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.4 (AS)

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.

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B.4. FURTHER INFORMATION

B.4.1. METHODS AND PRECAUTIONS CONCERNING HANDLING, STORAGE, TRANSPORT OR FIRE

Handling:
If large quantities are handled, avoid formation of dusty atmosphere (risk of explosion).
The tank must be correctly rinsed to avoid all traces of a preceding treatment. Fill the tank with water up to 50% of the given volume of pulverisation. Open the bottle of the preparation and add 15 mL of water in the bottle with the pipette.
Close the flask with the plastic stopper and mix to obtain a good solubilisation of the product, then pour the solution obtained in the tank and at least twice rinse the bottle with 15 mL of water.
It is recommended to empty in the tank flushing waters of the bottle. Finish filling the tank until given volume.
Storage:
PEL101GV is stable for two years in its original packaging when stored between + 5°C to + 35°C.
Transport:
Not concerned by UN Recommendations on the transport of dangerous goods.
Procedures for cleaning application equipment and protective clothing:
Application equipment and protective clothing:
Decontamination of equipment, packaging is achieved by washing with water plus detergent.

B.4.2. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION

Heptamaloxyloglucan is a naturally occurring substance which is readily biodegradable and without bioaccumulation potency. It is neither toxic nor ecotoxic. Destruction or decontamination is therefore not considered necessary.

B.4.3. EMERGENCY MEASURES IN CASE OF AN ACCIDENT

Personal Precautions:
Traditional individual protections.

Environmental Precaution:
Heptamaloxyloglucan is a substance extracted from plant. It does not have any other effect on grapevine than enhancing its natural resistance to cold. More particularly, it does not have pesticide, fungicide or bactericide activity. Heptamaloxyloglucan respects the environment because of the dose used and its biodegradability.

Methods of Cleaning Up:
Collect mechanically (sponge)

B.4.4. 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?
KCA 3.8/01	Elicityl	2018	Safety data sheet - Heptamaloxyloglucan technical EL101GV ELICITYL, France GLP non relevant unpublished	N	N	-	Elicityl	N, new version

[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).