

# **Document Title**

# Summary of the fate and behaviour in the environment

Ethephon SL 480 g/L

# Data Requirements Data Requirements Alation 1107/2009 & EU Regulation Document MCP ection 9: Fate and beliaviour in the environ According to the guidance document SANCO 10181/2013 for preparing dossers for the approval of schemical active substance Data Data Requirements According to the guidance document SANCO 10181/2013 for preparing dossers for the approval of schemical active substance Aur. Aur.



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Ethephon SL 480 g/L

# Version history

Date	Data points containing amendments or additions <sup>1</sup> and brief description	Document identifier and
2016-01-08	Initial document submitted for Annex I renewal Ethephon	M-544523-01-1
2017-07-25	Adsorption parameters for revised PEC <sub>gw</sub> values for ethephon and its metabolite HEPA Change of legal entity from Bayer CropScience AG to Bayer Ag Crop Science Division	M-3/44523-02-1
1		
SANCO/10180/2	Change of legal entity from Bayer CropScience AG to Bayer Ag Crop Science Division  hat applicants adopt a similar approach to showing revisions an 013 Chapter 4 How to revise an Assessment Report	

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### CP9 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 Zadata 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 A. information on the fate and behaviour in soil please refer & MC Section 7, data points 7.1.1 and 7.1.2.

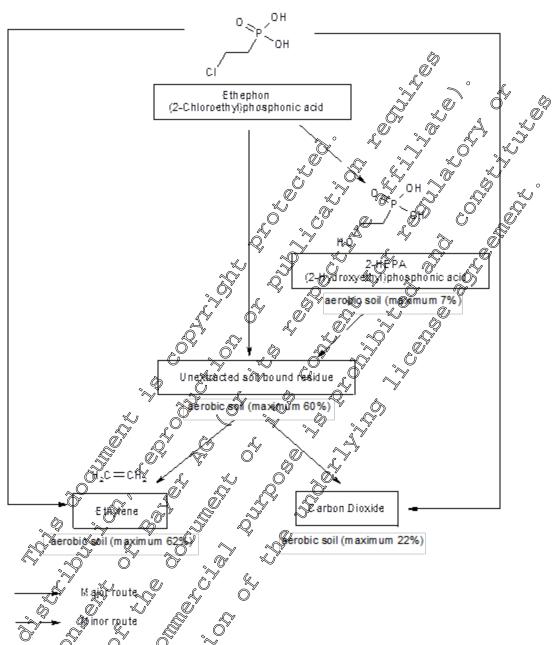
The main metabolic pathway of ethephon in soil was degradation to form etherene (maximum 62%) and non-extractable soil residues (maximum 60%). Significant mineralization to form carbon dioxide was observed in one soil (maximum 22%). A metabolite (2-hydroxyethyl) phosphonic acap (HEPA), was detected as a minor metabolite in aerobic soil at maximum of 7% at a single threpoint, 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 prinor metabolite (maximum 4%).

with HEPA or with HEPA or with HEPA or with HEPA or was readily degrad. Idigating that photolytic retected as a major metabo. I metabolite 55% at two cens. The property of the control of In a soil photolysis study, ethephon was readily degraded with a similar decline seen under irradiated conditions and in dark controls indicating that photogradation had only a minor effect on the degradation rate. HEPA was detected as a major metabolite in intadiated 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%,

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

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



CP 9.1.11 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 data from 7.14.1

# **CP 9.1.2.2** Lysimeter studies

For information on lysimeter studies please refer to MCA Section % data point 7.1.2.2.

# **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

, C		Application	
Representative crops	Rate per Season	Interval	Timing of application
	[g a.s. /ha]	Q [days]	BBCH Stage
Winter Cereals (early)	7 x 480	)	37-39
Winter Cereals (late)	1 x 480 💸	-	41-51
Spring Cereals (early)	2 1×360 Q	<u>-</u>	37-39
Spring Cereal (Tate)	x 360 ×	- -	41-51

# PECsoil modelling approach

The predicted environmental concentrations in soil (PEC<sub>soil</sub>) for the active substance ethephon were calculated haved on a simple first ther approach (Microsoft® Excel spreadsheet) assuming even distribution of the empound in the upper 0.5 cm soil layer. A standard soil density of 1.5 g/cm³ was assumed Derivation of kinetic modelling input values for ethephon and its metabolite are presented in MCA Section 7, point 1.2 (Documents KCA 7.1.2.1.1/03, M-534660-01-1 and KCA 7.1.2.1.2/02, M-534855-00-1). A summar of the modelling input parameters is given in the PEC<sub>soil</sub> report (KCP 9.1.3/01, M-539494-01-1).

# Predicted environmental concentrations in soil (PEC<sub>Soil</sub>) of ethephon and its metabolites

For PEC<sub>soil</sub> calculations ethephon and its metabolite HEPA were considered.



**Report:** KCP 9.1.3/02; ; 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, Onending 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 Late 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 (PC<sub>soil</sub>) of ethephon and its metabolite HEPA were calculated based on a first tien 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<sub>soil</sub> are compiled in Table 9.1.3-0.

Table 9.1.3-1: Application pattern and for QLC soil calculations of ether hon

	FOCUS		Ap/pli	cation S	7 2	Amount Reaching
Individual	Crop	A Rate	<b>Interval</b>	Plant	₿₿CH	the Soil per Season
Crop	Used for	per Season		Interception	<b>Stage</b>	the son per season
	Interception <sub>4</sub>	, [g a.s. (ba]	Qiays}	[%] <sup>*</sup>		[g a.s. /ha]
Winter Cereals	Winter &	1.3.480 🌣	7	Non and	37-39	1 x 96
(early)	Cereals			100	37-39	1 X 90
Winter Cereals	Winter	√ x 480 ×		b ogs	41-51	1 x 48
(late)	Cercals		W 0		41-31	1 X 40
Spring Cereals	Spring (	1 \$ \$60	% - L		37-39	1 x 72
(early)	Cereals \$	1 2 300		3.80	37-39	1 X / Z
Spring Cereals	Spring	Ø x 360€	Q,	90	41-51	1 x 36
(late)	Y Cereals	W X 300			41-31	1 X 30

**Substance Specific Parameters:** PEC<sub>soil</sub> calculations were based on a DT<sub>50</sub> value of 72.1 days (non-normalised, worst case laboratory DT<sub>50</sub> 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<sub>50</sub> value of 9 days (non-normalised, worst case laboratory DT<sub>50</sub> 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 <sub>50</sub>	[days]	72.1	Laboratory SFO DT <sub>50</sub> (20°C) value (worst case value, n=5, un-normalised) Document KCA 7.12 1.1/03 (2015), M-534660 01-1
Maximum occurence in soil	[% AR]	100	Parent Brbstance V V V
Molar mass correction factor	[-]	1	
НЕРА			
Molar mass	[g/mol]	126.05	
DT <sub>50</sub>	[days]	1.9 Ç	Laboratory SLODT <sub>50</sub> (20°C) value (worst case value, n=4, sin-normalised)  Document & CA 7 \( \frac{1}{2} \).1.2/02  2015) \( \frac{1}{2} \)-53485 \( \frac{1}{2} \)01-1
Maximum occurence in soil	[% AR]	\$\times \tilde{\pi}0.6	Maximum % of applied in soil photolysis study. Document k. A 7.14 3/01, (2001), M2 9951724-1.
Molar mass correction factor	[-]	0.\$724 <sub>E</sub>	

**Findings:** The maximum PEC<sub>sol</sub> 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

Uso nattown	, S			Ethephon		НЕРА
Use pattern	Ö	~			PECsoil	[mg/kg]
Winter Cereals (early	X 480	g <sup>©</sup> a.s./h <u>a</u>	Ö	,0.128	Ç,	0.012
Winter Cereals (late),	1 x 480g	a.s./ha		0.064	)*	0.006
Spring Cereals (early	), 1 360			0,0%		0.009
Spring Cereals (late)	₹ 360 g	3).s./ha 💍		<b>6.0</b> 48		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<sub>soil</sub> and TWAC<sub>soil</sub> of ethephon and its metabolite HEPA

Days	after	Ethe	phon	НЕРА		
maximum		PECsoil	TWACsoil	PECsoil 05	TWACsoil	
		[mg/kg]	[mg/kg]	[mg/kg] 🎺	∘ [mg/kg]	
Initial	0	0.128	-	0.012		
Short	1	0.127	0.127	0.008	° «∩∩1∩./°	
term	2	0.126	0.127	%° 0.0% %	0.008	
	4	0.123	0.126	© 003 ~	L 0,000	
Long	7	0.120	0.124	0.000	<b>29</b> .004 .	
term	14	0.112	0.120	<0.000 × × × × × × × × × × × × × × × × ×	0.002	
	21	0.105	0.116	© < <b>©</b> 001 ©	O.QQ	
	28	0.098	0.1120	♥ \$\sqrt{0.001}	<b>(20</b> 00)	
	42	0.085	0,195	<0.00	<b>0.001</b>	
	50	0.079	© 102 Q	© <0.901	< 0.001	
	100	0.049	0.082	♥ <b>%</b> 0.001 <b>@</b>	< 0.001	

