PEER REVIEW REPORT ON **CLOFENTEZINE** 10 02 2009

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| **01** | **All comments received on the DAR** | **01 clofentezine all comments** |
| 02 | Reporting table all sections | 02 clofentezine rep table rev 1-2 |
| 03 | All reports from PRAPeR Expert Meetings | 03 clofentezine all reports. |
| 04 | Evaluation table | 04 clofentezine eval table rev 2-1 |

Comments on the Draft Assessment Report on clofentezine (EAS)

RMS UK

End of commenting period: 24 April 2006 (MS, NOT)

| Date | Supplier | File |
|---|---|---|
| 19.04.2006 | Germany | 01 clofentezine comments DE 2006-04-19.doc |
| 21.04.2006 | Austria | 02 clofentezine comments AT 2006-04-21.doc |
| 24.04.2006 | Makhteshim-Agan ICC | 03 clofentezine comments NOT 2006-04-24.doc |
| 25.04.2006 | The Netherlands | 04 clofentezine comments NL 2006-04-25.doc |
| 02.05.2006 | Sweden | 05 clofentezine comments SE 2006-05-02.doc |
| 06.06.2006 | Juan José González | 06 clofentezine comments Gonzalez 2006-06-06.doc |
| 20.07.2006 | EFSA | 07 clofentezine comments EFSA 2006-07-20.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<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 3, IIA 2.9, Photochemical degradation | DE: In the study of Kelly (1985), borosilicate glass was used for the determination of the photochemical degradation. The notifier should be asked to confirm that the used glass is able to let UV light from 290 nm upwards through. Otherwise a new method with suitable method design should be submitted. | |

**2. Mammalian toxicology (B.6)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca. 10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 1, Appendix 3, List of Endpoints and Vol. 3, point B.6.6.1, Multigeneration study in rats | DE: Please check the NOAELs for parental, reproductive and neonatal toxicity (two generation study in Wistar rats). There are discrepancies in the DAR between Volume 3 and Volume 1 list of endpoints. | |

**3. Ecotoxicology (B.9)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca. 10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 3, point B.9.1.4, Risk assessment for birds | DE: Although most of the refinement steps presented by the notifier seem to be appropriate, the data or justification behind some of the refinement steps seems to be relatively scarce. Therefore, a need for further information (see requirements of the RMS summarised in Table B.9.1.24) can generally be supported. | |
| (2) | Vol. 3, point B.9.2.3, Risk assessment for aquatic organisms | DE: The risk assessment is acceptable, especially taking into account that the use of $PEC_{twa}$ values would result in clearly lower TER values. Since the RMS provided no summaries on the non-GLP acute studies with the as, it can, however, not be decided whether the exclusion of the results of these studies from the risk assessment due to solubility problems is appropriate. | |
| (3) | Vol. 3, point B.9.2.3, Risk assessment for aquatic organisms | DE: There is an inconsistency in the information given on the applied test substance between the list of endpoints and Vol. 3. For the endpoints, Rainbow trout 21-d and *Daphnia magna* 21-d (modified study) as test substance “active substance” is listed in the list of endpoints whereat in Vol. 3 it is described that this studies were executed with preparations. | |
| (4) | Vol. 3, point B.9.3, Effects on other terrestrial vertebrates | DE: A long-term NOAEL for mammals of 40 mg as/kg bw/d (rat, multi-generation study) is used for risk assessment. However, this endpoint is not present in the list of endpoints (Volume 1, Appendix 3). | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 1, 1.3.9, LOE, Vol. 4, C.1.2 a) minimum purity | AT: Why is minimum purity always specified in brackets as “dry material”? Is another form available? | |
| (2) | Vol. 1, LOE and Vol. 3, B.2.1.7 to B.2.1.9 appearance of active substance | AT: The purity must be specified and the appearance of the material, which is not reported. | |
| (3) | Vol. 1, LOE UV/VIS absorption | AT: ε at 538 nm should be quoted. | |
| (4) | Vol. 3 B.2.2.15 shelf life | AT: The wet sieve test should be included. | |
| (5) | Vol. 3 B.2.2.11 surface tension | AT: The concentration used should be reported. | |
| (6) | Vol. 3 B.2. tank mixes | AT: Nothing is reported. | |
| (7) | Vol. 3 B.5.1 analytical methods, TGAI and formulation | AT: The %RSD of accuracy is not reported. | |
| (8) | Vol. 3 B.5.2 and B.5.3 analytical methods, residues | AT: No information concerning specificity and linearity for all methods is given. Individual means of recoveries and %RSD for each fortification level is required according to SANCO 825/00. | |
| (9) | Vol. 3, B.5.5 evaluation and assessment | AT: A compilation of determined LOQs contra relevant residue data should be reported. | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (10) | Vol. 4 C.1.1 manufacturing process | AT: The source of starting materials is missing. As well as a description of the manufacturing process possibly used in the second plant (TGAI is produced in 2 plants UK and China). | |
| (11) | Vol. 4, C.1.2 c) batches | AT: A 5-batch analysis, specification of the technical material and an assessment of equivalence for the TGAI produced in the second plant is missing. | |
| (12) | Vol. 4, C.1.3 composition of the PPP | AT: The content of the TGAI should be corrected taking into account that the specified minimum purity is 98%. | |
| (13) | Vol. 4, C.1.4.1 analytical method, impurities | AT: The confirmation of analyte identification is not reported.<br>%RSD for accuracy should be reported. | |
| (14) | Vol. 4, C.1.4.1 analytical method, impurities c) | AT: How many samples are determined for the determination of accuracy? | |

section 2 - Mammalian toxicology (B.6)

**5. Mammalian toxicology (B.6)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

section 3 - Residues (B.7)

**6. Residues (B.7)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. #, <<data point>>, <<description>> | <<MS/notifier>>: <<comment>> | |

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

**7. Environmental fate and behaviour (B.8)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 1, list of endpoints, route of (aerobic) degradation in soil and Vol. 3, B.8.1.1.1. aerobic studies, b) | AT: Metabolites occurring in amounts > 10 % have to be identified and further assessed. The studies were conducted 20 years ago and therefore it might be useful to conduct new studies according to GLP and existing guidelines. | |
| (2) | Vol. 1, list of endpoints, route of degradation in soil – supplemental studies, soil photolysis | AT: The metabolite 2-chlorobenzonitril reaches its maximum occurrence of 5.5 % at the end of the study and therefore the metabolite should be mentioned in the list of endpoints : “metabolite 2-chlorobenzonitril: 5.5 % after 31 d” | |
| (3) | Vol .1, list of endpoints, rate of degradation in soil | AT: The $DT_{50lab}$ value for photolysis is missing and should be added. Since the degradation is very low, the following could be added: “DT50 (6.8-28.4°C, photolysis): not determined, limited degradation” or “DT50 (6.8-28.4°C, photolysis) > 31 d” | |
| (4) | Vol. 1, list of endpoints, rate of degradation in soil, field studies | AT: Only residues of the parent were determined and residues of metabolites were not investigated. This should be mentioned in the list of endpoints: “Metabolites were not investigated” | |
| (5) | Vol. 1., List of endpoints, mobility in soil, column leaching, second test | AT: in the leachate 0.49 – 2.05 % AR were detected, there fore it should be written “0.49 – 2.05 % AR” instead of “0.49 -0.99 % AR” | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (6) | Vol. 1., List of endpoints, route and rate of degradation in water, degradation in water/sediment and FOCUSsw PEC | AT: No method of calculation of DT50 for the whole system (water/sediment) was provided. The DT50 values for clofentezine and the metabolite AE C593600 in surface water and sediment were calculated with TopFit 2.0, but no calculation for the whole system was presented (e.g. $r^2$ value is missing). There is just the remark „first order“ in the list of endpoints. | |
| (7) | Vol. 1., List of endpoints, route and rate of degradation in water, degradation in water/sediment and FOCUSsw PEC Parent | AT: It should be clarified if the DT50 water and DT50 sediment values were derived from pseudo first order (degradation in water/sediment) or single first order kinetics (FOCUSsw PEC). | |
| (8) | Vol. 1., List of endpoints, route and rate of degradation in water, degradation in water/sediment and FOCUSsw PEC Metabolite AE C593600 | AT: It should be clarified if the DT50 water and DT50 sediment values were derived from pseudo first order (degradation in water/sediment) or single first order kinetics (FOCUSsw PEC). | |
| (9) | Vol. 1, List of endpoints, definition of the Residues | AT: The metabolites should also be mentioned. | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (10) | Vol.3, Annex B.8, B.8.1.2.1 Laboratory studies, a) | AT: the Rapporteur has calculated a single first order DT50 value for one soil (Speyer 2.3) only, a calculation for the second soil (Speyer 2.2) should also be provided. | |
| (11) | Vol. 3 Annex B.8, B.8.4.4 Water/Sediment studies | AT: A low material balance of 78.2 – 98.5 % was reached for labelled material, was there any explanation provided? | |
| (12) | Vol. 3 Annex B.8, B.8.4.4 Water/Sediment studies | AT: DT50-values for clofentezine in sediment was reported for one sediment only and DT50 values for the metabolite AE C593600 in surface water was reported for one system only. DT50-values should be provided for both systems or an explanation why the calculation was done for one system only should be provided. And this should be corrected in the list of endpoints: ”n=1” instead of “n=2”. | |
| (13) | Vol. 3, Annex B.8, B.8.5.1 PECgw, Table B8.38 | AT: A molecular weight of 240.7 is stated.<br>Since the molecular weight of the metabolite is 293.2, it has to be clarified, if the wrong value for the PECgw calculation has been used. If the wrong value has been used for the calculation the PECgw has to be recalculated. | |

section 5 - Ecotoxicology (B.9)

