Section A6.12.8 **Annex Point IIA VI.6.9.8**	**Medical data in anonymous form** Prognosis following poisoning	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	The active substance is not toxic and readily biodegradable. It is metabolised in human body as fatty acid and does not cause any poisoning if used appropriate. Therefore data on prognosis following poisoning ware not required.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A6.13 Annex Point IIIA VI.2	Toxic effects on livestock and pets	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	The active substance is not toxic and readily biodegradable. Lauric acid is one of the three most widely distributed naturally occurring saturated fatty acids. Sources of lauric acid include coconut and palm kernel oils, arecanut fat, other vegetable oils, strawberries and milk fats [12, 60, 61]. Because the fatty acid is present in milk that is drunk from young cows there is no danger or toxic effect on livestock and pets. Therefore the biocidal product is exclusively intended for application on humans and there will be no contact with livestocks and pet if the biocidal product is applied correctly.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A6.14 Annex Point IIIA XI.2	Other test(s) related to the exposure of humans	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [x] **Other justification** [ ]	
Detailed justification:	The active substance is not toxic and readily biodegradable. The two possible by-products of synthesis are Capric acid and Palmitic acid. Capric acid: It can cause irritation of sore throat, skin, eye and respiratory tract. But it is categorized under non-hazardous chemicals (LC 50 > 100 mg product/l at fish and EC 50 > 100 mg product/l) [62]. The concentration of Capric acid is about [redacted] of the active substance in the biocidal product ([redacted]) and it is not toxic in the application of the biocidal product, which contains about [redacted] mg of lauric acid in one bottle. In addition capric acid shows only a low acute oral toxicity in rats [63], low toxicity in repeated dose oral administration in rats and dogs [63] and a low dermal toxicity in rabbits. So it is not considered to be hazardous [62]. Palmitic acid: It can cause irritation to skin, eyes, and respiratory tract [64] . But it is only mild irritant when applied to human skin (75 mg total over 3 days) [65]. Shaving cream formulations containing 2.2% palmitic acid were not irritating in single or repeated (4 weeks) application studies with 101 subjects [65]. In addition palimitic acid is a natural fatty acid and therefore not toxic. The concentration of Palmitic acid is about [redacted] of the active substance in the biocidal product very low [redacted]). Therefore, in the case of using the biocidal product as a repellent (product type 19) on human skin, no more information is necessary.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	

