Document Title

Summary of the fate and behaviour in the environment

Ethephon SL 480 g/L

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

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[redacted]

Bayer AG
Crop Science Division

M-544523-02-2

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Version history

Date	Data points containing amendments or additions[1] and brief description	Document identifier and version number
2016-01-08	Initial document submitted for Annex I renewal Ethephon	M-544523-01-1
2017-07-25	Adsorption parameters for revised PEC_{gw} values for ethephon and its metabolite HEPA Change of legal entity from Bayer CropScience AG to Bayer Ag Crop Science Division	M-544523-02-1

[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

CP 9.1 Fate and behaviour in soil

For information on the fate and behaviour in soil please refer to MCA Section 7, data point 7.1.

CP 9.1.1 Rate of degradation in soil

The proposed degradation pathway of ethephon in soil is shown in Figure 9.1.1-1. For further information on the fate and behaviour in soil please refer to MCA Section 7, data points 7.1.1 and 7.1.2.

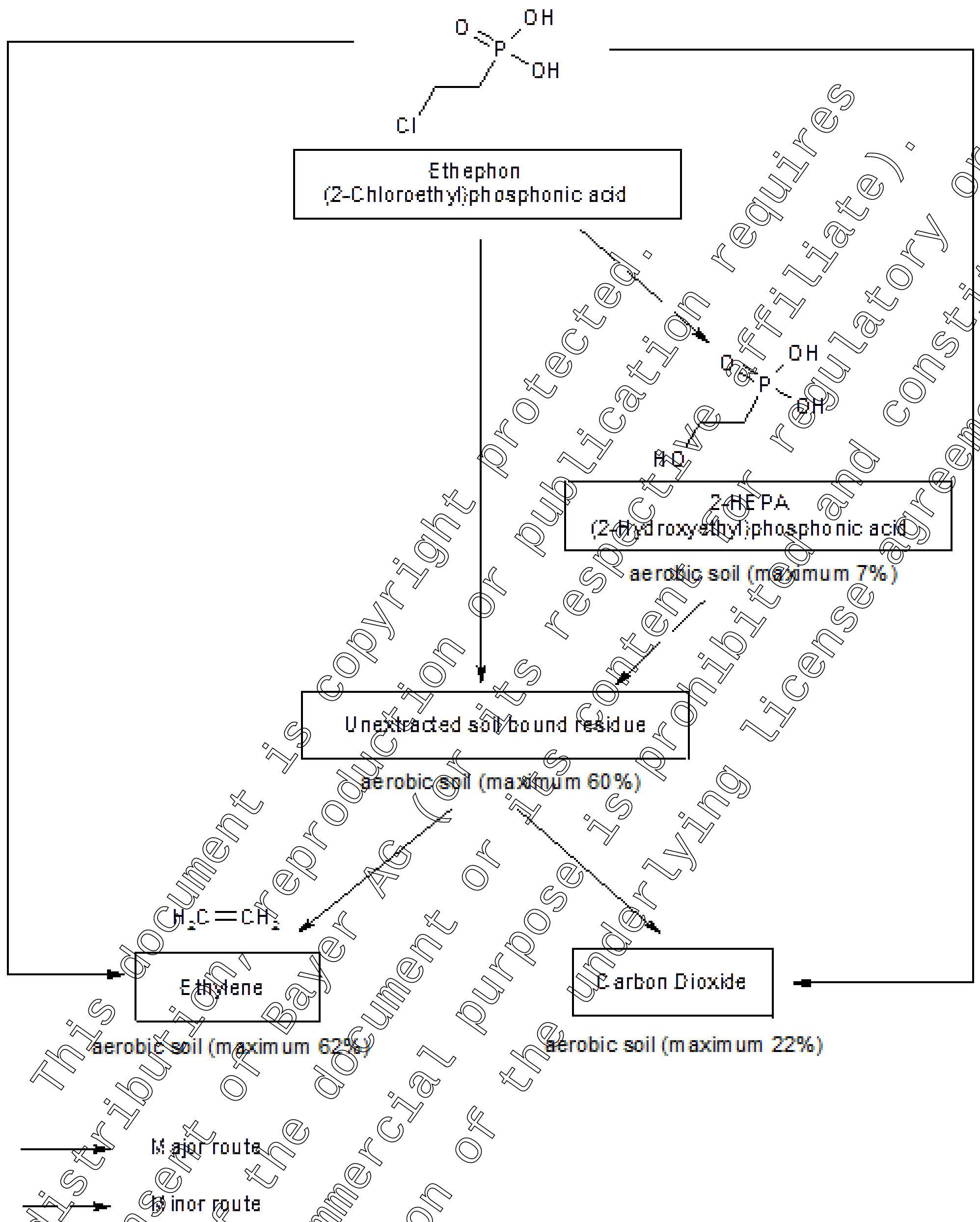
The main metabolic pathway of ethephon in soil was degradation to form ethylene (maximum 62%) and non-extractable soil residues (maximum 60%). Significant mineralization to form carbon dioxide was observed in one soil (maximum 22%). A metabolite, (2-hydroxyethyl) phosphonic acid (HEPA), was detected as a minor metabolite in aerobic soil at a maximum of 7% at a single timepoint, but otherwise did not exceed 5%.

A similar pathway was observed under anaerobic conditions, where ethephon was rapidly degraded to form mainly ethylene (maximum 94%), with HEPA observed as a minor metabolite (maximum 4%).

In a soil photolysis study, ethephon was readily degraded with a similar decline seen under irradiated conditions and in dark controls indicating that photolytic degradation had only a minor effect on the degradation rate. HEPA was detected as a major metabolite in irradiated samples (maximum 10.6% after 10 days) and as a minor metabolite > 5% at two consecutive timepoints in dark control samples (maximum 6% after 30 days). Ethylene and carbon dioxide were formed at maxima of 12% and 6%, respectively. No other metabolites exceeded 2%.

No other significant metabolites are detected in aerobic, anaerobic or soil photolysis laboratory studies.

Figure 9.1.1- 1: Proposed degradation pathway of ethephon in soil



CP 9.1.1.1 Laboratory studies

For information on laboratory studies please refer to MCA Section 7, data point 7.1.2.1.

CP 9.1.1.2 Field studies

For information on field studies please refer to MCA Section 7, data point 7.1.2.2.

CP 9.1.1.2.1 Soil dissipation studies

For information on field dissipation studies please refer to MCA Section 7, data point 7.1.2.2.1.

CP 9.1.1.2.2 Soil accumulation studies

For information on field accumulation studies please refer to MCA Section 7, data point 7.1.2.2.2.

CP 9.1.2 Mobility in the soil

For information on mobility studies please refer to MCA Section 7, data point 7.1.4.

CP 9.1.2.1 Laboratory studies

For information on laboratory studies please refer to MCA Section 7, data point 7.1.4.1

CP 9.1.2.2 Lysimeter studies

For information on lysimeter studies please refer to MCA Section 7, data point 7.1.4.2.

CP 9.1.2.3 Field leaching studies

For information on field leaching studies please refer to MCA Section 7, data point 7.1.4.3.

CP 9.1.3 Estimation of concentrations in soil

For the PEC calculations, the following representative uses were considered.

Representative crops	Application		
	Rate per Season [g a.s. /ha]	Interval [days]	Timing of application BBCH Stage
Winter Cereals (early)	1 x 480	-	37-39
Winter Cereals (late)	1 x 480	-	41-51
Spring Cereals (early)	1 x 360	-	37-39
Spring Cereals (late)	1 x 360	-	41-51

PEC$_{soil}$ modelling approach

The predicted environmental concentrations in soil (PEC$_{soil}$) for the active substance ethephon were calculated based on a simple first tier approach (Microsoft® Excel spreadsheet) assuming even distribution of the compound in the upper 0-5 cm soil layer. A standard soil density of 1.5 g/cm^3 was assumed. Derivation of kinetic modelling input values for ethephon and its metabolite are presented in MCA Section 7, point 7.1.2 (Documents KCA 7.1.2.1.1/03, M-534660-01-1 and KCA 7.1.2.1.2/02, M-534855-01-1). A summary of the modelling input parameters is given in the PEC$_{soil}$ report (KCP 9.1.3/01, M-539494-01-1).

Predicted environmental concentrations in soil (PEC$_{Soil}$) of ethephon and its metabolites

For PEC$_{soil}$ calculations ethephon and its metabolite HEPA were considered.

Report:	KCP 9.1.3/02; [redacted]; [redacted]; 2015; M-539494-01-1
Title:	Ethephon (ETP) and metabolite: PECsoil EUR - Use in winter cereals and spring cereals in Europe
Report No.:	EnSa-15-0806
Document No.:	M-539494-01-1
Guideline(s):	EU Commission, 1995, Directive 95/36/EC of 14 July 1995, amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market; EU Commission, 2000, Guidance Document on Persistence in Soil (Working Document), 9188/VI/97 rev.8; FOCUS, 1997, Soil persistence models and EU registration; FOCUS Groundwater, 2014, Generic Guidance for Tier 1 FOCUS Groundwater Assessments, Version 2.2; FOCUS Kinetics, 2014, Generic guidance for Estimating Trigger and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, Version 1.1, December, 2014
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Methods and Materials: The predicted environmental concentrations in soil (PEC_{soil}) of ethephon and its metabolite HEPA were calculated based on a first tier approach using a Microsoft® Excel spreadsheet. The use of ethephon on winter and spring cereals was assessed according to Good Agricultural Practice (GAP) under European cropping conditions. Detailed application data used for simulation of PEC_{soil} are compiled in Table 9.1.3-1.

