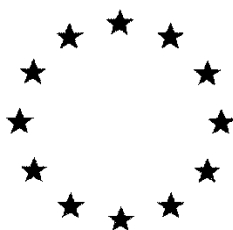


# *European Commission*



**Draft Renewal Assessment Report prepared according to  
Regulation (EC) N° 1107/2009**

## **Heptamaloxyloglucan**

### **Volume 2**

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

## Version History

When	What
2020-09	Initial DAR

The RMS is the author of the Assessment Report. The Assessment Report is based on the validation by the RMS, and the verification during the EFSA peer-review process, of the information submitted by the Applicant in the dossier, including the Applicant's assessments provided in the summary dossier. As a consequence, data and information including assessments and conclusions, validated and verified by the RMS experts, may be taken from the applicant's (summary) dossier and included as such or adapted/modified by the RMS in the Assessment Report. For reasons of efficiency, the Assessment Report should include the information validated/verified by the RMS, without detailing which elements have been taken or modified from the Applicant's assessment. As the Applicant's summary dossier is published, the experts, interested parties, and the public may compare both documents for getting details on which elements of the Applicant's dossier have been validated/verified and which ones have been modified by the RMS. Nevertheless, the views and conclusions of the RMS should always be clearly and transparently reported; the conclusions from the applicant should be included as an Applicant's statement for every single study reported at study level; and the RMS should justify the final assessment for each endpoint in all cases, indicating in a clear way the Applicant's assessment and the RMS reasons for supporting or not the view of the Applicant.

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## **A. LIST OF THE TESTS, STUDIES AND INFORMATION SUBMITTED**

### **A.1. IDENTITY**

<b>Data Point</b>	<b>Author(s)</b>	<b>Year</b>	<b>Title Report No. Document No. Source (where different from company) GLP/Officially recognised testing facilities<sup>2,3</sup> Published or not</b>	<b>Vertebrate study Y/N</b>	<b>Data protection claimed Y/N</b>	<b>Justification if data protection is claimed</b>	<b>Owner</b>	<b>Previously used<sup>1</sup> Y/N  If yes, for which data point?</b>
Document J CA 1.8/01	Deilhes, F.	2006	Method of manufacturing of EL101GV Elicityl, Crolles, France Report EL101GV-160106-02 No unpublished	N	N	-	ELICIT YL	Y, in DAR 2007
Document J CA 1.8/02	Anonymous	-	Nufri certificate Nufri, Spain Not relevant Unpublished	N	N	-	ELICIT YL	N, submitted for the purpose of renewal
Document J CA 1.8/03	Anonymous	-	Fiche de données de sécurité Pectinex® 3XL Novozymes, Bagsvaerd, Denmark Report Not relevant Unpublished	N	N	-	ELICIT YL	N, submitted for the purpose of renewal
Document J CA 1.8/04	Anonymous	-	SDS Sodium hydroxide ThermoFisher Scientific, Geel, Belgium Not relevant unpublished	N	N	-	ELICIT YL	N, submitted for the purpose of renewal
Document J CA 1.8/05	Anonymous	-	SDS Sodium borohydride ThermoFisher Scientific, Geel, Belgium Not relevant unpublished	N	N	-	ELICIT YL	N, submitted for the purpose of renewal
Document J CA 1.10/01	Havet, S.	2006	Impurity Study EL101GV Technical Active Substance Elicityl, Crolles, France Report EL101GV-160106-03 No unpublished	N	N	-	ELICIT YL	Y, in DAR 2007
Document J CA 1.10/02	Greloux, M.	2018	Rapport d'analyse n° AR-18-AA-196626-01 / 370-2018-	N	N	-	ELICIT YL	N, submitted for the purpose of renewal

			00215581 Eurofins, WEJ Contaminants GmbH, Germany Report n° AR-18- AA-196626- 01 / 370-2018- 00215581 No unpublished					
Document J CA 1.10/03	Balleix, M.	2018	Rapport d'analyse n° AR-18-AA- 196567-01 / 370-2018- 00215580 Eurofins, WEJ Contaminants GmbH, Germany Report n° AR-18- AA-196567- 01 / 370-2018- 00215580 No unpublished	N	N	-	ELICIT YL	N, submitted for the purpose of renewal
Document J CA 1.10/04	Balleix, M.	2018	Rapport d'analyse n° AR-18-AA- 196566-01 / 370-2018- 00215579 Eurofins, WEJ Contaminants GmbH, Germany Report n° AR-18- AA-196566- 01 / 370-2018- 00215579 No unpublished	N	N	-	ELICIT YL	N, submitted for the purpose of renewal
Document J CA 1.10/05	Balleix, M.	2018	Rapport d'analyse n° AR-18-AA- 196609-01 / 370-2018- 00215578 Eurofins, WEJ Contaminants GmbH, Germany Report n° AR-18- AA-196609- 01 / 370-2018- 00215578 No unpublished	N	N	-	ELICIT YL	N, submitted for the purpose of renewal
Document J CA 1.10/06	Guigou, B.	2006	Dossier : 63 897-1, Rapport N° : 71 195 Lara Europe Analyses, France Report n° 71 195 No unpublished	N	N	-	ELICIT YL	Y, in DAR 2007
Document J CA 1.10/07	Tannous J. et al.	2016	Patulin transformation products and last intermediates in its biosynthetic	N	N	-	-	N, submitted for the purpose of renewal

