Table A7_4_3_2-5: Test conditions

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

Table A7_4_3_2-6: Validity criteria for fish tests according to OECD Guidelines 210/212

	fulfilled	Not fullfilled
Concentration of dissolved oxygen > 60% saturation throughout the test	No decision is made, because no data of saturation are available.	
Difference of water temperature < 1.5% between test chambers or successive days at any time during test; temperature within range for specific test species	No decision is made, because no data of saturation are available, only the standard derivation of 0.5°C is known, but it does not make any statement about all absolute time differences.	
Overall survival of fertilized eggs in controls (and solvent controls) ≥ value, specified for the specific test species		x The test is not conducted with fertilized eggs
Test substance concentrations maintained within ± 20% of mean measured values	x	
No effect on survival nor any other adverse effect found in solvent control		x The only effect was the death of fishes.
Further criteria for poorly soluble test substances	x	

Table A7_4_3_2-7: Validity criteria for fish test according to OECD Guideline 215

	fulfilled	Not fullfilled
Concentration of dissolved oxygen in all test vessels > 60% saturation	No decision is made, because no data of saturation are available.	
Difference of water temperature < 1° C between test chambers at any time during test; temperature within a range of 2° C of the temperature for specific test species	No decision is made, because no data of saturation are available, only the standard derivation of 0.5°C is known, but it does not make any statement about all absolute time differences.	
Mortality of control animals <10%	x	
Increase of fish weight sufficient for detection of the minum variation of growth rate considered as significant		x
Criteria for poorly soluble test substances		
Special preparation of test solution is conducted.	x	

