## Section A7.1.3 Adsorption / Desorption screening test

**Annex Point IIA7.7**

[redacted]

Schüürmann G [154] calculated the error for the calculation of log P. The lowest error was found by Schüürmann G for [redacted].

Cheng H et al [155] examined the QSAR estimation of surfactants (alcohol ethoxylate). Cheng H et al found the lowest deviation from the experimental value for [redacted]

Data from the Hazardous Substance Data Bank (HSDB):

[redacted]

## Section A7.1.3 Adsorption / Desorption screening test

**Annex Point IIA7.7**

| | | |
|---|---|---|
| | | A further experimental test is not justifiable [redacted]. With the [redacted] the currently best available program is used [152]. Its estimation based on log P is a reliable way of estimation soil sorption and its log P estimation was found among the best in comparative studies [153, 155]. The use of [redacted] in its log P algorithm ensures that the pH dependency of the Koc is considered while the applicability of [redacted] substances has only been proven on few substances.<br>Altogether the [redacted] gives a reliable and plausible result for the Koc of lauric acid [152].<br>In addition, under REACH legislation annex IV "exception to mandatory registration" lauric acid is listed as a substance with minimal risk based on the inherent substance properties. This fact also justified not to conduct a further study, but to accept the QSAR model by [redacted]. |
| 5.2.1 | Adsorbed a.s. [%] | Not calculated [redacted]. |
| 5.2.2 | $K_a$ | Not calculated [redacted]. |
| 5.2.3 | $K_d$ | Not calculated [redacted]. |
| 5.2.4 | $K_{oc}$ | [redacted] |
| 5.2.5 | $K_a/K_d$ | Not calculated [redacted]. |
| 5.2.6 | Degradation products (% of a.s.) | Not applicable [redacted]. |
| **5.3** | **Conclusion** | |
| 5.3.1 | Reliability | 2 |
| 5.3.2 | Deficiencies | Not applicable. |

| **Evaluation by Competent Authorities** | |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | *Give date of action* |
| **Materials and Methods** | *State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.* |
| **Results and discussion** | *Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers* |
| **Conclusion** | *Adopt applicant's version or include revised version* |

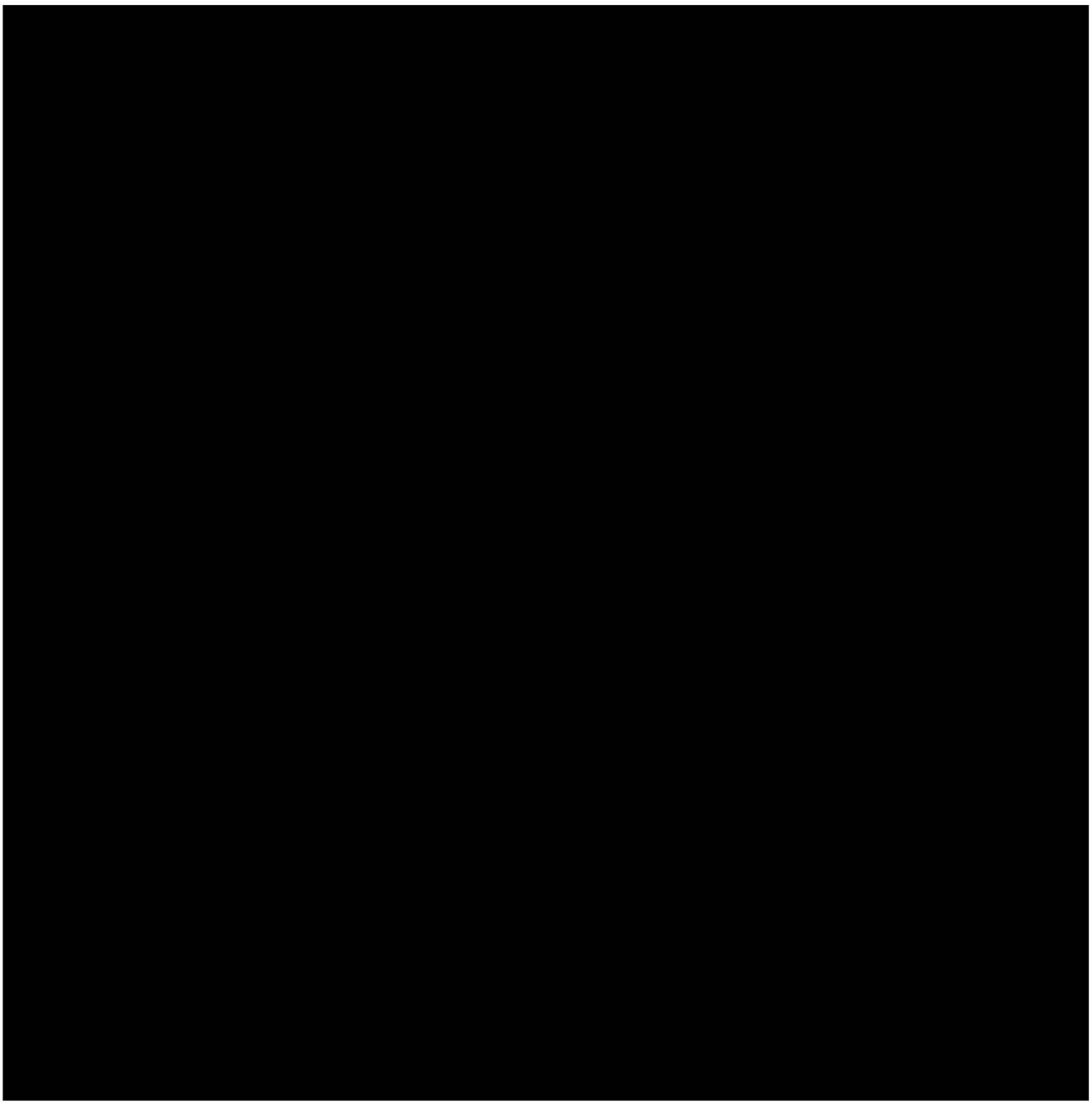
## Section A7.1.3 Adsorption / Desorption screening test

