

Monograph

May 2003

Laminarin

Volume 2

Listing of Data and
Information submitted

Rapporteur Member State: Belgium

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A.1 Identity

A.1.1 Identity of the active substance (Annex IIA 1; Annex IIIA 1, 3.1 to 3.4)

Annex 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 1.2/01	BLACK W.A.P., DEWAR E.T.	1954	Laminaran J.Sci. Food Agric., 5, 137-145 Non-GLP, published	N	-
IIA 1.4/01	Anonymous	1982	IUPAC-IUB Joint Commission on Biochemical Nomenclature (JCBN) - Polysaccharide Nomenclature - Recommendations 1980 European Journal of Biochemistry, 126, 439-441 Non-GLP, published	N	-
IIA 1.7/01	PAINTER T.J.	1983	<i>Algal Polysaccharides.</i> <i>in</i> The Polysaccharides – Eds G.O.Aspinall - Academic Press 197-285 Non-GLP, published	N	-
IIA 1.7/02	PERCIVAL E., MC DOWELL R.H.	1985	<i>Algal polysaccharides.</i> <i>in</i> Biochemistry of storage carbohydrates in green plants, 305-347- Eds P.M.Dey and R.A.Dixon- Academic Press Non-GLP, published	N	-
IIA 1.7/03	READ S.M., CURRIE G., BACIC A.	1996	Analysis of the structural heterogeneity of Laminarin by electrospray-ionisation-mass spectrometry. Carbohydrate Research, 281, 187-201 Non-GLP, published	N	-
IIA 1.10/01	Confidential information : <i>Please refer to Document J.</i>			N	-
IIA 1.10/02	Confidential information : <i>Please refer to Document J.</i>			N	-
IIA 1.10/03	Confidential information : <i>Please refer to Document J.</i>			N	-
IIA 1.11/01	TREBERT R.	2001	Confidential information : <i>Please refer to Document J.</i> SGS Laboratoire Crépin – Study N° BPL 200007/0395 GLP, unpublished	Y	GOË
IIA 1.11/02	TREBERT R. COUSIN C.	2002	Confidential information : <i>Please refer to Document J.</i> SGS Laboratoire Crépin – Study N° BPL 200111/0388 GLP, unpublished	Y	GOË

A.1.2 Identity of the formulations (Annex IIIA 1, 3.1 to 3.7, 3.9 and 12.1)

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A.2 Physical and chemical properties

A.2.1 Physical and chemical properties of the active substance (Annex IIA 2)

Annex 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IIA 2.1/01	LICATA-MESSANA L.	2000a	Laminarin – Melting point SEPC - Study N° 00-907005-003 GLP, unpublished	Y	GOË
IIA 2.1/02	LICATA-MESSANA L.	2000b	Laminarin – Boiling point SEPC - Study N° 00-907005-004 GLP, unpublished	Y	GOË
IIA 2.1/03 (location : IIA 2.1/01)	LICATA-MESSANA L.	2000a	Laminarin – Melting point SEPC - Study N° 00-907005-003 GLP, unpublished	Y	GOË
IIA 2.2/01	LICATA-MESSANA L.	2000c	Laminarin – Relative density SEPC - Study N° 00-907005-005 GLP, unpublished	Y	GOË
IIA 2.3/01	TREMAIN S.P.	2001	Laminarin: Determination of Vapour Pressure Safepharm Laboratories Limited Study N° SPL Project Number: 1303/005 GLP, unpublished	Y	GOË
IIA 2.3/02b	AMBROSI D.	2002	Calculation of Henry's law constant ASC - Non GLP, unpublished	Y	GOË
IIA, 2.4/01 (location : IIA 2.1/01)	LICATA-MESSANA L.	2000a	Laminarin – Melting point SEPC - Study N° 00-907005-003 GLP, unpublished	Y	GOË
IIA 2.4/02 (location : IIA 8.2/02)	LICATA-MESSANA L.	2001a	Laminarin – Acute toxicity in freshwater fish (96 hours) <i>Danio rerio</i> SEPC - Study N°00-907005-021 GLP, unpublished	Y	GOË
IIA 2.4/03 (location : IIA 2.11/01)	LICATA-MESSANA L.	2000d	Laminarin – Flammability of solids SEPC - Study N° 00-907005-016 GLP, unpublished	Y	GOË
IIA 2.5/01	CUTHBERT J.	2001	Laminarin - Determination of Spectra Safepharm Laboratories Limited Study N° 1476/001 GLP, unpublished	Y	GOË

