Regulation (EU) no 528/2012 concerning the making available on the market and use of biocidal products

Evaluation of active substances

Assessment Report

Lauric acid

Product-type 19
(Attractants and Repellents)

March 2014
Germany
Lauric acid (PT 19)

Assessment report

Finalised in the Standing Committee on Biocidal Products at its meeting on 13 March 2014

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1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Principle of evaluation

This assessment report has been established as a result of the evaluation of lauric acid as product-type 19 (attractants and repellents), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market\(^1\), with the original view to the possible inclusion of this substance into Annex I or IA to that Directive.

The evaluation has therefore been conducted in the view to determine whether it may be expected, in light of the common principles laid down in Annex VI to Directive 98/8/EC, that there are products in product-type 19 containing lauric acid that will fulfil the requirements laid down in Article 5(1) b), c) and d) of that Directive.

1.2. Purpose of the assessment

The aim of the assessment report is to support a decision on the approval of lauric acid for product-type 19, and should it be approved, to facilitate the authorisation of individual biocidal products in product-type 19 that contain lauric acid. In the evaluation of applications for product-authorisation, the provisions of Regulation (EU) No 528/2012 shall be applied, in particular the provisions of Chapter IV, as well as the common principles laid down in Annex VI.

The conclusions of this report were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Regulation (EU) No 528/2012.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Regulation (EU) No 528/2012, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Procedure followed

This assessment report has been established as a result of the evaluation of lauric acid as product-type 19 (attractants and repellents), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market, with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Lauric acid (CAS-No. 143-07-7) was notified as an existing active substance, by Dr. R. Pfleger Chemische Fabrik GmbH, hereafter referred to as the applicant, in product-type 19.

Commission Regulation (EC) No 1451/2007 of 4 December 2007 lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, Germany was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for lauric acid as an active substance in Product Type 19 was 30.04.2006, in accordance with Annex V of Regulation (EC) No 2032/2003.

On 23.02.2006, German competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 03.08.2006.

On 17.05.2010, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 22.06.2010. The competent authority report included a recommendation for the inclusion of lauric acid in Annex IA and Annex I to the Directive for product-type 19.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 06.07.2010. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

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In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 13 March 2014.
2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Identity, Physico-chemical Properties and Method of Analysis of lauric acid

The active substance of the biocidal product is lauric acid. Synonyms of this fatty acid are dodecanoic acid, laurostearic acid and dodecoic acid. The substance is CAS and EC listed (CAS-No. 143-07-7, EC-No 205-582-1). No isomerism of lauric acid is known. The concentration of lauric acid is in the range of 98 – 100 %.

Lauric acid is a solid waxy white substance with a weak characteristic acid odour. The melting point is 44 °C and it’s thermally stable at room temperature. The vapour pressure is determined to 0.0012 Pa at 25 °C. Lauric acid shows a very low solubility in water at 20 °C with a typical solubility profile. Only weak temperature dependence was determined. Because of the formation of micelles at pH > 7, the solubility is determined at pH-values 3, 5 and in an un-buffered system. In double distilled water as the test system an increase of the water solubility is observed due to extended preincubation time (48 h: 12.0 mg/l, 96 h: 21.1 mg/l, T = 20°C). The variations could not be minimised using extended preincubation times and are comparable for the different used temperatures. The partition coefficient n-octanol/water is dependent on the pH-value. For the unionised form of the substance at pH = 3 and 5 the log Pow is determined to 5.2 (4.98). The surface tension of 53.48 mN/m of a 90 % saturated test solution confirms the surface activity of the substance.

A GC-method conducted according the method C in the monograph “2.4.22 Composition of fatty acids by gas chromatography” (Ph. Eur.) is used for determination of identity, purity and assay of lauric acid and its impurities. The concentrations of solutions and the chromatographic conditions are prepared in order to obtain evaluable results. The quantitative determination is made by determining the area of the corresponding peak as a percentage of the sum of the areas of all the peaks.

Identity, Physico-chemical Properties and Method of Analysis of ContraZeck Zeckenschutz Lotion

The biocidal product is a white, smooth, shining and homogeneous lotion with a weak soapy not rancid odour and a content of the active substance of 10.00 %.

The product has no explosive or oxidising properties, because none of the components have explosive or oxidising properties. The flash-point of every component is over 100°C or the component is not flammable. The pH-value of a 1% aqueous solution was determined as 5.01, the acidity of the lotion is 0.197% H₂SO₄. The relative density is determined according to 92/69/EC A.3 to D⁰ 4 0.9604. The absolute density of the product is 960 kg/m³. According to 92/69/EC A.15 the ignition temperature was determined at 440°C.

The stated shelf-life of the lotion is 3 years as stability studies according to ICH Q1A have shown.
No test is conducted for compatibility with other products, because it is not intended to be used together with other products.

The technique of gas chromatography is used for determination of identity and assay of the active substance in the biocidal product. The method is validated according the current guideline ICH Q2A Validation and Analytical Methods: Definitions and Terminology.

2.1.2. Intended Uses and Efficacy

Lauric acid (CAS No. 143-07-7) is to be used as a repellent (PT 19). Its intended use is in lotions (10% w/w of lauric acid (purity 98 – 100%) in the biocidal product) to be applied on human skin with the aim of repelling hard ticks (Ixodes ricinus). Acceptable laboratory studies have been submitted indicating a sufficient efficacy of lauric acid in repelling the target organisms for the inclusion into Annex I of the directive 98/8/EC to be recommended. The assessment of the data provided in support of the effectiveness of the accompanying product establishes that the product may be expected to display efficacy. However, all claims made for the product will need to be supported at product authorisation stage. Relevant product performance assessment should be based on tests that offer reasonable predictions of the benefits when using the product, i.e. reasonably sound estimations of the “duration of the effect” and “re-application time”.

In addition, in order to facilitate the work of granting or reviewing authorisations, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

Classification and Labelling of lauric acid

The participant’s proposal for classification and labelling of lauric acid isn’t equivalent to the criteria of EU Directive 67/548/EEC and Regulation (EC) No. 1272/2008. Based on the data available for this evaluation the following classification/labelling is proposed by the RMS:

Table 1 Proposed classification of lauric acid based on Directive 67/548/EEC

<table>
<thead>
<tr>
<th>Hazard Symbols, Indications of danger</th>
<th>Classification</th>
<th>Wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xi</td>
<td></td>
<td>Irritant</td>
</tr>
<tr>
<td>N</td>
<td></td>
<td>Dangerous for the Environment</td>
</tr>
<tr>
<td>R-phrases</td>
<td>R38</td>
<td>Irritating to skin</td>
</tr>
<tr>
<td></td>
<td>R41</td>
<td>Risk of serious damage to eyes</td>
</tr>
<tr>
<td></td>
<td>R50</td>
<td>Very toxic to aquatic organisms</td>
</tr>
</tbody>
</table>

Remark: The proposed classification and labelling of lauric acid is a result of the evaluation done by the RMS.
Table 2  Proposed classification of lauric acid based on Regulation (EC) No 1272/2008

<table>
<thead>
<tr>
<th>Classification</th>
<th>Wording</th>
</tr>
</thead>
</table>
| Hazard classes, Hazard categories | Skin Irrit. 2  
Eye Dam. 1  
Aquatic Acute 1 |
| Hazard statements | H315  
H318  
H400 |

Causes skin irritation  
Causes serious eye damage  
Very toxic to aquatic life

Remark: The proposed classification and labelling of lauric acid is a result of the evaluation done by the RMS.

Table 3  Proposed labelling of lauric acid based on Directive 67/548/EEC

<table>
<thead>
<tr>
<th>Labelling</th>
<th>Wording</th>
</tr>
</thead>
</table>
| Hazard Symbols, Indications of danger | Xi  
N |
| R-phrases | R38  
R41  
R50 |
| S-phrases | (S2)  
S26  
S 37/39  
S60  
S61 |

Irritant  
Dangerous for the Environment  
Irritating to skin  
Risk of serious damage to eyes  
Very toxic to aquatic organisms  
(Keep out of the reach of children)  
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice  
Wear suitable gloves and eye/face protection  
Use appropriate container to avoid environmental contamination.  
Avoid release to the environment and refer to special instructions/safety data sheet

Remark: The proposed classification and labelling of lauric acid is a result of the evaluation done by the RMS.
Table 4  Proposed labelling of lauric acid based on Regulation (EC) No 1272/2008

<table>
<thead>
<tr>
<th>Labelling</th>
<th>Wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pictograms</td>
<td>GHS05</td>
</tr>
<tr>
<td></td>
<td>GHS09</td>
</tr>
<tr>
<td>Signal Word</td>
<td>Danger</td>
</tr>
<tr>
<td>Hazard statements</td>
<td>H315</td>
</tr>
<tr>
<td></td>
<td>H318</td>
</tr>
<tr>
<td></td>
<td>H400</td>
</tr>
<tr>
<td>Suppl. Hazard statements</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>-</td>
</tr>
<tr>
<td>Precautionary statements</td>
<td>(P102)</td>
</tr>
<tr>
<td></td>
<td>P273</td>
</tr>
<tr>
<td></td>
<td>P280</td>
</tr>
<tr>
<td></td>
<td>P302+P352</td>
</tr>
<tr>
<td></td>
<td>P332+P313</td>
</tr>
<tr>
<td></td>
<td>P305+P351+P33</td>
</tr>
<tr>
<td></td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>P310</td>
</tr>
<tr>
<td></td>
<td>P391</td>
</tr>
<tr>
<td></td>
<td>P501</td>
</tr>
<tr>
<td>(Keep out of reach of children.)</td>
<td>Avoid release to the environment.</td>
</tr>
<tr>
<td>Wear protective gloves/eye protection/face protection.</td>
<td>IF ON SKIN: Wash with plenty of soap and water.</td>
</tr>
<tr>
<td>If skin irritation occurs: Get medical advice/attention.</td>
<td>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</td>
</tr>
<tr>
<td>Immediately call a POISON CENTER or doctor/physician.</td>
<td>Collect spillage.</td>
</tr>
<tr>
<td>Dispose of contents/container to …</td>
<td></td>
</tr>
</tbody>
</table>

Remark:

In deviation to the participant’s classification of lauric acid, a classification as ‘Irritant’, ‘Irritating to skin - Risk of serious damage to eyes’ (Xi; R38-41) is proposed by the RMS, due to the observed effects from the acute skin and eye irritation studies and subacute/subchronic dermal toxicity tests.

