Hydrolysed Proteins

DOCUMENT N2

LIST OF END POINTS

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Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2020**	**Hydrolysed Proteins**

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	Animal tissue Hydrolysate (under the general term Hydrolysed Protein)
Function (*e.g.* fungicide)	Insect attractant

Rapporteur Member State	Spain
Co-rapporteur Member State	Greece

Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

Chemical name (IUPAC)	Not available
Chemical name (CA)	Not available
CIPAC No	901
CAS No	Not applicable
EC No (EINECS or ELINCS)	Not applicable
FAO Specification (including year of publication)	None
Minimum purity of the active substance as manufactured	252 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula	Not applicable
Molar mass	Not applicable
Structural formula	Not applicable

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Rapporteur Member State	Month and year	Active Substance (Name)
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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

Melting point (state purity)	Not relevant
Boiling point (state purity)	Not relevant
Temperature of decomposition (state purity)	Not applicable
Appearance (state purity)	Homogeneous brown opaque liquid (30% w/v)
Vapour pressure (state temperature, state purity)	Not applicable
Henry's law constant (state temperature)	Not applicable
Solubility in water (state temperature, state purity and pH)	Completely soluble
Solubility in organic solvents (state temperature, state purity)	Insoluble
Surface tension (state concentration and temperature, state purity)	39.9 mN/m ± 0.4 mN/m at 19.9 °C (30% w/v)
Partition coefficient (state temperature, pH and purity)	Not applicable
Dissociation constant (state purity)	Not relevant
UV/VIS absorption (max.) incl. ε (state purity, pH)	Not relevant
Flammability (state purity)	Not flammable (30% w/v)
Explosive properties (state purity)	Not explosive (30% w/v)
Oxidising properties (state purity)	Not oxidizing (30% w/v)

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Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2020**	**Hydrolysed proteins**

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*Hydrolysed proteins*) (Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		e.g. g safener/synergist per ha (f)
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	Southern zone	Citrus	F	Mediterranean Fruit Fly *Ceratitis capitata*	Foliar application	#	#	#	a) 1.5 b) #	a) 0.45 b) #	#	#	To be used in mixture with insecticides # corresponds to the GAP of the insecticide used in mixture
2	Southern zone	Persimmon	F	Mediterranean Fruit Fly *Ceratitis capitata*	Foliar application	#	#	#	a) 1.5 b) #	a) 0.45 b) #	#	#	To be used in mixture with insecticides # corresponds to the GAP of the insecticide used in mixture

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse 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) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(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. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

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Rapporteur Member State	Month and year	Active Substance (Name)
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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (*Hydrolysed proteins*)
Regulation (EC) N° 1107/2009 Article 8.1(g))

Not relevant.

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Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2020**	**Hydrolysed Proteins**

Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

Not relevant for renewal dossier

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

Not relevant for renewal dossier

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

Not relevant for renewal dossier

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

	Not relevant
Activity against target organism	Not relevant

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Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2020**	**Hydrolysed Proteins**

Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	Kjeldahl method
Impurities in technical a.s. (analytical technique)	Not relevant
Plant protection product (analytical technique)	Kjeldahl method

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

Food of plant origin		Not relevant. Not required.
Food of animal origin		Not relevant. Not required.
Soil		Not relevant. Not required.
Sediment		Not relevant. Not required.
Water	surface	Not relevant. Not required.
	drinking/ground	Not relevant. Not required.
Air		Not relevant. Not required.
Body fluids and tissues		Not relevant. Not required.

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not relevant. Not required.
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not relevant. Not required.
Soil (analytical technique and LOQ)	Not relevant. Not required.
Water (analytical technique and LOQ)	Not relevant. Not required.
Air (analytical technique and LOQ)	Not relevant. Not required.
Body fluids and tissues (analytical technique and LOQ)	Not relevant. Not required.

