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.2 (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 has been prepared according to Commission Regulation No.844/2012.

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B.2. PHYSICAL AND CHEMICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT PEL101GV

The claimed application rate is 140 mg product diluted in 100 L of water (0.00014 % w/v)
The claimed packaging is made of glass.

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.1. APPEARANCE						
Physical state and colour **B.2.1/01**	Visual examination Organoleptic determination	Batch No.AND0205 87.0 %	PEL101GV is a highly expanded white beige freeze dried cake The preparation has no odour	Acceptable	Y	Tieche, A., 2006b 05-905012-005
B.2.2. EXPLOSIVE AND OXIDIZING PROPERTIES						
Explosive properties **B.2.2/01**	Reasoning	-	Expert assessment showed no evidence of explosive properties due to very small amounts involved and proposed mode of use.	Acceptable, the product is not explosive.	N	Burosse, V., Ambrosi, D., 2006 ASC 05/23
Oxidizing properties **B.2.2/02**	Reasoning	-	Expert assessment showed no evidence of oxidising properties	Acceptable, the product does not have oxidising properties.	N	Burosse, V., Ambrosi, D., 2006 ASC 05/23
B.2.3. FLAMMABILITY AND AUTO-FLAMMABILITY						
Flash point of the liquids formulations **B.2.3/01**			Not required as the formulation is not liquid	-		
Flammability of solid formulations **B.2.3/02**	Reasoning	-	Expert assessment concluded that no flammability test should be required The product is not flammable.	Acceptable, the product is a combustible carbohydrate that is not classified as flammable	N	Burosse, V., Ambrosi, D., 2006

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
						ASC 05/23
Self-heating of formulation **B.2.3/03**	Reasoning	-	Expert assessment concluded that no auto-flammability test should be required	Acceptable, the product does not have functionalities that could bring self-heating properties	N	Burosse, V., Ambrosi, D., 2006 ASC 05/23
B.2.4. ACIDITY/ALKALINITY AND PH VALUE						
pH of the neat aqueous formulation **B.2.4/01**			Not applicable to solids	-		
pH of a 1 % dilution of the solid or non aqueous formulation **B.2.4/02**	-	Batch No.AND0205 87.0 %	The pH mean value of the test item at 1% w/v in standard water D was: <u>Before storage:</u> − 6.23 at 21.3°C after 1 min. − 7.02 at 21.3°C after 10 min <u>After 14 days at 54°C</u> − 6.58 at 20.7°C after 1 min. − 7.53 at 20.7°C after 10 min <u>After 2 years at 20°C</u> − 6.04 at 20.7°C after 1 min. − 7.09 at 20.9°C after 10 min	Acceptable, a 1% dilution in water has a nearly neutral pH.	Y Y Y	Tieche, A., 2006a 05-905012-004 Tieche, A., 2006b 05-905012-005 Ferron N. and Ricau H., 2009, Report No.05-905012-006
Acidity / Alkalinity **B.2.4/03**			Not required as pH is neither < 4 nor > 10	-		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
B.2.5. VISCOSITY AND SURFACE TENSION						
Viscosity of the liquid formulation **B.2.5/01**			Not applicable to solids	-		
Surface tension of the formulation **B.2.5/02**	EEC A5: ring method	Batch No.AND0205 87.0 %	The surface tension of the test item at 1 g/L in demineralized water was 72.6 ± 0.2 mN/m at 20°C.	Acceptable, the product is not a surface active material.	Y	Tieche, A., 2006a 05-905012-004
B.2.6. RELATIVE DENSITY AND BULK DENSITY						
Relative density of the liquid formulation **B.2.6/01**			Not applicable to solids	-		
Bulk density (pour and tap) of powder or granules **B.2.6/02**	EEC A3 OECD 109	Batch No.AND0205 87.0 %	Density was found ranging from 1.39 to 1.55 g/cm^3, but it was concluded that the method is not applicable to the test item, due to its physical appearance ("freeze-dried cake"). Bulk density is not relevant: required for powders and granules.	Acceptable, as the product is a lyophilisate the density is particularly variable.	Y	Tieche, A., 2006a 05-905012-004
B.2.7. STORAGE STABILITY AND SHELF-LIFE: EFFECTS OF TEMPERATURE ON TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
Stability after accelerated storage (54°C during 14 days, 8 weeks at 40°C, 12 weeks at 35°C or 18 weeks at 30°C) **B.2.7/01**	CIPAC MT 46 Determination of a.s. : analytical method 30987 ATP	Batch No.AND0205 87.0 %	Storage stability after 14 days at 54 ± 2°C: PEL101GV was found to be stable over 14 days at 54 ± 2°C. Content in Heptamaloxyloglucan was found to be (mean of duplicate): Before storage: 85.5% w/w After 14 days: 86.6% w/w (deviation of +1.3%). Other tests (pH – see CP 2.4,	Acceptable, the product is stable in glass after storage up to 14 days at 54 °C.	Y	Tieche, A., 2006b 05-905012-005