**Annex Point IIA7.7**

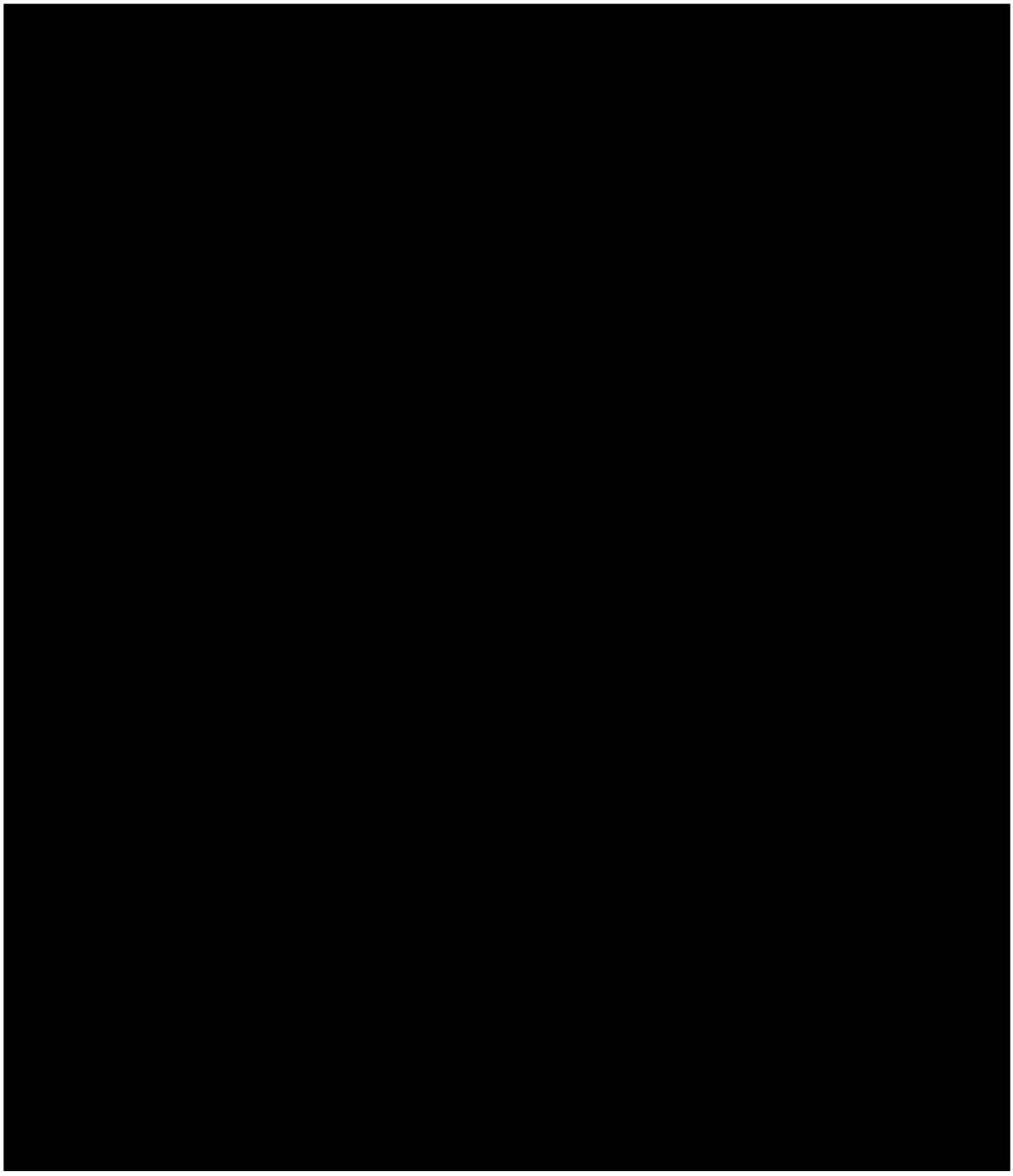
| | |
|---|---|
| **Reliability** | *Based on the assessment of materials and methods include appropriate reliability indicator* |
| **Acceptability** | acceptable / not acceptable<br>*(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)* |
| **Remarks** | |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Materials and Methods** | *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*<br>*Discuss if deviating from view of rapporteur member state* |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

## Annex 1:

[redacted]



## Annex 2:



## Section A7.1.3 Adsorption / Desorption screening test

**Annex Point IIA7.7**

Official use only

### 1 REFERENCE

| | | |
|---|---|---|
| **1.1** | **Reference** | Mills EAM, Mackenzie E, 2007, Lauric acid: Estimation of Adsorption Coefficient (Koc) on Soil and Sewage Sludge by HPLC (OECD 121), Report No. LJ/07/001, Battelle UK Ltd., unpublished [145]. |
| **1.2** | **Data protection** | Yes |
| 1.2.1 | Data owner | Dr. R. Pfleger Chemische Fabrik GmbH |
| 1.2.2 | Criteria for data protection | Data submitted to the MS after 13 May 2000 on existing active substance for the purpose of its authorisation. |

### 2 GUIDELINES AND QUALITY ASSURANCE

| | | |
|---|---|---|
| **2.1** | **Guideline study** | Yes<br>OECD-Test Guideline 121 |
| **2.2** | **GLP** | Yes |
| **2.3** | **Deviations** | No |

### 3 MATERIALS AND METHODS

| | | |
|---|---|---|
| **3.1** | **Test material** | Lauric acid |
| 3.1.1 | Lot/Batch number | Batch number 43256 |
| 3.1.2 | Specification | As given in section 2 |
| 3.1.3 | Purity | [redacted] |
| 3.1.4 | Further relevant properties | [redacted] |
| 3.1.5 | Method of analysis | [redacted] |
| **3.2** | **Degradation products** | [redacted] |
| 3.2.1 | Method of analysis for degradation products | [redacted] |
| **3.3** | **Reference substance** | [redacted] |

## Section A7.1.3 Adsorption / Desorption screening test

**Annex Point IIA7.7**

[redacted]

| | | |
|---|---|---|
| 3.3.1 | Method of analysis for reference substance | [redacted] *See 3.1.5 Method of analysis* |
| **3.4** | **Soil types** | No soil is used in the test according to OECD 121. |
| **3.5** | **Testing procedure** | |
| 3.5.1 | Test system | [redacted] *See 3.1.5 Method of analysis* |
| 3.5.2 | Test solution and Test conditions | [redacted] |
| **3.6** | **Test performance** | |
| 3.6.1 | Preliminary test | According to (a)"OECD 106": Not applicable, the test was performed according to OECD 121. |
| 3.6.2 | Screening test: Adsorption | According to (a)"OECD 106": Not applicable, the test was performed according to OECD 121. |
| 3.6.3 | Screening test: Desorption | According to (a)"OECD 106": Not applicable, the test was performed according to OECD 121. |
| 3.6.4 | HPLC-method | According to (a)"OECD [redacted] method"[1]: Yes according to OECD 121. *See 3.1.1. Test system* |
| 3.6.5 | Other test | The test was performed according to OECD 121. |

**4 RESULTS**

| | | |
|---|---|---|
| **4.1** | **Preliminary test** | Not applicable according to OECD 121. |
| **4.2** | **Screening test: Adsorption** | Not applicable according to OECD 121. |
| **4.3** | **Screening test: Desorption** | Not applicable according to OECD 121. |
| **4.4** | **Calculations** | |
| 4.4.1 | Ka , Kd | Not applicable according to OECD 121. |
| 4.4.2 | $K_{oc}$ | [redacted] |

[1] OECD (1999) OECD-Guidelines for the Testing of Chemicals. Proposal for a new guideline 121: Estimation of the adsorption coefficient ($K_{OC}$) on soil and on sewage sludge using High Performance Liquid Chromatography (HPLC), Draft Document (August 1999).

## Section A7.1.3 Adsorption / Desorption screening test

**Annex Point IIA7.7**

**Degradation product(s)** [redacted]

### 5 APPLICANT'S SUMMARY AND CONCLUSION

**5.1 Materials and methods**

The adsorption coefficient is determined with a [redacted] method according to OECD guideline for testing of chemicals no. 121. Reference substances were used for a calibration plot in order to determine the absorption coefficient of the test substance.

[redacted].

No deviations of the testing guideline had been made.

**5.2 Results and discussion**

[redacted].

[redacted]

According to the classification scheme [71], the calculated $K_{oc}$ values suggest that lauric acid as non-ionic form shows a [redacted] mobility in soil [55, 71].

[redacted].

