



Draft Assessment Report (DAR)

- public version -

**Initial risk assessment provided by the rapporteur Member State
Estonia for the existing active substance**

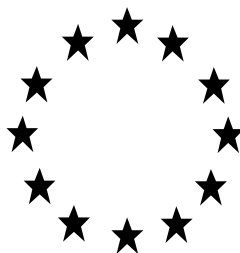
PHLEBIOPSIS GIGANTEA

**of the fourth stage of the review programme
referred to in Article 8(2) of Council Directive 91/414/EEC**

Volume 2, Annex A

September 2008

Draft Assessment Report



Phlebiopsis gigantea

Volume 2

Annex A

List of tests and studies submitted and of information available

Rapporteur Member State: Estonia

April 2007



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Level 2: Reasoned statement of the overall conclusions drawn by the Rapporteur Member State

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Phlebiopsis gigantea

Annex A: List of tests and studies submitted and of information available

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WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

Phlebiopsis gigantea
Annex A: List of tests and studies submitted and of information available

A.1 Identity

Annex II Data and Information

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner**
Anonymous	IIB 1.3.1	1993	ATCC Accession form no. 90304 Not GLP. Unpublished	Y	VRA
Anonymous	IIB 1.3.1	2004	DSMZ Accession form no. 16201 Not GLP. Unpublished	Y	VRA
Anonymous	IIB 1.3.1	2004	DSMZ Accession form no. 16202 Not GLP. Unpublished	Y	VRA
Anonymous	IIB 1.3.1	2004	DSMZ Accession form no. 16203 Not GLP. Unpublished	Y	VRA
Anonymous	IIB 1.3.1	2003	IMI Safe deposit certificate SD188 Not GLP. Unpublished	Y	FOC
Anonymous	IIB 1.3.1	2003	IMI Safe deposit certificate SD189 Not GLP. Unpublished	Y	FOC
Anonymous	IIB 1.3.1	2003	IMI Safe deposit certificate SD190 Not GLP. Unpublished	Y	FOC
Anonymous	IIB 1.3.1	2003	IMI Safe deposit certificate SD191 Not GLP. Unpublished	Y	FOC
Anonymous	IIB 1.3.1	2003	IMI Safe deposit certificate SD192 Not GLP. Unpublished	Y	FOC
Anonymous	IIB 1.3.1	2003	IMI Safe deposit certificate SD193 Not GLP. Unpublished	Y	FOC
Anonymous	IIB 1.3.1	2003	IMI Safe deposit certificate SD194 Not GLP. Unpublished	Y	FOC
Anonymous	IIB 1.3.1	2003	IMI Safe deposit certificate SD195 Not GLP. Unpublished	Y	FOC
Anonymous	IIB 1.3.1	2003	IMI Safe deposit certificate SD196 Not GLP. Unpublished	Y	FOC
Anonymous	IIB 1.3.1	2003	IMI Safe deposit certificate SD197 Not GLP. Unpublished	Y	FOC
Anonymous	IIB 1.3.1	2004	Identification of fungus cultures. DSMZ		
De Koker, T.H., Nakasone, K.K., Haarhof, J., Burdsall, H.H., Janse, B.J.H.	IIB 1.3	2003	Phylogenetic relationships of the genus <i>Phanerochaete</i> inferred from the internal transcribed spacer region. Mycol. Res. Vol, 107(9), pp. 1032-1040. Not GLP. Published.	N	
Eriksson, J. Hjortstam, K. Ryvarden, L.	IIB 1.3	1978	The Corticiaceae of North Europe. Vol. 5, pp. 1181 - 1183. Not GLP. Published.	N	
Eriksson, J. Hjortstam, K. Ryvarden, L.	IIB 1.3	1981	The Corticiaceae of North Europe. Vol. 6, pp. 1181 - 1183. Not GLP. Published.	N	
Grillo, R., Hantula, J., Korhonen, K.	IIB 1.3	2005	Interfertility between North American and European strains of <i>Phlebiopsis gigantea</i> . For. Path. Vol. 35, pp. 173-182. Not GLP. Published.	N	

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Hallaksela, A-M., Korhonen, K.	IIB 1.3.3	1992	Identification of the fungus from the biopreparate made by Kemira Oy for conifer stump treatment. Report. Finnish Forest Research Institute. 4 pp. Not GLP. Unpublished.	Y	VRA
Hoffman, P.	IIB 1.3.3	2004	Identification of fungus cultures. Certificate. DMSZ. Not GLP. Published	N	
Holmer, L. Stenlid, J.	IIB 1.3 IIB 1.3.3	2003	New isolates of <i>Phlebiopsis gigantea</i> ; methods and results. Report. Swedish University of Agricultural Sciences. 9 pp. Not GLP. Unpublished.	Y	VRA
Korhonen, K.	IIB 1.3.3	2003a	Identification of fungal isolates from the biopreparates 1984, 1985 and 1986, made by Verdera Oy for treating conifer stumps against <i>Heterobasidion</i> . Report. Finnish Forest Research Institute. 2 pp. Not GLP. Unpublished.	Y	VRA
Korhonen, K., Kauppila, P.	IIB 1.3	1988	The sexuality of <i>Phlebiopsis gigantea</i> Karstenia. Vol. 27, pp. 23 – 30. Not GLP. Published	N	
Parmasto, E., Hallenberg, N.	IIB 1.3	2000	A taxonomic study of phlebioid fungi (Basidiomycota). Nord. J. Bot. Vol. 20 (1), pp 105-118. Not GLP. Published.	N	
Thorpe, K.	IIB 1.3.3	2005a	SOP: Method for selection of isolates for PG Suspension. Forest Research, UK. Not. GLP. Unpublished.	Y	FOC
Vainio, E. Lipponen, K. Hantula, J.	IIB 1.3.3	2001	Persistence of a biological strain of <i>Phlebiopsis gigantea</i> in conifer stumps and its effects on within-species genetic diversity. For. Path. Vol. 31, pp. 285-295. Not GLP. Published.	N	
Vainio, E. J., Korhonen, K., Hantula, J.	IIB 1.3	1998	Genetic variation in <i>Phlebiopsis gigantea</i> as detected with random amplified microsatellite (RAMS) markers. Mycol. Res. Vol.102 (2), pp. 187 – 192. Not GLP. Published.	N	
Vainio, E. J., Hantula, J.	IIB 1.3	2000	Genetic differentiation between European and North American populations of <i>Phlebiopsis gigantea</i> . Mycologia. Vol. 92(3), pp 136-146. Not GLP. Published.	N	

Phlebiopsis gigantea

Annex A: List of tests and studies submitted and of information available

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Webber, J., Thorpe, K.	IIB 1.3 IIB 1.3.3	2003	Potential for biological control of <i>Heterobasidion annosum</i> in the UK using Rotstop. In: Laflamme <i>et al.</i> (eds.). Root and butt rots of forest trees. Proc. 10 th Int. conf. on root and butt rots. Quebec City, Canada, 2001, pp. 221 – 225. Not GLP. Published.	N	FOC

* Protection for 5 years claimed from date of decision concerning listing in Annex I - the study report has not been submitted in any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used in any of the Member States as the basis for decision on the initial authorization, or to maintain a given authorization, of a plant protection product before the date of submission of the dossier to Rapporteur Member State.

** Owners' code identifications and names (Code identification: VRA, Name: Verdera; FOC: Forestry Commission)

Annex III Data and Information

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Anonymous	IIIB 1.4	2003	Rotstop safety data sheet	Y	VRA

* Protection for 5 years claimed from date of decision concerning listing in Annex I - the study report has not been submitted in any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used in any of the Member States as the basis for decision on the initial authorization, or to maintain a given authorization, of a plant protection product before the date of submission of the dossier to Rapporteur Member State.

** Owners' code identifications and names (Code identification: VRA, Name: Verdera)

A.2 Biological, physical, chemical and technical properties

Annex II Data and Information

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Boyce, J.S.	IIB 2.1.2 IIB 2.5	1966	Sporulation by <i>Peniophora gigantea</i> with reference to control of Annosus root rot. For. Sci. Vol. 12 (1), pp. 2-70. Not GLP. Published.	N	
Briggs, L.H., Cambie, R.C., Dean, I.C., Dromgoole, S.H., Fergus, B.J., Ingram, K.G., Lewis, K.G., Small, C.W., Thomas, R. & Walker, D.A.	IIB 2.3 IIB 2.8	1975	Chemistry of fungi 10. Metabolites of some fungal species. N. Z. J. Sci. Vol. 18, pp. 565 – 576. Not GLP. Published.	N	
Burchby, J.	IIB 2.5	2001	The effect of mechanical application on the viability of <i>Phlebiopsis gigantea</i> for the control of <i>Heterobasidion annosum</i> root rot of <i>Pinus</i> species. Dissertation. University of Wales. 43 pp. Not GLP. Unpublished.	N	
Capretti, P., Mugnai, L.	IIB 2.3 IIB 2.8	1989	<i>In vitro</i> test of antagonism against <i>Heterobasidion annosum</i> (Fr.) Bref. Phytopath. Medit. Vol. 28, pp. 155 – 157. Not GLP. Published.	N	
Cartwright, K.,ST.G., Findlay, W.P.K.	IIB 2.5	1958	Decay of timber and its prevention. Forest Products Research Laboratory. 2nd Edition. Her Majesty's Stationery Office, London, pp.178-179. Not GLP. Published.	N	
Demchenko, S-I.	IIB 2.5	1999	Optimization of cultivation conditions for <i>Peniophora gigantea</i> (Fr) Mass. (Corticiaceae). Ukrains-kii-Botanichnii-Zurnal. Vol. 56(2), pp 192-197. Abstract. Not GLP. Published	N	
Gibbs, J.N., Greig, B.J.W., Pratt, J.E.	IIB 2.1.1	2002	Fomes root rot in Thetford Forest, East Anglia: past present and future. Forestry, Vol. 75(2), pp. 191 – 202. Not GLP. Published.	N	
Greig, B.J.W.	IIB 2.1.1	1976	Biological control of <i>Fomes annosus</i> by <i>Peniophora gigantea</i> . Eur. J. For. Path. Vol. 6(2), pp. 65 – 71. Not GLP. Published.	N	