Section A6.14 **Annex Point IIIA XI.2**	**Other test(s) related to the exposure of humans**
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.15.1 **Annex Point IIIA XI.1**	**Food and feedingstuffs** Identification of the residues, degradation and reaction products and of metabolites of the active substance in contaminated foods and feedingstuffs	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	In the case of using the biocidal product as a repellent (product type 19) on human skin, no more information is necessary because there will be no contact with food or feedingstuff.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A6.15.2 **Annex Point IIIA XI.1**	**Food and feedingstuffs** Behaviour of the residues of the active substance, its degradation and reaction products and where relevant, its metabolites on the treated or contaminated food or feedingstuffs including the kincetics of disappearance	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	In the case of using the biocidal product as a repellent (product type 19) on human skin as intended, no more information is necessary because there will be no contact with food or feedingstuff.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A6.15.3 **Annex Point IIIA XI.1**	**Food and feedingstuffs** Estimation of potential or actual exposure of the active substance to humans through diet and other means	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	In the case of using the biocidal product as a repellent (product type 19) on human skin as intended, no more information is necessary because there will be no contact with food or feedingstuff.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A6.15.4 **Annex Point IIIA XI.1.7**	**Food and feedingstuffs** Proposed acceptable residues and the justification of their acceptability	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	In the case of using the biocidal product as a repellent (product type 19) on human skin as intended, no more information is necessary because there will be no contact with food or feedingstuff. Moreover toxicity of lauric acid as well as the biocidal product is extremely low.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A6.15.5 **Annex Point IIIA XI.1**	**Food and feedingstuffs** Any other available information that is relevant	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification:	No other available information that are relevant are available and necessary.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A6.15.6 **Annex Point IIIA XI.1**	**Food and feedingstuffs** Summary and evaluation of data submitted under point 6.15	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [x]**	
Detailed justification:	The biocidal product is intended for using as repellent (product type 19) on human skin. Therefore there is no contact with food or feedingstuffs, and so there are no data necessary for - Identification of the residues, degradation and reaction products and of metabolites of the active substance in contaminated foods or feedstuffs. - Behaviour of the residues of the active substance, its degradation and reaction products and where relevant, its metabolites on the treated or contaminated food or feedingstuffs including the kincetics of disappearance. - Estimation of potential or actual exposure of the active substance to humans through diet and other means. - Proposed acceptable residues and the justification of their acceptability. Moreover, toxicity of lauric acid as well as the biocidal product is extremely low.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A6.16 **Annex Point IIIA VI.3.5**	**Any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, that are considered necessary to be required**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification:	No further information is available and necessary.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A6.17 **Annex Point IIIA VI.6**	**If the active substance is to be used in products for action against plants than tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in anmials shall be required**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	The active substance is used as biocidal product on human skin as repellent (product type 19) and not for action against plants, so no data are required.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A6.18 Annex Point IIA X.	Summary of mammalian toxicology and conclusions	Official use only
Results		
Oral toxicity	Lauric acid is widely used as a food ingredient. Correspondingly, lauric acid showed a low acute oral and i.v. toxicity in studies with mice and rats [12, 22, 23, 24]. Data on oral subchronic toxicity using a 10% lauric acid containing diet did not reveal any toxic effect in rats [42]; and likewise 2 year feeding of rats with 35% lauric acid did not led to negative chronic effects [49]. In additon, the U.S. Food and Drug Administration and the Joint FAO/WHO Expert Committee on Food Additives [86, 43] evalued lauric acid as safe when used as food additives.	
Dermal toxicity	Lauric acid is also widely used as a component of cosmetic products [12, 54]. The Cosmetic Ingredient Review (CIR) concluded lauric acid as to be safe in cosmetic products up to concentration of 25% [46]. Actually, studies in guinea pigs, rabbits and humans demonstrated significant irritative effects of lauric acid when applied subchronically in significant higher concentration to the skin [44, 45, 47, 48].	
Inhalation toxicity	Inhalation studies are not necessary, because the active substance is not volatile and there is no risk of inhalation both the raw material during manufacturing process and of the biocidal product in use.	
Skin irritation	Data from 2 studies on primary skin irritation in humans (patch tests) clearly show that dermal application of a lauric acid concentration of about 100mg/ml do not result in signs of skin irritation [28, 36]. In the second study with 30 volunteers the biocidal product *ContraZeck* was used.	
Eye irritation	The eye irritatin effects of lauric acid were determined in rats using both pure lauric acid and fractionated palm kernel oil (containing 48.3% lauric acid) [12, 34]. In both studies clear signs of irritation were observed. In contrast, in Draize test carried out with the biocidal product (10% lauric acid) only slight signs of irritation were observed [33]. According to the EC criteria for classification and labelling requirements for dangerous substances and preparations *ContraZeck* does not have to be classified and no obligatory labelling requirements are necessary.	
Skin sensitation	Volunteer tests on both existing sensitisation and potency of sensitisation after once daily use for 4 weeks did not show adverse skin reactions [28].	
Percutanous absorption and metabolism	Fatty acids as e.g. lauric acid, linoleic acid penetrate into the skin of rats and preterm humans babies [25, 27]. However, lauric acid as other fatty acids may act as a skin permeation enhancer for other substances [83, 84, 85], but this latter effect is out of relevance in the present case. The metabolism of fatty acids and its regulation have been extensively studied [12, 37, 38, 39, 40, 41], and there exist no clues that metabolism of lauric acid absorbed percutaneously may be metabolised different from that after oral intake.	
Mutagenicity, genotoxicity and dermal carcinogenicity	Lauric acid showed negative results in vitro in the modified Ames test [50]. In studies on the cancerogenic properties 20-40% lauric acid was not cancerogenic in mice after once daily dermal application [51]. In contrast, dermal applied lauric acid showed tumor promoting effects in mice after carcinogenic initiation [51]. On the other hand lauric acid did not show carcinogenic activity after subcutaneous injection in mice and displayed anti-tumor activities against Ehrlich ascites tumor [53].	

