Document Title

Summary of the ecotoxicological studies
Amidosulfuron WG 75

Data Requirements

EU Regulation 1107/2009 & EU Regulation 284/2013
Document MCP
Section 10: Ecotoxicological studies

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

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Version history

Date	Data points containing amendments or additions[1] and brief description	Document identifier and version number

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

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CP 10 ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

A dossier on active substance amidosulfuron was submitted February 2002 by Bayer CropScience to the EU RMS Austria for agricultural use as a herbicide. Amidosulfuron was included into Annex I of the Council Directive 91/414/EEC by the Commission Directive 2008/40/EC published 4 April 2008, with an entry into force by 1 January 2009[1].

This Supplementary Dossier contains only detailed summaries of studies which were not part of the dossier during the first Annex I inclusion of amidosulfuron and were, therefore, not evaluated during the first EU review of this compound. In order to facilitate discrimination between new and old information, the new information is written in black whereas greyshaded text indicates the previously reviewed information.

All studies, which have been already submitted by Bayer CropScience for the first Annex I inclusion, are contained in the Draft Assessment Report (DAR) and its Addenda and are included in the Baseline dossier provided by Bayer CropScience. The summaries on the different endpoints were taken from the Draft Assessment Report (DAR) and its Addenda and supplemented with new information (new studies, references, further comments).

The formulation Amidosulfuron WG 75 is the representative formulation for the inclusion of amidosulfuron at European level. The summaries of formulation studies and the risk assessment will be presented in this dossier.

Ecotoxicological endpoints used in the following risk assessment were derived from studies with the formulated product Amidosulfuron WG 75, the active substance amidosulfuron and its metabolites listed in the residue definition for risk assessment.

In this Dossier only endpoints used for the risk assessment are presented. For an overview of all available endpoints for amidosulfuron and its metabolites please refer to the respective section of the MCA document. In order to facilitate discrimination between new and information submitted during the Annex I inclusion process, *the previously evaluated information is written in grey letters*.

[1] **COMMISSION DECISION of 10 October 2008 correcting Directive 2008/40/EC amending Council Directive 91/414/EEC to include amidosulfuron and nicosulfuron as active substances** *(notified under document number C(2008) 5703)* **(Text with EEA relevance)** (2008/791/EC)

Use pattern considered in this risk assessment

Table CP 10- 1: Intended application pattern

Crop	Timing of application (range)	Number of applications	Application interval [days]	Maximum label rate per treatment [kg product/ha]	Application rate per treatment [g a.s./ha] Amidosulfuron
Winter cereals	BBCH 21-49[1)2)]	1	-	0.04	30
	BBCH 13-49[1)2)]	1	-	0.02	15
Spring cereals	BBCH 12-49[1)3)]	1	-	0.02-0.04	15-30
Flax	Before flower buds are visible	1	-	0.02-0.04	15-30
Grass/pasture (permanent grass)	Spring/Autumn	1	-	0.06	45

1) All EU except France/Italy (up to BBCH 32)
2) at the end of winter dormancy / onset of weed growth in spring vegetation period
3) Spring

Risk envelope
For envelope type risk assessment, the critical application pattern in cereals is defined as single application of 1 × 30 g a.s./ha in spring cereals at BBCH 12-49. The application patterns in winter cereals (1 × 30 g a.s./ha at BBCH 21-49 and 1 × 15 g a.s./ha at BBCH 13-49) are considered as less critical. To enable a possible differentiation in mitigation measures adapted to the use rate, TER calculations for the less critical application pattern will also be provided in domains where exposure mitigation via use restriction may be needed to pass risk assessment for the critical GAP (envelope rate).

Definition of the residue for risk assessment
Due to changes in the requirements under EU Regulation 1107/2009, additional degradation products were proposed to be included in the residue definition. All studies necessary to describe the ecotoxicological profile of these metabolites in the relevant environmental compartments are summarized in document MCA. The residue definition is presented in Table CP 10- 2.

Table CP 10- 2: Definition of the residue relevant for risk assessment*

Compartment	Residue Definition	Major Metabolite in
Soil	Amidosulfuron	*(parent substance)*
	A.-Desmethyl (AE F101630)	Aerobic soil, anaerobic soil
	A.-Desmethyl-chloropyrimidine (BCS-CO41838)	Aerobic soil
	A.-Guanidine (BCS-CO41839)	Aerobic soil
	A.-Biuret (BCS-CQ51287)	Aerobic soil
	A.-ADMP (AE F092944)	Aerobic soil
Groundwater	Amidosulfuron	*(parent substance)*
	A.-Desmethyl (AE F101630)	Aerobic soil, anaerobic soil
	A.-Desmethyl-chloropyrimidine (BCS-CO41838)	Aerobic soil
	A.-Guanidine (BCS-CO41839)	Aerobic soil
	A.-Biuret (BCS-CQ51287)	Aerobic soil
	A.-ADMP (AE F092944)	Aerobic soil
	A.-ADHP (AE F094206)	Lysimeter leachate
Surface Water	Amidosulfuron	*(parent substance)*
	A.-Desmethyl (AE F101630)	Aerobic water/sediment, Aerobic soil, anaerobic soil
	A.-Desmethyl-chloropyrimidine (BCS-CO41838)	Aerobic soil
	A.-Guanidine (BCS-CO41839)	Aerobic soil, Aerobic water/sediment
	A.-Biuret (BCS-CQ51287)	Aerobic water/sediment, Aerobic soil
	A.-ADMP (AE F092944)	Aerobic water/sediment, Aerobic soil
	A.-(Guanidinocarbonyl)sulfamic acid (BCS-BI49539)	Aerobic water/sediment
Air	Amidosulfuron	*(parent substance)*

*Justification for the residue definition for risk assessment see provided in MCA Sec.7, Point CA 7.4.

A list of metabolites, which contains the structures, the synonyms and code numbers attributed, is presented in Document N3 of this dossier.

CP 10.1 Effects on birds and other terrestrial vertebrates

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), referred to in the following as "EFSA GD 2009".

CP 10.1.1 Effects on birds

Ecotoxicological endpoints used in risk assessment
One acute toxicity test on birds has been conducted with the product. The results from this test, and from tests with the technical active substance amidosulfuron as reported in document MCA, will be used for risk assessment.

All studies were previously EU reviewed for the first Annex I inclusion of Amidosulfuron. No new data has been generated and is submitted in the context of application for approval renewal.

An overview of the information relevant to this chapter is provided in the following tables.

Table CP 10.1.1- 1: Endpoints of the formulation Amidosulfuron WG75 used in risk assessment

Test substance	Test organism	Study type	Endpoint		Reference
Amidosulfuron WG 75	**Acute toxicity to bird**				
	Japanese quail	acute, oral	LD_{50}	> 2000 mg prod./kg bw	[redacted]; 1989; M-123059-01-1 KCP 8.1.1.1 /01

prod. = product; bw = body weight

The study confirmed a low acute oral toxicity of the formulated product consistent with the data generated on the active substance and used in the detailed numeric risk assessments presented in the following.

Table CP 10.1.1- 2: Endpoints for the active substance amidosulfuron used in risk assessment

Test substance	Test organism	Study type	Endpoint		Reference
Amidosulfuron	**Acute toxicity to bird**				
	Japanese quail	acute, oral	LD_{50}	**> 2000 mg a.s./kg bw**	[redacted] 1987; M-120936-01-1 KCA 8.1.1.1 /01
	Bobwhite quail,				[redacted] 1989; M-123940-01-1 KCA 8.1.1.1 /02
	Mallard duck				[redacted] 1988; M-121564-01-1 KCA 8.1.1.1 /03
	Long-term toxicity to bird				
	Japanese quail	22 weeks feeding, chronic reproduction	NOEC	1000 ppm	[redacted] 1994; M-133167-01-1 KCA 8.1.1.3 /01
			NOEL	**100 mg a.s./kg bw/d**	

Bold values used for the risk assessment
a.s. = active substance; bw = body weight; ppm = parts per million; d = day

Risk assessment for birds

The intended use of the formulation is based on the proposed use pattern (see Table CP 10- 1). In the risk envelope, the product will be applied in a single application on spring cereals (covering the uses in winter cereals). The use on flax will be addressed by a risk assessment for surrogate crop oilseed rape.

Table CP 10.1.1- 3: Relevant generic avian focal species for risk assessment

Crop scenario	Scenario	Generic focal species	Representative species	Short cut values based on	
				RUD90	**RUDm**
Cereals, 1 x 0.030 kg/ha, BBCH 12-49	Early (shoots) BBCH 10-29	Large herbivorous bird "goose"	Pink-foot goose (*Anser brachyrhynchus*)	**30.5**	**16.2**
	BBCH 10-29	Small omnivorous bird "lark"	Woodlark (*Lullula arborea*)	**24.0**	**10.9**
	BBCH 30 -39	Small omnivorous bird "lark"	Woodlark (*Lullula arborea*)	12.0	5.4
	BBCH ≥ 40	Small omnivorous bird "lark"	Woodlark (*Lullula arborea*)	7.2	3.3
Oilseed rape (= surrogate crop for flax), 1 x 0.030 kg/ha, before flower buds are visible	Late-late (with seeds) BBCH 30-99	Small insectivorous bird "dunnock"	Dunnock (*Prunella modularis*)	**7.4**	**2.7**
	early (shoots) BBCH 10-19	Large herbivorous bird "goose"	Greylag goose (*Anser anser*)	**39.0**	**15.9**
	BBCH 10-29	Small omnivorous bird "lark"	Woodlark (*Lullula arborea)*	**24.0**	**10.9**
	BBCH 30-39	Small omnivorous bird "lark"	Woodlark (*Lullula arborea)*	7.2	3.3
	BBCH ≥ 40	Small omnivorous bird "lark"	Woodlark (*Lullula arborea)*	6.0	2.7
	BBCH 10-19	medium herbivorous/granivorous bird "pigeon"	Wood pigeon (*Columba palumbus)*	**55.6**	**22.7**
	BBCH 20-29	medium herbivorous/granivorous bird "pigeon"	Wood pigeon (*Columba palumbus)*	4.0	3.5
	BBCH 30-39	medium herbivorous/granivorous bird "pigeon"	Wood pigeon (*Columba palumbus*)	2.4	1.1
	BBCH ≥ 40	medium herbivorous/granivorous bird "pigeon"	Wood pigeon (*Columba palumbus*)	2.0	0.9
	BBCH 10-19	Small insectivorous bird "wagtail"	Yellow wagtail (*Motacilla flava*)	**10.9**	**5.9**
	BBCH 20-29	Small insectivorous bird "wagtail"	Yellow wagtail (*Motacilla flava*)	7.7	2.8
Grassland, 1 x 0.045 kg/ha, spring/autumn	New sown grass seeds	Small granivorous bird "Sparrow"	House sparrow (*Passer domesticus*)	**20.4**	**9.4**
	Late season (seed heads)	Small granivorous bird "finch"	Linnet (*Carduelis cannabina)*	**24.7**	**11.4**
	Growing shoots	Large herbivorous bird "goose"	Pink-foot goose (*Anser brachyrhynchus*)	**30.5**	**16.2**
	Growing shoots	Small insectivorous bird "wagtail"	Yellow wagtail (*Motacilla flava*)	**26.8**	**11.3**

Bold: Species considered in risk assessment (only worst case for each species)

ACUTE DIETARY RISK ASSESSMENT

Table CP 10.1.1- 4: Tier 1 acute risk assessment for birds

Crop scenario	Generic focal species	DDD			DDD	LD_{50} [mg a.s./kg bw]	TER_A	Trigger
		Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}				
Amidosulfuron								
Cereals early shoots BBCH 10-29	Large herbivorous bird "goose"	0.030	30.5	1.0	0.9	> 2000	> 2186	10
Cereals BBCH 10-29	Small omnivorous bird "lark"		24.0		0.7		> 2778	10
Oilseed rape# Late-late (with seeds) BBCH 30-99	Small insectivorous bird "dunnock"	0.030	7.4	1.0	0.2	> 2000	9009	10
Oilseed rape# early (shoots) BBCH 10-19	Large herbivorous bird "goose"		39.0		1.2		1709	10
Oilseed rape# BBCH 10-29	Small omnivorous bird "lark"		24.0		0.7		> 2778	10
Oilseed rape# BBCH 10-19	medium herbivorous/granivoros bird "pigeon"		55.6		1.7		> 1199	10
Oilseed rape# BBCH 10-19	Small insectivorous bird "wagtail"		10.9		0.3		> 6116	10
Grassland New sown grass seeds	Small granivorous bird "Sparrow"	0.045	20.4	1.0	0.9	> 2000	> 2179	10
Grassland Late season (seed heads)	Small granivorous bird "finch"		24.7		1.1		> 1799	10
Grassland Growing shoots	Large herbivorous bird "goose"		30.5		1.4		> 1457	10
Grassland Growing shoots	Small insectivorous bird "wagtail"		26.8		1.2		> 1658	10

surrogate crop for intended use on flax

The TER_A values calculated in the acute risk assessment on Tier 1 level exceed the *a-priori*-acceptability trigger of 10 for all evaluated scenarios. Thus, the acute risk to birds can be considered as low and acceptable without need for further, more realistic risk assessment.

Acute risk assessment for birds drinking contaminated water from pools in leaf whorls

In the EFSA GD 2009, section 5.5, step 1 the following guidance is given on the selection of relevant scenarios for assessing the risk of pesticides via drinking water to birds and mammals:

Leaf scenario: Birds taking water that is collected in leaf whorls after application of a pesticide to a crop and subsequent rainfall or irrigation.

Puddle scenario: Birds and mammals 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.

For the crops under assessment in this evaluation (cereals, oilseed rape (as surrogate for flax) and grassland) the leaf scenario is not considered relevant. The risk for birds from drinking water in puddles is addressed in Table CP 10.1.1- 6.

LONG-TERM REPRODUCTIVE RISK ASSESSMENT

Table CP 10.1.1- 5: Tier 1 reproductive risk assessment for birds

Crop	Generic focal species	DDD				DDD	NOEL [mg a.s./ kg bw/d]	TER_{LT}	Trigger
		Appl. rate [kg a.s./ha]	SV_m	MAF_m	f_{TWA}				
Amidosulfuron									
Cereals early shoots BBCH 10-29	Large herbivorous bird "goose"	0.030	16.2	1.0	0.53	0.3	100	388	5
Cereals BBCH 10-29	Small omnivorous bird "lark"		10.9			0.2		577	5
Oilseed rape# Late-late (with seeds) BBCH 30-99	Small insectivorous bird "dunnock"	0.030	2.7	1.0	0.53	0.04	100	2329	5
Oilseed rape# BBCH 10-19	Large herbivorous bird "goose"		15.9			0.3		396	5
Oilseed rape# BBCH 10-29	Small omnivorous bird "lark"		10.9			0.2		577	5
Oilseed rape# BBCH 10-19	medium herbivorous/granivoros bird "pigeon"		22.7			0.4		277	5
Oilseed rape# BBCH 10-19	Small insectivorous bird "wagtail"		59			0.1		1066	5
Grassland New sown grass seeds	Small granivorous bird "Sparrow"	0.045	9.4	1.0	0.53	0.2	100	446	5
Grassland Late season (seed heads)	Small granivorous bird "finch"		11.4			0.3		368	5
Grassland Growing shoots	Large herbivorous bird "goose"		16.2			0.4		259	5
Grassland Growing shoots	Small insectivorous bird "wagtail"		11.3			0.3		371	5

surrogate crop for intended use on flax

The TER_{LT} values calculated in the reproductive risk assessment on Tier 1 level exceed the *a-priori*-acceptability trigger of 5 for all evaluated scenarios. Thus, the risk to birds can be considered as low and acceptable without need for further, more realistic risk assessment.

Long-term risk assessment for birds drinking contaminated water in puddles

Table CP 10.1.1- 6: Evaluation of potential concern for exposure of birds drinking water (escape clause)

Crop	K_{oc} [L/kg]	Application rate * MAF [g as/ha]	NO(A)EL [mg as/ kg bw/d]	Ratio (Application rate * MAF) / NO(A)EL	"Escape clause" No concern if ratio	Conclusion
Amidosulfuron						
Cereals	36.4	30 * 1.0	100	0.3	**≤ 50**	No concern
Oilseed rape[#]	36.4	30 * 1.0	100	0.3	**≤ 50**	No concern
Grassland	36.4	45 * 1.0	100	0.45	**≤ 50**	No concern

[#] surrogate crop for intended use on flax

RISK ASSESSMENT OF SECONDARY POISONING

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for birds 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.

As the log P_{OW} of the active substance amidosulfuron and its metabolites is below the trigger (< 3), no evaluation of secondary poisoning is needed (see Sec.2, CA 2.7).

CP 10.1.1.1 Acute oral toxicity

Report: KCP 10.1.1.1/01 [redacted], [redacted]; 1989; M-123059-01-1
Title: Hoe 075032 - water dispersible granules (95 %) (Code: Hoe 075032 OH WG75 A1/S) Testing for acute oral toxicity in the male and female japanese quail (Coturnix coturnix japonica)
Report No.: 340434
Document No.: M-123059-01-1
Guideline(s): USEPA (=EPA): § 71-1
Guideline deviation(s): --
GLP/GEP: yes

[Study submitted and evaluated for the first inclusion of amidosulfuron on Annex I]

The study reports on an acute oral toxicity test for Japanese quail on the formulated product. No mortalities occurred, no intoxication symptoms were observed and no macroscopically visible findings were seen at necropsy. Accordingly, the 14-d LD_{50} was reported to be >2000 mg product/kg bw.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

An EU agreed endpoint for acute oral toxicity of formulation "Gratil" of LD_{50} > 2000 mg product/kg bw was derived from this test.

CP 10.1.1.2 Higher tier data on birds

No higher tier data on birds was generated, since risk assessments can be completed based on standard test results.

CP 10.1.2 Effects on terrestrial vertebrates other than birds

Ecotoxicological endpoints used in risk assessment

One acute toxicity test on rats has been conducted with the product. The results from this test, and from tests with the technical active substance amidosulfuron as reported in document MCA, will be used for risk assessment.

All studies were previously EU reviewed for the first Annex I inclusion of amidosulfuron. No new data has been generated and is submitted in the context of application for approval renewal.

An overview of the information relevant to this chapter is provided in the following tables.

Table CP 10.1.2- 1: Endpoints of the formulation Amidosulfuron WG75 used in risk assessment

Test substance	Test organism	Study type	Endpoint		Reference
Amidosulfuron WG 75	**Acute toxicity to mammals**				
	Rat	acute, oral	LD_{50}	>5000 mg prod./ kg bw	[redacted]; 1989; M-123295-01-1 KCP 5.1.1/01

prod. = product; bw = body weight

The study confirmed a low acute oral toxicity of the formulated product, consistent with the data generated on the active substance and used in the detailed numeric risk assessments presented in the following.

Table CP 10.1.2- 2: Endpoints of the active substance amidosulfuron used in risk assessment

Test substance	Test organism	Study type	Endpoint		Reference
Amido-sulfuron	**Acute toxicity to mammals**				
	Mouse	acute, oral	LD_{50}	**5000 mg a.s./kg bw**	[redacted] 1988; M-120196-01-1 KCA 5.2.1/02
	Long-term toxicity to mammals				
	Rat	2-generation dietary reproduction study	$NOAEL_{parental}$ $NOAEL_{repro}$ $NOEL_{pup}$	10 000 ppm 570 mg a.s./kg bw/d 10 000 ppm 570 mg a.s./kg bw/d 2000 ppm **153* mg a.s./kg bw/d**	[redacted] K.; 1992; M-135662-01-1 KCA 5.6.1 /02

a.s. = active substance; bw = body weight
Bold values used for the risk assessment
* Group mean intake of amidosulfuron (mg/kg bw/day) of F_0-females during gestation period at the dose level of 2000 ppm (Table B.6.6.1-4 in the Annex B.6 of the DAR)

Risk assessment for other terrestrial vertebrates

Table CP 10.1.2- 3: Relevant generic focal species for Tier 1 risk assessment

Crop group*	Scenario	Generic focal species	Representative species	Shortcut value	
				Long-term RA based on RUD$_m$	**acute RA based on RUD$_{90}$**
Cereals, 1 x 0.030 kg/ha, BBCH 12-49	BBCH 10-19	Small insectivorous mammal "shrew"	Common shrew (*Sorex araneus*)	**4.2**	**7.6**
	BBCH ≥ 20	Small insectivorous mammal "shrew"	Common shrew (*Sorex araneus*)	1.9	5.4
	BBCH ≥ 40	Small herbivorous mammal "vole"	Common vole (*Microtus arvalis*)	**21.7**	**40.9**
	Early (shoots)	Large herbivorous mammal "lagomorph"	Rabbit (*Oryctolagus cuniculus*)	**22.3**	**42.1**
	BBCH 10-29	Small omnivorous mammal "mouse"	Wood mouse (*Apodemus sylvaticus*)	**7.8**	**17.2**
	BBCH 30-39	Small omnivorous mammal "mouse"	Wood mouse (*Apodemus sylvaticus*)	3.9	8.6
	BBCH ≥ 40	Small omnivorous mammal "mouse"	Wood mouse (*Apodemus sylvaticus*)	2.3	5.2
Oilseed rape (=surrogate crop for flax), 1 x 0.030 kg/ha, before flower buds are visible	BBCH 10-19	Small insectivorous mammal "shrew"	Common shrew (*Sorex araneus*)	**4.2**	**7.6**
	BBCH ≥ 20	Small insectivorous mammal "shrew"	Common shrew (*Sorex araneus*)	1.9	5.4
	BBCH ≥ 40	Small herbivorous mammal "vole"	Common vole (*Microtus arvalis*)	**18.1**	**34.1**
	All season	Large herbivorous mammal "lagomorph"	Rabbit (*Oryctolagus cuniculus*)	**14.3**	**35.1**
	BBCH 10-29	Small omnivorous mammal "mouse"	Wood mouse (*Apodemus sylvaticus*)	**7.8**	**17.2**
	BBCH 30-39	Small omnivorous mammal "mouse"	Wood mouse (*Apodemus sylvaticus*)	2.3	5.2
	BBCH ≥ 40	Small omnivorous mammal "mouse"	Wood mouse (*Apodemus sylvaticus*)	1.9	4.3
Grassland, 1 x 0.045 kg/ha, spring/ autumn	All season	Large herbivorous mammal "lagomorph"	Brown Hare (*Lepus europaeus*)	**17.3**	**32.6**
	Late	Small insectivorous mammal "shrew"	Common shrew (*Sorex araneus*)	**1.9**	**5.4**
	All season	Small herbivorous mammal "vole"	Common vole (*Microtus arvalis*)	**72.3**	**136.4**
	Late season (seed heads)	Small omnivorous mammal "mouse"	Wood mouse (*Apodemus sylvaticus*)	**6.6**	**14.4**
	New sown grass seeds	Small omnivorous mammal "mouse"	Wood mouse (*Apodemus sylvaticus*)	6.6	14.4

Bold: Species considered in risk assessment (only worst case for each species)

ACUTE DIETARY RISK ASSESSMENT

Table CP 10.1.2- 4: Tier 1 acute DDD and TER calculation for mammals

Crop	Generic focal species	DDD			DDD	LD_{50} [mg/kg bw]	TER_A	Trigger
		Appl. rate [kg/ha[	SV_{90}	MAF_{90}				
Amidosulfuron								
Cereals BBCH 10-19	Small insectivorous mammal “shrew”	0.030	7.6	1.0	0.2	5000	21930	10
Cereals BBCH ≥ 40	Small herbivorous mammal “vole“		40.9		1.2		4075	10
Cereals Early (shoots)	Large herbivorous mammal “lagomorph”		42.1		1.3		3959	10
Cereals BBCH 10-29	Small omnivorous mammal “mouse”		17.2		0.5		9690	10
Oilseed rape[#] BBCH 10-19	Small insectivorous mammal “shrew”	0.030	7.6	1.0	0.2	5000	21930	10
Oilseed rape[#] BBCH ≥ 40	Small herbivorous mammal “vole“		34.1		1.0		4888	10
Oilseed rape[#] All season	Large herbivorous mammal “lagomorph”		35.1		1.1		4748	10
Oilseed rape[#] 10-29	Small omnivorous mammal “mouse”		17.2		0.5		9690	10
Grassland All season	Large herbivorous mammal “lagomorph”	0.045	32.6	1.0	1.5	5000	3408	10
Grassland Late	Small insectivorous mammal “shrew”		5.4		0.2		20576	10
Grassland All season	Small herbivorous mammal “vole“		136.4		6.1		815	10
Grassland Late season (seed heads)	Small omnivorous mammal “mouse”		14.4		0.6		7716	10

[#] surrogate crop for intended use on flax

The TER_A values calculated in the acute risk assessment on Tier 1 level exceed the *a-priori* acceptability trigger of 10 for all evaluated scenarios. Thus, the acute risk to mammals can be considered as low and acceptable without need for further, more realistic risk assessment.

LONG-TERM REPRODUCTIVE RISK ASSESSMENT

Table CP 10.1.2- 5: Tier 1 long-term DDD and TER calculation for mammals

Crop	Generic focal species	DDD				DDD	NO(A)EL [mg kg/bw/d]	TER_{LT}	Trigger
		Appl. rate [kg/ha	SV_m	MAF_m	f_{twa}				
Amidosulfuron									
Cereals BBCH 10-19	Small insectivorous mammal "shrew"	0.030	4.2	1.0	0.53	0.1	153	2291	5
Cereals BBCH ≥ 40	Small herbivorous mammal "vole"		21.7			0.3		443	5
Cereals Early (shoots)	Large herbivorous mammal "lagomorph"		22.3			0.4		432	5
Cereals BBCH 10-29	Small omnivorous mammal "mouse"		7.8			0.1		1234	5
Oilseed rape[#] BBCH 10-19	Small insectivorous mammal "shrew"	0.030	4.2	1.0	0.53	0.1	153	2294	5
Oilseed rape[#] BBCH ≥ 40	Small herbivorous mammal "vole"		18.1			0.3		532	5
Oilseed rape[#] All season	Large herbivorous mammal "lagomorph"		14.3			0.2		673	5
Oilseed rape[#] 10-29	Small omnivorous mammal "mouse"		7.8			0.1		1234	5
Grassland All season	Large herbivorous mammal "lagomorph"	0.045	17.3	1.0	0.53	0.4	153	371	5
Grassland Late	Small insectivorous mammal "shrew"		1.9			0.05		3376	5
Grassland All season	Small herbivorous mammal "vole"		72.3			1.7		88.7	5
Grassland Late season (seed heads)	Small omnivorous mammal "mouse"		6.6			0.2		972	5

[#] surrogate crop for intended use on flax

The TER_{LT} values calculated in the reproductive risk assessment on Tier 1 level exceed the *a-priori*-acceptability trigger of 5 for all evaluated scenarios. Thus, the risk to mammals can be considered as low and acceptable without need for further, more realistic risk assessment.

Long-term risk assessment for mammals drinking contaminated water

The puddle scenario is relevant for the long-term risk assessment.

Table CP 10.1.2- 6: Evaluation of potential concern for exposure of mammals drinking water

Crop	Koc [L/kg]	Application rate * MAF [g as/ha]	NO(A)EL [mg as/ kg bw/d]	Ratio (Application rate * MAF) / NO(A)EL	"Escape clause" No concern if ratio	Conclusion
Amidosulfuron						
Cereals	36.4	30 * 1.0	153	0.2	**≤ 50**	No concern
Oilseed rape[#]	36.4	30 * 1.0	153	0.2	**≤ 50**	No concern
Grassland	36.4	45 * 1.0	153	0.3	**≤ 50**	No concern

[#] surrogate crop for intended use on flax

RISK ASSESSMENT OF SECONDARY POISONING

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for mammals 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.

As the log P_{OW} of the active substance amidosulfuron and its metabolites is below the trigger (< 3), no evaluation of secondary poisoning is needed (see Sec.2, CA 2.7).

CP 10.1.2.1 Acute oral toxicity to mammals

One acute toxicity test for product Amidosulfuron WG75 on rats ([redacted]; 1989; M-123295-01-1); the study is found reported in the toxicology section of document MCP, study reference KCP 7.1.1/01. According to OECD guideline 401 the results of this study correspond to LD_{50} >5000 mg/kg body weight.

CP 10.1.2.2 Higher tier data on mammals

No higher tier data on birds was generated since risk assessments can be completed based on standard test results.

CP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

No additional studies are available or required under the data requirements of EC 1107/2009.

CP 10.2 Effects on aquatic organisms

The effect on aquatic organisms of the product Amidosulfuron WG75 has been characterised via a comprehensive set of studies, overview on which is shown in Table 10.2-1. All studies were previously EU reviewed for the first Annex I inclusion of amidosulfuron. No new data on the formulation has been generated and is submitted in the context of application for approval renewal.

Moreover, endpoints generated for the active substance and its individual metabolites will be used in risk assessments; an overview on this information is provided in Table 10.2-2, for study details reference is made to document MCA.

Metabolites

In the risk assessment for the aquatic compartment, the following metabolites of amidosulfuron have to be addressed:

Amidosulfuron-desmethyl (AE F101630), amidosulfuron-desmethyl-chloropyrimidine (BCS-CO41838), ADMP (AE F092944), amidosulfuron-guanidine (BCS-CO41839), amidosulfuron-biuret BCS-CQ51287) and guanidinocarbonyl sulfamic acid (BCS-BI49539).

* Complete acute experimental data set is available for the metabolites amidosulfuron-desmethyl, ADMP.
* Amidosulfuron-biuret, amidosulfuron-guanidine and amidosulfuron-desmethyl-chloropyrimidine were only tested on aquatic macrophytes, the most sensitive organism to the parent compound.
* No tests are available for the metabolite guanidinocarbonyl sulfamic acid.

* Despite the presence of the structural group responsible for sulfonylureas herbicidal activity (Sinclair, 2009[2]), tests demonstrated a lack of herbicidal activity for both a-desmethyl (KCA 8.6.1 /02) and a-desmethyl-chloropyrimidine (KCA 8.6.1 /06). Moreover, the same results were obtained for the metabolites characterised by a cleaved sulfonylurea moiety, i.e. ADMP (KCA 8.6.1 /08), ADHP (KCA 8.6.1 /03), or a disintegrated pyrimidine ring, i.e. a-guanidine (KCA 8.6.1 /06) and a-biuret (KCA 8.6.1 /07). Therefore all tested metabolites lost the toxophore responsible for the biological target activity (i.e. herbicidal activity). According to the risk assessment scheme for metabolites (pp 143-144) of the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA, 2013[3)], risk assessment for metabolites without toxophore can be based on active substance data.

No tests were performed to characterize neither the toxicity of guanidinocarbonyl sulfamic acid nor its herbicidal activity. It is a tertiary metabolite resulting from the degradation of amidosulfuron-guanidine and/or amidosulfuron-biuret which do not show any herbicidal activity. Consequently, it is assumed that the toxophore is no longer present in this metabolite and the risk assessment can be addressed using information from the parent substance.

* The trigger for chronic risk assessment (DT_{90} > 1d) is met for all metabolites. According to the AGD stepwise approach, the parent chronic endpoints can be used in the metabolite risk assessment as surrogate values for all tier 1 taxonomic groups. As a further refinement step non-testing methods, e.g. QSAR calculations, are possible before experimental chronic testing for metabolites is required. Thus the chronic risk assessment for all these metabolites is based on parent endpoints.

[2] CJ Sinclair PhD Thesis University of York Predicting the environmental fate and ecotoxicological and toxicological effects of pesticide transformation products
https://www.researchgate.net/publication/235934684_Predicting_the_environmental_fate_and_ecotoxicological_and_toxicological_effects_of_pesticide_transformation_products

[3] 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

Ecotoxicological endpoints used in risk assessment

Table CP 10.2- 1: Endpoints of the formulation Amidosulfuron WG75 used in risk assessment

Test substance	Test organism	Study type	Endpoint		References
Amidosulfuron WG 75	**Fish, acute**				
	Cyprinus carpio (Mirror carp)	acute static 96 h	LC_{50}	449 mg prod./$L_{(nom)}$	[redacted]; 1989; M-125130-01-1 KCP 10.2.1/03
	Oncorhynchus mykiss [former *Salmo gairdneri*] (rainbow trout)	acute static 96 h	LC_{50}	150 mg prod./L = 113.9 mg a.s./$L^{A}_{(nom)}$	[redacted]; 1989; M-125129-01-1 KCP 10.2.1/02
	Fish, long-term				
	Oncorhynchus mykiss [former *Salmo gairdneri*] (rainbow trout)	flow-through, juvenile growth, 21 d	NOEC growth	10 mg prod./L = 7.59 mg a.s./$L^{A}_{(nom)}$	[redacted]; 1989; M-125111-01-1 KCP 10.2.2/01
	Aquatic invertebrates, acute				
	Daphnia magna (water flea)	acute static 48 h	EC_{50}	187 mg prod./L = 142.9 mg a.s./$L^{A}_{(nom)}$	[redacted]; 1989; M-125182-01-1 KCP 10.2.1/03
	Aquatic invertebrates, long-term				
	Daphnia magna (water flea)	reproduction, 21 d	NOEC	32 mg prod./L = 24.3 mg a.s./L $^{A}_{(nom)}$	[redacted]; 1989; M-125137-01-1 KCP 10.2.2/02
	Daphnia magna (water flea)	reproduction, 21 d	Calculated mixture NOEC	1.3 mg prod./L	acc. EFSA Journal 11(7):3290 (2013)
	Algae				
	Scenedesmus subspicatus (green alga)	growth inhibition, 72 h	E_bC_{50} E_rC_{50}	33.8 mg prod./L = 25.8 mg a.s./L^{A} 122 mg prod./L = 93 mg a.s./$L^{A}_{(nom)}$	[redacted]; 1991; M-129467-01-1 KCP 10.2.2/04
	Aquatic macrophytes				
	Lemna gibba (duckweed)	growth inhibition, static, 7 d	E_bC_{50} E_rC_{50}	0.0101 mg prod./L = 0.00773 mg a.s./L^{A} 0.010 mg prod./L = 0.00765 mg a.s./L^{A}	[redacted]; 2003; M-231187-01-1 KCP 10.2.1/05

($_{nom}$) nominal concentration , prod. = product; a.s. = active substance
[A] EFSA Scientific Report (2007) 116, 1-86, Conclusion on the peer review of amidosulfuron

Mixture toxicity risk assessment according to the Aquatic Guidance document

The available data on the formulated product show that no synergy or antagonism (MDR between 0.2 and 5) is observed, except for the chronic study on *Daphnia magna*. The MDR for this study is 0.04 considering the amount of active substance in the formulation (Table JCP 1.4.1-1). The reason for this discrepancy is unknown; consequently the mixture toxicity long term risk assessment for invertebrates will also be conducted with the calculated mixture endpoint of 1.3 mg prod/L (i.e. based on the endpoint of the active substance and its amount in the formulation).

