

# **Hydrolysed proteins**

**DOCUMENT OCA**

**COMPLETENESS CHECK FORM**

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## Version history<sup>1</sup>

Date	Data points containing amendments or additions and brief description	Document identifier and version number

<sup>1</sup> 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

## OCA Evaluation Form Active Substance

for use in checking that all test and study reports required in accordance with SANCO/11802 have been provided

Active Substance: Hydrolysed proteins

Applicant: PHYTOPHYL.

Date: February 9<sup>th</sup> 2018

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
1	Identity of the active substance				
1.1	Applicant	yes			<input type="checkbox"/>
1.2	Producer	yes			<input type="checkbox"/>
1.3	Common name proposed or ISO-accepted and synonyms	yes			<input type="checkbox"/>
1.4	Chemical name (IUPAC and CA nomenclature)	not relevant			<input type="checkbox"/>
1.5	Producer's development code numbers	not relevant			<input type="checkbox"/>
1.6	CAS, EC and CIPAC numbers	not relevant			<input type="checkbox"/>
1.7	Molecular and structural formula, molar mass	not relevant			<input type="checkbox"/>
1.8	Method of manufacture (synthesis pathway) of the active substance	yes			<input type="checkbox"/>
1.9	Specification of purity of the active substance in g/kg	yes			<input type="checkbox"/>
1.10	Identity and content of additives (such as stabilisers) and impurities				
1.10.1	Additives	not relevant			<input type="checkbox"/>
1.10.2	Significant impurities	not relevant			<input type="checkbox"/>
1.10.3	Relevant impurities	not relevant			<input type="checkbox"/>
1.11	Analytical profile of batches	yes			<input type="checkbox"/>
2	Physical and chemical properties of the active substance				
2.1	Melting point and boiling point	not relevant			<input type="checkbox"/>
2.2	Vapour pressure and volatility	not relevant			<input type="checkbox"/>
2.3	Appearance (physical state, colour)	yes			<input type="checkbox"/>

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	<i>Data gap</i>
2.4	Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity	not relevant			<input type="checkbox"/>
2.5	Solubility in water	yes			<input type="checkbox"/>
2.6	Solubility in organic solvents	not relevant			<input type="checkbox"/>
2.7	Partition coefficient n-octanol/water	not relevant			<input type="checkbox"/>
2.8	Dissociation in water	not relevant			<input type="checkbox"/>
2.9	Flammability and self-heating	yes			<input type="checkbox"/>
2.10	Flash point	yes			<input type="checkbox"/>
2.11	Explosive properties	yes			<input type="checkbox"/>
2.12	Surface tension	yes			<input type="checkbox"/>
2.13	Oxidising properties	yes			<input type="checkbox"/>
2.14	Other studies	no			<input type="checkbox"/>
3	Further information on the active substance (function, mode of action, handling)				
3.1	Use of the active substance	yes			<input type="checkbox"/>
3.2	Function	yes			<input type="checkbox"/>
3.3	Effects on harmful organisms	yes			<input type="checkbox"/>
3.4	Fields of use envisaged	yes			<input type="checkbox"/>
3.5	Harmful organisms controlled and crops or products protected or treated	yes			<input type="checkbox"/>
3.6	Mode of action	yes			<input type="checkbox"/>
3.7	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies	not relevant			<input type="checkbox"/>
3.8	Methods and precautions concerning handling, storage transport or fire	yes			<input type="checkbox"/>
3.9	Procedures for destruction or decontamination	yes			<input type="checkbox"/>
3.10	Emergency measures in case of an accident	yes			<input type="checkbox"/>
4	Analytical methods				