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			wettability – see CP 2.8.1, dilution stability – see CP 2.8.4, wet sieving – see CP 2.8.1) confirmed that no significant change of the properties of the preparation were observed after accelerated storage.			
Effect of low temperature on stability of liquid formulation **B.2.7/02**			Not applicable to solids	-		
Shelf life following storage at ambient temperature **B.2.7/03**	According to GIFAP Technical Monograph No. 17	Batch No.AND0205 87.0 %	PEL101GV was found to be stable over 24 months on the ambient shelf life. At the start of the procedure of storage at 20 ± 2°C for 24 months, the concentration of heptamaloxyloglucan was 85.5% and 85.3% (w/w) at the end. Other tests (pH – see CP 2.4, wettability – see CP 2.8.1, dilution stability – see CP 2.8.4, wet sieving – see CP 2.8.1) confirmed that no significant change of the properties of the preparation were observed after accelerated storage.	Acceptable, the product is stable in glass after storage up to 2 years at 20 °C. This corresponds to the commercial packaging.	Y	Ferron N. and Ricau H., 2009, Report No.05-905012-006
B.2.8. TECHNICAL CHARACTERISTICS OF THE PLANT PROTECTION PRODUCT						
B.2.8.1. Wettability						
Wettability of solid formulation **B.2.8.1/01**	CIPAC MT 53.3	Batch No.AND0205 87.0 %	The wettability of PEL101GV has been determined in standard water D: Without swirling: immediate With swirling: immediate After 14 days at 54°C:	Acceptable	Y Y	Tieche, A., 2006a 05-9050-12-004 Tieche, A.,

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			Without swirling: immediate With swirling: immediate After 2 years days at 20°C: Without swirling: immediate With swirling: immediate		Y	2006b 05-9050-12-005 Ferron N. and Ricau H., 2009, Report No.05-905012-006
B.2.8.2. Persistence foaming						
Persistence of foaming of the diluted formulation **B.2.8.2/01**	CIPAC MT 47.2	Batch No.AND0205 87.0 %	Persistent foaming was determined at 1 g/L in standard water D and 30°C in duplicate. No foam was observed after 10s, 1 min and 3 min.	Acceptable	Y	Tieche, A., 2006a 05-905012-004
B.2.8.3. Suspensibility						
Suspensibility of water dispersible formulation **B.2.8.3/01**			Not applicable: the preparation is not a water dispersible product	-		
Spontaneity of dispersion of water dispersible formulation **B.2.8.3/02**			Not applicable: the preparation is not a water dispersible product	-		
Dispersion stability of SE, OD or EG formulation **B.2.8.3/03**			Not applicable: the preparation is not a water dispersible product	-		
B.2.8.4. Degree of dissolution and dilution stability						
Degree of dissolution of water soluble formulation **B.2.8.4/01**	CIPAC MT 179	Batch No.AND0205 87.0 %	Tests were performed at 1.2% w/w and at a temperature of 24.8-26.3°C in standard water D.	Acceptable, the product readily dissolves in water	Y	Tieche, A., 2006a 05-9050-12-