Annex 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 2.5/02	CHIZHOV A.O., DELL A., MORRIS H.R., REASON A.J., HASLAM S.M., McDOWELL R.A., CHIZHOV O.S., USOV A.I.	1998	Structural analysis of laminarans by MALDI and FAB mass spectrometry. Carbohydrate Research 310, 203-210 Non-GLP, published	N	-
IIA 2.5/03	DELOLME F.	2000	Analysis by MALDI-TOF mass spectrometry CNRS Report N° FC 000828 Non-GLP, unpublished	Y	GOË
IIA 2.5/04	CHEN P., BAKER A.G., NOVOTNY M.V.	1997	The use of osazones as matrices for the Matrix-Assisted Laser Desorption/Ionisation mass spectrometry of carbohydrates Analytical Biochemistry, 244, 144-151 Non-GLP, published	N	-
IIA 2.5/05 (location : IIA 1.7/03)	READ S.M., CURRIE G., BACIC A.	1996	Analysis of the structural heterogeneity of Laminarin by Electrospray-ionisation- mass spectrometry Carbohydrate Research, 281, 187-201 Non-GLP, published	N	-
IIA 2.6/01	LICATA-MESSANA L.	2001b	Laminarin – Solubility in water SEPC - Study N° 00-907005-008 GLP, unpublished	Y	GOË
IIA 2.6/02	ANDING C.	2002	Hydrosolubility of Laminarin DEFITRACES – Study N° SEP/01-069 GLP, unpublished	Y	GOË
IIA 2.7/01	LICATA-MESSANA L.	2001c	Laminarin – Solubility in n-Heptane SEPC - Study N° 00-907005-009 GLP, unpublished	Y	GOË
IIA 2.7/02	LICATA-MESSANA L.	2001d	Laminarin – Solubility in Xylene SEPC - Study N° 00-907005-010 GLP, unpublished	Y	GOË
IIA 2.7/03	LICATA-MESSANA L.	2001e	Laminarin – Solubility in 1,2 Dichloroethane SEPC - Study N° 00-907005-011 GLP, unpublished	Y	GOË
IIA 2.7/04	LICATA-MESSANA L.	2001f	Laminarin – Solubility in Methanol SEPC - Study N° 00-907005-012 GLP, unpublished	Y	GOË

Annex 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 2.7/05	LICATA-MESSANA L.	2001g	Laminarin – Solubility in Acetone SEPC -Study N° 00-907005-013 GLP, unpublished	Y	GOË
IIA 2.7/06	LICATA-MESSANA L.	2001h	Laminarin – Solubility in Ethyl acetate SEPC - Study N° 00-907005-014 GLP, unpublished	Y	GOË
IIA 2.8/01	QUINTELAS G.	2001a	Laminarin – Determination of the partition coefficient of Laminarin DEFITRACES – Study N° SEP/00-074 GLP, unpublished	Y	GOË
IIA 2.9/01	QUINTELAS G.	2001b	Laminarin –Abiotic degradation of Laminarin pH dependent hydrolysis (Test C7) DEFITRACES – Study N° SEP/00-075 GLP, unpublished	Y	GOË
IIA 2.9/02	COMB A.L .	2002	Laminarin – Abiotic degradation : hydrolysis as a function of pH Huntingdon Life Sciences – Study (protocol) N° GOM/004 GLP, unpublished	Y	GOË
IIA 2.11/01	LICATA-MESSANA L.	2000d	Laminarin – Flammability of solids SEPC - Study N° 00-907005-016 GLP, unpublished	Y	GOË
IIA 2.11/02	LICATA-MESSANA L.	2000e	Laminarin – Flammability in contact with water SEPC - Study N° 00-907005-017 GLP, unpublished	Y	GOË
IIA 2.11/03	LICATA-MESSANA L.	2000f	Laminarin – Self ignition temperature of solids SEPC - Study N° 00-907005-019 GLP, unpublished	Y	GOË
IIA 2.13/01	LICATA-MESSANA L.	2000g	Laminarin – Explosive properties Laminarin N° 00-907005-018 GLP,unpublished	Y	GOË
IIA 2.14/01	LICATA-MESSANA L.	2000h	Laminarin – Surface tension SEPC - Study N° 00-907005-007 GLP, unpublished	Y	GOË
IIA 2.15/01	LICATA-MESSANA L.	2000i	Laminarin – Oxidizing properties SEPC - Study N° 00-907005-020 GLP, unpublished	Y	GOË

A.2.2 Physical and chemical properties of the formulations (Annex IIIA 2)