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	<i>Data gap</i>
4	Introduction				
4.1	Methods used for the generation of pre-approval data	not relevant			<input type="checkbox"/>
4.1.1	Methods of the analysis of the active substance as manufactured	yes			<input type="checkbox"/>
4.1.2	Methods for risk assessment	not relevant			<input type="checkbox"/>
4.2	Methods for post-approval control and monitoring purposes	not relevant			<input type="checkbox"/>
5	Toxicological and toxicokinetic studies on the active substance				
5.1	Studies on absorption, distribution, excretion and metabolism in mammals				
5.1.1	Absorption, distribution, excretion and metabolism by oral route	no			<input type="checkbox"/>
5.1.2	Absorption, distribution, excretion and metabolism by other routes	yes			<input type="checkbox"/>
5.2	Acute toxicity				
5.2.1	Oral	yes			<input type="checkbox"/>
5.2.2	Dermal	yes			<input type="checkbox"/>
5.2.3	Inhalation	yes			<input type="checkbox"/>
5.2.4	Skin irritation	yes			<input type="checkbox"/>
5.2.5	Eye irritation	yes			<input type="checkbox"/>
5.2.6	Skin sensitization	yes			<input type="checkbox"/>
5.2.7	Phototoxicity	no			<input type="checkbox"/>
5.3	Short-term toxicity				
5.3.1	Oral 28-day study	no			<input type="checkbox"/>
5.3.2	Oral 90-day study	no			<input type="checkbox"/>
5.3.3	Other routes	in part			<input type="checkbox"/>
5.4	Genotoxicity				

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
5.4.1	<i>In vitro</i> studies	in part			<input type="checkbox"/>
5.4.2	<i>In vivo</i> studies in somatic cells	in part			<input type="checkbox"/>
5.4.3	<i>In vivo</i> studies in germ cells	in part			<input type="checkbox"/>
5.5	Long-term toxicity and carcinogenicity	yes			<input type="checkbox"/>
5.6	Reproductive toxicity				
5.6.1	Generational studies	yes			<input type="checkbox"/>
5.6.2	Developmental toxicity studies	yes			<input type="checkbox"/>
5.7	Neurotoxicity				
5.7.1	Neurotoxicity studies in rodents	no			<input type="checkbox"/>
5.7.2	Delayed polyneuropathy studies	no			<input type="checkbox"/>
5.8	Other toxicological studies				
5.8.1	Toxicity studies of metabolites as referred to in the introduction	no			<input type="checkbox"/>
5.8.2	Supplementary studies on the active substance	no			<input type="checkbox"/>
5.8.3	Endocrine disrupting properties	no			<input type="checkbox"/>
5.9	Medical data				
5.9.1	Medical surveillance on manufacturing plant personnel and monitoring studies	no			<input type="checkbox"/>
5.9.2	Data collected on humans	no			<input type="checkbox"/>
5.9.3	Direct observations	no			<input type="checkbox"/>
5.9.4	Epidemiological studies	no			<input type="checkbox"/>
5.9.5	Diagnosis of poisoning (determination of active substance, metabolites), specific signs of poisoning, clinical tests	no			<input type="checkbox"/>
5.9.6	Proposed treatment: first aid measures, antidotes, medical treatment	no			<input type="checkbox"/>
5.9.7	Expected effects of poisoning	no			<input type="checkbox"/>
6	Metabolism and residues data				

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6.1	Storage stability of residues	no			<input type="checkbox"/>
6.2.	Metabolism, distribution and expression of residues				
6.2.1	Plants	no			<input type="checkbox"/>
6.2.2	Poultry	no			<input type="checkbox"/>
6.2.3	Lactating ruminants	no			<input type="checkbox"/>
6.2.4	Pigs	no			<input type="checkbox"/>
6.2.5	Fish	no			<input type="checkbox"/>
6.3	Magnitude of residue trials in plants	no			<input type="checkbox"/>
6.4	Feeding studies				
6.4.1	Poultry	no			<input type="checkbox"/>
6.4.2	Ruminants	no			<input type="checkbox"/>
6.4.3	Pigs	no			<input type="checkbox"/>
6.4.4	Fish	no			<input type="checkbox"/>
6.5	Effects of processing				
6.5.1	Nature of the residue	no			<input type="checkbox"/>
6.5.2	Distribution of the residue in inedible peel/pulp	no			<input type="checkbox"/>
6.5.3	Magnitude of residues in processed commodities	no			<input type="checkbox"/>
6.6	Residues in rotational crops				
6.6.1	Metabolism in rotational crops	no			<input type="checkbox"/>
6.6.2	Magnitude of residues in rotational crops	no			<input type="checkbox"/>
6.7	Proposed residue definition and maximum residue levels				
6.7.1	Proposed residue definitions	no			<input type="checkbox"/>
6.7.2	Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed	no			<input type="checkbox"/>