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			After 5 minutes and 18 hours: the quantities of particles held on the 75 µm test sieve was negligible, the degree of dissolution of the preparation was estimated to be 100%. The same results were obtained after accelerated storage at 54°C for 14 days. After 2 years at 20°C The residue after 5 minutes was 0.1% w/w The residue after 18 hours was 0.0% w/w		Y Y	004 Tieche, A., 2006b 05-9050-12-005 Ferron N. and Ricau H., 2009, Report No.05-905012-006
Dilution stability of water soluble formulation **B.2.8.4/02**	CIPAC MT 179	Batch No.AND0205 87.0 %	Tests were performed at 1.2% w/w and at a temperature of 24.8-26.3°C in standard water D. After 5 minutes and 18 hours: the quantities of particles held on the 75 µm test sieve was negligible, the degree of dissolution of the preparation was estimated to be 100%. The same results were obtained after accelerated storage at 54°C for 14 days. After 2 years at 20°C	Acceptable, the diluted product remains physically stable	Y Y Y	Tieche, A., 2006a 05-9050-12-004 Tieche, A., 2006b 05-9050-12-005 Ferron N. and Ricau H.,

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			The residue after 5 minutes was 0.1% w/w The residue after 18 hours was 0.0% w/w			2009, Report No.05-905012-006
B.2.8.5. Particle size distribution, dust content, attrition and mechanical stability						
B.2.8.5.1. Particle size distribution						
Wet sieve test of water dispersible formulation **B.2.8.5.1/01**	CIPAC MT 59.3	Batch No.AND0205 87.0 %	Before storage All the test item passed through a 45-µm sieve (only rare white particles were observed on the 45-µm sieve but the mass of these particles was negligible) After storage 14 days at 54°C All the test item passed through a 45-µm sieve (only rare white particles were observed on the 45-µm sieve but the mass of these particles was negligible). After storage 2 years at 20°C Most of the test item passed through a 45-µm sieve (only few white/beige and some very fine grey particles were observed on the 45-µm sieve).	Acceptable	Y Y Y	Tieche, A., 2006a 05-9050-12-004 Tieche, A., 2006b 05-9050-12-005 Ferron N. and Ricau H., 2009, Report No.05-905012-006
Size distribution of particles of powder or suspension concentrate formulation **B.2.8.5.1/02**			Not applicable as the preparation is neither a powder nor a granule.	The product is a lyophilisate and should be considered as a water soluble powder (SP); however, particle size distribution is not a requirement for a SP formulation.		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
Nominal size range of granule **B.2.8.5.1/03**			Not applicable as the preparation is neither a powder nor a granule.	-		
B.2.8.5.2. Dust content						
Dust content of granular formulation **B.2.8.5.2/01**			Not applicable as the preparation is neither a powder nor a granule.	Not applicable to powders		
B.2.8.5.3. Attrition						
Attrition characteristics of granules and tablets **B.2.8.5.3/01**			Not applicable as the preparation is neither a granule nor a tablet.	Not applicable to powders		
B.2.8.5.4. Hardness and integrity						
Hardness of tablets **B.2.8.5.4/01**			Not required as PEL101GV is not a tablet.	-		
Integrity of tablets **B.2.8.5.4/02**			Not required as PEL101GV is not a tablet.	-		
B.2.8.6. Emulsifiability, re-emulsifiability, emulsion stability						
Emulsifiability, emulsion stability and re-emulsifiability of formulation **B.2.8.6/01**			Not applicable as the preparation does not form an emulsion.	-		
B.2.8.7. Flowability, pourability and dustability						
Flowability of granular formulation **B.2.8.7/01**			Not applicable as the preparation is not a granule, suspension concentrate, capsule suspension, oil in water emulsion, suspo-emulsion nor dustable powder.	-		
Pourability of suspensions **B.2.8.7/02**			Not applicable as the preparation is not a granule, suspension	-		

Test or Study & Data point	Guideline and method	Test material purity and specification	Used methods / Results	Comments (Acceptable / Non acceptable)	GLP	Reference
			concentrate, capsule suspension, oil in water emulsion, suspo-emulsion nor dustable powder.			
Dustability of dustable powders after accelerated storage **B.2.8.7/03**			Not applicable as the preparation is not a granule, suspension concentrate, capsule suspension, oil in water emulsion, suspo-emulsion nor dustable powder.	-		
B.2.9. PHYSICAL AND CHEMICAL COMPATIBILITY WITH OTHER PRODUCTS INCLUDING PLANT PROTECTION PRODUCTS WITH WHICH ITS USE IS TO BE AUTHORISED						
Physical and chemical compatibility of tank mixtures **B.2.9/01**			Not required. PEL101GV has been evaluated as solo preparation for Annex I listing.	-		
B.2.10. ADHERENCE AND DISTRIBUTION TO SEEDS						
Distribution and adhesion to seeds **B.2.9.10/01**			Not applicable, PEL101GV is not being registered for seed treatment.	-		
B.2.11. OTHER STUDIES						

