

Draft Assessment Report (DAR)

- public version -

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

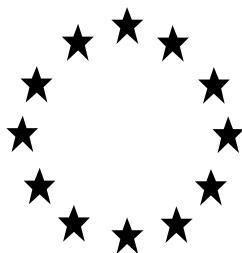
PHLEBIOPSIS GIGANTEA

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

Volume 3, Annex B, part 3, B.7

September 2008

Draft Assessment Report



Phlebiopsis gigantea

Volume 3

Annex B.7

Residue data

Rapporteur Member State: Estonia

April 2007



Volume 1

Level 1: Statement of subject matter and purpose for which the monograph was prepared

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

Appendix 1: Standard terms and abbreviations

Appendix 2: Specific terms and abbreviations

Appendix 3: List of endpoints

Level 3: Proposed decision with respect to the application for inclusion of the active substance in Annex I

Level 4: Further information to permit a decision to be made, or to support a review of the conditions and restrictions associated with the proposed inclusion in Annex I

Volume 2

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

Volume 3

Annex B: RMS summary, evaluation and assessment of the data and information

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Annex B.2: Biological, physical, chemical and technical properties

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Appendix 1: Standard terms and abbreviations

Appendix 2: Specific terms and abbreviations

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Phlebiopsis gigantea
Annex B.7: Residue data

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B.7 Residues in or on treated products, food and feed (Annex IIB 6 and IIIB 8)

B.7.1 Persistence and likelihood of multiplication in or on crops, feedingstuffs or foodstuffs (Annex IIB 6.1 and Annex IIIB 8)

P. gigantea is a specialised decay fungus with a narrow host range, specifically adapted to living in moribund wood. It is very common in temperate and boreal coniferous forests, where fruit bodies are commonly found on decayed wood, e.g. on fallen trees and branches, on stumps, and on the ends of stacked logs. Basidiospores liberated from ripe fruit bodies are widely dispersed by air. Except for periods when temperatures are below zero, spores of *P. gigantea* are abundant in the air. Freshly cut stumps are often naturally colonised by *P. gigantea* regardless of the application of any stump treatment agent.

P. gigantea is used in conifer forests for the control of *H. annosum* by treating the surface of freshly created stumps with an aqueous spore suspension. Stump treatment is done manually e.g. with a hand sprayer, or automatically with special spraying equipment mounted on a harvester. In both cases application of *P. gigantea* spores is targeted onto the stump surface, and spillage around the stump is minimised.

In principle, wild berries and mushrooms growing in treated forest stands may become exposed to some spray drift from the *P. gigantea* application, but amounts of spores that may end up on these edible crops after a stump treatment operation are negligible as compared to natural spore levels. Spore deposition in the range 10 to 20 spores per 100 cm² per hour have been measured in typical commercial pine forests, and such levels do not change significantly following stump treatment (see Volume 3, Annex B8: Fate and behaviour in the environment).

In conclusion, it is highly unlikely that *P. gigantea* would occur in any food/feedstuff in concentrations considerably higher than under natural conditions, and no further residue data are considered to be necessary.

B.7.2 Exposure to consumers (Annex IIB 6.2 and Annex IIIB 8)

B.7.2.1 Non-viable residues (Annex IIB 6.2.1)

P. gigantea is a saprophytic wood-rotting fungus, causing a typical white rot of coniferous timber. It is a primary coloniser of wood and one of the most common decay fungi in coniferous forests. When used as a stump treatment agent for the control of *Heterobasidion annosum*, *P. gigantea* acts through competition for the wood resource and does not depend on the production of toxins (see Volume 3, Annex B2: Biological, physical, chemical and technical properties).

There is only one published study on *P. gigantea*, which reports production of secondary fungal metabolites *in vitro*. However, these were compounds commonly produced by wood-inhabiting fungi or belonging to a class of substances widely distributed in nature. There are no other records of metabolites produced by *P. gigantea* that would be of concern for human health and/or the environment (Briggs *et al.* 1975).

In this study (Briggs *et al.* 1975), investigating metabolites produced by various fungi in liquid culture, Lup-19(22)-ene and Lupa-15,19(22)-diene were found in the neutral fraction of chloroform extract, and 2',3',5'-trimethoxy-p-terphenyl was detected in the neutral fraction of an ethyl acetate extract of the mycelium. According to Hütterman (1997), this compound is a typical secondary fungal metabolite, and substances like this have been found in almost all wood-inhabiting fungi that have been analysed for the presence of this kind of compounds. This particular compound definitely has a lower toxicity than many other secondary metabolites which have been isolated from fungi against which *P. gigantea* is antagonistic. It is not considered to pose any special harm in the following scenarios: (i) acute toxicity during application, (ii) toxicity on the treated stump, (iii) accumulation in the wood and on the forest floor. Lup-19(22)-ene and Lupa-15,19(22)-diene belong to a class of substances which are widely distributed in nature, e.g. in the bark of trees, in leaves and stems of annual plants, or in seeds. No high toxicity can be expected from these compounds in the case of stump treatment.

B.7.2.2 Viable residues (Annex IIB 6.2.2)

P. gigantea does not grow at vertebrate body temperatures, and viable *P. gigantea* was not recovered from the test animals used in acute oral and acute inhalation toxicity tests. This fungal species is not listed in standard texts as a toxic organism, it has been described as an edible fungus, and there have even been animal feeding experiments conducted with *P. gigantea* fungal mycelium. In the acute oral toxicity test there was no evidence of toxicity or infectivity/pathogenicity to rats given a single oral dose of *P. gigantea* (see (see Volume 3, Annex B6: Effects on human health)).

B.7.3 Summary and evaluation of residue behaviour (Annex IIB 6.3 and Annex IIIB 8)

In conclusion, the formulated product does not pose a cause for concern and no further residue data are considered to be necessary for Rotstop.

The active substance *P. gigantea* is a natural component of the forest ecosystems where it is intended for use, and the fungus is not considered to be hazardous to mammals. The co-formulants used in the formulated product are of food or feed grade (see Confidential information: Document C). Due to the localised application technique, it is considered highly unlikely that *P. gigantea* will occur in any food/feedstuff in concentrations considerably higher than under natural conditions.

Phlebiopsis gigantea
Annex B.7: Residue data

B.7.4 References

Annex point / reference number	Author(s)	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 **
Annex II and Annex III Data and Information					
IIB 6.2.1 IIIB 8	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.	1975	Chemistry of fungi 10. Metabolites of some fungal species. N. Z. J. Sci. Vol. 18, pp. 565 – 576. Not GLP. Published.	N	
IIB 6.2.1 IIIB 8	Hütterman, A.	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 any of the Member States in support of an application for authorization, or (though the study report has been submitted) has not been used 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: FOC – Forestry Commission