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

Individual Crop	FOCUS Crop Used for Interception	Application				Amount Reaching the Soil per Season
		Rate per Season	Interval	Plant Interception	BBCH Stage	
		[g a.s. /ha]	[days]	[%]		[g a.s. /ha]
Winter Cereals (early)	Winter Cereals	1 x 480	-	80	37-39	1 x 96
Winter Cereals (late)	Winter Cereals	1 x 480	-	90	41-51	1 x 48
Spring Cereals (early)	Spring Cereals	1 x 360	-	80	37-39	1 x 72
Spring Cereals (late)	Spring Cereals	1 x 360	-	90	41-51	1 x 36

Substance Specific Parameters: PEC_{soil} calculations were based on a DT_{50} value of 72.1 days (non-normalised, worst case laboratory DT_{50} value) for the parent compound ethephon. For the metabolite HEPA, the calculations were based on the maximum formation of 10.6% (observed under photolysis conditions) and a DT_{50} value of 1.9 days (non-normalised, worst case laboratory DT_{50} value). Substance parameters used as input in the calculations are summarised in Table 9.1.3- 2.

Table 9.1.3- 2: Compound input parameters as used for the calculation

Parameter	Unit	Value	Comment
Ethephon			
Molar mass	[g/mol]	144.49	-
DT_{50}	[days]	72.1	Laboratory SFO DT_{50} (20 °C) value (worst case value, n=5, un-normalised) Document KCA 7.1.2.1.1/03, [redacted] (2015), M-534660-01-1
Maximum occurence in soil	[% AR]	100	Parent substance
Molar mass correction factor	[-]	1	-
HEPA			
Molar mass	[g/mol]	126.05	-
DT_{50}	[days]	1.9	Laboratory SFO DT_{50} (20 °C) value (worst case value, n=4, un-normalised) Document KCA 7.1.2.1.2/02, [redacted] (2015), M-534855-01-1
Maximum occurence in soil	[% AR]	10.6	Maximum % of applied in soil photolysis study. Document KCA 7.1.1.3/01, [redacted] (2001), M-199517-01-1.
Molar mass correction factor	[-]	0.8724	-

Findings: The maximum PEC_{soil} values for ethephon and its metabolite HEPA are summarised in Table 9.1.3- 3.

Table 9.1.3- 3: Maximum PEC_{soil} of ethephon and its metabolite for the uses assessed

Use pattern	Ethephon	HEPA
	PEC_{soil} [mg/kg]	
Winter Cereals (early), 1 x 480 g a.s./ha	0.128	0.012
Winter Cereals (late), 1 x 480 g a.s./ha	0.064	0.006
Spring Cereals (early), 1 x 360 g a.s./ha	0.096	0.009
Spring Cereals (late), 1 x 360 g a.s./ha	0.048	0.004

The maximum, short-term and long-term PEC_{soil} values and the time weighted average values ($TWAC_{soil}$) of ethephon and its metabolite HEPA are presented in Table 9.1.3- 4 to Table 9.1.3- 7.

Winter Cereals (early), 1×480 g a.s./ha, 80% interception

Table 9.1.3- 4: PEC_{soil} and $TWAC_{soil}$ of ethephon and its metabolite HEPA

Days after maximum		Ethephon		HEPA	
		PECsoil [mg/kg]	TWACsoil [mg/kg]	PECsoil [mg/kg]	TWACsoil [mg/kg]
Initial	0	0.128	-	0.012	-
Short term	1	0.127	0.127	0.008	0.010
	2	0.126	0.127	0.006	0.008
	4	0.123	0.126	0.003	0.006
Long term	7	0.120	0.124	<0.001	0.004
	14	0.112	0.120	<0.001	0.002
	21	0.105	0.116	<0.001	0.002
	28	0.098	0.112	<0.001	0.001
	42	0.085	0.105	<0.001	< 0.001
	50	0.079	0.102	<0.001	< 0.001
	100	0.049	0.082	<0.001	< 0.001

Winter Cereals (late), 1×480 g a.s./ha, 90% interception

Table 9.1.3- 5: PEC_{soil} and $TWAC_{soil}$ of ethephon and its metabolite HEPA

Days after maximum		Ethephon		HEPA	
		PECsoil [mg/kg]	TWACsoil [mg/kg]	PECsoil [mg/kg]	TWACsoil [mg/kg]
Initial	0	0.064	-	0.006	-
Short term	1	0.063	0.064	0.004	0.005
	2	0.063	0.063	0.003	0.004
	4	0.062	0.063	0.001	0.003
Long term	7	0.060	0.062	<0.001	0.002
	14	0.056	0.060	<0.001	0.001
	21	0.052	0.058	<0.001	< 0.001
	28	0.049	0.056	<0.001	< 0.001
	42	0.043	0.053	<0.001	< 0.001
	50	0.040	0.051	<0.001	< 0.001
	100	0.024	0.041	<0.001	< 0.001

Spring Cereals (early), 1×360 g a.s./ha, 80% interception

Table 9.1.3- 6: PEC_{soil} and $TWAC_{soil}$ of ethephon and its metabolite HEPA

Days after maximum		Ethephon		HEPA	
		PECsoil [mg/kg]	TWACsoil [mg/kg]	PECsoil [mg/kg]	TWACsoil [mg/kg]
Initial	0	0.096	-	0.009	-
Short term	1	0.095	0.096	0.006	0.007
	2	0.094	0.095	0.004	0.006
	4	0.092	0.094	0.002	0.005
Long term	7	0.090	0.093	<0.001	0.003
	14	0.084	0.090	<0.001	0.002
	21	0.078	0.087	<0.001	0.001
	28	0.073	0.084	<0.001	< 0.001
	42	0.064	0.079	<0.001	< 0.001
	50	0.059	0.076	<0.001	< 0.001
	100	0.037	0.062	<0.001	< 0.001

Spring Cereals (late), 1×360 g a.s./ha, 90% interception

Table 9.1.3- 7: PEC_{soil} and $TWAC_{soil}$ of ethephon and its metabolite HEPA

Days after maximum		Ethephon		HEPA	
		PECsoil [mg/kg]	TWACsoil [mg/kg]	PECsoil [mg/kg]	TWACsoil [mg/kg]
Initial	0	0.048	-	0.004	-
Short term	1	0.048	0.048	0.003	0.004
	2	0.047	0.048	0.002	0.003
	4	0.046	0.047	0.001	0.002
Long term	7	0.045	0.046	<0.001	0.002
	14	0.042	0.045	<0.001	< 0.001
	21	0.039	0.043	<0.001	< 0.001
	28	0.037	0.042	<0.001	< 0.001
	42	0.032	0.039	<0.001	< 0.001
	50	0.030	0.038	<0.001	< 0.001
	100	0.018	0.031	<0.001	< 0.001

Conclusions

The results of the calculations for the maximum predicted concentrations of ethephon and HEPA in soil were:

Ethephon $PEC_{Soil, max}$ = 0.128 mg/kg

HEPA $PEC_{Soil, max}$ = 0.012 mg/kg.

CP 9.2 Fate and behaviour in water and sediment

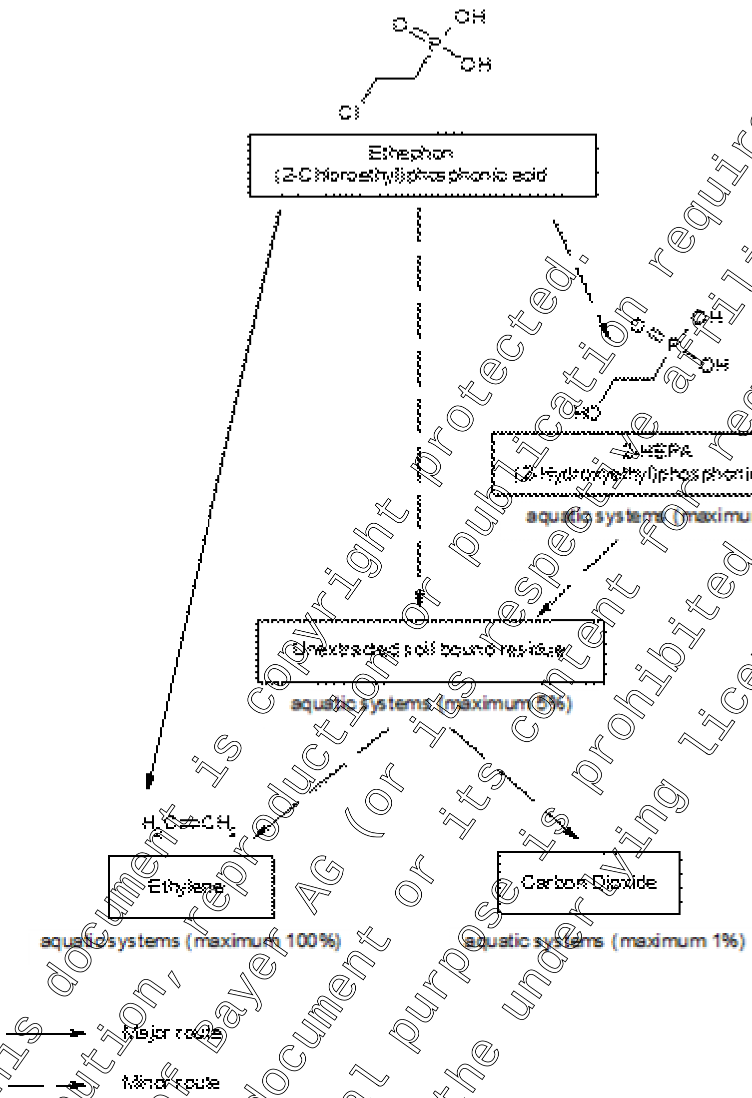
The proposed degradation pathway of ethephon in aquatic systems is shown in Figure 9.2- 1. For further information on the fate and behaviour in aquatic systems please refer to MCA Section 7, data points 7.2.1 and 7.2.2.