Days	aiter		nepnen	L, Q	HE (C)	PA .
maxii	num	PECsoil	O'	TWACsoil	PECSOII	TWACsoil
		[mg/kg]	y z	[mg/kg]	y mg/kg]	[mg/kg]
Initial	0	<b>QQ</b> 64		\$0.064	0.006	-
Short	1	©0.063 Å		,0,064 O	0.004	0.005
term	2	∞ 0.063	4Q1"	\$0.063 \$\text{\$\pi\$}	0.003	0.004
	4	0.682		0.063	0.001	0.003
Long	7 %	y \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	Ö	0.062	< 0.001	0.002
term	1,4	\$ 0.05€	20	Ø.060 S	< 0.001	0.001
	21	0.052	0,	y 0.0 <b>5</b> 8	< 0.001	< 0.001
	28 💡	(\$\sqrt{9}\) \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \		0.056	< 0.001	< 0.001
	42 0	0.043		0,053	< 0.001	< 0.001
	50	0.040		©0.051	< 0.001	< 0.001
	<u>_</u> 100	0.024		0.041	< 0.001	< 0.001
- S						



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

Table 9.1.3-6: PEC<sub>soil</sub> and TWAC<sub>soil</sub> of ethephon and its metabolite HEPA

Days	after	Ethe	ephon	НЕРА		
maximum		PECsoil	TWACsoil	PECsoil 0	TWACsoil	
		[mg/kg]	[mg/kg]	[mg/kg] 🎺	∘ [mg/kg]	
Initial	0	0.096	-	0.009		
Short	1	0.095	0.096	0.006	₹0.007 ₹	
term	2	0.094	0.095	%° 0.0694	0.006	
	4	0.092	0.094	© 002 ~	0,095	
Long	7	0.090	0.093	0.00	<b>29</b> .003 .	
term	14	0.084	0.090	<0.000 × ×	0.002	
	21	0.078	0.087	© ≤ <b>©</b> 001	O.QQV	
	28	0.073	0.0840	♥ \$\sqrt{0.001} \times	<i>&gt;</i> < <b>®</b> 001	
	42	0.064	0,079	<0.00	0.001	
	50	0.059	20.076 Q	Ø <0.901	< 0.001	
	100	0.037	0.062	\$\sqrt{9.001}	< 0.001	

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

Table 9.1.3- 7: PEC<sub>soil</sub> and TWAC<sub>soil</sub> of etheriton and its metabolite HEPA

Days after maximum		`Æ,the	phon ( )	Q HE	HEPA	
		PECsoil	TWACsoil	© PEC.	TWACsoil	
		[mg/kg]	[mg/kg]	ຶ∕y [mg/kg]	[mg/kg]	
Initial	0	0.048	~ · O ~ Q		-	
Short	1	0.048	Q.048	0.003	0.004	
term	2	0.047	U' \$\int_0.048   \qu	0.002	0.003	
	4	0.046	0.047	0.001	0.002	
Long	7 %	0.045	0.046 Q	< 0.001	0.002	
term	14	© 0.042 × ×	0 0045	< 0.001	< 0.001	
	21	0.039	0.043	< 0.001	< 0.001	
	28	Ø Ø Ø Ø Ø Ø Ø Ø Ø Ø Ø Ø Ø Ø Ø Ø Ø Ø Ø	0.04	< 0.001	< 0.001	
	42 💐	©0.032 V	0.039	< 0.001	< 0.001	
	50	0.03%	©.038	< 0.001	< 0.001	
	<u> 1</u> 100	0.018	<b>₹</b> 0.031	< 0.001	< 0.001	

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

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

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



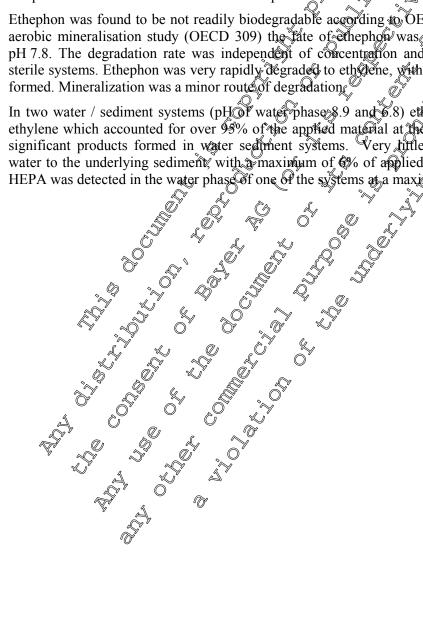
### **CP 9.2** Fate and behaviour in water and sediment

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 DTs 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 appH 5 and in matural water at pH 7.5 at 25 °C. The rate of degradation of ethephon was largely dependent of the test systems with similar half-lives observed in non-irradiated and incadiated experiments and it can be concluded that photolysis does not play a significant role in the Greakdown of emephon 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 24% AP. In in incidented samples it exceeded 5% at the two final timepoints.

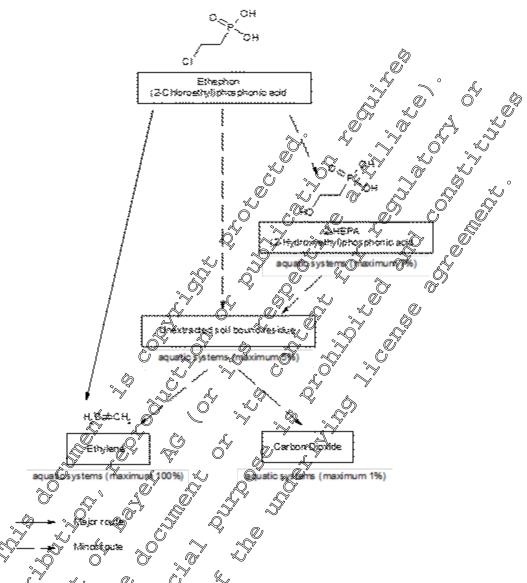
Ethephon was found to be not readily biodegradable according to OECD Test Condeline 201D. In an aerobic mineralisation study (OECD 309) the late of thephod was investigated in partural water at pH 7.8. The degradation rate was independent of concentration and very similar to the biotic and sterile systems. Ethephon was very rapidly degraded to ethodene, with no other significant metabolites

In two water / sediment systems (pHOF water phase \$ .9 and 5 .8) etherhon 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 segment systems. Very tittle 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.



Ethephon SL 480 g/L

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



# CP 9.2.1 Aerobie mineralisation in suotace water

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

# CP 9.2.2 Water sediment stody

For information on water/redimentatudies 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.

		Application	
Representative crops	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	- 07	37-39
Spring Cereals (late)	1 x 360	%° - 4	41-51 D

# PECgw modelling approach

The predicted environmental concentrations in groundwater (PPC<sub>gw</sub>) for the active subtaince etherhon were calculated using the simulation models PEARL, PELMO and MACRO (scenario Chateaudun) following the recommendations of the FOCUS wording group on groundwater scenarios.

The leaching calculations were run over 26 years, as proposed for people of the 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 treated field were evaluated and were taken as the relevant PEC<sub>gw</sub> values. In respect to the assessment of a potential goundwater 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 etherion and its metabolite are presented in MCA Section 7, point 7.12 (Documents & CA 7.2.1.1/6), M-\$24660-01-1 and KCA 7.1.2.1.2/02, M-534855-01-1). A summary of modelling input parameters is given in the PEC<sub>gw</sub> report (KCP 9.2.4.1).

# CP 9.2.4.1 Calculation of concentrations in groundwater

# Predicted environmental concentrations in groundwater (PECGW)

For PECgw calculations ethephon and its metabolite HEPA were considered.

Ethephon is a diprotic phosphonic acid (p $K_1$  = 2.8, p $K_{a2}$  = 7.2) and therefore can be present in either neutral an 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 parrow 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 (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<sub>gw</sub> values for ethephon and its metabolite HEPA were calculated in response to the RMS comments on the adsorption behaviour of ethephon in soil player 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 7.2.23). The new PEC<sub>gw</sub> calculations are summarised below (p.23).

**Report:** KCP 9.2.4.1/02; (2015) M-539255-01-10

Title: Ethephon (ETP) and metabolite: PECgw FQCUS 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 QANCQ/321/2000 rev. 2; FOCUS GW 2009.

SANCO/13144/2010 version 1; FOCUS GW, 2014@ Generic Guidance for Tier 1

FOCUS Groundwater Assessments, Version 2.2; FOCUS GW 2014b.

