1000 (Step 3) |
| Walker Exponent | | 0.7 |
| Max Occurrence | | |
| Water / Sediment | % | 100 |
| Soil | % | 100 |
| Effect of Temperature | | |
| Activation Energy | kJ/mol | 65400 |
| Exponent | 1/K | 0.095 |
| Q ₁₀ | | 2.58 |

Findings:

Table 9.7- 13: Maximum PEC_{sw} and PEC_{sed} values for mesosulfuron-methyl at Steps 1&2

| Use pattern | FOCUS scenario | Mesosulfuron-methyl | |
|------------------------------------|----------------------------|-----------------------------|-------------------------------|
| | | PEC _{sw} [µg/L] | PEC _{sed} [µg/kg] |
| Winter cereals 1 × 15 g a.s./ha | Step 1 | 4.745 | 2.948 |
| | Step 2 | | |
| | N-EU Single S-EU Single | 1.849 1.504 | 1.164 0.946 |
| Winter cereals 1 × 6 g a.s./ha | Step 1 | 1.898 | 1.179 |
| | Step 2 | | |
| | N-EU Single S-EU Single | 0.740 0.602 | 0.465 0.378 |



Table 9.7- 14: Maximum PEC_{sw} and PEC_{sed} of mesosulfuron-methyl for all scenarios at Step 3 after application to winter cereals

| Use pattern | Mesosulfuron-methyl | | | | | |
|----------------|----------------------------------|--------------------------|----------------------------|---------------------------------|--------------------------|----------------------------|
| | Winter cereals, 1 × 15 g a.s./ha | | | Winter cereals, 1 × 6 g a.s./ha | | |
| FOCUS scenario | Entry route* | PEC _{sw} [µg/L] | PEC _{sed} [µg/kg] | Entry route* | PEC _{sw} [µg/L] | PEC _{sed} [µg/kg] |
| D1 (ditch) | D | 0.187 | 0.407 | D | 0.075 | 0.165 |
| D1 (stream) | D | 0.132 | 0.237 | D | 0.053 | 0.096 |
| D2 (ditch) | D | 1.328 | 0.980 | D | 0.516 | 0.387 |
| D2 (stream) | D | 0.837 | 0.568 | D | 0.222 | 0.225 |
| D3 (ditch) | S | 0.096 | 0.022 | S | 0.038 | 0.009 |
| D4 (pond) | D | 0.035 | 0.096 | D | 0.013 | 0.036 |
| D4 (stream) | S | 0.080 | 0.039 | S | 0.032 | 0.012 |
| D5 (pond) | S | 0.016 | 0.042 | S | 0.006 | 0.017 |
| D5 (stream) | S | 0.081 | 0.019 | S | 0.032 | 0.008 |
| D6 (ditch) | S | 0.102 | 0.030 | S | 0.041 | 0.012 |
| R1 (pond) | R | 0.067 | 0.017 | R | 0.003 | 0.006 |
| R1 (stream) | R | 0.171 | 0.018 | R | 0.045 | 0.008 |
| R3 (stream) | R | 0.327 | 0.052 | R | 0.130 | 0.021 |
| R4 (stream) | R | 0.266 | 0.056 | R | 0.108 | 0.024 |

* Entry route: letters S, D, and R correspond to the dominant entry path – spray drift, drainage, and runoff

Graphical outputs of predicted environmental concentrations in surface water:

The model report provides in its Appendix 9.4 graphical presentations of the concentration timecourses of PEC_{sw}, calculated according to the FOCUS Surface Water procedure at Step 3 level. For each of the scenarios, two graphic files are provided: The overall time evolution of the whole TOXSWA simulation, and a detailed view at the period around the observed maximum (ca. 1 week before the maximum to 8 weeks after the maximum) are shown. These information may support ecotoxicological risk assessments, where time course information is considered of importance in addition to the maximum concentrations listed above. Diagrams of interest for risk assessment will be shown in the ecotoxicological section.

IIIA 9.7.1 Initial PEC_{sw} value for static water bodies

See comment under Point 9.7.

IIIA 9.7.2 Initial PEC_{sw} value for slow moving water bodies

See comment under Point 9.7.

IIIA 9.7.3 Short-term PEC_{sw} values for static water bodies (1-4 days after last application)

See comment under Point 9.7.

