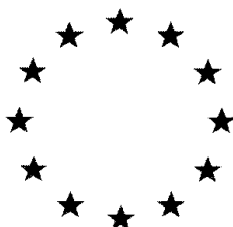


European Commission



VOLUME 2

Laminarin

Rapporteur Member State: The Netherlands

April 2016

**Draft Re-Assessment Report and Proposed decision of the Netherlands
prepared in the context of the possible renewal of laminarin under Regulation
(EC) 1107/2009**

Version history page

Date	Version history
April 2016	Initial RAR

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A. List of the tests, studies and information submitted**A.1 Identity**

Please refer to Volume 4 for the confidential studies submitted to support the identity section.

A.2 Physical and chemical properties**Reference for the active substance**

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CA 2.1/01	Licata-Messana L.	2000a	Laminarin – Melting point SEPC Report No.00-907005-003 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.1/02	Licata-Messana L.	2000b	Laminarin – Boiling point SEPC Report No.00-907005-004 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.2/01	Tremain S.P.	2001	Laminarin: Determination of Vapour Pressure SafePharm Laboratories Limited Report No.1303/005 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.4/01	Cuthbert J.E.	2001	Laminarin - Determination of Spectra SafePharm Laboratories Limited Report No.1476/001 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.4/02	Delolme F.	2000	Analysis by MALDI-TOF Mass Spectrometry CNRS Report No.FC000828 Non-GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.5/01	Anding C.	2002	Hydrosolubility of laminarin	N	N		Laboratoires Goëmar SAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Défitraces Report No.DEF/01-069 GLP, unpublished				
CA 2.6/01	Licata-Messana L.	2001a	Laminarin – Solubility in n-Heptane SEPC Report No.00-907005-009 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.6/02	Licata-Messana L.	2001b	Laminarin – Solubility in Xylene SEPC Report No.00-907005-010 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.6/03	Licata-Messana L.	2001c	Laminarin – Solubility in 1,2 Dichloroethane SEPC Report No.00-907005-011 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.6/04	Licata-Messana L.	2001d	Laminarin – Solubility in Methanol SEPC Report No.00-907005-012 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.6/05	Licata-Messana L.	2001e	Laminarin – Solubility in Acetone SEPC Report No.00-907005-013 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.6/06	Licata-Messana L.	2001f	Laminarin – Solubility in Ethyl acetate SEPC Report No.00-907005-014 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.7/01	Quintelas G.	2001a	Laminarin – Determination of the partition coefficient	N	N		Laboratoires Goëmar SAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			of Laminarin Defitraces Report No.SEP/00-074 GLP, unpublished				
CA 2.8/01	Quintelas G.	2001b	Laminarin – Abiotic degradation of Laminarin pH dependent hydrolysis (Test C7) Defitraces Report No.SEP/00-075 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.8/02	Comb A.I.	2003	Laminarin – Abiotic degradation : hydrolysis as a function of pH Huntingdon Life Sciences Report No.GOM/004 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.9/01	Licata-messana I.	2000c	Laminarin – Flammability of solids SEPC Report No.00-907005-016 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.9/02	Licata-messana I.	2000d	Laminarin – Flammability in contact with water SEPC Report No.00-907005-017 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.9/03	Licata-messana I.	2000e	Laminarin – Self ignition temperature of solids SEPC Report No.00-907005-019 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.11/01	Licata-messana I.	2000f	Laminarin – Explosive properties SEPC Report No.00-907005-018	N	N		Laboratoires Goëmar SAS

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GLP, unpublished				
CA 2.12/01	Licata-messana I.	2000g	Laminarin – Surface tension SEPC Report No.00-907005-007 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 2.13/01	Licata-messana I.	2000h	Laminarin – Oxidizing properties SEPC Report No.00-907005-020 GLP, unpublished	N	N		Laboratoires Goëmar SAS

