

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



FORAMSULFURON
Formulation: FRS + IDF OD 45
(Equip OD 45)

Volume 3
Annex B.9.
Risk assessment for non-target species

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

March 2015

Volume 1

Level 1: Statement of subject matter and purpose for which this report has been prepared and background information on the application

Level 2: Summary of active substance hazard and of product risk assessment

Level 3: Proposed decision with respect to the application

Appendix 1: Guidance documents used in this assessment

Appendix 2: Reference list

Volume 2

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

Volume 3

Annex B (Active Substance): Summary, evaluation and assessment of the data and information

Annex B.1 (AS): Identity

Annex B.2 (AS): Physical and chemical properties of the active substance

Annex B.3 (AS): Data on application

Annex B.4 (AS): Further information

Annex B.5 (AS): Methods of analysis

Annex B.6 (AS): Toxicology and metabolism data

Annex B.7 (AS): Residue data

Annex B.8 (AS): Environmental fate and behaviour

Annex B.9 (AS): Ecotoxicology data

Volume 3

Annex B (Plant Protection Product): Summary, evaluation and assessment of the data and information

Annex B.1 (PPP): Identity

Annex B.2 (PPP): Physical and chemical properties of the plant protection product

Annex B.3 (PPP): Data on application and efficacy

Annex B.4 (PPP): Further information

Annex B.5 (PPP): Methods of analysis

Annex B.6 (PPP): Toxicology and metabolism data and assessment of risks to humans

Annex B.7 (PPP): Residue data

Annex B.8 (PPP): Environmental fate and behaviour and environmental exposure assessment

Annex B.9 (PPP): Ecotoxicology data and assessment of risks for non-target species

Volume 4

Annex C: Confidential information and, where relevant, details of any task force formed for the purpose of generating tests and studies submitted

List of Endpoints

Version History

When	What
2015/March	First draft RAR

Table of contents

B.9. RISKASSESSMENT FOR NON-TARGET SPECIES.....	6
B.9.1. EFFECTS ON BIRDS AND OTHER TERRESTRIAL VERTEBRATES	12
B.9.1.1. Effects on birds	12
B.9.1.1.1. Toxicity endpoints for birds	12
B.9.1.2. Effects on terrestrial vertebrates other than birds.....	13
B.9.1.2.1. Toxicity endpoints	13
B.9.2. RISK ASSESSMENT FOR BIRDS AND OTHER TERRESTRIAL VERTEBRATES.....	13
B.9.2.1. Risk Assessment for birds	13
B.9.2.1.1. Calculations of DDD and TER for birds	13
B.9.2.1.2. Secondary poisoning risk assessment	17
B.9.2.1.3. Risk from drinking water	17
B.9.2.1.4. Co-RMS conclusion.....	18
B.9.2.2. Risk assessment for terrestrial vertebrates other than birds	18
B.9.2.2.1. Calculations of DDD and TER for mammals.....	19
B.9.2.2.2. Active substance bioconcentration in prey of birds and mammals	21
B.9.2.2.3. Risk from drinking water	22
B.9.2.2.4. Other data on effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians).....	22
B.9.2.2.5. Co-RMS conclusion.....	22
B.9.3. EFFECTS ON AQUATIC ORGANISMS	24
B.9.3.1. Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes	24
B.9.3.1.1. Acute toxicity to fish.....	24
B.9.3.1.2. Acute toxicity to aquatic invertebrates.....	25
B.9.3.1.3. Effects on algal growth	26
B.9.3.1.4. Effects on aquatic macrophytes.....	27
B.9.3.2. Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms	30
B.9.3.2.1. Long-term and chronic toxicity to fish.....	30
B.9.3.2.2. Long-term and chronic toxicity to <i>Daphnia magna</i>	30
B.9.3.2.3. Reproductive and development toxicity to an additional aquatic invertebrate species	31
B.9.3.2.4. Development and emergence in <i>Chironomus</i> species	31
B.9.3.3. Further testing on aquatic organisms.....	31
B.9.4. RISK ASSESSMENT FOR AQUATIC ORGANISMS	31
B.9.4.1. Co-RMS conclusion	48
B.9.4.2. RMS conclusion.....	49
B.9.5. EFFECTS ON ARTHROPODS.....	50
B.9.5.1. Effects on bees	50
B.9.5.2. Effects on non-target arthropods other than bees	51
B.9.6. RISK ASSESSMENT FOR ARTHROPODS	52
B.9.6.1. Risk assessment for bees	52
B.9.6.1.1. Toxicity data	52
B.9.6.1.2. HQ calculation.....	52
B.9.6.1.3. Co-RMS conclusion:	54
B.9.6.2. Risk assessment for other non-target arthropod species	54
B.9.6.2.1. Toxicity data for non-target arthropods in laboratory studies and field studies.....	54
B.9.6.2.2. Exposure in-field and off-field of non-target arthropods	55
B.9.6.2.3. Co-RMS conclusion:	57
B.9.7. EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA.....	58
B.9.7.1. Earthworms.....	58

B.9.7.1.1. Toxicity data	58
B.9.7.2. Effects on non-target soil meso- and macrofauna (other than earthworms).....	59
B.9.7.2.1. Toxicity data	59
B.9.7.3. Exposure (Predicted Environmental Concentrations in soil)	60
B.9.7.4. Risk assessment on non-target soil meso- and macrofauna	61
B.9.7.4.1. Risk assessment for earthworms.....	61
B.9.7.4.2. Co-RMS conclusion.....	62
B.9.7.4.3. Risk assessment for other soil non-target macro-organisms (other than earthworms).....	62
B.9.7.4.4. Co-RMS conclusion.....	62
B.9.8. EFFECTS ON SOIL NITROGEN TRANSFORMATION.....	63
B.9.8.1. Risk assessment for soil nitrogen transformation.....	63
B.9.8.2. Co-RMS conclusion:	63
B.9.9. EFFECTS ON TERRESTRIAL NON-TARGET HIGHER PLANTS.....	64
B.9.9.1. Summary of screening data.....	64
B.9.9.2. Testing on non-target plants.....	64
B.9.9.3. Extended laboratory studies on non-target plants.....	64
B.9.9.4. Semi-field and field tests on non-target plants	65
B.9.10. RISK ASSESSMENT FOR TERRESTRIAL NON-TARGET HIGHER PLANTS.....	65
B.9.10.1. Exposure.....	65
B.9.10.2. Risk assessment.....	65
B.9.10.3. Co-RMS conclusion	69
B.9.11. EFFECTS ON OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA).....	70
B.9.11.1. Response of <i>Arabidopsis thaliana</i> to 22 ALS inhibitors: Baseline toxicity and crossresistance of csr1-1 and csr1-2 resistant mutants.	70
B.9.11.2. Effectivity of the herbicide AE F130360 on entomology screening species.....	70
B.9.12. RISK ASSESSMENT FOR OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA).....	70
B.9.12.1. Effects on biological methods for sewage treatment	70
B.9.12.2. Risk assessment.....	71
B.9.12.2.1. Co-RMS conclusion.....	71
B.9.13. REFERENCES RELIED ON.....	72

B.9. RISKASSESSMENT FOR NON-TARGET SPECIES

CO-RMS SLOVAKIA HAS PERFORMED THE RISK ASSESSMENT, BUT HAS WORKED CLOSELY WITH THE RMS FINLAND.

SUMMARY OF USES AND PROPERTIES

This section summarises the ecotoxicological effects of foramsulfuron and its formulation Equip OD 45 and evaluates the potential risk to various representatives of terrestrial and aquatic organisms.

Foramsulfuron (FSN) is a herbicidally active sulfonyl urea. Foramsulfuron is used as a selective post-emergence herbicide in maize for the control of grass and dicotyledonous weed species after germination of the weeds. Foramsulfuron acts on the target weeds both via foliar uptake (major route) and from soil uptake (minor route).

The representative formulation in the AIR process will be Equip OD 45 (22.5 g/L foramsulfuron and 22.5 g/L of the safener isoxadifen-ethyl). This was the representative formulation used for the first inclusion.

Foramsulfuron was included into Annex I of Council Directive 91/414/EEC (Commission Directive 2003/23/EC; 25 March 2003). 1st of July 2003 entry into Force of the inclusion of Foramsulfuron into Annex I of Directive 91/414/EEC stated that - Member States should pay particular attention to the protection of aquatic plants and that risk mitigation measures should be applied, where appropriate

July 16, 2009: Bayer CropScience AG wrote to the Commission and expressed an intention to renew the approval of foramsulfuron. In accordance with Commission Regulation (EU) 1141/2010, this document summarises new information which are relevant for the renewal of the approval of foramsulfuron under Regulation (EC) 1107/2009.

Where new risk assessment guidance has been introduced since the original EU review of foramsulfuron, an updated evaluation of the active substance has been included.

Proposed maximum use of foramsulfuron within the European Union is summarised in Table B.9-1.

Table B.9-1: Proposed maximum use of foramsulfuron within the European Union

Crop	Timing of application (range)	Number of Applications	Application interval (days)	Maximum label rate (range) L/ha	Maximum application rate individual treatment (ranges) g/ha	
					foramsulfuron	isoxadifen-ethyl
Maize	BBCH 12 -18	1	-	2.6	60	60
Maize	BBCH 12 -18	2	7	1.3	30	30

Consideration of metabolites

The metabolites which require ecotoxicological assessment according to the EU review are given below (Table B.9-2).

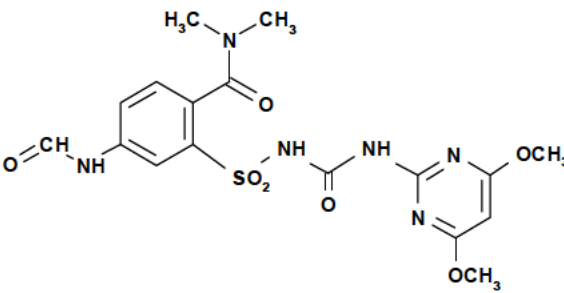
Table B.9-2: Definition of the residue for risk assessment

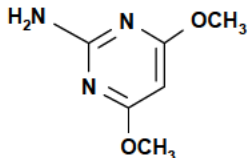
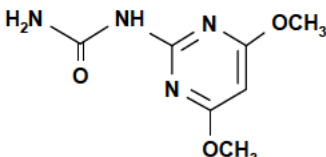
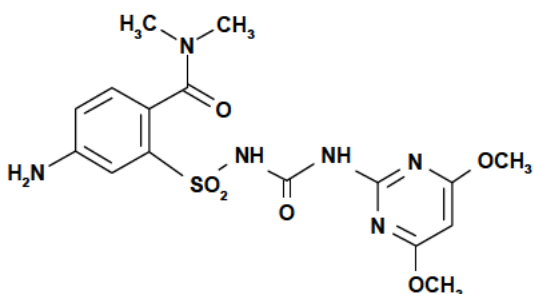
Compartment	Compound / Code
Soil	Foramsulfuron
	AE F092944
	AE F130619
	AE F153745
Groundwater	Foramsulfuron
	AE F092944

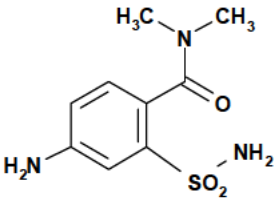
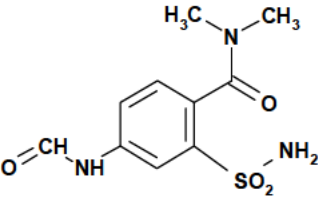
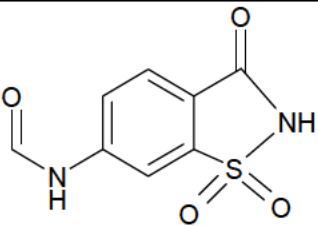
Compartment	Compound / Code
	AE F130619 AE F153745
Surface water	Foramsulfuron AE F092944 AE F130619 AE F153745 AE 0338795 AE F099095 4-Amino-N-methylbenzamide 4-Formamido-N-methylbenzamide Foramsulfuron sulfamic acid
Plant material	Foramsulfuron

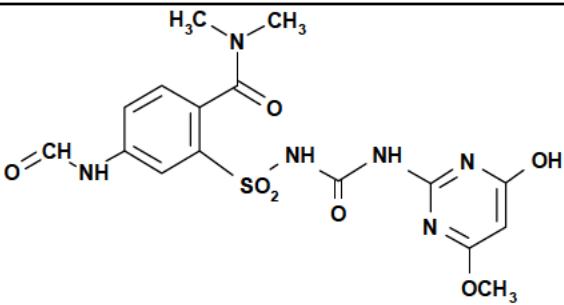
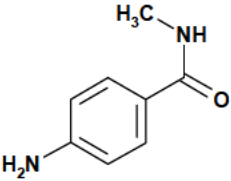
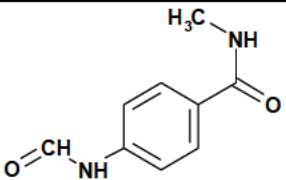
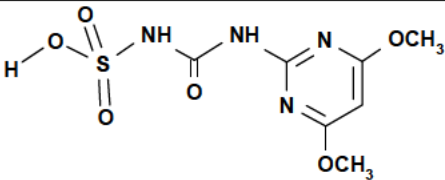
Molecular structures, names and codes of the active substance and metabolites occurring in environmental compartments are shown in the table below.

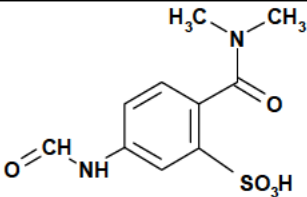
Table B.9-3: Molecular structures, names and codes of the active substance and metabolites occurring in environmental compartments

	Report name Structure IUPAC name CAS name [CAS registry number]	Molecular formula molar mass Other names / codes
a.s.	<p>Foramsulfuron (parent substance)</p>  <p>N,N-dimethyl-2-[3-(4,6-dimethoxypyrimidin-2-yl)ureidosulfonyl]-4-formylaminobenzamide (IUPAC) 2-[[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-4-formylaminobenzamide (CAS) CAS no: 173159-57-4</p>	<p>C₁₇ H₂₀ N₆ O₇ S 452.49 g/mol</p> <p>Foramsulfuron (common name) AE F130360 BCS-AH47626</p>

	Report name Structure IUPAC name CAS name [CAS registry number]	Molecular formula molar mass Other names / codes
M01	<p>AE F092944</p>  <p>2-amino-4,6-dimethoxypyrimidine (IUPAC) 4,6-Dimethoxy-2-pyrimidinamine (CAS) CAS no: 36315-01-2</p>	<p>C₆ H₉ N₃ O₂ 155.16 g/mol</p> <p>AE F092944 BCS-AA25052 Foramsulfuron-pyrimidinamine ADMP K-1782 Metabolite E</p>
M02	<p>AE F099095</p>  <p>4,6-dimethoxypyrimidin-2-ylurea (IUPAC) (4,6-dimethoxy-2-pyrimidinyl)urea (CAS) CAS no: 151331-81-6</p>	<p>C₇ H₁₀ N₄ O₃ 198.18 g/mol</p> <p>AE F099095 BCS-AB40283 Foramsulfuron-urea 05537 DMPU Metabolite B</p>
M03	<p>AE F130619</p>  <p>4-amino-2-[3-(4,6-dimethoxypyrimidin-2-yl)ureidosulfonyl]-N,N-dimethylbenzamide (IUPAC) 4-amino-2-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-N,N-dimethylbenzamide (CAS) CAS no: 190520-75-3</p>	<p>C₁₆ H₂₀ N₆ O₆ S 424.48 g/mol</p> <p>AE F130619 BCS-AU59648 Foramsulfuron-amine</p>

	Report name Structure IUPAC name CAS name [CAS registry number]	Molecular formula molar mass Other names / codes
M04	<p>AE F148003</p>  <p>4-amino-N,N-dimethyl-2-sulfamoylbenzamide (IUPAC) 4-amino-2-(aminosulfonyl)-N,N-dimethyl-benzamide (CAS) CAS no: 190521-44-9</p>	<p>C₉ H₁₃ N₃ O₃ S 243.31 g/mol</p> <p>AE F148003 BCS-AU73987</p>
M05	<p>AE F153745</p>  <p>4-formylamino-N,N-dimethyl-2-sulfamoylbenzamide (IUPAC) 2-(aminosulfonyl)-4-(formylamino)-N,N-dimethyl-benzamide (CAS) CAS no: 173159-94-9</p>	<p>C₁₀ H₁₃ N₃ O₄ S 271.32 g/mol</p> <p>AE F153745 BCS-AU80017</p>
M06	<p>AE 0014940</p>  <p>N-(1,1-dioxido-3-oxo-2,3-dihydro-1,2-benzothiazol-6-yl)formamide (IUPAC) 6-formamido-1,2-benzisothiazol-3(2H)-one 1,1-dioxide (IUPAC) CAS no: NA</p>	<p>C₈ H₆ N₂ O₄ S 226.21 g/mol</p> <p>AE 0014940 BCS-AW41697</p>

	Report name Structure IUPAC name CAS name [CAS registry number]	Molecular formula molar mass Other names / codes
M07	AE 0338795 	C ₁₆ H ₁₈ N ₆ O ₇ S 438.42 g/mol AE 0338795 BCS-AW78711 4-(formylamino)-2-[[[(4-hydroxy-6-methoxy-2-pyrimidinyl)amino]carbonyl]amino]sulfonyl]-N,N-dimethylbenzamide
M08	4-Amino-N-methylbenzamide 	C ₈ H ₁₀ N ₂ O 150.18 g/mol AMB BCS-CV29520
M09	4-Formamido-N-methylbenzamide 	C ₉ H ₁₀ N ₂ O ₂ 178.19 g/mol FMB BCS-CW90756
M10	Foramsulfuron sulfamic acid 	C ₇ H ₁₀ N ₄ O ₆ S 278.24 g/mol

	Report name Structure IUPAC name CAS name [CAS registry number]	Molecular formula molar mass Other names / codes
	[4,6-dimethoxypyrimidin-2-yl]carbamoyl]sulfamic acid (IUPAC) Sulfamic acid, N-[[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]- (CAS) CAS no: 591747-53-4	BCS-AW41401
M11	Sulfonic acid	
	 <p>2-(dimethylcarbamoyl)-5-formamidobenzenesulfonic acid (IUPAC) CAS no: NA</p>	<p>C₁₀ H₁₂ N₂ O₅ S 272.28 g/mol</p> <p>BCS: n.a. Foramsulfuron-sulfonic acid</p>

B.9.1. EFFECTS ON BIRDS AND OTHER TERRESTRIAL VERTEBRATES**B.9.1.1. Effects on birds****B.9.1.1.1. Toxicity endpoints for birds**

The risk assessment has been performed according to “European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA” (EFSA Journal 2009; 7(12):1438.

The relevant toxicity data for foramsulfuron are summarised in the **Table B.9.1.1.1-1** below.

Table B.9.1.1.1-1: Toxicity data for foramsulfuron

Species	Time scale	Test substance	LD ₅₀ /LC ₅₀ (nominal)	NOEL/NOEC (nominal)	Reference
Bobwhite quail	Acute (oral)	Foramsulfuron	LD ₅₀ > 2000 ¹ LD ₅₀ extrapol 3776 ² mg as/kg bw	2000 mg as/kg bw	█ 1998 M-143541-01-1 KCA 8.1.1.1 /01
Mallard duck	Acute (oral)	Foramsulfuron	LD ₅₀ > 2000 ¹ LD ₅₀ extrapol 3776 ² mg as/kg bw	2000 mg as/kg bw	█ 1997 M-142752-01-1 KCA 8.1.1.1 /02
Bobwhite quail	Short-term (5d) dietary	Foramsulfuron	LC ₅₀ > 5000 ¹ ppm = LDD ₅₀ > 985 mg as/kg bw	5000 ppm	█ 1998 M-147825-01-1 KCA 8.1.1.2 /01
Mallard duck	Short-term (5d) dietary	Foramsulfuron	LC ₅₀ > 5000 ¹ ppm = LDD ₅₀ > 1792 mg as/kg bw/d	5000 ppm	█ 1998 M-147826-01-1 KCA 8.1.1.2 /02
Bobwhite Quail	Reproduction (21w)	Foramsulfuron	-	NOEC > 1000 ppm = NOEL > 104 mg as/kg bw/d	█ 1999 M-194248-01-1 KCA 8.1.1.3 /01
Mallard duck	Reproduction (21w)	Foramsulfuron	-	NOEC > 1000 ppm = NOEL > 132 mg as/kg bw/d	█ 1999 M-194250-01-1 KCA 8.1.1.3 /02

Bold letters: Values considered relevant for risk assessment

¹) 10 birds per group

²) LD₅₀ extrapolated according to EFSA GD Birds & Mammals (2009) by applying a factor of 1.888 to the top dose in case 10 animals have been tested and no mortality occurred

Formulated product Equip OD has been tested for potential acute toxicity to Bobwhite quail. The endpoint from this study is presented in the **Table B.9.1.1.1-2**.

Table B.9.1.1.1-2: Toxicity data for formulated product Equip OD

Species	Time scale	Test substance	LD ₅₀ /LC ₅₀ (nominal)	NOEL/NOEC (nominal)	Reference
Bobwhite quail	Acute (oral)	formulated FSN + IDF OD 45 (22.5+ 22.5)	LD ₅₀ > 2000 mg product/kg bw	NOED 2000 mg product/kg bw	█ (2000) M-192635-01-1 KCP 10.1.1.1 /01

B.9.1.2. Effects on terrestrial vertebrates other than birds

B.9.1.2.1. Toxicity endpoints

EU Conclusions - Toxicity to terrestrial vertebrates other than birds of foramsulfuron and EQUIP OD are summarized in the Table B.9.1.2.1.-1.

Table B.9.1.2.1.-1: Toxicity data (nominal value) to terrestrial vertebrates other than birds of foramsulfuron (EU Conclusions)

Test substance	Study	Species	LD ₅₀ /LC ₅₀	NOAEL	Reference
Foramsulfuron	Acute oral	Rat	LD ₅₀ > 5000 ¹ mg/kg bw	-	██████ 1997 M-141959-01-1 KCA 5.2.1 /01
EQUIP OD	Acute oral	Rat	LD ₅₀ > 5000 mg product /kg bw	-	██████ 1999 M-192928-01-1 KCP 7.1.1 /01
Foramsulfuron	Reproductive, 2 generations	Rat	-	NO(A)EC ≥ 15 000 ppm NO(A)EL ≥ 1218 mg/kg bw/d ² (≥ 1038 mg/kg bw/d for males and ≥ 1430 mg/kg bw/d for females)	██████ 1999 M-187748-01-1 KCA 5.6.1 /01
Foramsulfuron	Teratogenicity	Rat	-	NO(A)EL _{maternal and developmental} ≥ 1000 mg as/kg/d	██████ 1997 M-147435-01 KCA 5.6.2 /02
Foramsulfuron	Teratogenicity (range finding study)	Rabbit	-	NOEL _{developmental} 500 mg as/kg/d	██████ 1997 M-143157-01 KCA 5.6.2 /01
Foramsulfuron	Teratogenicity	Rabbit	-	NOEL _{maternal} 50 mg as/kg/d NOEL _{developmental} ≥ 500 mg as/kg/d	██████ 1997 M-147441-01 KCA 5.6.2 /03

¹ 10 rats per group, no mortality occurred

² Geometric mean of male and female

B.9.2. RISK ASSESSMENT FOR BIRDS AND OTHER TERRESTRIAL VERTEBRATES

B.9.2.1. Risk Assessment for birds

B.9.2.1.1. Calculations of DDD and TER for birds

Equip OD was a representative formulation in the EU review of foramsulfuron. However, new risk assessment parameters are now considered in the assessment of risk to birds. The risk assessment for birds is carried out according to the latest draft of the 'EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)'. The acute and long-term risks of Equip OD to birds were assessed from toxicity exposure ratios between toxicity endpoints, estimated from studies with foramsulfuron, and maximum residues occurring on food items following single application (which represents worst case) according to the proposed use pattern.

Risk Assessment

Toxicity

Equip OD has been tested for potential acute toxicity to bobwhite quail. The endpoint from this study is presented in the Table B.9.1.1.5.1-2 above. The LD₅₀ of the formulation, higher than > 2000 mg product/kg bw,

shows that the formulation Equip OD seems to be not more toxic than the active substance ($LD_{50} > 2000$ LD_{50} extrapol 3776 mg a.s./kg bw). The risk assessment was conducted with the endpoint of the active substance.

Consideration of reproductive endpoints for foramsulfuron used in the risk assessment

According to the EFSA Guidance, an estimated reproductive endpoint should be obtained by using the acute oral LD_{50} (from a single species or geometric mean) and divided by 10 to obtain an $LD_{50}/10$. This $LD_{50}/10$ is used as an endpoint in the reproductive assessment to take account of the possibility of reproductive impairment due to sub-lethal effects on pair formation and breeding site selection, incubation, parental care of nestlings, and survival of fledgling birds (in accordance with **Appendix J** of the EFSA Guidance). If the $LD_{50}/10$ is lower than the lowest reproductive endpoint, then this should be used as the Screening Step reproductive endpoint. For foramsulfuron, the LD_{50} used in the acute risk assessment is > 2000 mg a.s./kg bw generating an $LD_{50}/10$ value of > 200 mg a.s./kg bw. The worst-case NOEL is > 104 mg/kg bw/day thus the NOEL will be used in the risk assessment (see Table B9.1.1.1-1).

Foramsulfuron metabolites

Since metabolites are formed at $< 10\%$ of parent level in edible crop parts, it can be concluded that the risk to birds will be low and no further risk assessment is conducted.

Exposure

Exposure of birds will be predominantly dietary, through the consumption of residues on food items. Direct exposure of birds to Equip OD applications is considered unlikely, since at the time of application and for a short period thereafter, most birds will leave the immediate vicinity of spray operations in response to the human disturbance. Exposure is calculated according to the **EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)**.

Screening assessment

The Screening step crop groupings and critical use patterns relevant to the uses of EQUIP OD are given in the table below (Table B.9.2.1.1-1).

Table B.9.2.1.1-1: Screening step crop groupings and critical use patterns relevant to the use of EQUIP OD

Crop group	GAP crop species	Indicator species	Critical use pattern		
			Rate (kg a.s./ha)	No. of apps	App. Interval (days)
Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, sunflower and bare soil	Maize	Small omnivorous bird	0.06	1	n.a.

The acute 'daily dietary dose' (DDD) is calculated by multiplying the Shortcut value (SV) based on the 90th percentile residues by the application rate in kg a.s./ha.

$$DDD = \text{application rate (kg a.s./ha)} \times SV$$

Daily dietary doses for acute exposure to foramsulfuron following use of EQUIP OD according to the proposed uses are given in the **Table B.9.2.1.1-2**.

Table B.9.2.1.1-2: Screening step – estimates of acute exposure to foramsulfuron

Test substance	Crop group	Indicator species	Shortcut value (mg a.s./kg bw/day)	App. rate (kg a.s./ha)	DDD (mg a.s./kg bw/day)
Foramsulfuron	Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, sunflower and bare soil	Small omnivorous bird	158.8	0.06	9.53

Acute toxicity exposure ratio (TER_A)

Acute risk is assessed by comparing the relevant DDD with the appropriate LD₅₀ endpoint to give an acute TER_A:

$$TER_A = \frac{LD_{50} \text{ (mg/kg bw)}}{DDD}$$

The resulting TERA values are given in the **Table B.9.2.1.1-3**.

Table B.9.2.1.1-3: Screening step - Acute risk (TER_A) to birds from foramsulfuron

Test Substance	Crop group	Indicator species	LD ₅₀ (mg a.s./kg bw)	DDD (mg a.s./kg bw/day)	TER _A	Trigger value
Foramsulfuron	Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, sunflower and bare soil	Small omnivorous bird	> 2000	9.53	>209.86	10

The TERA values for foramsulfuron for the indicator species are greater than the Annex VI trigger of 10, indicating that acute risk to birds is acceptable following use of EQUIP OD according to the proposed use pattern.

- **Comment (Co-RMS and RMS):** The TER_A values are greater than the Annex VI trigger of 10, indicating that acute risk to birds is acceptable following use of EQUIP OD according to the proposed use pattern. And first tier acute risk assessment is not necessary.

Short and long-term toxicity exposure ratio (TER_{ST} & TER_{LT})

EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) in the part 2.2, p. 16 states that when the dietary LD₅₀ is lower than the acute LD₅₀, the dietary LD₅₀ should be used in the acute risk assessment. For foramsulfuron, the lowest dietary LD₅₀ (> 985 mg a.s./kg bw/d) is below the acute endpoint (>2000 mg a.s./kg bw/d) and should be considered for risk assessment. However, Co-RMS considers that without mortality, clinical signs and pathological abnormal finding, this LD₅₀ is a NOEL and the risk assessment can be conducted according to the acute risk assessment.

Screening assessment for long-term exposure

The Screening step crop groupings and critical use patterns relevant to the uses of EQUIP OD are given in the table below (**Table B.9.2.1.1-4**).

The long-term ‘daily dietary dose’ (DDD) is calculated by multiplying the Shortcut value (SV) based on the mean residues by the application rate in kg a.s./ha.

$$\text{DDD} = \text{application rate (kg a.s./ha)} \times \text{SV} \times f_{\text{twa}}$$

The f_{twa} based upon a default DT_{50} of 10 days is 0.53, as given in the EFSA Guidance Document.

