BIOCEBO/BIO

DOCUMENT M-CP, Section 10

ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

Version history[1]

Date	Data points containing amendments or additions and brief description	Document identifier and version number
2005-26-06	Initial Document M version, submitted for application of approval of the active substance.	M-Hydr.Protein-AnnexIII IIIA.10. Ecotoxicological studies on the plant protection product
2018-01-09	Added the conclusions from the Draft Assessment Report from Greece, 2008.	DOCUMENT M-CP, Section 10

[1] It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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CP 10 ECOTOXICOLOGICAL STUDIES ON PLANT PROTECTION PRODUCTS

This document reviews the eco-toxicological studies for the product BIOCEBO, containing as active substance Hydrolysed proteins, which was included into Annex I of Directive 91/414/EEC (2009/153/EC). This document refers to the conclusions of the EU review of the Hydrolysed proteins, because the active substance data is relied upon in the risk assessment of the formulation.

The SANCO report for Hydrolysed proteins (SANCO/2615/08 rev 3) is considered to provide the relevant review information or a reference to where such information can be found. The overall conclusions included there, in point 3, states: ..."*there are clear indications that it may be expected that hydrolysed proteins does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, as set out in Annex VI of regulation (EC) 2229/2004 as last amended by Regulation (EC) 1095/2007".*

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on hydrolysed proteins (SANCO/2615/08 - rev 3) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health were taken into account. These concerns were addressed when the Annex III dossier for BIOCEBO was submitted to Spanish Authorities.

This section of the submission summarises the ecotoxicological effects of the formulation and evaluates the potential risk to various representatives of terrestrial, aquatic and soil organisms.

The Assessment Report for Hydrolysed proteins concludes as follows:

"*Regarding to ecotoxicology section, no risk is anticipated due to the use of hydrolyzed proteins to environmental organisms. In our opinion there is no additional data needed concerning the risk to birds and mammals, aquatic organisms, pollinators or non-target arthropods, earthworms, other soil non-target macro-organisms and micro-organisms, other non-target plants and sewage treatment plants of hydrolyzed proteins.*

We can conclude that no additional information needs to be provided to prove that BIOCEBO, when properly used will be devoid of any ecotoxicological risk or impact.

According to this, it is not expected that BIOCEBO, when used under proper conditions, could have any potential risk for:

- *birds,*
- *aquatic organisms (fish, invertebrates, algae, etc.),*
- *terrestrial vertebrates other than birds,*
- *bees,*
- *arthropods other than bees,*
- *earthworms and other non-target soil macro-organisms,*
- *non-target plants, and / or*

- *non-target species (Flora and Fauna).*

Moreover, in Ecotoxicological Expert Panel concluded in the Ecotoxicological area of the Spanish Registration Reports of BIOCEBO, reviewed under Uniform Principles, accepted the conclusions of the Final addendum to the DAR regarding the evaluation of the risk of the active substance Hydrolysed proteins:

Hydrolysed proteins degrade rapidly into simple metabolites which also have no insecticide activity. Residues are only superficial and disappear easily by straightforward washing or with rain. Their persistence in the environment is very short, and there is no bioaccumulation potential.

Biotic degradation of hydrolysed proteins results in simple metabolites called amino acids. These compounds are present in living cells and are not therefore considered residues because they may be used by cells in protein synthesis.

Plants and animals are mainly made up of proteins, which accounts for more than half the dry weight of a cell. Hydrolysed proteins come from the enzymatic hydrolysis of animal tissues, and they therefore pose no danger whatsoever to humans or animals in general.

Hydrolysed proteins were authorised by the EU to be used as an attractant in the production of baits combined with appropriate insecticides in ecological agriculture. This proves that these compounds are innocuous. The use of hydrolysed proteins is considered of low risk to terrestrial and aquatic life to ecosystems in general.

CP 10.1 Effects on Birds and Other Terrestrial Vertebrates

CP 10.1.1 Effects on birds

Not applicable.

Risk assessment for birds

CP 10.1.1.1 Acute oral toxicity

Not applicable.

CP 10.1.1.2 Higher tier data on birds

Not applicable.

CP 10.1.2 Effects on terrestrial vertebrates other than birds

Risk assessment for other terrestrial vertebrates

CP 10.1.2.1 Acute oral toxicity to mammals

Not applicable.

CP 10.1.2.2 Higher tier data on mammals

Not applicable.

CP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

Not applicable.

CP 10.2 Effects on Aquatic Organisms

Not applicable.

Risk assessment for aquatic organisms

CP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

Not applicable.

CP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Not applicable.

CP 10.2.3 Further testing on aquatic organisms

Not applicable.

CP 10.3 Effects on Arthropods

Not applicable.

CP 10.3.1 Effects on bees

Risk assessment for bees

Not applicable.

CP 10.3.1.1 Acute toxicity to bees

CP 10.3.1.1.1 Acute oral toxicity to bees

CP 10.3.1.1.2 Acute contact toxicity to bees

CP 10.3.1.2 Chronic toxicity to bees

CP 10.3.1.3 Effects on honey bee development and other honey bee life stages

CP 10.3.1.4 Sub-lethal effects

CP 10.3.1.5 Cage and tunnel tests

CP 10.3.1.6 Field tests with honeybees

CP 10.3.2 Effects on non-target arthropods other than bees

Risk assessment for other non-target arthropods

Not applicable.

CP 10.3.2.1 Standard laboratory testing for non-target arthropods

CP 10.3.2.2 Extended laboratory testing, aged residue studies with non-target arthropods

CP 10.3.2.3 Semi-field studies with non-target arthropods

CP 10.3.2.4 Field studies with non-target arthropods

CP 10.3.3 Other routes of exposure for non-target arthropods

CP 10.4 Effects on Non-Target Soil Meso- and Macrofauna

Not applicable.

CP 10.4.1 Earthworms

Risk assessment for earthworms

CP 10.4.1.1 Earthworms – sub-lethal effects

CP 10.4.1.2 Earthworms – field studies

CP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Risk assessment for other non-target soil meso- and macrofauna (other than earthworms)

CP 10.4.2.1 Species level testing

CP 10.4.2.2 Higher tier testing

CP 10.5 Effects on Soil Nitrogen Transformation

Not applicable.

Risk assessment for Soil Nitrogen Transformation

CP 10.6 Effects on Terrestrial Non-Target Higher Plants

Not applicable.

Risk assessment for Terrestrial Non-Target Higher Plants

CP 10.6.1 Summary of screening data

CP 10.6.2 Testing on non-target plants

CP 10.6.3 Extended laboratory studies on non-target plants

CP 10.6.4 Semi-field and field tests on non-target plants

CP 10.7 Effects on Other Terrestrial Organisms (Flora and Fauna)

Not applicable.

Risk assessment for Other Terrestrial Organisms (Flora and Fauna)

CP 10.8 Monitoring Data

Not applicable.