NUTREL/SIC

DOCUMENT M-CP, Section 9

FATE AND BEHAVIOUR IN THE ENVIRONMENT

Version history[1]

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 - SICIT 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

Introduction

This document summarises the information related to the fate and behaviour in the environment for the plant protection product NUTREL (registration number 11502), containing the active substances Hydrolysed proteins, which is included into Annex I of Directive 91/414 *(2008/127/EC)* 18 December 2008, with extension of approval till 31th August 2019 (please refer to Directive 2008/127/EC) for Hydrolysed proteins.

Data on Hydrolysed proteins are compiled in the AII data on Hydrolysed proteins submitted by the company SICIT 2000 SpA (Letter of access is not provided by the applicant because it is notifier), the Draft Assessment Report for Hydrolysed proteins[1], the Final Review Report of the active substance Hydrolysed proteins (SANCO/2615/08–rev.3, 27th October 2008) and the EFSA Scientific Report of 2012[2].

Hydrolysed Protein notified by three applicants seeking the inclusion of hydrolysed proteins in Annex I of Directive 91/414/EEC.

According to the Notifier (Sicit 2000 SpA), the product does not cause negative transformations in the environment if it is used following the suggested dosages and the suggested conditions. The product is completely degradable but if present in copious quantities can pollute ground and surface water: it is necessary to prevent concentrated product from penetrating into ground and surface waters. The product is constituted by natural substances and consequently is completely biodegradable. Reasonably there are not negative effects on the environment.

Concentrations of NUTREL in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, surface water, sediment, groundwater and air are provided. The long-term concentrations are based on results obtained for the active substance contained in the formulation. Full details of all the proposed uses pattern that will be assessed is included in Appendix 1 and summarised in Table 9-1.

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[1] Draft Assessment Report for Hydrolysed proteins , September 2008

[2] EFSA Journal 2012; 10(2): 2545 Conclusion on the peer review of pesticide risk assessment of the active substance hydrolysed proteins

Table 9-1 Critical use pattern of NUTREL

Use	Application rate (g ai/ha)	Application method	Number of applications	Minimum application interval (days)	Application timing
Olive trees	300 -1000 g	Broadcast air-assisted sprayer. Pressure water pumps with spear launches.	2 - 4	P*	BBCH 7°
Pome fruits	300 1000 g		2 - 4	P*	BBCH 7°
Stone fruits	300 1000 g		2 - 4	P*	BBCH 7°
Walnut	300 1000 g		2 - 4	P*	BBCH 7°
Citrus spp.	300 1000 g		2 - 4	P*	BBCH 7°
Fig	300 1000 g		2 - 4	P*	BBCH 7°
Kiwi	300 1000 g		2 - 4	P*	BBCH 7°
Blueberries	300 1000 g		2 - 4	P*	BBCH 7°

°Development of fruits, the growth stage depends on the authorized insecticide utilized in mixture (BBCH 71-79) * Not required for the active substance itself. Refer to the authorized insecticide utilized in mixture.

The impact of formulants is limited to short-term effects such as formation of stable spray dispersions or to facilitate uptake by target organisms, while their influence on long-term processes, such as degradation and distribution is negligible. Therefore, for the purposes of this risk assessment it is assumed that formulants do not influence the fate and behaviour of an active substance in the environment and are not considered further.

In concluded, the product is constituted by natural substances and consequently is completely degradable.

CP 9.1.1 Rate of degradation in soil

A GLP ready biodegradability study (Modified Sturm Test) according to the OECD 301 B Guideline (CO_2 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.

The information regarding the EU endpoints for the rate of degradation of Collagen Protein Hydrolysate are presented in the table below.

Agreed EU End-points used in the Evaluation (EFSA Journal 2012; 10(2):2545)

End-Point	**Hydrolysed proteins**
Geometric mean DT_{50} / DT_{90} (Aerobic conditions, Laboratory studies)	No data submitted
Geometric mean DT_{50} / DT_{90} (Aerobic conditions, Field studies)	No data submitted
DT_{50} / DT_{90} (Anaerobic conditions, Laboratory studies)	No data submitted Not required
pH dependence	No data submitted
Soil accumulation and plateau concentration	No data submitted
Soil adsorption/desorption	No data submitted

Summary

The rate of degradation in soil of **Hydrolysed proteins** was evaluated during the Annex I Inclusion. No additional studies have been performed.