Section A7.4.3.3.1 **Annex Point IIIA XIII.2.3**	**Bioaccumulation in an aquatic organism** Bioaccumulation in an appropriate species of fish	
	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 test is required when there is the risk for secondary poisoning. But active substance is readily biodegradable in soil and water [55, 68], so there is no risk for secondary poisoning and no need for a test of bioaccumulation.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.4.3.3.2 **Annex Point IIIA XIII.2.3**	**Bioaccumulation in an aquatic organism** Bioaccumulation in an appropriate invertebrate species	
	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 test is required for product types with direct release to marine/brackish water. The product is intended as repellent on human skin and there is no direct release to marine/brackish water, additional the active substance is readily biodegradable in soil and water [55, 68], so there is no need for a test of bioaccumulation.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.4.3.4 Annex Point IIIA XIII.2.4	Effects on reproduction and growth rate with an appropriate invertebrate spezies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [x]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The biocidal product is used occasionally for outdoor activities, no chronic exposure of invertebrate species is to be expected. In addition the active substance is readily biodegradable in soil and water [55, 68], so there is no risk of effects on reproduction and growth rate in aquatic organism.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.4.3.5.1 **Annex Point IIIA XIII.3.4**	**Effects on any other specific, non-target organisms believed to be at risk** Effects on sediment dwelling organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [x]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	The active substance is intended to be used as repellent on human skin. In the case of correct application the exposure of the active substance to sediment dwelling organisms is not likely and the concentration would be very low. Effects on sediment dwelling organisms are not to be expected. Additional the active substance 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 A7.4.3.5.2 **Annex Point IIIA XIII.3.4**	**Effects on any other specific, non-target organisms believed to be at risk** Aquatic plant toxicity	
	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 intended to be used as repellent on human skin. In the case of correct application the exposure of the active substance to aquatic plant is not likely and the concentration would be very low. So there will be no effect on aquatic plant. In addition the active substance 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 A7.4.3.5 Annex Point IIIA XIII.3.4	Effects on any other specific, non-target organisms believed to be at risk	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [x]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The active substance is intended to be used as repellent against hard ticks on human skin. Risk for other non-organisms is extremly 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 A7.5.1.1 **Annex Point IIA VII.7.4**	**Terrestrial toxicity, initial tests** Inhibition to microbiological activity	
	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 intended to be used as repellent on human skin. In addition the active substance is readily biodegradable in soil and water [55, 68] and a theoretical possible concentration in soil would be very low, so there is no influence to the microbiological activity in soil expectable.	
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 A7.5.1.2 **Annex Point IIA VII.7.4**	**Terrestrial toxicity, initial tests** Acute toxicity to earthworms or other soil non-target organisms	
	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 intended to be used as repellent on human skin. In addition the active substance is readily biodegradable in soil and water [55, 68] and a theoretical possible concentration in soil would be very low, so there is no acute toxicity to earthworms or other soil non-target organisms expectable.	
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 A7.5.1.3	Terrestrial toxicity, initial tests Acute toxicity to plants	
	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 intended to be used as repellent on human skin. In addition the active substance is readily biodegradable in soil and water [55, 68] and a theoretical possible concentration in soil would be very low, which reduces a theoretical potential toxicity.	
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 A7.5.2.1 **Annex Point IIIA XIII.3.2**	**Terrestrial tests, long-term tests** Reproduction study with other soil non-target macro-organisms	
	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 intended to be used as repellent on human skin. In addition the active substance is readily biodegradable in soil and water [55, 68] so no concern for terrestrial compartment is indicated. So no reproduction study with earthworms or other soil non-target macro-organisms is needed.	
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 A7.5.2.2 **Annex Point IIIA XIII.3.2**	**Terrestrial tests, long-term tests** Long-term test with terrestrial plants	
	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 intended to be used as repellent on human skin, no contact is intended with terrestrial plants. In the case of contact with terrestrial plants, e.g. by spilling some biocidal product or during walking through plants, the amounts of lauric acid on plants will be very low. In addition the active substance is readily biodegradable in soil and water [55, 68] so no concern for terrestrial compartment is indicated. So no long-term test with terrestrial plants is needed.	
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 A7.5.3.1.1 **Annex Point IIIA XIII.1.1**	**Effects on birds** Acute oral toxicity	
	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 intended to be used as repellent on human skin. In addition the active substance is readily biodegradable in soil and water [55, 68] so there will be no contact with birds which could ingest it orally.	
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 A7.5.3.1.2 **Annex Point IIIA XIII.1.2**	**Effects on birds** Short-term toxicity	
	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 intended to be used as repellent on human skin. In addition the active substance is readily biodegradable in soil and water [55, 68] so there will be no contact with birds which could ingest it orally.	
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 A7.5.3.1.3 **Annex Point IIIA XIII.1.3**	**Effects on birds** Effects on reproduction	
	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 intended to be used as repellent on human skin. In addition the active substance is readily biodegradable in soil and water [55, 68] so there will be no contact with birds which could ingest it orally.	
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 A7.5.4.1 **Annex Point IIIA XIII.3.1**	**Effects on honeybees** Acute toxicity to honeybees and other beneficial arthropods, for example predators	
	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 intended to be used as repellent on human skin. Data are required for insecticides, acaricides and substances in products to control other arthropods. Such tests are not needed for a repellent on human skin.	
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 A7.5.5.1 **Annex Point IIIA VII.7.5**	**Bioconcentration, terrestrial** Further studies	
	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 intended to be used as repellent on human skin. The use as repellent on human skin does not suggest a concern for predators with secondary poisoning, so no further studies are necessary.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.5.5 Annex Point IIIA VII.7.5	Bioconcentration, terrestrial	
	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 intended to be used as repellent on human skin. Data are required for substances or biocidal products that are released to soil. The use as repellent on human skin does not release the active substance to soil, so the terrestrial bioconcentration has not to be estimated.	
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 A7.5.6 Annex Point IIIA XIII.3	Effects on other terrestrial non-target organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [x]	
Limited exposure [ ]	**Other justification** [ ]	
Detailed justification:	The active substance is intended to be used as repellent on human skin. The use as repellent on human skin does not suggest a concern for terrestrial compartment, so no further studies are necessary.	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*Give date of action*	
Evaluation of applicant's justification	*Discuss applicant's justification and, if applicable, deviating view*	
Conclusion	*Indicate whether applicant's justification is acceptable or not. If unacceptable because of the reasons discussed above, indicate which action will be required, e.g. submission of specific test/study data*	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.5.7.1.1 **Annex Point IIIA XIII.3.4**	**Effects on mammals** Acute oral toxicity	
	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 intended to be used as repellent on human skin. While using the biocidal product as a repellent on human skin a directly and/or indirect exposure of mammals against relevant quantities of lauric acid or the biocidal product are not to be expected. So no data 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 A7.5.7.1.2 **Annex Point IIIA XIII.3.4**	**Effects on mammals** Short term toxicity	
	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 intended to be used as repellent on human skin. While using the biocidal product as a repellent on human skin a directly and/or indirect exposure of mammals against relevant quantities of lauric acid or the biocidal product are not to be expected. So no data 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 A7.5.7.1.3 **Annex Point IIIA XIII.3.4**	**Effects on mammals** Effects on reproduction	
	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 intended to be used as repellent on human skin. While using the biocidal product as a repellent on human skin a directly and/or indirect exposure of mammals against relevant quantities of lauric acid or the biocidal product are not to be expected. So no data 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 A7.5.7.1 **Annex Point IIIA XIII.3.4**	**Effects on mammals** For some product types, directly and/or indirect exposure for mammals is possible and some tests with mammals may be required in rare cases on the basis of concern for severe risk for the terrestrial environment	
	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 intended to be used as repellent on human skin. While using the biocidal product as a repellent on human skin a directly and/or indirect exposure of mammals against relevant quantities of lauric acid or the biocidal product are not to be expected. So no data 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 A7.6 Annex Point IIA X.	Summary of ecotoxicological effects and fate and behaviour in the environment	Official use only
Results		
Biodegradation	The active substance lauric acid is stable, but readily biodegradable in soil and water [55, 67]. A one-day theoretical BOD of 1.6% was determined for lauric acid. In activated sludge media [68], a 100% TOC reduction was observed [69, 55]. It was demonstrated in a study according to OECD test guideline 301 B that the tested biocidal product containing lauric acid in the intended concentration of 10% is readily biodegradable [127]. Lauric acid itself is readily biodegradable, too, as shown in the test according to OECD test guideline 301 B [144].	
Phototransformation	There will be no phototransformation in water, because the substance does not absorb light over 290 nm.	
Contamination of fresh water, soil and air	The biocidal product is intended for application on human skin, so no contamination of fresh water, soil or air is intended. AOP model calculation for phototransformation in air was conducted for lauric acid, which gave a kdegair-value of 0.537 d^{-1}, that shows there will be no accumulation in the air or transportation by the air to other areas.	
Adsorption/desorption	A K_{OC} of about 300 can be estimated for lauric acid using a structure activity relationship [55, 70]. According to a suggested classification scheme [71], this K_{OC} value suggests that lauric acid has medium soil mobility [55]. Further estimations confirm this value (Non-ionised form: 297 L/kg [PCKOCWIN], 4700 L/kg [Briggs equation] and ionised form: 40 L/kg [Briggs equation]) [145]. An adsorption/desorption test by HPLC did not reveal new results because micelles were formed by the molecule lauric acid [145].	
Phototransformation in air	Vapor-phase lauric acid will degrade in the ambient atmosphere by reaction with photochemically produced hydroxyl radicals with an estimated half-life of about 1.21 days [55, 72]. Moreover, physical removal from air throught wet deposition (e.g., rainfall, dissolution into clouds) may be possible [55, 73].	
Fate and behaviour in air	According to a suggested classification scheme [74], the value of Henry's Law constant indicates that volatilization of dodecanoic acid from water will not be rapid, but possibly important in swallow rivers [74]. Based on a estimated vapour pressure at 25°C, dodecanoid acid should exist in very small quantities in vapor and particulate phase in the ambient atmosphere [75]. A $kdeg_{air}$ = 0.537 d^{-1} is calculated which shows no danger of lauric acid for the air.	
Aquatic toxicity	The toxicity on fish was investigated by Egmond van R et al [77], who determined a LC50 > 10 mg/L after 96 hours. A BCF_{fish} = 741.3 is estimated, which does not take the natural occurrence of fatty acids in fishes into account [96, 121]. The effect of the biocidal product (containing 10% lauric acid) on algae and invertebrates were tested. For the algae the E_bC_{50} (inhibition of the biomass production to 50%) and the E_rC_{50} (inhibition of growth rate to 50%) were between 10 and 100 mg/L after 72 hours [132]. A further test was conducted to determine the growth inhibition rate on algae of the active substance lauric acid: E_rC_{50}: 8.64 mg/L [146]. An other further test was conducted with the biocidal product (containing 10% lauric acid) on algae according to OECD 201 (2006) with the following results: The nominal data after 72 hours were calculated as followed: E_rC_{50}=22.0 mg/L and E_yC_{50}=12.2 mg/L (resp. effective geometric mean exposure concentration after 24 h: E_rC_{50}= 0.30 mg/L) [151]. The study according to OECD test guideline 209 to determine the	