References for the PPP

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 2.1/01	Cage S.	2015	Laminarin Formulation, Vacciplant Fruits et Légumes Accelerated Storage Stability for 2 Weeks at 54°C Huntingdon Life Sciences Eye Research Centre Eye, Suffolk, UK Study No.DQU0006-report GLP - Unpublished	N	Y	A 10-year data protection period is claimed as this study : - is necessary for the registration of Vacciplant Fruits et Légumes - has not been submitted in the past - has been made in accordance with the GLP principles	Laboratoires Goëmar S.A.S.
CP 2.1/01b	Comb, A.L.	2009	Physpé Storage stability. Huntingdon Life Sciences	N	Y	A 10-year data protection period is claimed as this study :	Laboratoires Goëmar S.A.S.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			Eye Research Centre Eye, Suffolk, UK Study No.VKV0003 GLP - Unpublished			- is necessary to show that no auto-flammability/flammability/oxidizing/explosives properties are expected. - has not been submitted in the past	
CP 2.2/01	Ambrosi D., Michelet D.	2015	Literature review on auto-flammability, flammability, explosive properties, oxidising properties of the ingredients of the product Vacciplant Fruits et Légumes Ambrosi Scientific Consulting 71570 Chaintré, France A.S.C. Report No.14/22 Not GLP – Unpublished	N	Y	A 10-year data protection period is claimed as this study : - is necessary to show that no auto-flammability/flammability/oxidizing/explosives properties are expected. - has not been submitted in the past	Laboratoires Goëmar S.A.S.

A.3 Data on application and efficacy

No references submitted.

A.4 Further information

References for the PPP

Data point	Author(s)	Year	Title Source Company, Report No. GLP or GEP status Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
KCP 4.2/01	Anonymous	2015	Safety data sheet – Product: Vacciplant Fruits et Légumes Revision date 2015/01/23 Regulations (EC) No.1907/2006 – No.453/2010 GLP: no Published	N	N	-	Laboratoires Goëmar SAS

A.5 Methods of analysis

References for the active substance

Point / Reference number	Author(s)	Year	Title Testing facility, Report n°, GLP or GEP Status published or not	Data Protection Claimed Y/N	Owner
IIA 4.1/01	DUVAL P.	2001	Laminarin : measuring by ionic chromatography, amperometric detector SGS Laboratoire Crépin - Study N° ME- 0211A Non-GLP, unpublished	Y	GOË
IIA 4.1/02 (location : IIA 2.6/01)	QUINTELAS G.	2001a	Analysis of Laminarin in water samples after a hydrosolubility test (EEC A6) SEPC – Study N°00-907005-008 GLP, unpublished	Y	GOË
IIA 4.1/03	CRUZ F.	1998	Determination of pure Laminarin : global method Laboratoires GOËMAR S.A. Study N° FC98005 Non-GLP, unpublished	Y	GOË
IIA 4.1/03d	TREBERT R.	2002	Validation of the method of the dosage of pure Laminarin : Global method – GLP study SGS Laboratoire Crépin – Report N° BPL 200107/1309 – rev.2 GLP, unpublished	Y	GOË

Point / Reference number	Author(s)	Year	Title Testing facility, Report n°, GLP or GEP Status published or not	Data Protection Claimed Y/N	Owner
IIA 4.1/04	PORTAIL A.	2000a	Confidential information : <i>Please refer to Document J.</i> SGS Laboratoire Crépin -Study N° ME-0207B Non-GLP, unpublished	Y	GOË
IIA 4.1/05	DELACOURT H.M.	2000	Confidential information : <i>Please refer to Document J.</i> SGS Laboratoire Crépin -Study N° ME-0204B Non-GLP, unpublished	Y	GOË
IIA 4.1/06	TREBERT R.	2000a	Confidential information : <i>Please refer to Document J.</i> SGS Laboratoire Crépin -Study N° ME-0201A Non-GLP, unpublished	Y	GOË
IIA 4.1/07	PORTAIL A.	2000b	Confidential information : <i>Please refer to Document J.</i> SGS Laboratoire Crépin -Study N° ME-0205B Non-GLP, unpublished	Y	GOË
IIA 4.1/08	TREBERT R.	2000b	Confidential information : <i>Please refer to Document J.</i> SGS Laboratoire Crépin -Study N° ME-0202B Non-GLP, unpublished	Y	GOË

References for the PPP

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
Cage S.	CP 5.1.1/01	2015	Laminarin Formulation, Vacciplant Fruits et Légumes, Method Validation for the Assay of Active Substance, Laminarin Huntingdon Life Sciences Eye Research Centre Eye, Suffolk, UK Study No.DQU0005 - report GLP - Unpublished	N	Y	A 10-year data protection period is claimed as this study : - is necessary for the registration of Vacciplant Fruits et Légumes - has not been submitted in the past - has been made in accordance with the GLP principles	Laboratoires Goëmar S.A.S.