Section A6.18 Annex Point IIA X.	Summary of mammalian toxicology and conclusions	
	Cancerogenic properties were also investigated by using oral coconut oil in rats showing nonpromotional effects [87, 88, 89]. In summary, it can be concluded that cancer promoting effects of topically applied lauric acid, if any is may be restricted to the application of high doses which led to chronic skin irritation. Such chronic effects would not be accepted by the product users.	
Reproductive toxicity		
Teratogenicity	Studies with oral coconut oil containing lauric acid and caprylic acid did not show relevant embryotoxic effects [57, 58].	
Two generation reproduction study	Lauric acid is eaten by human beings for many generations through consumption of food and food additives, inter alia as cocnut oil, laurel oil, juniperus turkestanica essential oil, arecanut fat and strawberry jam [56, 59, 60, 61]. No undesired effect was detected until now, therefore no additional study is necessary.	
Neurotoxicity	No signs of toxic effects were detected in toxicity studies. Therefore no specific neurotoxicity study is necessary.	
Mechanistic study	No signs of specific toxic effects of lauric acid were detected in toxicity studies. Lauric acid is metabolised as fatty acids ingested by food. Therefore no additional studies to clarify specific toxic mechanisms are required.	
Other routes of administration	The general population is exposed to lauric acid by consumption of food, dermal contact with soaps, detergents, and cosmetics [12, 54, 55]. The user of the biocidal product will primarily be exposed to lauric acid by dermal contact. Toxic effects of this application were investigated. No other route of administration than the dermal application is intended or likely with the biocidal product.	
Medical data	The biocidal product is manufactured according to Good Manufacturing Practices (GMP). According to the GMP regulation there is no direct contact of persons with the biocidal product during manufacturing which could probably cause any hazard to the plant personnel. According to the manufacturer´s data sheet, lauric acid is not toxic and does not have any harmful properties [2]. In the case of accidental use the first aid measures are fresh air, cleaning with water and soap and rinse with water, depending on the kind of accident [2]. Lauric acid is a natural constituent of Juniperus turkestanica essential oils, mandarin oil, coconut oil, arecanut fat, Holoptelea integrifolia oil, and strawberries [55, 59, 60, 61] which are consumed by many people for years without any reported adverse effect. Poisoning or accidental poisoning by lauric acid is not to be expected when used as a biocidal product as already described. In addition, lauric acid will be metabolised in human body as other fatty acids ingested with food and it is non-toxic and readily biodegradable. Until today, the biocidal product was produced [redacted]. No information on sensitisation or allergenicity was observed. In different tests, no sensitisation was observed [28, 36].	
Toxic effects on livestocks and pets	Lauric acid is one of the three most widely distributed naturally occuring saturated fatty acids. Sources of lauric acid include coconut and palm kernel oils, arecanut fat, other vegetable oils, strawberries and milk fats [12, 59, 60, 61]. Because the fatty acid is present in milk that is drunk from young cows there is no danger or toxic effect on livestock and pets. Therefore the biocidal product is exclusively intended for application on humans and there will be no contact with livestocks and pet if the	

Section A6.18 Annex Point IIA X.	Summary of mammalian toxicology and conclusions	
	biocidal product is applied correctly.	
Other tests related to the exposure of humans	The active substance as well as both by-products (Capric acid and Palmitic acid) of synthesis are non-toxic. Therefore, when used as a repellent on human skin, no additional information is required.	
Food and feedingstuffs	In the case of using the biocidal product as intended as a repellent on human skin, no additional information is necessary because there will be no contact with food or feedingstuff. Moreover toxicity of lauric acid as well as the biocidal product is extremely low.	
Any other tests relating to the exposure of the active substance to human	No further information is available and necessary.	
Effects of metabolites	The active substance is used as biocidal product on human skin as repellent and not for action against plants, so no data are required.	
Conclusion	Lauric acid will not be toxic if used as repellent on human skin.	