The indicator species that are relevant for the proposed uses are considered with worst case application rates to calculate long-term DDD values as shown in the Table B.9.2.1.1-4.

Table B.9.2.1.1-4: Screening step - estimates of long-term exposure to foramsulfuron

Test substance	Crop group	Indicator species	Shortcut value (mg a.s./kg bw/day)	App. Rate (kg a.s./ha)	f_{twa}	DDD (mg a.s./kg bw/day)
Foramsulfuron	Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, sunflower and bare soil	Small omnivorous bird	64.8	0.06	0.53	2.06

Long-term toxicity exposure ratio (TER_{LT})

Long-term risk is assessed by comparing the long-term DDD with the worst case NOEC from the reproduction studies, expressed as daily dietary dose, to give a TER_{LT} :

$$\text{TER}_{\text{LT}} = \frac{\text{NOEL (mg/kgbw/day)}}{\text{DDD (mg/kgbw/day)}}$$

The EFSA Guidance Document indicates that the acute $\text{LD}_{50}/10$ should be used as an endpoint in long-term risk assessment where it is lower than the long-term endpoint. For foramsulfuron, the endpoint from the reproduction study has been used in calculation of the TER value since that value is lower than the $\text{LD}_{50}/10$ value for the acute LD_{50} endpoint used in the acute risk assessment. The TER values calculated for the crop groupings relevant for the use of EQUIP OD are given in the Table B.9.2.1.1-5:

Table B.9.2.1.1-5: Screening step – long-term (TER_{LT}) to birds from foramsulfuron

Test substance	Crop group	Indicator species	NOEL (mg a.s./kg bw/day)	DDD (mg a.s./kg bw/day)	TER_{LT}	Trigger value
Foramsulfuron	Bulbs and onion like crops, cereals, fruiting vegetables, leafy vegetables, legume forage, maize, oilseed rape, potatoes, pulses, root and stem vegetables, strawberries, sugar beet, sunflower and bare soil	Small omnivorous bird	> 104	2.06	> 50.48	5

TERs shown in bold fall below the relevant trigger

For foramsulfuron for the bulbs etc. group the TER_{LT} value is higher than the Annex VI trigger value of 5. Therefore a Tier 1 assessment is not required.

- **Comment (Co-RMS and RMS):** The long-term TER value in the screening step for foramsulfuron is greater than the Annex VI trigger of 5, indicating that the long-term risk to birds is acceptable following use of EQUIP OD according to the proposed use pattern.

B.9.2.1.2. Secondary poisoning risk assessment

According to EFSA Guidance Document on Risk Assessment for Birds and Mammals, 2009 substances with a log K_{OW} greater than 3 have potential for bioaccumulation. Foramsulfuron log K_{OW} is < 3 (log K_{OW} value 1.44 at pH 2; 0.78 at pH 7) indicating that a secondary poisoning risk assessment is not necessary. The log K_{OW} values for foramsulfuron metabolites are as follows: AE F130619 (log K_{OW} = 1.57 (pH 6)); AE 0338795 (log K_{OW} = - 2.33 (pH 7)); AE F092944 (log K_{OW} = 0.92); AE F153745 (log K_{OW} = - 0.62) indicating that a secondary poisoning risk assessment is not necessary.

B.9.2.1.3. Risk from drinking water

There are two scenarios provided in the EFSA Guidance Document for assessing the risk from drinking water. The 'Leaf scenario' is relevant for birds taking water that is collected in leaf whorls after application and applies to leafy vegetables forming heads or with a morphology that facilitates collection of rain/irrigation water sufficiently to attract birds. Since none of the proposed crop uses falls into these categories, the leaf scenario does not apply to the use of EQUIP OD. The 'Puddle scenario' is relevant for birds taking water from puddles formed on the soil surface of a field when a (heavy) rainfall event follows the application of a pesticide to a crop or bare soil. This is therefore relevant for all uses of EQUIP OD and should therefore be assessed.

Puddle scenario

It is stated in EFSA Guidance Document (ref. 5.5, Step 2b) that no specific calculations of exposure and TER are necessary if the ratio of effective application rate (in g/ha) to acute and long-term endpoint (in mg/kg bw/d) does not exceed 50 (K_{OC} < 500 L/kg). Ratios of effective application rate to endpoints for foramsulfuron following the use of EQUIP OD are shown in the Table B.9.2.1.3-1.

Table B.9.2.1.3-1: Ratios of effective application rate to endpoints for foramsulfuron following the use of EQUIP OD

Test Substance	K _{OC}	Application rate (g a.s/ha)	Acute endpoint (mg/kg bw)	Ratio of application rate to acute endpoint	Long-term endpoint (mg/kg bw/day)	Ratio of application rate to long-term endpoint	Ratio Trigger
Foramsulfuron	38-151	60	> 2000	< 0.03	> 104	<0.58	≤ 50

The resulting ratios fall below the trigger indicating that further assessment of the acute and long-term risk to birds from drinking water from puddles is not required for foramsulfuron.

Baits: Concentration of active substance in bait in mg/kg

EQUIP OD is intended for use as a foliar spray, and therefore this information is not required.

Pellets, granules, prills or treated seed

EQUIP OD is intended for use as a foliar spray, and therefore this information is not required.

Amount of active substance in or on each item

EQUIP OD is intended for use as a foliar spray, and therefore this information is not required.

Proportion of active substance LD₅₀ per 100 items and per gram of items

EQUIP OD is intended for use as a foliar spray, and therefore this information is not required.

Size and shape of pellet, granule or prill

EQUIP OD is intended for use as a foliar spray, and therefore this information is not required.

B.9.2.1.4. Co-RMS conclusion

Acute, 5-day dietary and reproduction toxicity tests in birds have been conducted with foramsulfuron. Results indicate a low acute toxicity of the active substance to the bobwhite quail ($LD_{50} > 2000$ mg/kg bw) and mallard duck ($LD_{50} > 2000$ mg/kg bw). Dietary toxicity tests were done in the bobwhite quail ($LC_{50} > 5000$ mg/kg diet, i.e. $LD_{50} > 985$ mg a.s./kg bw/d) and mallard duck ($LC_{50} > 5000$ mg/kg diet, i.e. $LD_{50} > 1792$ mg a.s./kg bw/d). Effects of foramsulfuron on the reproductive parameters were studied in the two species, the bobwhite quail and mallard duck. The NOEC- 21 wk in bobwhite quail and mallard duck were found to be > 1000 mg a.s./ kg diet (nominal concentration). For the purposes of risk assessment, toxicity endpoint - the NOEC > 1000 mg a.s./ kg diet (nominal concentration) for long-term reproduction studies was re-calculated in terms of daily dietary dose (mg/kg bw/day) as recommended in the EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) and NOEL is > 104 mg/kg bw/day for bobwhite quail as the most sensitive species and used in the risk assessment. One acute test with the formulated product EQUIP OD was available. LD_{50} is > 2000 mg EQUIP OD / kg bw (nominal concentration), equivalent to 45 mg a.s./kg bw.

The formulated product EQUIP OD is applied on emerging seedlings in spring. The exposure of birds mainly occurs by feeding insects, earthworms and emerging plants which ~~were~~ are oversprayed with the preparation. Since this preparation is intended for spray application, exposure via acceptance of bait, granules or treated seeds by birds is not expected.

Acute risk: Calculated TER_A value in the screening step for foramsulfuron ($TER_A > 209.86$) for the indicator species are greater than the Annex VI trigger of 10, indicating that acute risk to birds is acceptable following use of EQUIP OD according to the proposed use pattern.

Short-term risk: EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009) in the part 2.2, p. 16 states that when the dietary LD_{50} is lower than the acute LD_{50} , the dietary LD_{50} should be used in the acute risk assessment. For foramsulfuron, the lowest dietary LD_{50} (> 985 mg a.s./kg bw/d) is below the acute endpoint (2000 mg a.s./kg bw/d) and should be considered for risk assessment. However, Co-RMS mention that without mortality, clinical signs and pathological abnormal finding, this LD_{50} is a NOEL and the risk assessment can be conducted according to the acute risk assessment.

Long-term risk: The long-term TER value calculated in the screening step for indicator species relevant for the risk following use of EQUIP OD in maize is greater than the Annex VI trigger value of 5 ($TER_{LT} > 50.48$) indicating that the long-term risk to birds is acceptable following use of EQUIP OD according to the proposed use pattern.

Supervised cage or field trials: TER_A and TER_{LT} being > 10 and 5, respectively, no supervised cage or field trials are necessary.

Risks from drinking water: The resulting ratios of effective application rate to endpoints for foramsulfuron following the use of EQUIP OD fall below the trigger (≤ 50) indicating that further assessment of the acute and long-term risk to birds from drinking water from puddles is not required.

Bioconcentration: The log K_{ow} of foramsulfuron is low (log Kow value 1.44 at pH 2; 0.78 at pH 7). Thus, no risk of bioaccumulation is expected. In addition, no risk of bioaccumulation of metabolites is expected also due to their low Kow values.

Risk of secondary poisoning: Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for birds if feeding on contaminated prey like fish or earthworms. For organic chemicals, a log $P_{OW} > 3$ is used to trigger an in-depth evaluation of the potential for bioaccumulation. In addition, the potential for secondary poisoning is reduced due to low toxicity of the active substance.

B.9.2.2. Risk assessment for terrestrial vertebrates other than birds

Toxicity

Foramsulfuron has been tested for potential acute and long-term toxicity to the rat and rabbit. The endpoints from these studies are presented in Table B.9.1.2.1-1 in Section B.9.1.2.1.

The LD₅₀ of the formulation (LD₅₀ > 5000 mg product./kg bw) reflects the low toxicity of the active substance, therefore risk assessment was conducted with the endpoint of the active substance.

In two-generation study the NOEC was determined to be 15 000 ppm (which corresponds to NOEL ≥ 1038 mg/kg bw/d for males and ≥ 1430 mg/kg bw/d for females). In developmental studies the NOEL for teratogenic effects was 1000 mg a.s./kg bw for rat and 500 mg a.s./kg bw for rabbit, the highest tested concentrations. **EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)** in the part 4.4 p. 39 states that: If the lowest relevant endpoint from the developmental study is lower than the lowest endpoint from the 2-generation rat study, then use the developmental study endpoint as the endpoint for the Tier 1 reproductive assessment. Otherwise, use the lowest relevant endpoint from the 2-generation rat study. The lowest NOEL is from the teratogenicity study with rabbit. Therefore value of 500 mg/kg bw/d was used for the risk assessment.

Foramsulfuron metabolites

Since metabolites are formed at < 10% of parent level in edible crop parts, it can be concluded that the risk to mammals will be low and no further risk assessment is conducted (**Foramsulfuron; SANCO Scientific Report, 2002**).

Exposure

Exposure of mammals will be predominantly dietary, through the consumption of residues on food items. Direct exposure of mammals to EQUIP OD applications is considered unlikely, since at the time of application and for a short period thereafter, most mammals will leave the immediate vicinity of spray operations in response to the human disturbance.

Exposure is calculated according to the **EFSA Guidance Document on Risk Assessment for Birds and Mammals, 2009**.

B.9.2.2.1. Calculations of DDD and TER for mammals

Screening assessment

The Screening step crop groupings and critical use patterns relevant to the uses of EQUIP OD are given in the **Table B.9.2.2.1-1**.

Table B.9.2.2.1-1: Screening step crop groupings and critical use patterns relevant to the use of EQUIP OD

Crop group	GAP crop species	Indicator species	Critical use pattern		
			Rate (kg a.s./ha)	No. of apps	App. Interval (days)
Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses and vineyard	Maize	Small herbivorous mammal	0.06	1	n.a.

The acute 'daily dietary dose' (DDD) is calculated by multiplying the Shortcut value (SV) based on the 90th percentile residues by the application rate in kg a.s./ha.

$$\text{DDD} = \text{application rate (kg a.s./ha)} \times \text{SV}$$

Daily dietary doses for acute exposure to foramsulfuron following use of EQUIP OD according to the various crop groups are given in the **Table B.9.2.2.1-2**.

Table B.9.2.2.1-2: Screening step – estimates of acute exposure to foramsulfuron

Test substance	Crop group	Indicator species	Shortcut value (mg a.s./kg bw/day)	App. rate (kg a.s./ha)	DDD (mg a.s./kg bw/day)
Foramsulfuron	Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses and vineyard	Small herbivorous mammal	136.4	0.06	8.18

Toxicity exposure ratios**Acute toxicity exposure ratio (TER_A)**

The acute risk to mammals was assessed by calculation of TER_A according to the following equation:

$$TER_A = \frac{LD_{50} \text{ (mg/kg bw)}}{DDD \text{ (mg/kg bw/d)}}$$

Acute risk was calculated using the acute LD₅₀ value for the active substance. According to the Annex VI guidelines, a TER_A value below 10 indicates a potential acute risk to mammals. The result is presented in **Table B.9.2.2.1-3**.

Table B.9.2.2.1-3: Screening step - Acute risk (TER_A) to mammals from foramsulfuron and EQUIP OD

Test substance	Crop group	Indicator species	LD ₅₀ (mg a.s./kg bw)	DDD (mg a.s./kg bw/day)	TER _A	Trigger value
Foramsulfuron	Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/ nursery, pulses and vineyard	Small herbivorous mammal	> 5000	8.18	> 611.25	10

The TER_A value for foramsulfuron for the indicator species is greater than the Annex VI trigger of 10, indicating that acute risk to mammals is acceptable following use of EQUIP OD according to the proposed use pattern.

- **Comment (Co-RMS):** The TER_A values are greater than the Annex VI trigger of 10, indicating that acute risk to mammals is acceptable following use of EQUIP OD according to the proposed use pattern. And first tier acute risk assessment is not necessary.

Short-term toxicity exposure ratio (TER_{ST})

According to the **EFSA Guidance Document on Risk Assessment for Birds and Mammals 2009**, short-term risk to mammals is not presented as it is covered by the long-term risk assessment.

Long-term toxicity exposure ratio (TER_{LT})**Screening assessment**

The long-term 'daily dietary dose' (DDD) is calculated by multiplying the Shortcut value (SV) based on the mean residues by the application rate in kg a.s./ha.

$$DDD = \text{application rate (kg a.s./ha)} \times SV \times f_{\text{twa}}$$

The f_{twa} based upon a default DT_{50} of 10 days is 0.53, as given in the EFSA Guidance Document.

The indicator species that are relevant for the proposed uses are considered with worst case application rates to calculate acute DDD values as shown in Table B.9.2.2.1-4.

Table B.9.2.2.1-4: Screening step - estimates of long-term exposure to foramsulfuron

Test substance	Crop group	Indicator species	Shortcut value (mg a.s./kg bw/day)	App. rate (kg a.s./ha)	f_{twa}	DDD (mg a.s./kg bw/day)
Foramsulfuron	Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses and vineyard	Small herbivorous mammal	72.3	0.06	0.53	2.30

The long-term risk to mammals was assessed from long-term TER values, calculated according to the following equation:

$$TER_{LT} = \frac{\text{NOEL (mg/kg bw/day)}}{\text{Long-term DDD (mg/kg bw/day)}}$$

The NOEL value (≥ 500 mg/kg bw/d) for foramsulfuron was used to calculate the TER value in order to provide a worst-case scenario. The resulting TER_{LT} value is given in Table B.9.2.2.1-5.

Table B.9.2.2.1-5: Screening step - long-term risk (TER_{LT}) to mammals

Test substance	Crop group	Indicator species	NOAEL (mg a.s./kg bw/day)	DDD (mg/a.s./kg bw/day)	TER_{LT}	Trigger Value
Foramsulfuron	Cotton, fruiting vegetables, grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, pulses and vineyard	Small herbivorous mammal	≥ 500	2.30	≥ 217.39	5

The TER_{LT} value for foramsulfuron is higher than the Annex VI trigger value of 5, indicating that the long-term risk to mammals is acceptable following use of EQUIP OD according to the proposed use pattern.

- **Comment (Co-RMS):** The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk, thus indicating acceptable risk to mammals from the proposed use pattern of EQUIP OD.

B.9.2.2.2. Active substance bioconcentration in prey of birds and mammals

B.9.2.2.2.1. Secondary poisoning risk assessment

According to EFSA Guidance Document on Risk Assessment for Birds and Mammals, 2009 substances with a $\log K_{ow}$ greater than 3 have potential for bioaccumulation. Foramsulfuron $\log K_{ow}$ is < 3 ($\log K_{ow}$ value 1.44 at pH 2; 0.78 at pH 7) indicating that a secondary poisoning risk assessment is not necessary. The $\log K_{ow}$ values for foramsulfuron metabolites are as follows : AE F130619 ($\log K_{ow} = 1.57$ (pH 6)); AE 0338795 ($\log K_{ow} = -2.33$ (pH 7)); AE F092944 ($\log K_{ow} = 0.92$); AE F153745 ($\log K_{ow} = -0.62$) indicating that a secondary poisoning risk assessment is not necessary.

B.9.2.2.2. Biomagnification in Terrestrial Food Chains

For foramsulfuron the results from adsorption, distribution, metabolism and excretion studies did not indicate a potential for accumulation. Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for birds if feeding on contaminated prey like fish or earthworms. For organic chemicals, a $\log POW > 3$ is used to trigger an in-depth evaluation of the potential for bioaccumulation. In addition, the potential for secondary poisoning is reduced due low toxicity of the active substance.

B.9.2.2.3. Risk from drinking water

Only the puddle scenario is relevant for risk assessment for mammals through drinking water.

Puddle scenario

It is stated in EFSA Guidance Document (ref. 5.5, Step 2b) that no specific calculations of exposure and TER are necessary if the ratio of effective application rate (in g/ha) to acute and long-term endpoint (in mg/kg bw/d) does not exceed 50 ($K_{oc} < 500 \text{ L/kg}$).

Ratios of effective application rate to endpoints for foramsulfuron following the use of EQUIP OD are presented in the **Table B.9.2.2.3.-1**.

Table B.9.2.2.3-1: Ratios of effective application rate to endpoints for foramsulfuron following the use of EQUIP OD

Test substance	K_{oc}	Application rate (g a.s/ha)	Acute endpoint (mg/kg bw)	Ratio of application rate to acute endpoint	Long-term endpoint (mg/kg bw/day)	Ratio of application rate to longterm endpoint	Ratio trigger
Foramsulfuron	38-151	60	> 5000	< 0.012	≥ 500	≤ 0.12	≤ 50

The resulting ratios fall below the trigger indicating that further assessment of the acute and long-term risk to mammals from drinking water from puddles is not required for foramsulfuron.

Acceptance of bait, granules or treated seed (palatability testing)

No study on palatability with the formulation was performed. As EQUIP OD is intended for use as a spray, the acceptance of baits, granules and treated seed is not relevant.

Supervised cage or field trials

Supervised cage/field trials with the formulation were not performed, since low risk to mammals indicates that further studies are not required.

B.9.2.2.4. Other data on effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians)

Not required according to 1107/2009. Since foramsulfuron is of low toxicity in birds and laboratory rodents, no risk for reptiles and amphibians is to be expected.

B.9.2.2.5. Co-RMS conclusion

Acute oral and reproduction toxicity tests in mammals have been conducted with foramsulfuron. Results indicate a low acute toxicity of the active substance to rat ($LD_{50} > 5000 \text{ mg/kg bw}$). One acute test with the formulated product EQUIP OD has previously been reviewed, under the experimental conditions, the oral LD_{50} of the EQUIP OD is $> 5000 \text{ mg/kg bw}$. A two-generation reproductive toxicity study on male and female rats was

performed. The study was evaluated within the process of Annex I inclusion and were considered acceptable by the RMS Germany. The NOAEC and NOEC was determined to be 15 000 ppm (which corresponds to ≥ 1038 mg/kg bw/day for males as the most sensitive endpoint.). In developmental studies the NOEL for teratogenic effects was 1000 mg a.s./kg bw for rat and 500 mg a.s./kg bw for rabbit.

The formulated product EQUIP OD is applied on emerging seedlings in spring. The exposure of mammals mainly occurs by feeding emerging plants which were oversprayed with the preparation. Since this preparation is intended for spray application, exposure via acceptance of bait, granules or treated seeds by mammals is not expected.

Acute risk: Calculated TER_A value for foramsulfuron in the screening step ($TER_A > 611.25$) for the indicator species is greater than the Annex VI trigger of 10, indicating that acute risk to mammals is acceptable following use of EQUIP OD according to the proposed use pattern.

Short-term risk: According to the **EFSA Guidance Document on Risk Assessment for Birds and Mammals 2009**, short-term risk to mammals is not presented as it is covered by the long-term risk assessment.

Long-term risk: The long-term TER value calculated in the screening step for indicator species relevant for the risk following use of EQUIP OD in maize is greater than the Annex VI trigger value of 5 ($TER_{LT} \geq 217.39$) indicating that the long-term risk to mammals is acceptable following use of EQUIP OD according to the proposed use pattern.

Supervised cage or field trials: TER_A and TER_{LT} being > 10 and 5 , respectively, no supervised cage or field trials are necessary.

Risks from drinking water: The resulting ratios of effective application rate to endpoints for foramsulfuron following the use of EQUIP OD fall below the trigger (≤ 50) indicating that further assessment of the acute and long-term risk to mammals from drinking water from puddles is not required.

Bioconcentration: The log K_{ow} values of foramsulfuron and its metabolites are low (log K_{ow} foramsulfuron = 1.44 at pH 2; 0.78 at pH 7; log K_{ow} AE F130619 = 1.57 (pH 6); log K_{ow} AE 0338795 = - 2.33 (pH 7); log K_{ow} AE F092944 = 0.92; log K_{ow} AE F153745 = - 0.62). Thus, no risk of bioaccumulation is expected.

Risk of secondary poisoning: Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for birds if feeding on contaminated prey like fish or earthworms. For organic chemicals, a log POW > 3 is used to trigger an in-depth evaluation of the potential for bioaccumulation. In addition, the potential for secondary poisoning is reduced due low toxicity of the active substance.

B.9.3. EFFECTS ON AQUATIC ORGANISMS

Aquatic organisms have been tested with the active ingredient and the metabolites included in the residue definition for aquatic risk assessment. The risk assessment has been performed according to “Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC” (Sanco/3268/2001 rev.4 (final) 17 October 2002).

Metabolite testing for aquatic organisms

Data of the parent compound show unambiguously that the aquatic macrophyte species *Lemna gibba* is by far the most sensitive organism in the aquatic environment (the next sensitive organism, the blue-green alga *Anabaena flos-aqua*, is by a factor of about 8000 less sensitive to foramsulfuron than *Lemna*). The sensitivity of this macrophyte species is clearly driving the risk assessment for foramsulfuron.

The risk that one of the metabolites would be toxic to fish, Daphnia or algae to an extent that this could actually impact the risk assessment seems to be negligibly low. Therefore, it is considered justified that the testing for metabolites potentially reaching aquatic systems should be limited to this most sensitive species, *Lemna*.

The appropriateness of this strategy was confirmed by singular tests on fish, Daphnia and algae with the metabolites AE F095944 and AE 099095. Both metabolites turned out to be completely non-toxic to these species at relevant exposure levels, with all EC₅₀ values above the highest tested dose levels.

Definition of the residue for risk assessment is present in **Table B.9.3.-1**.

Table B.9.3.-1: Definition of the residue for risk assessment

Compartment	Compound / Code
Soil	Foramsulfuron AE F092944 AE F130619 AE F153745
Groundwater	Foramsulfuron AE F092944 AE F130619 AE F153745
Surface water	Foramsulfuron AE F092944 AE F130619 AE F153745 AE 0338795 AE F099095 4-Amino-N-methylbenzamide 4-Formamido-N-methylbenzamide Foramsulfuron sulfamic acid
Plant material	Foramsulfuron

Due to the fact that *Lemna* is by far the most sensitive standard aquatic organism to the parent compound, metabolite testing was confined to this species in most cases, with two exceptions: AE F092944 and AE F099095. These are common metabolites with one or more sulfonyl urea herbicides. Tests with further aquatic species have been performed in context of risk assessments for other parent compounds. Although for the risk assessment of foramsulfuron these studies on further species are not considered essential, they are provided for sake of completeness.

B.9.3.1. Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

B.9.3.1.1. Acute toxicity to fish

For foramsulfuron (AE F130 630) three acute toxicity studies on three different fish species were performed. The tested dose level in all studies was 100 mg a.s./L. No sublethal effects and only random mortality (in one study only) were observed in the treatment, resulting in an LC₅₀ of >100 mg a.s./L. For the metabolite AE F092944 one acute study on rainbow trout was conducted with test doses ranging from 18 to 1000 mg/L. The 96-hour-LC₅₀ was 254 mg/L. For the formulation Equip OD 45 two acute toxicity studies on two different fish species were performed. The 96-LC₅₀ was 14 mg product /L for rainbow trout and 7.8 mg product /L for bluegill sunfish.

Acute toxicity data of foramsulfuron and its metabolite AE F092944 to fish are summarized in Table B.9.3.1.1.-1 and for the Equip OD 45 in Table B.9.3.1.1.-2.

Table B.9.3.1.1.-1: Acute toxicity data of foramsulfuron and its metabolite AE F092944 to fish

Test species	Test system	Test duration	Endpoint [mg as/L]	Reference
Foramsulfuron-sodium				
<i>Oncorhynchus mykiss</i> (rainbow trout)	static acute	96 h	LC ₅₀ > 100	1997 A57725 1997 A57751 (Amendment) M-141405-02-1 KCA 8.2.1 /01
<i>Lepomis macrochirus</i> (bluegill sunfish)	static acute	96 h	LC ₅₀ > 100	1997 A57752 (Amendment) M-141406-02-1 KCA 8.2.1 /02
<i>Cyprinodon variegatus</i> (sheephead minnow)	static acute	96 h	LC ₅₀ > 100	1998 A59901 M-143551-01-1 KCA 8.2.1 /03
AE F092944				
<i>Oncorhynchus mykiss</i> (rainbow trout)	static acute	96 h	LC ₅₀ = 254	1993 A50396 M-131422-01-1 KCA 8.2.1 /04

Bold letters: Values considered relevant for risk assessment

Table B.9.3.1.1.-2: Endpoints of the formulation used in risk assessment

Test organism	Study type	Test duration	LC/EC ₅₀ [†] [mg product /L]	NOEC [‡] [mg product/L]	References
Acute toxicity to fish					
<i>Oncorhynchus mykiss</i> (rainbow trout)	static renewal acute	96 h	14	3.9	2000 B002796 M-238518-01-2 KCP 10.2.1 /01
<i>Lepomis macrochirus</i> (bluegill sunfish)	static renewal acute	96 h	7.8	3.9	2000 B002795 M-238517-01-2 KCP 10.2.1 /02

Bold letters: Values considered relevant for risk assessment

B.9.3.1.2. Acute toxicity to aquatic invertebrates

Acute toxicity to *Daphnia magna*

One acute toxicity study on *Daphnia magna* was performed with foramsulfuron and the product Equip OD 45. No mortality occurred at the tested dose level of 100 mg a.s./L, resulting in a NOEC of 100 mg a.s./L and an EC₅₀ > 100 mg a.s./L. In the test with Equip OD 45 a 48-hour EC₅₀ of 6.9 mg product/L was obtained. For the metabolite AE F092944 one acute study on *Daphnia magna* was conducted. The tested dose level ranged from 10 to 560 mg/L, the determined EC₅₀ was 223 mg/L.

Acute toxicity data of foramsulfuron and its metabolite AE F092944 to Daphnids are summarized in **Table B.9.3.1.2.-1** and for the Equip OD 45 in **Table B.9.3.1.2.-2**.

Table B.9.3.1.2.-1: Acute toxicity data of foramsulfuron and metabolite AE F092944 to *Daphnia magna*

Test species	Test system	Test duration	Endpoint [mg as/L]		Reference
Foramsulfuron-sodium					
Daphnia magna (water flea)	static acute	48 h	EC ₅₀	> 100	Stachura & Ruff, (1997) A57724 & A57750 (Amendment) M-141404-02-1 KCA 8.2.4.1 /01
AE F092944					
Daphnia magna (water flea)	static acute	48 h	EC ₅₀	223	Heusel, 1993 A50353 M-131382-01-1 KCA 8.2.4.1 /02

Bold letters: Values considered relevant for risk assessment

Table B.9.3.1.2.-2: Endpoints of the formulation used in risk assessment

Test organism	Study type	Test duration	EC ₅₀ ¹ [mg product /L]	NOEC ² [mg product/L]	References
Acute toxicity to aquatic invertebrates					
<i>Daphnia magna</i> (water flea)	static renewal acute	48 h	6.9	3.6	Boeri & Ward, 2000 B002797 M-238519-01-2 KCP 10.2.1 /03

Bold letters: Values considered relevant for risk assessment

B.9.3.1.3. Effects on algal growth

Potential effects of foramsulfuron on algal growth were investigated with four different algae species, a green alga, a blue-green alga and a freshwater and a marine diatom. The blue-green alga *Anabaena flos-aquae* was found to be, by a factor of 10, more sensitive than other algae species. The EC₅₀ of foramsulfuron for this species is 8.1 mg a.s./L (**Table B.9.3.1.3.-1**). Potential effects of product Equip OD 45 on algal growth were also investigated with green algae and the study resulted in a 96-hour ErC₅₀ greater than 5.0 mg/L, the highest tested concentration.

For metabolites AE F092944 and AE F0999095 studies were performed with green algae where in both cases the EC₅₀ was above the highest tested dose level (EC₅₀ > 560 and 100 mg/L, respectively) – and also clearly above the respective EC₅₀ for green algae of the parent compound (**Table B.9.3.1.3.-1**).

