Section A7.1.1.1.1/01 Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA, VII.7.6.2.1

Official use only

		1 REFERENCE
1.1	**Reference**	[redacted] (2002): *Test for Determination of the Hydrolysis of Art. Nr. 111887 (IR3535)*; [redacted], Doc. No. 711-001 (unpublished).
1.2	**Data protection**	Yes
1.2.1	Data owner	Merck KGaA
1.2.2	Companies with letter of access	None
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I for all references listed above.
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes. OECD Guideline for testing of chemicals No. 111: *Hydrolysis as a Function of pH*, adopted May 12, 1981.
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 MATERIAL AND METHODS
3.1	**Test material**	Art. Nr. 111887 (IR3535®)
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2.
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Further relevant properties	[redacted]
3.2	**Reference substance**	None
3.2.1	Initial concentration of reference substance	Not applicable
3.3	**Test solution**	See Table A7.1.1.1.1/01-1
3.4	**Testing procedure**	
3.4.1	Test system	See tables A7.1.1.1.1/01-2 and A7.1.1.1.1/01-3
3.4.2	Temperature	50 °C ± 0.5 °C: pre tests at pH 4, 7 and 9 50 °C ± 0.5 °C: main test at pH 9

Section A7.1.1.1.1/01 Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA, VII.7.6.2.1

		40 °C ± 0.8 °C: main test at pH 9
		30 °C ± 0.8 °C: main test at pH 9
3.4.3	pH	4, 7 and 9
3.4.4	Duration of the test	See table A7.1.1.1.1/01-4
3.4.5	Number of replicates	Two replicates per pH and temperature.
3.4.6	Sampling	See table A7.1.1.1.1/01-4
3.4.7	Analytical methods	Separation by HPLC with UV detection at 210 nm.
3.5	**Preliminary test**	In a preliminary test, the test item solutions were incubated at 50 ± 0.5 °C at three different pH values (4, 7 and 9) for 5 days. At pH 4 and 7 less than 10 % reaction was observed after 5 days and therefore the test item is considered hydrolytically stable at pH 4 and 7. At pH 9 an increasing reduction of the test item concentration was observed during the 5 days incubation period.
		4 RESULTS
4.1	**Concentration and hydrolysis values**	See Table A7.1.1.1.1/01-4
4.2	**Hydrolysis rate constant (k_h)**	Hydrolysis rate constants were only determined for pH 9: 25 °C* 0.0039226 h^{-1} 30 °C 0.0071 h^{-1} 40 °C 0.02007 h^{-1} 50 °C 0.05951 h^{-1} *k_h value at 25°C (not stated in the original report) was extrapolated according to the Arrhenius equation.
4.3	**Dissipation time**	Dissipation times of IR3535® at pH 9 at different incubation temperatures are presented in table A7.1.1.1.1/01-5. DT_{50} values ranged from 11.61 to 177 hours and DT_{90} values ranged from 38.7 to 587 hours.
4.4	**Concentration – time data**	See Table A7.1.1.1.1/01-4
4.5	**Specification of the transformation products**	Not indicated.
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The aqueous hydrolysis test was conducted according to the OECD guideline for testing of chemicals 111. The IR3535® stock solutions (in acetonitrile) were dissolved in buffer solutions of pH 4, 7 and 9 and incubated at 50 °C. Test solutions at pH 9 were additionally incubated at 40 °C and 30 °C.

Section A7.1.1.1.1/01 Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA, VII.7.6.2.1

5.2	**Results and discussion**	
5.2.1	k_H	The test substance IR3535® is not degradeable at pH 4 and pH 7. At pH 9 the hydrolysis rate contants k_H are: 25 °C* 0.0039226 h^{-1} 30 °C 0.0071 h^{-1} 40 °C 0.02007 h^{-1} 50 °C 0.05951 h^{-1} *k_h value at 25°C (not stated in the original report) was extrapolated according to the Arrhenius equation.
5.2.2	DT_{50}	The test substance IR3535® is not degradeable at pH 4 and 7. At pH 9 the half-life values are: 25 °C* 177 h 30 °C 97.6 h 40 °C 34.5 h 50 °C 11.7 h *k_h value at 25°C (not stated in the original report) was extrapolated according to the Arrhenius equation
5.3	**Conclusion**	Validity criteria can be considered as fulfilled. IR3535® was found to be stable under acidic and neutral conditions according to the criteria in the guideline. Under alkaline conditions IR3535® degrades with a DT_{50} value of 177 h at 25 °C.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	Formation of degradation products was not investigated. However, the study is acceptable to predict the hydrloysis rate constant and dissipation times of the parent substance IR3535®.

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	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 A7.1.1.1.1/01-1: Type and composition of buffer solutions

pH	Type of buffer (final molarity)	Composition
4	Citrate acid / Sodium hydroxide / Hydrochloric acid	280 mL citrate acid solution (10.5 g $C_6H_8O_7$*H_2O / 100 mL 1 mol/L sodium hydroxide solution) were mixed with 220 mL hydrchloric acid solution (0.1 mol/L).
7	Potassiumdihydrogenphosphate / Disodiumhydrogenphosphate	194 mL potassiumdihydrogenphosphate solution (2.26 g KH_2PO_4 / 250 mL HPLC-H_2O) were mixed with 306 mL disodiumhydrogenphosphate solution (5.933 g Na_2HPO_4*$2H_2O$ / 500 mL HPLC-H_2O).
9	Boric acid / Sodium hydroxide	500 mL boric acid solution (3.09 g H_3BO_3 + 3.72 g KCl in 500 mL HPLC-H_2O) were mixed with 210 mL sodiumhydroxide solution (0.1 mol/L NaOH)

Table A7.1.1.1.1/01-2: Description of test solution

Criteria	Details
Purity of water	Sterile solutions.
Preparation of test medium	Test items were dissolved in sterile buffer solutions.
Test concentrations (mg a.i./L)	Pre tests (50 °C): pH 4: 254.15 mg/L pH 7: 218 mg/L pH 9: 200.075 mg/L Main tests (pH 9): 30 °C: 1025 mg/L 40 °C: 947.9 mg/L 50 °C: 1040.1 mg/L
Temperature (°C)	50 °C: pre tests at pH 4, 7 and 9 50 °C: main test at pH 9 40 °C: main test at pH 9 30 °C: main test at pH 9
Controls	No controls were used in the test.
Identity and concentration of co-solvent	No co-solvents were used in the test.
Replicates	Two replicates.

Table A7.1.1.1.1/01-3: Description of test system

Glassware	Stopperd Erlenmeyer flasks (25mL) were used for carrying out the tests.
Other equipment	Analytical balance with an accuracy of 0.1 mg. The pH of each buffer solution was checked with a pH-meter
Method of sterilization	All glassware were sterilised. No more information provided

Table A7.1.1.1.1/01-4: Hydrolysis of test compound expressed as percentage of initial concentrations, at pH 4, pH 7 and pH 9.

pH 4 pre test

Compound	Sampling times (*hours*)							
	0	**2.5**	**5**	**24**	**48**	**72**	**96**	**120**
Part of initial concentrations of parent compound [%]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

pH 7 pre test

Compound	Sampling times (*hours*)							
	0	**2.5**	**5**	**24**	**48**	**72**	**96**	**120**
Part of initial concentrations of parent compound [%]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

pH 9 pre test

Compound	Sampling times (*hours*)							
	0	**2.5**	**5**	**24**	**48**	**72**	**96**	**120**
Part of initial concentrations of parent compound [%]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

n.a.: not applicable

pH 9 main test

Compound	Sampling times (*hours*)									
Part of initial concentrations of parent compound [%]	**30 °C**									
	0	**37**	**39**	**41**	**48**	**60**	**62**	**64**	**66**	**85.5**
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
	40 °C									
	0	**24**	**26**	**28**	**30**	**32**	**33.5**			
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]			
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]			
	50 °C									
	0	**3.5**	**5.5**	**7.5**	**7.5***	**9.5**	**10.5**	**11.5**	**12.3**	
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	

* [redacted]

Table A7.1.1.1.1/01-5: Dissipation times of IR3535® at pH 9 (expressed in hours)

25°C*		30 °C		40 °C		50 °C	
DT_{50}	DT_{90}	DT_{50}	DT_{90}	DT_{50}	DT_{90}	DT_{50}	DT_{90}
177	587	97.61	324**	34.53	115**	11.65	38.7**

* DT50/DT90 values at 25°C (not stated in the original report) were extrapolated according to the Arrhenius equation (see Table A7.1.1.1.1/01-6)

** DT_{90} values (not stated in the original report) were calculated through $DT_{90} = DT_{50}$ ln 10 / ln 2

Table A7.1.1.1.1/01-6: Calculated values that were not stated in the original report highlighted in grey

T [°C]	k_H [h^{-1}]	DT_{50} [h]	DT_{90} [h]***	T [K]	1/T [K^{-1}]	ln k_H*
30	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

Section A7.1.1.1.2/01 Phototransformation in water including identity of transformation products

Annex Point IIA, VII.7.6.2.1

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		1 REFERENCE
1.1	**Reference**	[redacted] (1997): *Direct Phototransformation of Insect-Repellent 3535 (TGAI) in Water*; [redacted] Doc. No. 712-001 (unpublished).
1.2	**Data protection**	Yes
1.2.1	Data owner	Merck KGaA
1.2.2	Companies with letter of access	None
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I for all references listed above.
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes. OECD Draft guidance document: *Direct Phototransformation of Chemicals in Water*, February 1995. Commission Directive 95/36/EC, Annex I, *Fate and Behaviour in the Environment*, 7.2.1.2: Photochemical degradation, 14 July 1995. EPA 712-C-95-022 (7101) August 1995. OPPTS 830.6313: *Stability to Sunlight, Normal and Elevated Temperature, Metals, and Metal Ions*. Public Draft. EPA Pesticide Assessment Guideline Subdivision D Sec 63-13: Stability.
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 MATERIAL AND METHODS
3.1	**Test material**	IR3535®
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in Section 2.
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Radiolabelling	[redacted]
3.1.6	UV/VIS absorption spectra and absorbance value	[redacted]

Section A7.1.1.1.2/01 Phototransformation in water including identity of transformation products

Annex Point IIA, VII.7.6.2.1

3.1.7	Further relevant properties	[redacted]
3.2	**Reference substance**	Two independently prepared standard solutions of IR3535® in methanol at an exactly known concentration of approximately 1 g / L were used. For calibration purposes, these solution were diluted with mobile phase prior to analysis.
3.3	**Test solution**	203 mg IR3535® were weighed, dissolved in the phosphate buffer (a 0.05 M buffer of pH 7 of KH_2PO_4 / NaOH) and brought up to a total volume of 200 ml with the phosphate buffer. The resultant solution was filter-sterilised through a 0.2 µm membrane filter and transferred into the sterilised reaction vessel. The reaction vessel was thereafter sealed with a quartz glass cover.
3.4	**Testing procedure**	
3.4.1	Test system	After preparation, the test solution was thermostatically controlled at 20.0 ± 3.0 °C and lighted in the Heraeus CPS+ suntester accelerated lighting unit. The dark control solution was placed in the dark under the same conditions as the test solution.
3.4.2	Properties of light source	Xenon lamp UV-filter to simulate sunlight spectrum (cut off at 290 nm)
3.4.3	Determination of irradiance	Actinometric measurement using the potassium ferrioxalate actinometer.
3.4.4	Temperature	20 ± 3 °C
3.4.5	pH	A 0.05 M phosphate buffer pH 7 (Dihydrogenphosphate / Sodium hydroxide) was used. From the test and dark control solution, the pH value at room temperature was 7.1 and at the end of the test 7.1 and 7.2, respectively. The temperature of the solution in the reaction vessel was measured each time after sampling.
3.4.6	Duration of the test	199.4 hours
3.4.7	Number of replicates	One
3.4.8	Sampling	0, 5.7, 22.0, 29.7, 51.2, 77.9, 146.8, 173.9 and 199.4 hours.
3.4.9	Analytical methods	HPLC: Column: LiCrospher 100 RP-18, 125 x 4 (I. D.) mm; d_p = 5 µm Mobile Phase: 50/50 (v/v) methanol (HPLC-grade, Labscan Limited Co., Dublin, Irreland) / Milli-Q water (Millipore Corp., Bedford, MA, USA) 1 ml / min; UV-detection at 210 nm; 10 µl injection volume
3.4.10	Calculations	The decrease was calculated using $[(C_0 - C_t)/C_0]$ x 100 % Relative concentraion: $C_r = [C_t/C_0]$ x 100 %
3.5	**Transformation products**	Not relevant, as no phototransformation occured.
3.5.1	Method of analysis for transformation	Not relevant, as no phototransformation occured.

