

ENTOMELA 50SL/ENT50

DOCUMENT M-CP, Section 9

FATE AND BEHAVIOUR IN THE ENVIRONMENT

Version history¹

Date	Data points containing amendments or additions and brief description	Document identifier and version number
November 2019	CP 9.1.3 and CP 9.2: new PECs, PECsw and PECgw calculations are provided.	M-CP Section 9 - ENT HP version 2

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

PHYTOPHYL manufactures “Hydrolysed Protein” which is made of Beet molasses and Urea. Both of them are used very widely for many years and have not ever classified as dangerous substances.

Beet molasses are a natural by-product of the sugar industry, defined as the end product of sugar manufacture or refining from which no more sugar may be economically crystallized by conventional means.

Beet molasses mainly used for two purposes, Animal feed additive and Alcohol Production.

There is no evidence in bibliography that Beet molasses are for some reason toxic, irritant or ecologically unsafe.

PHYTOPHYL & FORESTRY COMMISSION notified urea according to 91/414 and the substance is now approved under Reg. (EC) No 1107/2009. No toxicity studies were submitted but literature data about the toxicity of urea indicated limited toxicological potential.

During this first notification and inclusion Urea was not registered to ECHA but now has a full registration, the dossier is evaluated and there are 163 active registrants as a high volume chemical (production of 10.000 000 – 100.000.000 TONNES per year).

The annual application rate for urea, or hydrolysed protein in case of ENTOMELA 50SL for 6 applications per year according to the table of intended uses (CP 3.3) is:

Application rate per year for each active substance and total nitrogen content (6 applications/year)	
Hydrolysed protein	1.8kg – 2.08 kg/ha
Urea	0.576 kg – 0.648kg kg/ha
Total nitrogen content	0,288-0.333kg/ha

These rates are very low if we compare them to the annual application rates for urea as fertilizer which are reported to the ECHA site and are 60kg, 120kg, 180kg N/ha.

We can see that the use of Nitrogen fertilizers emits 180-540 times more nitrogen to the environment than the use of ENTOMELA 50SL for bait sprays and the quantities of urea and beet molasses that liberated to the environment are very low in comparison to the use of similar compounds as fertilizer or other uses, or even the quantities of them in wastewater of human origin or the excreta of animals.

PHYTOPHYL submit a DRR for ENTOMELA 50SL on 2015 according to reg. 1107/2009 and below are the Overall comments of zRMS on environmental fate section:

zRMS EL: We agree with applicant's argumentation. No Environmental Risk is expected through the use of the two active substances Urea & Hydrolysed protein.

CP 9.1.1 Rate of degradation in soil

A GLP ready biodegradability study (Modified Sturm Test) according to the OECD 301 B Guideline (CO₂ evolution test) has been performed by Noack Laboratorien. Based on personal communication with the study director, it was confirmed that the test item is 'readily biodegradable' according to the criteria specified in the OECD guideline. At the time of writing of this update, the final report of the OECD 301 B study was not yet available (foreseen March 2020). However, in the PEC calculations presented below, ready biodegradability was already assumed.

CP 9.1.1.1 Laboratory studies

CP 9.1.1.2 Field studies

CP 9.1.1.2.1 Soil dissipation studies

CP 9.1.1.2.2 Soil accumulation studies

CP 9.1.2 Mobility in soil

CP 9.1.2.1 Laboratory studies

CP 9.1.2.2 Lysimeter studies

CP 9.1.2.3 Field leaching studies

CP 9.1.3 Estimations of concentrations in soil

Predicted environmental concentrations in soil (PECs)

The PECs is calculated for the active substances hydrolysed proteins and urea according to the critical GAP shown below (Table 9.1.3-1).

Table 9.1.3-1: Critical use for PEC_{soil} calculations

Crop	Dose rate
Olive trees	6 x 347 g hydrolysed protein/ha and 6 x 108 g urea/ha, with a minimum interval of 15 days

CP 9.1.3.1 Active substance(s) and relevant metabolite(s)

The PECs calculations for hydrolysed protein are performed according to FOCUS guidelines. Tables 9.1.3-2 and 9.1.3-3 show the input parameters that were used in the calculation.

