

# **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: BIOIBERICA S.A.U.

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	Not applicable		<input type="checkbox"/>
1.4	Chemical name (IUPAC and CA nomenclature)	yes	Not applicable		<input type="checkbox"/>
1.5	Producer's development code numbers	yes	Not applicable		<input type="checkbox"/>
1.6	CAS, EC and CIPAC numbers	yes	Not applicable		<input type="checkbox"/>
1.7	Molecular and structural formula, molar mass	yes			<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	yes			<input type="checkbox"/>
1.10.2	Significant impurities	yes			<input type="checkbox"/>
1.10.3	Relevant impurities	yes			<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	yes			<input type="checkbox"/>

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
2.2	Vapour pressure and volatility	no	Not applicable		<input type="checkbox"/>
2.3	Appearance (physical state, colour)	yes			<input type="checkbox"/>
2.4	Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity	no	Not applicable		<input type="checkbox"/>
2.5	Solubility in water	yes			<input type="checkbox"/>
2.6	Solubility in organic solvents	yes			<input type="checkbox"/>
2.7	Partition coefficient n-octanol/water	yes			<input type="checkbox"/>
2.8	Dissociation in water	no	Not applicable		<input type="checkbox"/>
2.9	Flammability and self-heating	no	Not applicable		<input type="checkbox"/>
2.10	Flash point	yes			<input type="checkbox"/>
2.11	Explosive properties	no	Not applicable		<input type="checkbox"/>
2.12	Surface tension	no	Not applicable		<input type="checkbox"/>
2.13	Oxidising properties	no	Not applicable		<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"/>

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
3.7	Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies	yes	Not applicable		<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				
4	Introduction				
4.1	Methods used for the generation of pre-approval data	yes			<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	yes			<input type="checkbox"/>
4.2	Methods for post-approval control and monitoring purposes	no	Not applicable		<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	Not applicable		<input type="checkbox"/>
5.1.2	Absorption, distribution, excretion and metabolism by other routes	no	Not applicable		<input type="checkbox"/>
5.2	Acute toxicity				
5.2.1	Oral	no	Not applicable		<input type="checkbox"/>
5.2.2	Dermal	no	Not applicable		<input type="checkbox"/>
5.2.3	Inhalation	no	Not applicable		<input type="checkbox"/>
5.2.4	Skin irritation	no	Not applicable		<input type="checkbox"/>

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
5.2.5	Eye irritation	no	Not applicable		<input type="checkbox"/>
5.2.6	Skin sensitization	no	Not applicable		<input type="checkbox"/>
5.2.7	Phototoxicity	no	Not applicable		<input type="checkbox"/>
5.3	Short-term toxicity				
5.3.1	Oral 28-day study	yes			<input type="checkbox"/>
5.3.2	Oral 90-day study	no			<input type="checkbox"/>
5.3.3	Other routes	no			<input type="checkbox"/>
5.4	Genotoxicity				
5.4.1	<i>In vitro</i> studies	no	Not applicable		<input type="checkbox"/>
5.4.2	<i>In vivo</i> studies in somatic cells	no	Not applicable		<input type="checkbox"/>
5.4.3	<i>In vivo</i> studies in germ cells	no	Not applicable		<input type="checkbox"/>
5.5	Long-term toxicity and carcinogenicity	no	Not applicable		<input type="checkbox"/>
5.6	Reproductive toxicity				
5.6.1	Generational studies	no	Not applicable		<input type="checkbox"/>
5.6.2	Developmental toxicity studies	no	Not applicable		<input type="checkbox"/>
5.7	Neurotoxicity				
5.7.1	Neurotoxicity studies in rodents	no	Not applicable		<input type="checkbox"/>
5.7.2	Delayed polyneuropathy studies	no	Not applicable		<input type="checkbox"/>
5.8	Other toxicological studies				
5.8.1	Toxicity studies of metabolites as referred to in the introduction	no	Not applicable		<input type="checkbox"/>

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
5.8.2	Supplementary studies on the active substance	no	Not applicable		<input type="checkbox"/>
5.8.3	Endocrine disrupting properties	no	Not applicable		<input type="checkbox"/>
5.9	Medical data				
5.9.1	Medical surveillance on manufacturing plant personnel and monitoring studies	no	Not applicable		<input type="checkbox"/>
5.9.2	Data collected on humans	no	Not applicable		<input type="checkbox"/>
5.9.3	Direct observations	no	Not applicable		<input type="checkbox"/>
5.9.4	Epidemiological studies	no	Not applicable		<input type="checkbox"/>
5.9.5	Diagnosis of poisoning (determination of active substance, metabolites), specific signs of poisoning, clinical tests	no	Not applicable		<input type="checkbox"/>
5.9.6	Proposed treatment: first aid measures, antidotes, medical treatment	yes			<input type="checkbox"/>
5.9.7	Expected effects of poisoning	yes			<input type="checkbox"/>
6	Metabolism and residues data				
6.1	Storage stability of residues	no	Not applicable		<input type="checkbox"/>
6.2.	Metabolism, distribution and expression of residues				
6.2.1	Plants	no	Not applicable		<input type="checkbox"/>
6.2.2	Poultry	no	Not applicable		<input type="checkbox"/>
6.2.3	Lactating ruminants	no	Not applicable		<input type="checkbox"/>
6.2.4	Pigs	no	Not applicable		<input type="checkbox"/>
6.2.5	Fish	no	Not applicable		<input type="checkbox"/>