[redacted]Therefore the values determined by experiment can not be used for further evaluations.

| | | |
|---|---|---|
| 5.2.1 | Adsorbed a.s. [%] | Not applicable according to OECD 121. |
| 5.2.2 | $K_a$ | Not applicable according to OECD 121. |
| 5.2.3 | $K_d$ | Not applicable according to OECD 121. |

## Section A7.1.3 Adsorption / Desorption screening test

**Annex Point IIA7.7**

| | | |
|---|---|---|
| 5.2.4 | $K_{oc}$ | [redacted] |
| 5.2.5 | Ka/Kd | Not applicable according to OECD 121. |
| 5.2.6 | Degradation products (% of a.s.) | Not applicable according to OECD 121. |
| **5.3** | **Conclusion** | The test was conducted according to OECD Guideline 121 as instructed by the German authority baua (Federal Institute for Occupational Safety and Health). [redacted] |
| 5.3.1 | Reliability | 2 |
| 5.3.2 | Deficiencies | No |

| | **Evaluation by Competent Authorities** |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | *Give date of action* |
| **Materials and Methods** | *State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.* |
| **Results and discussion** | *Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers* |

## Section A7.1.3 Adsorption / Desorption screening test

**Annex Point IIA7.7**

| | |
|---|---|
| **Conclusion** | *Adopt applicant's version or include revised version* |
| **Reliability** | *Based on the assessment of materials and methods include appropriate reliability indicator* |
| **Acceptability** | acceptable / not acceptable<br>*(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)* |
| **Remarks** | |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Materials and Methods** | *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*<br>*Discuss if deviating from view of rapporteur member state* |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

| | | |
|---|---|---|
| **Section A7.1.4.1**<br>**Annex Point IIIA XII.2.1** | **Further studies on adsorption/desorption in water/sediment systems**<br>Field study on accumulation in the sediment | |
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| **Other existing data [ ]**<br>**Limited exposure [ ]** | **Technically not feasible [ ]** **Scientifically unjustified [x]**<br>**Other justification [ ]** | |
| **Detailed justification:** | Studies on adsorption and desorption in water/sediment systems will be necessary if the preliminary risk assessment indicates that it is necessary.<br>The biocidal product is intended for application on human skin, so no field study on accumulation in the sediment is necessary for this active substance in the intended product.<br>Additional the active substance is readily biodegradable in soil and water [55, 68] so there will be no accumulation in the sediment. | |
| **Undertaking of intended data submission [ ]** | | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | *Give date of action* | |
| **Evaluation of applicant's justification** | *Discuss applicant's justification and, if applicable, deviating view* | |
| **Conclusion** | *Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data* | |
| **Remarks** | | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* | |
| **Date** | *Give date of comments submitted* | |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* | |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* | |
| **Remarks** | | |

| Section A7.1.4<br>Annex Point IIIA XII.2.2 | **Further studies on adsorption/desorption in water/sediment systems** | |
|---|---|---|
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| **Other existing data [ ]**<br>**Limited exposure [ ]** | **Technically not feasible [ ]** **Scientifically unjustified [x]**<br>**Other justification [ ]** | |
| **Detailed justification:** | An estimated Koc value of 300 [55, 70] suggests that partitioning from the water column to sediment and supended material may occur [55], however, adsorption is expected to vary with pH [55, 70].<br>Studies on adsorption and desorption in water/sediment systems will be necessary if the preliminary risk assessment indicates that it is necessary.<br>The biocidal product is intended for application on human skin and it is readily biodegradable in soil and water [55, 68], so it is not necessary for this active substance in the intended product. | |
| **Undertaking of intended data submission [ ]** | | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | *Give date of action* | |
| **Evaluation of applicant's justification** | *Discuss applicant's justification and, if applicable, deviating view* | |
| **Conclusion** | *Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data* | |
| **Remarks** | | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* | |
| **Date** | *Give date of comments submitted* | |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* | |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* | |
| **Remarks** | | |

| | | |
|---|---|---|
| **Section A7.2.1**<br>**Annex Point IIIA XII.1.1** | **Fate and behaviour in soil**<br>Aerobic degradation in soil, initial study | |
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| **Other existing data [ ]**<br>**Limited exposure [ ]** | **Technically not feasible [ ]** **Scientifically unjustified [x]**<br>**Other justification [ ]** | |
| **Detailed justification:** | The active substance is intended to be used as repellent on human skin. The active substance is not used directly on, released to or disposed in/on soil in relevant amounts, and it is known that the fatty acid lauric acid is readily biodegradable in soil and water [55, 68], so no additional test on aerobic degradation in soil is necessary. | |
| **Undertaking of intended data submission [ ]** | | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | *Give date of action* | |
| **Evaluation of applicant's justification** | *Discuss applicant's justification and, if applicable, deviating view* | |
| **Conclusion** | *Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data* | |
| **Remarks** | | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* | |
| **Date** | *Give date of comments submitted* | |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* | |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* | |
| **Remarks** | | |

| | | |
|---|---|---|
| **Section A7.2.2.1**<br>**Annex Point IIIA XII.1.1, XII.1.4** | **Aerobic degradation in soil, further studies**<br>The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions | |
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| **Other existing data [ ]**<br>**Limited exposure [ ]** | **Technically not feasible [ ]** **Scientifically unjustified [x]**<br>**Other justification [ ]** | |
| **Detailed justification:** | The active substance is intended to be used as repellent on human skin. The active substance is not used directly on, released to or disposed in/on soil in relevant amounts, and it is known that the fatty acid lauric acid is readily biodegradable in soil and water [55, 68], so no additional test on the rate and the route of degradaton is necessary. | |
| **Undertaking of intended data submission [ ]** | | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | *Give date of action* | |
| **Evaluation of applicant's justification** | *Discuss applicant's justification and, if applicable, deviating view* | |
| **Conclusion** | *Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data* | |
| **Remarks** | | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* | |
| **Date** | *Give date of comments submitted* | |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* | |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* | |
| **Remarks** | | |

| | | |
|---|---|---|
| **Section A7.2.2.2**<br>**Annex Point IIIA XII.1.1** | **Aerobic degradation in soil, further studies**<br>Field soil dissipation and accumulation | |
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| **Other existing data [ ]**<br>**Limited exposure [ ]** | **Technically not feasible [ ]** **Scientifically unjustified [x]**<br>**Other justification [ ]** | |
| **Detailed justification:** | The active substance is intended to be used as repellent on human skin. The active substance is not used directly on, released to or disposed in/on soil in relevant amounts, and it is known that the fatty acid lauric acid is readily biodegradable in soil and water [55, 68], so no additional test on field soil dissipation and accumulation is necessary. | |
| **Undertaking of intended data submission [ ]** | | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | *Give date of action* | |
| **Evaluation of applicant's justification** | *Discuss applicant's justification and, if applicable, deviating view* | |
| **Conclusion** | *Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data* | |
| **Remarks** | | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* | |
| **Date** | *Give date of comments submitted* | |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* | |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* | |
| **Remarks** | | |

| | | |
|---|---|---|
| **Section A7.2.2.3**<br>**Annex Point IIIA XII.1.4** | **Aerobic degradation in soil, further studies**<br>Extend and nature of bound residues | |
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| **Other existing data [ ]**<br>**Limited exposure [ ]** | **Technically not feasible [ ]** **Scientifically unjustified [x]**<br>**Other justification [ ]** | |
| **Detailed justification:** | The active substance is intended to be used as repellent on human skin. The active substance is not used directly on, released to or disposed in/on soil in relevant amounts, and it is known that the fatty acid lauric acid is readily biodegradable in soil and water [55, 68], so no additional test on the extend and nature of bound residues is necessary. | |
| **Undertaking of intended data submission [ ]** | | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | *Give date of action* | |
| **Evaluation of applicant's justification** | *Discuss applicant's justification and, if applicable, deviating view* | |
| **Conclusion** | *Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data* | |
| **Remarks** | | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* | |
| **Date** | *Give date of comments submitted* | |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* | |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* | |
| **Remarks** | | |

| | | |
|---|---|---|
| **Section A7.2.2.4**<br>**Annex Point IIIA XII.1.4** | **Aerobic degradation in soil, further studies**<br>Other soil degradation studies | |
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| **Other existing data [ ]**<br>**Limited exposure [ ]** | **Technically not feasible [ ]** **Scientifically unjustified [x]**<br>**Other justification [ ]** | |
| **Detailed justification:** | The active substance is intended to be used as repellent on human skin. The active substance is not used directly on, released to or disposed in/on soil in relevant amounts, and it is known that the fatty acid lauric acid is readily biodegradable in soil and water [55, 68], so no other soil degradation studies are necessary. | |
| **Undertaking of intended data submission [ ]** | | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | *Give date of action* | |
| **Evaluation of applicant's justification** | *Discuss applicant's justification and, if applicable, deviating view* | |
| **Conclusion** | *Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data* | |
| **Remarks** | | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* | |
| **Date** | *Give date of comments submitted* | |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* | |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* | |
| **Remarks** | | |