SANCO/13 V4/2010 version 3; FOCUS Kinetics, 2014. Generic guidance for Extracting Frigger and Degradation Kinetics from Environmental Fate Studies on

Desticides in EU Registration, Version 1.1

Guideline deviation(s): \_\_\_hot applicable

GLP/GEP: no

Methods and Materials: Predicted environmental concentrations of the active substance ethephon and its metabolite HDPA in groundwater recharge (PEC $_{\rm gw}$ ) were calculated for use in Europe, using the simulation models EQCUS PEARL 4.4.4, FQCUS PELMO 5.5.3 and FOCUS MACRO 5.5.4. PEC $_{\rm gw}$  were evaluated as the 80 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<sub>gw</sub> are compiled in Table 9.2.4.

Table 9.2.4-1: Application pattern used for PEC<sub>gw</sub> calculations of ethephon

	FOCUS	Application			Amount Reaching	
Individual Crop	Crop Used for	Rate per Season	Interval	Plant Interception	BBCH Stage	the Soil per Season
Стор	Interception	[g a.s./ha]	[days]	[%]	Stage	[g a.s. /ha]
Winter Cereals	Winter	1 x 480		80	37-39/	- ° 1 v006
(early)	Cereals	1 X 460	_	80	3 1939	1 x 96
Winter Cereals	Winter	1 x 480		90	Ø1≥51 ×	
(late)	Cereals	1 X 480	-	90		1 x 48
Spring Cereals	Spring	1 x 360			27.20	1 x 42
(early)	Cereals	1 X 300	_		3 1-3 <del>3</del> %	
Spring Cereals (late)	Spring Cereals	1 x 360	-	© 90°	41-51	Ø

Input parameters for ethephon and its metabolite HEDA were used as summarised in Table 92.4-2

Table 9.2.4-2: Input parameters of ethephon and its metabolite for REC<sub>gw</sub> calculations

Parameter	Unit	Value	Comment
Ethephon			
Molar mass	[g/mol]	134.5 Q	p- 2 2 2
Water solubility	[mg/L]	\$00000	20 % pH 4 5
			Document & CA 2.5% (2002),
Vapour Pressure	(Pa)	8\00E-05 \%	√25 °C Ø
			Document KCA 2.2/03, (2015), M2514117-0121
Freundlich Exponent		0,862	Frithmen mean (n=4)
			Document KCA 7.1.3.1.1/02, (2015), M-539124-01-1
Plant uptake factor	[-log"		Conservative default value.
Walker Exponent	<u>[-]</u>	~0.7° ~	Befault value
PEARL Parameters (		, oʻ «	9
Substance code	[-] 🕡	ETP	-
$DT_{50}$	[days]	47.9	Laboratory SFO DT <sub>50</sub> (20 °C) value normalised to
			pF 2 (worst case value, n=5, acidic soil)
			Document KCA 7.1.2.1.1/03, (2015), M-534660-01-1
Molar Activation Energy @	[kJ/mol] @	65.4	Default value
K <sub>f</sub> V V	ØmL/g] ○″	10.0	Geometric mean (n=4)
			Document KCA 7.1.3.1.1/02, (2015), M-539124-01-1
PELMO Parameters	0		
Substance code	[-]	AS	-
Rate constant	[1/day]	0.01447	Laboratory rate constant (20 °C) normalised to pF 2
			(worst case value, n=5, acidic soil). Equivalent to
			a SFO DT <sub>50</sub> value of 47.9 d. Document KCA 7.1.2.1.1/03,
			(2015), M-534660-01-1.
Q <sub>10</sub>	[-]	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 (2002), M-206704-01-1
Vapour Pressure	[Pa]	8.00E-05	Ethephon vapour pressure at 25 °C used as detault.  Document KCA 2 2/03, (2015), M-514 17-01-1
Freundlich Exponent	[-]	0.943	Arithmetic mean (n=\$).  Document & CA 7 1-3.1.2/01
Plant uptake factor	[-]	0	Conscivative of ault value.
Walker Exponent	[-]	0.7 🖓	Despult valing
PEARL Parameters		*	
Substance code	[-]	PEPA 4	
DT <sub>50</sub>	[days]	1.5 L	Labaratory SEO DT <sub>50</sub> C20 °C) yalue normalised to
	<u></u>		pF2 (geometric mean, n=4)
		6	Document KCA Q 2.1.2 Q 2, (2005), M-53 4855-04 Q
Molar Activation Energy	[kJ/mol]	£ 65.4 ×	Defailt value
K <sub>om</sub>	[mal/g]	1868	Calculated from geometric mean K <sub>oc</sub> value assuming conversion factor of 1.724.
PELMO Parameters			
Substance code	[-] Q	O Al	- 01
Rate constant	[Joay]	0.46210	Caboratory rate constant (20 °C) normalised to pF 2
			geometric mean, n=4). Equivalent to a SFO DT <sub>50</sub>
Ö			value of 1.5 d.  Document KCA 7.1.2.1.2/02,
Rate constant  Q10			(2015), M-534855-01-1.
Q <sub>10</sub>	(4) 0	^2 <sub>5</sub> 8 ~	Default value
K <sub>oc</sub>	mL/g	3220	Geometric mean (n=5).
		O' 📡	Document KCA 7.1.3.1.2/01,
			(1996), M-166197-01-1.
Formation fraction	[-]	<b>3</b> 7.0	Worst-case default value
Degradation fraction from → (to (FOCUS AEARL & MACRO)		ŶŊĔTP -> HE	
Degradation rate from -X00			tive Substance -> A1
(FOCUS PEROO)		0.4620980 A	1 -> BR/CO2

The use of etherbon 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	Every Year	Every Year	Every Year	Every Year
Application Technique	Spray	Spray	Spra <b>y</b> Š	Spray
Scenario	1 <sup>st</sup> App. Date (Julian day)	1 <sup>st</sup> App. Date (Julian day)	1st App, Date (Julian day)	1st Aspp. Date (Julian day)
Chateaudun	02-May	08-May	©21-Apr	28-Apr
	(122)	(128)	(144))	Q
Hamburg	30-Apr	06-May	7 06-May	√l) <sup>™</sup> May
	(120)	(\$\tilde{\psi}_26) \times	(126)	Q (131),°
Jokioinen	01-Jun	106-Jun	11-Jun	0 14- <b>10</b> m
	(152)	(1,579)	(1 <b>%</b> 2)* (	(65)
Kremsmuenster	30-Apr	Q 06 May 😽	06-May 💸	Al May
	(120) 👟	<b>3</b> 126)	(126)	(131)
Okehampton	22-Apr	Q, 24-Ap	≫ 29- <b>A</b> pr	O3-May
	(112)	(1 <b>0)</b>	( <b>©</b> 19)	(123)
Piacenza	17 <b>=</b> Apr	21-Apr	~ ~ ~	-
	(V07) (V	(111)	. S	-
Porto	006-Apr	11-AQT ^	Ç 29- <b>⊘</b> pr	07-May
	(96) (96) °	(1 <del>0</del> 1)	<b>(1</b> 19)	(127)
Sevilla	√ 18≠Jan √	∫\$25-Jan 🍳	<u> </u>	-
$\mathcal{L}$	(18)	(25)\$	[ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	-
Thiva	√ 08-Mar	12-Mar 🔏	_	-
			<del>-</del>	-

Findings: PEC<sub>gw</sub> were evaluated as the 80<sup>th</sup> percentile of the mean annual leachate concentration at 1 m soil depth.

