Document Title

Summary of the fate and behaviour in the environment Amidosulfuron WG 75

Data Requirements

EU Regulation 1107/2009 & EU Regulation 284/2013 Document MCP Section 9: Fate and behaviour in the environment

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

Date

2016-05-31

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M-557157-01-2

OWNERSHIP STATEMENT

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 9 FATE AND BEHAVIOUR IN THE ENVIRONMENT

This document presents updated calculations for the predicted environmental concentrations of amidosulfuron and its metabolites in soil and water. The reports submitted for the first European approval, and the associated post-Annex I procedure, are only listed for formal completeness but are not discussed in this document as they are fully superseded by updated simulations and considered no longer relevant.

Use pattern considered in the environmental exposure and risk assessment

Table CP 9- 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) End of winter, beginning of spring vegetation period
3) Spring, post-emergent

Definition of the residue for risk assessment

Justification for the residue definition for risk assessment is provided in MCA Sec.7, Point 7.4.1.

Table CP 9- 2: Definition of the residue 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, anaerobic soil
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 water/sediment, Aerobic soil
	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..

CP 9.1 Fate and behaviour in soil

Fate and behaviour of amidosulfuron in soil were assessed in the MCA document (Section 7) of the current renewal dossier based on the application of the active substance in laboratory studies. The endpoints derived from studies with the active substance are considered as appropriate to assess the exposure of amidosulfuron after application of the formulation Amidosulfuron WG75.

CP 9.1.1 Rate of degradation in soil

CP 9.1.1.1 Laboratory studies

No laboratory route/rate studies were conducted with the formulation. See document MCA Section 7.1.2.1 for studies with the active substance.

CP 9.1.1.2 Field studies

Field dissipation tests at three locations were conducted with the formulation, however are reported in the document MCA, Section 7.1.2.2 because they are relevant for deriving an endpoint for the active substance amidosulfuron, and are not specific for any preparation. The data confirmed a rapid degradation of amidosulfuron under field conditions, but for reason of sample spacing did not allow for the calculation of DT_{50} and DT_{90} values.

CP 9.1.1.2.1 Soil dissipation studies

Please refer to Document MCA 7.1.2.2.

CP 9.1.1.2.2 Soil accumulation studies

Please refer to Document MCA 7.1.2.2.

CP 9.1.2 Mobility in the soil

CP 9.1.2.1 Laboratory studies

Experimental studies with the formulation have not been performed. Please refer to Document MCA 7.1.3. for studies with the active substance.

CP 9.1.2.2 Lysimeter studies

Please refer to Document MCA 7.1.4.2.

CP 9.1.2.3 Field leaching studies

Please refer to Document MCA 7.1.4.3.

CP 9.1.3 Estimation of concentrations in soil

Predicted environmental concentrations in soil (PECSoil)

Studies submitted and evaluated for the first inclusion of amidosulfuron on Annex I:

The below baseline dossier studies are listed for formal completeness, but are of no longer relevance for approval renewal. The studies are superseded by a new modelling evaluation KCP 9.1.3/03, to update for new substance information and modelling guidance.

Report:	KCP 9.1.3/01 [redacted] Q; 2003; M-228793-01-1
Title:	Predicted environmental concentrations of amidosulfuron and its main metabolites in soil (PECs) for representative uses in Europe Code: AE F075032, AE F101630, AE F128870
Report No.:	C030963
Document No.:	M-228793-01-1
Guideline(s):	--
Guideline deviation(s):	--
GLP/GEP:	**no**

Report:	KCP 9.1.3/02 [redacted] ,; 2004; M-231921-01-1
Title:	Predicted environmental concentrations of amidosulfuron and its main metabolites in soil (PECs) for representative uses in Europe: Re-calculation with new selection of substance parameters Codes: AE F075032; AE F101630; AE F128870
Report No.:	C042079
Document No.:	M-231921-01-1
Guideline(s):	--
Guideline deviation(s):	--
GLP/GEP:	**no**

Studies submitted and evaluated in the course of the post-Annex I procedure for amidosulfuron:

(none at EU level; updated modelling was submitted as part of the products re-approval procedure at zonal level)

Studies submitted for Annex I approval renewal:

To consider compound related input parameters from new experimental studies and kinetic evaluations, and to implement latest modeling guidance, updated PEC_{soil} calculations are presented for approval renewal, superseding all previous data evaluations.

Report:	KCP 9.1.3/03 [redacted] ,; 2016; M-553878-01-1
Title:	Amidosulfuron (AMS) and metabolites: PECsoil EUR - Use in winter and spring cereals, flax and grass in Europe
Report No.:	EnSa-16-0284 v1
Document No.:	M-553878-01-1
Guideline(s):	none
Guideline deviation(s):	none
GLP/GEP:	**no**

Methods and Materials:

The predicted environmental concentrations in soil (PECsoil) of amidosulfuron and its metabolites were estimated based on a first tier approach using a Microsoft® Excel spreadsheet. A bulk density of 1.5 kg/L and a soil mixing depth of 5 cm were used as recommended by FOCUS (1997) and EU Commission (1995, 2000). Crop interception was taken into account according to EFSA (2014).
The accumulation potential of amidosulfuron and its metabolites after long term use was also assessed, employing the mixing depth of 20 cm for the calculation of the background concentration.
Detailed application data used for simulation of PECsoil were compiled in Table CP 9.1.3- 1.

Table CP 9.1.3- 1: Application pattern used for PEC_{soil} calculations of amidosulfuron

Individual Crop	FOCUS Crop Used for Interception	Application				Amount reaching soil per season application
		Rate per Season [g a.s. /ha]	Interval [days]	Plant Interception [%]	BBCH Stage	[g a.s./ha]
Winter cereals, GAP	-	1 × 30	-	-	21-49	-
Winter cereals, Simulation	winter cereals	1 × 30	-	20	20-49	1 × 24.0
Winter cereals, GAP & Simulation	winter cereals	1 × 15	-	0	13-49	1 × 15.0
Spring cereals, GAP & Simulation	spring cereals	1 × 30	-	0	12-49	1 × 30.0
Flax, GAP	-	1 × 30	-	-	Before flower buds are visible	
Flax, Simulation	spring cereals	1 × 30	-	0	12-49	1 × 30.0
Grass, GAP	-	1 × 45	-	-	Spring-Autumn	-
Grass (spring), Simulation	grass	1 × 45	-	90	permanent grass	1 × 4.5
Grass (autumn), Simulation	grass	1 × 45	-	90		1 × 4.5

Substance Specific Parameters:
PEC_{soil} calculations were based on the non-normalised maximum DT_{50} from the kinetic evaluation of laboratory studies. For the metabolites, the (pseudo) application rate is calculated based on the maximum amount of the metabolite observed in soil degradation studies and the molar mass correction. Further compound specific input parameters are summarized below.

Table CP 9.1.3- 2: Input parameters of amidosulfuron and its metabolites for PEC_{soil}

Compound	DT_{50} 1) [days]	Max. occur. in soil [%]	Molar mass [g/mol]	Molar mass correction factor	Amount reaching soil per season application			
					Winter cereals 30 g a.s./ha	Winter cereals 15 g a.s./ha	Spring cereals and flax 30 g a.s./ha	Grass (spring and autumn) 45 g a.s./ha
Amidosulfuron	97.6	100	369.4	1	24	15	30	4.5
Amidosulfuron-desmethyl	23.8	49.6	355.4	0.9621	11.45	7.16	14.32	2.15
Amidosulfuron-desmethyl-chloropyrimidine	168	12.2	389.8	1.0552	3.09	1.93	3.86	0.58
Amidosulfuron-ADMP	166	9.9	155.2	0.4201	1	0.62	1.25	0.19
Amidosulfuron-guanidine	697	38.6	273.3	0.7398	6.85	4.28	8.57	1.29
Amidosulfuron-biuret	68	6.3	274.3	0.7426	1.12	0.7	1.4	0.21

1) Maximum non-normalised DT_{50} from kinetic evaluation of laboratory studies, for details please refer to CA 7.1.2.1

Findings:

The maximum PEC_{soil} values for amidosulfuron and its metabolites are summarised in the following table. The maximum, short-term and long-term PEC_{soil} values and the time weighted average values ($TWAC_{soil}$) are provided from Table CP 9.1.3- 3 to Table CP 9.1.3- 15.

Table CP 9.1.3- 3: Maximum PEC_{soil} of amidosulfuron and its metabolites for the uses assessed

Use pattern	Winter cereals, 1 × 30 g a.s./ha (20% interception) [mg/kg]	Winter cereals, 1 × 15 g a.s./ha (0% interception) [mg/kg]	Spring cereals and flax, 1 × 30 g a.s./ha (0% interception) [mg/kg]	Grass (spring and autumn), 1 × 45 g a.s./ha (90% interception) [mg/kg]
Amidosulfuron	0.032	0.020	0.040	0.006
Amidosulfuron-desmethyl	0.015	0.010	0.019	0.003
Amidosulfuron-desmethyl-chloropyrimidine	0.004	0.003	0.005	< 0.001
Amidosulfuron-ADMP	0.001	< 0.001	0.002	< 0.001
Amidosulfuron-guanidine	0.009	0.006	0.011	0.002
Amidosulfuron-biuret	0.001	< 0.001	0.002	< 0.001

Table CP 9.1.3- 4: Use in winter cereals: PEC_{soil} (actual) and $TWAC_{soil}$ of amidosulfuron

	Time [days]	**Amidosulfuron**			
		Winter cereals 1 × 30 g a.s./ha, 20% interception		**Winter cereals 1 × 15 g a.s./ha, 0% interception**	
		PEC_{soil} [mg/kg]	**$TWAC_{soil}$ [mg/kg]**	**PEC_{soil} [mg/kg]**	**$TWAC_{soil}$ [mg/kg]**
Initial	0	0.032	-	0.020	-
Short term	1	0.032	0.032	0.020	0.020
	2	0.032	0.032	0.020	0.020
	4	0.031	0.032	0.019	0.020
Long term	7	0.030	0.031	0.019	0.020
	14	0.029	0.030	0.018	0.019
	21	0.028	0.030	0.017	0.019
	28	0.026	0.029	0.016	0.018
	42	0.024	0.028	0.015	0.017
	50	0.022	0.027	0.014	0.017
	100	0.016	0.023	0.010	0.014

Table CP 9.1.3- 5: Use in spring cereals, flax and grass: PEC_{soil} (actual) and $TWAC_{soil}$ of amidosulfuron

	Time [days]	Amidosulfuron			
		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} [mg/kg]	$TWAC_{soil}$ [mg/kg]	PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]
Initial	0	0.040	-	0.006	-
Short term	1	0.040	0.040	0.006	0.006
	2	0.039	0.040	0.006	0.006
	4	0.039	0.039	0.006	0.006
Long term	7	0.038	0.039	0.006	0.006
	14	0.036	0.038	0.005	0.006
	21	0.034	0.037	0.005	0.006
	28	0.033	0.036	0.005	0.005
	42	0.030	0.035	0.004	0.005
	50	0.028	0.034	0.004	0.005
	100	0.020	0.029	0.003	0.004

Table CP 9.1.3- 6: Use in winter cereals: PEC_{soil} (actual) and $TWAC_{soil}$ of metabolite amidosulfuron-desmethyl

	Time [days]	Amidosulfuron-desmethyl			
		Winter cereals 1 × 30 g a.s./ha, 20% interception		Winter cereals 1 × 15 g a.s./ha, 0% interception	
		PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]	PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]
Initial	0	0.015	-	0.010	-
Short term	1	0.015	0.015	0.009	0.009
	2	0.014	0.015	0.009	0.009
	4	0.014	0.014	0.008	0.009
Long term	7	0.012	0.014	0.008	0.009
	14	0.010	0.013	0.006	0.008
	21	0.008	0.011	0.005	0.007
	28	0.007	0.010	0.004	0.007
	42	0.004	0.009	0.003	0.006
	50	0.004	0.008	0.002	0.005
	100	<0.001	0.005	<0.001	0.003

Table CP 9.1.3- 7: Use in spring cereals, flax and grass: PEC_{soil} (actual) and $TWAC_{soil}$ of metabolite amidosulfuron-desmethyl

	Time [days]	Amidosulfuron-desmethyl			
		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} [mg/kg]	$TWAC_{soil}$ [mg/kg]	PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]
Initial	0	0.019	-	0.003	-
Short term	1	0.019	0.019	0.003	0.003
	2	0.018	0.019	0.003	0.003
	4	0.017	0.018	0.003	0.003
Long term	7	0.016	0.017	0.002	0.003
	14	0.013	0.016	0.002	0.002
	21	0.010	0.014	0.002	0.002
	28	0.008	0.013	0.001	0.002
	42	0.006	0.011	<0.001	0.002
	50	0.004	0.010	<0.001	0.002
	100	0.001	0.006	<0.001	< 0.001