IIIA 9.7.4 Short-term PEC_{sw} values for slow moving water bodies (1-4 days after last application)

See comment under Point 9.7.

IIIA 9.7.5 Long-term PEC_{sw} values for static water bodies (7-42 days after last application)

See comment under Point 9.7.



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IIIA 9.7.6 Long-term PEC_{sw} values for slow moving water bodies (7-42 days after last application)

Please refer to point IIIA 9.7.

IIIA 9.8 Predicted Environmental Concentrations in Surface Water (PEC_{sw}) for Metabolites

Endpoints for PEC_{sw}

Table 9.8- 1: Comparison of proposed endpoints and modelling input parameters for mesosulfuron-methyl metabolites

| End-point | Active substance: mesosulfuron-methyl | |
|--|---------------------------------------|--------------------------|
| | Proposed EU endpoints (Document N2) | Value used for modelling |
| AE F154851 | | |
| Aqueous solubility [mg/L] | 200000 | 200000 |
| Vapour pressure [Pa] | 1.7×10^{-8} | 1.7×10^{-8} |
| DT ₅₀ soil [days] (geomean, lab) | 37.1 | 37.1 |
| K _{oc} / K _{om} [L/kg] (arith. mean) | 68.3 / 39.6 | 68.3 / 39.6 |
| 1/n (arith. mean) | 0.940 | 0.940 |
| Plant uptake factor | 0 | 0 |
| DT ₅₀ water/ sed. total system [days] (geomean) | 38.6 | 38.6 |
| DT ₅₀ water [days] (geomean) | 38.6 | 38.6 |
| DT ₅₀ sediment [days] (geomean) | 38.6 | 38.6 |
| Max. occurrence in water / sed. [%] | 4.9 | 4.9 |
| Max. occurrence in soil [%] | 16.2 | 16.2 |
| AE F160459 | | |
| Aqueous solubility [mg/L] | 10000 | 10000 |
| Vapour pressure [Pa] | 6.8×10^{-8} | 6.8×10^{-8} |
| DT ₅₀ soil [days] (geomean, lab) | 70.1 | 70.1 |
| K _{oc} / K _{om} [L/kg] (arith. mean) | 21.8 / 12.6 | 21.8 / 12.6 |
| 1/n (arith. mean) | 0.940 | 0.940 |
| Plant uptake factor | 0 | 0 |
| DT ₅₀ water/ sed. total system [days] (geomean) | 47.3 | 47.3 |
| DT ₅₀ water [days] (geomean) | 47.3 | 47.3 |
| DT ₅₀ sediment [days] (geomean) | 47.3 | 47.3 |
| Max. occurrence in water / sed. [%] | 21.6 | 21.6 |
| Max. occurrence in soil [%] | 8.9 | 8.9 |
| AE F099095 | | |
| Aqueous solubility [mg/L] | 190 | 190 |
| Vapour pressure [Pa] | 1.9×10^{-5} | 1.9×10^{-5} |
| DT ₅₀ soil [days] (geomean, lab) | 87.9 | 87.9 |
| K _{oc} / K _{om} [L/kg] (arith. mean) | 576 / 334 | 576 / 334 |
| 1/n (arith. mean) | 0.840 | 0.840 |
| Plant uptake factor | 0 | 0 |
| DT ₅₀ water/ sed. total system [days] (default value) | 1000 | 1000 |
| DT ₅₀ water [days] (default value) | 1000 | 1000 |
| DT ₅₀ sediment [days] (default value) | 1000 | 1000 |
| Max. occurrence in water / sed. [%] | 0.9 | 0.9 |