Section A7.1.1.1.2/01 Phototransformation in water including identity of transformation products

Annex Point IIA, VII.7.6.2.1

products

4 RESULTS

4.1	**Screening test**	[redacted]
4.2	**Actinometer data**	[redacted]
4.3	**Controls**	[redacted]
4.4	**Photolysis data**	[redacted]
4.4.1	Concentration values	[redacted]
		[redacted]
4.4.2	Mass balance	[redacted]
4.4.3	k^c_p	[redacted]
4.4.4	Kinetic order	[redacted]
4.4.5	k^c_p / k^a_p	[redacted]
4.4.6	Reaction quantum yield (ϕ^c_E)	[redacted]
4.4.7	k_{pE}	[redacted]
4.4.8	Half-life ($t_{1/2E}$)	[redacted]
4.5	**Specification of the transformation products**	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	IR3535® was dissolved in buffer solutions of pH 7 to a concentration of approx. 1 g / L. The test solution was thermostatically controlled at 20 °C and lighted in the accelerated lighting unit. The dark control was placed in the dark under the same conditions. Eight samples were taken until the end of the test after ca. 200 hours. The samples were diluted 100 times with mobile phase prior to HPLC analysis.
5.2	**Results and discussion**	The concentration values of IR3535® stayed constant in both, the test system and the dark control. There was no photodegradation.
5.2.1	k^c_p	Not indicated / not relevant (see 4.4.1).

Section A7.1.1.1.2/01 Phototransformation in water including identity of transformation products

Annex Point IIA, VII.7.6.2.1

5.2.2	K_{pE}	Not indicated / not relevant (see 4.4.1).
5.2.3	ϕ^c_E	Not indicated / not relevant (see 4.4.1).
5.2.4	$t_{1/2E}$	Not indicated / not relevant (see 4.4.1).
5.3	**Conclusion**	The test results show that IR3535® is not subject to photolytical degradation.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	None

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
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	

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2000): *Ready biodegradability of Art. 111887 (IR3535) in a closed bottle test*; [redacted] Doc. No. 713-001 (unpublished).	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Merck KGaA	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I for all references listed above.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes. Method C.4-E: Closed bottle test.	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	IR3535®	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in section 2.	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Further relevant properties	[redacted]	
3.1.6	Composition of Product	[redacted]	
3.1.7	TS inhibitory to microorganisms	[redacted]	
3.1.8	Specific chemical analysis	[redacted]	
3.2	**Reference substance**	Aniline	
3.2.1	Initial concentration of reference substance	2.0 mg / L	

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

3.3	**Testing procedure**	
3.3.1	Inoculum / test species	Details on inoculum are summarised in table A7.1.1.2/01-2.
3.3.2	Test system	Details on test system, laboratory equipment etc. are given in table A7.1.1.2/01-3.
3.3.3	Test conditions	Details on the relevant test conditions are given in table A7.1.1.2/01-4.
3.3.4	Method of preparation of test solution	The test material was dissolved in a mineral medium and inoculated with a mixed microbial population incubated under aerobic conditions in the dark at 20 + 1 °C for 28 days.
3.3.5	Initial TS concentration	2 mg / L
3.3.6	Duration of test	28 days
3.3.7	Analytical parameter	Dissolved oxygen
3.3.8	Sampling	0, 7, 14, 21 and 28 days
3.3.9	Intermediates/ degradation products	Not identified
3.3.10	Nitrate/nitrite measurement	No
3.3.11	Controls	Inoculum control: inoculum without test substance Procedure control: inoculum with reference substance Toxicity control: inoculum with test substance and with reference substance
3.3.12	Statistics	According to the relevant guideline.
		4 RESULTS
4.1	**Degradation of test substance**	
4.1.1	Graph	[redacted]
4.1.2	Degradation	[redacted]
4.1.3	Other observations	[redacted]
4.1.4	Degradation of TS in abiotic control	[redacted]
4.1.5	Degradation of reference substance	[redacted]
4.1.6	Intermediates/ degradation products	[redacted]

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	A closed bottle test was performed to investigate the ready biodegradeability of IR3535®. The test material was dissolved in a mineral medium and inoculated with a mixed microbial population incubated under aerobic conditions in the dark at 20 + 1 °C for 28 days.
5.2	**Results and discussion**	Within the study period of 28 days, a degradation of 11 % was determined for IR3535®.
5.3	**Conclusion**	IR3535® is to be classified as being "Not Readily Biodegradeable".
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
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 A7.1.1.2/01-1: Guideline-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
CO_2 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 A7.1.1.2/01-2: Inoculum / Test organism

Criteria	Details
Nature	Activated sewage sludge
Species	Not specified
Strain	Not applicable
Source	Effluent of municipal sewage treatment plant
Sampling site	STP of the city of Darmstadt (Germany)
Laboratory culture	Not applicable
Method of cultivation	Not applicable
Preparation of inoculum for exposure	Filtration through a coarse folded filter.
Pretreatment	Aeration for 5 days
Initial cell concentration	5 mL/L

Table A7.1.1.2/01-3: Test system

Criteria	Details
Culturing apparatus	Closed bottles.
Number of culture flasks/concentration	2 with inoculum only (inoculum control) 2 with inoculum and reference item at 2 mg / L (procedure control) 2 with inoculum and test item at 2 mg / L 2 with inoculum, test item at 1 mg / L and reference item 1 mg / L (toxicity control)
Aeration device	Consumed O_2 was not replaced.
Measuring equipment	Not specified
Test performed in closed vessels due to significant volatility of TS	The closed bottle test was performed.

Table A7.1.1.2/01-4: Test conditions

Criteria	Details
Composition of medium [g/L]	According to the Guideline (See 2.1): Mineral Medium. No detailed description given.
Additional substrate	No.
Test temperature	20 $\pm$ 1 °C
pH	Not indicated
Aeration of dilution water	Not indicated
Suspended solids concentration	Not indicated
Other relevant citeria	Not indicated

Table A7.1.1.2/01-5: 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 $ThCO_2$	-	X
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	-	X
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%	X	-
Percentage of removal of reference substance reaches pass level by day 14	81 %	-

Section A7.1.1.2.1/02 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2011): *Art. 111887 (IR3535) Ready biodegradability Modified Sturm Test*; [redacted] Doc. No. 713-003 (unpublished).	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Merck KGaA	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes. Method OECD 301 B: CO_2 Evolution Test	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	IR3535®, Art. 111887	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in section 2	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Further relevant properties	[redacted]	
3.1.6	Composition of Product	[redacted]	
3.1.7	TS inhibitory to microorganisms	[redacted]	
3.1.8	Specific chemical analysis	[redacted]	

Section A7.1.1.2.1/02 Biodegradability (ready)

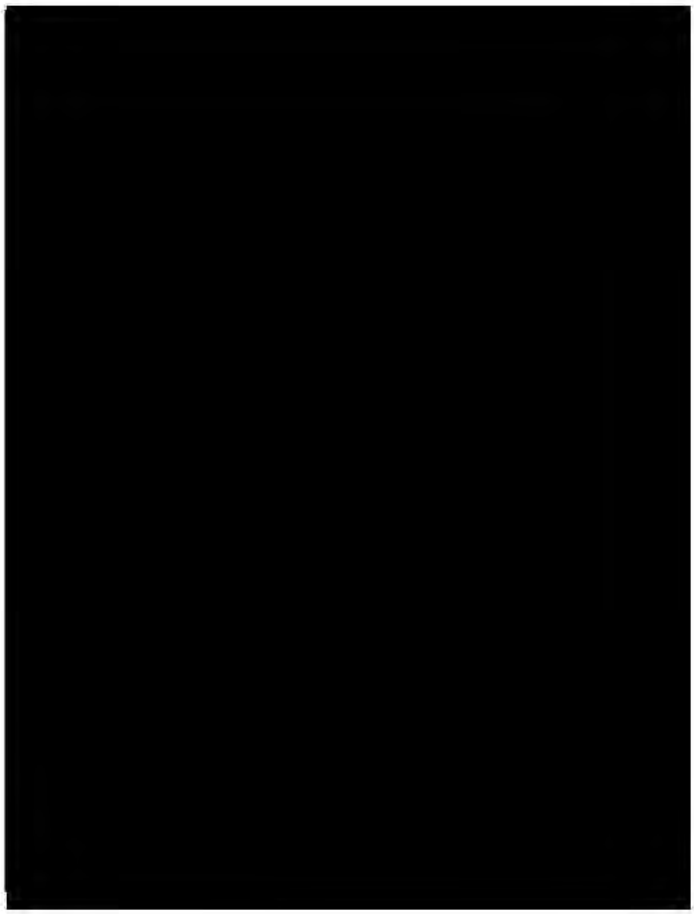
Annex Point IIA, VII.7.6.1.1

3.2	**Reference substance**	Sodium benzoate
3.2.1	Initial concentration of reference substance	20.0 mg/L
3.3	**Testing procedure**	
3.3.1	Inoculum / test species	Details on inoculum are summarised in table A7.1.1.2.1/02-2.
3.3.2	Test system	Details on test system, laboratory equipment, etc. are given in table A7.1.1.2.1/02-3.
3.3.3	Test conditions	Details on the relevant test conditions are given in table A7.1.1.2.1/02-4.
3.3.4	Method of preparation of test solution	The necessary amounts of test medium, bi-distilled water and the inoculum were placed into the incubation vessels, which were aerated for 24 hours with CO_2-free air. Thereafter, the incubation vessels were connected with the CO_2 adsorption vessels. Test and reference substance were weighed out and transferred into the incubation vessels with bi-distilled water. The vessels were then further connected to a system providing CO_2-free air.
3.3.5	Initial TS concentration	20.0 mg/L
3.3.6	Duration of test	28 days
3.3.7	Analytical parameter	CO_2 production
3.3.8	Sampling	6, 14, 21 and 28 days
3.3.9	Intermediates/ degradation products	Not identified
3.3.10	Nitrate/nitrite measurement	No
3.3.11	Controls	Inoculum control: inoculum without test substance Procedure control (functional control): inoculum with reference substance Toxicity control: inoculum with test substance and with reference substance
3.3.12	Statistics	According to the provisions of the test guideline.