			pathway, E- and Z-ascladiol, are not toxic to human cells Arch Toxicol DOI 10.1007/s00204-016-1900-y No Published					
Document J CA 1.11/01	Groult, R.	2006	Analytical profile of production batches CIT, Evreux, France Study 30994 ATP Yes unpublished	N	N	-	ELICIT YL	Y, in DAR 2007
Document J CA 1.11/02	Bastide L.	2018	CERTIFICAT D'ANALYSE Nom du produit : EL101GV Lot de Production : EA0035-SA11 Elicityl, Crolles, France No unpublished	N	N	-	ELICIT YL	N, submitted for the purpose of renewal
Document J CA 1.11/03	Bastide L.	2019a	CERTIFICAT D'ANALYSE Nom du produit : EL101GV Lot de Production : DA0155-RA50 Elicityl, Crolles, France No unpublished	N	N	-	ELICIT YL	N, submitted for the purpose of renewal
Document J CA 1.11/04	Bastide L.	2019b	CERTIFICAT D'ANALYSE Nom du produit : EL101GV Lot de Production : DA0161-RA50 Elicityl, Crolles, France No unpublished	N	N	-	ELICIT YL	N, submitted for the purpose of renewal
Document J CA 1.11/05	Bastide L.	2019c	CERTIFICAT D'ANALYSE Nom du produit : EL101GV Lot de Production : EB0182-RA50 Elicityl, Crolles, France No Unpublished	N	N	-	ELICIT YL	N, submitted for the purpose of renewal
Document J CA 1.11/06	Bastide L.	2019d	CERTIFICAT D'ANALYSE Nom du produit : EL101GV Lot de Production : EB0183-RA50 Elicityl, Crolles, France No unpublished	N	N	-	ELICIT YL	N, submitted for the purpose of renewal

<sup>1</sup> 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.

<sup>2</sup> See Art.3 of Annex of Regulation No 283/2013 and 284/2013

<sup>3</sup> 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).

## A.2. PHYSICAL AND CHEMICAL PROPERTIES

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/Officially recognised testing facilities <sup>2,3</sup> Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used <sup>1</sup> Y/N  If yes, for which data point?
KCA 2.1/01 (KCA 2.4/01)	Mourgues, L.	2006	Melting point, boiling point (DSC method) and UV/Visible spectrum of pure heptamalaxyloglucan Defitraces report N°05-905012-001 GLP: Yes Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCA 2.2/01	Fort S. and Ambrosi D.	2006	Physico-chemical, environmental and ecotoxicological properties of the active substance heptamalaxyloglucan ASC report N°05/24 GLP: No Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCA 2.3/01	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
KCA 2.4/01 (KCA 2.1/01)	Mourgues, L.	2006	Melting point, boiling point (DSC method) and UV/Visible spectrum of pure heptamalaxyloglucan Defitraces report N°05-905012-001 GLP: Yes Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCA 2.4/02	Havet, S.	2006	SPECTROSCOPY STUDY Elicityl report EL101GV-160106-01 GLP: No Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCA 2.5/01 (KCA 2.6/01)	Ricau, H.	2006	Determination of the solubility on the technical	N	N	-	Elicityl	Y, in DAR 2007



			Heptamaloxyloglucan in water and organic solvents Defitraces Report N°05-905012-002 GLP: Yes Published: No					
KCA 2.6/01 (KCA 2.5/01)	Ricau, H.	2006	Determination of the solubility on the technical Heptamaloxyloglucan in water and organic solvents Defitraces Report N°05-905012-002 GLP: Yes Published: No	N	N	-	Elicityl	Y, in DAR 2007
KCA 2.9/01 (KCA 2.11/01) (KCA 2.13/01)	Burosse, V. 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
KCA 2.11/01 (KCA 2.9/01) (KCA 2.13/01)	Burosse, V. 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
KCA 2.12/01	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
KCA 2.13/01 (KCA 2.9/01) (KCA 2.11/01)	Burosse, V. 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
KCA 2.14/01	Ricau, H.	2006	Abiotic degradation on the technical Heptamaloxyloglucan pH dependent hydrolysis (Test C7) Defitraces Addendum to	N	N	-	Elicityl	Y, in DAR 2007

			report N°05-905012-003 GLP: Yes Published: No					
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 Ambrosi D.	2006	Literature survey on flammability, explosive properties, oxidizing properties of the active substance heptamaloxylglucan 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 Published: No	N	N	-	Elicityl	N, submitted for the purpose of renewal
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	N	N	-	Elicityl	Y, in DAR 2007

			PEL101GV Defitraces report N°05-905012-004 GLP: Yes Published: No					
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 Ricaud 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, submitted for the purpose of renewal
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 Ricaud 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, submitted for the purpose of renewal
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	N	N	-	Elicityl	Y, in DAR 2007

			PEL101GV Defitraces report N°05-905012-004 GLP: Yes Published: No					
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 Ricaud 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, submitted for the purpose of renewal

<sup>1</sup> 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.

<sup>2</sup> See Art.3 of Annex of Regulation No 283/2013 and 284/2013

<sup>3</sup> 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).

## A.3. DATA ON APPLICATION AND EFFICACY

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities <sup>2,3</sup> Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used <sup>1</sup> Y/N If yes, for which data point?
KCA 3.3/01 (KCA 3.6.01)	Lienart, Y.	2006	EL101 GV - Mode of Action ELICITYL report EL101GV-150106-01 GLP: No Published: No	N	N	-	Elicityl	Y Previous DAR II 3.5/1
KCA 3.6/01 (KCA 3.3.01)	Lienart, Y.	2006	EL101 GV - Mode of Action ELICITYL report EL101GV-150106-01 GLP: No Published: No	N	N	-	Elicityl	Y Previous DAR II 3.5/1
KCP 3.5/01	Lasserre T.	2006	Droplet distribution study Elicityl PEL101GV-260406-01 GLP: non relevant Unpublished	N	N	-	Elicityl	N
KCP 3.5/02	Berthoud	2006	Sprintair – Speedair – Technical sheet Berthoud N°85357 BF - 08/99GLP: non relevant Unpublished	N	N	-	Elicityl	N
KCP 3.8/01	Anonymous	2018	Instructions for use Elicityl v.2018 GLP: non relevant Unpublished	N	N	-	Elicityl	N
KCP 3.8/02	Anonymous	2018	Notice d'utilisation Vigne Elicityl v.2018 GLP: non relevant	N	N	-	Elicityl	N