A.6 Toxicology and metabolism data**References for the active substance**

Point	Author(s)	Year	Title Testing facility, Report n°, GLP or GEP Status published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
B.6.1.1	Vetvicka V, Dvorak B, Vetvickova J, Richter J, Krizan J, Sima P, Yvin JC.	2007	Orally administered marine (1-->3)-beta-D-glucan Phycarine stimulates both humoral and cellular immunity. Non-GLP Published	Y	N		/
B.6.2.1	████████	1998	Acute toxicity study - Safety test in the rat by the oral route report N°.970352 ST GLP Unpublished	Y	N		Laboratoires Goëmar S.A.S.
B.6.2.1	Babíček K, Cechová I, Simon RR, Harwood M, Cox DJ	2007	Toxicological assessment of a particulate yeast (1,3/1,6)- beta-D-glucan in rats. Non-GLP Published	Y	N		/
B.6.2.2.	██████████ █	2001	H11 (Batch 99S24) - Acute dermal toxicity study in the rat ████████ Report n°2000698 ST GLP Unpublished	Y	N		Laboratoires Goëmar S.A.S.
B.6.2.2.	████████	1998	Phycarine® 96S51 - Acute toxicity study - Safety test in the rat by the sub-cutaneous route ████████ Report n°970353 ST GLP Unpublished	Y	N		Laboratoires Goëmar S.A.S.
B.6.2.3.	████████	1999	Evaluation of acute inhalation toxicity of Phycarine® in rats ████████ Report n°980001 EX GLP Unpublished	Y	N		Laboratoires Goëmar S.A.S.
B.6.2.4.	████████	1998a	Phycarine®96S51 - Cutaneous primary irritation in the rabbit ████████ Report n°970349 ST GLP Unpublished	Y	N		Laboratoires Goëmar S.A.S.

Point	Author(s)	Year	Title Testing facility, Report n°, GLP or GEP Status published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
B.6.2.5.	██████	1998b	Phycarine® 96S51-Ocular primary irritation in the rabbit ██████ Report n°970350 ST GLP Unpublished	Y	N		Laboratoires Goëmar S.A.S.
B.6.2.6.	██████	1998c	Phycarine® 96S51 - Study of cutaneous sensitisation using the Magnusson and Kligman maximisation test in the guinea pig ██████ Report n°970351 ST GLP Unpublished	Y	N		Laboratoires Goëmar S.A.S.
B.6.3.1.	██████	2000	H11 – 4-week oral toxicity study in rats ██████ Report n° RTC 7286/T/240/99 GLP Unpublished	Y	N		Laboratoires Goëmar S.A.S.
B.6.3.2.	██████ █	2001a	H11- 90-day repeated dose oral toxicity study in the rat ██████ Report n° 20000389T GLP Unpublished	Y	N		Laboratoires Goëmar S.A.S.
B.6.3.2	Babíček K, Cechová I, Simon RR, Harwood M, Cox DJ	2007	Toxicological assessment of a particulate yeast (1,3/1,6)- beta-D-glucan in rats. No GLP Published	Y	N		/
B.6.3.2	██████ █	2001b	H11- 90-day repeated dose oral toxicity study in the dog ██████ Report n° 20000390T GLP Unpublished	Y	N		Laboratoires Goëmar S.A.S.
B.6.4.	Marzin D.	2000	Mutagenicity test on bacteria (Salmonella typhimurium his and Escherichia coli trp) using B.N. Ames's technique with H11 Institut Pasteur de Lille Report n° IPL-R 991011/H11 GLP Unpublished	N	N		Laboratoires Goëmar S.A.S.
B.6.4.	Larripa et al.	1987	Biological activity in Macrocystis pyrifera from Argentina: sodium alginate, fucoidan and laminaran. II. Genotoxicity GLP Unpublished	N	N		Laboratoires Goëmar S.A.S.