Annex Point / Reference Number	Author(s)	Year	Title Testing facility, Report No., GLP or GEP Status published or not	Data Protection Claimed Y/N	Owner
IIIA 2.1/01 (location : IIIA, 2.7/01)	LICATA-MESSANA L.	2001g	Phyliq – Storage stability : accelerated procedure by heating (at +54°C for 14 days) SEPC Report No. 00-907005-034 GLP, unpublished	Y	GOË
IIIA 2.4/01	LICATA-MESSANA L.	2001a	Phyliq – Free acidity or alkalinity SEPC Report No. 00-907005-027 GLP, unpublished	Y	GOË
IIIA 2.4/02	LICATA-MESSANA L.	2001b	Phyliq – Determination of pH value of the test item SEPC Report No. 00-907005-026 GLP, unpublished	Y	GOË
IIIA 2.4/03	LICATA-MESSANA L.	2001c	Phyliq – Determination of pH value of a 1% aqueous dilution SEPC Report No. 00-907005-028 GLP, unpublished	Y	GOË
IIIA 2.5/01	LICATA-MESSANA L.	2001d	Phyliq – Viscosity SEPC Report No. 00-907005-029 GLP, unpublished	Y	GOË
IIIA 2.5/02	LICATA-MESSANA L.	2001e	Phyliq – Surface tension SEPC Report No. 00-907005-031 GLP, unpublished	Y	GOË
IIIA 2.6/01	LICATA-MESSANA L.	2001f	Phyliq – Relative density SEPC Report No. 00-907005-030 GLP, unpublished	Y	GOË
IIIA 2.7/01	LICATA-MESSANA L.	2001g	Phyliq – Storage stability : accelerated procedure by heating (at +54°C for 14 days) SEPC Report No. 00-907005-034 GLP, unpublished	Y	GOË

Annex Point / Reference Number	Author(s)	Year	Title Testing facility, Report No., GLP or GEP Status published or not	Data Protection Claimed Y/N	Owner
IIIA 2.7/02	LICATA-MESSANA L.	2001h	Phyliq – Free acidity or alkalinity After an accelerated storage procedure at +54°C for 14 days SEPC Report No. 00-907005-036 GLP, unpublished	Y	GOË
IIIA 2.7/03	LICATA-MESSANA L.	2001i	Phyliq – Determination of pH value of the test item <i>After an accelerated storage procedure at +54°C for 14 days</i> SEPC Report No. 00-907005-035 GLP, unpublished	Y	GOË
IIIA 2.7/04	LICATA-MESSANA L.	2001j	Phyliq – Determination of pH value of a 1% aqueous dilution <i>After an accelerated storage procedure at +54°C for 14 days</i> SEPC Report No. 00-907005-037 GLP, unpublished	Y	GOË
IIIA 2.7/05	LICATA-MESSANA L.	2001k	Phyliq – Persistent foaming <i>After an accelerated storage procedure at +54°C for 14 days</i> SEPC Report No. 00-907005-038 GLP, unpublished	Y	GOË
IIIA 2.7/06	LICATA-MESSANA L.	2001l	Phyliq – Dilution stability <i>After an accelerated storage procedure at +54°C for 14 days</i> SEPC Report No. 00-907005-039 GLP, unpublished	Y	GOË
IIIA 2.7/07	LICATA-MESSANA L.	2001m	Phyliq – Low temperature stability SEPC Report No. 00-907005-040 GLP, unpublished	Y	GOË
IIIA 2.7/08	MOURGUES L.	2002	Phyliq : physico-chemical tests before and after CIPAC MT 46 test 14 days at 54°C Defitraces Report N° 02-907005-001 GLP, unpublished	Y	GOË

Annex Point / Reference Number	Author(s)	Year	Title Testing facility, Report No., GLP or GEP Status published or not	Data Protection Claimed Y/N	Owner
IIIA 2.7/09	BUROSSE V.	2002	Phyliq – Bacteriological control : total germs, yeasts and moulds counting after 7 weeks storage at ambient temperature and +40°C Laboratoires Goëmar S.A. Report N° VB 0204-01 non-GLP, unpublished	Y	GOË
IIIA 2.8/01	LICATA-MESSANA L.	2001n	Phyliq – Persistent foaming SEPC Report No. 00-907005-032 GLP, unpublished	Y	GOË
IIIA 2.8/02	LICATA-MESSANA L.	2001o	Phyliq – Dilution stability SEPC Report No. 00-907005-033 GLP, unpublished	Y	GOË
IIIA 2.9/01	JOUBERT J.M.	2001a	Phyliq – Physical compatibility of tank mixes Laboratoires GOËMAR S.A. Report No. JMJ010111 Non-GLP, unpublished	Y	GOË
IIIA 2.9/02	JOUBERT J.M.	2001b	Phyliq – Chemical compatibility of tank mixes Laboratoires GOËMAR S.A. Report No. VB 0111-07 Non-GLP, unpublished	Y	GOË

A.3 F further information

A.3.1 Further information on the active substance (Annex IIA 3)