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities <sup>2,3</sup> Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used <sup>1</sup> Y/N  If yes, for which data point?
			Unpublished					
KCP 6/01	Lienart Y.	2006	Preliminary study of efficiency of ELICITYL, CROLLES, France Report PEL101GV-150106-02 GEP: no Unpublished	N	N	-	Elicityl	N
KCP 6/01 Appendix 9	Picault F.	2003	Etude de la Résistance au froid après application d'un Eliciteur STAGE, Tours, France Report 0311P1 GEP: no Unpublished	N	N	-	Elicityl	Y (national authorisation III A 6.1.2.1 III A 6.1.5)
KCP 6/01 Appendix 10	Picault F.	2004a	Etude de la Résistance au froid après application d'un Eliciteur STAPHYT, FONDETTES, France Report D04 116 01 GEP: no Unpublished	N	N	-	Elicityl	Y (national authorisation III A 6.1.2.2)
KCP 6/01 Appendix 7	Salvador P.	2005	Effect of PEL101GV on Vine ELICITYL, CROLLES, France Report internal Nov 17th, 2005 GEP: no Unpublished	N	N	-	Elicityl	Y (national authorisation III A 6.1.3.1)
KCP 6/01 Appendix 8	Picault F.	2004b	Etude de la Résistance au froid après application d'un Eliciteur STAPHYT, FONDETTES,	N	N	-	Elicityl	Y (national authorisation III A 6.1.3.2 III A 6.1.6.1)

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities <sup>2,3</sup> Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used <sup>1</sup>  Y/N  If yes, for which data point?
			France Report D04 116 06 GEP: no Unpublished					
KCP 6/02	Lienart Y.	2006	Efficiency study Elicityl, 38 920 Crolles, France Report PEL101GV-150106-03 GEP: no Unpublished	N	N	-	Elicityl	N
KCP 6/02 Appendix 4	Picault F.	2004b	Etude de la Résistance au froid après application d'un Eliciteur STAPHYT, FONDETTES, France Report D04 116 02 GEP: no Unpublished	N	N	-	Elicityl	Y (national authorisation III A 6.1.6.2)
KCP 6/02 Appendix 5	Picault F.	2004c	Pulvérisation foliaire de EL101GV hors période gélive sur Pinot noir pour suivi de développement de la plante STAPHYT, FONDETTES, France Report D04 116 04 GEP: no Unpublished	N	N	-	Elicityl	Y (national authorisation III A 6.2.5)
KCP 6.2.2/01	Lienart Y. and Salvador P.	2003	Plein champ CIVC (Champagne) Elicityl, 38 920 Crolles, France Report PEL101GV-050301 GEP: no Unpublished	N	N	-	Elicityl	Y (national authorisation III A 6.2.3.1)
KCP	Lienart Y.	2004a	Plein Champ	N	N	-	Elicityl	Y

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities <sup>2,3</sup> Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used <sup>1</sup> Y/N If yes, for which data point?
6.2.2/02	and Salvador P.		Chablis (coleor n° FELI 047333) Elicityl, 38 920 Crolles, France Report PEL101GV-050401 GEP: no Unpublished					(national authorisation III A 6.2.3.2)
KCP 6.2.2/03	Lienart Y. and Salvador P.	2004b	Plein champ Tracy Elicityl, 38 920 Crolles, France Report PEL101GV-040401 GEP: no Unpublished	N	N	-	Elicityl	Y (national authorisation III A 6.2.3.3)

<sup>1</sup> 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.

<sup>2</sup> See Art.3 of Annex of Regulation No 283/2013 and 284/2013

<sup>3</sup> 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).



## A.4. FURTHER INFORMATION

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities <sup>2,3</sup> Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used <sup>1</sup> 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 submitted for the purpose of renewal
KCP 4.2/01	Elicityl	2018	SDS PEL101GV Safety data sheet - PEL101GV technical ELICITYL, France GLP non relevant unpublished	N	N	-	Elicityl	N, submitted for the purpose of renewal
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, submitted for the purpose of renewal

<sup>1</sup> 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.

<sup>2</sup> See Art.3 of Annex of Regulation No 283/2013 and 284/2013

<sup>3</sup> 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).

## A.5. METHODS OF ANALYSIS

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities <sup>2,3</sup> Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used <sup>1</sup> Y/N  If yes, for which data point?
KCA 4.1/01	Ricau, H.	2006	Validation of the analytical method on the technical test item Heptamaloxyloglucan Defitraces, 69126 Brindas, France Addendum of April 2 <sup>nd</sup> , 2007 to the study report 05-905012-007 Yes unpublished	N	N	-	Elicityl	Y (DAR, 2007)
KCA 4.1/02	Groud, R.	2005	Validation of the analytical method for the determination of the active substance in technical material CIT, 27005 Evreux, France Study report 30987 No, but study conducted in the spirit of GLP unpublished	N	N	-	Elicityl	Y (DAR, 2007)
KCA 4.1/02	Groud, R	2006	Validation of the analytical method for the determination of the active substance in technical material Amendment n°1 CIT, 27005 Evreux, France Study report 30987 No, but study conducted in the spirit of GLP unpublished	N	N	-	Elicityl	Y (DAR, 2007)
B.5.1.1.2	Anonymous	1993	ISO 8128-1:1993 Apple juice, apple juice concentrates and drinks containing apple juice — Determination of patulin content — Part 1: Method using high-performance liquid chromatography	N	N	-		Y (Addendum of DAR, 2009)

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			NA Published					

<sup>1</sup> 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.