Section A7.6 Annex Point IIA X.	Summary of ecotoxicological effects and fate and behaviour in the environment	
	inhibition of lauric acid to microbial activity shows an EC_{50} > 1000 mg/L [147]. Because a concentration > 1000 mg/L will probably not be reached because of the small applied amounts and the high dilution effects, there will be no inhibition of microbial activity. The test with the biocidal product on acute immobilisation of daphnia magna showed an EC_{50} between 10 and 100 mg/L after 24 hours [133]. The EC_{50} after 48 hours was 103.3 mg/L [133]. The active substance is readily biodegradable in soil and water [55, 68]. In addition, Lauric acid is a well-known naturally occurring substance widely used in food and cosmetic products. Specific tests on aerobic and anaerobic biodegradation in sewage are not necessary, because on one hand lauric acid is readily biodegradable in soil and water [55, 68], and on the other hand the quantities reaching sewage by body washing after use of the biocidal product will be extremely low. Lauric acid salts are also constituents of soaps. Bioaccumulation will not be critical, because microorganisms will feed and use fatty acids for microbial lipid synthesis naturally [128, 129]. The active substance (fatty acid, saturated, not branched, C8-12 with a carboxyl group at the end) is classified as low hazardous to water (WGK 1) according to the German "Allgemeine Verwaltungsvorschrift zum Wasserhaushaltsgesetz über die Einstufung wassergefährdender Stoffe in Wassergefährdungsklassen (VwVwS)" from 17.05.1999, last change 27.07.2005. But the active substance is readily biodegradable. Summarising these results, the biocidal product is readily biodegradable, it does not show bioaccumulation or dermal toxicity and it does not influence the microbial activity. In the test with the biocidal product of the most sensitive organism (algae) an E_bC_{50} between 10 and 100 mg/L is determined after 72 hours. Therefore, the biocidal product is classified as low hazardous to waters (WGK 1, Hazard Class 1) according to the Annex 4 of the German General Administrative Regulation on the Classification of Substances Hazardous to Waters into Hazard Classes (Allgemeine Verwaltungsvorschrift zum Wasserhaushaltsgesetz über die Einstufung wassergefährdender Stoffe in Wassergefährdungsklassen) of 17.05.1999	
Effect on other species	Although the fatty acid lauric acid shows antibacterial activities with minimal inhibitory concentrations against some bacteria [12, 147], there will be no risk for aquatic organisms, organism in soil, mammals, birds, honeybees or any non-target organisms in the environment, because it is a naturally occuring substance [55, 56] and it is readily biodegradable [55, 68].	
Conclusion	Lauric acid will not be hazardous to environment if used as repellent on human skin.	