Table CP 10.2- 2: Endpoints for the active substance amidosulfuron and metabolites used in risk assessment

Test substance	Test organism	Test system	Endpoint		References
Amidosulfuron	**Fish, acute**				
	Oncorhynchus mykiss (rainbow trout)	Acute, static, 96 h	LC_{50}	> 100 mg a.s./$L_{(nom)}$	[redacted] 1987; M-117660-01-1 KCA 8.2.1 /01
	Lepomis macrochirus (bluegill sunfish)				[redacted]; 1987; M-119377-01-1 KCA 8.2.1 /02
	Cyprinodon variegates (sheepshead minnow)				[redacted]; 1988; M-120514-01-1 KCA 8.2.1 /03
					[redacted] 1989; M-123929-01-1 KCA 8.2.1 /04
	Fish, chronic				
	Oncorhynchus mykiss (rainbow trout)	early life stage test	NOEC	9.72 mg a.s./$L_{(mm)}$	[redacted]; 2015; M-538454-01-1 KCA 8.2.2 /01
	Aquatic invertebrates, acute				
	Daphnia magna (water flea)	Acute, static, 48 h	EC_{50}	36 mg a.s./$L_{(nom)}$[4]	[redacted]; 1987; M-119379-01-1 KCA 8.2.4 /02
	Aquatic invertebrates, chronic				
	Daphnia magna (water flea)	chronic, semi static, 21 d	NOEC	1.0 mg a.s./$L_{(nom)}$	[redacted]; 1991; M-130193-01-1 KCA 8.2.5.1 /01
	Algae				
	Scenedesmus subspicatus (green alga)	Growth inhibition, 48h	E_bC_{50}	145 mg a.s./$L_{(nom)}$[5]	[redacted]; 1988; M-120327-01-1 KCA 8.2.6.1 /01
					[redacted]; 2016; M-549424-01-1 KCA 8.2.6.1/08
	Aquatic plant				
	Lemna gibba (duck weed)	Growth inhibition, semi-static, 7d	E_rC_{50}	0.0092 mg a.s./L	[redacted]; 2002; M-208657-01-1 KCA 8.2.7 /02

[4] An acute study on *Mysidopsis bahia* is also available, the EC_{50} is 75 mg a.s./L. The lowest endpoint for aquatic invertebrates acute studies was selected for risk assessment (EC_{50} of 36 mg a.s./L on *Daphnia magna*). There is no need to perform a specific risk assessment with *Mysidopsis bahia* endpoint, because PECs are calculated for freshwater bodies only.

[5] The endpoint for the second algae species (*Navicula pelliculosa)* is an unbound value : E_rC_{50} > 84.2 mg a.s./L. It has not been selected for risk assessment because 84.2 mg/L is the NOEC. According to the Aquatic Guidance document, EC_{50} have to be used for the risk assessment on algae.The most sensitive species of the two algae species is clearly the green alga as effects were observed at 10 mg/L and above while no effects were observed up to 84.2 mg/L for the diatom.

Test substance	Test organism	Test system	Endpoint		References
Amidosulfuron-desmethyl	**Fish, acute**				
	Oncorhynchus mykiss (rainbow trout)	Acute, static, 96 h	LC_{50}	>100 mg p.m./L	[redacted]; 1993; M-131849-01-1 KCA 8.2.1 /05
	Fish, chronic				
	Oncorhynchus mykiss (rainbow trout) **Parent endpoint**	early life stage test	NOEC	9.72 mg a.s./L	[redacted]; 2015; M-538454-01-1 KCA 8.2.2 /01
	Aquatic invertebrates, acute				
	Daphnia magna (water flea)	Acute, static, 48 h	EC_{50}	> 55 mg p.m./L	[redacted]; 1993; M-131833-01-1 KCA 8.2.4 /04
	Aquatic invertebrates, chronic				
	Daphnia magna (water flea) **Parent endpoint**	chronic, semi static, 21 d	NOEC	1.0 mg a.s./L	[redacted]; 1991; M-130193-01-1 KCA 8.2.5.1 /01
	Algae				
	Scenedesmus subspicatus (green alga)	Growth inhibition, 72 h	E_rC_{50}	> 1000 mg p.m./L	[redacted]; 1993; M-132028-01-1 KCA 8.2.6.1 /02
	Aquatic plant				
	Lemna gibba (duck weed)	Growth inhibition, semi-static, 7 d	E_rC_{50}	0.92 mg p.m./L	[redacted]; 2003; M-213899-01-1 KCA 8.2.7 /03

[6] EC_{50} based on geomean measured concentration as some measurements were below 80% of nominal concentrations (see KCA 8.2.4.1/03 for further details).

Test substance	Test organism	Test system	Endpoint		References
Amidosulfuron-desmethyl-chloro-pyrimidine	**Fish, acute**				
	Oncorhynchus mykiss (rainbow trout) *Lepomis macrochirus* (bluegill sunfish) *Cyprinodon variegates* (sheepshead minnow) **Parent endpoint**	Acute, static, 96 h	LC_{50}	> 100 mg a.s./L	[redacted]; 1987; M-117660-01-1 KCA 8.2.1 /01 [redacted]; 1987; M-119377-01-1 KCA 8.2.1 /02 [redacted]; 1988; M-120514-01-1 KCA 8.2.1 /03 [redacted]; 1989; M-123929-01-1 KCA 8.2.1 /04
	Fish, chronic				
	Oncorhynchus mykiss (rainbow trout **Parent endpoint**	early life stage test	NOEC	9.72 mg a.s./L	[redacted]; 2015; M-538454-01-1 KCA 8.2.2 /01
	Aquatic invertebrates, acute				
	Daphnia magna (water flea) **Parent endpoint**	Acute, static, 48 h	EC_{50}	36 mg a.s./L	[redacted]; 1987; M-119379-01-1 KCA 8.2.4 /02
	Aquatic invertebrates, chronic				
	Daphnia magna (water flea) **Parent endpoint**	chronic, semi static, 21 d	NOEC	1.0 mg a.s./L	[redacted]; 1991; M-130193-01-1 KCA 8.2.5.1 /01
	Algae				
	Scenedesmus subspicatus (green alga) **Parent endpoint**	Growth inhibition, 48h	E_rC_{50}	145 mg a.s./L	[redacted]; 1988; M-120327-01-1 KCA 8.2.6.1 /01 [redacted]; 2016; M-549424-01-1 KCA 8.2.6.1/08
	Aquatic plant				
	Lemna gibba (duck weed)	Growth inhibition, static, 7 d	EC_{50}	> 100 mg p.m./L	[redacted]; 2010; M-365833-01-1 KCA 8.2.7 /06

Test substance	Test organism	Test system	Endpoint		References
Amidosulfuron-guanidine	**Fish, acute**				
	Oncorhynchus mykiss (rainbow trout) *Lepomis macrochirus* (bluegill sunfish) *Cyprinodon variegates* (sheepshead minnow) **Parent endpoint**	Acute, static, 96 h	LC_{50}	> 100 mg a.s./L	[redacted]; 1987; M-117660-01-1 KCA 8.2.1 /01 [redacted]; 1987; M-119377-01-1 KCA 8.2.1 /02 [redacted]; 1988; M-120514-01-1 KCA 8.2.1 /03 [redacted] 1989; M-123929-01-1 KCA 8.2.1 /04
	Fish, chronic				
	Oncorhynchus mykiss (rainbow trout) **Parent endpoint**	early life stage test	NOEC	9.72 mg a.s./L	[redacted]; 2015; M-538454-01-1 KCA 8.2.2 /01
	Aquatic invertebrates, acute				
	Daphnia magna (water flea) **Parent endpoint**	Acute, static, 48 h	EC_{50}	36 mg a.s./L	[redacted]; 1987; M-119379-01-1 KCA 8.2.4 /02
	Aquatic invertebrates, chronic				
	Daphnia magna (water flea) **Parent endpoint**	chronic, semi static, 21 d	NOEC	1.0 mg a.s./L	[redacted]; 1991; M-130193-01-1 KCA 8.2.5.1 /01
	Algae				
	Scenedesmus subspicatus (green alga) **Parent endpoint**	Growth inhibition, 48h	E_rC_{50}	145 mg a.s./L	[redacted]; 1988; M-120327-01-1 KCA 8.2.6.1 /01 [redacted]; 2016; M-549424-01-1 KCA 8.2.6.1/08
	Aquatic plant				
	Lemna gibba (duck weed)	Growth inhibition, static, 7 d	E_rC_{50}	> 100 mg p.m./L	[redacted]; 2010; M-365913-01-1 KCA 8.2.7 /07
Amidosulfuron-biuret	**Fish, acute**				
	Oncorhynchus mykiss (rainbow trout) *Lepomis macrochirus* (bluegill sunfish)	Acute, static, 96 h	LC_{50}	> 100 mg a.s./L	[redacted]; 1987; M-117660-01-1 KCA 8.2.1 /01 [redacted]; 1987; M-119377-01-1 KCA 8.2.1 /02

Test substance	Test organism	Test system	Endpoint		References
	Cyprinodon variegates (sheepshead minnow) **Parent endpoint**				[redacted]; 1988; M-120514-01-1 KCA 8.2.1 /03
					[redacted] 1989; M-123929-01-1 KCA 8.2.1 /02
	Fish, chronic				
	Oncorhynchus mykiss (rainbow trout) **Parent endpoint**	early life stage test	NOEC	9.72 mg a.s./L	[redacted] 2015; M-538454-01-1 KCA 8.2.2 /01
	Aquatic invertebrates, acute				
	Daphnia magna (water flea) **Parent endpoint**	Acute, static, 48 h	EC_{50}	36 mg a.s./L	[redacted]; 1987; M-119379-01-1 KCA 8.2.4 /02
	Aquatic invertebrates, chronic				
	Daphnia magna (water flea) **Parent endpoint**	chronic, semi static, 21 d	NOEC	1.0 mg a.s./L	[redacted]; 1991; M-130793-01-1 KCA 8.2.5.1 /01
	Algae				
	Scenedesmus subspicatus (green alga) **Parent endpoint**	Growth inhibition, 48h	E_rC_{50}	145 mg a.s./L	[redacted]; 1988; M-120327-01-1 KCA 8.2.6.1 /01
					[redacted]; 2016; M-549424-01-1 KCA 8.2.6.1/08
	Aquatic plant				
	Lemna gibba (duck weed)	Growth inhibition, static, 7 d	E_rC_{50}	10 mg p.m./L	[redacted]; 2015; M-510513-01-1 KCA 8.2.7 /08

Test substance	Test organism	Test system	Endpoint		References
Amidosulfuron-ADMP	**Fish, acute**				
	Oncorhynchus mykiss (rainbow trout)	Acute, static, 96 h	LC_{50}	169.2 mg p.m./L	[redacted]; 1993; M-131422-01-1 KCA 8.2.1 /06
					[redacted]; 2016; M-549001-01-1 KCA 8.2.1 /01
	Fish, chronic				
	Oncorhynchus mykiss (rainbow trout) **Parent endpoint**	early life stage test	NOEC	9.72 mg a.s./L	[redacted] 2015; M-538454-01-1 KCA 8.2.2 /01
	Aquatic invertebrates, acute				
	Daphnia magna (water flea)	Acute, static, 48 h	EC_{50}	223 mg p.m./L	[redacted]; 1992; M-131382-01-1 KCA 8.2.1 /05
	Aquatic invertebrates, chronic				
	Daphnia magna (water flea) **Parent endpoint**	chronic, semi static, 21 d	NOEC	1.0 mg a.s./L	[redacted]; 1991; M-130193-01-1 KCA 8.2.5.1 /01
	Algae				
	Desmodesmus subspicatus (syn. *Scenedesmus subspicatus*) (green alga)	Growth inhibition, 72 h	E_rC_{50}	> 560 mg p.m./L	[redacted]; 1993; M-131421-01-1 KCA 8.2.6.1 /05
	Aquatic plant				
	Lemna gibba (duck weed)	Growth inhibition, semi-static, 7 d	E_rC_{50}	100 mg p.m./L	[redacted] 2000; M-186916-01-1 KCA 8.2.7 /04

Test substance	Test organism	Test system	Endpoint		References
Amido-sulfuron - Guanidinocarbonyl sulfamic acid	**Fish, acute**				
	Oncorhynchus mykiss (rainbow trout) *Lepomis macrochirus* (bluegill sunfish) *Cyprinodon variegates* (sheepshead minnow) **Parent endpoint**	Acute, static, 96 h	LC_{50}	> 100 mg a.s./L	[redacted]; 1987; M-117660-01-1 KCA 8.2.1 /01
					[redacted]; 1987; M-119377-01-1 KCA 8.2.1 /02
					[redacted]; 1988; M-120514-01-1 KCA 8.2.1 /03
					[redacted]; 1989; M-123929-01-1 KCA 8.2.1 /04
	Fish, chronic				
	Oncorhynchus mykiss (rainbow trout) **Parent endpoint**	early life stage test	NOEC	9.72 mg a.s./L	[redacted]; 2015; M-538454-01-1 KCA 8.2.2 /01
	Aquatic invertebrates, acute				
	Daphnia magna (water flea) **Parent endpoint**	Acute, static, 48 h	EC_{50}	36 mg a.s./L	[redacted]; 1987; M-119379-01-1 KCA 8.2.4 /02
	Aquatic invertebrates, chronic				
	Daphnia magna (water flea) **Parent endpoint**	chronic, semi static, 21 d	NOEC	1.0 mg a.s./L	[redacted]; 1991; M-130193-01-1 KCA 8.2.5.1 /01
	Algae				
	Scenedesmus subspicatus (green alga) **Parent endpoint**	Growth inhibition, 48h	E_rC_{50}	145 mg a.s./L	[redacted]; 1988; M-120327-01-1 KCA 8.2.6.1 /01
					[redacted]; 2016; M-549424-01-1 KCA 8.2.6.1/08
	Aquatic plant				
	Lemna gibba (duck weed) **Parent endpoint**	Growth inhibition, semi-static, 7d	E_rC_{50}	0.0092 mg a.s./L	[redacted]; 2002; M-208657-01-1 KCA 8.2.7 /02

a.s. = active substance; p.m. = pure metabolite, ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration

Risk assessment for aquatic organisms

Predicted Environmental Concentrations used in risk assessment

Formulated product

For the formulated product, meaningful PECsw can only be calculated for the direct entry route drift exposure. Indirect routes involving secondary movements of a soil deposit, such as drainage and runoff, would not lead to an exposure of the aquatic environment to the intact formulated spray solution. When hitting soil, the formulation will be disintegrated via dilution in the pore water, differential adsorption and retention of its components by soil particles, and rapid biological degradation of coformulants. Therefore, experimental endpoints from the product are to be compared with the drift exposure PEC_{SW} of the product. These are calculated in a simple tier 1 approach, considering standard drift rates and a standard water body, which is 30 cm deep and without riparian vegetation.

Table CP 10.2- 3: Initial maximum PEC_{SW} values of the formulation, considering spray drift after one application as only route of entry relevant for the product (KCP 9.2.5/05; Table CP 9.2.5- 17)

Compound	Scenario	Drift rate (arable crops)	Winter cereals, 1 × 0.04 kg/ha	Winter cereals, 1 × 0.02 kg/ha	Spring cereals & Flax, 1 × 0.04 kg/ha	Grass (Spring/ Autumn) 1 × 0.06 kg/ha
			$PEC_{SW, max}$ [µg/L]	$PEC_{SW, max}$ [µg/L]	$PEC_{SW, max}$ [µg/L]	$PEC_{SW, max}$ [µg/L]
Amidosulfuron WG 75	small static ditch, at the edge of the treated field, water depth 0.3 m	2.77 % (no buffer)	**0.369**	**0.185**	**0.369**	**0.554**

PEC derived from calculation of entry in standard ditch via spray drift (water body of 30 cm depth), according to BBA (2006)[7]
Bold values were used for risk assessment

[7] [redacted]., (2006) Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden, http://www.jki.bund.de/de/startseite/institute/anwendungstechnik/abdrift-eckwerte.html

Active ingredient and metabolites

Table CP 10.2- 4: Initial max PECsw values of amidosulfuron and its metabolites – FOCUS Step 2 (KCP 9.2.5/05; Tables CP 9.2.5-10 and -11)

Compound	FOCUS Scenario	Winter cereals, 1 × 30 g/ha	Winter cereals, 1 × 15 g/ha	Spring cereals and flax 1 × 30 g/ha	Grass (Spring) 1 × 45 g/ha	Grass (Autumn) 1 × 45 g/ha
		$PEC_{SW, max}$ [µg/L]	$PEC_{SW, max}$ [µg/L]	$PEC_{SW, max}$ [µg/L]	$PEC_{SW, max}$ [µg/L]	$PEC_{SW, max}$ [µg/L]
Amidosulfuron	STEP 1	10.034	5.0170	10.034	15.051	15.051
	STEP 2 – North Single	1.5446	0.9353	1.8666	0.9889	**1.8944**
	STEP 2 – South Single	**2.8325**	**1.7382**	**3.4764**	**1.5925**	1.5925
Amidosulfuron-desmethyl	STEP 1	6.4826	3.2413	6.4826	9.7240	9.7240
	STEP 2 – North Single	0.8507	0.5267	1.0533	0.4400	**1.0100**
	STEP 2 – South Single	**1.6614**	**1.0334**	**2.0667**	**0.8200**	0.8200
Amidosulfuron-desmethyl-chloropyrimidine	STEP 1	1.2394	0.6197	1.2394	1.8590	1.8590
	STEP 2 – North Single	0.1893	0.1183	0.2366	0.0887	**0.2219**
	STEP 2 – South Single	**0.3786**	**0.2366**	**0.4733**	**0.1775**	0.1775
Amidosulfuron-ADMP	STEP 1	0.5686	0.2843	0.5686	0.8529	0.8529
	STEP 2 – North Single	0.0778	0.0481	0.0962	0.0405	**0.0924**
	STEP 2 – South Single	**0.1516**	**0.0943**	**0.1885**	**0.0751**	0.0751
Amidosulfuron-guanidine	STEP 1	4.3713	2.1857	4.3713	6.5570	6.5570
	STEP 2 – North Single	0.6882	0.4249	0.8499	0.3656	**0.8202**
	STEP 2 – South Single	**1.3348**	**0.8290**	**1.6581**	**0.6687**	0.6687
Amidosulfuron-biuret	STEP 1	1.2233	0.6116	1.2233	1.8349	1.8349
	STEP 2 – North Single	0.1845	0.1128	0.2256	0.1074	**0.2229**
	STEP 2 – South Single	**0.3488**	**0.2155**	**0.4310**	**0.1844**	0.1844
Amidosulfuron-(Guanidinocarbonyl) sulfamic acid	STEP 1	1.2063	0.6032	1.2063	1.8095	1.8095
	STEP 2 – North Single	0.1865	0.1126	0.2253	0.1200	**0.2290**
	STEP 2 – South Single	**0.3415**	**0.2095**	**0.4189**	**0.1926**	0.1926

Bold values were used for risk assessment

Table CP 10.2- 5: Maximum PECsw values of amidosulfuron – FOCUS Step 3 (KCP 9.2.5/05; Tables CP 9.2.5-12 and -13)

Use pattern	Winter cereals (late), 1 × 30 g a.s./ha		Winter cereals (early), 1 × 15 g a.s./ha	
FOCUS scenario	**Entry route***	**PECsw [µg/L]**	**Entry route***	**PECsw [µg/L]**
D1 (ditch)	S	0.2653	S	0.1321
D1 (stream)	D	0.2499	D	0.1035
D2 (ditch)	D	4.1960	D	2.0940
D2 (stream)	D	2.6770	D	1.3370
D3 (ditch)	S	0.1916	S	0.0957
D4 (pond)	S	0.0112	S	0.0054
D4 (stream)	S	0.1481	S	0.0738
D5 (pond)	S	0.0080	S	0.0040
D5 (stream)	S	0.1509	S	0.0753
D6 (ditch)	S	0.1939	S	0.0970
R1 (pond)	R	0.0079	R	0.0040
R1 (stream)	R	0.2550	R	0.1270
R3 (stream)	R	0.5171	R	0.2601
R4 (stream)	R	0.3395	R	0.1712

* Entry route spray drift (S), drainage (D), runoff (R)

Table CP 10.2- 6: Maximum PECsw values of amidosulfuron – FOCUS Step 3 (KCP 9.2.5/05; Tables CP 9.2.5-14)

Use pattern	Spring cereals & flax, 1 × 30 g a.s./ha	
FOCUS scenario	**Entry route***	**PECsw [µg/L]**
D1 (Ditch)	D	0.2973
D1 (Stream)	D	0.1953
D3 (Ditch)	S	0.1927
D4 (Pond)	S	0.0113
D4 (Stream)	S	0.1486
D5 (Pond)	S	0.0077
D5 (Stream)	S	0.1515
R4 (Stream)	S	0.1252

* Entry route spray drift (S), drainage (D), runoff (R)

Table CP 10.2- 7: Maximum PECsw values of amidosulfuron and its metabolites – FOCUS Step 3 (KCP 9.2.5/05; Tables CP 9.2.5-15 and Tables CP 9.2.5-16)

Use pattern	Grass (spring), 1 × 45 g a.s./ha		Grass (autumn), 1 × 45 g a.s./ha	
FOCUS scenario	**Entry route***	**PECsw [µg/L]**	**Entry route***	**PECsw [µg/L]**
D1 (Ditch)	S	0.3072	D	0.7153
D1 (Stream)	S	0.2524	D	0.4647
D2 (Ditch)	D	13.090	D	11.670
D2 (Stream)	D	8.7960	D	8.5990
D3 (Ditch)	S	0.2872	S	0.2941
D4 (Pond)	S	0.0105	D	0.0224
D4 (Stream)	S	0.2201	S	0.2466
D5 (Pond)	S	0.0112	D	0.2222
D5 (Stream)	S	0.2359	S	0.2661
R2 (Stream)	S	0.2461	R	0.3120
R3 (Stream)	S	0.2659	S	0.2630

* Entry route spray drift (S), drainage (D), runoff (R)

ACUTE RISK ASSESSMENT FOR AQUATIC ORGANISMS

Table CP 10.2- 8: RACsw; exposure calculations based on drift entry for the formulation and on FOCUS Step 2 for amidosulfuron and its metabolites

Test substance	Test species	Endpoint [µg a.s. or formulation/L]	$RAC_{sw;\ ac}$ (LC_{50}/100)	$PEC_{sw,\ max}$ [µg/L]	PEC/RAC
Winter cereals, 1 × 30 g a.s./ha					
Amidosulfuron WG 75	Fish, acute *Oncorhynchus mykiss*	LC_{50} 150000	1500	0.369	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 187000	1870	0.369	<0.1
Amidosulfuron	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	2.8325	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	2.8325	<0.1
Amidosulfuron -desmethyl	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	1.6614	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} > 55000	> 550	1.6614	<0.1
Amidosulfuron -desmethyl-chloro-pyrimidine	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	1000	0.3786	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.3786	<0.1
Amidosulfuron -guanidine	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	1000	1.3348	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	1.3348	<0.1
Amidosulfuron -biuret	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	0.3488	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.3488	<0.1
Amidosulfuron -ADMP	Fish, acute *Oncorhynchus mykiss*	LC_{50} 169200	1692	0.1516	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 223000	2230	0.1516	<0.1
Guanidinocarbonyl sulfamic acid	Fish, acute Oncorhynchus mykiss	LC_{50} > 100000	> 1000	0.3415	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.3415	<0.1

Test substance	Test species	Endpoint [µg a.s. or formulation/L]	$RAC_{sw;\ ac}$ (LC_{50}/100)	$PEC_{sw,\ max}$ [µg/L]	PEC/RAC
Winter cereals, 1 × 15 g a.s./ha					
Amidosulfuron WG 75	Fish, acute *Oncorhynchus mykiss*	LC_{50} 150000	1500	0.185	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 187000	1870	0.185	<0.1
Amidosulfuron	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	1.7382	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	1.7382	<0.1
Amidosulfuron -desmethyl	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	1.0334	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} > 55000	> 550	1.0334	<0.1
Amidosulfuron -desmethyl-chloro-pyrimidine	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	0.2366	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.2366	<0.1
Amidosulfuron -guanidine	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	0.8290	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.8290	<0.1
Amidosulfuron -biuret	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	0.2155	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.2155	<0.1
Amidosulfuron -ADMP	Fish, acute *Oncorhynchus mykiss*	EC_{50} 169200	1692	0.0943	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 223000	2230	0.0943	<0.1
Guanidinocarbonyl sulfamic acid	Fish, acute Oncorhynchus mykiss	LC_{50} > 100000	> 1000	0.2095	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.2095	<0.1

Test substance	Test species	Endpoint [µg a.s. or formulation/L]	$RAC_{sw;\ ac}$ (LC_{50}/100)	$PEC_{sw,\ max}$ [µg/L]	PEC/RAC
Spring cereals & Flax, 1 × 30 g a.s./ha					
Amidosulfuron WG 75	Fish, acute *Oncorhynchus mykiss*	LC_{50} 150000	1500	0.369	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 187000	1870	0.369	<0.1
Amidosulfuron	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	3.4764	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	3.4764	<0.1
Amidosulfuron -desmethyl	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	2.0667	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} > 55000	> 550	2.0667	<0.1
Amidosulfuron -desmethyl-chloro-pyrimidine	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	0.4733	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.4733	<0.1
Amidosulfuron -guanidine	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	1.6581	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	1.6581	<0.1
Amidosulfuron -biuret	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	0.4310	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.4310	<0.1
Amidosulfuron -ADMP	Fish, acute *Oncorhynchus mykiss*	LC_{50} 169200	1692	0.1885	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 223000	2230	0.1885	<0.1
Amido-sulfuron-Guanidinocarbonyl sulfamic acid	Fish, acute Oncorhynchus mykiss	LC_{50} > 100000	> 1000	0.4189	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.4189	<0.1

Test substance	Test species	Endpoint [µg a.s. or formulation/L]	$RAC_{sw;\ ac}$ (LC_{50}/100)	$PEC_{sw,\ max}$ [µg/L]	PEC/RAC
Grass (spring), 1 × 45 g a.s./ha					
Amidosulfuron WG 75	Fish, acute *Oncorhynchus mykiss*	LC_{50} 150000	1500	0.554	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 187000	1870	0.554	<0.1
Amidosulfuron	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	1.3925	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	1.5925	<0.1
Amidosulfuron -desmethyl	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	0.8200	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} > 55000	> 550	0.8200	<0.1
Amidosulfuron -desmethyl-chloro-pyrimidine	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	0.1775	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.1775	<0.1
Amidosulfuron -guanidine	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	0.6687	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.6687	<0.1
Amidosulfuron -biuret	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	0.1844	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.1844	<0.1
Amidosulfuron -ADMP	Fish, acute *Oncorhynchus mykiss*	LC_{50} 169200	1692	0.0751	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 223000	2230	0.0751	<0.1
Amido-sulfuron-Guanidinocarbonyl sulfamic acid	Fish, acute Oncorhynchus mykiss	LC_{50} > 100000	> 1000	0.1926	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.1926	<0.1

Test substance	Test species	Endpoint [µg a.s. or formulation/L]	$RAC_{sw;\ ac}$ (LC_{50}/100)	$PEC_{sw,\ max}$ [µg/L]	PEC/RAC
Grass (autumn), 1 × 45 g a.s./ha					
Amidosulfuron WG 75	Fish, acute *Oncorhynchus mykiss*	LC_{50} 150000	1500	0.554	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 187000	1870	0.554	<0.1
Amidosulfuron	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	1.8944	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	1.8944	<0.1
Amidosulfuron -desmethyl	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	1.0100	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} > 55000	> 550	1.0100	<0.1
Amidosulfuron -desmethyl-chloro-pyrimidine	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	0.2219	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.2219	<0.1
Amidosulfuron -guanidine	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	0.8202	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.8202	<0.1
Amidosulfuron -biuret	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 100000	> 1000	0.2229	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.2229	<0.1
Amidosulfuron -ADMP	Fish, acute *Oncorhynchus mykiss*	LC_{50} 169200	1692	0.0924	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 223000	2230	0.0924	<0.1
Amido-sulfuron-Guanidinocarbonyl sulfamic acid	Fish, acute Oncorhynchus mykiss	LC_{50} > 100000	> 1000	0.2290	<0.1
	Invertebrate, acute *Daphnia magna*	EC_{50} 36000	360	0.2290	<0.1

The quotient is always below 1 for all evaluated scenarios. Consequently, a safe use can be assumed according to the proposed GAP.