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Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed*	Owner **
Gremmen, J.	IIB 2.1.2 IIB 2.5	1963	Biological control of the root-rot fungus <i>Fomes annosus</i> (Fr.) Cke by <i>Peniophora gigantea</i> (Fr.) Masse. Med Barbow. Ned. Bosb. Tijdschr. Vol. 35(9), pp. 356-367. Not GLP. Published.	N	
Grillo, R., Hantula, J., Korhonen, K.	IIB 2.1.2	2005	Interfertility between North American and European strains of <i>Phlebiopsis gigantea</i> . For. Path. Vol. 35, pp. 173-182. Not GLP. Published.	N	
Grillo, R., Hantula, J., Korhonen, K.	IIB 2.1.2	2005	Interfertility between North American and European strains of <i>Phlebiopsis gigantea</i> . For. Path. Vol. 35, pp. 173-182. Not GLP. Published.	N	
Hallaksela, A.M.	IIB 2.1.2	1977	Microbial flora isolated from Norway spruce stumps. (Kuusen kantojen mikrobi-lajisto). Acta Forest. Fenn. Vol. 158, 50 pp. Not GLP. Published.	N	
Holdenrieder, O., Greig, B.J.W.	IIB 2.1.2 IIB 2.3 IIB 2.4 IIB 2.8	1998	Biological methods of control. In: Woodward <i>et al.</i> (eds). <i>Heterobasidion annosum</i> . Biology, Ecology, Impact and Control. CAB International, UK, pp. 235 – 258. Not GLP. Published.	N	
Holmer, L. Stenlid, J.	IIB 2.1.2	2003	New isolates of <i>Phlebiopsis gigantea</i> ; methods and results. Report. Swedish University of Agricultural Sciences. 9 pp. Not GLP. Unpublished.	Y	VRA
Hütterman, A.	IIB 2.3 IIB 2.8	1997	Possible toxicity of secondary metabolites produced by <i>Peniophora gigantea</i> in liquid culture. Expert statement, 2 pp. Not GLP. Unpublished.	Y	FOC
Ikeduigwu, F.E.O., Dennis, C., Webster, J.	IIB 2.3 IIB 2.8	1970	Hyphal interference by <i>Peniophora gigantea</i> and <i>Heterobasidion annosum</i> . Trans. Br. Mycol. Soc., Vol. 54 (2), pp. 307 – 309. Not GLP. Published.	N	
Jennison, M.W., Richberg, C.G., Krikszens, A.E.	IIB 2.3 IIB 2.8	1957	Physiology of wood-rotting basidiomycetes. II. Nutritive composition of mycelium grown in submerged culture. Appl. Microbiol. Vol. 5, pp. 87 – 95. Not GLP. Published.	N	

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Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed*	Owner **
Käärik, A. Rennerfelt, E.	IIB 2.1.2 IIB 2.3	1957	Investigation of the fungal flora of spruce and pine stumps. Meddelanden från Statens Skogsforskningsinstitut, Vol. 47, 88 pp. Not GLP. Published.	N	
Kallio, T.	IIB 2.1.2 IIB 2.5	1970	Aerial distribution of the root-rot fungus <i>Fomes annosus</i> (Fr.) Cooke in Finland. Acta Forest. Fenn. Vol 107, 55 pp. Not GLP. Published.	N	
Kallio, T., Hallaksela, A-M.	IIB 2.1.1 IIB 2.5	1979	Biological control of <i>Heterobasidion annosum</i> (Fr.) Bref. (<i>Fomes annosus</i>) in Finland. Eur. J. For. Path. 9(5), pp. 298-308. Not GLP. Published.	N	
Korhonen, K.	IIB 2.7	2003b	Simulated stump treatment experiments for monitoring of the efficacy of <i>Phlebiopsis gigantea</i> against <i>Heterobasidion</i> . In: Laflamme <i>et al.</i> (eds.). Root and butt rots of forest trees. Proc. 10th Int. Conf. on Root and Butt Rots, Quebec City, Canada, 2001, pp. 206-210. Not GLP. Published.	N	
Korhonen, K., Kauppila, P.	IIB 2.1.2 IIB 2.4	1988	The sexuality of <i>Phlebiopsis gigantea</i> Karstenia. Vol. 27, pp. 23 – 30. Not GLP. Published.	N	
Korhonen, K., Lipponen, K., Bendz, M, Johansson, M., Ryen, I., Venn, K. Seiskari, P., Niemi., M.	IIB 2.1.1	1994	Control of <i>Heterobasidion annosum</i> by stump treatment with Rotstop - a new commercial formulation of <i>Phlebiopsis gigantea</i> . Proc. 8th Int. Conf. Root and butt rots, Sweden & Finland 1993, pp. 675 – 685. SUAS, Uppsala. Not GLP. Published.	N	
Korhonen, K., Stenlid, J.	IIB 2.2	1998	Biology of <i>Heterobasidion annosum</i> . In: Woodward <i>et al.</i> (eds). <i>Heterobasidion annosum</i> . Biology, Ecology, Impact and Control. CAB International, UK, pp. 43 – 70. Not GLP. Published.	N	
Meredith, D.S.	IIB 2.1.2 IIB 2.5	1959	The infection of pine stumps by <i>Fomes annosus</i> and other fungi. Ann. Bot. Lond. (n.s), Vol. 23 (91) pp. 455 – 476. Not GLP. Published.	N	
Meredith, D.S.	IIB 2.1.2 IIB 2.5	1960	Further observations on fungi inhabiting pine stumps. Ann. Bot. Lond.(n.s), Vol. 24 (93), pp. 63-78. Not GLP. Published.	N	

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Niemi, M.	IIB 2.5	1992a	Effect of temperature on the growth of <i>Peniophora gigantea</i> and <i>Heterobasidion annosum</i> . Kemira Agro Oy, Espoo Research Centre. Test report 9241, 2 pp. Not GLP. Unpublished.	Y/N	VRA
Niemi, M.	IIB 2.5	1992b	Effect of high temperature on the viability of the spores of <i>Phlebiopsis gigantea</i> . Test report 9252, 1 p. Not GLP. Unpublished.	Y	VRA
Petäistö, R.-L.	IIB 2.1.2	1978	<i>Phlebia gigantea</i> and <i>Heterobasidion annosum</i> in pine stumps on cutting areas in Suomenniemi and Savitaipale. (<i>Phlebia gigantea</i> ja <i>Heterobasidion annosum</i> männynkannoissa hakkuualoilla Suomenniemen ja Savitaipaleen kunnissa). Folia For. 373, pp 1-9. Not GLP. Published.	N	
Pratt, J.E., Niemi, M., Sierota, Z.H.	IIB 2.1.1	2000	Comparison of three products based on <i>Phlebiopsis gigantea</i> for the control of <i>Heterobasidion annosum</i> in Europe. Biocontrol Science and Technology Vol. 10, pp. 467– 477. Not GLP. Published.	N	
Pratt, J.E., Gibbs, J.N., Webber, J.F.	IIB 2.1.2	1999	Registration of <i>Phlebiopsis gigantea</i> as a forest biocontrol agent in the UK: recent experience. Biocontrol Science & Technology. Vol. 9(1), pp. 113 – 118. Not GLP. Published.	N	
Pulkkanen, H.	IIB 2.9	1996	Antibiotic sensitivity of <i>Phlebiopsis gigantea</i> . Kemira Agro Oy, Espoo Research Centre. Test report 186/96. 3 pp. Not GLP. Unpublished.	Y	VRA
Rishbeth, J.	IIB 2.1.1 IIB 2.5	1963	Stump protection against <i>Fomes annosus</i> . III. Inoculation with <i>Peniophora gigantea</i> . Ann. Appl. Biol. Vol. 52 (1), pp. 63 – 77. Not GLP. Published.	N	
Rishbeth, J.	IIB 2.1.2 IIB 2.5	1959	Dispersal of <i>Fomes annosus</i> Fr and <i>Peniophora gigantea</i> (Fr.) Massee. Trans. Brit. mycol. Soc. Vol. 42 (2), pp. 243 – 260. Not GLP. Published.	N	
Roy, G., Laflamme, G., Bussières, G., Dessureault, M.	IIB 2.1.2 IIB 2.3	2003	Field tests on biological control of <i>Heterobasidion annosum</i> by <i>Phaeotheca dimorphospora</i> in comparison with <i>Phlebiopsis gigantea</i> . For. Path. 33, pp. 127-140. Not GLP. Published.	N	