4 RESULTS

4.1 Degradation of test substance --

4.1.1 Graph



4.1.2 Degradation

4.1.3 Other observations

[redacted]

4.1.4	Degradation of TS in abiotic control	[redacted]
4.1.5	Degradation of reference substance	[redacted]
4.1.6	Intermediates/ degradation products	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	A Modified Sturm Test acc. to OECD 301B Guideline was performed to investigate the ready biodegradability of IR3535®. The test material was dissolved in a mineral salt medium, inoculated with non adapted activated sludge and incubated over a test period of 28 days. The biodegradation of the test item was followed by titrimetric analysis of the quantity of CO_2 produced by the respiration of bacteria. The CO_2 production was calculated as percent of the theoretical CO_2 production ($ThCO_2$) of the test item.
5.2	**Results and discussion**	Within the study period of 28 days, a degradation of 18% was determined for IR3535®.
5.3	**Conclusion**	IR3535® is to be classified as being "Not readily biodegradable". The validity criteria are considered to be fulfilled, please refer to table A7.1.1.2.1/02-5.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
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 A7.1.1.2.1/02-1: Guideline-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
CO_2 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 A7.1.1.2.1/02-2: Inoculum / Test organism

Criteria	Details
Nature	Non adapted activated sludge
Species	Not specified
Strain	Not applicable
Source	Sewage treatment plant
Sampling site	Municipal sewage treatment plant, [redacted]
Laboratory culture	Not applicable
Method of cultivation	Not applicable
Preparation of inoculum for exposure	Washed twice with autoclaved tap water. After the second washing the settled sludge was re-suspended in mineral salts medium and homogenised with a blender.
Pre-treatment	The supernatant was decanted and maintained under aerobic conditions by aeration with CO_2-free air for 7 days.
Initial cell concentration	25 mL/L; 10^7 - 10^8 CFU/L in the test vessel

Table A7.1.1.2.1/02-3: Test system

Criteria	Details
Culturing apparatus	Incubation vessels with air outlets, which were connected to CO_2-adsorption vessels (gas-wash bottles, containing 100 mL of a 0.0125 mol/L $Ba(OH)_2$ solution).
Number of culture flasks/concentration	2 with inoculum only (inoculum control) 1 with inoculum and reference item at 20 mg / L (procedure control) 2 with inoculum and test item at 20 mg / L 1 with inoculum, test item and reference item in test concentrations (toxicity control)
Aeration device	Yes, system for the production of CO_2-free air, 30 - 100 mL/min.
Measuring equipment	Not specified
Test performed in closed vessels due to significant volatility of TS	No, vessels were closed in order to capture the CO_2 produced by the bacteria.

Table A7.1.1.2.1/02-4: Test conditions

Criteria	Details
Composition of medium [g/L]	Mineral salts medium acc. to OECD 301 B / CO_2 Evolution Test
Additional substrate	No
Test temperature	20.0 - 23.0 °C
pH	Not indicated
Aeration of dilution water	Not indicated
Suspended solids concentration	Not indicated
Other relevant citeria	Not indicated

Table A7.1.1.2.1/02-5: 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 $ThCO_2$	-	X
Pass values reached within 10-d window (within 28-d test period)	-	X
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%	X	-
If in a **toxicity test** only less than 25% degradation (based on total ThOD or $ThCO_2$) is found within 14 days, the substance is assumed to be inhibitory	TS is not inhibitory	
Percentage of removal of **reference substance** reaches pass level of 60% by day 14	X	-
The total CO_2 evolution in the **inoculum control** at the end of the test was < 40 mg/L	X	

Section A7.1.1.2.2 Annex Point IIA, VII.7.6.1.2	Biodegradability (inherent)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [...]**	
Detailed justification:	An STP simulation test was conducted with IR3535®. Therefore, a test on inherent biodegradability is not required according to the TGD.	X
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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, XII.2.1	Biodegradation in seawater	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]** **Detailed justification:**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [...]** According to the TNsG on data requirements a seawater biodegradation test is required if a substance is to be used or released in marine environments in considerable amounts (e.g. it is known to be repeatedly used or continuously released in marine environments). Due to the application scheme of IR3535®-based products, continuos release to marine environment and direct exposure of the marine compartment can be excluded. Therefore, a study on biodegradation in seawater is not regarded to be warranted.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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 A7.1.2.1.1/01 Aerobic biodegradation in biological sewage treatement

Annex Point IIIA, XI.2.1

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2006): Degradation of Art. 111887 (IR3535®) in an Aerobic Sewage Treatment Simulation Test in the Laboratory; [redacted] Doc. No. 713-002 (unpublished).
1.2	**Data protection**	Yes
1.2.1	Data owner	Merck KGaA
1.2.2	Companies with letter of access	None
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I for all references listed above.

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes. OECD guideline No. 303A: Coupled Unit test; DIN EN ISO 11733 (2004-11)
2.2	**GLP**	Yes
2.3	**Deviations**	Deviation 1: Dosage of the organic medium, test item unit In the running–in phase of the test item unit, the cooling system of the storage tank leaked. Therefore, the cooling liquid (ethylene glycol) fortified the DOC of the organic medium in the test item unit. No Effect on the Study is presumed, since the cooling liquid was not toxic to micro-organisms and the running system degraded the DOC and surplus DOC. The leak was repaired before the test item was added to the system. Deviation 2: On days 27 and 28, the dosage pump of the organic medium of the test item unit failed. Therefore the concentration of the test item increased by time. The increasing concentration of the test item resulted in a reduced degradation rate and the metabolite was found in raised concentrations. A break in the ultimate degradation curve was found. The activated sludge was not affected by the higher test item concentrations and the system recovered within one day

3 MATERIAL AND METHODS

3.1	**Test material**	IR3535®
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2.
3.1.3	Purity	[redacted]
3.1.4	Description of test	[redacted]

Section A7.1.2.1.1/01 Aerobic biodegradation in biological sewage treatement

Annex Point IIIA, XI.2.1

substance	
3.1.5 Further relevant properties	[redacted]
3.1.6 Composition of Product	[redacted]
3.1.7 TS inhibitory to micro-organisms	[redacted]
3.1.8 Specific chemical analysis	[redacted]
3.2 Reference substance	No
3.3 Testing procedure	
3.3.1 Inoculum / test species	Details on inoculum are summarised in table A7.1.1.2/01-2.
3.3.2 Test system	The elimination and the primary and/or ultimate biodegradation of Art. 111887 (IR3535®) by aerobic micro-organisms were tested in a continuously operated test system simulating the activated sludge process. An easily biodegradable organic medium and the organic test item were the sources of carbon and energy for the micro-organisms. The test was conducted by coupling the test units by exchanging activated sludge periodically (Coupling Units Test). The test unit was according to the Husmann unit and consists of an aeration vessel (about 4.6 L volume) and a separator (secondary clarifier, about 2.5 L). Further details on test system, laboratory equipment etc. are given in table A7.1.1.2/01-3.
3.3.3 Test conditions	Details on the relevant test conditions are given in table A7.1.1.2/01-4.
3.3.4 Method of preparation of test solution	Since the test item was soluble in water, a stock solution was prepared in pure water. For each organic medium batch a new batch of test item stock solution was prepared (Monday and Thursday).
3.3.5 Initial TS concentration	Phase 1: 79.3 mg/L (corresponding to 48.7 mg DOC/L) Phase 2: 23.79 mg/L (corresponding to 14.6 mg DOC/L). Since the results of the first weeks indicated an overload of the test unit, after 17 days of operation the test item concentration was reduced to 23.79 mg/L, corresponding to 14.60 mg carbon/L (phase 2). This concentration fits well within the recommended concentration range given by the guideline (10-20 mg/l DOC). The corresponding stock solution was 916 mg/L (nominal). This concentration was held until end of the test.

Section A7.1.2.1.1/01 Aerobic biodegradation in biological sewage treatement

Annex Point IIIA, XI.2.1

3.3.6 Duration of test	Evaluation time: day 21 to day 43 (about 3 weeks). The total duration of the experiment after addition of the test item: ~ 7 weeks.
3.3.7 Analytical parameter	Dissolved organic carbon, Art. 111887 (IR3535®) and IR3535-free acid
3.3.8 Sampling	The test item was applied on a Monday on the test unit. Until the plateau phase was reached, sampling was done Monday, Tuesday, Thursday and Friday. After plateau phase was reached, in addition Wednesday was a sampling date
3.3.9 Intermediates/ degradation products	IR3535-free acid
3.3.10 Nitrate/nitrite measurement	No
3.3.11 Controls	Inoculum control: inoculum without test substance
3.3.12 Statistics	According to the relevant guideline.

4 RESULTS

4.1 Degradation of test substance

4.1.1 Graph

[redacted]

Section A7.1.2.1.1/01 Aerobic biodegradation in biological sewage treatement

Annex Point IIIA, XI.2.1

[redacted]

4.1.2 Degradation

[redacted]

4.1.3 Other observations

[redacted]

4.1.4 Degradation of TS in abiotic control

[redacted]

4.1.5 Degradation of reference substance

[redacted]

4.1.6 Intermediates/ degradation products

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

A coupled unit test was performed to determine the elimination and the primary and/or ultimate biodegradation of Art. 111887 (IR3535®) by aerobic micro-organisms in a continuously operated test system

Section A7.1.2.1.1/01 Aerobic biodegradation in biological sewage treatement

Annex Point IIIA, XI.2.1

simulating the activated sludge process.

Art. 111887 (IR3535®) was given to a laboratory scale waste water treatment plant in three stages using two different concentrations of Art. 111887 (IR3535®). In the experiment besides DOC the Art. 111887 (IR3535®) and the IR3535-free acid concentration were measured by means of a specific HPLC-method. DOC elimination and the primarily degradation (based on test item and metabolite elimination measured by HPLC) were calculated.

5.2 Results and discussion

The removal of Art. 111887 (IR3535®) (primarily degradation) in the test unit was 78 % after eight days and reached a plateau after eleven days of more than 90 % elimination. Up from day 28, the elimination was 99 %.
The IR3535-free acid elimination rate decreased from a start value of 37 % to 12 % after 14 days, indicating an overload of the system. Up from day 15, the elimination rate increased. Nevertheless, after reducing the test item concentration, the metabolite elimination rate increased rapidly to 95 % and was constantly (with a technical caused break on days 28 and 29) at 95 %. The calculation of degradation rate was based on the theoretical residual amount of 0.1 mg/L as given by the LOD.

In the stage of 79.3 mg/L test item, the DOC removal of the control unit and Art. 111887 (IR3535®) unit were divergent, due to the incomplete degradation of the test item. Up from day 11, the DOC removal curve increased and reached the level of control after 18 days. Up from day 21, the DOC removal was on a high level within end of the experiment. The brake between days 27 and 32 was due to a failed organic medium maintenance in the test item unit. The degradation rate of Art. 111887 (IR3535®) recovered at a high level of 99 % and this was held until end of the experiment. The degradation rate of Art. 111887 (IR3535®) based on DOC removal was 97.9 % when calculated using the valid measuring points between days 21 and 43. If the break on days 28 and 29 is not considered, the degradation rate will be 99.8 %.

The sludge formation and dissolved oxygen concentration for both the control and the Art. 111887 (IR3535®) unit were in a typical range. This indicated an active sludge metabolism. No remarkable differences were found in the pH values. Thus, no toxic effects of Art. 111887 (IR3535®) on activated sludge microflora were observed in the experiment.