| | | |
|---|---|---|
| **Section A7.2.3.1**<br>**Annex Point IIIA XII.1.2** | **Adsorption and mobility in soil, further studies**<br>Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products | |
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| **Other existing data [ ]** | **Technically not feasible [ ]** **Scientifically unjustified [x]** | |
| **Limited exposure [ ]** | **Other justification [ ]** | |
| **Detailed justification:** | The active substance is intended to be used as repellent on human skin. The active substance is not used directly on, released to or disposed in/on soil in relevant amounts, and it is known that the fatty acid lauric acid is readily biodegradable in soil and water [55, 68], so no additional adsorption and mobility studies are necessary. | |
| **Undertaking of intended data submission [ ]** | | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | *Give date of action* | |
| **Evaluation of applicant's justification** | *Discuss applicant's justification and, if applicable, deviating view* | |
| **Conclusion** | *Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data* | |
| **Remarks** | | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* | |
| **Date** | *Give date of comments submitted* | |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* | |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* | |
| **Remarks** | | |

| | | |
|---|---|---|
| **Section A7.2.3.2**<br>**Annex Point IIIA XII.1.3** | **Adsorption and mobility in soil, further studies**<br>Mobility in at least three soil types and where relevant mobility of metabolites and degradation products | |
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| **Other existing data [ ]**<br>**Limited exposure [ ]** | **Technically not feasible [ ]** **Scientifically unjustified [x]**<br>**Other justification [ ]** | |
| **Detailed justification:** | The active substance is intended to be used as repellent on human skin. The active substance is not used directly on, released to or disposed in/on soil in relevant amounts, and it is known that the fatty acid lauric acid is readily biodegradable in soil and water [55, 68], so no additional adsorption and mobility studies are necessary. | |
| **Undertaking of intended data submission [ ]** | | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | *Give date of action* | |
| **Evaluation of applicant's justification** | *Discuss applicant's justification and, if applicable, deviating view* | |
| **Conclusion** | *Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data* | |
| **Remarks** | | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* | |
| **Date** | *Give date of comments submitted* | |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* | |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* | |
| **Remarks** | | |

| | | |
|---|---|---|
| **Section A7.3.1**<br>**Annex Point IIIA VII.5** | **Fate and behaviour in air**<br>Phototransformation in air including identification of breakdown products | |
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| **Other existing data [x]**<br>**Limited exposure [ ]** | **Technically not feasible [ ]** **Scientifically unjustified [x]**<br>**Other justification [ ]** | |
| **Detailed justification:** | Vapor-phase lauric acid will degrade in the ambient atmosphere by reaction with photochemically produced hydroxyl radicals with an estimated half-life of about 1.21 days [55, 72]. Moreover, physical removal from air throught wet deposition (e.g., rainfall, dissolution into clouds) may be possible [55, 73].<br>Additional data are not available, but the molecular structure of lauric acid has no C-C double bond which could be sensitive to radical species and carboxylic acids are generally resistant to aqueous environmental hydrolysis [66].<br>Generally, the active ingredient of the product is used as a repellent after topical application. Concentrations evaporated into the air will be very low and limited to the direct environment of the human body.<br>[redacted]:<br>The specific first order degradation rate constant of a substance with OH-radicals was estimated by the (Q)SAR-method [123]:<br>[redacted]<br>The [redacted] $kdeg_{air}$ shows the degradation of lauric acid in the air. So there will be no accumulation in the air or transportation by the air to other areas. | |
| **Undertaking of intended data submission [ ]** | | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | *Give date of action* | |
| **Evaluation of applicant's justification** | *Discuss applicant's justification and, if applicable, deviating view* | |
| **Conclusion** | *Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data* | |

| | |
|---|---|
| **Section A7.3.1**<br>**Annex Point IIIA VII.5** | **Fate and behaviour in air**<br>Phototransformation in air including identification of breakdown products |
| **Remarks** | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* |
| **Date** | *Give date of comments submitted* |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

| Section A7.3.2<br>Annex Point IIIA XII.3 | Fate and behaviour in air<br>Further studies | |
|---|---|---|
| | **JUSTIFICATION FOR NON-SUBMISSION OF DATA** | Official use only |
| **Other existing data [ ]**<br>**Limited exposure [ ]** | **Technically not feasible [ ]** **Scientifically unjustified [x]**<br>**Other justification [ ]** | |
| **Detailed justification:** | The Henry´s Law constant for dodecanoic acid can be estimated to be $9.3 \cdot 10^{-6}$ atm-$m^3$/mole [70]. According to a suggested classification scheme [74], this value of Henry´s Law constant indicates that volatilization of dodecanoic acid from water will not be rapid, but possibly important in shallow rivers [74].<br>Based on a estimated vapour pressure of $1.5 \cdot 10^{-5}$ mm Hg at 25°C, dodecanoid acid should exist in very small quantities in vapor and particulate phase in the ambient atmosphere [75].<br>The active substance is not used in preparations for fumigants and the active substance does not cause risk to the atmospheric environmental, because it is used on human skin.<br>Taking into consideration that Lauric acid is naturally released to the environment in emissions from animal waste, vegetation and tabacco smoke [76], no further studies on the behaviour in air are necessary. | |
| **Undertaking of intended data submission [ ]** | | |
| | **Evaluation by Competent Authorities** | |
| | *Use separate "evaluation boxes" to provide transparency as to the comments and views submitted* | |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** | |
| **Date** | *Give date of action* | |
| **Evaluation of applicant's justification** | *Discuss applicant's justification and, if applicable, deviating view* | |
| **Conclusion** | *Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data* | |
| **Remarks** | | |
| | **COMMENTS FROM OTHER MEMBER STATE** *(specify)* | |
| **Date** | *Give date of comments submitted* | |
| **Evaluation of applicant's justification** | *Discuss if deviating from view of rapporteur member state* | |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* | |
| **Remarks** | | |

## Section A7.4.1.1 Aquatic toxicity, initial tests
**Annex Point IIA VII.7.1** Acute toxicity to fish

Official use only

### 1 REFERENCE

| | | |
|---|---|---|
| **1.1** | **Reference** | Egmond van R, Hambling S, Marshall S: Bioconcentration, biotransformation, and chronic toxicity of sodium laurate to zebrafish (Danio rerio). Environ Toxicol Chem **18**(3): 466-473, 1999 (published) [77] |
| **1.10** | **Data protection** | No |
| 1.10.2 | Data owner | Not applicable. |
| 1.10.3 | Criteria for data protection | No data protection claimed |

### 2 GUIDELINES AND QUALITY ASSURANCE

| | | |
|---|---|---|
| **2.1** | **Guideline study** | Yes<br>OECD: Guideline for testing chemicals: Proposal for fish juvenile growth test. Draft Document. Paris, France, 1997.<br>OECD: Guideline for testing chemicals, Vol. 2, Sect. 3-Bioaccumulation: Flow through fish test. Guideline 305E. Paris, France, 1993. |
| **2.2** | **GLP** | No data available. |
| **2.3** | **Deviations** | A Zebrafish is used according the recommendation of the OECD Guideline for testing chemicals: Proposal for fish juvenile growth test. Draft Document. Paris, France, 1997.<br>The estimated time to reach 95% of steady state is made according the OECD Guideline for testing chemicals, Vol. 2, Sect. 3-Bioaccumulation: Flow through fish test. Guideline 305E. Paris, France, 1993. |