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	<i>Data gap</i>
6.7.3	Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed for imported products (import tolerances)	no			<input type="checkbox"/>
6.8	Proposed safety intervals	no			<input type="checkbox"/>
6.9	Estimation of the potential and actual exposure through diet and other sources	no			<input type="checkbox"/>
6.10	Other studies	no			<input type="checkbox"/>
6.10.1	Effect on the residue level in pollen and bee products	no			<input type="checkbox"/>
7	Fate and behaviour in the environment				
7.1.1	Fat and behaviour in soil				
7.1.1.1	Aerobic degradation	no			<input type="checkbox"/>
7.1.1.2	Anaerobic degradation	no			<input type="checkbox"/>
7.1.1.3	Soil photolysis	no			<input type="checkbox"/>
7.1.2	Rate of degradation in soil				
7.1.2.1	Laboratory studies				
7.1.2.1.1	Aerobic degradation of the active substance	no			<input type="checkbox"/>
7.1.2.1.2	Aerobic degradation metabolites, breakdown and reaction products	no			<input type="checkbox"/>
7.1.2.1.3	Anaerobic degradation of the active substance	no			<input type="checkbox"/>
7.1.2.1.4	Anaerobic degradation of metabolites, breakdown and reaction products	no			<input type="checkbox"/>
7.1.2.2	Field studies				
7.1.2.2.1	Soil dissipation studies	no			<input type="checkbox"/>
7.1.2.2.2	Soil accumulation studies	no			<input type="checkbox"/>
7.1.3	Adsorption and desorption in soil				
7.1.3.1	Adsorption and desorption				
7.1.3.1.1	Adsorption and desorption of the active substance	no			<input type="checkbox"/>



SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	<i>Data gap</i>
7.1.3.1.2	Adsorption and desorption of metabolites, breakdown and reaction products	no			<input type="checkbox"/>
7.1.3.2	Aged sorption	no			<input type="checkbox"/>
7.1.4	Mobility in soil				
7.1.4.1	Column leaching studies				
7.1.4.1.1	Column leaching of the active substance	no			<input type="checkbox"/>
7.1.4.1.2	Column leaching of metabolites, breakdown and reaction products	no			<input type="checkbox"/>
7.1.4.2	Lysimeter studies	no			<input type="checkbox"/>
7.1.4.3	Field leaching studies	no			<input type="checkbox"/>
7.2	Fate and behaviour in water and sediment				
7.2.1	Route and rate of degradation in aquatic systems (chemical and photochemical degradation)				
7.2.1.1	Hydrolytic degradation	no			<input type="checkbox"/>
7.2.1.2	Direct photochemical degradation	no			<input type="checkbox"/>
7.2.1.3	Indirect photochemical degradation	no			<input type="checkbox"/>
7.2.2	Route and rate of biological degradation in aquatic systems				
7.2.2.1	“Ready biodegradability”	no			<input type="checkbox"/>
7.2.2.2	Aerobic mineralisation in surface water	no			<input type="checkbox"/>
7.2.2.3	Water/sediment study	no			<input type="checkbox"/>
7.2.2.4	Irradiated water/sediment study	no			<input type="checkbox"/>
7.2.3	Degradation in the saturated zone	no			<input type="checkbox"/>
7.3	Fate and behaviour in air				
7.3.1	Route and rate of degradation in air	no			<input type="checkbox"/>
7.3.2	Transport via air	no			<input type="checkbox"/>
7.3.3	Local and global effects	no			<input type="checkbox"/>
7.4	Definition of the residue				

