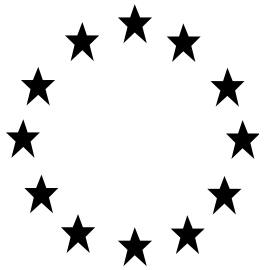
Regulation (EU) no 528/2012 concerning the making available on the market and use of biocidal products

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

CONTENTS

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 market1, 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 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

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[2], 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[3] 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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2 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

3 Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

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% H_2SO_4. The relative density is determined according to 92/69/EC A.3 to D^{20}_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

	Classification	Wording
Hazard Symbols, Indications of danger	Xi N	Irritant Dangerous for the Environment
R-phrases	R38 R41 R50	Irritating to skin Risk of serious damage to eyes Very toxic to aquatic organisms

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

	Classification	Wording
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

	Labelling	Wording
Hazard Symbols, Indications of danger	Xi N	Irritant Dangerous for the Environment
R-phrases	R38 R41 R50	Irritating to skin Risk of serious damage to eyes Very toxic to aquatic organisms
S-phrases	(S2) S26 S 37/39 S60 S61	(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

	Labelling	Wording
Pictograms	GHS05 GHS09	
Signal Word	Danger	
Hazard statements	H315 H318 H400	Causes skin irritation Causes serious eye damage Very toxic to aquatic life
Suppl. Hazard statements	-	-
Precautionary statements	(P102) P273 P280 P302+P352 P332+P313 P305+P351+P338 P310 P391 P501	(Keep out of reach of children.) Avoid release to the environment. Wear protective gloves/eye protection/face protection. IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/ attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician. Collect spillage. Dispose of contents/container to …

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 Verzehrsstudie 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)). (Remark: due to the employed method, the 95th percentile is no acute intake but represents the mean intake of high consumers; body weights derived from the data set of the NVS II.)

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

	Dermal exposure **(mg/kg bw or mg/kg bw/d)**	**ACCIDENTAL** **Oral exposure** **(mg/kg bw or mg/kg bw/d)**
Acute exposure – internal dose		
Adults	10.9	16
Infants	21.2	96
Chronic exposure – internal dose		
Adults	21.8	not applicable
Infants	42.4	not applicable

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

	Dermal exposure (mg/kg bw or mg/kg bw/d)	**Oral exposure (mg/kg bw or mg/kg bw/d)**
Acute exposure – internal dose		
Infants	0.654	0.404
Chronic exposure – internal dose		
Infants	1.307	0.808

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 CO_2- 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 $k_{STP} = 1\ h^{-1}$.

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 ($DT_{50\ surface\ water}$ = 15 days) and in soil ($DT_{50\ soil}$ = 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 ($k_{deg,\ air} = 0.61\ d^{-1}$ and a global 24-hours-mean of $c(OH)_{air} = 5 \times 10^5$ molecules/cm^3).

Distribution

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

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

K_{OC} = 10.1 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_{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 (sees 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_rC_{50} = 0.219 mg/L, E_rC_{10} = 0.079 mg/L for *Desmodesmus subspicatus*) and this represents the most sensitive endpoint for the aquatic compartment. The EC_{50} for acute toxicity towards invertebrates is 1.3 mg/L (*Daphnia magna*). For fish a LC_{50} 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_rC_{10} 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_{oc}-values for both the free acid and the anion of the active substance.

Proposed $PNEC_{sed}$ for the anion, K_{OC} = 10: $PNEC_{sed}$ = 1.58 µg as/kg ww

Proposed $PNEC_{sed}$ for the free acid, K_{OC} = 4900: $PNEC_{sed}$ = 170 µg as/kg ww

Inhibition of microbial activity (aquatic)

In a standard activated sludge respiration inhibition test with sludge from domestic sewage treatment plant an EC_{50} of > 1000 mg/L was found. A $PNEC_{microorganism, STP}$ = 10 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 $Pa \times m^3 \times mol^{-1}$ (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 $PNEC_{soil}$ for the anion, K_{OC} = 10: $PNEC_{soil}$ = 465 ng ai/kg ww

Proposed $PNEC_{soil}$ for the free acid, K_{OC} = 4900: $PNEC_{soil}$ = 137 µg ai/kg 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**.

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 K_{OC} 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 K_{OC} 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.

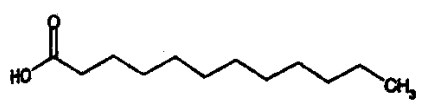
Appendix I: List of endpoints

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

Active substance (ISO Common Name)	Lauric acid
Function (*e.g.* fungicide)	Repellent

Rapporteur Member State	Germany

Identity (Annex IIA, point II.)

Chemical name (IUPAC)	Dodecanoic acid
Chemical name (CA)	Dodecanoic acid
CAS-No	143-07-7
EC No	205-582-1
Other substance No	
Minimum purity of the active substance as manufactured (g/kg or g/l)	980 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	
Molecular formula	$C_{12}H_{24}O_2$
Molecular mass	200.32 g/mol
Structural formula	

Physical and chemical properties (Annex IIA, point III., unless otherwise indicated)

Melting point (state purity)	44°C (purity not stated)
Boiling point (state purity)	298°C (101.3 kPa) (purity not stated)
Temperature of decomposition	—
Appearance (state purity)	Solid, waxy and white with a weak characteristic acid odour (purity: 98.7 %)
Relative density (state purity)	D_4^{20} = 0.883 (purity not stated)
Surface tension	53.48 mN/m (c = 90 % saturated concentration, T = 20°C, purity 99.6 %)
Vapour pressure (in Pa, state temperature)	0.0012 Pa (T=25°C), 0.0004 Pa (T=20°C) (purity: 99.6 %)
Henry's law constant (Pa m^3 mol^{-1})	0.0068 – 0.0039 Pa m^3 mol^{-1} (un-buffered system, T = 20°C), 0.036 Pa m^3 mol^{-1}(pH = 3, T = 20°C)
Solubility in water (g/l or mg/l, state temperature)	pH__3____: 2.5 mg/L at 10°C; 2.3 mg/L at 20°C; 3.1 mg/L at 30°C (purity: 99.6 %)
	pH__5____: 2.5 mg/L at 10°C; 4.3 mg/L at 20°C; 6.4 mg/L at 30°C (purity: 99.6 %)
	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/)
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	additional data, no test report is submitted
Stability in organic solvents used in biocidal products including relevant	additional data, no test report is submitted

breakdown products (IIIA, point III.2)	
Partition coefficient (log P_{OW}) (state temperature)	pH___3_: log P_{OW} = 5.10 (room temperature)
	pH___5_: log P_{OW} = 4.98 (room temperature)
	pH___7_: log P_{OW} = 2.35 (room temperature)
Hydrolytic stability (DT_{50}) (state pH and temperature) (point VII.7.6.2.1)	The active substance is stable in water.
Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)	additional data, no test report is submitted
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	The maximum absorption is at about 210 nm.
Photostability (DT_{50}) (aqueous, sunlight, state pH) (point VII.7.6.2.2)	No photodegradation of the active substance
Quantum yield of direct phototransformation in water at Σ > 290 nm (point VII.7.6.2.2)	—
Flammability	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).
Explosive properties	Explosive properties are not to be expected.