In sterile buffer solution at 25°C, ethephon was found to be stable to hydrolysis under acidic conditions but to hydrolyse rapidly to ethylene in neutral and alkaline conditions, with DT_{50} values of 73.5 days at pH 5, 2.4 days at pH 7 and 1.0 day at pH 9. The photolytic degradation of ethephon in water has been investigated under sterile conditions in acetate buffer solution at pH 5 and in natural water at pH 7.5 at 25 ºC. The rate of degradation of ethephon was largely dependent on the pH of the test systems with similar half-lives observed in non-irradiated and irradiated experiments and it can be concluded that photolysis does not play a significant role in the breakdown of ethephon in aquatic systems. Ethylene was the only major degradation product. In natural water the metabolite HEPA was detected in both irradiated samples and dark controls, at a maximum of 7.4% AR. In irradiated samples it exceeded 5% at the two final timepoints.

Ethephon was found to be not readily biodegradable according to OECD Test Guideline 301D. In an aerobic mineralisation study (OECD 309) the fate of ethephon was investigated in natural water at pH 7.8. The degradation rate was independent of concentration and very similar in the biotic and sterile systems. Ethephon was very rapidly degraded to ethylene, with no other significant metabolites formed. Mineralization was a minor route of degradation.

In two water / sediment systems (pH of water phase 8.9 and 6.8) ethephon was rapidly degraded to ethylene which accounted for over 95% of the applied material at the end of the study with no other significant products formed in water sediment systems. Very little ethephon transferred from the water to the underlying sediment, with a maximum of 6% of applied ethephon detected in sediment. HEPA was detected in the water phase of one of the systems at a maximum of 1.4% AR.

Figure 9.2- 1: Proposed degradation pathway of ethephon in aquatic systems



CP 9.2.1 Aerobic mineralisation in surface water

For information on aerobic mineralisation in surface water studies please refer to MCA Section 7, point 7.2.2.2.

CP 9.2.2 Water/sediment study

For information on water/sediment studies please refer to MCA Section 7, point 7.2.2.3.

CP 9.2.3 Irradiated water/sediment study

For information on irradiated water/sediment studies please refer to MCA Section 7, point 7.2.2.4.

CP 9.2.4 Estimation of concentrations in groundwater

For the PEC calculations, the following representative uses were considered.

Representative crops	Application		
	Rate per Season	Interval	Timing of application
	[g a.s. /ha]	[days]	BBCH Stage
Winter Cereals (early)	1 x 480	-	37-39
Winter Cereals (late)	1 x 480	-	41-51
Spring Cereals (early)	1 x 360	-	37-39
Spring Cereals (late)	1 x 360	-	41-51

PEC_{gw} modelling approach

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

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

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

Derivation of kinetic modelling input values for ethephon and its metabolite are presented in MCA Section 7, point 7.1.2 (Documents KCA 7.1.2.1.1/03, M-534660-01-1 and KCA 7.1.2.1.2/02, M-534855-01-1). A summary of modelling input parameters is given in the PEC_{gw} report (KCP 9.2.4.1).

CP 9.2.4.1 Calculation of concentrations in groundwater

Predicted environmental concentrations in groundwater (PEC_{GW})

For PEC_{gw} calculations ethephon and its metabolite HEPA were considered.

Ethephon is a diprotic phosphonic acid (pK_{a1} = 2.8, pK_{a2} = 7.2) and therefore can be present in either neutral or anionic forms with either single (monoanion) or double negative charge (dianion), depending on the pH value of the medium. In the soil environment ethephon will be present as either negatively charged monoanions or dianions. The adsorption of ethephon is predominantly based on non-specific interactions with the soil and binding to the soil organic matter is a subordinated process only. This is confirmed by the narrow range of K_f values (9.3 to 11.0 mL/g) measured across four soils, without correlation to organic carbon content. Thus adsorption coefficients K_f for ethephon were not normalised to the organic carbon content of the soil to calculate K_{foc} values.

No statistically significant correlation between the degradation half-life of ethephon and the pH value of the soils was detected using the German Input Decision tool ([redacted], 2012). However, higher degradation rates were found for the soils with high pH and the lowest degradation rate was found for the soil with the lowest pH.

As a precautionary approach two groundwater assessments for acidic and alkaline soils have been conducted for ethephon in agreement with FOCUS (2014) recommendations. For acidic soils the worst case DT_{50} of 47.9 days was used for ethephon (see KCP 9.2.4.1/01) and for alkaline soils a geometric mean DT_{50} of 3.8 days from two alkaline soils (see KCP 9.2.4.1/02). The geometric mean K_f of 10.0 mL/g was used for ethephon in each soil layer in both assessments, in combination with the arithmetic mean Freundlich exponent 1/n of 0.862. In both groundwater assessments geometric mean DT_{50} and K_{oc} values in combination with the arithmetic mean Freundlich exponent 1/n of 0.943 were used for the metabolite HEPA.

New PEC_{gw} values for ethephon and its metabolite HEPA were calculated in response to the RMS comments on the adsorption behaviour of ethephon in soil. Bayer AG provided a discussion on the validity of the adsorption data determined at pH above 6 as well as a discussion on the pH dependency of the adsorption process (please refer to MCA Section 7, data point 7.2.2.3). The new PEC_{gw} calculations are summarised below (p.23).

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Report:	KCP 9.2.4.1/02; [redacted]; [redacted]; 2015; M-539255-01-1
Title:	Ethephon (ETP) and metabolite: PECgw FOCUS PEARL, PELMO, MACRO EUR - Use in winter cereals and spring cereals in acidic soils in Europe
Report No.:	EnSa-15-0879
Document No.:	M-539255-01-1
Guideline(s):	FOCUS GW 2000; SANCO/321/2000 rev. 2; FOCUS GW 2009. SANCO/13144/2010 version 1; FOCUS GW, 2014a, Generic Guidance for Tier 1 FOCUS Groundwater Assessments, Version 2.2; FOCUS GW 2014b. SANCO/13144/2010 version 3; FOCUS Kinetics, 2014.Generic guidance for Estimating Trigger and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, Version 1.1
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Methods and Materials: Predicted environmental concentrations of the active substance ethephon and its metabolite HEPA in groundwater recharge (PEC_{gw}) were calculated for use in Europe, using the simulation models FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4. PEC_{gw} were evaluated as the 80^{th} 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.

Ethephon is intended for use as a plant growth regulator at specific growth stages to shorten and strengthen cereal stems, and thus increase resistance to lodging. Use on winter and spring cereals, both early and late in the season was investigated. Detailed application data used for simulation of PEC_{gw} are compiled in Table 9.2.4-1.

Table 9.2.4- 1: Application pattern used for PEC_{gw} calculations of ethephon

Individual Crop	FOCUS Crop Used for Interception	Application				Amount Reaching the Soil per Season
		Rate per Season	Interval	Plant Interception	BBCH Stage	
		[g a.s. /ha]	[days]	[%]		[g a.s. /ha]
Winter Cereals (early)	Winter Cereals	1 x 480	-	80	37-39	1 x 96
Winter Cereals (late)	Winter Cereals	1 x 480	-	90	41-51	1 x 48
Spring Cereals (early)	Spring Cereals	1 x 360	-	80	37-39	1 x 72
Spring Cereals (late)	Spring Cereals	1 x 360	-	90	41-51	1 x 36

Input parameters for ethephon and its metabolite HEPA were used as summarised in Table 9.2.4- 2.

Table 9.2.4- 2: Input parameters of ethephon and its metabolite for PEC_{gw} calculations

Parameter	Unit	Value	Comment
Ethephon			
Molar mass	[g/mol]	144.5	-
Water solubility	[mg/L]	800000	20 °C, pH 4 Document KCA 2.5/01, [redacted] (2002), M-206704-01-1
Vapour Pressure	[Pa]	8.00E-05	25 °C Document KCA 2.2/03, [redacted] (2015), M-514117-01-1
Freundlich Exponent	[-]	0.862	Arithmetic mean (n=4) Document KCA 7.1.3.1.1/02, [redacted] (2015), M-539124-01-1
Plant uptake factor	[-]	0	Conservative default value.
Walker Exponent	[-]	0.7	Default value
PEARL Parameters			
Substance code	[-]	ETP	-
DT_{50}	[days]	47.9	Laboratory SFO DT_{50} (20 ºC) value normalised to pF 2 (worst case value, n=5, acidic soil) Document KCA 7.1.2.1.1/03, [redacted] (2015), M-534660-01-1
Molar Activation Energy	[kJ/mol]	65.4	Default value
K_f	[mL/g]	10.0	Geometric mean (n=4) Document KCA 7.1.3.1.1/02, [redacted] (2015), M-539124-01-1
PELMO Parameters			
Substance code	[-]	AS	-
Rate constant	[1/day]	0.01447	Laboratory rate constant (20 ºC) normalised to pF 2 (worst case value, n=5, acidic soil). Equivalent to a SFO DT_{50} value of 47.9 d. Document KCA 7.1.2.1.1/03, [redacted] (2015), M-534660-01-1.
Q_{10}	[-]	2.58	Default value