### 3 MATERIALS AND METHODS

| | | |
|---|---|---|
| **3.1** | **Test material** | As given in section 2 |
| 3.1.1 | Lot/Batch number | No lot/batch number named. |
| 3.1.2 | Specification | As given in section 2 |
| 3.1.3 | Purity | 98% |
| 3.1.4 | Composition of Product | The pure active substance is used in the test. |
| 3.1.5 | Further relevant properties | A $^{14}C$ marked active substance is used for the test, too. |
| 3.1.6 | Method of analysis | The substance is stable, but with low water solubility, so the stock solutions were warmed above the Kraft point of 35-40°C. |
| **3.2** | **Preparation of TS solution for poorly soluble or volatile test substances** | Stock solutions were prepared by warming equimolar quantities of sodium hydroxide and lauric acid in destilled water in a water bath to keep the soap in solution. Radiolabeled lauric acid in dimethyl sulfoxide (DMSO) was added to each stock (final concentration, 0.5 µl DMSO/L) to give specific activities.<br>Effect concentrations in the growth rate test were therefore based on soluble laurate estimated after separation by centrifugation.<br>See table A7_4_1_1-1 |
| **3.3** | **Reference** | Not named. |

## Section A7.4.1.1 Aquatic toxicity, initial tests
**Annex Point IIA VII.7.1** Acute toxicity to fish

| | | |
|---|---|---|
| | **substance** | |
| 3.3.1 | Method of analysis for reference substance | Not named. |
| **3.4** | **Testing procedure** | |
| 3.4.1 | Dilution water | Give details on dilution water in tabular form, see table A7_4_1_1-2 |
| 3.4.2 | Test organisms | Give details on tested organisms in tabular form, see table A7_4_1_1-3<br>Number of test organisms: 16 per group |
| 3.4.3 | Test system | See table A7_4_1_1-4 |
| 3.4.4 | Test conditions | See table A7_4_1_1-5 |
| 3.4.5 | Duration of the test | 28 days |
| 3.4.6 | Test parameter | Concentration, tissue, mortality, growth, water quality |
| 3.4.7 | Sampling | Examination: For weighing procedure the fishes were temporarily anesthetized using 3-aminobenzoic acid ethyl ester (300 mg/L,< 1 min duration), gently blotted to remove excess moisture and weighed on a four-figure balance. The fishes were allowed to recover in clean water and then exposed to sodium laurate.<br>The fishes were not fed on day 13 and 27 and were reweighed on day 14 and 28. |
| 3.4.8 | Monitoring of TS concentration | Yes<br>Concentration of laurate in all the test media were determined frequently throughout the test (n=21, one sample per test concentration on each sampling occassion). Lauric acid was extracted from the water samples to determine if biodegradation products significantly contributed to total radioactivity (n=16, one sample from each concentration with surviving fish on four occassions). |
| 3.4.9 | Statistics | Mean weights and pseudospecific growth rates were compared using nonparametric analysis of variance (Kruskal-Wallis one-way ANOVA) followed by Dunn´s test (two-tailed test, comparison against a control group), as a test for normality (Shapiro-Wilk) indicated some of the data were not normally distributed. Toxicity data were analyzed by nonlinear interpolation, or if the data allowed, by the probit method. |

**4 RESULTS**

**Limit Test** Not named.

4.1.1 Concentration

| Nominal concentration | 0 mg/L | 2.0 mg/L | 3.6 mg/L | 6.4 mg/L | 11.2 mg/L | 20 mg/L |
|---|---|---|---|---|---|---|

4.1.2 Number/ percentage of animals showing adverse effects

| Nominal concentration | 0 mg/L | 2.0 mg/L | 3.6 mg/L | 6.4 mg/L | 11.2 mg/L | 20 mg/L |
|---|---|---|---|---|---|---|
| Effect | mean weight increase | mean weight increase, more than the control | mean weight increase, singificant more than the | mean weight increase, more than the control | mean weight increase after 14 days | mean weight increase after 14 days |

## Section A7.4.1.1 Aquatic toxicity, initial tests
**Annex Point IIA VII.7.1** Acute toxicity to fish

| | | fish | control fish | fish | | |
|---|---|---|---|---|---|---|
| Weight increase after 14 days | 18% | 29% | 33% | 24% | 3% | 13% |
| Weight increase after 28 days | 47% | 64% | 75% | 60% | - | - |
| Deaths | - | - | 6% | 14% | 75%* | 75%* |

*Fish surviving 15 d in the top two exposure concentrations were not further exposed.

4.1.3 Nature of adverse effects: Death

**Results test substance**

4.1.4 Initial concentrations of test substance

| Nominal concentration | 0 mg/L | 2.0 mg/L | 3.6 mg/L | 6.4 mg/L | 11.2 mg/L | 20 mg/L |
|---|---|---|---|---|---|---|

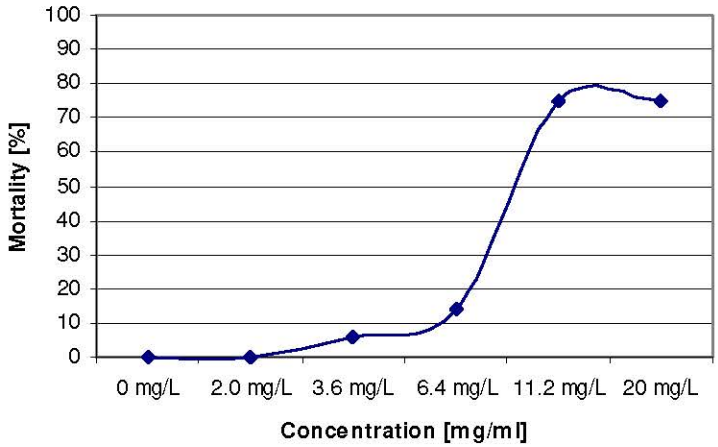
4.1.5 Actual concentrations of test substance

| Nominal concentration | 0 mg/L | 2.0 mg/L | 3.6 mg/L | 6.4 mg/L | 11.2 mg/L | 20 mg/L |
|---|---|---|---|---|---|---|
| Measured concentration | 0 mg/L | 2.2 mg/L | 3.7 mg/L | 6.6 mg/L | 12.9 mg/L | 20.1 mg/L |

4.1.6 Effect data (Mortality): No mortality/survival data at embryo, larval and juvenile stages as well as overall mortality/survival are reported.

For the reported effects see table in 4.1.2.

4.1.7 Concentration / response curve




4.1.8 Other effects: Low levels of lauric acid were also seen in control fish tissue from the growth rate test (0.03 and 0.04 mmol/kg) and are believed to be of natural origin.