Table CP 9.1.3- 8: Use in winter cereals: PEC_{soil} (actual) and $TWAC_{soil}$ of metabolite amidosulfuron-desmethyl-chloropyrimidine

	Time [days]	Amidosulfuron-desmethyl-chloropyrimidine			
		Winter cereals 1 × 30 g a.s./ha, 20% interception		Winter cereals 1 × 15 g a.s./ha, 0% interception	
		PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]	PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]
Initial	0	0.004	-	0.003	-
Short term	1	0.004	0.004	0.003	0.003
	2	0.004	0.004	0.003	0.003
	4	0.004	0.004	0.003	0.003
Long term	7	0.004	0.004	0.003	0.003
	14	0.004	0.004	0.002	0.003
	21	0.004	0.004	0.002	0.002
	28	0.004	0.004	0.002	0.002
	42	0.003	0.004	0.002	0.002
	50	0.003	0.004	0.002	0.002
	100	0.003	0.003	0.002	0.002

Table CP 9.1.3- 9: Use in spring cereals, flax and grass: PEC_{soil} (actual) and $TWAC_{soil}$ of metabolite amidosulfuron-desmethyl-chloropyrimidine

	Time [days]	Amidosulfuron-desmethyl-chloropyrimidine			
		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} [mg/kg]	$TWAC_{soil}$ [mg/kg]	PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]
Initial	0	0.005	-	<0.001	-
Short term	1	0.005	0.005	<0.001	< 0.001
	2	0.005	0.005	<0.001	< 0.001
	4	0.005	0.005	<0.001	< 0.001
Long term	7	0.005	0.005	<0.001	< 0.001
	14	0.005	0.005	<0.001	< 0.001
	21	0.005	0.005	<0.001	< 0.001
	28	0.005	0.005	<0.001	< 0.001
	42	0.004	0.005	<0.001	< 0.001
	50	0.004	0.005	<0.001	< 0.001
	100	0.003	0.004	<0.001	< 0.001

Table CP 9.1.3- 10: Use in winter cereals: PEC_{soil} (actual) and $TWAC_{soil}$ of metabolite amidosulfuron-ADMP

	Time [days]	Amidosulfuron-ADMP			
		Winter cereals 1 × 30 g a.s./ha, 20% interception		Winter cereals 1 × 15 g a.s./ha, 0% interception	
		PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]	PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]
Initial	0	0.001	-	<0.001	-
Short term	1	0.001	0.001	<0.001	< 0.001
	2	0.001	0.001	<0.001	< 0.001
	4	0.001	0.001	<0.001	< 0.001
Long term	7	0.001	0.001	<0.001	< 0.001
	14	0.001	0.001	<0.001	< 0.001
	21	0.001	0.001	<0.001	< 0.001
	28	0.001	0.001	<0.001	< 0.001
	42	0.001	0.001	<0.001	< 0.001
	50	0.001	0.001	<0.001	< 0.001
	100	<0.001	0.001	<0.001	< 0.001

Table CP 9.1.3- 11: Use in spring cereals, flax and grass: PEC_{soil} (actual) and $TWAC_{soil}$ of metabolite amidosulfuron-ADMP

	Time [days]	Amidosulfuron-ADMP			
		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} [mg/kg]	$TWAC_{soil}$ [mg/kg]	PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]
Initial	0	0.002	-	<0.001	-
Short term	1	0.002	0.002	<0.001	< 0.001
	2	0.002	0.002	<0.001	< 0.001
	4	0.002	0.002	<0.001	< 0.001
Long term	7	0.002	0.002	<0.001	< 0.001
	14	0.002	0.002	<0.001	< 0.001
	21	0.002	0.002	<0.001	< 0.001
	28	0.001	0.002	<0.001	< 0.001
	42	0.001	0.002	<0.001	< 0.001
	50	0.001	0.002	<0.001	< 0.001
	100	0.001	0.001	<0.001	< 0.001

Table CP 9.1.3- 12: Use in winter cereals: PEC_{soil} (actual) and $TWAC_{soil}$ of metabolite amidosulfuron-guanidine

	Time [days]	Amidosulfuron-guanidine			
		Winter cereals 1 × 30 g a.s./ha, 20% interception		Winter cereals 1 × 15 g a.s./ha, 0% interception	
		PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]	PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]
Initial	0	0.009	-	0.006	-
Short term	1	0.009	0.009	0.006	0.006
	2	0.009	0.009	0.006	0.006
	4	0.009	0.009	0.006	0.006
Long term	7	0.009	0.009	0.006	0.006
	14	0.009	0.009	0.006	0.006
	21	0.009	0.009	0.006	0.006
	28	0.009	0.009	0.006	0.006
	42	0.009	0.009	0.005	0.006
	50	0.009	0.009	0.005	0.006
	100	0.008	0.009	0.005	0.005

Table CP 9.1.3- 13: Use in spring cereals, flax and grass: PEC_{soil} (actual) and $TWAC_{soil}$ of metabolite amidosulfuron-guanidine

	Time [days]	Amidosulfuron-guanidine			
		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} [mg/kg]	$TWAC_{soil}$ [mg/kg]	PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]
Initial	0	0.011	-	0.002	-
Short term	1	0.011	0.011	0.002	0.002
	2	0.011	0.011	0.002	0.002
	4	0.011	0.011	0.002	0.002
Long term	7	0.011	0.011	0.002	0.002
	14	0.011	0.011	0.002	0.002
	21	0.011	0.011	0.002	0.002
	28	0.011	0.011	0.002	0.002
	42	0.011	0.011	0.002	0.002
	50	0.011	0.011	0.002	0.002
	100	0.010	0.011	0.002	0.002

Table CP 9.1.3- 14: Use in winter cereals: PEC_{soil} (actual) and $TWAC_{soil}$ of metabolite amidosulfuron-biuret

	Time [days]	Amidosulfuron-biuret			
		Winter cereals 1 × 30 g a.s./ha, 20% interception		Winter cereals 1 × 15 g a.s./ha, 0% interception	
		PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]	PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]
Initial	0	0.001	-	<0.001	-
Short term	1	0.001	0.001	<0.001	< 0.001
	2	0.001	0.001	<0.001	< 0.001
	4	0.001	0.001	<0.001	< 0.001
Long term	7	0.001	0.001	<0.001	< 0.001
	14	0.001	0.001	<0.001	< 0.001
	21	0.001	0.001	<0.001	< 0.001
	28	0.001	0.001	<0.001	< 0.001
	42	<0.001	0.001	<0.001	< 0.001
	50	<0.001	0.001	<0.001	< 0.001
	100	<0.001	< 0.001	<0.001	< 0.001

Table CP 9.1.3- 15: Use in spring cereals, flax and grass: PEC_{soil} (actual) and $TWAC_{soil}$ of metabolite amidosulfuron-biuret

	Time [days]	Amidosulfuron-biuret			
		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} [mg/kg]	$TWAC_{soil}$ [mg/kg]	PEC_{soil} [mg/kg]	$TWAC_{soil}$ [mg/kg]
Initial	0	0.002	-	<0.001	-
Short term	1	0.002	0.002	<0.001	< 0.001
	2	0.002	0.002	<0.001	< 0.001
	4	0.002	0.002	<0.001	< 0.001
Long term	7	0.002	0.002	<0.001	< 0.001
	14	0.002	0.002	<0.001	< 0.001
	21	0.002	0.002	<0.001	< 0.001
	28	0.001	0.002	<0.001	< 0.001
	42	0.001	0.002	<0.001	< 0.001
	50	0.001	0.001	<0.001	< 0.001
	100	<0.001	0.001	<0.001	< 0.001

Potential accumulation in soil:
The accumulation potential after long term use was also assessed. The results for a non-standard mixing depth of 20 cm for an arable crop with tillage are presented in the following table.

Table CP 9.1.3- 16: PEC_{soil} of amidosulfuron and its metabolites for the uses assessed, taking the effect of accumulation into account (non-standard mixing depth of 20 cm)

Use pattern	PEC_{soil}	Amidosulfuron [mg/kg]	Amidosulfuron-Desmethyl [mg/kg]	Amidosulfuron-Desmethyl-Chloropyrimidine [mg/kg]	Amidosulfuron-ADMP [mg/kg]	Amidosulfuron-Guanidine [mg/kg]	Amidosulfuron-Biuret [mg/kg]
Winter Cereals 1×30 g a.s./ha	plateau (20 cm) total*	<0.001 0.033	<0.001 0.015	<0.001 0.004	<0.001 0.001	0.005 0.014	<0.001 0.002
Winter Cereals 1×15 g a.s./ha	plateau (20 cm) total*	<0.001 0.020	<0.001 0.010	<0.001 0.003	<0.001 <0.001	0.003 0.009	<0.001 <0.001
Spring cereals and flax 1×30 g a.s./ha	plateau (20 cm) total*	<0.001 0.041	<0.001 0.019	<0.001 0.006	<0.001 0.002	0.007 0.018	<0.001 0.002
Grass (spring) 1×45 g a.s./ha	plateau (20 cm) total*	<0.001 0.006	<0.001 0.003	<0.001 <0.001	<0.001 <0.001	<0.001 0.003	<0.001 <0.001
Grass (autumn) 1×45 g a.s./ha	plateau (20 cm) total*	<0.001 0.006	<0.001 0.003	<0.001 <0.001	<0.001 <0.001	<0.001 0.003	<0.001 <0.001

* total = plateau (background concentration after multi-year use) + max. PEC_{soil} (see Table CP 9.1.3- 3)

****

Formulated Product:

Initial PECsoil for the formulated product is derived via simple spreadsheet calculation, considering homogenous distribution in 5 cm soil depth, at 1.5 g/mL soil density. No time dependent PEC values are applicable to the formulation, due to rapid disintegration of the formulation when in soil contact.

Table CP 9.1.3- 17: Maximum PEC_{soil} values for the formulated product

Compound	Winter cereals, 1 × 40 g prod./ha (20% interception)		Winter cereals, 1 × 20 g prod./ha (0% interception)		Spring cereals and flax, 1 × 40 g prod./ha (0% interception)		Grass (spring and autumn), 1 × 60 g prod./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	-	0.027	-	0.053	-	0.008	-

CP 9.2 Fate and behaviour in water and sediment

Fate and behaviour of amidosulfuron in water and sediment were assessed in the MCA document (Section 7) of the current renewal dossier based on the application of the active substance in laboratory studies. The endpoints derived from studies with the active substance are considered as appropriate to assess the exposure of amidosulfuron after application of the formulation Amidosulfuron WG75.

CP 9.2.1 Aerobic mineralisation in surface water

Please refer to Document MCA Section 7.2.2.2.

CP 9.2.2 Water/sediment study

No laboratory route/rate studies were conducted with the formulation. See document MCA Section 7.2.1 for studies with the active substance.

CP 9.2.3 Irradiated water/sediment study

Please refer to Document MCA Section 7.2.2.4.

CP 9.2.4 Estimation of concentrations in groundwater

CP 9.2.4.1 Calculation of concentrations in groundwater

Predicted environmental concentrations in groundwater (PEC_{GW})

Studies submitted and evaluated for the first inclusion of amidosulfuron on Annex I:

The below baseline dossier studies are listed for formal completeness, but are of no longer relevance for approval renewal. These studies are superseded by a new modelling evaluation KCP 9.2.4.1/12 and KCP 9.2.4.1/13, to update for new substance information and modelling guidance.