<sup>2</sup> See Art.3 of Annex of Regulation No 283/2013 and 284/2013

<sup>3</sup> 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).

## A.6. TOXICOLOGY AND METABOLISM DATA

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities <sup>2,3</sup> Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used <sup>1</sup> Y/N  If yes, for which data point?
KCA 5.1/01 (KCA 6.2.1/01)	Buchanan B.B., Gruissen W., and Jones R.L.	2000	Biochemistry and Molecular Biology of Plants Public literature (book) GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.1/02	Fry S. and al.	1993	Oligosaccharides as signals and substrates in the plant cell wall. Plant Physiol., Vol. 103 (1993), pp. 1-5 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.1/03	Hayashi T.	1989	Xyloglucans in the primary cell wall Annu. Rev. Plant Physiol. Plant Mol. Biol. 1989, 40:139-68 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.1/04	Wahbe T.G. and Christie D.L.	2006	Chapter 2: Basic aspects of digestion and absorption. Pediatric Gastrointestinal and Liver disease, 3 <sup>rd</sup> edition, Hardback edition, 1348 p., 2006 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.1/05	Heyraud A., Rinaudo M.	1981	Hydrolysis of oligosaccharides by polyelectrolytes. European polymer journal, Vol.17, pp.181-189, 1981 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.1/06	Havet S.	2007	EL101GC Hydrolysis study at pH 2.2 and 50°C during 2 days Elicityl SA, 38920 Crolles, France	N	N	-	-	Y (DAR, 2007)

			Study No. EL101GV- 31012007-01 No GLP Unpublished					
KCA 5.1/07	Alvarez E.E. and Sanchez P.G.	2006	Dietary fibre Nutrition Hospitalaria, Vol.21 (supl. 2), pp. 60-71, 2006 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.1/08	Macfarlane S. et al.	1998	Polysaccharide degradation by human intestinal bacteria during growth under multi-substrate limiting conditions in a three-stage continuous culture systems FEMS Microbiology Ecology, Vol. 26, pp. 231-243, 1998 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.1/09	Gardiner T.	2000a	Absorption, distribution, metabolism and excretion (ADME) of eight known dietary monosaccharides required for glycoprotein synthesis and cellular recognition processes. GlycoScience & nutrition., Vol 1 (12), pp. 1-7, 2000 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.1/10	Gardiner T.	2000b	Dietary fucose: Absorption, distribution, metabolism and excretion (ADME) and biological activity. GlycoScience & nutrition., Vol 1 (6), pp.1-4, 2000 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.1/11	Gardiner T.	2000c	Dietary galactose: Absorption, distribution, metabolism and excretion (ADME) and biological activity. GlycoScience & nutrition., Vol 1 (7), pp.1-4, 2000 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)

KCA 5.1/12	Gardiner T.	2000d	Dietary glucose: Absorption, distribution, metabolism and excretion (ADME) and biological activity. GlycoScience & nutrition., Vol 1 (18), pp.1-4, 2000 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.1/13	Gardiner T.	2000e	Dietary xylose: Absorption, distribution, metabolism and excretion (ADME) and biological activity. GlycoScience & nutrition., Vol 1 (5), pp.1-2, 2000 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.1/14	Ramberg J.	2005	Sorbitol GlycoScience. The nutrition science site. Web capture. Date Last modified : 2001 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.1/15	Topping D.L. and Clifton P.M.	2001	Short-chain fatty acids and human colonic function : roles of resistant starch and nonstarch polysaccharides Physiological Reviews, Vol. 81 (3), pp. 1031-1063, 2001 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.1/16	Kattak M.M.A.	2002	Physiological effects of dietary complex carbohydrates and its metabolites in certain diseases Pakistan Journal of Nutrition, Vol. 1 (4), pp. 161-168, 2002 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.2.1/01	*****	2006b	Acute oral toxicity in the rat : Acute toxicity class method (OECD 423) CERB Study 20030812ST GLP Unpublished	Y	N	-	Elicityl	Y (DAR, 2007)
KCA 5.2.2/01	*****	2006a	Acute dermal toxicity in the rat (OECD 402)	Y	N	-	Elicityl	Y (DAR, 2007)

			CERB Study 20050508STC GLP Unpublished					
KCA 5.2.3/01	Lamblin G. et al.	1992	Human respiratory mucins. <i>Eur Respir J</i> 199~. 5, 247-268 GLP non relevant (Public literature) Published	N	N	-	Elicityl	N
KCA 5.2.4/01	*****	2006c	Acute skin irritation in the rabbit (OEC404) CERB Study 200401148STC GLP Unpublished	Y	N	-	Elicityl	Y (DAR, 2007)
KCA 5.2.5/01	*****	2006d	Acute eyes irritation in the rabbit (OEC405) CERB Study 200401147STC GLP Unpublished	Y	N	-	Elicityl	Y (DAR, 2007)
KCA 5.2.6/01	*****.	2006	Evaluation of skin sensitization potential in mice using the local lymph node assay (LLNA) CIT Study 31168 TSS GLP Unpublished	Y	N	-	Elicityl	Y (DAR, 2007)
KCA 5.3.1/01	*****.	2006	EL101GV Repeated dose 28- day toxicity study in the rat by the oral route Centre de Recherches Biologiques (CERB) 20060118TRB GLP Unpublished	Y	N	-	Elicityl	Y (DAR, 2007)
KCA 5.3.2/01 (KCA 5.5/05)	Sano M, Miyata E, Tamano S, Hagiwara A, Ito N, Shirai T.	1996	Lack of carcinogenicity of tamarind seed polysaccharide in B6C3F1 mice. <i>Food Chem Toxicol.</i> 1996;34(5):463-7 GLP non relevant (Public literature) Published	Y	N	-	Elicityl	Y (DAR, 2007)
KCA 5.4.1/01	Le Curieux F.	2006	Bacterial test on Salmonella typhimurium His- (5 strains) using B.N. Ames's technique with EL101GV FSR-IPL 030207 / EL101GV / Elicityl GLP Unpublished	N	N	-	Elicityl	Y (DAR, 2007)
KCA 5.4.1/02	Hensel A, Meier K.	1999	Pectins and xyloglucans exhibit antimutagenic activities against	N	N	-	-	Y (DAR, 2007)