The fate and behaviour of **Hydrolysed proteins** in soil is discussed in detail in the corresponding document of the EU review dossier where the study references can be found.

Investigation of the route of degradation of **Hydrolysed proteins** did not show any metabolite needing further consideration with respect to soil or groundwater contamination.

Degradation rate experiments show that **Hydrolysed proteins** exhibits very low persistence in soil under laboratory conditions. Therefore:

Mineralization after 100 days	No data submitted
Non-extractable residue after 100 days	No data submitted
Metabolites requiring further consideration : name and/or code, % of applied (range and maximum)	No data submitted

Supplemental studies on Route of degradation in soil

Anaerobic degradation	
Mineralization after 100 days	No data submitted
Non-extractable residue after 100 days	No data submitted
Metabolites that may require further consideration for risk assessment: name and/or code, % of applied (range and maximum)	No data submitted
Soil photolysis	
Metabolites that may require further consideration for risk assessment: name and/or code, % of applied (range and maximum)	The photolysis in soil shows that is unlikely to be a significant route of dissipation compared with biotic degradation in the absence of light No data submitted

New annex II data must only be included if they are considered essential for the evaluation and in this case a full study summary must be provided.

CP 9.1.1.1 Laboratory studies
Aerobic degradation of the preparation in soil

The hydrolysed proteins are biodegradable, so their persistence in the environment is very short, without existing any tendency to bioaccumulation.

Studies on aerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. These data are summarised in the tables 9.1.1-1.

Table 9.1.1-1: Summary of aerobic degradation rates of Hydrolysed proteins in laboratory soils

Parent	Aerobic conditions						
Soil type	X[1]	pH ($CaCl_2$)	t °C / % MWHC	DT_{50} / DT_{90}	DT_{50} 20°C pF2/10kPa	St (r^2)	Method of calculation
Sandy loam		4.4	20°C/MWHC	/	/	/	Non linear model (SFO)
Silty clay loam		5.7	20°C/MWHC	/	/	/	Non linear model (SFO)
Sandy loam		7.4	20°C/MWHC	/	/	/	Non linear model (SFO)
Clay loam		7.4	20°C/MWHC	/	/	/	Non linear model (SFO)
Sandy loam		4.4	10°C/MWHC	/	/	/	Non linear model (SFO)
Geometric mean*				/	/		Non linear model (SFO)

**Geometnc mean based on the four values at 20°C*

Legend

MWHC: pF2: SFO: 10kPa :

Maximum Water Holding Capacity
Digital Flow Switch for Water: Series PF2W
A Toolbox for Submodular Function Optimization Pressure units

No data submitted

CP 9.1.1.1.1 Anaerobic degradation of the preparation in soil

Studies on anaerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. During the EU review, no study to investigate the behaviour of Hydrolysed Proteins was found to be required. The same applies to the formulation.

CP 9.1.1.2 Field studies

The rate of degradation in soil of Hydrolysed proteins in field studies was evaluated during the Annex I Inclusion. No additional studies have been performed. The information regarding the EU endpoints, calculated from the field studies, for Hydrolysed Proteins are presented in the table below.

Agreed EU End-points used in the Evaluation (EFSA Journal 2012; 10(2):2545)

End-Point	Hydrolysed Proteins
DT_{50} / DT_{90} (aerobic conditions, field)	No data submitted

Summary
The field dissipation rates of Hydrolysed proteins were evaluated during the Annex I Inclusion. No additional studies have been performed. Results from the field dissipation studies on Hydrolysed Proteins are given in Table 9.1.1.2.

Table 9.1.1.2: Summary of the field soil dissipation of Hydrolysed proteins

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used)	Location (Country)	X[1]	pH	Depth (cm)	DT_{50} actual (d)	DT_{90} actual (d)	St (r^2)	DT_{50} normall (b)	Method of calculation
Soil K / Loam	X		5.6	0-10	/	n.a-	n.a-	n.a-	Non linear model (SFO)
Soil P / Loam	X		5.1	0-10	/	n.a-	n.a-	n.a-	Non linear model (SFO)
Aritmetic mean / median					n.a-*				

**n.a. = not availableC*

No data submitted

CP 9.1.1.2.1 Soil dissipation studies
Soil dissipation testing on a range of representative soils

Studies on field dissipation rates with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. These data are summarised in the table 9.1.1.2 above.