Table 9.1.3-2: Input parameters related to application for PEC_{soil} calculations

Crop	Fruit trees (covering olive trees)
Application rate (g as/ha)	hydrolysed protein: 6 x 347 urea: 6 x 108
Number of applications/interval	Max. 6 applications with a min. interval of 15 days
Crop interception (%)	Interception values according to Appendix C of the EFSA Guidance to obtain DegT50 values (2014): Apple: 65% (BBCH \geq 71)
Depth of soil layer (cm)	5

Table 9.1.3-3: Input parameter for the active substance for PEC_{soil} calculations

Compound	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
Hydrolysed protein	30	Preliminary results of the biodegradability test (OECD 301/310) showed that both actives are readily biodegradable. Default DT ₅₀ value for readily biodegradable substances with a solid-water partition coefficient in soil (Kp _{soil}) <100 l/kg, in accordance with ECHA's Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment (Table R.16-12 for soil).
Urea	30	Note: Kp _{soil} can be calculated as Foc _{soil} x Koc, with Foc _{soil} =0.02 (default value) and Koc=10 (default value; worst case value when considering KOWWIN v. 1.68 (EPI Suite) QSAR predictions of octanol-water partition coefficients for amino acids and peptides (<0)).

Table 9.1.3-4: PEC_{soil} for hydrolysed protein on fruit trees (covering olive trees)

PEC _{soil} (mg/kg)		Fruit trees	
		Multiple applications	
		Actual	TWA
Initial		0.484	0.484
Short term	24h	0.473	0.478
	2d	0.462	0.473
	4d	0.441	0.462
Long term	7d	0.412	0.447
	14d	0.350	0.413
	21d	0.298	0.383
	28d	0.253	0.356
	50d	0.152	0.287
	100d	0.048	0.189

The max. PECs for hydrolysed proteins is 0.484 mg/kg. This value can be expressed as total nitrogen content by dividing it by a protein factor of 6.25. This leads to a maximum PECs of 0.077 mg/kg total nitrogen.

Table 9.1.3-5: PEC_{soil} for urea on fruit trees (covering olive trees)

PEC_{soil} (mg/kg)		Fruit trees	
		Multiple applications	
		Actual	TWA
Initial		0.151	0.151
Short term	24h	0.147	0.149
	2d	0.144	0.147
	4d	0.137	0.144
Long term	7d	0.128	0.139
	14d	0.109	0.129
	21d	0.093	0.119
	28d	0.079	0.111
	50d	0.047	0.089
	100d	0.015	0.059

The max. PECs for urea is 0.151 mg/kg. This value can be expressed as ureic nitrogen content by multiplying it by 28/60, which accounts for the ratio in molecular weight. This leads to a maximum PECs of 0.070 mg N/kg.

In this case the combined exposure for nitrogen cannot be calculated by summing the nitrogen content of the two a.s. because:

The hydrolysed protein content/6.25 = Total nitrogen content = Ureic nitrogen + Other nitrogen forms
 Since Ureic nitrogen is already a part of the total nitrogen used in the calculation of the hydrolysed proteins content, this total nitrogen content equals the combined exposure of nitrogen for the two active substances.

Therefore, the max total $PEC_{sw\text{ nitrogen}}$ = 0.077 $\mu\text{g /kg}$

CP 9.2 Fate and Behaviour in Water and Sediment

CP 9.2.1 Aerobic mineralisation in surface water

CP 9.2.2 Water/sediment study

CP 9.2.3 Irradiated water/sediment study

CP 9.2.4 Estimation of concentrations in groundwater

CP 9.2.4.1 Calculation of concentrations in groundwater

Predicted environmental concentrations in groundwater (PEC_{GW})

The PEC_{GW} is calculated for the active substances hydrolysed proteins and urea according to the critical GAP shown below (Table 9.2.4.1-1).

Table 9.2.4.1-1: Critical GAP for PEC_{GW} calculations

Crop	Dose rate
Olive trees	6 x 347 g hydrolysed protein/ha 6 x 108 g urea/ha

The PEC_{GW} is calculated for the active substances by means of FOCUS PEARL v4.4.4 and FOCUS PELMO v5.5.3 for the representative use. Tables 9.2.4.1-2 and 9.2.4.1-3 show the input parameters that were used in the calculation.