			nitroaromatic compounds. <i>Planta Med.</i> 1999, 65(5): 395-399 GLP non relevant (Public literature) Published					
KCA 5.4.1/03	Nesslany F.	2006	Mutation assay at the TK locus in L5178Y Mouse lymphoma cells using a microtiter cloning technique (Trifluorothymidine Resistance) carried out with EL101GV GLP Unpublished	N	N	-	Elicityl	Y (DAR, 2007)
KCA 5.5/01	Iida M, Matsunaga Y, Matsuoka N <i>et al.</i>	1978	Two years feeding toxicity study of tamarind seed polysaccharide in rats. <i>Journal of Toxicological Sciences.</i> 1978; 3:163-192 GLP non relevant (Public literature) Published	Y	N	-	-	Y (DAR, 2007)
KCA 5.5/02	Zhuang C, Mizuno T, Shimada A <i>et al.</i>	1993	Antitumor protein-containing polysaccharides from a Chinese mushroom Fengweigu or Houbitake, Pleurotus sajor-caju (Fr.) Sing. <i>Biosci Biotechnol Biochem.</i> 1993;57(6): 901-6 GLP non relevant (Public literature) Published	Y	N	-	-	Y (DAR, 2007)
KCA 5.5/03	Wasser SP.	2002	Medicinal mushrooms as a source of antitumor and immunomodulating polysaccharides. <i>Appl Microbiol Biotechnol.</i> 2002;60(3): 258-74 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.5/04	Mizuno T, Kinoshita T, Zhuang C, Ito H, Mayuzumi Y.	1995	Antitumor-active heteroglycans from shiitake mushroom, <i>Tricholoma giganteum</i> . <i>Biosci Biotechnol Biochem.</i> 1995;59(4):568-71 GLP non relevant (Public literature) Published	N	N	-	-	Y (DAR, 2007)
KCA 5.8.3/01	Guillot A.L.	2020	EDGD_Appendix-E1_hexamaloxylglucan_EDdata_v1 GLP non relevant Non published	Y	N	-	Elicityl	N



<sup>1</sup> 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.

<sup>2</sup> See Art.3 of Annex of Regulation No 283/2013 and 284/2013

<sup>3</sup> 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).

## A.7. RESIDUE DATA

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities <sup>2,3</sup> Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used <sup>1</sup> Y/N  If yes, for which data point?
KCA 6.2.1/01 (KCA 5.1/01)	Buchanan B.B., Gruissen W., and Jones R.L.	2000	Biochemistry and Molecular Biology of Plants Public literature (book) GLP non relevant (Public literature) Published	N	N	NA	NA Literature study	Yes in initial DAR
KCA 6.2.1/02 KCA 6.3.1/01	Jovanovic-Malinovska R., Kuzmanova S., Winkelhausen E.	2014	Oligosaccharide profile in fruits and vegetables as sources of prebiotics and functional foods International Journal of Food Properties, 17:949–965, 2014 GLP non relevant (Public literature) Published	N	N	NA	NA Literature study	No
KCA 6.2.1/03 KCA 6.3.1/02	Jovanovic-Malinovska R., Kuzmanova S., Winkelhausen E.	2015	Application of ultrasound for enhanced extraction of prebiotic oligosaccharides from selected fruits and vegetables Ultrasonics Sonochemistry 22 (2015) 446–453 GLP non relevant (Public literature) Published	N	N	NA	NA Literature study	No
KCA 6.5/01	Forgo P., Kiss A., Korózs M., Rapi S.,	2013	Thermal degradation and consequent fragmentation of widely applied oligosaccharides Microchemical	N	N	NA	NA Literature study	No

			Journal 107 (2013) 37–46 GLP non relevant (Public literature) Published					
KCA 6.5/02	Rondeau P., Gambiera F., Jolibert F., Brosse N.	2013	Compositions and chemical variability of grape pomaces from french vineyard Industrial Crops and Products 43 (2013) 251– 254 GLP non relevant (Public literature) Published	N	N	NA	NA Literature study	No

<sup>1</sup> 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.

<sup>2</sup> See Art.3 of Annex of Regulation No 283/2013 and 284/2013

<sup>3</sup> 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).