PEC<sub>gw</sub> values obtained with FOCUS PEORL, PEEMO 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: FOCES PEARL and FilmOreC<sub>gw</sub> results of ethephon and its metabolite (Winter Cereals (early), 1 × 480 g a.s./ha, 80% interception)

Scenario O		Ethephon			HEPA	
A	Ĉ PEARL	<b>DELMO</b>	MACRO	PEARL	PELMO	MACRO
	[µ <b>g</b> ]L] /	Ç [μg <b>∕]</b>	[µg/L]	[µg/L]	[µg/L]	[µg/L]
Chateaudun	≈ <b>0</b> .001	<b>&lt;0.001</b>	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg	<0.00	<b>≈</b> 0.001	-	< 0.001	< 0.001	-
Jokioinen «	<0,001	© <0.001	1	< 0.001	< 0.001	-
Kremsmuenster	<b>Q0</b> 001	< 0.001	-	< 0.001	< 0.001	-
Okehampton	<b>©</b> 0.001	< 0.001	-	< 0.001	< 0.001	-
Piacenza	< 0.001	< 0.001	-	< 0.001	< 0.001	-
Porto	< 0.001	< 0.001	1	< 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<sub>gw</sub> results of ethephon and its metabolite (Winter Cereals (late), 1 × 480 g a.s./ha, 90% interception)

Scenario		Ethephon	НЕРА			
	PEARL	PELMO	MACRO	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[fug/L]	[µg/L]
Chateaudun	< 0.001	< 0.001	< 0.001	< 0.001	~~~(0.00 <u>)</u>	<b>≈</b> 0.001
Hamburg	< 0.001	< 0.001	-	<0.001	<0.001	, - , W
Jokioinen	< 0.001	< 0.001	-	\$0.001	≪0.001 €	
Kremsmuenster	< 0.001	< 0.001	-	<0.001	\$\sqrt{0.001}\times	~~- ~~
Okehampton	< 0.001	< 0.001	- 4	J <0.001	<0.00	& -
Piacenza	< 0.001	< 0.001	0	Ø.001	<0.001	
Porto	< 0.001	< 0.001	- 💍	©<0.001	0.001	O.F
Sevilla	< 0.001	< 0.001		<0.001	<0.001	
Thiva	< 0.001	< 0.001		<b>€0,0</b> 01 <u> </u> (	<0.001	W -

Table 9.2.4- 6: FOCUS PEARL and PEL MO PECgw results of ethephon and its metabolite (Spring Cereals (early), 1 × 360 g a.s./ha 60% interception)

Scenario		Ethepkon			<b>INEPA</b>	
	PEARL	PEŁMO 👡	O MAÇ RO	PEARL	<b>P</b> ÉLMO	MACRO
	[µg/L]	[µg/L]	[ <b>pg</b> /L] (	[μ <b>g</b> Φ] _	🥎 [μg/L]	[µg/L]
Chateaudun	< 0.001	°>><0.004>	\$\langle 0.001 \tilde{\infty}	<b>20</b> .001	< 0.001	< 0.001
Hamburg	<0.001 🐇	.0.603	0.	©<0.001	< 0.001	-
Jokioinen	<0.001	<b>\$0</b> ,001		× <0.001	< 0.001	-
Kremsmuenster	<0.00	€0.001	0°	<b>₹0</b> >001	< 0.001	-
Okehampton	<0@01	<0.001	4 O	<b>3</b> 0.001	< 0.001	-
Porto	<b>20</b> .001 €	< 00001		<0.001	< 0.001	-

Table 9.2.4- 7: FOCUS PEARL and PELMO PECgw @sults of ethephon and its metabolite (Spring Cexeals (la@), 1 × 360 g a.s. ha, 90% interception)

Scenario	Ethephon V			НЕРА		
*	PEARL	~CPELMQ	<b>Ø</b> ÅCRO	PEARL	PELMO	MACRO
	[ <b>μg</b> /L]	<u></u> [μg( <b>Ε</b> ]	<b>(μg/L</b> ]	[µg/L]	[µg/L]	[µg/L]
Chateaudun O	\$0.001	<b>₹</b> 0.001 ⋅	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg	©<0.001	C 0.001	ı	< 0.001	< 0.001	-
Jokioine a	<0,001	( <0.00 J	ı	< 0.001	< 0.001	-
Kremsmuenster	≈ <b>0</b> .001	<b>&lt;0,0</b> 01	ı	< 0.001	< 0.001	-
Okehampton	₹<0.00°	<b>0</b> .001	-	< 0.001	< 0.001	-
Porto	~	@ <0.001	-	< 0.001	< 0.001	-

\*\*\*\*



**Report:** KCP 9.2.4.1/03; ; 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. Genetic 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 of

Pesticides in EU Registration, Version 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<sub>w</sub>) were calculated for use in Europe, using the simulation models FOCUS PEARL 4.42 FOCUS PELMO 5.53 and FOCUS MACRO 5.5.4. PEC<sub>gw</sub> were evaluated as the 80<sup>th</sup> 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 pant growth regulator it 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<sub>gw</sub> calculations in alkaline soils were identical to those used for acidio soils (see KCP 9.2.4.1/01). Application data used for PEC<sub>gw</sub> 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 ether hon 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 metalpolite for PECgw calculations

Parameter	Unit	Value	Comment
<b>Ethephon</b>	. *	J	
Molar mass	√g/mol}	144.5	¥-
Water solubility	[mg/L]	\$00000 \$	20 °C, pH 4
			Document KCA 2.5/01, (2002),
	W W		M-206704-01-1
Vapour Pressure	[Pa] 🍣	8-90E-05	25 °C
			Document KCA 2.2/03, (2015),
		<b>&gt;</b>	M-514117-01-1
Freundtich Exponent		0.862	Arithmetic mean (n=4)
			Document KCA 7.1.3.1.1/02, (2015),
			M-539124-01-1
Plant uptake factor	[-]	0	Conservative default value.
Walker Exponent	[-]	0.7	Default value
PEARL Parameters			
Substance code	[-]	ETP	-
DT <sub>50</sub>	[days]	3.8	Laboratory SFO DT <sub>50</sub> (20 °C) value normalised to
	_		pF 2 (geometric mean, n=2, alkaline soils).
			Document KCA 7.1.2.1.1/03,
			(2015), M-534660-01-1



Parameter	Unit	Value	Comment
Molar Activation Energy	[kJ/mol]	65.4	Default value
K <sub>f</sub>	[mL/g]	10.0	Geometric mean (n=4) Document KCA 7.1.3.1.1/02, (2015), M-539124-01-1
PELMO Parameters			
Substance code	[-]	AS	
Rate constant	[1/day]	0.18241	Laboratory rate constant (20°C) normalised to pF 2 (geometric mean n=2, alkaline soils). Equivalent to a SpG DT <sub>50</sub> value of 3/8 d.  Document KGA 7.1 Q.J. 1/03, [2015], M 534660-01-1.
Q <sub>10</sub>	[-]	2.58	Default value " 6 0 0
HEPA		4	
Molar mass	[g/mol]	126.1	
Water solubility	[mg/L]	800000	Define water solubility & 20 °C & pH 4 used as default Document KCA 2.5/07 (2002), M 206704-07-1
Vapour Pressure	[Pa]	8.00E-05	Ethephon vapour pessure v 25 °C used as default.  Document KCA 2.2/03, (2015),  M-5 117-0
Freundlich Exponent		0.943	Arithmetic fream (n=5).  130cumen KCA 3.1.2/01,  (1996) M-166407-01-1.
Plant uptake factor	<sup>*</sup> [-]		Conservative default value.
Walker Exponent	[-]0 *	7 0.7O	Default value
PEARL Parameters	~ ~	& C	
Substance code	(-) <u>J</u>	MEPA	r - S
DT 50			Laboratory SFO DT <sub>50</sub> (20 °C) value normalised to F 2 (geometric mean, n=4) Document KCA 7.1.2.1.2/02,
Molar Activation Energy &	U-1/@ <sub>∞</sub> 11	C (5 K)	(2015), M-534855-01-1 Default value
K <sub>om</sub>	[kJ/@ol]	0 65.4 1868	Calculated from geometric mean K <sub>oc</sub> value assuming conversion factor of 1.724.
PELMO Parameters		**************************************	-
Substance code O	[-] Ô	<b>♥</b> A1	-
Rate constant	A/day]	0.46210	Laboratory rate constant (20 °C) normalised to pF 2 (geometric mean, n=4). Equivalent to a SFO DT <sub>50</sub> value of 1.5 d.  Document KCA 7.1.2.1.2/02,  [(2015), M-534855-01-1.
$Q_{10}$	[-]	2.58	Default value
K <sub>oc</sub>	[mL/g]	3220	Geometric mean (n=5). Document KCA 7.1.3.1.2/01, (1996), M-166197-01-1.
Formation fraction	[-]	1.0	Worst-case default value
Degradation fraction from → to (FOCUS PEARL & MACRO)		1 ETP -> HE	PA .



Parameter	Unit	Value	Comment
Degradation rate from → to (FOCUS PELMO)			tive Substance -> A1 1 -> BR/CO2

**Findings:** PEC<sub>gw</sub> were evaluated as the 80<sup>th</sup> percentile of the mean annual leachate concentration at 1 m soil depth.

PEC<sub>gw</sub> values obtained with FOCUS PEARL, PELMO and MACRO for etherion 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- 15 to Table 9.2.4- 12 for the use in spring cereals.