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Hydrolysed Proteins	None

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Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2020**	**Hydrolysed Proteins**

Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][1]:	None. Low-risk active substance
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	None. Low-risk active substance

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[2] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2020**	**Hydrolysed Proteins**

Section 2 Mammalian Toxicology

Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	Not relevant. Not required.
Toxicokinetics	Not relevant. Not required.
Distribution	Not relevant. Not required.
Potential for bioaccumulation	Not relevant. Not required.
Rate and extent of excretion	Not relevant. Not required.
Metabolism in animals	Not relevant. Not required.
In vitro metabolism	Not relevant. Not required.
Toxicologically relevant compounds (animals and plants)	None.
Toxicologically relevant compounds (environment)	None.

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD_{50} oral	No data, not required.	
Rat LD_{50} dermal	No data, not required.	
Rat LC_{50} inhalation	No data, not required.	
Skin irritation	No data, not required.	
Eye irritation	No data, not required.	
Skin sensitisation	No data, not required.	
Phototoxicity	No data, not required.	

Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	Not required.	
Relevant oral NOAEL	Not required.	
Relevant dermal NOAEL	Not required.	
Relevant inhalation NOAEL	Not required.	

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

In vitro studies	No data, not required.	
In vivo studies	No data, not required.	

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Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2020**	**Hydrolysed Proteins**

Section 2 Mammalian Toxicology

Photomutagenicity	Not required.	
Potential for genotoxicity	Not required.	

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	No data, not required.	
Relevant long-term NOAEL	Not relevant. Not required.	
Carcinogenicity (target organ, tumour type)	Not carcinogenic	
Relevant NOAEL for carcinogenicity	Not carcinogenic	

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	Not teratogenic	
Relevant parental NOAEL	Not relevant. Not required.	
Relevant reproductive NOAEL	Not relevant. Not required.	
Relevant offspring NOAEL	Not relevant. Not required.	

Developmental toxicity

Developmental target / critical effect	Not teratogenic	
Relevant maternal NOAEL	Not relevant. Not required.	
Relevant developmental NOAEL	Not relevant. Not required.	

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	No data, not required.	
Repeated neurotoxicity	No data, not required.	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	No data, not required.	

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	No data, not required.
Endocrine disrupting properties	None
Studies performed on metabolites or impurities	No data, not required.

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

No data available. Not required.

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Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2020**	**Hydrolysed Proteins**

Section 2 Mammalian Toxicology

Summary[3] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	Not relevant	-	-
Acute Reference Dose (ARfD)	Not relevant	-	-
Acceptable Operator Exposure Level (AOEL)	Not relevant	-	-
Acute Acceptable Operator Exposure Level (AAOEL)	Not relevant	-	-

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulation	Not required.

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators	Not performed, not required.
Workers	Not performed, not required.
Bystanders and residents	Not performed, not required.

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance :	Hydrolysed Proteins
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][4] :	None. Low-risk active substance
Peer review proposal [5] for harmonised classification according to Regulation (EC) No 1272/2008:	None. Low-risk active substance

[3] If available include also reference values for metabolites

[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[5] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2020**	**Hydrolysed Proteins**

Section 3 Residues

Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

Primary crops (Plant groups covered) **OECD Guideline 501**	**Crop groups**	**Crop(s)**	**Application(s)**	**DAT** (days)
	Fruit crops	-	-	-
	Root crops	-	-	-
	Leafy crops	-	-	-
	Cereals/grass crops	-	-	-
	Pulses/Oilseeds	-	-	-
	Miscellaneous	-	-	-
	Not relevant. Not required.			

Rotational crops (metabolic pattern) **OECD Guideline 502**	**Crop groups**	**Crop(s)**	**PBI** (days)	**Comments**
	Root/tuber crops	-	-	-
	Leafy crops	-	-	
	Cereal (small grain)	-	-	
	Other	-	-	
Rotational crop and primary crop metabolism similar?	Not relevant. Not required.			