Parameter	Unit	Value	Comment
HEPA			
Molar mass	[g/mol]	126.1	-
Water solubility	[mg/L]	800000	Ethephon water solubility at 20 °C & pH 4 used as default. Document KCA 2.5/01, [redacted] (2002), M-206704-01-1
Vapour Pressure	[Pa]	8.00E-05	Ethephon vapour pressure at 25 °C used as default. Document KCA 2.2/03, [redacted] (2015), M-514117-01-1
Freundlich Exponent	[-]	0.943	Arithmetic mean (n=5). Document KCA 7.1.3.1.2/01, [redacted] (1996), M-166197-01-1.
Plant uptake factor	[-]	0	Conservative default value.
Walker Exponent	[-]	0.7	Default value
PEARL Parameters			
Substance code	[-]	HEPA	-
DT_{50}	[days]	1.5	Laboratory SFO DT_{50} (20 ºC) value normalised to pF 2 (geometric mean, n=4). Document KCA 7.1.2.1.2/02, [redacted] (2015), M-534855-01-1
Molar Activation Energy	[kJ/mol]	65.4	Default value
K_{om}	[mL/g]	1868	Calculated from geometric mean K_{oc} value assuming conversion factor of 1.724.
PELMO Parameters			
Substance code	[-]	A1	-
Rate constant	[1/day]	0.46210	Laboratory rate constant (20 ºC) normalised to pF 2 (geometric mean, n=4). Equivalent to a SFO DT_{50} value of 1.5 d. Document KCA 7.1.2.1.2/02, [redacted] (2015), M-534855-01-1.
Q_{10}	[-]	2.58	Default value
K_{oc}	[mL/g]	3220	Geometric mean (n=5). Document KCA 7.1.3.1.2/01, [redacted] (1996), M-166197-01-1.
Formation fraction	[-]	1.0	Worst-case default value
Degradation fraction from → to (FOCUS PEARL & MACRO)		1 ETP -> HEPA	
Degradation rate from → to (FOCUS PELMO)		0.014471 Active Substance -> A1 0.4620980 A1 -> BR/CO2	

The use of ethephon in winter cereals (early), winter cereals (late), spring cereals (early) and spring cereals (late) in Europe was assessed. The application dates are summarised in Table 9.2.4- 3.

Table 9.2.4- 3: Application dates used for the simulation runs with ethephon

Individual crop	Winter Cereals (early)	Winter Cereals (late)	Spring Cereals (early)	Spring Cereals (late)
Repeat Interval for App. Events Application Technique	Every Year Spray	Every Year Spray	Every Year Spray	Every Year Spray
Scenario	1st App. Date (Julian day)	1st App. Date (Julian day)	1st App. Date (Julian day)	1st App. Date (Julian day)
Chateaudun	02-May (122)	08-May (128)	21-Apr (111)	28-Apr (118)
Hamburg	30-Apr (120)	06-May (126)	06-May (126)	11-May (131)
Jokioinen	01-Jun (152)	06-Jun (157)	11-Jun (162)	14-Jun (165)
Kremsmuenster	30-Apr (120)	06-May (126)	06-May (126)	11-May (131)
Okehampton	22-Apr (112)	24-Apr (114)	29-Apr (119)	03-May (123)
Piacenza	17-Apr (107)	21-Apr (111)	- -	- -
Porto	06-Apr (96)	11-Apr (101)	29-Apr (119)	07-May (127)
Sevilla	18-Jan (18)	25-Jan (25)	- -	- -
Thiva	08-Mar (67)	12-Mar (71)	- -	- -

Findings: PEC_{gw} were evaluated as the 80th percentile of the mean annual leachate concentration at 1 m soil depth.

PEC_{gw} values obtained with FOCUS PEARL, PELMO and MACRO for ethephon and its metabolite HEPA are given in Table 9.2.4- 4 to Table 9.2.4- 5 for the use winter cereals and in Table 9.2.4- 6 to Table 9.2.4- 7 for the use in spring cereals.

Table 9.2.4- 4: FOCUS PEARL and PELMO PEC_{gw} results of ethephon and its metabolite (<u>Winter Cereals (early)</u>, 1 × 480 g a.s./ha, 80% interception)

Scenario	Ethephon			HEPA		
	PEARL [µg/L]	PELMO [µg/L]	MACRO [µg/L]	PEARL [µg/L]	PELMO [µg/L]	MACRO [µg/L]
Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	-	<0.001	<0.001	-
Jokioinen	<0.001	<0.001	-	<0.001	<0.001	-
Kremsmuenster	<0.001	<0.001	-	<0.001	<0.001	-
Okehampton	<0.001	<0.001	-	<0.001	<0.001	-
Piacenza	<0.001	<0.001	-	<0.001	<0.001	-
Porto	<0.001	<0.001	-	<0.001	<0.001	-
Sevilla	<0.001	<0.001	-	<0.001	<0.001	-
Thiva	<0.001	<0.001	-	<0.001	<0.001	-

Table 9.2.4- 5: FOCUS PEARL and PELMO PEC_{gw} results of ethephon and its metabolite (Winter Cereals (late), 1 × 480 g a.s./ha, 90% interception)

Scenario	Ethephon			HEPA		
	PEARL [µg/L]	PELMO [µg/L]	MACRO [µg/L]	PEARL [µg/L]	PELMO [µg/L]	MACRO [µg/L]
Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	-	<0.001	<0.001	-
Jokioinen	<0.001	<0.001	-	<0.001	<0.001	-
Kremsmuenster	<0.001	<0.001	-	<0.001	<0.001	-
Okehampton	<0.001	<0.001	-	<0.001	<0.001	-
Piacenza	<0.001	<0.001	-	<0.001	<0.001	-
Porto	<0.001	<0.001	-	<0.001	<0.001	-
Sevilla	<0.001	<0.001	-	<0.001	<0.001	-
Thiva	<0.001	<0.001	-	<0.001	<0.001	-

Table 9.2.4- 6: FOCUS PEARL and PELMO PEC_{gw} results of ethephon and its metabolite (Spring Cereals (early), 1 × 360 g a.s./ha, 80% interception)

Scenario	Ethephon			HEPA		
	PEARL [µg/L]	PELMO [µg/L]	MACRO [µg/L]	PEARL [µg/L]	PELMO [µg/L]	MACRO [µg/L]
Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	-	<0.001	<0.001	-
Jokioinen	<0.001	<0.001	-	<0.001	<0.001	-
Kremsmuenster	<0.001	<0.001	-	<0.001	<0.001	-
Okehampton	<0.001	<0.001	-	<0.001	<0.001	-
Porto	<0.001	<0.001	-	<0.001	<0.001	-

Table 9.2.4- 7: FOCUS PEARL and PELMO PEC_{gw} results of ethephon and its metabolite (Spring Cereals (late), 1 × 360 g a.s./ha, 90% interception)

Scenario	Ethephon			HEPA		
	PEARL [µg/L]	PELMO [µg/L]	MACRO [µg/L]	PEARL [µg/L]	PELMO [µg/L]	MACRO [µg/L]
Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	-	<0.001	<0.001	-
Jokioinen	<0.001	<0.001	-	<0.001	<0.001	-
Kremsmuenster	<0.001	<0.001	-	<0.001	<0.001	-
Okehampton	<0.001	<0.001	-	<0.001	<0.001	-
Porto	<0.001	<0.001	-	<0.001	<0.001	-

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Report:	KCP 9.2.4.1/03; [redacted]; [redacted]; 2015; M-539257-01-1
Title:	Ethephon (ETP) and metabolite: PECgw FOCUS PEARL, PELMO, MACRO EUR - Use in winter cereals and spring cereals in alkaline soils in Europe
Report No.:	EnSa-15-0880
Document No.:	M-539257-01-1
Guideline(s):	FOCUS GW 2000. SANCO/321/2000 rev. 2; FOCUS GW 2009. SANCO/13144/2010 version 1; FOCUS GW, 2014a. Generic Guidance for Tier 1 FOCUS Groundwater Assessments, Version 2.2; FOCUS GW 2014b. SANCO/13144/2010 version 3; FOCUS Kinetics, 2014 Generic guidance for Estimating Trigger and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, Version 1.1
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Methods and Materials: Predicted environmental concentrations of the active substance ethephon and its metabolite HEPA in groundwater recharge (PEC_{gw}) were calculated for use in Europe, using the simulation models FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4. 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.

Ethephon is intended for use as a plant growth regulator at specific growth stages to shorten and strengthen cereal stems, and thus increase resistance to lodging. Use on winter and spring cereals, both early and late in the season was investigated. The application patterns and dates used for PEC_{gw} calculations in alkaline soils were identical to those used for acidic soils (see KCP 9.2.4.1/01). Application data used for PEC_{gw} simulations are compiled in Table 9.2.4- 1 and application dates used in the model runs are summarised in Table 9.2.4- 3.

Input parameters for ethephon and its metabolite HEPA were used as summarised in Table 9.2.4- 8.