**8. Ecotoxicology (B.9)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 1, Appendix 3, List of endpoints | AT: Toxicity/exposure ratios for terrestrial vertebrates: Small herbivorous mammals are missing on the table. | Risk assessment has been done for small herbivorous and small insectivorous mammals but small herbivorous mammals have not been listed on the table. |
| (2) | Vol. 1, Appendix 3, List of endpoints | AT: Effects on other arthropod species - Field tests: Please indicate the application rates of the field data. | |
| (3) | Vol. 3, B.9.6., Effects on earthworms | AT: Acute toxicity study for relevant metabolite (AE C593600) is missing (13% AR at 30 d). | |
| (4) | Vol. 3, B.9.7., Effects on non-target soil macro-organisms | AT: Litter bag study has to be submitted (DT90 of the active ingredient > 365 d). | |
| (5) | Vol. 3, B.9.8., Effects on non-target soil micro-organisms | AT: Acute toxicity study for relevant metabolite (AE C593600) is missing (13% AR at 30 d). | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | P18, Vol. 1, 2.2.3: Analytical methods for residue analysis<br>P53, Vol. 1, LOEP: Analytical methods for residue, food/feed of animal origin<br>P82, Vol. 1, 3.1: Background to the proposed decision<br>P87, Vol. 1, 4.1.5: Methods of analysis<br>P54, Vol. 3, B 5.5:evaluation & assessment | The notifier will provide confirmatory methods for the determination of clofentezine in liver, muscle and kidney.<br>The notifier will provide an ILV for the enforcement animal method.<br>A report (R-17817) is available for submission and evaluation to meet this data requirement. | Ref: Chambers, J.G (2006). An independent laboratory validation of an analytical method for determination of clofentezine and its metabolites in animal tissues. Irvita Report no. R-17817 (Lab report no SYN/0801).<br>The original enforcement method for determination of clofentezine and 4-hydroxy clofentezine involved hydrolysis with hydrobromic acid and formation of 2-chlorobenzoic acid. This was derivatisated with diazomethane and analysed by GC-ECD.<br>For health & safety reasons this method was modified to include derivatisation with n-methyl-n- trimethylsilyltrifluroacetamide ( MSTFA) followed by GC-MS.<br>Thus Irvita Study R-17532 (Report 20041042/01-RVAT) should be considered the current enforcement method (not an ILV of the original enforcement method proposed in the dossier and reviewed in the DAR) and Irvita Study R-17817 (Report SYN/0801) is considered the ILV of this method and also provides details of the required confirmatory conditions.<br>Report R-17532 has already been submitted to the notifier but has not been evaluated. Report R-17817 is available for submission and evaluation. |
| (2) | P7, Vol.1, 1.4.5:Composition of the preparation | At a minimum purity of 98% the maximal amount of technical clofentezine is 510g/L. | |

**10. Mammalian toxicology (B.6)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | P16, Vol. 1, 2.1.4.2, Preparation Classification & labelling<br>P74, Vol. 1, App. 3, LOEP<br>P172, Vol. 3, Skin sensitisation<br>P176, Vol. 3, B6.13, toxicological data on non active substance | The classification Xi, R43, S24 for the preparation is not justified. The adjuvant Proxel XL2 contains ca 9.5% 1,2-benzisothiazolin-3-one (BIT) NOT 20%. Therefore the concentration of BIT in the preparation is <300 ppm (<0.03%w/w) NOT 500ppm and thus is well below the level (>500ppm) at which classification as a skin sensitiser is triggered.<br>Apollo 50SC does not trigger any classification. | The preparation was a non sensitiser in the Magnusson and Kligman Assay. However the notifier can agree that the available human data on BIT should be used to override the results from the guinea pig test if appropriate. However the RMS has used the incorrect level of BIT in the preparation in making the assessment against the human trigger value of >500ppm. See MSDS for Proxel XL2 provided in the dossier under Doc. J Annex 3 point 7.4/06. Here it is stated the concentration of BIT is approximately 9.5% or 285 ppm. Even using the worst case value from the range in the MSDS, 15% the concentration of BIT would still be <500ppm.<br>The source of the human data being used to justify the proposed classification has not been fully referenced in the DAR. |

section 2 - Mammalian toxicology (B.6)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (2) | P20, Vol.1, 2.3: Impact on human & animal health, genotoxicity studies<br>P70, Vol.1, LOEP: Genotoxicity<br>P82, Vol. 1, 3.1: Background to the proposed decision<br>P85, Vol. 1, 3.3: rationale for postponement of the decision…<br>P87, Vol.1, 4.1.6: Toxicology & metabolism<br>P106, Vol. 3 B6.4.1a: Bacterial reverse mutation | A repeat of the Ames test has been conducted to OECD 471 with adequate positive controls. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation. Clofentezine was non mutagenic in this test.<br>The report (R-17812) is available for submission and evaluation to meet this data requirement. | Ref: Bowles, A.J. (2005). Reverse mutation assay “Ames Test” using *Salmonella typhimurium*. Irvita Report no. : R-17812 (Lab. Report no. 2116/0002). |

section 2 - Mammalian toxicology (B.6)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (3) | P82, Vol. 1, 3.1: Background to the proposed decision<br>P85, Vol. 1, 3.3: rationale for postponement of the decision…<br>P87, Vol. 1, 4.1.6: Toxicology & metabolism | To expect a breakdown of impurities present in the batches used for tox. studies to the same standard as the analytical results for the batch analyses is not a fair and reasonable question when the analyses have been conducted some 20 years apart.<br>The majority of toxicology studies were conducted in the 1980's with a.i. of very high purity (>97%) and pre-date the requirement in 91/414/EEC to report the impurity levels in the technical material used for each study.<br>A statement on the equivalency of a.i. used in the tox. studies compared to today's manufactured a.i. will be provided. | The test material used in the tox. studies would almost certainly have been analysed for both purity and impurities internally but not necessarily formally reported. The study archives will be searched to see if any relevant raw data is available. |
| (4) | P21, Vol.1, 2.3.1: effects having relevance to human & animal health…. Other toxicological studies<br>P146, Vol. 3, B.6.8.3 b (iv), conclusion<br>P165, Vol.1, B6.10: summary of mammalian toxicology… Other toxicological studies | The DAR states *"However the doses in the mechanistic studies where hormonal effects were noted* ***were much higher*** *than those in the carcinogenicity study."*<br>Since 400 ppm was a dose tested in both types of study, (carcinogenicity and mechanistic) therefore the sentence should be amended to*"The doses in the mechanistic studies where hormonal effects were noted* ***were at the level or higher*** *than those in the carcinogenicity study."* | |

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section 2 - Mammalian toxicology (B.6)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (5) | P71, Vol. 1, LOEP: Other toxicological studies | This statement gives a false impression of the mechanistic work. If the mechanistic work is described here it should also note that at 400 ppm changes in liver weight and UDPGT (a bio effects marker of liver and thyroid toxicity) were seen and the dose level is **identical** to that used in the rat carcinogenicity study. Therefore the last part of the last sentence ", but only at high dose irrelevant to carcinogenicity" should be **deleted.** | |
| (6) | P23, Vol. 1, 2.3.2: Proposal for an ADI<br>P167, Vol. 3, B6.10.1: ADI | The sentence *"This gives an 860 fold factor over the LOAEL for thyroid tumors in male rats"* should be deleted as it is not relevant since it was concluded in the preceding paragraph that none of the effects were considered to be an indication of carcinogenicity. Also it is agreed that the observed effect is a species (rat) specific effect and therefore not related to human risk assessment. | |
| (7) | P70, Vol.1, LOEP: Acute toxicity | Whilst very slight irritation may have been detected in the study it was not sufficient to trigger any classification.<br>The entry here should be amended to *"very slight (not classifiable)"* | |