5.3 Conclusion

IR3535® is well biodegradable at about 99 % based on DOC-removal (primary degradation: 99 % based on LOQ) and does not affect the activity of the activated sludge. A complete mineralisation of IR3535® was indicated by the DOC-measurements under the given test conditions

5.3.1 Reliability

5.3.2 Deficiencies

No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	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 A7.1.1.2/01-1: Guideline-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
CO_2 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 A7.1.1.2/01-2: Inoculum / Test organism

Criteria	Details
Nature	Activated sewage sludge from a domestic waste water treatment plant
Species	Not specified
Strain	Not applicable
Source	Aeration tank
Sampling site	STP [redacted]
Laboratory culture	Not applicable
Method of cultivation	Not applicable
Preparation of inoculum for exposure	The activated sludge was stored overnight
Pre-treatment	The activated sludge was aerated with compressed air to reach a oxygen concentration of approximately 9 mg/L
Initial cell concentration	Inoculation of the test units: 2 g sludge dry matter per litre organic medium (municipal waste water) was used (397 mL activated sludge sediment per 4.6 L organic medium)

Table A7.1.1.2/01-3: Test system

Criteria	Details
Culturing apparatus	According to the Husmann unit and produced by Behr-Labortechnik GmbH, Düsseldorf
Number of culture flasks/concentration	Husmann unit: the type behrotest© KA 1 consists of an aeration vessel (about 4.6 L volume) and a separator (secondary clarifier, about 2.5 L). 1 test unit (with IR3535®) 1 control unit (without test item)
Aeration device	The aeration vessel was ventilated by a membrane pump via glass-frit in the bottom of the vessel. The re-feed of the activated sludge was done by an airlift-pump. The airflow is provided by a membrane pump using two separate flow-meters for the regulation (aeration vessel and airlift-pump).
Measuring equipment	Not specified

Table A7.1.1.2/01-4: Test conditions

Criteria	Details
Composition of medium [g/L]	Organic Medium: municipal waste water. No detailed description given.
Additional substrate	No.
Test temperature	19 °C to 20 °C (days –13 to 0) 20°C within the GLP-test phase
pH	pH 7.7 to 8.2 (days –13 to 0) pH 7.7 to 7.8 within the GLP-test phase
Aeration of dilution water	Not indicated
Suspended solids concentration	under steady state operating conditions: between 1 g/L and 3 g/L
Other relevant criteria	Not indicated

Section A7.1.2.1.2 Anaerobic biodegradation Annex Point IIIA, XII.2.1		
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [x]**	
Detailed justification:	According to the TNsG on data requirements, an anaerobic biodegradation study is required if exposure to anaerobic conditions is likely. IR3535® will only be used under aerobic conditions. Due to the application scheme, anaerobic situations for IR3535® are not likely. Therefore, a study on anaerobic biodegradation is not regarded to be warranted for IR3535®.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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**	**Aerobic aquatic degradation study**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification:	An aerobic aquatic degradation study is required if direct release into surface water may occur. Direct release of IR3535® to the aquatic compartment is not likely to occur: The main emission of IR3535® is from households where the substance is released to the facility drain and will pass an STP before release to surface water. The STP simulation test showed rapid degradation of IR3535® in the STP. If the product is applied outdoor, direct emission to a surface water is unlikely to occur as the substance is applied directly to the skin and the application takes place only on a punctual scale. In addition, the results of the risk assessment showed that the PEC/PNEC is << 0.1 for the aquatic compartment. It is therefore concluded that an aerobic aquatic degradation study is not required.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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 7.1.2.2.2 Water/sediment study under anaerobic conditions

Annex Point IIIA, XII.2.1

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [x]**	
Detailed justification:	A water sediment study under anaerobic conditions is required if the exposure of the substance to anaerobic conditions is very likely, e.g. when a major proportion of the substance is absorbed in sediment. Due to the physical/chemical properties of IR3535 an absorption to sediment is not likely to occur: The solubility of IR3535 is high (70 g/L) and the mean Koc was calculated to be 475.58. This values indicate that IR3535 will most likely remain in the water phase. In addition, the results of the risk assessment showed that the estimated $PEC/PNEC_{sediment}$ is << 0.1. It is therefore concluded that an anaerobic water/sediment study is not required.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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 A7.1.2.2.2/01
Annex Point IIIA XII 2.1

Rate of degradation in aquatic systems including identification of metabolites and degradation products
Aerobic Water/sediment degradation study

Official use only

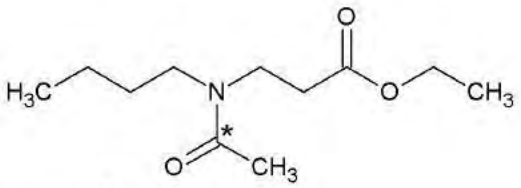
1 REFERENCE

1.1	**Reference**	Insect Repellent ^{14}C-IR3535® - Aerobic Transformation in Aquatic Sediment Systems using ^{14}C-labelled Test Item, [redacted], July 2012.
1.2	**Data protection**	Yes
1.2.1	Data owner	MERCK KGAA
1.2.2	Companies with letter of access	No companies with letter of access
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I.

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes: OECD Guideline 308 for Testing of Chemicals (April 2002)
2.2	**GLP**	Yes
2.3	**Deviations**	None

3 MATERIALS AND METHODS

3.1	**Test material**	Insect Repellent ^{14}C-IR3535®
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	3-[*N*-n-Butyl-*N*-acetyl]-aminopropionic acid-ethylester
3.1.3	Purity	[redacted]
3.1.4	Radiolabelling	

** = position of the ^{14}C-label*

3.1.5	Stability in vehicle	[redacted]
3.1.6	Further relevant properties	[redacted]

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3.1.7	TS inhibitory to microorganisms	[redacted]
3.2	**Reference substances**	Not applicable
3.3	**Testing procedure**	Water-sediment samples were treated with the test item and incubated in a gas flow through system in the dark under controlled laboratory conditions. After appropriate time intervals, replicates were removed and sediment, overlaying water and volatile traps were analysed for residual ^{14}C (test item and transformation products) and the DT_{50} and DT_{90} values were calculated. The mineralization was determined by trapping and analysis of the evolved $^{14}CO_2$.

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3.3.1 Water/sediment systems

Sediments and their associated waters (field fresh sampled) of the rivers ALTE LEINE[1)] and RÖSSING BACH[2)]. The sediments differ in their organic carbon content and texture.
Sediment parameters are:

1) ALTE LEINE: Low organic carbon content 0.9 – 1.7 % and coarse texture

	Particle size [mm]	Proportion [%]
Sand	2.0 - 0.063	77.3
Silt	0.063 – 0.002	21.3
Clay	< 0.002	0.7

2) RÖSSING BACH: High organic carbon content 2.1 – 3.0 % and fine texture

	Particle size [mm]	Proportion [%]
Sand	2.0 - 0.063	31.7
Silt	0.063 – 0.002	59.4
Clay	< 0.002	8.6

Origin

[1)] Water/Sediment "ALTE LEINE"
Sampling address: Redener Strasse, Koldingen, Germany
Coordinates: 52°16'48.25" N; 9°47'29.60" O

[2)] Water/Sediment "RÖSSING BACH"
Sampling address: Jägerweg, Rössing, Germany
Coordinates: 52°11'3.65" N, 9°49'13.47" O

The sampling sites were selected with respect to the regional biological and chemical water quality maps (interactive online version) of the LOWER SAXONY WATER MANAGEMENT, COASTAL DEFENCE AND NATURE CONSERVATION AGENCY (German: NLWKN). Both sampling sites were classified as unpolluted.

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3.3.2 Test system sampling

Sediment was collected according to the ISO/DIS guidance on sampling of bottom sediment. Samples were taken from the entire 5 to 10 cm upper layer of the sediment. The associated water was collected from the same site at the same time. Temperature, pH value and O_2 concentration of the water were measured at field sampling.

The sediment was separated from the water and manually cleared of large objects and then wet-sieved to a particle size of 2 mm. The specified amounts of sediments and water were mixed at the desired ratio (see test method) in the incubation flasks and prepared for the acclimation phase (see below).

The particle size distribution and the total organic carbon content (TOC) of the sediments was determined (non-GLP). Furthermore the pH-value and the microbial biomass (plate counts measurements) of the sediments were determined.

Freshly sampled sediment and water were used.

Water/sediment characteristics (measured at sampling date)

	Field sampling	Handling	Field sampling	Handling
Water	"ALTE LEINE"		"RÖSSING BACH"	
Temperature [°C]	9.3	-	7.1	-
pH-value	7.82	-	8.14	-
TOC [mg C/L]	-	6.46	-	1.57
O_2 concentration [mg O_2/L]	8.72	-	10.29	-
Microbial biomass [CfU/L]	-	$3.0*10^6$	-	$1.4*10^7$
Redox potential [mV]	-	225.3	-	141.4*
Sediment	ALTE LEINE"		"RÖSSING BACH"	
pH-value	-	7.61	-	7.40
TOC [%] #)	-	1.4	-	2.2
Microbial biomass [CfU/g wet sediment]	-	$1.3*10^7$	-	$1.7*10^7$
Redox potential [mV]	-	218.2	-	-198.4*
Sampling date	2011-10-17		2011-10-24	

* at application

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3.3.3	Test apparatus and preparation	Test vessels	Gas flow-through system: 500 mL glass flasks connected with a ethylene glycol trap for volatile organic transformation products and a series up to 4 sodium hydroxide traps for $^{14}CO_2$.
		Ethylene glycol trap	Crimped headspace bottle containing 50 mL ethylene glycol
		$^{14}CO_2$ trap	Up to 4 crimped headspace bottles containing 50 mL 1mol/L aqueous sodium hydroxide.
		Sediment/water ratio	1 : 3 Sediment: 100 g wet sediment per replicate, corresponding to 63.24 g DW for "ALTE LEINE" and 48.14 g dry weight (DW) for "RÖSSING BACH" corresponding to a sediment layer of 2.5 ± 0.5 cm Water: 300 mL corresponding to a water column of 7.5 ± 0.5 cm
3.3.4	Test system equilibration	The water/sediment samples were preincubated in the incubation vessels under test conditions for 15 days ("ALTE LEINE") and 10 days ("RÖSSING BACH") to allow stabilisation of the systems, as reflected by pH, O_2-concentration in water, redox potential of the sediment and water, and macroscopic separation of the phases. The microbial biomass (plate court measurements) of the water was determined at the start of the acclimatisation.	
3.3.5	Test conditions	Temperature	Nominal: 20 ± 2 °C Actual: 19 - 21 °C, short term deviations (< 12 h) to 18 °C and 22° C
		Aeration	The test vessels were continuously supplied with air by gentle bubbling with compressed, moistened air
3.3.6	Method of preparation of test solution	*Replicates for determination of the transformation rate:* Due to potential hydrolysis the test item was dissolved in ethanol by the sponsor. This storage solution was diluted with demineralised water to reach a concentration of 3 MBq/mL. 1 mL of this working solution was applied directly to the water water phase (300 mL) of each replicate, resulting in the concentration of 10 kBq/mL. *Replicates for identification of metabolites:* 1.02 mL of the storage solution and 1.5 mL of the stock solution (non-labelled test item) were applied directly to the water phase of each replicate, resulting in the test concentration of 30.1 mg/L.	