Report:	KCP 9.2.4.1/01 [redacted],; 2003; M-230939-01-1
Title:	Predicted environmental concentrations of amidosulfuron and its main metabolites in groundwater (PECgw) calculated with FOCUS-PEARL for representative uses in Europe Code: AE F075032, AE F101630, AE F128870
Report No.:	C032161
Document No.:	M-230939-01-1
Guideline(s):	--
Guideline deviation(s):	--
GLP/GEP:	**no**

Report:	KCP 9.2.4.1/02 [redacted],; 2001; M-203520-01-1
Title:	Standardisation of a lysimeter study with amidosulfuron to dutch standard conditions using the leaching model FOCUS PEARL version 1.1.1 Code: AE F075032, AE F101630, AE F128870
Report No.:	C017034
Document No.:	M-203520-01-1
Guideline(s):	--
Guideline deviation(s):	--
GLP/GEP:	**no**

Report:	KCP 9.2.4.1/03 [redacted] A; [redacted]; 2007; M-284484-01-1
Title:	Predicted environmental concentrations of amidosulfuron and its main metabolites AE F101630 and AE F128870 in groundwater recharge based on calculations with FOCUS-PELMO 3.3.2
Report No.:	MEF-07/085
Document No.:	M-284484-01-1
Guideline(s):	not applicable
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Report:	KCP 9.2.4.1/04 [redacted]; [redacted]; 2006; M-271158-01-1
Title:	Predicted environmental concentrations of amidosulfuron and Its soil metabolite AE F1569309 in groundwater recharge based on calculations with FOCUS-PEARL 2.2.2
Report No.:	MEF-06/188
Document No.:	M-271158-01-1
Guideline(s):	not applicable
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Report:	KCP 9.2.4.1/05 [redacted] O; [redacted]; 2007; M-284497-01-1
Title:	Predicted environmental concentrations of amidosulfuron and its soil metabolite AE 1569309 in groundwater recharge based on calculations with FOCUS-PELMO 3.3.2
Report No.:	MEF-07/087
Document No.:	M-284497-01-1
Guideline(s):	not applicable
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Report:	KCP 9.2.4.1/06 [redacted],; [redacted]; 2006; M-277177-01-1
Title:	Amidosulfuron Statement of Bayer Crop Science on exposure and relevance of the soil metabolite AE 1569309 in groundwater
Report No.:	M-277177-01-1
Document No.:	M-277177-01-1
Guideline(s):	91/414/EEC
Guideline deviation(s):	not specified
GLP/GEP:	**no**

Report:	KCP 9.2.4.1/07 [redacted],; [redacted]; 2007; M-283751-01-1
Title:	Predicted environmental concentrations of amidosulfuron and its soil metabolites "C" and "D" in groundwater recharge based on calculations with FOCUS-PEARL 3.3.3
Report No.:	MEF-07/041
Document No.:	M-283751-01-1
Guideline(s):	not applicable
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Report:	KCP 9.2.4.1/08 [redacted] B; [redacted]; 2007; M-282847-01-1
Title:	Amidosulfuron - Statement of Bayer CropScience on exposure and relevance of the soil metabolites "C" and "D" in groundwater
Report No.:	M-282847-01-1
Document No.:	M-282847-01-1
Guideline(s):	not specified
Guideline deviation(s):	not specified
GLP/GEP:	**no**

Report:	KCP 9.2.4.1/09 [redacted],; [redacted]; 2007; M-284488-01-1
Title:	Predicted environmental concentrations of amidosulfuron and its soil metabolites "C" and "D" in groundwater recharge based on calculations with FOCUS-PELMO 3.3.2
Report No.:	MEF-07/086
Document No.:	M-284488-01-1
Guideline(s):	not specified
Guideline deviation(s):	not specified
GLP/GEP:	**no**

Studies submitted and evaluated in the course of the post-Annex I procedure for amidosulfuron:

The below studies are listed as 'new studies' for formal completeness, but are of no longer relevance for approval renewal. These modelling activities were provided as part of the confirmatory data submission, and are found summarised and evaluated in the "Addendum to Monograph prepared in the context of post Annex I procedure (new Annex II data)", Dec. 2010, rev. 1 Feb. 2011. The studies are superseded by a new modelling evaluation KCP 9.2.4.1/12-13, to update for new substance information and modelling guidance.

Report:	KCP 9.2.4.1/10 [redacted],; 2010; M-365831-01-1
Title:	Predicted environmental concentrations in groundwater recharge (PECgw) of amidosulfuron (AE F075032) and its metabolites based on calculations with FOCUS PEARL and FOCUS PELMO - Use in winter cereals, spring cereals, and grass in Europe
Report No.:	MEF-10/189
Document No.:	M-365831-01-1
Guideline(s):	not applicable
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Report:	KCP 9.2.4.1/11 [redacted],; 2010; M-389084-01-1
Title:	Predicted environmental concentrations in groundwater recharge (PECgw) of amidosulfuron (AE F075032) and its metabolites based on calculations with FOCUS PEARL and FOCUS PELMO - Use in winter cereals, spring cereals and grass in Europe
Report No.:	MEF-10/573
Document No.:	M-389084-01-1
Guideline(s):	not applicable
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Studies submitted for Annex I approval renewal:

To consider compound related input parameters from new experimental studies and kinetic evaluations, and to implement latest modeling guidance, updated PECgw calculations are presented for approval renewal, superseding all previous data evaluations.

Report:	KCP 9.2.4.1/12 [redacted],; 2016; M-553864-01-1
Title:	Amidosulfuron (AMS) and metabolites: PECgw FOCUS PEARL, PELMO, MACRO EUR - Use in winter and spring cereals, flax and grass in Europe
Report No.:	EnSa-16-0282 v1
Document No.:	M-553864-01-1
Guideline(s):	none
Guideline deviation(s):	none
GLP/GEP:	**no**

Materials and Methods:
The predicted environmental concentrations in groundwater (PEC_{gw}) for amidosulfuron and its metabolites were calculated using the simulation model FOCUS PEARL (version 4.4.4), and FOCUS PELMO (version 5.5.3). In addition, FOCUS MACRO (version 5.5.4) calculations have been performed for the Chateaudun scenario. PEC_{gw} were evaluated as the 80th percentile of the mean annual leachate concentration at 1 m soil depth. Model parameters and scenarios consisting of weather, soil, and crop data were used as proposed by FOCUS (2009, 2014). Crop interception was taken into account according to the BBCH growth stage, as recommended by EFSA (2014).

Detailed application data used for simulation of PEC_{gw} were compiled in Table CP 9.2.4.1- 1.

Table CP 9.2.4.1- 1: Application pattern used for PEC_{gw} calculations

Individual Crop	FOCUS Crop Used for Interception	Application				Amount reaching soil per season application
		Rate per Season [g a.s. /ha]	Interval [days]	Plant Interception [%]	BBCH Stage	[g a.s./ha]
Winter cereals, GAP	-	1 × 30	-	-	21-49	-
Winter cereals, Simulation	winter cereals	1 × 30	-	20	20-49	1 × 24.0
Winter cereals, GAP & Simulation	winter cereals	1 × 15	-	0	13-49	1 × 15.0
Spring cereals, GAP & Simulation	spring cereals	1 × 30	-	0	12-49	1 × 30.0
Flax, GAP	-	1 × 30	-	-	Before flower buds are visible	
Flax, Simulation	spring cereals	1 × 30	-	0	12-49	1 × 30.0
Grass, GAP	-	1 × 45	-	-	Spring/ Autumn	-
Grass (spring), Simulation	grass	1 × 45	-	90	perma-nent grass	1 × 4.5
Grass (autumn), Simulation	grass	1 × 45	-	90		1 × 4.5

The application in **winter cereals** according to GAP is intended at the onset of the spring vegetation period, when climate conditions allow for resumption of crop and weed growth after winter dormancy. Treatment is made to well established crop, with use rate depending on crop BBCH stage reached at that time. No pre-defined event dates are implemented in the FOCUS model that would directly translate this cropping situation into discrete calendar dates for each groundwater scenario setting. To generate an adequate scenario-adapted representation with relative date setting, the following approach was therefore used: the simulated treatment was referenced relative to the tabulated crop emergence date of the earliest emerging spring crop (i.e. not necessarily cereals) that was defined by FOCUS for the respective scenario. An application timed 14 days before that date was then selected, considered suitable to represent the start of the vegetation period in the respective scenario environment. An overview of the date selection per scenario is presented in the table below; for technical reason, such application dates must be entered to the simulation model formally as 'absolute' dates, even though referencing was in fact of relative type.

Table CP 9.2.4.1- 2: Spring emergence dates of earliest crops in the FOCUS scenarios

Scenario	Crop	Tabulated Emergence date	Selected Application date for winter cereals
Châteaudun	spring cereals	10 Mar	24 Feb
Hamburg	carrots	10 Mar	24 Feb
Jokioinen	spring cereals	18 May	04 May
Kremsmuenster	carrots	10 Mar	24 Feb
Okehampton	field beans	15 Mar	01 Mar
Piacenza	sugar beet	20 Mar	06 Mar
Porto	carrots	28 Feb	14 Feb
Sevilla	cabbage	01 Mar	15 Feb
Thiva	potatoes	01 Mar	15 Feb

Following this procedure, the application dates are realistic and consistent with crop event dates and weather pertinent to the respective scenario as given by FOCUS (2009, 2014).

The application to **spring cereals and flax** was timed relative to FOCUS crop emergence date of spring cereals, considering an offset of 4 days to represent an early post-emergent situation.

For **spring use in grass**, the same approach as for spring application in winter cereals was used, i.e., the application is done at the beginning of the vegetation period.

For **autumn use in grass**, the application was set relative to FOCUS crop emergence date of winter cereals, timed 14 days before this date. For technical reason (reference crop is different to simulated crop), such application dates need to be entered to the simulation model formally as 'absolute' dates, event though refencing was in fact of relative type.

Table CP 9.2.4.1- 3: First application dates and related information for amidosulfuron as used for the simulation runs

Individual crop	Winter cereals 1 × 30 g a.s./ha BBCH 20-49	Winter cereals 1 × 15 g a.s./ha BBCH 13-49	Spring cereals and flax 1 × 30 g a.s./ha BBCH 12-49	Permanent grass (spring) 1 × 45 g a.s./ha BBCH 0-99	Permanent grass (autumn) 1 × 45 g a.s./ha BBCH 0-99
Repeat Interval for App. Events	Every Year	Every Year	Every Year	Every Year	Every Year
Application Technique	Spray	Spray	Spray	Spray	Spray
Absolute / Relative to	Absolute	Absolute	Emergence	Absolute	Absolute
Scenario	1st App. Date (Julian day) Offset	1st App. Date (Julian day) Offset	1st App. Date (Julian day) Offset	1st App. Date (Julian day) Offset	1st app. Date (Julian day) Offset
Chateaudun	24 Feb (55) -	24 Feb (55) -	14 Mar (73) 4	24 Feb (55) -	12 Oct (285) -
Hamburg	24 Feb (55) -	24 Feb (55) -	05 Apr (95) 4	24 Feb (55) -	18 Oct (291) -
Jokioinen	04 May (124) -	04 May (124) -	22 May (142) 4	04 May (124) -	06 Sep (249) -
Kremsmuenster	24 Feb (55) -	24 Feb (55) -	05 Apr (95) 4	24 Feb (55) -	22 Oct (295) -
Okehampton	01 Mar (60) -	01 Mar (60) -	05 Apr (95) 4	01 Mar (60) -	03 Oct (276) -
Piacenza	06 Mar (65) -	06 Mar (65) -	- - -	06 Mar (65) -	17 Nov (321) -
Porto	14 Feb (45) -	14 Feb (45) -	14 Mar (73) 4	14 Feb (45) -	16 Nov (320) -
Sevilla	15 Feb (46) -	15 Feb (46) -	- - -	15 Feb (46) -	16 Nov (320) -
Thiva	15 Feb (46) -	15 Feb (46) -	- - -	15 Feb (46) -	16 Nov (320) -

Substance specific and model related input parameters and detailed information about formation fractions and degradation rates for the different PEC_{gw} calculations are summarised in the following tables.

Table CP 9.2.4.1- 4: Substance specific and model related input parameter for PEC_{gw} calculation of amidosulfuron and its metabolites (model parameters not listed are kept as default)

Parameter	Unit	Amidosulfuron	Amidosulfuron-desmethyl	Intermediate metabolites	Amidosulfuron-desmethyl-chloropyrimidine
Common					
Molar Mass	[g/mol]	369.4	355.4	369.4	389.8
Water Solubility	[mg/L]	3070	30200	3070	15700
Vapour Pressure	[Pa]	1.30E-06	5.60E-08	1.30E-06	1.90E-08
Freundlich Exponent	[-]	0.939[1)]	0.934[1)]	1.000[4)]	0.920[1)]
Plant Uptake Factor	[-]	0.3	0.0	0.0	0.0
Walker Exponent	[-]	0.7	0.7	0.7	0.7
PEARL parameters					
Substance Code	[-]	AMS	desme	Inter	d-chl
DT_{50}	[days]	14.4[2)]	10.8[2)]	2.8[2)]	59.8[2)]
Molar Activ. Energy	[kJ/mol]	65.4	65.4	65.4	65.4
K_{om}	[mL/g]	10.8	10.0	0.0	16.9
K_f	[mL/g]	-	-	-	-
PELMO parameters					
Substance Code	[-]	AS	A1	B1	C1
Rate Constant	[1/day]	0.04814	0.06418	0.24844	0.01159
Q_{10}	[-]	2.58	2.58	2.58	2.58
K_{oc}	[mL/g]	18.6[3)]	17.3[3)]	0.0[4)]	29.1[3)]
MACRO parameters					
Substance code	[-]	AMS	desme	n.r.	d-chl
Exponent moisture	[-]	0.49	0.49	n.r.	0.49
Exponent temperature	[1/K]	0.0948	0.0948	n.r.	0.0948

1) Arithmetic mean value from different soils (for detailed values please refer to CA 7.1.3.1).
2) Geometric mean of normalised DT50 in aerobic soil under laboratory conditions (for detailed values please refer to CA 7.1.2.1).
3) Geometric mean value from different soils (for detailed values please refer to CA 7.1.3.1).
4) generic worst case value.
n.r. = not relevant

Table CP 9.2.4.1- 5: Substance specific and model related input parameter for PEC_{gw} calculation of amidosulfuron and its metabolites (model parameters not listed are kept as default) - continued