Classification and Labelling of ContraZeck Zeckenschutz Lotion

If the conventional method according to Directive 1999/45/EC was applied, a classification of the biocidal product as skin and eye irritant would be required. Due to the fact that their irritating effects result from their acidic and alkaline properties, which are buffered in the formulation, a classification and labelling is not appropriate. Additionally, studies performed with the product did also show no irritating effects.

Therefore, no classification of the biocidal product ContraZeck Zeckenschutz Lotion in respect to skin and eye irritation is required according to Directive 1999/45/EC and Regulation (EC) No. 1272/2008.
Summary & Conclusion:

Lauric acid is irritating to skin, possesses risk of serious damage to eyes and is toxic to aquatic organisms and readily biodegradable. Consequently it is classified according to Directive 67/548/EEC and Regulation (EC) No. 1272/2008. With regard to the content of lauric acid and its classification, the product does not have to be classified according to the Directive 1999/45/EC or Regulation (EC) No. 1272/2008.
2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

2.2.1.1. Effects assessment

Active Substance

Lauric acid is a saturated fatty acid naturally occurring in plants, animals, and humans. Natural sources of lauric acid in human food are e.g. coconut oil (48 % lauric acid), palm kernel oil (45 %), yeast extract (12 %) and butter (2.6 % lauric acid). It is also present in human mothers’ milk. For saturated fatty acids including lauric acid, the intake cited in the DAR under 91/414/EEC (2007, RMS IE, Table B.6-1) was 32.5 g/d for males and 23.3 g/d for females. The mean daily per capita intake of lauric acid as food additive has been estimated to be 0.6 and 1.2 mg/d in Europe and the USA, respectively, based on production statistics (WHO 1998). In another publication (Stofberg and Grundschober 1987), the intake of lauric acid from natural food sources in the USA is assumed to exceed that from the use as food additive by a factor of approx. 1250. By combining this information, one would arrive at an estimated daily consumption of about 1-1.5 g/person/d. For German population (age 14 – 80 yr), results of national dietary consumption study (‘Nationale Verzehrstudie II’) were used to estimate the mean daily intake of lauric acid. This representative study (N = 15371 persons) used dietary history method during a four week interval to survey mean dietary intake. Based on the answers of consumed meals, using standard recipes for preparation of such meals and composition of ingredients (taken from literature or food analyses), it was possible to calculate the mean daily intake of lauric acid: mean: 36.3 mg/kg bw/d (2.7 g/d; for combined sexes) (m: 38.9 mg/kg bw/d (3.1 g/d), f: 33.7 mg/kg bw/d (2.2 g/d)) and 95th percentile: 82.1 mg/kg bw/d (5.9 g/d; for combined sexes) (m: 89.5 mg/kg bw/d (6.7 g/d), f: 72.5 mg/kg bw/d (4.5 g/d)).

In contrast, in the context of the current dossier, the normal volume of biocidal product (containing 0.1 g lauric acid/mL) to be applied to a forearm is given by the applicant as 200 µl (cf. exposure assessment section, Doc IIB-3), which would be equivalent to 0.02 g lauric acid. Therefore, even if the b.p. would be applied to a larger part of the body surface, the resulting maximum additional exposure to lauric acid could still be assumed to be significantly lower than baseline exposure of the general population.

The generally low systemic toxicity profile of lauric acid has been established by a variety of international bodies/regulatory programs:

- Lauric acid has been evaluated by the 49th meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1997 together with other saturated aliphatic acyclic linear primary acids. The committee concluded that “…the substances in this group would not present safety concerns at the current levels of intake” (JECFA 1997, IPCS 1998). JECFA reviewed the available data for acute toxicity, short-term and chronic toxicity, genotoxicity and reproductive toxicity. Irritation and sensitisation were not covered be the report.

- The U.S. Food and Drug Administration (FDA) issued a statement that – subject to certain conditions not relevant in the context of this dossier – “…the food additive fatty
acids may be safely used in food and in the manufacture of food components...” (FDA 2005). The FDA assessment itself is not available to the German competent authorities.

- In 1987, an expert panel of the Cosmetic Ingredients Review (CIR), a US program funded by the Cosmetic, Toiletry, and Fragrance Association (CTFA), concluded that lauric acid and the other evaluated fatty acids were “...safe in present practices of use and concentration in cosmetics”. According to this publication, such practice would cover uses of up to 25 % lauric acid in cosmetic products (Anonymous 1987).
- Lauric acid is widely used and regarded as safe in household cleaning products as an emulsifier, soap or detergent according to an evaluation initiated by industry organisations CEFIC and A.I.S.E (HERA 2002). The CEFIC evaluation on C10-C22 fatty acids and its salts addressed acute toxicity, irritation/corrosion, sensitisation, repeated-dose toxicity, genotoxicity, carcinogenicity, reproduction and developmental toxicity.

For the greatest part, data on the toxicological profile of lauric acid as submitted by the notifier consist of published literature. Most of these data do not meet the quality standards of GLP and guideline studies, the reporting of the studies is often insufficient, in many cases only secondary literature is available, and/or the toxicological properties of the product formulation, instead of lauric acid, were investigated. Thus, only few studies are to some extent suitable for risk assessment purposes, and it is not possible to address every endpoint necessary for a complete evaluation.

In summary, from a formal point of view, most of the toxicological core data points as required by Dir. 98/8/EC were not sufficiently addressed by the dossier submitted by the applicant. Nevertheless, based on the generally accepted low systemic toxicity profile of the a.s., as well as the comparatively high baseline exposure of the general population, submission of further toxicity studies was not considered to be required by the RMS.

Absorption, Distribution, Excretion, and Metabolism

No reliable studies are available for gastrointestinal and skin absorption of lauric acid.

In the absence of valid studies, default absorption rates of 100 % are assumed for both routes.

As an endogenous fatty acid, lauric acid is widely distributed, it is catabolised via β-oxidation and tricarboxylic acid cycle pathways or metabolised to cholesterol and triacylglycerides. Alternative oxidation pathways are ω-oxidation (liver) and α-oxidation (brain). Degradation products from these pathways are either used as building blocks in endogenous biosynthesis or excreted, therefore a potential of lauric acid to accumulate in the body can be ruled out. A detailed description of these processes can be found in K. Stumpf, 1969. Metabolism of fatty acids. In: Annual Review of Biochemistry, 38: 159-212; in F. D. Gunstone, 1996. Fatty Acid and Lipid Chemistry, Blackie Academic and Professional, London or in F. D. Gunstone, 1967. An Introduction to the Chemistry and Biochemistry of Fatty Acids and Their Glycerides, 2. Edition, Chapman & Hall Limited, London.
**Acute Toxicity**

No suitable acute oral toxicity studies were submitted for the a.s. lauric acid. However, the LD50 reported in literature is > 10,000 mg/kg bw/d (Anonymous, J Amer Coll Toxicol 6(3):321-401, 1987).

With regard to acute dermal toxicity, only a study with the biocidal product was submitted. From this study it is concluded that the dermal LD50 of the lauric acid is > 200 mg/kg bw. Since no higher dose level was tested, information required for classification/labelling is incomplete.

Nevertheless, a low acute oral and dermal toxic potential of lauric acid can be assumed from the daily dietary intake and use of lauric acid-containing cosmetics, respectively, by the general population.

Non-submission of acute inhalation toxicity data is considered scientifically justified based on the lack of relevant inhalative exposure (low volatility of lauric acid).

No standard guideline tests for skin or eye irritation in rabbits were submitted for lauric acid.

Sato et al. investigated skin irritation by different carboxylic acids in 20 human volunteers and demonstrated a concentration-dependent increase in skin alterations. From this study and other published literature submitted by the applicant (Schaaf K and Gross F (1953), Z Physiol. Chem. 295, 119-128; Schaaf K and Gross F (1953), Dermatologia 106: 357-378; Kanaar P (1971), Dermatologica 142, 14-22, Schulz KH and Rose G (1957), Arch klin Exp Derm 205, 254-260), a skin irritating potential of lauric acid is evident (cf. Doc.IIIA-6). Repeated dermal application of the a.s. results in akanthosis and keratosis of the treated skin area as a result of continuing irritation.

In a review article, pure lauric acid was reported to have caused eye irritation with persistent corneal opacity, iritis, and mild conjunctivitis in a Draize test.

No data on the potential of lauric acid to induce respiratory irritation are available.

In human volunteers, in both a single-insult patch test and a 4-wk application study followed by a patch test no sensitising potential of the b.p. was observed. Generally, a negative patch test result would not be acceptable as the basis for not classifying a substance with respect to skin sensitisation, a.o. due to uncertainty about the pre-exposure status of test subjects. In the special case of lauric acid, however, the test substance being a common food and cosmetics ingredient, it can be assumed that all of the subjects tested would have been sufficiently exposed previous to being tested.

Based on the submitted tests it is therefore concluded that lauric acid is unlikely to be a skin sensitiser. No data on the potential of lauric acid to induce respiratory sensitisation are available.

**Medium-term Toxicity**

In an oral 18-wk rat study no effect of 100,000 ppm lauric acid (approx. 7.5 g/kg bw/d) on weight gain, organ weights, gross pathology, and mortality was observed.
In a dermal 6-wk study in rabbits inflammation and keratosis of skin areas (ears) treated with 5 % lauric acid in ethanol were observed. A dermal 8-10-d study in guinea pigs revealed acanthosis and skin irritation of the skin of animals treated with coconut oil (approx. 48 % lauric acid) or 50 % lauric acid. These findings reflect the skin irritating potential of lauric acid also observed in acute skin and eye irritation studies accounting for the proposed classification/labelling R38 (cf. “3.3 Irritation and corrosivity”). No NOAECs for local effects were identified in the dermal studies. However, in a repeated insult patch test for 4 weeks in humans investigating a product formulation with 10 % lauric acid no local effects were observed.

No further valid studies were submitted for this endpoint. However, in the view of the RMS, based on the fact that lauric acid is a common, naturally occurring food constituent and nutritional uptake is likely to exceed exposure via the biocidal product by far (cf. introductory section to this chapter), no further studies are required.

Genotoxicity

In vitro: Only one mutagenicity study was submitted for lauric acid, i.e. an Ames test with a negative test result.

In vivo: No studies available.