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section 2 - Mammalian toxicology (B.6)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (8) | P177, Vol. 3, B6.14 , exposure data | See comment 1; the notifier considers classification of the product as R43 is not justified. The last paragraph on p177 should be deleted.<br>However it is accepted that PPE (gloves) are required to protect the operators from potential levels of systemic exposure as determined by the modelled estimates presented in the DAR. | |
| (9) | P205, Vol. 3, B6.15: references relied on<br>P38-39, Vol. 2: lists of tests and studies | References IIIA 7.4/01-07 should be deleted from this section of the DAR (including any public version) as they are considered business confidential information and should appear in Vol. C only.<br>The RMS informed EFSA & the notifier on Feb 3 2006 of this error so it should have already been taken care of during the sanitisation of the DAR and is included here for completeness.. | |

section 3 - Residues (B.7)

**11. Residues (B.7)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | P88, Vol. 1, 4.2.7, Residues data<br>P258, Vol. 3, B7.6.2, Further residue trials data requirements | The notifier will develop these data for post Annex I national Member State review of the PPP. | |

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

**12. Environmental fate and behaviour (B.8)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| | | No comments from the notifier | |

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**13. Ecotoxicology (B.9)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | P32, Vol.1 2.6.3: Effects on bees & other arthropod species<br>P68, Vol. 1, LOEP: Effects on other arthropod species<br>P84, Vol. 1, 3.1: Background to proposed decision<br>P86, Vol.1, 3.3: Rationale for the postponement…<br>P87, Vol. 1, 4.1.9: Ecotoxicology<br>P422, Vol. 3, B9.5.2c: Conclusion | Studies on *C. septempunctata,*(including exposure of the egg) and on *A. bilineata* (eggs laid into treated soil) have been conducted. Both studies show NO effects at 200 g a.s./ha (highest rate tested). Hence, it should now be possible to complete the risk assessment and conclude that there is **no risk to non-target arthropods.** Both studies have been submitted to RMS (8th April 2005) but have not been evaluated thus far. | Ref: Taylor, K. (2005). Apollo 50 SC; Evaluation of the effect on the eggs of the ladybird, *C. septempunctata* in a laboratory study. Irvita Report no.: R-17808.<br><br>The ladybird is a foliar predator and ESCORT 2 recommended species.<br>Eggs were laid by the adult females onto tissue paper. The eggs were sprayed directly (whilst on the tissue paper) at 100 and 200 g a.s./ha. Hatching, larvae survival, pupation and adult emergence were assessed. There were no effects in the study.<br><br>Ref: Taylor, K. (2005). Apollo 50 SC; Evaluation of the effect on the Rove beetle, *Aleochara bilineata* in an extended laboratory study. Irvita Report no.: R-17809.<br><br>This is a ground-dweller (staphylinid) and ESCORT 2 recommended species. The test material was mixed into soil at equivalent to 100 and 200 g a.s./ha. Adult *A. bilineata* were added to the soil surface, and laid eggs into the treated soil. Larvae hatching from eggs then parasitised fly pupae, which had been added to the test systems. The number of emerging adults was counted. There were no effects in this study. |

section 5 - Ecotoxicology (B.9)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (2) | P32, Vol.1 2.6.4: Effects on earthworms & other soil macro-organisms<br>P84, Vol. 1, 3.1: Background to proposed decision<br>P86, Vol.1, 3.3: Rationale for the postponement…<br>P88, Vol. 1, 4.1.9: Ecotoxicology<br>P428, Vol. 3, B9.7.2: Risk assessment | As stated in the DAR the notifier will submit a litter- bag study. The study was initiated late April 2005. As the last sampling is one year after treatment (June 2005), the earliest time a final report can be submitted is 30 July 2006.<br><br>No differences were noted between control and Apollo 50 SC groups 6 months after treatment. | Ref: Carter, J.N. (2006). Clofentezine (Apollo 50 SC); Breakdown of organic matter in litter bags. Irvita Study no.: R-17802. |

section 5 - Ecotoxicology (B.9)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (3) | P32, Vol.1 2.6.1: Effects on terrestrial vertebrates<br>P65, Vol. 1, LOEP:Effects on terrestrial vertebrates<br>P84, Vol. 1, 3.1: Background to proposed decision<br>P86, Vol.1, 3.3: Rationale for the postponement…<br>P88, Vol. 1, 4.1.9: Ecotoxicology<br>P377-380, Vol. 3, B9.1.4: Risk assessment, recommendation | Regarding the long-term risk to birds, an avian ecology study in strawberry fields in Germany will be run in 2006. The protocol has been discussed with the RMS. The study will include radio-tracking of focal bird species, and analysis of dietary composition. This study will enable identification of appropriate focal species, and quantitative refinements to both PT and PD. Due to the seasonal nature of this type of study the earliest a report can be submitted is by 31 August 2006. | Focal species monitoring study (Irvita study no.: R-20182)<br>Radio-telemetry study of tagged birds (Irvita study no.: R-20183)<br>The studies have been timed to cover the normal application time for clofentezine on strawberries hence the proposed schedule is the earliest possible.<br>The objectives of the studies are to assess the importance of strawberry fields as a feeding habitat for the insectivorous bird species yellow wagtail and skylark (assessed in earlier study in 2005). The use will be extrapolated to provide a PT value (proportion of diet from treated area). It will also be determined what kind of arthropods (ground or leaf dwelling) are present to refine data on the dietary composition (PD) (proportion of diet made up of different food types). |
| (4) | P362-363, Vol.3, B9.1.4: Risk assessment, exposure scenarios and estimate theoretical exposures…. | An independent expert recently undertook a review of modern insect residues studies for ECPA. It is proposed that this review should be taken into account in the risk assessment for birds, particularly in the first tier long-term risk assessment. The report is available for immediate submission. | Ref: Schabacker, J. (2005). Review of initial residue levels of pesticides in arthropods sampled in field studies |

section 5 - Ecotoxicology (B.9)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (5) | P32 Vol. 1,<br>2.6.2: Effects on aquatic species<br>P67, Vol. 1, LOEP: TER'sfor the most sensitive aquatic organisms<br>P399-400, Vol. 3, B9.2.3:Risk assessment, chronic risk to fish | The chronic risk assessment for fish determines the overall outcome of the aquatic assessment. The proposed buffer zones are triggered by the limit of solubility, not by effects on fish. A new fish ELS study with the *formulation,* which enabled testing at greater than the limit of solubility, has been conducted. The study report is now available for submission. Based on the results new TER's >10 can be calculated, hence **no risk mitigation measures are needed.** | Ref: Cockroft, J. (2005). Clofentezine 50 SC; Fish early life stage toxicity test for fathead minnow. Irvita Report no.: R-17810.<br><br>The NOEC from a new fish ELS study using the formulation is 0.995 mg a.s./L This was the highest concentration tested, i.e. there were no effects in the study. Using the PECsw from FOCUSsw Step 1 of 0.047 mg a.s./L (Table B.9.2.19, p404), the TER is 0.995/0.047 = **21**. Hence, even using the extreme worst case exposure assessment at Step 1, the TER is greater than the Annex VI trigger of 10.<br><br>Based on the more realistic exposure assessment at FOCUSsw Step 3 the highest initial PECsw value is 0.018 mg a.s./L (Table B.9.2.19, p404), which gives a TER of 0.995/0.018 = **55**. TER values are greater than the trigger of10, indicating a low chronic risk to fish. In turn, it can be concluded **that there is a low risk to aquatic organisms**. Risk mitigation is not necessary. |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca. 10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 1, LOEP, solubility in water | NL: Temperature should be stated in LOEP | |
| (2) | Vol. 1, LOEP, partition coefficient | NL: ´Log Pow is independent of pH´ should be stated in LOEP | |
| (3) | Vol. 1, LOEP, partition coefficient | NL: ε at 538 nm should be stated in LOEP | |
| (4) | Vol. 1, LOEP, flammability | NL : Flammability should be determined according to EC method A10 | |
| (5) | Vol. 1, LOEP, Methods of analysis, impurities in technical as | NL: HPLC-UV method is also used for the determination of impurities in technical a.s., the detection method (FID) of the GC method should also be stated in LOEP | |
| (6) | Vol. 1, LOEP, Methods of analysis, food/feed of plant origin | NL: It should be stated that the analytical method is only validated for watery matrices (apples, pears, grapes, peaches and strawberries) | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca. 10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (7) | Vol. 1, LOEP, Methods of analysis, food/feed of animal origin | NL: It should be stated in the LOEP that there is a Data Requirement for a monitoring method for the determination of the residues of clfentazine in food/feed of animal origin as a monitoring method using diazomethane as methylation reagent is not acceptable.<br>The enforcement method for the determination of the residues of 4-hydroxyclofentazine should be mentioned in the LOEP as 4-hydroxyclofentazine is part of the residue defenition | |
| (8) | Vol. 1, LOEP, Methods of analysis, water | NL: The water types (drinking/surface/ground) for which the AM is validated should be stated in LOEP | |
| (9) | Vol.1, level 3, 3.3 and level 4, 4.1.5 | NL: A validated analytical method for the determination of the a.s. in food/feed of anima origin is required (including confirmatory method and ILV) as in the submitted method diazomethane is used as methylation reagent this is not acceptable. | |
| (10) | Vol.3, B.2.1.20 flammability and auto-flammability | NL: Flammability and auto-flammability should be determined according to EC methods A10 and A16 respectively. | |
| (11) | Vol.3, B.2.2.7 and 8 | NL: It should be avoided to name co-formulants as this is confidential information | |
| (12) | Vol.3, B.2.2.11, surface tension | NL: What is the concentration at which the surface tension has been determined? | |