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7.4.1	Definition of the residue for risk assessment	no			<input type="checkbox"/>
7.4.2	Definition of the residue for monitoring	no			<input type="checkbox"/>
7.5	Monitoring data	no			<input type="checkbox"/>
8	Ecotoxicological studies				
8.1	Effects on birds and other terrestrial vertebrates				
8.1.1	Effects on birds				
8.1.1.1	Acute oral toxicity to birds	in part			<input type="checkbox"/>
8.1.1.2	Short-term dietary toxicity to birds	no			<input type="checkbox"/>
8.1.1.3	Sub-chronic toxicity and reproductive to birds	no			<input type="checkbox"/>
8.1.2	Effects on terrestrial vertebrates other than birds				
8.1.2.1	Acute oral toxicity to mammals	in part			<input type="checkbox"/>
8.1.2.2	Long-term and reproductive toxicity to mammals	no			<input type="checkbox"/>
8.1.3	Effects of active substance bioconcentration in prey of birds and mammals	no			<input type="checkbox"/>
8.1.4	Effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians)	no			<input type="checkbox"/>
8.1.5	Endocrine disrupting properties	no			<input type="checkbox"/>
8.2	Effects on aquatic organisms				
8.2.1	Acute toxicity to fish	in part			<input type="checkbox"/>
8.2.2	Long-term and chronic toxicity to fish				
8.2.2.1	Fish early life stage toxicity test	no			<input type="checkbox"/>
8.2.2.2	Fish full life cycle test	no			<input type="checkbox"/>
8.2.2.3	Bioconcentration in fish	no			<input type="checkbox"/>
8.2.3	Endocrine disrupting properties	no			<input type="checkbox"/>
8.2.4	Acute toxicity to aquatic invertebrates				
8.2.4.1	Acute toxicity to <i>Daphnia magna</i>	in part			<input type="checkbox"/>

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8.2.4.2	Acute toxicity to an additional aquatic invertebrate species	no			<input type="checkbox"/>
8.2.5	Long term and chronic toxicity to aquatic invertebrates				
8.2.5.1	Reproductive and development toxicity to <i>Daphnia magna</i>	no			<input type="checkbox"/>
8.2.5.2	Reproductive and development toxicity to an additional aquatic invertebrate species	no			<input type="checkbox"/>
8.2.5.3	Development and emergence in <i>Chironomus species</i>	no			<input type="checkbox"/>
8.2.5.4	Sediment dwelling organisms	no			<input type="checkbox"/>
8.2.6	Effects on algal growth				
8.2.6.1	Effects on growth of green algae	in part			<input type="checkbox"/>
8.2.6.2	Effects on growth of an additional algal species	no			<input type="checkbox"/>
8.2.7	Effects on aquatic macrophytes	no			<input type="checkbox"/>
8.2.8	Further testing on aquatic organisms	no			<input type="checkbox"/>
8.3	Effects on arthropods				
8.3.1	Effects on bees				
8.3.1.1	Acute toxicity to bees				
8.3.1.1.1	Acute oral toxicity	no			<input type="checkbox"/>
8.3.1.1.2	Acute contact toxicity	no			<input type="checkbox"/>
8.3.1.2	Chronic toxicity to bees	no			<input type="checkbox"/>
8.3.1.3	Effects on honeybees development and other honeybee life stages	no			<input type="checkbox"/>
8.3.1.4	Sub-lethal effects	no			<input type="checkbox"/>
8.3.2	Effects on non-target arthropods other than bees	no			<input type="checkbox"/>
8.3.2.1	Effects on <i>Aphidius rhopalosiphi</i>	no			<input type="checkbox"/>
8.3.2.2	Effects on <i>Typhlodromus pyri</i>	no			<input type="checkbox"/>
8.4	Effects on non-target soil meso- and macrofauna				

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	<i>Data gap</i>
8.4.1	Earthworm – sub-lethal effects	no			<input type="checkbox"/>
8.4.2	Effects on non-target soil meso- and macrofauna (other than earthworms)	no			<input type="checkbox"/>
8.4.2.1	Species level testing	no			<input type="checkbox"/>
8.5	Effects on soil nitrogen transformation	no			<input type="checkbox"/>
8.6	Effects on terrestrial non-target higher plants				
8.6.1	Summary of screening data	no			<input type="checkbox"/>
8.6.2	Testing on non-target plants	no			<input type="checkbox"/>
8.7	Effects on other terrestrial organisms (flora and fauna)	no			<input type="checkbox"/>
8.8	Effects on biological methods for sewage treatment	no			<input type="checkbox"/>
8.9	Monitoring data	no			<input type="checkbox"/>
9	Literature data	yes			<input type="checkbox"/>
10	Classification and labelling	yes			<input type="checkbox"/>