Hydrolysed proteins

DOCUMENT M-CA, Section 7

FATE AND BEHAVIOUR IN THE ENVIRONMENT

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

[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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CA 7 FATE AND BEHAVIOUR IN THE ENVIRONMENT (BIO)

According to the document Draft Assessment Report (DAR), hydrolysed proteins are natural compounds of degradation from the hydrolysis of living organisms tissues, that can have vegetable or animal origin. Proteins are the most abundant organic molecules in cells. They constitute the 50% of the dry weight of cells, or even more. They can be found in every single cell, since they are fundamental in all aspects of the cell structure and function.

The hydrolysed proteins are biodegradable, so their persistence in the environment is very short, without existing any tendency to bioaccumulation.

Due to the nature of the hydrolysed proteins and its characteristics regarding its fate and behaviour in the Environment, it could be considered very unlikely the existence of relevant residues of hydrolysed proteins in the soil derived from the application of formulated products containing hydrolysed proteins. In addition, it is unlikely that leaching of hydrolysed proteins can occur or that residues can reach groundwater under the proposed conditions of use.

For this reason, it was required the exemption of carrying out the evaluation of the fate and behaviour in the environment of Hydrolysed proteins and it was accepted; the overall conclusion from the draft assessment report, the recommendations by the rapporteur Member State and the result of the examination in accordance with the provisions of Article 24a of Regulation 2229/2004 is that 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.

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CA 7 FATE AND BEHAVIOUR IN THE ENVIRONMENT (PHY)

PHYTOPHYL manufactures “Hydrolysed Protein” which is made of Beet molasses and Urea. Both of them are used very widely for many years and have not ever classified as dangerous substances.

Beet molasses are a natural by-product of the sugar industry, defined as the end product of sugar manufacture or refining from which no more sugar may be economically crystallized by conventional means.

Beet molasses mainly used for two purposes, Animal feed additive and Alcohol Production.

There is no evidence in bibliography that Beet molasses are for some reason toxic, irritant or ecologically unsafe.

PHYTOPHYL & FORESTRY COMISSION notified urea according to 91/414 and the substance is now approved under Reg. (EC) No 1107/2009. No toxicity studies were submitted but literature data about the toxicity of urea indicated limited toxicological potential.

During this first notification and inclusion Urea was not registered to ECHA but now has a full registration, the dossier is evaluated and there are 163 active registrants as a high volume chemical (production of 10.000 000 – 100.000.000 TONNES per year).

The annual application rate for urea, or hydrolysed protein in case of ENTOMELA 50SL for 6 applications per year according to the table of intended uses (CP 3.3) is:

Application rate per year for each active substance and total nitrogen content (6 applications/year)	
Hydrolysed protein	1.8kg – 2.08 kg/ha
Urea	0.576 kg – 0.648kg kg/ha
Total nitrogen content	0,288-0.333kg/ha

These rates are very low if we compare them to the annual application rates for urea as fertilizer which are reported to the ECHA site and are 60kg, 120kg, 180kg N/ha.

We can see that the use of Nitrogen fertilizers emits 180-540 times more nitrogen to the environment than the use of ENTOMELA 50SL for bait sprays and the quantities of urea and beet molasses that liberated to the environment are very low in comparison to the use of similar compounds as fertilizer or other uses, or even the quantities of them in wastewater of human origin or the excreta of animals.

PHYTOPHYL submit a DRR for ENTOMELA 50SL on 2015 according to reg. 1107/2009 and below are the Overall comments of zRMS on environmental fate section:

zRMS EL: We agree with applicant's argumentation. No Environmental Risk is expected through the use of the two active substances Urea & Hydrolysed protein.

No extra data on environmental fate section of hydrolysed protein presented, only for a.s. urea presented below the ECHA endpoint summary on this section:

ECHA endpoint summary for urea:

Urea is stable in aqueous solution. Hydrolysis is not seen and is not predicted based on a theoretical assessment of the structure of the molecule. Urea is considered to be readily biodegradable: the substance will be rapidly degraded by microorganisms present in the environment (as a nutrient and N-source) and subsequently incorporated into the nitrate cycle. Urea is additionally utilised as a N-source by terrestrial and aquatic plants.

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CA 7 FATE AND BEHAVIOUR IN THE ENVIRONMENT (SIC)

The product does not cause negative transformations in the environment if it is used following the suggested dosages and conditions. Hydrolysed proteins are completely biodegradable; Reasonably there are not negative effects on the environment and their persistence in the environment is very short, without existing any tendency to bioaccumulation. Anyway, if present in copious quantities can pollute ground and surface water: it is necessary to prevent concentrated product form penetrating into ground and surface waters. The product is constituted by natural substances and consequently is completely biodegradable.

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