Acute toxicity data of formulation Equip OD 45 to green algae are summarized in **Table B.9.3.1.3.-2**.

Table B.9.3.1.3.-1: Growth effect data of foramsulfuron and its metabolites AE F092944 and AE F0999095 to algae

Test species	Test system	Test duration	Endpoint [mg as/L]		Reference
Foramsulfuron-sodium					
<i>Pseudokirchneriella subcapitata</i> (syn. <i>Selenastrum capricornutum</i>) (green alga)	growth inhibition	72 h	ErC ₅₀ ¹⁾	75.0	Christ & Ruff, 1998 A59926 M-143574-01-1 KCA 8.2.6.1 /01
		96 h	ErC ₅₀ ¹⁾	86.2	
<i>Navicula pelliculosa</i> (diatom)	growth inhibition	72 h /96 h	ErC ₅₀ ¹⁾	> 112	Young & Ruff, 1999 C002422 M-184469-01-1 KCA 8.2.6.2 /01

<i>Anabaena flos-aquae</i> (blue-green algae)	growth inhibition	72 h	ErC ₅₀ ¹⁾	8.1	Christ & Ruff, 1999 C003699 M-186627-01-1 KCA 8.2.6.2 /02
		96 h	ErC ₅₀ ¹⁾	8.1	
<i>Skeletonema costatum</i> (marine diatom)	growth inhibition test	72 h /96 h	ErC ₅₀	> 105	Young & Ruff, 1999 C002436 M-184494-01-1 KCA 8.2.6.2 /03
AE F092944					
<i>Desmodesmus subspicatus</i> (syn. <i>Scenedesmus subspicatus</i>) (green alga)	growth inhibition	72 h	ErC ₅₀	> 560	Heusel, 1993 A50395 M-131421-01-1 KCA 8.2.6.1 /02
AE F099095					
<i>Pseudokirchneriella subcapitata</i> (green alga)	growth inhibition	72 h	ErC ₅₀	> 100	Dorgerloh, 2005 M-254084-01-1 KCA 8.2.6.1 /03

Bold letters: Values considered relevant for risk assessment

¹⁾ Since the new aquatic GD3 focusses on endpoints based on growth rates the old E_bC₅₀ figures were omitted from the table above.

Table B.9.3.1.3.-2: Endpoints of the formulation Equip OD 45 used in risk assessment

Test organism	Study type	Test duration	LC/EC ₅₀ [mg product/L]	NOEC [mg product /L]	References
Effects on algal growth					
<i>Selenastrum capricornutum</i> (green alga)	static	72 h	ErC ₅₀ ¹ : > 5.0	N/C	Boeri & Ward, 2000 B002798 M-238520-01-2 KCP 10.2.1 /04
		96 h	ErC ₅₀ ³ : > 5.0	1.3	

¹ ErC₅₀ = effect concentration calculated as rate from cell densities (numbers)

N/C = not calculated

Bold figures are used for risk assessments

B.9.3.1.4. Effects on aquatic macrophytes

For foramsulfuron, toxicity studies on different aquatic macrophytes were performed. Besides *Lemna gibba*, also *Myriophyllum spicatum* was tested as a second macrophyte species. In addition, an outdoor growth inhibition study was performed with a total of ten species representing different taxonomic groups. Since *Lemna gibba* turned out to be the most sensitive species to foramsulfuron, higher-tier studies (recovery, peak exposure, long-term exposure) were performed with this species (Table B.9.3.1.4.-1). Also potential effects of formulation Equip OD 45 on *Lemna gibba* growth were investigated (Table B.9.3.1.4.-2).

Metabolite testing for aquatic organisms

Studies investigating the toxicity to *Lemna gibba* were also performed for all metabolites of the residue definition for risk assessment in surface water. It was found that one metabolite, AE F130619, has a similar activity to *Lemna* as the parent compound, while all other metabolites turned out to be non-toxic to these organisms (Table B.9.3.1.4.-1).

Data of the parent compound show unambiguously that the aquatic macrophyte species *Lemna gibba* is by far the most sensitive organism in the aquatic environment (the next sensitive organism, the blue-green alga *Anabaena flos-aqua*, is by a factor of about 8000 less sensitive to foramsulfuron than *Lemna*). The sensitivity of this macrophyte species is clearly driving the risk assessment for foramsulfuron.

The risk that one of the metabolites would be toxic to fish, *Daphnia* or algae to an extent that this could actually impact the risk assessment seems to be negligibly low. Therefore, it is considered justified that the testing for metabolites potentially reaching aquatic systems should be limited to this most sensitive species, *Lemna*.

The appropriateness of this strategy was confirmed by singular tests on fish, Daphnia and algae with the metabolites AE F095944 and AE 099095 (Tables B.9.3.1.1.-1 and B.9.3.1.2.-1). Both metabolites turned out to be completely non-toxic to these species at relevant exposure levels, with all EC₅₀ values above the highest tested dose levels.

Table B.9.3.1.4.-1: Effect data of foramsulfuron and its metabolites to aquatic macrophytes

Test species	Test system	Test duration	Endpoint [mg as/L]	Reference
Foramsulfuron-sodium				
<i>Lemna gibba</i> (duck weed)	growth inhibition, static	7 d	ErC ₅₀ ¹⁾ = 1.01 µg/L	Christ & Ruff, 1998 A67514 Christ, 1999 C002148 (Amendment) M-147891-02-1 KCA 8.2.7 /01
<i>Lemna gibba</i> (duck weed)	growth inhibition + recovery	7 d+ 14 d	NOEC = 5 µg/L	Dorgerloh, 2005 MO-05-007405 M-250268-01-1 KCA 8.2.7 /05
<i>Lemna gibba</i> (duck weed)	growth inhibition, peak exposure	1 d + 6 d	ErC ₅₀ ¹⁾ > 56.7 µg/L	Bruns, 2013 EBFSN003 M-462569-01-1 KCA 8.2.7 /06
<i>Lemna gibba</i> (duck weed)	growth inhibition, mimicking exposure of outdoor study	42 d	ErC ₅₀ ¹⁾ = 1.18 µg/L	Bruns, 2013 EBFSL014 M-464150-01-1 KCA 8.2.7 /08
Aquatic macrophytes (10 species)	growth inhibition + recovery	2 d + 5.5 weeks	NOEC (6 weeks) = 0.1 µg/L NOEC (48 h peak) = 4.1 µg/L	Kirkwood, 2012 EBFSL012 M-429538-01-1 KCA 8.2.7 /07
<i>Myriophyllum spicatum</i> (aquatic plant)	growth inhibition	14 d	EC ₅₀ > 84	Banman et al., 2012 EBFSL004 M-431270-01-1 KCA 8.2.7 /09
AE F153745				
<i>Lemna gibba</i> (duck weed)	growth inhibition	7 d	EC ₅₀ > 100	Christ & Ruff, 2000 B002765 M-240924-01-2 KCA 8.2.7 /02
AE 0338795				
<i>Lemna gibba</i> (duck weed)	growth inhibition	7 d	ErC ₅₀ ¹⁾ = 27.2	Christ & Ruff, 2000 B002774 M-238498-01-2 KCA 8.2.7 /03
AE F092944				
<i>Lemna gibba</i> (duck weed)	growth inhibition	7 d	ErC ₅₀ ¹⁾ > 100	Sowig & Weller, O.; 2000, C003865 M-186916-01-1 KCA 8.2.7 /10
AE F099095				
<i>Lemna gibba</i> (duck weed)	growth inhibition	7 d	ErC ₅₀ ¹⁾ > 100	Dorgerloh, 2005 EBMMX091 M-254496-01-1 KCA 8.2.7 /11
AE F130619				
<i>Lemna gibba</i> (duck weed)	growth inhibition	7 d	ErC ₅₀ ¹⁾ = 0.889 µg/L	Bruns, 2013 EBFSL011 M-452669-01-1

Test species	Test system	Test duration	Endpoint [mg a.s./L]	Reference
				KCA 8.2.7 /12
4-Amino-N-methylbenzamide				
<i>Lemna gibba</i> (duck weed)	growth inhibition	7 d	ErC ₅₀ ¹⁾ > 10	Bruns, 2013 EBFSN010 M-464163-01-1 KCA 8.2.7 /13
4-Formylamido-N-methylbenzamide				
<i>Lemna gibba</i> (duck weed)	growth inhibition	7 d	ErC ₅₀ ¹⁾ > 10	Bruns, 2013 EBFSN011 M-464321-01-1 KCA 8.2.7 /14
Foramsulfuron-sulfamic acid				
<i>Lemna gibba</i> (duck weed)	growth inhibition	7 d	ErC ₅₀ > 10	Hoffmann, 2013 EBFSN012 M-464386-01-1 KCA 8.2.7 /15

Bold letters: Values considered relevant for risk assessment

¹⁾ Since the new aquatic GD focusses on endpoints based on growth rates the old EbC₅₀ figures were omitted from the table above.

Endpoints of the formulation used in risk assessment for aquatic macrophytes are summarized in **Table B.9.3.1.4.-2**. In case of *Lemna* the three ErC₅₀-figures for frond numbers (1.01, 1.1, and 1.56), obtained from studies with the formulation as test substance, result in a geometric mean of 1.20 µg foramsulfuron/L. This endpoint is very close to the *Lemna* endpoint of 1.01 µg a.s./L. obtained from the study with the active substance foramsulfuron as test substance. Therefore, for the refined risk assessment only the figure of 1.01 µg a.s./L was used.

Other two studies on *Lemna* were performed with a different formulation AE F130360 + AE F122006 + AE F115008 (**Table B.9.3.1.4.-2**).

Table B.9.3.1.4.-2: Endpoints of the formulation used in risk assessment for aquatic macrophytes

Test organism	Study type	Test duration	LC/EC ₅₀ ¹ [mg/L]	NOEC ² [mg/L]	References
Formulation Equip OD 45					
<i>Lemna gibba</i> (duck weed)	static-renewal	7d	ErC ₅₀ (frond#): 45 µg prod./L (corresponds to 1.01 µg a.s./L)	10 µg prod./L (corresponds to 0.225 µg a.s./L)	Boeri, Wyskiel & Ward, 2000 B002845 M-238581-01-1 KCP 10.2.1 /05
<i>Lemna gibba</i> (duck weed)	static-renewal	7d	ErC ₅₀ (frond#): 1.56 µg a.s./L ErC ₅₀ (weight): > 3.08 µg a.s./L	< 0.10 µg a.s./L	Banman et al., 2008 EBFSX011 M-296352-01-1 KCP 10.2.1 /09
<i>Lemna gibba</i> (duck weed)	static-renewal	7d	ErC ₅₀ ⁴⁾ : 1.1 µg a.s./L	0.2 µg a.s./L	Hoberg, 2002 B003893 M-240877-01-1 KCP 10.2.1 /08
<i>Lemna gibba</i> (duck weed)	static-renewal	7d	Geomean ErC₅₀: 1.20 µg a.s./L corresponding to 53.23 µg prod./L		KCP 10.2.1 /05 KCP 10.2.1 /08 KCP 10.2.1 /09
Formulation AE F130360 + AE F122006 + AE F115008					
<i>Lemna gibba</i> (duck weed)	growth inhibition	7 d	E _r C ₅₀ ⁴⁾ : 2.8 µg/L	1.0 µg/L	Madsen, T. J.; Bussard, J. B.; 2000

Test organism	Study type	Test duration	LC/EC ₅₀ ¹ [mg/L]	NOEC ² [mg/L]	References
	static renewal				M-238567-01 KCP 10.2.1 /06
<i>Lemna gibba</i> (duck weed)	growth inhibition static renewal	7 d	E _r C ₅₀ ⁴ : 4-8 µg/L	1.0 µg/L	Madsen, T. J.; Bussard, J. B.; 2000 M-238536-01 KCP 10.2.1 /07

¹ LC = lethal concentration, EC = effect concentration

² NOEC = No Observed Effects Concentration

³ E_rC₅₀ = effect concentration calculated as rate from cell densities (numbers)

⁴ Since the new aquatic GD¹ focusses on endpoints based on growth rates the old E_bC₅₀ figures were omitted from the table above.

Bold figures are used for risk assessments

µg a.s./L refers to µg foramsulfuron/L

B.9.3.2. Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

B.9.3.2.1. Long-term and chronic toxicity to fish

Two chronic studies on different fish species were performed. The maximum tested dose levels were 100 mg a.s./L in the chronic study with rainbow trout, and 10.5 mg a.s./L in the study on early life stage exposure with fathead minnow. In both studies no relevant treatment related effects were observed at the maximum dose level, resulting in a NOEC of 100 or 10.5 mg a.s./L, respectively (Table B.9.3.2.1-1).

Table B.9.3.2.1.-1: Chronic toxicity data of foramsulfuron to fish

Test species	Test system	Test duration	Endpoint [mg a.s./L]		Reference
<i>Oncorhynchus mykiss</i> (rainbow trout)	chronic	28 d	NOEC	100	██████████ 1999 C004117 M-187354-01-1 KCA 8.2.2.1 /01
<i>Pimephales promelas</i> (fathead minnow)	Early Life Stage flow-through	35 d	NOEC	10.5	██████████ 2004 B004606 M-241508-01-1 KCA 8.2.2.1 /02

Bold letters: Values considered relevant for risk assessment

Table B.9.3.2.1.-2: Chronic toxicity data of Equip OD 45 to fish

Test organism	Study type	Test duration	LC/EC ₅₀ ¹ [mg/L]	NOEC ² [mg a.s./L]	References
Prolonged toxicity to fish					
<i>Oncorhynchus mykiss</i> (rainbow trout)	Chronic Flow through	28 d	-	1.8	██████████ 2000 B002764 M-238492-01-2 KCP 10.2.2 /01

¹ LC = lethal concentration, EC = effect concentration

² NOEC = No Observed Effects Concentration

B.9.3.2.2. Long-term and chronic toxicity to *Daphnia magna*

One reproductive toxicity study on *Daphnia magna* was performed with active substance and one with the formulation. The active substance showed no chronic effects on the survival, growth or reproduction of the water

¹ EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 268 pp. doi:10.2903/j.efsa.2013.3290

flea at a concentration of 100 mg a.s./L (Table B.9.3.2.2.-1). In the test with Equip OD 45 a 21 day NOEC of 0.4 mg product/L was obtained (Table B.9.3.2.2.-2).

Table B.9.3.2.2.-1: Chronic toxicity data of foramsulfuron to *Daphnia magna*

Test substance	Test species	Test system	Test duration	NOEC [mg a.s./L]	Reference
Foramsulfuron	Invertebrate, chronic <i>Daphnia magna</i>	static renewal	21 d	> 100	Young & Ruff, 1999 B002180 M-237962-01-2 KCA 8.2.5.1 /01

Table B.9.3.2.2.-2: Chronic toxicity data of Equip OD 45 to *Daphnia magna*

Test substance	Test species	Test system	Test duration	NOEC [mg as product /L]	Reference
Equip OD 45	Invertebrate, chronic <i>Daphnia magna</i>	static renewal	21 d	0.4	Young & Ruff, 2000 B002760 M-238488-01-2 KCP 10.2.2 /02

Bold letters: Values considered relevant for risk assessment

B.9.3.2.3. Reproductive and development toxicity to an additional aquatic invertebrate species

Foramsulfuron has no insecticidal activity and no chronic effects on *Daphnia magna* have been observed. No additional chronic testing with aquatic invertebrate species is needed.

B.9.3.2.4. Development and emergence in Chironomus species

Foramsulfuron has no insecticidal activity, is not a growth regulator, and no chronic effects on *Daphnia magna* have been observed. No additional chronic testing with aquatic invertebrate species is needed.

B.9.3.3. Further testing on aquatic organisms

One acute study in a static system on Grass shrimp (*Palaemonetes pugio*) and one acute study under flow-through conditions on Eastern oyster (*Crassostrea virginica*) were performed. Details of all studies are provided in the Table B.9.3.3.-1.

Table B.9.3.3.-1: Effect data of foramsulfuron to aquatic organisms

Test species	Test system	Test duration	Endpoint [mg as/L]		Reference
<i>Palaemonetes pugio</i> (grass shrimp)	static acute	96 h	EC ₅₀	> 100	Stachura & Ruff, (1998) A59902 M-143552-01-1 KCA 8.2.8 /02
<i>Crassostrea virginica</i> (eastern oyster)	flow-through	96 h	EC ₅₀	118	Boeri, Magzeau & Ward, 1998 C000906 M-181443-01-1 KCA 8.2.8 /01

B.9.4. RISK ASSESSMENT FOR AQUATIC ORGANISMS

The risk assessment has been performed according to “Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC” (Sanco/3268/2001 rev.4 (final) 17 October 2002) and the “Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters” (EFSA Panel on Plant Protection Products and their Residues, 2013, EFSA Journal 2013; 11(7): 3290, 268 pp. has been considered where appropriate.

Ecotoxicological endpoints used in risk assessment

Ecotoxicological endpoints of the formulation used in risk assessment are summarized in the **Table B.9.4.-1**.

Table B.9.4.-1: Endpoints of the formulation used in risk assessment

Test organism	Study type	Test duration	LC/EC ₅₀ ¹ [mg/L]	NOEC ² [mg/L]	References
Acute toxicity to fish					
<i>Oncorhynchus mykiss</i> (rainbow trout)	static renewal acute	96 h	14	3.9	2000 B002796 M-238518-01-2 KCP 10.2.1 /01
<i>Lepomis macrochirus</i> (bluegill sunfish)	static renewal acute	96 h	7.8	3.9	2000 B002795 M-238517-01-2 KCP 10.2.1 /02
Prolonged toxicity to fish					
<i>Oncorhynchus mykiss</i> (rainbow trout)	Flow through	28 d	-	1.8	2000 B002764 M-238492-01-2 KCP 10.2.2 /01
Acute toxicity to aquatic invertebrates					
<i>Daphnia magna</i> (water flea)	static renewal acute	48 h	6.9	3.6	Boeri & Ward, 2000 B002797 M-238519-01-2 KCP 10.2.1 /03
Chronic toxicity to aquatic invertebrates					
<i>Daphnia magna</i> (water flea)	static renewal	21 d	-	0.4	Young & Ruff, 2000 B002760 M-238488-01-2 KCP 10.2.2 /02
Effects on algal growth					
<i>Selenastrum capricornutum</i> (green alga)	static	72 h	ErC ₅₀ ³ : > 5.0	N/C	Boeri & Ward, 2000 B002798 M-238520-01-2 KCP 10.2.1 /04
		96 h	ErC ₅₀ ³ : > 5.0	1.3	
Effects on aquatic macrophytes					
<i>Lemna gibba</i> (duck weed)	static-renewal	7d	ErC ₅₀ (frond#): 45 µg prod./L (corresponds to 1.01 µg a.s./L)	10 µg prod./L	Boeri, Wyskiel & Ward, 2000 B002845 M-238581-01-1 KCP 10.2.1 /05
<i>Lemna gibba</i> (duck weed)	static-renewal	7d	ErC ₅₀ : 1.1 µg a.s./L	0.2 µg a.s./L	Hoberg, 2002 B003893 M-240877-01-1 KCP 10.2.1 /08
<i>Lemna gibba</i> (duck weed)	static-renewal	7d	ErC ₅₀ (frond#): 1.56 µg a.s./L ErC ₅₀ (weight): > 3.08 µg a.s./L	< 0.10 µg a.s./L	Banman et al., 2008 EBFSX011 M-296352-01-1 KCP 10.2.1 /09
<i>Lemna gibba</i> (duck weed)	static-renewal	7d	Geomean ErC ₅₀ : 1.20 µg a.s./L corresponding to 53.23 µg prod./L		KCP 10.2.1 /05 KCP 10.2.1 /08 KCP 10.2.1 /09

¹ LC = lethal concentration, EC = effect concentration

² NOEC = No Observed Effects Concentration

³ ErC₅₀ = effect concentration calculated as rate from cell densities (numbers)

N/C = not calculated

Bold figures are used for risk assessments

µg a.s./L refers to µg foramsulfuron/L

According to the new aquatic guidance document (EFSA 2013) endpoints based on growth rates are regarded as relevant for risk assessments. In case of *Lemna* the three ErC_{50} -figures for frond numbers (1.01, 1.1, and 1.56), obtained from studies with the formulation Equip OD 45 as test substance, result in a geometric mean of 1.20 μg foramsulfuron/L. This endpoint is very close to the *Lemna* endpoint of 1.01 μg a.s./L. obtained from the study with the active substance foramsulfuron as test substance. Therefore, for the refined risk assessment only the figure of 1.01 μg a.s./L will be used.

Table B.9.4.-2: Endpoints of foramsulfuron and metabolites used in risk assessment

Test substance	Test species	Endpoint	mg a.s./L or μg a.s./L or mg/L	Reference
Foramsulfuron	Fish, acute <i>Oncorhynchus mykiss</i> , <i>Lepomis macrochirus</i>	LC_{50}	> 100 mg a.s./L	[REDACTED] 1997 A57725, A57751 (Amendment) M- 141405-02-1 KCA 8.2.1 /01 [REDACTED], 1997 A57726, A57752 (Amendment) M-141406-02-1 KCA 8.2.1 /02
	Fish, chronic <i>Pimephales promelas</i>	NOEC	10.5 mg a.s./L	[REDACTED] 2004 B004606 M-241508-01-1 KCA 8.2.2.1 /02
	Invertebrate, acute <i>Daphnia magna</i>	EC_{50}	> 100 mg a.s./L	Stachura & Ruff, 1997 A57724, A57750 (Amendment) M-141404-02-1 KCA 8.2.4.1 /01
	Invertebrate, chronic <i>Daphnia magna</i>	NOEC	> 100 mg a.s./L	Young & Ruff, 1999 B002180 M-237962-01-2 KCA 8.2.5.1 /01
	Algae <i>Anabaena flos-aquae</i>	ErC_{50}	8.1 mg a.s./L	Christ & Ruff, 1999 C003699 M-186627-01-1 KCA 8.2.6.2 /02
	Aquatic plant <i>Lemna gibba</i>	ErC_{50}	1.01 μg a.s./L NO ErC < 1.01 μg a.s./L	Christ & Ruff, 1998 A67514, C002148 (Amendment) M- 147891-02-1 KCA 8.2.7 /01
	Aquatic plant <i>Myriophyllum spicatum</i>	EC_{50}	> 84.0 μg a.s./L	Banman et al., 2012; M- 431270-01-1 KCA 8.2.7 /09
	Aquatic plant macrophyte outdoor growth inhibition study; ten species	NOEC (6 weeks) NOEC (48h peak)	0.1 μg a.s./L 4.1 μg a.s./L	Kirkwood, 2012; M- 429538-01-1 KCA 8.2.7 /07
	Aquatic plant <i>Lemna gibba</i> (6 week study; mimicking exposure of outdoor study)	ErC_{50} (frond number)	1.18 μg a.s./L	Bruns, 2013; M-464150-01-1 KCA 8.2.7 /08
	Aquatic plants (probabilistic risk assessment: macrophyte outdoor data plus 6-week	HC_5	0.652 μg a.s./L	KCA 8.2.7 /07 KCA 8.2.7 /08

Test substance	Test species	Endpoint	mg a.s./L or µg a.s./L or mg/L	Reference
	Lemna)			
	Aquatic plant <i>Lemna gibba</i> peak exposure; 24 h	ErC ₅₀	> 56.7 µg a.s./L	Bruns, 2013; M-462569-01-1 KCA 8.2.7 /06
AE F153745	Aquatic plant <i>Lemna gibba</i>	EC ₅₀	> 100 mg/L	Christ & Ruff, 2000 B002765 M-240924-01-2 KCA 8.2.7 /02
AE 0338795	Aquatic plant <i>Lemna gibba</i>	ErC ₅₀	27.2 mg/L	Christ & Ruff, 2000 B002774 M-238498-01-2 KCA 8.2.7 /03
AE F092944	Fish, acute <i>Oncorhynchus mykiss</i>	LC ₅₀	254 mg/L	██████ 1993 A50396 M-131422-01-1 KCA 8.2.1 /04
	Invertebrate, acute <i>Daphnia magna</i>	EC ₅₀	223 mg/L	Heusel, 1993 A50353 M-131382-01-1 KCA 8.2.4.1 /02
	Algae <i>Desmodesmus subspicatus</i>	ErC ₅₀	> 560 mg/L	Heusel, 1993 A50395 M-131421-01-1 KCA 8.2.6.1 /02
	Aquatic plant <i>Lemna gibba</i>	ErC ₅₀	> 100 mg/L	Sowig, 2000 C003865 M-186916-01-1 KCA 8.2.7 /10
AE F099095	Algae <i>Pseudokirchneriella subcapitata</i>	ErC ₅₀	> 100 mg/L	Dorgerloh, 2005 EBMMX092 M-254084-01-1 KCA 8.2.6.1 /03
	Aquatic plant <i>Lemna gibba</i>	ErC ₅₀	> 100 mg/L	Dorgerloh, 2005 EBMMX091 M-254496-01-1 KCA 8.2.7 /11
AE F130619	Aquatic plant <i>Lemna gibba</i>	ErC ₅₀	0.000889 mg/L	Bruns, 2013; M-452669-01-1 KCA 8.2.7 /12
4-amino-N-methylbenzamide	Aquatic plant <i>Lemna gibba</i>	ErC ₅₀	> 10 mg/L	Bruns, 2013; M-464163-01-1 KCA 8.2.7 /13
4-formamido-N-methylbenzamide	Aquatic plant <i>Lemna gibba</i>	ErC ₅₀	> 10 mg/L	Bruns, 2013; M-464321-01-1 KCA 8.2.7 /14
Foramsulfuron-sulfamic acid	Aquatic plant <i>Lemna gibba</i>	ErC ₅₀	> 10 mg/L	Bruns, 2013; M-464386-01-1 KCA 8.2.7 /15

Predicted Environmental Concentrations used in risk assessment**Table B.9.4.-3: Initial maximum PEC_{sw} values of the formulation, considering spray drift after one application as only route of entry relevant for the product**

Compound	Scenario	Drift rate (no buffer)	Maize, 1 x 2.6 L/ha	Maize, 2 x 1.3 L/ha
			PEC _{sw} , max [µg/L]	PEC _{sw} , max [µg/L]
FSN+IDF OD 45 (22.5+22.5)	small static ditch, at the edge of the treated field, water depth 0.3 m	2.77 % (arable crops)	23.17	11.59

Bold values were used for risk assessment

Table B.9.4.-4: Initial max PEC_{sw} values of foramsulfuron and metabolites – FOCUS Step 2

Compound	FOCUS Scenario	Maize, 1 x 60 g/ha	Maize, 2 x 30 g/ha
		PEC _{sw} , max [µg/L]	PEC _{sw} , max [µg/L]
Foramsulfuron	STEP 1	18.85	18.85
	STEP 2 – North Multi	-	2.291
	STEP 2 – South Multi	-	4.189
	STEP 2 – North Single	2.713	1.357
	STEP 2 – South Single	4.948	2.474
AE F130619	STEP 1	5.071	5.071
	STEP 2 – North Multi	-	0.149
	STEP 2 – South Multi	-	0.276
	STEP 2 – North Single	0.255	0.128
	STEP 2 – South Single	0.481	0.241
AE F092944	STEP 1	0.682	0.682
	STEP 2 – North Multi	-	0.090
	STEP 2 – South Multi	-	0.172
	STEP 2 – North Single	0.099	0.049
	STEP 2 – South Single	0.189	0.094
AE F153745	STEP 1	0.961	0.961
	STEP 2 – North Multi	-	0.068
	STEP 2 – South Multi	-	0.070
	STEP 2 – North Single	0.081	0.041
	STEP 2 – South Single	0.087	0.044
AE 0338795	STEP 1	0.127	0.127
	STEP 2 – North Multi	-	0.107
	STEP 2 – South Multi	-	0.107
	STEP 2 – North Single	0.127	0.063
	STEP 2 – South Single	0.127	0.063
AE F099095	STEP 1	0.085	0.085
	STEP 2 – North Multi	-	0.066
	STEP 2 – South Multi	-	0.066

Compound	FOCUS Scenario	Maize, 1 x 60 g/ha	Maize, 2 x 30 g/ha
		PEC _{sw} , max [µg/L]	PEC _{sw} , max [µg/L]
	STEP 2 – North Single	0.085	0.043
	STEP 2 – South Single	0.085	0.043
4-Amino-N-methylbenzamide	STEP 1	0.024	0.024
	STEP 2 – North Multi	-	0.021
	STEP 2 – South Multi	-	0.021
	STEP 2 – North Single	0.023	0.012
	STEP 2 – South Single	0.023	0.012
4-Formylamido-N-methylbenzamide	STEP 1	0.043	0.043
	STEP 2 – North Multi	-	0.038
	STEP 2 – South Multi	-	0.038
	STEP 2 – North Single	0.043	0.021
	STEP 2 – South Single	0.043	0.021
Foramsulfuron-sulfamic acid	STEP 1	0.060	0.060
	STEP 2 – North Multi	-	0.053
	STEP 2 – South Multi	-	0.053
	STEP 2 – North Single	0.060	0.030
	STEP 2 – South Single	0.060	0.030

Bold values were used for risk assessment

Table B.9.4.-5: Initial maximum PEC_{sw} values of foramsulfuron and metabolite AE F130619 – FOCUS Step 3