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Seiskari, P.	IIB 2.7	2005a	SOP 144-1. Maintenance and subculturing of microbial strains used in Rotstop production. Verdera Oy. 3pp. Not GLP. Unpublished.	Y	VRA
Sierota, Z.H.	IIB 2.1.1	2001	Efficiency of <i>Phlebiopsis gigantea</i> in PgIBL® Preparation to control the root rot disease in threatened Scots pine stands in the last decade of 2000. Bull. Polish Acad. Sci. Biol. Sci. Vol. 49(3), pp. 197-202. Not GLP: Published.	N	
Thomsen I., Jacobsen, J.B.	IIB 2.5	2003	Testing of Rotstop on Sitka spruce, Douglas-fir and larch. In: Laflamme <i>et al.</i> (eds.). Root and butt rots of forest trees. Proc.10th Int. Conf. on Root and Butt Rots. Quebec City, Canada, 2001, pp. 216-220. Not GLP. Published.	N	
Thor, M, Nohrstedt, H-O & Westlien, J.	IIB 2.3	1997b	Possible environmental effects of stump treatment with borate, <i>Phlebiopsis gigantea</i> and urea – a literature study. Skogforsk Report No. 1 59 pp. Not GLP: Published	N	
Thor, M.	IIB 2.1.1	2003	Operational stump treatment against <i>Heterobasidion annosum</i> in European forestry – current situation. In: Laflamme <i>et al.</i> (eds.). Root and butt rots of forest trees. Proc.10th Int. Conf. on Root and Butt Rots. Quebec City, Canada, 2001, pp. 170-175. Not GLP. Published.	N	
Thor, M., Stenlid, J.	IIB 2.1.1	1998	<i>Heterobasidion annosum</i> infection following mechanized first thinning and stump treatment in <i>Picea abies</i> . In: Delatour <i>et al.</i> (eds). Root and butt rots of forest trees. INRA Les Colloques. No. 89, pp. 397-407. Not GLP. Published.	N	
Thor, M., Bendz-Hellgren, M., Stenlid, J..	IIB 2.5	1997a	Sensitivity of root rot antagonist <i>Phlebiopsis gigantea</i> spores to high temperature or pressure. Scand. J. For. Res. 12, 356-361. Not GLP. Published.	N	
Thorpe, K.	IIB 2.5	2001	Linear growth rates of <i>Phlebiopsis gigantea</i> on artificial media. Forest Research, Alice Holt Lodge. Report PPP01020, 3 pp. Not GLP. Unpublished.	Y	FOC
Thorpe, K.	IIB 2.7	2005a	SOP: Method for selection of isolates for PG Suspension. Forest Research, UK. Not. GLP. Unpublished.	Y	FOC

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Vainio, E. Lipponen, K. Hantula, J.	IIB 2.3	2001	Persistence of a biological strain of <i>Phlebiopsis gigantea</i> in conifer stumps and its effects on within-species genetic diversity. For. Path. Vol. 31, pp. 285-295. Not GLP. Published.	N	
Vainio, E. J., Korhonen, K., Hantula, J.	IIB 2.1.2	1998	Genetic variation in <i>Phlebiopsis gigantea</i> as detected with random amplified microsatellite (RAMS) markers. Mycol. Res. Vol.102 (2), pp. 187 – 192. Not GLP. Published.	N	
Vainio, E. J., Hantula, J.	IIB 2.1.2	2000	Genetic differentiation between European and North American populations of <i>Phlebiopsis gigantea</i> . Mycologia. Vol. 92(3), pp 136-146. Not GLP. Published.	N	
Vainio, E., Hallaksela, A-M., Lipponen, K., Hantula, J	IIB 2.3	2005	Direct analysis of ribosomal DNA in denaturing gradients: application on the effects of <i>Phlebiopsis gigantea</i> treatment on fungal communities of conifer stumps Mycol. Res. Vol. 109 (1), 103-114 Not GLP; Published	N	
Varese G. C. Gonthier P. Nicolotti G.	IIB 2.3	2003	Impact of biological and chemical treatments against <i>Heterobasidion annosum</i> on non-target micro-organisms. In: Laflamme <i>et al.</i> (eds). Root and butt rots of forest trees. Proc. 10 th Int. Conference on Root and Butt Rots. Quebec City, Canada, 200, pp. 145-155. Not GLP; Published	N	
Vasiliauskas, R., Larsson, E., Larsson K. H., Stenlid, J.	IIB 2.3	2005	Persistence and long term impact of Rotstop biological control agent on mycodiversity in <i>Picea abies</i> stumps. Biological Control Vol. 32, 295-304 Not GLP; Published	N	
Vasiliauskas, R., Lygis, V., Thor, M., Stenlid, J.	IIB 2.3	2004	Impact of biological (Rotstop) and chemical (urea) treatments on fungal community structure. Biological Control Vol. 31 (3), 405-413 Not GLP; Published	N	
Webb, P.J.	IIB 2.1.1	1973	An alternative to chemical stump protection against <i>Fomes annosus</i> on pines in state and private forestry. Scottish Forestry, No. 1, vol. 27. Not GLP. Published.	N	

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Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed*	Owner **
Webber, J., Thorpe, K.	IIB 2.1.2	2003	Potential for biological control of <i>Heterobasidion annosum</i> in the UK using Rotstop. In: Laflamme <i>et al.</i> (eds.). Root and butt rots of forest trees. Proc. 10 th Int. conf. on root and butt rots. Quebec City, Canada, 2001, pp. 221 – 225. Not GLP. Published.	N	FOC
Worgan, J.T.	IIB 2.3	1968	Culture of higher fungi. In: Hockenhull, D.J.D. (Ed.): Progress in industrial microbiology. Vol. 8. pp. 73-140. J & A Churchill Ltd., London. Not GLP. Published.	N	
Worgan, J.T.	IIB 2.8	1968	Culture of higher fungi. In: Hockenhull, D.J.D. (Ed.): Progress in industrial microbiology. Vol. 8. pp. 73-140. J & A Churchill Ltd., London. Not GLP. Published.	N	
Wyllie, T.D. & Morehouse, L.G.	IIB 2.8	1977- 1978	Mycotoxic fungi, mycotoxins, mycotoxicoses: an encyclopedic handbook. Volumes 1-3. New York, Marcel Dekker.	N	

* Protection for 5 years claimed from date of decision concerning listing in Annex I - the study report has not been submitted in any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used in any of the Member States as the basis for decision on the initial authorization, or to maintain a given authorization, of a plant protection product before the date of submission of the dossier to Rapporteur Member State.

** Owners' code identifications and names (Code identification: VRA, Name: Verdera; FOC: Forestry Commission)

Annex III Data and Information

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed*	Owner **
Seiskari, P.	IIIB 2.2	2005j	Storage stability of Rotstop. Report-149-1. Verdera Oy. 2 pp. Not GLP. Unpublished.	Y	VRA
Woolley, A.J., Mullee, D.M.	IIIB 2.1 IIIB 2.2 IIIB 2.5 IIIB 2.7	2004a	Determination of accelerated storage stability. SPL Project number: 1841/005. SafePharm Laboratories. 27 pp. GLP Yes. Unpublished.	Y	VRA
Woolley, A.J., Mullee, D.M.	IIIB 2.1 IIIB 2.2 IIIB 2.5 IIIB 2.7	2004b	Determination of long-term storage stability. SPL Project number: 1841/006. SafePharm Laboratories. 27 pp. GLP Yes. Unpublished.	Y	VRA

* Protection for 5 years claimed from date of decision concerning listing in Annex I - the study report has not been submitted in any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used in

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Annex A: List of tests and studies submitted and of information available

any of the Member States as the basis for decision on the initial authorization, or to maintain a given authorization, of a plant protection product before the date of submission of the dossier to Rapporteur Member State.