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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<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca. 10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (13) | Vol.3, B.2.2.15, shelf life | NL: It is not clear if the shelf life test has been carried out in the commercial HDPE-packaging | |
| (14) | Vol. 3, B.5.2, AM for food/feed of plant origin | NL: It is unclear from the presented data (table B.5.2) if the analytical methods fulfil the validation requirements according to Sanco/825/00: no linearity data are presented, it is not clear what the individual and mean recovery is per concentration level and what the repeatability is per concentration level. Repeatability data of method e (confirmation and ILV method) are missing. A description of method Wende, 2001 is missing.<br>Only fully validated AM (suitable as enforcement methods for the analytes as mentioned in the residue definition) should be presented in a separate table for clarity. | |

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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<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca. 10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (15) | Vol.3, B.5.3.1, residues in soil | NL: Type and source of the soil used for the validation of the AM for the determination of residues in soil should be described.<br>It is unclear from the presented data (table 5.3) if the analytical methods fulfil the validation requirements according to Sanco/825/00: no linearity data are presented, it is not clear what the individual and mean recovery is per concentration level and what the repeatability is per concentration level.<br>Only fully validated AM (suitable as enforcement methods for the analytes as mentioned in the residue definition) should be presented in a separate table for clarity | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca. 10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (16) | Vol.3, B.5.3.2, residues in water | NL: Source and characteristics of the surface water used for the validation of the AM for the determination of residues in water should be described.<br>It is unclear from the presented data (table 5.3) if the analytical methods fulfil the validation requirements according to Sanco/825/00: no linearity data are presented, it is not clear what the individual and mean recovery is per concentration level and what the repeatability is per concentration level.<br>Only fully validated AM (suitable as enforcement methods for the analytes as mentioned in the residue definition) should be presented in a separate table for clarity | |
| (17) | Vol.3, B.5.3.3, residues in air | NL: It is unclear from the presented data (table 5.3) if the analytical methods fulfil the validation requirements according to Sanco/825/00: no linearity data are presented, it is not clear what the individual and mean recovery is per concentration level and what the repeatability is per concentration level.<br>Only fully validated AM (suitable as enforcement methods for the analytes as mentioned in the residue definition) should be presented in a separate table for clarity | |

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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<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca. 10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (18) | Vol. 3, B.5.4.1, residues in animal tissues and products | NL: The methods a,b,c and e are not suitable as enforcement methods as diazomethane is used as methylation reagent.<br>It is unclear from the presented data (table 5.4) if the analytical methods fulfil the validation requirements according to Sanco/825/00: no linearity data are presented, it is not clear what the individual and mean recovery is per concentration level and what the repeatability is per concentration level.<br>Only fully validated AM (suitable as enforcement methods for the analytes as mentioned in the residue definition) should be presented in a separate table for clarity | |

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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<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca. 10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (19) | Vol. 3, B.5.5 Evaluation and assessment | NL: d) residues in animal tissues and products<br>The submitted AM´s (a,b,c,e) for the determination of clofentezine (hydrolysed to 2-chlorobenzoic acid) are not suitable as enforcement method.<br>A description of method g is missing in paragraph B.5.4.1<br>The submitted AM (d) for the determination of 4-hydroxy-clofentezine is validated for milk **and fat**. It is not clear if this method is fully validated (see comment above), however it is clear that an ILV is missing.<br>The data requirement should therefore be changed into:<br>A fully validated method according to Sanco/825/00, including a confirmation method and an ILV should be submitted for the determination of clofentezine and 4-hydroxy-clofentezine in animal tissues and products. | |
| (20) | Vol.4, C.1.3, detailed specification of the preparation | NL: Note 1 states that te minimum purity of technical substance is 96%, this is not in line with the specification as mentioned in C.1.2 (98%). Accordingly, the maximum amount of technical clofentezine is 510.2 g/l. | |

**15. Mammalian toxicology (B.6)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca. 10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 1, List of Endpoints | NL: At 'toxicologically significant compounds' it is stated 'none'. This should be 'parent compound'. | |
| (2) | Vol. 3, B.6.1.3, summary of ADME | NL: On page 81 it is concluded that there were no signs for bio-accumulation. However, on page 75, under Table B.6.19 and in Vol. 1 in the List of Endpoints it was concluded that there was a slight suggestion of an accumulation in fat.<br>However, looking at the values in Table B.6.19 and B.6.20, a strange peak is observed at day 20, not only in fat, but also in other organs. This cannot be easily explained. It almost seems that there was a deviation of the study protocol? | |
| (3) | Vol. 3, B.6.1.3, summary of ADME | NL: It is not clear how the value of 50% for oral absorption was derived. | |
| (4) | Vol. 3, B.6.1.3, summary of ADME | NL: A figure with the metabolism scheme is not presented (although in this case it is a simple scheme, presentation is still appreciated). | |

section 3 - Residues (B.7)

**16. Residues (B.7)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca. 10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 1, pag 9, table 1.5.3<br>Vol. 3, page 239, B.7.5<br>Vol 1, LoEP page 51 | NL: The table with the intended use is not usable. The amount kg as/hL, the amount of water/ha and the amount of kg as/ha are not in accordance with each other. As it is unknown which of the numbers is correct, it can not be deducted/calculated what the doses should be[1]. The residue section can therefore not be evaluated completely. | |
| (2) | Vol. 1, pag 9, table 1.5.3<br>Vol. 3, page 239, B.7.5<br>Vol 1, LoEP page 51 | NL: The PHI for grapes should agree with the class distribution as stated in Guideline 7039/VI/95 of 22/7/1997, in this case 28 or 35 days in stead of 30 days. | |
| (3) | Vol. 3, B.7.6 | NL: Residue trials cannot be checked at this moment as the table of intended use is incorrect | |

[1] This was also reported to Mr. David Richardson (PSD) by e-mail from Mr. Hans Mulder (CTB) dated 10 April 2006.

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

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

**17. Environmental fate and behaviour (B.8)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol.1 List of end points; PECsw | NL: According to EPCO manual D4 those PEC values should be reported on which the ecotox risk assessment is based. Therefore for early pome/stone fruit also Step 3 calculations must be reported here. | |
| (2) | Vol. 3, B.8.1.1.1, Route of degradation, aerobic studies, Tables B.8.1 and B.8.3. | NL: MWHC >100%, what do these values represent? | |
| (3) | Vol.4, B.8.5.2 PEC surface water, Table B.8.44, Note to the table | NL: It is stated here that the maximum peak clofentezine PECsw occurred on day 1.. This is however on day 0. | |
| (4) | Vol.4, B.8.5.2 PEC surface water, Tables B.8.46, B.8.47 and B.8.48, Note to the tables | NL: The notes to the tables can be removed. | |
| (5) | Vol.4, B.8.5.2 PEC surface water, Tables B.8.46 and B.8.47 | NL: It is stated that the peak concentrations are highlighted, but almost all values for TWA-PEC are highlighted. | |

section 5 - Ecotoxicology (B.9)