**Results of controls**

4.1.9 Number/ percentage of animals showing adverse effects: 16

4.1.10 Nature of adverse: Low levels of lauric acid were also seen in contro fish tissue from the

## Section A7.4.1.1 Aquatic toxicity, initial tests
**Annex Point IIA VII.7.1** Acute toxicity to fish

| | | |
|---|---|---|
| | effects | growth rate test (0.03 and 0.04 mmol/kg) and are believed to be of natural origin. |
| **Test with reference substance** | | Not performed |
| 4.1.11 | Concentrations | Not applicable. |
| 4.1.12 | Results | Not applicable. |

### 5 APPLICANT'S SUMMARY AND CONCLUSION

| | | |
|---|---|---|
| **5.1** | **Materials and methods** | OECD: Guideline for testing chemicals: Proposal for fish juvenile growth test. Draft Document. Paris, France, 1997: A Zebrafish is used according the recommendation of the guideline.<br>OECD: Guideline for testing chemicals, Vol. 2, Sect. 3-Bioaccumulation: Flow through fish test. Guideline 305E. Paris, France, 1993: The estimated time to reach 95% of steady state. |
| **5.2** | **Results and discussion** | Mortality is higher with a concentration of 11.2 mg/L and 20 ml/L compared to the lower concentrations, but there is no real trend in the growth rate detectable.<br>Soaps such as lauric acid are difficult substances to test in natural water because of formation of calcium salts, which have low solubility products. It is likely that soluble lauric acid causes almost all the toxic effects, whereas particulate laurate makes an insignificant contribution because of its low bioavailability. Effects on the growth rate were therefore based on the soluble laurate estimated after separation by centrifugation. |
| 5.2.2 | $LC_0$ | Not determined. |
| 5.2.3 | $LC_{50}$ | After 4, 8, 15, 28 day median lethal concentration is:<br>>20 , 12, 9.9 and 9.8 mg/L |
| 5.2.4 | $LC_{100}$ | Not determined. |
| **5.3** | **Conclusion** | A relation between the concentration of lauric acid and the mortality is seen. There is a high increase of mortality over a concentration of 6.4 mg/L, but no great difference between the concentration of 11.2 ml/L and 20 ml/L.<br>Concerning the weight increase, there is no relation between increasing concentration of lauric acid and increasing weight, the weight is increasing in the concentrations from 0 ml/L to 3.6 ml/L. It is detectable that the weight increase after 28 days is higher than after 14 days. |
| 5.3.1 | Other Conclusions | The active substance is readily biodegradable in soil and water [55, 68] although it is classified as low hazardous to water (WGK 1) according the German "Allgemeine Verwaltungsvorschrift zum Wasserhaushaltsgesetz über die Einstufung wassergefährdender Stoffe in Wassergefährdungsklassen (VwVwS)" from 17.05.1999, last change 27.07.2005.<br>As shown in the subchronic toxicity study, there is no acute toxicity, too.<br>The intended use as repellent and the low hazardous to water which is no danger to environment because the concentration of LC50 or NOEC will never be obtained if the active substance is used in the biocidal product as a repellent on human skin. |
| 5.3.2 | Reliability | 1 |
| 5.3.3 | Deficiencies | Yes |

## Section A7.4.1.1 Aquatic toxicity, initial tests
**Annex Point IIA VII.7.1** Acute toxicity to fish

Although no decision can made whether all guidelines are fulfilled, the given results are adequate to show the nontoxicity of lauric acid to fish.

There are some deviations from the guidelines, but the main results, that the concentrations of NOEC and LC50 will not be reached by application and use of the biocidal product is not influenced. So there is no need for more studies of reproduction and growth rate of fish.

In addition lauric acid is readily biodegradable [55, 68], so that there will be no hazardous concentration for a longer period.

| | Evaluation by Competent Authorities |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | Evaluation by Rapporteur Member State |
| **Date** | Give date of action |
| **Materials and Methods** | State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion. |
| **Results and discussion** | Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers |
| **Conclusion** | Adopt applicant's version or include revised version |
| **Reliability** | Based on the assessment of materials and methods include appropriate reliability indicator |
| **Acceptability** | acceptable / not acceptable<br>(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.) |
| **Remarks** | |
| | Comments from ... |
| **Date** | Give date of comments submitted |
| **Materials and Methods** | Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br>Discuss if deviating from view of rapporteur member state |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

**Table A7_4_1_1-1: Preparation of TS solution for poorly soluble or volatile test substances**

| Criteria | Details |
|---|---|
| Dispersion | No |
| Vehicle | No |
| Concentration of vehicle | Not applicable. |
| Vehicle control performed | No |
| Other procedures | Stock solutions were prepared by warming equimolar quantities of sodium hydroxide and lauric acid in destilled water in a water bath to keep the soap in solution. Radiolabeled lauric acid in dimethyl sulfoxide (DMSO) was added to each stock (final concentration, 0.5 µl DMSO/L) to give specific activities. |

**Table A7_4_1_1-2: Dilution water**

| Criteria | Details |
|---|---|
| Source | Tap water, carbon-filtered for the control fish and for dilution of stock solution,<br>Distilled water for the preparation of the stock solutions of lauric acid. |
| Salinity | Not relevant. |
| Hardness | 96.5 mg/L $CaCO_3$ as mean during the test |
| pH | 7.6 as mean during the test |
| Oxygen content | 8 mg/L as mean during the test |
| Conductance | No data available. |
| Holding water different from dilution water | No data available. |

**Table A7_4_1_1-3: Test organisms**

| Criteria | Details |
|---|---|
| Species/strain | Zebrafish (Danio Rerio), no data available about the strain. |
| Source | No data available. |
| Wild caught | No data available. |
| Age/size | Juvenile fish (about 2 month old) |
| Kind of food | Proprietary fish food (Tetramin®) and Artemia |
| Amount of food | During week: 2% of their wet weight Tetramin and Artemia<br>Weekend: only Tetramin at 4% of their body weight |
| Feeding frequency | Once daily |
| Post-hatch transfer time | No data available. |
| Time to first feeding | No data available. |

**Table A7_4_1_1-4: Test system**

| Criteria | Details |
|---|---|
| Test type | Flow-through |
| Renewal of test solution | Flow rate: 170-180 ml/min<br>One volume replacement occurred every 28 min.<br>Continous flowing media were supplied by pumping sodium laurate stocks with peristaltic pumps and diluting them with carbon filtered tap-water, which was gravity fed. Sodium laurate stock solutions were mixed with dilution water in sidearm flasks (stirred with magnetic stirrer) before flowing into the test vessel. |
| Volume of test vessels | 5 L |
| Volume/animal | No data available. |
| Number of animals/vessel | No data available. |
| Number of vessels/ concentration | No data available. |
| Test performed in closed vessels due to significant volatility of TS | No data available. |

**Table A7_4_1_1-5: Test conditions**

| Criteria | Details |
|---|---|
| Test temperature | Mean temperature of solution: 35-40°C, dilution water: 21.5°C |
| Dissolved oxygen | 8 mg/L as mean during the test (see above) |
| pH | 7.6 as mean during the test (see above) |
| Adjustment of pH | No data available. |
| Aeration of dilution water | No data available. 8 mg/L as mean during the test |
| Intensity of irradiation | No data available. |
| Photoperiod | 16-h-light/8-h-dark photoperiod |

**Table A7_4_1_1-6: Mortality data**

**Not applicable.**

**Table A7_4_1_1-7: Effect data**

| | 4 d | 8 d | 15 d | 28 d |
|---|---|---|---|---|
| $LC_0$ | not determined | not determined | not determined | not determined |
| $LC_{50}$ | > 20 mg/L (n) | 12 mg/L (n) | 9.9 mg/L (n) | 9.8 mg/L (n) |
| $LC_{100}$ | not determined | not determined | not determined | not determined |

effect data are based on nominal (n) or measured (m) concentrations

**Table A7_4_1_1-8: Validity criteria for acute fish test according to OECD Guideline 203**

| | fulfilled | Not fullfilled |
|---|---|---|
| Mortality of control animals <10% | x | |
| Concentration of dissolved oxygen in all test vessels > 60% saturation | No decision is made, because no data of saturation are available | |
| Concentration of test substance ≥80% of initial concentration during test | x | |

| | | |
|---|---|---|
| Criteria for poorly soluble test substances | | |
| Special preparation of test solution is conducted. | x | |
| | | |

## Section A7.4.1.2 Acute toxicity to invertebrates

**Annex Point IIA7.2** Daphnia magna

Official use only

### 1 REFERENCE

| | | |
|---|---|---|
| **1.1** | **Reference** | Hafner C, 2006, Daphnia immobilisation test with ContraZeck Lotion according to OECD-Test Guideline 202, unpublished [133]. |
| **1.2** | **Data protection** | Yes |
| 1.2.1 | Data owner | Dr. R. Pfleger Chemische Fabrik GmbH |
| 1.2.2 | Criteria for data protection | Data submitted to the MS after 13 May 2000 on existing active substance for the purpose of its authorisation. |