Processed commodities (standard hydrolysis study) **OECD Guideline 507**	**Conditions**	-	-	-	-
	20 min, 90°C, pH 4	-	-	-	-
	60 min, 100°C, pH 5	-	-	-	-
	20 min, 120°C, pH 6	-	-	-	-
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not relevant. Not required.				

Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Not relevant. Not required.
Plant residue definition for risk assessment (RD-RA)	Not relevant. Not required.
Conversion factor (monitoring to risk assessment)	Not relevant. Not required.

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Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2020**	**Hydrolysed Proteins**

Section 3 Residues

Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

OECD Guideline 503 and SANCO/11187/2013 rev. 3 (fish)	Animal	Dose (mg/kg bw/d)	Duration (days)	N rate/comment
Animals covered	Laying hen	-	-	-
	Goat/Cow	-	-	-
	Pig	-	-	-
	Fish	-	-	-
	Not relevant. Not required.			

Time needed to reach a plateau concentration in milk and eggs (days)	Not relevant. Not required.
Animal residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Not relevant. Not required.
Animal residue definition for risk assessment (RD-RA)	Not relevant. Not required.
Conversion factor (monitoring to risk assessment)	Not relevant. Not required.
Metabolism in rat and ruminant similar (Yes/No)	Not relevant. Not required.
Fat soluble residues (Yes/No) **(FAO, 2009)**	Not relevant. Not required.

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) **OECD Guideline 502**	Not relevant. Not required.
Field rotational crop study **OECD Guideline 504**	Not relevant. Not required.

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Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2020**	**Hydrolysed Proteins**

Section 3 Residues

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)
OECD Guideline 506

Plant products (Category)	**Commodity**	**T** (°C)	**Stability** (Month/Year)			
			-	-	-	-
High water content	-	-	-	-	-	-
High oil content	-	-	-	-	-	-
High protein content	-	-	-	-	-	-
High starch content	-	-	-	-	-	-
High acid content	-	-	-	-	-	-
Not relevant. Not required.						

Animal	**Animal commodity**	**T** (°C)	**Stability** (Month/Year)			
			-	-	-	-
-	Muscle	-	-	-	-	-
-	Liver	-	-	-	-	-
-	Kidney	-	-	-	-	-
-	Milk	-	-	-	-	-
-	Egg	-	-	-	-	-
Not relevant. Not required.						

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Rapporteur Member State	Month and year	Active Substance (Name)
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Section 3 Residues

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

Crop	**Region/ Indoor** (a)	**Residue levels** (mg/kg) **observed in the supervised residue trials relevant to the supported GAPs** (b)	**Recommendations/comments** (OECD calculations)	**MRL** proposals (mg/kg)	**HR** (mg/kg) (c)	**STMR** (mg/kg) (d)
Summary of the data on formulation equivalence OECD Guideline 509						
Crop	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
-	-	Not relevant. Not required.	-	-	-	-
Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)						
Product(s)	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
-	-	Not relevant. Not required.	-	-	-	-

(a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.
(b): Residue levels in trials conducted according to GAP reported in ascending order (*e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Mo**nitoring and **R**isk **A**ssessment.
(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).
(d): **STMR:** Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets ($STMR_{Mo}$).

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Section 3 Residues

Inputs for animal burden calculations

Not relevant. Not required.

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Rapporteur Member State	Month and year	Active Substance (Name)
Spain	February 2020	**Hydrolysed Proteins**

Section 3 Residues

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

Not relevant. Not required.

STMR calculations

Ruminant	Pig/Swine	Poultry	Fish
Not relevant. Not required.			