CHRONIC RISK ASSESSMENT FOR AQUATIC ORGANISMS

Table CP 10.2- 9: RAC_{SW}; exposure calculations based on drift entry for the formulation and on FOCUS Step 2 for amidosulfuron and its metabolites

Test substance	Test species	Endpoint [µg a.s. or formulation /L]		$RAC_{SW;\ LT}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{SW,\ max}$ [µg/L]	PEC/RAC
Winter cereals, 1 × 30 g a.s./ha						
Amidosulfuron WG 75	Fish, chronic *Oncorhynchus mykiss*	NOEC	10000	1000	0.369	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC NOEC	32000[8] 1300[9]	3200 130	0.369	<0.1 <0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	122000	12200	0.369	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	10	1	0.369	0.4
Amidosulfuron	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	2.8325	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	2.8325	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	2.8325	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	9.2	0.92	2.8325	**3.1**
Amidosulfuron -desmethyl	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	1.6614	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	1.6614	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	>1000000	>100000	1.6614	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	920	92	1.6614	<0.1
Amidosulfuron -desmethyl-	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.3786	<0.1

8 Observed NOEC from the study with formulated product

9 Calculated mixture toxicity based on the active substance endpoint and its amount in the formulated product

Test substance	Test species	Endpoint [µg a.s. or formulation /L]		$RAC_{SW;\ LT}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{SW,\ max}$ [µg/L]	PEC/RAC
chloro-pyrimidine	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.3786	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.3786	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>100000	>10000	0.3786	<0.1
Amidosulfuron-guanidine	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	1.3348	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	1.3348	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	1.3348	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>100000	>10000	1.3348	<0.1
Amidosulfuron-biuret	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.3488	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.3488	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.3488	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>10000	>1000	0.3488	<0.1
Amidosulfuron-ADMP	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.1516	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.1516	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	>560000	>56000	0.1516	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>100000	>10000	0.1516	<0.1
Amido-sulfuron-	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.3415	<0.1

Test substance	Test species	Endpoint [µg a.s. or formulation /L]		$RAC_{SW;\ LT}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{SW,\ max}$ [µg/L]	PEC/RAC
Guanidinocarbonyl sulfamic acid	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.3415	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.3415	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	9.2	0.92	0.3415	0.4
Winter cereals, 1 × 15 g a.s./ha						
Amidosulfuron WG 75	Fish, chronic *Oncorhynchus mykiss*	NOEC	10000	1000	0.185	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC[10] NOEC[11]	32000 1300	3200 130	0.185	<0.1 <0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	122000	12200	0.185	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	10	1	0.185	0.2
Amidosulfuron	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	1.7382	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	1.7382	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	1.7382	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	9.2	0.92	1.7382	**1.9**
Amidosulfuron -desmethyl	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	1.0334	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	1.0334	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	>1000000	>100000	1.0334	<0.1

10 Observed NOEC from the study with formulated product

11 Calculated mixture toxicity based on the active substance endpoint and its amount in the formulated product

Test substance	Test species	Endpoint [µg a.s. or formulation /L]		$RAC_{SW; LT}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{SW, max}$ [µg/L]	PEC/RAC
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	920	92	1.0334	<0.1
Amidosulfuron -desmethyl-chloro-pyrimidine	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.2366	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.2366	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.2366	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>100000	>10000	0.2366	<0.1
Amidosulfuron -guanidine	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.8290	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.8290	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.8290	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>100000	>10000	0.8290	<0.1
Amidosulfuron -biuret	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.2155	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.2155	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.2155	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>10000	>1000	0.2155	<0.1
Amidosulfuron -ADMP	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.0943	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.0943	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	>560000	>56000	0.0943	<0.1

Test substance	Test species	Endpoint [µg a.s. or formulation /L]		$RAC_{SW;\ LT}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{SW,\ max}$ [µg/L]	PEC/RAC
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>100000	>10000	0.0943	<0.1
Amido-sulfuron-Guanidinocarbonyl sulfamic acid	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.2095	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.2095	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.2095	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	9.2	0.92	0.2095	0.2
Spring cereals & Flax, 1 × 30 g a.s./ha						
Amidosulfuron WG 75	Fish, chronic *Oncorhynchus mykiss*	NOEC	10000	1000	0.369	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC NOEC	32000[12] 1300[13]	3200 130	0.369	<0.1 <0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	122000	12200	0.369	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	10	1	0.369	0.4
Amidosulfuron	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	3.4764	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	3.4764	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	3.4764	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	9.2	0.92	3.4764	**3.8**
Amidosulfuron -desmethyl	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	2.0667	<0.1

12 Observed NOEC from the study with formulated product

13 Calculated mixture toxicity based on the active substance endpoint and its amount in the formulated product

Test substance	Test species	Endpoint [µg a.s. or formulation /L]		$RAC_{SW;\ LT}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{SW,\ max}$ [µg/L]	PEC/RAC
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	2.0667	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	>1000000	>100000	2.0667	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	920	92	2.0667	<0.1
Amidosulfuron -desmethyl-chloro-pyrimidine	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.4733	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.4733	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.4733	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>100000	>10000	0.4733	<0.1
Amidosulfuron -guanidine	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	1.6581	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	1.6581	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	1.6581	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>100000	>10000	1.6581	<0.1
Amidosulfuron -biuret	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.4310	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.4310	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.4310	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>10000	>1000	0.4310	<0.1
Amidosulfuron -ADMP	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.1885	<0.1

Test substance	Test species	Endpoint [µg a.s. or formulation /L]		$RAC_{SW;\ LT}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{SW,\ max}$ [µg/L]	PEC/RAC
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.1885	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	>560000	>56000	0.1885	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>100000	>10000	0.1885	<0.1
Amido-sulfuron-Guanidinocarbonyl sulfamic acid	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.4189	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.4189	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.4189	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	92	9.2	0.4189	0.5
Grass (spring), 1 × 45 g a.s./ha						
Amidosulfuron WG 75	Fish, chronic *Oncorhynchus mykiss*	NOEC	10000	1000	0.554	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC[14] NOEC[15]	32000 1300	3200 130	0.554	<0.1 <0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	122000	12200	0.554	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	10	1	0.554	0.6
Amidosulfuron	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	1.5925	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	1.5925	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	1.5925	<0.1

14 Observed NOEC from the study with formulated product

15 Calculated mixture toxicity based on the active substance endpoint and its amount in the formulated product

Test substance	Test species	Endpoint [µg a.s. or formulation /L]		$RAC_{SW;\ LT}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{SW,\ max}$ [µg/L]	PEC/RAC
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	9.2	0.92	1.5925	**1.7**
Amidosulfuron -desmethyl	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.8200	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.8200	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	>1000000	>100000	0.8200	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	920	92	0.8200	<0.1
Amidosulfuron -desmethyl-chloro-pyrimidine	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.1775	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.1775	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.1775	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>100000	>10000	0.1775	<0.1
Amidosulfuron -guanidine	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.6687	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.6687	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.6687	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>100000	>10000	0.6687	<0.1
Amidosulfuron -biuret	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.1844	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.1844	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.1844	<0.1

Test substance	Test species	Endpoint [µg a.s. or formulation /L]		RAC$_{SW; LT}$ (NOEC/10) (E_rC_{50}/10)	PEC$_{SW, max}$ [µg/L]	PEC/RAC
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>10000	>1000	0.1844	<0.1
Amidosulfuron -ADMP	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.0751	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.0751	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	>560000	>56000	0.0751	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>100000	10000	0.0751	<0.1
Amido-sulfuron-Guanidinocarbonyl sulfamic acid	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.1926	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.1926	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.1926	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	9.2	0.92	0.1926	0.2
Grass (autumn), 1 × 45 g a.s./ha						
Amidosulfuron WG 75	Fish, chronic *Oncorhynchus mykiss*	NOEC	10000	1000	0.554	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC NOEC	32000[16] 1300[17]	3200 130	0.554	<0.1 <0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	122000	12200	0.554	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	10	1	0.554	0.6
Amidosulfuron	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	1.8944	<0.1

16 Observed NOEC from the study with formulated product

17 Calculated mixture toxicity based on the active substance endpoint and its amount in the formulated product

Test substance	Test species	Endpoint [µg a.s. or formulation /L]		$RAC_{SW;\ LT}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{SW,\ max}$ [µg/L]	PEC/RAC
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	1.8944	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	1.8944	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	9.2	0.92	1.8944	**2.1**
Amidosulfuron -desmethyl	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	1.0100	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	1.0100	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	>1000000	>100000	1.0100	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	920	92	1.0100	<0.1
Amidosulfuron -desmethyl-chloro-pyrimidine	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.2219	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.2219	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.2219	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>100000	>10000	0.2219	<0.1
Amidosulfuron -guanidine	Fish, chronic *Oncorhynchus mykiss*	NOEC	9720	972	0.8202	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC	1000	100	0.8202	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50}	145000	14500	0.8202	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50}	>100000	>10000	0.8202	<0.1

Test substance	Test species	Endpoint [µg a.s. or formulation /L]	$RAC_{SW;\ LT}$ (NOEC/10) (E_rC_{50}/10)	$PEC_{SW,\ max}$ [µg/L]	PEC/RAC
Amidosulfuron -biuret	Fish, chronic *Oncorhynchus mykiss*	NOEC 9720	972	0.2229	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC 1000	100	0.2229	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50} 145000	14500	0.2229	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50} >10000	>1000	0.2229	<0.1
Amidosulfuron -ADMP	Fish, chronic *Oncorhynchus mykiss*	NOEC 9720	972	0.0924	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC 1000	100	0.0924	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50} >560000	>56000	0.0924	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50} >100000	>10000	0.0924	<0.1
Amido-sulfuron-Guanidinocarbonyl sulfamic acid	Fish, chronic *Oncorhynchus mykiss*	NOEC 9720	972	0.2290	<0.1
	Invertebrate, chronic *Daphnia magna*	NOEC 1000	100	0.2290	<0.1
	Green algae, chronic *Scenedesmus subspicatus*	E_rC_{50} 145000	14500	0.2290	<0.1
	Aquatic plants, chronic *Lemna gibba*	E_rC_{50} 9.2	0.92	0.2290	0.2

The risk quotient is below 1 in the evaluations for all intended uses and organism types other than aquatic plants. For the latter, only the parent substance amidosulfuron leads to trigger exceedances.

Therefore, a refined risk assessment is required specifically for active substance amidosulfuron and aquatic plants. Such assessment, conducted via the consideration of the more realistic FOCUS STEP 3 surface water concentrations, is presented below.

Table CP 10.2- 10: RAC_{SW}; exposure calculations based on FOCUS Step 3

Species	Endpoint [µg/L]	$RAC_{SW;\ LT}$ (E_rC_{50}/10)	$PEC_{SW,max}$ [µg/L]	FOCUS scenario	PEC/RAC
Amidosulfuron, winter cereals, 1 × 30 g a.s./ha					
Aquatic plants, chronic *Lemna gibba*	E_rC_{50} 9.2	0.92	0.2653	D1 (ditch)	0.3
			0.2499	D1 (stream)	0.3
			4.1960	D2 (ditch)	**4.6**
			2.6770	D2 (stream)	**2.9**
			0.1916	D3 (ditch)	0.2
			0.0172	D4 (pond)	0.0
			0.1481	D4 (stream)	0.2
			0.0080	D5 (pond)	0.0
			0.1509	D5 (stream)	0.2
			0.1939	D6 (ditch)	0.2
			0.0079	R1 (pond)	0.0
			0.2550	R1 (stream)	0.3
			0.5171	R3 (stream)	0.6
			0.3395	R4 (stream)	0.4
Amidosulfuron, winter cereals, 1 × 15 g a.s./ha					
Aquatic plants, chronic *Lemna gibba*	E_rC_{50} 9.2	0.92	0.1321	D1 (ditch)	0.1
			0.1035	D1 (stream)	0.1
			2.0940	D2 (ditch)	**2.3**
			1.3370	D2 (stream)	**1.5**
			0.0957	D3 (ditch)	0.1
			0.0054	D4 (pond)	0.0
			0.0738	D4 (stream)	0.1
			0.0040	D5 (pond)	0.0
			0.0753	D5 (stream)	0.1
			0.0970	D6 (ditch)	0.1
			0.0040	R1 (pond)	0.0
			0.1270	R1 (stream)	0.1
			0.2601	R3 (stream)	0.3
			0.1712	R4 (stream)	0.2

Species	Endpoint [µg/L]	$RAC_{SW;\ LT}$ (E_rC_{50}/10)	$PEC_{SW,max}$ [µg/L]	FOCUS scenario	PEC/RAC
Amidosulfuron, spring cereals & Flax, 1 × 30 g a.s./ha					
Aquatic plants, chronic *Lemna gibba*	E_rC_{50} 9.2	0.92	0.2973	D1 (Ditch)	0.3
			0.1953	D1 (Stream)	0.2
			0.1927	D3 (Ditch)	0.2
			0.0113	D4 (Pond)	0.0
			0.1486	D4 (Stream)	0.2
			0.0077	D5 (Pond)	0.0
			0.1513	D5 (Stream)	0.2
			0.1252	R4 (Stream)	0.1
Amidosulfuron, grass (spring), 1 × 45 g a.s./ha					
Aquatic plants, chronic *Lemna gibba*	E_rC_{50} 9.2	0.92	0.3072	D1 (Ditch)	0.3
			0.2524	D1 (Stream)	0.3
			13.090	D2 (Ditch)	**14.2**
			8.7960	D2 (Stream)	**9.6**
			0.2872	D3 (Ditch)	0.3
			0.0105	D4 (Pond)	0.0
			0.2201	D4 (Stream)	0.2
			0.0112	D5 (Pond)	0.0
			0.2359	D5 (Stream)	0.3
			0.2461	R2 (Stream)	0.3
			0.2659	R3 (Stream)	0.3

Species	Endpoint [µg/L]	$RAC_{SW;\ LT}$ (E_rC_{50}/10)	$PEC_{SW,max}$ [µg/L]	FOCUS scenario	PEC/RAC
Amidosulfuron, grass (autumn), 1 × 45 g a.s./ha					
Aquatic plants, chronic *Lemna gibba*	E_rC_{50} 9.2	0.92	0.7153	D1 (Ditch)	0.8
			0.4647	D1 (Stream)	0.5
			11.670	D2 (Ditch)	**12.7**
			8.5990	D2 (Stream)	**9.3**
			0.2941	D3 (Ditch)	0.3
			0.0224	D4 (Pond)	0.0
			0.2460	D4 (Stream)	0.3
			0.2222	D5 (Pond)	0.2
			0.2661	D5 (Stream)	0.3
			0.3120	R2 (Stream)	0.3
			0.2630	R3 (Stream)	0.3

Bold values: trigger is not met and further refinement is required

The refined risk assessment of amidosulfuron for all intended use situations passes all FOCUS Step 3 scenarios, except D2. Since the PEC values simulated for scenario D2 are driven by the entry route drainage, mitigation options as implemented in FOCUS Step 4 (e.g. drift buffer zones, vegetated filter strips) would not reduce the aquatic exposure to amidosulfuron for this particular scenario situation. Therefore, no further risk assessment based on FOCUS Step 4 calculations is presented. In the MSs concerned with the D2 scenario, this situation will be addressed in the national dossiers to be submitted in the post Approval re-registration process.

CP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Report: KCP 10.2.1/01 [redacted]C; 1989; M-125130-01-1
Title: Hoe 075032 water dispersible granule (Hoe 075032 00 WG75 A103) Effect to Cyprinus carpio (Mirror carp) in a Static-Acute Toxicity Test (method OECD)
Report No.: A42091
Document No.: M-125130-01-1
Guideline(s): OECD 203, (1984)
Guideline deviation(s): --
GLP/GEP: yes

The study reports on an acute oral toxicity test for mirror carp on the formulated product. No dead individuals were observed in the control and in the test concentrations up to 320 mg/L. 90 % and 100 % of the fish died at the treatment levels of 560 mg/L and 1000 mg/L. The 96 h LC_{50} was reported to be 449 mg product/L.

Although the fish used for testing were slightly larger than recommended by OECD guideline 203, the study was accepted in the EU review for the first inclusion of amidosulfuron on Annex I. A study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test, since a lower endpoint resulted from the corresponding study on rainbow trout, KCP 10.2.1/02.

Report:	KCP 10.2.1/02[redacted]; 1989; M-125129-01-1
Title:	Hoe 075032 - water dispersible granule (Hoe 075032 00 WG75 A103) Effect to Salmo gairdneri (Rainbow trout) in a Static-Acute Toxicity Test (method OECD)
Report No.:	A42090
Document No.:	M-125129-01-1
Guideline(s):	OECD: 203 (1984)
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on an acute oral toxicity test for rainbow trout on the formulated product. No dead individuals were observed in the control and in the test concentrations up to 100 mg/L. 80 % of the animals were found dead at a concentration of 180 mg/L and 100 % of the fish died at the treatment levels of 320 mg/L - 1000 mg/L. The 96 h LC_{50} was reported to be 150 mg product/L.

The study was evaluated in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

The study was considered to be acceptable. An EU agreed formulation endpoints, expressed on pure active substance equivalent basis, of LC_{50} = 113.9 mg a.s./L for *Oncorhynchus mykiss* was derived based on this test.
It is to be noted that aquatic exposure for the present product is clearly driven by the entry routes drainage (maximum PEC values observed for scenarios D1, D2 ditch/stream), and runoff (maximum PEC values for scenarios R3 and R4 stream). Both of these predominant entry routes are indirect paths to surface water, via secondary movements of a deposit from infiltrated soil to water bodies, they will therefore not lead to an actual exposure of the aquatic environment to the intact formulated product. When in soil contact, the formulation will be disintegrated via dilution in the pore water, differential adsorption and retention of its components by soil particles, and biological degradation of its coformulants. The endpoint most relevant for risk assessment therefore is considered to originate from the corresponding studies on pure active substance, KCA 8.2.1 /01...04.

Report:	KCP 10.2.1/03[redacted]B; 1989; M-125182-01-1
Title:	Hoe 075032 - water dispersible granule (Hoe 075032 00 WG75 A103) Effect to Daphnia magna (Waterflea) in a Static-Acute Toxicity Test (method OECD)
Report No.:	A42147
Document No.:	M-125182-01-1
Guideline(s):	OECD: 202 (1984)
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a static-acute toxicity test for *Daphnia magna* on the formulated product. No mortality was observed in concentrations up to 100 mg/L and in the control. 30 % and 100 % of animals died within 24 hours in test concentrations of 320 mg/L and higher. After 48 hours 45 % of the animals exposed to 180 mg/L were immobile and all animals were found dead at concentrations of 320 mg/L and higher. The 48 h EC_{50} was reported to be 187 mg product/L, the 48 h NOEC was 100 mg product/L.

The study was evaluated in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

The study was considered to be acceptable. An EU agreed formulation endpoint, expressed on pure active substance equivalent basis, of LC_{50} = 141.9 mg a.s./L for *Daphnia magna* was derived based on this test.
It is to be noted that aquatic exposure for the present product is clearly driven by the entry routes drainage (maximum PEC values were observed for scenarios D1, D2 ditch/stream), and runoff (maximum PEC values for scenarios R3 and R4 stream). Both of these predominant entry routes are indirect paths to surface water, via secondary movements of a deposit from infiltrated soil to water bodies, they will therefore not lead to an actual exposure of the aquatic environment to the intact formulated product. When in soil contact, the formulation will be disintegrated via dilution in the pore water, differential adsorption and retention of its components by soil particles, and biological degradation of its coformulants. The endpoint most relevant for risk assessment therefore is considered to originate from the corresponding study on pure active substance, KCA 8.2.4 /02.

Report:	KCP 10.2.1/04 [redacted]; 1991; M-129467-01-1
Title:	Hoe 075032 - water dispersible granule 75% (Hoe 075032 00 WG75 0104) Effect to Scenedesmus subspicatus (Green alga) in a Growth Inhibition Test (method OECD)
Report No.:	A45325
Document No.:	M-129467-01-1
Guideline(s):	OECD: 201 (1984)
Guideline deviation(s):	--
GLP/GEP:	**yes**

Report:	KCP 10.2.1/06 [redacted] 2016; M-549414-01-1
Title:	Validity check for amidosulfuron 75 WG study on Desmodesmus subspicatus (M-129467-01-1, [redacted], 1991)
Report No.:	M-549414-01-1
Document No.:	M-549414-01-1
Guideline(s):	none
Guideline deviation(s):	none
GLP/GEP:	**no**

The study reports on a static 72-hour growth inhibition test for *Scenedesmus subspicatus* on the formulated product.

The study was performed in 3 steps. The first definitive test was conducted without pH adjustment with concentrations ranging from 10 to 320 mg/L.

As pH decreased in the first test and no NOEC was reached, the second test included 2 lower concentrations (from 3.2 to 320 mg/L) and pH was adjusted to 7.6 (except for 3.2 and 5.6 mg/L).

This concentration range did not allow to reach the NOEC.

Consequently, the third test was performed with concentrations ranging from 0.56 to 1.8 mg/L.

The 72 h E_bC_{50}/E_rC_{50} values were calculated by approximate EC_{50} and binomial test to be 33.8 (95 % confidence limits 32 – 56 mg/L) and 122 mg/L (95 % confidence limits 100 – 180 mg/l) for the concentrations tested without pH adjustment. The 72 h E_bC_{50}/E_rC_{50} values for the test concentrations with pH adjustment were calculated as 39.2 mg/L (95 % confidence limits 32 – 56 mg/L) and 157 mg/L (95 % confidence limits 100 – 180 mg/L). The 72 h NOEC was assessed as 1.8 mg/L (without pH adjustment).

The validity criteria of the new version of the OECD guideline 201 (July 2011) have been checked for this study on the 3 consecutive tests:

	Test 1	Test 2	Test 3	Criteria
Biomass increase in control	Factor 117	Factor 114	Factor 117	Factor > 16
Mean coefficient of variation for section-by-section specific growth rates in control	14.6%	19.8%	24.6%	35%
Coefficient of variation of average specific growth rates during the whole test period in control	4.1%	1.8%	2.0%	7%

All 3 criteria were met, the study is considered to be valid (M-549414-01-1).

The study was evaluated in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006). The study was considered to be acceptable. An EU agreed formulation endpoint, expressed on pure active substance equivalent basis, of E_bC_{50} = 25.8 mg a.s./L and E_rC_{50} = 93 mg a.s./L for *Scenedesmus subspicatus* were derived based on this test.

It is to be noted that aquatic exposure for the present product is clearly driven by the entry routes drainage (maximum PEC values were observed for scenarios D1, D2 ditch/stream), and runoff (maximum PEC values for scenarios R3 and R4 stream). Both of these predominant entry routes are indirect paths to surface water, via secondary movements of a deposit from infiltrated soil to water bodies, they will therefore not lead to an actual exposure of the aquatic environment to the intact formulated product. When in soil contact, the formulation will be disintegrated via dilution in the pore water, differential adsorption and retention of its components by soil particles, and biological degradation of its coformulants. The endpoint most relevant for risk assessment therefore is considered to originate from the corresponsding study on pure active substance, KCA 8.2.6.1 /01.

Report: KCP 10.2.1/05 [redacted]; 2003; M-231187-01-1
Title: Influence of amidosulfuron WG75 on the growth of Lemna gibba G3 in a static test
Code: AE F093032 00 WG75 A112
Report No.: C032295
Document No.: M-231187-01-1
Guideline(s): OECD: 221
Guideline deviation(s): none
GLP/GEP: **yes**

The study reports on a growth inhibition test for *Lemna gibba* on the formulated product. The frond numbers in the control reached an average of 184 fronds after 7 days corresponding to a doubling time of 1.8 days. Chlorosis, smaller fronds and inhibited separation of daughter plants were observed at a concentration of 2.96 µg formulation/L and above. No significant effects on growth (growth rates based on frond counts, log area under the growth curve and dry weights) were observed up to a test substance concentration of 2.96 µg/L. A 7-d E_bC_{50} = 10.1 µg/L, a E_rC_{50} = 10 µg/L, 7-d NOEC (visual effects) = 0.98 µg/L and a 7-d NOEC (growth) = 2.96 µg/L were reported.

The study was evaluated in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

The study was considered to be acceptable. EU agreed formulation endpoints, expressed on pure active substance equivalent basis, of E_bC_{50} = 0.00773 mg a.s./L and E_rC_{50} = 0.00765 mg a.s./L for *Lemna gibba* were derived based on this test.

It is to be noted that aquatic exposure for the present product is clearly driven by the entry routes drainage (maximum PEC values were observed for scenarios D1, D2 ditch/stream), and runoff

(maximum PEC values for scenarios R3 and R4 stream). Both of these predominant entry routes are indirect paths to surface water, via secondary movements of a deposit from infiltrated soil to water bodies, they will therefore not lead to an actual exposure of the aquatic environment to the intact formulated product. When in soil contact, the formulation will be disintegrated via dilution in the pore water, differential adsorption and retention of its components by soil particles, and biological degradation of its coformulants. Endpoint most relevant for risk assessment therefore is considered to originate from the corresponding study on pure active substance, KCA 8.2.7 /02.

CP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Report:	KCP 10.2.2/01 [redacted]; 1989; M-125111-01-1
Title:	Hoe 075032 - water dispersible granule (Hoe 075032 00 WG 75 A100) Effects to Salmo gairdneri (Rainbow trout) in a 21-day Prolonged Toxicity Test (method OECD)
Report No.:	A42066
Document No.:	M-125111-01-1
Guideline(s):	OECD: 204 (1984)
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a flow-through 21-day prolonged toxicity test for rainbow trout on the formulated product. Some fish showed slow reactions and swimming at the water surface and reduced uptake of feed at a concentration of 5 mg/L and above. No intoxication symptoms were observed up to a concentration of 1 mg/L. The growth was significantly reduced at a concentration level of 50 mg/L. Dead fish were observed at the highest test concentration of 50 mg/L only. A 21-d LC_{50} = 30.1 mg/L, a 21-d NOEC (growth) = 10 mg/L (= 7.59 mg a.s./L) and a 21-d NOEC (intoxication symptoms) = 1 mg/L (= 0.759 mg a.s./L) were reported.

The study was evaluated in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

The OECD Guideline 203 suggests an upper limit for the total water hardness of 250 mg $CaCO_3$. This limit was clearly exceeded and could have potentially influenced the test results. Nevertheless, the study was considered to be acceptable because amidosulfuron is of low acute toxicity to fish and the results of the chronic study with the unformulated a.s. suggest that the results of the chronic study with the formulated product are plausible. An EU agreed formulation endpoint, expressed on pure active substance equivalent basis, of NOEC (growth) = 7.59 mg a.s./L for *Oncorhynchus mykiss* was derived based on this test.

It is to be noted that aquatic exposure for the present product is clearly driven by the entry routes drainage (maximum PEC values were observed for scenarios D1, D2 ditch/stream), and runoff (maximum PEC values for scenarios R3 and R4 stream). Both of these predominant entry routes are indirect paths to surface water, via secondary movements of a deposit from infiltrated soil to water bodies, they will therefore not lead to an actual exposure of the aquatic environment to the intact formulated product. When in soil contact, the formulation will be disintegrated via dilution in the pore water, differential adsorption and retention of its components by soil particles, and biological degradation of its coformulants. The endpoint most relevant for risk assessment therefore is considered to originate from the corresponding study on pure active substance, KCA 8.2.2 /01.

Report:	KCP 10.2.2/02[redacted]B; 1989; M-125137-01-1
Title:	Hoe 075032 - water dispersible granule (Hoe 075032 00 WG75 A103) Effect to Daphnia magna (Waterflea) in a 21-day Reproduction Test (method OECD)
Report No.:	A42100
Document No.:	M-125137-01-1
Guideline(s):	OECD: 202 (1984)
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a static renewal 21-day reproduction test for *Daphnia magna* on the formulated product. The mortality was not statistically different from the control. A reduced reproduction rate was found at a concentration of 10 mg/L on day 12. At day 16 this was compensated by a higher reproduction rate on day 16 and no significant difference was evident for this treatment level at the end of test. After 21 days a significant effect on the reproduction rate was observed at the highest treatment level only. A 21-d NOEC (reproduction) = 32 mg/L (= 24.3 mg a.s./L) was reported.

The study was evaluated in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

The study was considered to be acceptable. However, no EU agreed endpoint was derived from this test.
It is to be noted that aquatic exposure for the present product is clearly driven by the entry routes drainage (maximum PEC values were observed for scenarios D1, D2 ditch/stream), and runoff (maximum PEC values for scenarios R3 and R4 stream). Both of these predominant entry routes are indirect paths to surface water, via secondary movements of a deposit from infiltrated soil to water bodies, they will therefore not lead to an actual exposure of the aquatic environment to the intact formulated product. When in soil contact, the formulation will be disintegrated via dilution in the pore water, differential adsorption and retention of its components by soil particles, and biological degradation of its coformulants. Endpoint most relevant for risk assessment therefore is considered to originate from the corresponding study on pure active substance, KCA 8.2.5.1 /01.

CP 10.2.3 Further testing on aquatic organisms

Further data on the formulation are not required under Commission Regulation (EU) No 284/2013 in accordance with Regulation (EC) No 1107/2009.

CP 10.3 Effects on arthropods

CP 10.3.1 Effects on bees

The risk assessment has been performed according to the existing guidance in force at the time of the preparation and submission of this dossier namely the EU Guidance Document on Terrestrial Ecotoxicology (SANCO/ 10329/2002 rev 2) and EPPO Standard PP 3/10 (3) Environmental Risk Assessment Scheme for Plant Protection Products - Chapter 10: honey bees.

Commission Regulations (EU) 283/2013 and 284/2013 require where bees are likely to be exposed, testing by both acute (oral and contact) and chronic toxicity, including sub-lethal effects, to be conducted. Consequently in addition to the standard toxicity studies performed with adult bees (OECD 213 and 214) the following additional studies are also provided:

- Acute oral and contact toxicity of amidosulfuron and the representative formulation Amidosulfuron WG 75,

- Acute oral and contact toxicity of amidosulfuron to adult bumble bees under laboratory conditions,
- Chronic 10 day toxicity test with of Amidosulfuron WG 75 on adult bees under laboratory conditions,
- Colony feeding study with Amidosulfuron WG 75 according to [redacted] *et al.* 1992 (using a realistic worse case spray solution concentration and covering exposure for effects on brood (eggs, young and old larvae) and their development,
- Semi-field brood feeding study with Amidosulfuron WG 75 following OECD GD 75 (using a more realistic spray scenario onto flowering *Phacelia tanacetifolia* at the maximum application rate for the approval renewal of amidosulfuron and covering exposure for effects on brood (eggs) and their development and colony parameters).

Details of the honey bee testing with amidosulfuron are presented together with the ecotoxicological endpoints in Document MCA 8, point 8.3.1, as well as within the existing Draft Assessment Report (DAR) and the updated EU List of Endpoints of December 2010. Furthermore, oral and contact laboratory toxicity data for bumble bees indicated that non-*Apis* bees are not more sensitive than honey bees and consequently the risk assessment for honey bees is considered to be protective to other bees.

An acute oral laboratory study with Amidosulfuron WG 75 ([redacted]; 1991; M-135739-01-2, KCP 10.3.1.1.1 /01) had been already available but was described and rated as invalid due to deficiencies in the test design (missing toxic standard) in the EU review for the first inclusion of amidosulfuron on Annex I. Furthermore, several laboratory studies had been available in the DAR, which however followed outdated test guidelines or had been performed following test designs that are no longer applicable today and in consequence do not meet current validity criteria and/or data requirements (i.e. contact exposure via filter paper or via direct overspray). Therefore, all these studies which are either invalid and not performed according to state-of-the-art methods are presented in the following table for reasons of completeness but are consequently superseded in the approval renewal process by a new guideline-conform state-of-the-art acute oral and contact toxicity test on honey bees ([redacted]; 2011; M-403727-01-1, KCP 10.3.1.1.1 /04 and KCP 10.3.1.1.2 /07) that was performed with Amidosulfuron WG 75.

A summary of the critical endpoints for amidosulfuron and the formulated product Amidosulfuron WG 75 are provided in the following table. Endpoints shown in bold are considered relevant for risk assessment.

Table CP 10.3.1- 1: Endpoints of the active substance amidosulfuron (techn. and representative formulation Amidosulfuron WG 75)

Test substance	Test organism	Study type	Endpoint	Reference
Acute toxicity to honey bees				
Amidosulfuron, tech.	*Apis mellifera*	oral, 48 h	LD_{50} > 916.4 µg a.s./bee [1]	[redacted]; 1989; M-124106-01-1 KCA 8.3.1.1.1 /01
		oral, 48 h	LD_{50} **> 109.2 µg a.s./bee**	[redacted]; 2014; M-503119-01-1 KCA 8.3.1.1.1 /02 KCA 8.3.1.1.2 /02
		contact, 48 h	LD_{50} **> 100 µg a.s./bee**	
		contact, 48 h	LD_{50} > 100 µg a.s./bee [2]	[redacted]; 1989; M-124103-01-1 KCA 8.3.1.1.2 /01
Amidosulfuron WG 75	*Apis mellifera*	oral, 48 h	LD_{50} > 106.6 µg a.s./bee	[redacted]; 2011; M-403727-01-1 KCP 10.3.1.1.1 /04 KCP 10.3.1.1.2 /07
		contact, 48 h	LD_{50} > 100 µg a.s./bee	
		oral, 48 h	LD_{50} > 200 µg a.s./bee [3]	[redacted]; 1991; M-135739-01-2 KCP 10.3.1.1.1 /01
		oral [2] [4], 72 h	LD_{50} > 100 µg prod./bee = > 95 µg a.s./bee	[redacted]; 1992; M-130984-01-1 KCP 10.3.1.1.1 /02 KCP 10.3.1.1.2 /01
		contact [3] [4], 72 h	No effect of 0.04 % solution	
		oral [2] [4], 72 h	LD_{50} > 135 µg prod./bee > 101 µg a.s./bee	[redacted] 1991; M-130976-01-2 KCP 10.3.1.1.1 /03 KCP 10.3.1.1.2 /03
		contact [3] [5], 72 h	No effect of 0.04 % solution	
		contact [3], 72 h	No effect of 0.04 % solution	[redacted] 1991; M-130728-01-2 KCP 10.3.1.1.2 /04
		contact [5], 72 h	No effect of 0.04 % solution	[redacted] 1991; M-130674-01-2 KCP 10.3.1.1.2 /02
Acute toxicity to bumble bees				
Amidosulfuron, tech.	*Bombus terrestris*	oral, 48 h	LD_{50} > 203 µg a.s./bee	[redacted]; 2016; M-545712-01-1 KCA 8.3.1.1.1 /03
		contact, 48 h	LD_{50} > 100 µg a.s./bee	[redacted]; 2015; M-525139-01-1 KCA 8.3.1.1.2 /03
Chronic toxicity to adult honey bees				
Amidosulfuron WG 75	*Apis mellifera*	10 d adult feeding study	LC_{50} > 3333 mg a.s./kg LDD_{50} > 78.4 µg a.s./bee/d	[redacted]; 2016; M-549770-01-1 KCA 8.3.1.2 /01 KCP 10.3.1.2/01

Test substance	Test organism	Study type	Endpoint	Reference
Honey bee brood feeding study				
Amidosulfuron WG 75	*Apis mellifera*	Honey bee brood feeding ([redacted] *et al*., 1992)	No adverse effects on bee mortality (adult, pupae and larvae), bee brood development (eggs, young larvae, old larvae), and behaviour, by feeding honey bee colonies sugar syrup at a concentration typically present in the spray tank (0.114 g a.s./L)	[redacted]; 2014; M-482118-01-1 KCA 8.3.1.3/01 KCP 10.3.1.3/01
Semi field honey bee brood study				
Amidosulfuron WG 75	*Apis mellifera*	Semi-field honey bee brood study (OECD No. 75; forced exposure conditions) in Phacelia; application during full-bloom and bees actively foraging	No adverse effects on mortality (adults, pupae and larvae), foraging activity, behaviour, colony condition, colony strength and bee brood development at 45 g a.s./ha	[redacted]; 2016; M-545720-01-1 KCA 8.3.1.3 /02 KCP 10.3.1.3/02

a.s. = active substance; prod. = product **Bold:** values used in risk assessment
[1)] Study not considered valid
[2)] Study performed according to outdated guideline, not an appropriate test design to derive endpoints for use in current regulatory risk assessment
[3)] Direct contact of the bees to the residues of the test substance on filter paper, not an appropriate test design to derive endpoints for use in current regulatory risk assessment
[4)] EU agreed endpoint according to the updated EU List of Endpoints from December 2010
[5)] Direct spraying of the test substance on the honey bees, not an appropriate test design to derive endpoints for use in current regulatory risk assessment

Risk assessment for bees

The risk assessment for bees is based on the maximum application rate of 1 × 30 g amidosulfuron/ha in cereals, for the maximum application rate of 1 × 30 g amidosulfuron/ha in flax and for the maximum application rate of 1 × 45 g amidosulfuron/ha in grassland.

Hazard Quotients

The risk assessment is based on Hazard Quotient approach (Q_H) by calculating the ratio between the application rate (expressed in g a.s./ha or in g total substance/ha) and the laboratory contact and oral LD_{50} (expressed in µg a.s./bee or in µg total substance/bee).

Q_H values can be calculated using data from the studies performed with the active substance and with the formulation. Q_H values higher than 50 indicate the need of higher tiered activities to clarify the actual risk to honey bees.