CP 9.1.1.2.2 Soil accumulation studies
Soil accumulation testing

Soil accumulation studies are not triggered. Therefore no studies were conducted with the formulation. No such study was performed since they are not required.

CP 9.1.1.2.2-1 Soil residue testing

No such study was performed since they are not required.

CP 9.1.1.2.2-2 Aquatic (sediment) field dissipation

This is not an EC data requirement / not required by Directive 91/414/EEC.

CP 9.1.1.2.2-3 Forestry field dissipation

This is not an EC data requirement / not required by Directive 91/414/EEC.

CP 9.1.2 Mobility in soil
Mobility of the Plant Protection Product in Soil

The information regarding the EU endpoints for the mobility of Hydrolysed proteins are presented in the table below.

Agreed EU End-points used in the Evaluation (EFSA Journal 2012; 10(2):2545)

End-Point	Hydrolysed proteins
Kf arithmetic mean (mL/g)	No data submitted
Kfoc arithmetic mean (mL/g)	No data submitted
Kf median (mL/g)	No data submitted
Kfoc median (mL/g)	
1/n arithmetic mean	No data submitted
1/n median	No data submitted
pH dependence, Yes or No	No

Summary

The mobility in soil of Hydrolysed proteins was evaluated during the Annex I Inclusion. No additional studies have been performed.

A summary of the available studies on adsorption/desorption of Hydrolysed proteins in soil is given in Table 9.1.2. The results from available studies indicate that Hydrolysed proteins may be considered to be medium to low mobile in soil on the basis of batch adsorption/desorption experiments.

Table 9.1.2: K_{foc} and 1/n (Freundlich exponent) values for Hydrolysed proteins in different sets of soils

Parent							
Soil type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Clay loam	/	/			/	/	/
Silty clay loam	/	/			/	/	/
Clay loam	/	/			/	/	/
Loamy sand	/	/			/	/	/
Aritmetic mean / median					/	/	/
pH dependence, Yes or No			No				

No data submitted

CP 9.1.2.1 Laboratory studies
Column leaching

Since reliable adsorption/desorption data were available for Hydrolysed proteins and this active substance is considered of low to medium mobility in soil, soil column leaching were not required during the EU review. Therefore no column leaching study on the formulation was submitted

CP 9.1.2.1-1 Volatility – Laboratory study

Studies on volatility with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. Based on the low vapour pressure and the low DT_{50} in air, no significant volatilisation of Hydrolysed proteins is expected. A study to determine the volatility in laboratory is not required and is not performed.

CP 9.1.2.2 Lysimeter studies

Since reliable adsorption/desorption data were available for Hydrolysed proteins and this active substance is considered of low to medium mobility in soil, lysimeter studies were not required during the EU review. Therefore no lysimeter study on the formulation was submitted.

CP 9.1.2.3 Field leaching studies

Since reliable adsorption/desorption data were available for Hydrolysed proteins and this active substance is considered of low to medium mobility in soil, field leaching studies were not required during the EU review. Therefore no field leaching study on the formulation was submitted.

CP 9.1.2.3-1 Volatility – Field study

Studies on volatility with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. Based on the low vapour pressure and the low DT_{50} in air, no significant volatilisation of Hydrolysed proteins is expected. A study to determine the volatility in field is not required and is not performed.

CP 9.1.3 Estimation of concentrations in soil
Predicted environmental concentrations in soil (PEC_S) for the Active Substance

The PECs is calculated for the active substance 'hydrolysed proteins' for the critical use in blueberries (lowest crop interception value, cf. Table 9.1.3-1).