**18. Ecotoxicology (B.9)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 3, table B.9.1.20, p 372 | NL: NMSs should be SMSs | |
| (2) | Vol.3, B.9.2.1, plant protection products, acute toxicity to fish, b; p:384 | NL: Measured concentrations were 64% of nominal. Therefore results should be in measured concentrations. | |
| (3) | Vol.3, B.9.2.1, plant protection products, acute toxicity to algae, p:385-386 | NL: Since the initial measured concentrations ranged between 46 and 87.5% of the nominal; the NOEC of 34 mg a.s./L is preferred. | |
| (4) | Vol.3, B.9.2.2, chronic toxicity, fish, a, p:388, concluding sentence | NL: NOEC is 0.007 mg a.s./L in stead of 0.07 mg a.s./L | |
| (5) | Vol.3, B.9.6.1, earthworm fieldstudy | NL: It is unclear whether the field study could be used for risk assessment. | Study was not performed under GLP and used an inhouse methodology. This alone is not enough to reject te study. However, earthworms numbers are too low after 1 month, No starting population number is given, no information about time (season) of application and no information about the earthworm composition is given. Altogether, the study does not seem acceptable for risk assessment. |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | The whole DAR: Vapour pressure, water solubility, Henrys laws constant, photochemical oxidative degradation in air, PECair | **SE comment**: We question the judgement of how clofentezine behave in the air. A similar judgement was made for e.g. fenpropimorf. The Henrys laws constant of fenpropimorph is 0.27 Pa $m^3$/mol compared to 0.17 Pa $m^3$/mol for clofentezine and these are very similar. Fenpropimorph is now measured within the Swedish monitoring programme as one of the pesticides having the highest diffuse (background sampling station) deposition flux from air (5.2 µg/$m^2$, during 4 month in S. Sweden year 2004; Törnquist et al., Ekohydrologi 87).<br><br>It seems as this type of judgement does not describe the field situation very accurate. One reason for this may be that the relatively low vapour pressure cause binding to aerosol particles in the atmosphere, which means a lower proportion in the gas phase and a longer half-life. The Atkinsons-rate estimates apply only to the fraction in the gas phase.<br><br>Also note that the vapour pressure reported for clofentezine (1,4 µPa) is for the solid state, while it is for the liquid state of fenpropimorf (7,0 mPa). In the environment, it is the liquid state which describes the fate. The Henrys law constant is independent of physical state as long as both vapour pressure and water solubility relate to the same | Törnquist M, Kreuger J, Adielsson S, Kylin H. 2006. Bekämpningsmedel i vatten och sediment från typområden och åar samt i nederbörd under 2004. Ekohydrologi 87, 2005. (“Pesticides in water and sediment from type areas and streams, and i precipitation under 2004” available in Swedish at http://www.mv.slu.se/Vv/publ/Ekohydrologi_87.pdf) |

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| | | physical state ($P_{liquid}$/$S_{liquid}$ or $P_{solid}$/$S_{solid}$). Thus the Henrys laws constants can be compared, but the vapour pressure and the water solubility can not, unless they are recalculated to the liquid state.<br><br>Our comment not only apply to the DAR for clofentezine and fenpropimorph, but to many active substances, and we recommend it be discussed on an expert meeting concerning fate assessment. | |

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

**20. Environmental fate and behaviour (B.8)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | The whole DAR: Vapour pressure, water solubility, Henrys laws constant, photochemical oxidative degradation in air, PECair | **SE comment**: We question the judgement of how clofentezine behave in the air. A similar judgement was made for e.g. fenpropimorf. The Henrys laws constant of fenpropimorph is 0.27 Pa $m^3$/mol compared to 0.17 Pa $m^3$/mol for clofentezine and these are very similar. Fenpropimorph is now measured within the Swedish monitoring programme as one of the pesticides having the highest diffuse (background sampling station) deposition flux from air (5.2 µg/$m^2$, during 4 month in S. Sweden year 2004; Törnquist et al., Ekohydrologi 87).<br><br>It seems as this type of judgement does not describe the filed situation very accurate. One reason for this may be that the relatively low vapour pressure cause binding to aerosol particles in the atmosphere, which means a lower proportion in the gas phase and a longer half-life. The Atkinsons-rate estimates apply only to the fraction in the gas phase.<br><br>Also note that the vapour pressure reported for clofentezine (1,4 µPa) is for the solid state, while it is for the liquid state of fenpropimorf (7,0 mPa). In the environment, it is the liquid state which describes the fate. The Henrys law constant is independent of physical state as long as both vapour pressure and water solubility relate to the same | Törnquist M, Kreuger J, Adielsson S, Kylin H. 2006. Bekämpningsmedel i vatten och sediment från typområden och åar samt i nederbörd under 2004. Ekohydrologi 87, 2005. (“Pesticides in water and sediment from type areas and streams, and i precipitation under 2004” available in Swedish at http://www.mv.slu.se/Vv/publ/Ekohydrologi_87.pdf) |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| | | physical state ($P_{liquid}$/$S_{liquid}$ or $P_{solid}$/$S_{solid}$). Thus the Henrys laws constants can be compared, but the vapour pressure and the water solubility can not, unless they are recalculated to the liquid state.<br><br>Our comment not only apply to the DAR for clofentezine and fenpropimorph, but to many active substances, and we recommend it be discussed on an expert meeting concerning fate assessment. | |

section 3 - Residues (B.7)

**21. Residues (B.7)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 3, B.7, Residue definition | Juan José González: After my first e-fate comment, the 2-chlorobenzoic acid should be considered in soil residue definition | |

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

**22. Environmental fate and behaviour (B.8)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 3, B.8.1, Route and rate of degradation. | Juan José González: 2-chlorobenzoic acid is a minor soil metabolite because its maximum amount, expressed as %TAR, is below 10%. Because of this compound contains one half of the original radiolabel, its molar fraction should be considered instead of %TAR. After this correction, the maximum amount of 2-chlorobenzoic acid in two studies is above 10% of the applied dose and therefore 2-chlorobenzoic acid should be considered a major soil metabolite. | |
| (2) | Vol. 3, B.8.1, Route and rate of degradation. | Juan José González: On page 326, it is mentioned that the water/sediment study was fitted to a five compartment model using inverse parameter estimation. No stadistical data are provided to support the goodness of fit. The assessment of this complex model should include a goodness of fit analysis and a determination of the accurary of the parameters. | A goodness of fit analysis is not enough because the non-linear regression of models with exchange between compartments usually provides estimated parameters with a high level of uncertainty.<br>The fitted exchange of AE C593600 is three orders of magnitude higher than its formation or degradation. In these cases it is not possible to assess in which compartment occurs the formation or degradation of AE C593600. This fact introduces a high level of uncertainty in the calculation of surface water and sediment degradation DT50s for AE C593600. |

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

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 1, General | EFSA: RMS should consider to use the current harmonised version of the list of end points. | |
| (2) | Vol. 1, list of end points, list of representative uses, p. 56 | EFSA: Taken into account that the proposed decision is that clofentezine cannot be included in Annex I, the uses should be highlighted in grey as described in EPCO Manual E4. | |
| (3) | Vol. 3, B.2 Physical and chemical properties and B.5 Analytical methods, General | EFSA: RMS to consider in future DARs or a corrigendum to list in the references relied on only studies that were needed for the assessment, i.e. no invalid studies or studies that do not address a data requirement, should be mentioned (as it is done in the "List of information, tests and studies"). | |
| (4) | Vol.3, B.2.1.5 Vapour pressure, p. 8 | EFSA: For transparency, it should be mentioned which of the listed method in EEC A4 was used. | |
| (5) | Vol. 3, Appearance, p. 8 | EFSA: Being aware that the given data could be regarded as sufficient, but at least a comment why the studies were accepted should be given, taken into account that according to the Directive the data are required for both the technical material as well as for the pure material. | |

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| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (6) | Vol. 3, B.2.1.10 Spectra, p. 9 | EFSA: The status of the data from Johnson (1989) is unclear. Are they acceptable? Clarification is needed. | |
| (7) | Vol. 3, B.5.2 and B.5.3 analytical methods (residues), p. 46ff | EFSA: There is a lack of detail in the presentation of the validation data of the analytical methods, which makes it not easy to confirm the assessment. This was discussed already before. Therefore, the EFSA would like to ask UK to consider previous comments on this issue for further DARs. | |
| (8) | Vol. 3, B.5.1 Analytical methods for technical material and formulation analysis, Table B.5.1, p. 46 | EFSA: Could the RMS clarify the entry in the column "linearity" for the ppp. It seems that the entry and the heading of the column are not really connected. | It is assumed that the entry in the box means 80 % to 110% of the content in the ppp. However, even if this is correct, it is not reliable from the table itself. |
| (9) | Vol. 3, B.5.3 analytical methods (residues), p. 48ff in relation to B.5.6 references relied on | EFSA: Data generation methods should not be listed in the references relied on (unless they are use as confirmatory method), since this section covers only monitoring methods i.e.:<br>- soil: methods c (Wende, 2001) is not an enforcement method.<br>- water: method c (Wende, 2001c) is not an enforcement<br>In addition, it is unclear whether both "air-methods" were accepted or not. It seems that the first method does not fulfil the requirements of SANCO/825/00. | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (10) | Vol. 3, B.5.3.1 Residues in soil, p. 48 | EFSA: Could the RMS clarify why method a (Manley and Snowdon, 1985c) is not mentioned in the list of end points. It seems that the method is valid. | |
| (11) | Vol. 3, B.5.4.1 Residues in animal tissues and products, p. 50f | EFSA: It seems that none of the methods meets the criteria. Either they are not specific or the LOQs are too high to monitor the proposed MRLs (taken the LOQs for clofentezine and 4-hydroxyclofentezine into account). | |
| (12) | Vol. 4, C.1 detailed information on the manufacturing process, p. 3ff | EFSA: Could the RMS please confirm that there is only one manufacturing site. It seems that according the quoted report (Shaw, 2000a) only material was analysed which was produced in the first site (mentioned on p. 3, Vol. 4). Where are the batches from the other mentioned source? | |
| (13) | Vol. 4, C.1 detailed information on the manufacturing process, p. 3f | EFSA: It seems that some chemical drawings are missing for stage 2 to 4. | |
| (14) | Vol. 4, C.1.1 detailed information on the manufacturing process, p. 3f | EFSA: Data on the starting material (purity, commercial availability) are missing. | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (15) | Vol. 4, C.1.2 detailed specification of the active substance | EFSA: RMS should clarify the accepted specification based on dry material. It is unclear whether or not always the dry material is used as no drying step is mentioned in the manufacturing process. | |
| (16) | Vol. 4, C.1.2 detailed specification of the preparation, p. 9f | EFSA: The minimum purity given in the note 1 needs to be clarified since it is below the specified minimum purity of the technical material. | |
| (17) | Vol. 4 (MAK), C.1.1 detailed information on the manufacturing process, p. 8f | EFSA: Data on the starting material (purity, commercial availability) are missing. | |