** Owners' code identifications and names (Code identification: VRA, Name: Verdera)

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

A.3 Further Information

Annex II Data and Information

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Anonymous	IIB 3.7 IIB 3.8 IIB 3.9	2004	Rotstop safety data sheet	Y	VRA
Capretti, P., Mugnai, L.	IIB 3.5	1989	<i>In vitro</i> test of antagonism against <i>Heterobasidion annosum</i> (Fr.) Bref. Phytopath. Medit. Vol. 28, pp. 155 – 157. Not GLP. Published.	N	
Gremmen, J	IIB 3.5	1963	Biological control of the root-rot fungus <i>Fomes annosus</i> (Fr.) Cke by <i>Peniophora gigantea</i> (Fr.) Masse. Med Barbouw. Ned. Bosb. Tijdschr. Vol. 35(9), pp. 356-367. Not GLP. Published.	N	
Hallaksela, A- M., Korhonen, K.	IIB 3.6	1992a	Identification of the fungus from the biopreparate made by Kemira Oy for conifer stump treatment. Report. Finnish Forest Research Institute. 4 pp. Not GLP. Unpublished.	Y	VRA
Holdenrieder, O., Greig, B.J.W	IIB 3.5	1998	Biological methods of control. In: Woodward <i>et al.</i> (eds). <i>Heterobasidion annosum</i> . Biology, Ecology, Impact and Control. CAB International, UK, pp. 235 – 258. Not GLP. Published.	N	
Ikeduigwu, F.E.O.	IIB 3.5	1976	The interface in hyphal interference by <i>Peniophora gigantea</i> against <i>Heterobasidion annosum</i> . Trans. Br. Mycol. Soc. Vol. 66, pp. 291 - 296. Not GLP. Published.	N	
Ikeduigwu, F.E.O., Dennis, C., Webster, J.	IIB 3.5	1970	Hyphal interference by <i>Peniophora</i> <i>gigantea</i> and <i>Heterobasidion annosum</i> . Trans. Br. Mycol. Soc., Vol. 54 (2), pp. 307 – 309. Not GLP. Published.	N	
Korhonen, K.	IIB 3.5	2003a	Identification of fungal isolates from the biopreparates 1984, 1985 and 1986, made by Verdera Oy for treating conifer stumps against <i>Heterobasidion</i> . Report. Finnish Forest Research Institute. 2 pp. Not GLP. Unpublished.	Y	VRA

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Annex A: List of tests and studies submitted and of information available

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Korhonen, K.	IIB 3.5 IIB 3.6	2003b	Simulated stump treatment experiments for monitoring of the efficacy of <i>Phlebiopsis gigantea</i> against <i>Heterobasidion</i> . In: Laflamme <i>et al.</i> (eds.). Root and butt rots of forest trees. Proc. 10th Int. Conf. on Root and Butt Rots, Quebec City, Canada, 2001, pp. 206-210. Not GLP. Published.	N	
Korhonen, K.	IIB 3.5	2005	Results of billet experiments and stump treatment experiments including <i>P. gigantea</i> isolates from Sweden, Canada and UK. Finnish Forest research Institute. Report, 5 pp. Not GLP. Unpublished.	Y	VRA
Korhonen, K., Kauppila, P.	IIB 3.5	1988	The sexuality of <i>Phlebiopsis gigantea</i> Karstenia. Vol. 27, pp. 23 – 30. Not GLP. Published.	N	
Korhonen, K., Lipponen, K., Bendz, M., Johansson, M., Ryen, I., Venn, K., Seiskari, P., Niemi, M.	IIB 3.5	1994	Control of <i>Heterobasidion annosum</i> by stump treatment with Rotstop - a new commercial formulation of <i>Phlebiopsis gigantea</i> . Proc. 8th Int. Conf. Root and butt rots, Sweden & Finland 1993, pp. 675 – 685. SUAS, Uppsala. Not GLP. Published.	N	
Korhonen, K., Stenlid, J.	IIB 3.5	1998	Biology of <i>Heterobasidion annosum</i> . In: Woodward <i>et al.</i> (eds). <i>Heterobasidion annosum</i> . Biology, Ecology, Impact and Control. CAB International, UK, pp. 43 – 70. Not GLP. Published.	N	
Meredith, D.S.	IIB 3.5	1960	Further observations on fungi inhabiting pine stumps. Ann. Bot. Lond.(n.s), Vol. 24 (93), pp. 63-78. Not GLP. Published.	N	
Rishbeth, J	IIB 3.5	1963	Stump protection against <i>Fomes annosus</i> . III. Inoculation with <i>Peniophora gigantea</i> . Ann. Appl. Biol. Vol. 52 (1), pp. 63 – 77. Not GLP. Published.	N	
Seiskari, P.	IIB 3.6	2005a	SOP 144-1. Maintenance and subculturing of microbial strains used in Rotstop production. Verdera Oy. 3pp. Not GLP. Unpublished.	Y	VRA
Seiskari, P.	IIB 3.6	2005c	SOP 147-1. Rotstop test on agar plates. Verdera Oy. 4 pp. Not GLP. Unpublished.	Y	VRA

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Annex A: List of tests and studies submitted and of information available

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Thorpe, K.	IIB 3.6	2005a	SOP: Method for selection of isolates for PG Suspension. Forest Research, UK. Not GLP. Unpublished.	Y	FOC

* Protection for 5 years claimed from date of decision concerning listing in Annex I - the study report has not been submitted in any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used in any of the Member States as the basis for decision on the initial authorization, or to maintain a given authorization, of a plant protection product before the date of submission of the dossier to Rapporteur Member State.

** Owners' code identifications and names (Code identification: VRA, Name: Verdera; FOC: Forestry Commission)

Annex III Data and Information

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Anonymous	IIIB 4.4 IIIB 4.5 IIIB 4.6	2004	Rotstop safety data sheet	Y	VRA
Capretti, P., Mugnai, L.	IIIB 3.2	1989	<i>In vitro</i> test of antagonism against <i>Heterobasidion annosum</i> (Fr.) Bref. Phytopath. Medit. Vol. 28, pp. 155 – 157. Not GLP. Published.	N	
Gremmen, J	IIIB 3.2	1963	Biological control of the root-rot fungus <i>Fomes annosus</i> (Fr.) Cke by <i>Peniophora gigantea</i> (Fr.) Masse. Med Barbouw. Ned. Bosb. Tijdschr. Vol. 35(9), pp. 356-367. Not GLP. Published.	N	
Holdenrieder, O., Greig, B.J.W	IIIB 3.2	1998	Biological methods of control. In: Woodward <i>et al.</i> (eds). <i>Heterobasidion annosum</i> . Biology, Ecology, Impact and Control. CAB International, UK, pp. 235 – 258. Not GLP. Published.	N	
Ikeduigwu, F.E.O.	IIIB 3.2	1976	The interface in hyphal interference by <i>Peniophora gigantea</i> against <i>Heterobasidion annosum</i> . Trans. Br. Mycol. Soc. Vol. 66, pp. 291 - 296. Not GLP. Published.	N	
Ikeduigwu, F.E.O., Dennis, C., Webster, J.	IIIB 3.2	1970	Hyphal interference by <i>Peniophora gigantea</i> and <i>Heterobasidion annosum</i> . Trans. Br. Mycol. Soc., Vol. 54 (2), pp. 307 – 309. Not GLP. Published.	N	

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Annex A: List of tests and studies submitted and of information available

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Meredith, D.S.	IIIB 3.2	1960	Further observations on fungi inhabiting pine stumps. Ann. Bot. Lond.(n.s), Vol. 24 (93), pp. 63-78. Not GLP. Published.	N	
Palin-Holmberg, G.	IIIB 4.1	2001/ 2002	Shelf life test for biocontrol products in paper-EVOH-laminate. Test report 01244-ETs. Kemira Oyj, Espoo Research Centre. 7 pp. Not GLP. Unpublished.	Y	VRA
Rishbeth, J	IIIB 3.2	1963	Stump protection against <i>Fomes annosus</i> . III. Inoculation with <i>Peniophora gigantea</i> . Ann. Appl. Biol. Vol. 52 (1), pp. 63 – 77. Not GLP. Published.	N	

* Protection for 5 years claimed from date of decision concerning listing in Annex I - the study report has not been submitted in any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used in any of the Member States as the basis for decision on the initial authorization, or to maintain a given authorization, of a plant protection product before the date of submission of the dossier to Rapporteur Member State.

** Owners' code identifications and names (Code identification: VRA, Name: Verdera)

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Annex A: List of tests and studies submitted and of information available

A.4 Proposals for classification, packaging and labelling**Annex II Data and Information**

Technical grade of the MPCA is a hypothetical stage of a continuous production process and no MSDS for the active substance is available.

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **

* Protection for 5 years claimed from date of decision concerning listing in Annex I - the study report has not been submitted in any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used in any of the Member States as the basis for decision on the initial authorization, or to maintain a given authorization, of a plant protection product before the date of submission of the dossier to Rapporteur Member State.

** Owners' code identifications and names (Code identification: VRA, Name: Verdera; FOC: Forestry Commission)

Annex III Data and Information

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Anonymous	B.4.2	2003	Rotstop safety data sheet	Y	VRA

* Protection for 5 years claimed from date of decision concerning listing in Annex I - the study report has not been submitted in any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used in any of the Member States as the basis for decision on the initial authorization, or to maintain a given authorization, of a plant protection product before the date of submission of the dossier to Rapporteur Member State.