Hazard Quotient, oral:

$$Q_{HO} = \frac{\text{max. appl. rate}}{LD_{50}\ \text{oral}} = \frac{[\text{g a.s./ha or g total substance/ha}]}{[\mu\text{g a.s./bee or } \mu\text{g total substance/bee}]}$$

Hazard Quotient, contact: $Q_{HC} = \frac{\text{max. appl. rate}}{LD_{50}\ \text{contact}} = \frac{[\text{g a.s./ha or g total substance/ha}]}{[\mu\text{g a.s./bee or } \mu\text{g total substance/bee}]}$

Table CP 10.3.1- 2: Hazard quotients for bees – oral exposure

	Crop	LD_{50} [µg/bee]	Application rate [g/ha]	Hazard quotient Q_{HO}	Trigger
Amidosulfuron	Cereals	> 109.2	30	< 0.3	50
	Flax		30	< 0.3	50
	Grassland		45	< 0.4	50

The hazard quotients for oral exposure are below the validated trigger value for higher tier testing (i.e. $Q_{HO} < 50$). Risk to bees from oral exposure is therefore acceptable for the intended product uses.

Table CP 10.3.1- 3: Hazard quotients for bees – contact exposure

	Crop	LD_{50} [µg/bee]	Application rate [g/ha]	Hazard quotient Q_{HO}	Trigger
Amidosulfuron	Cereals	> 100	30	< 0.3	50
	Flax		30	< 0.3	50
	Grassland		45	< 0.45	50

The hazard quotients for contact exposure are below the validated trigger value for higher tier testing (i.e. $Q_{HC} < 50$). Risk to bees from contact exposure is therefore acceptable for the intended product uses.

Further considerations for the risk assessment

In addition to acute laboratory studies with adult honey bees, amidosulfuron was further subjected to acute oral toxicity ([redacted]; 2016; M-545712-01-1; in CA 8.3.1.1.1) and acute contact toxicity ([redacted]; 2015; M-525139-01-1; in CA 8.3.1.1.2) bumble bee testing. The studies resulted in an oral LD_{50} of > 203 µg a.s./bumble bee and a contact LD_{50} of > 100 µg a.s./bumble bee and did not reveal sensitivity differences between honey bee and bumble bee foragers.

Moreover, amidosulfuron (tested as Amidosulfuron WG 75) was further subjected to chronic laboratory testing with adult honey bees ([redacted]; 2016; M-549770-01-1; in CA 8.3.1.2).
This chronic study was designed as a limit test by exposing young worker bees for 10 consecutive days to a nominal concentration of 3333 mg amidosulfuron/kg feeding solution, respectively. The actual test was conducted by using the formulated product Amidosulfuron WG 75. After exposing honey bees for ten consecutive days exclusively to sugar solution containing amidosulfuron, the 10 day LC_{50} (Lethal Concentration) was determined to be > 3333 mg amidosulfuron/kg, which corresponds to a LDD_{50} (Lethal Dietary Dose) of >78.4 µg a.s./bee/day. The respective NOEC (No Observed Effect Concentration) for mortality was determined to be ≥ 3333 mg amidosulfuron/kg, which corresponds to the NOEDD (No Observed Effect Dietary Dose) of ≥ 78.4 µg a.s./bee/day.

In order to reveal whether amidosulfuron poses a risk to immature honey bee life stages, a bee brood feeding study ([redacted]; 2014; M-482118-01-1, in CA 8.3.1.1.3) has been conducted by following the provisions/method of [redacted]. (OEPP/EPPO Bulletin 22:613-616 (1992)), which require, amongst other parameters to "*...use formulated products only... products are fed at a concentration recommended for high-volume use...*". The honey bee brood feeding test is a worst-case screening test, by feeding the honey bees directly in the hive with a treated sugar solution which contains the test substance at a concentration typically present in the spray tank (and as such at a very high concentration) and by investigating the development of eggs, young and old larvae by employing digital photo imaging technology.

This particular study was conducted with Amidosulfuron WG 75. The administration of amidosulfuron at a concentration of 0.114 g a.s to honeybee colonies via feeding of 1 litre spiked sucrose solution has neither resulted in adverse effects on brood development, worker, larval or pupal mortality compared to the control. Regarding brood development, the brood termination rates of the test item treatment were overall on a low level with 21.6, 11.1 and 6.2 % for eggs, young larvae and old larvae, respectively, which were not statistically significant different to the control with brood termination rates of 17.8, 10.2 and 6.4 % for eggs, young larvae and old larvae, respectively at the end of the brood observation period.

In order to clarify whether amidosulfuron poses a risk to honey bee brood and colony development in particular as well as on honey bees in general under realistic worst-case conditions, a higher tier semi-field honey bee brood study (according to the provisions of the OECD Guidance Document 75) was conducted under forced/confined exposure conditions using the formulation Amidosulfuron WG 75, by application of 45 g a.s./ha under tunnel conditions to the full flowering and highly bee attractive surrogate crop *Phacelia tanacetifolia* ([redacted], 2016; M-545720-01-1; in CA 8.3.1.3).

The study included three treatment groups: Control (tap water), Test item (45 g a.s./ha) and Reference item (300 g fenoxycarb/ha) with all applications being carried out with a spray volume of 400 L water/ha. For all treatment groups, four replicates (tunnels) were set up. The application of all treatments was conducted during daily bee flight activity at the time of full flowering of the crop. Thereafter, the bees were kept for 3 days within the tunnels (confined exposure phase) and were then relocated out of the tunnels and transferred to a monitoring site without flowering crops and intensive agricultural area for further monitoring (day 4 to day 41 after treatment). Throughout the confined exposure phase, mortality of worker bees, larvae and pupae was assessed daily along with assessments of foraging activity and behaviour. Daily mortality assessments were continued along with behaviour around the hive during the post-exposure observation period (day 4 to day 27 after treatment). Colony assessments (food stores, brood areas, colony strength) were made one day after application, on 5 occasions after application and at the end of the study in order to cover two whole bee brood cycles. Detailed brood assessments (brood development, brood termination rate, brood index and brood compensation index) by employing digital photo imaging technology, investigating the fate of 250 individually marked cells was performed on 5 occasions throughout the study, covering an entire brood cycle of honey bees.

The application of amidosulfuron at the rate of 45 g a.s./ha under tunnel conditions to the full flowering and highly bee attractive surrogate crop *Phacelia tanacetifolia* did not cause any adverse effects on mortality of worker bees or pupae, foraging activity, behaviour, colony development, colony strength, as well as on bee brood development (brood termination rate: 47.4 %, brood index: 2.6, compensation index: 3.8 in test item compared to the control with brood termination rate: 29.7%, brood index: 3.5, compensation index: 3.9). Neither brood termination rate nor brood or compensation index were significantly different in the test item as compared to the control, indicating that these indices performed comparable to the control, including compensations of previous brood losses.

All in all, it can be concluded from the acute and chronic laboratory studies in adult honey bees as well as from the bee brood feeding study ([redacted] *et al.* and OECD Guidance Document 75) investigating side-effects on immature honey bee life stages, that amidosulfuron is of low general intrinsic toxicity to honey bees.

Synopsis

Amidosulfuron is of low acute toxicity to honey bees, with LD_{50} (oral and contact) above the highest tested dose levels.

The calculated Hazard Quotients for amidosulfuron are below the validated trigger value which would indicate the need for a refined risk assessment; no adverse effects on honey bee mortality are to be

expected at the maximum envisaged application rate. This conclusion is confirmed by the results of the bee brood feeding study as well as by the results of the bee brood semi-field study, which covered the maximum application rate of 45 g a.s./ha.

The acute laboratory studies conducted with bumble bees revealed no sensitivity differences between honey bee and bumble bee foragers.

It can be concluded from the acute and chronic laboratory studies in adult honey bees as well as from the bee brood feeding study ([redacted] *et al.*) and bee brood semi-field study (OECD 75), investigating side-effects on immature honey bee life stages that amidosulfuron is of low general intrinsic toxicity to honey bees.

Regarding potential side effects of amidosulfuron on immature honey bee life stages, the conducted bee brood feeding study ([redacted] *et al.*, 1992) found no statistically significant differences between test item and control in brood termination rates of eggs, young and old larvae at 0.114 g a.s./L. Overall the study revealed no adverse effects on the survival of adult bees and pupae. Thus, when considering the severity of the exposure situation in this worst-case screening test in combination with the absence of effects on the overall development of bee brood, it can be concluded even on the basis of this worst-case screening study that the use of amidosulfuron does not pose an unacceptable risk for adult honey bees, immature honey bee life stages and honey bee colonies.

In order to clarify whether the conclusions on the basis of lower tiered honey bee studies are correct, amidosulfuron was subjected to confined semi-field testing (according to the provisions of OECD Guidance Document No. 75), by applying the rate of 45 g a.s./ha to full flowering *Phacelia* during honey bees actively foraging on the crop. This study design is from an apidological and apicultural point of view more realistic than an in-hive feeding of the test compound via a treated sugar solution, which contains the test substance at a concentration typically present in the spray tank (and as such at a very high concentration). The results of this higher tier semi-field study confirmed the conclusions made above on the basis of the outcome of the lower-tiered studies, as no adverse direct or delayed effects on mortality of worker bees or pupae, foraging activity, behaviour, colony strength and colony development as well as the development of bee brood were observed, even under aggravated, forced exposure conditions and by digitally following-up in a very detailed manner the fate of individually marked brood cells (digital photographic assessment) from egg stage until emergence.

Conclusions
Overall, it can be concluded that amidosulfuron, when applied in cereals and flax at the maximum application rate of 30 g a.s./ha and on grassland at the maximum rate of 45 g a.s./ha, as foreseen for the use of Amidosulfuron WG 75, does not pose an unacceptable risk to honey bees and honey bee colonies.

CP 10.3.1.1 Acute toxicity to bees

CP 10.3.1.1.1 Acute oral toxicity to bees

Report:	KCP 10.3.1.1.1/01[redacted]; 1991; M-135739-01-2
Title:	Hoe 075032; water dispersible granules; 75 % (Hoe 075032 00 WG75 A104) Investigating the oral toxicity to the honey bee Apis mellifera L.
Report No.:	A51977
Document No.:	M-135739-01-2
Guideline(s):	MAFF: Working Document 7/3 (1986)
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on the acute oral LD_{50} of the formulated product AE F075032 00 WG75 A104 to be > 1400 µg a.s./bee (48 h). However due to deficiencies in the test design (missing toxic standard) this study was rated invalid in the first EU review.

In consequence, no EU agreed endpoint for acute oral toxicity was derived from this test.

For approval renewal, the study is superseded by a new guideline-conform oral acute toxicity test on honey bees for the formulation, see reported below under KCP 10.3.1.1.1 /04.

Report:	KCP 10.3.1.1.1/02 [redacted],; [redacted]; 1992; M-130984-01-1
Title:	Toxicity testing of HOE 075032 00 WG 75 A104 to honey bees (Apis mellifera L.) (Hymenoptera, Apidae) in laboratory
Report No.:	A47036
Document No.:	M-130984-01-1
Guideline(s):	BBA: Part VI, 23-1
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on toxicity tests with the formulated product AE F075032 00 WG75 A104 in four laboratory trials: exposure to vapour, to residues on treated filter paper, to direct spray treatment and oral intake of contaminated food. The study confirmed an overall low toxicity of the formulation upon inhalation and contact exposure. In the oral toxicity part, an LD_{50} > 100 µg product/bee (72 h) was concluded.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Monograph. Since the previous EU endpoint for oral acute toxicity of the formulation was based on the result of study KCP 10.3.1.1.1/03 (see below), no formal EU endpoint was based on this test. However, since the study was performed according to an outdated guideline it is superseded by a new guideline-conform study performed with the product.

Report:	KCP 10.3.1.1.1/03 [redacted],; 1991; M-130976-01-2
Title:	Investigating the side-effects of HOE 075032 00 WG75 A104 on the honey bee (Apis mellifera) in the laboratory
Report No.:	GAM515
Document No.:	M-130976-01-2
Guideline(s):	BBA: Part VI, 23-1
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on toxicity tests with the formulated product AE F075032 00 WG75 A104 in four different laboratory trials: exposure to vapour, to residues on treated filter paper, to direct spray treatment and oral intake of contaminated food. The study confirmed an overall low toxicity of the formulation upon inhalation and contact exposure. In the oral toxicity part, an LD_{50} > 135 µg product/bee (72 h) was concluded.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Monograph.

An EU agreed endpoint for oral acute LD_{50} of > 101 µg a.s./bee - expressed in units of a.s.-was derived from this test. However, this study was performed according to an outdated test guideline and is superseded by a new guideline-conform study performed with the product (see KPC 10.3.1.1.1. /04). The findings from the new study confirm the low toxicity of the product and are in agreement with the previously obtained findings.

New study:
The study that is summarized below was performed according to currently accepted and valid test guidelines and supersedes all previous performed studies that were conducted with Amidosulfuron WG 75 according to outdated or invalid test guidelines.

Report:	KCP 10.3.1.1.1/04 [redacted].; 2011; M-403727-01-1
Title:	Effects of amidosulfuron WG 75 W (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory
Report No.:	60671035
Document No.:	M-403727-01-1
Guideline(s):	OECD 213 and 214 (1998)
Guideline deviation(s):	none
GLP/GEP:	**yes**

Executive Summary:
The purpose of this study was to determine the acute contact and oral toxicity of Amidosulfuron WG 75 to the honey bee (*A. mellifera* L.) under laboratory conditions following the current valid test guideline (OECD 213 and 214). For this purpose 50 female worker bees were exposed for 48 hours to a single dose of 100.0 µg a.s. per bee by topical application (contact test) and to a single dose of 106.6 µg a.s. per bee by feeding (oral test, value based on the actual intake of the test item). Mortality of the bees was used as the toxic endpoint. Sublethal effects, such as changes in behaviour, were also monitored.

The contact LD_{50} (48 h) was > 100.0 µg a.s./bee. The oral LD_{50} (48 h) was > 106.6 µg a.s./bee.

Material and methods:
Test item: Amidosulfuron WG 75 W; Specification No.: 102000000550-02; Batch ID: EFKE001914; Analysed content of amidosulfuron (AE F075032): 74.8 % w/w; Sample description: TOX 08735-00.

Test units were stainless steel cages of 10 cm x 8.5 cm x 5.5 cm (length x width x height). 10 bees were used per test unit. 5 test units were used per test item dose level, control and reference item dose level, respectively. 50 worker bees (*Apis mellifera*) were exposed for 48 hours to a single dose of 100.0 µg a.s. per bee by topical application (contact test) and 50 worker bees were exposed for 48 hours to a single dose of 106.6 µg a.s. per bee by feeding (oral test, value based on the actual intake of the test item).

For the contact test, one 5 µL droplet of Amidosulfuron WG 75 in an appropriate carrier (tap water + 0.5 % Adhäsit) was placed on the dorsal bee thorax. For the control one 5 µL droplet of tap water containing 0.5 % Adhäsit was used. The reference item was also applied in 5 µL tap water (dimethoate made up in tap water containing 0.5 % Adhäsit).

For the oral test, aqueous stock solutions of the test item and reference item were prepared and mixed with ready-to-use sugar syrup (30 % sucrose, 31 % glucose, 39 % fructose) at a concentration of 50 % (w/w). For the control, water and sugar syrup was used at the same ratio (1 + 1). The treated food was offered in syringes, which were weighed before and after introduction into the cages. After a maximum of 35 minutes, the uptake was complete (duration of uptake was 35 minutes for the test item treatments) and the syringes containing the treated food were removed, weighed and replaced by ones containing fresh, untreated food.

The number of dead bees was recorded after 4 hours (first day); 24 and 48 hours. Behavioural abnormalities (e.g. vomiting, apathy, intensive cleaning) were assessed after 4 hours (first day); 24 and 48 hours. Temperature during the test was 24 – 25 °C; relative humidity was 55 – 92 %. Bees were kept in darkness (except during observation).

Dates of work: August 18, 2010 – August 25, 2010

Results:

Table CP 10.3.1.1.1- 1: Validity criteria

Validity Criteria		Recommended	Obtained
Control mortality	Contact Test		
	CO_2/water control	< 10%	0.0%
	Oral Test		
	Water/sugar control	< 10%	0.0%
LD_{50} of reference item (24 h)	Contact Test		
		0.10 - 0.30 µg a.s./bee	0.19 µg a.s./bee
	Oral Test		
		0.10 - 0.35 µg a.s./bee	0.19 µg a.s./bee

The contact and oral test is considered valid as the control mortality in each case was < 10% and the LD_{50} values obtained with the reference item (dimethoate) were within the required ranges.

Biological results:

Contact Test:
At the end of the contact toxicity test (48 hours after application) no mortality occurred at 100.0 µg a.s./bee. There was also no mortality in the control group (water + 0.5 % Adhäsit).

Oral Test:
In the oral toxicity test, the maximum nominal test level of amidosulfuron WG 75 W (100 µg a.s./bee) corresponded to an actual intake of 106.6 µg a.s./bee. This dose level led to no mortality after 48 hours. In the control group (50 % sugar solution), also no mortality occurred.

No test item induced behavioural effects were observed at any time.

Table CP 10.3.1.1.1- 2: Toxicity of Amidosulfuron WG 75 to honey bees; contact and oral laboratory test

Test Item	Amidosulfuron WG 75	
Test Object	*Apis mellifera*	
Exposure	**contact (solution in Adhäsit (0.5 %)/ water)**	**oral (sugar solution)**
Application rate µg a.s./bee	100.0	106.6
LD_{50} µg a.s./bee	> 100.0	> 106.6
LD_{20} µg a.s./bee*	> 100.0	> 106.6
LD_{10} µg a.s./bee*	> 100.0	> 106.6
NOED µg a.s./bee*	≥ 100.0	≥ 106.6

* Since no mortality was observed at the tested dose, the values for NOED, LD_{20} and LD_{10} values are extrapolated to be above the tested dose.

The contact and oral LD_{50} (24 h) values of the reference item (dimethoate) were calculated to be 0.19 µg a.s./bee, respectively.

Conclusions:
The toxicity of Amidosulfuron WG 75 was tested in both, an acute contact and an acute oral toxicity test on honey bees. The contact LD_{50} (48 h) was > 100.0 µg a.s./bee. The oral LD_{50} (48 h) was > 106.6 µg a.s./bee.

CP 10.3.1.1.2 Acute contact toxicity to bees

Report:	KCP 10.3.1.1.2/01 [redacted],; [redacted]; 1992; M-130984-01-1
Title:	Toxicity testing of HOE 075032 00 WG 75 A104 to honey bees (Apis mellifera L.) (Hymenoptera, Apidae) in laboratory
Report No.:	A47036
Document No.:	M-130984-01-1
Guideline(s):	BBA: Part VI, 23-1
Guideline deviation(s):	--
GLP/GEP:	**yes**

A brief study description has been provided in the section before, see KCP 10.3.1.1.1 /02.

The study reports on toxicity tests performed with the formulated product AE F075032 00 WG75 A104 in four laboratory trials: exposure to vapour, to residues on treated filter paper, to direct spray treatment and oral intake of contaminated food. The study confirmed an overall low toxicity of the formulation upon contact exposure (residues on treated filter paper, direct spray).

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study review is found in the previous Monograph. Since the study by its design does not deliver contact toxicity endpoints suitable for standard risk assessment, no formal EU endpoint for acute contact toxicity was derived based on this test. However, the study was performed according to an outdated guideline and is superseded by a guideline-conform study performed with the product, see KCP 10.3.1.1.2 /07.

Report:	KCP 10.3.1.1.2/02 [redacted]イ; 1991; M-130674-01-2
Title:	Hoe 075032; water dispersible granules; 75 % (Hoe 075032 00 WG75 A104) Investigating the effects on the honey bee Apis mellifera L. caused by direct spraying
Report No.:	GH1492
Document No.:	M-130674-01-2
Guideline(s):	BBA: Part VI, 23-1
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a contact toxicity test with formulated product AE F075032 00 WG75 A104 directly over sprayed to the bees. It was concluded that the LD_{50} after direct overspray with the product is > 0.04 % (72h).

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study review is found in the previous Monograph. Since the study by its design does not deliver contact toxicity endpoints suitable for standard risk assessment, no formal EU endpoint was derived based on this test.

Report:	KCP 10.3.1.1.2/03 [redacted],; 1991; M-130976-01-2
Title:	Investigating the side-effects of Hoe 075032 00 WG75 A104 on the honey bee (Apis mellifera) in the laboratory
Report No.:	C001514
Document No.:	M-130976-01-2
Guideline(s):	BBA: Part VI, 23-1
Guideline deviation(s):	--
GLP/GEP:	**yes**

A brief study description has been provided in the section before, see KCP 10.3.1.1.1 /03.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study review is found in the previous Monograph. Since the study by its design does not deliver contact toxicity endpoints suitable for standard risk assessment, no formal EU endpoint for contact toxicity was derived based on this test.

This study was performed according to an outdated test guideline and is superseded by a new guideline-conform study performed with the product (see KPC 10.3.1.1.2. /07).

Report:	KCP 10.3.1.1.2/04 [redacted],; 1991; M-130728-01-2
Title:	Hoe 075032; water dispersible granules; 75 % (Hoe 075032 00 WG75 A104) Investigating the contact toxicity to the honey bee Apis mellifera L. by surface treatment (filter paper)
Report No.:	A51982
Document No.:	M-130728-01-2
Guideline(s):	BBA: Part VI, 23-1
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a contact toxicity test with formulated product AE F075032 00 WG75 A104 with surface exposure via soaked filter paper disks. It was concluded that the LD_{50} with the product is > 0.04 % (72h).

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study review is found in the previous Monograph. Since the study by its design does not deliver contact toxicity endpoints suitable for standard risk assessment, no formal EU endpoint was derived based on this test.

Report:	KCP 10.3.1.1.2/05 [redacted]; 1991; M-130675-01-2
Title:	Investigating the effects as respiratory poison on the honey bee (Apis mellifera L.) Hoe 075032 water dispersible granules 75% Code: Hoe 075032 00 WG75 A104
Report No.:	C001495
Document No.:	M-130675-01-2
Guideline(s):	--
Guideline deviation(s):	--
GLP/GEP:	**yes**

Report amended by:

Report:	KCP 10.3.1.1.2/06 [redacted],; 1993; M-138714-01-2
Title:	Investigating the effects as respiratory poison on the honey bee (Apis mellifera L.) (addendum 01 to report CW91/052) Hoe 075032 water dispersible granules 75% Code: Hoe 075032 00 WG75 A104
Report No.:	C001496
Document No.:	M-138714-01-2
Guideline(s):	--
Guideline deviation(s):	--
GLP/GEP:	**no**

The study reports on a toxicity test with formulated product AE F075032 00 WG75 A104 with exposure via respiratory uptake. No substance-related effects were observed after 72 hours in control, treatment, and toxic reference groups. The report amendment corrects a typing error only and remains with no effect on the study outcome (included for formal completeness only).

The study was rated not valid in the EU review for the first inclusion of amidosulfuron on Annex I, because of the low mortality in the toxic reference group. No EU endpoint was derived based on this test.

Report:	KCP 10.3.1.1.2/07 [redacted]; 2011; M-403727-01-1
Title:	Effects of amidosulfuron WG 75 W (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory
Report No.:	60671035
Document No.:	M-403727-01-1
Guideline(s):	OECD 213 and 214 (1998)
Guideline deviation(s):	none
GLP/GEP:	**yes**

The study reports on a combined test covering aspects of both data points acute oral (CP 10.3.1.1.1) and acute contact (CP 10.3.1.1.2) toxicity to honey bees.

A study summary has been provided before under point KCP 10.3.1.1.1 /04.

Study endpoint for acute contact toxicity for honey bee: LD_{50} > 100 µg a.s./bee.

CP 10.3.1.2 Chronic toxicity to bees

Report:	KCP 10.3.1.2/01 [redacted]; 2016; M-549770-01-1
Title:	Amidosulfuron WG 75A W: 10-day chronic feeding test on the honey bee (Apis mellifera L.) in the laboratory
Report No.:	M-549770-01-1
Document No.:	M-549770-01-1
Guideline(s):	Regulation (EC) No. 1107/2009 OECD 213 (1998) and CEB No. 230 with current recommendations of the ring test group by [redacted] (2015) Directive 2003-01 (Canada/PMRA) US EPA OCSPP Not Applicable
Guideline deviation(s):	none
GLP/GEP:	**yes**

This study has been previously summarised and evaluated on document MCA level, to deliver information on the active substance amidosulfuron. Please refer to data point KCA 8.3.1.2 /01.

CP 10.3.1.3 Effects on honey bee development and other honey bee life stages

Report:	KCP 10.3.1.3/01 [redacted]; [redacted]; 2014; M-482118-01-1
Title:	Amidosulfuron WG 75A W (750 g/kg): Effects on honey bee brood (Apis mellifera L.) - Brood feeding test
Report No.:	M-482118-01-1
Document No.:	M-482118-01-1
Guideline(s):	[redacted], 1992
Guideline deviation(s):	none
GLP/GEP:	**yes**

This study has been previously summarised and evaluated on document MCA level, to deliver information on the active substance amidosulfuron. Please refer to data point KCA 8.3.1.3 /01.

Report:	KCP 10.3.1.3/02[redacted]; 2016; M-545720-01-1
Title:	Amidosulfuron WG 75A W (750 g/kg): Effects on honey bee brood (Apis mellifera L.) under semi-field conditions - Tunnel Test - Final report
Report No.:	EBBEN041
Document No.:	M-545720-01-1
Guideline(s):	OECD No. 75 (2007); OEPP/EPPO No. 170 (4)(2010)
Guideline deviation(s):	Yes, see report
GLP/GEP:	**yes**

This study has been previously summarised and evaluated on document MCA level, to deliver information on the active substance amidosulfuron. Please refer to data point KCA 8.3.1.3 /02.

CP 10.3.1.4 Sub-lethal effects

There is no particular study design / test guideline to assess "sub-lethal effects" in honey bees. However, in each laboratory study as well as in any higher-tier study, sub-lethal effects, if occurring, are described and reported.

CP 10.3.1.5 Cage and tunnel tests

Not necessary considering the outcome of the risk assessment and the results of lower-tiered studies.
A semi-field brood tunnel study according to the provisions of the OECD Guidance Document 75 ([redacted]P; 2016; M-545720-01-1) has been conducted. This study is summarized under KCA 8.3.1.3 /02.

CP 10.3.1.6 Field tests with honeybees

Not necessary considering the outcome of the risk assessment and the results of lower-tiered studies.
A honey bee brood feeding study according to the provisions of [redacted] *et al*. ([redacted]F; [redacted]; 2014; M-482118-01-1) has been conducted. This study is summarized under KCA 8.3.1.3 /01.

CP 10.3.2 Effects on non-target arthropods other than bees

Toxicity tests on non-target arthropods were conducted with the product on the sensitive standard species *Typhlodromus pyri* and *Aphidius rhopalosiphi,* and five additional species.

All studies were previously EU reviewed for the first Annex I inclusion of Amidosulfuron. No new data has been generated and is submitted in the context of application for approval renewal.

A summary of the information is provided in the following table.

Table CP 10.3.2- 1: Endpoints of the formulation Amidosulfuron WG75

Test species, Edition Number Reference	Tested Formulation, study type, Duration, exposure	Ecotoxicological Endpoint
Aphidius rhopalosiphi [redacted],; 1996; M-140500-01-1 Rep.No: 961048014 KCP 10.3.2.1/01	WG 75 Laboratory, glass plates 14d 60 g prod/ha	LR_{50}> 60 [g product/ha] ER_{50}> 60 [g product/ha] corr. Mortality 48h [%]: 33.3 Effect on Reproduction [%]: 16.2
Aphidius rhopalosiphi [redacted]B; 1999; M-184320-01-1 Rep.No: 98331/01-NLAp KCP 10.3.2.1/02	WG 75 Laboratory, glass plates 11d 40 g prod/ha	LR_{50}> 40 [g product/ha] ER_{50}> 40 [g product/ha] corr. Mortality 48h [%]: 24.3 Effect on Reproduction [%]: 44.6
Aphidius rhopalosiphi [redacted],; 2003; M-227766-01-1 Rep.No: 15741002 KCP 10.3.2.2/01	WG75 Extended Lab., exposure on potted barley plants 14d 3.75 g prod/ha 7.5 g prod/ha 15 g prod/ha 30 g prod/ha 60 g prod/ha	LR_{50} > 60 [g product/ha] Corr. Mortality [%] / Effect on Reproduction [%]: 0 / 6.9 3.3 / -0.4[B] 0 / -18.1[B] 0 / 4.8 0 / 6.4
Typhlodromus pyri [redacted],; 1998; M-181417-01-1 Rep.No:CW98/050 KCP 10.3.2.1/03	WG 75 Laboratory, glass plates 14d Control 60 g prod/ha	LR_{50} > 60 [g product/ha] ER_{50}> 60 [g product/ha] Corr. Mortality [%] / Effect on Reproduction [eggs/female]: - / 8.81 2.3 / 7.14
Chrysoperla carnea [redacted],; 1992; M-136220-01-2 Rep.No: CW91/116 KCP 10.3.2.1/06	WG 75 Laboratory, glass plates 14d Control 60 g prod/ha	LR_{50} > 60 [g product/ha] Corr. Mortality [%] / Eggs/Female/Day / Hatching [%]: - / 118 / - -7.5[A] / 94 / 25.7
Coccinella septempunctata [redacted],; 1992; M-137157-01-2 Rep.No:CW91/122 KCP 10.3.2.1/07	WG 75 Laboratory, glass plates 14d Control 80 g prod/ha	LR_{50} > 80 [g product/ha] Corr. Mortality [%] / Eggs/Female/Day: - / 91 46.1 / 310
Episyrphus balteatus [redacted],; 1993; M-133073-01-2 Rep.No:253011-Eb KCP 10.3.2.1/12	WG 75 Laboratory, glass plates 14d 60 g prod/ha	Corr. Mortality [%]: 12 Effect on Reproduction [%]: 100[A]
[A]: EFSA conclusion (2007, page 25) stated: "A study with the dipteran *Episyrphus balteatus* showed a high impact on reproduction while the effect on survival was low. According to ESCORT II test systems with Diptera (*Episyrphus balteatus* is explicitly mentioned) are not appropriate due to high variability in reproduction and therefore the applicant and the RMS argued that these results should not be taken as an indication of reproduction effects caused by amidosulfuron since in the studies with other arthropods no indication of effects on reproduction was found." Overall it was concluded that the risk to non-target arthropods is low for the representative uses evaluated.		

Test species, Edition Number Reference	Tested Formulation, study type, Duration, exposure	Ecotoxicological Endpoint
Aleochara bilineata [redacted]; 1992; M-136106-01-1 Rep.No: CW91/111 KCP 10.3.2.1/05	WG75 Laboratory, spray deposits on quartz sand 28d Control 60 g prod/ha	ER_{50} > 60 [g product/ha] Effect on Reproduction [%] -109[B]
Aleochara bilineata [redacted]; 1993; M-132685-01-2 Rep.No: CW93/061 KCP 10.3.2.1/04	WG75 Laboratory, spray deposits on quartz sand 29d Control 60 g prod/ha	ER_{50} > 60 [g product/ha] Effect on Reproduction [%] -1.4[B]
Poecilus cupreus [redacted]; 1992; M-136107-01-2 Rep.No:CW91/112 KCP 10.3.2.1/08	WG75 Laboratory, spray deposits on quartz sand 15d Control 60 g prod/ha	LR_{50} > 60 [g product/ha] Corr. Mortality [%] Feeding Rate [pupae/beetle] - 3.83 0 5.00
Poecilus cupreus [redacted]; [redacted]; [redacted]; 1991; M-135791-01-1 Rep.No: CW91/099 KCP 10.3.2.1/09	WG75 Laboratory, spray deposits on quartz sand 15d Control 60 g prod/ha	LR_{50} > 60 [g product/ha] Corr. Mortality [%] Feeding Rate [pupae/beetle] - 4.63 0 4.57

[A]: A negative value indicates a lower mortality in the treatment than in the control
[B]: A negative value indicates a higher reproduction rate in the treatment than in the control.

Risk assessment for other non-target arthropods
The risk assessment was performed according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) and to the Guidance Document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods (ESCORT 2).

In-field hazard quotient (HQ) tier 1 risk assessment
The following equation was used to calculate the hazard quotient (HQ) for the in-field scenario:

In field-HQ = max. single application rate * MAF / LR_{50}

For the risk assessment of the product Amidosulfuron WG 75 on non-target arthropods in (winter and spring) cereals and flax, the worst-case application rate of 1 × 40 g product/ha at BBCH 12-49 in spring cereals has been taken into account. This use pattern is considered to cover also the single applications in winter cereals (1 × 0.40 g product/ha at BBCH 21-49 and 1 × 0.20 g product/ha at BBCH 13-49) and flax (1 × 0.40 g product/ha before the flower buds are visible) as given in the intended use pattern for this product (see Table CP 10- 1). In addition, the product is applied at 1 × 60 g product/ha in grassland. The multiple application factors (MAF) for the worst-case use in spring cereals and the use on grassland were 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 CP 10.3.2- 2: HQ for terrestrial non-target arthropods for the in-field scenario

Crop	Species	Appl. rate [g product/ha]	MAF	LR_{50} [g product/ha]	HQ	Trigger
Cereals Flax	*A. rhopalosiphi*	40	1.0	> 60	< 0.7	2
	T. pyri			> 60	< 0.7	2
Grassland	*A. rhopalosiphi*	60	1.0	> 60	< 0.7	2
	T. pyri			> 60	< 0.7	2

The in-field HQ values for *Typhlodromus pyri* and *Aphidius rhopalosiphi* are below the trigger of concern, indicating that **no unacceptable risk is to be expected for non-target arthropods in the in-field area** from the use of Amidosulfuron WG 75 according to the proposed use pattern.