## A.8. ENVIRONMENTAL FATE AND BEHAVIOUR

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities <sup>2,3</sup> Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used  Y/N  If yes, for which data point?
CA 7.1.1.1/01	Warren R.A.J.	1996	Microbial hydrolysis of polysaccharides GLP: No Published: Yes	N	N	-	Literature study	Y, same data point
CA 7.1.1.1/02	De Vries R. & Visser J.	2001	Aspergillus enzymes involved in degradation of plant cell wall polysaccharides GLP: No Published: Yes	N	N	-	Literature study	Y, same data point
CA 7.1.1.1/03	Wershaw R.	2004	Evaluation of conceptual models of natural organic matter (humus) from a consideration of the chemical and biochemical processes of humification GLP: No Published: Yes	N	N	-	Literature study	Y, same data point
CA 7.1.1.1/04	Karroum M. et al.	2004	Importance and fate of biopolymers (lignins and polysaccharides) in soils of Fagus sylvatica stands of various ages in Fougères forest GLP: No Published: Yes	N	N	-	Literature study	Y, same data point
CA 7.1.1.1/05	Pérez J. & Muñoz- Dorado J.	2002	Biodegradation and biological treatments of cellulose, hemicellulose and lignin: an overview GLP: No Published: Yes	N	N	-	Literature study	Y, same data point
CA 7.1.1.1/06	Aro N. et al.	2005	Transcriptional regulation of plant cell wall degradation by filamentous fungi GLP: No Published: Yes	N	N	-	Literature study	Y, same data point
CA 7.1.1.1/07	Tuomela M. et al.	2000	Biodegradation of lignin in a compost environment: a review GLP: No Published: Yes	N	N	-	Literature study	Y, same data point
CA 7.1.1.1/08	Kelker N.E. & Anderson R.L.	1971	Sorbitol metabolism in Aerobacter aerogenes GLP: No Published: Yes	N	N	-	Literature study	Y, same data point
CA 7.1.1.1/09	Brechtel E. et al.	2002	L-Glucitol catabolism in Stenotrophomonas maltophilia Ac GLP: No Published: Yes	N	N	-	Literature study	Y, same data point
CA	Galloway	2018	Xyloglucan is released by	N	N	-	Literature	N

7.1.1.1/10	A. et al.		plants and promotes soil particle aggregation GLP: No Published: Yes				study	
CA 7.1.1.1/11	Valinhas et al.	2018	Xylose fermentation to ethanol by new <i>Galactomyces geotrichum</i> and <i>Candida akabanensis</i> strains. GLP: No Published: Yes	N	N	-	Literature study	N
CA 7.1.1.1/12	Veras H.C. et al.	2017	Comparative assessment of fermentative capacity of different xylose-consuming yeasts. GLP: No Published: Yes	N	N	-	Literature study	N
CA 7.1.1.1/13	Yamaguchi et al.	2000	Differences in the recognition of glucan elicitor signals between rice and soybean: b-glucan fragments from the rice blast disease fungus <i>pyricularia oryzae</i> that elicit phytoalexin biosynthesis in suspension-cultured rice cells GLP: No Published: Yes	N	N	-	Literature study	N
CA 7.1.1.3/01	Baker, N. R., & Allison, S. D.	1996	Ultraviolet photodegradation facilitates microbial litter decomposition in a Mediterranean climate GLP: No Published: Yes	N	N	-	Literature study	N
CA 7.1.1.3/02	L. A. Brandt, J. Y. King, S. E. Hobbie, D. G. Milchunas and R. L. Sinsabaugh	2010	The Role of Photodegradation in Surface Litter Decomposition Across a Grassland Ecosystem Precipitation Gradient GLP: No Published: Yes	N	N	-	Literature study	N
CA 7.1.1.3/03	Yang Lin . Jennifer Y. King . Steven D. Karlen . John Ralph	2015	Using 2D NMR spectroscopy to assess effects of UV radiation on cell wall chemistry during litter decomposition GLP: No Published: Yes	N	N	-	Literature study	N
CA 7.1.1/ additional information	Havet and Salvador	2007	Heptamaloxyloglucan quantification in pomace enzymatic hydrolysis solution GLP: No Published: No	N	N	-	Elicityl	N
CA 7.2.1.1/01	Ricau H.	2005	Abiotic degradation on the technical heptamaloxyloglucan, pH dependent hydrolysis (Test C7) GLP: Yes Published: No	N	N	-	Elicityl	Y, same data point

CA 7.2.2.1/01	L'Haridon, J.	2006	Determination of the ready biodegradability CO2 evolution test GLP: Yes Published: No	N	N	-	Elicityl	Y, same data point
CA 7.2.2.3/01	A. Freixa, E. Ejarque, S. Crognale, S. Amalfitano, S. Fazi, A. Butturini, A. M. Romani	2016	Sediment microbial communities rely on different dissolved organic matter sources along a Mediterranean river continuum GLP: No Published: Yes	N	N	-	Literature study	N
CA 7.2.2.3/02	Anna M. Romani, Stefano Amalfitano, Joan Artigas, Stefano Fazi, Sergi Sabater, Xisca Timoner, Irene Ylla, Annamaria Zoppini	2012	Microbial biofilm structure and organic matter use in Mediterranean streams GLP: No Published: Yes	N	N	-	Literature study	N
CA 7.2.2.3/03	Younes K., Abdelli G., Araj N., Grasset L.	2015	Comparison of thermochemical and chemical methods for the analysis of carbohydrates in an ombrotrophic peatland GLP: No Published: Yes	N	N	-	Literature study	N
Impact of water treatment procedure/01	Wang W., Zhang C., Tong S., Cui Z., Liu P	2018	Enhanced enzymatic hydrolysis and structural features of corn stover by NaOH and ozone combined pretreatment GLP: No Published: Yes	N	N	-	Literature study	N
Impact of water treatment procedure/02	Yao S., Wang C., Gao C., Shi L. Nie S. Qin C.	2018	Molecular simulation of reaction mechanism for hemicellulose model compound during chlorine dioxide bleaching GLP: No Published: Yes	N	N	-	Literature study	N