Section A8 **Annex Point IIA VIII.8**	**Measures to be adopted to protect man, animals, and the environment**	
		Official use only
Section A8.1 Annex Point IIA VIII.8.1		
Recommended methods and precautions concerning handling, use, storage, transport	No special protective measures are necessary for handling. Avoid formation of dust. Store the active substance in the original container under cool and dry conditions, protected from light and air. Avoid extrem temperatures. Do not store together with strong oxidants.	
Section A8.2 Annex Point IIA VIII.8.2		
In case of fire, nature of reaction products, combustion gases etc.	Extinguishing agent: foam, dry powder or CO_2. Do not use water! Protection equipment: protective clothing and respiratory mask are recommended for firemen.	
Section A8.3 Annex Point IIA VIII.8.3		
Emergency measures in case of an accident	No special measures are necessary in case of an accident. Avoid the flow into streets or canalisation and drain. Measures for cleaning/adsorption: Transfer the product in labelled waste container. Remove residues and small amounts of product with water and cleaning agent. No dangerous substances will be released.	
Section A8.4 Annex Point IIA VIII.8.4		
Possibility of destruction or decontamination following release in or on the following: **(a) air** **(b) water, including drinking water** **(c) soil**	No dangerous substances will be released at unintended release. Additonal the active substance is easily biodegradable, so there will be no contamination of air, water and soil. The intended use as repellent on human skin will not result in a contamination of air, water or soil, which needs any methods for decontamination or destruction.	
Section A8.5 Annex Point IIA VIII.8.5		
Procedures for waste management of the active substance for industry or professional users		
8.5.1 Possibility of re-use or recycling	No data available.	
8.5.2 Possibility of neutralisation effects	No data available, but the active substance is readily biodegradable.	
8.5.3 Conditions for controlled discharge including leachate qualities on disposal	No data available, but the active substance is readily biodegradable.	
8.5.4 Conditions for controlled incineration	No data available, but the active substance is readily biodegradable.	

Section A8 **Annex Point IIA VIII.8**	**Measures to be adopted to protect man, animals, and the environment**
Section A8.6 Annex Point IIA VIII.8.6 **Observation on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms**	No data available.
Section A8.7 Annex Point IIA VIII.8.7 **Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of ground water against pollution caused by certain dangerous substances**	Biocidal active substances are general summarised in List II, but the active substance lauric acid is easily biodegradable and classified as "low hazardous to water" according the German WHG §19g, para. 5 and the German VwVwS annex 2.