Point	Author(s)	Year	Title Testing facility, Report n°, GLP or GEP Status published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
B.6.4.2	██████████	2001	LAMINARIN: Bone marrow micronucleus test by oral route in mice ██████████, Report n°21149 GLP Unpublished	N	N		Laboratoires Goëmar S.A.S.
B.6.6.2	██████████ d	2001c	H11-Study for the effects on embryo-foetal development in the rat by the oral route. ██████████ Report n°20000387 T GLP Unpublished	Y	N		Laboratoires Goëmar S.A.S.
B.6.6.2	██████████	2001e	H11-Study for the effects on embryo-foetal development in the rabbit by the oral route. ██████████ Report n°20000388T GLP Unpublished	Y	N		Laboratoires Goëmar S.A.S.
B.6.8.2	Toklu HZ, Sehirli AO, Velioğlu-Oğünç A, Cetinel S, Sener G.	2006	Acetaminophen-induced toxicity is prevented by beta-D-glucan treatment in mice No GLP Published	Y	N		/
B.6.9.2	Beijer L. and Rylander R.	2004	(1→3)-β-D-Glucan Does Not Induce Acute Inflammation After Nasal Deposition No GLP Published	Y	N		/
B.6.9.2	Douwes J.	2005	1→3)-Beta-D-glucans and respiratory health: a review of the scientific evidence No GLP Published	N	N		/

A.7 Residue data

No references submitted.

A.8 Environmental fate and behaviour**References for the active substance**

Point	Author(s)	Year	Title Testing facility, Report n°, GLP or GEP Status published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
CA 7.1.1.1.	Clarke et al.	1963	Chemistry and Biochemistry of β 1-3- glucan. A review. Non-GLP Published	N	N		/
CA 7.1.1.1.	Bull and Chesters	1966	The biochemistry of laminarin and the nature of laminarinase Non-GLP Published	N	N		/
CA 7.1.1.1.	Lethbridge et al	1980	Glucanase activity in soil Non-GLP Published	N	N		/
CA 7.1.1.1.	Micthell	1963	Lysis of soil fungi by bacteria Non-GLP Published	N	N		/
CA 7.1.1.1.	Hayano	1972	A method for the determination of β - glucosidase activity in soil Non-GLP Published	N	N		/
CA 7.2.2	LICATA- MESSANA L	2000	Ready Biodegradability – Modified Sturm test SEPC Report n°00-907005- 024 GLP Unpublished	N	N		Laboratoires Goëmar S.A.S

References for the PPP

Data point	Author(s)	Year	Title Source Company, Report No. GLP or GEP status Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
KCP 9.2.5/01	Rousseau C. and Grimaldi A.	2015	Laminarin: Computer simulation with FOCUS SW Step 1 and Step 2 for PEC calculation in surface water and sediment according to FOCUS Scenarios for elicitor of the crop's self defence mechanisms applications on cereals, orchards, vines, leafy vegetables and fruiting vegetables. Report No.14/33 GLP not relevant Unpublished	N	Y	A 10-year data protection period is claimed as this study : - is necessary to estimate environmental fate of the product. - has not been submitted in the past	Laboratoires Goëmar SAS

A.9 Ecotoxicology data

References for the active substance

Data point	Author(s)	Year	Title Source Company, Report No. GLP or GEP status Published or not	Vertebrate study Y/N	Data Protection Claimed Y/N	Justification if data protection is claimed	Owner
CA 8.1.1/01	██████████	2002a	Laminarin – Acute oral toxicity (LD ₅₀) to the Bobwhite quail ██████████ Study N°GOM 001/022173 GLP, unpublished	Y	N		Laboratoires Goëmar SAS