FOCUS Scenario STEP 3	Foramsulfuron			AE F130619	
	Entry route*	PEC _{sw} , max [µg/L]	PEC _{sw} , max [µg/L]	PEC _{sw} , max [µg/L]	PEC _{sw} , max [µg/L]
Maize, 1 x 60 g/ha		Single application	Multiple applications	Single application	Multiple applications
D3 (ditch)	S	0.314	-	0.032	-
D4 (pond)	S	0.013	-	0.001	-
D4 (stream)	S	0.271	-	0.001	-
D5 (pond)	S	0.015	-	0.002	-
D5 (stream)	S	0.251	-	<0.001	-
D6 (ditch)	S	0.316	-	0.032	-
R1 (pond)	R	0.025	-	0.004	-
R1 (stream)	R	1.284	-	0.081	-
R2 (stream)	R	0.972	-	0.106	-
R3 (stream)	R	2.225	-	0.178	-
R4 (stream)	R	2.341	-	0.202	-
Maize, 2 x 30 g/ha		Single application	Multiple applications	Single application	Multiple applications
D3 (ditch)	S	0.157	0.136	0.016	0.014
D4 (pond)	S	0.006	0.010	<0.001	<0.001
D4 (stream)	S	0.136	0.118	<0.001	0.001
D5 (pond)	S	0.007	0.013	<0.001	0.001
D5 (stream)	S	0.126	0.117	<0.001	0.001

FOCUS Scenario STEP 3	Foramsulfuron			AE F130619	
	Entry route*	PEC _{sw} , max [µg/L]	PEC _{sw} , max [µg/L]	PEC _{sw} , max [µg/L]	PEC _{sw} , max [µg/L]
Maize, 1 x 60 g/ha		Single application	Multiple applications	Single application	Multiple applications
D6 (ditch)	S	0.158	0.138	0.016	0.014
R1 (pond)	R	0.013	0.062	0.002	0.010
R1 (stream)	R	0.622	1.281	0.040	0.099
R2 (stream)	R	0.456	0.456	0.052	0.052
R3 (stream)	R	1.084	1.084	0.089	0.089
R4 (stream)	R	1.151	1.315	0.101	0.121

* Letters S, D, and R correspond to the dominant entry path – spray drift, drainage, and runoff

Bold values were used for risk assessment (worst-case from single and multiple applications for each scenario)

Table B.9.4.-6: Initial maximum PEC_{sw} values of foramsulfuron and metabolite AE F130619 – FOCUS Step 4

Compound	FOCUS Scenario	Buffer [m]	Maize, 1 x 60 g/ha PEC _{sw} , max [µg/L]	Maize, 2 x 30 g/ha PEC _{sw} , max [µg/L]	
				Single application	Multiple applications
Foramsulfuron	D3 (ditch)	10 m SD + RO	0.055	0.027	0.022
	D4 (pond)		0.008	0.004	0.006
	D4 (stream)		0.061	0.030	0.025
	D5 (pond)		0.010	0.005	0.009
	D5 (stream)		0.057	0.028	0.026
	D6 (ditch)		0.058	0.029	0.034
	R1 (pond)		0.012	0.006	0.027
	R1 (stream)		0.547	0.265	0.580
	R2 (stream)		0.426	0.200	0.200
	R3 (stream)		1.006	0.490	0.490
	R4 (stream)		1.065	0.523	0.598
	D3 (ditch)	20 m SD + RO	0.028	0.014	0.012
	D4 (pond)		0.006	0.003	0.004
	D4 (stream)		0.032	0.016	0.013
	D5 (pond)		0.008	0.004	0.007
	D5 (stream)		0.030	0.015	0.014
	D6 (ditch)		0.032	0.016	0.034
	R1 (pond)		0.007	0.004	0.014
	R1 (stream)		0.279	0.135	0.303
	R2 (stream)		0.221	0.104	0.104
	R3 (stream)		0.526	0.256	0.256
	R4 (stream)		0.558	0.274	0.313
AE F130619	D3 (ditch)	10 m SD + RO	<0.001	<0.001	<0.001
	D4 (pond)		<0.001	<0.001	<0.001
	D4 (stream)		0.001	<0.001	0.001
	D5 (pond)		<0.001	<0.001	0.001
	D5 (stream)		<0.001	<0.001	0.001
	D6 (ditch)		0.008	0.004	0.008
	R1 (pond)		<0.001	<0.001	0.002
	R1 (stream)		0.035	0.017	0.045
	R2 (stream)		0.046	0.023	0.023
	R3 (stream)		0.080	0.040	0.040
	R4 (stream)		0.092	0.046	0.055
	D3 (ditch)	20 m SD + RO	<0.001	<0.001	<0.001
	D4 (pond)		<0.001	<0.001	<0.001

Compound	FOCUS Scenario	Buffer [m]	Maize, 1 x 60 g/ha	Maize, 2 x 30 g/ha	
			PEC _{sw} , max [µg/L]	PEC _{sw} , max [µg/L]	
				Single application	Multiple applications
	D4 (stream)		0.001	<0.001	0.001
	D5 (pond)		<0.001	<0.001	0.001
	D5 (stream)		<0.001	<0.001	0.001
	D6 (ditch)		0.008	0.004	0.008
	R1 (pond)		<0.001	<0.001	<0.001
	R1 (stream)		0.018	0.009	0.024
	R2 (stream)		0.024	0.012	0.012
	R3 (stream)		0.042	0.021	0.021
	R4 (stream)		0.048	0.024	0.029

SD = spray drift buffer; RO = runoff buffer

Bold values are worst-case from single and multiple applications for each scenario**Acute risk assessment for aquatic organisms****Table B.9.4.-7: TER_A calculations based on drift entry for the formulation and on FOCUS Step 2 values for foramsulfuron and metabolite AE F092944 for fish and invertebrates**

Compound		Endpoint [µg/L]	PEC _{sw} ,max [µg/L]	TER _A	Trigger
Maize, 1 x 60 g a.s./ha					
FSN + IDF OD 45 (22.5+22.5)	Fish, acute	LC ₅₀ = 7 800	23.17 ¹⁾	337	100
	Invertebrate, acute	LC ₅₀ = 6 900	23.17 ¹⁾	298	100
Foramsulfuron	Fish, acute	LC ₅₀ > 100 000	4.948	> 20 210	100
	Invertebrate, acute	LC ₅₀ > 100 000	4.948	> 20 210	100
AE F092944	Fish, acute	LC ₅₀ = 254 000	0.189	1 343 915	100
	Invertebrate, acute	LC ₅₀ = 223 000	0.189	1 179 894	100
Maize, 2 x 30 g a.s./ha					
FSN + IDF OD 45 (22.5+22.5)	Fish, acute	LC ₅₀ = 7 800	11.59 ¹⁾	673	100
	Invertebrate, acute	LC ₅₀ = 6 900	11.59 ¹⁾	595	100
Foramsulfuron	Fish, acute	LC ₅₀ > 100 000	4.189	> 23 872	100
	Invertebrate, acute	LC ₅₀ > 100 000	4.189	> 23 872	100
AE F092944	Fish, acute	LC ₅₀ = 254 000	0.172	1 476 744	100
	Invertebrate, acute	LC ₅₀ = 223 000	0.172	1 296 512	100

Bold values require further refinement¹⁾ Based on spray drift values of 2.77 % for the formulation (see Table B.9.4-3)

Chronic risk assessment for aquatic organisms**Table B.9.4.-8: TER_{LT} calculations based on drift entry for the formulation and on FOCUS Step 2 values for foramsulfuron and metabolites for fish, invertebrates, algae and *Lemna***

Compound	Species	Endpoint [µg/L]	PEC _{sw} , max [µg/L]	TER _{LT}	Trigger
Maize, 1 x 60 g a.s./ha					
FSN + IDF OD 45 (22.5+22.5)	Fish, chronic	NOEC = 1 800	23.17 ¹⁾	78	10
	Invertebrate, chronic	NOEC = 400	23.17 ¹⁾	17	10
	Green algae, chronic	ErC ₅₀ > 5 000	23.17 ¹⁾	> 216	10
	Aquatic plants, chronic	ErC ₅₀ = 53.23	23.17 ¹⁾	2.30	10
Foramsulfuron	Fish, chronic	NOEC = 10 500	4.948	2 122	10
	Invertebrate, chronic	NOEC > 100 000	4.948	> 20 210	10
	Green algae, chronic	ErC ₅₀ = 8100	4.948	1637	10
	Aquatic plants, chronic	ErC ₅₀ = 1.01	4.948	0.204	10
AE F092944	Green algae, chronic	ErC ₅₀ > 560 000	0.189	> 2 962 963	10
	Aquatic plants, chronic	EC ₅₀ > 100 000	0.189	> 529 101	10
AE F099095	Green algae, chronic	ErC ₅₀ > 100 000	0.085	> 1 176 471	10
	Aquatic plants, chronic	EC ₅₀ > 100 000	0.085	> 1 176 471	10
AE F153745	Aquatic plants, chronic	EC ₅₀ > 100 000	0.087	> 1 149 425	10
AE 0338795	Aquatic plants, chronic	ErC ₅₀ = 27 200	0.127	214 173	10
AE F130619	Aquatic plants, chronic	EC ₅₀ = 0.889	0.481	1.85	10
4-Amino-N-methylbenzamide	Aquatic plants, chronic	ErC ₅₀ > 10 000	0.023	> 434 783	10
4-Formylamido-N-methylbenzamide	Aquatic plants, chronic	ErC ₅₀ > 10 000	0.043	> 232 558	10
Foramsulfuron sulfamic acid	Aquatic plants, chronic	ErC ₅₀ > 10 000	0.060	> 166 667	10
Maize, 2 x 30 g a.s./ha					
FSN + IDF OD 45 (22.5+22.5)	Fish, chronic	NOEC = 1 800	11.59 ¹⁾	155	10
	Invertebrate, chronic	NOEC = 400	11.59 ¹⁾	35	10
	Green algae, chronic	ErC ₅₀ > 5 000	11.59 ¹⁾	> 431	10
	Aquatic plants, chronic	ErC ₅₀ = 53.23	11.59 ¹⁾	4.60	10
Foramsulfuron	Fish, chronic	NOEC = 10 500	4.189	2 507	10
	Invertebrate, chronic	NOEC > 100 000	4.189	> 23 872	10
	Green algae, chronic	ErC ₅₀ = 8100	4.189	1934	10
	Aquatic plants, chronic	ErC ₅₀ = 1.01	4.189	0.24	10
AE F092944	Green algae, chronic	ErC ₅₀ > 560 000	0.172	> 3 255 814	10
	Aquatic plants, chronic	EC ₅₀ > 100 000	0.172	> 581 395	10
AE F099095	Green algae, chronic	ErC ₅₀ > 100 000	0.066	> 1 515 152	10
	Aquatic plants, chronic	EC ₅₀ > 100 000	0.066	> 1 515 152	10
AE F153745	Aquatic plants, chronic	EC ₅₀ > 100 000	0.070	> 1 428 571	10
AE 0338795	Aquatic plants, chronic	ErC ₅₀ = 27 200	0.107	254 206	10
AE F130619	Aquatic plants, chronic	EC ₅₀ = 0.889	0.276	3.22	10
4-Amino-N-methylbenzamide	Aquatic plants, chronic	ErC ₅₀ > 10 000	0.021	> 476 190	10
4-Formylamido-N-methylbenzamide	Aquatic plants, chronic	ErC ₅₀ > 10 000	0.038	> 263 158	10
Foramsulfuron sulfamic acid	Aquatic plants, chronic	ErC ₅₀ > 10 000	0.053	> 188 679	10

Bold values require further refinement¹⁾ Based on spray drift values of 2.77 % for the formulation (see Table B.9.4.-3)

RMS notices that the TER calculations based only on spray drift of the formulation causes unacceptable risk for aquatic plants. However, since the formulation is equally toxic compared to the technical active substance, based on active substance content (Table B.9.4.-1 for formulation: geomean ErC_{50} 1.20 $\mu\text{g a.s./L}$ and Table B.9.4.-2 for the active substance: ErC_{50} 1.01 $\mu\text{g a.s./L}$), it is justified to further refine the risk based only on toxicity of the active substance and FOCUS simulations.

Table B.9.4.-9: TER_{LT} calculations based on FOCUS Step 3 for foramsulfuron and metabolite AE F130619 for aquatic plants

Species	Endpoint [µg/L]	PEC _{sw,max} [µg/L]	FOCUS scenario	TER _{LT}	Trigger
Foramsulfuron, Maize, 1 x 60 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 1.01	0.314	D3 (ditch)	3.2	10
		0.013	D4 (pond)	78	10
		0.271	D4 (stream)	3.7	10
		0.015	D5 (pond)	67.3	10
		0.251	D5 (stream)	4.0	10
		0.316	D6 (ditch)	3.2	10
		0.025	R1 (pond)	40.4	10
		1.284	R1 (stream)	0.8	10
		0.972	R2 (stream)	1.0	10
		2.225	R3 (stream)	0.5	10
2.341	R4 (stream)	0.4	10		
AE F130619, Maize, 1 x 60 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 0.889	0.032	D3 (ditch)	27.8	10
		0.001	D4 (pond)	889	10
		0.001	D4 (stream)	889	10
		0.002	D5 (pond)	445	10
		<0.001	D5 (stream)	>889	10
		0.032	D6 (ditch)	27.8	10
		0.004	R1 (pond)	222.3	10
		0.081	R1 (stream)	11.0	10
		0.106	R2 (stream)	8.4	10
		0.178	R3 (stream)	5.0	10
0.202	R4 (stream)	4.4	10		
Foramsulfuron, Maize, 2 x 30 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 1.01	0.157	D3 (ditch)	6.4	10
		0.010	D4 (pond)	101.0	10
		0.136	D4 (stream)	7.4	10
		0.013	D5 (pond)	77.7	10
		0.126	D5 (stream)	8.0	10
		0.158	D6 (ditch)	6.4	10
		0.062	R1 (pond)	16.3	10
		1.281	R1 (stream)	0.8	10
		0.456	R2 (stream)	2.2	10
		1.084	R3 (stream)	0.9	10
1.315	R4 (stream)	0.8	10		
AE F130619, Maize, 2 x 30 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 0.889	0.016	D3 (ditch)	55.6	10
		<0.001	D4 (pond)	>889	10
		0.001	D4 (stream)	889	10
		0.001	D5 (pond)	889	10
		0.001	D5 (stream)	889	10
		0.016	D6 (ditch)	55.6	10

Species	Endpoint [µg/L]	PEC _{sw,max} [µg/L]	FOCUS scenario	TER _{LT}	Trigger
		0.010	R1 (pond)	88.9	10
		0.099	R1 (stream)	9.0	10
		0.052	R2 (stream)	17.1	10
		0.089	R3 (stream)	10.0	10
		0.121	R4 (stream)	7.3	10

Bold values require further refinement

Refined chronic risk assessment for aquatic plants

Foramsulfuron

In addition to the tier 1 test with *Lemna gibba*, resulting in the E_rC₅₀ of 1.01 µg a.s./L, four further macrophyte studies have been conducted with foramsulfuron technical and the formulation Foramsulfuron WG50, respectively.

- Aim of the 14 d laboratory study with *Myriophyllum spicatum* (Banman et al., 2012; M-431270-01-1, KCA 8.2.7 /09) was to investigate the sensitivity of a dicotyledonous macrophyte species to foramsulfuron. In this study *Myriophyllum spicatum* showed low sensitivity to the compound with maximum inhibitions of the growth parameters (shoot length, wet weight, dry weight) being less than 20% up to the maximum test concentration (84 µg a.s./L).

- The 6 weeks (42 d) bioassay with *Lemna gibba* (Bruns, 2013; M-464150-01-1, KCA 8.2.7/ 08) has been performed to generate an endpoint which can be compared to the macrophyte species tested in the outdoor pond study (see below). Since *Lemna gibba* insufficiently grows under the mesotrophic conditions in outdoor ponds, decreasing concentrations of foramsulfuron as observed in the pond study were mimicked in the laboratory in 20 x APP nutrient medium under sterile conditions. Every week, duckweed plants were transferred to new test vessels with stepwise lower foramsulfuron content. The total test duration of the bioassay was equal to the duration of the pond study. As the most sensitive response variable frond number, a 42 d E_rC₅₀ of 1.18 µg a.s./L was obtained.

- The 24h- peak exposure study with *Lemna gibba* (Bruns, 2013; M-462569-01-1, KCA 8.2.7/06) has been conducted to specifically address peak exposure patterns as predicted e.g. for runoff scenarios. The study should reveal expected differences in the magnitude and duration of effects between a constant exposure as given in a *Lemna* standard test and an exposure for a very limited time span. *Lemna gibba* was exposed to the compound for 24 h. Afterward the plants were transferred to untreated growth medium in which they were kept for further six days. The E_rC₅₀ was greater than 56.7 µg a.s./L, the NOEC of growth rates in the period between day 2 and day 7 (post-exposure after the peak) was 2.42 µg a.s./L. These endpoints refer to growth rates of both parameters, frond number and total frond area.

- In the macrophyte pond study (Kirkwood, 2012; M-429538-01-1, KCA 8.2.7 /07), ten different macrophyte species were exposed to foramsulfuron applied as WG 50 formulation under outdoor conditions. The aim of the study was to deliver an appropriate number of endpoints for an HC₅ calculation. The study included two different exposure regimes:

- 1) Constant exposure over 6 weeks with natural degradation of the compound in the ponds; this part was conducted in an ECx design.
- 2) 48 h peak exposure (two peak concentrations 1.6 and 3.9 µg a.s./L, measured) with subsequent replacement of the test solutions with untreated dilution water in the ponds. As with the *Lemna* peak exposure study, this second regime aimed at mimicking short runoff or drift peaks and their effects on macrophytes.

Endpoints relevant for the refined risk assessment are presented in **Table B.9.4.-2**. Although the study has been started with ten species, the data for *Nymphaea odorata* were omitted from the analysis due to poor emergence even in the controls. The evaluation was done with the remaining nine species.

Probabilistic risk assessment: SSD and HC₅ calculation for foramsulfuron

The refined risk assessment for foramsulfuron is mainly based on the results of the multispecies outdoor pond study and the associated 6-weeks laboratory bioassay with *Lemna gibba*. The data of the two studies have been used to generate a species sensitivity distribution (SSD) and calculate an HC₅. Since endpoints in the *Lemna* bioassay have been calculated based on nominal concentrations, also from the pond study the nominal endpoints were used.

The outdoor pond study yielded EC₅₀ values ranging from 1.5 µg a.s./L to > 61 µg a.s./L. For the variable shoot length growth rate, definitive EC₅₀ values could be calculated only for two of the ten species tested. However, for the variable dry weight growth rate definitive EC₅₀ figures were obtained for seven species. According to the new aquatic guidance document (EFSA, 2013, p. 93) greater-than figures should be included in an SSD calculation, if they are outside the range of already available endpoints. In the present case this applies to *Mentha aquatica* and *Cabomba caroliniana* which both delivered E_rC₅₀ values of > 61 µg a.s./L. The highest definitive endpoint was 60 µg a.s./L and was obtained for *Glyceria maxima*. As a pragmatic and conservative approach, the E_rC₅₀ of > 61 µg a.s./L was included in the SSD only once.

As mentioned above the lowest endpoint from the 6-weeks *Lemna* bioassay is 1.18 µg a.s./L (E_rC₅₀ for frond number). This endpoint was added to the overall eight endpoints from the pond study. The complete data set used for generating the SSD is shown in the table below (B.9.4-10).

Table B.9.4.-10: Refined species included in the SSD and their relevant EC₅₀ value

Species	Endpoint [µg a.s./L]	
<i>Lemna gibba</i>	ErC ₅₀	1.18
<i>Elodea canadensis</i>	ErC ₅₀	1.5
<i>Salvinia minima</i>	ErC ₅₀	2.8
<i>Sagittaria latifolia</i>	ErC ₅₀	4.6
<i>Stuckenia pectinata</i>	ErC ₅₀	7.7
<i>Ceratophyllum demersum</i>	ErC ₅₀	21.0
<i>Myriophyllum heterophyllum</i>	ErC ₅₀	41.0
<i>Glyceria maxima</i>	ErC ₅₀	60.0
<i>Mentha aquatica</i> / <i>Cabomba caroliniana</i>	ErC ₅₀	> 61.0
HC₅	0.652	

The HC₅ calculation is based on the method of Aldenberg & Jaworska (2000). A median HC₅ of 0.652 µg a.s./L was calculated (Table B.9.4.-10).

HC₅ calculation

The respective HC₅ calculation have been conducted using the computer program ETX 2.0 by rivm (RIVM, 2004). In the first step, the toxicity data (EC₅₀) were subjected to three different goodness of fit tests (Anderson-Darling, Kolmogorov-Smirnov and the Cramer von Mises), where normality at the 0.01 significance level was checked. The analysis of the EC₅₀ values show normal distribution of the data. The results of the ETX^{2.0} calculation based on the EC₅₀ values and the respective graphs of aquatic plants sensitivity distribution are presented below.

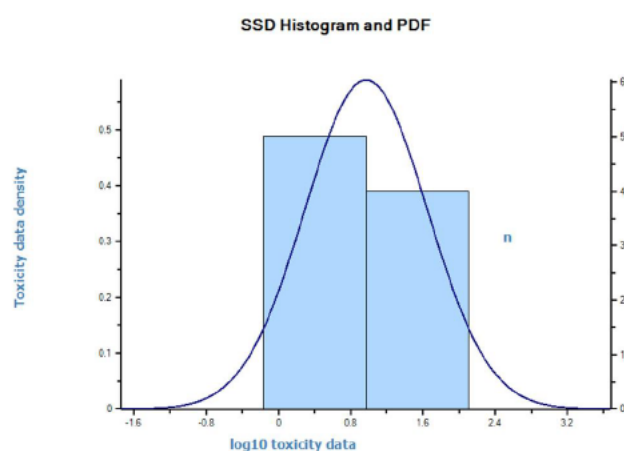
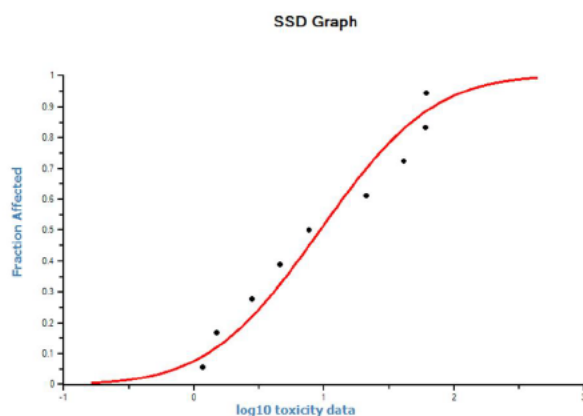
Analysis of normality for macrophytes species

Parameters of the log-normal distribution for data set of aquatic plants

Name	Value	Description
mean	0.971429	mean of the log toxicity values
s.d.	0.677009	sample standard deviation
n	9	sample size

Goodness of fit tests - results for macrophytes

Sign. level	Tests for normality n = 9					
	Anderson-Darling		Kolmogorov-Smirnov		Cramer von Mises	
0.1	0.631	Accepted	0.819	Accepted	0.104	Accepted
0.05	0.752	Accepted	0.895	Accepted	0.126	Accepted
0.025	0.873	Accepted	0.995	Accepted	0.148	Accepted
0.01	1.035	Accepted	1.035	Accepted	0.179	Accepted
Statistic	0.371107		0.528969		0.04047	

Figure 9.4.-1: SSD Histogram for macrophytes**Figure 9.4.-2: Species sensitivity distribution for macrophytes**

HC₅ results [μg foramsulfuron/L] for macrophytes

Name	Value [μg a.s./L]	log ₁₀ (Value)	Description
LL HC ₅	0.083034	-1.08074	lower estimate of the HC ₅
HC ₅	0.6522	-0.18562	median estimate of the HC ₅
UL HC ₅	2.001132	0.301276	upper estimate of the HC ₅
sprHC ₅	24.10017	1.38202	spread of the HC ₅ estimate

The calculated HC₅ value for macrophytes is **0.6522 μg a.s./L**.

Refined aquatic risk assessment for foramsulfuron

For the refined risk assessment **long-term exposure scenarios** and **peak exposure scenarios** were considered separately. In order to distinguish long-term exposure scenarios from peak exposure scenarios the temporal patterns of PEC-figures (Vrbka 2013; M-468841-02-1) were analysed. Peak scenarios showed a dominant peak (primary peak) that lasted not longer than 24 hours. In some scenarios this primary peak was followed by one or a few smaller peaks called secondary peaks in the following text. The following scenarios were considered as peak-scenarios: D4 stream, D5 stream, D6 ditch, R1 stream, R2 stream, R3 stream and R4 stream (see dRAR_19_Vol 3 CP: Appendix 1).

Report:	KCP 10.2 /01; Vrbka, L.; 2013; M-468841-02; Amended: 2013-11-18
Title:	Foramsulfuron (FSN) and metabolite: PEC _{sw, sed} FOCUS EUR (graphical outputs) - Use in maize in Europe
Report No:	EnSa-13-0880
Document No:	M-468841-02-1
Guidelines:	not applicable
GLP/GEP:	no

Predicted environmental concentrations of the active substance foramsulfuron and its metabolites for the use in maize in Europe were calculated and reported in the study report KCP 9.2.5/02. This report KCP 10.2/01 supplements the original document and provides graphical representation of time evolution of PEC_{sw} concentrations for all calculated uses and scenarios at Step3 level for parent and its metabolite AE F130619.

For **the long-term scenarios**, the calculated HC₅ was compared to Focus Step 3 max. PEC_{sw} figures. The results of these calculations are provided in **Table B.9.4.-12**. According to the new aquatic guidance document (EFSA, 2013a, p. 100), an assessment factor of 3 should be applied in conjunction with the median HC₅ to derive the regulatory acceptable concentration. In case that further refinement is required as the risk assessment based on the median HC₅ combined with FOCUS Step 3 PECvalues is not passed in a second step a risk assessment is performed with Focus Step 4 max. PEC_{sw} figures considering a 10 m buffer zone to mitigate spray drift and run-off entry.

The **peak scenarios** were considered separately. For the TER calculations the peak ErC₅₀ > 56.7 μg a.s./L from the *Lemna* peak study was taken into account. Regarding the derivation of a regulatory acceptable concentration from a refined exposure laboratory test, the new aquatic guidance document (EFSA, 2013a, p. 110) proposes an assessment factor of 10 in conjunction with the EC₅₀ for plants. This approach is reasonable because:

1. *Lemna* is the most sensitive aquatic macrophyte species,
2. *Lemna* is also most sensitive to peak exposures. The peak NOEC of 3.9 μg a.s./L from the pond study is higher than the NOEC of 2.42 μg a.s./L obtained from the *Lemna*-peak study.

A refined risk assessment based on the comparison of the 24 h *Lemna*-peak study with primary peak (PEC_{max}) from peak exposure patterns described by Vrbka (2013; M-468841-02-1) can be justified for the following reasons:

1. The primary peak lasted not longer than 24 hours.
2. The secondary peaks (if they occurred at all) did not exceed the NOEC of 2.42 μg a.s./L.
3. The temporal distance between primary and secondary peaks was greater or equal than three days (with exception of the R2 stream scenarios, where a slight peak (< 0.1 μg a.s./L) occurred after two days

already). Figures 1 and 3 in the *Lemna* peak study (Bruns 2013; M-462569-01-1, KCA 8.2.7 /06) reveal that the growth curves (“growth lines” in the semi-logarithmic plots) even between day 2 and 5 are running parallel to the control at concentrations up to 2.42 µg a.s./L indicating a rapid recovery within a few days. Taking into account that the secondary peaks are far less than 2.42 µg/L and a fast recovery of *Lemna*-growth after a preceding exposure has been observed, it can be concluded that the secondary peaks can be neglected.

The RMS does not agree that an endpoint from a single pulse exposure is suitable to be used for a comparison with a PEC_{SW}. The exposure profiles of many scenarios suggest that at least two to three peaks are available. Although many scenarios suggests only a limited number of exposure peaks, patterns of peaks in the profiles are a result of weather data used in the FOCUS simulations. These may not represent a worst case exposure scenario in a realistic field situation, especially not for hydrophilic substances such as sulfonylureas where aquatic exposure is a result of not just spray drift but also of drainage and run-off. Due to only 16 month weather data in FOCUS-models RMS considers that the models are not valid towards actual field at this resolution and therefore it is not scientifically justified to mimic the exposure profiles from FOCUS modelling in higher tier studies.

Hence, the RMS does not agree to refine risks to aquatic organisms based on the peak pattern of the FOCUS profiles. However, the risk refinement has been presented below.

AE F130619

No higher tier-data are available for AE F130619. Both compounds, AE F130619 and its parent compound foramsulfuron, have a very similar molecular structure, and it has been shown that the *Lemna*-ErC₅₀ of AE F130619 is very close to the respective endpoint of the parent. Although no peak-exposure study has been conducted with AE F130619, it can be assumed, that the result would be similar. It is therefore reasonable to use the endpoint of foramsulfuron from the *Lemna* peak exposure study, the ErC₅₀ of > 56.7 µg/L also to evaluate peak exposure scenarios of AE F130619. In order to address the higher uncertainty resulting from the fact that only a similar but not the exact chemical structure was tested, an increased assessment factor of 20 is proposed.

