

**BIOCEBO (BIO)**

**DOCUMENT OCP**

**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

## OCP Evaluation Form Plant Protection Product

for use in checking that all test and study reports required in accordance with SANCO/11803 have been provided

Active Substance: Hydrolysed proteins Applicant: BIOIBERICA S.A.U.  
February 18<sup>th</sup> 2018

Date:

Preparation: SL

SANCO/ 11803 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
1	Identity of the plant protection product				
1.1	Applicant	yes			<input type="checkbox"/>
1.2	Producer of the plant protection product and the active substances	yes			<input type="checkbox"/>
1.3	Trade name or proposed trade name and producer's development code number of the plant protection product if appropriate	yes			<input type="checkbox"/>
1.4	Detailed quantitative and qualitative information on the composition of the plant protection product				
1.4.1	Composition of the plant protection product	yes			<input type="checkbox"/>
1.4.2	Information on the active substances	yes			<input type="checkbox"/>
1.4.3	Information on safeners, synergists and co-formulants	no	yes		<input type="checkbox"/>
1.5	Type and code of the plant protection product	yes			<input type="checkbox"/>
1.6	Function	yes			<input type="checkbox"/>
2	Physical and chemical properties of the plant protection product				
2.1	Appearance	yes			<input type="checkbox"/>
2.2	Explosive and oxidising properties	yes			<input type="checkbox"/>
2.3	Flammability and self-heating	no	Not applicable		<input type="checkbox"/>
2.4	Acidity/alkalinity and pH value	yes			<input type="checkbox"/>
2.5	Viscosity and surface tension	yes			<input type="checkbox"/>

SANCO/ 11803 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
2.6	Relative density and bulk density	yes			<input type="checkbox"/>
2.7	Storage stability and shelf-life: effects of temperature on technical characteristics of the plant protection product	yes			<input type="checkbox"/>
2.8	Technical characteristics of the plant protection product				
2.8.1	Wettability	no	Not applicable		<input type="checkbox"/>
2.8.2	Persistent foaming	yes			<input type="checkbox"/>
2.8.3	Suspensibility, spontaneity and dispersion stability	no	Not applicable		<input type="checkbox"/>
2.8.4	Degree of dissolution and dilution stability	yes			<input type="checkbox"/>
2.8.5	Particle size distribution, dust content, attrition and mechanical stability				
2.8.5.1	Particle size distribution	no	Not applicable		<input type="checkbox"/>
2.8.5.2	Dust content	no	Not applicable		<input type="checkbox"/>
2.8.5.3	Attrition	no	Not applicable		<input type="checkbox"/>
2.8.5.4	Hardness and integrity	no	Not applicable		<input type="checkbox"/>
2.8.6	Emulsifiability, re-emulsifiability, emulsion stability	no	Not applicable		<input type="checkbox"/>
2.8.7	Flowability, pourability and dustability	no	Not applicable		<input type="checkbox"/>
2.9	Physical and chemical compatibility with other products including plant protection products with which its use is to be authorised	yes			<input type="checkbox"/>
2.10	Adherence and distribution to seeds	no	Not applicable		<input type="checkbox"/>
2.11	Other studies	yes			<input type="checkbox"/>
3	Data on application				

SANCO/ 11803 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
3.1	Fields of use envisaged	yes			<input type="checkbox"/>
3.2	Effects on harmful organisms	yes			<input type="checkbox"/>
3.3	Details of intended use	yes			<input type="checkbox"/>
3.4	Application rate and concentration of the active substance	yes			<input type="checkbox"/>
3.5	Method of application	yes			<input type="checkbox"/>
3.6	Number and timing of applications and duration of protection	yes			<input type="checkbox"/>
3.7	Necessary waiting periods and other precautions to avoid phytotoxic effects on succeeding crops	no	Not applicable		<input type="checkbox"/>
3.8	Proposed instructions for use	yes			<input type="checkbox"/>
4	Further information on the plant protection product				
4.1	Safety intervals and other precautions to protect humans, animals and the environment	no	Not applicable		<input type="checkbox"/>
4.2	Recommended methods and precautions	yes			<input type="checkbox"/>
4.3	Emergency measures in the case of an accident	yes			<input type="checkbox"/>
4.4	Packaging, compatibility of the plant protection product with proposed packaging materials	yes			<input type="checkbox"/>
4.5	Procedures for destruction or decontamination of the plant protection product and its packaging				
4.5.1	Neutralisation procedure	no	Not applicable		<input type="checkbox"/>
4.5.2	Controlled incineration	yes			<input type="checkbox"/>
5	Analytical methods				
5.1	Methods used for the generation of pre-authorisation data				
5.1.1	Analysis of the plant protection product	yes			<input type="checkbox"/>
5.1.2	Methods for the determination of residues	yes	Not applicable		<input type="checkbox"/>
5.2	Methods for post-authorisation control and monitoring purposes	yes	Not applicable		<input type="checkbox"/>