section 2 - Mammalian toxicology (B.6)

**24. Mammalian toxicology (B.6)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 1 Level 2, point 2.3.1 | EFSA: since data on bioavailability of clofentezine is not conclusive, and since the issue is important for the definition of the AOEL, the need of a data requirement should be considered. | |
| (2) | Vol. 1 Level 4, point 4.1.6 Data required before inclusion in Annex I | EFSA supports the requirement made by the RMS that further information of the batches of clofentezine used in mammalian toxicity studies is needed. | |
| (3) | Vol. 1 Level 4, point 4.1.6 Data required before inclusion in Annex I | EFSA supports the requirement made by the RMS that an Ames test should be repeated due to inadequate positive controls in the submitted reverse mutation assay. | |
| (4) | Vol. 3, B.6.1.3 Summary of ADME | EFSA: the reasons given to support the non relevance of the metabolite 2-chlorobenzonitrile cannot be considered exhaustive | |
| (5) | Vol. 3, B.6.2 Acute toxicity, irritancy and skin sensitisation | EFSA: the RMS considered the studies submitted in this section acceptable, despite of some weaknesses and the pre-GLP status. This might be scientifically acceptable, but for the skin sensitisation study in Guinea pig this is hardly acceptable, since the purity of the test is not specified. | |

section 2 - Mammalian toxicology (B.6)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (6) | Vol. 3 B.6.3.2 Oral short term studies in mice | EFSA: the RMS concludes that the relevant NOAEL from the 90-day study in the mouse NOAEL is 1000 ppm, based on effects on liver weight at 5000 ppm. The increase in relative weights starts already at 1000 ppm and it is statistically significant. | |
| (7) | Vol. 3 B.6.3.3 Oral short term studies in dog | EFSA: to clarify why the effects on RBC and platelets in males are considered of no toxicological relevance and therefore not considered in setting the NOAEL from the 1-year dog study. | |
| (8) | Vol. 3 B.6.14.1.1.2 Supported use of Apollo 50 SC on protected crops. | EFSA: the reliability of a single study to conclude on operator exposure/risk assessment for activities in greenhouses might be questionable and should be further commented. | |
| (9) | Vol. 3, B.6.8 Studies on metabolites | EFSA : The apparent degradation pathway in plants is based on photodegradation to 2-chlorobenzonitrile. This compound is further degraded to 2-chlorobenzoic acid, 2-chlorobenzylalcohol, 2-chlorobenzaldehyde. These compounds are not present in the rat metabolism and their amounts is one order of magnitude lower than that of clofentezine; a major metabolite (2-chlorobenzoic acid (2-chlorobenzylidene) hydrazide) is formed under sterilisation conditions.<br>These metabolites should be regarded as relevant unless it is proven they are not. | |

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section 2 - Mammalian toxicology (B.6)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| | | RMS to provide information (e.g. literature search) to assess their toxicological properties. | |

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section 3 - Residues (B.7)

**25. Residues (B.7)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 3, B.7 | EFSA : As general comment the acceptability of studies is not commented in this section of the DAR | |
| (2) | Vol. 3, B.7.1.1, Metabolism in apples | EFSA : On foliage a metabolite NC 22505 was identified. The structure of this metabolite should be given in the DAR for transparency. This metabolite was identified only in apple foliage. Was it used as reference compound in the other metabolism studies? | |
| (3) | Vol. 3, B.7.1.5, Summary/assessment of metabolism in plants | EFSA : The proposed metabolic pathway in plants should be given in more details as other degradation products were identified (NC 22505, 2-chlorobenzoic acid, 2-chlorobenzylalcohol, 2-chlorobenzaldehyde) | |
| (4) | Vol. 3, B.7.2 Metabolism in animals | EFSA : The results of the metabolism studies should be reported in a tabular form, in order to improve the comprehensibility. | |
| (5) | Vol. 3, B.7.2.1, Metabolism in cattle | EFSA : Is there an explanation for the large difference in TTR present in renal fat (0.262 mg/kg) and subcutaneous fat (0.020 mg/kg)? | |
| (6) | Vol. 3, B.7.2.2, Metabolism in goats | EFSA : It is mentioned at the end of this point that ‘conflicting data had been noted between the cow and goat milk studies’… This cannot be clearly understood. | |

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section 3 - Residues (B.7)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (7) | Vol. 3, B.7.2<br>Metabolism in animals | EFSA : In the proposed metabolic pathway presented in figure 7.2.2 some metabolites are present that were not mentioned in the evaluated studies. | |
| (8) | Vol. 3, B.7.3, Residue definition in plants | EFSA : Depending on the toxicological relevance of the metabolites, the residue definition for risk assessment for raw plant commodities and the relevance of the supervised residue trials should be reconsidered. | |
| (9) | Vol. 3, B.7.3, Residue definition in animals | EFSA : The classification of residues as fat soluble or non fat soluble should be discussed. Information on log Pow of 4-hydroxyclofentezine would be useful. High content of residues in renal fat in goat as well as in poultry fat should be considered. | |

section 3 - Residues (B.7)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (10) | Vol. 3, B.7.6, Supervised residue trials | EFSA : there is a lack of consistency in the underlined values in the summary of supervised trials and those reported in the list of end points: Apples North: the underlined values 0.11 and 0.07 are not present in the list of end points, 0.06 in the list of end points is not found as underlined value in vol. 3.; Plums North: the underlined value 0.03 is not present in the LOE, 3 results at 35 d in Germany should be underlined (0.10, <0.01, 0.07) in vol. 3,0.02 in the list of end points is not found as underlined value in vol. 3; Grapes North: 0.12 in the list of end points is not found as underlined value in vol. 3; | |
| (11) | Vol. 3, B.7.6, Supervised residue trials | EFSA : Data should be generated concerning the actual level of compounds resulting from photodegradation of clofentezine | |
| (12) | Vol. 3, B.7.6.2, Summary of residues resulting from trials | EFSA : Supports the data requirement for 4 trials on plums in Southern Europe and 8 trials on strawberries under glass. | |

section 3 - Residues (B.7)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (13) | Vol. 3, B.7.6.2, Summary of residues resulting from trials | EFSA : The RMS is of opinion that there is no distinct differences in residues on grapes between Northern and Southern regions. However comparing the average results, we have 0.58 mg/kg for the North (4 results considered, 0.12 mg/kg disregarded) and 0.28 mg/kg for the South (9 results considered). Therefore a data requirement for an additional set of 4 trials in Northern region should be fixed. | |
| (14) | Vol. 3, B.7.7.1, Storage stability of residues in apples | EFSA : The study reported has been carried out with radioactive material. The given results provide information on the evolution of extractability of residues, but not on the storage stability of clofentezine as such. | |
| (15) | Vol. 3, B.7.7.2 and 3, Storage stability of residues in peaches and almonds | EFSA : these studies give erratic results. Their interpretation is difficult and should be reconsidered on the basis of information on procedural recoveries. | |
| (16) | Vol. 3, B.7.8.1, Processing, effect on the nature of residues | EFSA : Depending on the toxicological relevance of 2-chlorobenzoic acid (2-chlorobenzylidene) hydrazide, the residue definition for risk assessment for processed commodities and the relevance of the available processing studies should be reconsidered. | |