## A.9. ECOTOXICOLOGY DATA

Data Point	Author(s)	Year	Title Report No. Document No. Source (where different from company) GLP/ Officially recognised testing facilities <sup>2,3</sup> Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previously used <sup>1</sup> Y/N  If yes, for which data point?
CA 8.1/01	Buchanan B.B. <i>et al</i>	2000	Chapter 2: The Biochemistry and molecular Biology of Plants B. Buchanan, W. Gruissem, R. Jones, Eds. 2000, pp 52-89 Not GLP, published	N	N	-	-	Y
CA 8.1/02	Fry S. and al.	1993	Oligosaccharides as signals and substrates in the plant cell wall. Plant Physiol., Vol. 103 (1993), pp. 1-5 GLP non relevant (Public literature) Published	N	N	-	-	Y
<b>Erreur ! Source du renvoi introuvable.</b> <sup>3</sup>	Stevens C.E., Hume I.D.	1998	Contributions of microbes in vertebrate gastrointestinal tract to production and conservation of nutrients Physiol.Rev., 1998 Apr, 78(2), pp 393-427 Not GLP, published	Y	N	-	-	Y
<b>Erreur ! Source du renvoi introuvable.</b> <sup>4</sup>	Morgan N.K., Keerqin C., Wallace A., Wu S.B., Choct	2019	Effect of arabinoxylo-oligosaccharides and arabinoxylans on net energy	Y	N	-	-	N

	M.		and nutrient utilization in broilers Animal Nutrition 5 (2019) 56-62 Not GLP, published					
CA 8.1/05	Suo <i>et al.</i>	2015	Effectiveness of dietary xylo oligosaccharides for broilers fed a conventional 2 corn-soybean meal diet community Journal of Integrative Agriculture Doi : 10.1016/S2095-3119(15)61101-7 Not GLP, published	Y	N	-	-	N
CA 8.1/06	Yuan, L. <i>et al.</i>	2018	Effects of xylo-oligosaccharide and flavomycin on the immune function of broiler chickens PeerJ, DOI 10.7717/peerj.4435 Not GLP, published	Y	N	-	-	N
CA 8.2.1/01	*****	2006a	EL101GV: Acute toxicity in the Rainbow trout under semi-static conditions CIT, BP 563, 27005 Evreux, France 30711 EAP GLP, unpublished	Y	N	-	Elicityl	Y
CA 8.2.1/02	Geraylou Z., <i>et al.</i>	2012	Effects of arabinoxylan-oligosaccharides (AXOS) on juvenile Siberian	Y	N	-	-	N



			sturgeon ( <i>Acipenser baerii</i> ) performance, immune responses and gastrointestinal microbial community E Fish & Shellfish Immunology 33 (2012) 718- 724 Not GLP, published					
CA 8.2.1/03	Geraylou Z., <i>et al.</i>	2013	Effects of dietary arabinoxylan- oligosaccharide s (AXOS) and endogenous probiotics on the growth performance, non-specific immunity and gut microbiota of juvenile Siberian sturgeon ( <i>Acipenser baerii</i> ) Fish & Shellfish Immunology 35 (2013) 766- 775 Not GLP, published	Y	N	-	-	N
CA 8.2.1/04	Hoseinifar, S. <i>et al.</i>	2014	Effects of dietary fructo- oligosaccharide supplementatio n on the growth performance, haemato- immunological parameters, gut microbiota and stress resistance of common carp ( <i>Cyprinus carpio</i> ) fry British Journal of Nutrition (2014), 112,	Y	N	-	-	N

			1296–1302 Not GLP, published					
CA 8.2.1/05	Ye, J.D <i>et al.</i>	2011	Single or combined effects of fructo- and mannan oligosaccharide supplements and <i>Bacillus clausii</i> on the growth, feed utilization, body composition, digestive enzyme activity, innate immune response and lipid metabolism of the Japanese flounder <i>Paralichthys olivaceus</i> . Aquaculture Nutrition 2011 17; e902–e911 Not GLP, published	Y	N	-	-	N
CA 8.2.4/01	L'Haridon J.	2006b	EL101GV: Acute toxicity in <i>Daphnia magna</i> under static conditions CIT, BP 563, 27005 Evreux, France 30710 EAD GLP, unpublished	N	N	-	Elicityl	Y
CA 8.2.6/01	L'Haridon J	2006c	EL101GV: Algal growth inhibition test. CIT, BP 563, 27005 Evreux, France 30709 EAA GLP, unpublished	N	N	-	Elicityl	Y
CA 8.3.1.1/01	Servajean E.	2006a	Laboratory determination of the contact and oral acute toxicity of a formulation to	N	N	-	Elicityl	Y

			honey bees ( <i>Apis mellifera</i> ) (OECD 213 and OECD 214, september 1998) Phytosafe unpublished Report number 05-27-064-ES GLP, unpublished					
CA 8.3.1/01	Winston M.L. <i>et al.</i>	1987	The biology of the honey bee Harvard University Press, 1987, 281 pp Not GLP, published	N	N	-	-	Y
CA 8.3.1/02	Haydak M.H. <i>et al.</i>	1970	Honey bee nutrition Annu. Rev. Entomol., Vol. 15, pp. 143- 156, 1970 Not GLP, published	N	N	-	-	Y
CA 8.3.1/03	Barker R.J. <i>et al.</i>	1977	Some carbohydrates found in pollen and pollen substitutes are toxic to honey bees J. Nutr., Vol. 107, pp. 1859- 1862, 1977 Not GLP, published	N	N	-	-	Y
CA 8.3.1/04	Smessaert J. <i>et al.</i>	2019	Monitoring pollinator activity in an apple and pear orchard, linked with the analysis of the nectar composition Acta Hortic. 1231. ISHS 2019. DOI 10.17660/Acta Hortic.2019.12 31.11 Proc. II Int. Workshop on Floral Biology	N	N	-	-	N