Table 9.1.3-1: Identification of critical use for PEC_{soil} calculations (in bold)

Crop	Dose rate (g hydrolysed protein/ha)	Crop interception (%)	Dose reaching soil (g hydrolysed protein/ha)
Blueberries	**4 x 907.2**	**60**	**4 x 362.88**
Pome fruits, stone fruits, walnut, fig, kiwi, olive trees	4 x 907.2	65	4 x 317.52
Citrus fruit	4 x 907.2	80	4 x 181.44

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	Pome fruit, stone fruit, citrus, olive, fig, walnut, olive, kiwi, blueberries
Application rate (g as/ha)	hydrolysed protein: 907.2
Number of applications/interval	Max. 4 applications with min. 10 days interval
Crop interception (%)	Interception values according to Appendix C of the EFSA Guidance to obtain $DegT_{50}$ values (2014): Apple: 65% (BBCH≥71) Citrus: 80% (all BBCH stages) Bushberries: 60% (BBCH≥10) => worst case used in PECs calculations
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 the active substance is readily biodegradable. Default DT_{50} value for readily biodegradable substances with a solid-water partition coefficient in soil (Kpsoil) <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).

Compound	**DT50 (days)**	**Value in accordance to EU endpoint y/n/ Reference**
		Note: Kpsoil 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)).

CP 9.1.3.2 Hydrolysed protein

The results of the PECs calculations for ‘hydrolysed proteins’ are presented in Table 9.1.3-4.

Table 9.1.3-4: PEC_{soil} for hydrolysed protein on blueberries (covering fruit trees, citrus, fig, walnut, olive, kiwi)

PEC_{soil} (mg/kg)		blueberries	
		Multiple applications	
		Actual	TWA
Initial		1.415	1.415
Short term	24h	1.382	1.398
	2d	1.351	1.382
	4d	1.290	1.351
Long term	7d	1.203	1.306
	14d	1.024	1.209
	21d	0.871	1.121
	28d	0.741	1.042
	50d	0.446	0.839
	100d	0.140	0.552

CP 9.1.3.3 Predicted Environmental Concentrations in Soil (PECs) for Relevant Metabolites

Not applicable since there are no relevant soil metabolites for Hydrolysed proteins.

CP 9.1.3.4 CP 9.1.3.5 Initial PECs values

Not applicable since there are no relevant soil metabolites for Hydrolysed proteins.

CP 9.1.3.5 CP 9.1.3.6 Short-term PECs values (1-4 days after last application)

Not applicable since there are no relevant soil metabolites for Hydrolysed proteins.

CP 9.1.3.6 CP 9.1.3.7 Long-term PECs values (from 7-100 days after last application)

Not applicable since there are no relevant soil metabolites for Hydrolysed proteins.

CP 9.2 Fate and Behaviour in Water and Sediment
Predicted environmental concentrations in soil (PEC_{GW})

The PEC_{GW} is calculated for the active substance hydrolysed proteins.

Table 9.2-1: Critical GAP for PEC_{GW} calculations

Crop	Dose rate
Pome fruits, stone fruits, walnut, fig, kiwi, citrus fruit, olive trees	Max. 4 applications at a dose rate of 907.2 g hydrolysed protein/ha, with a minimum interval of 10 days

The PEC_{GW} is calculated for the active substance by means of FOCUS PEARL v4.4.4 and FOCUS PELMO v5.5.3 for the different representative uses. Tables 9.2-2 and 9.2-3 show the input parameters that were used in the calculation.

Table 9.2-2: Input parameters related to application for PEC_{gw} calculations

Crop	Apple (covering pome fruit, stone fruit, walnut, fig, olive trees, kiwi) Bush berries (covering blueberries) Citrus
Application rate (g as/ha)	Hydrolysed protein: 4 x 907.2
Number of applications/interval (d)	Maximum 4 applications, minimum 10 days interval
Application dates	Worst-case: first application on the 1st of April
Crop interception (%)	Apple: 65% → appl. rate of 4 x 318 g/ha of hydrolysed protein Bush berries: 60% → appl. rate of 4 x 363 g/ha of hydrolysed protein Citrus: 80% → appl. rate of 4x 182 g/ha of hydrolysed protein
Frequency of application	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3

Table 9.2-3: 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 (Kpsoil) <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 9.2-4 and 9.2-5 summarise the results of the PEC_{GW} calculations for 'hydrolysed proteins' with FOCUS PEARL and FOCUS PELMO respectively.