From a formal point of view, insufficient data on genotoxicity were submitted. However, the expected exposure to lauric acid via the biocidal product is considerably lower than the estimated daily uptake via food. Furthermore, lauric acid is a common, naturally occurring food constituent and nutritional uptake is likely to exceed exposure via the biocidal product by far (cf. introductory section to this chapter). There are no reasons to expect lauric acid to be genotoxic based on structure and on the testing results of other fatty acids. Therefore, submission of further genotoxicity studies is not considered to be required.

Chronic Toxicity/ Carcinogenicity

In a 21-months mouse study accepted as supplementary information no differences in body weight, mortality, lipid peroxidation and hepatic lipid composition were seen between mice receiving a diet containing 15 % coconut oil (~ 7.5 % lauric acid) and control groups fed without additional fat or receiving 15 % safflower oil.

No further valid studies were submitted by the notifier. In the view of the RMS, based on the fact that lauric acid is a common, naturally occurring food constituent and nutritional uptake is likely to exceed exposure via the biocidal product by far (cf. introductory section to this chapter), no further studies are required.

Reproduction Toxicity

No valid studies were submitted for this endpoint. However, in the view of the RMS, based on the fact that lauric acid is a common, naturally occurring food constituent and nutritional uptake is likely to exceed exposure via the biocidal product by far (cf. introductory section to this chapter), no further studies are required.
**Neurotoxicity**

No data were submitted. No further studies are required, since there is no evidence of a neurotoxic potential.

**Mechanistic Studies**

No data were submitted. However, in the view of the RMS, based on the fact that lauric acid is a common, naturally occurring food constituent and nutritional uptake is likely to exceed exposure via the biocidal product by far (cf. introductory section to this chapter), no further studies are required.

For other fatty acids, some toxicity data are available and summarised in the respective assessment reports (CA report on nonanoic acid and DAR on fatty acids).

**Medical Data**

Cases of intoxication with lauric acid are not reported in the published literature, as far as available to the applicant and RMS. In the light of the high baseline exposure of almost the entire human population, this is interpreted as a further piece of evidence for the generally low toxicity of the a.s..

**Summary & Conclusion**

Lauric acid is an endogenous fatty acid of generally low systemic toxicity. It is, however, considered to be a skin and eye irritant.

Due to the low systemic toxicity of lauric acid, and as exposure is estimated to be clearly below baseline exposure of the general population via food (daily consumption between 1.0 and 1.5 g/person/d - estimate for USA/Europe or 36.3 mg/kg bw/d - estimate derived from German dietary survey 2008), derivation of any toxicological reference dose was considered unnecessary. No residues in food are likely to arise from the foreseen use of the biocidal product. Therefore, neither an ADI nor an ARfD have been set. Derivation of an AEC for local (dermal) effects is considered not necessary by TM.

Summarising the study results and all considerations above, the a.s. lauric acid requires classification/labelling according to Directive 67/548/EEC and Regulation (EC) 1272/2008 (GHS) as follows:

**Xi; R38/41**

Skin Irrit. 2, H315; Eye Dam. 1, H318
2.2.1.2. Exposure assessment

*Exposure of Professionals*

Since the biocidal product ContraZeck Zeckenschutz Lotion is a ready for use consumer product an exposure assessment for professionals has not been performed.

*Exposure of Non-Professionals*

Primary use scenarios for non-professionals are dermal exposure by normal application and accidental oral ingestion. No data for such scenarios exists in TNsG. Assumptions base on instructions for use provided by the applicant and on simplified assumptions by RMS for accidental exposure.

*Summary of primary internal exposure values of the general public (consumer) to lauric acid from ContraZeck Zeckenschutz Lotion*

<table>
<thead>
<tr>
<th></th>
<th>Dermal exposure (mg/kg bw or mg/kg bw/d)</th>
<th>ACCIDENTAL Oral exposure (mg/kg bw or mg/kg bw/d)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute exposure – internal dose</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adults</td>
<td>10.9</td>
<td>16</td>
</tr>
<tr>
<td>Infants</td>
<td>21.2</td>
<td>96</td>
</tr>
<tr>
<td><strong>Chronic exposure – internal dose</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adults</td>
<td>21.8</td>
<td>not applicable</td>
</tr>
<tr>
<td>Infants</td>
<td>42.4</td>
<td>not applicable</td>
</tr>
</tbody>
</table>

Secondary exposure occurs if infants take up the biocidal product by licking hands or by skin-to-skin contact. Since no scenario and data are found in TNsG or any other validated source, estimate was performed on simplified assumptions by RMS.
Summary of secondary internal exposure of the general public (consumer) to lauric acid from ContraZeck Zeckenschutz Lotion

<table>
<thead>
<tr>
<th></th>
<th>Dermal exposure (mg/kg bw or mg/kg bw/d)</th>
<th>Oral exposure (mg/kg bw or mg/kg bw/d)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute exposure – internal dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infants</td>
<td>0.654</td>
<td>0.404</td>
</tr>
<tr>
<td>Chronic exposure – internal dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infants</td>
<td>1.307</td>
<td>0.808</td>
</tr>
</tbody>
</table>

2.2.1.3. Risk characterisation

Risk Assessment for Professionals

Since the biocidal product ContraZeck Zeckenschutz Lotion is a ready for use consumer product no risk characterisation for professionals is required.

Risk Assessment for Non-Professionals

Due to the very low toxicity of lauric acid, derivation of any toxicological reference doses was considered unnecessary. The estimated daily intake from natural sources (e.g. food) is 1.0 to 1.5 g/person/d (equivalent to 17 to 25 mg/kg bw/d), which is in the same order of magnitude or lower as the primary or secondary exposure to lauric acid by the biocidal product according to very conservative Tier I approach and even if ingested accidentally. Thus, it is concluded that there is no risk to human health by lauric acid from the primary and secondary exposure to the biocidal product.

Safety Measures for Non-Professionals

No specific measures will be required if the biocidal product is used as intended.
2.2.2. **Environmental Risk Assessment**

2.2.2.1. Fate and distribution in the environment

**Biodegradation**

The active substance, lauric acid, was classified as readily biodegradable according to the CO₂-evolution test as the ultimate biodegradation rate mounts up to > 60% within 28 days, fulfilling the 10-day window. The resulting rate constant in STP is \( k_{\text{STP}} = 1 \, \text{h}^{-1} \).

In view of the ready biodegradability, no further biodegradation tests are considered necessary by the RMS since the PEC/PNEC ratios in all environmental compartments are less than 1.

For PEC-calculations half-lives for biodegradation in surface water (\( DT_{50 \text{ surface water}} = 15 \) days) and in soil (\( DT_{50 \text{ soil}} = 30 \) days) may be derived as default values according to TGD for new and existing chemicals (2003), chapter 2.3.6.5, tables 7 and 8.

**Abiotic Degradation**

The fatty acid lauric acid is stable in water because the functional group of carboxylic acid is generally resistant to hydrolysis and no further hydrolysable functional group is available.

Photolytic degradation in water is excluded for lauric acid as it does not display chromophore properties at wavelengths above 290 nm.

An estimation of photochemical degradation of lauric acid in air resulted in a half-life of 27.5 hours (\( k_{\text{deg, air}} = 0.61 \, \text{d}^{-1} \) and a global 24-hours-mean of \( c(\text{OH})_{\text{air}} = 5 \times 10^5 \) molecules/cm³).

**Distribution**

The \( K_{\text{OC}} \) was determined by a QSAR-method implemented in the ACD software (Advanced Chemistry Development, Inc.). With ACD software following \( K_{\text{OC}} \) values were calculated for the environmentally relevant pH values:

\[
K_{\text{OC}} = 4878 \, \text{L/kg for the non-ionised form at pH 5 (free acid) and}
\]

\[
K_{\text{OC}} = 10.1 \, \text{L/kg for the ionised form at pH 8 (anion)}
\]

Experimental tests on adsorption/desorption behaviour of lauric acid could be conducted. Nevertheless, the RMS decided to accept the calculated results from the ACD software instead of requiring a test according to OECD Test Guideline 106 with radio labelled material due to the following reasons: the restricted intended use of the biocidal product, the low production volume of lauric acid for the use in PT 19 and the intrinsic properties of lauric acid (e.g. readily biodegradable, low solubility in water) probably causing technical and analytical problems when performing the test. The RMS points out that the decision for the determination of the \( K_{\text{OC}} \) of lauric acid is a special case.
The rounded $K_{OC}$ values of 10 L/kg and 4900 L/kg were used for the PEC calculation. The following risk assessment is carried out based on this range of determined PEC values. If there had been a concern for any environmental compartment, the RMS would have decided to request the adsorption / desorption test (with C14-labelled lauric acid) according to OECD TG 106. This approach has been agreed on via an e-mail consultation and at the TM III 08 (see Final Minutes, 8. Outcome of e-consultation: regarding substitution of the adsorption/desorption test by QSAR for formaldehyde and lauric acid, p. 50). Thus, lauric acid is classified as very high mobile for the anion form and slightly mobile for the free acid form in soil.

**Bioaccumulation**

The log $K_{OW}$ of 2.35 at pH 7 and the calculated BCF values for the aquatic (BCF$_{fish}$ = 19.86) and terrestrial compartment (BCF$_{earthworm}$ = 3.53), which are calculated on the basis of the physico-chemical properties, indicate that lauric acid is not expected to bioaccumulate extensively in the environment under pH-neutral conditions. It should be considered that lauric acid ionises in water and indicate a potential for bioaccumulation under acid pH-conditions with increasing log $K_{OW}$-values to 4.98 (at pH 5) and 5.2 (at pH 3). For PBT and bioaccumulation potential assessment the value for the dissociated molecule determined around a pH of 7 is considered more realistic. Therefore the risk for secondary poisoning via ingestion of contaminated food by birds or mammals is assumed to be low.

For an ultimate assessment of the bioaccumulation behaviour a bioconcentration study in fish according to OECD guideline 305 should be performed, but is not considered to be necessary by the RMS for this evaluation as lauric acid is readily biodegradable and exposure to the environment is limited based on the data for the biocidal product used as a repellent on human skin.

2.2.2.2. Effects assessment

**Aquatic Compartment**

The effect assessment of the aquatic compartment is based on a prolonged flow-through study with zebrafish (*Danio rerio*), an acute static study with *Daphnia magna* and on tests with the green algae *Desmodesmus subspicatus*. Two of the aquatic ecotoxicity studies (invertebrates and algae) were conducted with the biocidal product ContraZeck Zeckenschutz Lotion as a consequence of the fast disappearance of lauric acid in the test systems and the low solubility of the active substance itself.