Summary and Conclusions

The plant protection product PEL101GV is made of 100% technical active substance EL101GV.
The preparation is a highly expanded white beige odourless freeze dried cake that is not surface active. Based on literature, structural formula and oxygen balance, it is concluded that the preparation is not flammable, not explosive and does not possess oxidizing or auto-flammability properties. However, as a potential risk of dust explosion cannot be excluded due to the physical form of EL101GV (combustible fine particles), the precautionary statement P271 is proposed.

When dispersed at 1% w/v in water, it has a pH of 7.02 and the density of the solid preparation is included between 1.39 and 1.55 g/cm^3. The preparation has an immediate wettability and during a wet sieve test, none material remains on a 75 µm sieves. At 1 g/L in water, no foam remains after 3 minutes, indicating that the preparation is not a foaming product. The dilution stability was demonstrated, the degree of dilution was 100% at 1.2% w/w in water.
The physical and chemical properties of the preparation were stable after an accelerated storage procedure (14 days at 54°C) in commercial packaging (glass bottle). The shelf life stability of 24 months at ambient temperature is also demonstrated in commercial packaging (glass bottle).

B.2.12. 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 2.1/01	Tieche, A.	2006	Accelerated storage procedure for 14 days at 54±2°C and physico-chemical tests after the storage procedure on the preparation PEL101GV Defitraces report N°05-905012-005 GLP: Yes Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCP 2.2/01 KCP 2.3/01	Burosse, V. and and Ambrosi D.	2006	Literature survey on flammability, explosive properties, oxidizing properties of the active substance heptamaloxyloglucan ASC report N°06/02 GLP: No Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCP 2.4/01	Tieche, A.	2006	Physico-chemical tests on the preparation PEL101GV Defitraces report N°05-905012-004 GLP: Yes Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCP 2.4/02	Tieche, A.	2006	Accelerated storage procedure for 14 days at 54±2°C and physico-chemical tests after the storage procedure on the preparation PEL101GV Defitraces report N°05-905012-005 GLP: Yes Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCP 2.4/03	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	N	N	-	Elicityl	N

			Published: No					
KCP 2.5/01	Tieche, A.	2006	Physico-chemical tests on the preparation PEL101GV Defitraces report N°05-905012-004 GLP: Yes Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCP 2.6/01	Tieche, A.	2006	Physico-chemical tests on the preparation PEL101GV Defitraces report N°05-905012-004 GLP: Yes Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCP 2.7/01	Tieche, A.	2006	Accelerated storage procedure for 14 days at 54±2°C and physico-chemical tests after the storage procedure on the preparation PEL101GV Defitraces report N°05-905012-005 GLP: Yes Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCP 2.7/02	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
KCP 2.8.1/01	Tieche, A.	2006	Physico-chemical tests on the preparation PEL101GV Defitraces report N°05-905012-004 GLP: Yes Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCP 2.8.1/02	Tieche, A.	2006	Accelerated storage procedure for 14 days at 54±2°C and physico-chemical tests after the storage procedure on the preparation PEL101GV Defitraces report N°05-905012-005 GLP: Yes Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCP 2.8.1/03	Ferron N. and Ricau H.	2009	Chemical stability for 2 years at 20 ± 2 °C and physico-chemical tests after the storage procedure	N	N	-	Elicityl	N

			on the preparation PEL101GV Defitraces report N°05-905012-006 GLP: Yes Published: No					
KCP 2.8.2/01	Tieche, A.	2006	Physico-chemical tests on the preparation PEL101GV Defitraces report N°05-905012-004 GLP: Yes Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCP 2.8.4/01	Tieche, A.	2006	Physico-chemical tests on the preparation PEL101GV Defitraces report N°05-905012-004 GLP: Yes Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCP 2.8.4/02	Tieche, A.	2006	Accelerated storage procedure for 14 days at 54±2°C and physico-chemical tests after the storage procedure on the preparation PEL101GV Defitraces report N°05-905012-005 GLP: Yes Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCP 2.8.4/03	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).