Table B.9.4.-11: Summary: Rationale for setting of assessment factors for refined risk assessment

Endpoint	Proposed assessment factor	Reference and further comments
Foramsulfuron		
HC₅ of 0.652 µg/L derived from EC ₅₀ -levels obtained in the outdoor macrophyte study and the 6-week <i>Lemna</i> study. <i>Lemna</i> is the most sensitive species. The HC ₅ is used for the risk assessments of long-term exposure scenarios .	3	The HC ₅ is calculated from a total of nine endpoints obtained from a wide variety of different aquatic macrophytes. The assessment factor of 3 is proposed on page 100 in new aquatic guidance document (EFSA 2013).
ErC₅₀ > 56.7 µg/L obtained from <i>Lemna</i> -peak exposure study. The short-term exposure is comparable to peak exposures scenarios .	10	The peak exposure study has been done with the most sensitive species (<i>Lemna</i>). Regarding the derivation of a regulatory acceptable concentration from a refined exposure laboratory test, the new aquatic guidance document (EFSA, 2013a, p. 110) proposes an assessment factor of 10 in conjunction with the EC ₅₀ for plants.
AE F130619		
ErC₅₀ > 56.7 µg/L obtained from <i>Lemna</i> -peak exposure study with foramsulfuron. The short-term exposure is comparable to peak exposure scenarios.	20	The similar molecular structure of this metabolite compared to the parent and the similar endpoint obtained from the standard <i>Lemna</i> -growth inhibition study justifies the use of the same endpoint for peak exposure as for the parent. In order to address the additional uncertainty an assessment factor of 20 instead of 10 is proposed.

Table B.9.4.-12: Refined TER_{LT} calculations based on FOCUS Step 3 and refined ecotox endpoints

Species	Endpoint [µg/L]	PEC _{sw} max [µg/L]	FOCUS scenario	TER _{LT}	Trigger
Foramsulfuron, Maize, 1 x 60 g/ha					
Aquatic plants, chronic	long-term exposure HC ₅ : 0.652	0.314	D3 (ditch)	2.1	3
		0.013	D4 (pond)	50.2	3
		0.015	D5 (pond)	43.5	3
		0.025	R1 (pond)	26.1	3
	peak exposure peak ErC ₅₀ : > 56.7	0.271	D4 (stream)	> 209.2	10
		0.251	D5 (stream)	> 226	10
		0.316	D6 (ditch)	> 179.4	10
		1.284	R1 (stream)	> 44.2	10
		0.972	R2 (stream)	> 58.3	10
		2.225	R3 (stream)	> 25.5	10
		2.341	R4 (stream)	> 24.2	10
AE F130619, Maize, 1 x 60 g/ha					
Aquatic plants, chronic	peak exposure peak ErC ₅₀ : > 56.7	0.106	R2 (stream)	> 535	20
		0.178	R3 (stream)	> 319	20
		0.202	R4 (stream)	> 281	20
Foramsulfuron, Maize, 2 x 30 g/ha					
Aquatic plants, chronic	long-term exposure HC ₅ : 0.652	0.157	D3 (ditch)	4.2	3
		0.010	D4 (pond)	65.2	3
		0.013	D5 (pond)	50.2	3
		0.062	R1 (pond)	10.5	3
	peak exposure peak ErC ₅₀ : > 56.7	0.136	D4 (stream)	> 417	10
		0.126	D5 (stream)	> 450	10
		0.158	D6 (ditch)	> 359	10
		1.281	R1 (stream)	> 44.3	10
		0.456	R2 (stream)	> 124.3	10
		1.084	R3 (stream)	> 52.3	10
		1.315	R4 (stream)	> 43.1	10
AE F130619, Maize, 2 x 30 g/ha					
Aquatic plants, chronic	peak exposure peak ErC ₅₀ : > 56.7	0.052	R2 (stream)	> 1090	20
		0.089	R3 (stream)	> 637	20
		0.121	R4 (stream)	> 469	20

Bold TER values require further refinement

Scenario D3 ditch for foramsulfuron, Maize, 1 x 60 g/ha is the only scenario that requires a further refinement.

Higher-tier risk assessment based on Focus Step 4

Table B.9.4.-13: TER_{LT} calculations based on FOCUS Step 4

Species	Endpoint [µg/L]	PEC _{sw} max [µg/L]	FOCUS scenario	TER _{LT}	Trigger
Foramsulfuron, Maize, 1 x 60 g/ha; 10 m spray drift & runoff buffer					
Aquatic plants, chronic	long-term exposure HC ₅ : 0.652	0.055	D3 (ditch)	11.9	3

In conclusion, no mitigation measure is required to pass the aquatic risk assessment in case of the 2-fold application in maize (2 x 30 g a.s./ha), while in case of the single application (1 x 60 g a.s./ha) **a 10 m non-spray and vegetated buffer zone is necessary to pass scenario D3.**

Since RMS does not agree that an endpoint from a single pulse exposure is suitable to be used for a comparison with a PEC_{sw}, RMS has performed TER_{LT} calculations based on FOCUS Step 4 PEC_{sw} values for

foramsulfuron and metabolite AE F130619 together with the SSD HC₅ value of 0.652 µg/L and AF 3 (Tables B.9.4-14 and B.9.5-15 10 & 20 m spray drift & runoff buffers, respectively).

Table B.9.4.-14: TER_{LT} calculations based on FOCUS Step 4 for foramsulfuron and metabolite AE F130619 (10 m spray drift & runoff buffer)

Species	Endpoint [µg/L]	PEC _{sw,max} [µg/L]	FOCUS scenario	TER _{LT}	Trigger
Foramsulfuron, Maize, 1 x 60 g/ha; 10 m spray drift & runoff buffer					
Aquatic plants, chronic	ErC ₅₀ = 0.652	0.055	D3 (ditch)	11.855	3
		0.008	D4 (pond)	81.500	3
		0.061	D4 (stream)	10.689	3
		0.010	D5 (pond)	65.200	3
		0.057	D5 (stream)	11.439	3
		0.058	D6 (ditch)	11.241	3
		0.012	R1 (pond)	54.333	3
		0.547	R1 (stream)	1.192	3
		0.426	R2 (stream)	1.531	3
		1.006	R3 (stream)	0.648	3
		1.065	R4 (stream)	0.612	3
AE F130619, Maize, 1 x 60 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 0.889	<0.001	D3 (ditch)	>889.0	10
		<0.001	D4 (pond)	>889.0	10
		0.001	D4 (stream)	889.0	10
		<0.001	D5 (pond)	>889.0	10
		<0.001	D5 (stream)	>889.0	10
		0.008	D6 (ditch)	111.1	10
		<0.001	R1 (pond)	>889.0	10
		0.035	R1 (stream)	25.4	10
		0.046	R2 (stream)	19.3	10
		0.080	R3 (stream)	11.1	10
		0.092	R4 (stream)	9.7	10
Foramsulfuron, Maize, 2 x 30 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 0.652	0.027	D3 (ditch)	24.01	3
		0.006	D4 (pond)	108.7	3
		0.030	D4 (stream)	21.7	3
		0.009	D5 (pond)	72.4	3
		0.028	D5 (stream)	23.3	3
		0.034	D6 (ditch)	19.2	3
		0.027	R1 (pond)	24.1	3
		0.580	R1 (stream)	1.1	3
		0.200	R2 (stream)	3.3	3
		0.490	R3 (stream)	1.3	3
		0.598	R4 (stream)	1.1	3
AE F130619, Maize, 2 x 30 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 0.889	<0.001	D3 (ditch)	>889.0	10
		<0.001	D4 (pond)	>889.0	10
		0.001	D4 (stream)	889.0	10
		0.001	D5 (pond)	889.0	10
		0.001	D5 (stream)	889.0	10
		0.008	D6 (ditch)	111.1	10
		0.002	R1 (pond)	444.5	10
		0.045	R1 (stream)	19.8	10

Species	Endpoint [µg/L]	PEC _{sw} ,max [µg/L]	FOCUS scenario	TER _{LT}	Trigger
		0.023	R2 (stream)	38.7	10
		0.040	R3 (stream)	22.2	10
		0.055	R4 (stream)	16.2	10

Bold values require further refinement

Table B.9.4.-15: TER_{LT} calculations based on FOCUS Step 4 for foramsulfuron and metabolite AE F130619 (20 m spray drift & runoff buffer)

Species	Endpoint [µg/L]	PEC _{sw} ,max [µg/L]	FOCUS scenario	TER _{LT}	Trigger
Foramsulfuron, Maize, 1 x 60 g/ha; 20 m spray drift & runoff buffer					
Aquatic plants, chronic	ErC ₅₀ = 0.652	0.279	R1 (stream)	2.3	3
		0.221	R2 (stream)	3.0	3
		0.526	R3 (stream)	1.2	3
		0.558	R4 (stream)	1.2	3
AE F130619, Maize, 1 x 60 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 0.889	0.048	R4 (stream)	18.5	10
Foramsulfuron, Maize, 2 x 30 g/ha					
Aquatic plants, chronic	ErC ₅₀ = 0.652	0.303	R1 (stream)	2.2	3
		0.256	R3 (stream)	2.5	3
		0.313	R4 (stream)	2.1	3

Bold values require further refinement

For foramsulfuron the risk is unacceptable with 10 m spray drift & runoff buffer for run-off stream scenarios R1, R2, R3 and R4 with application rate of 1 x 60 g a.s./ha and for stream scenarios R1, R3 and R4 with application rate of 2 x 30 g a.s./ha. Using PEC_{sw} values of 20 m spray drift & runoff buffer the risk will become acceptable only in stream scenario R2 with application rate of 1 x 60 g a.s./ha while remaining unacceptable in run-off stream scenarios R1, R3 and R4 with both application rates of 1 x 60 g a.s./ha and 2 x 30 g a.s./ha.

For the metabolite AE F130619 the risk is unacceptable with 10 m spray drift & runoff buffer only in stream scenario R4 with application rate of 1 x 60 g a.s./ha, but becomes acceptable with 20 m spray drift & runoff buffer. With the multiple application pattern of 2 x 30 g a.s./ha the risk is acceptable with 10 m spray drift & runoff buffer in all scenarios.

B.9.4.1. Co-RMS conclusion

Toxicity studies are available with the active substance foramsulfuron, the metabolites AE F153745, AE 0338795, AE F092944, AE F099095, AE F130619, 4-amino-N-methylbenzamide, 4-formamido-N-methylbenzamide, Foramsulfuron-sulfamic acid and the formulation FSN+IDF OD 45 (22.5+22.5 g/L).

Foramsulfuron has low toxicity to fish and aquatic invertebrates. In all acute fish studies no sublethal effects and only random mortality were observed in the highest dose level treatment, resulting in an LC₅₀ of > 100 mg a.s./L. Likewise in both chronic fish studies no relevant treatment related effects were observed at the maximum dose level, resulting in a NOEC of 100 or 10.5 mg a.s./L.

Also for *Daphnia*, no mortality occurred in the acute studies and no chronic effects on survival, growth or reproduction were observed in the reproductive study at the tested dose level of 100 mg a.s./L, resulting in a NOEC of > 100 mg a.s./L and an EC₅₀ > 100 mg a.s./L.

Potential effects of foramsulfuron on algal growth were investigated with four different algae species, a green alga, a blue-green alga and a freshwater and a marine diatom. The blue-green alga *Anabaena flos-aquae*, was

found to be, by a factor of 10, more sensitive than other algae species. The EC_{50} of foramsulfuron for this species is 8.1 mg a.s./L.

As expected for an herbicide, foramsulfuron has been significantly toxic to aquatic macrophytes. Besides *Lemna*, 10 different macrophyte species were tested. In these tests *Lemna gibba* turned out to be the most sensitive aquatic species to foramsulfuron. Also for metabolites potentially occurring in aquatic systems, studies investigating the toxicity to *Lemna gibba* were also performed for all metabolites of the residue definition for risk assessment in surface water. It was found that one metabolite, AE F130619, has a similar activity to *Lemna* as the parent compound ($E_rC_{50} = 0.000889$ mg/L), while all other metabolites turned out to be non-toxic to these and other aquatic organisms.

The risk assessment has been performed according to “Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC” (Sanco/3268/2001 rev.4 (final) 17 October 2002).

The “Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters” (EFSA Panel on Plant Protection Products and their Residues, 2013, EFSA Journal 2013; 11(7): 3290, 268 pp. has been considered where appropriate.

The risk assessment of foramsulfuron for aquatic organisms is driven by effects on *Lemna* as most sensitive aquatic species. While acute and chronic risk assessments for fish, *Daphnia* and algae are passed with standard ecotoxicological endpoints and PEC_{sw} at FOCUS Step 2 level, for *Lemna* refinement based on higher tier aquatic studies and FOCUS step 4 calculations is required.

For all metabolites except AE F130619 the assessment also for *Lemna* is passed on FOCUS Step 2 level. For AE F130619 which has a similar effect on *Lemna* as the parent compound, Step 3 calculations and refinement based on higher tier aquatic studies is required.

Considering these higher tier aquatic studies no mitigation measure is required in case of the 2-fold application in maize (2 x 30 g a.s./ha), while in case of the single application (1 x 60 g a.s./ha) **a 10 m non-spray and vegetated buffer zone is necessary to pass scenario D3.**

B.9.4.2. RMS conclusion

The RMS does not agree that an endpoint from a single pulse exposure is suitable to be used for a comparison with a PEC_{sw} . The exposure profiles of many scenarios suggest that at least two to three peaks are available. Although many scenarios suggests only a limited number of exposure peaks, patterns of peaks in the profiles are a result of weather data used in the FOCUS simulations. These may not represent a worst case exposure scenario in a realistic field situation, especially not for hydrophilic substances such as sulfonylureas where aquatic exposure is a result of not just spray drift but also of drainage and run-off. RMS considers that FOCUS-models are not validated towards actual field at this resolution and therefore it is not scientifically justified to mimic the exposure profiles from FOCUS modelling in higher tier studies. Hence, the RMS does not agree to refine risks to aquatic organisms based on the peak pattern of the FOCUS profiles.

Classification:

The active substance foramsulfuron should be classified according to the CLP Regulation (EC) No 1272/2008 as Aquatic Acute 1 (ErC_{50} for *Lemna* 1.01 μ g a.s./L) and Aquatic Chronic 1 (NOErC for *Lemna* < 1.01 μ g a.s./L). H410: Very toxic to aquatic life with long lasting effects (P273, P501).

The product Equip OD 45 should be classified according to the CLP Regulation (EC) No 1272/2008 as **Aquatic Acute 1 and Aquatic Chronic 1, H410 Very toxic to aquatic life with long lasting effects (PP273, P501).**

B.9.5. EFFECTS ON ARTHROPODS

B.9.5.1. Effects on bees

Toxicity data (EU agreed endpoints included) are summarised in the table below.

Table B.9.5.1-1: Summary of acute toxicity data

Test substance	Type of test	Toxicity value
foramsulfuron tech.	72 h Oral	LD50 > 163.09 µg a.s./bee
	72 h Contact	LD50 > 100 µg a.s./bee
	48 h Oral	LD50 > 110.1 µg a.s./bee
	48 h Contact	LD50 > 100 µg a.s./bee
foramsulfuron as formulation foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L)	72 h Oral	LD50 > 226.3 µg product/bee ^{*1} (LD50 > 5.8 µg a.s./bee)
	72 h Contact	LD50 > 392.2 µg product/bee ^{*1} (LD50 > 10.1 µg a.s./bee)
	48 h Oral	LD50 > 214.4 µg product/bee (LD50 > 5.0 µg a.s./bee ^{*2})
	48 h Contact	LD50 > 200 µg product/bee (LD50 > 4.66 µg a.s./bee ^{*2})

^{*1} EU agreed endpoints

^{*2} new proposed endpoints, based on the analysed content of active ingredient of 2.33 % w/w, resp. 22.41 g/L

Table B.9.5.1-2: Summary of chronic toxicity data

Chronic toxicity to adult bees (laboratory)			
Foramsulfuron WG 50	10 d chronic adult feeding study	LC ₅₀ > 120 mg a.s./kg NOEC ≥ 120 mg a.s./kg	Kling, (2013) M-470639-01-1 KCA 8.3.1.2/01
In vitro honey bee larvae (laboratory)			
Foramsulfuron WG 50	In vitro honey bee larvae laboratory study, single exposure test design	LD ₅₀ > 100 µg a.s./larva NOED ≥ 100 µg a.s./larva	Przygoda & Nikolakis, (2013) M-470485-01-1 KCA 8.3.1.3/01
Bee brood feeding test			
Foramsulfuron WG 50	Honey bee brood feeding (Oomen <i>et al.</i> , 1992)	Slightly, but statistically significantly increased termination rate of young and old larvae, which is not biologically relevant; no adverse effects on the survival of adult bees and pupae, behaviour, colony strength, condition of the colonies, brood index and brood compensation index by feeding honey bee colonies sugar syrup at a foramsulfuron-concentration at a concentration typically present in the spray tank (100 ppm)	Jeker, (2013) M-465326-01-1 KCA 8.3.1.3/02
Cage and tunnel studies			

Foramsulfuron + Isoxadifen-ethyl OD 45 (22.5 + 22.5)	Semi-field honey bee brood study (according to OECD 75; forced exposure conditions) in <i>Phacelia</i> ; application during full-bloom and bees actively foraging	No adverse effects on mortality, flight intensity, behaviour, brood development (brood termination rate, brood index, compensation index) as well as on colony vitality at maximum application rate (2.67 L product/ha)	Schmitzer (2013) M-468794-01-1 KCA 8.3.1.3/03
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B.9.5.2. Effects on non-target arthropods other than bees

EQUIP OD 45 is a representative formulation in the EU review of foramsulfuron. Toxicity tests on non-target arthropods were conducted with FSN + IDF OD 45 on the sensitive standard species *Typhlodromus pyri* and *Aphidius rhopalosiphii*. In addition, tests on further species are available (*Chrysoperla carnea*, *Aleochara bilineata*, *Poecilus cupreus*, *Pardosa sp.*). Testing and risk assessment strategy used here follows the approach recommended in the ESCORT 2 guidance document (Candolfi *et al.* 2001) as proposed by EC Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC, SANCO/10329, 17 October 2002.

Two new studies which have been carried out with formulation foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) are summarised below in the table together with EU agreed endpoints (Foramsulfuron: SANCO Scientific Report, 2001).

Table B.9.5.2-1: Effect of foramsulfuron (foramsulfuron + isoxadifen-ethyl OD 45) on non-target arthropods

Species and stage	Test type, material and duration	Dose rate	Effect	References file No.
Laboratory tests				
<i>Typhlodromus pyri</i> Protonymphs	Tier I Glass plate	267 mL to 2670 mL FSN + IDF OD 45 /ha	LR ₅₀ > 2670 mL f.p./ha (equivalent to LR ₅₀ >62.2 g a.s./ha)	Röhlig (2013)* M-457360-01-1
<i>Typhlodromus pyri</i> Protonymphs	Tier I Glass plate	233 mL and 2330 mL FSN + IDF OD 45 /ha	Corrected M = 53 % at 2330 mL f.p./ha (equivalent to LR ₅₀ >60 g a.s./ha)	Waltersdorfer (1999) M-191384-01-1
<i>Aphidius rhopalosiphii</i> Adult	Tier I Glass plate	3.6 g, 45 g and 90 g foramsulfuron/ha	Corr. M = 26 % at 3.6 g a.s./ha Corr. M = 100 % at 45 g and 90 g a.s./ha	Kleiner (1999) M-191908-01-1
<i>Aphidius rhopalosiphii</i> Adult	Tier I Glass plate	35 mL to 2670 mL FSN + IDF OD 45 /ha in two test run	LR ₅₀ 241 mL f.p./ha (equivalent to LR ₅₀ >5.6 g a.s./ha)	Röhlig (2013)* M-461455-01-1
Extended laboratory tests				
<i>Typhlodromus pyri</i> Protonymphs	Tier II Extended lab., exposure on <i>Polygonum convolvulus</i> leaves	1750 and 3500 mL FSN + IDF OD 45 /ha	LR ₅₀ > 3500 mL f.p./ha (equivalent to LR ₅₀ >90 g a.s./ha)	Waltersdorfer (1999) M-192822-01-1
<i>Aphidius rhopalosiphii</i>	Tier II spray	107 mL, 2000 mL and 2670 mL FSN + IDF OD	LR ₅₀ > 2670 mL f.p./ha (equivalent to LR ₅₀ >60 g a.s./ha)	Barth (2000) M-198973-01-1

Species and stage	Test type, material and duration	Dose rate	Effect	References file No.
Adult	deposits on potted maize plants	45 /ha		
<i>Chrysoperla carnea</i> Larvae	Tier II 2D study	160 mL, 2000 mL and 4000 mL FSN + IDF OD 45 /ha	LR ₅₀ > 4000 mL f.p./ha (equivalent to LR ₅₀ > 90 g a.s./ha)	Kleiner (2000) M-194627-01-1
<i>Aleochara bilineata</i> Adults	Tier II 2D study	160 mL, 2000 mL and 4000 mL FSN + IDF OD 45 /ha	ER ₅₀ > 4000 mL f.p./ha (equivalent to ER ₅₀ > 90 g a.s./ha)	Kleiner (1999) M-186968-01-1
<i>Poecilus cupreus</i> Adults	Tier II 2D study	2330 mL and 4660 mL FSN + IDF OD 45 /ha	LR ₅₀ > 4660 mL f.p./ha (equivalent to LR ₅₀ > 120 g a.s./ha)	Waltersdorfer (1999) M-186968-01-1
<i>Pardosa sp.</i> Adults	Tier II 2D study	160 mL, 2000 mL and 4000 mL FSN + IDF OD 45 /ha	LR ₅₀ > 4000 mL f.p./ha (equivalent to LR ₅₀ > 90 g a.s./ha)	Kleiner (1999) M-188675-01-1

* new study;

f.p. formulated product

M mortality

B.9.6. RISK ASSESSMENT FOR ARTHROPODS

B.9.6.1. Risk assessment for bees

B.9.6.1.1. Toxicity data

Toxicity data (EU agreed endpoints included) are summarised in the table below.

Table B.9.6.1.1-1: Summary of acute toxicity data

Test substance	Type of test	Toxicity value
foramsulfuron tech.	72 h Oral	LD50 > 163.09 µg a.s./bee
	72 h Contact	LD50 > 100 µg a.s./bee
	48 h Oral	LD50 > 110.1 µg a.s./bee
	48 h Contact	LD50 > 100 µg a.s./bee
foramsulfuron as formulation foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L)	72 h Oral	LD50 > 226.3 µg product/bee ^{*1} (LD50 > 5.8 µg a.s./bee)
	72 h Contact	LD50 > 392.2 µg product/bee ^{*1} (LD50 > 10.1 µg a.s./bee)
	48 h Oral	LD50 > 214.4 µg product/bee (LD50 > 5.0 µg a.s./bee ^{*2})
	48 h Contact	LD50 > 200 µg product/bee (LD50 > 4.66 µg a.s./bee ^{*2})

^{*1} EU agreed endpoints

^{*2} new proposed endpoints, based on the analysed content of active ingredient of 2.33 % w/w, resp. 22.41 g/L

B.9.6.1.2. HQ calculation

Applications of pesticides can potentially result in exposure of bees either through direct over-spray or by contact with residues on plants whilst forage bees are foraging for food. The acute risk to honeybees from use of

foramsulfuron was assessed using the maximum single field use rate (60 g foramsulfuron/ha) and the LD₅₀ value to calculate a hazard quotient as follows:

$$\text{Hazard Quotient} = \frac{\text{max. application rate (g a.s./ha)}}{\text{LD}_{50} (\mu\text{g a.s./bee})}$$

Hazard quotients were calculated for oral exposure (Q_{HO}) and contact exposure (Q_{HC}) to foramsulfuron. A hazard quotient of less than 50 indicates a low risk to bees in the field (EPPO, 2003).

The hazard quotient for oral and contact exposure of honeybees is given in table below:

Table B.9.6.1.2-1: HQ for honeybees

Test substance	Type of test	Toxicity endpoint ($\mu\text{g a.s./bee}$)	Exposure (g a.s./ha)	HQ
foramsulfuron	48h Oral	> 110.1	60	< 0.5
	48h Contact	> 100		< 0.6
foramsulfuron as formulation foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L)	48h Oral	> 5.0	60	< 12
	48h Contact	> 4.66		< 13

Further considerations for the risk assessment

In addition to acute laboratory studies with adult honey bees, notifier presented chronic laboratory tests. The chronic study was designed as a limit test by exposing adult honey bees for 10 consecutive days to a concentration of nominally 120 mg foramsulfuron a.s./kg in aqueous sugar solution, which corresponded to about the concentration of foramsulfuron in the spray tank of a high-volume use. Because of low solubility of a.s. tech., the test was conducted by using the formulated product Foramsulfuron WG 50. The results show no adverse lethal-, sub-lethal, behavioural or delayed effects were found by exposing adult honey bees for 10 consecutive days exclusively to sugar solution, containing 120 ppm foramsulfuron (nominal).

A bee brood feeding study done by Oomen *et al.* (1992) was done to observe the effect of foramsulfuron to immature honey bee life stages. This screening test, when bee colony was fed by feeder from the top of the hive with a treated sugar solution (1L) which contains the test substance (Foramsulfuron WG 50 W together with formulated safener cyprosulfamide, as Cyprosulfamide SC 500) at a concentration typically present in the spray tank (and as such at a very high concentration). The results show statistically significantly increased termination rate of young and old larvae when compared to the control treatment. No adverse effects on the survival of adult bees and pupae, behaviour, colony strength, condition of the colonies, colony development, brood index and brood compensation index was observed.

On the basis of results obtained from brood feeding study done by Oomen *et al.* (1992), notifier decided to do *in-vitro* larval test following the OECD Draft Test Guideline on Honey Bee (*Apis mellifera*) Larval Toxicity Test, Single Exposure (Version of 21 February 2013) and the current draft version of the Post-WNT25 Approved Larval Honey Bee Test, dated April 2013, which is the Draft-version of the OECD 237-guideline (Adopted: 26 July 2013). The *in-vitro* larvae study was conducted with Foramsulfuron WG 50, as technical foramsulfuron was not well soluble in water. The potential effects on larval development were investigated at a level of 100 $\mu\text{g a.s./larva}$, i.e. the (highest) dose recommended for a limit test. In order to achieve this dose, the foramsulfuron concentration in the larval diet was about 3000 ppm. Result show no adverse effects on larvae mortality (in both, in the control and in the foramsulfuron treatment group mortality was max. 2.1%, respectively; the toxic reference treatment resulted in at least 89.6 % larval mortality). Based on these findings, the observations in the honey bee brood feeding study are rather to be attributed to natural variability than being test-item related.

A higher tier semi-field honey bee brood study (OECD 75, 2007) was conducted by applying the maximum rate (2.68 L) of Foramsulfuron + Isoxadifen-ethyl OD 45 (22.5 + 22.5 g/L) under tunnel conditions to the full flowering and highly bee attractive surrogate crop *Phacelia tanacetifolia*. The test was designed as a replicated

tunnel study to assess potential effects of foramsulfuron to honey bee colonies, including a very detailed assessment of brood development. The study was carried out using four tunnels (i.e. replicates) for the test item treatment, the control and the reference item treatment (Insegar, 250 g/kg fenoxycarb), respectively. The confined exposure phase of the honey bees inside the treated crop was only 4 days following the test item application (not 7 days), because at the end of the 4th day after application, due to the herbicide mode of action of the test item, the *Phacelia*-crop was no longer attractive to bees (faded) and did not longer support the confined colonies. Ontogenesis of the bees from egg to adult workers was observed for a period of 22 days (i.e. one complete honey bee brood cycle) using an assessment of digital picture of the brood comb. Results show no adverse effects on mortality of worker or pupae, foraging activity, behaviour, nectar- and pollen storage as well as on queen survival. No effects on colony development, colony strength or bee brood were also observed.

Overall, it can be concluded that foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L), when applied at the maximum application rate of 60 g a.s./ha even during the flowering period of potentially bee-attractive weeds inside the cropping area, does not pose an unacceptable risk to honey bees and honey bee colonies.

B.9.6.1.3. Co-RMS conclusion:

No further investigation is considered necessary. Co-RMS concludes that the risk to bees from foramsulfuron is acceptable following the use of EQUIP OD 45 according to the proposed use pattern supported in this submission.

B.9.6.2. Risk assessment for other non-target arthropod species

The toxicity of foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) to non-target arthropods has been investigated by carrying out a Tier I test on *Aphidius rhopalosiphi* and a Tier I test on *Typhlodromus pyri*. These two species are tested, in accordance with ESCORT 2, as representative non-target arthropods since they have been found to be particularly sensitive species, and therefore can be considered as indicators of potential effects to the most sensitive non-target arthropods in the field.

The potential risk posed by foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) has been assessed according to the principles of the ESCORT 2 Guidance Document (Candolfi et al, 2001).

B.9.6.2.1. Toxicity data for non-target arthropods in laboratory studies and field studies

Two new studies which have been carried out with formulation foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) are summarised below in the table together with EU agreed endpoints (Foramsulfuron: SANCO Scientific Report, 2001).