Off-field hazard quotient (HQ) tier 1 risk assessment
The following equation was used to calculate the hazard quotient (HQ) for the off-field scenario:

Off-field HQ = max. single application rate * MAF * (drift factor/VDF)*correction factor / LR_{50}

MAF (multiple application factor) = 1 (single application)
Drift factor = 0.0277 (90^{th} percentile for 1 application in field crops, 1m distance; ESCORT 2)
VDF (vegetation distribution factor) = 10
Correction factor = 10 (uncertainty factor for the extrapolation from indicator species to other off-field non-target arthropods; default value for tier 1 risk assessment according to the Terrestrial Guidance Document)

The risk is considered acceptable if the calculated HQ is < 2.

Table CP 10.3.2- 3: HQ for terrestrial non-target arthropods for the off-field scenario

Crop	Species	Appl. Rate [g product/ha]	MAF	Drift [%]	VDF	Corr. factor	LR_{50} [g product/ha]	HQ	Trigger
Cereals Flax	*A. rhopalosiphi*	40	1.0	2.77	10	10	> 60	< 0.02	2
	T. pyri	40			10	10	> 60	< 0.02	2
Grassland	*A. rhopalosiphi*	60	1.0	2.77	10	10	> 60	< 0.03	2
	T. pyri	60			10	10	> 60	< 0.03	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 off-field area** from the use of Amidosulfuron WG 75 according to the proposed use pattern.

CP 10.3.2.1 Standard laboratory testing for non-target arthropods

Aphidius rhopalosiphi:

Report:	KCP 10.3.2.1/01[redacted],; 1996; M-140500-01-1
Title:	Toxicity to the parasitoid Aphidius rhopalosiphi (DESTEFANI-PEREZ) / Imagines according to IOBC Guideline (MEAD-BRIGGS 1992) HOE 075032 00 WG75 A110
Report No.:	A56711
Document No.:	M-140500-01-1
Guideline(s):	IOBC: Mead-Briggs 1992
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a laboratory acute toxicity test for the parasitoid *Aphidius rhopalosphi* on the formulated product. The parasitation efficacy of the surviving wasps of the treatment group was slightly reduced. The mean number of parasitized aphids per female wasp in the control group was 7.33. The mean number of parasitized aphids per female wasp in the treatment group was 6.14.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

An EU agreed endpoint for acute oral toxicity of the active substance amidosulfuron of LR_{50} > 45 g a.s./ha was derived from this test.
The effect on reproduction as 16.2%.

In the context of approval renewal an endpoint for acute oral toxicity of the formulated product of LR_{50} > 60 g product/ha was used for the risk assessment for non-target arthropods.

Report:	KCP 10.3.2.1/02[redacted]R; 1999; M-184320-01-1
Title:	HOE F075032 00 WG75 A110: Acute Toxicity to the Aphid Parasitoid, Aphidius rhopalosiphi (Hymenoptera, Braconidae) in the Laboratory
Report No.:	C062335
Document No.:	M-184320-01-1
Guideline(s):	ESCORT 1994
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a laboratory acute toxicity test for the parasitoid *Aphidius rhopalosphi* on the formulated product. The exposure of Aphidius rhopalosiphi to the formulated product at a rate of 30 g a.s./ha resulted in a corrected mortality after 48 h of 24.3% and and effect on reproduction of 44.6%.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

Typhlodromus pyri:

Report:	KCP 10.3.2.1/03 [redacted]; 1998; M-181417-01-1
Title:	Amidosulfuron water dispersible granule 75% Toxicity to the predatory mite Typhlodromus pyri SCHEUTEN (Acari, Phytoseiidae) in the laboratory Code AE F075032 00 WG75 A110
Report No.:	C000890
Document No.:	M-181417-01-1
Guideline(s):	ESCORT: 1994
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a laboratory acute toxicity test for the predatory mite *Typhlodromus pyri* on the formulated product. The combined effect on mortality and reproduction was calculated as 20.84 %.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

An EU agreed endpoint for acute oral toxicity of the active substance amidosulfuron of LR_{50} > 45 g a.s./ha was derived from this test.

In the context of approval renewal an endpoint for acute oral toxicity of the formulated product of LR_{50} > 60 g product/ha was used for the risk assessment for non-target arthropods.

Aleochara bilineata:

Report:	KCP 10.3.2.1/04 [redacted]; 1993; M-132685-01-2
Title:	Testing for side effects of Hoe 075032 00 WG75 A104 on the staphylinid Aleochara bilineata Gyll. (Coleoptera, Staphilinidae) in the laboratory
Report No.:	C001493
Document No.:	M-132685-01-2
Guideline(s):	BBA: , Part VI 3-2.1.8
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a laboratory toxicity test for the staphylinid *Aleochara bilineata* on the formulated product. The mean emergency rate from the number of added pupae as indicator of the parasitation efficiency was 35.2 % in the treated variant and therefore slightly higher than that from the control variant (34.7 %). No negative impact was observed after treatment with the product at 58.5 g/ha.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

Report:	KCP 10.3.2.1/05 [redacted]B; 1992; M-136106-01-1
Title:	Effects of Hoe 075032 00 WG75 A104 on the reproduction of Aleochara bilineata Gyll. (Coleoptera, Staphylinidae) in laboratory
Report No.:	A47612
Document No.:	M-136106-01-1
Guideline(s):	IOBC: Naton E. 1988
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a laboratory toxicity test for the staphylinid *Aleochara bilineata* on the formulated product. The average parasitation of pupae of *Delia antiqua* was 83 % in the treated variants and 77 % in the control. Hence, no negative impact was obvious after treatment with the product at 60 g/ha.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

Chrysoperla carnea:

Report:	KCP 10.3.2.1/06[redacted]; 1992; M-136220-01-2
Title:	Determination of side-effects of Hoe 075032 00 WG75 A104 on the green lacewing Chrysoperla carnea Steph. in the laboratory
Report No.:	A51987
Document No.:	M-136220-01-2
Guideline(s):	--
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a laboratory toxicity test for the green lacewing *Chrysoperla carnea* on the formulated product. Mortalities in the control and the test item treatment group were 17.3 % and 11.1 %, respectively. The pre-imaginal mortality of *Chrysoperla carnea* was therefore not increased as compared to the control, the corrected mortality rate is -7.5 %. The egg-laying capacity of the test organisms was 81 fertile eggs per female on the average as compared with 109 fertile eggs per female in the control. This is equivalent to a decrease of 25.7 %. Based on these values, the relative decrease of beneficial effects for *Chrysoperla carnea* was calculated to be 20.5 %.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

Coccinella septempunctata:

Report:	KCP 10.3.2.1/07[redacted]; 1992; M-137157-01-2
Title:	Determination of side-effects of Hoe 075032 00 WG75 A103 on the seven spot ladybird Coccinella septempunctata L. in the laboratory
Report No.:	A51997
Document No.:	M-137157-01-2
Guideline(s):	BBA: Part VI, 23-1.15
Guideline deviation(s):	
GLP/GEP:	**yes**

The study reports on a laboratory toxicity test for the ladybird *Coccinella septempunctata* on the formulated product. Mortalities in the control and the test item treatment group were 20 % and 56.9 %, respectively. The corrected pre-imaginal mortality of *Coccinella septempunctata* was 46.1 %. The egg-laying capacity of the test organisms was 310 fertile eggs per female on the average as compared with 91 fertile eggs per female in the control. This is equivalent with an increase of 240.7 %. Both values, however, are within the natural range of variation and different stress conditions might be responsible for the varying reproductive capacity (higher density and strong competition in the control group). In the report the overall effect on the beneficial capacity was calculated to be -38.8 % (the negative figure is equivalent to an enhancement). This value should be regarded cautiously, however, the observed effects on ladybirds were not detrimental.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

Poecilus cupreus:

Report:	KCP 10.3.2.1/08[redacted]; 1992; M-136107-01-2
Title:	Determination of the side-effects of Hoe 075032 00 WG75 A004 on the ground beetle Poecilus cupreus L. in the laboratory
Report No.:	A51988
Document No.:	M-136107-01-2
Guideline(s):	BBA: Part VI, 23-2.1.8
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a laboratory toxicity test for the ground beetle *Poecilus cupreus* on the formulated product. No mortality occurred among the beetles from the control and the test item treated group, while 90 % of the animals of the toxic standard died within 2 days. A mean of 3.83 and 5.00 pupae were consumed per beetle in the control and test item group, respectively. Hence, no test substance related effect on food-consumption was observed.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

Report:	KCP 10.3.2.1/09[redacted]; 1991; M-135791-01-1
Title:	The Effects of HOE 075032 00 WG75 A104 on Imagines of POECILUS CUPREUS L. (COLEOPTERA : CARABIDAE) in the Laboratory
Report No.:	A47377
Document No.:	M-135791-01-1
Guideline(s):	BBA: VI, 23-2.1.8
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a laboratory toxicity test for the ground beetle *Poecilus cupreus* on the formulated product. No mortality occurred among the beetles from the control and the test item treated group, while 76.7 % of the animals of the toxic standard died within 2 days. No intoxication symptom was observed among beetles of the treatment group and no test substance related effect on food-consumption was observed.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

Pardosa amentata:

Report:	KCP 10.3.2.1/10[redacted],; 1995; M-138327-03-1
Title:	Effects of HOE 075032 00 WG 75 A104 on Pardosa amentata (Clerck) (Araneae, Lycosidae) in Laboratory
Report No.:	A49259
Document No.:	M-138327-03-1
Guideline(s):	BBA: Draft guideline (1992)
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a laboratory toxicity test for the wolf spider *Pardosa amentata* on the formulated product.

The study was evaluated in the EU review for the first inclusion of amidosulfuron on Annex I. The evaluation resulted in the conclusion that **the study has to be considered invalid** due the high control mortality (42%). The study review has been provided in the previous Draft Assessment Report (2006).

Syrphus corollae:

Report:	KCP 10.3.2.1/11[redacted],(1993; M-132620-01-1
Title:	The Effects of Larval and Pupal Exposure to HOE 075032 00 WG 75 A 104 on Syrphus corollae Fabr. (syn.: Eupeodes corollae) (Diptera: Syrphidae) in the Laboratory
Report No.:	A51711
Document No.:	M-132620-01-1
Guideline(s):	BBA: Part VI, 23-2.1.7
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a laboratory toxicity test for *Syrphus corolla* Fabr. on the formulated product.

The study was evaluated in the EU review for the first inclusion of amidosulfuron on Annex I. The evaluation resulted in the conclusion that **the study has to be considered invalid** due the high control mortality (45.8%). The study review has been provided in the previous Draft Assessment Report (2006).

Episyrphus balteatus:

Report:	KCP 10.3.2.1/12[redacted],; 1993; M-133073-01-2
Title:	Side effects of Hoe 075032 00 WG75 A104 on larvae of the hover-fly (Episyrphus balteatus) (DEG.) in the laboratory
Report No.:	C001471
Document No.:	M-133073-01-2
Guideline(s):	BBA: Part VI, 23-2.1.7
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a laboratory toxicity test for the hover-fly *Episyrphus balteatus* on the formulated product. Pre-imaginal mortalities were 20 % and 29.6 % in the control and the test item treatment group, respectively. The corrected pre-imaginal mortality of *Episyrphus balteatus* following exposure to the formulated product was 12.0%. The mean number of eggs laid per female in the test item variant was 12.4, but they did not hatch out. The number of eggs laid in the control was considerably higher, with a mean value of 102.8. The number of fertile eggs/female was 67.5.

An impairment of reproduction of 100 % was obtained for the females of the test item variant. The results of the fecundity test are difficult to assess, because the reproductive capacity in hover flies is determined by a complex pattern of internal and external stimuli. As is reported by the study author, this may lead to a high individual variation of egg numbers. As a consequence the observed impairment of reproduction cannot be attributed to one single factor, i.e. the formulated product alone.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

EFSA conclusion (2007, page 25) stated: "A study with the dipteran Epishyrphus balteatus showed a high impact on reproduction while the effect on survival was low. According to ESCORT II test systems with Diptera (Epishyrphus balteatus is explicitly mentioned) are not appropriate due to high variability in reproduction and therefore the applicant and the RMS argued that these results should not be taken as an indication of reproduction effects caused by amidosulfuron since in the studies with other arthropods no indication of effects on reproduction was found."

CP 10.3.2.2 Extended laboratory testing, aged residue studies with non-target arthropods

Report: KCP 10.3.2.2/01 [redacted]; 2003; M-227766-01-1
Title: Effects of ... F075[redacted]2 00 WG 75 A112 on the parasitoid Aphidius rhopalosiphi, extended laboratory study - Dose response test -
Report No.: C030320
Document No.: M-227766-01-1
Guideline(s): IOBC: WPRS 2000
Guideline deviation(s): none
GLP/GEP: yes

The study reports on an extended laboratory test for the parasitoid *Aphidius rhopalosiphi* on the formulated product. The effects of the product on mortality and parasitation of *Aphidius rhopalosiphi* are presented in the following table.

Table CP 10.3.2.2-1: Effects of Amidosulfuron WG 75 on mortality and parasitation of *Aphidius rhopalosiphi* under extended laboratory conditions

Group	Corrected mortality (48 h) [%]	Mummies/female	Reduction of parasitation efficiency* [%]
Control	-	56.3	-
3.75 g product/ha	0	52.4	6.9
7.5 g product/ha	3.3	56.5	-0.4
15 g product/ha	0	66.5	-18.1
30 g product/ha	0	53.6	4.8
60 g product/ha	0	52.7	6.4
Toxic reference	70	-	-

* negative value means increased parasitation efficiency compared to control

No behavioural abnormalities and no repellent effect were observed. Differences between the product treated groups and the control were not statistically significant. The LR_{50} of the product under extended laboratory conditions is reported to be > 60 g product/ha.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

No EU agreed endpoint was derived from this test.

CP 10.3.2.3 Semi-field studies with non-target arthropods

In view of the results presented above, no semi-field studies were deemed necessary.

CP 10.3.2.4 Field studies with non-target arthropods

In view of the results presented above, no field studies were deemed necessary.

CP 10.3.2.5 Other routes of exposure for non-target arthropods

The exposure routes of non-target arthropod as assessed in chapter CP 10.3.2 are considered the main route of exposure for non-target arthropods.

CP 10.4 Effects on non-target soil meso- and macrofauna

The risk assessment procedure follows the requirements as given in the EU Regulation 1107/2009 and the Guidance Document on Terrestrial Ecotoxicology.

Predicted environmental concentrations used in risk assessment
Predicted environmental concentrations of the active substance and the metabolites in soil (PEC_{soil}) values were calculated and reported in MCP 9.1.3.

The relevant PEC values considered for TER calculations are summarised in the table below. Maximum values are used for risk assessments.

Table CP 10.4- 1: Maximum PEC_{soil} values

Compound	Winter cereals, 1 × 30 g a.s./ha (20% interception)		Winter cereals, 1 × 15 g a.s./ha (0% interception)		Spring cereals and flax, 1 × 30 g a.s./ha (0% interception)		Grass (spring and autumn), 1 × 45 g a.s./ha (90% interception)	
	$PEC_{soil,max}$ [mg/kg]	$PEC_{soil,accu}$ [mg/kg]	$PEC_{soil,max}$ [mg/kg]	$PEC_{soil,accu}$ [mg/kg]	$PEC_{soil,max}$ [mg/kg]	$PEC_{soil,accu}$ [mg/kg]	$PEC_{soil,max}$ [mg/kg]	$PEC_{soil,accu}$ [mg/kg]
Amidosulfuron WG 75	**0.043**[A]	-	0.027[B]	-	**0.053**[C]	-	**0.008**[D]	-
Amidosulfuron	0.032	**0.033**	0.020	0.020	0.040	**0.041**	0.006	**0.006**
Amidosulfuron-desmethyl	0.015	**0.015**	0.010	0.010	0.019	**0.019**	0.003	**0.003**
Amidosulfuron-desmethyl-chloropyrimidine	0.004	**0.004**	0.003	0.003	0.005	**0.006**	< 0.001	**< 0.001**
Amidosulfuron-ADMP	0.001	**0.001**	< 0.001	0.001	0.002	**0.002**	< 0.001	**< 0.001**
Amidosulfuron-guanidine	0.009	**0.014**	0.006	0.009	0.011	**0.018**	0.002	**0.003**
Amidosulfuron-biuret	0.001	**0.002**	< 0.001	< 0.001	0.002	**0.002**	< 0.001	**< 0.001**

Bold values: worst case considered in risk assessment

[A] Based on an application rate of 0.04 kg product/ha, considering 5 cm soil depth, 1.5 g/mL soil density and 20 % crop interception.

[B] Based on an application rate of 0.02 kg product/ha, considering 5 cm soil depth, 1.5 g/mL soil density and no crop interception.

[C] Based on an application rate of 0.04 kg product/ha, considering 5 cm soil depth, 1.5 g/mL soil density and no crop interception.

[D] Based on an application rate of 0.06 kg product/ha, considering 5 cm soil depth, 1.5 g/mL soil density and 90 % crop interception.

CP 10.4.1 Earthworms

Ecotoxicological endpoints used in risk assessment

Table CP 10.4.1- 1: Endpoints of the formulation Amidosulfuron WG75 used in risk assessment

Test substance	Test organism	Study type	Endpoint	References
	Earthworm, chronic			
Amidosulfuron WG 75	*Eisenia fetida*	reproduction, 56 d (10% peat in test soil), test item mixed into soil	NOEC **56 mg prod./kg dws**	[redacted]; 2015; M-524933-01-1 KCP 10.4.1.1/02

dws = dry weight soil; prod. = product

Bold values used for the risk assessment

Table CP 10.4.1- 2: Endpoints of the active substance amidosulfuron and metabolites used in risk assessment

Test substance	Test organism	Study type	Endpoint	References
Amidosulfuron WG 75	**Earthworm, chronic**			
	Eisenia fetida	reproduction, 56 d (10% peat in test soil), test item mixed into soil	NOEC **42.5 mg a.s./kg dws**	[redacted]; 2015; M-524933-01-1 KCA 8.4.1/03
Amidosulfuron-desmethyl	*Eisenia fetida*	reproduction, 56 d (10% peat in test soil), test item mixed into soil	NOEC **≥ 95.8 mg p.m./kg dws**[A)]	[redacted]; 2015; M-529709-01-1 KCA 8.4.1/04
Amidosulfuron-desmethyl-chloropyrimidine	*Eisenia fetida*	reproduction, 56 d (10% peat in test soil), test item mixed into soil	NOEC **≥ 887 mg p.m./kg dws**[B)]	[redacted]; 2009; M-359724-01-1 KCA 8.4.1/01
Amidosulfuron-guanidine	*Eisenia fetida*	reproduction, 56 d (10% peat in test soil), test item mixed into soil	NOEC **≥ 983 mg p.m./kg dws**[C)]	[redacted]; 2009; M-358183-01-1 KCA 8.4.1/02
Amidosulfuron-biuret (**estimated from amidosulfuron-guanidine**, **endpoint divided by 10)**	*Eisenia fetida*	reproduction, 56 d (10% peat in test soil), test item mixed into soil	NOEC **≥ 98.3 mg p.m./kg dws** [C)]	[redacted]; 2009; M-358183-01-1 KCA 8.4.1/02
Amidosulfuron-ADMP	*Eisenia fetida*	reproduction, 56 d (10% peat in test soil), test item mixed into soil	NOEC **9.98 mg p.m./kg dws**[D)]	[redacted]; 2013; M-461051-01-1 KCA 8.4.1/05
Amidosulfuron-ADHP	*Eisenia fetida*	reproduction, 56 d (10% peat in test soil), test item mixed into soil	NOEC **≥ 99.5 mg p.m./kg dws**[E)]	[redacted]; 2015; M-533011-01-1 KCA 8.4.1/06

dws = dry weight soil; a.s. = active substance; p.m. = pure metabolite
[A)] corrected to an anlysed purity of 96.8 %
[B)] corrected to an anlysed purity of 88.7 %
[C)] corrected to an anlysed purity of 98.3 %. NOEC for Amidosulfuron-biuret has been estimated from the NOEC for Amidosulfuron-guanidine by dividing this values by 10.
[E)] corrected to an anlysed purity of 99.8 %
[E)] corrected to an anlysed purity of 99.5 %
Bold values used for the risk assessment

The metabolite **amidosulfuron-biuret** was detected as a minor and transient soil metabolite. Maximum occurrence detected in soil was 6.3 %. No potential for persistence of amidosulfuron-biuret is indicated based on the soil half-life calculated to range from 18.6 to 65.7 days.

The chemical structure of amidosulfuron-biuret is very close to the structure of the metabolite amidosulfurone-guanidine, so that similar ecotoxicological properties of both substances may be expected. The latter component, being formed in soil in more relevant quantity and being characterized by longer degradation half-life, has been tested in reproductive toxicity studies on *Eisenia fetida* and indicated a low toxicity (NOEC ≥ 983 mg p.m./kg dws). Therefore, for amidosulfuron-biuret no reproductive toxicity testing on *Eisenia fetida* was deemed required. Formal risk assessment for this component will be based on the endpoint estimated from amidosulfurone-guanidine which has been divided by a factor of 10.

The metabolite **amidosulfuron-ADHP** was observed exclusively in the anaerobic soil metabolism study, where an abundance of 10.9 % of applied was reported for day 90 after soil flooding. Due to the only limited relevance of anaerobic conditions for the use pattern of the present product, and due to the fact that the earthworm endpoint measured for amidosulfuron-ADHP (NOEC ≥ 99.5 mg p.m./kg dws) is even greater than that of the parent substance (NOEC 42.5 mg a.s./kg dws), it can be concluded that this metabolite does not pose an unacceptable risk and a quantitative risk assessment for amidosulfuron-ADHP is not considered to be necessary.

Risk assessment for earthworms

Based on the endpoints in the table above the TER values are calculated using the following equations:

$TER_{LT} = NOEC / PEC_{soil}$

The risk is considered acceptable if the TER_{LT} is >5.

Table CP 10.4.1- 3: TER calculations for earthworms

Compound	Species	Endpoint [mg/kg soil]	$PEC_{soil,max}$ [mg/kg soil]	TER_{LT}	Trig-ger
Winter cereals					
Amidosulfuron WG 75	Earthworm, reproduction	NOEC 56	0.043	1302	5
Amidosulfuron[A)]	Earthworm, reproduction	NOEC 42.5	0.033	1288	5
Amidosulfuron-desmethyl	Earthworm, reproduction	NOEC ≥ 95.8	0.015	≥ 6387	5
Amidosulfuron-desmethyl-chloropyrimidine	Earthworm, reproduction	NOEC ≥ 887	0.004	≥ 221750	5
Amidosulfuron-guanidine	Earthworm, reproduction	NOEC ≥ 983	0.014	≥ 70214	5
Amidosulfuron-biuret [B)]	Earthworm, reproduction	NOEC ≥ 98.3	0.002	≥ 499150	5
Amidosulfuron-ADMP	Earthworm, reproduction	NOEC 9.98	0.001	9980	5
Spring cereals and flax					
Amidosulfuron WG 75	Earthworm, reproduction	NOEC 56	0.053	1057	5
Amidosulfuron[A)]	Earthworm, reproduction	NOEC 42.5	0.041	1037	5
Amidosulfuron-desmethyl	Earthworm, reproduction	NOEC ≥ 95.8	0.019	≥ 5042	5
Amidosulfuron-desmethyl-chloropyrimidine	Earthworm, reproduction	NOEC ≥ 887	0.006	≥ 147833	5
Amidosulfuron-guanidine	Earthworm, reproduction	NOEC ≥ 983	0.018	≥ 54611	5
Amidosulfuron-biuret [B)]	Earthworm, reproduction	NOEC ≥ 98.3	0.002	≥ 499150	5
Amidosulfuron-ADMP	Earthworm, reproduction	NOEC 9.98	0.002	4990	5
Grass (spring and autumn)					
Amidosulfuron WG 75	Earthworm, reproduction	NOEC 56	0.008	7000	5
Amidosulfuron[A)]	Earthworm, reproduction	NOEC 42.5	0.006	7083	5
Amidosulfuron-desmethyl	Earthworm, reproduction	NOEC ≥ 95.8	0.003	≥ 31933	5
Amidosulfuron-desmethyl-chloropyrimidine	Earthworm, reproduction	NOEC ≥ 887	< 0.001	≥ 887000	5
Amidosulfuron-guanidine	Earthworm, reproduction	NOEC ≥ 983	0.003	≥ 327667	5
Amidosulfuron-biuret [B)]	Earthworm, reproduction	NOEC ≥ 98.3	0.001	≥ 998300	5
Amidosulfuron-ADMP	Earthworm, reproduction	NOEC 9.98	< 0.001	> 9980	5

A) conducted with the formulation Amidosulfuron WG 75
B) endpoint from amidosulfuron-guanidine divided by 10

All TER values exceed the trigger value of 5 indicating that no unacceptable adverse effects on earthworms are to be expected from the intended use of the product.

CP 10.4.1.1 Earthwormssub-lethal effects

Report:	KCP 10.4.1.1/02[redacted]; 2015; M-524933-01-1
Title:	Amidosulfuron WG 75 W: Effects on survival, growth and reproduction of the earthworm Eisenia fetida tested in artificial soil
Report No.:	kra/Rg-R-164/14
Document No.:	M-524933-01-1
Guideline(s):	International Standards ISO 11268-2: 1998 (E); OECD 222 (2004); Regulation (EC) No. 1107/2009 US EPA OCSPP Not Applicable
Guideline deviation(s):	minor
GLP/GEP:	**yes**

This study has been previously summarised and evaluated on document MCA level, to deliver information on the active substance amidosulfuron. Please refer to data point KCA 8.4.1/03.

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Supportive information contained in the baseline dossier and in the List of Endpoints from the first EU review but no longer required for risk assessment according Regulation (EU) 1107/2009:

Report:	KCP 10.4.1.1/01[redacted]; 1990; M-127021-01-1
Title:	Hoe 075032 - water dispersible granule 75% (Hoe 075032 00 WG75 A104) Effect to Eisenia fetida (Earthworm) in a 14 day (Artificial Soil Test method OECD)
Report No.:	A44101
Document No.:	M-127021-01-1
Guideline(s):	OECD: 207 (1984)
Guideline deviation(s):	--
GLP/GEP:	**yes**

This study has been previously evaluated on document MCA level, to deliver information on the active substance amidosulfuron.

The study was rated valid in the EU review for the first inclusion of amidosulfuron on Annex I, a study review is found in the previous Monograph.

An EU agreed endpoint of LC_{50} > 1000 mg a.s./kg d.w.soil was derived from this test.

Note: In context of application for EU approval renewal of amidosulfuron, this endpoint is ranked as supportive information, since acute earthworm testing and risk assessment is no longer a data requirement under Regulation 1107/2009. The updated List of Endpoints will include only data from a corresponding chronic earthworm test.

CP 10.4.1.2 Earthwormsfield studies

Not required as the risk to earthworms is acceptable.

CP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Ecotoxicological endpoints used in risk assessment

Table CP 10.4.2- 1: Endpoints of the formulation Amidosulfuron WG75 used in risk assessment

Test substance	Test organism	Study type	Endpoint	References
Amidosulfuron WG 75	**Soil meso- and macrofauna (other than earthworms)**			
	Hypoaspis aculeifer (soil mite)	reproduction test	NOEC **≥ 1000 mg prod./kg dws**	[redacted]; 2015; M-507488-01-1 KCP 10.4.2.1/01
	Folsomia candida (collembolan)	reproduction test	NOEC **≥ 1000 mg prod./kg dws**	[redacted]; 2014; M-506088-01-1 KCP 10.4.2.1/02

dws = dry weight soil; prod. = product; a.s. = active substance
Bold values used for the risk assessment

Table CP 10.4.2- 2: Endpoints of the active substance amidosulfuron and metabolites used in risk assessment

Test substance	Test organism	Study type	Endpoint	References
Amidosulfuron WG75	**Soil meso- and macrofauna (other than earthworms)**			
	Hypoaspis aculeifer (soil mite)	reproduction test	NOEC ≥ 1000 mg prod./kg dws **≥ 759 mg a.s./kg dws**	[redacted]; 2015; M-507488-01-1 KCP 10.4.2.1/01
	Folsomia candida (collembolan)	reproduction test	NOEC ≥ 1000 mg prod./kg dws **≥ 759 mg a.s./kg dws**	[redacted]; 2014; M-506088-01-1 KCP 10.4.2.1/02
Amidosulfuron-desmethyl	*Hypoaspis aculeifer* (soil mite) **(extimated from amidosulfuron, endpoint divided by 10)**	reproduction test	NOEC **≥ 75.9 mg p.m./kg dws** B)	[redacted]; 2015; M-507488-01-1 KCP 10.4.2.1/01
	Folsomia candida (collembolan)	reproduction test	NOEC **8 mg p.m./kg dws**	[redacted]; 2016; M-551645-01-1 KCA 8.4.2.1/03
Amidosulfuron-desmethyl-chloropyrimidine	*Hypoaspis aculeifer* (soil mite)	reproduction test	NOEC **≥89 mg p.m./kg dws**	[redacted]; 2015; M-507479-01-1 KCA 8.4.2.1/04
	Folsomia candida (collembolan)	reproduction test	NOEC **56 mg p.m./kg dws**	[redacted]; 2015; M-524473-01-1 KCA 8.4.2.1/05
Amidosulfuron-guanidine	*Hypoaspis aculeifer* (soil mite)	reproduction test	NOEC **≥ 100 mg p.m./kg dws**	[redacted]; 2014; M-503851-01-1 KCA 8.4.2.1/06

Test substance	Test organism	Study type	Endpoint	References
	Folsomia candida (collembolan)	reproduction test	NOEC **≥ 100 mg p.m./kg dws**	[redacted]; 2014; M-506089-01-1 KCA 8.4.2.1/07
Amidosulfuron-biuret **(estimated from amidosulfuron-guanidine, endpoints divided by 10)**	*Hypoaspis aculeifer* (soil mite)	reproduction test	NOEC **≥ 10 mg p.m./kg dws** C)	[redacted]; 2014; M-503851-01-1 KCA 8.4.2.1/06
	Folsomia candida (collembolan)	reproduction test	NOEC **≥ 10 mg p.m./kg dws** C)	[redacted]; 2014; M-506089-01-1 KCA 8.4.2.1/07
Amidosulfuron-ADMP	*Hypoaspis aculeifer* (soil mite)	reproduction test	NOEC **≥ 99.8 mg p.m./kg dws** D)	[redacted]; 2013; M-454043-01-1 KCA 8.4.2.1/08
	Folsomia candida (collembolan)	reproduction test	NOEC **≥ 99.8 mg p.m./kg dws** D)	[redacted]; 2013; M-451142-01-1 KCA 8.4.2.1/09

dws = dry weight soil; prod. = product; a.s. = active substance; p.m. = pure metabolite
A) conducted with WG 75 formulation
B) Endpoint derived from amidosulfuron divided by 10
C) Endpoint derived from amidosulfuron-guanidine divided by 10
D) corrected to an anlysed purity of 99.8 %
Bold values used for the risk assessment

Testing metabolite **amidosulfuron-desmethyl** with *Hypoaspis aculeifer* is not considered to be required since *Folsomia candida* and earthworms have been tested with this metabolite and available test results for earthworms, *Folsomia candida*, and *Hyposaspis aculeifer* of the parent compound and the other metabolites indicate a low sensitivity of *Hypoaspis aculeifer* following the exposure to these compounds. Formal risk assessment for *Hyposaspis aculeifer* and amidosulfuron-desmethyl will be based on the endpoint estimated from amidosulfuron which has been divided by a factor of 10.

The metabolite **amidosulfuron-biuret** was detected as a minor and transient soil metabolite. Maximum occurrence detected in soil was 6.3 %. No potential for persistence of amidosulfuron-biuret is indicated based on the soil half-life calculated to range from 18.6 to 65.7 days.
The chemical structure of amidosulfuron-biuret is very close to the structure of the metabolite amidosulfurone-guanidine, so that similar ecotoxicological properties of both substances may be expected. The latter component, being formed in soil in more relevant quantity and being characterized by longer degradation half-life, has been tested in *Folsomia candida*, and *Hyposaspis aculeifer* studies and indicated a low toxicity (NOEC ≥ 100 mg p.m./kg dws). Therefore, for amidosulfuron-biuret no testing on *Folsomia candida* and *Hyposaspis* was deemed required. Formal risk assessment for this component will be based on the endpoint estimated from amidosulfuron-guanidine which has been divided by a factor of 10.

The metabolite **amidosulfuron-ADHP** was observed exclusively in the anaerobic soil metabolism study, where an abundance of 10.9 % of applied was reported for day 90 after soil flooding. Due to the only limited relevance of anaerobic conditions for the use pattern of the present product, and due to the fact that the earthworm endpoint measured for amidosulfuron-ADHP (NOEC ≥ 99.5 mg p.m./kg dws) is even greater than that of the parent substance (NOEC 42.5 mg a.s./kg dws), it can be concluded that this metabolite does not pose an unacceptable risk to soil meso- and macro-organisms and testing of *Folsomia candida* and *Hypoaspis aculeifer* with amidosulfuron-ADHP is not considered to be required.

Risk assessment for other non-target soil meso- and macrofauna (other than earthworms)

Ecotoxicological endpoints and PEC_{soil} values used for TER calculations for soil non-target macro-organisms are summarised below. TER values were calculated using the equation:

$TER = NOEC / PEC_{soil}$

The risk is considered acceptable if the TER is >5.