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| End-point | Active substance: mesosulfuron-methyl | |
|---|--|--------------------------|
| | Proposed EU endpoints [Document N2] | Value used for modelling |
| Max. occurrence in soil [%] | 29.2 | 29.2 |
| AE F092944 | | |
| Aqueous solubility [mg/L] | 5200 | 5200 |
| Vapour pressure [Pa] | 2.6×10^{-2} | 2.6×10^{-2} |
| DT ₅₀ soil [days] (geomean, lab) | 60.4 | 60.4 |
| K _{oc} / K _{om} [L/kg] (arith. mean) | 447 / 260 | 447 / 260 |
| 1/n (arith. mean) | 0.72 | 0.72 |
| Plant uptake factor | 0 | 0 |
| DT ₅₀ water/sed. total system [days] (max. value) | 25.9 | 25.9 |
| DT ₅₀ water [days] (max. value) | 25.9 | 25.9 |
| DT ₅₀ sediment [days] (max. value) | 25.9 | 25.9 |
| Max. occurrence in water / sed. [%] | 3.2 | 3.2 |
| Max. occurrence in soil [%] | 10.7 | 10.7 |
| AE F160460 | | |
| Aqueous solubility [mg/L] | 100000 | 100000 |
| Vapour pressure [Pa] | 2.6×10^{-7} | 2.6×10^{-7} |
| DT ₅₀ soil [days] (geomean, lab) | 25.6 | 25.6 |
| K _{oc} / K _{om} [L/kg] (arith. mean) | 14.7 / 8.2 | 14.1 / 8.2 |
| 1/n (arith. mean) | 0.900 | 0.900 |
| Plant uptake factor | 0 | 0 |
| DT ₅₀ water/sed. total system [days] (geomean) | 38.3 | 38.3 |
| DT ₅₀ water [days] (geomean) | 38.3 | 38.3 |
| DT ₅₀ sediment [days] (geomean) | 38.3 | 38.3 |
| Max. occurrence in water / sed. [%] | 8.4 | 8.4 |
| Max. occurrence in soil [%] | 8.6 | 8.6 |
| AE F140584 | | |
| Aqueous solubility [mg/L] | 100 | 100 |
| Vapour pressure [Pa] | 1.3×10^{-6} | 1.3×10^{-6} |
| DT ₅₀ soil [days] (geomean, lab) | 3.6 | 3.6 |
| K _{oc} / K _{om} [L/kg] (default value) | 0.0 / 0.0 | 0.0 / 0.0 |
| 1/n (default value) | 1.000 | 1.000 |
| Plant uptake factor | 0 | 0 |
| DT ₅₀ water/sed. total system [days] (default value) | 1000 | 1000 |
| DT ₅₀ water [days] (default value) | 1000 | 1000 |
| DT ₅₀ sediment [days] (default value) | 1000 | 1000 |
| Max. occurrence in water / sed. [%] | 1.9 | 1.9 |
| Max. occurrence in soil [%] | 7.1 | 7.1 |
| AE F147447 | | |
| Aqueous solubility [mg/L] | 150000 | 150000 |
| Vapour pressure [Pa] | 1.0×10^{-8} | 1.0×10^{-8} |
| DT ₅₀ soil [days] (geomean, lab) | 97.7 | 97.7 |
| K _{oc} / K _{om} [L/kg] (arith. mean) | 5.2 / 3.0 | / 3.0 |
| 1/n (default value) | 1.000 | 1.000 |
| Plant uptake factor | 0 | 0 |
| DT ₅₀ water/sed. total system [days] (max. value) | 205 | 205 |
| DT ₅₀ water [days] (max. value) | 205 | 205 |
| DT ₅₀ sediment [days] (max. value) | 205 | 205 |
| Max. occurrence in water / sed. [%] | 10.9 | 10.9 |
| Max. occurrence in soil [%] | 6.5 | 6.5 |



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PEC_{sw} for mesosulfuron-methyl metabolites

According to the definition of residues relevant for surface water risk assessment, the following degradates were considered for PEC_{gw} calculation: AE F154851, AE F160459, AE F099095, AE F092944, AE F160460, AE F140584, and AE F147447.

| | |
|---------------------|---|
| Report: | [REDACTED];2014;M-481626-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{sw, sed} FOCUS EUR Use in winter cereals in Europe |
| Report No: | EnSa-14-0230 |
| Document No: | M-481626-01-1 |
| Guidelines: | not applicable;not applicable |
| GLP/GEP: | no |

Materials and Methods: PEC_{sw} and PEC_{sed} for the metabolites of mesosulfuron-methyl were calculated using the approach, scenarios and application rates described for the calculations for the parent compound in Point 9.7.

Substance specific parameters for the mesosulfuron-methyl metabolites are summarized in Table 9.8- 2.

