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00	Cover page	00 heptamaloxyloglucan cover
01	**All comments received on the DAR**	**01 heptamaloxyloglucan all comments**
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Comments on the Draft Assessment Report on heptamaloxyloglucan (NAS)

RMS FR

End of commenting period: 21 April 2008 (MS, NOT)

Date	Supplier	File
21.04.2008	United Kingdom	01 heptamaloxyloglucan comments UK 2008-04-21.doc
22.04.2008	The Netherlands	02 heptamaloxyloglucan comments NL 2008-04-22.doc
23.04.2008	Austria	03 heptamaloxyloglucan comments AT 2008-04-23.doc
13.01.2009	EFSA	04 heptamaloxyloglucan comments EFSA 2009-01-13.doc

section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 4, C.1.1.2.3, analytical profile of batches	UK: The requirement for a specification for mycotoxins in technical material needs to be discussed at an expert meeting and the need for a method of analysis/batch analysis data.	
(2)	Vol 4, C.1.1.2.3, analytical profile of batches	UK: Methods of analysis for the determination of impurities must appear in Vol 4 and consideration should be given to further characterization of these impurities	
(3)	Vol 3, B.2.2.7.3, shelf life	UK: We agree with rapporteur's data requirement for a 2 year shelf life study	
(4)	Vol 3, B.5.1.2, methods of analysis for impurities.	UK: Impurities method must be moved to volume 4	

section 2 - Mammalian toxicology (B.6)

2. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 3, B.6.2.6, skin sensitisation	UK: In addition to this assay, it would be useful to have some assurance that none of the enzymes used in manufacture remain in the final product.	
(2)	Vol 3, B.6.4.1, In vitro genotoxicity, bacterial studies	UK: Please can the RMS provide the positive control data for the Ames assay.	
(3)	Vol 3, B.6.4.1, In vitro genotoxicity, bacterial studies	The *in vitro* assay provides assurance that not only the active is not mutagenic but also any impurities- RMS to comment	
(4)	Vol 3, B.6.10.10, ADI	UK: We are content no ADI is required based comparison with intakes from apple juice.	
(5)	Vol 3, B 6.10.11, AOEL	UK: Overall the proposed value is the derived in an appropriate manner. However, given the nature of the active substance we are not convinced there is a need in this case to apply an additional 10 fold safety factor. The derivation of the 'ADI' makes clear that consumers may be exposed to higher levels than the RMS proposed AOEL.	
(6)	Vol. 3, B.6.14.2 Operator exposure estimates UK POEM	UK: As 'PEL 101 GV' is applied in water volumes ranging from 100 to 400 l/ha, it may be appropriate to present an additional exposure estimate using the high volume version of the UK POEM for broadcast air-assisted sprayers, as this version of the model often predicts higher exposure levels.	

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section 2 - Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(7)	Vol. 3, B.6.14.5.1 Estimation of worker exposure	UK: It is not appropriate to assume that levels of worker re-entry exposure will be negligible because operator exposure levels are predicted to be very low. A worker exposure estimate should be presented taking into account the maximum total dose resulting from repeated applications.	

section 3 - Residues (B.7)

3. Residues (B.7)

No comments

section 4 - Environmental fate and behaviour (B.8)

4. Environmental fate and behaviour (B.8)

No comments

section 5 - Ecotoxicology (B.9)

5. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 3, B.9.1.7.5. long term risk to birds	UK: Potential to bioaccumulate should not be confused with long term risk. The reason why it can be concluded that the long term risk is acceptable without the need for long term effects data is that i) the persistence of the active substance is short so continuous exposure over long periods will not occur ii) acute risk is low so the effect of repeated short term exposure is unlikely to be of concern.	
(2)	Vol 3, B.9.2.2.1. Chronic toxicity to fish	UK: The meaning of the sentence ‘ As no toxicological pattern from acute….’ could perhaps be re-phrased to read more clearly „as there was no evidence of acute toxicity and....“	
(3)	Vol 3, B.9.35.3.2, long term risk assessment for mammals	UK:. Potential to bioaccumulate should not be confused with long term risk. The reason why it can be concluded that the long term risk is acceptable without the need for long term effects data is that i) the persistence of the active substance is short so continuous exposure over long periods will not occur ii) acute risk is low so the effect of repeated short term exposure is unlikely to be of concern.	