Table 9.2.4- 9: FOCUS PEARL and PELMO PECgw results of ethephon and its metabolite (Winter Cereals (early), 1 × 480 g a.s./ha, 8% interception)

Scenario		Ethephon	() ()		HEPA	
	PEARL	PELMO	MACRO	<i>@</i> ₩EARL	POLIMO O	MACRO
	[µg/L]	[µg/L]	[µg(L] ->	<u></u> [μg/ <b>L</b> ]	L [μg/L]	μg/L]
Chateaudun	< 0.001	< 0.001	<0.001	\$ <b>0</b> ; <b>0</b> 01 €	<0.001	<b>(</b> 0.001
Hamburg	< 0.001	< 0.001	~ ~ ~	©0.001, ©°	<b>₹0</b> .001	-
Jokioinen	< 0.001	<0.001	5 - 4	<0.001	<b>⊘</b> <0.001	-
Kremsmuenster	< 0.001	<0.001		♥ <0.001 ×	<0.091	1
Okehampton	< 0.001	<0.00	- 4	<b>20</b> .001	<b><q< b=""><b>0</b>001</q<></b>	1
Piacenza	< 0.001	<0,001	Õ - O	\$\langle 0.007	<b>©</b> 0.001	-
Porto	< 0.001	<0.001		O.001	<0.001	ı
Sevilla	< 0.001	~ \$0.00 <u>1</u> O	-	<b>50</b> ,001	<b>∀</b> <0.001	-
Thiva	< 0.001	<0.00°	0, - 4,	<0.001 (S)	< 0.001	-

Table 9.2.4-10: FOCUS PEAR and PELMO PCCgw results of etherhon and its metabolite (Winter Cereals (late), 1 × 480 g a.s./ha/90% interception)

Scenario		Ethephon &	\$ .Q .		HEPA	
	PEARL	<b>PELMO</b>	Macro S	PEARL	PELMO	MACRO
<b>%</b>		Ø [μg/ <b>L</b> ]	Pptg/L]	[µg/L]	[µg/L]	[µg/L]
Chateaudun	< <b>0</b> 001 <sup>(k)</sup>	/ <0.001	× <0.00¥	< 0.001	< 0.001	< 0.001
Hamburg	0.001	<0.001	<u> </u>	< 0.001	< 0.001	ı
Jokioinen	<0.00	~~~0.00 <b>)</b>	~ -	< 0.001	< 0.001	ı
Kremsmuenster		√″<0. <b>061</b> ″	<u>-</u>	< 0.001	< 0.001	ı
Okehampton	Ø.001 🖔	<b>≤6</b> 0001 . €	) <sup>8</sup> -	< 0.001	< 0.001	ı
Piacenza	©<0.001	&0.001	-	< 0.001	< 0.001	ı
Porto S	<0.001	<0.000	-	< 0.001	< 0.001	ı
Sevilla		√	-	< 0.001	< 0.001	-
Thiva	4<0.001	<b>≜</b> 0.001	-	< 0.001	< 0.001	-

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

Scenario	Ethephon			НЕРА			
	PEARL	PELMO	MACRO	PEARL	PELMO	MACRO	
	[µg/L]	[µg/L]	[µg/L]	[µg/L]	[[ug/L]	[µg/L]	
Chateaudun	< 0.001	< 0.001	< 0.001	< 0.001	<0.001	<b>№</b> 0.001	
Hamburg	< 0.001	< 0.001	-	<0.001	<0:001	, - , O,	
Jokioinen	< 0.001	< 0.001	-	\$0.001	≪0.001 €		
Kremsmuenster	< 0.001	< 0.001	-	©*<0.001	~ 0.001 O	~~-	
Okehampton	< 0.001	< 0.001	- 4	<0.001	<0.00	& -	
Porto	< 0.001	< 0.001	0	<b>20</b> .001	₹	Ž V.	

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

Scenario		Ethephon			HEPA 6	Î
	PEARL	PELMO 🔊	MACRO	Q PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	(D)g/L] ©	[ <b>kg/</b> L] , *	ં [μ <b>g</b> /L]	[µg/L]
Chateaudun	< 0.001	<0.000	<0.001	≪\$0.00 <u>1</u> ~Q	<b>Q</b> :001	< 0.001
Hamburg	< 0.001	<0.001 %		~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	్లి 0.001	-
Jokioinen	< 0.001	€0.001 €	** (	/ <0.901 A	<0.001	ı
Kremsmuenster	< 0.001	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	L - B	<b>Q</b> .001	< 0.001	-
Okehampton	<0.001 🖔	/ <0.001 ·		© <0.001	< 0.001	ı
Porto	<0.001	<b>%</b> .001		<0.001	< 0.001	=

# **Conclusion:**

As a precautionary approach two ground cater assessments for acidic and alkaline soils have been conducted for ethephon. A worst case  $D_{50}$  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<sub>sw</sub> values for etherhon and HEPA considering pH dependent adsorption.

New PEC<sub>gw</sub> values for emphon, 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:



980 (n=7, geometric mean) Geometric mean  $K_{Foc}$  (L/kg) at pH < 7

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<sub>50</sub> value of 9.18 days (geometric mean of 12 soils<sup>1</sup>) was used as proposed in the Ethephon (traft RAR 18 Volume 3 CP. New PEC<sub>gw</sub> calculations were only performed for pH > 7 as this was the worstcase approach. All resulting PEC<sub>gw</sub> values were  $< 0.1 \mu g/L$ .

The details of the calculations are summarized in the following table

Table 9.2.4- 13: Application pattern used for PECgw calculations of etherhon

			Applic	ea Coon		
Individual Crop	FOCUS Crop Used for Interception	Rate per Season «	<b>A</b> terval	Plant Inter- ception	BBCH Stage	Amount Reaching the Soil per Season
		[g a.s./hat]	[days]	<b>6</b> [%] &	~ "0	g a.s. /ha]
Winter Cereals (early) (fixed date)	Winter Cereals	1 x 2 80	<u> </u>	800	<b>7</b> -39	1 x 96
Winter Cereals (late)	Winter Cereals	<del>1</del> 480	- 4	<b>3</b> 0	<b>7</b> 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 Cerea	1 & 360	- ,		41-51	1 x 36

**Table 9.2.4-14:** Application dates used for the simulation runs with ethephon Winter Individual crop Winter Winter Spring

06-Apr

15-Apr

11-Apr

29-Apr

15-May

07-May

**Spring Spring** Cereals Cereals Cereals Cereals Cereals Cereals (early) (fixed date) (Dåte) / (early) (fixed date) (late) Every Year Repeat Interval for App. Every Year **Every Year** Exery Year **Every Year Every Year Events** Application Tecknique Spray Spray Spray Spray Spray Spray App. Scenario 1 App. 1st App. 1st App. 1st App. 1st App. Date Date Date Date Date Date Julian (ay) (Julian day (Julian day) (Julian day) (Julian day) (Julian day) Chateaudun 🦏 15-Apr 08-May 21-Apr 15-May 02 May 28-Apr ©(122) (105) (128)(111)(135)(118)**Hamburg ⊘**30-Apr© 15-Apr 06-May 06-May 15-May 11-May  $\sim$ (105) (120) (126)(126)(135)(131)Jokioinen Of Jun 15-Apr 06-Jun 11-Jun 15-May 14-Jun ×152) 🔏 (105)(157)(162)(135)(165)30-Apr 15-Apr 06-May 15-May 11-May Kremsmuenster 06-May (120)(105)(126)(126)(135)(131)Okehampton 22-Apr 24-Apr 15-Apr 29-Apr 15-May 03-May (112)(105)(114)(119)(135)(123)Piacenza 17-Apr 15-Apr 21-Apr (107)(105)(111)

Porto



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
<b>Application Technique</b>	Spray	Spray	Spray	Spray	Spray .	Spray
Scenario	1st App.	1st App.	1st App.	1st App.	1st App.	App
	Date (Julian day)	Date (Julian day)	Date (Julian day)	Date (Julian day)	Date (Judan day)	Date (Julian day)
	(96)	(105)	(101)	(119)	y (135) O	<u>\$</u> (1/27)
Sevilla	18-Jan	15-Apr	25-Jan	\$ - \Q		<b>4</b> -
	(18)	(105)	(2) S	~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~	<u></u>	? Z,°
Thiva	08-Mar	15-Apr	<b>X</b> 2-Mar €	- "	<u>6</u> - 0	Ş
	(67)	(105)	(71)		<u> </u>	<b>~</b> -

Table 9.2.4- 15: Alkaline assessment (for pH 7), Kov = 102 mL/kg, O

FOCUS PEARL, PELM and MACRO PECgw results of thephon for pH > 7) and its metabolite 2-HEPA Winter Cereals (carly), \$\infty 480 g@s./ha, 80% interception).

	s inclabonic 2	<b>A</b>	Circuis (gu	117 ), 100 5	(//)	iter ception).
Scenario		Ethephon			HÆPA	
	PEARL	<b>FELMO</b>	MACRO	<b>VPEAR</b>	PELMO	MACRO
	[µg/L]	C [µg/k]	/[µg/L]	[proved]	© [μg/L]	[µg/L]
Chateaudun	0.001 🗞	<0.001	<sup>∞</sup> <0.001	£0.001 ~	< 0.001	< 0.001
Hamburg	0.055	<b>0</b> .001		Q0.005	< 0.001	-
Jokioinen	0.050	0.00 N	~~- ~ ()	<0.6Q1 <sup>-</sup>	< 0.001	-
Kremsmuenster	<b>©</b> 12	0.001	<b>₹</b> *	<b>≤0</b> .001	< 0.001	-
Okehampton	<b>3</b> 0.068 <b>3</b>	0.001		₹0.001	< 0.001	-
Piacenza	0.013	<b>₹</b> 0.001 <b>₹</b>		<b>©</b> ″ 0.001	< 0.001	-
Porto	Q_Q,47	<0.00		< 0.001	< 0.001	-
Sevilla	©.001 <sub>0</sub> 0	<0.001	- ·	< 0.001	< 0.001	-
Thiva	<0.001	©.001	Y Q	< 0.001	< 0.001	-

Table 9.2.4- 16: FOCUS PEABL, PELATO and MACRO PECgw results of ethephon (for pH > 7) and its metabolic 2-HEFA (Winter Cereals (late), 1 × 480 g a.s./ha, 90% interception).