Parameter	Unit	Amidosulfuron-ADMP	Amidosulfuron-guanidine	Amidosulfuron-biuret
Common				
Molar Mass	[g/mol]	155.2	273.3	274.3
Water Solubility	[mg/L]	5200	2100	81000
Vapour Pressure	[Pa]	2.60E-02	5.20E-08	2.70E-05
Freundlich Exponent	[-]	0.760[1)]	0.903[2)]	1.000[6)]
Plant Uptake Factor	[-]	0.0	0.0	0.0
Walker Exponent	[-]	0.7	0.7	0.7
PEARL parameters				
Substance Code	[-]	ADMP	guani	biure
DT_{50}	[days]	14.6[4)]	399.0[3)]	26.0[3)]
Molar Activ. Energy	[kJ/mol]	65.4	65.4	65.4
K_{om}	[mL/g]	160.0	8.9	0.0
K_f	[mL/g]	-	-	-
PELMO parameters				
Substance Code	[-]	D1	B2	C2
Rate Constant	[1/day]	0.04748	0.00174	0.02666
Q_{10}	[-]	2.58	2.58	2.58
K_{oc}	[mL/g]	276.0[1)]	15.4[5)]	0.0[6)]
MACRO parameters				
Substance code	[-]	ADMP	guani	biure
Exponent moisture	[-]	0.49	0.49	0.49
Exponent temperature	[1/K]	0.0948	0.0948	0.0948

1) Arithmetic mean Freundlich exponent and geometric mean KOC value from different soils (for detailed values please refer to CA 7.1.3.1 and the EFSA conclusions of foramsulfuron (EFSA Journal 2016;14(3):4421)).
2) Arithmetic mean value from different soils (for detailed values please refer to CA 7.1.3.1).
3) Geometric mean of normalised DT_{50} in aerobic soil under laboratory conditions (for detailed values please refer to CA 7.1.2.1).
4) Geometric mean of normalised DT_{50} in aerobic soil under laboratory conditions (for detailed values please refer to CA 7.1.2.1) and of normalised DT_{50} published in the EFSA conclusions of foramsulfuron (EFSA Journal 2016;14(3):4421).
5) Geometric mean value from different soils (for detailed values please refer to CA 7.1.3.1).
6) worst case value from different soils (for detailed values please refer to CA 7.1.3.1).

Table CP 9.2.4.1- 6: Degradation pathway related parameters for amidosulfuron and its metabolites

Degradation fraction from → to (-) (FOCUS PEARL)	AMS -> desme: 0.291 AMS -> Inter: 0.564 AMS -> ADMP: 0.121 Inter -> d-chl: 0.268 Inter -> guani: 0.539 Inter -> biure: 0.193
Degradation rate from → to (1/day) (FOCUS PELMO)[1)]	Active Substance -> A1: 0.0140073 Active Substance -> B1: 0.0271483 Active Substance -> D1: 0.0058244 Active Substance -> BR/CO2: 0.0011552 A1 -> BR/CO2: 0.0641803 B1 -> C1: 0.0665819 B1 -> B2: 0.1339091 B1 -> C2: 0.0479489 C1 -> BR/CO2: 0.0115911 D1 -> BR/CO2: 0.0474758 B2 -> BR/CO2: 0.0017372 C2 -> BR/CO2: 0.0266595

1) Calculated as *ln(2) / DT50 × formation fraction*

For simulation of sequential metabolites in MACRO, (pseudo) application rates were calculated based on the maximum amount of the metabolite observed in soil degradation studies and the molar mass correction (see Table CP 9.1.3- 2 in Point CP 9.1.3). The rates used in the simulations are given in the table below. The metabolites were then handled in MACRO as parent substance applied at the application dates given in Table CP 9.2.4.1- 3.

Table CP 9.2.4.1- 7: FOCUS MACRO: Calculation of metabolite application rates

Compound	**Parent**	**Amidosulfuron-desmethyl**	**Amidosulfuron-desmethyl-chloropyrimidine**	**Amidosulfuron-ADMP**	**Amidosulfuron-guanidine**	**Amidosulfuron-biuret**
Crop / rate	**(g a.s./ha)**	**(g/ha)**	**(g/ha)**	**(g/ha)**	**(g/ha)**	**(g/ha)**
Winter Cereals (30 g/ha)	1×24.000	1×11.45	1×3.09	1×1.00	1×6.85	1×1.12
Winter Cereals (15 g/ha)	1×15.000	1×7.16	1×1.93	1×0.62	1×4.28	1×0.70
Spring cereals and flax	1×30.000	1×14.32	1×3.86	1×1.25	1×8.57	1×1.4
Permanent grass (spring)	1×4.500	1×2.15	1×0.58	1×0.19	1×1.29	1×0.21
Permanent grass (autumn)	1×4.500	1×2.15	1×0.58	1×0.19	1×1.29	1×0.21

Findings:
PEC_{gw} were evaluated as the 80^{th} percentile of the mean annual leachate concentration at 1 m soil depth. FOCUS PEARL, PELMO and MACRO PEC_{gw} results for amidosulfuron and its metabolites are given in the following tables.

Table CP 9.2.4.1- 8: Winter cereals: FOCUS PEARL, PELMO & MACRO PEC_{gw} results of amidosulfuron and its metabolites

Use Pattern	Winter cereals, 1 × 30 g a.s./ha, 1 × 20% interception			
	Amidosulfuron	**Amidosulfuron-desmethyl**	**Intermediate metabolites**	**Amidosulfuron-desmethyl-chloropyrimidine**
FOCUS PEARL	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	0.011	0.007	0.003	**0.160**
Hamburg	0.071	0.043	0.023	**0.332**
Jokioinen	0.054	0.033	0.030	**0.269**
Kremsmuenster	0.049	0.029	0.010	**0.245**
Okehampton	0.086	0.049	0.020	**0.291**
Piacenza	0.029	0.018	0.007	**0.177**
Porto	0.041	0.022	0.018	**0.161**
Sevilla	<0.001	<0.001	<0.001	0.005
Thiva	0.003	0.002	<0.001	0.093
FOCUS PELMO	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	0.008	0.005	0.002	**0.146**
Hamburg	0.087	0.046	0.030	**0.329**
Jokioinen	0.053	0.031	0.041	**0.259**
Kremsmuenster	0.062	0.037	0.016	**0.279**
Okehampton	**0.119**	0.064	0.033	**0.313**
Piacenza	0.040	0.020	0.016	**0.214**
Porto	0.059	0.025	0.047	**0.166**
Sevilla	<0.001	<0.001	<0.001	0.016
Thiva	0.001	0.001	<0.001	0.055
FOCUS MACRO	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	0.006	<0.001	n.r.	0.055

n.r. = not relevant
In **bold:** values exceeding the trigger value of 0.1 µg/L

Table CP 9.2.4.1- 9: Winter cereals - continued: FOCUS PEARL, PELMO & MACRO PEC_{gw} results of amidosulfuron and its metabolites

Use Pattern	**Winter cereals, 1 × 30 g a.s./ha, 1 × 20% interception**		
	Amidosulfuron-ADMP	**Amidosulfuron-guanidine**	**Amidosulfuron-biuret**
FOCUS PEARL	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	<0.001	**3.159**	0.089
Hamburg	<0.001	**2.225**	**0.246**
Jokioinen	<0.001	**3.138**	**0.471**
Kremsmuenster	<0.001	**1.360**	**0.149**
Okehampton	<0.001	**1.202**	**0.148**
Piacenza	<0.001	**1.907**	0.083
Porto	<0.001	**1.335**	**0.103**
Sevilla	<0.001	**1.872**	0.006
Thiva	<0.001	**3.916**	0.034
FOCUS PELMO	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	<0.001	**2.765**	0.071
Hamburg	0.001	**2.002**	**0.209**
Jokioinen	<0.001	**2.049**	**0.367**
Kremsmuenster	<0.001	**1.567**	**0.156**
Okehampton	<0.001	**1.176**	**0.152**
Piacenza	<0.001	**2.233**	0.093
Porto	<0.001	**1.130**	0.081
Sevilla	<0.001	**1.499**	0.009
Thiva	<0.001	**2.375**	0.017
FOCUS MACRO	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	<0.001	**3.41**	0.026

In **bold**: values exceeding the trigger value of 0.1 µg/L

Table CP 9.2.4.1- 10: Winter cereals: FOCUS PEARL, PELMO & MACRO PEC_{gw} results of amidosulfuron and its metabolites

Use Pattern	Winter cereals, 1 × 15 g a.s./ha, 1 × 0% interception			
	Amidosulfuron	**Amidosulfuron-desmethyl**	**Intermediate metabolites**	**Amidosulfuron-desmethyl-chloropyrimidine**
FOCUS PEARL	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	0.006	0.004	0.002	0.095
Hamburg	0.042	0.025	0.014	**0.200**
Jokioinen	0.031	0.019	0.018	**0.160**
Kremsmuenster	0.029	0.018	0.006	**0.150**
Okehampton	0.052	0.030	0.012	**0.177**
Piacenza	0.017	0.011	0.004	**0.106**
Porto	0.024	0.013	0.011	0.095
Sevilla	<0.001	<0.001	<0.001	0.002
Thiva	0.002	0.001	<0.001	0.054
FOCUS PELMO	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	0.004	0.003	0.001	0.087
Hamburg	0.052	0.028	0.018	**0.198**
Jokioinen	0.031	0.018	0.026	**0.158**
Kremsmuenster	0.037	0.022	0.009	**0.170**
Okehampton	0.071	0.038	0.020	**0.192**
Piacenza	0.024	0.012	0.010	**0.129**
Porto	0.035	0.015	0.029	0.100
Sevilla	<0.001	<0.001	<0.001	0.009
Thiva	0.001	0.001	<0.001	0.033
FOCUS MACRO	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	0.004	0.001	n.r.	0.032

n.r. = not relevant
In **bold**: values exceeding the trigger value of 0.1 µg/L

Table CP 9.2.4.1- 11: Winter cereals - continued: FOCUS PEARL, PELMO & MACRO PEC_{gw} results of amidosulfuron and its metabolites

Use Pattern	**Winter cereals, 1 × 15 g a.s./ha, 1 × 0% interception**		
	Amidosulfuron-ADMP	**Amidosulfuron-guanidine**	**Amidosulfuron-biuret**
FOCUS PEARL	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	<0.001	**1.936**	0.055
Hamburg	<0.001	**1.374**	**0.154**
Jokioinen	<0.001	**1.914**	**0.294**
Kremsmuenster	<0.001	**0.841**	0.093
Okehampton	<0.001	**0.746**	0.092
Piacenza	<0.001	**1.184**	0.052
Porto	<0.001	**0.833**	0.064
Sevilla	<0.001	**1.131**	0.004
Thiva	<0.001	**2.417**	0.021
FOCUS PELMO	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	<0.001	**1.703**	0.044
Hamburg	<0.001	**1.236**	**0.130**
Jokioinen	<0.001	**1.261**	**0.230**
Kremsmuenster	<0.001	**0.977**	0.097
Okehampton	<0.001	**0.731**	0.095
Piacenza	<0.001	**1.390**	0.058
Porto	<0.001	**0.695**	0.051
Sevilla	<0.001	**0.937**	0.005
Thiva	<0.001	**1.472**	0.011
FOCUS MACRO	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	<0.001	**2.09**	0.017

In **bold**: values exceeding the trigger value of 0.1 µg/L

Table CP 9.2.4.1- 12: Spring cereals and flax: FOCUS PEARL, PELMO & MACRO PEC$_{gw}$ results of amidosulfuron and its metabolites

Use Pattern	Spring cereals and flax, 1 × 30 g a.s./ha, 1 × 0% interception			
	Amidosulfuron	**Amidosulfuron-desmethyl**	**Intermediate metabolites**	**Amidosulfuron-desmethyl-chloropyrimidine**
FOCUS PEARL	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**
Chateaudun	0.010	0.007	0.003	**0.158**
Hamburg	0.092	0.057	0.033	**0.468**
Jokioinen	0.058	0.036	0.044	**0.341**
Kremsmuenster	0.071	0.043	0.014	**0.330**
Okehampton	0.065	0.040	0.015	**0.309**
Porto	0.010	0.006	0.004	**0.127**
FOCUS PELMO	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**
Chateaudun	0.005	0.003	0.002	**0.121**
Hamburg	0.034	0.022	0.011	**0.272**
Jokioinen	0.061	0.037	0.060	**0.290**
Kremsmuenster	0.056	0.034	0.013	**0.299**
Okehampton	0.068	0.038	0.017	**0.269**
Porto	0.021	0.013	0.009	**0.143**
FOCUS MACRO	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**
Chateaudun	0.008	0.002	n.r.	0.061

n.r. = not relevant
In **bold:** values exceeding the trigger value of 0.1 µg/L

Table CP 9.2.4.1- 13: Spring cereals and flax - continued: FOCUS PEARL, PELMO & MACRO PEC$_{gw}$ results of amidosulfuron and its metabolites