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Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2020**	**Hydrolysed Proteins**

Section 3 Residues

Conversion Factors (CF) for monitoring to risk assessment

Animal products

Table to be deleted if not relevant (RD-Mo = RD-RA)

Conversion factors derived from the livestock feeding studies at the different feeding levels								
Study	**Ruminant/Pig**				**Poultry**			
Feeding levels	Level 1	Level 2	Level 3	Level 4	Level 1	Level 2	Level 3	Level 4
Muscle	-	-	-	-	-	-	-	-
Fat	-	-	-	-	-	-	-	-
Liver	-	-	-	-	-	-	-	-
Kidney	-	-	-	-	-	-	-	-
Milk	-	-	-	-				
Egg					-	-	-	-
Comments (up to 250 characters)	Not relevant. Not required.							

Plant products

Table to be deleted if not relevant (RD-Mo = RD-RA)

Mean Conversion Factors (CF) calculated at the different PHIs in the supervised residues trials[a] **OECD Guidance, series on Pesticides No 66**								
PHI[b] (days)	-	-	-	-	-	-	-	**Comments**
Not relevant. Not required.								

[a]: CF calculated at the supported PHI are underlined.
[b]: 0-/0+ for samples collected just before/after the last application

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Section 3 Residues

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies[a]	Processing Factor (PF)		Conversion Factor (CF_P) for RA[b]
		Individual values	Median PF	
Not relevant. Not required.				

[a]: Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)
[b]: When the residue definition for risk assessment differs from the residue definition for monitoring

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

Including all uses (representative uses and uses related to an MRL application).

ADI	Not relevant. Not required.
TMDI according to EFSA PRIMo	Not relevant. Not required.
NTMDI, according to (to be specified)	Not relevant. Not required.
IEDI (% ADI), according to EFSA PRIMo	Not relevant. Not required.
NEDI (% ADI), according to (to be specified)	Not relevant. Not required.
Factors included in the calculations	Not relevant. Not required.
ARfD	Not relevant. Not required.
IESTI (% ARfD), according to EFSA PRIMo	Not relevant. Not required.
NESTI (% ARfD), according to (to be specified)	Not relevant. Not required.
Factors included in IESTI and NESTI	Not relevant. Not required.

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Code[a]	Commodity/Group	MRL/Import tolerance[b] (mg/kg) and Comments
Plant commodities		
Not relevant. Not required.		

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005
(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.

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Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2020**	**Hydrolysed Proteins / SMVA14-004**

Section 4 Environmental fate and behaviour

Environmental fate and behaviour

Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	Not relevant. Not required.
Non-extractable residues after 100 days	Not relevant. Not required.
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	Not relevant. Not required.

Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	Not relevant. Not required.
Non-extractable residues after 100 days	Not relevant. Not required.
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not relevant. Not required.

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not relevant. Not required.
Mineralisation at study end	Not relevant. Not required.
Non-extractable residues at study end	Not relevant. Not required.

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Not relevant. Not required.

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Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2020**	**Hydrolysed Proteins / SMVA14-004**

Section 4 Environmental fate and behaviour

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Not relevant. Not required.

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Not relevant. Not required.

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Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Spain	**February 2020**	**Hydrolysed Proteins / SMVA14-004**

Section 4 Environmental fate and behaviour

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)	Not relevant. Not required.
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)	Not relevant. Not required.
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean	Not relevant. Not required.

* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration	Not relevant. Not required.

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Not relevant. Not required.

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Not relevant. Not required.

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3

Not relevant. Not required.

List of end points

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Spain	**February 2020**	**Hydrolysed Proteins / SMVA14-004**

Section 4 Environmental fate and behaviour

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Not relevant. Not required.

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Not relevant. Not required.

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	Not relevant. Not required.
	Not relevant. Not required.

Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	Not relevant. Not required.
	Not relevant. Not required.

Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies	Not relevant. Not required.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
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Section 4 Environmental fate and behaviour

Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1

Hydrolytic degradation of the active substance and metabolites > 10 %	Not relevant. Not required.

Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %	Not relevant. Not required.
Quantum yield of direct phototransformation in water at λ > 290 nm	Not relevant. Not required.

'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable (yes/no)	Yes

Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Not relevant. Not required.