Lauric acid is acute and chronic toxic to algae ($E_{C50} = 0.219$ mg/L, $E_{C10} = 0.079$ mg/L for *Desmodesmus subspicatus*) and this represents the most sensitive endpoint for the aquatic compartment. The $E_{C50}$ for acute toxicity towards invertebrates is 1.3 mg/L (*Daphnia magna*). For fish a $L_{C50}$ for acute toxicity of > 10 mg/L and a NOEC for long term toxicity of 2.0 mg/L were derived from the same prolonged test with *Danio rerio*.

Under consideration of all available aquatic data, a PNEC$_{water}$ of 1.58 µg as/L can be derived from the $E_{C10}$ for algae and using an assessment factor of 50.
**Sediment**

No data on sediment organisms were available. As a screening approach, a calculation according to the equilibrium partitioning method was performed under consideration of K\text{oc}\text{-} values for both the free acid and the anion of the active substance.

Proposed PNEC\text{sed} for the anion, K\text{OC} = 10: \quad \text{PNEC}_{\text{sed}} = 1.58 \, \mu g / kg \, \text{ww}

Proposed PNEC\text{sed} for the free acid, K\text{OC} = 4900: \quad \text{PNEC}_{\text{sed}} = 170 \, \mu g / kg \, \text{ww}

**Inhibition of microbial activity (aquatic)**

In a standard activated sludge respiration inhibition test with sludge from domestic sewage treatment plant an EC\text{50} of > 1000 mg/L was found. A PNEC\text{microorganism, STP} = 10 \, \text{mg/L} was derived, considering an assessment factor of 100.

**Atmosphere**

Lauric acid is not considered to be used as fumigant. Based on an estimated vapour pressure of 0.0012 Pa (T = 25 °C) or 0.0004 Pa (T = 20 °C), lauric acid will remain in very small quantities in the vapour phase in the ambient atmosphere. The Henry’s Law constant between 0.0068 and 0.0039 Pa⋅m\text{3}⋅mol\text{−1} (unbuffered system, T = 20 °C) point to potential of volatility from water.

With a half-life in air of 27.5 h, an accumulation of lauric acid in air is not to be expected.

On the basis of its physical and chemical properties, as e.g. absence of absorption bands in the so-called atmospheric window (800-1200 nm), short half-life, and absence of Cl, F, N or S substituents in the molecule, lauric acid is not expected to display adverse abiotic effects on the atmospheric environment.

**Terrestrial Compartment**

No studies on terrestrial organisms were conducted. Lauric acid may be released into terrestrial compartment via spreading of dry sewage sludge from municipal sewage treatment plant onto soil. The equilibrium partitioning method provides a preliminary PNEC value for both the free acid and the anion of the active substance.

Proposed PNEC\text{soil} for the anion, K\text{OC} = 10: \quad \text{PNEC}_{\text{soil}} = 465 \, \text{ng ai/kg ww}

Proposed PNEC\text{soil} for the free acid, K\text{OC} = 4900: \quad \text{PNEC}_{\text{soil}} = 137 \, \mu g / kg \, \text{ww}

2.2.2.3. PBT assessment

The PBT- and vPvB-Assessment for lauric acid was performed according to the guidance given in the TGD on risk assessment (2003) as described in part II, chapter 4.4 as well as following the new REACH legislation.
**P criterion:** Half life > 40 d freshwater or > 120 d in freshwater sediment

> 120 d in soil (according to the new REACH legislation)

According to ready biodegradability tests, lauric acid is considered to be readily biodegradable. On the basis of this classification, the P criterion is not fulfilled.

**B criterion:** BCF > 2000

At pH 7 the log $K_{OW}$ value for lauric acid is lower than 3. The bioconcentration factor was calculated by QSAR modelling according to the TGD and is 19.86 L/kg wet fish for fish and for earthworm BCF = 3.53 L/kg wet earthworm. Therefore, the B criterion can be considered to be not fulfilled under pH-neutral conditions.

Lauric acid ionises in water at neutral conditions (pKa 5.3) but at lower pH values a higher $K_{OW}$ has to be considered for the acid itself. With increasing $K_{OW}$ values of log $K_{OW} = 4.98$ at pH 5 and log $K_{OW} = 5.2$ at pH 3, a potential for bioaccumulation under acidic conditions is indicated.

**T criterion:** Long-term NOEC for freshwater organism < 0.01 mg/L or CMR or endocrine disrupting effects

The lowest long-term NOEC is 0.079 mg/L for the algae *Desmodesmus subspicatus*. Hence, its toxicity does not exceed the trigger. There are no indications for CMR or endocrine disrupting properties. Therefore, the T criterion is not fulfilled.

**Conclusion:** The active substance lauric acid is neither a PBT- nor a vP/vB-candidate.

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2.2.2.4. Exposure assessment

For environmental exposure estimation data about the biocidal product are provided by the applicant. For the life cycle stage “production”, no exposure assessment has been performed as the active substance is produced outside the EU. Information about the formulation process of ContraZeck Zeckenschutz Lotion is stated as confidential, the estimated PECs concerning the formulation process are listed in the directory for confidential data (confidential annex to Doc.II-8.3). No determination of regional concentrations was made, since the repellent’s use outlined is not considered to be of sufficiently large scale.

The estimation of environmental exposure during use of the repellent is made by calculating the emissions and then the concentrations for each environmental compartment on basis of the intended use. For this life cycle stage there are two main pathways of release into the environment, an indirect path via STP, called “body cleaning” - release pathway, and a direct path into surface water, called “swimming” – release pathway. Until now no specific
document or guidance are developed for products belonging to PT 19. Therefore, the environmental exposure assessment for the “body cleaning” – release pathway follows in many aspects the proposals published in the Emission Scenario Document and in the Technical Guidance Document on Risk Assessment (European Commission, 2003); for the “swimming” – release pathway the RMS developed a use-specific approach in agreement with the applicant (details explained in Doc II, chapter 8.3 and in the confidential annex to Doc.II-8.3). An alternative approach to calculate these two release pathways would be based on the amount of product daily used per person. This so-called consumption based approach has been checked by the RMS (see Doc II, chapter 8.3). From a reverse back calculation it becomes obvious that the consumption based approach results in a distinct overestimation of the total tonnage of a.s. brought on the market. Thus, this approach was rejected by RMS in the environmental risk assessment.

In the view of RMS the special case of KOC estimation of lauric acid for the estimation of environmental exposure has to be considered and is explained in chapter 2.2.2.1 (Distribution and Mobility).

2.2.2.5. Risk characterisation

For lauric acid the applicant provided data for the biocidal product used as a repellent on human skin for protecting against biting of hard ticks. For the production process of lauric acid no environmental exposure assessment and thus no risk characterisation was carried out.

In spite of no risk characterisation is required in the frame of the BPD 98/8/EC an environmental exposure assessment was accomplished for the formulation process of ContraZeck Zeckenschutz Lotion. Within the scope of the product authorization it has to be checked again whether the production and formulation processes as described by the applicant still apply.

Air Compartment

The PEC of lauric acid in air from its use as repellent against biting of hard ticks is considered to be negligible based on its physico-chemical properties. Moreover, lauric acid is not expected to have adverse abiotic or biotic effects on the atmosphere (please see chapter 2.2.2.2 of this document). In summary, no risk for the air compartment could be identified.

Aquatic Compartment including Sediment

Two different emission pathways were identified regarding the aquatic compartment:

- Emission via wastewater to STP and subsequently to surface water and sediment (“body cleaning” – release pathway)
- Emission directly to surface water and subsequently to sediment (“swimming”-release pathway).

The risk characterization for the aquatic and sediment compartment was done by comparing the PECs of the compartments with the relevant PNECs. For both emission pathways no unacceptable risk for the aquatic compartment including the STP was identified.
In summary, there is no risk for the aquatic compartment including sediment considering the $K_{OC}$ range between 10 and 4900 related to the use of lauric acid.

**Terrestrial Compartment including Groundwater**

Only one emission pathway was identified regarding the terrestrial compartment:

- Emission via wastewater to STP leading to releases to soil via sewage sludge deposition and subsequently to groundwater (“body cleaning” – release pathway)

In this scenario for the “swimming” – release pathway the terrestrial compartment is not concerned. The risk characterization for the aquatic and sediment compartment was done by comparing the PECs of the compartments with the relevant PNECs. For the “body cleaning” – release pathway with releases to soil from sewage sludge application no unacceptable risk for the terrestrial compartment including groundwater was identified.

In summary, no risk for the terrestrial compartment including groundwater is identified for the use of lauric acid considering the $K_{OC}$ range between 10 and 4900.

**Non Compartment specific Effects relevant to the Food Chain (Secondary Poisoning)**

With regard to the calculated values of $BCF_{fish}$ (19.86 L/kg wet fish) and $BCF_{earthworm}$ (3.53 kg wet earthworm) at pH 7, lauric acid is not expected to accumulate extensively in the environment under pH-neutral conditions. But it should be considered that lauric acid ionises in water and indicate a potential for bioaccumulation under acid pH-conditions with increasing log $K_{OW}$-values to 4.98 (at pH 5) and 5.2 (at pH 3). The risk for secondary poisoning is therefore assumed to be low via ingestion of contaminated food by birds or mammals.

**2.2.3. List of endpoints**

In order to facilitate the work of Member States in granting or reviewing authorisations, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.
3. PROPOSED DECISION

3.1. Background to the proposed decision

Article 10 of the Biocides Directive 98/8/EC addresses the inclusion of an active substance in the Annexes I, IA or IB. For the decision of inclusion or non-inclusion, it has to be examined if the criteria of article 10 (1) are fulfilled.

The biocidal product ContraZeck Zeckenschutz Lotion contains 10 % of the active substance lauric acid and is used as a repellent on human skin in order to protect against biting of hard ticks. The repellent is only intended for use of the general public.

Lauric acid is intended for use in lotions to be applied externally on human skin to repel hard ticks. Acceptable laboratory studies have been submitted indicating a sufficient efficacy of lauric acid in repelling the target organisms (Ixodes ricinus) for Annex I-inclusion to be recommended. The assessment of the data provided in support of the effectiveness of the accompanying product establishes that the product may be expected to display efficacy. However, all claims made for the product will need to be supported at product authorisation stage.