Table B.6.2.1-1: Effect of foramsulfuron (foramsulfuron + isoxadifen-ethyl OD 45) on non-target arthropods

Species and stage	Test type, material and duration	Dose rate	Effect	References file No.
Laboratory tests				
<i>Typhlodromus pyri</i> Protonymphs	Tier I Glass plate	267 mL to 2670 mL FSN + IDF OD 45 /ha	LR ₅₀ > 2670 mL f.p./ha (equivalent to LR ₅₀ >62.2 g a.s./ha)	Röhlig (2013)* M-457360-01-1
<i>Typhlodromus pyri</i> Protonymphs	Tier I Glass plate	233 mL and 2330 mL FSN + IDF OD 45 /ha	Corrected M = 53 % at 2330 mL f.p./ha (equivalent to LR ₅₀ >60 g a.s./ha)	Waltersdorfer (1999) M-191384-01-1
<i>Aphidius rhopalosiphi</i> Adult	Tier I Glass plate	35 mL to 2670 mL FSN + IDF OD 45 /ha in two test run	LR ₅₀ 241 mL f.p./ha (equivalent to LR ₅₀ >5.6 g a.s./ha)	Röhlig (2013)* M-461455-01-1
<i>Aphidius rhopalosiphi</i>	Tier I Glass plate	3.6 g, 45 g and 90 g foramsulfuron/ha	Corr. M = 26 % at 3.6 g a.s./ha Corr. M = 100 % at 45 g and 90 g	Kleiner (1999) M-191908-01-1

Species and stage	Test type, material and duration	Dose rate	Effect	References file No.
Adult			a.s./ha	
Extended laboratory tests				
<i>Typhlodromus pyri</i> Protonymphs	Tier II Extended lab., exposure on <i>Polygonum convolvulus</i> leaves	1750 and 3500 mL FSN + IDF OD 45 /ha	LR ₅₀ > 3500 mL f.p./ha (equivalent to LR ₅₀ >90 g a.s./ha)	Waltersdorfer (1999) M-192822-01-1
<i>Aphidius rhopalosiphi</i> Adult	Tier II spray deposits on potted maize plants	107 mL, 2000 mL and 2670 mL FSN + IDF OD 45 /ha	LR ₅₀ > 2670 mL f.p./ha (equivalent to LR ₅₀ >60 g a.s./ha)	Barth (2000) M-198973-01-1
<i>Chrysoperla carnea</i> Larvae	Tier II 2D study	160 mL, 2000 mL and 4000 mL FSN + IDF OD 45 /ha	LR ₅₀ > 4000 mL f.p./ha (equivalent to LR ₅₀ >90 g a.s./ha)	Kleiner (2000) M-194627-01-1
<i>Aleochara bilineata</i> Adults	Tier II 2D study	160 mL, 2000 mL and 4000 mL FSN + IDF OD 45 /ha	ER ₅₀ > 4000 mL f.p./ha (equivalent to ER ₅₀ >90 g a.s./ha)	Kleiner (1999) M-186968-01-1
<i>Poecilus cupreus</i> Adults	Tier II 2D study	2330 mL and 4660 mL FSN + IDF OD 45 /ha	LR ₅₀ > 4660 mL f.p./ha (equivalent to LR ₅₀ >120 g a.s./ha)	Waltersdorfer (1999) M-186968-01-1
<i>Pardosa sp.</i> Adults	Tier II 2D study	160 mL, 2000 mL and 4000 mL FSN + IDF OD 45 /ha	LR ₅₀ > 4000 mL f.p./ha (equivalent to LR ₅₀ >90 g a.s./ha)	Kleiner (1999) M-188675-01-1

* new study

f.p. formulated product

M mortality

B.9.6.2.2. Exposure in-field and off-field of non-target arthropods

Foliar application of pesticides may potentially result in exposure of arthropods either through direct over-spray or *via* residues on plants and soil. Tiered risk assessment has been conducted according to ESCORT 2 guidance and uses a trigger value of 2. Within ESCORT 2 exposure is normally calculated in-field and off-field using the equations presented below:

$$PER_{in-field} = \text{max. application rate (g a.s./ha)} \times \text{MAF}$$

$$PER_{off-field} = \frac{\text{max. application rate (g a.s./ha)} \times \text{MAF} \times \text{Drift factor}}{\text{Vegetation distribution factor}}$$

These equations are appropriate when assessing the PER on soil and foliage, to which non-target arthropods may be exposed following multiple foliar applications on crops.

EQUIP OD 45 is intended to be applied once with an application rate of 2.6 L product/ha. Therefore, the multiple application factor (MAF) was set at 1.0. Resulting HQ values are presented in the following table. The risk is considered acceptable if the calculated HQ is < 2.

Table B.9.6.2.2-1: HQ for terrestrial non-target arthropods for the in-field scenario

Crop	Species	Appl. rate [g a.s./ha]	MAF	LR ₅₀ [g a.s./ha]	HQ	Trigger
Maize	<i>T. pyri</i>	60	1	> 62.2	<1.0	2
	<i>A. rhopalosiphi</i>			5.6	10.8	2

The in-field HQ value for *Typhlodromus pyri* is below the trigger of concern. However, the in-field HQ value for *Aphidius rhopalosiphi* is above the trigger of 2, indicating a need for refinement.

In-field tier 2 risk assessment:

The risk is considered acceptable if effects on mortality and reproduction are <50% at the in-field PECmax (application rate x MAF).

Table B.9.6.2.2-2: Tier 2 in-field risk assessment (based on study results from extended laboratory studies with the standard species *Typhlodromus pyri* and *Aphidius rhopalosiphi* and laboratory studies with additional species)

Test Species	in-field PECmax [mL product/ha]	LR50/ER50 [mL/ha]	Risk acceptable if:	Refined assessment required?
<i>Aphidius rhopalosiphi</i>	2600	>2670	Effects are < 50%	no
<i>Typhlodromus pyri</i>	2600	>3500	Effects are < 50%	no
<i>Chrysoperla carnea</i>	2600	>4000	Effects are < 50%	no
<i>Aleochara bilineata</i>	2600	>4000	Effects are < 50%	no
<i>Poecilus cupreus</i>	2600	>4660	Effects are < 50%	no
<i>Pardosa</i> sp.	2600	>4000	Effects are < 50%	no

An extended laboratory aged residue study performed on *Aphidius rhopalosiphi* (Barth, 2000; M-198973-01-1) indicates that no unacceptable effects on mortality or reproduction, even directly after application.

An extended laboratory study with *Typhlodromus pyri* (Waltersdorfer, 1999; M-192822-01-1) resulted in 20% corrected mortality at a rate of 3500 mL product/ha and a higher reproduction rate than in the control, confirming the results of the tier 1 assessment and showing that no adverse effects on reproduction of *Typhlodromus pyri* are to be expected.

Further tests on additional arthropod species resulted in LR₅₀ and ER₅₀ values above the intended application rate of 2600 mL product/ha.

Off-field hazard quotient (HQ) tier 1 risk assessment

The risk is considered acceptable if the calculated HQ is < 2 (see table below).

Table B.9.6.2.2-3: HQ for terrestrial non-target arthropods for the off-field scenario

Crop	Species	Appl. rate [mL product/ha]	MAF	Drift [%]	VDF	Corr. factor	LR50 [mL product/ha]	HQ	Trigger
Maize	<i>T. pyri</i>	2600	1	2.77	10	10	> 2670	0.03	2
	<i>A. rhopalosiphi</i>				10	10	241	0.3	2

The calculated HQ values are below the trigger of concern, indicating that **no unacceptable risk is to be expected for non-target arthropods in the in-field and off-field area** from the use of foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) according to the proposed use pattern.

B.9.6.2.3. Co-RMS conclusion:

No further investigation is considered necessary. Co-RMS concludes that the risk to non-target arthropods in the in-field and off-field area from foramsulfuron is acceptable following the use of EQUIP OD 45 according to the proposed use pattern supported in this submission.

B.9.7. EFFECTS ON NON-TARGET SOIL MESO- AND MACROFAUNA

B.9.7.1. Earthworms

B.9.7.1.1. Toxicity data

Table B.9.7.1.1-1: Summary of earthworm acute toxicity data

Test material	Species	Test	LC ₅₀ mg/kg dry soil	NOEC mg/kg dry soil	Autors
foramsulfuron	<i>Eisenia fetida</i>	acute	>1000	1000	Heusel, R.; 1998 M-142934-01-1 KCA 8.4 /01
AE F153745	<i>Eisenia fetida</i>	acute	> 1000	> 1000	Sowig., P., Gosch, H.; 1999 M-192813-01-1 KCA 8.4 /02
Formulation (AE F130360 01 1K05 A304)	<i>Eisenia fetida</i>	acute	452.95	319	Nienstedt, K. M.; 1998 M-193746-01-1 KCP 10.4.1 /01

For FSN + IDF OD 45, foramsulfuron and its metabolites AE F092944, AE F153745 and AE F130619 reproductive toxicity studies on *Eisenia fetida* were performed. In all studies no mortality occurred. NOEC levels ranged from > 2.75 mg/kg dws for the parent compound to > 100 mg/kg dws for metabolite AE F153745. Details of all studies are provided in the following table.

Table B.9.7.1.1-2: Reproductive toxicity data of foramsulfuron and metabolites to *Eisenia fetida*

Test substance	Test species, test design	Endpoint (NOEC)	Reference
foramsulfuron	<i>Eisenia fetida</i> reproduction, 56 d (10% peat in test soil), test item sprayed on soil surface	≥600 g a.s./ha ≥2.75 mg a.s./kg dws ¹⁾	Sowig & Gosch, 2000 M- 193508-01-1 KCA 8.4.1 /01
AE F092944	<i>Eisenia fetida</i> reproduction, 56 d (10% peat in test soil), test item mixed into soil	10 mg/kg dws	Kratz, 2013 M-461051-01-1 KCA 8.4.1 /02
AE F130619	<i>Eisenia fetida</i> reproduction, 56 d (10% peat in test soil), test item mixed into soil	56 mg/kg dws	Kratz, 2013 M-461453-01-1 KCA 8.4.1 /03
AE F153745	<i>Eisenia fetida</i> reproduction, 56 d (10% peat in test soil), test item mixed into soil	> 100 mg/kg dws	Kratz, 2013 M-459518-01-1 KCA 8.4.1 /04
Formulation FSN + IDF OD 45	<i>Eisenia fetida</i> reproduction, 56 d (10% peat in test soil), test item mixed into soil	> 370 mg/kg dws	Witte, B., 2013 M-464888-01-1 KCP 10.4.1.1 /01

¹⁾ Considering a jar surface area of 283.4 cm² and an amount of 618 g dry soil per jar - BCS calculation results in 2.75 mg a.s./kg dws. dws = dry weight soil

Bold letters: Values considered relevant for risk assessment

B.9.7.2. Effects on non-target soil meso- and macrofauna (other than earthworms)**B.9.7.2.1. Toxicity data**

For foramsulfuron and its metabolites AE F092944, AE F153745 and AE F130619 reproductive toxicity studies on *Hypoaspis aculeifer* and *Folsomia candida* were performed. In the tests with the soil mite *Hypoaspis aculeifer* no effects were observed at the highest tested dose levels when either the parent compound or the metabolites were tested. Resulting NOEC values were >1000 mg a.s./kg dws for foramsulfuron and > 100 mg/kg dws for the soil metabolites.

The collembolan species *Folsomia candida* was slightly more sensitive to the parent compound foramsulfuron than the soil mite, with a NOEC of 178 mg a.s./kg dws, while for the metabolites again no effects were observed at the highest tested dose level of 100 mg/kg dws.

Details of all studies are provided in the following table.

Table B.9.7.2.1-1: Reproductive toxicity data of foramsulfuron and metabolites to other non-target macro-organisms

Test substance	Test species	Endpoint (NOEC)	Reference
Foramsulfuron	<i>Hypoaspis aculeifer</i>	≥1000 mg a.s./kg dws	Kratz, 2012 M-443308-01-1 KCA 8.4.2.1/01
	<i>Folsomia candida</i>	178 mg a.s./kg dws	Frommholz, 2012 M- 443369-01-1 KCA 8.4.2.1/02
AE F092944	<i>Hypoaspis aculeifer</i>	≥100 mg/kg dws	Schulz, 2013 M-454043-01-1 KCA 8.4.2.1/03
	<i>Folsomia candida</i>	≥100 mg/kg dws	Friedrich, 2013 M- 451142-01-1 KCA 8.4.2.1/04
AE F130619	<i>Hypoaspis aculeifer</i>	≥100 mg/kg dws	Schulz, 2013 M-454051-01-1 KCA 8.4.2.1/05
	<i>Folsomia candida</i>	≥100 mg/kg dws	Friedrich, 2013 M- 450824-01-1 KCA 8.4.2.1/06
AE F153745	<i>Hypoaspis aculeifer</i>	≥100 mg/kg dws	Schulz, 2013 M-447606-01-1 KCA 8.4.2.1/07
	<i>Folsomia candida</i>	≥100 mg/kg dws	Friedrich, 2013 M- 450830-01-1 KCA 8.4.2.1/08
FSN + IDF OD 45	<i>Hypoaspis aculeifer</i>	> 370 product /kg dws	Witte, B., 2013 M-462835-01-1 KCP 10.4.2.1 /02
	<i>Folsomia candida</i>	142 mg product/kg dws	Witte, B., 2013 M-462827-01-1 KCP 10.4.2.1 /01

Bold letters: Values considered relevant for risk assessment
dws = dry weight soil

B.9.7.3. Exposure (Predicted Environmental Concentrations in soil)

The predicted environmental concentrations for the active substance and for the major metabolites in soil have been calculated and presented in Vol 3_CP Point B.8.2. The worst case maximum PEC_{sw} values are also given in Tables B.9.7.3-2 and B.9.7.3-3.

Method of calculation

TopFit multi-compartment calculation using first order kinetics; worst case normalised laboratory DT₅₀ 82 days; 5 cm soil depth; without interception

Application rate

See Table B.9.7.3-1

Table B.9.7.3-1: Intended application pattern

Crop	Timing of application (range)	Number of applications	Application interval [days]	Maximum label rate (range) [L/ha]	Maximum application rate, individual treatment (ranges) [g/ha]	
					Foramsulfuron	Isoxadifen-ethyl
Maize	BBCH 12-18	1	-	2.6	60	60
Maize	BBCH 12-18	2	7	1.3	30	30

Table B.9.7.3-2: Predicted environmental concentrations in soil (worst case application 1 x 60 g as/ha)

PEC(s) mg/kg	Single application Actual	Single application Time weighted average
Initial	0.080	0.080
Short term		
24 h	0.079	0.079
2 d	0.078	0.079
4 d	0.077	0.079
Long term 7 d		
	0.075	0.078
28 d	0.063	0.071
50 d	0.052	0.065
100 d	0.034	0.052

Table B.9.7.3-3: Maximum PECS of foramsulfuron and its metabolites

Use pattern	Maximum PEC _s			
	foramsulfuron	AE F130619	AE F153745	AE F092944
Maize. 1x60 g a.s./ha	0.060	0.016	0.003	0.004
Maize. 2x30 g a.s./ha	0.058	0.015	0.002	0.004

B.9.7.4. Risk assessment on non-target soil meso- and macrofauna

B.9.7.4.1. Risk assessment for earthworms

Acute risk

The estimation of acute risk towards the active substance and the formulation including the safener indicates there no acute risk for earthworms is given (see Table B.9.7.4.1-1)

The TER_{acute} was calculated as follows:

$$TER_{acute} = \frac{LC_{50} \text{ (mg/kg)}}{PEC_s \text{ (mg/kg)}}$$

The resulting TER_{acute} values are shown below.

Table B.9.7.4.1-1: Acute TER values for earthworms

Test material	LC ₅₀ (mg/kg)	PEC _{initial/accu} (mg/kg)	TER _{acute}	Annex VI trigger
as foramsulfuron	> 1000	0.08	> 12500	10
AE F153745	> 1000	0.003	> 333 334	10
formulation (AE F130360 01 1K05 A304)	453	3.5	129	10

All the acute TER values are higher than the Annex VI acute trigger value of 10, indicating that the acute risk to earthworms is acceptable following use foramsulfuron, AE F153745 or formulation (AE F130360 01 1K05 A304) according to the proposed use pattern.

Long-term risk

The summary of the toxicity of FSN + IDF OD 45, foramsulfuron and its soil metabolites to earthworms is provided in Table B.9.7.4.1-2. Details of the studies with the active substance and the metabolites are presented above.

The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC \text{ (mg/kg)}}{PEC_s \text{ (mg/kg)}}$$

The resulting TER_{LT} values are presented below:

Table B.9.7.4.1-2: Long-term TER values for earthworms

Compound, test design	Endpoint NOEC (mg a.s./kg dws)	PEC _{soil,max/accu} [mg/kg]	TER _{LT}	Trigger
foramsulfuron reproduction	> 2.75	0.063	> 43.7	5
AE F092944 reproduction	10	0.004	2 500	5
AE F153745 reproduction	> 100	0.003	> 33 333	5
AE F130619 reproduction	56	0.016	3 500	5
FSN + IDF OD 45 reproduction	> 370	2.499	> 148	5

Long-term TER values of FSN + IDF OD 45, foramsulfuron, metabolites AE F092944, AE F153745 and AE F130619 exceed the Annex VI long-term trigger value of 5, indicating that the long-term risk to earthworms is acceptable following use according to the proposed use pattern.

B.9.7.4.2. Co-RMS conclusion

All the acute TER values are higher than the Annex VI acute trigger value of 10, indicating that the acute risk to earthworms is acceptable following use foramsulfuron, AE F153745 or formulation (AE F130360 01 1K05 A304) according to the proposed use pattern.

Long-term TER values of FSN + IDF OD 45, foramsulfuron, metabolites AE F092944, AE F153745 and AE F130619 exceed the Annex VI long-term trigger value of 5, indicating that the long-term risk to earthworms is acceptable following use according to the proposed use pattern.

B.9.7.4.3. Risk assessment for other soil non-target macro-organisms (other than earthworms)

The risk to Collembola and predatory soil mite from foramsulfuron and its metabolites AE F092944, AE F153745 and AE F130619 was assessed by calculating toxicity exposure ratios (TER) based on the NOEC and PEC_S.

The TER_{LT} was calculated as follows:

$$TER_{LT} = \frac{NOEC \text{ (mg/kg)}}{PEC_S \text{ (mg/kg)}}$$

The resulting TER_{LT} value is presented below:

Table B.9.7.4.3-1: TER_{LT} of foramsulfuron and its metabolites AE F092944, AE F153745 and AE F130619 for *Folsomia candida* and *Hypoaspis (Geolaelaps) aculeifer*

Compound	Species	Endpoint (NOEC)	PEC _{soil,max/accu} [mg/kg]	TER	Trigger
FSN + IDF OD 45	<i>Folsomia candida</i>	142 mg product/kg dws	2.499	56.8	5
	<i>Hypoaspis aculeifer</i>	> 370 product /kg dws	2.499	> 148	5
Foramsulfuron	<i>Folsomia candida</i>	178 mg a.s./kg dws	0.063	2 825	5
	<i>Hypoaspis aculeifer</i>	> 1000 mg a.s./kg dws	0.063	> 15 873	5
AE F092944	<i>Folsomia candida</i>	> 100 mg/kg dws	0.004	> 25 000	5
	<i>Hypoaspis aculeifer</i>	> 100 mg/kg dws	0.004	> 25 000	5
AE F153745	<i>Folsomia candida</i>	> 100 mg/kg dws	0.003	> 33 333	5
	<i>Hypoaspis aculeifer</i>	> 100 mg/kg dws	0.003	> 33 333	5
AE F130619	<i>Folsomia candida</i>	> 100 mg/kg dws	0.016	> 6 250	5
	<i>Hypoaspis aculeifer</i>	> 100 mg/kg dws	0.016	> 6 250	5

The TER_{LT} values of foramsulfuron and its metabolites AE F092944, AE F153745 and AE F130619 are above the trigger, indicating no unacceptable risk for soil non-target macro-organisms, i.e. collembola and soil mites.

B.9.7.4.4. Co-RMS conclusion

The TER_{LT} values of product FSN + IDF OD 45, foramsulfuron and its metabolites AE F092944, AE F153745 and AE F130619 are above the trigger, indicating no unacceptable risk for soil non-target macro-organisms, i.e. collembola and soil mites

B.9.8. EFFECTS ON SOIL NITROGEN TRANSFORMATION

For foramsulfuron and its metabolites AE F092944, AE F153745 and AE F130619 studies on the effect on soil nitrogen transformation were performed. In none of the studies unacceptable effects were found at the highest tested dose level which ranged from 0.137 mg/kg dws to 0.735 mg/kg dws. Details of all studies are provided in the table below.

Table B.9.8-1 Toxicity data of foramsulfuron and metabolites to soil non-target micro-organisms

Test item	Test design	Ecotoxicological endpoint		Reference
N-transformation				
FSN + IDF OD 45	28 d	no unacceptable effects	≥18.59 L prod./ha ≥0.6 mg a.s./kg dws	Van der Kolk, 1999 M-193742-01-1 KCP 10.5/01
Foramsulfuron, tech.	28 d	no unacceptable effects	≥0.3 mg a.s./kg dws	Heusel, 1997 M-142972-01-1 KCA 8.5/01
Foramsulfuron + bound residues	28 d	no unacceptable effects	≥0.735 mg a.s./kg dws	Sowig & Gildemeister, 2000 M-193916-01-1 KCA 8.5/02
AE F153745	28 d	no unacceptable effects	≥0.240 mg/kg dws	Schulz, 2013 M-453508-01-1 KCA 8.5/07
AE F130619	28 d	no unacceptable effects	≥0.375 mg/kg dws	Schulz, 2013 M-453568-01-1 KCA 8.5/06
AE F092944	28 d	no unacceptable effects	≥0.137 mg/kg dws	Schulz, 2013 M-453511-01-1 KCA 8.5/05

dws = dry weight soil

B.9.8.1. Risk assessment for soil nitrogen transformation

According to current regulatory requirements the risk is considered acceptable if the effect on nitrogen mineralisation at the recommended application rate of a compound/product is $\leq 25\%$ after 100 days.

In no case did deviations from the control exceed 25% 28 days after application, indicating low risk to soil micro-organisms. A study testing effects of bound residues of foramsulfuron on nitrogen transformation (Sowig & Gildemeister, 2000; M-193916-01-1) measured nitrogen turnover for 28 days starting from the time point when a plateau concentrations of bound residues had been reached in the test soil. No deviations from the control exceeding 25% occurred.

B.9.8.2. Co-RMS conclusion:

No further investigation is then considered necessary. Co-RMS concludes that the risk to organic matter breakdown from foramsulfuron and its soil metabolites AE F092944, AE F153745 and AE F130619 is acceptable following the use of EQUIP OD 45 according to the proposed use pattern supported in this submission.

B.9.9. EFFECTS ON TERRESTRIAL NON-TARGET HIGHER PLANTS

B.9.9.1. Summary of screening data

For foramsulfuron, a screening study on higher plant species was performed. As expected for a sulfonyl urea herbicide the compound showed significant herbicidal activity to several plants (post-emergence application: grass plants more susceptible than broadleaf plants. Pre-emergence application: some broadleaf plants are quite susceptible to dosage range of ≥ 20 g a.s./ha).

B.9.9.2. Testing on non-target plants

For herbicides and plant growth regulators, it is considered unprofitable to conduct tier 1 studies as it is inevitable that these will lead to tier 2 or dose response studies in order to generate data suitable for deterministic or probabilistic risk assessments, i.e. ER50 values for 6-10 species, representing a broad range of plant species.

Ecological endpoints: The endpoints from the tier 2 studies used for the risk assessment are summarised in following table:

Table B.9.9.2-1: Survey of non-target plant tests performed with FSN + IDF OD 45

Number of species tested (species)	Test method Test substance Application rate	Effects	Reference
Dicotyledoneae: 6 (bean, cabbage, radish, tomato, soybean, lettuce) Monocotyledoneae: 4 (rye grass, corn, wheat, onion)	Seedling emergence FSN + IDF OD 45 0 (control) and 60 g prod./ha with observations of emergence on Days 10, 14 and 21, with observations of height and condition on Day 21 and measurement of dry weight on Day 21	Reduction > 25 % (emergence) in onion and rye grass; reductions > 25 % (height and weight of seedlings, signs of phytotoxicity) in cabbage, lettuce, onion, radish, rye grass, tomato and wheat seedlings	Porch, Kendall & Krueger, 1999; B002673 M-238408-01-2 KCP 10.6.2/01
Dicotyledoneae: 6 (bean, cabbage, radish, tomato, soybean, lettuce) Monocotyledoneae: 4 (rye grass, corn, wheat, onion)	Tier 2 vegetative vigour FSN + IDF OD 45 0 (control), 0.25, 0.74, 2.2, 6.7, 20 and 60 g prod./ha with height and condition observations on Days -1 or 0 (prior to application), 7, 14 and 21, dry weight measurements on Day 21	Most sensitive species = radish; lowest EC ₅₀ 1.88 g sum of a.s./ha ¹	Porch, Kendall & Krueger, 1999; B002710 M-238444-01-2 KCP 10.6.2/01
Dicotyledoneae: 4 (cabbage, radish, tomato, lettuce) Monocotyledoneae: 3 (rye grass, wheat, onion)	Tier 2 seedling emergence FSN + IDF OD 45 0 (control), 0.25, 0.74, 2.2, 6.7, 20 and 60 g prod./ha with observations of emergence on Days 10 and 14, with observations of height and condition on Day 14 and measurement of dry weight on Day 14	Most sensitive species = lettuce; lowest EC ₅₀ 38.8 g sum of a.s./ha ¹	Porch, Kendall & Krueger, 2000; B002819 M-238550-01-1 KCP 10.6.2/02

Remark: In all studies endpoints are given in g a.i./ha. Descriptions of the experimental design in the two seedling emergence studies indicate that the endpoints are given as g (AE F130360 + AE F122006) per hectare.

B.9.9.3. Extended laboratory studies on non-target plants

Not relevant according to SANCO/10329/2002 rev2 final, 2002.

B.9.9.4. Semi-field and field tests on non-target plants

Not relevant according to SANCO/10329/2002 rev2 final, 2002.

B.9.10. RISK ASSESSMENT FOR TERRESTRIAL NON-TARGET HIGHER PLANTS

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area. Spray drift from the treated areas may lead to residues of a product in off-crop areas.

B.9.10.1. Exposure

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates derived by the *BBA (2000)*² from the spray-drift predictions of *Ganzelmeier & Rautmann (2000)*³. Only a single application was considered as factors such as plant growth will reduce residues per unit area between multiple applications. For a single application to maize, 2.77% of the application rate was assumed to reach areas at the edge of the crop (0 meter buffer zone; worst-case scenario). For a 5 m buffer zone a drift rate of 0.57% is assumed.

The highest single application rate of foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) is 2.7 L product/ha (corresponding to 120 g foramsulfuron + isoxadifen a.i./ha), giving a maximum off-field predicted environmental rate (PER_{off-field}) of 3.324 g sum of a.i./ha.

Table B.9.10.1-1: Off-crop exposure for non-target terrestrial plants

Crop	Application rate (g as/ha)	Distance (m)	Drift (%)	PER _{off-field} (g a.s./ha)
Maize	120.0 g sum of as/ha	1	2.77	3.324
		5	0.57	0.684
		10	0.29	0.348

B.9.10.2. Risk assessmentDeterministic Risk assessment

According to the Terrestrial Guidance Document⁴, the risk to non-target plants is evaluated by comparing the lowest ER₅₀ observed in the laboratory studies with the drift rates (PER_{off-field}) inclosing a safety factor of 5. In addition, the usage of drift reducing nozzles is considered.

² BBA (2000) Bundesanzeiger Jg. 52 (Official Gazette), Nr 100, S. 9879-9880 (25.05.2000) Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden. Public domain.

³ Ganzelmeier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Aspects of Applied Biology 57, 2000, Pesticide Application. Public domain.

⁴ Anonymous (2002b). Guidance Document on terrestrial ecotoxicology under council directive 91/414/EEC. SANCO/10329/2002. 17 October 2002.

Table B.9.10.2-1: Deterministic risk assessment for foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) based on effects on seedling emergence

arable field crops, one application, 120.0 g sum of a.i./ha; lowest ER ₅₀ = 38.8 g sum of a.i./ha						
Distance	Drift	PER	TER			
[m]	(%)	no drift reduction [g sum of a.i./ha]	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
1	2.77	3.324	11.67	23.35	46.69	116.73
5	0.57	0.684	56.73	113.45	226.90	567.25
10	0.29	0.348	111.49	222.99	445.98	1114.94

Table B.9.10.2-2: Deterministic risk assessment for foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) based on effects on vegetative vigour

arable field crops, one application, 120.0 g sum of a.i./ha; lowest ER ₅₀ = 1.880 g sum of a.i./ha						
Distance	Drift	PER	TER			
[m]	(%)	no drift reduction [g sum of a.i./ha]	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
1	2.77	3.324	0.57	1.13	2.26	5.66
5	0.57	0.684	2.75	5.50	10.99	27.49
10	0.29	0.348	5.40	10.80	21.61	54.02

Probabilistic Risk assessment

In addition to the deterministic risk assessment the Terrestrial Guidance Document recommends the use of the HC5 (the concentration below which less than 5% of the species will be harmed above the EC₅₀ level) which can be calculated from the data sets of ER₅₀ growth inhibition levels. The EU guidance document for terrestrial ecotoxicology states that *if the ED₅₀ for less than 5 % of the species is below the highest predicted exposure level, the risk for terrestrial plants is assumed to be acceptable*. Thus, the HC5 itself (TER=1) can be regarded to be protective.