Use Pattern	Spring cereals and flax, 1 × 30 g a.s./ha, 1 × 0% interception		
	Amidosulfuron-ADMP	**Amidosulfuron-guanidine**	**Amidosulfuron-biuret**
FOCUS PEARL	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**
Chateaudun	<0.001	**2.740**	0.087
Hamburg	<0.001	**3.405**	**0.416**
Jokioinen	<0.001	**2.772**	**0.580**
Kremsmuenster	<0.001	**1.828**	**0.198**
Okehampton	<0.001	**1.456**	**0.173**
Porto	<0.001	**1.154**	0.054
FOCUS PELMO	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**
Chateaudun	<0.001	**2.361**	0.061
Hamburg	<0.001	**1.988**	**0.184**
Jokioinen	<0.001	**2.112**	**0.449**
Kremsmuenster	<0.001	**1.794**	**0.165**
Okehampton	<0.001	**1.220**	**0.136**
Porto	<0.001	**0.992**	0.060
FOCUS MACRO	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**
Chateaudun	<0.001	**2.94**	0.029

In **bold**: values exceeding the trigger value of 0.1 µg/L

Table CP 9.2.4.1- 14: Permanent grass (spring): FOCUS PEARL, PELMO & MACRO PEC_{gw} results of amidosulfuron and its metabolites

Use Pattern	Permanent grass (spring), 1 × 45 g a.s./ha, 1 × 90% interception			
	Amidosulfuron	Amidosulfuron-desmethyl	Intermediate metabolites	Amidosulfuron-desmethyl-chloropyrimidine
FOCUS PEARL	PEC_{gw} [µg/L]	PEC_{gw} [µg/L]	PEC_{gw} [µg/L]	PEC_{gw} [µg/L]
Chateaudun	0.004	0.003	<0.001	0.036
Hamburg	0.010	0.006	0.004	0.058
Jokioinen	0.009	0.006	0.007	0.059
Kremsmuenster	0.006	0.004	0.001	0.040
Okehampton	0.010	0.006	0.003	0.046
Piacenza	0.005	0.003	0.001	0.035
Porto	0.005	0.003	0.003	0.024
Sevilla	<0.001	<0.001	<0.001	0.016
Thiva	<0.001	<0.001	<0.001	0.019
FOCUS PELMO	PEC_{gw} [µg/L]	PEC_{gw} [µg/L]	PEC_{gw} [µg/L]	PEC_{gw} [µg/L]
Chateaudun	0.002	0.001	<0.001	0.025
Hamburg	0.010	0.005	0.004	0.038
Jokioinen	0.008	0.005	0.007	0.042
Kremsmuenster	0.005	0.003	0.001	0.035
Okehampton	0.013	0.008	0.005	0.046
Piacenza	0.015	0.006	0.006	0.040
Porto	0.012	0.005	0.009	0.024
Sevilla	<0.001	<0.001	<0.001	0.011
Thiva	<0.001	<0.001	<0.001	0.015
FOCUS MACRO	PEC_{gw} [µg/L]	PEC_{gw} [µg/L]	PEC_{gw} [µg/L]	PEC_{gw} [µg/L]
Chateaudun	0.002	0.000	n.r.	0.010

n.r. = not relevant

Table CP 9.2.4.1- 15: Permanent grass (spring) - continued: FOCUS PEARL, PELMO & MACRO PEC_{gw} results of amidosulfuron and its metabolites

Use Pattern	Permanent grass (spring), 1 × 45 g a.s./ha, 1 × 90% interception		
	Amidosulfuron-ADMP	Amidosulfuron-guanidine	Amidosulfuron-biuret
FOCUS PEARL	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	<0.001	**0.327**	0.023
Hamburg	<0.001	**0.474**	0.051
Jokioinen	<0.001	**0.532**	**0.107**
Kremsmuenster	<0.001	**0.281**	0.023
Okehampton	<0.001	**0.215**	0.025
Piacenza	<0.001	**0.377**	0.018
Porto	<0.001	**0.166**	0.017
Sevilla	<0.001	**0.312**	0.005
Thiva	<0.001	**0.390**	0.005
FOCUS PELMO	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	<0.001	**0.287**	0.013
Hamburg	<0.001	**0.263**	0.025
Jokioinen	<0.001	**0.362**	0.069
Kremsmuenster	<0.001	**0.236**	0.021
Okehampton	<0.001	**0.188**	0.024
Piacenza	<0.001	**0.184**	0.022
Porto	<0.001	**0.144**	0.018
Sevilla	<0.001	**0.267**	0.003
Thiva	<0.001	**0.242**	0.003
FOCUS MACRO	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	<0.001	**0.387**	0.006

In **bold**: values exceeding the trigger value of 0.1 µg/L

Table CP 9.2.4.1- 16: Permanent grass (autumn): FOCUS PEARL, PELMO & MACRO PEC$_{gw}$ results of amidosulfuron and its metabolites

Use Pattern	**Permanent grass (autumn), 1 × 45 g a.s./ha, 1 × 90% interception**			
	Amidosulfuron	**Amidosulfuron-desmethyl**	**Intermediate metabolites**	**Amidosulfuron-desmethyl-chloropyrimidine**
FOCUS PEARL	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**
Chateaudun	0.014	0.007	0.006	0.050
Hamburg	0.067	0.025	0.045	**0.110**
Jokioinen	0.046	0.022	0.065	**0.113**
Kremsmuenster	0.025	0.011	0.009	0.060
Okehampton	0.071	0.025	0.023	0.065
Piacenza	0.033	0.012	0.011	0.059
Porto	0.075	0.023	0.029	0.033
Sevilla	0.014	0.006	0.008	0.026
Thiva	0.005	0.002	0.002	0.036
FOCUS PELMO	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**
Chateaudun	0.009	0.004	0.004	0.038
Hamburg	0.066	0.023	0.052	0.074
Jokioinen	0.049	0.019	0.086	0.066
Kremsmuenster	0.029	0.011	0.013	0.056
Okehampton	0.072	0.024	0.026	0.056
Piacenza	0.075	0.019	0.024	0.045
Porto	**0.105**	0.026	0.040	0.027
Sevilla	0.016	0.005	0.010	0.021
Thiva	0.005	0.002	0.004	0.029
FOCUS MACRO	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**	**PEC$_{gw}$ [µg/L]**
Chateaudun	0.015	0.003	n.r.	0.019

n.r. = not relevant

In **bold**: values exceeding the trigger value of 0.1 µg/L

Table CP 9.2.4.1- 17: Permanent grass (autumn) - continued: FOCUS PEARL, PELMO & MACRO PEC_{gw} results of amidosulfuron and its metabolites

Use Pattern	**Permanent grass (autumn), 1 × 45 g a.s./ha, 1 × 90% interception**		
	Amidosulfuron-ADMP	**Amidosulfuron-guanidine**	**Amidosulfuron-biuret**
FOCUS PEARL	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	<0.001	**0.346**	0.036
Hamburg	<0.001	**0.550**	0.079
Jokioinen	<0.001	**0.588**	**0.155**
Kremsmuenster	<0.001	**0.296**	0.034
Okehampton	<0.001	**0.225**	0.051
Piacenza	<0.001	**0.421**	0.031
Porto	<0.001	**0.165**	0.029
Sevilla	<0.001	**0.322**	0.020
Thiva	<0.001	**0.437**	0.014
FOCUS PELMO	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	<0.001	**0.298**	0.028
Hamburg	0.001	**0.312**	0.055
Jokioinen	<0.001	**0.369**	**0.108**
Kremsmuenster	<0.001	**0.273**	0.032
Okehampton	<0.001	**0.190**	0.044
Piacenza	0.001	**0.190**	0.030
Porto	<0.001	**0.121**	0.028
Sevilla	<0.001	**0.253**	0.017
Thiva	<0.001	**0.293**	0.012
FOCUS MACRO	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**	**PEC_{gw} [µg/L]**
Chateaudun	<0.001	**0.41**	0.019

In **bold**: values exceeding the trigger value of 0.1 µg/L

Conclusion:

Amidosulfuron: PEC_{gw} simulations did not reach or exceed the parametric trigger value of 0.1 µg/L in any European scenario for the intended uses on winter cereals (15 g/ha), spring cereals and flax (30 g/ha), and spring use on grass (45 g/ha). For the intended uses on winter cereals (30 g/ha), and autumn treatment of grass (45 g/ha), no exceedances resulted in the calculations based on the PEARL and MACRO models, however a slight breach was noted for a single scenario situation when using the alternative simulation model PELMO:

- winter cereals (30 g/ha), PELMO simulation for scenario Okehampton: 0.119 µg/L
- autumn use grass (45 g/ha), PELMO simulation for scenario Porto: 0.105 µg/L

These situations are left unresolved for the purpose of the present approval renewal document, and will be addressed at national level in the phase of product re-registrations post-Annex I approval.

Amidosulfuron-desmethyl, amidosulfuron-ADMP: PEC_{gw} simulations for all intended uses did not reach or exceed the parametric trigger value of 0.1 µg/L in any European scenario, any simulation model. Thus, further assessment on the potential relevance in groundwater is not required for these components.

Amidosulfuron-desmethyl-chloropyrimidine, amidosulfuron-guanidine, amidosulfuron-biuret:
The parametric trigger value of 0.1 µg/L was exceeded in the simulations for various scenario situations. Detailed assessments of the potential relevance in groundwater following the stepwise procedure of guidance SANCO 221/2000 were therefore made and are provided in Document N4,

brief tabular overview summaries hereon are given below. For all three components, the assessments clearly concluded no relevance for groundwater.

Summary of relevance assessment for metabolite amidosulfuron-desmethyl-chloropyrimidine

	Assessment step		Result of assessment	
	STEP 1		Metabolite of <u>no</u> concern?	No
Quantification of groundwater contamination	STEP 2		Max PECgw Based on	0.468 µg/L FOCUS PEARL simulation, Hamburg scenario, use on spring cereals/flax, 30 g a.s./ha, 20 % CI
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite ?	Non-genotoxic
		Stage 3	Toxic properties of metabolite; Classification of parent	Not classified (opinion ECHA/RAC/CLH-O-0000002509-70-01/F of 08 March 2012)
			Classification of metabolite	None proposed. Low toxicity expected based on DEREK / LHASA prediction, and experimental information available for structurally similar component AE F128721.
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	PECgw is less than 0.75 µg/L, therefore consumer exposure assessment is not required. The threshold of concern approach applies.
	STEP 5		Refined risk assessment Predicted exposure (% of ADI) ADI based on	Not required. Not required. Not required.

Summary of relevance assessment for metabolite amidosulfuron-guanidine

	Assessment step		**Result of assessment**	
	STEP 1		Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2		Max PECgw Based on	3.916 µg/L FOCUS PEARL simulation, Thiva scenario, use on winter cereals, 30 g a.s./ha, 20 % CI
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite ?	Non-genotoxic
		Stage 3	Toxic properties of metabolite; Classification of parent	Not classified. (opinion ECHA/RAC/CLH-O-0000002509-70-01/F of 08 March 2012)
			Classification of metabolite	None proposed. rat oral acute toxicity: LD_{50} > 2000 mg/kg rat oral 28 day toxicity: no treatment related effects up to the highest dose tested (10,000 ppm; 778 mg/kg bw/d for male, and 867 mg/kg bw/d for females).
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	Adult (60 kg bw, 2 L): 0.131 µg/kg bw/day Child (10 kg bw, 1 L): 0.392 µg/kg bw/day Infant (5 kg bw, 0.75 L): 0.587 µg/kg bw/day no relevant contribution via food
	STEP 5		Refined risk assessment Predicted exposure (% of ADI) ADI based on	Adult (60 kg bw, 2 L): 0.1 % ADI Child (10 kg bw, 1 L): 0.2 % ADI Infant (5 kg bw, 0.75 L): 0.3 % ADI NOEL from 28 day rat study.

Summary of relevance assessment for metabolite amidosulfuron-biuret

	Assessment step		Result of assessment	
	STEP 1		Metabolite of no concern?	No
Quantification of groundwater contamination	STEP 2		Max PECgw Based on	0.580 µg/L FOCUS PEARL simulation, Jokioinen scenario, use on winter cereals, 30 g a.s./ha, 20 % CI
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite ?	Non-genotoxic
		Stage 3	Toxic properties of metabolite; Classification of parent	Not classified. (opinion ECHA/RAC/CLH-O-0000002509-70-01/F of 08 March 2012)
			Classification of metabolite	None proposed. Low toxicity expected based on DEREK / LHASA prediction, and experimental information available for structurally similar component amidosulfuron-guanidine.
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	PECgw is less than 0.75 µg/L, therefore consumer exposure assessment is not required. The threshold of concern approach applies.
	STEP 5		Refined risk assessment Predicted exposure (% of ADI) ADI based on	Not required. Not required. Not required.