Table 9.2.4- 8: Input parameters of ethephon and its metabolite for PEC_{gw} calculations

Parameter	Unit	Value	Comment
Ethephon			
Molar mass	[g/mol]	144.5	-
Water solubility	[mg/L]	800000	20 °C, pH 4 Document KCA 2.5/01, [redacted] (2002), M-206704-01-1
Vapour Pressure	[Pa]	8.00E-05	25 °C Document KCA 2.2/03, [redacted] (2015), M-514117-01-1
Freundlich Exponent	[-]	0.862	Arithmetic mean (n=4) Document KCA 7.1.3.1.1/02, [redacted] (2015), M-539124-01-1
Plant uptake factor	[-]	0	Conservative default value.
Walker Exponent	[-]	0.7	Default value
PEARL Parameters			
Substance code	[-]	ETP	-
DT_{50}	[days]	3.8	Laboratory SFO DT_{50} (20 ºC) value normalised to pF 2 (geometric mean, n=2, alkaline soils). Document KCA 7.1.2.1.1/03, [redacted] (2015), M-534660-01-1

Parameter	Unit	Value	Comment
Molar Activation Energy	[kJ/mol]	65.4	Default value
K_f	[mL/g]	10.0	Geometric mean (n=4) Document KCA 7.1.3.1.1/02, [redacted](2015), M-539124-01-1
PELMO Parameters			
Substance code	[-]	AS	-
Rate constant	[1/day]	0.18241	Laboratory rate constant (20 ºC) normalised to pF 2 (geometric mean, n=2, alkaline soils). Equivalent to a SFO DT_{50} value of 3.8 d. Document KCA 7.1.2.1.1/03, [redacted] (2015), M-534660-01-1.
Q_{10}	[-]	2.58	Default value
HEPA			
Molar mass	[g/mol]	126.1	-
Water solubility	[mg/L]	800000	Ethephon water solubility at 20 °C & pH 4 used as default. Document KCA 2.5/01, [redacted](2002), M-206704-01-1
Vapour Pressure	[Pa]	8.00E-05	Ethephon vapour pressure at 25 °C used as default. Document KCA 2.2/03, [redacted](2015), M-514117-01-1
Freundlich Exponent	[-]	0.943	Arithmetic mean (n=5). Document KCA 7.1.3.1.2/01, [redacted] (1996), M-166197-01-1.
Plant uptake factor	[-]	0	Conservative default value.
Walker Exponent	[-]	0.7	Default value
PEARL Parameters			
Substance code	[-]	HEPA	-
DT_{50}	[days]	1.5	Laboratory SFO DT_{50} (20 ºC) value normalised to pF 2 (geometric mean, n=4) Document KCA 7.1.2.1.2/02, [redacted](2015), M-534855-01-1
Molar Activation Energy	[kJ/mol]	65.4	Default value
K_{om}	[mL/g]	1868	Calculated from geometric mean K_{oc} value assuming conversion factor of 1.724.
PELMO Parameters			
Substance code	[-]	A1	-
Rate constant	[1/day]	0.46210	Laboratory rate constant (20 ºC) normalised to pF 2 (geometric mean, n=4). Equivalent to a SFO DT_{50} value of 1.5 d. Document KCA 7.1.2.1.2/02, [redacted](2015), M-534855-01-1.
Q_{10}	[-]	2.58	Default value
K_{oc}	[mL/g]	3220	Geometric mean (n=5). Document KCA 7.1.3.1.2/01, [redacted] (1996), M-166197-01-1.
Formation fraction	[-]	1.0	Worst-case default value
Degradation fraction from → to (FOCUS PEARL & MACRO)		1 ETP -> HEPA	

Parameter	Unit	Value	Comment
Degradation rate from → to (FOCUS PELMO)		0.014471 Active Substance -> A1 0.4620980 A1 -> BR/CO2	

Findings: PEC_{gw} were evaluated as the 80th percentile of the mean annual leachate concentration at 1 m soil depth.

PEC_{gw} values obtained with FOCUS PEARL, PELMO and MACRO for ethephon and its metabolite HEPA are given in Table 9.2.4- 9 to Table 9.2.4- 10 for the use winter cereals and in Table 9.2.4- 11 to Table 9.2.4- 12 for the use in spring cereals.

Table 9.2.4- 9: FOCUS PEARL and PELMO PEC_{gw} results of ethephon and its metabolite (Winter Cereals (early), 1 × 480 g a.s./ha, 80% interception)

Scenario	Ethephon			HEPA		
	PEARL	PELMO	MACRO	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]
Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	-	<0.001	<0.001	-
Jokioinen	<0.001	<0.001	-	<0.001	<0.001	-
Kremsmuenster	<0.001	<0.001	-	<0.001	<0.001	-
Okehampton	<0.001	<0.001	-	<0.001	<0.001	-
Piacenza	<0.001	<0.001	-	<0.001	<0.001	-
Porto	<0.001	<0.001	-	<0.001	<0.001	-
Sevilla	<0.001	<0.001	-	<0.001	<0.001	-
Thiva	<0.001	<0.001	-	<0.001	<0.001	-

Table 9.2.4- 10: FOCUS PEARL and PELMO PEC_{gw} results of ethephon and its metabolite (Winter Cereals (late), 1 × 480 g a.s./ha, 90% interception)

Scenario	Ethephon			HEPA		
	PEARL	PELMO	MACRO	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]
Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	-	<0.001	<0.001	-
Jokioinen	<0.001	<0.001	-	<0.001	<0.001	-
Kremsmuenster	<0.001	<0.001	-	<0.001	<0.001	-
Okehampton	<0.001	<0.001	-	<0.001	<0.001	-
Piacenza	<0.001	<0.001	-	<0.001	<0.001	-
Porto	<0.001	<0.001	-	<0.001	<0.001	-
Sevilla	<0.001	<0.001	-	<0.001	<0.001	-
Thiva	<0.001	<0.001	-	<0.001	<0.001	-

Table 9.2.4- 11: FOCUS PEARL and PELMO PEC_{gw} results of ethephon and its metabolite (Spring Cereals (early), 1 × 360 g a.s./ha, 80% interception)

Scenario	Ethephon			HEPA		
	PEARL [µg/L]	PELMO [µg/L]	MACRO [µg/L]	PEARL [µg/L]	PELMO [µg/L]	MACRO [µg/L]
Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	-	<0.001	<0.001	-
Jokioinen	<0.001	<0.001	-	<0.001	<0.001	-
Kremsmuenster	<0.001	<0.001	-	<0.001	<0.001	-
Okehampton	<0.001	<0.001	-	<0.001	<0.001	-
Porto	<0.001	<0.001	-	<0.001	<0.001	-

Table 9.2.4- 12: FOCUS PEARL and PELMO PEC_{gw} results of ethephon and its metabolite (Spring Cereals (late), 1 × 360 g a.s./ha, 90% interception)

Scenario	Ethephon			HEPA		
	PEARL [µg/L]	PELMO [µg/L]	MACRO [µg/L]	PEARL [µg/L]	PELMO [µg/L]	MACRO [µg/L]
Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	<0.001	<0.001	-	<0.001	<0.001	-
Jokioinen	<0.001	<0.001	-	<0.001	<0.001	-
Kremsmuenster	<0.001	<0.001	-	<0.001	<0.001	-
Okehampton	<0.001	<0.001	-	<0.001	<0.001	-
Porto	<0.001	<0.001	-	<0.001	<0.001	-

Conclusion:

As a precautionary approach two groundwater assessments for acidic and alkaline soils have been conducted for ethephon. A worst case DT_{50} of 47.9 days was used for ethephon in the groundwater assessments in acidic soils and a geometric mean DT_{50} of 3.8 days in the groundwater assessments in alkaline soils. All other parameters remained the same in the two assessments.

All PEC_{gw} values for ethephon and its metabolite HEPA for use in spring and winter cereals were <0.001 µg/L in both acidic and alkaline soils. Based on FOCUS groundwater calculations with PEARL, PELMO and MACRO models, it can be concluded the use of ethephon on cereals poses no unacceptable risk to groundwater at 1 m depth.

Calculation of PEC_{gw} values for ethephon and HEPA considering pH dependent adsorption.

New PEC_{gw} values for ethephon and its metabolite HEPA were calculated in response to the RMS comments on the adsorption behaviour of ethephon in soil. The RMS set a data gap for ethephon adsorption at pH above 6 and proposed a provisional risk assessment using a K_{Foc} of 10 L/kg as a worst-case.

Bayer AG provided a discussion on the validity of the adsorption data determined at pH above 6 as well as a discussion on the pH dependency of the adsorption process (please refer to MCA Section 7, data point 7.2.2.3). Based on this discussion the following adsorption parameters for ethephon were proposed:

Geometric mean K_{Foc} (L/kg) at pH < 7	980 (n=7, geometric mean)
Geometric mean K_{Foc} (L/kg) at pH > 7	102 (worst-case, n= 1, pH 7.3)
Arithmetic mean 1/n at pH < 7	0.992 (n=7, arithmetic mean)
Arithmetic mean 1/n at pH > 7	1.0 (worst-case, n= 1, pH 7.3)

A DT_{50} value of 9.18 days (geometric mean of 12 soils[1]) was used as proposed in the Ethephon draft RAR 18 Volume 3 CP. New PEC_{gw} calculations were only performed for pH > 7 as this was the worst-case approach. All resulting PEC_{gw} values were < 0.1 µg/L.

