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 (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.

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B.4. FURTHER INFORMATION

B.4.1. SAFETY INTERVALS AND OTHER PRECAUTIONS TO PROTECT HUMANS, ANIMALS AND THE ENVIRONMENT

Pre-harvest interval (in days) for each relevant crop:
The pre-harvest interval for the envisaged area of application is covered by the application conditions and the growing period remaining between the envisaged application and use; it is not considered necessary to indicate a pre-harvest interval in days (document 7039/VI/9 EN of 22/07/1997).
This information is indicated by F* in the Table 4.1-1.

Table CA 4.1-1: Pre-harvest intervals (PHIs)

Crop/ (EU region)	EU region	PHI (days)
Vine	France, Southern MS	F

Re-entry period (in days) for livestock, to areas to be grazed:
Not applicable. The recommended crops are not grazed by livestock.

Re-entry period (in hours or days) for man to crops, buildings or spaces treated:
Within the meaning of the directive 96/68/CE (21 October 1996), there are no potential residues, i.e. no significant residue being able to have a toxicological incidence on the man.
So re-entry period for man to crops treated is not required.

Withholding period (in days) for animal feeding stuffs:
Not applicable.

Waiting period (in days) between application and handling of treated products:
Within the meaning of the directive 96/68/CE (21 October 1996), there are no potential residues, i.e. no significant residue being able to have a toxicological incidence on the man.
So it is not considered necessary to set waiting periods before handling treated products.

Waiting period (in days) between last application and sowing or planting succeeding crops:
There are no potential residues.
Moreover heptamaloxyloglucan have a strong potential of degradation in the environment, conferring a very short lifespan to the substance after its application (a few hours). Its nature and its structure make a molecule of it entirely neutral monosaccharide degradable metabolisable and not toxic.
The methods of application and in particular the very low concentration of the active substance in the spray (recommended good agricultural practice) leave the molecule to the state of trace. Moreover it is not bioaccumulable.
So waiting period between last application and sowing or planting succeeding crops is not required.

Information on specific conditions under which the preparation may or may not be used:
The product must be applied between 12 and 48 hours before the occurrence of freezing temperatures. PEL101GV is efficient up to – 5°C.

B.4.2. RECOMMENDED METHODS AND PRECAUTIONS

Report:	Safety data sheet – PEL101GV technical ELICITYL, France unpublished
Guidelines:	Regulations (EC) No.1907/2006 – (EU) No.2015/830
GLP:	No, not subject to GLP regulations

The plant protection product PEL101GV is made of 100% technical active substance EL101GV. Therefore the safety data sheet of the plant protection product PEL101GV is the same than the safety data sheet of the technical active substance EL101GV presented in Vol. 4.

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.4.3. EMERGENCY MEASURES IN CASE OF AN ACCIDENT

Personal Precautions:
Traditional individual protections.

Environmental Precaution:
PEL101GV is a product 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. PEL101GV respects the environment because of the dose used and its biodegradability.

Methods of Cleaning Up:
Collect mechanically (sponge)

B.4.4. PACKAGING, COMPATIBILITY OF THE PLANT PROTECTION PRODUCT WITH PROPOSED PACKAGING MATERIALS

Material:	Glass borosilicate flask KG-33
Capacity:	20 mL
Type of closure	Crimped hermetically
and size of opening:	1.3 cm

Long-term storage stability (24 months at 20 ± 2°C) on the plant protection product PEL101GV in its commercial packaging has been provided and demonstrated the compatibility of the preparation with the commercial packaging.

Reference number:	Ferron N. and Ricau H., 2009, Report No.05-905012-006
Report:	Chemical stability for 2 years at 20 +/- 2 °C and physico-chemical tests after the storage procedure on the preparation PEL101GV Ferron N., Ricau H. unpublished
Guidelines:	GIFAP Monograph No. 17
GLP:	Yes

The results of the long-term storage stability (24 months at 20 ± 2°C) on the plant protection product PEL101GV in its commercial packaging are presented in document M-CP, Section 2.

B.4.5. PROCEDURES FOR DESTRUCTION OR DECONTAMINATION OF THE PLANT PROTECTION PRODUCT AND ITS PACKAGING

Unwanted amounts of heptamaloxyloglucan and technical material EL101GV can be destroyed best by combustion in a licensed incinerator.
Decontamination of equipment, packaging a.s.o. is achieved by washing with water plus detergent.

B.4.5.1. Neutralisation procedure

The formulation is neither alcaline nor acidic, therefore no neutralisation is necessary.

B.4.5.2. Controlled incineration

The halogen content of heptamaloxyloglucan and technical substance (EL101GV) is below 60%. Approx. 1100°C with a residence time of 2 seconds are advised as incineration temperature. Expected combustion products are CO_2/CO, and H_2O.
Combustion in a licensed incinerator is the only disposal recommended.

B.4.6. 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?
KCP 4.2/01	Elicityl	2018	SDS PEL101GV Safety data sheet – PEL101GV technical ELICITYL, France GLP non relevant unpublished	N	N	-	Elicityl	N
KCP 4.4/01	Ferron N. and Ricau H.	2009	Chemical stability for 2 years at 20 ± 2°C and physico-chemical tests after the storage procedure on the preparation PEL101GV Defitraces report N°05-905012-006 GLP: Yes Published: No	N	N	-	Elicityl	N

[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).