Table 9.2.4.1-2: Input parameters related to application for PEC_{gw} calculations

Crop	Apple (covering olive trees)
Application rate (g as/ha)	Hydrolysed protein: 6 x 347 Urea: 6 x 108
Number of applications/interval (d)	6 applications, minimum 15 days interval
Application dates	Worst-case: first application on the 1 st of April
Crop interception (%)	Apple: 65% → appl. rate of 6 x 122 g/ha of hydrolysed protein and 6 x 38 g/ha urea
Frequency of application	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3

Table 9.2.4.1-3: Input parameters related to active substance hydrolysed protein for PEC_{gw} calculations

Compound	Hydrolysed protein	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	105.1	lowest molecular weight for an amino acid as worst case value
Water solubility (g/L):	1000	FOCUS default
Saturated vapour pressure (Pa):	1×10^{-5}	Chosen as non-volatile as a worst-case approach
DT ₅₀ in soil (d)	30	Preliminary results of the biodegradability test (OECD 301/310) showed that both actives are readily biodegradable. Default DT ₅₀ value for readily biodegradable substances with a solid-water partition coefficient in soil (K _{psoil}) <100 l/kg, in accordance with ECHA's Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment (Table R.16-12 for soil)
K _{foc} (mL/g)/K _{fom}	10/5.9	FOCUS default
1/n	1	FOCUS default
Plant uptake factor	0	FOCUS default

Table 9.2.4.1-4: Input parameters related to active substance urea for PEC_{gw} calculations

Compound	Urea	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	60.1	
Water solubility (g/L):	1000	FOCUS default
Saturated vapour pressure (Pa):	159.99×10^{-5}	
DT ₅₀ in soil (d)	30	Default DT ₅₀ value for readily biodegradable substances with a solid-water partition coefficient in soil (K _{psoil}) <100 l/kg, in accordance with ECHA's Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment (Table R.16-12 for soil)
K _{foc} (mL/g)/K _{fom}	10/5.9	FOCUS default
1/n	1	FOCUS default
Plant uptake factor	0	FOCUS default

Tables 9.2.5.1-5 and 9.2.4.1-6 summarise the results of the PEC_{GW} calculations for 'hydrolysed proteins' with FOCUS PEARL and FOCUS PELMO respectively.

Table 9.2.4.1-5: PEC_{gw} for hydrolysed protein on apple (with FOCUS PEARL 4.4.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)
		Hydrolysed protein
Apple 6 x 347 g/ha	Châteaudun	53.77
	Hamburg	94.02
	Jokioinen	72.39
	Kremsmünster	39.01
	Okehampton	34.74
	Piacenza	23.53
	Porto	14.61
	Sevilla	39.13
	Thiva	30.29

Table 9.2.4.1 -6: PEC_{gw} for hydrolysed protein on apple (with FOCUS PELMO 5.5.3)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)
		Hydrolysed protein
Apple 6 x 347 g/ha	Châteaudun	42.81
	Hamburg	40.70
	Jokioinen	52.39
	Kremsmünster	39.04
	Okehampton	39.50
	Piacenza	32.97
	Porto	18.42
	Sevilla	30.70
	Thiva	24.21

Tables 9.2.5.1-7 and 9.2.4.1-8 summarise the results of the PEC_{GW} calculations for urea with FOCUS PEARL and FOCUS PELMO respectively.

Table 9.2.4.1-7: PEC_{gw} for urea on apple (with FOCUS PEARL 4.4.4)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)
		urea
Apple 6 x 108 g/ha	Châteaudun	16.75
	Hamburg	29.29
	Jokioinen	22.55
	Kremsmünster	12.15
	Okehampton	10.82
	Piacenza	7.33
	Porto	4.55
	Sevilla	12.19
	Thiva	9.43

Table 9.2.4.1-8: PEC_{gw} for urea on apple (with FOCUS PELMO 5.5.3)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)
		urea
Apple 6 x 108 g/ha	Châteaudun	13.33
	Hamburg	12.68
	Jokioinen	16.32
	Kremsmünster	12.14
	Okehampton	12.30
	Piacenza	10.27
	Porto	5.74
	Sevilla	9.56
	Thiva	7.55

The highest PEC_{gw} value for urea results from the PEARL calculations Hamburg scenario, which amounts to 29.29 µg/L. When the exposure is expressed in nitrogen content, the max PEC_{gw} equalizes 13.67 µg N/L.

For hydrolysed proteins the highest PEC_{gw} value is also observed for the PEARL Hamburg scenario, i.e. 94.02 µg/L. When expressed in nitrogen content, the max PEC_{gw} for hydrolyzed proteins amounts to 15.04 µg N/L.

In this case the combined exposure for nitrogen cannot be calculated by summing the nitrogen content of the two a.s. because:

The hydrolysed protein content/6.25= Total nitrogen content = Ureic nitrogen + Other nitrogen forms

Since Ureic nitrogen is already a part of the total nitrogen used in the calculation of the hydrolysed proteins content, this total nitrogen content equals the combined exposure of nitrogen for the two active substances.