Table 9.8- 2: Substance parameters used for mesosulfuron-methyl metabolites at Steps 1&2 level

| Parameter | Unit | AE F154851 | AE F160459 | AE F099095 | AE F092944 | AE F160460 | AE F140584 | AE F147447 |
|------------------|-------|------------|------------|------------|------------|------------|------------|------------|
| Molar Mass | g/mol | 489.5 | 489.5 | 198.2 | 155.2 | 475.5 | 322.4 | 290.3 |
| Water Solubility | mg/L | 20000 | 10000 | 90 | 5200 | 100000 | 100 | 150000 |
| K _{oc} | ml/g | 68.3 | 21.8 | 576 | 4.9 | 14.1 | 0 | 5.2 |
| Degradation | | | | | | | | |
| Soil | days | 37.1 | 70.1 | 87.9 | 60.4 | 25.6 | 3.6 | 97.7 |
| Total System | days | 38.6 | 47.3 | 1000 | 25.9 | 38.3 | 1000 | 205 |
| Water | days | 38.6 | 47.3 | 1000 | 25.9 | 38.3 | 1000 | 205 |
| Sediment | days | 38.6 | 47.3 | 1000 | 25.9 | 38.3 | 1000 | 205 |
| Max Occurrence | | | | | | | | |
| Water / Sediment | % | 4.9 | 21.8 | 0.9 | 3.2 | 8.4 | 1.9 | 10.9 |
| Soil | % | 16.2 | 8.0 | 29.2 | 10.1 | 8.6 | 7.1 | 6.5 |

Findings

Steps 1&2: PEC_{sw} and PEC_{sed} values of mesosulfuron-methyl metabolites at FOCUS Steps 1&2 for the use in winter cereals are summarised in Table 9.8- 3 (PEC_{sw}) and Table 9.8- 4 (PEC_{sed}).



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.8- 3: Maximum PEC_{sw} of mesosulfuron-methyl metabolites at Steps 1&2

| Crop | Scenario | AE F154851 | AE F160459 | AE F099095 | AE F092944 | AE F160460 | AE F140584 | AE F147447 |
|------------------------------------|-------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | | PEC _{sw} [µg/L] | PEC _{sw} [µg/L] | PEC _{sw} [µg/L] | PEC _{sw} [µg/L] | PEC _{sw} [µg/L] | PEC _{sw} [µg/L] | PEC _{sw} [µg/L] |
| Winter cereals 1 × 15 g a.s./ha | Step 1 | 0.728 | 0.449 | 0.326 | 0.099 | 0.410 | 0.229 | 0.195 |
| | Step 2 | | | | | | | |
| | N-EU Single | 0.173 | 0.128 | 0.079 | 0.024 | 0.100 | 0.028 | 0.054 |
| | S-EU Single | 0.140 | 0.108 | 0.063 | 0.020 | 0.082 | 0.023 | 0.044 |
| Winter cereals 1 × 6 g a.s./ha | Step 1 | 0.291 | 0.180 | 0.130 | 0.040 | 0.164 | 0.092 | 0.078 |
| | Step 2 | | | | | | | |
| | N-EU Single | 0.069 | 0.051 | 0.032 | 0.010 | 0.040 | 0.011 | 0.022 |
| | S-EU Single | 0.056 | 0.042 | 0.025 | 0.008 | 0.033 | 0.009 | 0.016 |

Table 9.8- 4: Maximum PEC_{sed} of mesosulfuron-methyl metabolites at Steps 1&2

| Crop | Scenario | AE F154851 | AE F160459 | AE F099095 | AE F092944 | AE F160460 | AE F140584 | AE F147447 |
|------------------------------------|-------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | | PEC _{sed} [µg/kg] | PEC _{sed} [µg/kg] | PEC _{sed} [µg/kg] | PEC _{sed} [µg/kg] | PEC _{sed} [µg/kg] | PEC _{sed} [µg/kg] | PEC _{sed} [µg/kg] |
| Winter cereals 1 × 15 g a.s./ha | Step 1 | 0.493 | 0.092 | 1.872 | 0.436 | 0.056 | <0.001 | 0.010 |
| | Step 2 | | | | | | | |
| | N-EU Single | 0.117 | 0.027 | 0.435 | 0.107 | 0.014 | <0.001 | 0.003 |
| | S-EU Single | 0.094 | 0.023 | 0.364 | 0.086 | 0.011 | <0.001 | 0.002 |
| Winter cereals 1 × 6 g a.s./ha | Step 1 | 0.193 | 0.037 | 0.749 | 0.174 | 0.023 | <0.001 | 0.004 |
| | Step 2 | | | | | | | |
| | N-EU Single | 0.047 | 0.011 | 0.482 | 0.043 | 0.006 | <0.001 | 0.001 |
| | S-EU Single | 0.038 | 0.009 | 0.146 | 0.034 | 0.005 | <0.001 | <0.001 |