Table 9.2-4: PEC_{gw} for hydrolysed protein on various crops (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)
		Hydrolysed protein
Apple 4 x 907.2	Châteaudun	94.39
	Hamburg	146.97
	Jokioinen	115.08
	Kremsmünster	69.66
	Okehampton	60.59
	Piacenza	41.70
	Porto	28.49
	Sevilla	69.97
	Thiva	49.37
Bush berries 4 x 907.2	Jokioinen	82.42
Citrus	Piacenza	19.75

4 x 907.2	Porto	14.66
	Sevilla	13.74
	Thiva	8.73

Table 9.2 -5: PEC$_{gw}$ for hydrolysed protein on various crops (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)
		Hydrolysed protein
Apple 4 x 907.2	Châteaudun	77.71
	Hamburg	65.38
	Jokioinen	84.88
	Kremsmünster	67.66
	Okehampton	69.81
	Piacenza	61.17
	Porto	38.47
	Sevilla	53.74
	Thiva	40.62
Bush berries 4 x 907.2	Jokioinen	66.35
Citrus 4 x 907.2	Piacenza	22.50
	Porto	14.51
	Sevilla	9.58
	Thiva	8.56

The highest PECgw value for hydrolysed proteins results from the PEARL calculations Hamburg scenario for apple, which amounts to 146.97 µg/L. When the exposure is expressed in nitrogen content, the max PECgw equalizes 23.52 µg/L.

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 23.52 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/L nitrogen, is almost 1000 times higher than the max total PECgw of 23.52 µg/L.

Moreover, the acceptable risk is confirmed by the fact that the total amount of nitrogen applied per hectare per year is 581 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 9.2-1 Active substance

Please refer to point 9.2 for the input parameters, results and conclusion.

ModellingComments: IIIA 9.2.1/01	
Conclusion PEC_{gw} (active substance): IIIA 9.2.1	

CP 9.2-2 Relevant metabolites

Not relevant since there are no relevant soil metabolites for Hydrolysed proteins.

Modelling Comments: IIIA 9.2.2/01	
Conclusion PECgw (metabolite/s): IIIA 9.2.2	

CP 9.2-3 Additional field testing

Based on the results discussed above additional field testing is not indicated.

CP 9.2-4 Information on impact on water treatment procedures

This assessment is not required at the moment.

CP 9.2.1 Aerobic mineralisation in surface water
Predicted environmental concentrations in surface water (PEC_{SW})

The PEC_{SW} is calculated for the active substance ‘hydrolysed proteins’.

Table 9.2.1-1: Critical GAP for PEC_{SW} calculations

Crop	Dose rate
Pome fruits, stone fruits, walnut, fig, kiwi, citrus fruit, olive trees	Max. 4 applications at a dose rate of 907.2 g hydrolysed protein/ha, with a minimum interval of 10 days

CP 9.2.1.1 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

The PECsw is calculated for the active substance by means of FOCUS Steps 1-2 for the different crop types. Tables 9.2-2 and 9.2-3 show the input parameters that were used in the calculations.

Table 9.2.1-2 Input parameters related to $PEC_{SW/sed}$ calculations

Crop types	Pome/stone fruit (late application) Citrus Olives
Application rate (g as/ha)	Hydrolysed protein: 4 x 907.2
Number of applications/interval (d)	Maximum 4 applications, minimum 10 days interval
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 9.2.1-3 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 (m²/d)	4.3×10^{-5}	FOCUS default
Diffusion coefficient in air (m²/d)	0.43	FOCUS default
K_{foc} (mL/g)	10 (for PECsw)/10000 (for PECsed)	FOCUS defaults
Freundlich Exponent 1/n	1	FOCUS default
Plant Uptake	0	FOCUS default
$DT_{50,soil}$ (d)	30	Preliminary results of the biodegradability test (OECD 301/310) showed that the active substance is readily biodegradable. Default DT_{50} value for readily biodegradable substances with a solid-water partition coefficient in soil (Kpsoil) <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	Preliminary results of the biodegradability test (OECD 301/310) showed that the active substance is readily biodegradable. 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 9.2.1-4.