** Owners' code identifications and names (Code identification: VRA, Name: Verdera)

A.5 Analytical methods

Annex II Data and Information

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Hallaksela, A-M., Korhonen, K	IIB 4.1.1 IIB 4.1.5	1992a	Identification of the fungus from the biopreparate made by Kemira Oy for conifer stump treatment. Report. Finnish Forest Research Institute. 4 pp. Not GLP. Unpublished.	Y	VRA
Hallaksela, A-M., Korhonen, K.	IIB 4.1.2	1992b	Isolation of <i>P. gigantea</i> from a tree stump or log. Finnish Forest Research Institute. 1 p. Not GLP. Unpublished.	N	METLA
Hoffman, P.	IIB 4.1.1	2004	Identification of fungus cultures. Certificate. DMSZ. Not GLP. Published	N	
Holmer, L. Stenlid, J.	IIB 4.1.1	2003	New isolates of <i>Phlebiopsis gigantea</i> ; methods and results. Report. Swedish University of Agricultural Sciences. 9 pp. Not GLP. Unpublished.	Y	VRA
Korhonen, K.	IIB 4.1.1	2003a	Identification of fungal isolates from the biopreparates 1984, 1985 and 1986, made by Verdera Oy for treating conifer stumps against <i>Heterobasidion</i> . Report. Finnish Forest Research Institute. 2 pp. Not GLP. Unpublished.	Y	VRA
Korhonen, K.	IIB 4.1.2	2003b	Simulated stump treatment experiments for monitoring the efficacy of <i>Phlebiopsis gigantea</i> against <i>Heterobasidion</i> . In: Laflamme <i>et al.</i> (eds.). Root and butt rots of forest trees. Proc. 10th Int. Conf. on Root and Butt Rots. Quebec City, Canada, 2001, pp 206-210. Not GLP. Not GLP. Published	N	
Lahdenperä, M-L.	IIB 4.1.6	2005	SOP 165-1. Method for surveying viable microbes in the indoor air in the production facilities of Rotstop. Verdera Oy. 1 p. Not GLP. Unpublished.	Y	VRA
Seiskari, P.	IIB 4.1.5	2004	SOP 101-1. Viability determination of biological pesticides. Verdera Oy, 4 pp. Not GLP. Unpublished.	Y	VRA
Seiskari, P.	IIB 4.1.2 IIB 4.1.4	2005a	SOP 144-1. Maintenance and subculturing of microbial strains used in Rotstop production. Verdera Oy. 3pp. Not GLP. Unpublished.	Y	VRA

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Annex A: List of tests and studies submitted and of information available

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Seiskari, P.	IIB 4.1.5 IIB 4.1.6	2005b	SOP 120-2 Viability determination of biological pesticides using MPN-method. Verdera Oy. 4 pp. Not GLP. Unpublished.	Y	VRA
Seiskari, P.	IIB 4.1.5	2005h	SOP 143-1. Quality control of Rotstop production. Verdera Oy. 3 pp. Not GLP. Unpublished. Confidential information (Document C)	Y	VRA
Seiskari, P.	IIB 4.1.2	2005c	SOP 147-1. Rotstop test on agar plates. Verdera Oy. 4 pp. Not GLP. Unpublished.	Y	VRA
Seiskari, P.	IIB 4.1.6	2005d	SOP 163-3. Quality control in Rotstop production facilities. Verdera Oy. 1 p. Not GLP. Unpublished.	Y	VRA
Seiskari, P.	IIB 4.1.7	2005e	Analysis of pathogenic contaminants in Rotstop. Report 159-1. Verdera Oy. 1 p. + 4 appendices. GLP Yes. Unpublished.	Y	VRA
Seiskari, P.	IIB 4.1.8	2005f	SOP 161-1. Storage stability of biological control agents. Verdera Oy. 1 p. Not GLP. Unpublished.	Y	VRA
Seiskari, P.	IIB 4.1.8	2005j	Storage stability of Rotstop. Report-149-1 Verdera Oy. 2 pp. Not GLP. Unpublished.	Y	VRA
Thorpe, K.	IIB 4.1.1 IIB 4.1.2 IIB 4.1.4 IIB 4.1.5	2005a	SOP: Method for selection of isolates for PG Suspension. Forest Research, UK. Not GLP. Unpublished.	Y	FOC
Vainio, E. Lipponen, K. Hantula, J.	IIB 4.1.1	2001	Persistence of a biological strain of <i>Phlebiopsis gigantea</i> in conifer stumps and its effects on within-species genetic diversity. For. Path. Vol. 31, pp. 285-295. Not GLP. Published.	N	
Webber, J., Thorpe, K.	IIB 4.1.1	2003	Potential for biological control of <i>Heterobasidion annosum</i> in the UK using Rotstop. In: Laflamme <i>et al.</i> (eds.). Root and butt rots of forest trees. Proc. 10 th Int. conf. on root and butt rots. Quebec City, Canada, 2001, pp. 221 – 225. Not GLP. Published.	N	FOC

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** Owners' code identifications and names (Code identification: VRA, Name: Verdera; FOC: Forestry Commission, METLA - Finnish Forest Research Institute)

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Annex A: List of tests and studies submitted and of information available

Annex III Data and Information

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner**
Briggs, L.H., Cambie, R.C., Dean, I.C., Dromgoole, S.H., Fergus, B.J., Ingram, K.G., Lewis, K.G., Small, C.W., Thomas, R. & Walker, D.A.	IIIB 5	1975	Chemistry of fungi 10. Metabolites of some fungal species. N. Z. J. Sci. Vol. 18, pp. 565 – 576. Not GLP. Published.	N	
Capretti, P., Mugnai, L.	IIIB 5	1989	<i>In vitro</i> test of antagonism against <i>Heterobasidion annosum</i> (Fr.) Bref. Phytopath. Medit. Vol. 28, pp. 155 – 157. Not GLP. Published.	N	
Holdenrieder, O., Greig, B.J.W.	IIIB 5	1998	Biological methods of control. In: Woodward <i>et al.</i> (eds). <i>Heterobasidion annosum</i> . Biology, Ecology, Impact and Control. CAB International, UK, pp. 235 – 258. Not GLP. Published.	N	
Ikediegwu, F.E.O., Dennis, C., Webster, J.	IIIB 5	1970	Hyphal interference by <i>Peniophora gigantea</i> and <i>Heterobasidion annosum</i> . Trans. Br. Mycol. Soc., Vol. 54 (2), pp. 307 – 309. Not GLP. Published.	N	
Pulkkanen, H	IIIB 5.1.4	1995	Effect of temperature changes during storage and transportation on shelf-life of Rotstop. Memorandum 95093-Esp-Me. Kemira Agro Oy. 3 pp. Not GLP. Unpublished.	Y	VRA
Seiskari, P.	IIIB 5.1.4	2005f	SOP 161-1. Storage stability of biological control agents. Verdera Oy. 1 p. Not GLP. Unpublished.	Y	VRA
Seiskari, P.	IIIB 5.1.4	2002	Sedimentation test with Rotstop preparations made of Swedish <i>Phlebiopsis</i> strains. Test report. Verdera Oy. Not GLP. Unpublished.	Y	VRA
Seiskari, P.	IIIB 5.1.4	2005k	Tap density of Rotstop. Report-150-1. Verdera Oy. 1 p. Not GLP. Unpublished.	Y	VRA
Woolley, A.J., Mullee, D.M.	IIIB 5.1.4	2004a	Determination of accelerated storage stability. SPL Project number: 1841/005. SafePharm Laboratories. 27 pp. GLP Yes. Unpublished.	Y	VRA

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Annex A: List of tests and studies submitted and of information available

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner ** VRA
Woolley, A.J., Mullee, D.M.	IIIB 5.1.4	2004b	Determination of long-term storage stability. SPL Project number: 1841/006. SafePharm Laboratories. 27 pp. GLP Yes. Unpublished.	Y	VRA

* Protection for 5 years claimed from date of decision concerning listing in Annex I - the study report has not been submitted in any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used in any of the Member States as the basis for decision on the initial authorization, or to maintain a given authorization, of a plant protection product before the date of submission of the dossier to Rapporteur Member State.

** Owners' code identifications and names (Code identification: VRA, Name: Verdera)

Phlebiopsis gigantea
Annex A: List of tests and studies submitted and of information available

A.6 Effects on human health

Annex II Data and Information

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner**
Allen, S.	IIB 5.2.1	1996	Rotstop skin sensitisation in the guinea pig. Huntingdon Life Sciences Ltd. Company report No.: HLS RKY 131/960116/SS. GLP; Unpublished	Y	VRA
Blanchard, E.	IIB 5.2.2.3	2002	Rotstop: Acute intraperitoneal toxicity and pathogenicity to the rat. Huntingdon Life Sciences Ltd Company report No.: HLS KEY 008/023033/AC GLP; Unpublished	Y	VRA
Briggs, L.H., Cambie, R.C., Dean, I.C., Dromgoole, Fergus, S.H., Ingram, B.J., Lewis, K.G., Small, K.G., Thomas, C.W., Walker, D.A.	IIB 5.1.	1975	Chemistry of fungi 10. Metabolites of some fungal species. N. Z. J. Sci. Vol. 18, pp. 565 – 576. Not GLP. Published.	N	
Capretti, P., Mugnai, L.	IIB 5.1.	1989	<i>In vitro</i> test of antagonism against <i>Heterobasidion annosum</i> (Fr.) Bref. Phytopath. Medit. Vol. 28, pp. 155 – 157. Not GLP. Published.	N	
Greig, B.J.W	IIB 5.1.3	1992	<i>Peniophora gigantea</i> . Letter to Pekko Seiskari from B.J.W Greig with Extracts from <i>Peniophora</i> data sheet. Ref: PAT.175 Not GLP; Unpublished	Y	FOC
Holdenrieder, O Greig, B.J.W.	IIB 5.1.	1998	Biological methods of control. In: Woodward <i>et al.</i> (eds). <i>Heterobasidion annosum</i> . Biology, Ecology, Impact and Control. CAB International, UK, pp. 235 – 258. Not GLP. Published.	N	
Hütterman, A	IIB 5.1.	1998	Possible toxicity of secondary metabolites produced by <i>Peniophora gigantea</i> in liquid culture. Expert statement, 2 pp. Not GLP. Unpublished.	N	
Ikediugwu, F.E.O., Dennis, C., Webster, J.	IIB 5.1.	1970	Hyphal interference by <i>Peniophora gigantea</i> and <i>Heterobasidion annosum</i> . Trans. Br. Mycol. Soc., Vol. 54 (2), pp. 307 – 309. Not GLP. Published.	N	
Jennison, M.W., Richberg, C.G. Krikszens, A.E.	IIB 5.1.	1957	Physiology of wood-rotting basidiomycetes. II. Nutritive composition of mycelium grown in submerged culture. Appl. Microbiol. Vol. 5, pp. 87 – 95. Not GLP. Published.	N	