Step 3: No calculations at Step 3 were made for the metabolites of mesosulfuron-methyl, since no refinement was required to pass ecotoxicological risk assessments

Alternative PEC_{sw} simulation using RMS requested modelling parameters:

| | |
|--------------|--|
| Report: | [redacted] 2015-M-517481-01 |
| Title: | Mesosulfuron-methyl (MSM) and metabolites: PEC _{sw, sed} FOCUS EUR Use in winter cereals in Europe |
| Report No: | EnSa 15-031 |
| Document No: | M-517481-01-1 |
| Guidelines: | not applicable; not applicable |
| GLP/GEP: | no |

The document reports an alternative calculation of predicted environmental concentrations in surface water following the methodology presented under KIIIA 9.7/01 before, but applying a set of modelling parameters requested by the RMS.

Materials and Methods: reference is made to KIIIA 9.7./02

Substance specific parameters:



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Iodosulfuron-methyl-sodium + Mesosulfuron-methyl + Mefenpyr-diethyl OD 42 (2+10+30 g/L)

Table 9.8- 5: Substance parameters used for mesosulfuron-methyl metabolites at Steps 1&2 level

| Parameter | Unit | AE | AE | AE | AE | AE | AE | AE |
|------------------|-------|---------|---------|---------|---------|---------|---------|---------|
| | | F154851 | F160459 | F099095 | F092944 | F160460 | F140584 | F147447 |
| Molar Mass | g/mol | 489.5 | 489.5 | 198.2 | 155.2 | 475.5 | 322.4 | 290.3 |
| Water Solubility | mg/L | 200000 | 10000 | 190 | 5200 | 100000 | 100 | 150000 |
| K _{oc} | mL/g | 65 | 19.3 | 351 | 336 | 12.2 | 0 | 51 |
| Degradation | | | | | | | | |
| Soil | days | 52.8 | 84.9 | 104.3 | 39.8 | 29.3 | 43 | 162.3 |
| Total System | days | 56.4 | 87.9 | 1000 | 1000 | 325.9 | 1000 | 1000 |
| Water | days | 56.4 | 87.9 | 1000 | 1000 | 325.9 | 1000 | 1000 |
| Sediment | days | 56.4 | 87.9 | 1000 | 1000 | 325.9 | 1000 | 1000 |
| Max Occurrence | | | | | | | | |
| Water / Sediment | % | 4.9 | 21.6 | 0.9 | 3.2 | 8.4 | 1.9 | 10.9 |
| Soil | % | 16.2 | 8.9 | 2.2 | 10.1 | 6.6 | 7.1 | 5.8 |

Findings:

Table 9.8- 6: Maximum PEC_{sw} of mesosulfuron-methyl metabolites at Steps 1&2

| Crop | Scenario | AE | AE | AE | AE | AE | AE | AE |
|------------------------------------|-------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|-------------------|
| | | F154851 | F160459 | F099095 | F092944 | F160460 | F140584 | F147447 |
| | | PEC _{sw} | PEC _{sw} | PEC _{sw} | PEC _{sw} | PEC _{sw} | PEC _{sw} | PEC _{sw} |
| | | [µg/L] | [µg/L] | [µg/L] | [µg/L] | [µg/L] | [µg/L] | [µg/L] |
| Winter cereals 1 × 15 g a.s./ha | Step 1 | 0.734 | 0.451 | 0.392 | 0.109 | 0.411 | 0.229 | 0.175 |
| | Step 2 | | | | | | | |
| | N-EU Single | 0.281 | 0.190 | 0.153 | 0.041 | 0.156 | 0.049 | 0.074 |
| | S-EU Single | 0.226 | 0.158 | 0.122 | 0.033 | 0.127 | 0.040 | 0.061 |
| Winter cereals 1 × 6 g a.s./ha | Step 1 | 0.293 | 0.180 | 0.157 | 0.044 | 0.164 | 0.092 | 0.070 |
| | Step 2 | | | | | | | |
| | N-EU Single | 0.112 | 0.076 | 0.061 | 0.017 | 0.063 | 0.020 | 0.030 |
| | S-EU Single | 0.090 | 0.063 | 0.049 | 0.015 | 0.051 | 0.016 | 0.024 |