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
6.3	Magnitude of residue trials in plants	no	Not applicable		<input type="checkbox"/>
6.4	Feeding studies				
6.4.1	Poultry	no	Not applicable		<input type="checkbox"/>
6.4.2	Ruminants	no	Not applicable		<input type="checkbox"/>
6.4.3	Pigs	no	Not applicable		<input type="checkbox"/>
6.4.4	Fish	no	Not applicable		<input type="checkbox"/>
6.5	Effects of processing				
6.5.1	Nature of the residue	no	Not applicable		<input type="checkbox"/>
6.5.2	Distribution of the residue in inedible peel/pulp	no	Not applicable		<input type="checkbox"/>
6.5.3	Magnitude of residues in processed commodities	no	Not applicable		<input type="checkbox"/>
6.6	Residues in rotational crops				
6.6.1	Metabolism in rotational crops	no	Not applicable		<input type="checkbox"/>
6.6.2	Magnitude of residues in rotational crops	no	Not applicable		<input type="checkbox"/>
6.7	Proposed residue definition and maximum residue levels				
6.7.1	Proposed residue definitions	no	Not applicable		<input type="checkbox"/>
6.7.2	Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed	no	Not applicable		<input type="checkbox"/>
6.7.3	Proposed maximum residue levels (MRLs) and justification of the acceptability of the levels proposed for imported products (import tolerances)	no	Not applicable		<input type="checkbox"/>



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6.8	Proposed safety intervals	no	Not applicable		<input type="checkbox"/>
6.9	Estimation of the potential and actual exposure through diet and other sources	no	Not applicable		<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	Not applicable		<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	Not applicable		<input type="checkbox"/>
7.1.1.2	Anaerobic degradation	no	Not applicable		<input type="checkbox"/>
7.1.1.3	Soil photolysis	no	Not applicable		<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	Not applicable		<input type="checkbox"/>
7.1.2.1.2	Aerobic degradation metabolites, breakdown and reaction products	no	Not applicable		<input type="checkbox"/>
7.1.2.1.3	Anaerobic degradation of the active substance	no	Not applicable		<input type="checkbox"/>
7.1.2.1.4	Anaerobic degradation of metabolites, breakdown and reaction products	no	Not applicable		<input type="checkbox"/>
7.1.2.2	Field studies				
7.1.2.2.1	Soil dissipation studies	no	Not applicable		<input type="checkbox"/>
7.1.2.2.2	Soil accumulation studies	no	Not applicable		<input type="checkbox"/>
7.1.3	Adsorption and desorption in soil				
7.1.3.1	Adsorption and desorption				

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
7.1.3.1.1	Adsorption and desorption of the active substance	no	Not applicable		<input type="checkbox"/>
7.1.3.1.2	Adsorption and desorption of metabolites, breakdown and reaction products	no	Not applicable		<input type="checkbox"/>
7.1.3.2	Aged sorption	no	Not applicable		<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	Not applicable		<input type="checkbox"/>
7.1.4.1.2	Column leaching of metabolites, breakdown and reaction products	no	Not applicable		<input type="checkbox"/>
7.1.4.2	Lysimeter studies	no	Not applicable		<input type="checkbox"/>
7.1.4.3	Field leaching studies	no	Not applicable		<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	Not applicable		<input type="checkbox"/>
7.2.1.2	Direct photochemical degradation	no	Not applicable		<input type="checkbox"/>
7.2.1.3	Indirect photochemical degradation	no	Not applicable		<input type="checkbox"/>
7.2.2	Route and rate of biological degradation in aquatic systems				
7.2.2.1	“Ready biodegradability”	no	Not applicable		<input type="checkbox"/>
7.2.2.2	Aerobic mineralisation in surface water	no	Not applicable		<input type="checkbox"/>
7.2.2.3	Water/sediment study	no	Not applicable		<input type="checkbox"/>