### 2 GUIDELINES AND QUALITY ASSURANCE

| | | |
|---|---|---|
| **2.1** | **Guideline study** | Yes |
| **2.2** | **GLP** | Yes |
| **2.3** | **Deviations** | Yes, the preliminary tests for range finding was performed without GLP. |

### 3 MATERIALS AND METHODS

| | | |
|---|---|---|
| **3.1** | **Test material** | As given in section B2 [redacted] |
| 3.1.1 | Lot/Batch number | 43232 |
| 3.1.2 | Specification | As given in section B2 [redacted] |
| 3.1.3 | Purity | [redacted] |
| 3.1.4 | Composition of Product | As given in section B2 [redacted] |
| 3.1.5 | Further relevant properties | [redacted] |
| 3.1.6 | Method of analysis | [redacted] |
| **3.2** | **Preparation of TS solution for poorly soluble or volatile test substances** | [redacted] See table A7_4_1_2-1 |

## Section A7.4.1.2 Acute toxicity to invertebrates

**Annex Point IIA7.2** Daphnia magna

| | | |
|---|---|---|
| **3.3** | **Reference substance** | Yes, [redacted] |
| 3.3.1 | Method of analysis for reference substance | Not applicable. |
| **3.4** | **Testing procedure** | |
| 3.4.1 | Dilution water | See table A7_4_1_2-2 |
| 3.4.2 | Test organisms | See table A7_4_1_2-3 |
| 3.4.3 | Test system | See table A7_4_1_2-4 |
| 3.4.4 | Test conditions | See table A7_4_1_2-5 |
| 3.4.5 | Duration of the test | [redacted] |
| 3.4.6 | Test parameter | [redacted] |
| 3.4.7 | Sampling | [redacted] |
| 3.4.8 | Monitoring of TS concentration | Yes [redacted] |
| 3.4.9 | Statistics | [redacted] |

**4 RESULTS**

| | | |
|---|---|---|
| **Limit Test** | | Not performed. |
| 4.1.1 | Concentration | Not applicable, [redacted] |
| 4.1.2 | Number/ percentage of animals showing adverse effects | Not applicable, [redacted] |
| 4.1.3 | Nature of adverse effects | Not applicable, [redacted] |
| **Results test substance** | | |
| 4.1.4 | Initial concentrations of test substance | [redacted] |

4.1.5 Actual concentrations of test substance

[redacted]

4.1.6 Effect data (Immobilisation)

[redacted]

4.1.7 Concentration / response curve

[redacted]

[redacted]

[redacted]

4.1.8 Other effects

[redacted]

**Results of controls**

[redacted]

| | | |
|---|---|---|
| [redacted] | [redacted] | |
| | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |

See table A7_4_1_2-6

**Test with reference substance**

Not performed.

4.1.9 Concentrations

Not applicable.

4.1.10 Results

Not applicable.

## 5 APPLICANT'S SUMMARY AND CONCLUSION

**5.1 Materials and methods**

The test was conducted according to OECD-Test Guideline 202 without deviations.

[redacted]

**5.2 Results and discussion**

[redacted]

The results are confirmed by literature data [134], [redacted]

[redacted]. But the active substance is readily biodegradable in soil and water [55, 68].

In addition only very small quantities will be isolated in aquatic systems when used by humans as a repellent.

[redacted]

| | | |
|---|---|---|
| 5.2.1 | $EC_0$ | [redacted] |
| 5.2.2 | $EC_{50}$ | [redacted] |
| 5.2.3 | $EC_{100}$ | [redacted] |
| **5.3** | **Conclusion** | All validity critiera are considered to be fulfilled. |
| 5.3.1 | Reliability | 1 |
| 5.3.2 | Deficiencies | No |

| | **Evaluation by Competent Authorities** |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | *Give date of action* |
| **Materials and Methods** | *State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.* |
| **Results and discussion** | *Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers* |
| **Conclusion** | *Adopt applicant's version or include revised version* |
| **Reliability** | *Based on the assessment of materials and methods include appropriate reliability indicator* |
| **Acceptability** | acceptable / not acceptable<br>*(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)* |

| Remarks | |
|---|---|
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Materials and Methods** | *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*<br>*Discuss if deviating from view of rapporteur member state* |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |

**Table A7_4_1_2-1: Preparation of TS solution for poorly soluble or volatile test substances**

| Criteria | Details |
|---|---|
| Dispersion | [redacted] |
| Vehicle | [redacted] |
| Concentration of vehicle | [redacted] |
| Vehicle control performed | [redacted] |
| Other procedures | [redacted] |

**Table A7_4_1_2-2: Dilution water**

| Criteria | Details |
|---|---|
| Source | [redacted] |
| Alkalinity | [redacted] |
| Hardness | [redacted] |
| pH | [redacted] |
| Ca / Mg ratio | [redacted] |
| Na / K ratio | [redacted] |
| Oxygen content | [redacted] |
| Conductance | [redacted] |
| Holding water different from dilution water | [redacted] |

**Table A7_4_1_2-3: Test organisms**

| Criteria | Details |
|---|---|
| Strain | Daphnia magna Strauss |
| Source | [redacted] |
| Age | [redacted] |
| Breeding method | [redacted] |
| Kind of food | [redacted] |
| Amount of food | [redacted] |
| Feeding frequency | [redacted] |
| Pretreatment | [redacted] |
| Feeding of animals during test | [redacted] |

**Table A7_4_1_2-4: Test system**

| Criteria | Details |
|---|---|
| Renewal of test solution | [redacted] |
| Volume of test vessels | [redacted] |
| Volume/animal | [redacted] |
| Number of animals/vessel | [redacted] |
| Number of vessels/ concentration | [redacted] |
| Test performed in closed vessels due to significant volatility of TS | [redacted] |

**Table A7_4_1_2-5: Test conditions**

| Criteria | Details |
|---|---|
| Test temperature | [redacted] |
| Dissolved oxygen | [redacted] |
| pH | [redacted] |
| Adjustment of pH | [redacted] |
| Aeration of dilution water | [redacted] |
| Quality/Intensity of irradiation | [redacted] |
| Photoperiod | [redacted] |

**Table A7_4_1_2-6: Immobilisation data**

| Test-Substance Concentration (nominal/effective) [1] [mg/l] | Immobile *Daphnia* | | | | | | |
|---|---|---|---|---|---|---|---|
| | Number | | Percentage | | Oxygen [mg/l] | pH | Tempera-ture [°C] |
| | [redacted] h | [redacted] h | [redacted] h | [redacted] h | [redacted] h | [redacted] h | [redacted] h |
| [redacted] | | | | | | | |
| [redacted] | | | | | | | |
| [redacted] | | | | | | | |
| [redacted] | | | | | | | |
| [redacted] | | | | | | | |
| [redacted] | | | | | | | |
| | | | | | | | |

[1] specify, if TS concentrations were nominal or measured

**Table A7_4_1_2-7: Effect data**

| | $EC_{50}$ [1] | 95% c.l. | $EC_0$ [1] | $EC_{100}$ [1] |
|---|---|---|---|---|
| [redacted] | | | | |
| [redacted] | | | | |

[1] indicate if effect data are based on nominal (n) or measured (m) concentrations