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6	Efficacy data				
6.1	Preliminary test	yes	Not applicable		<input type="checkbox"/>
6.2	Testing effectiveness	yes			<input type="checkbox"/>
6.3	Information on the occurrence or possible occurrence of the development of resistance	no	Not applicable		<input type="checkbox"/>
6.4	Adverse effects on treated crops				
6.4.1	Phytotoxicity to target plants (including different cultivars), or to target plant products	no	Not applicable		<input type="checkbox"/>
6.4.2	Effects on the yield of treated plants or plant products	yes			<input type="checkbox"/>
6.4.3	Effects on the quality of plants or plant product	yes			<input type="checkbox"/>
6.4.4	Effects on transformation processes	no	Not applicable		<input type="checkbox"/>
6.4.5	Impact on treated plants or plant products to be used for propagation	no	Not applicable		<input type="checkbox"/>
6.5	Observations on other undesirable or unintended side-effects				
6.5.1	Impact on succeeding crops	no	Not applicable		<input type="checkbox"/>
6.5.2	Impact on other plants, including adjacent crops	no	Not applicable		<input type="checkbox"/>
6.5.3	Effects on beneficial and other non-target organisms	no	Not applicable		<input type="checkbox"/>
7	Toxicological studies				
7.1	Acute toxicity				
7.1.1	Oral toxicity	yes			<input type="checkbox"/>
7.1.2	Dermal toxicity	yes			<input type="checkbox"/>
7.1.3	Inhalation toxicity	yes			<input type="checkbox"/>
7.1.4	Skin irritation	yes			<input type="checkbox"/>
7.1.5	Eye irritation	yes			<input type="checkbox"/>

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7.1.6	Skin sensitisation	yes			<input type="checkbox"/>
7.1.7	Supplementary studies on the plant protection product	no			<input type="checkbox"/>
7.1.8	Supplementary studies for combinations of plant protection products	no			<input type="checkbox"/>
7.2	Data on exposure				
7.2.1	Operator exposure				
7.2.1.1	Estimation of operator exposure	yes			<input type="checkbox"/>
7.2.1.2	Measurement of operator exposure	yes			<input type="checkbox"/>
7.2.2	Bystander and resident exposure				
7.2.2.1	Estimation of bystander and resident exposure	yes			<input type="checkbox"/>
7.2.2.2	Measurement of bystander and resident exposure	yes			<input type="checkbox"/>
7.2.3	Worker exposure				
7.2.3.1	Estimation of worker exposure	yes			<input type="checkbox"/>
7.2.3.2	Measurement of worker exposure	yes			<input type="checkbox"/>
7.3	Dermal absorption	no	Not applicable		<input type="checkbox"/>
7.4	Available toxicological data relating to co-formulant	no	Not applicable		<input type="checkbox"/>
8	Metabolism and residues data				
9	Fate and behaviour in the environment				
9.1	Fate and behaviour in soil				
9.1.1	Rate of degradation in soil				
9.1.1.1	Laboratory studies	no	Not applicable		<input type="checkbox"/>
9.1.1.2	Field studies	no	Not applicable		<input type="checkbox"/>
9.1.2	Mobility in the soil				

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9.1.2.1	Laboratory studies	no	Not applicable		<input type="checkbox"/>
9.1.2.2	Lysimeter studies	no	Not applicable		<input type="checkbox"/>
9.1.2.3	Field leaching studies	no	Not applicable		<input type="checkbox"/>
9.1.3	Estimations of concentrations in soil	no	Not applicable		<input type="checkbox"/>
9.2	Fate and behaviour in water and sediment				
9.2.1	Aerobic mineralisation in surface water	no	Not applicable		<input type="checkbox"/>
9.2.2	Water/sediment study	no	Not applicable		<input type="checkbox"/>
9.2.3	Irradiated water/sediment study	no	Not applicable		<input type="checkbox"/>
9.2.4	Estimation of concentrations in groundwater				
9.2.4.1	Calculation of concentrations in groundwater	no	Not applicable		<input type="checkbox"/>
9.2.4.2	Additional field tests	no	Not applicable		<input type="checkbox"/>
9.2.5	Estimation of concentrations in surface water and sediment	no	Not applicable		<input type="checkbox"/>
9.3	Fate and behaviour in air				
9.3.1	Route and rate of degradation in air and transport via air	no	Not applicable		<input type="checkbox"/>
9.4	Estimation of concentrations for other routes of exposure	no	Not applicable		<input type="checkbox"/>
10	Ecotoxicological studies				
10.1	Effects on birds and other terrestrial vertebrates				
10.1.1	Effects on birds				
10.1.1.1	Acute oral toxicity	no	Not applicable		<input type="checkbox"/>