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

	Indication of danger and R-phrases	wording
Classification	—	—

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

	Labelling	wording
Indication of danger and R-phrases	—	—
S phrases	—	—

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

	Hazard pictograms and hazard statements (HS)	wording
Classification	—	—

with regard to toxicological data

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

	Indication of danger and R-phrases	wording
Classification	Xi; R38/41	Irritant; Irritating to skin; Risk of serious damage to eyes

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

	Labelling	wording
Indication of danger and R-phrases	Xi; R38/41	Irritant; Irritating to skin; Risk of serious damage to eyes
S phrases	S26 S37/39	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice Wear suitable gloves and eye/face protection

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

	Hazard pictograms and hazard statements (HS)	wording
Classification	 GHS05 Skin Irrit. 2, H315 Eye Dam. 1, H318	Danger Causes skin irritation Causes serious eye damage

with regard to fate and behaviour data

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

	Indication of danger and R-phrases	wording
Classification	—	—

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

	Labelling	wording
Indication of danger and R-phrases	—	—
S phrases	—	—

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

	Hazard pictograms and hazard statements (HS)	wording
Classification	—	—

with regard to ecotoxicological data

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

	Indication of danger and R-phrases	wording
Classification	N R50	Dangerous for the Environment Very toxic to aquatic organisms

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

	Labelling	wording
Indication of danger and R-phrases	N R50	Dangerous for the Environment Very toxic to aquatic organisms
S phrases	S60 S61	The material and its container must be disposed of as hazardous waste Avoid release to the environment and refer to special instructions

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

	Hazard pictograms and hazard statements (HS)	wording
Classification	 GHS09	Warning Hazardous to the aquatic environment
	H400 – Acute Hazard Category I	Very toxic to aquatic life

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

	Hazard pictograms and hazard statements (HS)	wording
Classification		Warning Hazardous to the aquatic environment
	H400 – Acute Hazard Category I	Very toxic to aquatic life
Precautionary Statements	P273 P391 P501	Avoid release to the environment Collect spillage. Dispose of contents/container to …

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method) (Annex IIA, point 4.1)	A gas chromatographic method is used for identification, purity and assay of lauric acid.
Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)	A gas chromatographic method is used for identification, purity and assay of lauric acid.

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)	not required
Air (principle of method and LOQ) (Annex IIA, point 4.2)	not required
Water (principle of method and LOQ) (Annex IIA, point 4.2)	not required
Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)	not required
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	not required
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)	not required

Chapter 3: Impact on Human Health

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

Rate and extent of oral absorption:	100 % (default value), no data
Rate and extent of dermal absorption:	100 % (default value), no data
Distribution:	Widely distributed
Potential for accumulation:	No evidence for accumulation
Rate and extent of excretion:	Complete
Metabolism	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).
Toxicologically significant metabolite	None

Acute toxicity (Annex IIA, point 6.1)

Rat LD_{50} oral	No data, justification accepted	
Rat LD_{50} dermal	No data, justification accepted	
Rat LC_{50} inhalation	No data, justification accepted	
Skin irritation	Irritant	R38
Eye irritation	Irritant	R41
Skin sensitisation (test method used and result)	Not sensitising (patch test, human)	

Repeated dose toxicity (Annex IIA, point 6.3)

Species/target/critical effect	No systemic effects observed (oral admin., limited data) Local effects (dermal exposure): Rabbit: inflammation, keratosis Guinea pig: skin irritation, acanthosis Man: no effects observed
Lowest relevant subacute/subchronic oral NOAEL	7.5 g/kg bw/d in a 18-wk rat study
Lowest relevant chronic oral NOAEL	11 g/kg bw/d in a 21-mo mouse study
Lowest relevant dermal NOAEL	Systemic effects: no data, justification given Local effects: Rabbit: NOAEC: not identified, LOAEC: 5 % in a 6-wk study Man: NOAEC: 10 % in 4-wk study with product formulation (repeated insult patch test)
Lowest relevant inhalation NOAEC	No data, justification accepted

Genotoxicity (Annex IIA, point 6.6)	Not mutagenic in the Ames test

Carcinogenicity (Annex IIA, point 6.4)

Species/type of tumour	No data, justification accepted
Lowest dose with tumours	No data, justification accepted

Reproductive toxicity (Annex IIA, point 6.8)

Species/Reproduction target/critical effect	No data, justification accepted

Relevant parental NOAEL	No data, justification accepted
Relevant reproductive NOAEL	No data, justification accepted
Relevant offspring NOAEL	No data, justification accepted

Developmental toxicity (Annex IIA, point 6.8)

Species/Developmental target/critical effect	No data, justification accepted
Relevant maternal NOAEL	No data, justification accepted
Relevant developmental NOAEL	No data, justification accepted

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

Species/ target/critical effect	No data – not required
Relevant neurotoxicity NOAEL(s)	No data – not required

Further studies (Annex IIIA, VI/XI)

No data – not required

Medical data (Annex IIA, point 6.9)

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.

Summary (Annex IIA, point 6.10)

	Value	Study	Safety factor
AEL_{acute}	Not allocated – not necessary		
$AEL_{medium\text{-}term}$	Not allocated – not necessary		
$AEL_{long\text{-}term}$	Not allocated – not necessary		
ADI (if residues in food or feed)	Not allocated – not necessary		
ARfD (if residues in food or feed)	Not allocated – not necessary		
Professional user			
Reference value for inhalation (proposed OEL)	Not allocated – not necessary		
Reference value for dermal absorption	Not allocated – not necessary		

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	<u>Acute exposure:</u> 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 <u>Chronic exposure:</u>

	Adult, dermal, application of b.p. acc. to instructions: 21.8 mg/kg bw/d Infant, dermal, application of b.p. acc. to instructions: 42.4 mg/kg bw/d Uptake via use of the b.p. is in the same order of magnitude than uptake via food.
Indirect exposure as a result of use (eg via food or feed)	<u>Acute exposure:</u> Infant, oral, licking fingers after application: 0.404 mg/kg bw Infant, dermal, from adults after use of b.p.: 0.654 mg/kg bw/d <u>Chronic exposure:</u> Infant, oral, licking fingers after application: 0.808 mg/kg bw/d Infant, dermal, from adults after use of b.p.: 1.307 mg/kg bw/d Uptake via use of the b.p. is one to two orders of magnitude lower than uptake via food.
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)

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	The active substance is stable in water.
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	No photodegradation of the active substance
Readily biodegradable (yes/no)	Yes
Biodegradation in seawater	not required
Non-extractable residues	not required
Distribution in water / sediment systems (active substance)	not required
Distribution in water / sediment systems (metabolites)	not required