Lauric acid is a solid waxy white substance with a weak characteristic acid odour and an endogenous fatty acid of generally low toxicity. It is, however, considered to be a skin and eye irritant. Due to the low toxicity of lauric acid, and as exposure is estimated to be clearly below baseline exposure of the general population via food, derivation of any toxicological reference dose was considered unnecessary. No residues in food are likely to arise from the foreseen use of the biocidal product. Therefore, neither an ADI nor an ARfD have been set.

The active substance has no hazardous physico-chemical properties. The physico-chemical data of the substance are acceptable.

No risk for the air compartment could be identified. Moreover, there is no risk for the aquatic compartment including sediment and for the terrestrial compartment including groundwater considering the KOC range between 10 and 4900 related to the use of lauric acid. Additionally, the risk for secondary poisoning is assumed to be low via ingestion of contaminated food by birds or mammals.

Lauric acid is readily biodegradable, shows no considerably potential for bioaccumulation based on physicochemical properties under pH-neutral conditions and meets none of the PBT criteria. Furthermore, all criteria for Annex I, inclusion are fulfilled and the PEC/PNEC ratios for all environmental compartments are < 0.1.

Lauric acid is not considered as having endocrine-disrupting properties in the sense of Article 5(3), second and third subparagraphs.

Lauric acid is an endogenous fatty acid of generally low systemic toxicity. Due to the low systemic toxicity of lauric acid, and as exposure is estimated to be clearly below baseline exposure of the general population via food, derivation of any toxicological reference dose was considered unnecessary. No residues in food are likely to arise from the foreseen use of the biocidal product, therefore neither an ADI nor an ARfD have been set.
The substance fulfils the criteria for inclusion in Annex IA of article 10 paragraph 1 of Directive 98/8/EC under specific conditions. The classification with “risk of serious damage to eyes” and labelling with “R 41” in concentrations > 10 % in products and the environmental risk assessment has led to the conclusion Annex IA inclusion could apply under the following conditions: the concentrations of lauric acid in products have to be equal or less than 10 % and the production amounts do not increase in a manner that PEC/PNEC ratios for the concerning environmental compartments exceed 0,1.

In conclusion, lauric acid would fulfil the criteria for inclusion into Annex IA laid down in Article 10 (1) of Directive 98/8/EC.

3.2. Proposed decision

The overall conclusion from the evaluation of lauric acid for use in product-type 19 (Repellents and attractants), is that it may be possible to issue authorisations of products containing lauric acid in accordance with the conditions laid down in Article 5(1) b), c) and d) of Dir. 98/8/EC.

It is therefore proposed to approve lauric acid as an active substance for use in product-type 19 (Repellents and attractants), subject to the following specific conditions:

The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

Lauric acid is proposed to be classified as toxic to aquatic life of acute category 1. Therefore, although lauric acid would fulfil the criteria for inclusion into IA laid down in Article 10 (1) of Directive 98/8/EC, it can however not be proposed to be included in category 6 of Annex I of Regulation (EC) No. 528/2012 according to Article 28(1) and (2)(a).

3.3. Elements to be taken into account when authorising products

For the representative biocidal product ContraZeck Zeckenschutz Lotion no test for the technical characteristics was submitted. The only general description of emulsifiability und flowability/pourability could not be validated as these presented not results of accepted test methods. This was accepted by the RMS in line with the decision of the 22nd CA meeting that for the purposes of inclusion into Annex I of directive 98/8/EC, an entirely complete product dossier is not mandatory. Further information about the applicability of the validation data to the technical material could be requested by the corresponding MS CA at product authorisation stage.

Currently, no valid test for the determination of the adsorption coefficient KOC for lauric acid is available. The environmental exposure assessment was performed with calculated results by a QSAR-method implemented in the ACD software for the non-ionised form as well as for the ionised form of lauric acid (please see chapter 2.2.2.1 of this document). This topic was discussed on TM III 08 and the decision can be found in the Final Minutes of TM III 08 (8.
Outcome of e-consultation: regarding substitution of the adsorption/desorption test by QSAR for formaldehyde and lauric acid. When authorising products a refinement of Koc might become necessary by demanding an adsorption-desorption test according OECD Guideline No. 106.

As soon as the new ESD for PT 19 is endorsed at EU level, before authorising products containing lauric acid, the direct emission pathway to surface water in the environmental risk assessment should be considered when uses of products suggest this release pathway to be relevant.

The assessment of the data provided in support of the effectiveness of the accompanying product establishes that the product may be expected to display efficacy. However, all claims made for the product will need to be supported at product authorisation stage. Relevant product performance assessment should be based on tests that offer reasonable predictions of the benefits when using the product, i.e. reasonably sound estimations of the “duration of the effect” and “re-application time”.

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the approval.

For the stage of product authorisation a refinement of the environmental exposure assessment may be necessary. Additionally studies about the technical characteristics of the biocidal products need to be submitted.

Therefore, the RMS suggests to perform the following studies for the stage of product authorisation:

- Adsorption-Desorption test according OECD Guideline 106 with radio labelled material.
- Bioaccumulation study in fish according to OECD Guideline 305, unless a risk for bioaccumulation can be excluded by other data.
- Technical characteristics of the biocidal product.

3.5. Updating this Assessment Report

This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information submitted in relation with Regulation (EU) No 528/2012. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the approval of lauric acid.
## Appendix I: List of endpoints

### Chapter 1: Identity, Physical and Chemical Properties, Further Information, and Proposed Classification and Labelling

<table>
<thead>
<tr>
<th>Active substance (ISO Common Name)</th>
<th>Lauric acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function (e.g. fungicide)</td>
<td>Repellent</td>
</tr>
</tbody>
</table>

| Rapporteur Member State           | Germany     |

### Identity (Annex IIA, point II.)

<table>
<thead>
<tr>
<th>Chemical name (IUPAC)</th>
<th>Dodecanoic acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name (CA)</td>
<td>Dodecanoic acid</td>
</tr>
<tr>
<td>CAS-No</td>
<td>143-07-7</td>
</tr>
<tr>
<td>EC No</td>
<td>205-582-1</td>
</tr>
<tr>
<td>Other substance No</td>
<td></td>
</tr>
<tr>
<td>Minimum purity of the active substance as manufactured (g/kg or g/l)</td>
<td>980 g/kg</td>
</tr>
<tr>
<td>Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)</td>
<td></td>
</tr>
<tr>
<td>Molecular formula</td>
<td>C₁₂H₂₄O₂</td>
</tr>
<tr>
<td>Molecular mass</td>
<td>200.32 g/mol</td>
</tr>
<tr>
<td>Structural formula</td>
<td><img src="image" alt="Structural formula" /></td>
</tr>
</tbody>
</table>
### Physical and chemical properties (Annex IIA, point III., unless otherwise indicated)

<table>
<thead>
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<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting point (state purity)</td>
<td>44°C (purity not stated)</td>
</tr>
<tr>
<td>Boiling point (state purity)</td>
<td>298°C (101.3 kPa) (purity not stated)</td>
</tr>
<tr>
<td>Temperature of decomposition</td>
<td>—</td>
</tr>
<tr>
<td>Appearance (state purity)</td>
<td>Solid, waxy and white with a weak characteristic acid odour (purity: 98.7 %)</td>
</tr>
<tr>
<td>Relative density (state purity)</td>
<td>D° = 0.883 (purity not stated)</td>
</tr>
<tr>
<td>Surface tension</td>
<td>53.48 mN/m (c = 90 % saturated concentration, T = 20°C, purity 99.6 %)</td>
</tr>
<tr>
<td>Vapour pressure (in Pa, state temperature)</td>
<td>0.0012 Pa (T=25°C),</td>
</tr>
<tr>
<td></td>
<td>0.0004 Pa (T=20°C)</td>
</tr>
<tr>
<td></td>
<td>(purity: 99.6 %)</td>
</tr>
<tr>
<td>Henry’s law constant (Pa m³ mol⁻¹)</td>
<td>0.0068 – 0.0039 Pa m³ mol⁻¹ (un-buffered system, T = 20°C),</td>
</tr>
<tr>
<td></td>
<td>0.036 Pa m³ mol⁻¹ (pH = 3, T = 20°C)</td>
</tr>
<tr>
<td>Solubility in water (g/l or mg/l, state temperature)</td>
<td>pH__3____: 2.5 mg/L at 10°C; 2.3 mg/L at 20°C;</td>
</tr>
<tr>
<td></td>
<td>3.1 mg/L at 30°C (purity: 99.6 %)</td>
</tr>
<tr>
<td></td>
<td>pH__5____: 2.5 mg/L at 10°C; 4.3 mg/L at 20°C;</td>
</tr>
<tr>
<td></td>
<td>6.4 mg/L at 30°C (purity: 99.6 %)</td>
</tr>
<tr>
<td></td>
<td>pH__7____: 12.0 mg/l – 21.1 mg/l (T = 20 °C, pH = un-buffered, 5.48 – 6.08) no temperature dependency, increase of the water solubility with extended preincubation times (48 h: 12.0 mg/l, 96 h: 21.1 mg/l)</td>
</tr>
<tr>
<td>Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)</td>
<td>additional data, no test report is submitted</td>
</tr>
<tr>
<td>Stability in organic solvents used in biocidal products including relevant</td>
<td>additional data, no test report is submitted</td>
</tr>
</tbody>
</table>
breakdown products (IIIA, point III.2)

<table>
<thead>
<tr>
<th>Partition coefficient (log $P_{\text{OW}}$) (state temperature)</th>
<th>pH__3__ : $\log P_{\text{OW}} = 5.10$ (room temperature)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pH__5__ : $\log P_{\text{OW}} = 4.98$ (room temperature)</td>
</tr>
<tr>
<td></td>
<td>pH__7__ : $\log P_{\text{OW}} = 2.35$ (room temperature)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hydrolytic stability ($DT_{50}$) (state pH and temperature) (point VII.7.6.2.1)</th>
<th>The active substance is stable in water.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)</th>
<th>additional data, no test report is submitted</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>UV/VIS absorption (max.) (if absorption $&gt; 290$ nm state $\varepsilon$ at wavelength)</th>
<th>The maximum absorption is at about 210 nm.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Photostability ($DT_{50}$) (aqueous, sunlight, state pH) (point VII.7.6.2.2)</th>
<th>No photodegradation of the active substance</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Quantum yield of direct phototransformation in water at $\sum &gt; 290$ nm (point VII.7.6.2.2)</th>
<th>—</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Lauric acid was found not to be highly flammable and to have no self-ignition temperature up to the melting point (44 °C at ambient pressure).</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Explosive properties</th>
<th>Explosive properties are not to be expected.</th>
</tr>
</thead>
</table>
Classification and proposed labelling (Annex IIA, point IX.)

