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0. General

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
0 (1)	Vol. 1, 3.1, background	NL: Paragraph on identity, physico-chemical properties and methods of analysis should be inserted.	January 2009 RMS : it was corrected in a corrigendum (vol1 level 3 corrigendum 1)	Addressed.

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

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(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).	January 2009 RMS disagrees with NL. All batches have a content higher than 78%, therefore the certified value for active substance at 78% is acceptable.	Addressed.
1(2)	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.	January 2009 RMS : As indicated in the DAR (vol4), the apple residue is dehydrated with a thermal dryer which diminishes the percent of humidity to $A_w < 0.5$ and helps in preventing the development of microorganisms like fungi responsible for the production of mycotoxins. Moreover, all potential contaminants product will be eliminated by the nanofiltration during the fractioning step and a control to evaluate the rate of patulin in the raw material used for each batch is performed.	Open point: The issue of mycotoxin contamination should be considered by a meeting of experts.
1(3)	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.	January 2009 RMS disagrees with AT. The impurities were characterized and have a structure similar to xyloglucan.	Open point: The meeting of experts should consider the specification in particular the 20 % of the TGAI that has not been identified.

Identity (B.1, Annex C)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(4)	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).	January 2009 RMS does not agree. See N°1	Addressed.
1(5)	Vol. 1, List of Endpoints, molecular formula	NL: Please use subscripts for numbers.	January 2009 RMS : it was corrected in a revised LOEP	Addressed.
1(6)	Vol. 1, LOE representative uses	AT: The common name of the active substance should be inserted between the brackets.	January 2009 RMS : it was corrected in a revised LOEP	Open point: The common name of the active substance should be inserted between the brackets.
1(7)	Vol. 1, List of Endpoints, minimum purity	NL: This should be marked as an open point (see above comments).	January 2009 RMS does not agree. See n°1	Addressed.
1(8)	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).	January 2009 RMS dose not agree. See N°1	Addressed.

Physical and chemical properties of the active substance (B.2.1)				
1(9)	Vol. 1, LOE melting point	AT: The value should be corrected to "**plus"** 172 °C.	January 2009 RMS : it was corrected in a revised LOEP	Addressed.

Physical and chemical properties of the active substance (B.2.1)				
1(10)	Vol. 1, List of Endpoints, melting points and temperature of decomposition	NL: The purity of the test material was >99% (not 99% as stated).	January 2009 RMS : it was corrected in a revised LOEP	Open point: Temperature of decomposition purity should read >99% in the LoEP.
1(11)	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.	January 2009 RMS : it was corrected in a revised LOEP	Addressed.
1(12)	Vol. 1, List of Endpoints, solubility in water	NL: The purity of the test material was >87% (not 87% as stated).	January 2009 RMS : it was corrected in a revised LOEP	Addressed.
1(13)	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.	January 2009 RMS : it was corrected in a revised LOEP	Addressed.
1(14)	Vol. 1, List of Endpoints, solubility in organic solvents	NL: The RSD values should be removed.	January 2009 RMS : it was corrected in a revised LOEP	Addressed.
1(15)	Vol. 1, List of Endpoints, surface tension	NL: The ±0.2 can be removed.	January 2009 RMS : it was corrected in a revised LOEP	Addressed.
1(16)	Vol. 1, List of Endpoints, UV/Vis absorption	NL: The line with µA values should be removed (depends on concentration, is not an endpoint).	January 2009 RMS : it was corrected in a revised LOEP	Addressed.

Physical and chemical properties of the active substance (B.2.1)				
1(17)	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.	January 2009 RMS : it was corrected in a revised LOEP	Addressed.
1(18)	Vol. 1, 4.2, further information	NL: A test on flammability of the technical active substance is required.	January 2009 RMS : according to the structure of xyloglucan (close to oligosaccharide) and the literature, RMS is of the opinion that the flammability test is not required.	Addressed.
1(19)	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.'	January 2009 RMS agree with EFSA. This sentence does not bring scientific data, therefore it was deleted to vol3, B2.1.1/03. See corrigendum (vol3 Annex B2 corrigendum1)	Addressed.
1(20)	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.	January 2009 RMS : it was corrected in a corrigendum (vol3 Annex B2 corrigendum 1)	Addressed.
1(21)	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.	January 2009 RMS : The values of log Pow at -15.96 or -4.36, not change the conclusion on the possibility of bioaccumulation. Therefore, the necessity to request the experimentally test of log Pow could be discussed in praper meeting	Addressed.