Annex 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 3.5/01	KLARZYNSKI O., PLESSE B., JOUBERT J.M., YVIN J.C., KOPP M., KLOAREG B., FRITIG B.	2000	Linear β -1,3 glucans are elicitors of defense responses in Tobacco. Plant Physiology, vol 124, 1027-1037 Non-GLP, published	N	-
IIA 3.5/02	ALBERSHEIM P., DARVILL A., AUGUR C., CHEONG J.J., EBERHARD S., HAHAN M.G., MARFA V., MOHNEN D., O'NEILL M.A., SPIRO M.D., YORK W.S.	1992	Oligosaccharins : oligosaccharide regulatory molecules Acc. Chem. Res. 25, 77-83 Non-GLP, published	N	-
IIA 3.5/03	BULL A.T.	1967	The enzymatic degradation of β -glucans. Int. Biodetn Bull., 3, (1), 3-12 Non-GLP, published	N	-
IIA 3.5/04	CÔTE F., HAHN M.G.	1994	Oligosaccharins : structures and signal transduction. Plant Molecular Biology 26 , 1379-1411 Non-GLP, published	N	-
IIA 3.5/05	SHEVCHENKO N.M., ZVYAGINTSEVA T.N., ELYAKOVA L.A.	1986	Mode of action of endo-(1 \rightarrow 3)- β -D-glucanases from marine molluscs on the laminarin from <i>Laminaria cichorioides</i> : the structure and teh inhibitory effect of the resulting (1 \rightarrow 3;1 \rightarrow 6)- β -D-glucosaccharides. Carbohydrate Research, 148, 57-62 Non-GLP, published	N	-

A.4 Classification, packaging and labelling

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A.5 Methods of analysis

A.5.1 Methods of analysis for the active substance (Annex IIA 4)

Annex 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
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

Annex 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 4.1/08	TREBERT R.	2000b	Confidential information : <i>Please refer to Document J.</i> SGS Laboratoire Crépin -Study N° ME-0202B Non-GLP, unpublished	Y	GOË

A.5.2 Methods of analysis for the formulation (Annex IIIA 5)

Annex Point / Reference Number	Author(s)	Year	Title Testing facility, Report No., GLP or GEP Status published or not	Data Protection Claimed Y/N	Owner
IIIA 5.1/01	CRUZ F.	1999	Laminarin - Determination in the preparation Phylig - total hydrolysis method Laboratoires GOËMAR S.A. Report N° VB001210 Non-GLP, unpublished	Y	GOË
IIIA 5.1/02	CRUZ F.	2000	Laminarin - Determination in the preparation Phylig - global method Laboratoires GOËMAR S.A. Report N° VB001211 Non-GLP, unpublished	Y	GOË
IIIA 5.1/02c	TREBERT R. COUSIN C.	2002	Validation of the method of the dosage of pure Laminarin in a formulation PHYLIQ : Global method – GLP study SGS Laboratoire Crépin – Report N° BPL 200110/0352 – rev.2 GLP, unpublished	Y	GOË
IIIA 5.1/03 (location : IIIA 2.7/01)	QUINTELAS G.	2001b	Quantification of Laminarin in Phylig after a MT46 CIPAC test DEFITRACES Study No. SEPC 00-907005-034 GLP, unpublished	Y	GOË

A.6 Toxicology and metabolism (Annex IIA 5; Annex IIIA 7)

A.6.1 Toxicology and metabolism of the active substance (Annex IIA 5)

Annex 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, 5.1/01	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	-
IIA, 5.1/02	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	-
IIA, 5.1/03	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	-
IIA, 5.1/04	BLACK W.A.P., DEWAR E.T.	1954	Laminaran J.Sci. Food Agri., 5, 137-145 Non-GLP, published	N	-
IIA, 5.1/05	IBARROLA I., NAVARRO E., IGLESIAS J.I.P., URRUTIA M.B.	1999	Time-course of digestive-enzyme acclimation in the cockle <i>Cerastoderma edule</i> . Marine Biology, 135, 47-56 Non-GLP, published	N	-
IIA, 5.1/06	SABOROWSKI R., BUCHHOLZ F.	1999	A laboratory study on digestive processes in the Antarctic krill, <i>Euphausia superba</i> , with special regard to chitinolytic enzymes. Polar Biol., 21, 295-304 Non-GLP, published	N	-
IIA, 5.1/07	ERASMUS J.H., COOK P.A., COYNE V.E.	1997	The role of bacteria in the digestion of seaweed by the abalone <i>Haliotis midae</i> . Aquaculture, 155, 377-386 Non-GLP, published	N	-
IIA, 5.1/08	STURMBAUER C.	1991	Different enzymes for laminarine digestion in <i>Chondrostoma nasus</i> (Cyprinidae) and <i>Oreochromis</i> sp. (Cichlidae).	N	-