The details of the calculations are summarized in the following tables:

Table 9.2.4- 13: Application pattern used for PEC_{gw} calculations of ethephon

Individual Crop	FOCUS Crop Used for Interception	Application: Rate per Season [g a.s. /ha]	Application: Interval [days]	Application: Plant Inter-ception [%]	Application: BBCH Stage	Amount Reaching the Soil per Season [g a.s. /ha]
Winter Cereals (early) (fixed date)	Winter Cereals	1 x 480	-	80	37-39	1 x 96
Winter Cereals (late)	Winter Cereals	1 x 480	-	90	41-51	1 x 48
Spring Cereals (early) (fixed date)	Spring Cereals	1 x 360	-	80	37-39	1 x 72
Spring Cereals (late)	Spring Cereals	1 x 360	-	90	41-51	1 x 36

Table 9.2.4- 14: Application dates used for the simulation runs with ethephon

Individual crop	Winter Cereals (early)	Winter Cereals (fixed date)	Winter Cereals (late)	Spring Cereals (early)	Spring Cereals (fixed date)	Spring Cereals (late)
Repeat Interval for App. Events	Every Year	Every Year	Every Year	Every Year	Every Year	Every Year
Application Technique	Spray	Spray	Spray	Spray	Spray	Spray
Scenario	1st App. Date (Julian day)	1st App. Date (Julian day)	1st App. Date (Julian day)	1st App. Date (Julian day)	1st App. Date (Julian day)	1st App. Date (Julian day)
Chateaudun	02-May (122)	15-Apr (105)	08-May (128)	21-Apr (111)	15-May (135)	28-Apr (118)
Hamburg	30-Apr (120)	15-Apr (105)	06-May (126)	06-May (126)	15-May (135)	11-May (131)
Jokioinen	01-Jun (152)	15-Apr (105)	06-Jun (157)	11-Jun (162)	15-May (135)	14-Jun (165)
Kremsmuenster	30-Apr (120)	15-Apr (105)	06-May (126)	06-May (126)	15-May (135)	11-May (131)
Okehampton	22-Apr (112)	15-Apr (105)	24-Apr (114)	29-Apr (119)	15-May (135)	03-May (123)
Piacenza	17-Apr (107)	15-Apr (105)	21-Apr (111)	- -	- -	- -
Porto	06-Apr	15-Apr	11-Apr	29-Apr	15-May	07-May

1

Individual crop	Winter Cereals (early)	Winter Cereals (fixed date)	Winter Cereals (late)	Spring Cereals (early)	Spring Cereals (fixed date)	Spring Cereals (late)
Repeat Interval for App. Events	Every Year	Every Year	Every Year	Every Year	Every Year	Every Year
Application Technique	Spray	Spray	Spray	Spray	Spray	Spray
Scenario	1st App. Date (Julian day)	1st App. Date (Julian day)	1st App. Date (Julian day)	1st App. Date (Julian day)	1st App. Date (Julian day)	1st App. Date (Julian day)
	(96)	(105)	(101)	(119)	(135)	(127)
Sevilla	18-Jan	15-Apr	25-Jan	-		-
	(18)	(105)	(25)	-	-	
Thiva	08-Mar	15-Apr	12-Mar	-	-	-
	(67)	(105)	(71)	-	-	-

Table 9.2.4- 15: Alkaline assessment (for pH > 7), Koc = 102 mL/kg
FOCUS PEARL, PELMO and MACRO PEC_{gw} results of ethephon (for pH > 7) and its metabolite 2-HEPA (Winter Cereals (early), 1 × 480 g a.s./ha, 80% interception).

Scenario	Ethephon			HEPA		
	PEARL	PELMO	MACRO	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]
Chateaudun	0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	0.055	<0.001	-	0.005	<0.001	-
Jokioinen	0.010	<0.001	-	<0.001	<0.001	-
Kremsmuenster	0.012	0.001	-	<0.001	<0.001	-
Okehampton	0.068	0.001	-	<0.001	<0.001	-
Piacenza	0.013	<0.001	-	0.001	<0.001	-
Porto	0.047	<0.001	-	<0.001	<0.001	-
Sevilla	<0.001	<0.001	-	<0.001	<0.001	-
Thiva	<0.001	<0.001	-	<0.001	<0.001	-

Table 9.2.4- 16: FOCUS PEARL, PELMO and MACRO PEC_{gw} results of ethephon (for pH > 7) and its metabolite 2-HEPA (Winter Cereals (late), 1 × 480 g a.s./ha, 90% interception).

Scenario	Ethephon			HEPA		
	PEARL	PELMO	MACRO	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]
Chateaudun	0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	0.055	<0.001	-	0.005	<0.001	-
Jokioinen	0.010	<0.001	-	<0.001	<0.001	-
Kremsmuenster	0.012	<0.001	-	<0.001	<0.001	-
Okehampton	0.067	0.001	-	<0.001	<0.001	-
Piacenza	0.013	<0.001	-	0.001	<0.001	-
Porto	0.047	<0.001	-	<0.001	<0.001	-
Sevilla	<0.001	<0.001	-	<0.001	<0.001	-
Thiva	<0.001	<0.001	-	<0.001	<0.001	-

Table 9.2.4- 17: FOCUS PEARL, PELMO and MACRO PEC_{gw} results of ethephon (for pH > 7) and its metabolite 2-HEPA (Winter Cereals (application on April 15th), 1 × 480 g a.s./ha, 80% interception).

Scenario	Ethephon			HEPA		
	PEARL	PELMO	MACRO	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]
Chateaudun	0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	0.055	<0.001	-	0.005	<0.001	-
Jokioinen	0.010	<0.001	-	<0.001	<0.001	-
Kremsmuenster	0.012	<0.001	-	<0.001	<0.001	-
Okehampton	0.067	0.001	-	<0.001	<0.001	-
Piacenza	0.013	<0.001	-	0.001	<0.001	-
Porto	0.047	<0.001	-	<0.001	<0.001	-
Sevilla	<0.001	<0.001	-	<0.001	<0.001	-
Thiva	<0.001	<0.001	-	<0.001	<0.001	-

Table 9.2.4- 18: FOCUS PEARL, PELMO and MACRO PEC_{gw} results of ethephon (for pH > 7) and its metabolite 2-HEPA (Spring Cereals (early), 1 × 360 g a.s./ha, 80% interception).

Scenario	Ethephon			HEPA		
	PEARL	PELMO	MACRO	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]
Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	0.005	<0.001	-	<0.001	<0.001	-
Jokioinen	0.001	<0.001	-	<0.001	<0.001	-
Kremsmuenster	0.003	<0.001	-	<0.001	<0.001	-
Okehampton	0.007	0.001	-	<0.001	<0.001	-
Porto	<0.001	<0.001	-	<0.001	<0.001	-

Table 9.2.4- 19: FOCUS PEARL, PELMO and MACRO PEC_{gw} results of ethephon (for pH > 7) and its metabolite 2-HEPA (Spring Cereals (late), 1 × 360 g a.s./ha, 90% interception).

Scenario	Ethephon			HEPA		
	PEARL	PELMO	MACRO	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]
Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	0.005	<0.001	-	<0.001	<0.001	-
Jokioinen	0.001	<0.001	-	<0.001	<0.001	-
Kremsmuenster	0.003	<0.001	-	<0.001	<0.001	-
Okehampton	0.007	<0.001	-	<0.001	<0.001	-
Porto	<0.001	<0.001	-	<0.001	<0.001	-

Table 9.2.4- 20: FOCUS PEARL, PELMO and MACRO PEC_{gw} results of ethephon (for pH > 7) and its metabolite 2-HEPA (Spring Cereals (May 15th), 1 × 360 g a.s./ha, 80% interception).

Scenario	Ethephon			HEPA		
	PEARL	PELMO	MACRO	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]
Chateaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hamburg	0.005	<0.001	-	<0.001	<0.001	-
Jokioinen	0.001	<0.001	-	<0.001	<0.001	-
Kremsmuenster	0.003	<0.001	-	<0.001	<0.001	-
Okehampton	0.007	0.001	-	<0.001	<0.001	-
Porto	<0.001	<0.001	-	<0.001	<0.001	-

CP 9.2.4.2 Additional field tests

No additional field studies were performed.

CP 9.2.5 Estimation of concentrations in surface water and sediment

For the PEC calculations, the following representative uses were considered.

Representative crops	Application		
	Rate per Season	Interval	Timing of application
	[g a.s. /ha]	[days]	BBCH Stage
Winter Cereals (early)	1 x 480	-	37-39
Winter Cereals (late)	1 x 480	-	41-51
Spring Cereals (early)	1 x 360	-	37-39
Spring Cereals (late)	1 x 360	-	41-51

PECsw modelling approach

Calculation of PEC values for the active substance according to FOCUS

$FOCUS_{sw}$ is a four step tiered approach:

Step 1: In this, the most conservative step, all inputs are considered as a single loading to the water body and a worst-case PEC_{sw} and PEC_{sed} is calculated.

Step 2: Individual loadings into the water body from different entry routes are considered. Scenarios are also considered for Northern and Southern Europe separately but no specific crop scenarios are defined.

Step 3: An exposure assessment using realistic worst-case scenarios is made. The scenarios are representative of agricultural conditions in Europe and consider weather, soil, crop and different water-bodies. Simulations use the models PRZM, MACRO and TOXSWA.

Step 4: PEC values are refined by considering mitigation measures or specific scenario descriptions on a case-by-case basis.

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

For PEC_{sw} and PEC_{sed} calculations ethephon and its metabolite HEPA were considered.