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6. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 4, C.1.1.2.1, specification purity active substance	NL: The mean content of 6 batches was 87.4%, with SD 5.8%, and3xSD = 17%. Therefore the minimum purity should not be 78%, but lower. Based on (mean –3SD), the minimum purity may be set at 70% (700 g/kg).	
2	Vol. 3, B.1.2.1, minimum purity	NL: The mean content of 6 batches was 87.4%, with SD 5.8%, and3xSD = 17%. Therefore the minimum purity should not be 78%, but lower. Based on (mean –3SD), the minimum purity may be set at 70% (700 g/kg).	
3	Vol. 3, B.2.1.4a, physical state, odour	NL: Comment on GLP status can be removed, these tests need not be performed under GLP.	
4	Vol. 3, B.2.2.1.10, stability in air	NL: Please state the hydroxyl-ion concentration used for estimation of the DT50.	
5	Vol. 3, B.2.1.11.1, flammability	NL: Is there an EC classification of “oligosaccharides “? A test according to EEC method A.10 is required, unless more detailed information on EC classification of comparable oligosaccharides is provided (i.e. information from official public source on flammability of oligosaccharides of comparable monomer composition and chain length).	
6	Vol. 3, B.2.2.1.1, physical state, odour	NL: Comment on GLP status can be removed, these tests need not be performed under GLP.	

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section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
7	Vol. 3, B.2.2.4.2, pH	NL: According to B.2.3.2, after 10 minutes the pH is 7.02 . Please include this value rather than the value of 7.	
8	Vol. 3, B.2.2.7.1, accelerated storage stability	NL: Comment on GLP status can be removed, these tests need not be performed under GLP.	
9	Vol. 3, B.2.2.7.1, accelerated storage stability	NL: The container material should be stated.	
10	Vol. 3, B.3.5.1.1, specification packaging	NL: What type of opening is “crimped hermetically”? Please provide more detail. What material is used to seal the opening? Please clarify.	
11	Vol. 3, B.3.5.4, Storage	NL: There is no evidence that the product is stable in the packaging for one year. Please state: no data.	
12	Vol. 1, 1.3.9, minimum purity	NL: The mean content of 6 batches was 87.4%, with SD 5.8%, and3xSD = 17%. Therefore the minimum purity should not be 78%, but lower. Based on (mean –3SD), the minimum purity may be set at 70% (700 g/kg).	
13	Vol. 1, List of Endpoints, minimum purity	NL: This should be marked as an open point (see above comments).	
14	Vol. 1, List of Endpoints, molecular formula	NL: Please use subscripts for numbers.	
15	Vol. 1, List of Endpoints, melting points and temperature of decomposition	NL: The purity of the test material was >99% (not 99% as stated).	

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section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
16	Vol. 1, List of Endpoints, appearance	NL: Only the technical active substance was tested (>87%), the line on purity of the purified active substance can be deleted.	
17	Vol. 1, List of Endpoints, solubility in water	NL: The purity of the test material was >87% (not 87% as stated).	
18	Vol. 1, List of Endpoints, solubility in water	NL: According to B.2.1.6, the temperature was ambient temperature, not 20°C. Please change.	
19	Vol. 1, List of Endpoints, solubility in organic solvents	NL: The RSD values should be removed.	
20	Vol. 1, List of Endpoints, surface tension	NL: The ±0.2 can be removed.	
21	Vol. 1, List of Endpoints, UV/Vis absorption	NL: The line with µA values should be removed (depends on concentration, is not an endpoint).	
22	Vol. 1, List of Endpoints, UV/Vis absorption	NL: According to B.2.1.5.1a, the purity was >99% not 99.9%. Please harmonise.	
23	Vol. 1, List of Endpoints, Methods of analysis	NL: The method for the technical active substance is also valid for the plant protection product. Hence change “no data” to HPAEC-PAD.	
24	Vol. 1, List of Endpoints, Methods of analysis, residues	NL: Remove “Thus, as”. Also remove comma at end of statement.	
25	Vol. 1, List of Endpoints, Methods of analysis, monitoring/enforcement methods	NL: Please replace “none” by “not required”.	

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section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
26	Vol. 1, 3.1, background	NL: Paragraph on identity, physico-chemical properties and methods of analysis should be inserted.	
27	Vol. 1, 4.1, further information	NL: The minimum purity should be revised.	
28	Vol. 1, 4.2, further information	NL: A test on flammability of the technical active substance is required.	

section 2 - Mammalian toxicology (B.6)

7. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
1.			

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section 3 - Residues (B.7)

8. Residues (B.7)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
1.		NL: No comments.	

section 4 - Environmental fate and behaviour (B.8)

9. Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
1	Vol. 1 level 2, 2.5.1 residue definition	NL: Please add compartments groundwater and sediment. See B8.8 for agreed residue definition.	
2	Vol. 1 level 2 LoEP	NL: In box residues requiring further assessment, it is agreed (for instance during PRAPeR meetings) that also the parent should be included (although the box refers to metabolites). See B8.8 for agreed residue definition. In fact, the same assumptions DT50soil and Kom could have been used to perform a STEP1-2 PECsw/sed calculations, with the additional assumptions of a water/sediment/system DT50 of default 1000 (however this is not deemed necessary by NL)	
3	Vol. 1 level 3	NL: Agreed	
4	Vol. 1 level 4	NL: Agreed	

section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
5	Vol. 3 B.8.6.1 PECgw	NL: The extrapolation of the ready biodegradability half-life to degradation in soil seems more unlikely than extrapolation of this value to half-life in water/sediment. Yet it was chosen to extrapolate only to soil and not to surface water/sediment. The factor of 2 from ready biodegradability to soil only accounts for the fact that the a.s. is not the only carbon source but it does not account for the differences in the medium in which the degradation is supposed to occur (e.g, moisture conditions). Although the approach is considered acceptable in this case for soil, NL wonders why the same assumption was not made for water/sediment (which would appear more logical). The location of the DT50 estimation would be more appropriate at the ready test itself. The Koc estimation of 20 L/kg is not really sustained (but could be sufficiently worst-case, this cannot be judged without more argumentation). Please provide more argumentation.	

section 4 - Environmental fate and behaviour (B.8)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
6	Vol. 3 B.8.6.2 PECsw	NL: As stated above, it appears inconsistent to indicate at the PECsw section that no data are available for DT50 and Kom while in the previous section they were estimated for soil. However it is agreed that run-off and drainage routes do no seem important for this kind of substance with this application, and the conservative drift calculation provided is considered acceptable and can be used for RA.	

section 5 - Ecotoxicology (B.9)

10. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca. 10 lines)	Column 3 Further explanations
1	Vol.1, LoEP	NL: Please insert >-signs in front of aquatic toxicity values.	

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section 1 - Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

11. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, LOE melting point	AT: The value should be corrected to "**plus"** 172 °C.	
(2)	Vol. 1, LOE representative uses	AT: The common name of the active substance should be inserted between the brackets.	
(3)	Vol. 3, B.2.1.8/01 log Pow	AT: The value given in the DAR differ to that reported in the MSDS (-15.96 to -4.36). Clarification is requested. It should be considered to determine the value experimentally.	
(4)	Vol. 4, C.1.1.2.3 analytical profile of batches	AT: The technical specification should be discussed by a meeting of experts, since about 20 % of the TGAI are not identified.	

section 5 - Ecotoxicology (B.9)

12. Ecotoxicology (B.9)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	General comment	AT: We agree with the RMS evaluation and think that the reduced data set sufficiently confirms the low risk that can be expected from this substance.	

section 1: Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

13. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol 4. C.1.1.2.3, Batch analysis	EFSA: The most important aspect of the specification has to be mycotoxin contamination. Mycotoxins that could be present are patulin, alterariol and alternariol monomethyl. It should also be considered what the fate of these compounds is during the manufacturing process.	
(2)	Vol. 3, B.2.1.1/03c, temperature of decomposition.	EFSA: What does it mean ‘This sticky paste had a little tendency to blow up.’	

section 2: Mammalian toxicology (B.6)

14. Mammalian toxicology (B.6)

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 3 B.6.2.6 Skin sensitisation (p.136)	EFSA: Skin sensitisation has been assessed only in the LLNA assay which is currently not accepted as a "stand-alone" assessment method in the EU.	
2	Vol. 3 B.6.5. – 6.6. Long term toxicity (p. 148) and reprotoxicity (p.149)	EFSA: Justification for data waiving should be confirmed at a meeting of experts.	
3	Vol. 3 B.6.10.11- 12 ADI, AOEL, ARfD (p. 155)	EFSA: The setting of AOEL and the waiving of the ADI should be confirmed at a meeting of experts.	

section 3: Residues (B.7)

15. . **Residues**

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		EFSA: No comments	

section 4: Fate and behaviour (B.8)

16. . Fate and behaviour

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.8.6.1, Predicted environmental concentration in groundwater	EFSA: On page 205 to Vol. 3 the case from the applicant regarding the low potential for groundwater exposure is presented and EFSA agrees that this case made by the applicant is reasonable in the context of the applied for use. However in addition on pages 205 to 207 of Vol. 3, FOCUS groundwater modelling carried out by the RMS is presented. Whilst EFSA can understand why the RMS chose to do this, EFSA has to comment that the use of a half life for soil in simulations estimated from a ready biodegradability study is not appropriate. The biodegradation potential of a sewage sludge inoculum and the optimised conditions of the test do not represent degradation potential that would be expected in soil. In addition it is unclear to EFSA on what basis the soil adsorption value assumed by the RMS is very conservative.	

section 5: Ecotoxicology (B.9)

17. . Ecotoxicology

No.	Column 1 Reference to draft assessment report *	Column 2 Comment * (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Volume 3, B.9.1, pag 217	EFSA: RMS stated that there is not information on the quantity of xyloglucans or oligosaccharides molecules in a bird usual diet. A robust justification would be necessary to waive studies on birds.	