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

Mineralization (aerobic)	not required
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): not required
	DT_{90lab} (20°C, aerobic): not required
	DT_{50lab} (10°C, aerobic): not required
	DT_{50lab} (20°C, anaerobic): not required
	degradation in the saturated zone: not required
Field studies (state location, range or median with number of measurements)	DT_{50f}: not required
	DT_{90f}: not required
Anaerobic degradation	not required

Soil photolysis	not required
Non-extractable residues	not required
Relevant metabolites - name and/or code, % of applied ai (range and maximum)	not required
Soil accumulation and plateau concentration	not required

Adsorption/desorption (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2)

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	K_{OC} was determined by QSAR-method of ACD software. RMS decided to use the rounded values: 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)

Direct photolysis in air	not required
Quantum yield of direct photolysis	not required
Photo-oxidative degradation in air	tropospherical half-life of lauric acid: 27.5 h (according to Atkinson, reaction with OH radicals, concentration: 5 x 10^5 OH/cm^3)
Volatilization	Henry's law constant indicates moderately volatility.

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

Soil (indicate location and type of study)	not available
Surface water (indicate location and type of study)	not available

Ground water (indicate location and type of study)	not available
Air (indicate location and type of study)	not available

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)

Species	Time-scale	Endpoint	Toxicity
Fish			
Danio rerio	96 h, flow-through	LC_{50}	> 10 mg as/L
	28 d, flow-through	NOEC	2 mg as/L
Invertebrates			
Daphnia magna	48 h, static	EC_{50}	1.9 mg as/L (mean measured)
Algae			
Desmodesmus subspicatus	48 h, static	E_rC_{50}	0.219 mg as/L (mean measured)
	48 h, static	E_rC_{10}	0.079 mg as/L (mean measured)
Micro-organisms			
Activated sludge from sewage treatment plant (treating predominantly domestic sewage)	3 h, static	respiration inhibition	EC_{50} > 1000 mg/L (nominal) NOEC ≥ 1000 mg/L (nominal)

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)

Nitrogen mineralization	not available
Carbon mineralization	not available

Effects on terrestrial vertebrates

Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	refer to mammalian toxicity package
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	not available
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	not available
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	not available

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

Acute oral toxicity	not available
Acute contact toxicity	not available

Effects on other beneficial arthropods (Annex IIIA, point XIII.3.1)

Acute oral toxicity	not available
Acute contact toxicity	not available
Acute toxicity to	not available

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor (BCF)	estimated on basis of log K_{ow} = 2.35 at pH 7 (QSAR) according to TGD on Risk Assessment (2003): BCF_{fish} (calc.) = 19.86 L/kg $_{wet\ fish}$ at pH 7 (eq. 74) $BCF_{earthworm}$ (calc..) = 3.53 L/kg$_{wet\ earthworm}$ at pH 7 (eq. 82d)
Depration time (DT_{50}) (DT_{90})	not available
Level of metabolites (%) in organisms accounting for > 10 % of residues	not available

Chapter 6: Other End Points

Appendix II: List of Intended Uses

Summary of intended uses

Object and/or situation (a)	Member State or Country	Product name	Organisms controlled (c)	Formulation		Application			Applied amount per treatment			Remarks: (m)
				Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	number min max (k)	interval between applications (min)	g a.s./L min max	water L/m^2 min max	g a.s./m^2 min max	
Repellent against ticks Prevention from Contacting and Biting		ContraZeck Zecken-schutz Lotion	Hard ticks (Ixodes ricinus)	Lotion	10% (m/m)	Skin treatment with lotion	1 or 2 per day, 0 ml -2 ml	6 to 8 h	Up to 0.7 g	p.a.	0.3 to 0.4 g a.s. / m^2 skin	The product is applied thinly on all parts of the skin that should be protected.

(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

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A2.10, A4.1, A6.1.2, A6.4.1.2, A6.5, A6.8.1.1, A7.4.2, A7.6/No. 121	Gunstone FD	1996	The majour sources of oils, fats, and other lipids. In: Gunstone FD, Fatty acid and lipid chemistry, London: Blackie academic & Professionals, 61-86, published.	No	No owner
A2.10, B7.1, A7.3.2	LYMAN et al.	1983	Handbook of chemical property estimation methods, McGraw-Hill Inc.; New York, published.	No	No owner
A3/ No. 4	Merck	2003	Sicherheitsdatenblatt gemäß 91/155/EWG, unpublished.	No	Merck
A3/ No.1	Gustav Heess	2000	Produkt-Spezifikation, Gustav Heess, unpublished.	No	Gustav Heess
A3/No. 114	Hunten KW, Maass O	1929	Investigation of surface tension constants in an homologous series from the point of view of surface orientation. Journal of the American Chemical Society, **51** (2): 153-165, published.	No	No owner
A3/No. 139	Möller M	2007	Study report: Vapour pressure, unpublished.	Yes	Dr. R. Pfleger GmbH
A3/No. 140	Schulze M	2007	Study report: Surface tension, unpublished.	Yes	Dr. R. Pfleger GmbH
A3/No. 141	Roos M	2007	Study report: Characterization of the molecular structure of lauric acid, unpublished.	Yes	Dr. R. Pfleger GmbH
A3/No. 142	Lange J	2007	Study report: Water solubility in dependance of pH and temperature (flask method), unpublished.	Yes	Dr. R. Pfleger GmbH
A3/No. 143	Lange J	2007	Study report: Partition coefficient (n-octanol/water) using HPLC method, unpublished.	Yes	Dr. R. Pfleger GmbH

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3/No. 149	Nyren V, Back E	1958	The ionisation constant, solubility product and solubility of lauric and myristic acid. Acta Chemica Scandinavica, **12** (6), 1305-1311, published.	No	No owner
A4.1/No. 92	Council of Europe (ed.)	2004	Monograph 2.4.22 Composition of fatty acids by gas chromatography. In: European Pharmacopoeia, Strasbourg: Council of Europe, 110-111, published.	No	No owner
A6.1.5, A6.4.2, A6.18/No. 45	Kanaar P	1971	Follicular-keratogenic properties of fatty acids in the external ear canal of the rabbit. Dermatologica **142:** 14-22, published.	No	No owner
A6.11, A6.18/No. 54	Parmeggiani L (ed.)	1983	Acids and anhydrids, organic, Saturated monocarboxylic acids. In: Encylopaedia of occupational health and safety, 3rd edition, 44-49, published.	No	No owner
A6.14/No. 62	Hazardous Substance Data Bank (HSDB) of the National Library of Medicine´s TOXNET system	2006	Report of Capric acid, from: http://toxnet.nih.gov/cgi-bin/sis/search/f?./temp/~tVG63D:29 :BASIC (10.01.2006), published.	No	No owner
A6.14/No. 63	Tan V, P.T. Musim Mas	2004	Material Safety Data Sheet Capric acid, from: http://www.musimmas.com/imgProduct/msds/CapricAcid.pdf (10.01.2006)	No	No owner
A6.14/No. 64	Environmental Health & Safety, Mallinckrodt Backer, Inc.	2003	Material Safety Data Sheet Palmitic acid, from: http://www.jtbaker.com/msds/englishhtml/p0011.htm (26.01.2006), published.	No	No owner
A6.14/No. 65	Hazardous Substance Data Bank (HSDB) of the National Library of Medicine´s TOXNET system	2006	Report of Palmitic acid, from: http://toxnet.hlm.nih.gov/cgi-bin/sis/search/f?./temp/~tVG63D:57 :htox (10.01.2006)	No	No owner
A6.18/No. 83	Green PG, Guy RH, Hadgraft J	1988	In vitro and in vivo enhancement of skin penetration with oleic and lauric acid. International Journal of Pharmaceutics, **48**: 103-111, published.	No	No owner