Table B.9.10.2-3: The vegetative vigour EC₅₀ values for 10 species exposed to foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L)

Species	M/D	Vegetative Vigour Test EC ₅₀ [g as/ha], 21 days	
		Shoot Length	Shoot Dry Weight
<i>Brassica oleracea</i>	D	6.2	2.43
<i>Lactuca sativa</i>	D	5.6	2.12
<i>Allium cepa</i>	M	60.0	38.5
<i>Raphanus sativus</i>	D	> 0.66	1.88
<i>Lolium perenne</i>	M	> 3.5	2.38
<i>Lycopersicon esculentum</i>	D	3.4	1.97
<i>Triticum aestivum</i>	M	19.9	4.10
<i>Zea mays</i>	M	> 60	> 60
<i>Phaseolus vulgaris</i>	D	5.4	5.21
<i>Glycine max</i>	D	12.6	15.2

M = Monocotyledoneous, D = Dicotyledoneous

The HC5 was calculated according to $HC5 = 10 \exp^{(avg-ks*std)}$

With:

avg=mean of log10 transformed EC₅₀ values

std=standard deviation of log10 transformed EC₅₀ values

ks = extrapolation factor

From the data sets of ER₅₀-levels obtained from the tests with foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) only the vegetative vigour(shoot dry weight) data are applicable for an HC5-calculation. The seedling- emergence data contain too many greater-than figures.

HC₅ calculation

The respective HC₅ calculation have been conducted using the computer program ETX 2.0 by rivm (RIVM, 2004). In the first step, the toxicity data (EC₅₀) were subjected to three different goodness of fit tests (Anderson-Darling, Kolmogorov-Smirnov and the Cramer von Mises), where normality at the 0.01 significance level was accepted. The analysis of the EC₅₀ values show normal distribution of the data. The results of the ETX^{2.0} calculation based on the EC₅₀ values and the respective graphs of terrestrial plants sensitivity distribution are presented below.

Analysis of normality for terrestrial plants

Parameters of the log-normal distribution for data set of terrestrial plants

Name	Value	Description
mean	0.753222	mean of the log toxicity values
s.d.	0.562441	sample standard deviation
n	10	sample size

Goodness of fit tests - results for macrophytes

Sign. level	Tests for normality n = 9					
	Anderson-Darling		Kolmogorov-Smirnov		Cramer von Mises	
0.1	0.631	Rejected	0.819	Rejected	0.104	Rejected
0.05	0.752	Rejected	0.895	Rejected	0.126	Rejected
0.025	0.873	Rejected	0.995	Rejected	0.148	Accepted
0.01	1.035	Accepted	1.035	Accepted	0.179	Accepted
Statistic	0.887717		0.832407		0.139795	

Figure B.9.10.2-1: SSD Histogram for macrophytes

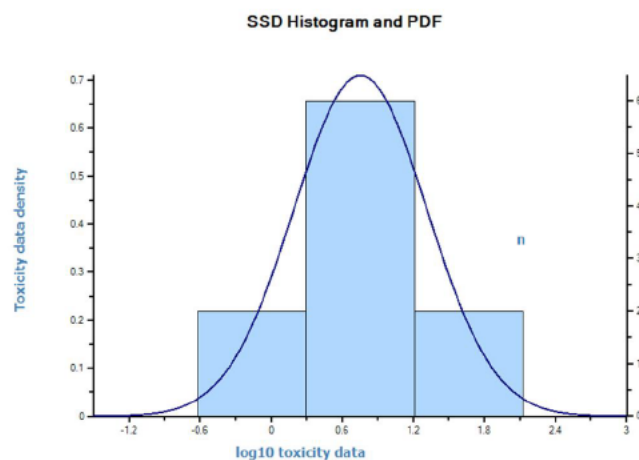
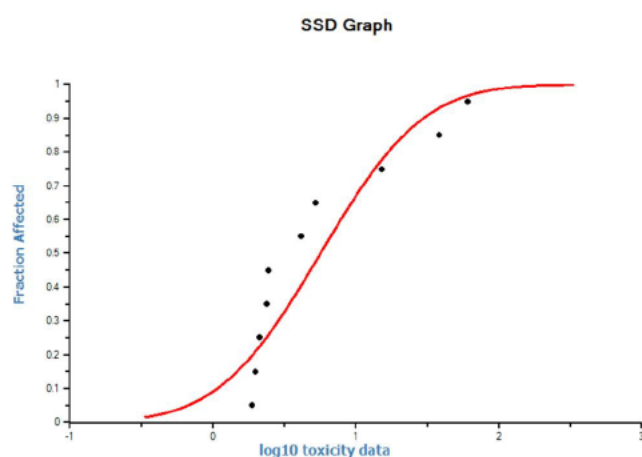


Figure B.9.10.2-2: Species sensitivity distribution for macrophytes

**HC₅ results [μg foramsulfuron/L] for macrophytes**

Name	Value [μg a.s./L]	log ₁₀ (Value)	Description
LL HC ₅	0.13061	-0.88402	lower estimate of the HC ₅
HC ₅	0.625395	-0.20385	median estimate of the HC ₅
UL HC ₅	1.51723	0.181052	upper estimate of the HC ₅
sprHC ₅	11.61648	1.065075	spread of the HC ₅ estimate

Table B.9.10.2-4: HC₅-figures for seedling-emergence and vegetative vigour with foramsulfuron + isoxadifen- ethyl OD 45 (22.5+22.5 g/L).

HC ₅	Seedling emergence	Vegetative vigour
HC ₅ based on endpoint from all species	n.a.	0.625(0.131-1.517) g sum of a.s./ha

Table B.9.10.2-5: Probabilistic risk assessment for foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) based on effects on vegetative vigour

arable field crops, one application, 120.0 g sum of a.i./ha; HC5 = 0.625 g sum of a.s/ha						
Distance	Drift	PER	TER			
[m]	(%)	no drift reduction [g sum of a.i./ha]	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
1	2.77	3.324	0.19	0.38	0.75	1.88
5	0.57	0.684	0.91	1.83	3.65	9.14
10	0.29	0.348	1.80	3.59	7.18	17.96

Since foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) has stronger effects on the vegetative vigour of young plants than on the seedling emergence, the vegetative vigour data determine the risk assessment. From Tables B.9.11.2-4 and B.9.11.2-5 it becomes obvious, that a 10-m buffer zone is sufficient to protect terrestrial non-target plants if conventional spraying equipment is used. With the use of 50% drift reducing nozzles the buffer zone can be reduced to 5 m. With the use of 90% drift reducing nozzles no buffer zone is required.

Foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) poses no unacceptable risk to terrestrial non-target plants in off-crop areas following the proposed uses after implementing risk mitigation measures.

B.9.10.3. Co-RMS conclusion

Concerning the submission for the Renewal of the Approval of foramsulfuron, the tests have been performed with the representative formulation: foramsulfuron + isoxadifen-ethyl OD 45. For seedlings emergence, a tier 1 and a tier 2 study have been performed with the representative formulation (Porch, 1999; Porch, 2000). For vegetative vigour, only a tier 2 study was performed (Porch, 1999). From both tier2- studies a most sensitive species and a respective lowest EC₅₀ were used in the risk assessment.

The seedling emergence test is available on seven non-target plants species: Monocots (rye grass, wheat, onion) and Dicots (cabbage, radish, tomato, lettuce). The most sensitive species observed in the study was lettuce with EC₅₀ = 38.8 g sum of a.i./ha. The vegetative vigour test is available on ten non-target plant species: Monocots (rye grass, corn, wheat, onion) and Dicots (bean, cabbage, radish, tomato, soybean, lettuce). The most sensitive species observed in the study was radish with EC₅₀ = 1.88 g sum of a.i./ha.

All seedling emergence TER values based on ER₅₀ for the most sensitive tested species lettuce (worst case) compared to PER values are greater than the Annex VI trigger value of 5, indicating an acceptable risk to the emergence of non-target plant seedlings following use of EQUIP OD according to the proposed use pattern.

Vegetative vigour TER values are above the Annex VI trigger of 5 are therefore acceptable for most sensitive dicot species(radish) assuming a 10 m buffer distance (without drift reduction). Considering drift reduction in the risk assessment, with the use of 50% drift reducing nozzles the buffer zone can be reduced to 5 m. With the use of 90% drift reducing nozzles no buffer zone is required.

B.9.11. EFFECTS ON OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA)**B.9.11.1. Response of *Arabidopsis thaliana* to 22 ALS inhibitors: Baseline toxicity and cross-resistance of *csr1-1* and *csr1-2* resistant mutants.**

The literature search revealed a paper by Roux et al. (2005) which presented effects of 22 ALS- inhibitors, one of which was foramsulfuron, on different mutants of *Arabidopsis thaliana*.

Although the paper as a whole can be regarded as reliable, the endpoints presented in this paper are not considered in the risk assessment for foramsulfuron for the following reasons:

1. The test was conducted with strains which were susceptible to ALS-inhibitors and not to naturally occurring phenotypes of *A. thaliana*.
2. As far as described in the paper the test method used does not fully apply to OECD 2017. Especially the plant density (40 plants in a 1 L pot) was exceptionally high.

For more details, please see Vol 3 for CA B.9.6.1.1.5: Literature search.

B.9.11.2. Effectivity of the herbicide AE F130360 on entomology screening species

For foramsulfuron a screening study on entomology species was performed. Details of the study are provided in the following table.

Table B.9.11.2-1: Effect data of a straight foramsulfuron WG50 to entomology screening species presented in this chapter

Test design	Test species	Ecotoxicological endpoint	Reference (see IIA, Point 8)
Foramsulfuron, formulated as WG 50			
Root systemicity test, different treated stages (eggs, larvae, all stages), 6 d	<i>Spodoptera littoralis</i> , <i>Heliothis virescens</i> , <i>Apis fabae</i> , <i>Nilaparvata lugens</i> , <i>Diabrotica undecimpunctata</i> , <i>Meloidogyne incognita</i> , <i>Tetranychus urticae</i> , <i>Aphis fabae</i> (root systemic activity)	The test item is not effective on any tested species, most sensitive species: <i>Meoidogyne incognita</i> (larvae)	Thoenessen, 2000 M-194770-01-1 KCA 8.7 /01

B.9.12. RISK ASSESSMENT FOR OTHER TERRESTRIAL ORGANISMS (FLORA AND FAUNA)**B.9.12.1. Effects on biological methods for sewage treatment**

For foramsulfuron, one study with activated sludge has been conducted. Details of all studies are provided in the following table.

Table B.9.12.1-1: Effect data of foramsulfuron to activated sludge presented in this chapter

Test species	Test design	Ecotoxicological endpoint	Reference
Foramsulfuron			
Activated sludge	Respiration inhibition, 3 h, static (OECD 209)	Activated sludge, inhibition of respiratory activity : EC ₂₀ > 625.0 mg/L EC ₅₀ > 625.0 mg/L EC ₈₀ > 625.0 mg/L	Reinhardt, 1997 M-142587-01-1 KCA 8.8. /01

The endpoint from this study was not mentioned in the Review Report for foramsulfuron (SANCO/10324/2002-Final).

B.9.12.2. Risk assessment

It can be assumed that adverse effects on methods of sewage treatment are unlikely when EQUIP OD is applied according to GAP. No further investigation is then considered necessary.

It concludes to acceptable risk for methods of sewage treatment when EQUIP OD is applied in accordance with the uses supported in this submission.

B.9.12.2.1. Co-RMS conclusion

It concludes to acceptable risk for methods of sewage treatment when EQUIP OD is applied in accordance with the uses supported in this submission.

B.9.13. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 8.1.1.1 /01	[REDACTED]	1998	Code: Hoe 130360 00 ZC98 0001 - Bobwhite quail acute oral toxicity study [REDACTED] Report No.: A59886, Report includes Trial Nos.: 96.0762 TOX96116 Edition Number: M-143541-01-1 EPA MRID No.: 45109733 Date: 1998-01-05 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y
KCA 8.1.1.1 /02	[REDACTED]	1997	Hoe 130360 (AE F130360); Code: Hoe 130360 00 ZC98 0001 - Mallard duck acute oral toxicity study [REDACTED] [REDACTED] Report No.: A59045, Report includes Trial Nos.: 96.0763 TOX96280 Edition Number: M-142752-01-1 EPA MRID No.: 45109734 Date: 1997-06-25 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y
KCP 10.1.1.1 /01	[REDACTED]	2000	Bobwhite quail acute oral toxicity (LD50) AE F130360 + AE F122006 flowable oil 22.5 + 22.5 g/l Code: AE F130360 01 1K05 A3 [REDACTED] Report No.: C005783, Report includes Trial Nos.: Tox99230 Edition Number: M-192635-01-1 Date: 2000-01-17 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 8.1.1.2 /01		1998	Bobwhite quail dietary LC50 study Code: AE F130360 00 1C98 0001 Report No.: A67441, Report includes Trial Nos.: 96.0781 Tox96117 Edition Number: M-147825-01-1 EPA MRID No.: 45109735 Date: 1998-04-17 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y
KCA 8.1.1.2 /02		1998	Mallard duck dietary LC50 study Code: AE F130360 00 1C98 0001 Report No.: A67442, Report includes Trial Nos.: 96.0780 Tox96118 Edition Number: M-147826-01-1 EPA MRID No.: 45109736 Date: 1998-03-09 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y
KCA 8.1.1.3 /01		1999	Northern Bobwhite quail dietary reproduction study AE F130360 Code: AE F130360 00 1C97 0002 Report No.: C006593, Report includes Trial Nos.: TOX96125 Edition Number: M- 194248-01-1 EPA MRID No.: 45109901 Date: 1999-12-16 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y
KCA 8.1.1.3 /02		1999	Mallard duck dietary reproduction study AE F130360 Code: AE F130360 00 1C97 0002 Report No.: C006594, Report includes Trial Nos.: TOX96127 Edition Number: M- 194250-01-1 EPA MRID No.: 45109902 Date: 1999-12-16 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 5.2.1 /01		1997	Hoe 130360 (AE F130360); Code: Hoe 130360 00 ZC98 0001 - Rat acute oral toxicity Bayer CropScience, Report No.: A58267, Report includes Trial Nos.: TOX96110 Edition Number: M-141959-01-1 EPA MRID No.: 45109433 Date: 1997-01-24 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y
KCP 7.1.1 /01		1999	Rat acute oral toxicity AE F130360 + AE F122006 oil flowable 22.5 + 22.5 g/l Code: AE F130360 01 1K05 A3 Report No.: C005915, Report includes Trial Nos.: TOX95126 Edition Number: M-192928-01-1 Date: 1999-11-19 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 5.6.1 /01		1999	Rat dietary two-generation reproductive toxicity study AE F130360 Code: AE F130360 00 1C99 0002 Report No.: C004338, Report includes Trial Nos.: TOX96123 Edition Number: M-187748-01-1 EPA MRID No.: 45109616 Date: 1999-10-22 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y
KCA 5.6.2 /02		1997	Rat oral development toxicity (teratogenicity) study Code: Hoe 130360 00 ZC98 0001 Report No.: A67035, Report includes Trial Nos.: TOX95390 Edition Number: M-147435-01 Date: 1997-12-10 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 5.6.2 /01	[REDACTED]	1997	Hoe 130360 (AE F130360); Code: Hoe 130360 00 ZC98 0001 - Rabbit oral developmental toxicity (teratogenicity) range finding study [REDACTED] Report No.: A 59486, Report includes Trial Nos.: TOX95391 Edition Number: M-143157-01 Date: 1997-09-30 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y
KCA 5.6.2 /03	[REDACTED]	1997	Code: Hoe 130360 00 ZC98 0001 - Rabbit oral developmental toxicity (teratogenicity) study [REDACTED] Report No.: A 67041, Report includes Trial Nos.: TOX95392 Edition Number: M-147441-01 Date: 1997-12-17 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 5.6.2 /04		2000	1st Addendum to Report number TOX/98/262-25 Rabbit oral developmental toxicity (teratogenicity) study: Provision of historical control body weight data as requested by the EU Code: Hoe 130360 00 ZC98 0001 Report No.: C 010603, Edition Number: M-199311-01	Y	N	Not relevant	Bayer CropScience	Y
KCA 8.2.1 /01		1997	96 hour acute toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , in a static renewal system AE F130360 technical 98.6 % w/w Code: AE F130360 00 1C98 0001 Report No.: A57725, Edition Number: M-141405-02-1 Date: 1997-05-13 ...Amended: 1997-06-05 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 8.2.1 /02		1997	AE F130360; technical 98.6 percent w/w; Code: AE F130360 00 1C98 0001 - 96 hour acute toxicity to the bluegill sunfish, <i>Lepomis macrochirus</i> , in a static renewal system Report No.: A57726, Edition Number: M-141406-02-1 Date: 1997-05-13 ...Amended: 1997-06-05 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y
KCA 8.2.1 /03		1998	96 hour acute toxicity to the Sheepshead minnow (<i>Cyprinodon variegatus</i>) in a static system AE F130360 technical 94.2% w/w Code: AE F130360 00 1C94 0001 Report No.: A59901, Edition Number: M-143551-01-1 EPA MRID No.: 45109927 Date: 1998-05-14 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y
KCA 8.2.1 /04		1993	Hoe 092944 - substance, technical (Hoe 092944 00 ZD99 0001) Effect to <i>Oncorhynchus mykiss</i> (Rainbow trout) in a Static-Acute Toxicity Test (method OECD) Report No.: A50396, Edition Number: M-131422-01-1 Date: 1993-04-13 GLP/GEP: yes, unpublished	Y	Y	New data requirement according to Regulations 91/414 and 1107/2009 – address aquatic toxicity of soil metabolite	Bayer CropScience	N

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 8.2.2.1 /01	[REDACTED]	1999	Prolonged toxicity to the rainbow trout, <i>Oncorhynchus mykiss</i> , in a flow through system AE F130360 technical 95.8 % w/w Code: AE F130360 00 1C96 0002 [REDACTED] Report No.: C004117, Edition Number: M-187354-01-1 EPA MRID No.: 45109905 Date: 1999-08-16 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y
KCA 8.2.2.1 /02	[REDACTED]	2004	Early Life Stage Toxicity of Foramsulfuron (AE F130360) Technical to the Fathead Minnow (<i>Pimephales promelas</i>) Under Flow-Through Conditions [REDACTED] Report No.: B004606, Report includes Trial Nos.: EBFSX001 (A3841201) Edition Number: M-241508-01-1 Date: 2004-03-17 GLP/GEP: yes, unpublished	Y	Y	New requirement according to Regulation 1107/2009	Bayer CropScience	N
KCA 8.2.4.1 /01	Stachura, B. J.; Ruff, D. F.	1997	AE F130360; technical 98.4 percent w/w; Code: AE F130360 00 1C98 0001 - The 48 hour acute toxicity to <i>Daphnia magna</i> , in a static renewal system AgrEvo USA Company, Pikeville, NC, USA Report No.: A57724, Edition Number: M-141404-02-1 Date: 1997-05-09 ...Amended: 1997-06-05 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 8.2.4.1 /02	Heusel, R.	1993	Hoe 092944 - substance, technical (Hoe 092944 00 ZD99 0001) Effect to <i>Daphnia magna</i> (waterflea) in a Static -Acute Toxicity Test (method OECD) Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A50353, Edition Number: M-131382-01-1 Date: 1993-04-13 GLP/GEP: yes, unpublished	N	Y	New data requirement according to Regulations 91/414 and 1107/2009 – address aquatic toxicity of soil metabolite	Bayer CropScience	N
KCA 8.2.5.1 /01	Young, B. M.; Ruff, D. F.	1999	Effects on life-cycle of the water flea (<i>Daphnia magna</i>) in a static renewal system AE F130360 technical 95.8% w/w AgrEvo USA Company, Ecotoxicology, Pikeville, NC, USA Report No.: B002180, Report includes Trial Nos.: CF99W537 Edition Number: M-237962-01-2 Date: 1999-07-21 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y
KCA 8.2.6.1 /01	Christ, M. T.; Ruff, D. F.	1998	Effect to <i>Pseudokirchneriella subcapitata</i> (green alga) in a growth inhibition test AE F130360 technical 94.2% w/w AgrEvo USA Company, Ecotoxicology, Pikeville, NC, USA Report No.: A59926, Edition Number: M-143574-01-1 EPA MRID No.: 45109908 Date: 1998-06-26 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 8.2.6.1 /02	Heusel, R.	1993	Hoe 092944 - substance, technical (Hoe 092944 00 ZD99 0001) Effect to <i>Scenedesmus subspicatus</i> (Green alga) in a Growth Inhibition Test (method OECD) Hoechst AG, Frankfurt am Main, Germany Bayer CropScience, Report No.: A50395, Edition Number: M-131421-01-1 Date: 1993-04-13 GLP/GEP: yes, unpublished	N	Y	New data requirement according to Regulations 91/414 and 1107/2009 – address aquatic toxicity of soil metabolite	Bayer CropScience	N
KCA 8.2.6.1 /03	Dorgerloh, M.	2005	<i>Pseudokirchneriella subcapitata</i> - growth inhibition test with AE F099095 00 1B99 0001 Bayer CropScience, Report No.: EBMMX092, Edition Number: M-254084-01-1 Date: 2005-07-08 GLP/GEP: yes, unpublished	N	Y	To address aquatic toxicity of a new aquatic metabolite	Bayer CropScience	N
KCA 8.2.6.2 /01	Young, B. M.; Ruff, D. F.	1999	Effect to <i>Navicula pelliculosa</i> (freshwater diatom) in a growth inhibition test AE F130360 technical 94.6% w/w Code: AE F130360 00 1C94 0001 AgrEvo USA Company, Ecotoxicology, Pikeville, NC, USA Report No.: C002422, Edition Number: M-184469-01-1 EPA MRID No.: 45109910 Date: 1999-06-07 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 8.2.6.2 /02	Christ, M. T.; Ruff, D. F.	1999	Effect to <i>Anabaena flos-aquae</i> (blue-green alga) in a growth inhibition test technical 94.6% w/w Code: AE F130360 00 1C94 0001 AgrEvo USA Company, Ecotoxicology, Pikeville, NC, USA Report No.: C003699, Edition Number: M-186627-01-1 EPA MRID No.: 45109909 Date: 1999-07-01 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y
KCA 8.2.6.2 /03	Young, B. M.; Ruff, D. F.	1999	Effect to <i>Skeletonema costatum</i> (Marine Diatom) in a growth inhibition test AE F130360 technical 94.6 % w/w Code: AE F130360 00 1C94 0001 AgrEvo USA Company, Ecotoxicology, Pikeville, NC, USA Report No.: C002436, Edition Number: M-184494-01-1 Date: 1999-06-25 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y
KCA 8.2.7 /01	Christ, M. T.; Ruff, D. F.	1998	Effect to <i>Lemna gibba</i> (duckweed), in a growth inhibition test AE F130360 technical 96.1% w/w Code: AE F130360 00 1C96 0002 AgrEvo USA Company, Ecotoxicology, Pikeville, NC, USA Report No.: A67514, Report includes Trial Nos.: CF98W507 Edition Number: M-147891-02-1 EPA MRID No.: 45109911 Date: 1998-08-14 ...Amended: 1999-04-20 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 8.2.7 /02	Christ, M. T.; Ruff, D. F.	2000	Effect to <i>Lemna gibba</i> (duckweed) in a growth inhibition test: AE F153745 technical 97.8% w/w Aventis CropScience USA LP, Ecotoxicology, Pikeville, NC, USA Report No.: B002765, Report includes Trial Nos.: CF99W565 Edition Number: M-240924-01-2 Date: 2000-02-11 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y
KCA 8.2.7 /03	Christ, M. T.; Ruff, D. F.	2000	Effect to <i>Lemna gibba</i> (duckweed) in a growth inhibition test: AE 0338795 technical 90.2 percent w/w: AE 0338795 00 1C90 0001 Aventis CropScience USA LP, Ecotoxicology, Pikeville, NC, USA Report No.: B002774, Report includes Trial Nos.: CF99W566 Edition Number: M-238498-01-2 Date: 2000-02-23 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y
KCA 8.2.7 /04	Sowig, P.; Gildemeister, H.	2000	Effects on growth of rooted aquatic macrophytes (<i>Valisneria spec.</i>) bound residues of AE F130360 substance, technical Code: AE F130360 00 1C98 0002 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: C006439, Edition Number: M-193919-01-1 EPA MRID No.: 45109939 Date: 2000-02-17 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 8.2.7 /05	Dorgerloh, M.	2005	<i>Lemna gibba</i> G3 Exposure and recovery test with Foramsulfuron (tech.) (code: AE F130360 00 1D97 0001) BCS, Report No.: EBFSX010, Edition Number: M-250268-01-1 Date: 2005-04-26 GLP/GEP: yes, unpublished	N	Y	Study performed to refine risk assessment for aquatic plants (<i>Lemna</i>)	Bayer CropScience	N
KCA 8.2.7 /06	Bruns, E.	2013	<i>Lemna gibba</i> G3 - Growth inhibition test with foramsulfuron (tech) (AE F 130360) under peak exposure conditions Bayer CropScience, Report No.: EBFSN003, Edition Number: M-462569-01-1 Date: 2013-08-13 GLP/GEP: yes, unpublished	N	Y	Study performed to refine risk assessment for aquatic plants (<i>Lemna</i>)	Bayer CropScience	N
KCA 8.2.7 /07	Kirkwood, A.	2012	Outdoor growth inhibition and recovery of aquatic plants exposed to foramsulfuron WG 50 percent Smithers Viscient, Wareham, MA, USA Bayer CropScience, Report No.: EBFSL012, Edition Number: M-429538-01-1 EPA MRID No.: 48869701 Date: 2012-04-13 GLP/GEP: yes, unpublished	N	Y	Study performed to refine risk assessment for aquatic plants (<i>Lemna</i>)	Bayer CropScience	N

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 8.2.7 /08	Bruns, E.	2013	<i>Lemna gibba</i> G3 - Prolonged growth inhibition test with foramsulfuron (AE F130360) with stepwise decreasing concentrations over an 6 week test duration Bayer CropScience, Report No.: EBFSL014, Edition Number: M-464150-01-1 Date: 2013-09-10 GLP/GEP: yes, unpublished	N	Y	Study performed to refine risk assessment for aquatic plants (<i>Lemna</i>)	Bayer CropScience	N
KCA 8.2.7 /09	Banman, C. S. Alexander, T. M.; Lam, C. V.	2012	Toxicity of foramsulfuron technical to the aquatic macrophyte, <i>Myriophyllum spicatum</i> Bayer CropScience LP, Stilwell, KS, USA Bayer CropScience, Report No.: EBFSL004, Edition Number: M-431270-01-1 Date: 2012-05-17 GLP/GEP: yes, unpublished	Y	Y	New requirement data according to Regulation 1107/2009	Bayer CropScience	N
KCA 8.2.7 /10	Sowig, P.; Weller, O.	2000	Duckweed (<i>Lemna gibba</i> G3) growth inhibition test AE F092944 (metabolite of ethoxysulfuron and amidosulfuron) substance technical Code: AE F092944 00 1C99 0001 Aventis CropScience GmbH, Frankfurt am Main, Germany Bayer CropScience, Report No.: C003865, Edition Number: M-186916-01-1 Date: 2000-11-03 GLP/GEP: yes, unpublished	N	Y	New requirement data according to Regulation 1107/2009 – address aquatic toxicity of soil metabolite	Bayer CropScience	N

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 8.2.7 /11	Dorgerloh, M.	2005	<i>Lemna gibba</i> G3 - growth inhibition test with AE F099095 under static conditions (Code: AE F099095 00 1B99 0001) BCS, Report No.: EBMMX091, Edition Number: M-254496-01-1 Date: 2005-07-14 GLP/GEP: yes, unpublished	N	Y	To address aquatic toxicity of a new aquatic metabolite	BCS	N
KCA 8.2.7 /12	Bruns, E.	2013	<i>Lemna gibba</i> G3 - Growth inhibition test with with AE F130619 (metabolite of foramsulfuron) under static conditions Bayer CropScience, Report No.: EBFSL011, Edition Number: M-452669-01-1 Date: 2013-04-15 GLP/GEP: yes, unpublished	N	Y	New data requirement according to Regulations 91/414 and 1107/2009 – address aquatic toxicity of soil metabolite	Bayer CropScience	N
KCA 8.2.7 /13	Bruns, E.	2013	<i>Lemna gibba</i> G3 - Growth inhibition test with BCS-CV29520 (metabolite of foramsulfuron) under static conditions Bayer CropScience, Report No.: EBFSN010, Edition Number: M-464163-01-1 Date: 2013-08-29 GLP/GEP: yes, unpublished	N	Y	To address aquatic toxicity of a new aquatic metabolite	Bayer CropScience	N
KCA 8.2.7 /14	Bruns, E.	2013	<i>Lemna gibba</i> G3 - Growth inhibition test with BCS-CW90756 (metabolite of foramsulfuron) under static conditions Bayer CropScience, Report No.: EBFSN011, Edition Number: M-464321-01-1 Date: 2013-08-29 GLP/GEP: yes, unpublished	N	Y	To address aquatic toxicity of a new aquatic metabolite	Bayer CropScience	N