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 A9	Classification and labelling	Official use only
Classification and Labelling	No sign of danger or risk and no phrases of danger or risk are necessary.	
Justification:	The active substance is classified and labelled by the manufacturer of the active substance according the principles of the Directive 98/8/EC, Article 20. In addition, a dermal toxicity study is conducted with the biocidal product, [redacted], according to OECD guideline 402 (see following pages). The result of the study shows, that the biocidal product does not require any classification according to EC-Commission directive 67/548/EEC and its subsequent amendments [redacted]).	

Section A9 Classification and labelling

Official use only

1 REFERENCE

1.1	**Reference**	Chevalier F, 2006, [redacted] unpublished [130].
1.2	**Data protection**	Yes
1.2.1	**Data owner**	Dr. R. Pfleger Chemische Fabrik GmbH
1.2.3	**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 Guideline 402 - EC method B.3 (92/69/EEC) - OECD Principles of Good Laboratory Practice, Document Nos. 1 and 13 - Japanese Guidelinie for Non-clinical Studies of Drugs Manual 1995; Guidelinies for Toxicity Studies of Drugs. Japanese Ministry of Health and Welfare.
2.2	**GLP**	Yes - Good Laboratory Practice Regulations of the EC enacted in Germany in the "Chemikaliengesetz" [Chemical Acts], current edition. - United States Food and Drug Administration Good Laboratory Practice Regulations – 21 Code of Federal Regulations, Part 58, current edition.
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Test material**	
3.1.1	Lot/Batch number	Batch No. [redacted]
3.1.2	Specification	As given in section II of Annex IIB of Directive 98/8/EC, Annex IIB.
3.1.3	Description	[redacted]
3.1.4	Purity	As defined by the manufacturer of the biocidal product
3.1.5	Stability	[redacted]
3.2	**Method**	
3.2.1	Species	Rat
3.2.2	Strain	[redacted]
3.2.3	Number of animals	[redacted])
3.2.4	Group	[redacted]
3.2.5	Body weight (at dosing)	Male: [redacted] Female: [redacted]
3.2.6	Age (at dosing)	Male: [redacted] Female: [redacted]
3.2.7	Identification of animals	By coloured marks and cage label

Section A9 Classification and labelling

3.2.8 Duration [redacted]

3.2.9 Diet

3.2.9.1 Food [redacted]

3.2.9.2 Water [redacted]

3.2.10 Housing

3.2.10.1 Bedding material [redacted]

3.2.10.2 Cages [redacted]

3.3 Administration

3.3.1 Dose [redacted]

3.3.2 Route of administration [redacted]

3.3.3 Vehicle [redacted]

3.3.4 Administration volume [redacted]

3.3.4 Dose level [redacted]

3.3.5 Frequency [redacted]

3.3.6 Exposure time [redacted]

3.3.7 Postexposure time [redacted]

3.3.8 Occlusion [redacted]

4 RESULTS

4.1 Dose level [redacted]

4.2 Erythema [redacted]

43 Oedema [redacted]

Section A9 Classification and labelling

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[redacted]

5.2 Results and discussion

[redacted]

5.3 Conclusion

According to EC-Commission directive 67/548/EEC and its subsequent amendments the results obtained under the present test conditions show that the biocidal product requires no classification [redacted]

Section A9 Classification and labelling

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	*Adopt applicant's version or include revised version. If necessary, discuss 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 (the text in section 4.4.2.5.1 gives guidance on this point)*
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 the 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*

Product labelling
(see following pages for printings)

Labelling on the front of the biocidal product:

100 ml

Active substance: Lauric acid

[redacted]

- protects reliably up to 8 hours
- good cutaneous tolerance

Labelling on the back of the biocidal product:

100 ml

[redacted]

Repellent against ticks

Containing [redacted] lauric acid per 100 ml lotion

Proved efficacy

- patented active substance with intense-efficacy
- scientifically documented (IS Insect Service, Berlin)
- protects reliably up to 8 hours

Cutanous tolerance

- Protection against ticks with skincare effects
- without preserving agent
- dermatological tested
- [redacted] is to be spread easy and good, it permeates quickly without residue and does not grease.

Dosage/Application: Apply a thin film on all parts of the skin that should be protected – also under clothes (border area). Please note: sensitive persons (e.g. babies) should test the tolerance in the crook of the arm before using. Do not apply in the area of the eyes. For a long lasting protection repeat the application after 6 – 8 hours.

Duration of protection: Reliable protection up to 8 hours.

Use [redacted] Zeckenschutz Lotion in a safe way.

It can be disposed with the household waste.

Available only in pharmacies.

Registration number: I- 51589

Pfleger, 96045 Bamberg

Lot/Expiration date: xx xx

PZN -3973447