Section A7.1.1.1.1 **Annex Point IIA VII.7.6.2.1**	**Degradation, Abiotic** Hydrolysis	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	The fatty acid lauric acid is stable and insoluble in water. It is stable, because the functional group of carboxylic acid is generally resistant to hydrolysis [66] and no further hydrolyzable functional group is available, so no test on hydrolysis as a function of pH is necessary.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.1.1.1.2 Annex Point IIA VII.7.6.2.2	Degradation, Abiotic Phototransformation in water	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	To focus on environmental photochemistry at or near the earth´s surface, the wavelength regime of importance can be further narrowed, because the stratospheric ozone layer effectively prevents UV irradiation of less than 290 nm from reaching the ecosphere. Thus, only the light of 290-750 nm wavelength absorbed by a molecule can potentially lead to photochemical transformation of a molecule in the enivronment. At earth´s surface, light of < 290 nm wavelength has such a low intensity that direct photochemical activation at these wavelength is improbable [67]. The active substance lauric acid has no extended conjugated hydrocarbon system or aromatic system, which could be a chromophore. Therefore phototransformation of lauric acid in water is not very probable. So, as seen in the UV spectra (see section A3), the maximum absorption of lauric acid is at [redacted] where normally the absorption for a test of phototransformation is measured according US-EPA-Guideline OPPTS 835.2210 Direct Photolysis Rate in Water by Sunlight, no relevant absorption could be measured.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.1.1.2.1 Biodegradability, Biotic

Annex Point IIA VII.7.6.1.1 Ready

Official use only

1 REFERENCE

1.1	**Reference**	Kronenberg-Schäfer K, 2007, Report: Biodegradability in the CO2-evolution test according to OECD 301 B (July 1992), Report No. 473, Hydrotox, unpublished [144].
1.2	**Data protection**	Yes
1.2.1	Data owner	Dr. R. Pfleger Chemische Fabrik GmbH
1.2.2	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing active substance for the purpose of its authorisation.

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes OECD-Test Guideline 301 B
2.2	**GLP**	Yes
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Test material**	Lauric acid
3.1.1	Lot/Batch number	Batch number 43256
3.1.2	Specification	As given in section 2
3.1.3	Purity	About [redacted] (w/w)
3.1.4	Further relevant properties	Not applicable.
3.1.5	Composition of Product	[redacted]
3.1.6	TS inhibitory to microorganisms	[redacted]
3.1.7	Specific chemical analysis	Not applicable.
3.2	**Reference substance**	[redacted]
3.2.1	Initial concentration of reference substance	[redacted] of a stock solution of [redacted] was added into the reference vessel. This corresponds to a concentratoin of [redacted] organic carbon.
3.3	**Testing procedure**	
3.3.1	Inoculum / test species	Activated sludge from the municipal sewage treatment plant [redacted]. See table A7_1_1_2-2
3.3.2	Test system	[redacted]. See table A7_1_1_2-3

Section A7.1.1.2.1 Biodegradability, Biotic

Annex Point IIA VII.7.6.1.1 Ready

3.3.3	Test conditions	[redacted]. See table A7_1_1_2-4
3.3.4	Method of preparation of test solution	[redacted] (1) [redacted] (2) [redacted] (3) [redacted] (4) [redacted]. [redacted]
3.3.5	Initial TS concentration	Test solution: [redacted]
3.3.6	Duration of test	[redacted]
3.3.7	Analytical parameter	[redacted]
3.3.8	Sampling	[redacted]
3.3.9	Intermediates/ degradation products	[redacted]
3.3.10	Nitrate/nitrite measurement	[redacted]
3.3.11	Controls	[redacted]
3.3.12	Statistics	[redacted]

4 RESULTS

4.1 Degradation of test substance

Section A7.1.1.2.1 Biodegradability, Biotic

Annex Point IIA VII.7.6.1.1 Ready

4.1.1 Graph

[redacted]

4.1.2 Degradation

[redacted]

For all flasks the 10-days-window was met.

4.1.3 Other observations [redacted].

4.1.4 Degradation of TS in abiotic control [redacted].

4.1.5 Degradation of reference substance

[redacted]

For all flasks the 10-days-window was met.

4.1.6 Intermediates/ degradation products

Not applicable, [redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The test was conducted according to the "CO_2-Evolution-Test" described in the OECD Test Guideline 301 B (CO_2 scrubbing apparatus).