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
KCA 8.2.7 /15	Hoffmann, K.	2013	<i>Lemna gibba</i> G3 - Growth inhibition test with BCS-AW41401 under static conditions Bayer CropScience, Report No.: EBFSN012, Edition Number: M-464386-01-1 Date: 2013-08-29 GLP/GEP: yes, unpublished	N	Y	To address aquatic toxicity of a new aquatic metabolite	Bayer CropScience	N
KCA 8.2.8 /01	Boeri, R. L.; Magazu, J. P.; Ward, T. J.	1998	Flow-through mollusc shell deposition test AE F130360 Wilbury Laboratories, Inc., Marblehead, MA, USA Report No.: C000906, Edition Number: M-181443-01-1 EPA MRID No.: 45109929 Date: 1998-11-24 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y
KCA 8.2.8 /02	Stachura, B. J.; Ruff, D. F.	1998	96 hour acute toxicity to the Grass Shrimp, <i>Palaemonetes pugio</i> , in a static system AE F130360 technical 94.2% w/w Code: AE F130360 00 1C94 0001 AgrEvo USA Company, Ecotoxicology, Pikeville, NC, USA Report No.: A59902, Edition Number: M-143552-01-1 EPA MRID No.: 45109928 Date: 1998-05-08 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
AIII-A- 10.2.1	Hoberg, J.R.	2002	Foramsulfuron Oil Flowable 22,5 g/L Formulation (AE F130360 01 1K05 A304) - Toxicity to Duckweed, <i>Lemna gibba</i> Berichts-Nr.: B003893 GLP: yes unpublished WAT2002-392	N	Y		AVD	Y
KCP 10.2.1 /01	[REDACTED]	2000	Static renewal toxicity with the rainbow trout, <i>Oncorhynchus mykiss</i> : AE F130360 + AE F122006: AE F130360 01 1K05 A304 [REDACTED] Report No.: B002796, Report includes Trial Nos.: 1889-AG CF00W543 Edition Number: M-238518-01-2 Date: 2000-03-09 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y
KCP 10.2.1 /02	[REDACTED]	2000	Static renewal toxicity with the bluegill sunfish, <i>Lepomis macrochirus</i> : AE F130360 + AE F122006: AE F130360 01 1K05 A304 [REDACTED] Report No.: B002795, Report includes Trial Nos.: 1888-AG CF99W542 Edition Number: M-238517-01-2 Date: 2000-03-09 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y

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KCP 10.2.1 /03	Boeri, R. L.; Ward, T. J.	2000	Growth and reproduction toxicity test with the freshwater alga, <i>Selenastrum capricornutum</i> : AE F130360 + AE F122006: AE F130360 01 1K05 A304 Wilbury Laboratories, Inc., Marblehead, MA, USA Report No.: B002798, Report includes Trial Nos.: 1891-AG CF00W545 Edition Number: M-238520-01-2 Date: 2000-03-06 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y
KCP 10.2.1 /05	Boeri, R.; Wyskiel, D.; Ward, T.	2000	Toxicity to the Duckweed, <i>Lemna gibba</i> : AE F130360 + AE F122006 flowable: AE F130360 01 1K05 Wilbury Laboratories, Inc., Marblehead, MA, USA Bayer CropScience, Report No.: B002845, Report includes Trial Nos.: 1928-AG CF99W571 Edition Number: M-238581-01-1 Date: 2000-06-09 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y

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KCP 10.2.1 /06	Madsen, T. J.; Bussard, J. B.	2000	Toxicity of AE F130360 + AE F122006 + AE F115008, water dispersible granule, 30 + 30 + 2 percent w/w including a methylated rapeseed oil surfactant to duckweed, <i>Lemna gibba</i> G3 determined under static renewal test conditions: AE F130360 02 WG62 A10 ABC Laboratories, Inc., Columbia, MO, USA Bayer CropScience, Report No.: B002838, Report includes Trial Nos.: 45737 Edition Number: M-238567-01-1 Date: 2000-03-30 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y
KCP 10.2.1 /07	Madsen, T. J.; Bussard, J. B.	2000	Toxicity of AE F130360 + AE F122006 + AE F115008, water dispersible granule, 30+ 30 + 2 percent w/w, Code: AE F130360 02 WG62 A104 to duckweed, <i>Lemna gibba</i> G3, determined under static renewal test conditions: AE F130360 02 WG62 A104 Aventis CropScience USA LP, Ecotoxicology, Pikeville, NC, USA Bayer CropScience, Report No.: B002810, Report includes Trial Nos.: CF99W572 Edition Number: M-238536-01-1 Date: 2000-03-10 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y

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KCP 10.2.1 /08	Hoberg, J. R.	2002	Foramsulfuron Oil Flowable 22.5 g/L Formulation (AE F130360 01 1K05 A304) - Toxicity To Duckweed, <i>Lemna gibba</i> Springborn Smithers Laboratories, Snow Camp, NC, USA Report No.: B003893, Report includes Trial Nos.: 13726.6166 Edition Number: M-240877-01-1 Date: 2002-05-21 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y
KCP 10.2.1 /09	Banman, C. S.; Hoffmann, J. M.; Lam, C. V.	2008	Toxicity of foramsulfuron + isoxadifen-ethyl OD 22.5+22.5 g/L (AE F130360 01 1K05 A9) to duckweed (<i>Lemna gibba</i> G3) under static- renewal conditions Bayer CropScience LP, Stilwell, KS, USA BCS, Report No.: EBFSX011, Edition Number: M-296352-01-1 Date: 2008-01-14 GLP/GEP: yes, unpublished	N	Y	Test on sensitive species	BCS	N
KCP 10.2.2 /01	[REDACTED]	2000	Prolonged toxicity to the rainbow trout , <i>Oncorhynchus mykiss</i> , in a flow through system: AE F130360 + AE F122006 oil flowable 22.5 + 22.5 g/L: AE F130360 01 1K05 A304 [REDACTED] Report No.: B002764, Report includes Trial Nos.: CF99W541 Edition Number: M-238492-01-2 Date: 2000-02-16 GLP/GEP: yes, unpublished	Y	N	Not relevant	Bayer CropScience	Y

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KCP 10.2.2 /02	Young, B. M.; Ruff, D. F.	2000	Effects on life-cycle of the water flea (<i>Daphnia magna</i>) in a static renewal system: AE F130360 + AE F122006, oil flowable 22.5 + 22.5 g/L : AE F130360 01 1K05 A304 Aventis CropScience USA LP, Ecotoxicology, Pikeville, NC, USA Report No.: B002760, Report includes Trial Nos.: CF99W540 Edition Number: M-238488-01-2 Date: 2000-02-16 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y
KCP 10.2 /01	Vrbka, L.	2013	Foramsulfuron (FSN) and metabolite: PECsw,sed FOCUS EUR (graphical outputs) - Use in maize in Europe Bayer CropScience, Report No.: EnSa-13-0880, Edition Number: M-468841-02-1 Date: 2013-11-05 ...Amended: 2013-11-18 GLP/GEP: no, unpublished	N	N	Not relevant	Bayer CropScience	N
KCA 8.3.1.1.1 /01	Waltersdorfer A.	1998	AE130360 00 1C98 0001 Sustance technical Oral toxicity (LD 50) to honey bees (<i>Apis mellifera</i> L.). Hoechst Schering AgrEvo GmbH, Umweltforschung Oekobiologie, D-65926 Frankfurt am Main, Germany Report No. CW96/031 GLP, unpublished Bayer file No. M-143626-01-1	N	N	Not relevant	Bayer Crop Science	Y

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KCA 8.3.1.1.2 /01	Waltersdorfer A.	1997	AE130360 00 1C98 0001 Sustance technical Contact toxicity (LD 50) to honey bees (<i>Apis mellifera</i> L.). Hoechst Schering AgrEvo GmbH, Umweltforschung Oekobiologie, D-65926 Frankfurt am Main, Germany Report No. CW96/130 GLP, unpublished Bayer file No. M-143215-01-1	N	N	Not relevant	Bayer Crop Science	Y
KCA 8.3.1.1.2 /02	Schmitzer S.; Sekine T.	2012	Effects of foramsulfuron tech. (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany Report No. EBFSN009 GLP, unpublished Bayer File No: M-444765-01-1	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009 and EFSA draft guidance document on the risk assessment of plant protection products on bees	Bayer Crop Science	N
KCP 10.3.1.1.1 /01	Waltersdorfer A.	1999	Oral toxicity (LD50) to honey bees (<i>Apis mellifera</i> L.) AE F130360 + AE F122006 oil flowable 22.5 + 22.5 g/L Hoechst Schering AgrEvo GmbH, Umweltforschung Oekobiologie, D-65926 Frankfurt am Main, Germany Report No. CW98/111 GLP, unpublished Bayer file No.: M-187295-01-1	N	N	Not relevant	Bayer Crop Science AG	Y

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KCP 10.3.1.1.2 /01	Waltersdorfer A.	1999	Contact toxicity (LD50) to honey bees (<i>Apis mellifera</i> L.) AE F130360 + AE F122006 oil flowable 22.5 + 22.5 g/L Hoechst Schering AgrEvo GmbH, Umweltforschung Oekobiologie, D-65926 Frankfurt am Main, Germany Report No. CW98/109 GLP, unpublished Bayer file No.: M-187293-01-1	N	N	Not relevant	Bayer Crop Science AG	Y
KCP 10.3.1.1.1 /02	Sekine T.	2013	Effects of foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5) G (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory. IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany Report No. EBFSN048 GLP, unpublished Bayer File No: M-465361-01-1	N	Y	New requirement data	Bayer Crop Science AG	N
KCA 8.3.1.2 /01	Kling A.	2013	Foramsulfuron WG 50 W - Assessment of chronic effects to the honeybee, <i>Apis mellifera</i> L., in a 10 days continuous laboratory feeding limit test EurofinsAgroscience Services, EcoChem GmbH, Eutinger Straße 24, 75223 Niefern-Öschelbronn, Germany Report No. EBFSN022 GLP, unpublished Bayer File No: M-470639-01-1	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009 and EFSA draft guidance document on the risk assessment of plant protection products on bees	Bayer Crop Science	N

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KCA 8.3.1.3 /01	Przygoda D.; Nikolakis A.	2013	Foramsulfuron WG 50 W: Effects of a single exposure to spiked diet on honey bee larvae (<i>Apis mellifera carnica</i>) in an in vitro laboratory testing design Bayer CropScience AG, BCS-AG-D-EnSa-Testing, 40789 Monheim, Germany Report No. EBFSN044 GLP, unpublished Bayer File No: M-470485-01-1	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009 and EFSA draft guidance document on the risk assessment of plant protection products on bees	Bayer Crop Science	N
KCA 8.3.1.3/02	Jeker L.	2013	Foramsulfuron WG 50 W - honeybee brood feeding study to evaluate potential effects on brood development and mortality of the honeybee, <i>Apis mellifera</i> L. (Hymenoptera: Apidae) Innovative Environmental Services (IES) Ltd, Benkenstrasse 260, 4108 Witterswil, Switzerland Report No. EBFSL013 GLP, unpublished Bayer File No: M-465326-01-1	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009 and EFSA draft guidance document on the risk assessment of plant protection products on bees	Bayer Crop Science	N
KCA 8.3.1.3 /03	Schmitzer S.	2013	Foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L): Effects on honey bee brood (<i>Apis mellifera</i> L.) under semi-field conditions - Tunnel test – IBACON GmbH, Arheilger Weg 17, 64380 Rossdorf, Germany Report No. EBFSN034 GLP, unpublished Bayer File No: M-468794-01-1	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009 and EFSA draft guidance document on the risk assessment of plant protection products on bees	Bayer Crop Science	N

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KCP 10.3.2.1./02	Waltersdorfer A.	1999	Toxicity to the predatory mite <i>Typhlodromus pyri</i> Scheuten (Acari, Phytoseiidae) in the laboratory AE F130360 + AE F122006 oil flowable 22.5 + 22.5 g/L AE F130360 01 1K05 A301 Hoechst Schering AgrEvo GmbH, Umweltforschung Oekobiologie, D-65926 Frankfurt am Main, Germany Report No. CW99/003 GLP, unpublished Bayer file No.: M-191384-01-1	N	N	Not relevant	Bayer Crop Science	Y
KCP 10.3.2.2./01	Waltersdorfer A.	1999	Toxicity to the predatory mite <i>Typhlodromus pyri</i> SCHEUTEN (Acari, Phytoseiidae) using an extended laboratory test AEF130360+ AEF122006 Oil flowable 22.5 + 22.5 g/L Hoechst Schering AgrEvo GmbH, Umweltforschung Oekobiologie, D-65926 Frankfurt am Main, Germany Report No. CW99/092 GLP, unpublished Bayer file No.: M-192822-01-1	N	N	Not relevant	Bayer Crop Science	Y
KCA 8.3.2.2 /03	Roehlig U.	2013	Effects of foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) on the predatory mite <i>Typhlodromus pyri</i> SCHEUTEN in a laboratory test BioChem agrar, Labor für biologische und chemische Analytik GmbH Kupferstraße 604827 Gerichshain, Germany Report No. 13 10 48 031 A GLP, unpublished Bayer file No.: M-457360-01-1	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer Crop Science	N

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KCP 10.3.2.1./01	Kleiner R.	1999	Toxicity to the <i>parasitoid</i> <i>Aphidius rhopalosiphi</i> (DESTEFANI-PEREZ) / adults under laboratory conditions according to IOBC Guidelines (MEAD-BRIGGS 1992/1997) AE F130360 01 1K05 A304 using an extended laboratory test AEF130360+ AEF122006 Oil flowable 22.5 + 22.5 g/L BioChem agrar, Labor für biologische und chemische Analytik GmbH Kupferstraße 604827 Gerichshain, Germany Report No. 991048029 GLP, unpublished Bayer file No.: M-191908-01-1	N	N	Not relevant	Bayer Crop Science	Y
KCP 10.3.2.2./02	Barth M.	2000	Toxicity of AE F130360 01 1K05 A304 to the cereal aphid parasitoid <i>Aphidius rhopalosiphi</i> (DESTEFANI-PEREZ) (extended laboratory test/"aged residue test") to the <i>parasitoid</i> <i>Aphidius rhopalosiphi</i> (DESTEFANI-PEREZ) / adults under laboratory conditions according to IOBC Guidelines(MEAD-BRIGGS 1992/1997) AE F130360 01 1K05 A304 using an extended laboratory test AEF130360+ AEF122006 Oil flowable 22.5 + 22.5 g/ BioChem agrar, Labor für biologische und chemische Analytik GmbH Kupferstraße 604827 Gerichshain, Germany Report No. 1048067 GLP, unpublished Bayer file No.: M-198973-01-1	N	N	Not relevant	Bayer Crop Science	Y

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KCA 8.3.2.1./03	Roehlig U.	2013	Effects of foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5 g/L) on the parasitic wasp <i>Aphidius rhopalosiphi</i> (DESTEFANI-PEREZ) in a laboratory BioChem agrar, Labor für biologische und chemische Analytik GmbH Kupferstraße 604827 Gerichshain, Germany Report No. 131048030A GLP, unpublished Bayer file No.: M-461455-01- 1	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer Crop Science	N
KCA 8.3.2./04	Kleiner R.	2000	Toxicity to the foliage dwelling predator <i>Chrysoperla carnea</i> STEPH. (laboratory) following the IOBC Guideline (BiGLER 1988), ringtest method (VOGT <i>et al.</i> 1997) and OECD Guideline proposal (VOGT <i>et al.</i> 1999) AE F130360 01 1K05 A304 BioChem agrar, Labor für biologische und chemische Analytik GmbH Kupferstraße 604827 Gerichshain, Germany Report No. 991048098 GLP, unpublished Bayer file No.: M-194627-01- 1	N	N	Not relevant	Bayer Crop Science	Y
KCA 8.3.2.1./04	Waltersdorfer A.	1999	Toxicity to the ground dwelling predator <i>Poecilus cupreus</i> L. (Coleoptera, Carabidae) in the laboratory AEF130360+ EF122006 Oil flowable 22.5 + 22.5 g/L Hoechst Schering AgrEvo GmbH, Umweltforschung Oekobiologie, D-65926 Frankfurt am Main, Germany Report No. CW98/112 GLP, unpublished Bayer file No.: M-186968-01-1	N	N	Not relevant	Bayer Crop Science	Y

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KCA 8.3.2./04	Kleiner R.	2000	Toxicity to the ground dwelling predator <i>Aleochara bilineata</i> GYLL. (laboratory) according to IOBC Guideline (MORETH & NATON 1992) AE F130360 01 1K05 A304 BioChem agrar, Labor für biologische und chemische Analytik GmbH Kupferstraße 604827 Gerichshain, Germany Report No. 991048095 GLP, unpublished Bayer file No.: M-193482-01- 1	N	N	Not relevant	Bayer Crop Science	Y
KCA 8.3.2./01	Kleiner R.	1999	Toxicity to the ground dwelling predator <i>Pardosa</i> spp. (laboratory) according to IOBC Guideline (WEHLING <i>et al.</i> 1998) AE F130360 01 1K05 A304 BioChem agrar, Labor für biologische und chemische Analytik GmbH Kupferstraße 604827 Gerichshain, Germany Report No. 991048030 GLP, unpublished Bayer file No.: M-188675-01- 1	N	N	Not relevant	Bayer Crop Science	Y
KCA 8.4 /01	Heusel, R.	1998	Acute toxicity to earthworms (<i>Eisenia fetida</i>) AE F130360 substance, technical Code: AE F130360 00 1C98 0002 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: A59245, Edition Number: M-142934-01-1 EPA MRID No.: 45109923 Date: 1998-04-03 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y

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KCA 8.4 /02	Sowig, P.; Gosch, H.	1999	Acute toxicity to earthworms (<i>Eisenia fetida</i>) AE F153745 (impurity of AE F130360) substance, technical Code: AE F153745 00 1C98 0001 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: C005859, Edition Number: M-192813-01-1 EPA MRID No.: 45109924 Date: 1999-12-17 GLP/GEP: yes, unpublished	N	Y	Study submitted to provide complete view on available data set	Bayer CropScience	Y
KCP 10.4.1 /01	Nienstedt, K. M.	1999	A 14-day acute toxicity test with the earthworm (<i>Eisenia fetida</i>) Code: AE F130360 01 1K05 A304 Springborn Laboratories (Europe) AG, Horn, Switzerland Report No.: C006356, Edition Number: M-193746-01-1 Date: 1999-12-07 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y
KCA 8.4.1 /01	Sowig, P.; Gosch, H.	2000	Effects on growth and reproduction of earthworms (<i>Eisenia fetida</i>) AE F130360 substance, technical Code: AE F130360 00 1C98 0002 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: C006218, Edition Number: M-193508-01-1 Date: 2000-01-28 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer CropScience	Y
KCA 8.4.1 /02	Kratz, M. A.	2013	AE F092944 (BCS-AA25052): Effects on survival, growth and reproduction of the earthworm <i>Eisenia fetida</i> tested in artificial soil Bayer CropScience, Report No.: kra/Rg-R-147/13, Edition Number: M-461051-01-1 Date: 2013-07-31 GLP/GEP: yes, unpublished	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer CropScience	N
KCA 8.4.1 /03	Kratz, M. A.	2013	AE F130619 (BCS-AU59648): Effects on survival, growth and reproduction of the earthworm <i>Eisenia fetida</i> tested in artificial soil Bayer CropScience, Report No.: kra/Rg-R-138/13, Edition Number: M-461453-01-1 Date: 2013-08-14 GLP/GEP: yes, unpublished	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer CropScience	N

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KCA 8.4.1 /04	Kratz, M. A.	2013	Foramsulfuron-AE F153745 (BCS-AU80017): Effects on survival, growth and reproduction on the earthworm <i>Eisenia fetida</i> tested in artificial soil Bayer CropScience, Report No.: kra/Rg-R-140/13, Edition Number: M-459518-01-1 Date: 2013-07-17 GLP/GEP: yes, unpublished	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer CropScience	N
KCP 10.4.1.1 /01	Witte, B.	2013	Foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5) G: Effects on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 83352022, Edition Number: M-464888-01-1 Date: 2013-08-21 GLP/GEP: yes, unpublished	N	Y	New data requirement	Bayer CropScience	N
KCA 8.4.2.1 /01	Kratz, M. A.	2012	Foramsulfuron (AE F130360) a.s.: Influence on mortality and reproduction on the soil mite species <i>Hypoaspis aculeifer</i> tested in artificial soil Bayer CropScience, Report No.: KRA-HR-78/12, Edition Number: M-443308-01-1 Date: 2012-12-10 GLP/GEP: yes, unpublished	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer CropScience	<u>N</u>
KCA 8.4.2.1 /02	Frommholz, U.	2012	Foramsulfuron (AE F130360) a.s.: Influence on the reproduction of the collembolan species <i>Folsomia candida</i> tested in artificial soil Bayer CropScience, Report No.: FRM-Coll-147/12, Edition Number: M-443369-01-1 Date: 2012-12-12 GLP/GEP: yes, unpublished	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer CropScience	N
KCA 8.4.2.1 /03	Schulz, L.	2013	AE F092944 (BCS-AA25052): Effects on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 044 S, Edition Number: M-454043-01-1 Date: 2013-05-02 GLP/GEP: yes, unpublished	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer CropScience	N

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KCA 8.4.2.1 /04	Friedrich, S.	2013	AE F092944 (BCS-AA25052): Effects on the reproduction of the collembolan <i>Folsomia candida</i> BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 045 S, Edition Number: M-451142-01-1 Date: 2013-03-28 GLP/GEP: yes, unpublished	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer CropScience	N
KCA 8.4.2.1 /05	Schulz, L.	2013	Foramsulfuron-AE F130619 (BCS-AU59648): Effects on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 046 S, Edition Number: M-454051-01-1 Date: 2013-05-02 GLP/GEP: yes, unpublished	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer CropScience	N
KCA 8.4.2.1 /06	Friedrich, S.	2013	Foramsulfuron-AE F130619 (BCS-AU59648): Effects on the reproduction of the collembolan <i>Folsomia candida</i> BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 047 S, Edition Number: M-450824-01-1 Date: 2013-03-28 GLP/GEP: yes, unpublished	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer CropScience	N
KCA 8.4.2.1 /07	Schulz, L.	2013	Foramsulfuron-AE F153745 (BCS-AU80017): Effects on the reproduction of the predatory mite <i>Hypoaspis aculeifer</i> BioChem agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 048 S, Edition Number: M-447606-01-1 Date: 2013-02-22 GLP/GEP: yes, unpublished	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer CropScience	N

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KCA 8.4.2.1 /08	Friedrich, S.	2013	Foramsulfuron-AE F153745 (BCS-AU80017): Effects on the reproduction of the collembolan <i>Folsomia candida</i> BioChem agrar, Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 049 S, Edition Number: M-450830-01-1 Date: 2013-03- 28 GLP/GEP: yes, unpublished	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer CropScience	N
KCP 10.4.2.1 /01	Witte, B.	2013	Foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5) G (FSN+IDF OD 45 (22.5+22.5) G): Effects on reproduction of the collembola <i>Folsomia candida</i> in artificial soil IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 83353016, Edition Number: M-462827-01-1 Date: 2013-07- 23 GLP/GEP: yes, unpublished	N	Y	New data requirement	Bayer CropScience	N
KCP 10.4.2.1 /02	Witte, B.	2013	Foramsulfuron + isoxadifen-ethyl OD 45 (22.5+22.5) G (FSN+IDF OD 45 (22.5+22.5) G): Effects on reproduction of the predatory mite <i>Hypoaspis aculeifer</i> in artificial soil IBACON GmbH, Rossdorf, Germany Bayer CropScience, Report No.: 83351089, Edition Number: M-462835-01-1 Date: 2013-07- 23 GLP/GEP: yes, unpublished	N	Y	New data requirement	Bayer CropScience	N
KCA 8.5 /01	Heusel, R.	1997	AE F130360; substance, technical; Code: AE F130360 00 1C98 0002 - Effects on soil microbial activity (nitrogen turn-over) Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: CE97/006 GLP/GEP: yes, unpublished Bayer file No.: M-142972-01-1	N	N	Not relevant	Bayer Crop Science	Y

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KCA 8.5 /02	Sowig, P.; Gildemeister, H.	2000	Effects on soil microbial activity (nitrogen turn-over) bound residues of AE F130360 substance, technical Code: AE F130360 00 1C98 0002 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: CE99/102 GLP/GEP: yes, unpublished Bayer file No.: M-193916-01-1	N	N	Not relevant	Bayer Crop Science	Y
KCA 8.5 /03	Heusel, R.	1998	AE F130360; substance, technical; Code: AE F130360 00 1C98 0002 - Effects on soil microbial activity (short-term respiration) Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: CE97/005 GLP/GEP: yes, unpublished Bayer file No.: M-142971-01-1	N	N	Not relevant	Bayer Crop Science	Y
KCA 8.5 /04	Sowig, P.; Gildemeister, H.	2000	Effects on soil microbial activity (short-term respiration) bound residues of AE F130360 substance, technical Code: AE F130360 00 1C98 0002 Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: CE99/101 GLP/GEP: yes, unpublished Bayer file No.: M-193914-01-1	N	N	Not relevant	Bayer Crop Science	Y

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KCA 8.5 /05	Schulz, L.	2013	AE F092944 (BCS-AA25052): Effects on the activity of soil microflora (Nitrogen transformation test) BioChem Agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 018 N, GLP/GEP: yes, unpublished Bayer file No.: M-453511-01-1	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer Crop Science	N
KCA 8.5 /06	Schulz, L.	2013	Foramsulfuron-AE F130619 (BCS-AU59648): Effects on the activity of soil microflora (nitrogen transformation test) BioChem Agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 13 10 48 019 N GLP/GEP: yes, unpublished Bayer file No.: M-453568-01-1	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer Crop Science	N
KCA 8.5 /07	Schulz, L.	2013	Foramsulfuron-AE F153745 (BCS-AU80017): Effects on the activity of soil microflora (Nitrogen transformation test) BioChem Agrar GmbH, Gerichshain, Germany Bayer CropScience, Report No.: 1321048020N GLP/GEP: yes, unpublished Bayer file No.: M-453508-01-1	N	Y	Study conducted to fulfil new data requirement acc. 1107/2009	Bayer Crop Science	N

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KCP 10.5 /01	van der Kolk, J.	1999	The effects on the respiration and nitrification of soil microflora Code: AE F130360 01 1K05 A304 Springborn Laboratories (Europe) AG, Horn, Switzerland Report No.: C006355 GLP/GEP: yes, unpublished Bayer file No.: : M-193742-01-1	N	N	Not relevant	Bayer Crop Science	Y
KCA 8.6.1 /01	Bieringer, H	1999	Effectivity of the herbicide AE F130360 on higher plant species as applied under greenhouse conditions Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: C005291, Edition Number: M-191762-01-1 EPA MRID No.: 45109401 GLP/GEP: no, unpublished ...also filed: KCA 3.3 /01	N	N	Not relevant	Bayer Crop Science	Y
KCP 10.6.2 /01	Porch, J. R.; Kendall, T. Z.; Krueger, H. O	1999	AE F130360 + AE F122006; oil flowable; 22.5 + 22.5 g/l. CODE: AE F130360 01 1K05 A304: A toxicity test to determine the effects of the test substance on seedling emergence of ten species of plants Wildlife International Limited, 8598 Commerce Drive, Easton, Maryland 21601, USA, Report No: B002673 Edition Number: M-238408-01-2, Date: 1999- 11-22 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer Crop Science	Y

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KCP 10.6.2 /01	Porch, J. R.; Kendall, T. Z.; Krueger, H. O.	1999	A Tier II toxicity test to determine the effects of the test substance on vegetative vigor of ten species of plants: AE F130360 + AE F122006, oil flowable, 22.5+22.5 g/L Wildlife International, Ltd., Easton, MD, USA Report No.: B002710, Report includes Trial Nos.: 312-122 Edition Number: M-238444-01-2 Date: 1999-12-08 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer Crop Science	Y
KCP 10.6.2 /02	Porch, J. R.; Kendall, T. Z.; Krueger, H. O.	2000	A tier II toxicity test to determine the effects of the test substance on seedling emergence of seven species of plants: AE F130360 + AE F122006 oil flowable 22.5 + 22.5 g/L: AE F130360 01 1K05 A304 Wildlife International, Ltd., Easton, MD, USA Report No.: B002819, Report includes Trial Nos.: 312-123 CF00E582 Edition Number: M-238550-01-1 EPA MRID No.: 45109933 Date: 2000-03-08 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer Crop Science	Y

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KCA 8.6.2 /01	Roux, F.; Matejicek, A.; Reboud, X.	2005	Response of Arabidopsis thaliana to 22 ALS inhibitors: Baseline toxicity and cross-resistance of csr1-1 and csr1-2 resistant mutants. Journal: Weed Res., Volume:45, Issue:3, Pages:220-227, Year:2005, Report No.: M-458576-01-1, Edition Number: M-458576-01-1 Date: 2005-12-31 GLP/GEP: no, published	N	N	Not relevant	Public	N
KCA 8.7 /01 KCP 10.3.2.1 /07	Thoenessen, M. T.	2000	Effectivity of the herbicide AE F130360 on entomology screening species Hoechst Schering AgrEvo GmbH, Frankfurt am Main, Germany Report No.: C006863, Edition Number: M-194770-01-1 EPA MRID No.: 45109935 GLP/GEP: no, unpublished	N	N	Not relevant	Bayer Crop Science	N
KCA 8.8 /01	Reinhardt, J.	1997	Testing the respiration inhibition of activated sludge: Bacteria toxicity. Test substance: AE F130360, substance technical Hoechst AG, Frankfurt am Main, Germany Report No.: A58873, Edition Number: M-142587-01-1 EPA MRID No.: 45109936 Date: 1997-05-07 GLP/GEP: yes, unpublished	N	N	Not relevant	Bayer Crop Science	N