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.18/No. 84	Green PG, Handgraft J, Wolff M	1989	Physicochemical aspects of the transdermal delivery of Bupranolol. International Journal of Pharmaceutics, **55**: 265-269, published.	No	No owner
A6.18/No. 85	Smith SW, Anderson BD	1995	Human skin permeability enhancement by lauric acid under equilibrium aqueous conditions. Journal of Pharmaceutical Sciences, **84** (5): 551-556, published.	No	No owner
A6.18/No. 86	U.S. Food and Drug Administration	2005	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	No	No owner
A6.18/No. 87	Reddy BS, Maeura Y	1984	Tumor promotion by dietary fat in azoxymethane-induced colon carcinogenesis in female F344 rats: influence of amount and source of dietary fat. JNCl, **72**(3): 745-750, published.	No	No owner
A6.18/No. 88	Cohen LA, Thompson DO, Maeura Y, Choi K, Blank ME, Rose DP	1986	Dietary fat and mammary cancer. I. Promoting effects of different dietary fats on N-nitrosomethylurea induced rat mammary tumorigenesis. JNCI, **77** (1): 33-42, published.	No	No owner
A6.18/No. 89	Cohen LA, Thompson DO, Choi K, Karmali RA, Rose DP	1986	Dietary fat and mammary cancer. II. Modulation of serum and tumor lipid composition and tumor prostaglandins by different dietary fats: association with tumor incidence patterns. JNCI, **77** (1): 43-51, published.	No	No owner
A6.2, A6.18/No. 38	Beierwaltes WH, Ice RD, Shaw MJ, Ryo UY	1975	Myocardial uptake of labeled oleic and linoleic acids. Nucl Med, **16**(9): 842-845, published.	No	No owner
A6.2, A6.18/No. 39	Goldberg M, Escaig F	1984	An autoradiographic study of the in-vivo incorporation of [3H]-Palmitic acid into the dentine and enamel lipids of rat incisors, with a comparison of rapid-freezing freeze-substitution fixation and aldehyde fixation. Arch oral Biol. Vol. **29** (No. 9): 691-695, published.	No	No owner

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.4.1, A6.18/No. 42	Fitzhugh OG, Schouboe PJ, Nelson AA	1960	Oral toxicity of lauric acid and certain lauric acid derivates, Toxicol Appl Pharmacol **2**: 59-67, published.	No	No owner
A6.4.1, A6.18/No. 43	Joint FAO/WHO Expert Committee on Food Additives	2003	Summary of Evaluation Performed by the Joint FAO/WHO Expert Committee on Food Additives, Report TRS 884-JECFA 49/29, (www.inchem.org/documents/jecfa/jeceval/jec_1170.htm, 12.01.2006), published.	No	No owner
A6.4.1.2, A6.5/No. 115	Cox C, Sutherland W, Mann J, de Jong S, Chisholm A, Skeaff M	1998	Effects of dietary coconut oil, butter and safflower oil on plasma lipids, lipoproteins and lathosterol levels. European Journal of Clinical Nutrition, **52**, 650-654, published .	No	No owner
A6.4.1.2/No. 116	Assman G, Schriewer H, Schmitz G, Hägele EO	1983	Quantification of high-density-lipoprotein cholesterol by precipitation with phosphotungstic Acid/MgCl2. Clinical Chemistry, 29/12, 2026-2030, published.	No	No owner
A6.4.1.2/No. 117	Siedel J	1988	Immunoturbidimetric method for routine determinations of apolipoproteins A-I, A-II, and B in normo- and hyperlipemic sera compared with immunonephelometry. Clinical Chemistry, 34/9, 1821-1825, published.	No	No owner
A6.4.1.2/No. 118	Sutherland WHF	1991	Plasma noncholesterol sterols in male distance runners and sedentary men. European Journal of Applied Physiology, **63**: 119-123, published.	No	No owner
A6.4.2, A.6.5, A.6.6.2, A6.6.3, A6.18/No. 46	The Cosmetic, Toiletry & Fragrance Association (CTFA), U.S. Food & Drug Administration and the Consumer Federation of America	2005	Cosmetic Ingredient Review (http://www.cir-safety.org/staff_files/safeasused.pdf, 18.01.2006), published	No	No owner
A6.4.2, A6.18/No. 44	Gross F, Schaaf K	1953	Verhalten der Haut gegen Fettsäuren mittlerer Kettenlänge. Z Physiol Chem **295**: 119-128, published.	No	No owner

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.4.2, A6.18/No. 47	Schaaf F, Gross F	1953	Tierexperimentelle Untersuchungen mit Salben und Salbengrundlagen. Dermatologia **106**: 357-378, published.	No	No owner
A6.4.2, A6.18/No. 48	Schulz KH, Rose G	1957	Untersuchungen über die Reizwirkung von Fettsäuren und Alkylsulfaten definierter Kettenlänge auf die menschliche Haut. Arch klin Exp Derm **205**: 254-260, published.	No	No owner
A6.5, A6.18/No. 49	Verschuren K	1983	Lauric acid. In: Handbook of environmental data on organic chemicals. Van Nostrand Reinhold Company, New York, 791-798, 1983, published.	No	No owner
A6.5/ No. 122	Kaunitz H, Dayrit CS	1992	Coconut oil consumption and coronary heart disease. Philippine Journal of Internal Medicine, **30**: 165-171, published.	No	No owner
A6.5/No. 119	Morin RJ	1967	Longevity, Hepatic lipid peroxidation and hepatic fatty acid compositioin of mice fed saturated or unsaturated fat-supplemented diets. Experientia, **23**(12): 1003-1004, published.	No	No owner
A6.5/No. 120	Stofberg J, Grundschober F	1987	Consumption ratio and food predominance of flavoring materials. Perfumer & Flavorist, **12**, 27-68, published.	No	No owner
A6.6.1, A6.18/No. 50	Zeiger E, Anderson B, Haworth S, Lawlor & Mortelmans K	1988	Salmonella mutagenicity test: IV. Results from the testing of 300 chemicals. Environ Mol Mutagen **11** (suppl. 21): 1-158, published.	No	No owner
A6.7, A6.18/No. 51	Holsti P	1959	Tumor promoting effects of some long chain fatty acids in experimental skin carcinogenesis in mouse. Acta Pathol Microbiol Scand. **46**: 51-59, published.	No	No owner
A6.7, A6.18/No. 53	Swern D, Wieder R, McDonough M, Meranze DR, Skimkin MB	1970	Investigation of Fatty Acids and Derivatives for Carcinogenic Activity. Cancer Research **30**: 1037-1046, published.	No	No owner