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7.2.2.4	Irradiated water/sediment study	no	Not applicable		<input type="checkbox"/>
7.2.3	Degradation in the saturated zone	no	Not applicable		<input type="checkbox"/>
7.3	Fate and behaviour in air				
7.3.1	Route and rate of degradation in air	no	Not applicable		<input type="checkbox"/>
7.3.2	Transport via air	no	Not applicable		<input type="checkbox"/>
7.3.3	Local and global effects	no	Not applicable		<input type="checkbox"/>
7.4	Definition of the residue				
7.4.1	Definition of the residue for risk assessment	no	Not applicable		<input type="checkbox"/>
7.4.2	Definition of the residue for monitoring	no	Not applicable		<input type="checkbox"/>
7.5	Monitoring data	no	Not applicable		<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	no	Not applicable		<input type="checkbox"/>
8.1.1.2	Short-term dietary toxicity to birds	no	Not applicable		<input type="checkbox"/>
8.1.1.3	Sub-chronic toxicity and reproductive to birds	no	Not applicable		<input type="checkbox"/>
8.1.2	Effects on terrestrial vertebrates other than birds				
8.1.2.1	Acute oral toxicity to mammals	no	Not applicable		<input type="checkbox"/>
8.1.2.2	Long-term and reproductive toxicity to mammals	no	Not applicable		<input type="checkbox"/>

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
8.1.3	Effects of active substance bioconcentration in prey of birds and mammals	no	Not applicable		<input type="checkbox"/>
8.1.4	Effects on terrestrial vertebrate wildlife (birds, mammals, reptiles and amphibians)	no	Not applicable		<input type="checkbox"/>
8.1.5	Endocrine disrupting properties	no	Not applicable		<input type="checkbox"/>
8.2	Effects on aquatic organisms				
8.2.1	Acute toxicity to fish	no	Not applicable		<input type="checkbox"/>
8.2.2	Long-term and chronic toxicity to fish				
8.2.2.1	Fish early life stage toxicity test	no	Not applicable		<input type="checkbox"/>
8.2.2.2	Fish full life cycle test	no	Not applicable		<input type="checkbox"/>
8.2.2.3	Bioconcentration in fish	no	Not applicable		<input type="checkbox"/>
8.2.3	Endocrine disrupting properties	no	Not applicable		<input type="checkbox"/>
8.2.4	Acute toxicity to aquatic invertebrates				
8.2.4.1	Acute toxicity to <i>Daphnia magna</i>	yes			<input type="checkbox"/>
8.2.4.2	Acute toxicity to an additional aquatic invertebrate species	yes			<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	Not applicable		<input type="checkbox"/>
8.2.5.2	Reproductive and development toxicity to an additional aquatic invertebrate species	no	Not applicable		<input type="checkbox"/>
8.2.5.3	Development and emergence in <i>Chironomus species</i>	no	Not applicable		<input type="checkbox"/>
8.2.5.4	Sediment dwelling organisms	no	Not applicable		<input type="checkbox"/>
8.2.6	Effects on algal growth				

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
8.2.6.1	Effects on growth of green algae	no	Not applicable		<input type="checkbox"/>
8.2.6.2	Effects on growth of an additional algal species	no	Not applicable		<input type="checkbox"/>
8.2.7	Effects on aquatic macrophytes	no	Not applicable		<input type="checkbox"/>
8.2.8	Further testing on aquatic organisms	yes			<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	Not applicable		<input type="checkbox"/>
8.3.1.1.2	Acute contact toxicity	no	Not applicable		<input type="checkbox"/>
8.3.1.2	Chronic toxicity to bees	no	Not applicable		<input type="checkbox"/>
8.3.1.3	Effects on honeybees development and other honeybee life stages	no	Not applicable		<input type="checkbox"/>
8.3.1.4	Sub-lethal effects	no	Not applicable		<input type="checkbox"/>
8.3.2	Effects on non-target arthropods other than bees	no	Not applicable		<input type="checkbox"/>
8.3.2.1	Effects on <i>Aphidius rhopalosiphi</i>	no	Not applicable		<input type="checkbox"/>
8.3.2.2	Effects on <i>Typhlodromus pyri</i>	no	Not applicable		<input type="checkbox"/>
8.4	Effects on non-target soil meso- and macrofauna				
8.4.1	Earthworm – sub-lethal effects	no	Not applicable		<input type="checkbox"/>
8.4.2	Effects on non-target soil meso- and macrofauna (other than earthworms)	no	Not applicable		<input type="checkbox"/>
8.4.2.1	Species level testing	no	Not applicable		<input type="checkbox"/>

SANCO/ 11802 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	<i>Data gap</i>
8.5	Effects on soil nitrogen transformation	no	Not applicable		<input type="checkbox"/>
8.6	Effects on terrestrial non-target higher plants				
8.6.1	Summary of screening data	no	Not applicable		<input type="checkbox"/>
8.6.2	Testing on non-target plants	no	Not applicable		<input type="checkbox"/>
8.7	Effects on other terrestrial organisms (flora and fauna)	no	Not applicable		<input type="checkbox"/>
8.8	Effects on biological methods for sewage treatment	no	Not applicable		<input type="checkbox"/>
8.9	Monitoring data	no	Not applicable		<input type="checkbox"/>
9	Literature data	yes			<input type="checkbox"/>
10	Classification and labelling	yes			<input type="checkbox"/>