For details see 3.1.7 Specific chemical analysis

5.2 Results and discussion

[redacted]

It is know that the fatty acid lauric acid is readily biodegradable in soil and water [55, 68]. A one-day theoretical BOD of 6.1% was determined for lauric acid in a Warburg respirometer using activated sludge inocula [68]. In activated sludge media, a 100% TOC reduction was observed

Section A7.1.1.2.1 Biodegradability, Biotic

Annex Point IIA VII.7.6.1.1 Ready

		within 100 hrs [69].
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	1
5.3.2	Deficiencies	No

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

Table A7_1_1_2-1: Guidline-methods of EC and OECD for tests on ready/inherent biodegradability (according to OECD criteria); simulation test

Test	EC-method	OECD-Guideline	Test on ready/inherent biodegradability
DOC Die-Away-Test	C.4-A	301A	ready
CO2 Evolution-Test (Modified Sturm Test)	C.4-C	301B	ready
Modified OECD-Screening-Test	C.4-B	301E	ready
Manometric Respirometry	C.4-D	301F	ready
MITI-I-Test	C.4-F	301C	ready
Closed-Bottle-Test	C.4-E	301D	ready
Zahn-Wellens-test	C.9	302B	Inherent
Modified MITI-Test (II)	-	302C	Inherent
Modified SCAS-Test	C.12	302A	Inherent
Simulation Test with activated Sewage (Coupled Units-Test)	C.10	302A	Simulation Test[1)]

[1)] Test for the determination of the ultimate degradation of test material under conditions which simulate the treatment in an activated sludge plant

Table A7_1_1_2-2: Inoculum / Test organism

Criteria	Details
Nature	[redacted]
Species	Not applicable, because activated sludges are complex mixtures of many different species of bacteria and protozoa.
Strain	Not applicable, see above.
Source	[redacted]
Sampling site	[redacted]
Laboratory culture	[redacted]
Method of cultivation	[redacted]
Preparation of inoculum for exposure	[redacted]
Pretreatment	[redacted]
Initial cell concentration	[redacted]

Table A7_1_1_2-3: Test system

Criteria	Details
Culturing apparatus	[redacted]
Number of culture flasks/concentration	[redacted]
Aeration device	[redacted]
Measuring equipment	[redacted]
Test performed in closed vessels due to significant volatility of TS	[redacted]

Table A7_1_1_2-4: Test conditions

Criteria	Details
Composition of medium	[redacted]
Additional substrate	[redacted]
Test temperature	[redacted]
pH	[redacted]
Aeration of dilution water	[redacted]
Suspended solids concentration	[redacted]
Other relevant citeria	[redacted]

Table A7_1_1_2-5: Pass levels and validity criteria for tests on ready biodegradability

	fulfilled	not fulfilled
Pass levels		
70% removal of DOC resp. 60% removal of ThOD or $ThCO_2$	[redacted]	
Pass values reached within 10-d window (within 28-d test period) - not applicable to MITI-I-Test - 14-d window acceptable for Closed-Bottle-Test	[redacted]	
Criteria for validity		
Difference of extremes of replicate values of TS removal at plateau (at the end of test or end of 10-d window) < 20%	[redacted]	
Percentage of removal of reference substance reaches pass level by day 14	[redacted]	

Criteria for poorly soluble test substances		
[redacted]		
[redacted]		

Table A7_1_1_2-6: Pass levels and validity criteria for inherent biodegradability tests

	fulfilled	not fulfilled
Pass levels		
20% removal (DOC or COD);	[redacted]	
Pass values reached within 10-d window (within 28-d test period)	[redacted]	
Removal of reference substance (DOC or COD) > 70 % within 14 d	[redacted]	
Criteria for validity		
Percentage of DOC/COD-removal of reference compound ≥ 70 % within 14 days (OECD 302 B)	[redacted]	
Percentage of DOC-removal of reference compound ≥ 40 % within 7 days and ≥ 65 % within 14 days Average residual amount of test compound in blank tests ≥ 40 % (OECD 302 C)	[redacted]	
Removal curve of DOC or COD in the test suspension indicative for biodegradation (gradual elimination over days/weeks)	[redacted]	

Criteria for poorly soluble test substances		
[redacted]		
[redacted]		

