

## **ANNEX B**

### **Laminarin**

#### **Addendum to the monograph (October 2003)**

## **B.2 Physical and chemical properties**

### **B.2.1.14 Hydrolysis rate at pH 4, 7 and 9 under sterile conditions in the absence of light (IIA 2.9.1)**

#### Reference :

Laminarin – Abiotic degradation : Hydrolysis as a function of pH (Comb, 2003)

#### Guidelines/Methods :

EEC C7

#### GLP :

GLP-compliance stated

#### Findings :

purified a.s. (98% pure) :

*Preliminary tests at 50°C at pH 4, 7 and 9 :*

at all pH : hydrolytic stability (= less than 10% degradation of Laminarin after 5 days)

→ no further tests required

#### Evaluation and conclusion :

Acceptable.

Laminarin is hydrolytically stable at environmentally relevant pH-values.

**B.9 Ecotoxicology****B.9.1.8 Summary of effects to birds - exposure and risk assessment for birds (Annex IIIA 10.1)**

These endpoints are already discussed in the DAR.

Tab. B.9.1.8-1 : Summary of effects of Laminarine to birds.

Test species	Test System	Results	References
Bobwhite quail	Acute oral toxicity	LD <sub>50</sub> > 2000 mg a.s./kg bw	Rodgers M.H., 2002
Bobwhite quail	8 day dietary toxicity	LC <sub>50</sub> (5d) > 5000 ppm	Rodgers M.H., 2001

The risk assessment for birds is based on the new Guidance Document for birds and Mammals Under Council Directive 91/414/EEC of September 2002. As a worst-case scenario it was assumed that the birds obtained 100% of their diet in the treated area.

The LC<sub>50</sub> was recalculated from ppm into mg a.s./kg bw. Based on a mean bodyweight of 19.4 g and a mean food consumption of 3.8 g/bird/day, 5000 ppm becomes 980 mg a.s./kg bw.

Tab. B.9.1.8-2 : Estimated oral uptake of Laminarine by birds

Target crop	Bird type	Time scale	FIR/bw	RUD (90%)	MAF	ETE (mg a.s./kg bw/day)	Toxicity Exposure Ratio
Cereals 1 x 37 g a.s./ha	Herbivorous bird (early)	acute	0.44	142	1	2.31	865
	Insectivorous bird	acute	1.04	52	n.a.	2.00	1000
	Herbivorous bird (early)	short term	0.44	76	1	1.24	792
	Insectivorous bird (late)	short term	1.04	29	n.a.	1.12	875

The risk for birds resulting from the exposure to the a.s., sprayed in cereals, is negligible.

This conclusion is confirmed by references in literature. See DAR p 9-5. Egg laying is not discussed in these articles as they focus on feed conversion. But Laminarin is a beta-1-3 glucan. This type of polysaccharide with 25-30 glycosyl units is found in a wide range of organisms (bacteria, higher plants, yeast, fungi, algae...) and in addition it is found that barley grain contains 30 g/kg total beta-glucan (Bergh, *et al.*, 1999). The grain yield of one hectare barley (8000 kg) would contain 240 kg beta-glucan. Other plant parts, weeds, litter... have also to be considered. Therefore we concluded that beta-glucan forms part of natural bird diets and hence further (long term) testing was not considered necessary.

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**References relied on**

<b>Annex point(s) 91/414/EEC</b>	<b>Author (s)</b>	<b>Title Generated by (company or organization), Submitted by (company (ies) or organization), Report/File n°. Of submitting company Date of report: For publication: reference</b>	<b>Data protection claimed:</b>	<b>GLP/ GEP</b>	<b>Publish ed or not</b>
IIA 2.9.1	Comb	Laminarin – Abiotic degradation : Hydrolysis as a function of pH Huntingdon Life Sciences Ltd Goemar, GOM004/032710 2003 GLP – yes Not Published	yes	yes	No