Table CP 10.4.2- 3: TER calculations for other non-target soil meso- and macrofauna

Compound	Species	Endpoint [mg/kg soil]		$PEC_{soil,max}$ [mg/kg soil]	TER_{LT}	Trigger
Winter cereals						
Amidosulfuron WG 75	*Hypoaspis aculeifer*	NOEC	≥ 1000	0.043	≥ 23256	5
	Folsomia candida	NOEC	≥ 1000	0.043	≥ 23256	5
Amidosulfuron	*Hypoaspis aculeifer*	NOEC	759	0.033	≥ 23000	5
	Folsomia candida	NOEC	≥ 759	0.033	≥ 23000	5
Amidosulfuron-desmethyl	*Hypoaspis aculeifer*	NOEC	≥ 75.9 [A)]	0.015	≥ 5060	5
	Folsomia candida	NOEC	8	0.015	533	5
Amidosulfuron-desmethyl-chloropyrimidine	*Hypoaspis aculeifer*	NOEC	≥ 89	0.004	≥ 22250	5
	Folsomia candida	NOEC	56	0.004	14000	5
Amidosulfuron-guanidine	*Hypoaspis aculeifer*	NOEC	≥ 100	0.014	≥ 7143	5
	Folsomia candida	NOEC	≥ 100	0.014	≥ 7143	5
Amidosulfuron-biuret	*Hypoaspis aculeifer*	NOEC	≥ 10 [B)]	0.002	≥ 5000	5
	Folsomia candida	NOEC	≥ 10 [B)]	0.002	≥ 5000	5
Amidosulfuron-ADMP	*Hypoaspis aculeifer*	NOEC	99.8	0.001	≥ 99800	5
	Folsomia candida	NOEC	≥ 99.8	0.001	≥ 99800	5
Spring cereals and flax						
Amidosulfuron WG 75	*Hypoaspis aculeifer*	NOEC	1000	0.053	≥ 18868	5
	Folsomia candida	NOEC	≥ 1000	0.053	≥ 18868	5
Amidosulfuron	*Hypoaspis aculeifer*	NOEC	≥ 759	0.041	≥ 18512	5
	Folsomia candida	NOEC	≥ 759	0.041	≥ 18512	5
Amidosulfuron-desmethyl	*Hypoaspis aculeifer*	NOEC	≥ 75.9 [A)]	0.019	≥ 3995	5
	Folsomia candida	NOEC	8	0.019	421	5
Amidosulfuron-desmethyl-chloropyrimidine	*Hypoaspis aculeifer*	NOEC	≥ 89	0.006	≥ 14833	5
	Folsomia candida	NOEC	56	0.006	9333	5
Amidosulfuron-guanidine	*Hypoaspis aculeifer*	NOEC	≥ 100	0.018	≥ 5556	5
	Folsomia candida	NOEC	≥ 100	0.018	≥ 5556	5
Amidosulfuron-biuret	*Hypoaspis aculeifer*	NOEC	≥ 10 [B)]	0.002	≥ 5000	5
	Folsomia candida	NOEC	≥ 10 [B)]	0.002	≥ 5000	5
Amidosulfuron-ADMP	*Hypoaspis aculeifer*	NOEC	≥ 99.8	0.002	≥ 49900	5
	Folsomia candida	NOEC	≥ 99.8	0.002	≥ 49900	5

Compound	Species	Endpoint [mg/kg soil]		$PEC_{soil,max}$ [mg/kg soil]	TER_{LT}	Trigger
Grass (spring and autumn)						
Amidosulfuron WG 75	*Hypoaspis aculeifer*	NOEC	≥ 1000	0.008	≥ 125000	5
	Folsomia candida	NOEC	≥ 1000	0.080	≥ 12500	5
Amidosulfuron	*Hypoaspis aculeifer*	NOEC	≥ 759	0.006	≥ 126500	5
	Folsomia candida	NOEC	≥ 759	0.006	≥ 126500	5
Amidosulfuron-desmethyl	*Hypoaspis aculeifer*	NOEC	≥ 75.9 [A)]	0.003	≥ 25300	5
	Folsomia candida	NOEC	8	0.003	2667	5
Amidosulfuron-desmethyl-chloropyrimidine	*Hypoaspis aculeifer*	NOEC	≥ 89	< 0.001	≥ 89000	5
	Folsomia candida	NOEC	56	< 0.001	56000	5
Amidosulfuron-guanidine	*Hypoaspis aculeifer*	NOEC	≥ 100	0.003	≥ 33333	5
	Folsomia candida	NOEC	≥ 100	0.003	≥ 33333	5
Amidosulfuron-biuret	*Hypoaspis aculeifer*	NOEC	≥ 10 [B)]	0.001	≥ 10000	5
	Folsomia candida	NOEC	≥ 10 [B)]	0.001	≥ 10000	5
Amidosulfuron-ADMP	*Hypoaspis aculeifer*	NOEC	≥ 99.8	< 0.001	≥ 99800	5
	Folsomia candida	NOEC	≥ 99.8	< 0.001	≥ 99800	5

[A)] Endpoint estimated from amidosulfuron divided by 10
[B)] Endpoint estimated from amidosulfuron-guanidin divided by 10

All TER values clearly exceed the trigger value of 5 indicating that no unacceptable adverse effects on soil macro-organisms are to be expected from the intended use of the product.

CP 10.4.2.1 Species level testing

Report: KCP 10.4.2.1/01 [redacted]; 2015; M-507488-01-1
Title: Amidosulfuron WG 75 W: Influence on mortality and reproduction of the soil mite species Hypoaspis aculeifer tested in artificial soil
Report No.: LAR-HR-109/14
Document No.: M-507488-01-1
Guideline(s): OECD 226 (2008)
US EPA OCSPP: Not Applicable
Guideline deviation(s): Yes, but acceptable
GLP/GEP: **yes**

This study has been previously summarised and evaluated on document MCA level, to deliver information on the active substance amidosulfuron. Please refer to data point KCA 8.4.2.1/01.

Report: KCP 10.4.2.1/02 [redacted]; 2014; M-506088-01-1
Title: Amidosulfuron WG 75 W: Influence on the reproduction of the collembolan species Folsomia candida tested in artificial soil
Report No.: FRM-Coll-178/14
Document No.: M-506088-01-1
Guideline(s): OECD 232 (2009)
US EPA OCSPP Not Applicable
Guideline deviation(s): Yes, but acceptable
GLP/GEP: **yes**

This study has been previously summarised and evaluated on document MCA level, to deliver information on the active substance amidosulfuron. Please refer to data point KCA 8.4.2.1/02.

CP 10.4.2.2 Higher tier testing

Not required as the risk for other non-target soil meso- and macro-organisms is acceptable.

CP 10.5 Effects on soil nitrogen transformation

Ecotoxicological endpoints used in risk assessment

Table CP 10.5- 1: Endpoints of the formulation Amidosulfuron WG75 used in risk assessment

Test substance	Test design	Ecotoxicological endpoint		References
	Soil nitrogen transformation			
Amidosulfuron WG 75	28 d	no unacceptable effects	≥ 0.4 mg prod./kg dws ≥ 0.3 mg a.s./kg dws	[redacted]; 2009; M-356874-01-1 KCP 10.5/01

dws = dry weight soil; prod. = product, a.s. = active substance

Table CP 10.5- 2: Endpoints of the active substance amidosulfuron and metabolites used in risk assessment

Test substance	Test design	Ecotoxicological endpoint		References
	Soil nitrogen transformation			
Amidosulfuron	28 d	no unacceptable effects	≥0.8 mg a.s./kg dws	[redacted] 1987; M-119378-01-2 KCA 8.5 /01
Amidosulfuron-desmethyl	28 d	no unacceptable effects	≥ 0.29 mg p.m./kg dws	[redacted]; 2015; M-527883-01-1 KCA 8.5 /11
Amidosulfuron-desmethyl-chloropyrimidine	28 d	no unacceptable effects	≥ 0.39 mg p.m./kg dws	[redacted]; 2009; M-359509-01-1 KCA 8.5/06
Amidosulfuron-guanidine	28 d	no unacceptable effects	≥ 0.29 mg p.m./kg dws	[redacted]; 2009; M-359398-01-1 KCA 8.5/07
Amidosulfuron-biuret	28 d	no unacceptable effects	≥ 0.30 mg p.m./kg dws	[redacted]; 2014; M-504115-01-1 KCA 8.5 /08
Amidosulfuron-ADMP	28 d	no unacceptable effects	≥ 0.137 mg p.m./kg dws	[redacted]; 2013; M-453511-01-1 KCA 8.5/09
Amidosulfuron-ADHP	28 d	no unacceptable effects	≥ 0.10 mg p.m./kg dws	[redacted]; 2015; M-541593-01-1 KCA 8.5/10

dws = dry weight soil; prod. = product, a.s. = active substance; p.m. = pure metabolite
Bold values used for the risk assessment

The metabolite **amidosulfuron-ADHP** was observed exclusively in the anaerobic soil metabolism study, where an abundance of 10.9 % of applied was reported for day 90 after soil flooding. Due to the only limited relevance of anaerobic conditions for the use pattern of the present product and a no adverse effect level (<25%) at 0.1 mg p.m./kg dws in the nitrogen transformation study it can be concluded that this metabolite does not pose an unacceptable risk to soil micro-organisms and a formal risk assessment is not considered to be required.

Risk assessment for Soil Nitrogen Transformation

Table CP 10.5- 3: Risk Assessment for soil micro-organisms

Compound	Species	Endpoint	$PEC_{soil,max}$ [mg/kg]	Refinement required
Winter cereals				
Amidosulfuron WG 75	Soil micro-organisms	≥ 0.4 mg prod./kg dws	0.043	No
Amidosulfuron	Soil micro-organisms	≥ 0.8 mg a.s./kg dws	0.035	No
Amidosulfuron-desmethyl	Soil micro-organisms	≥ 0.29 mg p.m./kg dws	0.015	No
Amidosulfuron-desmethyl-chloropyrimidine	Soil micro-organisms	≥ 0.39 mg p.m./kg dws	0.004	No
Amidosulfuron-guanidine	Soil micro-organisms	≥ 0.29 mg p.m./kg dws	0.014	No
Amidosulfuron-biuret	Soil micro-organisms	≥ 0.30 mg p.m./kg dws	0.002	No
Amidosulfuron-ADMP	Soil micro-organisms	≥ 0.137 mg p.m./kg dws	0.001	No
Spring cereals and flax				
Amidosulfuron WG 75	Soil micro-organisms	≥ 0.4 mg prod./kg dws	0.053	No
Amidosulfuron	Soil micro-organisms	≥ 0.8 mg a.s./kg dws	0.041	No
Amidosulfuron-desmethyl	Soil micro-organisms	≥ 0.29 mg p.m./kg dws	0.019	No
Amidosulfuron-desmethyl-chloropyrimidine	Soil micro-organisms	≥ 0.39 mg p.m./kg dws	0.006	No
Amidosulfuron-guanidine	Soil micro-organisms	≥ 0.29 mg p.m./kg dws	0.018	No
Amidosulfuron-biuret	Soil micro-organisms	≥ 0.30 mg p.m./kg dws	0.002	No
Amidosulfuron-ADMP	Soil micro-organisms	≥ 0.137 mg p.m./kg dws	0.002	No

Compound	Species	Endpoint	$PEC_{soil,max}$ [mg/kg]	Refinement required
Grass (spring and autumn)				
Amidosulfuron WG 75	Soil micro-organisms	≥ 0.4 mg prod./kg dws	0.008	No
Amidosulfuron	Soil micro-organisms	≥ 0.8 mg a.s./kg dws	0.006	No
Amidosulfuron-desmethyl	Soil micro-organisms	≥ 0.29 mg p.m./kg dws	0.003	No
Amidosulfuron-desmethyl-chloropyrimidine	Soil micro-organisms	≥ 0.39 mg p.m./kg dws	< 0.001	No
Amidosulfuron-guanidine	Soil micro-organisms	≥ 0.29 mg p.m./kg dws	0.003	No
Amidosulfuron-biuret	Soil micro-organisms	≥ 0.30 mg p.m./kg dws	< 0.001	No
Amidosulfuron-ADMP	Soil micro-organisms	≥ 0.137 mg p.m./kg dws	< 0.001	No

a.s. = active substance, p.m. = pure metabolite, prod. = product, dws = dry weight soil

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 ≤ 25% after 100 days.

In no case did deviations from the control exceed the threshold level of 25% at 28 days after application. The tested concentrations by far exceeded the maximum predicted environmental concentrations in soil of the respective components. This indicates acceptable risk to soil micro-organisms for the intended uses.

Report: KCP 10.5/0[redacted]; 2009; M-356874-01-1
Title: Amidosulfuron WG 75 W: Determination of effects on nitrogen transformation in soil
Report No.: FRM-N-126/09
Document No.: M-356874-01-1
Guideline(s): OECD/OCDE Guideline No 216, adopted: 21st January 2000, OECD Guideline for the testing of chemicals, soil microorganisms: nitrogen transformation test
Guideline deviation(s): none
GLP/GEP: **yes**

Executive Summary:
The objective of this study was to determine the influence of Amidosulfuron WG 75 on the activity of soil microflora with regard to nitrogen transformation in a laboratory test. The test was performed in accordance with OECD guideline 216 (2000) by measuring the nitrogen turnover.

A loamy sand soil (according to DIN ‘mittel lehmiger Sand’, texture: 10.4 % clay, 17.4 % silt, 72.2 % sand, 1.57 % org. carbon content) was exposed for 28 days to 0.08 and 0.40 mg test item/kg soil dry weight. Application rates were equivalent to 0.06 and 0.30 kg test item/ha. Lucerne-grass-green meal was added to the soil (5 g/kg dry weight soil) to stimulate nitrogen transformation.

During the 28-day test, 0.08 mg test item/kg dry weight soil and the 0.4. mg test item/kg dry weight soil had no relevant influence on nitrogen transformation in a loamy sand soil supplemented with Lucerne-grass-green meal. In none of the time intervals analysed during the 28 day exposure the difference in the daily nitrate-N rates exceeds the trigger value of 25 %. If used as recommended, Amidosulfuron WG 75 should not have an impact on nitrogen transformation in soils.

Materials and Methods:
Test item: Amidosulfuron WG 75 W; Short name: AMS WG 75 W; Specification No.: 102000000550; Batch/FL.-No.: EFKE001675; Material No.: 05938848; TOX-No.: 08561-00; Analysed quantity of a.s. in product: 75.3 % w/w.

A loamy sand soil (according to DIN 'mittel lehmiger Sand', texture: 10.4 % clay, 17.4 % silt, 72.2 % sand, 1.57 % org. carbon content) was exposed for 28 days to 0.08 and 0.40 mg test item/kg soil dry weight. Application rates were equivalent to 0.06 and 0.30 kg test item/ha. Lucerne-grass-green meal was added to the soil (5 g/kg dry weight soil) to stimulate nitrogen transformation. Soil samples of 300 g dry weight per incubation flask were used. Three replicates were prepared per treatment. Sodium chloride was used as a reference standard in the tests. The soil was held in the dark at 20 ± 2 °C and about 40-50 % of the maximum water holding capacity (WHC_{max}). Immediately after treatment and after 7, 14 and 28 days, the soil in each jar was mixed by shaking. Moist samples (10 g dry soil dry weight) were extracted with KCl, the content of ammonium-N, nitrite-N and nitrate-N plus nitrite-N were determined using a continuous flow Analysis system.

Dates of work: July 23, 2009 – August 26, 2009

Results:
Validity Criteria:
The coefficient of variation in the control at the end of the study was 1 %. Therefore the validity criteria for the study, which requires a coefficient of variation ≤ 15 % in the control, was fulfilled.

In separate tests (non-GLP) the reference standard sodium chloride was used. In these tests with the agricultural soil, 16 g NaCl/kg dry weight soil had a distinct and long-term (> 28 days) influence on microbial mineralization of nitrogen.

Nitrogen transformation:
During the 28-day test, 0.08 mg Amidosulfuron WG 75 W/kg dry weight soil and the 0.4. mg test item/kg dry weight soil had no relevant influence on nitrogen transformation in a loamy sand soil supplemented with Lucerne-grass-green meal. In none of the time intervals analysed during the 28 day exposure the difference in the daily nitrate-N rates exceeds the trigger value of 25 %.

Table CP 10.5- 4: Effects on nitrogen transformation in soil after treatment with Amidosulfuron WG 75

Time Interval (days)	Application rates Amidosulfuron WG 75 W										
	Control			0.08 mg/kg dry weight soil				0.40 mg/kg dry weight soil			
	Nitrate-N[1)]			Nitrate-N[1)]			% difference to control	Nitrate-N[1)]			% difference to control
0-7	-1.92	±	0.17	-1.75	±	0.07	**9** n.s.w	-1.63	±	0.01	**15***w
7-14	1.12	±	0.08	1.13	±	0.13	**3** n.s.	1.08	±	0.18	**3** n.s.
14-28	1.64	±	0.02	1.71	±	0.05	**4** n.s.	1.71	±	0.10	**4** n.s.

[1)] Rate: Nitrate-N in mg/kg dry weight soil/time interval/day, mean of 3 replicates and standard deviation
*w = Statistically significant difference to the control (Welch-t Test for inhomogeneous variances, two-sided, α = 0.05).
n.s.w = No statistically significant difference to the control (Welch-t Test for inhomogeneous variances, two-sided, α = 0.05).
n.s. = No statistically significant difference to the control (Student-t Test, two-sided, α = 0.05).

Conclusion:
If used as recommended, Amidosulfuron WG 75 should not have an impact on nitrogen transformation in soils.

CP 10.6 Effects on terrestrial non-target higher plants

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.

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. ER_{50} values for 6-10 species, representing a broad range of plant species.

Overall, four Tier 2 dose response tests have been conducted with the formulation Amidosulfuron WG 75, including three vegetative vigour studies and one seedling emergence study. Furthermore, one higher tier semi-field test and one field test with the most sensitive species under realistic outdoor conditions have been conducted with the formulation. An overview of the studies and the endpoints relevant for the non-target plant risk assessment is provided in the table below.

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

Table CP 10.6- 1: Survey of non-target plant tests performed with Amidosulfuron WG 75

Number of species tested (species)	Test method Test substance Application rate	Effects	Reference
vegetative vigour			
Dicotyledoneae: 4 (cabbage, soybean, tomato, turnip) Monocotyledoneae: 2 (oat, perennial ryegrass)	vegetative vigour; Tier 2 dose response 0 (control), 5.1, 10, 20, 42, 25 and 81 g a.s./ha for cabbage, perennial ryegrass and tomato 0 (control), 0.33, 1.3, 5.1, 20 and 81 g a.s./ha for soybean 0 (control) and 81 g a.s./ha for oat and turnip with observations on mortality and morphological abnormalities at test termination, evaluation of the effects on shoot dry weight 21 days after application	most sensitive species: soybean; **lowest ER_{50}: 67 g a.s./ha**	[redacted],; 2002; M-240817-01-1 KCP 10.6.2/01
Dicotyledoneae: 3 (sugar beet, cucumber, sunflower) Monocotyledoneae: 1 (onion)	vegetative vigour; Tier 2 dose response 0 (control), 1.41, 2.81, 5.63, 11.25, 22.5 and 45 g a.s./ha for sugar beet, cucumber and onion 0 (control), 1.41, 2.81, 5.63, 11.25, 22.5 and 45 g a.s./ha for sunflower (1st run) 0 (control), 0.18, 0.35, 0.7, 1.41, 2.81 and 5.63 g a.s./ha for sunflower (2nd run) 0 (control), 0.044, 0.088, 0.18, 0.35, 0.7 and 1.41 g a.s./ha for sunflower (3rd run) with assessments (phytotoxicity ratings, survival) 7, 14 and 21 days after application, shoot dry weight and growth stages were determined at the final assessment	most sensitive species: sunflower; **lowest ER_{50}: 0.11 g a.s./ha**	[redacted],; 2010; M-366958-01-1 KCP 10.6.2/03
Dicotyledoneae: 5 (non-crop species (*Asteraceae*))	vegetative vigour; Tier 2 dose response 0 (control) 0.022, 0.044, 0.088, 0.18, 0.35 and 0.7 g a.s./ha for *Bellis perennis* 0 (control), 0.044, 0.088, 0.18, 0.35, 0.7 and 1.41 g a.s./ha for *Achillea millefolium* 0 (control), 0.088, 0.18, 0.35, 0.7, 1.41 and 2.81 g a.s./ha for *Centaurea cyanus*, *Matricaria chamomilla*, *Senecio vulgaris* with assessments (survival, visual phytotoxicity, plant growth stage and shoot dry weight) 7, 14 and 21 days after application	most sensitive species: *Achillea millefolium*; **lowest ER_{50}: 0.461 g a.s./ha**	[redacted],; 2010; M-389517-01-1 KCP 10.6.2/05
Dicotyledoneae: 5 (non-crop species (*Asteraceae*, *Amaranthaceae*, *Caryophyllaceae*))	vegetative vigour; Tier 2 dose response 0 (control) 0.09, 0.18, 0.35, 0.70, 1.41 and 2.81 g a.s./ha for *Amaranthus retroflexus* 0 (control), 0.18, 0.35, 0.70, 1.41, 2.81 and 5.63 g a.s./ha for *Stellaria media* 0 (control), 0.35, 0.70, 1.41, 2.81, 5.63 and 11.25 g a.s./ha for *Bellis perennis* 0 (control), 1.41, 2.81, 5.63, 11.25, 22.5 and 45 g a.s./ha for *Centaurea cyanus, Senecio vulgaris*	most sensitive species: *Amaranthus retroflexus*; **lowest ER_{50}: 0.07 g a.s./ha**	[redacted],; 2011; M-405630-01-1 KCP 10.6.2/04

Number of species tested (species)	**Test method** **Test substance** **Application rate**	**Effects**	**Reference**
vegetative vigour			
	with assessments (survival, visual phytotoxicity, plant growth stage and shoot dry weight) 7, 14 and 21 days after application.		
Dicotyledoneae: 1 (sunflower)	vegetative vigour; Tier 3 semi-field 0 (control) 0.044, 0.088, 0.18 and 0.35g a.s./ha for sunflower with assessments (survival, visual phytotoxicity, plant growth stage and shoot dry weight) 7, 10, 14 and 22 days after application.	no significant effects up to the highest rate tested of 0.35 g a.s. /ha	[redacted],; [redacted]; 2010; M-389529-01-1 KCP 10.6.4/01
Dicotyledoneae: 1 (sunflower)	vegetative vigour; Tier 3 field 0 (control) 0.4, 0.8, 0.16 and 0.32g a.s./ha for sunflower with assessments (survival, visual phytotoxicity, plant growth stage and shoot dry weight) 7, 14 and 19 days after application.	**lowest ER_{50} (shoot dry weight): 1.69 g a.s./ha**	[redacted],; 2015; M-548832-01-1 KCP 10.6.4/02
seedling emergence			
Dicotyledoneae: 7 (cabbage, cucumber, turnip, soybean, sugar beet, sunflower, tomato) Monocotyledoneae: 3 (oat, onion, ryegrass)	seedling emergence Tier 2 dose response 0 (control), 1.41, 2.81, 5.63, 11.25, 22.5 and 45 g a.s./ha for sugar beet, cabbage, turnip, cucumber, soybean, tomato, onion, oat, sunflower and ryegrass 0 (control), 0.18, 0.35, 0.7, 1.41, 2.81 and 5.63 g a.s./ha for sunflower with daily assessment of emergence until 70 % emergence of control seedlings, assessments of emergence, survival and phytotoxicity 7 and 14 days after 70 % emergence, assessments of total emergence, survival of emerged seedlings, visual phytotoxicity, growth stages and shoot dry weight at test termination	most sensitive species: sunflower; **lowest ER_{50}: 1.08 g a.s./ha**	[redacted]; 2010; M-366951-01-1 KCP 10.6.2/06

a.s. = active substance

<u>**Tier 2 studies**</u>

The first study ([redacted],; 2002; M-240817-01-1) was confined to a vegetative vigour test with six species. In order to meet actual regulatory requirements, four additional species were tested ([redacted]; 2010; M-366958-01-1) and a seedling emergence test was performed with the whole set of ten species ([redacted]; 2010; M-366951-01-1), to have effects on vegetative vigour and seedling emergence tested with an identical spectrum of ten species. The ER_{50} with regard to dry weight reduction turned out to be the lowest endpoint in all tests and for all species.

The sunflower turned out to be the most sensitive species in both tests, vegetative vigour and seedling emergence. A lowest endpoint of 0.11 g a.s./ha was obtained in the vegetative vigour test. Therefore, five additional wild species from the same family as sunflower (Asteraceae) were tested in a vegetative vigour test ([redacted],; 2010; M-389517-01-1). All five wild Asteraceae-species turned out to be less sensitive than sunflower. However, only two additional ER_{50}-figures were obtained, since

the test rates were too low. The three wild species of Asteraceae for which no ER_{50} were obtained in the first test run were tested in a further study with higher rates. Upon a request of a national authority, *Stellaria media* and *Amaranthus retroflexus* were included in this test ([redacted]; 2011; M-405630-01-1). This study led to an ER_{50} of 0.07 g a.s./ha for *Amaranthus*, which is the lowest ER_{50} within the whole set of NTP-data for Amidosulfuron WG75.

Conducting a seedling emergence test with wild species is not applicable, because seed germination in wild species is subject to high biological variability and cannot be synchronized. Further details of the studies are given in the summary at Point CP 10.6.2 below.

Table CP 10.6- 2: Survey of effects of Amidosulfuron WG 75 on non-target plants, based on Tier 2 studies

Species	ER_{50} vegetative vigour dry weight reduction [g a.s./ha]	ER_{50} seedling emergence dry weight reduction [g a.s./ha]
sugar beet	> 45	1.56
cabbage	> 45	7.09
turnip	> 45	8.32
Stellaria media	2.04	n.d.
cucumber	> 45	9.75
Amaranthus retroflexus	**0.07**	n.d.
soy bean	> 45	> 45
sunflower	0.11	**1.08**
Achillea millefolium	0.461	n.d.
Bellis perennis	0.52	n.d.
Centaurea cyanus	25.46	n.d.
Matricaria chamomilla	0.585	n.d.
Senecio vulgaris	2.29	n.d.
tomato	> 45	13.23
onion	> 45	4.42
oat	> 45	> 45
ryegrass	> 45	17.27

a.s. = active substance; n.d. = not determined

The vegetative vigour data reveal a wide range of sensitivities between the species. Nine species were not affected by more than 50% up to the full application rate and higher.

Higher-tier studies

For the vegetative vigour a further higher-tier risk assessment is required, which will be based on results of a semi-field (KCP 10.6.4/01) and a field (KCP 10.6.4/02) test for Amidosulfuron WG75 with sunflower. These tests are considered to also cover the sensitivity of amaranth, for the reasons discussed below.

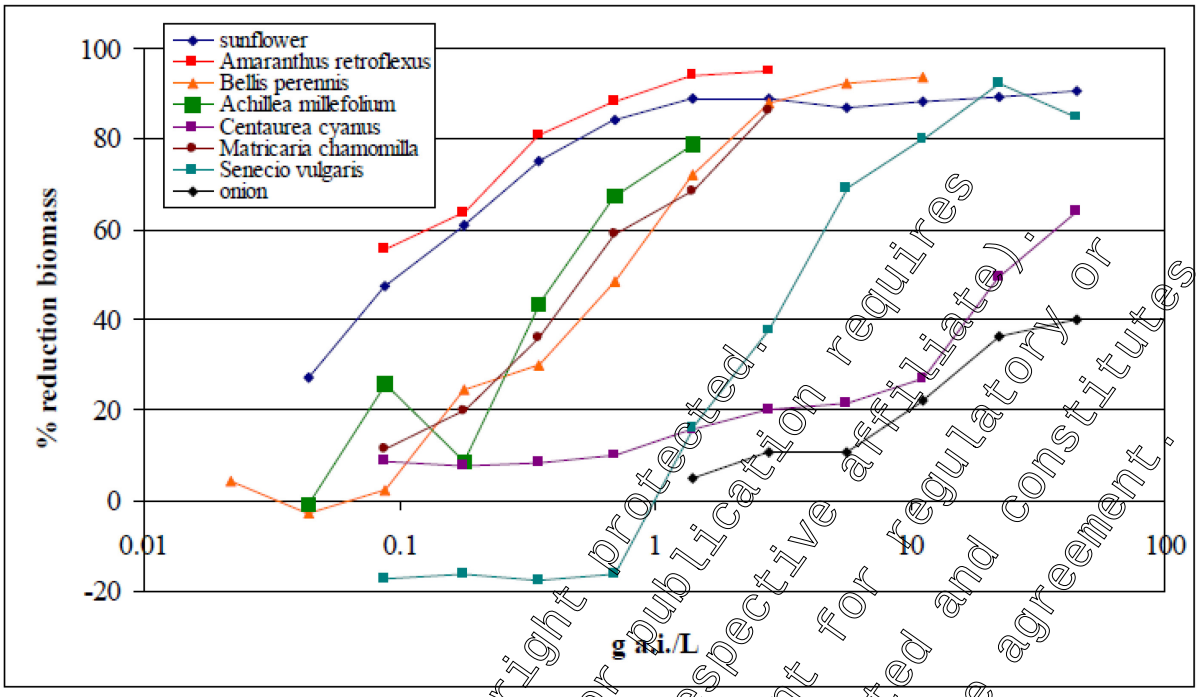

Fig 1: Dose-response curves of all species with an ER_{50} < 45 g a.i./ha (greenhouse tests)

Figure 1 reveals that the dose-response curves for amaranth and sunflower are very close. The following comparison of the sensitivity for both species was conducted

1. by comparing the 95% confidence limits (see figure 2) and
2. by comparing the difference between the biomass results via a pseudo-individual analysis (see figure 3).

In order to run a statistical evaluation, the biomass inhibition pseudo-individual data were created by comparing the biomass for each replicates with the mean biomass in the control.
% inhibition = 100 (mean$biomass_{control}$ – $biomass_{treatment}$)/mean$biomass_{control}$

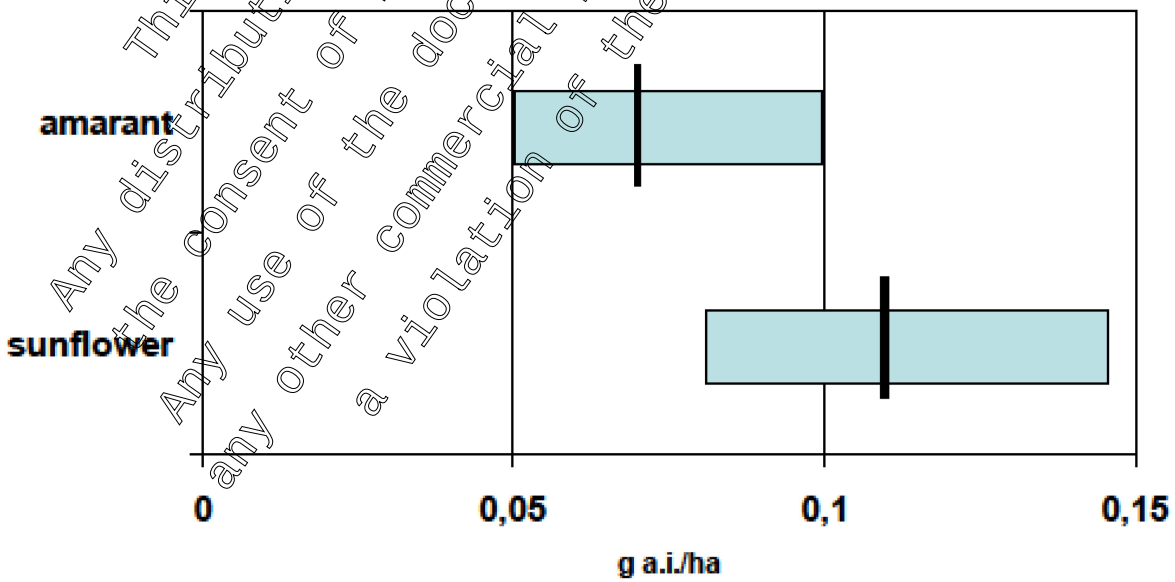

Fig 2: ER_{50}-levels and 95% confidence limits for amaranth and sunflower (greenhouse tests)

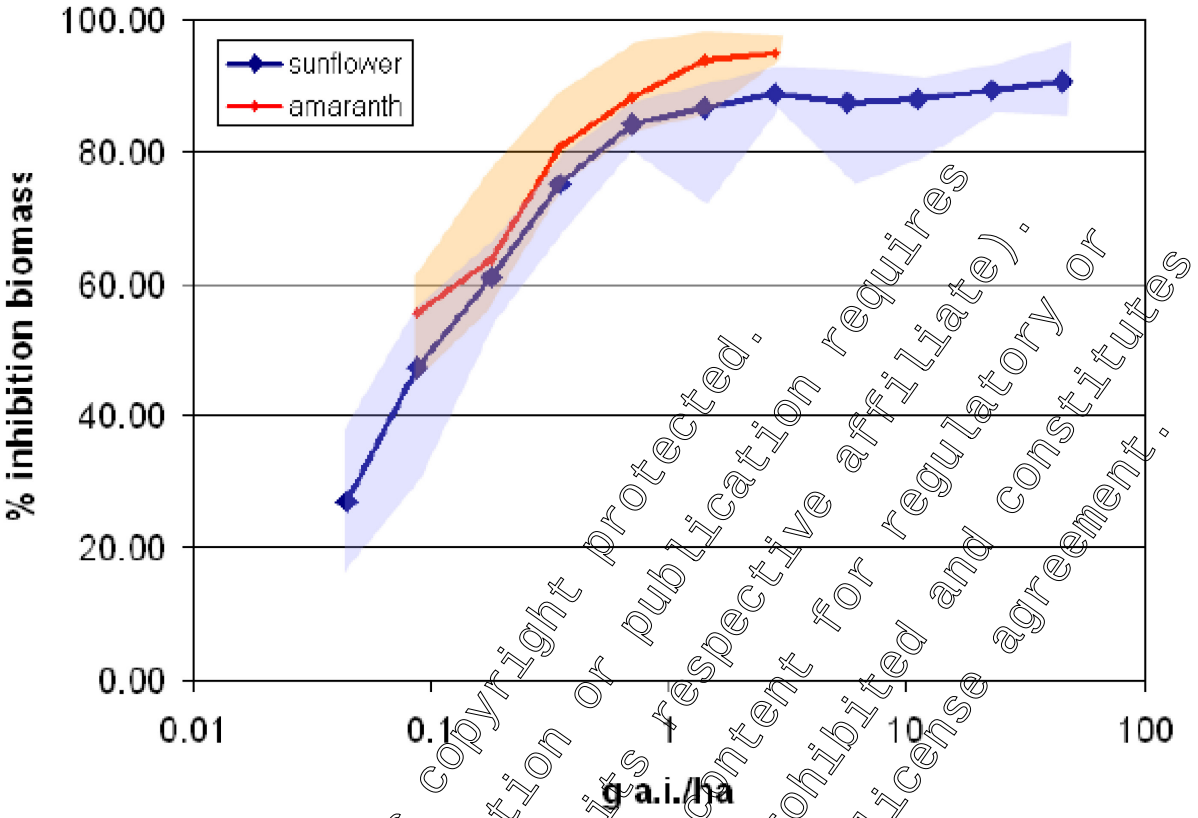

Fig 3: Mean and variation of % inhibition of biomass for amaranth and sunflower (greenhouse tests). The shaded areas indicate the range between minimum and maximum values.