Section A7.1.1.2.1 Biodegradability, Biotic

Annex Point IIA VII.7.6.1.1 Ready

Official use only

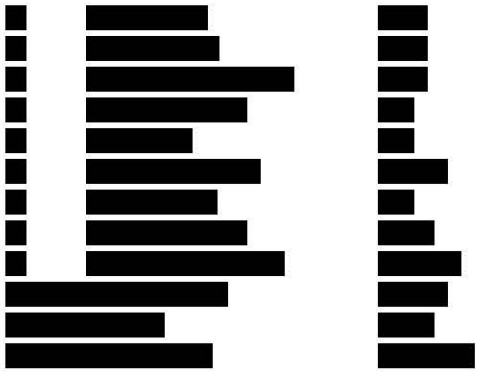
6 REFERENCE

6.1	**Reference**	Lebertz H, 2006, Study on "ready Biodegradability" of "ContraZeck (Ch.- B. 42945)" according to OECD-Test Guideline 301B (CO_2 Evolution Test), Study No. IF-06/00580286, Institut Fresenius, unpublished [127].
6.2	**Data protection**	Yes
6.2.1	Data owner	Dr. R. Pfleger Chemische Fabrik GmbH
6.2.2	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing active substance for the purpose of its authorisation.

7 GUIDELINES AND QUALITY ASSURANCE

7.1	**Guideline study**	Yes OECD-Test Guideline 301 B
7.2	**GLP**	Yes
7.3	**Deviations**	No

8 MATERIALS AND METHODS

8.1	**Test material**	As given in section B2 [redacted]
8.1.1	Lot/Batch number	Batch number 42945
8.1.2	Specification	As given in section B2 [redacted]
8.1.3	Purity	[redacted]
8.1.4	Further relevant properties	[redacted]. No other properties are relevant.
8.1.5	Composition of Product	As given in section B2 
8.1.6	TS inhibitory to microorganisms	[redacted]
8.1.7	Specific chemical analysis	[redacted]
8.2	**Reference substance**	[redacted]

Section A7.1.1.2.1 Biodegradability, Biotic

Annex Point IIA VII.7.6.1.1 Ready

8.2.1	Initial concentration of reference substance	[redacted]
8.3	**Testing procedure**	
8.3.1	Inoculum / test species	[redacted] See table A7_1_1_2-2
8.3.2	Test system	[redacted] See table A7_1_1_2-3
8.3.3	Test conditions	[redacted] See table A7_1_1_2-4
8.3.4	Method of preparation of test solution	[redacted]
8.3.5	Initial TS concentration	[redacted]
8.3.6	Duration of test	[redacted]
8.3.7	Analytical parameter	[redacted]
8.3.8	Sampling	[redacted]
8.3.9	Intermediates/ degradation products	[redacted]
8.3.10	Nitrate/nitrite measurement	[redacted]
8.3.11	Controls	[redacted]
8.3.12	Statistics	[redacted]

Section A7.1.1.2.1 Biodegradability, Biotic

Annex Point IIA VII.7.6.1.1 Ready

[redacted]

9 RESULTS

9.1 Degradation of test substance

9.1.1 Graph [redacted]

[redacted]

9.1.2 Degradation [redacted]

9.1.3 Other observations [redacted].

9.1.4 Degradation of TS in abiotic control [redacted].

9.1.5 Degradation of reference substance [redacted]

9.1.6 Intermediates/ degradation products [redacted]

10 APPLICANT'S SUMMARY AND CONCLUSION

10.1 Materials and methods

The test was conducted according to the "CO_2-Evolution-Test" described in the OECD Test Guideline 301 B (CO_2 scrubbing apparatus).

For details see 3.1.7 Specific chemical analysis

Section A7.1.1.2.1 Biodegradability, Biotic

Annex Point IIA VII.7.6.1.1 Ready

10.2	**Results and discussion**	[redacted] It is know that the fatty acid lauric acid is readily biodegradable in soil and water [55, 68]. A one-day theoretical BOD of 6.1% was determined for lauric acid in a Warburg respirometer using activated sludge inocula [68]. In activated sludge media, a 100% TOC reduction was observed within 100 hrs [69]. [redacted]
10.3	**Conclusion**	[redacted]
10.3.1	Reliability	1
10.3.2	Deficiencies	No