SANCO/ 11803 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
10.1.1.2	Higher tier data for birds	no	Not applicable		<input type="checkbox"/>
10.1.2	Effects on terrestrial vertebrates other than birds				
10.1.2.1	Acute oral toxicity to mammals	no	Not applicable		<input type="checkbox"/>
10.1.2.2	Higher tier data on mammals	no	Not applicable		<input type="checkbox"/>
10.2	Effects on aquatic organisms				
10.2.1	Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes	no	Not applicable		<input type="checkbox"/>
10.2.2	Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms	no	Not applicable		<input type="checkbox"/>
10.2.3	Further testing on aquatic organisms	no	Not applicable		<input type="checkbox"/>
10.3	Effects on arthropods				
10.3.1	Effects on bees				
10.3.1.1	Acute toxicity to bees				
10.3.1.1.1	Acute oral toxicity to bees	no	Not applicable		<input type="checkbox"/>
10.3.1.1.2	Acute contact toxicity to bees	no	Not applicable		<input type="checkbox"/>
10.3.1.2	Chronic toxicity to bees	no	Not applicable		<input type="checkbox"/>
10.3.1.3	Effects on honey bee development and other honey bee life stages	no	Not applicable		<input type="checkbox"/>
10.3.1.4	Sublethal effects	no	Not applicable		<input type="checkbox"/>
10.3.1.5	Cage and tunnel tests	no	Not applicable		<input type="checkbox"/>
10.3.1.6	Field tests with honeybees	no	Not applicable		<input type="checkbox"/>
10.3.2	Effects on non-target arthropods other than bees				

SANCO/ 11803 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	Data gap
10.3.2.1	Standard laboratory testing for non-target arthropods	no	Not applicable		<input type="checkbox"/>
10.3.2.2	Extended laboratory testing, aged residue studies with non-target arthropods	no	Not applicable		<input type="checkbox"/>
10.3.2.3	Semi-field studies with non-target arthropods	no	Not applicable		<input type="checkbox"/>
10.3.2.4	Field studies with non-target arthropods	no	Not applicable		<input type="checkbox"/>
10.3.2.5	Other routes of exposure for non-target arthropods	no	Not applicable		<input type="checkbox"/>
10.4	Effects on non-target soil meso- and macrofauna				
10.4.1	Earthworms				
10.4.1.1	Earthworms – sub-lethal effects	no	Not applicable		<input type="checkbox"/>
10.4.1.2	Earthworms – field studies	no	Not applicable		<input type="checkbox"/>
10.4.2	Effects on non-target soil meso- and macrofauna (other than earthworms)				
10.4.2.1	Species level testing	no	Not applicable		<input type="checkbox"/>
10.4.2.2	Higher tier testing	no	Not applicable		<input type="checkbox"/>
10.5	Effects on soil nitrogen transformation	no	Not applicable		<input type="checkbox"/>
10.6	Effects on terrestrial non-target higher plants				
10.6.1	Summary of screening data	no	Not applicable		<input type="checkbox"/>
10.6.2	Testing on non-target plants	no	Not applicable		<input type="checkbox"/>
10.6.3	Extended laboratory studies on non-target plants	no	Not applicable		<input type="checkbox"/>
10.6.4	Semi-field and field tests on non-target plants	no	Not applicable		<input type="checkbox"/>

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SANCO/ 11803 data point	Information, test or study	Information, test or study provided	Justification provided	Undertaking provided	<i>Data gap</i>
10.7	Effects on other terrestrial organisms (flora and fauna)	no	Not applicable		<input type="checkbox"/>
10.8	Monitoring data	no	Not applicable		<input type="checkbox"/>
11	Literature data	yes			<input type="checkbox"/>
12	Classification and labelling	yes			<input type="checkbox"/>