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.7/No. 52	Ando K, Kato A, Kimura T, Suzuki S, Tamura G, Arima K	1970	Antitumor activity of fatty acids and their esters. I. Evaluation of antitumor activity of fatty acids. In: Progress in antimicrobial andt anticancer chemotherapie, Volume II, Baltimore, Maryland and Manchester: University Park Press, 136-141, published.	No	No owner
A6.8.1, A6.18/No. 57	Erickson KL, McNeill CJ, Gershwin ME, Ossmann JB	1980	Influence of dietary fat concentration and saturation on immune ontogeny in mice. J nutr **110**: 1555-1572, published.	No	No owner
A6.8.1, A6.18/No. 58	Nau H, Löscher W	1986	Pharmacologic evaluation of various metabolites and analoges of valproic acid: teratogenic potencies in mice.Fundam Appl Toxicol **6**: 669-676, published.	No	No owner
A7.1.1.1.1, A7.3.1/No. 66	Harris JC	1990	Rate of hydrolysis, In: Handbook of chemical property estimation methods, Washington DC: American Chemical Society, 7-4, published.	No	No owner
A7.1.1.1.2/ No. 67	Harris JC	1990	Rate of aqueous photolysis, In: Handbook of chemical property estimation methods, Washington DC: American Chemical Society, 8-4, 8-10, 8-12, published.	No	No owner
A7.1.1.2.1, 7.6, B7.1/No. 144	Kronenberg-Schäfer K	2007	Study report: Biodegradability in the CO2-evolution test according to OECD 301 B (July 1992), Report No. 473, unpublished.	Yes	Dr. R. Pfleger GmbH
A7.1.1.2.1, A7.1.3, A7.6/No. 69	Yonezawa Y	1982	Biodegradability of linear fatty acids by non-acclimated activated sludge. Kogai Shigene Kenkyusho Iho **12**: 85-91, published.	No	No owner
A7.1.3, 7.6/No. 145	Mills EAM, Mackenzie E	2007	Study report: Lauric acid: Estimation of adsorption coefficient (Koc) on soil and sewage sludge by HPLC (OECD 121), DRAFT Report No. LJ/07/001, unpublished.	Yes	Dr. R. Pfleger GmbH
A7.1.3, 7.6/No. 148	McCall PJ, Swann RL, Laskowski DA, Unger SM, Vrona SA, Dishburger HJ	1980	Estimation of chemical mobility in soil from liquid chromatographic retention times, Bull. Environm. Contam. Toxicol. **24**(1), 190-195, published	No	No owner

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.1.3, A7.1.4, A7.3.2, A7.6/No. 70	Melyan W, Howard PH	1992	Molecular Topology/Fragment Contribution Method for Predicting Soil Sorption Coeffizients. Environ Sci Technol **26**: 1560-1567, published.	No	No owner
A7.1.3, A7.6/No. 71	Swann RL, Laskowski, McCall PJ, Kuy KV, Dishburger HJ	1983	A rapid method for the estimation of the environmental parameters octanol/water partition coefficient, soil sorption constant, water to air ratio, and water solubility. In: Residue Reviews, **85**: 17-85, published.	No	No owner
A7.3.1, A7.6/No. 72	Atkinson R	1987	A structure-activity relationship for the estimation of rate constants for the gas-phase reactions of OH radicals with organic compunds. International Journal of Chemical Kinetics, **19**: 799-828, published.	No	No owner
A7.3.1, A7.6/No. 73	Winkeler HD, Puttins U, Levsen K	1988	Organic coumpons in rainwater. In: Vom Wasser, Weinheim, VCH, **70**: 107-117, published.	No	No owner
A7.3.1/No. 123	Atkinson R	1988	Estimation of gas-phase hydroxyl radical rate constants for organic chemicals. Environmental Toxicology and Chemistry, **7**: 435-442, published.	No	No owner
A7.3.2, A7.6/No. 74	Thomas RG	1990	Volatilization from water, In: Handbook of chemical property estimation methods, Washington DC: American Chemical Society, 15-15, 15-19, 15-32, published.	No	No owner
A7.3.2, A7.6/No. 75	Eisenreich SJ	1981	Airborne organic contaminations in the Great Lakes ecosystem. Environmental Science & Technology, **15**:30-38, published.	No	No owner
A7.3.2/No. 76	Graedel TE, Hawkins DT, Claxton LD	1986	Atmospheric Chemical Compounds, Sorces, Occurrence, and Bioassay, Orlando: Academic Press Inc, 1986, published.	No	No owner
A7.4.1.2/No. 134	Radix P, Leonard M, Papanthoniou C, Roman G, Saouter E, Gallotti-Schmitt S, Thiebaud H, Vasseur P	1999	Comparison of bachionus calyciflorus 2-D and microtox chronic 22-H tests with daphnia magna 21-D test for the chronic toxicity assessment of chemicals. Environmental Toxicology and Chemistry, **18**(10): 2178-2185, published.	No	No owner

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A7.4.1.3, 7.6/No. 146	Hafner C	2007	Study report: Algae, Growth Inhibition test with lauric acid, according to OECD 201 (2006), Report No. 475, unpublished.	Yes	Dr. R. Pfleger GmbH
A7.4.1.3, B7.7.1.1/No. 151	Hafner C	2008	Study report: Algae, Growth Inhibition Test with ContraZeck according to OECD 201 (2006), Report No. 540, unpublished	Yes	Dr. R. Pfleger GmbH
A7.4.1.4, 7.6/No. 147	Brunswike-Titze A	2007	Study report: Report: Activated sludge respiration inhibition test according to Guidline OECD 209 (April 1984), Report No. 474, unpublished.	Yes	Dr. R. Pfleger GmbH
A7.4.14/No. 124	Kitahara T, Aoyama Y, Hirakata Y, Shimeru K, Kohono S, Ichikawa N, Nakashima M, Sasaki H, Higuchi S	2006	In vitro activity of lauric acid or myristylamine in combination with six antimicrobial agents against methicillin-resistant Staphylococcus aureus (MRSA). International Journal of Antimicrobiological Agents, **27**: 51-57, published.	No	No owner
A7.4.14/No. 125	Kitahara T, Koyama N, Matsuda J, Aoyama Y, Hirakata Y, Kamihira S, Kohno S, Nakashima M, Sasaki H	2004	Antimicrobial activity of saturated fatty acids and fatty amines against methicillin-resistant Staphylococcus aureus. Biological & Pharmaceutical Bulletin, **27** (9): 1321-1326, published.	No	No owner
A7.4.2, A9/No. 131	Duschl A	2006	Primärstoffwechsel, from: http://www.natur.sbg.ac.at/arnulf/biochem/vlpdf/VL%20Biochemie%2010hi.pdf (04.07.2006), published.	No	No owner
A7.4.2/No. 126	Veith GD, DeFoe DL, Bergstedt BV	1979	Measuring and Estimating the Bioconcentration Factor of Chemicals in Fish. Journal of the Fisheries Research Board of Canada, **36**: 1040-1048, published.	No	No owner
A7.6/No. 128	Demeyeer DI, Hederson C, Prins RA	1978	Relative significance of exogenous and de novo synthesized fatty acids in the formation of rumen microbial lipids in vitra. Applied and Environmental Microbiology, **35**(1): 24-31, published.	No	No owner
A7.6/No. 129	Hawke J	1971	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.	No	No owner