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

Section A7.1.1.2.1 Biodegradability, Biotic

Annex Point IIA VII.7.6.1.1 Ready

Acceptability	acceptable / not acceptable *(give reasons if necessary, e.g. if a study is considered acceptable despite a poor reliability indicator. Discuss the relevance of deficiencies and indicate if repeat is necessary.)*
Remarks	

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

Table A7_1_1_2-1: Guidline-methods of EC and OECD for tests on ready/inherent biodegradability (according to OECD criteria); simulation test

Test	EC-method	OECD-Guideline	Test on ready/inherent biodegradability
DOC Die-Away-Test	C.4-A	301A	ready
CO2 Evolution-Test (Modified Sturm Test)	C.4-C	301B	ready
Modified OECD-Screening-Test	C.4-B	301E	ready
Manometric Respirometry	C.4-D	301F	ready
MITI-I-Test	C.4-F	301C	ready
Closed-Bottle-Test	C.4-E	301D	ready
Zahn-Wellens-test	C.9	302B	Inherent
Modified MITI-Test (II)	-	302C	Inherent
Modified SCAS-Test	C.12	302A	Inherent
Simulation Test with activated Sewage (Coupled Units-Test)	C.10	302A	Simulation Test1)

1) Test for the determination of the ultimate degradation of test material under conditions which simulate the treatment in an activated sludge plant

Table A7_1_1_2-2: Inoculum / Test organism

Criteria	Details
Nature	[redacted]
Species	Not applicable, because activated sludges are complex mixtures of many different species of bacteria and protozoa.
Strain	Not applicable, see above.
Source	[redacted]
Sampling site	[redacted]
Laboratory culture	[redacted]
Method of cultivation	[redacted]
Preparation of inoculum for exposure	[redacted]
Pretreatment	[redacted]
Initial cell concentration	[redacted]

Table A7_1_1_2-3: Test system

Criteria	Details
Culturing apparatus	[redacted]
Number of culture flasks/concentration	[redacted]
Aeration device	[redacted]
Measuring equipment	[redacted]
Test performed in closed vessels due to significant volatility of TS	[redacted]

Table A7_1_1_2-4: Test conditions

Criteria	Details
Composition of medium	[redacted]
Additional substrate	[redacted]
Test temperature	[redacted]
pH	[redacted]
Aeration of dilution water	[redacted]
Suspended solids concentration	[redacted]
Other relevant citeria	[redacted]

Table A7_1_1_2-5: Pass levels and validity criteria for tests on ready biodegradability

	fulfilled	not fulfilled
Pass levels		
70% removal of DOC resp. 60% removal of ThOD or $ThCO_2$	[redacted]	
Pass values reached within 10-d window (within 28-d test period) - not applicable to MITI-I-Test - 14-d window acceptable for Closed-Bottle-Test	[redacted]	
Criteria for validity		
Difference of extremes of replicate values of TS removal at plateau (at the end of test or end of 10-d window) < 20%	[redacted]	
Percentage of removal of reference substance reaches pass level by day 14	[redacted]	

Criteria for poorly soluble test substances		
[redacted]		
[redacted]		

Table A7_1_1_2-6: Pass levels and validity criteria for inherent biodegradability tests

	fulfilled	not fulfilled
Pass levels		
20% removal (DOC or COD);	▮	
Pass values reached within 10-d window (within 28-d test period)	▮	
Removal of reference substance (DOC or COD) > 70 % within 14 d	▮	
Criteria for validity		
Percentage of DOC/COD-removal of reference compound ≥ 70 % within 14 days (OECD 302 B)	▮	
Percentage of DOC-removal of reference compound ≥ 40 % within 7 days and ≥ 65 % within 14 days Average residual amount of test compound in blank tests ≥ 40 % (OECD 302 C)	▮	
Removal curve of DOC or COD in the test suspension indicative for biodegradation (gradual elimination over days/weeks)	▮	

