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.1 (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 present draft renewal assessment report has be prepared according to Commission Regulation No.844/2012.

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B.1. IDENTITY

B.1.1. IDENTITY OF THE ACTIVE SUBSTANCE

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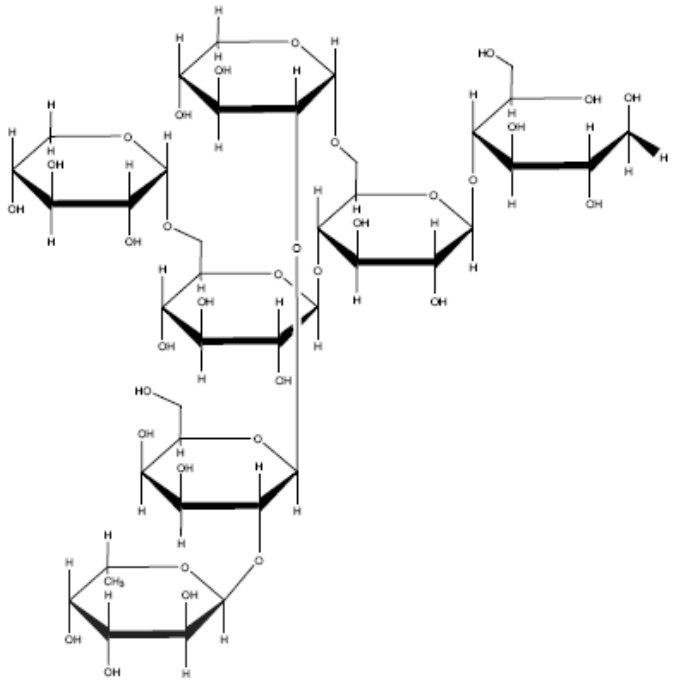
B.1.1.1. Common name proposed or ISO-accepted and synonyms	Heptamaloxyloglucan
B.1.1.2. Chemical name (IUPAC and CA nomenclature)	
IUPAC	*{[α-D-Xyl p-*(1→6)]-*β-D-Glc p-*(1→4)}{[*α-L- Fuc p-*(1→2)-*β-D-Gal p-*(1→2)-*α-D-Xyl p-*(1→6)]-*β-D-Glc p-*(1→4)}*-D-Glc-ol* Xyl p: xylopyranosyl Glc p: glucopyranosyl Fuc p: fucopyranosyl Gal p: galactopyranosyl Glc-ol: glucitol
CA	/
B.1.1.3. Producer's development code number	EL101GV EL101GV xyloglucan
B.1.1.4. CAS, EEC and CIPAC numbers	
CAS	870721-81-6
EEC	Not available
CIPAC	Not available
B.1.1.5. Molecular and structural formula, molecular mass	
Molecular formula	$C_{40}H_{70}O_{33}$

Structural formula	
Molecular mass	1078.96 g/mol
B.1.1.6. Method of manufacture (synthesis pathway) of the active substance	Considered as confidential information please refer to Vol. 4
B.1.1.7. Specification of purity of the active substance in g/kg	≥ 780 g/kg
B.1.1.8. Identity and content of additives (such as stabilisers) and impurities	
B.1.1.9. Additives	Considered as confidential information please refer to Vol. 4
B.1.1.10. Significant impurities	Considered as confidential information please refer to Vol. 4
B.1.1.11. Relevant impurities	Patulin (max 50 µg/kg)
B.1.1.12. Analytical profile of batches	Considered as confidential information please refer to Vol. 4

B.1.2. REFERENCES RELIED ON

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing	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?

			facilities[2,3] Published or not					
			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).