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B 4.1/No.136	Fuchs D	2006	Validation report, unpublished	Yes	Dr. R. Pfleger GmbH
B 7.7.1.1, B7.1/No. 132	Lebertz H	2006	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.	Yes	Dr. R. Pfleger GmbH
B 7.7.1.1, B7.1/No. 133	Hafner C	2006	Daphnia immobilistation test with ContraZeck Lotion according to OECD-Test Guideline 202, unpublished.	Yes	Dr. R. Pfleger GmbH
B.7.7.1.2/ No. 40	Masoro EJ	1977	Lipids and lipid metabolism, Ann Rev Physiol **39**: 301-321, published.	No	No owner
B.7.7.1.2/ No. 41	Aoyama T, Hardwick JP, Imaoka S, Funae Y, Gelboin HV, Gonzalez FJ	1990	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.	No	No owner
B2.10, B6.7, B7.4, B7.6.1, B7.7.1.1, B7.7.1.1.1/ No. 55	Hazardous Substance Data Bank (HSDB) of the National Library of Medicine´s TOXNET system	1993	Report of Dodecanoic acid, from: http://toxnet.nlm.nih.gov/cgi-bin/sis/search/f?./temp/~rTJzCf:1 (18.01.2006), published.	No	No owner
B2.10, B7.4, B7.6.1, B7.7.1.1, B7.7.1.1.1/ No. 68	Malaney GW, Gerhold RM	1962	Structural determinants in the oxidative breakdown of aliphatic compounds by domestic activated sludges. Proc 17th Ind Waste Conf. Purdue Univ Ext Ser 112: 249-57 (1962): 249-257, published.	No	No owner
B2.10, B7.4/No. 127	Lebertz H	2006	Study on the "ready biodegradablility" of "ContraZeck (Ch.-B. 42945)", Study No. IF-06/00580286, unpublished.	Yes	Dr. R. Pfleger GmbH

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B2.10.1, B4.2, B6.1.2, B6.7.1.1, B6.7.1.2, B7.1, B7.7.1.1.2, B7.7.1.1.3, B7.7.1.2, B7.7.1.3, B7.2/No. 2	Gustav Heess	2000	Sicherheitsdatenblatt gemäß 91/155/EWG, Gustav Heess, unpublished.	No	Gustav Heess
B3, B5.10/No. 91	Gall A	2006	Stability data of the biocidal product, unpublished.	Yes	Dr. R. Pfleger GmbH
B3/ No. 10	Council of Europe (ed.)	2004	Monograph 2.2.10 Rotating Viscometer method. In: European Pharmacopoeia, Strasbourg: Council of Euorpe, 30, published.	No	No owner
B3/ No. 3	Hemmerich M	2005	Standardarbeitsanweisung: Allgemeine Merkmale Bulkware, unpublished.	Yes	Dr. R. Pfleger GmbH
B3/ No. 5	Council of Europe (ed.)	2004	Monograph 2.2.3 Potential determination of pH. In: European Pharmacopoeia, Strasbourg: Council of Euorpe, 26-27, published.	No	No owner
B3/ No. 6	Council of Europe (ed.)	2004	Monograph 2.2.5 Relative density. In: European Pharmacopoeia, Strasbourg: Council of Euorpe, 27-28, published.	No	No owner
B3/ No. 7	Habermann H	2005	Prüfanweisung PA052900 Laurinsäure, unpublished.	No	Dr. R. Pfleger GmbH
B3/ No. 8	Habermann H	2006	Prüfanweisung PS701510 ContraZeck, unpublished.	No	Dr. R. Pfleger GmbH
B3/No. 113	Opel N	2006	Test report of OrgaLab, Report no. 2006-1004-00001, unpublished.	Yes	Dr. R. Pfleger GmbH
B3/No.137	Schulze M	2007	Study report: Determination of Acidity or Alkalinity and pH value, unpublished.	Yes	Dr. R. Pfleger GmbH
B3/No.138	Schulze M	2007	Study report: Determination of the density, unpublished.	Yes	Dr. R. Pfleger GmbH
B4.1/ No. 9	Habermann H	2006	Prüfanweisung PA701510 ContraZeck, unpublished.	No	Dr. R. Pfleger GmbH

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B4.1/No. 135	Fuchs D	2006	Auswertung GC-Gehaltsbestimmungen, unpublished	Yes	Dr. R. Pfleger GmbH
B4.2, B5/No. 11	Dautel H, Hilker M, Kahl O, Siems K	2001	Verwendung von Dodecansäure als Zeckenrepellent (Patentschrift), published.	No	Dautel H, Hilker M, Kahl O, Siems K
B4.2, B6.1.1, B6.1.2, B6.2.1, B6.2.2, B6.7, B6.7.1.1, B6.7.1.2/ No.12	Anonymous	1987	Final report on the safety assessment of Oleic acid, Lauric acid, Palmitic acid, Myristic acid, and Stearic acid, J Amer Coll Toxicol **6**(3): 321-401, published.	No	No owner
B5, B5.10/ No. 16	Dautel H	2003	Prüfung der zeckenabschreckenden Wirkung zweier Formulierungen. Interal report of Insect Services GmbH, unpublished.	Yes	Dr. R. Pfleger GmbH
B5, B5.10/ No. 17	Dautel H	2003	Prüfung der repellierenden Wirkung dreier Formulierungen auf Ixodes ricinius Zecken, Interal report of Insect Services GmbH, unpublished.	Yes	Dr. R. Pfleger GmbH
B5, B5.10/ No.18	Dautel H	2004	Prüfung der repellierenden Wirkung von Charge 040088 auf Ixodes ricinus Zecken. Internal report of Insect Service GmbH, unpublished.	Yes	Dr. R. Pfleger GmbH
B5, B5.10/ No.19	Dautel H	2005	Vergleich der repellierenden Wirkung von PU 030022 und Zanzarin ® im Moving-Object Bioassay auf Ixodes ricinus Zecken. Internal Report of Insect Service GmbH, unpublished.	Yes	Dr. R. Pfleger GmbH
B5, B5.10/ No.20	Dautel H	2005	Prüfung der repellierenden Wirkung von PU 03002 auf Ixodes ricinus Zecken. Internal Report of Insect Service GmbH, unpublished.	Yes	Dr. R. Pfleger GmbH
B5, B5.10/ No.21	Dautel H	2005	Vergleich der repellierenden Wirkung von Charge 040108 und Charge 050030 auf Ixides ricinus Zekcen im Moving Object Bioassay. Internal Report of Insect Service GmbH, unpublished.	Yes	Dr. R. Pfleger GmbH