The max PECgw for total nitrogen content exceeds the threshold of 0.1 µg/L. However, this does not cause an unacceptable risk to groundwater, since the max PECgw of 15.04 µg/L is far below the threshold set for nitrogen in the Council Directive 91/676/EEC concerning the protection of waters against pollution caused by nitrates from agricultural sources. This limit, which equals 22.58 mg N/L, is almost 1000 times higher than the max PECgw, which is 15.04 µg N/L.

Moreover, the acceptable risk is confirmed by the fact that the total amount of nitrogen applied per hectare per year is 333 g for the representative product, which is well below the limit set of 77 kg/ha nitrogen, which is the total amount of nitrogen that - according to the Nitrate Directive - can be applied in nitrate vulnerable zones.

CP 9.2.4.1 Additional field tests**CP 9.2.5 Estimation of concentrations in surface water and sediment****Predicted environmental concentrations in surface water (PEC_{sw})****Predicted environmental concentrations in sediment (PEC_{sed})**

The PEC_{sw} is calculated for the active substance hydrolysed proteins whereby a risk envelope approach is used with a worst-case use with only one application at a higher, lumped dose rate.

For the second active substance urea, in accordance with hydrolysed protein, also only one application equal to the total individual dose rates is assumed.

Table 9.2.5-1: Critical GAP for PEC_{GW} calculations

Crop	Dose rate
Olive trees	1 x 3629 g Hydrolysed protein/ha 1 x 108 g urea/ha

CP 9.2.5.1 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

The PEC_{sw} is calculated for the active substance by means of FOCUS Steps 1-2 for the representative use in olives. Tables 9.2.5-2 and 9.2.5-3 show the input parameters that were used in the calculations.

Table 9.2.5-2 Input parameters related to PEC_{sw/sed} calculations

Crop	Olives
Application rate (g as/ha)	Hydrolysed protein: 6 x 347 Urea: 6 x 108
Number of applications/interval (d)	Maximum 6 applications with a minimum interval of 15 days
Application window	Mar – May/Jun-Sep Southern Europe
Application method	Spraying
Interception class (relevant for STEP 2)	Average cover
Models used for calculation	FOCUS STEP 1-2

Table 9.2.5-3 Input parameters related to hydrolysed protein for $PEC_{SW/sed}$ calculations

Compound	Hydrolysed protein	Value in accordance to EU endpoint / Reference
Water solubility (g/L)	1000	FOCUS default
Diffusion coefficient in water (m ² /d)	4.3×10^{-5}	FOCUS default
Diffusion coefficient in air (m ² /d)	0.43	FOCUS default
K_{foc} (mL/g)	10 (for PEC_{sw})/10000 (for PEC_{sed})	FOCUS default
Freundlich Exponent 1/n	1	FOCUS default
Plant Uptake	0	FOCUS default
$DT_{50,soil}$ (d)	30	Default DT_{50} value for readily biodegradable substances with a solid-water partition coefficient in soil (K_{psoil}) <100 l/kg, in accordance with ECHA's Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment (Table R.16-12 for soil).
$DT_{50,water}$ (d)	15	Default DT_{50} value for readily biodegradable substances, in accordance with ECHA's Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment (Table R.16-11 for surface water).
$DT_{50,sed}$ (d)	1000	FOCUS default
$DT_{50,whole\ system}$ (d)	1000	FOCUS default

Table 9.2.5-4 Input parameters related to urea for $PEC_{SW/sed}$ calculations

Compound	Urea	Value in accordance to EU endpoint / Reference
Water solubility (g/L)	1000	FOCUS default
Diffusion coefficient in water (m ² /d)	4.3×10^{-5}	FOCUS default
Diffusion coefficient in air (m ² /d)	0.43	FOCUS default
K_{foc} (mL/g)	10 (for PEC_{sw})/10000 (for PEC_{sed})	FOCUS default

Compound	Urea	Value in accordance to EU endpoint / Reference
Freundlich Exponent 1/n	1	FOCUS default
Plant Uptake	0	FOCUS default
DT _{50,soil} (d)	30	Default DT ₅₀ value for readily biodegradable substances with a solid-water partition coefficient in soil (K _{psoil}) <100 l/kg, in accordance with ECHA's Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment (Table R.16-12 for soil).
DT _{50,water} (d)	15	Default DT ₅₀ value for readily biodegradable substances, in accordance with ECHA's Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment (Table R.16-11 for surface water).
DT _{50,sed} (d)	1000	FOCUS default
DT _{50,whole system} (d)	1000	FOCUS default

Predicted concentrations in surface water and sediment were determined using FOCUS Steps 1-2 calculations. The results are shown in Table 9.2.5-5 (hydrolysed proteins) and Table 9.2.5-6 (urea).

