

# **BIOCEBO/BIO**

## **DOCUMENT M-CP, Section 12**

### **CLASSIFICATION AND LABELLING OF THE PLANT PROTECTION PRODUCT**

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

Date	Data points containing amendments or additions and brief description	Document identifier and version number
2005-06-26	Initial Document M version, submitted for application of approval of the active substance.	M-Hydr.Protein-AnnexIII
2018-01-09	BIOCEBO as a mixture was reclassified according to the new criteria established in Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures amending	DOCUMENT M-CP Section 12  CP 12 Classification and Labelling of the active substance (Former Section IIIA.11.3 Justified proposals for the classification and labelling).

<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

## Table of Contents

<b>CP 12</b>	<b>CLASSIFICATION AND LABELLING OF THE PLANT PROTECTION PRODUCT.....</b>	<b>4</b>
--------------	--	----------

## CP 12 CLASSIFICATION AND LABELLING OF THE PLANT PROTECTION PRODUCT

The classification and labelling apply to both the active substance and the final plant protection product, taking into consideration BIOCEBO composition.

During the last years, Annex III of BIOCEBO has been updated to adapt to Uniform Principles, according to Annex VI of the Directive 91/414.

Besides, Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures amending Regulation n° 1907/2006 established a new classification which should be applied to all mixtures from 1<sup>st</sup> of June 2015.

To comply with this Regulation, BIOCEBO as a mixture was reclassified according to the new criteria, changing the format of the pictograms and the precautionary statements. BIOCEBO is registered as a plant protection product in Spain since 02/08/2000 with the registration number 22.270.

All the information of BIOCEBO to adapt to Uniform Principles, including the new classification of the product, was sent to Spanish Ministry of Agriculture, Fisheries, Food and Environment.

Spanish Authorities reviewed all the information and expedited the Registration Report which include the following conclusions about the Classification and labelling of BIOCEBO in Toxicology data section:

### **Modification of the approval of a plant protection product. Review under uniform principles.**

*In reply to your official letter requesting a review under uniform principles of the plant protection product with Case No. 22.270, named BIOCEBO, the proprietor of which is BIOIBERICA, S.A.U., following inclusion of hydrolysed proteins in the Annex to Implementing Regulation (EU) 540/2011, please advise as follows:*

*According to the state of the art, bearing in mind the documentation submitted as provided for in Royal Decree 2163/94 and Regulation (EC) N° 1107/2009 and having regard to the provisions of Royal Decree 1311/2012 and Regulations (EC) N° 1272/2008 and (EU) No. 547/2011, this Office of the Director General has decided to approve the aforementioned product subject to the following requirements:*

#### **1. CLASSIFICATION AND LABELLING**

##### **Classification based on health effects and physical and chemical properties**

##### **Signal word**

---

---

### Symbols

-----

### Hazard statements

-----

### Precautionary statements

P261: Avoid inhaling the spray.

P262: Avoid contact with the eyes, skin, and clothes.

P280: Wear gloves and protective clothing.

Bioiberica internally decided to include also the following precautionary statements:

P102: Keep out of reach of children.

P270: When using, do not eat, drink or smoke.

## 2. CLASSIFICATION AND LABELLING

### Other components in addition to the technical-grade active ingredient

-----

### Other phrases and statements

*EUH401: To avoid risks to human health and the environment, comply with the instructions for use.*

### Recommendations in cases of intoxication or accident.

#### First-aid measures:

- *If in eye, rinse with plenty of water for at least 15 minutes. Do not forget to remove contact lenses.*
- *If on skin, rinse with plenty of water and soap, but do not scrub*
- *If necessary transfer the casualty to a medical centre and take the label or the container with you.*

**DO NOT LEAVE THE AFFECTED PERSON ALONE UNDER ANY CIRCUMSTANCES.**

### Therapeutic information for doctors and healthcare personnel:

- Symptomatic treatment

**IN CASE OF ACCIDENT OR ILLNESS, CALL THE NATIONAL POISON CENTRE. TELEPHONE 91-562.04.20. In both cases, have the container or the label at hand.**

### User category

*Professional use*

## 3. TYPES OF CONTAINER