

ENTOMELA 50SL/ENT50

DOCUMENT M-CP, Section 8

RESIDUES IN OR ON TREATED PRODUCTS, FOOD OR FEED

Version history¹

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

CP 8 RESIDUES IN OR ON TREATED PRODUCTS, FOOD AND FEED

Guidance in Annex to SANCO/11803/2010/Rev.7-PPP:

Data and information on residues in or on treated products, food and feed in accordance with Section 6 of Part A of the Annex to Regulation (EU) No XXX [*Office of Publications please insert number of* “**Commission Regulation setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market**”] shall be submitted, unless it is justified that the data and information already submitted for the active substance can be applied.

All data and evaluation must be provided in the KCA Section 4 and MCA Section 4 (Data Point CA 6) of the active substance(s) dossier.

Clear cross reference to the relevant active substance documentation must be provided here.

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 COMMISSION 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.

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

Reviewer's comments: IIIA 8	<p>EL: According to EFSA Journal 2012; 10(2):2545, hydrolysed proteins as a plant protection product is likely to be of low toxicity and a quantitative consumer risk assessment is not needed unless the required technical specification raises a toxicological concern.</p> <p>EL: According to EFSA Journal 2012;10(1):2523, Urea can be used as a fungicide to be applied on fresh-cut stumps of conifers in forests. It can also be used as an insect attractant for the control and the suppression of the olive fruit fly and the Mediterranean fruit fly in olive trees as a spot bait spray treatment in combination with an insecticide. The spray application is recommended on the tree trunk and/or on a small area of the tree foliage. Contact with fruits must be avoided. Urea is also used as a mass trapping agent inside liquid traps. When applied under these conditions, insignificant residues of urea are expected on olive fruits. Therefore a quantitative consumer dietary risk assessment is not necessary due to the specific kinds of application.</p>
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On EFSA Journal 2017;15(11):5046 we see that EFSA prepared a statement explaining that for these nine active substances a review of MRLs is no longer necessary and refer for urea:

“For urea, EFSA in its opinion (EFSA, 2012a) considered that a quantitative consumer dietary risk assessment was not necessary due to the specific methods of application of that substance. Urea (carbamide) is approved as a food additive in accordance with Regulation (EU) No 1129/2011 of the European Parliament and of the Council.⁶ In addition, the natural exposure to that substance is far higher than the one linked to the use of urea as a PPP. In view of this, it was considered appropriate to include this substance in Annex IV to Regulation (EC) No 396/2005 via Commission Regulation (EU) 2015/1608.”