CA 8.1.1/02	██████████	2002b	Laminarin – Dietary toxicity (LC ₅₀) to the Bobwhite quail ██████████ Study N°GOM 002/014410 GLP, unpublished	Y	N		Laboratoires Goëmar SAS
CA 8.1.1/03	Bergh M.O., Razdan A., Aman P.	1998	Nutritional influence of broiler chicken diets based on covered normal, waxy and high amylose barleys with or without enzyme supplementation. Animal Feed Science and Technology, 78, 215-226 Non-GLP, published	N	N		-
CA 8.1.1/04	Annison G.	1992	Commercial enzyme supplementation of wheat-based diets raises ileal glycanase activities and improves apparent metabolisable energy, starch and pentosan digestibilities in broiler chickens. Animal Feed Science and Technology, 38, 105-121 Non-GLP, published	N	N		-

CA 8.1.1/05	Vukic-Vranjes M., Wenk C.	1995	The influence of extruded vs. untreated barley in the feed, with and without dietary enzyme supplement on broiler performance. Animal Feed Science and Technology, 54, 21-32 Non-GLP, published	N	N	-
CA 8.1.1/06	Philip J.S., Gilbert H.J., Smithard R.R.	1995	Growth, viscosity and beta-glucanase activity of intestinal fluid in broiler chickens fed on barley-based diets with or without exogenous beta- glucanase. British Poultry Science, 36, 599- 603 Non-GLP, published	N	N	-
CA 8.2.1/01	██████ ██████	2001a	Laminarin – Acute toxicity in freshwater fish (96 hours) <i>Oncorhynchus mykiss</i> ██████ - Study N° 00-907005-022 GLP, unpublished	Y	N	-
CA 8.2.1/02	██████ ██████.	2001b	Laminarin – Acute toxicity in freshwater fish (96 hours) <i>Danio rerio</i> ██████ - Study N° 00-907005-021 GLP, unpublished	Y	N	-

CA 8.2.2/01	Ingebrigsten K., Horsberg T.E., Dalmo R., Seljelid R.	1993	Tissue distribution of the immunomodulator aminated β 1-3 polyglucose in Atlantic salmon (<i>Salmo salar</i>) after intravenous, intraperitoneal and peroral administration. Aquaculture, 117, 29-35 Non-GLP, published	N	N	-
CA 8.2.2/02	Dalmo R.A., Ingebrigsten K., Bogwald J., Horsberg T.E., Seljelid R.	1995	Accumulation of immunomodulatory laminaran [β 1-3-D- glucan] in the spleen and kidney of Atlantic salmon, <i>Salmo salar</i> L. Journal of Fish Diseases, 18, 545- 553 Non-GLP, published	N	N	-
CA 8.2.2/03	Dalmo R.A., Ingebrigsten K., Sveinbjornsson B., Seljelid R.	1996	Accumulation of immunomodulatory laminaran [β 1-3-D- glucan] in the heart, spleen and kidney of Atlantic cod, <i>Gadus morhua</i> L. Journal of Fish Diseases, 19, 129- 136 Non-GLP, published	N	N	-
CA 8.2.2/04	Black W.A.P., Dewar E.T.	1954	Laminaran J.Sci. Food Agri., 5, 137-145 Non-GLP, published	N	N	-
CA 8.2.2/05	Sturmbauer C.	1991	Different enzymes for laminarine digestion in <i>Chondrostoma</i> <i>nasus</i> (Cyprinidae) and <i>Oreochromis</i> sp. (Cichlidae). Comp. Biochem. Physiol, Vol.100A, No.1, 199-202 Non-GLP, published	N	N	-

CA 8.2.4/01	Hertl J.	2001	Acute toxicity of LAMINARIN to <i>Daphnia magna</i> in a 48-hour immobilization test IBACON GmbH - Study N° 10041220 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 8.2.6/01	Gnemi P.	2000	H 11- Algal growth inhibition study CERB - Study N° 990705 EX GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 8.2.7/01	Allen R.	2015	Protocol : Laminarin : Higher Plant (<i>Lemna</i>) Growth Inhibition Semi-static Test according to OECD 221 (2006) Huntingdon LifeSciences, England Report No. DQU0009 GLP Unpublished	N	Y	A 10-year data protection period is claimed as this study : - is necessary to show that Laminarin has a low toxicity to aquatic higher plants - has not been submitted in the past - has been made in accordance with the GLP principles.	Laboratoires Goëmar SAS
CA 8.2.7/02	Allen R.	2015	E-mail results of range-finding test on <i>Lemna</i> exposed to Laminarin (for report No.DQU0009)	N	Y	A 10-year data protection period is claimed as this study : - is necessary to show that Laminarin has a low toxicity to aquatic higher plants - has not been submitted in the past	Laboratoires Goëmar SAS
CA 8.3.1/01	Kling A.	2000	Assesment of Side Effects of Laminarin to the Honey Bee, <i>Apis mellifera</i> L. in	N	N		Laboratoires