Physical and chemical properties of the active substance (B.2.1)				
1(22)	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).	January 2009 RMS does not agree. See N°22	Addressed. It's a sugar.
1(23)	Vol. 3, B.2.2.1.10, stability in air	NL: Please state the hydroxyl-ion concentration used for estimation of the DT50.	January 2009 RMS : The value is 1.5 10^6 OH/cm^3 This value was added in a corrigendum (vol3 Annex B2 corrigendum 1)	Addressed.
Physical, chemical and technical properties of the formulation (B.2.2)				
1(24)	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.	January 2009 RMS : it was corrected in a corrigendum (vol3 Annex B2 corrigendum 1)	Addressed.
1(25)	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.	January 2009 RMS : it was corrected in a corrigendum (vol3 Annex B2 corrigendum 1)	Addressed.
1(26)	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.	January 2009 RMS : it was corrected in a corrigendum (vol3 Annex B2 corrigendum 1)	Addressed.

Physical, chemical and technical properties of the formulation (B.2.2)				
1(27)	Vol. 3, B.2.2.7.1, accelerated storage stability	NL: The container material should be stated.	January 2009 RMS : the packaging is a amber glass flask. It was added in a corrigendum. (vol3 Annex B2 corrigendum 1)	Addressed.

Further information (B.3)				
1(28)	Vol. 1, 4.1, further information	NL: The minimum purity should be revised.	January 2009 RMS does not agree. See N°1	Addressed.
1(29)	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.	January 2009 RMS : More detail on the material used to seal the opening can be required at member state level.	Open point: What type of opening is “crimped hermetically”? Please provide more detail. What material is used to seal the opening?
1(30)	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.	January 2009 RMS : A new study on shelf life was provided by the notifier. See the addendum 1 (vol3 Annex B2)	Open point: Meeting of experts should consider the new study on shelf life. See the addendum 1 (vol3 Annex B2)

Classification and labelling (B.4)

For comments on classification and labelling see the relevant sections.

Methods of analysis (B.5)				
1(31)	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.	January 2009 RMS : it was corrected in a revised LOEP	Addressed.

Methods of analysis (B.5)				
1(32)	Vol. 1, List of Endpoints, Methods of analysis, residues	NL: Remove “Thus, as”. Also remove comma at end of statement.	January 2009 RMS : it was corrected in a revised LOEP	Addressed.
1(33)	Vol. 1, List of Endpoints, Methods of analysis, monitoring/enforcement methods	NL: Please replace “none” by “not required”.	January 2009 RMS : it was corrected in a revised LOEP	Addressed.

2. Mammalian toxicology

Acute toxicity (B.6.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(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.	RMS (Jan 2009): the purity of the batch used for this assay was 78.2 % (which is comparable to the purity grade of > 78 % determined in the 5 batches analyses), therefore it can be anticipated that all potentially sensitising impurities, including enzymes used in manufacture, were also tested.	Open point: The comparison of the current specification and the batches tested in the mammalian toxicity data package; and the potential toxicological relevance of impurities has to be confirmed by the experts.
2(2)	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.	RMS (Jan 2009): "The 29th ATP took place in April 2004 and involved the inclusion in Annex V of 13 new or updated methods", including "the Local Lymph Node Assay as alternative to the classical method for skin sensitisation".	Addressed.