Mineralisation and non extractable residues (for parent dosed experiments)
Not relevant. Not required.

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Parent	Not relevant. Not required.

Mineralisation and non extractable residues (from parent dosed experiments)
Not relevant. Not required.

List of end points

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Section 4 Environmental fate and behaviour

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air	Not required.
Photochemical oxidative degradation in air	Not required.
Volatilisation	Not required.
	Not required.
Metabolites	Not required.

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	None.

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5

Soil (indicate location and type of study)	Not relevant. Not required.
Surface water (indicate location and type of study)	Not relevant. Not required.
Ground water (indicate location and type of study)	Not relevant. Not required.
Air (indicate location and type of study)	Not relevant. Not required.

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent Method of calculation	DT_{50} (d): - Kinetics: - Field or Lab: -
Application data	Crop: Persimmon (worst case) Depth of soil layer: 5cm Soil bulk density: 1.5g/cm^3 % plant interception: 65 Number of applications: 1 Interval (d): - Application rate(s): 450 g/ha

List of end points

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Section 4 Environmental fate and behaviour

PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.210			

PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	No calculation performed, not required.
Application rate	-

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Parent	Exposure route: spray drift
Application rate	Crop: Citrus/Persimmon Number of applications: 1 Interval (d): - Application rate(s): 450 g a.s./ha Application window: -

PEC$_{(sw)}$ (µg/L)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	23.550			

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation	Not relevant. Not required.

PEC

Maximum concentration	Not relevant. Not required.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Spain	**February 2020**	**Hydrolysed Proteins / SMVA14-004**

Section 5 Ecotoxicology

Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
-	-	Acute	-	No data, not required
-	-	Dietary	-	No data, not required
-	-	Reproductive	-	No data, not required
Mammals				
Rat	-	Acute	-	No data, not required
-	-	Dietary	-	No data, not required
-	-	Reproductive	-	No data, not required
Endocrine disrupting properties (Annex Part A, points 8.1.5) Not relevant. Not required.				
Additional higher tier studies (Annex Part A, points 10.1.1.2): Not relevant. Not required.				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): Not relevant. Not required.				

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	-	Acute	-	-	10
All	-	Long-term	-	-	5
Tier 1 (Birds)					
-	-	-	-	-	-
Higher tier (birds):					
-	-	-	-	-	-
Screening Step (Mammals)					
All	-	Acute	-	-	10
All	-	Long-term	-	-	5
Tier 1 (Mammals)					
-	-	-	-	-	-
Higher tier (Mammals):					
-	-	-	-	-	-
Risk from bioaccumulation and food chain behaviour					

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
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Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Indicator or focal species		Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds		Long-term	-	-	5
Earthworm-eating mammals		Long-term	-	-	5
Fish-eating birds		Long-term	-	-	5
Fish-eating mammals		Long-term	-	-	5
Higher tier : -					
Risk from consumption of contaminated water					
Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Leaf scenario	Birds	acute	-	-	5
Puddle scenario, Screening step					
Puddle scenario	Birds	acute	-	-	10
Puddle scenario	Mammals	acute	-	-	10
Puddle scenario	Birds	Long-term	-	-	5
Puddle scenario	Mammals	Long-term	-	-	5

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Laboratory tests				
Fish				
Danio rerio	SVMA14-004	96h, s	EC50	> 100 mg/L
Aquatic invertebrates				
Daphnia magna	SVMA14-004	48h	EC50	> 100 mg/L_{nom}
Sediment-dwelling organisms				
-	-	-	-	No data, not required
Algae				
Pseudokirchneriella subcapitata	SVMA14-004	48h	EC50	313.493 mg/L
Higher plant				
-	-	-	-	No data, not required
Further testing on aquatic organisms Not required, not relevant				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3)				
Not required, not relevant				

[1] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; prep.: preparation; a.s.: active substance

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2020**	**Hydrolysed Proteins / SMVA14-004**