			the Laboratory. GAB Biotechnologie GmbH Study N° 20001342/01-BLEU GLP, unpublished				Goëmar SAS
CA 8.3.2/01	Tessier C.	2001a	Phyliq. The effects of Phyliq (37 g/L Laminarin) on <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) on artificial substrate in laboratory : LR ₅₀ estimation and reproduction assessment. PROMO-VERT- Study N° 01APGOL25 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 8.3.2/02	Tessier C.	2001b	Phyliq. The effects of Phyliq (37 g/L Laminarin) on <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) on artificial substrate in laboratory : LR ₅₀ estimation and reproduction assessment. PROMO-VERT- Study N° 01TYGOL24 GLP, unpublished	N	N		Laboratoires Goëmar SAS
CA 8.4.1/01	Winkelmann G.	2015	Laminarin – Earthworm (<i>Eisenia fetida</i>), Effects on Reproduction Dr. U. Noack- Laboratorien, Sarstedt, Germany Report No. RBN16029 GLP Unpublished	N	Y	A 10-year data protection period is claimed as this study : - is necessary to show that Laminarin has a low toxicity to earthworm - has not been submitted in the past - has been made in accordance with the GLP	Laboratoires Goëmar SAS

						principles.	
CA 8.5/01	Black W.A.P., Dewar E.T.	1954	Laminaran J.Sci.Food Agric., 5, 137-145 Non-GLP, published	N	N		-
CA 8.5/02	Ivanova E.P., Kiprianova E.A., Mikhailov V.V., Levanova G.F., Garagulya A.D., Gorshkova N.M., Vysotskii M.V., Nicolau D.V., Yumoto N., Taguchi T., Yoshikawa S.	1998	Phenotypic diversity of <i>Pseudoalteromonas citrea</i> from different marine habitats and emendation of the description. International Journal of Systematic Bacteriology 48, 247-256 Non-GLP, published	N	N		-
CA 8.5/03	Mizuno K., Awazu N., Tachiki T.	1998	Purification and some properties of p-nitrophenyl-β-D- glucoside- hydrolyzing enzymes in culture filtrate of <i>Bacillus circulans</i> KA-304 grown on cell-wall preparation of <i>Schizophyllum commune</i> Biosci. Biotechnol. Biochem., 62(1), 39-43 Non-GLP, published	N	N		-
CA 8.6.1/01	Letouze P. and Dubois J.	2006	Essai d'efficacité d'une spécialité GOEMAR, nommée PHYSPE1 contre la rouille (<i>Puccinia porri</i>) sur poireau de plein champ SILEBAN, France Report No.VFPCPI06SL1	N	Y	A 10-year data protection period is claimed as this study : - is necessary to show that Laminarin based product has no phytotoxic effect - has not been submitted in the past - has been made in accordance	Laboratoires Goëmar SAS

						with the GEP principles.	
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References for the PPP

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
CP 10.2/01	██████████	2008a	Fish, Acute toxicity test (OECD 203, July 1992), GLP, Unpublished	Y	N		Laboratoires Goëmar SAS
CP 10.2/02	Servajean E	2008b	Daphnia sp., Acute immobilisation test (OECD 202, April 2004) GLP, Unpublished	N	N		Laboratoires Goëmar SAS
CP 10.2/03	Servajean E	2008c	Freshwater alga, Growth inhibition test (OECD 201, March 2006) GLP, Unpublished	N	N		Laboratoires Goëmar SAS