Table 9.2.1-4 FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for hydrolysed protein following four applications (4 x 907.2 g/ha) to pome fruits, citrus and olive trees

Pome fruit					
Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	1380	---	1370	9760
Step 2	---		---		
Southern Europe	March-May	248.64		159.79	2110
	June-Sept	200.91		129.09	1770
Citrus					
Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	1380	---	1370	9760
Step 2	---		---		
Southern Europe	March-May	121.36		77.92	1210
	June-Sept	105.45		67.69	1100
Olives					
Scenario FOCUS	**Waterbody**	**Max PEC_{sw} (µg/L)**	**Dominant entry route**	**21 d- $PEC_{sw,twa}$ (µg/L)**	**Max PEC_{sed} (µg/kg)**
Step 1	---	1380	---	1370	9760
Step 2	---		---		
Southern Europe	March-May	153.18		98.39	1440
	June-Sept	129.32		83.04	1270

The max PECsw for pome fruit to be used in the risk assessment for pome/stone fruit, walnut, fig and kiwi is 248.64 µg/L, resulting from Step 2 scenario March-May, which amounts to 39.78 µg/L expressed asn total nitrogen.

The max PECsw for citrus to be used in the risk assessment for citrus is 121.36 µg/L, resulting from Step 2 scenario March-May, which amounts to 19.42 µg/L expressed as total nitrogen.

The max PECsw for olives to be used in the risk assessment for olives is 153.18 µg/L, resulting from Step 2 scenario March-May, which amounts to 24.5 µg/L expressed as total nitrogen.

CP 9.2.3 Irradiated water/sediment study
Initial PECsw value for static water bodies

Reference is made to the point CP 9.2 above where the initial PECsw values were provided.

Modelling Comments: IIIA 9.2.3/01	
Conclusion (PEC_{sw} and PEC_{sed}) (active substance): IIIA 9.2.3	

CP 9.2.3.1 Initial PECsw value for slow moving water bodies

Not relevant.
Reference is made to the point CP 9.2 above where the initial PECsw values were provided.

CP 9.2.3.2 Short-term PECsw values for static water bodies (1-4 days after last application)

Not relevant.
Reference is made to the point CP 9.2 above where the short-term PECsw values were provided.

CP 9.2.3.3 Short-term PECsw values for slow moving water bodies (1-4 days after last application)

Not relevant.
Reference is made to the point CP 9.2 above where the short-term PECsw values were provided.

CP 9.2.3.4 Long-term PECsw values for static water bodies (7-42 days after last application)

Not relevant.
Reference is made to the point CP 9.2 above where the long-term PECsw values were provided.

CP 9.2.3.5 Long-term PECsw values for slow moving water bodies (7-42 days after last application)

Not relevant.
Reference is made to the point CP 9.2 above where the long-term PECsw values were provided.

CP 9.2.4 Estimation of concentrations in groundwater

CP 9.2.4.1 Calculation of concentrations in groundwater
Predicted environmental concentrations in soil (PEC_{GW})

CP 9.2.4.2 Additional field tests

CP 9.3.5 Estimation of concentrations in surface water and sediment

Predicted environmental concentrations in soil (PEC_{SW})

Predicted environmental concentrations in soil (PEC_{SED})

CP 9.2.4 Estimation of concentrations in groundwater
Predicted Environmental Concentrations in Surface Water (PECsw) for Metabolites

Not relevant since there are no relevant metabolites for Hydrolysed proteins in water or soil.

CP 9.2.4.1 Calculation of concentrations in groundwater

Initial PECsw value for static water bodies

Not relevant since there are no relevant metabolites for Hydrolysed proteins in water or soil.

Modelling Comments: IIIA 9.2.4.1/01.	
Conclusion PEC_{sw} and PEC_{sed} (metabolite/s): IIIA 9.2.4.1	

CP 9.2.4.2 Additional field tests

Not necessary since the risk to aquatic organisms was found to be acceptable based on the modelling data provided above.

CP 9.2.5 Estimation of concentrations in surface water and sediment

Predicted environmental concentrations in soil (PEC_{SW})

Predicted environmental concentrations in soil (PEC_{SED})

CP 9.2.5.1 Not relevant since there are no relevant metabolites for Hydrolysed proteins in water or soil.

CP 9.2.5.2 Short-term PECsw values for static water bodies 1-4 days after last application)

Not relevant since there are no relevant metabolites for Hydrolysed proteins in water or soil.