In overall conclusion, the intended uses of the formulation do not pose a concern with regards to groundwater exposure of metabolites of amidosulfuron.

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Specific PECgw simulation for metabolite Amidosulfuron-ADHP:
Metabolite amidosulfuron-ADHP is reported to have been observed

- in leachate samples of a lysimeter study treated with amidosulfuron, at max. 0.25 µg a.i.-equiv./L in an individual sample, annual average to be expected notably lower but not calculable (cf. Document MCA, Section CA 7.1.4.2), and
- in an anaerobic soil metabolism study dosed with amidosulfuron, at abundance of 10.9% at 90 days after flooding (cf. Document MCA, Section CA 7.1.1.2).

The component was however not detected in any of the laboratory aerobic soil degradation studies on amidosulfuron. Therefore, a formation fraction in soil cannot be easily derived, and the component cannot be implemented in the standard metabolic pathway simulation assessment.

To nevertheless provide an estimate of the potential worst case groundwater exposure to amidosulfuron-ADHP for the intended uses of the present product, the subsequent individual component modelling simulation is provided based on the overconservative assumption of 100% formation :

Report:	KCP 9.2.4.1/13 [redacted].; 2016; M-553879-02-1
Title:	Amidosulfuron (AMS) and metabolite: PECgw FOCUS PEARL, PELMO, MACRO EUR - Use in winter and spring cereals, flax and grass in Europe
Report No.:	EnSa-16-0353 v1
Document No.:	M-553879-02-1
Guideline(s):	none
Guideline deviation(s):	none
GLP/GEP:	**no**

Materials and Methods:
PEC_{gw} for the metabolite amidosulfuron ADHP was calculated using the approach, scenarios and application rates described for the calculations for the parent compound, summarised under KCP 9.2.4.1/12 above.

As there is no information on formation fraction and maximum occurrence of the metabolite amidosulfuron-ADHP from aerobic soil metabolism studies on amidosulfuron, worst case assumptions were used for the calculations (FF of 1 and maximum occurrence of 100%). It should be clearly noted that values predicted using the combination of worst-case assumption on both degradation and formation of the amidosulfuron-ADHP may represent a very conservative estimation and would be overprotective for the actual field conditions.

Table CP 9.2.4.1- 18: Substance specific and model related input parameter for PECgw calculation of amidosulfuron and its metabolite (model parameters not listed are kept as default)

Parameter	Unit	Amidosulfuron-ADHP
Common		
Molar Mass	[g/mol]	127.1
Water Solubility	[mg/L]	66.0
Vapour Pressure	[Pa]	2.70E-03
Freundlich Exponent	[-]	0.919
Plant Uptake Factor	[-]	0.0
Walker Exponent	[-]	0.7
PEARL parameters		
Substance Code	[-]	ADHP
DT_{50}	[days]	30.9
Molar Activ. Energy	[kJ/mol]	65.4
Kom	[mL/g]	150.3
Kf	[mL/g]	-
PELMO parameters		
Substance Code	[-]	A1
Rate Constant	[1/day]	0.02243
Q_{10}	[-]	2.58
K_{oc}	[mL/g]	259.1
MACRO parameters		
Substance code	[-]	desme
Exponent moisture	[-]	0.49
Exponent temperature	[1/K]	0.0948

Table CP 9.2.4.1- 19: Degradation pathway related parameters for amidosulfuron and its metabolite

Degradation fraction from → to (-) (FOCUS PEARL)	AMS -> ADHP: 1
Degradation rate from → to (1/day) (FOCUS PELMO) a)	Active Substance -> A1: 0.0481350 A1 -> BR/CO2: 0.0224320

a) Calculated as *ln(2) / DT50 × formation fraction*

For simulation of sequential metabolites in MACRO, (pseudo) application rates were calculated based on the respective conversion factor as given in Table CP 9.2.4.1.-19.The rates used in the simulations are given in Table CP 9.2.4.1-20. The metabolites were then handled in MACRO as parent substance applied at the application dates given in Table CP 9.2.4.1- 3.

Table CP 9.2.4.1- 20: Calculation of metabolite application rates (FOCUS MACRO)

Compound	Parent	Amidosulfuron-ADHP
Crop / rate	**(g a.s./ha)**	**(g/ha)**
Winter Cereals (30 g/ha)	1×24.000	1×8.26
Winter Cereals (15 g/ha)	1×15.000	1×5.16
Spring cereals and flax	1×30.000	1×10.32
Permanent grass (spring)	1×4.500	1×1.55
Permanent grass (autumn)	1×4.500	1×1.55

Findings:

PEC_{gw} were evaluated as the 80[th] percentile of the mean annual leachate concentration at 1 m soil depth. FOCUS PEARL, PELMO and MACRO PEC_{gw} results for amidosulfuron and its metabolites are given in the following tables.

Table CP 9.2.4.1- 21: Winter cereals: FOCUS PEARL, PELMO & MACRO PEC_{gw} results of the lysimeter metabolite amidosulfuron-ADHP

Use Pattern	Winter cereals, 1 × 30 g a.s./ha, 1 × 20% interception
	Amidosulfuron-ADHP
FOCUS PEARL	**PEC_{gw} [µg/L]**
Chateaudun	<0.001
Hamburg	0.011
Jokioinen	0.003
Kremsmuenster	0.010
Okehampton	0.016
Piacenza	0.009
Porto	0.004
Sevilla	<0.001
Thiva	<0.001
FOCUS PELMO	**PEC_{gw} [µg/L]**
Chateaudun	0.001
Hamburg	0.014
Jokioinen	0.003
Kremsmuenster	0.012
Okehampton	0.018
Piacenza	0.010
Porto	0.006
Sevilla	<0.001
Thiva	<0.001
FOCUS MACRO	**PEC_{gw} [µg/L]**
Chateaudun	<0.001

In **bold:** values exceeding the trigger value of 0.1 µg/L

Table CP 9.2.4.1- 22: Winter cereals: FOCUS PEARL, PELMO & MACRO PEC_{gw} results of the lysimeter metabolite amidosulfuron-ADHP

Use Pattern	Winter cereals, 1 × 15 g a.s./ha, 1 × 0% interception
	Amidosulfuron-ADHP
FOCUS PEARL	**PEC_{gw} [µg/L]**
Chateaudun	<0.001
Hamburg	0.007
Jokioinen	0.002
Kremsmuenster	0.006
Okehampton	0.009
Piacenza	0.005
Porto	0.003
Sevilla	<0.001
Thiva	<0.001
FOCUS PELMO	**PEC_{gw} [µg/L]**
Chateaudun	0.001
Hamburg	0.008
Jokioinen	0.002
Kremsmuenster	0.007
Okehampton	0.010
Piacenza	0.006
Porto	0.004
Sevilla	<0.001
Thiva	<0.001
FOCUS MACRO	**PEC_{gw} [µg/L]**
Chateaudun	<0.001

In **bold**: values exceeding the trigger value of 0.1 µg/L

Table CP 9.2.4.1- 23: Spring cereals and flax: FOCUS PEARL, PELMO & MACRO PEC_{gw} results of the lysimeter metabolite amidosulfuron-ADHP

Use Pattern	Spring cereals and flax, 1 × 30 g a.s./ha, 1 × 0% interception
	Amidosulfuron-ADHP
FOCUS PEARL	**PEC_{gw} [µg/L]**
Chateaudun	<0.001
Hamburg	0.013
Jokioinen	0.004
Kremsmuenster	0.012
Okehampton	0.009
Porto	<0.001
FOCUS PELMO	**PEC_{gw} [µg/L]**
Chateaudun	0.001
Hamburg	0.005
Jokioinen	0.003
Kremsmuenster	0.008
Okehampton	0.007
Porto	0.001
FOCUS MACRO	**PEC_{gw} [µg/L]**
Chateaudun	<0.001

Table CP 9.2.4.1- 24: Permanent grass (spring): FOCUS PEARL, PELMO & MACRO PEC_{gw} results of the lysimeter metabolite amidosulfuron-ADHP

Use Pattern	Permanent grass (spring), 1 × 45 g a.s./ha, 1 × 90% interception
	Amidosulfuron-ADHP
FOCUS PEARL	**PEC_{gw} [µg/L]**
Chateaudun	<0.001
Hamburg	0.001
Jokioinen	<0.001
Kremsmuenster	<0.001
Okehampton	0.001
Piacenza	0.001
Porto	<0.001
Sevilla	<0.001
Thiva	<0.001
FOCUS PELMO	**PEC_{gw} [µg/L]**
Chateaudun	<0.001
Hamburg	0.001
Jokioinen	<0.001
Kremsmuenster	0.001
Okehampton	0.002
Piacenza	0.004
Porto	0.002
Sevilla	<0.001
Thiva	<0.001
FOCUS MACRO	**PEC_{gw} [µg/L]**
Chateaudun	<0.001

Table CP 9.2.4.1- 25: Permanent grass (autumn): FOCUS PEARL, PELMO & MACRO PEC_{gw} results of the lysimeter metabolite amidosulfuron-ADHP

Use Pattern	**Permanent grass (autumn), 1 × 45 g a.s./ha, 1 × 90% interception**
	Amidosulfuron-ADHP
FOCUS PEARL	**PEC_{gw} [µg/L]**
Chateaudun	0.002
Hamburg	0.014
Jokioinen	0.004
Kremsmuenster	0.004
Okehampton	0.007
Piacenza	0.009
Porto	0.003
Sevilla	0.001
Thiva	0.001
FOCUS PELMO	**PEC_{gw} [µg/L]**
Chateaudun	0.001
Hamburg	0.011
Jokioinen	0.003
Kremsmuenster	0.004
Okehampton	0.007
Piacenza	0.010
Porto	0.003
Sevilla	0.001
Thiva	0.001
FOCUS MACRO	**PEC_{gw} [µg/L]**
Chateaudun	<0.001

Conclusion:

Amidosulfuron-ADHP: For all intendend uses in (winter and spring) cereals, flax, and permanent grass (spring and autumn) the results for the PEC_{gw} calculations do not reach or exceed the PEC_{gw} trigger of 0.1 µg/L in any European scenario. Thus, further assessment on the substance relevance in groundwater would not be triggered by this modelling similation. However, due to the reported maximum detect in an individual lysimeter leachate sample at 0.25 µg/L, and the unavailability of (to be expected notably lower) annual average data for a formal trigger comparison, a groundwater relevance assessment for the component has nevertheless been established in Document N4, of which a tabular overview summary is provided here below. Based on these information, amidosulfuron-ADHP was demonstrated to have no relevance for groundwater.

Summary of relevance assessment for metabolite amidosulfuron-ADHP

	Assessment step		Result of assessment	
	STEP 1		Metabolite of <u>no</u> concern?	No
Quantification of groundwater contamination	STEP 2		Max PECgw Based on	<0.1 µg/L FOCUS scenario simulations for intended uses max. 0.25 µg/L a.s.-equiv. detect in individual sample of lysimeter test
Hazard assessment	STEP 3	Stage 1	Biological activity comparable to the parent?	No
		Stage 2	Genotoxic properties of metabolite ?	Non-genotoxic
		Stage 3	Toxic properties of metabolite; Classification of parent	Not classified. (opinion ECHA/RAC/CLH-O-0000002509-70-01/F of 08 March 2012)
			Classification of metabolite	None proposed. rat oral acute toxicity: LD_{50} > 5000 mg/kg
Consumer health risk assessment	STEP 4		Estimated consumer exposure via drinking water and other sources; threshold of concern approach	PECgw is less than 0.75 µg/L, therefore consumer exposure assessment is not required. The threshold of concern approach applies.
	STEP 5		Refined risk assessment Predicted exposure (% of ADI) ADI based on	Not required. Not required. Not required.

Overall, there is no concern for groundwater from amidosulfuron-ADMP from the intended uses of the present product.

CP 9.2.4.2 Additional field tests

Additional field tests to assess the leaching behaviour of amidosulfuron and its metabolites are not considered necessary, safe use was demonstrated based on laboratory information.

CP 9.2.5 Estimation of concentrations in surface water and sediment

Predicted environmental concentrations in surface water (PEC_{SW})
Predicted environmental concentrations in sediment (PEC_{SED})

Studies submitted and evaluated for the first inclusion of amidosulfuron on Annex I:

The below baseline dossier studies are listed for formal completeness, but are of no longer relevance for approval renewal. These studies are superseded by a new modelling evaluation KCP 9.2.5/05, to update for new substance information and modelling guidance.