Table 9.8- 7: Maximum PEC_{sed} of mesosulfuron-methyl metabolites at Steps 1&2

| Crop | Scenario | AE | AE | AE | AE | AE | AE | AE |
|------------------------------------|-------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|
| | | F154851 | F160459 | F099095 | F092944 | F160460 | F140584 | F147447 |
| | | PEC _{sed} | PEC _{sed} | PEC _{sed} | PEC _{sed} | PEC _{sed} | PEC _{sed} | PEC _{sed} |
| | | [µg/kg] | [µg/kg] | [µg/kg] | [µg/kg] | [µg/kg] | [µg/kg] | [µg/kg] |
| Winter cereals 1 × 15 g a.s./ha | Step 1 | 0.471 | 0.281 | 1.374 | 0.361 | 0.049 | <0.001 | 0.009 |
| | Step 2 | | | | | | | |
| | N-EU Single | 0.181 | 0.059 | 0.536 | 0.138 | 0.019 | <0.001 | 0.004 |
| | S-EU Single | 0.146 | 0.050 | 0.429 | 0.111 | 0.016 | <0.001 | 0.003 |
| Winter cereals 1 × 6 g a.s./ha | Step 1 | 0.188 | 0.033 | 0.550 | 0.145 | 0.020 | <0.001 | 0.003 |
| | Step 2 | | | | | | | |
| | N-EU Single | 0.073 | 0.015 | 0.215 | 0.055 | 0.008 | <0.001 | 0.002 |
| | S-EU Single | 0.058 | 0.012 | 0.172 | 0.044 | 0.006 | <0.001 | 0.001 |

Step 3: No calculations at Step 3 were made for the metabolites of mesosulfuron-methyl, since no refinement was required to pass ecotoxicological risk assessments.



IIIA 9.8.1 Initial PEC_{sw} value for static water bodies

See comment under Point 9.7.

IIIA 9.8.2 Initial PEC_{sw} value for slow moving water bodies

See comment under Point 9.7.

IIIA 9.8.3 Short-term PEC_{sw} values for static water bodies 1-4 days after last application)

See comment under Point 9.7.

IIIA 9.8.4 Short-term PEC_{sw} values for slow moving water bodies 1-4 days after last application)

See comment under Point 9.7.

IIIA 9.8.5 Long-term PEC_{sw} values for static water bodies 7-42 days after last application)

See comment under Point 9.7.

IIIA 9.8.6 Long-term PEC_{sw} values for slow moving water bodies 7-42 days after last application)

See comment under Point 9.7.

IIIA 9.8.7 Additional field testing

No additional field studies on the formulation have been performed or are required.

IIIA 9.9 Fate and Behaviour in Air

Based on the very low vapour pressure (3.5×10^{-12} Pa, 20 °C) mesosulfuron-methyl is virtually non-volatile and would not be expected to volatilise. Any mesosulfuron-methyl that might nevertheless reach the atmosphere would be steadily degraded, e.g. by hydroxyl radical reaction. According to the methodology developed by Atkinson, a gas phase atmospheric half-life of 1.8 hours was calculated for a typical OH radical concentration of 0.5×10^6 radicals/cm³.

IIIA 9.9.1 Spray droplet size spectrum – laboratory studies

This is not an EC data requirement / not required by Directive 91/414/EEC.

IIIA 9.9.2 Drift – field evaluation

This is not an EC data requirement / not required by Directive 91/414/EEC.

IIIA 9.10 Other/Special Studies

IIIA 9.10.1 Laboratory studies

This is not an EC data requirement / not required by Directive 91/414/EEC.

IIIA 9.10.2 Field studies

This is not an EC data requirement / not required by Directive 91/414/EEC.