Scenario Q		Ethephon	-		HEPA	
	PEARL	<b>PELMO</b>	MACRO	PEARL	PELMO	MACRO
	[µg/L]	[pg/L]	[µg/L]	[µg/L]	[µg/L]	[µg/L]
Chateaugun	0.001	0.001	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg 🔷 🔦	) 0.0 <b>85</b>	<0.001	-	0.005	< 0.001	-
Jokioinen	<b>*0.0</b> 10 A	< 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<sub>gw</sub> 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	PPLMO	MACRO		
	[µg/L]	[µg/L]	[µg/L]	[µg/L]	<mark>. «/μg/L] 。</mark>	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	- %	° <0.0 <b>%</b>	<b>₹0.001</b>			
Kremsmuenster	0.012	< 0.001	- 20	<0.001	<0.0 <b>%</b> 1	~~ -		
Okehampton	0.067	0.001	- 0	~\$0.001 €	<0.001	k)		
Piacenza	0.013	< 0.001		<b>2</b> 0.001	Ø.001			
Porto	0.047	< 0.001	O- C	<0,001	<u> </u>	<b>Q</b> '-		
Sevilla	< 0.001	< 0.001	Q - ~	≤0.001	<0.001	<u></u>		
Thiva	< 0.001	<0.001 🐇		0.001	<b>50</b> 001	<del>/</del> -		

Table 9.2.4-18: FOCUS PEARL, PELMO and MACRO PECgw results of Chephon (for pH > 7) and its metabolite 2-HEPA (Spring Cereals Carly), 1 360 g a.s./ha, 80% interception).

Scenario		Ethephon			<b>E</b> PA	•
	PEARL	PELMO	MACRO	PEARL	PELMO	MACRO
	[µg/L]	[µg/L]	°>/[μg/L]Ĉ		y [μg/L]	[µg/L]
Chateaudun	<0.001	<b>20</b> ,001	<0.0001	0.001	< 0.001	< 0.001
Hamburg	0.005	©0.001		<0.061	< 0.001	-
Jokioinen	0,001	<0.001	- ×	<0.001	< 0.001	-
Kremsmuenster	Ø.003	<0.001	~_@	<b>≈</b> 0.001	< 0.001	-
Okehampton	<mark>උ 0.007</mark>	0.001	O ~	© <sup>*</sup> <0.001	< 0.001	-
Porto	<0.001	<sub>4</sub> ©<0.004\$	<b>%</b> - &	< 0.001	< 0.001	-

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

Scenario Scenario		Éthephon			HEPA	
4,"	<b>KEARL</b>	PELMO	MACRO	PEARL	PELMO	MACRO
	© [μg/k]	(pug/L)	[µg/L]	[µg/L]	[µg/L]	[µg/L]
Chateaudun	<sup>9</sup> < 0001	<0.00D	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg 4	905 <sub>P</sub>	<0.001	-	< 0.001	< 0.001	-
Jokioine	© 0.001	<b>0</b> .001	-	< 0.001	< 0.001	-
Kremsmuenster	0.00	0.001	1	< 0.001	< 0.001	-
Okehampton	<b>20.0</b> 07 £	<0.001	-	< 0.001	< 0.001	-
Porto	Q <sub>0.001</sub>	< 0.001	-	< 0.001	< 0.001	-

Table 9.2.4- 20: FOCUS PEARL, PELMO and MACRO PEC<sub>gw</sub> 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			НЕРА		
	PEARL	PEARL PELMO		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	<b>~</b> 0001 <u></u>	*	
Jokioinen	0.001	< 0.001	- %	>° <0.0 <b>%</b>	<b>₹0.001</b>		
Kremsmuenster	0.003	< 0.001	- J	<0.001	<0.0 <b>€</b> U	- ×	
Okehampton	0.007	0.001	- 0	~ 9.001 W	< 0.001	<u> </u>	
Porto	< 0.001	< 0.001	£)	<b>2</b> <0.0010°	Ø.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 sedimen

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

		OApplication /	
Representative crops	Rate per Season	🏂 Interval	Timing of application
\$	joa.s./hap	& [days]	BBCH Stage
Winter Cereals (early)	1 x 480	~ <u>-</u>	37-39
Winter Cereals (late)	1/180		41-51
Spring Cereals (early)	1 x 360 x	o" <sub>~</sub> 0" -	37-39
Spring Cereals (late)	©1 x 360	)	41-51

# PECsw modelling approach

Calculation of PEC Quiues for the active substance according to FOCUS

FOCUS<sub>sw</sub> 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 and PEC sed is calculated.

Step 2: Individual loadings into the water body from different entry routes are considered. Scenarios are also considered for worthern 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.

<u>Step 4:</u> 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<sub>SW</sub>) and sediment (PEC<sub>SED</sub>)

For PEC<sub>sw</sub> and PEC<sub>sed</sub> 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 1823 requires a  $K_f$  value of 10.0 mL/g and the organic carbon content of 5% assumed for sediment at Steps 1824. Although FOCUS Step 3 calculations were not required for surface water risk assessments, a pseudo  $K_{on}$  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 the plant and the pH value of the soils was detected using the German Input Decision tool (JBA, 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 we surface water assessments for acidic and alkaline soils have been conducted for ethephon in agreement with FQCUS (2014) recommendations: For acidic soils the worst case DT<sub>50</sub> of 47.9 days was used for ethephon (see KCP 9.2.5/01) and for alkaline soils a geometric mean DT<sub>50</sub> of 3.8 days from two alkaline soils was used (see KCP 9.2.5/02).

In both surface water assessments geometric mean DT and K values were used for the metabolite HEPA.

**Report:** KCP 9.2.5%02; (2010) (3.2010)

Title: Ethephon (ETP and metabolite: PPCsw, sed FOCU PEUR - Use in winter cereals and

spring cereals in acidic soils in Europe

Report No.: En  $(3^{7}-15-0)$  Document No.: (53926 - 2)

Guideline(s): FOCUS 2001. SANCO/4802/2000 Fev2; FOCUS 2014: Generic Guidance for

Estimating Persistence and Degradation Onetics from Environmental Fate Studies on Pestizides in EU Regulation, Persion 197; 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 HCPA in surface water (PEC<sub>sw</sub>) and sediment (PEC<sub>sed</sub>) were calculated for the use in Europe, employing the tiered FOCUS surface Water approach (FOCUS 2001). All relevant entry routes of compound into surface water oprincipally a combination of spray drift and runoff/erosion or drain row) were considered in these calculations. FOCUS Steps 1 & 2 (version 3.2) were used to calculated values for ethephon and HEPA.

Ethephon is intended focuse 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 (MarMay)	Average crop cover
Winter Cereals	-	1 x 480	Cereals, winter (Arable crops)	Spring (MarMay)	Full canopy
Spring Cereals	-	1 x 360	Cereals, spring (Arable crops)	Spring (MarMay)	Average crop
Spring Cereals	-	1 x 360	Cereals, spring (Arable exops)	Spring (MarMay)	Full camppy

Substance input parameters are summarized in Table 9.2.52.

