European Commission

Combined Draft Renewal Assessment Report prepared according to Regulation (EC) N° 1107/2009
and
Proposal for Harmonised Classification and Labelling (CLH Report) according to Regulation (EC) N° 1272/2008

HEPTAMALOXYLOGLUCAN

Volume 3 – B.5 (PPP) – PEL101GV

Rapporteur Member State: France
Co-Rapporteur Member State: Spain

Version History

When	What
2020-09	Initial RAR

Introduction
The applicant Elicityl prepared a draft renewal assessment report to support the renewal of inclusion of the active substance Heptamaloxyloglucan.

Heptamaloxyloglucan was included in Annex I of Directive 91/414/EEC under Commission Directive 2010/14/EU, which entered into force on 01 June 2010. According to Regulation (EU) No 540/2011, heptamaloxyloglucan is deemed to have been approved under Regulation (EC) No 1107/2009. An extension of approval has been granted by Regulation (EU) 2017/1527 until 31/05/2021.

The Annex I Inclusion Directive for Heptamaloxyloglucan (2010/14/EU) provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation:
For the implementation of the uniform principles of Annex VI, the conclusions of the review report on heptamaloxyloglucan (SANCO/10502/09 – final, 27/11/2009), and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27/11/2009 shall be taken into account.

Heptamaloxyloglucan is included in AIR 4 program (SANTE-2016-10616–rev 9, June 2018). The rapporteur Member State is France and the co-rapporteur Member State is Spain (Commission Implementing Regulation (EU) 2016/183 of 11 February 2016).

The draft renewal assessment report will be prepared according to Commission Regulation No.844/2012.

Table of contents

B.5. METHODS OF ANALYSIS

B.5.1. METHODS USED FOR THE GENERATION OF PRE-AUTHORISATION DATA

B.5.1.1. Analysis of the plant protection product

B.5.1.1.1 Methods for the determination of the active substance in the plant protection product

As the plant protection product PEL101GV is made of 100% technical active substance EL101GV, the method for determining the composition of the plant protection product is identical to the method used for the determination of heptamaloxyloglucan in the technical active substance.
The analytical method for the determination of the active substance in the technical material EL101GV has been validated by two studies: Ricau 2005 and Groult 2006, and is described in Vol 3CA B.5.

CIPAC Methods:
No CIPAC methods exist for the analysis of Heptamaloxyloglucan in either technical or formulated material.

B.5.1.1.2. Methods for determination of relevant impurities in the plant protection product

The preparation PEL101GV is represented by technical heptamaloxyloglucan itself; therefore the method for determining the relevant impurities in the plant protection product is identical to the method used for the determination of the relevant impurities in the technical active substance. It is described in Vol. 3CA B.5.

B.5.1.2. Methods for the determination of residues

Heptamaloxyloglucan is a branched xyloglucan molecule extracted from apples without additive nor chemical product. It is composed of 7 hexose residues: glucopyranosyl, fucopyranosyl, xylopyranosyl and galactopyranosyl. The terminal glucose residue is reduced as a glucitol residue.

All these hexose and hexol residues are natural components of the apple and of other dicotyledone plants, where they are major constituents of cellulose and hemicellulose molecules, which are themselves the principal components of cell walls.
It is reasonable to consider that these different natural substances are rapidly degraded by soil macro- and micro-organisms as a natural component of humus. This degradation leads to simple components also present in the natural environment.

Therefore, analytical methods for risk assessment could not be validated properly in any case, especially for this natural substance for which a natural background would have to be taken into account.

B.5.2. METHODS FOR POST-APPROVAL CONTROL AND MONITORING PURPOSES

The preparation PEL101GV, which contains 100% EL101GV (technical substance active, nominal at 78.0% heptamaloxyloglucan), will be used as an agricultural frost-protecting agent on grapevines with an application rate of 0.00054 to 0.437 g/ha.

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It is reasonable to consider that these different natural substances are rapidly degraded by soil macro- and micro-organisms as a natural component of humus. This degradation leads to simple components also present in the natural environment.

Thus, as heptamaloxyloglucan is a naturally occurring non-toxic active substance, and that no LMR are set in plants, no analytical methods are required in plants, soil, water and air, according to guideline SANCO 825/00 rev. 6. No methods are required for residues in animal human body fluids and tissues as the active substance heptamaloxyloglucan is not classified as toxic or highly toxic.
Also, for plants, heptamaloxyloglucan is applied on vines at stages BBCH 07-16 when no edible part of the crop is formed and the compound is not systemic.

For the different compartments of the environment calculated PECs are below the trigger values for LOQs:
Soil: PECs < 0.01 mg/kg
Water: PECsw < 0.1 µg/L
Therefore analytical methods for monitoring purposes could in any case not be validated properly, especially for this natural substance for which a natural background would have to be taken into account.

B.5.3. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities[2,3] Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used[1] Y/N If yes, for which data point?
			No data submitted for this section					

[1] In order to facilitate the compilation of the final list of the tests and studies relied upon and the corresponding data protection, indicate whether the study was used in the previous DAR/RAR or, when the information is available, whether the study was already submitted in the framework of national authorisations.
[2] See Art.3 of Annex of Regulation No 283/2013 and 284/2013
[3] The RMS shall check that the GLP statement has been properly signed in the study report, that the study results are properly reported in accordance with GLP standards and following the relevant guidance by OECD on the review of the GLP status of non-clinical safety data (currently under development).