Fig. 2 reveals a distinct overlap of confidence limits of the ER_{50}-levels for both species. Fig 3 illustrates that both species show a clear dose-response. The dose-response curve of amaranth is slightly shifted to the left compared to the curve of sunflower. For each test rate where both species were tested the pseudo-individual inhibition percentages were compared with an U-test. The % inhibition of biomass were not significantly different at treatment levels of 0.09, 0.18, 0.35 and 0.7 g a.s./ha indicating no difference in sensitivity between the two species at those levels relevant for ER50 calculation. It can be concluded that the difference in sensitivity between sunflower and amaranth can therefore be regarded as negligible.

The higher-tier risk assessment is based on the outcome of the **field test** with sunflower. At the highest test rate in the **semi-field study** that was 0.35 g a.s./ha, sunflower were inhibited by 10.5%. Although no higher rates have been tested, the rate leading to 50% effect can be estimated to be considerably higher than 0.35 g/ha. It can therefore be concluded that **the ER_{50}>0.35 g a.s./ha covers the effects on *Amaranthus retroflexus* as well**, although no semi-field test has been conducted with this species. The outdoor field ER_{50} of 1.69 g a.s./ha is in-line with the findings from the semi-field study.

In the risk assessment based on the outdoor field ER_{50} of 1.69 g a.s./ha the assessment factor of 5 can be justified according to the Notifier for the following reasons:

1. Sunflower is the 2nd most sensitive species among 17 species tested.
2. As presented above the potential effects on amaranth are covered.

A comparison of the effects on sunflower within the standard test in the greenhouse compared to sunflowers grown under outdoor conditions is given in the table below.

Table CP 10.6- 3: Comparison of % dry weight reduction compared to the untreated control on sunflower in the greenhouse and under outdoor-conditions.

rate [g a.s./ha]	greenhouse			semi-field	field
	1st run	2nd run	3rd run		
0.044			27.04	-14.2	
0.088			47.34	-12.2	
0.18		61.0		-19.5	
0.35		74.3	75.83	10.5	
0.4					5.9
0.7		83.6	85.05		
0.8					36.1
1.41	84.8	88.0	87.38		
1.6					51.8
2.81	88.6	89.1			
3.2					63.7
5.63	87.3				
11.25	88.1				
22.5	89.2				
45	90.6				

The results clearly indicate that the ER_{50} is >0.35 g a.s./ha for sunflower under outdoor conditions. Since no definitive ER_{50} could have been determined from the semi-field study, a field study ([redacted].; 2015; M-548832-01-1) has been conducted. This study led to an ER_{50} of 1.69 g a.s./ha. This endpoint shall be used for the risk assessment. Since this endpoint is derived from a higher tier study with the most sensitive species an assessment factor of 5 can be used.

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)*[18] from the spray drift predictions of [redacted] *(2000)*[19]. 2.77%, 0.57% and 0.29% of the full application rates of 30 g a.s./ha in cereals, 30 g a.s./ha in flax and 45 g a.s./ha on grass and pastures (calculations below given in g a.s./ha for reasons of readability) are assumed to reach areas at 1 m, 5 m and 10 m from the edge of the crop, respectively. The corresponding off-field predicted environmental rates ($PER_{off\text{-}field}$) are presented in the table below.

[18] 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.

[19] [redacted] (2000) Drift, drift-reducing sprayers and sprayer testing. Aspects of Applied Biology 57, 2000, Pesticide Application. Public domain.

Table CP 10.6- 4: Predicted environmental rates (PER) at 1m and 5 m distance from the field edge

Crop	Timing of application	Number of applications	Maximum application rate [g a.s./ha]	MAF_{mean}*	PER at 1m distance [g/ha]	PER at 5m distance [g/ha]	PER at 10m distance [g/ha]
Cereals (winter and spring)	winter cereals BBCH 13-49	1	15	1.0	0.416	0.086	0.044
	winter cereals BBCH 21-49 spring cereals BBCH 12-49	1	30	1.0	0.831	0.171	0.087
Flax	Before flower buds are visible	1	30	1.0	0.831	0.171	0.087
Grass/ pasture	Spring	1	45	1.0	1.247	0.257	0.131

* MAF = Multiple application factor (1 application), acc. to EFSA (2009): Guidance Document on Risk Assessment for Birds & Mammals.

Deterministic Risk assessment

According to the Terrestrial Guidance Document[20], the risk to non-target plants is evaluated by comparing the lowest ER_{50} observed in the laboratory studies with the drift rates ($PER_{off\text{-}field}$) inclosing a safety factor of 5. In addition, the usage of drift reducing nozzles is considered.

Table CP 10.6- 5: Deterministic risk assessment for Amidosulfuron WG 75 based on effects on vegetative vigour

Distance	Drift[2)]	PER	TER			
[m]	(%)	no drift reduction [g a.s./ha]	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
Cereals (winter) and flax, 1 × 15 g a.s./ha; ER_{50} = 1.69 g a.s./ha						
1[1)]	2.77	0.416	**4.07**	8.13	16.27	40.67
5	0.57	0.086	19.77	39.53	79.06	197.66
Cereals (winter and spring) and flax, 1 × 30 g a.s./ha; ER_{50} = 1.69 g a.s./ha						
1[1)]	2.77	0.831	**2.03**	**4.07**	8.13	20.34
5	0.57	0.171	9.88	19.77	39.53	98.83
Grass and pasture, 1 × 45 g a.s./ha; ER_{50} = 1.69 g a.s./ha						
1[1)]	2.77	1.247	**1.36**	**2.71**	5.42	13.56
5	0.57	0.257	6.59	13.18	26.35	65.89

1) 1 m distance is defined as "no in-crop buffer zone"
2) BBA drift values (for 1 application, field crops), see Terr. Guidance Doc. SANCO/10329/2002 rev 2 final
In bold: TERs below the trigger of 5.

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

Table CP 10.6- 6: Deterministic risk assessment for Amidosulfuron WG 75 based on effects on <u>seedling emergence</u>

Distance	Drift[2)]	PER	TER			
[m]	(%)	no drift reduction [g a.s./ha]	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
Cereals (winter) and flax, 1 × 15 g a.s./ha; lowest ER_{50} = 1.08 g a.s./ha						
1[1)]	2.77	0.416	**2.60**	5.20	10.40	25.99
5	0.57	0.086	12.63	25.26	50.53	126.32
Cereals (winter and spring) and flax, 1 × 30 g a.s./ha; lowest ER_{50} = 1.08 g a.s./ha						
1[1)]	2.77	0.831	**1.30**	**2.60**	5.20	13.00
5	0.57	0.171	6.32	12.63	25.26	63.16
Grass and pasture, 1 × 45 g a.s./ha; lowest ER_{50} = 1.08 g a.s./ha						
1[1)]	2.77	1.247	**0.87**	**1.73**	**3.47**	8.66
5	0.57	0.257	**4.21**	8.42	16.84	42.11
10	0.29	0.131	8.28	16.55	33.10	82.76

1) 1 m distance is defined as "no in-crop buffer zone"
2) BBA drift values (for 1 application, field crops), see Terr. Guidance Doc. SANCO/10329/2002 rev 2 final
In bold: TERs below the trigger of 5.

<u>Probabilistic Risk assessment</u>

In addition to the deterministic risk assessment the Terrestrial Guidance Document recommends the use of the HR_5 (the rate below which less than 5% of the species will be harmed above the ER_{50} level) which can be calculated from the data sets of ER_{50} growth inhibition levels. The EU guidance document for terrestrial ecotoxicology states: If the ED_{50}[21] 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 HR_5 itself (TER = 1) can be regarded to be protective.

The HR_5 was calculated according to
$HR_5 = 10 \exp(avg - ks * std)$ [22]
with
avg = mean of log10 transformed ER_{50} values
std = standard deviation of log10 transformed ER_{50} values
ks = extrapolation factor

The HR_5 calculations were based on ER_{50}-values for shoot dry weight. 'Greater than' figures, which did not allow to calculate an HR_5, were excluded from the HR_5 calculation.

<u>Vegetative vigour:</u>

Since the risk assessment for vegetative vigour is based on higher tier study data for a single sensitive species (sunflower field study), a probabilistic assessment is not applicable to this case. The probabilistic risk assessment will be conducted for seedling emergence data only, see below.

[21] The ER_{50} is meant

[22] [redacted]. (2000): Uncertainty of the hazardous concentration and fraction affected for normal species sensitivity distributions. Ecotoxicology and Environmental Safety, 46: 1-18.

Seedling emergence:
The HR_5 calculation for the shoot dry weight-ER_{50}-values from the seedling emergence study leads to a HR_5 value of 1.015 g a.s./ha, see Table CP 10.6-7.

Table CP 10.6- 7: HR_5-calculation for seedling emergence with Amidosulfuron WG 75.

Species	ER_{50} seedling emergence dry weight reduction [g a.s./ha]
sugar beet	1.56
cabbage	7.09
turnip	8.32
cucumber	9.75
soy bean	>45*
sunflower	1.08
tomato	13.23
onion	4.42
oat	> 45*
ryegrass	17.27
HR_5 (g/ha)	**1.015**

a.s. = active substance.
* The 'greater than' figures were excluded from the calculation

The TER calculations for probabilistic risk assessment are summarised in the following table.

Table CP 10.6- 8: Probabilistic risk assessment for Amidosulfuron WG 75 based on effects on <u>seedling emergence</u>

Distance	Drift[2)]	PER	TER			
[m]	(%)	no drift reduction [g a.s./ha]	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
Cereals (winter) and flax, 1 × 15 g a.s./ha; HR_5 = 1.015 g a.s./ha						
1[1)]	2.77	0.416	2.44	4.89	9.77	24.43
Cereals (winter and spring) and flax, 1 × 30 g a.s./ha; HR_5 = 1.015 g a.s./ha						
1[1)]	2.77	0.831	1.22	2.44	4.89	12.21
Grass and pasture, 1 × 45 g a.s./ha; HR_5 = 1.015 g a.s./ha						
1[1)]	2.77	1.247	**0.81**	1.63	3.26	8.14
5	0.57	0.257	3.96	7.91	15.83	39.57

1) 1 m distance is defined as "no-in-crop-buffer zone"
2) BBA drift values (for 1 application, field crops), see Terr. Guidance Doc. SANCO/10329/2002 rev 2 final
In bold: TERs below the trigger of 1.

<u>Overall Conclusions of risk assessment for non-target terrestrial plants:</u>
Based on the deterministic risk assessment for vegetative vigour based on the sunflower field study, and the probabilistic risk assessment for seedling emergence based on HR_5 derived from the data on shoot dry weight, the following overall conclusions can be drawn:

	vegetative vigour, deterministic assessment based on sunflower field data		**seedling emergence,** probabilistic assessment based on HC_5 of Tier 2 study data on 10 species	
	nozzle type	**drift buffer**	**nozzle type**	**drift buffer**
Cereals (winter) and flax, **1 × 15 g a.s./ha**	**50% drift reduction**	**none**	conventional	none
	conventional	**5m buffer**		
Cereals (winter and spring) and flax, **1 × 30 g a.s./ha**	**75% drift reduction**	**none**	conventional	none
	conventional	**5m buffer**		
Grass and pasture, **1 × 45 g a.s./ha**	**90% drift reduction**	**none**	50% drift reduction	none
	50% drift reduction	**5m buffer**		
	conventional	**10m buffer**	conventional	5m buffer

Since Amidosulfuron WG 75 has stronger effects on the vegetative vigour of young plants than on the seedling emergence, the vegetative vigour data determine the risk assessment. Considering mitigation options for drift reduction as summarised above, Amidosulfuron WG 75 poses no unacceptable risk to terrestrial non-target plants in off-crop areas following the proposed uses.

CP 10.6.1 Summary of screening data

Report: KCP 10.6.1/01 [redacted]s; 2007; M-295670-01-1
Title: Soil mix crop screening test PPI-07008 - AE F075032 00 WG75 A1 (charge EFKE001341) - Amidosulfuron - Specification number 102000000550
Report No.: PPI-07008
Document No.: M-295670-01-1
Guideline(s): not applicable
Guideline deviation(s): not specified
GLP/GEP: **no**

Executive Summary:
The aim of this study was to determine potential effects of soil incorporated Amidosulfuron WG 75 on phytotoxicity and fresh weight of seedlings from 14 crop species under standard glasshouse conditions. The methods are based upon the EPPO guideline PPl/207 1998 and, more specifically, the Report 29 of the Biologische Bundesanstalt (BBA) - [redacted], 1997.

The test item was mixed into standard sandy-loam soil in the concentrations of 0.156, 0.625, 2.5, 10.0 and 40.0 g product/ha (equivalent to 0.117, 0.468, 1.875, 7.5 and 30 g a.s./ha) referring to 0.11, 0.44, 1.75, 7.0, and 28.0 µg product/kg soil. An untreated control was also included. On the following day, Seeds of 14 grass and broad-leaved crop species (EPPO code) *Hordium vulgare* (HORVS), *Lolium multiflorum* (LOLMU), *Secale cereale* (SECCW), *Triticum aestivum* (TRZAW), *Zea mays* var. *Vulgaris* (ZEAMA), *Beta vulgaris* (BEAVA), *Brassica napus* (BRSNW), *Glycine max* (GLXMA), *Helianthus annuus* (HELAN), *Lens culinaris* (LENCU), *Linium usitatissium* (LIUUT), *Phaseolus vulgari*s (PHSVN), *Pisum sativum* (PIBST), *Sinapis alba* (SINAL) were sown into the 5 soil concentrations and untreated soil into 4 replicate pots. The number of seedlings that emerged was counted in each pot. After emergence, the vigour of the seedlings was assessed visually on a percentage basis 15 days and 29 days after sowing. After the final visual assessment the shoot fresh

weight was measured. The percentage herbicidal effects obtained at various concentrations were used to calculate the selectivity thresholds (EC10).
Under standardized test conditions, 14 grass and broad-leaved crops showed a range of sensitivities towards soil incorporated Amidosulfuron WG 75. Based on phytotoxicity assessment and reduction of fresh weight the most sensitive crops are sugar-beet, sunflower, lentils, field peas, white mustard and oilseed rape. The first three crops require 6 half life times to reach the EC10 values shown in this study. The other sensitive crops mentioned here need 3-4 half life times to reach the EC10 values determined in this study. All grains were less sensitive.

Material and Methods:
Test item: Amidosulfuron WG 75 (AE F075032 00 WG75 A1).

Test species: 14 grass and broad-leaved crop species (EPPO code): *Hordium vulgare* (spring barley, HORVS), *Lolium multiflorum* (ryegrass, LOLMU), *Secale cereale* (winter rye, SECCW), *Triticum aestivum* (winter wheat, TRZAW), *Zea mays* var. *Vulgaris* (maize, ZEAMA), *Beta vulgaris* (sugar beet, BEAVA), *Brassica napus* (winter oilseed rape, BRSNW), *Glycine max* (soybean, GLXMA), *Helianthus annuus* (sunflower, HELAN), *Lens culinaris* (lentil, LENCU), *Linium usitatissium* (linseed, LIUUT), *Phaseolus vulgaris* (bean, PHSVN), *Pisum sativum* (field pea, PIBST), *Sinapis alba* (mustard white, SINAL).

The sample of Amidosulfuron WG 75 was diluted in water and mixed in the concentrations of 0.156, 0.625, 2.5, 10.0 and 40.0 g product/ha (equivalent to 0.117, 0.468, 1.875, 7.5 and 30 g a.s./ha) referring to 0.11, 0.44, 1.75, 7.0, and 28.0 µg product/kg soil (mixed in 10 cm soil depth with a bulk density of 1.43 g/cm³) into a standard sandy loam soil (20% sand, 57% silt, 23% clay at pH 6.8 and 1.4% organic matter). On the following day, seeds of 14 crop species (see above) were sown into the soil. The test run with four replicates in 9 cm diameter pots.

After sowing, the pots were placed in a greenhouse at 22°C ± 2°C day and 17°C ± 2°C night. As required, the pots were irrigated from above so as to keep the soil sufficiently moist for good plant growth but avoid any excess water draining from the pots. The number of seedlings that emerged was counted in each pot. After emergence, the vigour of the seedlings was assessed visually on a percentage basis (0 = no effect; 100 = complete kill) 15 days after sowing (DAS) and then 29 DAS. After the final visual assessment the shoot fresh weight was measured.

Results:
EC_{10} values were calculated based on visual phytotoxicity and on % fresh weight reduction and are given in the following table.

Table CP 10.6.1- 1: EC_{10} values for Amidosulfuron WG 75 based percent phytotoxicity (ratings and fresh weight harvest at 29 DAT) – EC_{10} values expressed as well as µg formulated product/kg soil and as mg formulated product/ha

	HORVS	LOLMU	SECCW	TRZAW	ZEAMA	BEAVA	BRSNW	GLXMA	HELAN	LENCU	LIUUT	PHSVN	PIBST	SINAL
EC_{10} values (in µg/kg formulated product mixed in soil – use rate 28 µg/kg soil) for Amidosulfuron WG 75 based on % phytotoxicity – ratings and fresh weight harvest at 29 DAT														
% Phytotox	>28	>28	19.2	>28	2.46	0.19	2.85	4.66	0.32	0.61	2.98	>28	0.72	1.90
Fresh Weight	>28	>28	>28	>28	>28	0.52	2.50	>28	0.54	0.64	>28	>28	8.61	1.94
EC_{10} values (in g/ha formulated product mixed in soil – use rate 40 g/ha) for Amidosulfuron WG 75 based on % phytotoxicity – ratings and fresh weight harvest at 29 DAT														
% Phytotox	>40	>40	27.4	>40	3.51	0.27	4.07	6.66	0.46	0.87	4.26	>40	1.03	2.72
Fresh Weight	>40	>40	>40	>40	>40	0.74	3.57	>40	0.77	0.92	>40	>40	12.3	2.77

<u>Effect of the concentrations of soil incorporated formulated product on the emergence of the 14 crops:</u>
Only on peas, a significant reduction in the number of emerged plants was observed with the highest concentration otherwise no significant response could be observed on the emergence of any of the crops.

<u>Average percentage crop effects from the visual assessments (15 and 29 DAS):</u>
From the data it can be seen that the most sensitive crops are peas (PIBST), oilseed rape (BRSNW), sugar beet (BEAVA), sunflower (HELAN), lentils (LENCU) and white mustard (SINAL). Soybeans (GLXMA) and corn (ZEAMA) where quite sensitive and the monocot crops and linseed (LIUUT) and the bean (PHSVN) where not very sensitive at all. For most of the crops there was no recovery from damage recorded at 15 days to the 29-day assessment. Trial was terminated at 29 days after sowing. Cereal crops were amongst the least sensitive crops. The observed phytotoxicity with the higher rates may have been accentuated by having the formulation incorporated into the soil. It demonstrates also the high crop sensitivity in general with these model type greenhouse studies.

<u>Effects from the assessment of fresh weight data:</u>
The fresh weight data showed little effect on the monocot crops and with soybean (GLXMA), linseed (LIUUT) and the bean (PHSVN) there were no significant differences recorded. In the case of the dicot. crops significant reductions in fresh weight were seen in sugar beet (BEAVA), oilseed rape (BRSNW), sunflower (HELAN), lentils (LENCU), field peas (PIBST) and white mustard (SINAL) but only at the highest two or three dose rates. Generally there were no significant reductions below the dose of 1.8 µg /kg of soil.

Conclusion:
Under standardized test conditions, 14 grass and broad-leaved crops showed a range of sensitivities towards Amidosulfuron WG 75 incorporated in a sandy loam soil. Based on phytotoxicity assessment and reduction of fresh weight the most sensitive crops are sugar-beet (BEAVA), sunflower (HELAN), lentils (LENCU), field peas (PIBST), white mustard (SINAL) and oilseed rape (BRSNW). The first three crops require 6 half life times to reach the EC_{10} values shown in this study. The other sensitive crops mentioned here need 3-4 half life times to reach the EC_{10} values determined in this study. All grains were less sensitive.

CP 10.6.2 Testing on non-target plants

Vegetative vigour

Report:	KCP 10.6.2/01 [redacted],; 2002; M-240817-01-1
Title:	Determination of Effects on Vegetative Vigor of Six Plant Species AE F075032 00 WG75 A1
Report No.:	B003815
Document No.:	M-240817-01-1
Guideline(s):	OECD: 208, Part B
Guideline deviation(s):	--
GLP/GEP:	**yes**

The study reports on a vegetative vigour test for 6 species of non-target plants on the formulated product. Soybean (*Glycine max*) has been identified as the most sensitive species to the formulated product.

The study was considered acceptable in the EU review for the first inclusion of amidosulfuron on Annex I, a study summary is found in the previous Draft Assessment Report (2006).

An EU agreed endpoint of ER_{50} = 67 g a.s./ha for the toxicity of the formulation "Gratil" to six plant species during vegetative growth was derived from this test.

No changes to this endpoint are proposed in the context of approval renewal.

Report:	KCP 10.6.2/02 [redacted]; [redacted]; [redacted]; 2002; M-214455-01-1
Title:	Effect of AE F075032 08 WG26 A205 on vegetative vigour of eleven species of terrestrial plants
Report No.:	GR28006
Document No.:	M-214455-01-1
Guideline(s):	OECD: 208 B veg. vigor
Guideline deviation(s):	--
GLP/GEP:	**yes**

Study listed for formal reason only, since referenced in the baseline dossier. The tested formulation AE F075032 08 WG26 A205 is a co-formulation with a second sulfonylurea-type active substance iodosulfuron-methyl-sodium and a crop safener mefenpyr-diethyl, and does not deliver endpoints applicable for the representative formulation Amidosulfuron WG75.

The study was included in the EU review for the first inclusion of amidosulfuron on Annex I, the DAR (2006) concluded "This study was not evaluated because the formulation used is not comparable with Gratil (12.6% amidosulfuron + 2 additional active substances) and the highest rate tested is lower than the intended rate of amidosulfuron.".

Report:	KCP 10.6.2/03 [redacted],; 2010; M-366958-01-1
Title:	Amidosulfuron WG 75 W - Effect on the vegetative vigour of four species of non-target terrestrial plants (Tier 2)
Report No.:	VV09/032
Document No.:	M-366958-01-1
Guideline(s):	OECD Guidelines for the testing of chemicals; Guideline 227 Terrestrial plant Test: Vegetative vigour Test. July 2006, adopted
Guideline deviation(s):	none
GLP/GEP:	**yes**

Executive Summary:
The purpose of this specific study was to evaluate the effect of Amidosulfuron WG 75 on the vegetative vigour of four plant species representing three dicotyledonous and one monocotyledonous plant families. The test was performed in accordance with OECD guideline 227 (2006).

Plants of four species were tested in this vegetative vigour test under glasshouse conditions including three dicotyledonous and one monocotyledonous species representing four different plant families. At the 2-4 leaf stage, plants were sprayed once at test initiation with doses of Amidosulfuron WG 75 ranging from 45 g a.s./ha down to 0.044 g a.s./ha using a laboratory track sprayer at a volume rate of 200 L/ha. There were six treatment levels for each species and a water treated control. The application rates for sugar beet, cucumber and onion were 45, 22.5, 11.25, 5.63, 2.81 and 1.41g a.s./ha. Due to the high sensitivity of sunflower in the first study (45, 22.5, 11.25, 5.63, 2.81 and 1.41g a.s./ha), this species was repeated with lower rates in a 2nd run (5.63, 2.81, 1.41, 0.7, 0.35 and 0.18g a.s./ha) and in a 3rd run (1.41, 0.70, 0.35, 0.18, 0.088 and 0.044g a.s./ha). Eight pots per treatment group for all species with four plants each were used. In total 32 plants per treatment group were tested. Plants were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day, and 18 ± 8°C at night with a 16 h photoperiod.

Assessments were made 7, 14 and 21 days after application against the water treated controls. Statistical analysis of data was performed to obtain NOER, LR/ER_{25} and LR/ER_{50} values for survival and shoot dry weight, using ToxRat statistics.

All species treated with Amidosulfuron WG 75 showed phytotoxic symptoms visible as chlorosis, necrosis, leaf deformation and stunting. The severity of these symptoms differed with application rates and species sensitivity to the product. Sunflower was the most sensitive species with the lowest ER50 of 0.110 g a.s./ha for shoot dry weight.

Material and methods:
Test item: Amidosulfuron WG 75 W; FT-Code: AMIDOSULFURON WG 75 % w/w; Workorder: 09008721; Sample description: TOX 08561-00; Batch ID: EFKE001675; Specification No.: 102000000550; Analysed content of a.s.: 75.3 % w/w amidosulfuron.

Plants from four species; sugar beet (*Beta vulgaris*), cucumber *(Cucumis sativus),* sunflower *(Helianthus annuus)* and onion *(Allium cepa)* were sprayed with Amidosulfuron WG 75 at the 2-4 leaf stage. Serial dilutions were sprayed with application rates ranging from 45 g a.s./ha down to 0.044 g a.s./ha using a laboratory track sprayer at a volume rate of 200 L/ha. There were six treatment levels for each species and a water treated control. The application rates for sugar beet, cucumber and onion were 45, 22.5, 11.25, 5.63, 2.81 and 1.41g a.s./ha. Due to the high sensitivity of sunflower in the first study (45, 22.5, 11.25, 5.63, 2.81 and 1.41g a.s./ha), this species was repeated with lower rates in a 2nd run (5.63, 2.81, 1.41, 0.7, 0.35 and 0.18g a.s./ha) and in a 3rd run (1.41, 0.70, 0.35, 0.18, 0.088 and 0.044g a.s./ha). Eight pots per treatment group for all species with four plants each were used. In total 32 plants per treatment group were tested. Plants were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day, and 18 ± 8°C at night with a 16 h photoperiod.

Visual phytotoxicity ratings and number of plants that survived after application were assessed 7, 14 and 21 days after application. Growth stages and shoot dry weight were determined at the final assessment. Statistical analysis of data was performed to obtain NOER, LR/ER_{25} and LR/ER_{50} values for survival and shoot dry weight, using ToxRat statistics.

Dates of experimental work: April 23, 2009 – November 26, 2009

Results:

Validity criteria:

This study can be considered valid as the specified validity criterion of 90% survival during the study period of the untreated controls was achieved for all species.

Table CP 10.6.2- 1: Validity criteria in the untreated control for the vegetative vigour test with Amidosulfuron WG 75

	Survival of untreated controls
Validity criteria	**≥ 90 %**
Sugar beet	100 %
Cucumber	100 %
Sunflower (1st run)	100 %
Sunflower (2nd run)	100 %
Sunflower (3rd run)	100 %
Onion	100 %

Analytical results:

Analysis of the highest application rate revealed it to be 95.1 - 98.2% of nominal.

Biological results:

All species treated with Amidosulfuron WG 75 showed phytotoxic symptoms visible as chlorosis, necrosis, leaf deformation and stunting. The severity of these symptoms differed with application rates and species sensitivity to the product.

Sunflower was the most sensitive species with biomass measured as shoot dry weight being the most sensitive endpoints.

The following table summarises the NOER, ER/LR_{25} and ER/LR_{50} for survival and shoot dry weight. Endpoints are expressed as g a.s./ha.

Table CP 10.6.2- 2: The effect of Amidosulfuron WG 75 on four plant species

	[g a.s./ha]					
	Survival			**Shoot dry weight**		
Plant species	**NOER**	**LR_{25}**	**LR_{50}**	**NOER**	**ER_{25}**	**ER_{50}**
Dicotyledonae						
Sugar beet	45	>45#	>45#	<1.41	n.d.	>45#
Cucumber	45#	>45#	>45#	45	>45#	>45#
Sunflower 1st	1.41	3.60	11.72	<1.41	<1.41#	<1.41#
Sunflower 2nd	1.41	2.06	4.21	<0.18	<0.18#	<0.18#
Sunflower 3rd	1.41#	>1.41#	>1.41#	<0.044	0.034	0.110
Monocotyledonae						
Onion	45	>45#	>45#	5.63	14.44	>45#

#: calculated values were outside the range tested or not determined

Conclusions:

Based on the results of this vegetative vigour study in which the effect of Amidosulfuron WG 75 on four plant species was tested under glasshouse conditions the most sensitive species was sunflower with the lowest ER_{50} of 0.110g a.s./ha for shoot dry weight.

Report:	KCP 10.6.2/04 [redacted] ,; 2011; M-405630-01-1
Title:	Amidosulfuron WG 75 W - Effect on the vegetative vigour of five non-crop species of non-target terrestrial plants (Tier 2)
Report No.:	VV10/058
Document No.:	M-405630-01-1
Guideline(s):	OECD Guideline for the testing of Chemicals, Terrestrial Plant Test ; OECD 227: Vegetative Vigour Test, July 2006
Guideline deviation(s):	none
GLP/GEP:	**yes**

Executive Summary:
The purpose of this specific study was to evaluate the phytotoxic effect of Amidosulfuron WG 75 on the vegetative vigour of five non-crop species of non-target terrestrial plants following a post - emergence application of the product onto the foliage of plants at the 2-4 leaf stage. The test was performed in accordance with OECD guideline 227 (2006).

Plants of five non-crop species were tested in this vegetative vigour test under glasshouse conditions including five dicotyledonous species representing five different plant families. At the 2-4 leaf stage, plants were sprayed once at test initiation with doses of Amidosulfuron WG 75 ranging from 45 g a.s./ha down to 0.09 g a.s./ha using a laboratory track sprayer at a volume rate of 200 L/ha. There were 4 plants per pot and 8 replicate pots per treatment. The application rates for *Amaranthus retroflexus* were 2.81, 1.41, 0.70, 0.35, 0.18 and 0.09 g a.s./ha. The application rates for *Stellaria media* were 5.63, 2.81, 1.41, 0.70, 0.35 and 0.18 g a.s./ha. The application rates for *Bellis perennis* were 11.25, 5.63, 2.81, 1.41, 0.70 and 0.35 g a.s./ha. The application rates for *Centaurea cyanus* and *Senecio vulgaris* were 45, 22.5, 11.25, 5.63, 2.81 and 1.41 g a.s./ha. Control pots were sprayed with 200 L/ha deionised water. Plants were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day, and 18 ± 8°C at night with a 16 h photoperiod.
Assessments (survival, visual phytotoxicity, plant growth stage and shoot dry weight) were made 7, 14 and 21 days after application against the water treated controls. The study was terminated 21 days after application. Statistical analysis of data was performed to obtain NOER, LR/ER_{25} and LR/ER_{50} values for survival and shoot dry weight, using ToxRat statistics.

The species treated with Amidosulfuron WG 75 showed phytotoxic symptoms visible as chlorosis, necrosis, leaf deformation or stunting. The severity of these symptoms differed with application rate and species sensitivity to the product. The most sensitive species was *Amaranthus retroflexus* with the lowest ER_{50} of <0.09 g a.s./ha extrapolated as 0.07 g a.s./ha for shoot dry weight.

Material and methods:
Test item: Amidosulfuron WG 75 W; FT-Code: AMIDOSULFURON WG 75 % w/w; Workorder: 09008721; Sample description: TOX 08561-00; Batch ID: EFKE001675; Specification No.: 102000000550; Analysed content of a.s.: 75.3 % w/w amidosulfuron.