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B5.10, No. 82	US Environmental Protection Agency	2000	Insect repellents for human skin and outdoor premises. Guideline OPPTS 810.3700, from: http://www.epa.gov/oscpmont/sap/2000/april/insectguid.pdf (06.02.2006), published.	No	No owner
B5.10.2/No.150	Dautel H	2007	Comments on the questions concerning approval of Lauric acid (CAS-Nr. 143-07-7) as tick repellent, unpublished	Yes	Dr. R. Pfleger GmbH
B5.10.2/No.152	Abbott WS	1925	A method of computing the effectiveness of an insecticide. J. Econ. Entomol. **18**, 265-267, published.	No	No owner
B5.10.2/No.153	Govere JM, Durrheim DN	2006	Techniques for evaluating repellents. In: Debboun M, Frances SP, Strickman D (ed): Insect Repellents. Principles, methods, uses, Boca Raton: CRC Press, 147-159, published.	No	No owner
B5.10/No. 78	Dautel H, Kahl O, Siems K, Oppenrieder M, Müller-Kuhrth L, Milker M	1999	A novel test system for detection of tick repellents. Entomologia Experimentalis et Applicata **91**: 431-441, published.	No	No owner
B5.10/No. 79	Dautel H	2000	In vivo test method for repellents against hard tick, ixodes ricinus (Acari: Ixodidae), main vector of lyme borreliosis and TBE in europe. In: Proceedings of the 4th Conference on Urban Pests (Jones SC, Zhai J, Robinson WH eds.): 387-398, Pocahonta Press, Blacksburg, USA, published.	No	No owner
B5.10/No. 80	Dautel H	2004	Mini-Review: Test system for tick repellents. Int J Med Microbiol **293**, Suppl. 37, 182-188, published.	No	No owner
B5/No. 13	Gingl E, Tichy H	2001	Infrared sensitivity of thermoreceptors, J Comp Physiol A **187**(6): 467-475, published.	No	No owner
B5/No. 14	Romanenko VN	2005	Visual possibilities of the tick hyalomma asiaticum (ixodidae), Parazitologiia **39**(3): 186-190, published, translation to German is submitted, too.	No	No owner

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B5/No. 15	Caroll JF, Klun JA, Debboun M	2005	Repellency of deet and SS220 applied to skin involves olfactory sensing by two species of ticks, Med Vet Entomol. **19**(1), 101-106, published.	No	No owner
B6.1.1, B6.1.2, B6.5/No. 104	OECD SIDS (ed.)	2002	SIDS Initial Assessment Report for SIAM 14: Sodium hydroxide. OECD SIDS, UNEP Publications: 1-112, 2002	No	No owner
B6.1.1, B6.1.2, B6.5/No. 96	Daskalakis SA	1994	Xanthan gum. In: Handbook of Pharmaceutical Excipients, 2nd Ed: 562-563, published.	No	No owner
B6.1.1, B6.1.2, B6.5/No. 99	Joint FAO/WHO Expert Committee on Food Additives (ed.)	1973	Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thicking agents, WHO food additives series no. 5, (www.inchem.org/documents/jecfa/jecmono/v05je86.htm, 12.07.200), published.	No	No owner
B6.1.1, B6.1.2/No. 105	Lewis RJ	1996	Sax´s dangerous properties of industrial materials. In: 9 th ed. Volumes 1-3, 1990, published.	No	No owner
B6.1.1, B6.1.2/No. 106	Joint FAO/WHO Expert Committee on Food Additives (ed.)	No data	Xanthan gum, (www.inchem.org/documents/jecfa/jecmono/v21je13.htm, 18.01.2006), published.	No	No owner
B6.1.1, B6.5/No. 100	Anonymous	2000	Application Data. PURAC Environmental and toxicological data, Purac Germany, published.	No	No owner
B6.1.1, B6.5/No. 101	Bauer K	2003	Isopropylmyristat. In: HagerROM 2003, Springer, Heidelberg, published.	No	No owner
B6.1.1, B6.5/No. 102	Hartke K, Pindur U, Schäfer-Korting M	1994	Isopropylmyristat, Isopropylis myristas. In: Kommentar zum DAB, Stuttgart, I37: 1-2, published.	No	No owner
B6.1.1, B6.5/No. 103	Gattefosse (ed.)	2003	4.34 EMULFREE CBG, Data Sheet. Gatefossé GmbH, Weil am Rhein March, published.	No	No owner
B6.1.1, B6.5/No. 93	Farkas WR, Lorch V, Conover III WR, Al-Ansari HMH, Abney LK, Painter III PC, Reyniers JP, Congdon CC	1991	Polysorbat Toxicity in Neonatal Rats and Mice. Short Communication, Pharmacology & Toxicology 1991, **68**, 154-156, published.	No	No owner