section 3 - Residues (B.7)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (17) | Vol. 3, B.7.8.1, Processing, effect on the nature of residues | EFSA : Processing data should be produced with analysis of 2-chlorobenzoic acid (2-chlorobenzylidene) hydrazide in order to get more information on its actual level in practice. | |
| (18) | Vol. 3, B.7.8.2, Processing, effect on the residue level (apples) | EFSA : The study reported under c) should not be used for defining processing factors as apples were washed before analysis, resulting in residues below the LOQ in the raw commodity. We agree with RMS. | |
| (19) | Vol. 3, B.7.8.2, Processing, effect on the residue level (apples) | EFSA : According to the list of end points, 4 trials are available for calculating the transfer factor from apple to apple sauce. However, in Vol. 3, only 2 results seem to be available. This needs to be clarified and depending on this clarification, the list of end points should be amended. | |

section 3 - Residues (B.7)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (20) | Vol. 3, B.7.8.2, Processing, effect on the residue level (grapes) | EFSA : The processing studies submitted for grape juice are not conclusive (calculated transfer factors are 0, 1.9 and 1.6). An explanation is given related to the presence of particules in one trial. Could it be verified whether juice was pasteurised in each trial? For wine production apparently only one study is available for Reisling, the other studies showing residues in raw grapes at too low level for an appropriate calculation of transfer factors.<br>Based on these comments the number of appropriate studies for juice and wine production should be reconsidered and the list of end points should be amended accordingly. | |
| (21) | Vol. 3, B.7.8.3, Summary/assessment of processing | EFSA : For transparency the individual values from which the average transfer factors mentioned in table B.7.37 should be mentioned in that table or identified as underlined or bold values in the evaluated studies. | |

section 3 - Residues (B.7)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (22) | Vol. 3, B.7.9, Livestock feeding studies | EFSA : The amount of residues in tissues are reported as clofentezine equivalents. However as the method of analysis is not described, it is not possible to deduce which compounds are actually included in these results. Do they comply to the proposed residue definition (sum of parent + 4-OHclofentezine)? | |
| (23) | Vol. “, B.7.10, Residues in rotational crops | EFSA : The results of the mentioned study by Allen (1997), investigating the scenario of the use of clofentezine for 3 successive years followed by leafy vegetables in the late summer of the third year are not reported. | |
| (24) | Vol. 3, B.7.13, Proposed MRLs | EFSA : The reason for proposing 0.1 mg/kg for kidneys is not understandable as the residues in this tissue was below the LOQ of 0.05 mg/kg in the feeding study. | |
| (25) | Vol. 3, B.7.16.1, Intakes by domestic animals | EFSA : Normally as fruit pomace is a processed commodity resulting for a mixture of different producers, the STMR should had been used as starting residue level in apples. Nevertheless, this has no influence on the final conclusion | |

section 3 - Residues (B.7)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (26) | Vol. 3, B.7.16.2.1, chronic exposure assessment | EFSA : According to WHO guidelines, TMDI calculations should be done using the proposed MRLs rather than the HR. Nevertheless, given the low level of ADI exhaustion, this has no influence on the final outcome of risk assessment.<br>EFSA : In addition it should be specified whether the figures mentioned in table B.7.47 were obtained using the HR or the STMR. | |

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

**26. Environmental fate and behaviour (B.8)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol 1. List of end points. p.54 Rate of degradation in soil. | EFSA: The kinetic employed should be specified for each single value reported in the list of end points (both for laboratory and field studies). | |
| (2) | B.8.1.1.1. Aerobic studies. a) p. 289 | EFSA: The study is considered only supported information but it seems that its results have used both for the route and the rate of clofendizene, even when half lives are extrapolated beyond the duration of the study.<br>Some study drawbacks and deviations of guidelines are:<br>-short duration (only 67 d).<br>-artificial formation of AE C522505<br>-application of non labelled AE C522505 together of the test substance.<br>- very harsh extraction (soxhlet extraction 1- $CH_2Cl_2$ and 2- MeOH/$H_2O$)<br>-temperature of 15 ºC<br>-Recovery far below 90 % after 67 d<br><br>If finally found not acceptable the study would need to be removed from the list of studies. | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (3) | B.8.1.1.1. Aerobic studies. b) p. 292 | EFSA: The extraction method employed in this study is very harsh (soxhlet extraction 1- $CH_2Cl_2$, 2- MeOH/$H_2O$ and CH3CN/ $H_2O$). In principle it cannot be excluded that some of these extraction steps may have an impact on the nature of the residue (for example second and third extraction steps may eventually contribute to the hydrolysis of the product). No information on the procedural recovery of the extraction and analytical method is provided in the DAR. | |
| (4) | B.8.1.1.1. Aerobic studies. b) p. 293 | EFSA: Data at day 0/1 is either not available or shows levels of clofentezine much lower than the ones would be expected from the half lives calculated. | |
| (5) | B.8.1.1.1. Aerobic studies. b) Table B.8.4 and B.8.5 | EFSA: Values for Unextracted, CO2 and total recovery in Table B.8.4 and B.8.5 do not match. Please clarify. | |
| (6) | B.8.1.1.1. Aerobic studies. a) b) | EFSA: How representative are soils with MWHC (%) above 100 %. FOCUS GW guidance considers a MWHC of 50 % to be representative for a clay soil. | |
| (7) | B.8.1.1.2. Anaerobic study a) | EFSA: The same three soils than for the aerobic conditions were tested under anaerobic conditions, however only the results for an unspecified soil are provided in the DAR (see table B.8.7). | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (8) | B.8.1.1.2. Anaerobic study a) | EFSA: Values for Unextracted, $CO_2$ and total recovery in Table 8.6 and B.8.7 do not match. Please clarify. | |
| (9) | B.8.1.2.1 Rate of degradation. Laboratory studies. a) p 296 | EFSA: Extraction procedures employed in this study are considerably milder than the ones employed for the route studies. Results are not necessarily comparable. | |
| (10) | B.8.1.2.1 Rate of degradation. Laboratory studies. a) p 297 | EFSA: First order half life has only been calculated by the RMS for the Speyer 2.3 soil, not for the Speyer 2.2. Fitting to first order of the Speyer 2.2 soils seems to be good enough for risk assessment. | |
| (11) | B.8.1.2.1 Rate of degradation. Laboratory studies. a) Table B.8.12 p 298 | EFSA: Rates of degradation from study Leake and Arnold 1983 a (considered as supplementary information by the RMS) should not be used in the risk assessment. Furthermore, there are redundant since degradation in the same soils were investigated in the Leake and Arnold 1983 b following a better methodology. | |
| (12) | B.8.1.3. Field studies. Field dissipation. | EFSA: From the summary of these studies in the DAR it is not clear if cores at higher depths than the ones reported (10 cm in most of the cases) were sampled for each trial. | |
| (13) | B.8.1.3. Field studies. Field dissipation. Table B.8.13 | EFSA: Does Top fit 1-comp model refers to first order kinetics? | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (14) | B.8.1.3. Field studies. Field accumulation. | EFSA: It needs to be clarified how plateau concentrations were derived. Was $DT_{90}$ = 640.5 converted in a pseudo first order $DT_{50}$ ≈ 200.2 d and then first order kinetic used for the accumulation calculation? | |
| (15) | B.8.2.1 Adsorption and desorption. | EFSA: No batch studies on adsorption of clofentezine in soil have been provided based on the low water solubility. Does the addition of small quantities of co-solvent have been attempted? | |
| (16) | B.8.2.2.1 Column leaching. a) | EFSA: LOQ of the analytical method employed for clofentezine in the leachate is 20 μg / L. Therefore, this studies are not relevant to assess potential ground water contamination above 0.1 μg / L. | |
| (17) | B.8.2.2.1 Column leaching. b) | EFSA: 2-chlorobenzoic acid (AE C500233) is found in the leachate of the column leaching study. There is no reason or data to support the argument that this should be an impurity of the treatment solution and not a genuine clorofentezine metabolite. | |
| (18) | B.8.2.2.2 Aged residue column leaching<br>a) | EFSA: Due to the low overall recovery (72 – 78 % AR) and the lack of information on the LOQ for leachate analytical method no conclusion may be derived with respect to potential ground water contamination form this study. | |