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Annex A: List of tests and studies submitted and of information available

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner**
Kallunki, H., Kangas, J., Laitinen, S., Mäkinen, M., Susitaival, K.O	IIB 5.1.3	2002	Exposure to and health effects of chemical and biological agents in mechanical wood harvesting. Final report (In Finnish, English summary and relevant translated sections submitted). Not GLP; Published	N	KATTL
Kallunki, S., Mäkinen, M., Ojanen, K., Kaitinen, S., Kangas, J.	IIB 5.1.3	2004	Exposure to biological fungicides, environmental microorganisms and oils in forestry harvesting. Scand. J. For. Res. Vol. 19, pp. 82-88 Not GLP; Published	N	KATTL
Kangas, J., Laitinen, S., Louhelainen, K., Seuri, M.	IIB 5.1.3	1997	Investigation of the health effects of fungi and oil mist spread by harvester heads. Final report 26 May 1997, Kuopio Regional Occupational Health Institute. Not GLP; Published	N	KATTL
Korhonen, K., Kauppila, P.	IIB 5.1.	1988	The sexuality of <i>Phlebiopsis gigantea</i> Karstenia. Vol. 27, pp. 23-30. Not GLP. Published.	N	
Korhonen, K., Lipponen, K.	IIB 5.1.3	2000	Sensitization of <i>Phlebiopsis gigantea</i> Memo dated 6 July 2000 Not GLP; Unpublished	Y	METLA
McRae, L.	IIB 5.2.2.1	1996a	Rotstop acute oral toxicity and pathogenicity to the rat. Huntingdon Life Sciences Ltd. Company report No.: HLS RKY 132/953004/AC GLP; Unpublished	Y	VRA
McRae, L.	IIB 5.2.2.2	1996b	Rotstop acute pulmonary toxicity and pathogenicity to the rat. Huntingdon Life Sciences Ltd. Company report No.:HLS RKY 133/953005/AC GLP; Unpublished	Y	VRA
Neild, V.S.	IIB 5.1.3	1996	Eric Tridgell Letter to Mr J.E. Pratt 11 September 1996 Not GLP; Unpublished	Y	FOC
Nelson, S.M	IIB 5.1.3	1995	Application for clearance to use <i>Peniophora gigantea</i> : Search of chainsawyers personal health records. Letter to Mr J. Pratt from Mrs S.M. Nelson Ref: SMN/AT/E19/8/1 Not GLP; Unpublished	Y	FOC
Niemi, M.	IIB 5.1.	1992a	Effect of temperature on the growth of <i>Peniophora gigantea</i> and <i>Heterobasidion annosum</i> . Kemira Agro Oy, Espoo Research Centre. Test report 9241, 2 pp. Not GLP. Unpublished.	Y	VRA
Niemi, M.	IIB 5.1.	1992b	Effect of high temperature on the viability of the spores of <i>Phlebiopsis gigantea</i> . Test report 9252, 1 p. Not GLP. Unpublished.	Y	VRA

Phlebiopsis gigantea
Annex A: List of tests and studies submitted and of information available

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Salfelder, K., De Roman, A.R., de Mendelovici, M., Silberborg, S.B.	IIB 5.2.2.3	1975	Inoculation of basidiomycetes into mice: Tissue reaction and survival of fungi in tissues Mykosen. Vol. 18 (10). pp 417-424 Not GLP; Published	N	-
Salfelder, K., Schwarz, J.	IIB 5.2.2.3	1976	Basidiomycetes as infectious agents Mykosen. Vol. 19 (10), pp 373-382. Not GLP; Published	N	-
Salonen, J.O.	IIB 5.1.3	2000	Medical Certificate 8 May 2000 Not GLP; Unpublished	Y	VRA
Seiskari, P.	IIB 5.1.3	1994	Sensitization of <i>Phlebia gigantea</i> Statement 23.6.1994 Not GLP; Unpublished	Y	VRA
Thorpe, K.	IIB 5.1.3	2005e	Operator questionnaire. Ref: PG Suspension for use against <i>Fomes</i> root and butt rot. Forest Research, Alice Holt Lodge. 22 pp. Not GLP; Unpublished	Y	FOC
Tolonen, A.	IIB 5.1.3	2005	Medical certificate. Mediavire Työterveyspalvelut Oy. Not GLP. Unpublished.	Y	VRA

* Protection for 5 years claimed from date of decision concerning listing in Annex I - the study report has not been submitted in any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used in any of the Member States as the basis for decision on the initial authorization, or to maintain a given authorization, of a plant protection product before the date of submission of the dossier to Rapporteur Member State.

** Owners' code identifications and names (Code identification: VRA, Name: Verdera; FOC: Forestry Commission)

Not submitted reference list

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Anon.	IIB 5.1.3	1997	Investigation of the health effects of fungi and oil mist spread by harvester heads. Final report 26 May 1997, Kuopio Regional Occupational Health Institute. Press release 29 May 97. Full report submitted as IIM 5.2.1/05 Published	N	KATTL
Hallaksela, A. M. Korhonen, Lipponen, K. K.	IIB 5.1.3	1992	Pronouncement about the sensitization of <i>Phlebia gigantea</i> . 1 p. Finnish Forest Research Institute. Superseded by update submitted as IIM 5.2.1/07 Unpublished.	Y	METLA

Phlebiopsis gigantea

Annex A: List of tests and studies submitted and of information available

Annex III Data and Information

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Allen, S.	IIIB 7.2.3	1996	Rotstop skin sensitisation in the guinea pig. Huntingdon Life Sciences Ltd. Company report No.: HLS RKY 131/960116/SS. GLP; Unpublished	Y	VRA
Blanchard, E.	IIIB 7.1.3	2002	Acute dermal toxicity/pathology to the rat. Huntingdon Life Sciences Ltd. Company report No.: KEY 009/022717/AC GLP; Unpublished	Y	VRA
McRae, L.	IIIB 7.1.1	1996a	Rotstop acute oral toxicity and pathogenicity to the rat. Huntingdon Life Sciences Ltd. Company report No.: HLS RKY 132/953004/AC GLP; Unpublished	Y	VRA
McRae, L.	IIIB 7.1.2	1996b	Rotstop acute pulmonary toxicity and pathogenicity to the rat. Huntingdon Life Sciences Ltd. Company report No.: HLS RKY 133/953005/AC GLP; Unpublished	Y	VRA
Parcell, B.	IIIB 7.2.1	1996a	Rotstop: Skin irritation to the rabbit. Huntingdon Life Sciences Ltd. Company report No.: RKY 130/960291/SE GLP; Unpublished	Y	VRA
Parcell, B.	IIIB 7.2.2	1996b	Rotstop: Eye irritation to the rabbit. Huntingdon Life Sciences Ltd. Company report No.: RKY 138/960815/SE GLP; Unpublished	Y	VRA

* Protection for 5 years claimed from date of decision concerning listing in Annex I - the study report has not been submitted in any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used in any of the Member States as the basis for decision on the initial authorization, or to maintain a given authorization, of a plant protection product before the date of submission of the dossier to Rapporteur Member State.

** Owners' code identifications and names (Code identification: VRA, Name: Verdera; FOC: Forestry Commission)

Phlebiopsis gigantea
Annex A: List of tests and studies submitted and of information available

A.7 Residue data

Annex II and Annex III Data and Information

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Briggs, L.H., Cambie, R.C., Dean, I.C., Dromgoole, S.H., Fergus, B.J., Ingram, K.G., Lewis, K.G., Small, C.W., Thomas, R. & Walker, D.A.	IIB 6.2.1 IIIB 8	1975	Chemistry of fungi 10. Metabolites of some fungal species. N. Z. J. Sci. Vol. 18, pp. 565 – 576. Not GLP. Published.	N	
Hütterman, A.	IIB 6.2.1 IIIB 8	1997	Possible toxicity of secondary metabolites produced by <i>Peniophora</i> <i>gigantea</i> in liquid culture. Expert statement, 2 pp. Not GLP. Unpublished.	Y	FOC

* Protection for 5 years claimed from date of decision concerning listing in Annex I - the study report has not been submitted in any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used in any of the Member States as the basis for decision on the initial authorization, or to maintain a given authorization, of a plant protection product before the date of submission of the dossier to Rapporteur Member State.