with regard to physical/chemical data

Proposed classification of lauric acid based on Directive 67/548/EEC

<table>
<thead>
<tr>
<th>Classification</th>
<th>Indication of danger and R-phrases</th>
<th>wording</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Proposed labelling of lauric acid based on Directive 67/548/EEC

<table>
<thead>
<tr>
<th>Labelling</th>
<th>Indication of danger and R-phrases</th>
<th>wording</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

S phrases

<table>
<thead>
<tr>
<th>S phrases</th>
<th>wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>S26</td>
<td>In case of contact with eyes, rinse immediately with plenty of water and seek medical advice</td>
</tr>
<tr>
<td>S37/39</td>
<td>Wear suitable gloves and eye/face protection</td>
</tr>
</tbody>
</table>

Proposed classification of lauric acid based on REGULATION (EC) No. 1272/2008

<table>
<thead>
<tr>
<th>Classification</th>
<th>Hazard pictograms and hazard statements (HS)</th>
<th>wording</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hazard pictograms and hazard statements (HS)</th>
<th>wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>GHS05</td>
<td>Danger</td>
</tr>
<tr>
<td>Skin Irrit. 2, H315</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>Eye Dam. 1, H318</td>
<td>Causes serious eye damage</td>
</tr>
</tbody>
</table>

with regard to toxicological data

Proposed classification of lauric acid based on Directive 67/548/EEC

<table>
<thead>
<tr>
<th>Classification</th>
<th>Indication of danger and R-phrases</th>
<th>wording</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Xi; R38/41</td>
<td>Irritant; Irritating to skin; Risk of serious damage to eyes</td>
</tr>
</tbody>
</table>

Proposed labelling of lauric acid based on Directive 67/548/EEC

<table>
<thead>
<tr>
<th>Labelling</th>
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S phrases

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Proposed classification of lauric acid based on REGULATION (EC) No. 1272/2008

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<thead>
<tr>
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<tbody>
<tr>
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</tr>
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<th>Hazard pictograms and hazard statements (HS)</th>
<th>wording</th>
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<td>Causes skin irritation</td>
</tr>
<tr>
<td>Eye Dam. 1, H318</td>
<td>Causes serious eye damage</td>
</tr>
</tbody>
</table>
with regard to fate and behaviour data

Proposed classification of lauric acid based on Directive 67/548/EEC

<table>
<thead>
<tr>
<th>Classification</th>
<th>Indication of danger and R-phrases</th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

Proposed labelling of lauric acid based on Directive 67/548/EEC

<table>
<thead>
<tr>
<th>Indication of danger and R-phrases</th>
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<tr>
<td>—</td>
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Proposed classification of lauric acid based on REGULATION (EC) No. 1272/2008

<table>
<thead>
<tr>
<th>Classification</th>
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<tbody>
<tr>
<td></td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

with regard to ecotoxicological data

Proposed classification of lauric acid based on Directive 67/548/EEC

<table>
<thead>
<tr>
<th>Classification</th>
<th>Indication of danger and R-phrases</th>
<th>wording</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N R50</td>
<td>Dangerous for the Environment Very toxic to aquatic organisms</td>
</tr>
</tbody>
</table>

Proposed labelling of lauric acid based on Directive 67/548/EEC

<table>
<thead>
<tr>
<th>Indication of danger and R-phrases</th>
<th>Labelling</th>
<th>wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>S60</td>
<td>The material and its container must be disposed of as hazardous waste</td>
</tr>
<tr>
<td>R50</td>
<td>S61</td>
<td>Avoid release to the environment and refer to special instructions</td>
</tr>
</tbody>
</table>
Proposed classification of lauric acid based on REGULATION (EC) NO. 1272/2008

<table>
<thead>
<tr>
<th>Classification</th>
<th>Hazard pictograms and hazard statements (HS)</th>
<th>wording</th>
</tr>
</thead>
<tbody>
<tr>
<td>GHS09</td>
<td></td>
<td>Warning Hazardous to the aquatic environment</td>
</tr>
<tr>
<td>H400 – Acute Hazard Category I</td>
<td>Very toxic to aquatic life</td>
<td></td>
</tr>
</tbody>
</table>

Proposed labelling of lauric acid based on REGULATION (EC) No. 1272/2008

<table>
<thead>
<tr>
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<th>wording</th>
</tr>
</thead>
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<td></td>
<td>Warning Hazardous to the aquatic environment</td>
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<tr>
<td>H400 – Acute Hazard Category I</td>
<td>Very toxic to aquatic life</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Precautionary Statements</th>
<th>P273</th>
<th>P391</th>
<th>P501</th>
<th>wording</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Avoid release to the environment</td>
<td>Collect spillage.</td>
<td>Dispose of contents/container to …</td>
<td></td>
</tr>
</tbody>
</table>
### Chapter 2: Methods of Analysis

#### Analytical methods for the active substance

<table>
<thead>
<tr>
<th>Technical active substance (principle of method) (Annex IIA, point 4.1)</th>
<th>A gas chromatographic method is used for identification, purity and assay of lauric acid.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)</td>
<td>A gas chromatographic method is used for identification, purity and assay of lauric acid.</td>
</tr>
</tbody>
</table>

#### Analytical methods for residues

<table>
<thead>
<tr>
<th>Soil (principle of method and LOQ) (Annex IIA, point 4.2)</th>
<th>not required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Air (principle of method and LOQ) (Annex IIA, point 4.2)</td>
<td>not required</td>
</tr>
<tr>
<td>Water (principle of method and LOQ) (Annex IIA, point 4.2)</td>
<td>not required</td>
</tr>
<tr>
<td>Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)</td>
<td>not required</td>
</tr>
<tr>
<td>Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)</td>
<td>not required</td>
</tr>
<tr>
<td>Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)</td>
<td>not required</td>
</tr>
</tbody>
</table>
Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate and extent of oral absorption:</td>
<td>100 % (default value), no data</td>
</tr>
<tr>
<td>Rate and extent of dermal absorption:</td>
<td>100 % (default value), no data</td>
</tr>
<tr>
<td>Distribution:</td>
<td>Widely distributed</td>
</tr>
<tr>
<td>Potential for accumulation:</td>
<td>No evidence for accumulation</td>
</tr>
<tr>
<td>Rate and extent of excretion:</td>
<td>Complete</td>
</tr>
<tr>
<td>Metabolism</td>
<td>As an endogenous fatty acid, lauric acid is catabolised via β-oxidation and tricarboxylic acid cycle or metabolised to cholesterol and triacylglycerides. Alternate oxidation pathways are ω-oxidation (liver: CYP4A) and α-oxidation (brain).</td>
</tr>
<tr>
<td>Toxicologically significant metabolite</td>
<td>None</td>
</tr>
</tbody>
</table>

Acute toxicity (Annex IIA, point 6.1)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat LD$_{50}$ oral</td>
<td>No data, justification accepted</td>
</tr>
<tr>
<td>Rat LD$_{50}$ dermal</td>
<td>No data, justification accepted</td>
</tr>
<tr>
<td>Rat LC$_{50}$ inhalation</td>
<td>No data, justification accepted</td>
</tr>
<tr>
<td>Skin irritation</td>
<td>Irritant</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>Irritant</td>
</tr>
<tr>
<td>Skin sensitisation (test method used and result)</td>
<td>Not sensitising (patch test, human)</td>
</tr>
</tbody>
</table>
**Repeated dose toxicity** (Annex IIA, point 6.3)

<table>
<thead>
<tr>
<th>Species/target/critical effect</th>
<th>No systemic effects observed (oral admin., limited data)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Local effects (dermal exposure):</td>
</tr>
<tr>
<td>Rabbit</td>
<td>inflammation, keratosis</td>
</tr>
<tr>
<td>Guinea pig</td>
<td>skin irritation, acanthosis</td>
</tr>
<tr>
<td>Man</td>
<td>no effects observed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lowest relevant subacute/subchronic oral NOAEL</th>
<th>7.5 g/kg bw/d in a 18-wk rat study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lowest relevant chronic oral NOAEL</td>
<td>11 g/kg bw/d in a 21-mo mouse study</td>
</tr>
<tr>
<td>Lowest relevant dermal NOAEL</td>
<td>Systemic effects: no data, justification given</td>
</tr>
<tr>
<td></td>
<td>Local effects: Rabbits NOAEC: not identified, LOAEC: 5 % in a 6-wk study</td>
</tr>
<tr>
<td></td>
<td>Man: NOAEC: 10 % in 4-wk study with product formulation (repeated insult patch test)</td>
</tr>
<tr>
<td>Lowest relevant inhalation NOAEC</td>
<td>No data, justification accepted</td>
</tr>
</tbody>
</table>

**Genotoxicity** (Annex IIA, point 6.6)

<table>
<thead>
<tr>
<th>Species/type of tumour</th>
<th>Not mutagenic in the Ames test</th>
</tr>
</thead>
</table>

**Carcinogenicity** (Annex IIA, point 6.4)

<table>
<thead>
<tr>
<th>Species/type of tumour</th>
<th>No data, justification accepted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lowest dose with tumours</td>
<td>No data, justification accepted</td>
</tr>
</tbody>
</table>

**Reproductive toxicity** (Annex IIA, point 6.8)

<table>
<thead>
<tr>
<th>Species/Reproduction target/critical effect</th>
<th>No data, justification accepted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant parental NOAEL</td>
<td>No data, justification accepted</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>Relevant reproductive NOAEL</td>
<td>No data, justification accepted</td>
</tr>
<tr>
<td>Relevant offspring NOAEL</td>
<td>No data, justification accepted</td>
</tr>
</tbody>
</table>

**Developmental toxicity (Annex IIA, point 6.8)**

<table>
<thead>
<tr>
<th>Species/Developmental target/critical effect</th>
<th>No data, justification accepted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant maternal NOAEL</td>
<td>No data, justification accepted</td>
</tr>
<tr>
<td>Relevant developmental NOAEL</td>
<td>No data, justification accepted</td>
</tr>
</tbody>
</table>

**Neurotoxicity/Delayed neurotoxicity (Annex IIIA, point VI.1)**

<table>
<thead>
<tr>
<th>Species/ target/critical effect</th>
<th>No data – not required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant neurotoxicity NOAEL(s)</td>
<td>No data – not required</td>
</tr>
</tbody>
</table>