Ethephon is a diprotic phosphonic acid (pK_{a1} = 2.8, pK_{a2} = 7.2) and therefore can be present in either neutral or anionic forms with either single (monoanion) or double negative charge (dianion), depending on the pH value of the medium. In the soil environment ethephon will be present as either negatively charged monoanions or dianions. The adsorption of ethephon is predominantly based on non-specific interactions with the soil and binding to the soil organic matter is a subordinated process only. This is confirmed by the narrow range of K_f values (9.3 to 11.0 mL/g) measured across four soils, without correlation to organic carbon content. As FOCUS Steps 1&2 requires a K_{oc} value as input, a pseudo K_{oc} value of 200.0 mL/g was calculated from the geometric mean K_f value of 10.0 mL/g and the organic carbon content of 5% assumed for sediment at Steps 1&2. Although FOCUS Step 3 calculations were not required for surface water risk assessments, a pseudo K_{om} value of 111.1 mL/g was calculated for Step 3 from the organic matter content of 9% assumed for sediment in the FOCUS Step 3 scenarios.

No statically significant correlation between the degradation half-life of ethephon and the pH value of the soils was detected using the German Input Decision tool (UBA, 2012). However, higher degradation rates were found for the soils with high pH and the lowest degradation rate was found for the soil with the lowest pH. As a precautionary approach two surface water assessments for acidic and alkaline soils have been conducted for ethephon in agreement with FOCUS (2014) recommendations: For acidic soils the worst case DT_{50} of 47.9 days was used for ethephon (see KCP 9.2.5/01) and for alkaline soils a geometric mean DT_{50} of 3.8 days from two alkaline soils was used (see KCP 9.2.5/02).

In both surface water assessments geometric mean DT_{50} and K_{oc} values were used for the metabolite HEPA.

Report:	KCP 9.2.5/02; [redacted]; [redacted]; 2015; M-539264-02-1
Title:	Ethephon (ETP) and metabolite: PECsw,sed FOCUS EUR - Use in winter cereals and spring cereals in acidic soils in Europe
Report No.:	EnSa-15-0888
Document No.:	M-539264-02-1
Guideline(s):	FOCUS 2001. SANCO/4802/2001-rev2; FOCUS 2014: Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, version 1.1; FOCUS 2015: Generic guidance for FOCUS surface water Scenarios, version 1.4.
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Methods and Materials: Predicted environmental concentrations of the active substance ethephon and its metabolite HEPA in surface water (PEC_{sw}) and sediment (PEC_{sed}) were calculated for the use in Europe, employing the tiered FOCUS Surface Water approach (FOCUS 2001). 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. FOCUS Steps 1 & 2 (version 3.2) were used to calculated values for ethephon and HEPA.

Ethephon is intended for use as a plant growth regulator at specific growth stages to shorten and strengthen cereal stems, and thus increase resistance to lodging. Use on winter and spring cereals, both early and late in the season was investigated. Detailed application parameters are presented in Table 9.2.5- 1.

Table 9.2.5- 1: General and FOCUS specific data on the use pattern of ethephon in Europe (for FOCUS Step 1&2)

Crop	Interval [days]	Rate per Season [g a.s. /ha]	FOCUS crop (Crop group)	Season	Crop cover
Winter Cereals	-	1 x 480	Cereals, winter (Arable crops)	Spring (Mar.-May)	Average crop cover
Winter Cereals	-	1 x 480	Cereals, winter (Arable crops)	Spring (Mar.-May)	Full canopy
Spring Cereals	-	1 x 360	Cereals, spring (Arable crops)	Spring (Mar.-May)	Average crop cover
Spring Cereals	-	1 x 360	Cereals, spring (Arable crops)	Spring (Mar.-May)	Full canopy

Substance input parameters are summarized in Table 9.2.5-2.

Table 9.2.5- 2: Substance parameters used for ethephon and its metabolite at Steps 1-2 level

Parameter	Unit	Value	Comment
Ethephon			
Molar mass	[g/mol]	144.49	-
Water solubility	[mg/L]	800000	20 °C, pH 4 Document KCA 2.5/01, [redacted] (2002), M-206704-01-1
K_{oc}	[mL/g]	200	Calculated from the geometric mean K_f value of 10.0 (n=4) based on an organic carbon content of 5% in sediment.
DT_{50} soil	[days]	47.9	Laboratory SFO DT_{50} (20 ºC) value normalised to pF 2 (worst case value, n=5, acidic soil) Document KCA 7.1.2.1.1/03, [redacted] (2015), M-534660-01-1
DT_{50} total system	[days]	2.79	Laboratory SFO DT_{50} (20 ºC) value (geometric mean, n=2, total system, P-I) Document KCA 7.2.2.3/02, [redacted] (2015), M-534853-01-1
DT_{50} water	[days]	2.79	Laboratory SFO DT_{50} (20 ºC) value (geometric mean, n=2, total system, P-I) Document KCA 7.2.2.3/02, [redacted] (2015), M-534853-01-1
DT_{50} sediment	[days]	2.79	Laboratory SFO DT_{50} (20 ºC) value (geometric mean, n=2, total system, P-I) Document KCA 7.2.2.3/02, [redacted] (2015), M-534853-01-1
Maximum occurence in water sediment systems	[% AR]	100	Parent substance
Maximum occurence in soil	[% AR]	100	Parent substance
HEPA			
Molar mass	[g/mol]	126.05	-
Water solubility	[mg/L]	800000	Ethephon water solubility at 20 °C & pH 4 used as default. Document KCA 2.5/01, [redacted] (2002), M-206704-01-1
K_{oc}	[mL/g]	3220	Geometric mean (n=5). Document KCA 7.1.3.1.2/03, [redacted] (1996), M-166197-01-1.

Parameter	Unit	Value	Comment
DT_{50} soil	[days]	1.5	Laboratory SFO DT_{50} (20 ºC) value normalised to pF 2 (geometric mean, n=4) Document KCA 7.1.2.1.2/02, [redacted] (2015), M-534855-01-1
DT_{50} total system	[days]	1000	Worst-case default value
DT_{50} water	[days]	1000	Worst-case default value
DT_{50} sediment	[days]	1000	Worst-case default value
Maximum occurence in water sediment systems	[% AR]	7.4	Maximum % of applied in natural water aqueous photolysis study. Document KCA 7.2.1.3/01, [redacted] (2005), M-249376-01-1.
Maximum occurence in soil	[% AR]	10.6	Maximum % of applied in soil photolysis study. Document KCA 7.1.1.3/01, [redacted] (2001), M-199517-01-1.

Findings:

FOCUS Step 1 and 2: The maximum PEC_{sw} and PEC_{sed} values for FOCUS Step 1 and 2 are given in the tables below for ethephon (Table 9.2.5- 3) and its metabolite HEPA (Table 9.2.5- 4).

Table 9.2.5- 3: Summary of the PEC_{sw} and PEC_{sed} values for ethephon (FOCUS Steps 1-2)

Crop Usage	Scenario	Ethephon					
		PEC_{sw}	PEC_{sed}	7d TWA_{sw}	7d TWA_{sed}	21d TWA_{sw}	21d TWA_{sed}
		[µg/L]	[µg/kg]	[µg/L]	[µg/kg]	[µg/L]	[µg/kg]
Cereals, winter 1 × 480 g a.s./ha	Step 1	130.7	252.6	61.68	122.7	24.79	49.38
Average crop cover	Step 2 N-EU	20.46	40.00	9.709	19.35	3.904	7.787
Spring (Mar. - May)	S-EU	39.54	78.15	18.80	37.53	7.559	15.10
Cereals, winter 1 × 480 g a.s./ha	Step 1	130.7	252.6	61.68	122.7	24.79	49.38
Full canopy	Step 2 N-EU	8.540	16.16	4.029	7.993	1.620	3.218
Spring (Mar. - May)	S-EU	15.69	30.46	7.437	14.81	2.991	5.959
Cereals, spring 1 × 360 g a.s./ha	Step 1	98.05	189.5	46.26	92.04	18.60	37.03
Average crop cover	Step 2 N-EU	15.35	30.00	7.282	14.51	2.928	5.840
Spring (Mar. - May)	S-EU	29.65	58.61	14.10	28.15	5.669	11.32
Cereals, spring 1 × 360 g a.s./ha	Step 1	98.05	189.5	46.26	92.04	18.60	37.03
Full canopy	Step 2 N-EU	6.405	12.12	3.022	5.995	1.215	2.414
Spring (Mar. - May)	S-EU	11.77	22.85	5.578	11.11	2.243	4.469

Table 9.2.5- 4: Summary of the PEC_{sw} and PEC_{sed} values for HEPA (FOCUS Steps 1-2)

Crop Usage	Scenario	HEPA					
		PEC_{sw}	PEC_{sed}	7d TWA_{sw}	7d TWA_{sed}	21d TWA_{sw}	21d TWA_{sed}
		[µg/L]	[µg/kg]	[µg/L]	[µg/kg]	[µg/L]	[µg/kg]
Cereals, winter 1 × 480 g a.s./ha Average crop cover Spring (Mar. - May)	Step 1 Step 2 N-EU S-EU	5.031 0.440 0.805	154.5 13.48 25.22	4.805 0.419 0.784	154.1 13.44 25.16	4.771 0.416 0.779	153.4 13.38 25.04
Cereals, winter 1 × 480 g a.s./ha Full canopy Spring (Mar. - May)	Step 1 Step 2 N-EU S-EU	5.031 0.285 0.349	154.5 6.133 10.54	4.805 0.161 0.328	154.1 6.118 10.51	4.771 0.180 0.326	153.4 6.088 10.46
Cereals, spring 1 × 360 g a.s./ha Average crop cover Spring (Mar. - May)	Step 1 Step 2 N-EU S-EU	3.774 0.330 0.604	115.8 10.11 18.92	3.604 0.314 0.588	115.6 10.08 18.87	3.578 0.312 0.584	115.1 10.03 18.78
Cereals, spring 1 × 360 g a.s./ha Full canopy Spring (Mar. - May)	Step 1 Step 2 N-EU S-EU	3.774 0.214 0.261	115.8 4.600 7.904	3.604 0.121 0.246	115.6 4.589 7.885	3.578 0.135 0.244	115.1 4.566 7.846

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Report:	KCP 9.2.5/03; [redacted]; [redacted]; 2015; M-539294-02-1
Title:	Ethephon (ETP) and metabolite: PECsw,sed FOCUS EUR - Use in winter cereals and spring cereals in alkaline soils in Europe
Report No.:	EnSa-15-0899
Document No.:	M-539294-02-1
Guideline(s):	FOCUS 2001, SANCO/4802/2001-rev2; FOCUS 2014: Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, version 1.1; FOCUS 2015: Generic guidance for FOCUS surface water Scenarios, version 1.4.
Guideline deviation(s):	not applicable
GLP/GEP:	**no**

Methods and Materials: Predicted environmental concentrations of the active substance ethephon and its metabolite HEPA in surface water (PEC_{sw}) and sediment (PEC_{sed}) were calculated for the use in Europe, employing the tiered FOCUS Surface Water approach (FOCUS 2001). 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. FOCUS Steps 1 & 2 (version 3.2) were used to calculated values for ethephon and HEPA.