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3.3.7	Rate of application	*Replicates for determination of the transformation rate:* 10 kBq/mL corresponding to 1.02 mg/L *Replicates for identification of metabolites:* 30.1 mg/L, composed of 50 kBq/mL (5.1 mg/L) ^{14}C-labelled test item and 25 mg/L non-labelled test item
3.3.8	Duration of test	104 days ("ALTE LEINE") 103 days ("RÖSSING BACH")
3.3.9	Sampling and replicates	Sampling for determination of the transformation rate was carried out directly after application and at 8 additional sampling points. The sampling points were chosen in such a way that the pattern of decline of the test item could be established. The samplings of the water/sediment system "ALTE LEINE" were done on day 3, 7, 14, 28, 42, 57, 77 and 104 of the exposure phase. The samplings of the water/sediment system "RÖSSING BACH" were done on day 4, 7, 14, 28, 42, 56, 77 and 103 of the exposure phase 2 test item replicates were sacrificed at each sampling time. The water phase was carefully decanted to avoid disturbances of the sediment and the sediment and water were analysed separately. The sediment was homogenised by thorough stirring with a spatula. The corresponding traps were analysed for volatile transformation products (^{14}C). The residual ^{14}C in the water phase was quantified by LSC (Liquid Scintillation Counting) and the residual ^{14}C in the sediment was quantified by LSC after combustion in a sample oxidizer. Two sub-samples of the water phase and 5 sub-samples of the sediment were analysed. From sampling day 57 ("ALTE LEINE") and day 56 ("RÖSSING BACH") on, additionally 2 sub-samples of each replicate were acidified with conc. HCl, aerated for at least 3 h to exhaust dissolved CO_2 and the remaining radioactivity was determined. Further 2 sub-samples were mixed with a $Ba(OH)_2$ (2 mol/L), filtered and the remaining radioactivity was determined. Residual ^{14}C and $^{14}CO_2$ in the traps were determined by LSC. The amount of test item and transformation products (as % of applied radioactivity (AR)) in the water phase and the sediment (after extraction, for details see chapter 4.2) was determined by HPLC-FSA. The non-extractable residues (NER) as % of AR was determined by LSC after combustion of the extracted sediment. Sampling for separation of metabolites was done at test end.

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Rate of degradation in aquatic systems including identification of metabolites and degradation products

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3.3.10 Extraction and sample preparation

PREPARATION OF SAMPLES FOR LSC ANALYSIS

Radioactivity in Water:

10 mL of water were mixed with 10 mL of UltimaGold XR in a LSC-vial and measured with LSC.

Sediment Radioactivity:

The radioactivity in sediment samples was determined via LSC after combustion with a sample oxidiser. A wet sample of 0.7 g was directly weighed in 3 interlocked combusto cones. The combusto cones were combusted for 3 min. using the sample oxidizer. The produced CO_2 was trapped in 10 mL of Carbosorb E, mixed with
10 mL Permafluor E+ and measured by LSC.

Sediment Extracts:

100 µL of the sediment extracts after extraction (see below) was mixed with 10 mL of UltimaGold XR and analysed via LSC.

Carbon Dioxide Traps:

3 mL of the sodium hydroxide traps were mixed with 15 mL Hionic-Fluor in a LSC-vial and measured with LSC.

Traps for Volatiles:

2 mL of the ethylene glycol trap were mixed with 8 mL of HPLC-water in a LSC-vial followed by addition of 10 mL UltimaGold XR.

Non Extractable Residues (NER):

0.2 – 0.5 g of the air dried extracted sediments were weighted in 3 combusto pads, moistened and treated as described before for the unextracted sediment samples (see sediment radioactivity).

PREPARATION OF SAMPLES FOR HPLC-FSA ANALYSIS

Radioactivity in Water :

1 mL of water was stabilised with an equal amount of ethanol and filtered over a disposable syringe filter (Chromafil RC-45/15 MS) prior to analysis.

Sediment Radioactivity:

25 g wet sediment were extracted in a soxhlet extractor with refluxing acetonitrile between 4 and 8 h. The extract was evaporated to dryness using a rotary evaporator. The residue was dissolved in 5 mL of a 1:1 mixture of ethanol and HPLC water and filtered over a disposable syringe filter (Chromafil RC-45/15 MS) prior to analysis.

3.3.11 Analytical methods

The amount of applied radioactivity of Insect Repellent ^{14}C-IR3535® in the water phase and sediment was determined by liquid scintillation counting (LSC) and HPLC coupled to a flow scintillation analyser (FSA). Prior to LSC analysis aliquots of sediment samples were combusted with an oxidizer. Prior to HPLC-FSA aliquots of wet sediment were extracted by refluxing acetonitrile in a soxhlet extractor. The ethylene glycol traps for volatile compounds and the sodium hydyroxide traps for carbon dioxide were analysed by LSC only.

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3.3.12 Transformation products

Transformation products in water and sediment were determined by HPLC coupled to a flow scintillation analyser (FSA). Prior to HPLC-FSA aliquots of wet sediment were extracted by refluxing acetonitrile in a soxhlet extractor

4 RESULTS

4.1 Test conditions during incubation

[redacted]

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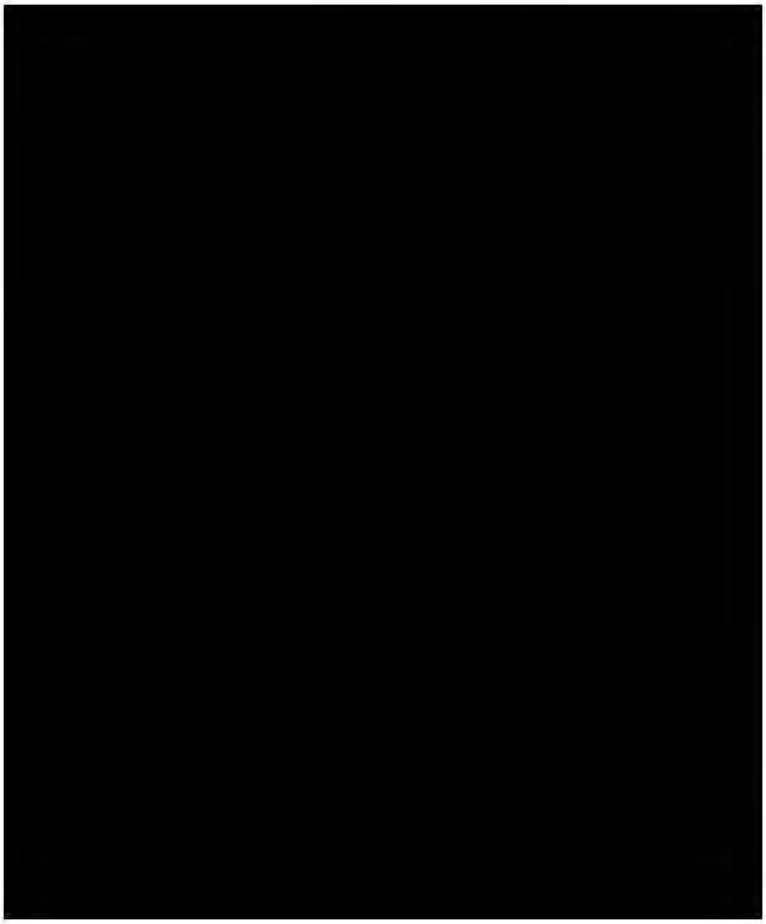
4.2 Material Balance



[redacted]

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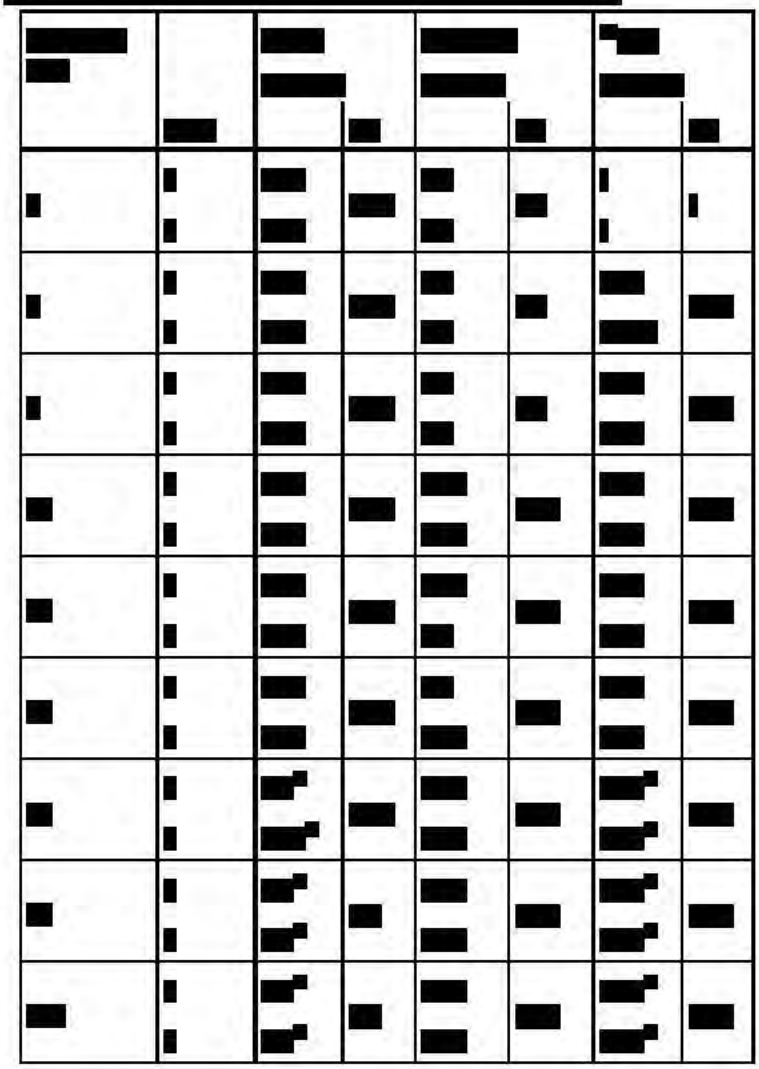
4.3 Distribution of radioactivity and Mineralisation

[redacted]



[redacted]

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[redacted]

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4.4 Identification of radioactivity

[redacted]