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B6.1.1, B6.5/No. 94	Nürnberg E	1998	Polysorbat 20. In: Kommentar zur PH.EUR NT 1998, P78: 1-4, Stuttgart 1999, published.	No	No owner
B6.1.1, B6.5/No. 95	Nürnberg E	2002	Polysorbat 60. In: Kommentar zur PH.EUR NT 2001, P79: 1-4, Stuttgart 2002, published.	No	No owner
B6.1.1, B6.5/No. 97	Van Dyne CA	2003	Summaries of xanthan gum safety studies of CP Kelco KELTROL CG Xanthan gum, published.	No	No owner
B6.1.1, B6.5/No. 98	Petersen W	2004	Sicherheitsbewertung eines Parfümöles im Rahmen der Produktangaben gemäss Richtlinie 76/768, geändert durch Richtlinie 93/35/EWG, Dr. Straetmans Chemische Produkte GmbH, published.	No	No owner
B6.1.1/ No. 23	Schaefer EW, Bowles WA	1985	Acute oral toxicity and repellency of 933 chemicals to house and deer mice. Arch Environ Contam Toxicol **14**: 111-129, published.	No	No owner
B6.1.1/ No. 24	Joint FAO/WHO Expert Committee on Food Additives	1998	Safety evaluation of certain food additives and contaminants, WHO food additives series 40, www.inchem.org/documents/jecfa/jecmono/v040je10.htm (18.01.2006), published.	No	No owner
B6.1.1/No. 22	Öro L, Wretlind A	1961	Pharmacological Effects of Fatty Acids, Triolein and Cottonseed Oil. Act pharmacol et toxicol **18**: 141-152, 1961, published.	No	No owner
B6.1.2, B6.2.1, B6.3/No. 28		2005	Report on a human patch test: Test on primary skin irritation and allergic hypersensitivity on human subjects. Internal Report of Dermatest- Gesellschaft für allergologische Forschung mbH, Münster, unpublished.	Yes	Dr. R. Pfleger GmbH
B6.1.2, B6.2.1, B6.3/No. 29	Schnuch A, Aberer W, Agathos M, Brasch J, Frosch PJ, Fuchs Th, Richter G	2001	Leitlinien der Deutschen Dermatologischen Gesellschaft (DDG) zur Durchführung des Epikutantests mit Kontaktallergenen. Der Hautarzt, **52**:864-866, published.	No	No owner
B6.1.2, B6.4/No. 25	Butcher EO	1953	The penetration of fats and fatty acids into the skin of the rat. J Invest Dermatol **21**: 43-48, published.	No	No owner

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B6.1.2, B6.5/No. 107	U.S. Environmental Protection Agency	2002	HPV Data Set, Lactic acid, CAS # 50-21-5, Dossier number 50215 (www.epa.gov/chemrtk/lactacid/c13462rs.pdf, 15.02.2006), published.	No	No owner
B6.1.2, B7.7.1.3, B7.8.1/No. 109	Symrise (ed.)	2003	Hydrolyte-5, Survey of safety studies, published.	No	No owner
B6.1.2/No. 110	Symrise (ed.)	2005	Dragoxat-89, Survey of safety studies, published.	No	No owner
B6.1.2/No. 130		2006	Acute dermal toxicity study of ContraZeck in CD rats, Report no. 20051/06, unpublished.	Yes	Dr. R. Pfleger GmbH
B6.1.2/No. 26	Butcher EO	1951	The effects of various substances in the epidermis of the rat. J Invest Dermatol **16**: 85-90, published.	No	No owner
B6.1.2/No. 27	Fernandes AR, Geetha K, Patil N, Mondkar JA, Swar BD	2005	Transcutanous absorption of oil in preterm babies- a pilot study. Indian Pediatr **42**(3): 255-258, published.	No	No owner
B6.1.3/No. 30	The Physical and Theoretical Chemistry Laboratory Oxford University	2005	Safety (MSDS) data for lauric acid, from: http://physchem.ox.ac.uk/MSDS/LA/lauric_acid.html (18.01.2006), published.	No	No owner
B6.2.1, A6.1.4/No. 32	European Commission, Scientific Committee on Consumer Products	2005	Memorandum of the Scientific Committee on Consumer Products, Classification and categorization of skin sensitisers and grading of test reactions. European Commission, Directorate C – Public Health and Risk Assessment, SCCP/0919/05, published.	No	No owner
B6.2.1/No. 31	Sato A. et al	1996	Evaluation of human skin irritation by carboxylic acids, alcohols, esters and aldehydes, with nitrocellulose-replica method and closed patch testing. Contact Dermatitis, **34**: 12-16, published.	No	No owner
B6.2.2,/No. 33		2006	Acute eye irritation/Corrosion, unpublished.	Yes	Dr. R. Pfleger GmbH
B6.2.2/No. 34	Khadzhai JI	1975	In investigation of hydrogenated palm-kernel oil as innocuous suppository base. Farmatsiya **24**, 13-15, published, translation to German is submitted, too.	No	No owner

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B6.2.2/No. 35	Johnson W	2000	Final report on the safety assessment of Elaeis Guineensis (palm) oil, Elaeis Guineensis (palm) kernel oil, hydrogenated palm oil and hydrogenated palm kernel oil. Int. J. Tox. **19**(Suppl. 2): 7-28, published.	No	No owner
B6.3/No.36		2006	Report on an application test with final epicutantest on human subjects. Internal Report of Dermatest- Gesellschaft für allergologische Forschung mbH, Münster, unpublished.	Yes	Dr. R. Pfleger GmbH
B6.7, B6.7.1.1, B6.7.1.2/No. 60	Budavari S (ed.)	1989	Lauric acid. In: The Merck Index. Rahway, USA: Merck & Co., Inc., 849, published.	No	No owner
B6.7, B6.7.1.1, B6.7.1.2/No. 61	Lesschaeve E, Langlois D, Etievant P	1991	Volatile compounds in strawberry jam: influence of cooking on volatiles. Journal of Food Science 56: 1393-1398, published.	No	No owner
B6.7/No. 56	Sax NI, Lewis RJ	1987	Lauric acid. In: Hawley´s Condensed Chemical Dictionary, 11th edition, New York: Van Nostrand Reinhold Company, 685, published.	No	No owner
B6.7/No. 59	Nicholas HJ	1973	Miscellaneous Volatile Plant Products. In: Phytochemistry, Volume II, New York: Van Nostrand Reinhold Company, 381-399, published.	No	No owner
B7.7.1.1, B7.7.1.1.1/ No. 77	Egmond van R, Hambling S, Marshall S	1999	Bioconcentration, biotransformation, and chronic toxicity of sodium laurate to zebrafish (Danio rerio). Environmental Toxicology and Chemistry, **18**(3): 466-473, published.	No	No owner
B7.7.1.2/No. 37	Stumpf PK	1969	Metabolism of fatty acids. In: Annual Review of Biochemistry, Esmond ES et al (editor), **38**: 159-212, published.	No	No owner
B8/No. 108	Kröckel U	2006	Test report: Test on efficacy of ContraZeck Zeckenschutz Lotion from Dr. R. Pfleger GmbH in a cagetest with the southern house gnat Culex quinquefasciatus, unpublished.	Yes	Dr. R. Pfleger GmbH

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No. 111	Keles S, Kaygusuz K, Sari A	2005	Lauric and myristic acids eutectic mixture as phase change material for low-temperature heating applications. International Journal of Energy research, **29**: 857-870, published.	No	No owner
No. 112	Feldman D, Shapiro MM, Banu D, Fuks CJ	1989	Fatty acids and their thermal mixtures as phase-change materials for thermal energy storage. Solar Energy Materials, **18**: 201-216, published.	No	No owner
No. 81	Anonymous	2001	Bissige Biester, Test von Mitteln gegen Zecken. Test 4: 44-49, published.	No	No owner
No. 90	Marquardt H	1994	Chemische Kanzerogenese. In: Marquardt H, Schäfer SG (ed.): Lehrbuch der Toxikologie, Mannheim: Wissenschaftsverlag, 124-147, published.	No	No owner