			Comp. Biochem. Physiol ,Vol.100A, N°1, 199-202 Non-GLP, published		
IIA, 5.1/09	KUDA T., FUJII T., HASEGAWA A., OKUZUMI M.	1992	Effect of degraded products of laminaran by <i>Clostridium ramosum</i> on the growth of intestinal bacteria. Nippon Suisan Gakkaishi, 58 (7), 1307-1311 Non-GLP, published	N	-
IIA, 5.1/10	MICHEL C., BENARD C., LAHAYE M., FORMAGLIO D., KAEFFER B., QUEMENER B., BEROT S., YVIN J.C., BLOTTIERE H.M., CHERBUT C.	1999	Les oligosides algaux comme aliments fonctionnels : étude <i>in vitro</i> de leurs effets cellulaires et fermentaires. Sciences des Aliments, 19, 311-332 Non-GLP, published	N	-
IIA, 5.1/10	KUDA T., FUJII T., SAHEKI K., HASEGAWA A., OKUZUMI M.	1992	Effects of brown algae on faecal flora of rats. Nippon Suisan Gakkaishi 58(2), 307-314 Non-GLP. Published	N	-
IIA, 5.1/12	FUJII T., KUDA T., SAHEKI K., OKUZUMI M.	1992	Fermentation of water-soluble polysaccharides of brown algae by human intestinal bacteria <i>in vitro</i> . Nippon Suisan Gakkaishi 58(1), 147-152 Non-GLP. Published	N	-
IIA, 5.2/01	DELILLE M.	1998a	Phycarine® 96S51- Acute toxicity study- Safety test in the rat by the oral route CERB - Study N° 970352 ST GLP, unpublished	Y	GOË MAR
IIA, 5.2/02	DELILLE M.	1998b	Phycarine® 96S51- Acute toxicity study- Safety test in the rat by the subcutaneous route CERB - Study N° 970353 ST GLP, unpublished	Y	GOË MAR
IIA, 5.2/03	MÜLLER W.	1999	Evaluation of acute inhalation toxicity with Phycarine® in rats CERB - Study N° 980001 EX GLP, unpublished	Y	GOË MAR
IIA, 5.2/04	BAUDET L.	1998a	Phycarine® 96S51- Cutaneous primary irritation in the rabbit CERB - Study N° 970349 ST GLP, unpublished	Y	GOË MAR
IIA, 5.2/05	BAUDET L.	1998b	Phycarine® 96S51- Ocular primary irritation in the rabbit CERB - Study N° 970350 ST GLP, unpublished	Y	GOË MAR
IIA, 5.2/06	BAUDET L.	1998c	Phycarine® 96S51- Study of cutaneous sensitisation using the Magnusson and Kligman	Y	GOË MAR

			maximisation test in the guinea pig CERB - Study N° 970351 ST GLP, unpublished		
IIA, 5.2/07	AUDEVAL GERARD C.	2001d	H11 (Batch 99S24) – Acute dermal toxicity study in the rat CERB - Study N° 20000698 ST GLP, unpublished	Y	GOË MAR
IIA, 5.3/01	LONGOBARDI C.	2000	4-week oral toxicity study in rats RTC - Study N° 7286 GLP, unpublished	Y	GOË MAR
IIA, 5.3/02	AUDEVAL GERARD C.	2001a	H11 - 90-Day repeated dose oral toxicity study in the rat. CERB - Study N° 20000389 T GLP, unpublished	Y	GOË MAR
IIA, 5.3/03	AUDEVAL GERARD C.	2001b	H11 - 90-Day repeated dose oral toxicity study in the dog. CERB - Study N° 20000390 T GLP, unpublished	Y	GOË MAR
IIA, 5.4/01	MARZIN D.	2000	Mutagenicity test on bacteria (<i>Salmonella</i> <i>typhimurium</i> his and <i>Escherichia coli</i> trp) using B.N. Ames's technique with H11 Institut Pasteur de Lille Study N° IPL-R 991011/H11 GLP, unpublished	Y	GOË MAR
IIA, 5.4/02	LARRIPA I.B., MUDRY DE PARGAMENT M., LABAL DE VINUESA M., MAYER A.M.S.	1987	Biological activity in <i>Macrocystis pyrifera</i> from Argentina : sodium alginate, fucoïdan and laminaran. II. Genotoxicity. Hydrobiologia 151/152, 491-496 Non-GLP, Published	N	-
IIA, 5.4/03	HADDOUK H.	2001	Laminarin: Bone Marrow Micronucleus Test by Oral Route in Mice CIT - Study N° 21149 MAS GLP, unpublished	Y	GOË MAR
IIA, 5.5/02	SELJELID R.	1986	A water-soluble aminated β 1-3D-Glucan derivative causes regression of solid tumors in mice. Bioscience Reports, Vol 6, N°9, 845-851 Non-GLP, Published	N	-
IIA, 5.6/01	AUDEVAL GERARD C.	2001c	H11 - Study for the effects on embryo-fœtal development in the rat by the oral route CERB - Study N° 20000387T GLP, unpublished	Y	GOË MAR
IIA, 5.6/02	AUDEVAL GERARD C.	2001e	H11 - Study for the effects on embryo-fœtal development in the rabbit by the oral route CERB - Study N° 20000388T GLP, unpublished	Y	GOË MAR