Table 9.2.5-5 FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for hydrolysed protein following six applications (6 x 347 g/ha) to olive trees

Olives					
Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
Step 1	---	794	---	786.9	5600
Step 2	---		---		
Southern Europe	March-May	54.69		35.14	620.25
	June-Sept	45.37		29.14	554.35

Table 9.2.5-6 FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for urea following six applications (6 x 108 g/ha) to olive trees

Olives					
Scenario	Waterbody	Max PEC _{sw} (µg/L)	Dominant entry route	21 d- PEC _{sw, twa} (µg/L)	Max PEC _{sed} (µg/kg)
FOCUS					
Step 1	---	247.12	---	244.9	1740
Step 2	---		---		

Olives					
Scenario	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- PEC_{sw, twa} (µg/L)	Max PEC_{sed} (µg/kg)
FOCUS					
Southern Europe	March-May	17.02		10.94	193.05
	June-Sept	14.12		9.07	172.54

The max PEC_{sw} for hydrolysed proteins for olives to be used in the risk assessment is 54.69 µg/L, resulting from Step 2 scenario March-May, which amounts to 8.75 µg/L expressed as total nitrogen.

The max PEC_{sw} for urea for olives to be used in the risk assessment is 17.02 µg/L, resulting from Step 2 scenario March-May, which amounts to 7.94 µg/L expressed as total nitrogen.

In this case the combined exposure for nitrogen cannot be calculated by summing the nitrogen content of the two a.s. because:

The hydrolysed protein content/6.25= Total nitrogen content = Ureic nitrogen + Other nitrogen forms
 Since Ureic nitrogen is already a part of the total nitrogen used in the calculation of the hydrolysed proteins content, this total nitrogen content equals the combined exposure of nitrogen for the two active substances.

Therefore, the max total PEC_{sw nitrogen} = 8.75 µg /L

CP 9.3 Fate and Behaviour in Air

The 'hydrolysed proteins' are a complex mixture, mainly containing amino acids and peptides. Vapour pressure is a physico-chemical parameter that cannot be measured for mixtures. Hence, the data requirement for a study on vapour pressure is waived, based on the fact that such a study is not technically feasible. A reasoned case is presented below to describe the volatility based on the composition of the respective sources of 'hydrolysed proteins', e.g. amino acids and urea.

A relevant parameter to describe the potential volatilization of the components from the technical active substance (aqueous solution) is Henry's Law Constant, as this describes the partitioning between the aqueous and the gas phase.

For amino acids, Henry's Law Constants at 25°C are reported to be between 10^7 and 10^{13} M/atm (ref. 1), corresponding to 10^2 to 10^8 mol/(m³.Pa). Expressed in its dimensionless form (i.e. as the ratio of concentration in the aqueous phase to the concentration in the gas phase) this gives 2.5×10^5 to 2.5×10^{11} .

For urea, the Henry's Law Constant at 25°C is estimated as 1.74×10^{-12} atm-cu m/mole (SRC) based upon its vapor pressure of 1.20×10^{-5} mmHg, and water solubility of 5.45×10^5 mg/l (ref. 2). This corresponds to 6×10^6 mol/(m³.Pa) or 1×10^{10} in its dimensionless form.

Taken together, the main components of the hydrolysed proteins mixtures have a ratio of concentration in the aqueous phase to concentration in the gas phase of $>10^5$. Therefore, they can be considered to have a very low potential for volatilisation from water, as well as from moist soil.

In addition, amino acids are very short-lived in air, going by their estimated half-lives in air due to reaction with hydroxyl radicals. According to estimations with AOPWin v. 1.92a (Sept 2010) (EPISuite 4.1; US EPA), the half-life of e.g. arginine at 25°C is 0.946 hours, for leucine 3.034 hours, for glycine 4.578 hours.

It is noted that the putative mode of action of the 'hydrolysed proteins' is to attract insects, following spraying of the 'hydrolysed proteins' formulations and subsequent evolvment of small-molecule volatile compounds with organoleptic qualities attracting flies (e.g. NH₃). These biologically active compounds only emerge on-site in minor quantities.

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

Predicted environmental concentrations from airborne transport

CP 9.4 Estimation of Concentrations for Other Routes of Exposure

¹ Compilation of Henry's Law Constants for Inorganic and Organic Species of Potential Importance in Environmental Chemistry; R. Sander; Air Chemistry Department Max-Planck Institute of Chemistry, Mainz, Germany. Version 3 (February 17, 1999).

² Hazardous Substance Database (HSDB) : urea