** Owners' code identifications and names (Code identification: FOC: Forestry Commission)

A.8 Fate and behaviour in the environment

Annex II and Annex III Data and Information

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Capretti, P., Mugnai, L.	IIB 7 IIIB 9	1989	<i>In vitro</i> test of antagonism against <i>Heterobasidion annosum</i> (Fr.) Bref. Phytopath. Medit. Vol. 28, pp. 155 – 157. Not GLP. Published.	N	
Cartwright, K., ST.G., Findlay, W.P.K.	IIB 7 IIIB 9	1958	Decay of timber and its prevention. Forest Products Research Laboratory. 2nd Edition. Her Majesty's Stationery Office, London, pp.178-179. Not GLP. Published.	N	
Gibbs, J., Webber, J., Greig, B., Thompson, D.	IIB 7.1.2 IIIB 9	1996	Fungal stain and decay in wet stored logs In: Water storage of timber: Forestry Commission Bulletin 117. Not GLP; Published	N	
Gremmen, J.	IIB 7 IIIB 9	1963	Biological control of the root-rot fungus <i>Fomes annosus</i> (Fr.) Cke by <i>Peniophora gigantea</i> (Fr.) Masse. Med Barbouw. Ned. Bosb. Tijdschr. Vol. 35(9), pp. 356-367. Not GLP. Published.	N	
Ikediugwu, F.E.O.	IIB 7 IIIB 9	1976	The interface in hyphal interference by <i>Peniophora gigantea</i> against <i>Heterobasidion annosum</i> . Trans. Br. Mycol. Soc. Vol. 66, pp. 291 - 296. Not GLP. Published.	N	
Ikediugwu, F.E.O., Dennis, C., Webster, J.	IIB 7 IIIB 9	1970	Hyphal interference by <i>Peniophora gigantea</i> and <i>Heterobasidion annosum</i> . Trans. Br. Mycol. Soc., Vol. 54 (2), pp. 307 – 309. Not GLP. Published.	N	
Käärik, A. Rennerfelt, E.	IIB 7.1 IIIB 9	1957	Investigation of the fungal flora of spruce and pine stumps. Meddelanden från Statens Skogsforskningsinstitut, Vol. 47, 88 pp. Not GLP. Published.	N	
Kallio, T.	IIB 7.1.3 IIIB 9	1970	Aerial distribution of the root-rot fungus <i>Fomes annosus</i> (Fr.) Cooke in Finland. Acta Forest. Fenn. Vol 107, 55 pp. Not GLP. Published.	N	
Meredith, D.S.	IIB 7 IIB 7.1.3 IIIB 19	1960	Further observations on fungi inhabiting pine stumps. Ann. Bot. Lond.(n.s), Vol. 24 (93), pp. 63-78. Not GLP. Published.	N	

Phlebiopsis gigantea
Annex A: List of tests and studies submitted and of information available

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Meredith, D.S.	IIB 7.1.3 IIIB 9	1959	The infection of pine stumps by <i>Fomes annosus</i> and other fungi. Ann. Bot. Lond. (n.s), Vol. 23 (91) pp. 455 – 476. Not GLP. Published.	N	
Niemi, M.	IIB 7 IIIB 9	1992a	Effect of temperature on the growth of <i>Peniophora gigantea</i> and <i>Heterobasidion annosum</i> . Kemira Agro Oy, Espoo Research Centre. Test report 9241, 2 pp. Not GLP. Unpublished.	Y	VRA
Niemi, M.	IIB 7 IIIB 9	1992b	Effect of high temperature on the viability of the spores of <i>Phlebiopsis gigantea</i> . Test report 9252, 1 p. Not GLP. Unpublished.	Y	VRA
Rishbeth, J.	IIB 7 IIIB 9	1959	Dispersal of <i>Fomes annosus</i> Fr and <i>Peniophora gigantea</i> (Fr.) Massee. Trans. Brit. mycol. Soc. Vol. 42 (2), pp. 243– 260. Not GLP. Published.	N	
Rishbeth, J.	IIB 7 IIB 7.1.1 IIIB 9	1963	Stump protection against <i>Fomes annosus</i> . III. Inoculation with <i>Peniophora gigantea</i> . Ann. Appl. Biol. Vol. 52 (1), pp. 63 – 77. Not GLP. Published.	N	
Roy, G., Cormier, M., Hamelin, R. C., Dessureault, M.	IIB 7 IIIB 9	1997	Comparison of RAPD technique and somatic incompatibility tests for the identification of <i>Phlebiopsis gigantea</i> strains Can. J. Bot. Vol. 75, 2097-2104 Not GLP; Published	N	
Roy, G., Laflamme, G., Bussieres, G., Dessureault, M.	IIB 7.1.3 IIIB 9	2003	Field tests on biological control of <i>Heterobasidion annosum</i> by <i>Phaeothea dimorphospora</i> in comparison with <i>Phlebiopsis gigantea</i> . For. Path. 33, pp. 127-140. Not GLP. Published.	N	
Thor, M., Bendz- Hellgren, M., Stenlid, J..	IIB 7.1.2 IIIB 9	1997a	Sensitivity of root rot antagonist <i>Phlebiopsis gigantea</i> spores to high temperature or pressure. Scand. J. For. Res. 12, 356-361. Not GLP. Published.	N	
Thorpe, K.	IIB 7 IIIB 9	2001	Linear growth rates of <i>Phlebiopsis gigantea</i> on artificial media. Forest Research, Alice Holt Lodge. Report PPP01020, 3 pp. Not GLP. Unpublished.	Y	FOC
Vainio, E. Lipponen, K. Hantula, J.	IIB 7.1.3 IIB 7.2 IIIB 9	2001	Persistence of a biological strain of <i>Phlebiopsis gigantea</i> in conifer stumps and its effects on within-species genetic diversity. For. Path. Vol. 31, pp. 285-295. Not GLP. Published.	N	

Phlebiopsis gigantea

Annex A: List of tests and studies submitted and of information available

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Vainio, E., Hallaksela, A- M., Lipponen, K., Hantula, J	IIB 7 IIIB 9	2005	Direct analysis of ribosomal DNA in denaturing gradients: application on the effects of <i>Phlebiopsis gigantea</i> treatment on fungal communities of conifer stumps Mycol. Res. Vol. 109 (1), 103-114 Not GLP; Published	N	
Vasiliauskas, R., Juska, E., Vasiliauskas, A., Stenlid, J.	IIB 7 IIIB 9	2002	Community of aphyllophorales and root rot in stumps of <i>Picea abies</i> on clear- felled forest sites in Lithuania. Scand. J. For. Res. Vol. 117, 398-407 Not GLP; Published	N	
Vasiliauskas, R., Larsson, E., Larsson K. H., Stenlid, J	IIB 7 IIIB 9	2005	Persistence and long-term impact of Rotstop biological control agent on mycodiversity in <i>Picea abies</i> stumps. Biological Control Vol. 32, 295-304 Not GLP; Published	N	
Vasiliauskas, R., Lygis, V., Thor, M., Stenlid, J.	IIB 7 IIIB 9	2004	Impact of biological (Rotstop) and chemical (urea) treatments on fungal community structure. Biological Control Vol. 31 (3), 405-413 Not GLP; Published	N	

* Protection for 5 years claimed from date of decision concerning listing in Annex I - the study report has not been submitted in any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used in any of the Member States as the basis for decision on the initial authorization, or to maintain a given authorization, of a plant protection product before the date of submission of the dossier to Rapporteur Member State.

** Owners' code identifications and names (Code identification: VRA, Name: Verdera; FOC: Forestry Commission)

A.9 Effects on non-target organisms

Annex II and Annex III Data and Information

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner**
Asiegbu, F.O., Daniel, G. Johansson, M.	IIB 8.7 IIIB 10.7	1996	Cellular interaction between the saprotroph <i>Phlebiopsis gigantea</i> and non-suberised roots of <i>Picea abies</i> Mycol. Res. Vol. 100, 409-417 Not GLP; Published	N	
Bailey, P.J., Woodward, S. Pratt, J.E.	IIB 8.7 IIIB 10.7	2003	Colonisation and degradation of Sitka spruce sapwood by the Rotstop strain of <i>Phlebiopsis gigantea</i> . In: Laflamme <i>et al.</i> (eds). Root and butt rots of forest trees. Proc. 10 th Int. Conference on Root and Butt Rots. Quebec City, Canada, 2001 pp. 200-205. Not GLP; Published	N	
Brandeis, T.J., Newton, M., Filip, G.M. & Cole, E.C.	IIB 8.1 IIIB 10.1	2002	Cavity-nester habitat development in artificially made Douglas-fir snags J. Wildlife Management 66(3), 625-633 Not GLP; Published	N	
Briggs, L.H., Cambie, R.C., Dean, I.C., Dromgoole, S.H., Fergus, B.J., Ingram, K.G., Lewis, K.G., Small, C.W., Thomas, R. & Walker, D.A.	IIB 8.1 IIIB 10.1 IIB 8.2.1 IIIB 10.2 IIB 8.2.2 IIIB 10.2 IIB 8.2.3 IIIB 10.2 IIB 8.2.4 IIIB 10.2 IIB 8.3 IIIB 10.3 IIB 8.5 IIIB 10.5 IIB 8.6 IIIB 10.6	1975	Chemistry of fungi 10. Metabolites of some fungal species. N. Z. J. Sci. Vol. 18, pp. 565 – 576. Not GLP. Published.	N	
Hallaksela, A.M.	IIB 8.1 IIIB 10.1	1977	Microbial flora isolated from Norway spruce stumps. (Kuusen kantojen mikrobi-lajisto). Acta Forest. Fenn. Vol. 158, 50 pp. Not GLP. Published.	N	
Holdenrieder, O., Greig, B.J.W.	IIB 8.1 IIIB 10.1 IIB 8.5 IIIB 10.5	1998	Biological methods of control. In: Woodward <i>et al.</i> (eds). <i>Heterobasidion annosum</i> . Biology, Ecology, Impact and Control. CAB International, UK, pp. 235 – 258. Not GLP. Published.	N	