A.6.2 Toxicology and metabolism of the formulation (Annex IIIA 7)

Annex Point /Reference Number	Author(s)	Year	Title Testing facility, Report No., GLP or GEP Status published or not	Data Protection Claimed Y/N	Owner
IIIA, 7.1/01	AUDEVAL-GERARD C.	2000a	Phyliq - Acute oral toxicity study in the rat. CERB Report No. 990762 ST GLP, unpublished	Y	GOËMAR
IIIA, 7.1/02	AUDEVAL-GERARD C.	2000b	Phyliq - Acute dermal toxicity in the rat. CERB Report No. 990763 ST GLP, unpublished	Y	GOËMAR
IIIA, 7.1/03	AUDEVAL-GERARD C.	2000c	Phyliq - Acute skin irritation study in the rabbit. CERB Report No. 990759 ST GLP, unpublished	Y	GOËMAR
IIIA, 7.1/04	AUDEVAL-GERARD C.	2000d	Phyliq - Acute eye irritation study in the rabbit. CERB Report No. 990760 ST GLP, unpublished	Y	GOËMAR
IIIA, 7.1/05	AUDEVAL-GERARD C.	2000e	Phyliq - Skin sensitisation study in the guinea pig (Magnusson-Kligman maximisation) CERB Report No. 990761 ST GLP, unpublished	Y	GOËMAR

A.6.3 Toxicology and metabolism – Open literature

Annex point/ reference number	Author(s)	year	Title Source Company, report no GLP or GEP Published or not	Data protection claimed	Owner
IIA,5.1/01 and IIA,5.1/02	Black and Dewar	1954	Laminaran. J. Sci. Food Agric., 5, 137-145 Not GLP, published	N	-

IIA,5.8.1/01	Collic, S., Fischer, A.M., Tapon- Bretaudière, J., Boisson, C., Duran D, P and Jozefonvicz, J.	1991	Anticoagulant properties of fucoidan fraction Tromb. Res,64 (2):143-154 Not GLP, published	N	-
IIA,5.1/01	Cook S.I. and Sellin, J.H.	1998	Review article: short-chain fatty acids in health and disease. Aliment Pharmacol Ther. , 12(6); 499-507. Not GLP, published	N	-
IIA,5.1/01	Cummings, J.H., Macfarlane, G.T., and Englyst, H.N.	2001	Prebiotic digestion and fermentation Am.J. Clin. Nutr. 73 (suppl): 415S-420S Not GLP, published	N	-
IIA,5.1/04	Dalmo R.A., Ingebrigsten, K., Sveinbjornsson, B., and Seljelid, R.	1995	Accumulation of immunomodulatory laminaran [$\beta(1,3)$ -D-glucan] in the spleen and kidney of atlantic salmon <i>Salmo salar</i> L. J.Fish Dis., 18, 545-553 Not GLP, published	N	-
IIA,5.1/01 and IIA,5.1/03	D'Argenio, G., and Mazzacca, G.	1999	Short-chain fatty acids in the human colon. Reaction to inflammatory bowel disease and colon cancer. Adv. Exp. Med. Biol, 472, 149-158. Not GLP, published	N	-
IIA,5.1/01	Djouzi et al.,	1995	Degradation and fermentation of gluco- oligosaccharides by bacterial strains from human colon: <i>in vitro</i> and <i>in vivo</i> studies in gnotobiotic rats; J.Applied Bacteriol, 79, 117-127 Not GLP, published	N	-
IIA,5.3.2/02	Greger, J.L.	1999	Nondigestible carbohydrates and mineral bioavailability. J.Nutr., 129, 1434S-1435S Not GLP, published	N	-
IIA,5.8.1/01	Haroun- Bouhedja, F., Ellouali, M., Siquin, C., Boisson- Vidal, C.	2000	Relationship between sulfate groups and biological activities of fucans. Tromb. Res.100, 453-459 Not GLP, published	N	-