Section 5 Ecotoxicology

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Hydrolysed Proteins	-	-	-
$logP_{O/W}$	-	-	-	-
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	-	-	-	-
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)	-	-	-	-
Annex VI Trigger for the bioconcentration factor	-	-	-	-
Clearance time (days) (CT_{50})	-	-	-	-
(CT_{90})	-	-	-	-
Level and nature of residues (%) in organisms after the 14 day depuration phase	-	-	-	-
Higher tier study				
Not required, not relevant				

* based on total ^{14}C or on specific compounds

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Spain	**February 2020**	**Hydrolysed Proteins**

Section 5 Ecotoxicology

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

	Fish acute	**Invertebrates acute**	**Algae**
Test species	*Danio rerio*	*Daphnia magna*	*Pseudokirchneriella subcapitata*
Endpoint (µg/L)	> 100000	> 100000	313493
AF	100	100	100
RAC (µg/L)	> 1000	> 1000	3134.93
PECsw initial			
43.800	0.044	0.044	0.014

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Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Spain	**February 2020**	**Hydrolysed Proteins / SMVA14-004**

Section 5 Ecotoxicology

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	toxicity
-	-	-	-	No data, not required
-	-	-	-	No data, not required

Potential for accumulative toxicity: Not relevant.
Higher-tier studies (tunnel test, field studies)
Not required

Risk assessment

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Not performed, not required				

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
Typhlodromus pyri	-	-	No data, not required
Aphidius thopalosiphi	-	-	No data, not required

First tier risk assessment

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
-	*Typhlodromus pyri*	-	-	-	2
-	*Aphidius rhopalosiphi*	-	-	-	2

[1]indicate distance assumed to calculate the drift rate

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)[1,2]	End point	% effect[3]	ER_{50}
-	-	-	-	-	-	-	-

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation
[3] indicate if positive percentages relate to adverse effects or not

List of end points

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Section 5 Ecotoxicology

Risk assessment

Species	ER_{50} (g/ha)	In-field rate	Off-field rate[1]
Not performed, not required			

[1]indicate distance assumed to calculate the drift rate and if 3D or 2D.

Semi-field tests
Not required
Field studies
Not required
Additional specific test
Not required

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Earthworms					
-	-	-	-	-	No data, not required
Other soil macroorganisms					
-	-	-	-	-	No data, not required

[1]To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).

Higher tier testing (e.g. modelling or field studies): No data, not required

Nitrogen transformation	-	-	No data, not required

Toxicity/exposure ratios for soil organisms

[Representative use] at [application rate] g a.s./ha [x number of applications]

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
-	-	-	-	-	5
Other soil macroorganisms					
-	-	-	-	-	5

[1]indicate which PEC soil was used (e.g. plateau PEC)

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Spain	**February 2020**	**Hydrolysed Proteins / SMVA14-004**

Section 5 Ecotoxicology

Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

No data, not required

Laboratory dose response tests

Species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
-	-	-	-	-	-	-
Extended laboratory studies: Not required Semi-field and field test: Not required						

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	Not required.
Activated sludge	Not required.
Pseudomonas sp	Not required.

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Not relevant. Not required.

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds[1]

Compartment	
soil	Not relevant. Not required.
water	Not relevant. Not required.
sediment	Not relevant. Not required.
groundwater	Not relevant. Not required.

[1] metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

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Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
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Section 5 Ecotoxicology

Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance	Hydrolysed Proteins
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][6]:	None. Low-risk active substance
Peer review proposal[7] for harmonised classification according to Regulation (EC) No 1272/2008:	None. Low-risk active substance

[6] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[7] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2020**	**Hydrolysed Proteins**

Appendix

Used compounds code(s)

Code/Trivial name*	**IUPAC name/SMILES notation**	**Structural formula**
-	-	-

* The compound code / trivial name in bold is the name used in the list of endpoints