**Further studies (Annex IIIA, VI/XI)**

<table>
<thead>
<tr>
<th></th>
<th>No data – not required</th>
</tr>
</thead>
</table>

**Medical data (Annex IIA, point 6.9)**

<table>
<thead>
<tr>
<th></th>
<th>No cases of intoxication reported in spite of high dietary background exposure of the population; no effects in volunteers following 4 wk dermal exposure to product formulation with 10 % lauric acid.</th>
</tr>
</thead>
</table>
**Summary** (Annex IIA, point 6.10)

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>Study</th>
<th>Safety factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>AEL\textsubscript{acute}</td>
<td>Not allocated – not necessary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AEL\textsubscript{medium-term}</td>
<td>Not allocated – not necessary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AEL\textsubscript{long-term}</td>
<td>Not allocated – not necessary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADI (if residues in food or feed)</td>
<td>Not allocated – not necessary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARfD (if residues in food or feed)</td>
<td>Not allocated – not necessary</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Professional user**

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>Study</th>
<th>Safety factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference value for inhalation (proposed OEL)</td>
<td>Not allocated – not necessary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference value for dermal absorption</td>
<td>Not allocated – not necessary</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Acceptable exposure scenarios** (including method of calculation)

**Professional users**

- Production of active substance: Not allocated – not necessary
- Formulation of biocidal product: Not allocated – not necessary
- Intended uses: Not allocated – not necessary
- Secondary exposure: Not allocated – not necessary

**Non-professional users**

- **Acute exposure:**
  - Adult, dermal, application of b.p. acc. to instructions: 10.9 mg/kg bw
  - Infant, dermal, application of b.p. acc. to instructions: 21.2 mg/kg bw
  - Adult, oral, accidental intake of b.p.: 16 mg/kg bw
  - Infant, oral, accidental intake of b.p.: 96 mg/kg bw

- **Chronic exposure:**
Indirect exposure as a result of use (e.g. via food or feed)

<table>
<thead>
<tr>
<th></th>
<th>Adult, dermal, application of b.p. acc. to instructions: 21.8 mg/kg bw/d</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Infant, dermal, application of b.p. acc. to instructions: 42.4 mg/kg bw/d</td>
</tr>
<tr>
<td>Uptake via use of the b.p. is in the same order of magnitude than uptake via food.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Acute exposure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant, oral, licking fingers after application:</td>
<td>0.404 mg/kg bw</td>
</tr>
<tr>
<td>Infant, dermal, from adults after use of b.p.:</td>
<td>0.654 mg/kg bw/d</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Chronic exposure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant, oral, licking fingers after application:</td>
<td>0.808 mg/kg bw/d</td>
</tr>
<tr>
<td>Infant, dermal, from adults after use of b.p.:</td>
<td>1.307 mg/kg bw/d</td>
</tr>
<tr>
<td>Uptake via use of the b.p. is one to two orders of magnitude lower than uptake via food.</td>
<td></td>
</tr>
</tbody>
</table>

Combined Exposure

|                                | Combined exposure has not been assessed due to the low toxicity of lauric acid. Intake from other (natural) sources (e.g. food) is in the same order of magnitude than exposure related to biocidal use. |
Chapter 4:  Fate and Behaviour in the Environment

Route and rate of degradation in water (Annex IIA, point 7.6, IIIA, point XII.2.1, 2.2)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrolysis of active substance and relevant metabolites (DT$_{50}$) (state pH and temperature)</td>
<td>The active substance is stable in water.</td>
</tr>
<tr>
<td>Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites</td>
<td>No photodegradation of the active substance</td>
</tr>
<tr>
<td>Readily biodegradable (yes/no)</td>
<td>Yes</td>
</tr>
<tr>
<td>Biodegradation in seawater</td>
<td>not required</td>
</tr>
<tr>
<td>Non-extractable residues</td>
<td>not required</td>
</tr>
<tr>
<td>Distribution in water / sediment systems (active substance)</td>
<td>not required</td>
</tr>
<tr>
<td>Distribution in water / sediment systems (metabolites)</td>
<td>not required</td>
</tr>
</tbody>
</table>

Route and rate of degradation in soil (Annex IIIA, point VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineralization (aerobic)</td>
<td>not required</td>
</tr>
<tr>
<td>Laboratory studies (range or median, with number of measurements, with regression coefficient)</td>
<td>DT$_{50,lab}$ (20°C, aerobic): not required</td>
</tr>
<tr>
<td></td>
<td>DT$_{90,lab}$ (20°C, aerobic): not required</td>
</tr>
<tr>
<td></td>
<td>DT$_{50,lab}$ (10°C, aerobic): not required</td>
</tr>
<tr>
<td></td>
<td>DT$_{50,lab}$ (20°C, anaerobic): not required</td>
</tr>
<tr>
<td></td>
<td>degradation in the saturated zone: not required</td>
</tr>
<tr>
<td>Field studies (state location, range or median with number of measurements)</td>
<td>DT$_{50,c}$: not required</td>
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<tr>
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<td>DT$_{90,c}$: not required</td>
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<tr>
<td>Anaerobic degradation</td>
<td>not required</td>
</tr>
</tbody>
</table>
Soil photolysis
Non-extractable residues
Relevant metabolites - name and/or code, % of applied ai (range and maximum)
Soil accumulation and plateau concentration

| Adsorption/desorption (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2) |
|-----------------------------|-----------------------------|
| $K_a$, $K_d$                | $K_{OC}$ was determined by QSAR-method of ACD software. RMS decided to use the rounded values: |
| $K_{aoc}$, $K_{doc}$        |
| pH dependence (yes / no) (if yes type of dependence) | $K_{OC} = 4900$ L/kg (non-ionised form at pH 5, free acid) |
|                             | $K_{OC} = 10$ L/kg (ionised form at pH 8, anion) |
|                             | Yes, lower mobility at lower pH. |

Fate and behaviour in air (Annex IIIA, point VII.3, VII.5)

<table>
<thead>
<tr>
<th>Direct photolysis in air</th>
<th>not required</th>
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</thead>
<tbody>
<tr>
<td>Quantum yield of direct photolysis</td>
<td>not required</td>
</tr>
<tr>
<td>Photo-oxidative degradation in air</td>
<td>tropospherical half-life of lauric acid: 27.5 h (according to Atkinson, reaction with OH radicals, concentration: $5 \times 10^5$ OH/cm$^3$)</td>
</tr>
<tr>
<td>Volatilization</td>
<td>Henry’s law constant indicates moderately volatility.</td>
</tr>
</tbody>
</table>

Monitoring data, if available (Annex VI, para. 44)

<table>
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<tr>
<th>Soil (indicate location and type of study)</th>
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<td>Surface water (indicate location and type of study)</td>
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<tr>
<td>Ground water (indicate location and type of study)</td>
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<tr>
<td>Air (indicate location and type of study)</td>
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</table>
**Chapter 5: Effects on Non-target Species**

**Toxicity data for aquatic species** (most sensitive species of each group)

(Annex IIA, point 8.2, Annex IIIA, point 10.2)

<table>
<thead>
<tr>
<th>Species</th>
<th>Time-scale</th>
<th>Endpoint</th>
<th>Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fish</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><em>Danio rerio</em></td>
<td>96 h, flow-through</td>
<td>LC$_{50}$</td>
<td>&gt; 10 mg as/L</td>
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<tr>
<td></td>
<td>28 d, flow-through</td>
<td>NOEC</td>
<td>2 mg as/L</td>
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<tr>
<td><strong>Invertebrates</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Daphnia magna</em></td>
<td>48 h, static</td>
<td>EC$_{50}$</td>
<td>1.9 mg as/L (mean measured)</td>
</tr>
<tr>
<td><strong>Algae</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>Desmodesmus subspicatus</em></td>
<td>48 h, static</td>
<td>EC$_{50}$</td>
<td>0.219 mg as/L (mean measured)</td>
</tr>
<tr>
<td></td>
<td>48 h, static</td>
<td>EC$_{10}$</td>
<td>0.079 mg as/L (mean measured)</td>
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<tr>
<td><strong>Micro-organisms</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Activated sludge from sewage treatment plant (treating predominantly domestic sewage)</td>
<td>3 h, static</td>
<td>respiration inhibition</td>
<td>EC$_{50}$ &gt; 1000 mg/L (nominal)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>NOEC $\geq$ 1000 mg/L (nominal)</td>
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</tbody>
</table>

**Effects on earthworms or other soil non-target organisms**

Acute toxicity to

(Annex IIIA, point XIII.3.2) not available

Reproductive toxicity to

(Annex IIIA, point XIII.3.2) not available
### Effects on soil micro-organisms (Annex IIA, point 7.4)

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<th>Process</th>
<th>Status</th>
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<tr>
<td>Nitrogen mineralization</td>
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<tr>
<td>Carbon mineralization</td>
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### Effects on terrestrial vertebrates

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<th>Effect</th>
<th>Details</th>
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<tr>
<td>Acute toxicity to mammals</td>
<td>(Annex IIIA, point XIII.3.3) refer to mammalian toxicity package</td>
</tr>
<tr>
<td>Acute toxicity to birds</td>
<td>(Annex IIIA, point XIII.1.1) not available</td>
</tr>
<tr>
<td>Dietary toxicity to birds</td>
<td>(Annex IIIA, point XIII.1.2) not available</td>
</tr>
<tr>
<td>Reproductive toxicity to birds</td>
<td>(Annex IIIA, point XIII.1.3) not available</td>
</tr>
</tbody>
</table>

### Effects on honeybees (Annex IIIA, point XIII.3.1)

<table>
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<th>Details</th>
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<tr>
<td>Acute oral toxicity</td>
<td>not available</td>
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<tr>
<td>Acute contact toxicity</td>
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### Effects on other beneficial arthropods (Annex IIIA, point XIII.3.1)

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<tr>
<td>Acute oral toxicity</td>
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</tr>
<tr>
<td>Acute contact toxicity</td>
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<tr>
<td>Acute toxicity to</td>
<td>not available</td>
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</tbody>
</table>