IIA,5.1/02	Hrmova, M., Banik, M., Harvey A.J., Garrett, T.P., Varghese, J.N., Hoj, P.B., Osmond, G.	1997	Polysaccharide hydrolases in germinated barley and their role in the depolymerization of plant and fungal cell walls. Int. J; Biol. Macromol, 21, 67-72 Not GLP, published	N	-
IIA,5.1/01	Kuda, T., Fujii, T., Hasegawa, A. and Okuzumi, M.	1992	Effect of degraded products of laminaran by <i>Clostridium ramosum</i> on the growth of intestinal bacteria. Nippon Suisan Gakkaishi, 58,1307-1311 Not GLP, published	N	-
IIA,5.4.1/03	Larripa et al	1987	Biological activity in <i>Macrocystis oyryfera</i> from Argentina: sodium alginate, fucoidan and laminaran. II. Genotoxicity. Hydrobiologia 151/152: 491-49B.B.6. Not GLP, published	N	-
IIA,5.1/01 and IIA,5.3/02 and IIA,5.8.1/01	Michel, C., and Macfarlane, G.T.	1996	A review: digestive fate of soluble polysaccharides from marine macroalgae: involvement of the colonic microflora and physiological consequences for the host. J.Applied Bacteriol.,80, 349-369. Not GLP, published	N	-
IIA,5.8.1/01	Nishino, T., Aizu, Y., Nagumo, T.	1991	The influence of sulfate and molecular weight of a fucan sulfate from the brown seaweed <i>Ecklonia kurome</i> on its antithrombine activity. Tromb. Res,64 (6):723-731 Not GLP, published	N	-
IIA,5.1/01	Scheppach, W.	1994	Effects of short chain fatty acids on gut morphology and function. Gut, 35(1): S35-S38. Not GLP, published	N	-
IIA,5.1/02	Sturmbauer, Ch.	1991	Different enzymes for Laminarin digestion in <i>Chondrostoma nasus</i> (Cyprinidae) and <i>Oreochromis</i> SP (Cichlidae) Comp.Biochem.Physiol., 100A, 199-202. Not GLP, published	N	-
IIA,5.1/01	Szepesi, B.	1996	Present knowledge in nutrition. 7 th edition, ILSI Press, Washington, DC. In Ziegler, E., Filer, L.J. Eds. Chapter 5, pp 33-43 : Carbohydrates Not GLP, published	N	-
IIA,5.3.2/03	Tang, Z.L., and Shen, S.F.	1989	A study of <i>Laminaria digitata</i> powder on experimental hyperlipoproteinemia and its hemorheology Zhong Xi Yi Jie He Za Zhi, 9 (4) , 223-225 Not GLP, published	N	-

A.7 Residue data

A.7.1 Residue data for the active substance (Annex IIA 6)

Annex 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, 6.1/01	BLACK W.A.P., DEWAR E.T.	1954	Laminaran J.Sci. Food Agri., 5, 137-145 Non-GLP, published	N	-
IIA, 6.1/02	PRABHA T.N., BHAGYALA KSHMI N.	1998	Carbohydrate metabolism in ripening banana fruit. Phytochemistry, Vol 48, N°6, 915-919 Non-GLP, published	N	-
IIA, 6.1/03	PRABHA T.N., NEELWARN E B., THARANAT HAN R.N.	1998	Carbohydrate changes in ripening <i>Capsicum annuum</i> in relation to textural degradation. Z. Lebensm. Unters Forsch A, 206, N° 2, 121-125 Non-GLP, published	N	-

A.8 Environmental fate and behaviour

A.8.1 Environmental fate and behaviour of the active substance (Annex IIA 7)

Annex 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, 7.1/01	MOUNTFOR T D.O., RHODES L.L.	1991	Anaerobic growth and fermentation characteristics of <i>Paecilomyces lilacinus</i> isolated from Mullet Gut. Applied and Environmental Microbiology, Vol 57, N°7, 1963-1968 Non-GLP, published	N	-
IIA, 7.1/02	CLARKE A.F., STONE B.A.	1963	Chemistry and biochemistry of β -1,3-glucans. Reviews of Pure and Applied Chemistry, 13 134-156 Non-GLP, published	N	-
IIA, 7.1/03	BULL A.T., CHESTERS C.G.C.	1966	The biochemistry of laminarin and the nature of laminarinase. Adv. Enzym. 28 , 325-364 Non-GLP, published	N	-
IIA, 7.1/04	LETHBRIDG E G., BULL A.T., BURNS R.G.	1980	1,3- β -glucanase activity in soil and its response to soil amendment. Rev. Ecol. Biol. Sol, 17 (4), 479-489 Non-GLP, published	N	-
IIA, 7.1/05	HAYANO K.	1973	A method for the determination of β - glucosidase activity in soil. Soil Sci. Plant Nutr., 19(2), 103-108 Non-GLP, published	N	-
IIA, 7.1/06	JONES D., WEBLEY D.M.	1968	A new enrichment technique for studying lysis of fungal cell walls in soil. Plant and Soil XXVIII, n°1, 147-156 Non-GLP, published	N	-
IIA, 7.1/07	MITCHELL R., ALEXANDE R M.	1963	Lysis of soil fungi by bacteria. Canadian Journal of Microbiology, volume 9, 169-177. Non-GLP, published	N	-
IIA, 7.1/08	MITCHELL R.	1963	Addition of fungal cell-wall components to soil for biological disease control. Phytopathol., 53, 1068-1070 Non-GLP, published	N	-
IIA, 7.1/09	LETHBRIDG E G., BULL A.T., BURNS R.G.	1978	Assay and properties of 1,3- β -glucanase in soil. Soil Biol. Biochemistry, vol 10, 389-391 Non-GLP, published	N	-

