

Hydrolysed proteins

DOCUMENT M-CA, Section 10

CLASSIFICATION AND LABELLING OF THE ACTIVE SUBSTANCE

Version history¹

A) BIO

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-AnnexII
2018-01-09	Hydrolysed proteins 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-CA Section 10 Hydrolysed proteins CP 10 Classification and Labelling of the active substance (Former Section 6A of the Document M, Annex IIA.9).

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

B) PHY

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

C) SIC

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

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CA 10 CLASSIFICATION AND LABELLING OF THE ACTIVE SUBSTANCE (BIO)

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 1st 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

CA 10 CLASSIFICATION AND LABELLING OF THE ACTIVE SUBSTANCE (PHY)

In first inclusion of hydrolysed protein DACONA (registered in Spain) was the representative ppp because it was the registered ppp with the higher content of beet molasses and the lower content of urea. In this renewal we replaced DACONA with ENTOMELA 50SL as the representative ppp because this is now the registered ppp with the same characteristics means the registered ppp with the highest beet molasses protein content.

In case of Hydrolysed proteins the a.s. and the ppp are identical, the physical and chemical properties of a.s. are similar to the properties of formulated product. For more detailed information refer on formulation process on Document J - PHY and for detailed physical and chemical properties refer to MC-P Section 2 – ENT50.

PHYTOPHYL submit a DRR for ENTOMELA 50SL on 2015 according to reg. 1107/2009

The composition of ENT50 by the specifications data given shows a product which is not dangerous. Beet molasses and urea are never classified as toxic substances.

The classification and labeling of the active substance is in accordance with the EC Directive on dangerous preparations 1999/45/EC as amended and according to Regulation (EC) No 1272/2008 are presented below:

GHS Pictogram:

GHS07

Signal word:

WARNING

According to Regulation (EC) 1272/2008 as last amended by Regulation (EC) 286/2011:

Hazard statements (because of the use with insecticides on bait application):

H317	May cause an allergic skin reaction (Cat. 1)
EUH401	To avoid risks to human health and the environment, comply with the instructions for use.

Precautionary statements:

P102+405	Keep out of the reach of Children. Store locked up
P270	Do not eat, drink or smoke when using this product
P280	Wear protective gloves/protective clothing/eye protection/face protection
P301+312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P302 + 352	IF ON SKIN: Wash with plenty of soap and water
P333 + P313	If skin irritation or rash occurs: Get medical advice/attention
P305+351+ 338	IF IN EYES: Rinse cautiously with water for several minutes Remove contact lenses, if present and easy to do. Continue rinsing
P363	Wash contaminated clothing before reuse

P370+260 In case of fire: Do not breathe dust/fume/gas/mist/vapours/spray

Other phrases

Other precautionary phrases because of the use with insecticide:

- Take all the necessary measures for the insecticide.
- Do not spray against the wind.
- After use wash with water and soap.
- Do not spill in watercourse or water irrigating systems.

**CA 10 CLASSIFICATION AND LABELLING OF THE ACTIVE
SUBSTANCE (SIC)****Hazard symbol:**

none

Indication of danger:

none

Risk phrases:

none

Safety phrases:

P102: Keep out of reach of children.

P220: Store away from food, feed, beverage

P270: Do not eat, drink or smoke when using this product.