### Bioconcentration (Annex IIA, point 7.5)

<table>
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<th>Bioconcentration factor (BCF)</th>
<th>Details</th>
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<tr>
<td>estimated on basis of log $K_{ow} = 2.35$ at pH 7 (QSAR) according to TGD on Risk Assessment (2003):</td>
<td>BCF&lt;sub&gt;fish&lt;/sub&gt; (calc.) = 19.86 L/kg&lt;sub&gt;fish&lt;/sub&gt; at pH 7 (eq. 74)</td>
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<tr>
<td></td>
<td>BCF&lt;sub&gt;earthworm&lt;/sub&gt; (calc.) = 3.53 L/kg&lt;sub&gt;earthworm&lt;/sub&gt; at pH 7 (eq. 82d)</td>
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<tr>
<td>Depratation time (DT&lt;sub&gt;50&lt;/sub&gt;) (DT&lt;sub&gt;90&lt;/sub&gt;)</td>
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<tr>
<td>Level of metabolites (%) in organisms accounting for &gt; 10 % of residues</td>
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</table>
Chapter 6: Other End Points
### Appendix II: List of Intended Uses

#### Summary of intended uses

<table>
<thead>
<tr>
<th>Object and/or situation</th>
<th>Member State or Country</th>
<th>Product name</th>
<th>Organisms controlled</th>
<th>Formulation</th>
<th>Application</th>
<th>Applied amount per treatment</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Repellent against ticks Prevention from Contacting and Biting</td>
<td>(a)</td>
<td>ContraZeck Zecken-schutz Lotion</td>
<td>Hard ticks (Ixodes ricinus)</td>
<td>Lotion</td>
<td>10% (m/m) Skin treatment with lotion</td>
<td>1 or 2 per day, 0 ml–2 ml</td>
<td>6 to 8 h Up to 0.7 g p.a.</td>
</tr>
</tbody>
</table>

(a) e.g. biting and sucking insects, fungi, molds; (b) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(c) GCPF Codes - GIFAP Technical Monograph No 2, 1989 ISBN 3-8263-3152-4; (d) All abbreviations used must be explained

(e) g/kg or g/l (f) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench;

(g) Kind, e.g. overall, broadcast, aerial spraying, row, bait, crack and crevice equipment used must be indicated;

(h) Indicate the minimum and maximum number of application possible under practical conditions of use;

(i) Remarks may include: Extent of use/economic importance/restrictions
Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked “Y” in the “Data Protection Claimed” column of the table below. These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

Reference list of studies on the active substance

<table>
<thead>
<tr>
<th>Section No / Reference No</th>
<th>Author(s)</th>
<th>Year</th>
<th>Title.</th>
<th>Source (where different from company)</th>
<th>Company, Report No.</th>
<th>GLP (where relevant) / (Un)Published</th>
<th>Data Protection Claimed (Yes/No)</th>
<th>Owner</th>
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<tbody>
<tr>
<td>A2.10, B7.1, A7.3.2</td>
<td>LYMAN et al.</td>
<td>1983</td>
<td>Handbook of chemical property estimation methods, McGraw-Hill Inc.; New York, published.</td>
<td>No</td>
<td>No owner</td>
<td>No</td>
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<tr>
<td>A3/ No.1</td>
<td>Gustav Heess</td>
<td>2000</td>
<td>Produkt-Spezifikation, Gustav Heess, unpublished.</td>
<td>No</td>
<td>No owner</td>
<td>No</td>
<td>Gustav Heess</td>
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<tr>
<td>Section No/Reference No</td>
<td>Author(s)</td>
<td>Year</td>
<td>Title.</td>
<td>Source (where different from company)</td>
<td>Company, Report No. GLP (where relevant) / (Un)Published</td>
<td>Data Protection Claimed (Yes/No)</td>
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<tr>
<td>A3/No. 149</td>
<td>Nyren V, Back E</td>
<td>1958</td>
<td>The ionisation constant, solubility product and solubility of lauric and myristic acid. Acta Chemica Scandinavica, <strong>12</strong> (6), 1305-1311, published.</td>
<td>No</td>
<td>No owner</td>
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<tr>
<td>A6.1.5, A6.4.2, A6.18/No. 45</td>
<td>Kanaar P</td>
<td>1971</td>
<td>Follicular-keratogenic properties of fatty acids in the external ear canal of the rabbit. Dermatologica <strong>142</strong>: 14-22, published.</td>
<td>No</td>
<td>No owner</td>
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<tr>
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<td>GLP (where relevant) / (Un)Published</td>
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<td>A6.18/No. 86</td>
<td>U.S. Food and Drug Administration</td>
<td>2005</td>
<td>Title 21 - Food and drugs, Chapter I - Food and drug administration department of health and human services, Subchapter B - Food for human consumption (continued), Part 172 - Food additives permitted for direct addition to food for human consumption</td>
<td>No</td>
<td>No owner</td>
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<td>A6.18/No. 87</td>
<td>Reddy BS, Maeura Y</td>
<td>1984</td>
<td>Tumor promotion by dietary fat in azoxymethane-induced colon carcinogenesis in female F344 rats: influence of amount and source of dietary fat. JNCI, 72(3): 745-750, published.</td>
<td>No</td>
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<td>A6.4.1.2/No. 116</td>
<td>Assman G, Schriewer H, Schmitz G, Hägele EO</td>
<td>1983</td>
<td>Quantification of high-density-lipoprotein cholesterol by precipitation with phosphotungstic Acid/MgCl2. Clinical Chemistry, 29/12, 2026-2030, published.</td>
<td>No</td>
<td>No owner</td>
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<tr>
<td>A6.5/No. 119</td>
<td>Morin RJ</td>
<td>1967</td>
<td>Longevity, Hepatic lipid peroxidation and hepatic fatty acid composition of mice fed saturated or unsaturated fat-supplemented diets. Experientia, 23(12): 1003-1004, published.</td>
<td>No</td>
<td>No owner</td>
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<tr>
<td>A6.5/No. 120</td>
<td>Stofberg J, Grund schober F</td>
<td>1987</td>
<td>Consumption ratio and food predominance of flavoring materials. Perfumer &amp; Flavorist, 12, 27-68, published.</td>
<td>No</td>
<td>No owner</td>
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<td>A7.1.1.1.1, A7.3.1/No. 66</td>
<td>Harris JC</td>
<td>1990</td>
<td>Rate of hydrolysis, In: Handbook of chemical property estimation methods, Washington DC: American Chemical Society, 7-4, published.</td>
<td>No</td>
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<td>A7.1.1.2/No. 67</td>
<td>Harris JC</td>
<td>1990</td>
<td>Rate of aqueous photolysis, In: Handbook of chemical property estimation methods, Washington DC: American Chemical Society, 8-4, 8-10, 8-12, published.</td>
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<td>A7.1.2.1, 7.6, B7.1/No. 144</td>
<td>Kronenberg-Schäfer K</td>
<td>2007</td>
<td>Study report: Biodegradability in the CO2-evolution test according to OECD 301 B (July 1992), Report No. 473, unpublished.</td>
<td>Yes</td>
<td>Dr. R. Pfleger GmbH</td>
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<td>Hafner C</td>
<td>2007</td>
<td>Study report: Algae, Growth Inhibition test with lauric acid, according to OECD 201 (2006), Report No. 475, unpublished.</td>
<td>Yes</td>
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<td>Hafner C</td>
<td>2008</td>
<td>Study report: Algae, Growth Inhibition Test with ContraZeck according to OECD 201 (2006), Report No. 540, unpublished</td>
<td>Yes</td>
<td>Dr. R. Pfleger GmbH</td>
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<td>A7.6/No. 129</td>
<td>Hawke J</td>
<td>1971</td>
<td>The incorporation of long-chain fatty acids into lipids by rumen bacteria and the effect on biohydrogenation. Biochimica et Biophysica Acta, 248: 167-170, published.</td>
<td>No</td>
<td>No owner</td>
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<td>B 4.1/No.136</td>
<td>Fuchs D</td>
<td>2006</td>
<td>Validation report, unpublished</td>
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<td>Dr. R. Pfleger GmbH</td>
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<td>B 7.7.1.1, B7.1/No. 132</td>
<td>Lebertz H</td>
<td>2006</td>
<td>Study on the “toxicity towards algae” of “ContraZeck (Ch.-B. 42945)” according to OECD-Test Guideline 201 (Algae, Growth Inhibition Test), Study No. IF-06/00634469, unpublished.</td>
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<td>Yes</td>
<td>Dr. R. Pfleger GmbH</td>
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<td>B 7.7.1.1, B7.1/No. 133</td>
<td>Hafner C</td>
<td>2006</td>
<td>Daphnia immobilisation test with ContraZeck Lotion according to OECD-Test Guideline 202, unpublished.</td>
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<td>Yes</td>
<td>Dr. R. Pfleger GmbH</td>
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<td>B.7.7.1.2/ No. 41</td>
<td>Aoyama T, Hardwick JP, Imaoka S, Funae Y, Gelboin HV, Gonzalez FJ</td>
<td>1990</td>
<td>Clofibrate-induced rat hepatic P450s IVA1 and IV3 catalyze the ω- and (ω1)-hydroxylation of prostaglandins E1 and F2α. Journal of Lipid Research 31: 1477-1482, published.</td>
<td></td>
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<td>No</td>
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<tr>
<td>B2.10, B7.4/No. 127</td>
<td>Lebertz H</td>
<td>2006</td>
<td>Study on the &quot;ready biodegradability&quot; of &quot;ContraZeck (Ch.-B. 42945)&quot;, Study No. IF-06/00580286, unpublished.</td>
<td></td>
<td></td>
<td>Yes</td>
<td>Dr. R. Pfleger GmbH</td>
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<td>Author(s)</td>
<td>Year</td>
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<td>Source (where different from company)</td>
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<td>B3, B5.10/No. 91</td>
<td>Gall A</td>
<td>2006</td>
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<td>2005</td>
<td>Standardarbeitsanweisung: Allgemeine Merkmale Bulkware, unpublished.</td>
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<td>Prüfanweisung PA052900 Laurinsäure, unpublished.</td>
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<td>Study report: Determination of Acidity or Alkalinity and pH value, unpublished.</td>
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<td>Prüfanweisung PA701510 ContraZeck, unpublished.</td>
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<td>Fuchs D</td>
<td>2006</td>
<td>Auswertung GC-Gehaltsbestimmungen, unpublished</td>
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<td>2007</td>
<td>Comments on the questions concerning approval of Lauric acid (CAS-Nr. 143-07-7) as tick repellent, unpublished</td>
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<td>Kröckel U</td>
<td>2006</td>
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