			and S-Incompatibility in Fruit Species Eds.: E. Ortega Pastor, J. Halász and P. De Franceschi Not GLP, published					
CA 8.3.1/05	Pavlova T. <i>et al.</i>	2018	Quality characteristics of honey: a review Proceedings of university of ruse - 2018, volume 57, book 10.2. Not GLP, published	N	N	-	-	N
CA 8.3.1/06	Machado De-Melo A. A. <i>et al.</i>	2017	Composition and properties of <i>Apis mellifera</i> honey: A review. Journal of Apicultural Research, 2017 - <a href="https://doi.org/10.1080/00218839.2017.1338444">https://doi.org/10.1080/00218839.2017.1338444</a> Not GLP, published	N	N	-	-	N
CA 8.3.1/07	Lee F.J. <i>et al.</i>	2014	Saccharide breakdown and fermentation by the honey bee gut microbiome Environmental Microbiology (2014) - <a href="https://doi.org/10.1111/1462-2920.12526">doi:10.1111/1462-2920.12526</a> . Not GLP, published	N	N	-	-	N
CA 8.3.1/08	Dmitruk M. <i>et al.</i>	2019	Flowering, nectar secretion, and structure of the nectary in the flowers of <i>Acer pseudoplatanus</i> L. Acta Agrobot.	N	N	-	-	N

			2019;72(3):178 7 Not GLP, published					
CA 8.3.1/09	Somme L. <i>et al.</i>	2016	Food in a row : urban trees offer valuable floral resources to pollinating insects Urban Ecosyst - DOI 10.1007/s1125 2-016-0555-z Not GLP, published	N	N	-	-	N
CA 8.3.1/10	Tomczyk M. <i>et al.</i>	2019	The influence of geographical origin on honey composition studied by Polish and Slovak honeys Food Analysis, Food Quality and Nutrition Czech Journal of Food Sciences, 37, 2019 (4): 232– 238 - <a href="https://doi.org/10.17221/40/2019-CJFS">doi.org/10.17221/40/2019-CJFS</a> Not GLP, published	N	N	-	-	N
CA 8.3.1/11	Val A. <i>et al.</i>	1998	Enzymatic Determination of Galactose and Lactose in Honey J. Agric. Food Chem. 1998, 46, 1381-1385 Not GLP, published	N	N	-	-	N
CA 8.4/01	Lattaud C. <i>et al.</i>	1997	Activities of the digestive enzymes in the gut and in tissue culture of a tropical geophagous earthworm, <i>Polypheretima elongata</i> (megascloecid ae)	N	N	-	-	Y

			Soil Biol. Biochem., Vol 29 (3/4), pp 335-339, 1997 Not GLP, published					
CA 8.4/02	Zhang B.G. <i>et al.</i>	1993	Activity and origin of digestive enzymes in gut of tropical earthworm <i>Pontoscolex corethrurus</i> Eur. J. Soil Biol., Vol 29 (1), pp 7-11, 1993 Not GLP, published	N	N	-	-	Y
CA 8.4/03	Garvin M.H. <i>et al.</i>	2000	Activity of glycolytic enzymes in the gut of <i>Hormogaster elisae</i> (Oligochaeta, Hormogastridae) Soil Biology & Biochemistry, Vol. 32, pp 929-934, 2000 Not GLP, published	N	N	-	-	Y
CA 8.5/01	Robertson G.P. <i>et al.</i>	2015	Nitrogen transformations . Pages 421-446 in E. A. Paul, editor. Soil microbiology, ecology and biochemistry. Fourth edition. Academic Press, Burlington, Massachusetts, USA Not GLP, published	N	N	-	-	N
CA 8.5/02	Veras H.C.T <i>et al.</i>	2017	Comparative assessment of fermentative capacity of different xylose-consuming	N	N	-	-	N

			yeasts Veras <i>et al.</i> Microb Cell Fact (2017) 16:153 Not GLP, published					
CA 8.6/01	L'Haridon J. (interim report) Servajean E.. (final report)	2006	Semi-field assessment of the side-effect of a substance on the vegetative growth of terrestrial plants CIT unpublished report number 05-27-072-ES 05-27-072-ES Not GLP, unpublished	N	N	-	Elicityl	Y
CA 8.6/02	Jovanovic- Malinovsk a R <i>et al.</i>	2014	Oligosaccharid e profile in fruits and vegetables as sources of prebiotics and functional foods. International Journal of Food Properties, 17:949–965, 2014 Not GLP, published	N	N	-	-	N
CA 8.6/03	Jovanovic- Malinovsk a R <i>et al.</i>	2015	Application of ultrasound for enhanced extraction of prebiotic oligosaccharide s from selected fruits and vegetables Ultrasonics Sonochemistry 22 (2015) 446– 453 Not GLP, published	N	N	-	-	N
CA 8.6/04	Kollárová R <i>et al.</i>	2009	Impact of galactoglucom annan oligosaccharide s on elongation	N	N	-	-	N

			growth in intact mung bean plants Plant Science 177 (2009) 324–330 Not GLP, published					
CA 8.6/05	Kollárová R <i>et al.</i>	2018	Impact of galactoglucan oligosaccharides and Cd stress on maize root growth parameters, morphology, and structure Journal of Plant Physiology 222 (2018) 59–66 Not GLP, published	N	N	-	-	N

<sup>1</sup> 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.

<sup>2</sup> See Art.3 of Annex of Regulation No 283/2013 and 284/2013

<sup>3</sup> 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).