Report:	KCP 9.2.5/01[redacted],; 2003; M-228794-01-1
Title:	Predicted environmental concentrations of amidosulfuron and its main metabolites in surface water and sediment (PECsw, PECsed) for representative uses in Europe. Entry via spray drift Code: AE F075032, AE F101630
Report No.:	C030965
Document No.:	M-228794-01-1
Guideline(s):	not applicable
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Report:	KCP 9.2.5/02[redacted],;[redacted]; 2004; M-237687-01-1
Title:	Predicted environmental concentrations in surface water and sediment of amidosulfuron and its main metabolites according to FOCUS
Report No.:	C046140
Document No.:	M-237687-01-1
Guideline(s):	not applicable
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Report:	KCP 9.2.5/03[redacted],; 2004; M-237686-01-1
Title:	Aquatic risk assessment for amidosulfuron, based on exposure calculations according to FOCUS Code: AE F075032
Report No.:	C046139
Document No.:	M-237686-01-1
Guideline(s):	--
Guideline deviation(s):	--
GLP/GEP:	**no**

Report:	KCP 9.2.5/04[redacted];[redacted]; 2007; M-283755-01-1
Title:	Predicted environmental concentrations in surface water and sediment of amidosulfuron metabolite AE 1569309 based on calculations with FOCUS Step 1&2 Spray applications in cereals and grassland
Report No.:	MEF-07/043
Document No.:	M-283755-01-1
Guideline(s):	not applicable
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Studies submitted and evaluated in the course of the post-Annex I procedure for amidosulfuron:

(none at EU level; updated modelling was submitted as part of the product re-approval procedure at zonal level)

Studies submitted for Annex I approval renewal:

To consider compound related input parameters from new experimental studies and kinetic evaluations, and to implement latest modeling guidance, updated PEC_{sw} calculations are presented for approval renewal, superseding all previous data evaluations.

Report:	KCP 9.2.5/05 [redacted],; 2016; M-554554-01-1
Title:	Amidosulfuron (AMS) and metabolites: PECsw,sed FOCUS EUR - Use in winter cereals, spring cereals, flax and grass in Europe
Report No.:	EnSa-16-0283 v1
Document No.:	M-554554-01-1
Guideline(s):	none
Guideline deviation(s):	none
GLP/GEP:	**no**

Material and methods:

Predicted environmental concentrations of the herbicide amidosulfuron and its metabolites in surface water (PEC_{sw}) and sediment (PEC_{sed}) were calculated for the use in Europe, according the tiered FOCUS Surface Water (SW) approach (FOCUS 2001, 2015). All relevant entry routes of a compound into surface water (principally a combination of spray drift and runoff/erosion or drain flow) were considered in these calculations.

Details of the application patterns assessed are summarised in Table CP 9.2.5- 1.

Table CP 9.2.5- 1: Application pattern used for $PEC_{sw,sed}$ calculations (FOCUS Step 1&2)

Individual Crop	FOCUS Crop Used for Interception	Application				Amount reaching soil per season application
		Rate per Season [g a.s. /ha]	Interval [days]	Plant Interception [%]	BBCH Stage	[g a.s./ha]
Winter cereals, GAP & Simulation	cereals, winter (arable crops)	1 × 30	-	average crop cover (20%)	21-49	1 × 24
Winter cereals, GAP & Simulation	cereals, winter (arable crops)	1 × 15	-	min. crop cover (0%)	13-49	1 × 15
Spring cereals /Flax GAP & Simulation	cereals, spring (arable crops)	1 × 30	-	min. crop cover (0%)	12-49	1 × 30
Grass (spring), GAP & Simulation	grass / alfalfa (arable crops)	1 × 45	-	full canopy (75%)	Spring	1 × 11.25
Grass (autumn), GAP & Simulation	grass / alfalfa (arable crops)	1 × 45	-	full canopy (75%)	Autumn	1 × 11.25

At FOCUS Step 1&2 the application was timed to the default periods 'March to May' for the intended spring uses, or 'October to February' for the intended autumn use on grass

At FOCUS Step 3 actual application dates are generally determined by the PAT (pesticide application timer) included within SWASH, considering crop event dates.
For the application to **spring cereals and flax,** PAT start date was timed relative to FOCUS crop emergence date of spring cereals, considering an offset of 3 days to represent an early post-emergent situation.
The application in **winter cereals** according to GAP is intended at the onset of the spring vegetation period, when climate conditions allow for resumption of crop and weed growth after winter dormancy. Treatment is made to well established crop, with use rate depending on crop BBCH stage reached at that time. However, no pre-defined event dates are implemented in the FOCUS model that would directly translate this cropping situation into discrete calendar dates for each surface water scenario setting. To generate an adequate scenario-adapted representation with relative date setting, the

following approach was therefore used: the simulated treatment was referenced relative to the tabulated crop emergence date of the earliest emerging spring crop (i.e. not necessarily cereals) that was defined by FOCUS for the respective scenario. Start of the PAT window was then set 14 days before that date, considered suitable to represent the start of the vegetation period in the respective scenario environment. An overview of the date selections per scenario is presented in the tables below.

Similarly, for **spring use on grass** the application was timed using the earliest crops emergence dates.

Table CP 9.2.5- 2: Spring emergence dates of earliest crops in the FOCUS scenarios

Scenario	Location	Crop	Emergence date
D1	Lanna	spring cereals	05-May
D2	Brimstone	spring cereals a)	15-Mar a)
D3	Vredepeel	spring cereals	01-Apr
D4	Skousbo	field beans	15-Apr
D5	La Jailliere	spring cereals	15-Mar
D6	Thiva	root vegetables	25-Feb
R1	Weiherbach	field beans	10-Apr
R2	Porto	bulb vegetables	28-Feb
R3	Bologna	root vegetables	26-Feb
R4	Roujan	root vegetables	26-Feb

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

For **autumn use in grass**, the PAT start date was set relative to the emergence date of winter cereals (Table CP 9.2.5- 3). For technical reason (reference crop is different to simulated crop), such application dates need to be entered to the simulation model formally as 'absolute' dates, even though refencing was in fact of relative type.

Table CP 9.2.5- 3: Emergence dates of winter cereals in the FOCUS scenarios

Scenario	Location	Emergence date
D1	Lanna	25-Sep
D2	Brimstone	25-Oct
D3	Vredepeel	21-Nov
D4	Skousbo	22-Sep
D5	La Jailliere	10-Nov
D6	Thiva	30-Nov
R1	Weiherbach	12-Nov
R2	Porto	01-Dec a)
R3	Bologna	01-Dec
R4	Roujan	10-Nov

Details of the parameters used in all Step 3 calculations are summarised in Table CP 9.2.5- 6.

Table CP 9.2.5- 4: Application dates of amidosulfuron for the FOCUS Step 3 calculations – Winter cereals (late & early)

Parameter	Winter cereals (1 × 30 g a.s./ha) (late)		Winter cereals (1 × 15 g a.s./ha) (early)	
PAT start date rel./absolute Appl. method (appl. type) No of appl. PAT window range	Absolute Ground spray (CAM 2 - appln foliar linear, 4 cm) 1 30		Absolute Ground spray (CAM 2 - appln foliar linear, 4 cm) 1 30	
Application Details	PAT start/end date (Julian day)	Appl. Date	PAT start/end date (Julian day)	Appl. Date
D1 Ditch/Stream	21-Apr/21-May (111/141)	25-Apr	21-Apr/21-May (111/141)	25-Apr
D2 Ditch/Stream	01-Mar/31-Mar (60/90)	12-Mar	01-Mar/31-Mar (60/90)	12-Mar
D3 Ditch	18-Mar/17-Apr (77/107)	17-Mar	18-Mar/17-Apr (77/107)	17-Mar
D4 Pond/Stream	01-Apr/01-May (91/121)	18-Apr	01-Apr/01-May (91/121)	18-Apr
D5 Pond/Stream	01-Mar/31-Mar (60/90)	07-Mar	01-Mar/31-Mar (60/90)	07-Mar
D6 Ditch	11-Feb/13-Mar (42/72)	27-Feb	11-Feb/13-Mar (42/72)	27-Feb
R1 Pond/Stream	27-Mar/26-Apr (86/116)	26-Apr	27-Mar/26-Apr (86/116)	26-Apr
R2 Stream	-	-	-	-
R3 Stream	12-Feb/14-Mar (43/73)	19-Feb	12-Feb/14-Mar (43/73)	19-Feb
R4 Stream	12-Feb/14-Mar (43/73)	02-Mar	12-Feb/14-Mar (43/73)	02-Mar

Table CP 9.2.5- 5: Application dates of amidosulfuron for the FOCUS Step 3 calculations – spring cereals, flax and grass (spring)

Parameter	Spring cereals / Flax (1 × 30 g a.s./ha)		Grass (spring) (1 × 45 g a.s./ha)	
PAT start date rel./absolute	Relative: 3 days after emergence		Absolute	
Appl. method (appl. type)	Ground spray (CAM 2 - appln foliar linear, 4 cm)		Ground spray (CAM 2 - appln foliar linear, 4 cm)	
No of appl.	1		1	
PAT window range	30		30	
Application Details	PAT start/end date (Julian day)	Appl. Date	PAT start/end date (Julian day)	Appl. Date
D1 Ditch/Stream	08-May/07-Jun (128/158)	14-May	05-May/04-Jun (125/155)	14-May
D2 Ditch/Stream	-	-	15-Mar/14-Apr (74/104)	15-Mar
D3 Ditch	04-Apr/04-May (94/124)	04-Apr	01-Apr/01-May (91/121)	04-Apr
D4 Pond/Stream	29-Apr/29-May (119/149)	05-May	15-Apr/15-May (105/135)	18-Apr
D5 Pond/Stream	18-Mar/17-Apr (77/107)	08-Apr	15-Mar/14-Apr (74/104)	08-Apr
D6 Ditch	-	-	-	-
R1 Pond/Stream	-	-	-	-
R2 Stream	-	-	28-Feb/30-Mar (59/89)	06-Mar
R3 Stream	-	-	26-Feb/28-Mar (57/87)	26-Feb
R4 Stream	18-Mar/17-Apr (77/107)	21-Mar	-	-

Table CP 9.2.5- 6: Application dates of amidosulfuron for the FOCUS Step 3 calculations –grass (autumn)

Parameter	Grass autumn (1 × 45 g a.s./ha)	
PAT start date rel./absolute	Absolute	
Appl. method (appl. type)	Ground spray (CAM 2 - appln foliar linear, 4 cm)	
No of appl.	1	
PAT window range	30	
Application Details	PAT start/end date (Julian day)	Appl. Date
D1 Ditch/Stream	25-Sep/25-Oct (268/298)	03-Oct
D2 Ditch/Stream	25-Oct/24-Nov (298/328)	03-Nov
D3 Ditch	21-Nov/21-Dec (325/355)	22-Nov
D4 Pond/Stream	22-Sep/22-Oct (265/295)	28-Sep
D5 Pond/Stream	10-Nov/10-Dec (314/344)	27-Nov
D6 Ditch	-	-
R1 Pond/Stream	-	-
R2 Stream	01-Dec/31-Dec (335/365)	14-Dec
R3 Stream	01-Dec/31-Dec (335/365)	05-Dec
R4 Stream	-	-

Substance related parameters used for amidosulfuron and its metabolites in the calculations at FOCUS SW Steps 1, 2 and 3 levels are summarized below.

Table CP 9.2.5- 7: Substance parameters used at FOCUS Steps 1&2

Parameter	Unit	Amidosulfuron	Amidosulfuron-Desmethyl	Amidosulfuron-Desmethyl-Chloropyrimidine	Amidosulfuron-ADMP
Molar mass	[g/mol]	369.38	355.4	389.8	155.2
Water solubility	[mg/L]	3070	30200	15700	5200
Koc	[mL/g]	18.6	17.3	29.1	276
Degradation					
Soil	[days]	14.4	10.8	59.8	14.5
Total system	[days]	50.1	13.4	1000	4.1
Water	[days]	50.1	13.4	1000	4.1
Sediment	[days]	50.1	13.4	1000	4.1
Max occurrence					
Water / sediment	[%]	100	18.8	0	8.3
Soil	[%]	100	49.6	12.2	9.9

Table CP 9.2.5- 8: (contd.) Substance parameters used at FOCUS Steps 1&2

Parameter	Unit	Amidosulfuron-Guanidine	Amidosulfuron-Biuret	(Guanidinocarbonyl) sulfamic acid
Molar mass	[g/mol]	273.3	274.3	182.2
Water solubility	[mg/L]	2100	81000	100000 [a)]
Koc	[mL/g]	15.4	0.0001	0.0001
Degradation				
Soil	[days]	399	26	1000
Total system	[days]	142	1000	111
Water	[days]	142	1000	111
Sediment	[days]	142	1000	111
Max occurrence				
Water / sediment	[%]	21.1	9.9	23.8
Soil	[%]	38.6	6.3	0

[a)] unknown, worst case assumed

Table CP 9.2.5- 9: Substance parameters used for amidosulfuron at Step 3

Parameter	Unit	Parent
Substance		Amidosulfuron
SWASH code		AMS
General		
Molar mass	[g/mol]	369.4
Water solubility (temp.)	[mg/L]	3070 (20 °C)
Vapour pressure (temp.)	[Pa]	1.3E-06 (20 °C)
Crop processes		
Coefficient for uptake by plant (TSCF)	[-]	0,31
Wash-off factor	[1/m]	50
Sorption		
K_{OC}	[mL/g]	18.6
K_{OM}	[mL/g]	10.8
Freundlich exponent (1/n)	[-]	0.939
Transformation		
DT_{50} in soil	[days]	14.4
temperature	[°C]	20
moisture content (pF)	[log[cm]]	2
formation fraction in soil	[-]	-
DT_{50} in water	[days]	50.1
temperature	[°C]	20
formation fraction in water	[-]	-
DT_{50} in sediment	[days]	1000
temperature	[°C]	20
formation fraction in sediment	[-]	-
DT_{50} on canopy	[days]	10
Exponent for the effect of moisture		
PRZM and TOXSWA (Walker exp.)	[-]	0.7
MACRO (calibrated value)	[-]	0.49
Effect of temperature		
TOXSWA (molar activation energy)	[kJ/mol]	65.4
MACRO (effect of temperature)	[1/K]	0.0948
PRZM (Q10)	[-]	2.58

Findings:

Steps 1 and 2: The maximum PEC_{sw} and PEC_{sed} values for amidosulfuron and its metabolites at Steps 1 and 2 are given in the following tables.