CP 9.2.5.3 Short-term PECsw values for slow moving water bodies 1-4 days after last application)

Not relevant since there are no relevant metabolites for Hydrolysed proteins in water or soil.

CP 9.2.5.4 Long-term PECsw values for static water bodies 7-42 days after last application)

Not relevant since there are no relevant metabolites for Hydrolysed proteins in water or soil.

CP 9.2.5.5 Long-term PECsw values for slow moving water bodies 7-42 days after last application)

Not relevant since there are no relevant metabolites for Hydrolysed proteins in water or soil.

CP 9.3 Fate and Behaviour in Air

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

CP 9.3 Fate and Behaviour in Air

Studies on the fate and behaviour in air with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

End-Point	Hydrolysed proteins
Direct photolysis in air	No data. Not required.
Quantum yield of direct phototransformation	No data. Not required.
Photochemical oxidative degradation in air	No data. Not required.
Volatilisation	No data. Not required.

Summary

The fate and behaviour in air of Hydrolysed proteins was evaluated during the Annex I Inclusion. No additional studies have been performed. The data on the active substance are summarised below.

The vapour pressure of Hydrolysed proteins not was determined. The atmospheric half-life of Hydrolysed proteins not was calculated. The Hydrolysed proteins are biodegradable, so their persistence in the environment is very short, without existing any tendency to bioaccumulation.

The physico-chemical characteristics of the Hydrolysed proteins demonstrate the relatively low volatility and a low tendency to partition from water to air. Therefore, it is concluded that little residue of Hydrolysed proteins will reach air and no study of degradation in air was performed. This is also the reason why no PEC_{air} was calculated.

The applications of NUTREL are therefore safe with regards to the potential short-range or long range transport of Hydrolysed proteins.

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.

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. 3), corresponding to 10^2 to 10^8 mol/(m^3.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 $2.5x10^5$ to $2.5x\ 10^{11}$.

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 evolvement of small-molecule volatile compounds with organoleptic qualities attracting flies (e.g. NH_3). These biologically active compounds only emerge on-site in minor quantities.

[3] 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).

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

Predicted environmental concentrations from airborne transport

Spray droplet size spectrum - Laboratory studies

This is not an EC data requirement / not required by Directive 91/414/EEC.

CP 9.4 Estimation of Concentrations for Other Routes of Exposure

Drift - Field evaluation

This is not an EC data requirement / not required by Directive 91/414/EEC.

CP 9.4.1 Other/Special Studies

There are no additional European requirements for formulated products.

CP 9.4.2 Laboratory studies

This is not an EC data requirement / not required by Directive 91/414/EEC.

CP 9.4.3 Field studies

This is not an EC data requirement / not required by Directive 91/414/EEC.

Appendix 1: Critical Uses – justification and GAP tables

DETAILS OF INTENDED USES AND CONDITIONS OF USE (GAP INFORMATION – IT – January 2018)

Tradename: NUTREL
Active Ingredient: Hydrolysed proteins 30% (= 378 g/L)

Crop and/ or situation (a)	Member State or Country	Product name	F, G, or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage (j)	number min max (k)	interval between applications (min)	kg as/hL max	water L/ha min max	kg as/ha max		
Olea europaea L. (olive) *Malus pumila* Mill., *Pyrus communis* L. (Pome fruits) *Prunus* spp, *Persica vulgaris* Mill., (stone fruits) *Juglans regia* L. (walnut) *Citrus* spp (citrus) Fig, Actinidia and Blueberries	Italy, Spain, Greece, Portugual, France	NUTREL	F	Adult insects (Dyptera) laying eggs on fruits	SL (n)	378 g/l	Normal volume spraying, / high pressure	7 (o)	2 - 4	10 - 30	-	100-200	0.907	(p)	(2.4 L product/ ha)
				Mass trapping			Product in Traps	Development of fruits	N.A.	N.A.	90 Traps/Ha	N.A.	8,5	N.A.	(22.5 L product/ ha).

Remarks: (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4); including where relevant, information on season at the time time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use / economic importance / restrictions
(n) Soluble Liquid (Water solution)
(o) Development of fruits, the growth stage depends on the authorized insecticide utilized in mixture
(p) Not required for the active substance itself. Refer to the authorized insecticide utilized in mixture