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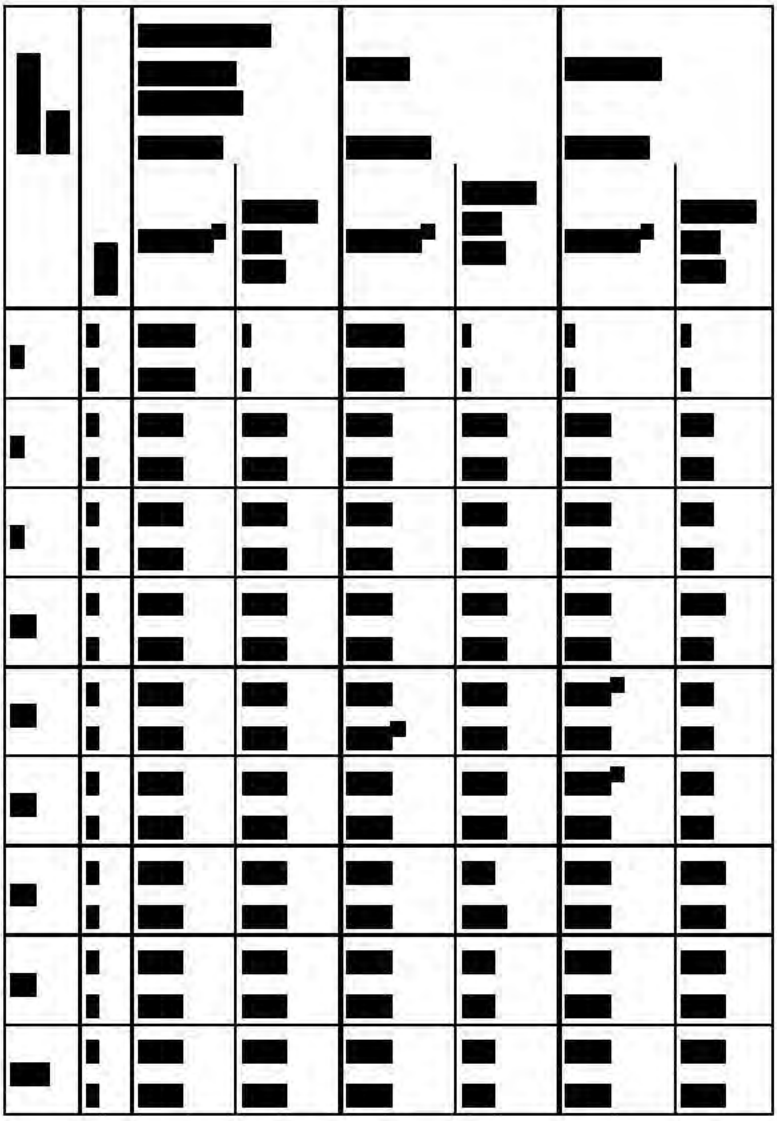
4.4.3 Degradation of the test substance and formation of degradation products

[redacted]



[redacted]

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[redacted]

Exposure [redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							

[redacted]

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4.4.4 Non-extractable residues (NER)

[redacted]

[redacted]

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[redacted]

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4.5 Half-life of the test substance and main degradation product

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]			
[redacted]			
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]			
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

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4.6 Degradation route

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The aerobic transformation of Insect Repellent ^{14}C-IR3535® was determined in two different aquatic sediment systems. Samples of two different aquatic sediment systems were treated with Insect Repellent ^{14}C-IR3535® and incubated in the dark under aerobic, controlled laboratory conditions for 103 and 104 days, respectively. Water sediment systems of the rivers "ALTE LEINE" and "RÖSSING BACH" were used. The sediments differ in their organic carbon content and texture. The sediment of "ALTE LEINE" has a low organic carbon content and a coarse texture and the sediment "RÖSSING BACH" had a high organic carbon content and fine texture. After appropriate time intervals (0, 3, 7, 14, 28, 42, 57, 77, and 104 days for the "ALTE LEINE" system and 0, 4, 7, 14, 28, 42, 56, 77 and 103 days for the "RÖSSING BACH" system) duplicate samples of the water and sediment phase were analysed for residual radioactivity and transformation products. The mineralization was determined by trapping and analysis of the evolved $^{14}CO_2$. The DT_{50} and DT_{90}, the disappearance time within the test item concentration is reduced by 50 % and 90 %, respectively was calculated with a single first order model (SFO). For the calculation of the mass balance and distribution between the water and sediment phase the radioactivity of the sediments, their associated water and evolved $^{14}CO_2$ was determined by LSC.

5.2 Results and discussion

A mass balance of 90 - 110 % (as % of applied radioactivity = AR) was obtained up to day 42 for the water sediment system "Alte Leine" and up to day 77 for the water sediment system "Rössing Bach". At day 57 ("Alte Leine") and day 103 ("Rössing Bach") sudden rapid CO_2 formation was determined. This $^{14}CO_2$ formation resulted in a decrease of the mass balance < 90 %, as a significant amount of $^{14}CO_2$ accumulated in the headspace of the test vessels and was lost during sampling. Moreover, it was determined that during the rapid degradation phase a high amount of $^{14}CO_2$ was dissolved in the water phase and even associated with the sediment. It is assumed, that further losses of CO_2 during sampling can be attributed to this behaviour.

At the test system "Alte Leine" up 11.2 % of the AR diffused from the water phase into the sediment until day 14, whereas the $^{14}CO_2$ formation was < 1 %. Up to day 42 the amount of AR in the sediment remained at 10.1 – 11.2 and a slowly increasing $^{14}CO_2$ formation was determined. Between day 42 and 57 the radioactivity determined in the water phase decreased rapidly from 82.0 % of AR to 11.3 % of AR. At the same time the amount of AR in the sediment increased to 19.9 % and rapid $^{14}CO_2$ formation was determined. Until day 77 the amount of AR in the sediment decreased to 13.4 % and was 12.4 % at test end.

With the "Rössing Bach" system 14.0 % of the AR diffused from the water phase into the sediment until day 28. The amount of AR in the sediment remained in the range 13.2 – 14.6 %. The $^{14}CO_2$ formation was slow until day 14 (1.15 %) and increased steadily until day 77 (18.9 %). Simultaneously the amount of AR in the water phase decreased. Between day 77 and 103 the

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radioactivity determined in the water phase decreased rapidly from 59.5 % of AR to 0.7 % of AR. At the same time rapid $^{14}CO_2$ formation was determined.

With both sediment systems, ^{14}C-IR3535 was transformed in the water phase until day 28. As main transformation product ^{14}C-IR3535 free acid was determined. In general, the maximum concentration of IR3535 free acid was determined on day 28. With the test system "Alte Leine" a slow decrease of ^{14}C-IR3535 free acid was determined between day 28 and day 42. Simultaneously the $^{14}CO_2$ formation increased. During the further course of the study the transformation of ^{14}C-IR3535 free acid and the $^{14}CO_2$ formation increased rapidly, and at test end ^{14}C-IR3535 free acid was completely transformed and not detectable in the water phase. No further metabolites were determined in the water phase. The same transformation kinetics was observed with the "Rössing Bach" system, however, the complete transformation of ^{14}C-IR3535 free acid and rapid $^{14}CO_2$ formation was observed between days 77 and 103. In the sediment extract samples of both systems ^{14}C-IR3535 free acid was determined as main ^{14}C compound. In general, the concentration of extractable ^{14}C-IR3535® was throughout the study below 1 % of the applied radioactivity. A minor metabolite (< 0.5 % of AR) was determined on day 57 ("Alte Leine") and day 77 (both systems) in the sediment. The concentration of ^{14}C-IR3535 free acid remained at a plateau until day 42 or day 77 in the system "Alte Leine" and "Rössing Bach", respectively, only a slow decrease could be determined. Thereafter, the concentration decreased rapidly and only < 1 % of AR could be determined as ^{14}C-IR3535 free acid. The decrease could be associated with the formation of NER and $^{14}CO_2$.

Evaluation of HPLC-FSA chromatograms of the water and sediment extract samples did not indicate any relevant additional peak (> 1 %) for both test systems.

In both systems, the transformation of ^{14}C-IR3535® followed single first order (SFO) kinetics in the total system and the water phase. The transformation of ^{14}C-IR3535 free acid showed generally two phases, a lag phase was followed by rapid and complete transformation. As these two phases cannot appropriately be described by one kinetic model, the kinetic evaluations were done separately for each phase. Both phases followed single first order kinetics. The DT_{50} values for ^{14}C-IR3535® were 7.68 and 6.06 days for the total system in the "Alte Leine" and "Rössing Bach", respectively. For the ^{14}C-IR3535® free acid, the DT_{50} values for the phase 1 and the phase 2 were 158 and 5.51 days ("Alte Leine") and 145 and 3.53 days ("Rössing Bach"), respectively.

5.3 Conclusion

^{14}C-IR3535® rapidly dissipated in this aerobic transformation system in two aquatic sediment systems. A significant transfer of ^{14}C-IR3535® to the sediment could not be observed.The only relevant metabolite formed, ^{14}C-IR3535® free acid, was also rapidly and completely transformed after a lag time. A very high rate of mineralization of the test item was observed. Radioactive $^{14}CO_2$ accounted for 54- 60% in both systems at the end of the incubation period.

5.3.1 Reliability

[redacted]

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

COMMENTS FROM ...

Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A7.1.3/01 Adsorption / Desorption screening test

Annex Point IIA, VII.7.7

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2002): *Determination of the Adsorption / Desorption Behaviour of Art. Nr. 111887 (IR3535)*, [redacted] Doc. No. 731-001 (unpublished).	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Merck KGaA	
1.2.2	Companies with letter of access	None	
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I for all references listed above.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes EEC-No. C.18 and OECD Guideline No. 106	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	Art. Nr. 111887 (IR3535®)	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in section 2	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Further relevant properties	[redacted]	
3.1.6	Method of analysis	[redacted]	X
3.2	**Degradation products**	Degradation products tested: No	
3.2.1	Method of analysis for degradation products	Not applicable	
3.3	**Reference substance**	No	
3.3.1	Method of analysis for reference substance	Not applicable	

3.4	**Soil types**	See Table A7.1.3/01-1.	X
		[redacted]	
3.5	**Testing procedure**		
3.5.1	Test system	The adsorption behaviour of the test item was determined by shaking soil in a 0.01 M $CaCl_2$ solution of the test item. The decrease in the concentration of the test item in the aqueous solution indicated the adsorption rate. Following the pre-test to determine the soil to solution ratio, the time for reaching the adsorption equilibrium was estimated (adsorption kinetic). Subsequent the desorption behaviour was determined by extracting the test item from the soil with 0.01 M $CaCl_2$ solution. In further experiments, the adsorption isotherms were estimated. For this purpose the adsorption of the test item was measured at different concentrations of the test item in aqueous solution. In a further step the desorption isotherms were estimated.	
3.5.2	Test solution and Test conditions	0.01 M $CaCl_2$ was used in the aqueous solvent phase. Deionised water was used to prepare the $CaCl_2$ solution. All tests were run with centrifugation glasses. The glasses were closed with caps.	
3.6	**Test performance**		
3.6.1	Preliminary test	According to (a)"OECD 106": Yes A pre-test was conducted to determine the optimum soil / solution ratio for the main test. Two soil types and three soil/solution ratios were used. The soil to solution ratios used were 1:1, 1:5 and 1:25. 50 g, 10 g and 2 g of the soils, respectively and 45 mL of 0.01 M $CaCl_2$ were shaken for approximately 23 hours. Afterwards 5 mL of a test item solution in 0.01 M $CaCl_2$ was added and it was shaken again for 24 hours. Each experiment was done in duplicate. The aqueous solution was analysed immediately.	
3.6.2	Screening test: Adsorption	According to (a)"OECD 106": Yes **Adsorption Kinetics:** Five soils differing in soil texture, organic carbon content and pH were used. The soil / solution ratio, the weight of the soil sample, the volume of the aqueous phase in contact with the soil and the concentration of the test item were chosen based on the results of the pre-test. A soil solution ratio of 1/5 (m/m) was used. All tests were run with centrifugation glasses. The glasses were closed with caps. About 2.5 g of each soil was weighed into the glass and equilibrated with 10 mL of 0.01 M $CaCl_2$ solution. Then 2.5 mL of a 0.01 M $CaCl_2$ solution containing a known concentration of the test item was added. One control with only the test item in $CaCl_2$ solution (without soil) and one blank run per soil with the same amount of soil and the total volume of $CaCl_2$ solution were subjected to the same procedure. The containers were shaken automatically for time intervalls of 4 h, 24 h and 48 h. After centrifugation and filtration the remaining concentration of the test item in the aqueous phase was determined by means of HPLC. Each experiment was done in duplicate. Details can be found in tables A7.1.3/01-3 - A7.1.3/01-7.	