Plants from five non-crop species; redroot pigweed (*Amaranthus retroflexus*), Daisy (*Bellis perennis*), cornflower (*Centaurea cyanus*), common groudsel (*Senecio vulgaris*) and common chickweed (*Stellaria media*) were sprayed with Amidosulfuron WG 75 at the 2-4 leaf stage. Serial dilutions were sprayed with application rates ranging from 45 g a.s./ha down to 0.09 g a.s./ha using a laboratory track sprayer at a volume rate of 200 L/ha. There were 4 plants per pot and 8 replicate pots per treatment. Each plant species was treated with 6 application rates. The application rates for *Amaranthus retroflexus* were 2.81, 1.41, 0.70, 0.35, 0.18 and 0.09 g a.s./ha. The application rates for *Stellaria media* were 5.63, 2.81, 1.41, 0.70, 0.35 and 0.18 g a.s./ha. The application rates for *Bellis perennis* were 11.25, 5.63, 2.81, 1.41, 0.70 and 0.35 g a.s./ha. The application rates for *Centaurea cyanus* and *Senecio vulgaris* were 45, 22.5, 11.25, 5.63, 2.81 and 1.41 g a.s./ha. Control pots were sprayed with 200 L/ha deionised water. Plants were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day, and 18 ± 8°C at night with a 16 h photoperiod.

Assessments were made 7, 14 and 21 days after application against the water treated controls. The study was terminated 21 days after application. The parameters measured were survival, visual phytotoxicity, plant growth stage and shoot dry weight. Statistical analysis of data was performed to obtain NOER, ER/LR_{25} and ER/LR_{50} values for survival and shoot dry weight, using ToxRat statistical software.

Dates of experimental work: October 21, 2010 – February 02, 2011

Results:

Validity criteria:

This study can be considered valid as the validity criterion of at least 90% survival throughout the study period was achieved for the untreated controls of all species tested.

Table CP 10.6.2- 3: Validity criteria in the untreated control for the vegetative vigour test with Amidosulfuron WG 75

	Survival (% of untreated control plants throughout the study)
Validity criteria	**≥ 90 %**
Amaranthus retroflexus	100 %
Bellis perennis	100 %
Centaurea cyanus	100 %
Senecio vulgaris	100 %
Stellaria media	100 %

Analytical results:

Measured concentrations of amidosulfuron in the highest application rate ranged from 95.4 to 95.9% of the nominal test concentration.

Biological results:

The species treated with Amidosulfuron WG 75 showed phytotoxic symptoms visible as chlorosis, necrosis, leaf deformation or stunting. The severity of these symptoms differed with application rate and species sensitivity to the product.

The following table summarises the NOER, ER/LR_{25} and ER/LR_{50} for survival and shoot dry weight. Endpoints are expressed as g a.s./ha.

Table CP 10.6.2- 4: The effect of Amidosulfuron WG 75 on five non-crop plant species

	[g a.s./ha]					
	Survival			Shoot dry weight		
Plant species	**NOER**	**LR_{25}**	**LR_{50}**	**NOER**	**ER_{25}**	**ER_{50}**
Dicotyledonae						
Amaranthus retroflexus	0.70	1.01	2.27	<0.09	<0.09[a]	**0.07[b]**
Bellis perennis	2.81	6.35	>11.25[a]	<0.35	<0.35[a]	0.52
Centaurea cyanus	45	>45[a]	>45[a]	<1.41	5.91	25.46
Senecio vulgaris	11.25	18.51	28.82	<1.41	<1.41[a]	2.29
Stellaria media	5.63[a]	>5.63[a]	>5.63[a]	0.18	0.51	2.04

[a]: calculated values were outside the range tested or not determined

[b]: extrapolated value

Conclusions:
Based on the results of this tier 2 vegetative vigour study in which the effects of Amidosulfuron WG 75 on five non-crop species were tested under glasshouse conditions the most sensitive species was *Amaranthus retroflexus* with the lowest ER_{50} of <0.09 g a.s./ha extrapolated as 0.07 g a.s./ha for shoot dry weight.

Report:	KCP 10.6.2/05[redacted]=; 2010; M-389517-01-1
Title:	Amidosulfuron WG 75 W - Effect on the vegetative vigour of five non-crop species of non-target terrestrial plants (Tier 2).
Report No.:	VV10/066
Document No.:	M-389517-01-1
Guideline(s):	OECD Guideline for the testing of Chemicals, Terrestrial Plant Test: OECD 227: Vegetative Vigour Test, July 2006
Guideline deviation(s):	none
GLP/GEP:	**yes**

Executive Summary:
The purpose of this specific study was to evaluate the phytotoxic effect of Amidosulfuron WG 75 on the vegetative vigour of five non-crop species of non-target terrestrial plants following a post - emergence application of the product onto the foliage of plants at the 2-4 leaf stage. The test was performed in accordance with OECD guideline 227 (2006).

Plants of five non-crop species were tested in this vegetative vigour test under glasshouse conditions representing the plant family Asteraceae. At the 2-4 leaf stage, plants were sprayed once at test initiation with doses of Amidosulfuron WG 75 ranging from 2.81 g a.s./ha down to 0.022 g a.s./ha using a laboratory track sprayer at a volume rate of 200 L/ha. There were 4 plants per pot and 8 replicate pots per treatment. The application rates for *Bellis perennis* were 0.70, 0.35, 0.18, 0.088, 0.044 and 0.022 g a.s./ha. The application rates for *Achillea millefolium* were 1.41, 0.70, 0.35, 0.18, 0.088 and 0.044 g a.s./ha. The application rates for *Centaurea cyanus*, *Matricaria chamomilla* and *Senecio vulgaris* were 2.81, 1.41, 0.70, 0.35, 0.18 and 0.088 g a.s./ha. Control pots were sprayed with 200 L/ha deionised water. Plants were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day, and 18 ± 8°C at night with a 16 h photoperiod.
Assessments (survival, visual phytotoxicity, plant growth stage and shoot dry weight) were made 7, 14 and 21 days after application against the water treated controls. The study was terminated 21 days after application. Statistical analysis of data was performed to obtain NOER, LR/ER_{25} and LR/ER_{50} values for survival and shoot dry weight, using ToxRat statistics.

The species treated with Amidosulfuron WG 75 showed phytotoxic symptoms visible as chlorosis, necrosis or stunting. The severity of these symptoms differed with application rate and species sensitivity to the product. The most sensitive species was *Achillea millefolium* with the lowest ER_{50} of 0.461 g a.s./ha for shoot dry weight.

Material and methods:
Test item: Amidosulfuron WG 75 W; FT-Code: AMIDOSULFURON WG 75 % w/w; Workorder: 09008721; Sample description: TOX 08561-00; Batch ID: EFKE001675; Specification No.: 102000000550; Analysed content of a.s.: 75.3 % w/w amidosulfuron.

Plants from five non-crop species representing the plant family Asteraceae; common yarrow (*Achillea millefolium*), Daisy (*Bellis perennis*), cornflower (*Centaurea cyanus*), wild chamomile (*Matricaria chamomilla*) and common groundsel (*Senecio vulgaris*) were sprayed with Amidosulfuron WG 75 at the 2-4 leaf stage. Serial dilutions were sprayed with application rates ranging from 2.81 g a.s./ha down to 0.022 g a.s./ha using a laboratory track sprayer at a volume rate of 200 L/ha. There were 4 plants per pot and 8 replicate pots per treatment. Each plant species was treated with 5 application rates. The application rates for *Bellis perennis* were 0.70, 0.35, 0.18, 0.088, 0.044 and 0.022 g a.s./ha. The application rates for *Achillea millefolium* were 1.41, 0.70, 0.35, 0.18, 0.088 and 0.044 g a.s./ha.

The application rates for *Centaurea cyanus*, *Matricaria chamomilla* and *Senecio vulgaris* were 2.81, 1.41, 0.70, 0.35, 0.18 and 0.088 g a.s./ha. Control pots were sprayed with 200 L/ha deionised water. Plants were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day, and 18 ± 8°C at night with a 16 h photoperiod.

Assessments were made 7, 14 and 21 days after application against the water treated controls. The study was terminated 21 days after application. The parameters measured were survival, visual phytotoxicity, plant growth stage and shoot dry weight. Statistical analysis of data was performed to obtain NOER, ER/LR_{25} and ER/LR_{50} values for survival and shoot dry weight, using ToxRat statistical software.

Dates of experimental work: June 24, 2010 – July 22, 2010

Results:

Validity criteria:

This study can be considered valid as the validity criterion of at least 90% survival throughout the study period was achieved for the untreated controls of all species tested.

Table CP 10.6.2- 5: Validity criteria in the untreated control for the vegetative vigour test with Amidosulfuron WG 75

	Survival (% of untreated control plants throughout the study)
Validity criteria	**≥ 90 %**
Achillea millefolium	96.9 %
Bellis perennis	90.6 %
Centaurea cyanus	100 %
Matricaria chamomilla	96.9 %
Senecio vulgaris	100 %

Analytical results:

Analysis of amidosulfuron in the highest tested application rate revealed it to be 98.7% of nominal.

Biological results:

The species treated with Amidosulfuron WG 75 showed phytotoxic symptoms visible as chlorosis, necrosis or stunting. The severity of these symptoms differed with application rate and species sensitivity to the product. *Achillea millefolium* was the most sensitive species with shoot dry weight being the most sensitive endpoint.

The following table summarises the NOER, ER/LR_{25} and ER/LR_{50} for survival and shoot dry weight. Endpoints are expressed as g a.s./ha.

Table CP 10.6.2- 6: The effect of Amidosulfuron WG 75 on five non-crop plant species representing the plant family Asteraceae

	[g a.s./ha]					
	Survival			Shoot dry weight		
Plant species	**NOER**	**LR_{25}**	**LR_{50}**	**NOER**	**ER_{25}**	**ER_{50}**
Asteraceae						
Achillea millefolium	1.41	>1.41[#]	>1.41[#]	0.18	0.195	0.461
Bellis perennis	0.7	>0.7[#]	>0.7[#]	0.35	0.34	>0.7[#]
Centaurea cyanus	2.81	>2.81[#]	>2.81[#]	2.81	>2.81[#]	>2.81[#]
Matricaria chamomilla	2.81[#]	>2.81[#]	>2.81[#]	0.088	0.213	0.585
Senecio vulgaris	2.81[#]	>2.81[#]	>2.81[#]	1.41	>2.81[#]	>2.81[#]

[#]: calculated values were outside the range tested or not determined

Conclusions:

Based on the results of this tier 2 vegetative vigour study in which the effect of Amidosulfuron WG 75 on five non-crop species was tested under glasshouse conditions the most sensitive species was *Achillea millefolium* with the lowest ER_{50} of 0.461 g a.s./ha for shoot dry weight.

Seedling emergence

Report:	KCP 10.6.2/06 [redacted]; 2010; M-366951-01-1
Title:	Amidosulfuron WG 75 W - Effect on the seedling emergence and seedling growth of ten species of non-target terrestrial plants (Tier 2)
Report No.:	SE09/031
Document No.:	M-366951-01-1
Guideline(s):	OECD 208 (July 2006): Guideline for the testing of chemicals, Terrestrial Plant Test: Seedling emergence and seedling growth Test
Guideline deviation(s):	none
GLP/GEP:	**yes**

Executive Summary:

The purpose of this specific study was to evaluate the effect of Amidosulfuron WG 75 on the seedling emergence and seedling growth of ten plant species representing a broad range of both dicotyledonuous and monocotyledonous plant families. The test was performed in accordance with OECD guideline 208 (2006).

A total of ten species were tested in this seedling emergence test under glasshouse conditions including seven dicotyledonous and three monocotyledonous species representing eight different plant families. The seeds were sown in a mixture of 90% silt loam + 10% washed sand prior to application of Amidosulfuron WG 75 to the soil surface. Five seeds were sown in each pot and there were 8 pots (replicates for each species) giving a total of 40 seeds per treatment level. Serial dilutions of Amidosulfuron WG 75 were sprayed with application rates ranging from 45 g a.s./ha down to 1.41 g a.s./ha and 5.63 g a.s./ha down to 0.18 g a.s./ha in the first and second run of the study, respectively. Application was conducted using a laboratory track sprayer at a volume rate of 200 L/ha. The application rates for sugarbeet, cabbage, turnip, cucumber, soybean, tomato, onion, oat, sunflower and ryegrass were 45, 22.5, 11.25, 5.63, 2.81 and 1.41g a.s./ha. Due to the high dose response for shoot dry weight with sunflower in the first study, this species was repeated with lower rates: 5.63, 2.81, 1.41, 0.7, 0.35 and 0.18g a.s./ha in order to generate more reliable endpoints. Plants were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day and 18 ± 8°C at night with a 16 h photoperiod.

Emergence was assessed daily until 70% emergence of control seedlings. Emergence, survival and phytotoxicity were recorded 7 and 14 days after this time. The study was terminated 14 days after 70% emergence. At test termination, total emergence, survival of emerged seedlings, visual phytotoxicity, growth stages and shoot dry weight were assessed. Statistical analysis of data was performed to obtain NOER, LR/ER_{25} and LR/ER_{50} values for emergence, survival and shoot dry weight, using ToxRat statistics.

All species, excepted oat, treated with Amidosulfuron WG 75 showed phytotoxic symptoms visible as chlorosis, necrosis, leaf deformation and stunting. The severity of these symptoms differed with application rates and species sensitivity to the product. The most sensitive dicotylenonous species was sunflower with the lowest ER_{50} of 1.08 g a.s./ha for shoot dry weight and most sensitive monocotyledonous species was onion with the lowest calculated ER_{50} of 4.42 g a.s./ha for shoot dry weight.

Material and methods:
Test item: Amidosulfuron WG 75 W; FT-Code: AMIDOSULFURON WG 75 % w/w; Workorder: 09008721; Sample description: TOX 08561-00; Batch ID: EFKE001675; Specification No.: 102000000550; Analysed content of a.s.: 75.3 % w/w amidosulfuron.

Seeds of ten species; sugar beet (*Beta vulgaris*), cabbage (*Brassica oleraceae*), turnip (*Brassica rapa*), cucumber (*Cucumis sativus*), soybean (*Glycine max*), sunflower (*Helianthus annuus*), tomato (*Lycopersicum esculentum*), onion (Allium cepa), oat (*Avena sativa*) and ryegrass (*Lolium perenne*) were sown in a mixture of 90% silt loam + 10% washed sand prior to application of Amidosulfuron WG 75 to the soil surface. Five seeds were sown in each 10.5 cm diameter pot and there were 8 pots (replicates for each species) giving a total of 40 seeds per treatment level. Serial dilutions of Amidosulfuron WG 75 were sprayed with application rates ranging from 45 g a.s./ha down to 1.41 g a.s./ha and 5.63 g a.s./ha down to 0.18 g a.s./ha in the first and second run of the study, respectively. Application was conducted using a laboratory track sprayer at a volume rate of 200 L/ha. There were six treatment levels for each species and a water treated control. The application rates for sugar beet, cabbage, turnip, cucumber, soybean, tomato, onion, oat, sunflower and ryegrass were 45, 22.5, 11.25, 5.63, 2.81 and 1.41 g a.s./ha. Due to the high dose response for shoot dry weight with sunflower in the first study, this species was repeated with lower rates: 5.63, 2.81, 1.41, 0.7, 0.35 and 0.18 g a.s./ha in order to generate more reliable endpoints. Plants were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8ºC during day and 18 ± 8ºC at night with a 16 h photoperiod.

Following the application, emergence was assessed daily until 70% emergence of control seedlings. Emergence, survival and phytotoxicity were recorded 7 and 14 days after this time. The study was terminated 14 days after 70% emergence. At test termination, total emergence, survival of emerged seedlings, visual phytotoxicity, growth stages and shoot dry weight were assessed. Statistical analysis of data was performed to obtain NOER, LR/ER_{25} and LR/ER_{50} values for emergence, survival and shoot dry weight, using ToxRat statistics.

Dates of experimental work: April 23, 2009 – August 05, 2009

Results:
Validity criteria:
This study can be considered as valid as the validity criteria of 70% emergence and 90% survival of emerged seedlings during the study period of the controls was achieved for all species.

Table CP 10.6.2- 7: Validity criteria in the untreated control for the seedling emergence test with Amidosulfuron WG 75

	Emergence (% of sown)	Survival (%)
Validity criteria	**≥ 70**	**≥ 90**
Sugar beet	90.0	100
Cabbage	70.0	100
Turnip	100	100
Cucumber	100	97.5
Soybean	97.5	100
Sunflower (1st run)	95	100
Sunflower (2nd run)	95	100
Tomato	90.0	100
Onion	72.5	100
Oat	100	100
Ryegrass	87.5	100

Analytical results:
Analysis of the highest application rate revealed it to be 95.1 – 98.2% of nominal.

Biological results:
All species, excepted oat, treated with Amidosulfuron WG 75 showed phytotoxic symptoms visible as chlorosis, necrosis, leaf deformation and stunting. The severity of these symptoms differed with application rates and species sensitivity to the product.

The following table summarises the NOER, ER/LR_{25} and ER/LR_{50} for emergence, survival and shoot dry weight. Endpoints are expressed as g a.s./ha.

Two studies were conducted with sunflower due to high shoot dry weight reductions at all application rates tested in the initial study. Both studies are reported.

Table CP 10.6.2- 8: The effect of Amidosulfuron WG 75 on ten species of non-target terrestrial plants

	[g a.s./ha]								
	Emergence			Survival			Shoot dry weight		
Species	**NOER**	**LR_{25}**	**LR_{50}**	**NOER**	**ER_{25}**	**ER_{50}**	**NOER**	**ER_{25}**	**ER_{50}**
Dicotyledonae									
Cabbage	45[1]	>45[1]	>45[1]	45	>45[1]	>45[1]	<1.41	3.18	6.95
Cucumber	45	>45[1]	>45[1]	45[1]	>45[1]	>45[1]	<1.41	2.68	9.75
Turnip	5.63	10.17	21.77	45[1]	>45[1]	>45[1]	1.41	3.62	8.32
Soybean	45	>45[1]	>45[1]	45[1]	>45[1]	>45[1]	11.25	24.72	>45[1]
Sugar beet	45	>45[1]	>45[1]	2.81	39.85	>45[1]	<1.41	<1.41[1]	1.56
Sunflower 1st	45	>45[1]	>45[1]	45	>45[1]	>45[1]	<1.41	<1.41[1]	<1.41[1]
Sunflower 2nd	5.63[1]	>5.63[1]	>5.63[1]	5.63[1]	>5.63[1]	>5.63[1]	<0.18	0.33	1.08
Tomato	45	>45[1]	>45[1]	45[1]	>45[1]	>45[1]	2.81	6.71	13.23
Monocotyledonae									
Oat	45	>45[1]	>45[1]	45[1]	>45[1]	>45[1]	45	>45[1]	>45[1]
Onion	1.41[2]	6.97	18.40	45[3]	>45[1]	>45[1]	<1.41[4]	<1.41[1]	4.42
Ryegrass	5.63	7.37	14.51	2.81	>45[1]	>45[1]	2.81[5]	6.98	17.27

1) calculated values were outside the range tested or not determined.
2) corrected value: The NOER for this endpoint was proposed by ToxRat as being 11.25 g a.s./ha but is set at 1.41 g a.s./ha which is biologically more relevant because of the reduction in emegence at higher application rates.
3) corrected value: The NOER for this endpoint was proposed by the program as being 1.41 g a.s./ha. However, this result is considered as not reliable because of the absence of significance at all the other application rates tested and is clearly not dose-response related for all application rates tested. Therefore, a corrected value of NOER 45 g a.s./ha is given.
4) corrected value: The NOER for this endpoint was proposed by the program as 1.41 g a.s./ha but is set at <1.41 g a.s./ha which is biologically relevant because of the 25.1% shoot dry weight reduction at the application rate of 1.41 g a.s./ha.
5) corrected value: The NOER for this endpoint was proposed by the program as 5.63 g a.s./ha but is set to 2.81 g a.s./ha which is biologically relevant because of the 28.3 % shoot dry weight reduction at the application rate of 5.63 g a.s./ha.

Conclusions:
Based on the results of this study in which the effect of Amidosulfuron WG 75 on ten plant species was tested under glasshouse conditions the most sensitive dicotylenonous species was sunflower which was tested twice and with the lowest ER_{50} of 1.08 g a.s./ha for shoot dry weight and most sensitive monocotyledonous species was onion with the lowest calculated ER_{50} of 4.42 g a.s./ha for shoot dry weight.

CP 10.6.3 Extended laboratory studies on non-target plants

Considering the findings reported above, and the semi-field / field test information presented under CP 10.6.4, no further studies are required.

CP 10.6.4 Semi-field and field tests on non-target plants

Report:	KCP 10.6.4/01 [redacted] .; [redacted] ; 2010; M-389529-01-1
Title:	Amidosulfuron WG 75 W - Effect on the vegetative vigour of sunflower (Helianthus annuus) grown under semi-field conditions
Report No.:	VV10/033
Document No.:	M-389529-01-1
Guideline(s):	OECD Guideline for the testing of Chemicals, Terrestrial Plant Test ; OECD 227: Vegetative Vigour Test, July 2006
Guideline deviation(s):	none
GLP/GEP:	**no**

Executive Summary:
The purpose of this study was to evaluate the potential effects of Amidosulfuron WG 75 on survival, dry weight and phytotoxicological symptoms of sunflower (*Helianthus annuus*) following a post - emergence application of the product onto the foliage of plants at the 6 leaf stage grown under semi-field conditions. The test was performed in accordance with OECD guideline 227 (2006) (modified for testing under semi-field conditions). Sunflowers (*Helianthus annuus*, Asteraceae) were sown in groups (8 replicates per test item group and 2 x 6 replicates per control group) in seed beds at the test site.

Four application rates 0.35, 0.18, 0.088, 0.044 g a.s./ha of Amidosulfuron WG 75 were sprayed onto the foliage of the plants using a Plot sprayer at a volume rate of 400 L/ha. Control groups were sprayed with 400 L/ha deionised water. Following application, the plants were grown and maintained under semi-field conditions (with natural rain and additional watering when needed).

Assessments were made 7, 10, 14 and 22 days after application against the water treated controls. The study was terminated 22 days after application. The parameters measured were survival, visual phytotoxicity, plant growth stage and shoot dry weight.

The plants treated with the lowest rate of 0.044 g a.s. /ha showed no phytotoxic symptoms. All other plants treated with Amidosulfuron WG 75 showed phytotoxic symptoms visible as chlorosis, leaf deformation and stunting. The severity of these symptoms was mainly slight and differed among application rates. No statistically significant effects of Amidosulfuron WG 75 on sunflower were observed up to the highest rate tested of 0.35 g a.s. /ha.

Material and methods:
Test item: Amidosulfuron WG 75 W; FI-Code: AMIDOSULFURON WG 75 % w/w; Workorder: 09023760; Sample description: TOX 08735-00; Material No.: 05938848; Batch ID: EFKE001914; Specification No.: 102000000550-02; Analysed content of a.s.: 74.8 % w/w amidosulfuron.

Sunflowers (*Helianthus annuus*, Asteraceae) were sown in groups (representing the replicates) in seed beds at the test site. Four application rates 0.35, 0.18, 0.088, 0.044 g a.s./ha of Amidosulfuron WG 75 were sprayed onto the foliage of the plants using a Plot sprayer at a volume rate of 400 L/ha. Control groups were sprayed with 400 L/ha deionised water. Following application, the plants were grown and maintained under semi-field conditions (with natural rain and additional watering when needed).

Assessments were made 7, 10, 14 and 22 days after application against the water treated controls. The study was terminated 22 days after application. The parameters measured were survival, visual phytotoxicity, plant growth stage and shoot dry weight. Statistical analysis of data was performed to obtain NOER, ER/LR_{25} and ER/LR_{50} values for survival and shoot dry weight, using ToxRat statistical software.

Dates of experimental work: May 25, 2010 – June 28, 2010

Results:
Biological results:

Survival: The foliar application of Amidosulfuron WG 75 had no impact on the survival of treated sunflower (*Helianthus annuus*) plants at any application rate tested. The NOER for this endpoint was set as 0.35 g a.s./ha. The ER_{25} and ER_{50} values for survival were both set as >0.35 g a.s./ha.

Phytotoxicity: At test termination (at day 22) there were no phytotoxic symptoms observed at the application rate of 0.044 g a.s./ha. Slight phytotoxic symptoms visualised as stunting were observed at day 22 at the application rate of 0.088 g a.s./ha. Moderate to severe phytotoxic symptoms visualised as leave deformation and stunting were observed at day 22 at the application rates of 0.18 and 0.35 g a.s./ha.

Growth stage: At test termination (at day 22) there were slight effects on growth stage development of the treated plants in comparison with the untreated controls at and above the application rate of 0.088 g a.s./ha.

Shoot dry weight: Shoot dry weight was not significantly reduced at any application rate tested. The NOER for this endpoint was calculated as 0.35 g a.s./ha. The ER_{25} and ER_{50} values for shoot dry weight were both set as >0.35 g a.s./ha.

The following table summarizes the findings for survival and shoot dry weight.

Table CP 10.6.4- 1: The effect of Amidosulfuron WG 75 on sunflower (*Helianthus annuus*) under semi-field conditions

	[g a.s./ha]					
	Survival			Shoot dry weight		
Plant species	**NOER**	**LR_{25}**	**LR_{50}**	**NOER**	**ER_{25}**	**ER_{50}**
Helianthus annuus	0.35	>0.35[#]	>0.35[#]	0.35[#]	>0.35[#]	>0.35[#]

[#]: calculated values were not determined

Conclusions:
Based on the results of this semi-field vegetative vigour study in which the effect of Amidosulfuron WG 75 on sunflower (*Helianthus annuus*) was tested, no statistically significant effects were observed up to the highest rate tested of 0.35 g a.s./ha.

Report: KCP 10.6.4/02 [redacted]; 2015; M-548832-01-1
Title: Amidosulfuron WG 75 percent w/w - Effects on the vegetative vigour of Helianthus annuus plants grown under field conditions (Field trial - Non-GLP)
Report No.: HT14/028
Document No.: M-548832-01-1
Guideline(s): The study considers the recommendations of the OECD 227 guideline for the testing of chemicals: Terrestrial Plant Test: Vegetative vigour (July 2006) and of the US EPA Ecological Effects Test Guideline OCSPP 850.4150
Guideline deviation(s): not applicable
GLP/GEP: **no**

Executive summary:
The purpose of this field study was to evaluate the effect of Amidosulfuron WG 75 on the vegetative vigour of *Helianthus annuus* (sunflower), following a post-emergence spray application of the test item onto the foliage of the plants at the 6 leaf stage in a field test. The study considers the recommendations of the OECD Guideline 227 and of the US EPA Ecological Effects Test Guideline OCSPP 850.4150.

Sunflower (*Helianthus annuus*) plants were grown under field conditions and were treated at the 6 leaf stage. No soil parameters are available from the test site. The total field size was 4000 m^2, a part of it was divided in 10 plots of 100 m^2 each (10 m x 10 m). 13 seeds/m² were sown (1300 seeds/plot). 27 days after sowing the plants were treated with 4 different application rates and a deionized water control at the 6-leaf BBCH stage. The test item was applied in 300 L/ha of deionized water at rates of 0.4, 0.8, 1.6 and 3.2 g a.s./ha, whereas control plots were applied with 300 L/ha deionized water only. An additional rate of 6.4 g a.s./ha was set up for analytical purposes only. Assessments were carried out on day 7, 14 and 19 after application. Final assessments were made for plant survival, visual phytotoxicity, plant growth stage and shoot dry weight.

Statistical analysis of data was performed to obtain NOER, ER_{25} and ER_{50} values for emergence, survival and shoot dry weight, using ToxRat statistical software.

No effect on the survival of *Helianthus annuus* plants was observed at any application rate tested (NOER = 3.2 g/ha). The ER_{50} for shoot dry weight was calculated to be 1.69 g a.s./ha.

Material and Methods:
Test item: Amidosulfuron WG 75% w/w; Sample description: TOXX10124-00; Specification No.: 102000000550; Analyzed contents of a.s.: 75.9 % w/w amidosulfuron; Batch-ID: EFKE002307; Workorder: 13005778; Material No.: 05938848.

Sunflower (*Helianthus annuus)* was tested in this vegetative vigour test under field conditions between May, 30th 2014 and June, 20th 2014 at an experimental field at the trial site of Bayer CropScience AG in [redacted] (Hessen, Germany). The plants were grown under field conditions and were treated at the 6 leaf stage. No soil parameters are available from the test site. The soil on an adjacent field is a silty loam. The total field size was 4000 m^2, a part of it was divided in 10 plots of 100 m^2 each (10 m x 10 m). 13 seeds/m² were sown (1300 seeds/plot).

The test item was applied in 300 L/ha of deionized water at rates of 0.4, 0.8, 1.6 and 3.2 g a.s./ha, whereas control plots were applied with 300 L/ha deionized water only. Two replicates were established per test group (test item and control). An additional rate of 6.4 g a.s./ha was set up for analytical purposes only.

Assessments were carried out on day 7, 14 and 19 after application. Final assessments were made for plant survival, visual phytotoxicity, plant growth stage (BBCH) and shoot dry weight.

Statistical analysis of data was performed to obtain NOER (No observed effect rate), ER_{25} (rate producing 25% effect) and ER_{50} (rate producing 50% effect) values for emergence, survival and shoot dry weight, using ToxRat statistical software.

Dates of experimental work: May 30, 2014 – June 20, 2014

Results:
Validity Criteria:
The test requires a minimum control plant survival of 90% to be valid. In the present test 100.0% of the plants survived, thus the study is considered valid.
In accordance with OECD guideline (OECD 227) and US EPA guideline (OCSPP 850.4150), there was no visible phytotoxicity and a normal growth in the control. The control represented a normal variation in growth, plant development and morphology.
The environmental conditions during the test time were identical within one species.

Analytical results:
The analysis of amidosulfuron content in the initial test item application solution revealed measured concentrations of 112.3% of nominal.

Biological results:
Typical symptoms observed at the final assessment in this study (on day 19 after application) were chlorosis, necrosis, deformation and stunting. The severity and occurrence differed between application rates. The visual observations during the final assessment (19 days after application) are summarised in the following tables.

Table CP 10.6.4- 2: The effect of Amidosulfuron WG 75 on growth of sunflower (*Helianthus annuus*) under field conditions

Growth stage (BBCH) Min-Max at application rates (in g a.s/ha) at the final assessment					
Species	**Control**	**0.4**	**0.8**	**1.6**	**3.2**
Helianthus annuus	51	51	19-51	19-51	16-18

Table CP 10.6.4- 3: The phytotoxicity effect of Amidosulfuron WG 75 on sunflower (*Helianthus annuus*) under field conditions

Phytotoxicity summary (min-max damage and symptoms) at application rates (in g a.s./ha) at the final assessment					
Species	**Control**	**0.4**	**0.8**	**1.6**	**3.2**
Helianthus annuus	0	A B de	C abde	D abde	D abde

Key:
0: no injury or effect
A: slight symptom (s)
B: moderate symptom (s)
C: severe symptom (s)
D: total-plant symptom (s)
E: moribund
Any plant considered as being dead was not rated for phytotoxicity.

Phytotoxicity symptoms:
a: chlorosis (yellowing of green shoot tissue)
b: necrosis (brown shoot tissue)
c: bleaching (shoot tissue without pigmentation)
d: deformation (e.g. leaf curl, abnormal leaf shape, abnormal plant habitus)
e: stunting (plant height reduced with shorter internode length)
f: reddening of green shoot tissue

At the application rate of 0.4 g a.s./ha mostly slight to moderate phytotoxic symptoms were observed (deformation, stunting). Mostly severe phytotoxic symptoms were observed at the application rate of 0.8 g a.s./ha (chlorosis, necrosis, deformation, stunting). At the application rate of 1.6 and 3.2 g a.s./ha total-plant phytotoxic symptoms were observed (chlorosis, necrosis, deformation, stunting). Slight growth retardation was observed at the application rates of 0.8 and 1.6 g a.s./ha. More obvious growth retardation was observed at 3.2 g a.s./ha, the highest application rate tested.

The no observed effect rate (NOER), ER_{25} and ER_{50} values expressed in g a.s./ha are summarised in the following table for the final assessment (on day 19 after application).

Table CP 10.6.4- 4: The effect of Amidosulfuron WG 75 on survival and shoot dry weight of sunflower (*Helianthus annuus*) under field conditions

Species	g a.s./ha					
	Survival			Shoot dry weight		
	NOER	ER_{25}	ER_{50}	NOER	ER_{25}	ER_{50}
Helianthus annuus	3.2	>3.2[a]	>3.2[a]	0.4	0.67	1.69

[a] : Since no effect was observed, no further computations were performed for 21d

The foliar application of the test item had no statistically significant effect on the survival of *Helianthus annuus* plants at any application rate tested. The NOER for this endpoint was not calculated and is reported to be 3.2 g a.s./ha. Both the ER_{25} and the ER_{50} value for this endpoint were not calculated and are reported to be >3.2 g a.s./ha.

Shoot dry weight was statistically significantly affected at the application rates of 0.8, 1.6 and 3.2 g a.s./ha. The NOER for this endpoint was calculated to be 0.4 g a.s./ha and the LOER 0.8 g a.s./ha. The ER_{25} was calculated to be 0.67 g a.s./ha and the ER_{50} value for shoot dry weight was calculated to be 1.69 g a.s./ha.

Conclusion:
In a higher Tier vegetative vigour and growth study, Amidosulfuron WG 75 was tested under field conditions for effects on the survival, growth and shoot dry weight of *Helianthus annuus*, following a post-emergence spray application of the test item onto the foliage of plants at the 6 leaf stage.
No effect on the survival of *Helianthus annuus* plants was observed at any application rate tested. The ER_{50} for shoot dry weight was calculated to be 1.69 g a.s./ha.

CP 10.7 Effects on other terrestrial organisms (flora and fauna)

No studies are required based on current data requirements.

CP 10.8 Monitoring data

No monitoring data are available and are not triggered by current data requirements.