**Table A7_4_1_2-8: Validity criteria for acute daphnia immobilistaion test according to OECD Guideline 202**

| | fulfilled | Not fullfilled |
|---|---|---|
| Immobilisation of control animals <10% | [redacted] | |
| Control animals not staying at the surface | [redacted] | |
| Concentration of dissolved oxygen in all test vessels > 60% of starting concentration | [redacted] | |
| Concentration of test substance ≥80% of initial concentration during test | | [redacted] |

| | | |
|---|---|---|
| Criteria for poorly soluble test substances completed | | |
| - Special preparation of testing solution | [redacted] | |

## Section A7.4.1.3 Growth inhibition test on algae

**Annex Point IIA7.3**

Official use only

### 1 REFERENCE

| | | |
|---|---|---|
| **1.1** | **Reference** | Hafner C, 2007, Report: Algae, Growth Inhibition Test with Lauric acid, according to OECD 201 (2006), Report No. 540, Hydrotox, unpublished [151]. |
| **1.2** | **Data protection** | Yes |
| 1.2.1 | Data owner | Dr. R. Pfleger Chemische Fabrik GmbH |
| 1.2.2 | Criteria for data protection | Data submitted to the MS after 13 May 2000 on existing active substance for the purpose of its authorisation. |

### 2 GUIDELINES AND QUALITY ASSURANCE

| | | |
|---|---|---|
| **2.1** | **Guideline study** | Yes<br>OECD-Test Guideline 201 (2006) |
| **2.2** | **GLP** | Yes |
| **2.3** | **Deviations** | No |

### 3 MATERIALS AND METHODS

| | | |
|---|---|---|
| **3.1** | **Test material** | ContraZeck [redacted] |
| 3.1.1 | Lot/Batch number | Batch number 47851 |
| 3.1.2 | Specification | As given in section B3 (Doc. III-B) |
| 3.1.3 | Purity | [redacted] |
| 3.1.4 | Composition of Product | As given in section B2 (Doc. III-B): [redacted] |
| 3.1.5 | Further relevant properties | [redacted] |
| 3.1.6 | Method of analysis | [redacted] |
| **3.2** | **Preparation of TS solution for poorly soluble or volatile test substances** | [redacted] |
| **3.3** | **Reference** | [redacted] |

## Section A7.4.1.3 Growth inhibition test on algae

**Annex Point IIA7.3**

| | | |
|---|---|---|
| | **substance** | [redacted]. |
| 3.3.1 | Method of analysis for reference substance | [redacted]. |
| **3.4** | **Testing procedure** | |
| 3.4.1 | Culture medium | [redacted]: 1) [redacted] (A1) [redacted]. 2) [redacted] (A2) [redacted]. 3) [redacted] (A3) [redacted]. [redacted]. 4) [redacted] (A4) [redacted]. [redacted] |
| 3.4.2 | Test organisms | *See table A7_4_1_3-2* |
| 3.4.3 | Test system | *See table A7_4_1_3-3* |
| 3.4.4 | Test conditions | *See table A7_4_1_3-4* |
| 3.4.5 | Duration of the test | [redacted] |
| 3.4.6 | Test parameter | [redacted] |
| 3.4.7 | Sampling | [redacted]. |
| 3.4.8 | Monitoring of TS concentration | [redacted]. |

## Section A7.4.1.3 Growth inhibition test on algae

**Annex Point IIA7.3**

[redacted]

3.4.9 Statistics

[redacted]

**4 RESULTS**

| | | |
|---|---|---|
| **4.1** | **Limit Test** | Not performed |
| 4.1.1 | Concentration | Not applicable, [redacted]. |
| 4.1.2 | Number/ percentage of animals showing adverse effects | Not applicable, [redacted]. |
| **4.2** | **Results test substance** | |
| 4.2.1 | Initial concentrations of test substance | Nominal concentration: |
| 4.2.2 | Actual concentrations of test substance | Testing with alges: |

| [redacted] nominal [mg/L] | | | | | | |
|---|---|---|---|---|---|---|
| Effective concentration of lauric acid [redacted] | | | | | | |
| Effective concentration of lauric acid [redacted] | | | | | | |
| Effective | | | | | | |

## Section A7.4.1.3 Growth inhibition test on algae
**Annex Point IIA7.3**

| | | | | | | |
|---|---|---|---|---|---|---|
| concentration of lauric acid [redacted] | | | | | | |

LOQ = 0.05 mg/l, n.d. = not detected

Testing without alges:

| [redacted] nominal [mg/l] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
|---|---|---|---|---|---|---|
| Effective concentration of lauric acid [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Effective concentration of lauric acid [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] | [redacted] |
| Effective concentration of lauric acid [redacted] | [redacted] | - | - | - | - | - |

[redacted]

4.2.3 Growth curves

[redacted]

4.2.4 Concentration / response curve

[redacted]

## Section A7.4.1.3 Growth inhibition test on algae

**Annex Point IIA7.3**

[redacted]

| | | |
|---|---|---|
| 4.2.5 | Cell concentration data | See table A7_4_1_3-5 |
| 4.2.6 | Effect data (cell multiplication inhibition) | [redacted] |
| 4.2.7 | Other observed effects | Not applicable. |

## Section A7.4.1.3 Growth inhibition test on algae

**Annex Point IIA7.3**

**4.3 Results of controls**

[redacted]

**4.4 Test with reference substance**

[redacted]

4.4.1 Concentrations

[redacted]

4.4.2 Results

[redacted]

**5 APPLICANT'S SUMMARY AND CONCLUSION**

**5.1 Materials and methods**

The test was conducted according to the OECD-Test Guideline 201 after having discussed with and agreed by the German Umweltbundesamt (Federal Environment Agency)

[redacted]

**5.2 Results and discussion**

[redacted]

## Section A7.4.1.3 Growth inhibition test on algae

**Annex Point IIA7.3**

[redacted]

As the beginning of the food chain of aquatic organisms, the influence of the test item on algae will not have further consequences for aquatic organisms, because the algae toxicity is not high.

5.2.1 $NOEC_r$

[redacted]

5.2.2 $E_rC_{50}$

[redacted]

5.2.3 $E_bC_{50}$

[redacted]

**5.3 Conclusion**

[redacted]

In addition, the active substance lauric acid is omnipresent in the daily life, therefore the product [redacted] is not a special danger to the environment.

[redacted]

But the active substance is readily biodegradable in soil and water [55, 68]. [redacted]

The test was conducted after a discussion and is in agreement with the

## Section A7.4.1.3 Growth inhibition test on algae

**Annex Point IIA7.3**

| | | |
|---|---|---|
| | | German Umweltbundesamt (Federal Environment Agency) and therefore no further studies are necessary. |
| 5.3.1 | Reliability | 1 |
| 5.3.2 | Deficiencies | No |

| | Evaluation by Competent Authorities |
|---|---|
| | Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |
| | **EVALUATION BY RAPPORTEUR MEMBER STATE** |
| **Date** | *Give date of action* |
| **Materials and Methods** | *State if the applicants version is acceptable or indicate relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.* |
| **Results and discussion** | *Adopt applicant's version or include revised version. If necessary, discuss relevant deviations from applicant's view referring to the (sub)heading numbers* |
| **Conclusion** | *Adopt applicant's version or include revised version* |
| **Reliability** | *Based on the assessment of materials and methods include appropriate reliability indicator* |
| **Acceptability** | acceptable / not acceptable<br>*(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)* |
| **Remarks** | |
| | **COMMENTS FROM ...** |
| **Date** | *Give date of comments submitted* |
| **Materials and Methods** | *Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.*<br>*Discuss if deviating from view of rapporteur member state* |
| **Results and discussion** | *Discuss if deviating from view of rapporteur member state* |
| **Conclusion** | *Discuss if deviating from view of rapporteur member state* |
| **Reliability** | *Discuss if deviating from view of rapporteur member state* |
| **Acceptability** | *Discuss if deviating from view of rapporteur member state* |
| **Remarks** | |