Adsorption Isotherms:

The test procedure is similar to that of the Adsorption Kinetics test. Five different concentrations of about 500 – 10000 mg/L were used. Details can be found in tables A7.1.3/01-13 - A7.1.3/01-17.

3.6.3 Screening test: Desorption

According to (a)"OECD 106": Performed

Desorption Kinetics:

The same soils as for the adsorption test were used and mixed with test item solution. About 2.5 g of each soil was weighed into the glass and equilibrated with 10 mL of 0.01 M $CaCl_2$ solution. Then 2.5 mL of a 0.01 M $CaCl_2$ solution containing a known concentration of the test item was added.

All the mixtures of the soil with the solution were agitated until to reach adsorption equilibrium as determined before in the adsorption kintetics test.

Then, the phases were separated by centrifugation and the aqueous phases were removed. The removed volume was measured and was replaced by an equal volume of 0.01 M $CaCl_2$ solution without test item and the new mixtures were agitated again. After each contact time the suspension was centrifuged. An aliquot was removed for determination of the test item. The volume of solution removed was replaced by an equal volume of 0.01 M $CaCl_2$ solution without test item and the new mixtures were agitated again. The removed aqueous phase was measured after 4 h and 24 h. In contrast to the information given in the study report, the experiment was ended after 24 h and not after 48 h.

Desorption Isotherms:

Freundlich desorption isotherms were determined on the soils loaded in the adsorption isotherms experiment. The test procedure is similar to that of the desorption kinetics test. The removed volume was measured and was replaced by 10 mL of 0.01 M $CaCl_2$ solution (12.5 mL in the case of Lufa 2.1 and Eurosoil 2) without test item and the new mixtures were agitated again for 48 hours. Afterwards the suspension was centrifuged and filtered to obtain a clear solution. The aqueous solution was analysed immediately. Details can be found in tables A7.1.3/01-18 - A7.1.3/01-22.

3.6.4 HPLC-method

It is stated in the study report that the analytical method concerning the determination of the test item was provided by the sponsor and was modified as necessary to suit the purpose and the instrumentation available at the performing laboratory. A detailed description of this method is also provided in the dossier in Section A4.1 (Doc. No. 114-004). No information about a pre-treatment of the solutions, before they were analysed is given in the study report. X

HPLC System:	LaChrom, Merck Hitachi
Column:	Ultrasep ES RP 18, 125 * 3 mm
Oven Temperature:	25 or 30 °C
Detector:	UV Detector
Monitoring Wave Length:	210 nm
Mobile Phase:	50% methanol / 50% water
Flow Rate:	0.5 mL/min or 0.75 mL/min
Injection Volume:	10 µL
Integration Software:	Merck L-7000 Workstation

3.6.5 Other test

Mass Balance: Soil type 1 and 5 were used. An adsorption step was undertaken in the same way as in the adsorption kinetic experiments. The phases were separated by centrifugation and the aqueous phases were removed as much as possible.

Afterwards the soil was extracted twice by acetonitrile (10 mL).

The remaining concentration of the test item in the removed aqueous phase and in the acetonitrile phases were determined by means of HPLC.

4 RESULTS

4.1 Preliminary test

[redacted]

4.2 Screening test: Adsorption

[redacted]

4.3 Screening test: Desorption

Desorption kinetics:

[redacted]

[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]

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

[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

4.4 Calculations

4.4.1 K_{ads} , K_{des}

[redacted]

4.4.2 $Kads_{oc}$, $Kdes_{oc}$

[redacted]

4.5 Degradation product(s)

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The adsorption/desorption behaviour of IR3535® on soil was determined according to the OECD Guideline for the testing of chemicals No. 106 "Adsorption – Desorption Using a Batch Equilibrium Method". The tests from Tier 1 to Tier 3 were performed.

5.2	**Results and discussion**	IR3535® was easily adsorbed on the soils used in this study. The adsorption $Kads_{oc}$ values range from 31.9 to ~~1141~~1144. Only for Eurosoil 1 and 5 meaningful results were obtained in the desorption kinetics experiments, i.e. desorptions were detected in both desorption steps after 4 and 24 hours in at least one replicate. Problems occurred with the desorption isotherms experiments (see 4.3). IR3535® adsorption did not appear to be highly correlated with soil organic matter content, clay content or cation exchange capacity.		
5.2.1	Adsorbed a.s. [%]	21.8 – 84.2		
5.2.2	K_{ads}	1.41 – 27.3	mean: 9.516	
5.2.3	$Kads_{oc}$	31.9 – 1144	mean: 475.25	
5.2.4	K_F^{ads}	2.54 – 349	mean: 97.8	
5.2.5	$K_F^{ads}{}_{OC}$	57.3 – 38778	mean: 8821	
5.2.6	K_{des}	K_{des} values at equilibrium were not stated in the study. The values were calculated according to the equation given in 4.4.1. Only for Eurosoil 1 and Eurosoil 5 the data allowed the calculation of an overall K_{des} value after 24 hours.		
		Eurosoil 1:	Rep. 1: 60.385*	
			Rep. 2: 54.2	mean 57.3
		Eurosoil 5:	Rep. 1: 17.33	
			Rep. 2: 29.75	mean 23.54
		*For Eurosoil 1 in Replicate 1 after 24 hours a negative desorption was detected. This value was very low, so that the values of test item concentration in the solution before and after the desorption step can be considered to be equal, hence the desorption is 0 and the overall K_{des} is already given by the K_{des} value after 4 hours in this case.		
		K_{des}: mean 40.4		
5.2.7	$Kdes_{oc}$	Eurosoil 1: 1741	Eurosoil 5: 531	mean: 1136
5.2.8	K_F^{des}	Eurosoil 5: 2.20		
5.2.9	$K_F^{des}{}_{OC}$	Eurosoil 5: 49.7		
5.2.10	K_{ads}/K_{des}	0.236		
5.2.11	Degradation products (% of a.s.)	No degradation was observed. See 4.5.		
5.3	**Conclusion**	Validity criteria can be considered as fulfilled. The adsorption coefficients $Kads_{oc}$ of IR3535® on soil, determined with the batch equilibrium method, were found to range from 31.9 to 1144. IR3535® adsorption did not appear to be highly correlated with soil organic matter content, clay content or cation exchange capacity.		
5.3.1	Reliability	[redacted]		
5.3.2	Deficiencies	In the adsorption step and the time until the desorption experiment was started, no equilibrium was reached in case of LUFA 2.1. However, the desorption experiment was started for all soils. Results for desorption step were only available for two soils. In case of the Desorption Isotherms experiments, results were only obtained for Eurosoil 5 (nevertheless values Freundlich Desorption Isotherms for all soils are stated in the original report).		

	According to the TNsG on data requirements Chapter 2: Core data set / Part A (7.1.3) "A screening test is always required according to, for example, to the new EC method C.18 or the corresponding OECD guideline 106 tier 2 [...]". The OECD guideline 106 Tier 2 requires: "Screening test: the adsorption is studied in five different soil types by means of adsorption kinetics at a single concentration and determination of distribution coefficients [...]". Desorptions kinetics and Freundlich desorption isotherms are part of tier 3. Therefore the studie fulfils the data requirements and the reliability of the study is not affected.	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
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 A7.1.3/01-1: Classification and physico-chemical properties of soils used as adsorbents

	Soil 1	Soil 2	Soil 3	Soil 4	Soil 5
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					

Table A7.1.3/01-2: Results of preliminary test with Lufa 2.1 and Eurosoil 5:

[redacted]

Table A7.1.3/01-3: Results of screening test - adsorption: Lufa 2.1

[redacted]

Table A7.1.3/01-4: Results of screening test - adsorption: Eurosoil 1

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

Table A7.1.3/01-5: Results of screening test - adsorption: Eurosoil 2

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

Table A7.1.3/01-6: Results of screening test - adsorption: Eurosoil 3

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

Table A7.1.3/01-7: Results of screening test - adsorption: Eurosoil 5

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

Table A7.1.3/01-8: Results of screening test - desorption: Lufa 2.1

[redacted]

[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				

[redacted]

Table A7.1.3/01-9: Results of screening test - desorption: Eurosoil 1

[redacted]

[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				

[redacted]

Table A7.1.3/01-10: Results of screening test - desorption: Eurosoil 2

[redacted]

[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				

[redacted]

Table A7.1.3/01-11: Results of screening test - desorption: Eurosoil 3

[redacted]

[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				

[redacted]

Table A7.1.3/01-12: Results of screening test - desorption: Eurosoil 5

[redacted]

[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				

Table A7.1.3/01-13: Results of the Adsorption Isotherms for Lufa 2.1

[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						

[redacted]

Table A7.1.3/01-14: Results of the Adsorption Isotherms for Eurosoil 1

Table A7.1.3/01-15: Results of the Adsorption Isotherms for Eurosoil 2

Table A7.1.3/01-16: Results of the Adsorption Isotherms for Eurosoil 3

[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						

[redacted]

Table A7.1.3/01-17: Results of the Adsorption Isotherms for Eurosoil 5

[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						
[redacted]						

[redacted]

Table A7.1.3/01-18: Results of the Desorption Isotherms for Lufa 2.1

[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					

[redacted]

Table A7.1.3/01-19: Results of the Desorption Isotherms for Eurosoil 1

[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					

[redacted]

[redacted]

Table A7.1.3/01-20: Results of the Desorption Isotherms for Eurosoil 2

[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					

[redacted]

Table A7.1.3/01-21: Results of the Desorption Isotherms for Eurosoil 3

[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					

[redacted]

Table A7.1.3/01-22: Results of the Desorption Isotherms for Eurosoil 5

[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					

[redacted]

Section A7.1.4.1 Annex Point IIIA, XII.2.1	Field study on accumulation in the sediment	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [ ]	**Other justification** [x]	
Detailed justification:	The risk assessment indicates that there is no risk for aquatic organisms. Thus, a field study on accumulation in the sediment is not required.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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 7.2.1 Annex Point IIIA, VII.4, XII.1.1	Aerobic degradation in soil, initial study	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ]	
Limited exposure [x]	**Other justification [...]**	
Detailed justification:	A PEC_{soil} of 0.00068 mg/kg soil was calculated for IR3535® in the in-door scenario. In the outdoor scenario, a PEC_{soil} of 0.0159 mg/kg for the upper 5 cm of soil was calculated. Taking into account the $PNEC_{soil}$ of 4.54 mg/kg calculated on the basis of the equilibrium partitioning method as described in the TNsG, a $PEC/PNEC_{soil}$ of 1.5 x 10^{-4} results for the in-house scenario and a $PEC/PNEC_{soil}$ of 0.0035 results for the outdoor scenario. Thus, the calculated $PEC/PNEC_{soil}$ is well below 0.1 for both scenarios. There is not unacceptable risk and the conduction of an aerobic degradation study in soil is therefore not considered to be necessary.	X
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.2.2 **Annex Point IIIA, VII.4, XII.1.1, XII.1.4**	**Aerobic degradation in soil, further studies:** The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions

JUSTIFICATION FOR NON-SUBMISSION OF DATA — Official use only

Other existing data [ ] **Technically not feasible** [ ] **Scientifically unjustified** [ ]

Limited exposure [ ] **Other justification** [x]

Detailed justification:

The conduct of further studies on aerobic degradation in soil is only necessary, if an initial study on aerobic degradation in soil is necessary. However, as stated under Doc. IIIA chapter A7.2.1, an initial study on aerobic degradation is not required for the following reasons:

A PEC_{soil} of 0.00068 mg/kg soil was calculated for IR3535® in the in-in-door scenario. In the outdoor scenario, a PEC_{soil} of 0.0159 mg/kg for the upper 5 cm of soil was calculated.