Ethephon is intended for use as a plant growth regulator at specific growth stages to shorten and strengthen cereal stems, and thus increase resistance to lodging. Use on winter and spring cereals, both early and late in the season was investigated. The detailed application parameters used for PEC_{sw} calculations in alkaline soils were identical to those used for acidic soils (see KCP 9.2.5/01). Detailed application parameters are presented in Table 9.2.5- 1.

Substance input parameters are summarized in Table 9.2.5- 5.

Table 9.2.5- 5: Substance parameters used for ethephon and its metabolite at Steps 1-2 level

Parameter	Unit	Value	Comment
Ethephon			
Molar mass	[g/mol]	144.49	-
Water solubility	[mg/L]	800000	20 °C, pH 4 Document KCA 2.5/01, [redacted] (2002), M-206704-01-1
K_{oc}	[mL/g]	200	Calculated from the geometric mean K_f value of 10.0 (n=4) based on an organic carbon content of 5% in sediment.
DT_{50} soil	[days]	3.8	Laboratory SFO DT_{50} (20 ºC) value normalised to pF 2 (geometric mean, n=2, alkaline soils). Document KCA 7.1.2.1.1/03, [redacted] (2015), M-534660-01-1
DT_{50} total system	[days]	2.79	Laboratory SFO DT_{50} (20 ºC) value (geometric mean, n=2, total system, P-I) Document KCA 7.1.2.2/02, [redacted] (2015), M-534853-01-1
DT_{50} water	[days]	2.79	Laboratory SFO DT_{50} (20 ºC) value (geometric mean, n=2, total system, P-I) Document KCA 7.2.2.3/02, [redacted] (2015), M-534853-01-1
DT_{50} sediment	[days]	2.79	Laboratory SFO DT_{50} (20 ºC) value (geometric mean, n=2, total system, P-I) Document KCA 7.2.2.3/02, [redacted] (2015), M-534853-01-1
Maximum occurence in water sediment systems	[% AR]	100	Parent substance
Maximum occurence in soil	[% AR]	100	Parent substance
HEPA			
Molar mass	[g/mol]	126.05	-
Water solubility	[mg/L]	800000	Ethephon water solubility at 20 °C & pH 4 used as default. Document KCA 2.5/01, [redacted] (2002), M-206704-01-1
K_{oc}	[mL/g]	3220	Geometric mean (n=5). Document KCA 7.1.3.1.2/01, [redacted] (1996), M-166197-01-1.
DT_{50} soil	[days]	1.5	Laboratory SFO DT_{50} (20 ºC) value normalised to pF 2 (geometric mean, n=4) Document KCA 7.1.2.1.2/02, [redacted] (2015), M-534855-01-1
DT_{50} total system	[days]	1000	Worst-case default value
DT_{50} water	[days]	1000	Worst-case default value
DT_{50} sediment	[days]	1000	Worst-case default value
Maximum occurence in water sediment systems	[% AR]	7.4	Maximum % of applied in natural water aqueous photolysis study. Document KCA 7.2.1.3/01, [redacted] (2005), M-249376-01-1.
Maximum occurence in soil	[% AR]	10.6	Maximum % of applied in soil photolysis study.

Parameter	Unit	Value	Comment
			Document KCA 7.1.1.3/01, [redacted] (2001), M-199517-01-1.

Findings:

FOCUS Step 1 and 2: The maximum PEC_{sw} and PEC_{sed} values for FOCUS Step 1 and 2 are given in the tables below for ethephon (Table 9.2.5- 6) and its metabolite HEPA (Table 9.2.5- 7).

Table 9.2.5- 6: Summary of the PEC_{sw} and PEC_{sed} values for ethephon (FOCUS Steps 1-2)

Crop Usage	Scenario	Ethephon					
		PEC_{sw}	PEC_{sed}	7d TWA_{sw}	7d TWA_{sed}	21d TWA_{sw}	21d TWA_{sed}
		[µg/L]	[µg/kg]	[µg/L]	[µg/kg]	[µg/L]	[µg/kg]
Cereals, winter 1 × 480 g a.s./ha Average crop cover Spring (Mar. - May)	Step 1 Step 2 N-EU S-EU	130.7 11.13 20.87	252.6 21.34 40.82	61.68 5.264 9.906	122.7 10.46 19.75	24.79 2.116 3.983	49.38 4.211 7.945
Cereals, winter 1 × 480 g a.s./ha Full canopy Spring (Mar. - May)	Step 1 Step 2 N-EU S-EU	130.7 5.041 8.695	252.6 9.157 16.46	61.68 2.362 4.103	122.7 4.659 8.140	24.79 0.950 1.650	49.38 1.877 3.277
Cereals, spring 1 × 360 g a.s./ha Average crop cover Spring (Mar. - May)	Step 1 Step 2 N-EU S-EU	98.05 8.348 15.66	189.5 16.00 30.62	46.26 3.948 7.429	92.04 7.846 14.81	18.60 1.587 2.988	37.03 3.158 5.959
Cereals, spring 1 × 360 g a.s./ha Full canopy Spring (Mar. - May)	Step 1 Step 2 N-EU S-EU	98.05 3.781 6.521	189.5 6.868 12.35	46.26 1.772 3.077	92.04 3.494 6.105	18.60 0.712 1.237	37.03 1.408 2.458

Table 9.2.5- 7: Summary of the PEC_{sw} and PEC_{sed} values for HEPA (FOCUS Steps 1-2)

Crop Usage	Scenario	HEPA					
		PEC_{sw}	PEC_{sed}	7d TWA_{sw}	7d TWA_{sed}	21d TWA_{sw}	21d TWA_{sed}
		[µg/L]	[µg/kg]	[µg/L]	[µg/kg]	[µg/L]	[µg/kg]
Cereals, winter 1 × 480 g a.s./ha Average crop cover Spring (Mar. - May)	Step 1 Step 2 N-EU S-EU	5.031 0.296 0.517	154.5 8.837 15.95	4.805 0.276 0.496	154.1 8.816 15.91	4.771 0.273 0.493	153.4 8.773 15.83
Cereals, winter 1 × 480 g a.s./ha Full canopy Spring (Mar. - May)	Step 1 Step 2 N-EU S-EU	5.031 0.285 0.285	154.5 4.394 7.060	4.805 0.134 0.176	154.1 4.383 7.043	4.771 0.135 0.204	153.4 4.362 7.009
Cereals, spring 1 × 360 g a.s./ha Average crop cover Spring (Mar. - May)	Step 1 Step 2 N-EU S-EU	3.774 0.222 0.387	115.8 6.628 11.96	3.604 0.207 0.372	115.6 6.612 11.93	3.578 0.205 0.369	115.1 6.580 11.87
Cereals, spring 1 × 360 g a.s./ha Full canopy Spring (Mar. - May)	Step 1 Step 2 N-EU S-EU	3.774 0.214 0.214	115.8 3.295 5.295	3.604 0.101 0.132	115.6 3.287 5.282	3.578 0.101 0.153	115.1 3.271 5.256

Conclusion:

To ensure a consistent approach with groundwater assessments, two surface water assessments for acidic and alkaline soils have been conducted for ethephon. A worst case DT_{50} of 47.9 days was used for ethephon in the surface water assessments in acidic soils and a geometric mean DT_{50} of 3.8 days in the surface water assessments in alkaline soils. All other parameters remained the same in the two assessments.

The results of calculations for the maximum predicted concentrations of ethephon and its metabolite HEPA in surface water according to FOCUS requirements were:

$PEC_{sw,\ max}$ Ethephon Step 1 = 130.7 µg/L
Step 2 = 39.54 µg/L

$PEC_{sw,\ max}$ HEPA Step 1 = 5.03 µg/L
Step 2 = 0.805 µg/L

CP 9.3 Fate and behaviour in air

For information on the fate and behaviour in air please refer to MCA Section 7, data point 7.3.

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

For information on route and rate of degradation in air and transport via air please refer to MCA Section 7, data points 7.3.1 and 7.3.2.

CP 9.4 Estimation of concentrations for other routes of exposure

There are no other routes of exposure if the product is used according to good agricultural practice. Therefore no further estimations are considered necessary.