Table CP 9.2.5- 10: Maximum PEC_{sw} and PEC_{sed} values for amidosulfuron and its metabolites at Steps 1 & 2

Use pattern	FOCUS scenario	Amidosulfuron		Amidosulfuron-desmethyl		Amidosulfuron-desmethyl-chloropyrimidine		Amidosulfuron-ADMP	
		PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
Winter cereals 1 × 30 g a.s./ha	Step 1	10.034	1.8394	6.4826	1.1129	1.2394	0.3607	0.5686	1.5428
	Step 2								
	N-EU Single	1.5446	0.2830	0.8507	0.1449	0.1893	0.0551	0.0778	0.2110
	S-EU Single	2.8325	0.5192	1.6614	0.2831	0.3786	0.1102	0.1516	0.4148
Winter cereals 1 × 15 g a.s./ha	Step 1	5.0170	0.9197	3.2413	0.5564	0.6197	0.1803	0.2843	0.7714
	Step 2								
	N-EU Single	0.9333	0.1710	0.5267	0.0900	0.1183	0.0344	0.0481	0.1310
	S-EU Single	1.7382	0.3187	1.0334	0.1776	0.2366	0.0689	0.0943	0.2583
Spring cereals and flax 1 × 30 g a.s./ha	Step 1	10.034	1.8394	6.4826	1.1129	1.2394	0.3607	0.5686	1.5428
	Step 2								
	N-EU Single	1.8666	0.3420	1.0533	0.1799	0.2366	0.0689	0.0962	0.2619
	S-EU Single	3.4764	0.6374	2.0667	0.3552	0.4733	0.1377	0.1885	0.5166
Grass (Spring) 1 × 45 g a.s./ha	Step 1	15.051	2.7592	9.7240	1.6693	1.8590	0.5410	0.8529	2.3142
	Step 2								
	N-EU Single	0.9889	0.1808	0.4400	0.0727	0.0887	0.0258	0.0405	0.1064
	S-EU Single	1.5925	0.2916	0.8200	0.1384	0.1775	0.0517	0.0751	0.2019
Grass (Autumn) 1 × 45 g a.s./ha	Step 1	15.051	2.7592	9.7240	1.6693	1.8590	0.5410	0.8529	2.3142
	Step 2								
	N-EU Single	1.8944	0.3469	1.0100	0.1713	0.2219	0.0646	0.0924	0.2496
	S-EU Single	1.5925	0.2916	0.8200	0.1384	0.1775	0.0517	0.0751	0.2019

Table CP 9.2.5- 11: (contd): Maximum PEC_{sw} and PEC_{sed} values for amidosulfuron and its metabolites at Steps 1 & 2

Use pattern	FOCUS scenario	Amidosulfuron-guanidine		Amidosulfuron-biuret		(Guanidinocarbonyl) sulfamic acid	
		PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]	PEC_{sw} [µg/L]	PEC_{sed} [µg/kg]
Winter cereals 1 × 30 g a.s./ha	Step 1	4.3713	0.6698	1.2233	<0.0001	1.2063	<0.0001
	Step 2						
	N-EU Single	0.6882	0.1054	0.1845	<0.0001	0.1865	<0.0001
	S-EU Single	1.3348	0.2045	0.3488	<0.0001	0.3415	<0.0001
Winter cereals 1 × 15 g a.s./ha	Step 1	2.1857	0.3349	0.6116	<0.0001	0.6032	<0.0001
	Step 2						
	N-EU Single	0.4249	0.0651	0.1128	<0.0001	0.1126	<0.0001
	S-EU Single	0.8290	0.1270	0.2155	<0.0001	0.2095	<0.0001
Spring cereals and flax 1 × 30 g a.s./ha	Step 1	4.3713	0.6698	1.2233	<0.0001	1.2063	<0.0001
	Step 2						
	N-EU Single	0.8499	0.1302	0.2256	<0.0001	0.2253	<0.0001
	S-EU Single	1.6581	0.2541	0.4310	<0.0001	0.4189	<0.0001
Grass (Spring) 1 × 45 g a.s./ha	Step 1	6.5570	1.0047	1.8349	<0.0001	1.8095	<0.0001
	Step 2						
	N-EU Single	0.3656	0.0560	0.1074	<0.0001	0.1200	<0.0001
	S-EU Single	0.6687	0.1024	0.1844	<0.0001	0.1926	<0.0001
Grass (Autumn) 1 × 45 g a.s./ha	Step 1	6.5570	1.0047	1.8349	<0.0001	1.8095	<0.0001
	Step 2						
	N-EU Single	0.8202	0.1256	0.2229	<0.0001	0.2290	<0.0001
	S-EU Single	0.6687	0.1024	0.1844	<0.0001	0.1926	<0.0001

Step 3: The maximum PEC_{sw} and PEC_{sed} values for relevant FOCUS Step 3 scenarios are given in the following tables.

Table CP 9.2.5- 12: Winter cereals (late): Maximum PEC_{SW}, PEC_{sed} and 7d-TWA_{SW} values for amidosulfuron at Step 3

Use pattern	Winter cereals (late), 1 × 30 g a.s./ha			
FOCUS scenario	Entry route*	PEC_{SW} [µg/L]	7d-TWA_{SW} [µg/L]	PEC_{sed} [µg/kg]
D1 (ditch)	S	0.2653	0.2433	0.2116
D1 (stream)	D	0.2499	0.1239	0.1044
D2 (ditch)	D	4.1960	2.2770	1.0130
D2 (stream)	D	2.6770	1.2660	0.5749
D3 (ditch)	S	0.1916	0.0266	0.0219
D4 (pond)	S	0.0112	0.0109	0.0134
D4 (stream)	S	0.1481	0.0054	0.0079
D5 (pond)	S	0.0080	0.0076	0.0071
D5 (stream)	S	0.1509	0.0014	0.0037
D6 (ditch)	S	0.1939	0.0186	0.0186
R1 (pond)	R	0.0079	0.0076	0.0071
R1 (stream)	R	0.2550	0.0150	0.0227
R3 (stream)	R	0.5171	0.0360	0.0457
R4 (stream)	R	0.3395	0.0392	0.0404

* Entry route spray drift (S), drainage (D), runoff (R); relevant only for parent substance

Table CP 9.2.5- 13: Winter cereals (early): Maximum PEC_{SW}, PEC_{sed} and 7d-TWA_{SW} values for amidosulfuron at Step 3

Use pattern	Winter cereals (early), 1 × 15 g a.s./ha			
FOCUS scenario	Entry route*	PEC_{SW} [µg/L]	7d-TWA_{SW} [µg/L]	PEC_{sed} [µg/kg]
D1 (ditch)	S	0.1321	0.1211	0.0970
D1 (stream)	D	0.1035	0.0522	0.0477
D2 (ditch)	D	2.0940	1.1270	0.5137
D2 (stream)	D	1.3370	0.6260	0.2919
D3 (ditch)	S	0.0957	0.0132	0.0110
D4 (pond)	S	0.0054	0.0053	0.0065
D4 (stream)	S	0.0738	0.0026	0.0039
D5 (pond)	S	0.0040	0.0038	0.0036
D5 (stream)	S	0.0753	0.0007	0.0019
D6 (ditch)	S	0.0970	0.0093	0.0095
R1 (pond)	R	0.0040	0.0038	0.0036
R1 (stream)	R	0.1270	0.0075	0.0115
R3 (stream)	R	0.2601	0.0181	0.0233
R4 (stream)	R	0.1712	0.0198	0.0207

* Entry route spray drift (S), drainage (D), runoff (R); relevant only for parent substance

Table CP 9.2.5- 14: Spring cereals & flax: Maximum PEC_{SW}, PEC_{sed} and 7d-TWA_{SW} values for amidosulfuron at Step 3

Use pattern	Spring cereals & flax, 1 × 30 g a.s./ha			
FOCUS scenario	Entry route*	PEC_{SW} [µg/L]	7d-TWA_{SW} [µg/L]	PEC_{sed} [µg/kg]
D1 (Ditch)	D	0.2973	0.2853	0.2008
D1 (Stream)	D	0.1953	0.1756	0.1083
D3 (Ditch)	S	0.1927	0.0292	0.0241
D4 (Pond)	S	0.0113	0.0109	0.0146
D4 (Stream)	S	0.1486	0.0056	0.0080
D5 (Pond)	S	0.0077	0.0074	0.0068
D5 (Stream)	S	0.1515	0.0012	0.0037
R4 (Stream)	S	0.1252	0.0032	0.0064

* **Entry route spray drift (S), drainage (D), runoff (R); relevant only for parent substance**

Table CP 9.2.5- 15: Grass (spring): Maximum PEC_{SW}, PEC_{sed} and 7d-TWA_{SW} values for amidosulfuron at Step 3

Use pattern	Grass (spring), 1 × 45 g a.s./ha			
FOCUS scenario	Entry route*	PEC_{SW} [µg/L]	7d-TWA_{SW} [µg/L]	PEC_{sed} [µg/kg]
D1 (Ditch)	S	0.3072	0.2898	0.1967
D1 (Stream)	S	0.2524	0.0435	0.0446
D2 (Ditch)	D	13.090	6.9300	3.1910
D2 (Stream)	D	8.7960	3.6280	1.5890
D3 (Ditch)	S	0.2872	0.0530	0.0363
D4 (Pond)	S	0.0105	0.0101	0.0087
D4 (Stream)	S	0.2201	0.0022	0.0058
D5 (Pond)	S	0.0112	0.0108	0.0099
D5 (Stream)	S	0.2359	0.0022	0.0062
R2 (Stream)	S	0.2461	0.0026	0.0072
R3 (Stream)	S	0.2659	0.0143	0.0188

* Entry route spray drift (S), drainage (D), runoff (R); relevant only for parent substance

Table CP 9.2.5- 16: Grass (autumn): Maximum PEC_{SW}, PEC_{sed} and 7d-TWA_{SW} values for amidosulfuron at Step 3

Use pattern	Grass (autumn), 1 × 45 g a.s./ha			
FOCUS scenario	Entry route*	PEC_{SW} [µg/L]	7d-TWA_{SW} [µg/L]	PEC_{sed} [µg/kg]
D1 (Ditch)	D	0.7153	0.6786	0.6394
D1 (Stream)	D	0.4647	0.4248	0.3012
D2 (Ditch)	D	11.670	7.6190	2.8160
D2 (Stream)	D	8.5990	4.5300	1.7960
D3 (Ditch)	S	0.2941	0.0493	0.0408
D4 (Pond)	D	0.0224	0.0224	0.0307
D4 (Stream)	S	0.2466	0.0486	0.0273
D5 (Pond)	D	0.2222	0.2204	0.2296
D5 (Stream)	S	0.2661	0.1561	0.0752
R2 (Stream)	R	0.3120	0.0290	0.0372
R3 (Stream)	S	0.2630	0.0096	0.0153

* Entry route spray drift (S), drainage (D), runoff (R); relevant only for parent substance

<u>PECsw of Formulated Product</u>

For the formulated product, meaningful PEC_{sw} 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 9.2.5- 17: Initial maximum PEC_{SW} values of the formulation, considering spray drift after one application as only route of entry relevant for the product

Compound	Scenario	Drift rate	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
		(arable crops)	$PEC_{SW, max}$ [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)[1]

CP 9.3 Fate and behaviour in air

No volatility studies on the preparation have been performed. Details of volatility for the active substance and its metabolites are given in Document MCA Section 2.

CP 9.3.1 Route and rate of degradation in air and transport via air

Please refer to Document MCA 7.3.2.

Predicted environmental concentrations from airborne transport
Due to the low half-life in air and the very low vapour pressure no exposure via air is expected.

CP 9.4 Estimation of concentrations for other routes of exposure

No data for other routes of exposure were generated or required for Amidosulfuron WG 75.

[1] [redacted]D., (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