Genotoxicity (B.6.4)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(3)	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.	RMS (Jan 2009): data not available	Data requirement: Applicant to submit historical control data for the in vitro Ames Assay.
2(4)	Vol 3, B.6.4.1, In vitro genotoxicity, bacterial studies	UK: The *in vitro* assay provides assurance that not only the active is not mutagenic but also any impurities- RMS to comment	RMS (Jan 2009): the purity of the batch used for the Ames test was 78.2 % (which is comparable to the purity grade of > 78 % determined in the 5 batches analyses), therefore it can be anticipated that all impurities were also tested.	See open point 2(1).

Long-term toxicity and carcinogenicity (B.6.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(5)	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.	RMS (Jan 2009): to be discussed in a meeting of experts	Open point: Data waivers on long term toxicity and carcinogenicity studies to be confirmed at a meeting of experts.

Reproductive toxicity (B.6.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(6)	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.	RMS (Jan 2009): to be discussed in a meeting of experts	Open point: Data waivers on reprotoxicity studies to be confirmed at a meeting of experts.

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(7)	Vol 3, B.6.10.10, ADI	UK: We are content no ADI is required based comparison with intakes from apple juice.	RMS (Jan 2009): noted	Addressed

Summary of mammalian toxicology and setting of ADI, AOEL and ARfD (B.6.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(8)	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.	RMS (Jan 2009): SF to be discussed in a meeting of experts	See open point on point 2(9)
2(9)	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.	RMS (Jan 2009): to be discussed in a meeting of experts	Open point: Reference values (ADI, ARfD and AOEL) to be agreed on at a meeting of experts.

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(10)	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.	RMS (Jan 2009): to be recalculated by the RMS after an AOEL is agreed at a meeting of experts.	Open point: Operator, worker and bystander exposure to be confirmed at a meeting of experts.

Exposure data (B.6.14)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(11)	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.	RMS (Jan 2009): the RMS will provide an estimate of worker re-entry exposure after an AOEL is agreed at a meeting of experts. The RMS fully disagrees with taking into account the maximum total dose resulting from repeated applications.	See open point on point 2(10).

3. Residues

No comments received for this section.

4. Environmental fate and behaviour

Route and rate of degradation in soil (B.8.1)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
No comment received				

Adsorption, desroption and mobility in soil (B.8.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
No comment received				

PEC in soil (B.8.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
No comment received				

Fate and behaviour in water and impact on water treatment procedures (B.8.4-B.8.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
No comment received				

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(1)	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.	RMS: Extrapolated DT50 and Koc were submitted to estimate the PEC groundwater only as indicative information. No ADI and MRL were defined so the limit of 0.1 µg/L is not applicable for PECgw. No PECgw calculations are necessary. The PEC surface water and sediment will be estimated with worst-case parameters . This is done in a corrigendum. (see also answer to 4(3)).	Open point: RMS to consider if they might wish to provide any argumentation why a Koc of 20 L/kg might be appropriate for use in a leaching assessment. Open point: Member state experts to discuss and conclude if the results of the available ready biodegradability study on heptamaloxyloglucan can be used to estimate a credible soil degradation rate for use in a leaching estimate. See also reporting table comment 4(2). Open point: Member state experts to discuss and conclude if the case made by the applicant regarding the potential for groundwater contamination as reported in the DAR on page 205 to Vol. 3 is sufficient to conclude groundwater contamination >0.1 µg/L is unlikely. See also reporting table comment 4(2).

PEC in surface water and in ground water (B.8.6)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(2)	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.	RMS: Extrapolated DT50 and Koc were submitted to estimate the PEC groundwater only as indicative information. No ADI and MRL were defined so the limit of 0.1 µg/L is not applicable for PECgw. No PECgw calculations are necessary.	Open point: Member state competent authorities to consider if they would wish to request their risk managers to consult legal advice, so they will be able to provide a view to the working group legislation whether the drinking water limit of 0.1 µg/L would or would not apply to heptamaloxyloglucan (the active substance)? Note: EFSA understands that whether 0.1 µg/L applies has nothing to do with whether an MRL or ADI is defined, i.e. if their might be any risk. The only issue is whether heptamaloxyloglucan is a 'pesticide' according to the definition in Council Directive 98/83/EC.
4(3)	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.	RMS: PEC surface water and sediment are updated in the corrigendum (see also answer to 4(1)).	Open point: EFSA to refer to the more conservative FOCUSsw and sed step 1 calculations included in corrigendum 1 to the DAR (January 2009) in its conclusion.