IIA, 7.2/01	LICATA- MESSANA L.	2000	Laminarin – Ready Biodegradability- Modified Sturm test SEPC - Study N° 00-907005-024 GLP, unpublished	Y	GOËMAR
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A.9 Ecotoxicology

A.9.1 Ecotoxicology of the active substance (Annex IIA 8)

Annex 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, 8.1/01	BERGH M.O., RAZDAN A., AMAN P.	1999	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	-
IIA, 8.1/02	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	-
IIA, 8.1/03	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	-
IIA, 8.1/04	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	-
IIA, 8.2/01	LICATA- MESSANA L.	2001a	Laminarin – Acute toxicity in freshwater fish (96 hours) <i>Oncorhynchus mykiss</i> SEPC - Study N° 00-907005-022 GLP, unpublished	Y	GOËMAR
IIA, 8.2/02	LICATA- MESSANA L.	2001b	Laminarin – Acute toxicity in freshwater fish (96 hours) <i>Danio rerio</i> SEPC - Study N° 00-907005-021 GLP, unpublished	Y	GOËMAR
IIA, 8.2/03	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	Y	GOËMAR
IIA, 8.2/04	GNEMI P.	2000	H 11- Algal growth inhibition study	Y	GOËMAR

			CERB - Study N° 990705 EX GLP, unpublished		
IIA, 8.3/01	KLING A.	2000	Assesment of Side Effects of Laminarin to the Honey Bee, <i>Apis mellifera</i> L. in the Laboratory. GAB Biotechnologie GmbH Study N° 20001342/01-BLEU GLP, unpublished	Y	GOËMAR
IIA, 8.3/02	TESSIER C.	2001a	Phyliq. The effects of Phyliq (37 g/L Laminarin) on <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) on artificial substrate in laboratory : LR50 estimation and reproduction assessment. PROMO-VERT- Study N° 01APGOL25 GLP, unpublished	Y	GOËMAR
IIA, 8.3/03	TESSIER C.	2001b	Phyliq. The effects of Phyliq (37 g/L Laminarin) on <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) on artificial substrate in laboratory : LR50 estimation and reproduction assessment. PROMO-VERT- Study N° 01TYGOL24 GLP, unpublished	Y	GOËMAR
IIA, 8.5/01	BLACK W.A.P., DEWAR E.T.	1954	Laminaran J.Sci.Food Agric., 5, 137-145 Non-GLP, published	N	-
IIA, 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	-
IIA, 8.5/03	MIZUNO K., AWAZU N., TACHIKI T.	1998	Purification and some properties of p-nitrophenyl- α -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	-

A.9.2 Ecotoxicology of the formulation (Annex IIIA 10)

Annex Point / Reference Number	Author(s)	Year	Title Testing facility, Report No., GLP or GEP Status published or not	Data Protection Claimed Y/N	Owner
IIIA, 10.5/01 (location : IIA, 8.3/02)	TESSIER C.	2001a	Phyliq - The effects of Phyliq (37 g/L Laminarin) on <i>Aphidius rhopalosiphi</i> (Hymenoptera, Braconidae) on artificial substrate in laboratory : LR50 estimation and reproduction assessment. PROMO-VERT Report No. 01APGOL25 GLP, unpublished	Y	GOËMAR
IIIA, 10.5/02 (location : IIA, 8.3/03)	TESSIER C.	2001b	Phyliq - The effects of Phyliq (37 g/L Laminarin) on <i>Typhlodromus pyri</i> (Acari, Phytoseiidae) on artificial substrate in laboratory : LR50 estimation and reproduction assessment. PROMO-VERT Report No. 01TYGOL24 GLP, unpublished	Y	GOËMAR