Phlebiopsis gigantea
Annex A: List of tests and studies submitted and of information available

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Hunt, R. S, Cobb, F. W.	IIB 8.4 IIIB 10.4	1982	Potential arthropod vectors and competing fungi of <i>Fomes annosus</i> in pine stumps. Can. J. Plant Path. Vol. 4, 247-253. Not GLP: Published	N	
Jennison, M.W., Richberg, C.G. Krikszens, A.E.	IIB 8.1 IIIB 10.1	1957	Physiology of wood-rotting basidiomycetes. II. Nutritive composition of mycelium grown in submerged culture. Appl. Microbiol. Vol. 5, pp. 87 – 95. Not GLP. Published.	N	
Käärik, A. Rennerfelt, E.	IIB 8.7 IIIB 10.7	1957	Investigation of the fungal flora of spruce and pine stumps. Meddelanden från Statens Skogsforskningsinstitut, Vol. 47, 88 pp. Not GLP. Published.	N	
Kallio, T.	IIB 8.1 IIIB 10.1	1970	Aerial distribution of the root-rot fungus <i>Fomes annosus</i> (Fr.) Cooke in Finland. Acta Forest. Fenn. Vol 107, 55 pp. Not GLP. Published.	N	
Kallio, T.	IIB 8.7 IIIB 10.7	1973	<i>Peniophora gigantea</i> (Fr. Masee.) and wounded spruce (<i>Picea abies</i> L.) Karst. Acta Forest. Fenn. Vol. 133 28pp. Not GLP; Published	N	
Kallio, T.	IIB 8.7 IIIB 10.7	1976	<i>Peniophora gigantea</i> (Fr.) Masee and wounded spruce (<i>Picea abies</i> (L.) Karst.). Part II. Acta Forest. Fenn. Vol. 149. 16 pp. Not GLP; Published	N	
Meredith, D.S.	IIB 8.1 IIIB 10.1	1959	The infection of pine stumps by <i>Fomes</i> <i>annosus</i> and other fungi. Ann. Bot. Lond. (n.s), Vol. 23 (91) pp. 455 – 476. Not GLP. Published.	N	
Petäistö, R-L.	IIB 8.1 IIIB 10.1	1978	<i>Phlebia gigantea</i> and <i>Heterobasidion</i> <i>annosum</i> in pine stumps on cutting areas in Suomenniemi and Savitaipale. (<i>Phlebia gigantea</i> ja <i>Heterobasidion</i> <i>annosum</i> männynkannoissa hakkuualoilla Suomenniemen ja Savitaipaleen kunnissa). Folia For. 373, pp 1-9. Not GLP. Published.	N	

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Annex A: List of tests and studies submitted and of information available

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Pratt, J.E., Gibbs, J.N., Webber, J.F.	IIB 8.1 IIIB 10.1	1999	Registration of <i>Phlebiopsis gigantea</i> as a forest biocontrol agent in the UK: recent experience. Biocontrol Science & Technology. Vol. 9(1), pp. 113 – 118. Not GLP. Published.	N	
Rishbeth, J.	IIB 8.1 IIIB 10.1	1959	Dispersal of <i>Fomes annosus</i> Fr and <i>Peniophora gigantea</i> (Fr.) Massee. Trans. Brit. mycol. Soc. Vol. 42 (2), pp. 243 – 260. Not GLP. Published.	N	
Rishbeth, J.	IIB 8.1 IIIB 10.1	1963	Stump protection against <i>Fomes annosus</i> . III. Inoculation with <i>Peniophora gigantea</i> . Ann. Appl. Biol. Vol. 52 (1), pp. 63 – 77. Not GLP. Published.	N	
Roll-Hansen F. Roll-Hansen H.	IIB 8.7 IIIB 10.7	1980	Micro-organisms which invade <i>Picea abies</i> in seasonal stem wounds 1. General aspects. Hymenomycetes E. J. For. Path. Vol. 10, 321-339 Not GLP: Published	N	
Roy, G., Laflamme, G., Bussieres, G., Dessureault, M.	IIB 8.7 IIIB 10.7	2003	Field tests on biological control of <i>Heterobasidion annosum</i> by <i>Phaeotheca dimorphospora</i> in comparison with <i>Phlebiopsis gigantea</i> . For. Path. 33, pp. 127-140. Not GLP. Published.	N	
Skrzecz, I	IIB 8.4 IIIB 10.4	1996	Impact of <i>Phlebia gigantea</i> (Fr.:Fr) Donk on the colonization of Scots pine (<i>Pinus sylvestris</i> L.) stumps by the large pine weevil (<i>Hylobius abietis</i> L.). Folia Forestalia Polonica Vol. 38, 89- 101 Not GLP; Published	N	
Skrzecz, I	IIB 8.4 IIIB 10.4	2001	Large pine weevil (<i>Hylobius abietis</i> L.) abundance and the extent of damage in plantations established on clearcuts with pine stumps treated with the fungus <i>Phlebiopsis gigantea</i> (Fr.:Fr.) Julich. Folia Forestalia Polonica Series A – Forestry No. 43. Not GLP: Published	N	
Taylor, K.	IIB 8.3 IIIB 10.3	2005	Rotstop Acute toxicity to honey bees. Huntingdon Life Sciences Ltd. Report No: PHE 0001/053566 GLP: Yes Unpublished	Y	PGT

Phlebiopsis gigantea

Annex A: List of tests and studies submitted and of information available

Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Thor, M, Nohrstedt, H- O & Westlien, J.	IIB 8.7 IIIB 10.7	1997b	Possible environmental effects of stump treatment with borate, <i>Phlebiopsis gigantea</i> and urea – a literature study. Skogforsk Report No. 1 59 pp. Not GLP: Published	N	
Vainio, E. Lipponen, K. Hantula, J.	IIB 8.7 IIIB 10.7	2001	Persistence of a biological strain of <i>Phlebiopsis gigantea</i> in conifer stumps and its effects on within-species genetic diversity. For. Path. Vol. 31, pp. 285- 295. Not GLP. Published.	N	
Vainio, E., Hallaksela, A- M., Lipponen, K., Hantula, J	IIB 8.7 IIIB 10.7	2005	Direct analysis of ribosomal DNA in denaturing gradients: application on the effects of <i>Phlebiopsis gigantea</i> treatment on fungal communities of conifer stumps Mycol. Res. Vol. 109 (1), 103-114 Not GLP; Published	N	
Varese G. C. Gonthier P. Nicolotti G.	IIB 8.7 IIIB 10.7	2003	Impact of biological and chemical treatments against <i>Heterobasidion annosum</i> on non-target micro- organisms. In: Laffamme <i>et al.</i> (eds). Root and butt rots of forest trees. Proc. 10 th Int. Conference on Root and Butt Rots. Quebec City, Canada, 200, pp. 145-155. Not GLP; Published	N	
Vasiliauskas, R., Larsson, E., Larsson K. H., Stenlid, J.	IIB 8.7 IIIB 10.7	2005	Persistence and long term impact of Rotstop biological control agent on mycodiversity in <i>Picea abies</i> stumps. Biological Control Vol. 32, 295-304 Not GLP; Published	N	
Vasiliauskas, R., Lygis, V., Thor, M., Stenlid, J.	IIB 8.7 IIIB 10.7	2004	Impact of biological (Rotstop) and chemical (urea) treatments on fungal community structure. Biological Control Vol. 31 (3), 405-413 Not GLP; Published	N	
Wainhouse, D. Evans, H., Moore, R., Webber, J, Thorpe, K. Staley, J.	IIB 8.4 IIIB 10.4	2002	The integrated forest management programme Forest Research Annual Report and Accounts 2000-2001. Not GLP: Published	N	

Phlebiopsis gigantea

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Author(s)	Annex point / reference number	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed* Y/N	Owner **
Westlund, A. Nohrsredt, H. O.	IIB 8.7 IIIB 10.7	2000	Effects of stump treatment substances for root rot control on ground vegetation and soil properties in a <i>Picea abies</i> forest in Sweden. Scand. J .Fore.Res. Vol. 15, 550-560 Not GLP: Published	N	
Worgan, J.T.	IIB 8.1 IIIB 10.1	1968	Culture of higher fungi. In: Hockenhull, D.J.D. (Ed.): Progress in industrial microbiology. Vol. 8. pp. . 73-140. J & A Churchill Ltd., London. Not GLP. Published.	N	

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