Fate and behaviour in air and PEC in air (B.8.7-8.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
No comment received				

Definition of the residues (B.8.9)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(4)	Vol. 1 level 2, 2.5.1 residue definition	NL: Please add compartments groundwater and sediment. See B8.8 for agreed residue definition.	RMS: This is done in the corrigendum.	Addressed

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(5)	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)	RMS: We agree to add the active substance in the box "residue requiring further assessment" to be in accordance with discussion of PRAPeR meeting. The PEC surface water/sediment calculations are presented in the corrigendum with worst-case parameters.	Addressed. The LoEP dated January 2009 was appropriately updated addressing the comments made.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(6)	Vol. 1 level 3	NL: Agreed	RMS: Noted	Addressed.
4(7)	Vol. 1 level 4	NL: Agreed	RMS: Noted	Addressed.

5. Ecotoxicology

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(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.	RMS: Risk assessment done with mammals toxicity data indicate a large margin of safety between toxicity to mammals and toxicity to birds. To have an unacceptable TER, toxicity of birds should be 20000 fold in acute and 7000-fold in short-term smaller than toxicity to mammals. No acute and short-term risks were expected on birds.	Addressed.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(2)	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.	RMS: A lot of evaluation points of the DAR are based on assumptions. The long term risk have not been confused with the potential to bioaccumulate. The long term risk have been considered as a whole comprising the long term toxicity, risk for reproduction, risk of secondary poisoning and possible bioaccumulation. The risk of repeated short term exposure over long periods could be linked to the potential of bioaccumulation. In the case of heptamaloxyloglucan and due to its low bioaccumulation potential, it is unlikely that the exposure will increase with time. Moreover the persistence of the active substance was assumed to be short. Only the easily biodegradability was quantitatively assessed. The acute risk was based on margin of safety between exposure and mammalian toxicity data for acute and short term. The acute risk is then expected to be low. The long term risk to birds (B.9.1.7.5) has however been modified in the corrigendum in order to consider the comments of UK.	Addressed. It is not clear how the long term risk to birds (B.9.1.7.5) was modified in the corrigendum in order to consider the comments of UK.

Birds and mammals (B.9.1 and B.9.3)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(3)	Vol 3, B.9.3.5.3.2, 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.	RMS: A lot of evaluation points of the DAR are based on assumptions. The long term risk has not been confused with the potential to bioaccumulate. The long term risk have been considered as a whole comprising the long term toxicity, risk for reproduction, risk of secondary poisoning and possible bioaccumulation. The risk of repeated short term exposure over long periods could be linked to the potential of bioaccumulation. In the case of heptamaloxyloglucan and due to its low bioaccumulation potential, it is unlikely that the exposure will increase with time. Moreover the persistence of the active substance was assumed to be short. Only the easily biodegradability was quantitatively assessed. The long term risk for mammals (B.9.3.5.3.2) has however been modified in the corrigendum in order to consider the comments of UK.	Addressed. It is not clear how the long term risk to mammals (B.9.3.5.3.2) was modified in the corrigendum in order to consider the comments of UK.

Aquatic organisms (B. 9.2)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(4)	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....“	RMS: Agree. This is done in the corrigendum.	Addressed.

Bees and non-target arthropods (B. 9.4 and B.9.5)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
No comment received				

Earthworms and other soil non-target organisms (macro and micro) (B. 9.6, B.9.7 and B.9.8)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
No comment received				

Other non-target organisms (flora and fauna), sewage treatment (B.9.9 and B.9.10)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
No comment received				

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(5)	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.	RMS: Noted	Addressed.

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(6)	Vol.1, LoEP	NL: Please insert >-signs in front of aquatic toxicity values.	RMS: agree. This is done in the corrigendum.	Addressed.