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

Parameter	Unit	Value	S Comment &
Ethephon		<u> </u>	
Molar mass	[g/mol]	144,49	
Water solubility	[mg/L]	~ <b>\$60</b> 0000	<sup>2</sup> 20 °C O H 4
			Dogument K.C.A 2.5/01, (2002), M-20670401-1
Koc	[mL/g]	<b>29</b> 0	Calculated from the geometric mean K <sub>f</sub> value of
			10.0 © 4) based on an organic carbon content of 5% or sediment.
DT <sub>50</sub> soil	[ďays]	47.09	Reportator SFO DT <sub>50</sub> (20 °C) value normalised to
			pF 2 (worst case value, n=5, acidic soil)  Document KCA 7.1.2.1.1/03,
Q Q		Ö 4	(2015), M-53 (660-01-1
DT <sub>50</sub> total system	[days]	© 2.79°	Laboratory SFO DT <sub>50</sub> (20 °C) value (geometric
	4	* (	Onean (15%), total system, P-I
			Document KCA 7.2.2.3/02,
DT S		2.79	(2008), M-534853-01-1
DT <sub>50</sub> water	[ďaýs] Ĉ	2.1 <b>%</b>	Laboratory SFO DT <sub>50</sub> (20 °C) value (geometric mean, n=2, total system, P-I)
			Document KCA 7.2.2.3/02,
	<i>@</i> 1		(2015), M-534853-01-1
DT <sub>50</sub> sediment	[flays]	<i>2.1</i> 9 °	Laboratory SFO DT <sub>50</sub> (20 °C) value (geometric
		Ş	mean, n=2, total system, P-I)
		~~	Document KCA 7.2.2.3/02, (2015), M-534853-01-1
Maximum occurence in water	[% AR] ©	ر ۲ 100	Parent substance
sediment systems	S AKJ	100	1 arent substance
Maximum occurence in soil	[% A <b>k</b> }/	100	Parent substance
HEPA O			
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, (2002), M-206704-01-1
Koc	[mL/g]	3220	Geometric mean (n=5).
			Document KCA 7.1.3.1.2/03, (1996), M-166197-01-1.



Parameter	Unit	Value	Comment
DT <sub>50</sub> soil	[days]	1.5	Laboratory SFO DT <sub>50</sub> (20 °C) value normalised to
			pF 2 (geometric mean, n=4) Document KCA 7.1.2.1.2/02,
			(2015), M-534855-01
DT <sub>50</sub> total system	[days]	1000	Worst-case default value
DT <sub>50</sub> water	[days]	1000	Worst-case default value
DT <sub>50</sub> sediment	[days]	1000	Worst-case default value
Maximum occurence in water sediment systems	[% AR]	7.4	Maximum % of applied in natural water agricous photogosis study.  Document Ko A 7.2.4.3/01, (2005), M-249376-01-1.
Maximum occurence in soil	[% AR]	10.6	Maximum % of applied in soil photolysis study.  Document KQA 7.1.1.3 01,  (200,1), M-149517-01-1.

# **Findings:**

FOCUS Step 1 and 2: The maximum PEC and BEC sed values for FOCUS Step 1 and 2 are given in the tables below for ethephon (Table 9.25-3) and its metabolite BEPA (Table 9.25-4).

Table 9.2.5- 3: Summary of the PECsw and ECsed values for ether hon (FOCUS Steps 1-2)

Crop Usage	Scenario	Q X		© Ethe	phon		
		PEC	FEC <sub>sed</sub>	7d°S TVYAsw	7d WAsed	21d TWA <sub>sw</sub>	21d TWA <sub>sed</sub>
		fμg/Ll	[µg/kg]	[µg/L] 🐧	¶μg/kg]	[µg/L]	[µg/kg]
Cereals, winter	Step 1	130.7	2\$\textit{2}.6	© 61.68	122.7	24.79	49.38
1 × 480 g a.s./ha	Step 2	L	<b>4</b> 0				
Average crop cover	) N-ĘU	<b>20</b> .46 _	$\bigcirc$ 40.0 $\bigcirc$	<b>9</b> 009	19.35	3.904	7.787
Spring (Mar May)	<b>S</b> ÆŬ	¥39.54 €	78.45°	\$\\.80	37.53	7.559	15.10
Cereals, winter 1 × 480 g a.s./ha	Step 1	130,	<b>2</b> 2.6	61.68	122.7	24.79	49.38
1 × 480 g a.s./ha	Step 2						
Full canopy	y Natu	<b>%</b> 540 a	<sub>≫</sub> ″ 16.1 <b>6</b> €	4.029	7.993	1.620	3.218
Spring (Mar May)	s-Eu	[] 15.69 S	30.46	7.437	14.81	2.991	5.959
Cereals, spring	Step 1	98.05	₿9.5	46.26	92.04	18.60	37.03
1 × 360 g a.s./ha	®tep 2 ≪	( Q'					
Average crop cover	Ø N⊱EU	<b>1</b> \$.35	30.00	7.282	14.51	2.928	5.840
Spring (Mar. May)	<b>S</b> -EU	<b>2</b> 9.65 ~	58.61	14.10	28.15	5.669	11.32
Cereals, spring	Step 1	98.05	189.5	46.26	92.04	18.60	37.03
1 × 360 & a.s./ha	Østep 2 🎸						
Full canopy	Ď Ŋ <b>-</b> ØÚ	°,6,405	12.12	3.022	5.995	1.215	2.414
Spring (Mar. May)	<u>"</u> Š*ĚU	∡¥1.77	22.85	5.578	11.11	2.243	4.469



Table 9.2.5- 4: Summary of the PEC<sub>sw</sub> and PEC<sub>sed</sub> values for HEPA (FOCUS Steps 1-2)

Crop Usage	Scenario	HEPA					
		PECsw	PECsed	7d TWA <sub>sw</sub>	7d TWAsed	21d ©TWAsw	21d TWAsed
		[µg/L]	[µg/kg]	[µg/L]	[µg/kg]	<b>[μg/L]</b>	<sub>e</sub> [μg/kg]
Cereals, winter 1 × 480 g a.s./ha	Step 1 Step 2	5.031	154.5	4.805	154	771	153. <b>4</b>
Average crop cover Spring (Mar May)	N-EU S-EU	0.440 0.805	13.48 25.22	0.419 0. <b>%</b> Å	25.16	0.416	13-38 
Cereals, winter 1 × 480 g a.s./ha	Step 1 Step 2	5.031	154.5	4.805 0	7 154 17	<b>4</b> 771	7 153.4
Full canopy Spring (Mar May)	N-EU S-EU	0.285 0.349	6.133 10.54	0.161	10.51	0.180	6.988 70.46
Cereals, spring 1 × 360 g a.s./ha	Step 1 Step 2	3.774	115%	3,604	115.6	3.578	115.1
Average crop cover Spring (Mar May)	N-EU S-EU	0.330 0.604	40.11 2 \$18.92	0.314	#0.08 4.18.87	0.312	10.03 18.78
Cereals, spring 1 × 360 g a.s./ha	Step 1 Step 2	3.774	115(8	3.604 K	, 115.6	3.578	115.1
Full canopy Spring (Mar May)	N-EU S-EU	0.245 0.261	4.600 7.904	0.1210	**************************************	0.135 0.244	4.566 7.846

**Report:** KCP \$2.5/03; \$\ \text{KCP} \$2.5/03; \$\ \text{KCP} \$2.5/03; \$\ \text{Report}\$

Title: Ethernon (ETP) and metabolite: PECsw sed FOCUS EUR - Use in winter cereals and

spring cereals in alkaline soils in Europe

Report No.: DnSa-15-0899
Document No.: M-539294-02-1

Guideline(s): FOCUS 2001. SANCS ANCS FOCUS 2014: Generic Guidance for

Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on

Resticide in EU Registration, version 1.1; FOCUS 2015: Generic guidance for

FOCUS surface water Scenarios version 1.4.

Guideline dex arion(s) not appricable

GLP/GEP: no

Methods and Materials: Predicted environmental concentrations of the active substance ethephon and its metabolite HEPA in surface water (PEC<sub>sw</sub>) and sediment (PEC<sub>sed</sub>) were calculated for the use in Europe employing the liered 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 steps, 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<sub>sw</sub> 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	- <u>©</u>
Water solubility	[mg/L]	800000	20 °C, pH 4 Document KCA 2.5/0 (2002), M-206704-01-1
Koc	[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 <sub>50</sub> soil	[days]	3.8	Laboratory SFO DT 50 (20 °C) value normalised to pt 2 (geometric mean, n=2 alkaline soils).  Document KCA 7.1.2.1 (93, 120) (2015), M-534060-01.1
DT <sub>50</sub> total system	[days]	2.79	Laboratory SFO DT <sub>50</sub> (20 °C) Value (geometric spean, n=2, total system, Pa) Document KCA 7.1.2.202, (2015) M-534853-01
DT <sub>50</sub> water	[days]	2.790	Laboratory SFO DTS (20 °C) Value (geometric mean, n=2, total system, Pas) Document KCA 7.2.2.3 (2), (2019, M-53853-01-
DT <sub>50</sub> sediment		2.79	Laboratory SFO DT (20 °C) value (geometric racan, n=2 total system, P-I) Document KC (2.2.3/02, (2015), M-534853-01-1
Maximum occurence in water sediment systems	[%]	100	Parent substance
Maximum occurence in oil	[% AR]	00	Paren Substance
HEPA			Ĵ
Molar mass 🦃 🦮	[gRopol]	126:95	$\bar{Q}_{\ell}$
Water solubility	(Img/L)	\$ <b>99</b> 000 %	Ethephon water solubility at 20 °C & pH 4 used as default.  Document KCA 2.5/01, (2002),
		0	M-206704-01-1
Koc W	[mL/g]	\$\frac{3}{2}20	Geometric mean (n=5).  Document KCA 7.1.3.1.2/01,  (1996), M-166197-01-1.
DT <sub>50</sub> soit	[days]	1.5	Laboratory SFO DT <sub>50</sub> (20 °C) value normalised to pF 2 (geometric mean, n=4) Document KCA 7.1.2.1.2/02,  (2015), M-534855-01-1
DT <sub>50</sub> total system	[days]	1000	Worst-case default value
DT <sub>50</sub> water	[days]	1000	Worst-case default value
DT <sub>50</sub> 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, (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, (2001), M-199517-01-1.