Criteria for poorly soluble test substances		
▮		
▮		

Section A7.1.1.2.2 **Annex Point IIA VII.7.6.1.2**	**Biodegradability, Biotic** Inherent	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	It is know that the fatty acid lauric acid is readily biodegradable in soil and water [55, 68], so no additional test on inherent biodegradability is necessary.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.1.1.2.3 **Annex Point IIIA X.II2.1**	**Biodegradability, Biotic** In seawater	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	The active substance is not used or released or intended to use or release in marine environment for the production and use of the biocidal product, so no test on biodegradation in seawater is necessary. Additional it is known that the fatty acid lauric acid is readily biodegradable in soil and water [55, 68]. However, only very small amounts of lauric acid will be released to seawater if a person who has applied the repellent before will go swimming in the sea or a bottle will be fall into the sea accidentally.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.1.2.1.1 **Annex Point IIIA XII.2.1**	**Biological sewage treatment** Aerobic biodegradation	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	It is known that the fatty acid lauric acid is readily biodegradable in soil and water [55, 68]. Moreover the quantities of lauric acid reaching sewage after using the product will be very limited (body washing).	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.1.2.1.2 **Annex Point IIIA XII.2.1**	**Biological sewage treatment** Anaerobic biodegradation	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	Exposure to anaerobic conditions is not likely when used as a repellent, so no anaerobic degradation study is necessary.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.1.2.2.1 **Annex Point IIIA XII.2.1**	**Biodegradability in freshwater** Aerobic aquatic degradation study	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	The biocidal product is intended for application on human skin, so no contamination of freshwater in higher quantities is possible. In addition it is known that the fatty acid lauric acid is readily biodegradable in soil and water [55, 68].	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.1.2.2.2 **Annex Point IIIA XII.2.1**	**Biodegradability in freshwater** Water/sediment degradation study	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [x]** **Other justification [ ]**	
Detailed justification:	The biocidal product is intended for application on human skin, so no contamination of freshwater in higher quantities is possible. In addition it is known that the fatty acid lauric acid is readily biodegradable in soil and water [55, 68].	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.1.3 Adsorption / Desorption screening test

Annex Point IIA7.7

			Official use only
		1 REFERENCE	
1.1	**Reference**	Weidenauer M, 2008, Justification for the use of ACD software to estimate the Koc of Lauric acid, unpublished [152]; Dearden J, Worth A, 2007, In Silico Prediction of Physicochemical Properties, *http://ecb.jrc.ec.europa.eu/documents/QSAR/EUR_23051_EN.pdf*, published [153]; Schürrmann G, Vorhersage physikalisch-chemischer Stoffeigenschaften aus der Molekülstruktur, 2006, 11. BUA-Kolloquium „Expositionsmodellierung und QSAR-Anwendungen in der Chemikalienbewertung", published [154]; Cheng H, Kontogeorgis GM, Stenby EH, 2005, Correlation and Prediction of Environmental Properties of Alcohol Ethoxylate Surfactants Using the UNIFAC Method, , Industrial & Engineering Chemical Research, 44: 7255-7261, published [155].	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Dr. R. Pfleger Chemische Fabrik GmbH	
1.2.2	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing active substance for the purpose of its authorisation.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No	
2.2	**GLP**	No	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Lauric acid	
3.1.1	Lot/Batch number	Not applicable.	
3.1.2	Specification	As given in section 2	
3.1.3	Purity	Not applicable.	
3.1.4	Further relevant properties	[redacted]	
3.1.5	Method of analysis	[redacted]	
3.2	**Degradation products**		
3.2.1	Method of analysis for degradation products	Not applicable.	
3.3	**Reference substance**		
3.3.1	Method of analysis for reference substance	Not applicable.	
3.4	**Soil types**	Not applicable.	
3.5	**Testing procedure**		

Section A7.1.3 Adsorption / Desorption screening test

Annex Point IIA7.7

3.5.1	Test system	[redacted]
3.5.2	Test solution and Test conditions	Not applicable.
3.6	**Test performance**	
3.6.1	Preliminary test	Not applicable.
3.6.2	Screening test: Adsorption	Not applicable.
3.6.3	Screening test: Desorption	Not applicable.
3.6.4	HPLC-method	Not applicable.
3.6.5	Other test	Computer simulated test.

4 RESULTS

4.1	**Preliminary test**	Not applicable.
4.2	**Screening test: Adsorption**	Not applicable.
4.3	**Screening test: Desorption**	Not applicable.
4.4	**Calculations**	
4.4.1	K_a , K_d	[redacted].
4.4.2	K_{oc}	[redacted]
Degradation product(s)		Not applicable.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]