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

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|---|---|---|---|
| (19) | B.8.3 PEC soil calculation. | EFSA: $DT_{50}$ used for PEC soil calculation is 130d. However, accumulation is calculated based on $DT_{90}$ = 640. 5 d. These two approaches do not match each other. | |
| (20) | B.8.4.1 Hydrolysis studies.<br>a) | EFSA: Hydrolysis studies were performed at concentrations of 14 to 26 μg/L, whereas the solubility of clofentezine is below 3 μg/L for any pH between 5 and 9. In fact the low solubility is used to justify the absence of soil adsorption /desorption studies. A clarification is needed on the methodology employed in this study and the potential contribution of precipitation to apparent degradation. Acceptability of the study is doubtful. | |
| (21) | B.8.4.1 Hydrolysis studies.<br>b) | EFSA: concentration of test substance used in the study is not reported in the DAR. | |
| (22) | B.8.4.1 Hydrolysis studies. | EFSA: References Kelly, 1985a; Smith and Kelly, 1985b and van der Gaauw, 2001 are not in the list of information, test and studies which are considered as relied upon by the RMS. | |
| (23) | B.8.4.2 Aqueous photolysis p.322 a) | EFSA: Acceptability of this photolysis study is highly questionable due to the lack of control on the experimental conditions and the high concentration of test substance employed (250 μg/L; solubility < 3 μg/L). | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (24) | B.8.4.2 Aqueous photolysis p.323 Quantum yield a) | EFSA: It is doubtful that the quality of the photolysis study allows determining any reliable quantum yield. | |
| (25) | B.8.4.2 Aqueous photolysis a) / Quantum yield a) | EFSA: Kelly, 1985 b; Buerkle, 1999a and Maurer, 2000 are not in the list of information, test and studies which are considered as relied upon by the RMS. However, it is not clear from the text that these three studies are considered not reliable by the RMS. | |
| (26) | B.8.4.4. Water/sediment studies. p. 324. a) | EFSA: A higher ratio of sediment than recommended by SETA guidelines is used in this study. Due to the high adsorption to sediment by this compound this may affect the result with respect to the dissipation from the water phase. | |
| (27) | B.8.4.4. Water/sediment studies. p. 324. a) | EFSA: In the two systems investigated the water pH is > 8. Due to the fact the hydrolysis is pH dependent a new water / sediment study at neutral or slightly acidic pH would be necessary. | |
| (28) | B.8.4.4. Water/sediment studies. p. 324. a) | EFSA: If the microcosm vessels were fully filled of water, the volume of water would be: 0.235 L. Therefore, the minimum concentration applied is of 847 μg/L whereas the solubility at this pH is < 2 μg/L. | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (29) | B.8.4.4. Water/sediment studies. p. 324. a) | EFSA: A WP formulation is used in this study instead of the technical active substance. Applicability of this study to assess the representative SC formulation may need to consider the effect of the different co-formulants on the solubility of the compound. | |
| (30) | B.8.4.4. Water/sediment studies. p. 324. a) | EFSA: Three traps for volatiles are used: ethanodiol. ethanolamine and sulphuric acid. However, the separated results for each trap are not presented in the results tables in the DAR. It should be clarified if all volatiles were assumed to be $CO_2$ and if any test to check the identity of volatiles was performed. | |
| (31) | B.8.4.4. Water/sediment studies. p. 326. a) Jene (2001) | EFSA: The number of data points (6 per compound and compartment) is clearly insufficient to fit a multi compartmental model as the one pictured in Fig B.8.2. SETAC and OCDE guidance require a minimum of six data points but FOCUS kinetics recommends a higher number of samples for hydrophobic substances and to derive kinetic information on the metabolites. | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (32) | B.8.4.4. Water/sediment studies. p. 326. a) Jene (2001)<br>B.8.5.2 PEC SW | EFSA: Whole system DT50 needs to be provided to finalise the surface water risk assessment. Following FOCUS Kinetics recommendations, for FOCUS SW a half life of 1000 d should be used for the sediment and the whole system half life for the water phase when it is not possible to obtain reliable degradation parameters for the separated phases. | |
| (33) | B.8.5.1 PEC GW | EFSA: Only one FOCUS model has been used to assess the potential ground water contamination by fluopicolide and its metabolites. At least results of two models are needed to complete the risk assessment. (**Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS groundwater models. The EFSA Journal (2004) 93, 1-20.)** | |
| (34) | B.8.5.2 PEC SW | EFSA: It is not clear where the water / sediment whole system DT50 used for FOCUS step 1 calculations (7 d) comes from. Whole system $DT_{50}$ is not calculated in the water/sediment system (EFSA calculated whole system DT50 of 13.4 and 7.9 d). | |

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

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (35) | B.8.5.2 PEC SW | EFSA: Since no standard approach is still adopted at EU level, Step 4 run off reductions by vegetative buffer zones need to be specifically justified in the DAR. The papers quoted need to be summarized and RMS should assess if the proposed reduction on runoff mass loadings are justified for the representative uses. | |
| (36) | B.8.6 Fate and behaviour in air. | EFSA: van der Gaauw, 1990 seems to be listed as van der Gaauw, A, 2001 b in the list of information, test and studies which are considered as relied upon by the RMS; please clarify. | |

section 5 - Ecotoxicology (B.9)

**27. Ecotoxicology (B.9)**

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (1) | Vol. 1, Level 4,<br>Data requirements | EFSA: Data requirements were identified in Vol.3. to support the suggested refinement steps for the long-term risk assessement for insectivorous birds e.g. PD, PT, focal species. These data requirements should be listed in Vol. 1, Level 4 | |
| (2) | Vol. 1, Level 2,<br>List of Endpoints | EFSA: TERs for aquatic organisms. It would be beneficial to include all uses where the trigger is not met for the worst case use. From the provided list it is not possible to see if the long-term TER is above 10 for fish for the use in pome fruit and vine and which buffer zones are needed. | |
| (3) | Vol. 1, Level 2,<br>List of Endpoints | EFSA: HQ values for non-target arthropods should be included in the LOEP. It is stated that data from field or semi-field tests indicate that overall effect is less than 50%. However no study summaries were provided in Vol. 3, B9. | |
| (4) | Vol. 3, B.9.1.4,<br>Risk assessment for birds | EFSA: No risk assessment was conducted for the uptake of contaminated drinking water. | |
| (5) | Vol. 3, B.9.2,<br>Risk assessment for mammals | EFSA: No risk assessment was conducted for the uptake of contaminated drinking water. | |

* When mentioning page numbers of the DAR in your comments, **the page numbers should refer to the pdf-version** (not the WORD-version) of the DAR to ensure consistency among the Member States.

section 5 - Ecotoxicology (B.9)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (6) | Vol. 3, B. 9.2.1,<br>Acute toxicity to aquatic organisms | EFSA: More information on the studies with aquatic organisms should be given: e.g: batch no., tested concentrations, analytical methods, number of replicates, water parameters (hardness, pH, oxygen saturation, temperature) photoperiod, loading rate, feeding, observation of sublethal effects, statistical methods. | |
| (7) | Vol. 3, B. 9.2.3,<br>Aquatic risk assessment | EFSA: The relevance of the NOEC of 0.025 mg a.s./L for the risk assessment for daphnids is questionable (only one concentration tested) since a higher NOEC of 0.25 mg a.s./L from a test with the formulation is available. However, the observed higher endpoint could also be due to the presence of sediment. It may be helpful for the decision on the appropriate endpoint to report the tested concentrations from the second 21d chronic study with the formulation. | |

section 5 - Ecotoxicology (B.9)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (8) | Vol. 3, B. 9.2.3, Aquatic risk assessment | EFSA: No risk assessment was conducted for the metabolite 2-chlorobenzonitrile (AE F023666). The metabolite is formed via photolysis up to 74.6% of AR. The RMS argues that a risk assessment is not necessary because the metabolite was not found in the water/sediment study. However, the water/sediment study was conducted under dark conditions. Solar irradiation could promote the formation of 2-chlorobenzonitrile under natural conditions. Therefore a risk assessment is considered necessary by EFSA. | |
| (9) | Vol. 3, B.9.5.1, Risk assessment for other non-target arthropods | EFSA: The field studies with *Typhlodromus pyri* are not summarized in Vol. 3. But in the LOEP it is stated that the data from the field studies indicate that the overall effect is < 50%. To verify this assessment the studies should be reported in the DAR. The field studies may provide information to conclude on the risk to non adult life stages. | |

section 5 - Ecotoxicology (B.9)

| No. | Column 1<br>Reference to draft assessment report * | Column 2<br>Comment * (restricted to 500 characters, ca.10 lines) | Column 3<br>Further explanations |
|---|---|---|---|
| (10) | Vol. 3, B.9.6.2,<br>Risk assessment for earthworms | EFSA: It is not clear if the long-term risk to earthworms is fully addressed. The NOEC from the study of Stäbler (2002) would result in a TER of 3.7. If the NOEC from the study of Rodgers (2001) is used the TER would be 11. However only one application rate was tested in this study. At least some argumentation should be provided why this higher NOEC is more appropriate. A more detailed reporting of the earthworm field study may help to conclude whether the long-term risk to earthworms is sufficiently addressed. | |