# **Findings:**

**FOCUS Step 1 and 2:** The maximum PEC<sub>sw</sub> and PEC<sub>sed</sub> 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 PECsw and PECsed values for ethepholy (FOCOS Steps 1/2)

Cereals, winter   Step 1   130.7   252%   516.8%   122.7   24.79   49.38   1 × 480 g a.s./ha   Step 2   1 × 66.9   16.4%   19.7%   1	Cuan Haara	Caararia			Ethe	<b>X</b>	- X)	
Lag   Lag	Crop Usage	Scenario		T				
Lag   Lag			PECsw	PECsed	7d 🔊	7d	21d	
Cereals, winter         Step 1         130.7         252.6         61.68         122.7         24.79         49.38           1 × 480 g a.s./ha         Average crop cover Spring (Mar May)         N-EU         11.13         21.34         5.264         10.46         2.105         4.211           Spring (Mar May)         S-EU         20.87         40.82         906         19.75         3.983         7.945           Cereals, winter 1 × 480 g a.s./ha 1 × 480 g a.s./ha Full canopy         Step 2         9.157         2.362         4.659         0.950         1.877					1 W Asw	U	I WAS	n Y
1 × 480 g a.s./ha       Step 2         Average crop cover Spring (Mar May)       N-EU Sep 2         1 × 480 g a.s./ha       Step 1 Step 2         1 × 480 g a.s./ha       Step 1 Step 2         Full canopy       N-EU Step 2 N-EU Step 2         1 × 480 g a.s./ha       N-EU Step 2 Step 2         9.157       2.362         4.211         4.211         1 × 480 g a.s./ha       Step 2 Step 2 Step 2         9.157       2.362         4.659       0.950         1.877				~ %/	.[µg/L]	Uμg/kg		<i>.</i>
Average crop cover Spring (Mar May)  Cereals, winter  1 × 480 g a.s./ha  S-EU  11.13  21.34  5.264  10.46  2.106  4.211  7.945  Cereals, winter  1 × 480 g a.s./ha  1 × 480 g a.s./ha  Step 2  Full canopy  N-EU  5.644  9.157  2.362  4.659  0.950  1.877			130.7		<b>☆</b> 61.68,*>	122.7	<b>2</b> 4.79	49.38
Spring (Mar May)         S-EU         20.87         40.82         2006         19.75         3.983         7.945           Cereals, winter 1 × 480 g a.s./ha Full canopy         Step 1 Step 2 N-EU         130.7         253.6         61.68         1227         224.79         49.38           Full canopy         N-EU         5.04         9.157         2.362         4.659         0.950         1.877			11 12			l " O"		4 21 1
Cereals, winter 1 × 480 g a.s./ha Step 2					3. <i>0</i> 004 90006	A	2.1000 3.0083	
1 × 480 g a.s./ha Full canopy  Step 2 N-EU  5.044  9.157  2.362  4.659  0.950  1.877	1 0 1			¥∕ .ſſ		/		
Full canopy N-EU 5.0 2,362 4.659 0 0.950 1.877			130.7		( 01.08 × v	1 2201	Q24.79	49.38
Spring (Mar May)  S-EU  695  16.46  703  8.140  1.650  3.277  Cereals, spring 1 × 360 g a.s./ha Average crop cover Spring (Mar May)  Cereals, spring 1 × 360 g a.s./ha Full canopy S-EU  8.388  98.05  16.00  3.948  7.846  1.587  3.158  5.959  Cereals, spring 1 × 360 g a.s./ha Full canopy S-EU  8.381  8.482  98.05  1.89/5  46.26  92.04  18.60  37.03  3.948  7.846  1.587  3.158  5.959  Cereals, spring 1 × 360 g a.s./ha Full canopy S-EU  8.381  8.686  8.142  3.494  0.712  1.408  Spring (Mar May)  S-BU  8.581  8.581  8.688  8.140  1.587  3.158  3.158  5.959  1.481  2.988  5.959  1.481  2.988  5.959  1.401  1.587  3.158  3			5.00 °	\$9.157 <sub>@</sub>	2,362	A.659	0.950	1.877
Step 1	1.0		<b>©</b> 695 %	16.46	<b>©</b> 103 §	\$\text{8.140}		
1 × 360 g a.s./ha         Step 2         N-EU         8.648         16.00         3.948         9.846         1.587         3.158           Spring (Mar May)         Step 1         98.05         18.66         30.62         92.04         18.60         37.03           Cereals, spring 1 × 360 g a.s./ha         Step 2         98.05         18.95         46.26         92.04         18.60         37.03           Step 2         N-EU         3.481         6.868         1.72         3.494         0.712         1.408           Spring (Mar May)         S-BU         8.521         12.35         3.077         6.105         1.237         2.458	Cereals, spring	Step 1	گُر 98.05 م	189.5	46.26	92.04	18.60	37.03
Average crop cover Spring (Mar May)  Cereals, spring 1 × 360 g a.s./ha Full canopy Spring (Mar May)  Sept	1 × 360 g a.s./ha	Step 2		4	) Q'			
Spring (Mar May)  Sept	Average crop cover	N-EU	8 948	Q16.00	3.948			
Cereals, spring 1 × 360 g a.s./ha Full canopy Spring (Mar May) Sel 1 × 98.05   189.5   46.26   92.04   18.60   37.03   1.408   1.40	Spring (Mar May)	Sepa	(P3.66)	30.62	**************************************	/		
Full canopy N-EU 3.481	Cereals, spring	Step 1	98.05	189%.5	@ 46.26	92.04	18.60	37.03
Spring (Mar May) Set 12.35 2.458  Spring (Mar May) Set 2.458	1 × 360 g a.s./na Full canony	N-FII	- 3.∜81		1.79	3 494	0.712	1 408
	Spring (Mar May)	S-BU	48.521 <i>6</i>	12.35	3977			



Table 9.2.5- 7: Summary of the PECsw and PECsed values for HEPA (FOCUS Steps 1-2)

Crop Usage	Scenario	НЕРА					
		PECsw	PECsed	7d TWA <sub>sw</sub>	7d TWA <sub>sed</sub>	21d	21d TWA <sub>sed</sub>
		[µg/L]	[µg/kg]	[µg/L]	[µg/kg]	<b>[μg/L]</b>	[μg/kg]
Cereals, winter 1 × 480 g a.s./ha	Step 1 Step 2	5.031	154.5	4.805	154	<b>4</b> ,771	5 153. <b>₽</b>
Average crop cover Spring (Mar May)	N-EU S-EU	0.296 0.517	8.837 15.95	0.276 0. <b>49</b> 6	\$2816 \$15.91	0.273 0.493	8.773 5.83
Cereals, winter 1 × 480 g a.s./ha	Step 1 Step 2	5.031	154.5	4.805	7 154 17	<b>4</b> 771	7 153.4
Full canopy Spring (Mar May)	N-EU S-EU	0.285 0.285	4.394 7.060	0.134) 0.176	7.043 0	0.1350° 0.2694°	4%3/62 7.009
Cereals, spring 1 × 360 g a.s./ha	Step 1 Step 2	3.774	115%	*3,604 £	115.6	3.578	115.1
Average crop cover Spring (Mar May)	N-EU S-EU	0.222 0.387	%6,628 \$11.96,	0.207	612	0.205	6.580 11.87
Cereals, spring 1 × 360 g a.s./ha	Step 1 Step 2	3.774	115(8	\$.604 <	) 115.66	3.578	115.1
Full canopy Spring (Mar May)	N-EU S-EU	0.214	3.295 5.295	0.101	3287 3.282 0	0.101 0.153	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<sub>50</sub> of 47.9 days was used for ethephon in the surface water assessments in acidic soils and a geometric mean DT<sub>50</sub> 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 FOCD'S requirements were:

### **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.

# Route and rate of degradation in air and transport via @ir **CP 9.3.1**

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

# Estimation of concentrations for other outes of exposure **CP 9.4**

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