Taking into account the $PNEC_{soil}$ of 4.54 mg/kg calculated on the basis of the equilibrium partitioning method as described in the TNsG, a $PEC/PNEC_{soil}$ of 1.5×10^{-4} results for the in-house scenario and a $PEC/PENC_{soil}$ of 0.0035 results for the outdoor scenario.

Thus, the calculated $PEC/PNEC_{soil}$ is well below 0.1 for both scenarios. There is not unacceptable risk and the conduction of an aerobic degradation study in soil is therefore not considered to be necessary.

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date [redacted]

Evaluation of applicant's justification [redacted]

Conclusion [redacted]

Remarks [redacted]

COMMENTS FROM OTHER MEMBER STATE *(specify)*

Date *Give date of comments submitted*

Evaluation of applicant's justification *Discuss if deviating from view of rapporteur member state*

Conclusion *Discuss if deviating from view of rapporteur member state*

Remarks

Section A7.2.3 **Annex Point IIIA, XII.1.2**	**Adsorption and mobility in soil, further studies:** Adsorption and desorption in at least three soil types and, where relevant, the adsorption and desorption of metabolites and degradation products	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
	A full scale adsorption test for IR3535® in five different soils is available and described in detail in Meinerling & Fieseler (2002), Doc. No. 731-001 Doc. IIIA, Section A7.1.3/01. There were no relevant metabolites and degradation products detected. The conduct of further studies on the adsorption and mobility in soil is only required if • PEC/PNEC > 1 in soil. In the risk assessment for soil a PEC/PNEC of 1.5 x 10^{-4} was calculated for the indoor application and a PEC/PNEC of 0.0035 was calculated for the outdoor application. In both cases the PEC/PNEC for soil is far below 0.1. • Leaching to groundwater occurs In the risk assessment for groundwater a PEC_{gw} of 9.85 x 10^{-2} µg/L was calculated for the indoor application under very conservative assumptions as given in the TGD. Due to the different application scheme, the PEC_{gw} of the outdoor scenario was calculated with FOCUS PELMO. A PEC_{gw} of < 0.0001 µg/L was calculated. Both PEC_{gw} are below 0.1 µg/L, thus it can be concluded that IR3535® does not leach to groundwater. • Direct release to soil occurs This is the case for IR3535® in the outdoor scenario. IR3535® is applied to human skin once per day. During the application a certain amount of IR3535® might get in direct contact with soil on an estimated are of ~ 1 m² around the person applying IR3535®. Due very punctual application, exposure to soil is very limited. In addition, the PEC and PEC/PNEC values calculated in the risk assessment for soil are very low. Therefore it can be concluded that IR3535® does not pose any risk for the soil compartment. It is therefore concluded that the conduct of further studies on the adsorption and mobility in soil is not required.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	

Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2005): Estimation of photochemical degradation of IR3535® using the Atkinson method; [redacted] Doc. No. 743-001; 06.09.2005; (unpublished)
1.2	**Data protection**	Yes
1.2.1	Data owner	Merck KGaA
1.2.2	Companies with letter of access	No companies with letter of access
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I.

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Not applicable; model calculation according to the Atkinson calculation method.
2.2	**GLP**	No; study is a model calculation.
2.3	**Deviations**	Not applicable.

3 MATERIAL AND METHODS

3.1	**Test material**	Not applicable.
3.2	**Reference substance**	Not applicable.
3.3	**Test solution**	Not applicable.
3.4	**Testing procedure**	The photochemical and oxidative decomposition of IR3535® in air was evaluated based on theoretical grounds by a calculation according to Atkinson. The calculation was performed with the help of the program AOPWIN, Atmospheric Oxidation Programme v1.91 for Microsoft Windows 3.1, Windows 95/98, Windows NT (© 2000 US Environmental Protection Agency).

4 RESULTS

4.1	**OH radical reaction rate constant k_{OH}**	[redacted]

Section A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

4.2	Ozone reaction rate constant k_{Ozone}	[redacted]
4.3	Atmospheric half-life using k_{OH}	[redacted] X
4.4	Atmospheric half-life using k_{Ozone}	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	Materials and methods	The photochemical and oxidative decomposition of IR3535® in air was evaluated based on theoretical grounds by a calculation according to Atkinson.
5.2	Results and discussion	
5.2.1	Reaction rate constant	$k_{OH} = 29.2693 \times 10^{-12}$ cm^3 molecule^{-1} sec^{-1}. No Ozone reaction is estimated for IR3535®
5.2.2	Tropospherical half life	The DT_{50} for IR3535® in air was estimated to be 4.385 hours using k_{OH}. No Ozone reaction is estimated for IR3535®
5.3	Conclusion	IR3535® degrades in the atmosphere by reaction with OH radicals, having a DT_{50} value of 4.385 hours. As the active substance contains no olefinic carbon-carbon double and acetylic triple bonds, IR3535® is not supposed to react with ozone.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

Section A7.3.1/01 Phototransformation in air (estimation method)

Annex Point IIIA, VII.5

Evaluation by Competent Authoritiess	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS ~~FROM ..~~ [redacted]
	[redacted]
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS RMS
	[redacted]
Date	[redacted]
Materials and Methods	
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	

Section A7.3.2 Annex Point IIIA, XII.3	Fate and behaviour in air, further studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [x]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [...]**	
Detailed justification:	According to the TNsG on data requirements an experimental estimation of the fate and behaviour in air is only required if the active substance is to be used in preparations form fumigants or causes risk to the atmospheric environment. Due to the fact that IR3535® is an insect repellent which is not intended to be formulated as fumigants and which showed no relevant risk based on the Atkinson calculation, further studies on fate and behaviour of IR3535® in air are not required.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.4.1.1/01 Acute toxicity to fish

Annex Point IIA, VII.7.1 Zebra fish (*Brachydanio rerio*)

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2000): Art. 111887 (IR3535) – Acute toxicity in Zebra fish; [redacted] Doc. No. 821-001 (unpublished)	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Merck KGaA	
1.2.2	Companies with letter of access	No	
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes EU Commission Directive 92/96/EEC, C.2 OECD 203	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	Insect Repellent IR3535®	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in Section 2.	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Composition of Product	[redacted]	
3.1.6	Further relevant properties	[redacted]	
3.1.7	Method of analysis	HPLC: LiChrosorb® RP-18 column, 5 µm film thickness Mobile phase: Acetonitrile/water (31:69), flow rate 1.0 ml/min Gradient Program: isocratic Detection: UV; 220 nm	X
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Details are given in table A7.4.1.1/01-1	
3.3	**Reference**	No details given	

Section A7.4.1.1/01 Acute toxicity to fish

Annex Point IIA, VII.7.1 Zebra fish (*Brachydanio rerio*)

	substance	
3.3.1	Method of analysis for reference substance	Not applicable
3.4	**Testing procedure**	
3.4.1	Dilution water	Details are given in table A7.4.1.1/01-2
3.4.2	Test organisms	Zebra fish (*Brachydanio rerio*). Details are given in table A7.4.1.1/01-3
3.4.3	Test system	Details are given in table A7.4.1.1/01-4
3.4.4	Test conditions	Details are given in table A7.4.1.1/01-5
3.4.5	Duration of the test	96 hours
3.4.6	Test parameter	Mortality and sublethal effects
3.4.7	Sampling	Water samples were taken at the beginning (0 hours) and at the end of the test (96 hours).
3.4.8	Monitoring of TS concentration	Concentration of test substance was measured at the beginning (0 hours) and at the end of the test (96 hours).
3.4.9	Statistics	Not applicable, because LC_{50} was higher than the highest test concentration
		4 RESULTS
4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]
4.1.3	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Effect data (Mortality)	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Other effects	[redacted]

Section A7.4.1.1/01 Acute toxicity to fish

Annex Point IIA, VII.7.1 Zebra fish (*Brachydanio rerio*)

		[redacted]
4.3	**Results of controls**	[redacted]
4.3.1	Number/ percentage of animals showing adverse effects	[redacted]
4.3.2	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to EU Commission Directive 92/96/EEC, C.2 and OECD 203. It was a static test-system and the Zebra fish (*Brachydanio rerio*) was used as test organism.
5.2	**Results and discussion**	The analysis of test media indicated a sufficient stability of the test substance during the course of the test. Therefore, toxicity data are based on nominal concentrations.
5.2.1	NOEC (96 hours)	0.0669 g/L
5.2.2	LC_{50} (96 hours)	> 0.100 g/L
5.2.3	LC_{100} (96 hours)	Not applicable
5.3	**Conclusion**	No mortalities were observed in the control. Also the dissolved oxygen was > 60 % of the air saturation at the temperature used. Therefore, the validity criteria can be considered as fulfilled. For details please refer to table A7.4.1.1/01-9.
5.3.1	Other Conclusions	Not applicable
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Section A7.4.1.1/01 Acute toxicity to fish

Annex Point IIA, VII.7.1 Zebra fish (*Brachydanio rerio*)

	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 A7.4.1.1/01-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	No, test substance was dissolved in test water
Concentration of vehicle	Not applicable
Vehicle control performed	Not applicable
Other procedures	No

Table A7.4.1.1/01-2: Dilution water

Criteria	Details
Source	Fully demineralized water
Alkalinity	Proportion Ca : Mg ions 4:1 Proportion Na : K ions 10:1
Hardness	Not given
pH	7.8
Oxygen content	95.8 % at the start of the test
Conductance	Not given
Holding water different from dilution water	No

Table A7.4.1.1/01-3: Test organisms

Criteria	Details
Species/strain	Zebra fish (*Brachydanio rerio*), CRL/ZF1
Source	[redacted]
Wild caught	No
Age/size	Juveniles/2.0 +/- 1.0 cm
Kind of food	Dry commercial food
Amount of food	Not given
Feeding frequency	Daily
Pre-treatment	Acclimatisation period of 14 days
Feeding of animals during test	No

Table A7.4.1.1/01-4: Test system

Criteria	Details
Test type	Static
Renewal of test solution	No
Volume of test vessels	6 L test solution
Volume/animal/day	0.86 L/fish/day
Number of animals/vessel	7
Number of vessels/ concentration	1
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.1/01-5: Test conditions

Criteria	Details
Test temperature	24 °C
Dissolved oxygen	84.6 – 95.8 %
pH	7.88 – 7.47
Adjustment of pH	No
Aeration of dilution water	No
Intensity of irradiation	Not given
Photoperiod	12 hours light, 12 hours dark

Table A7.4.1.1/01-6: Actual concentrations of test substance

Nominal concentrations of test substance (g/L)	Measured concentration (mg/L)			
	0 hour	96 hour	Mean	Percent of Nominal
0.0200	0.0199	0.0188	0.0194	97 %
0.0447	0.0444	0.0424	0.0434	97 %
0.1000	0.0991	0.0940	0.0965	96.5 %

Table A7.4.1.1/01-7: Mortality data

[redacted]	[redacted]							
	[redacted]				[redacted]			
	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]				

Table A7.4.1.1/01-8: Effect data

	48 h [g/L][1]	**95 % C.L.**	**96 h [g/L][1]**	**95 % C.L.**
NOEC	–	–	–	–
LC_{50}	> 0.100	–	> 0.100	–
LC_{100}	–	–	–	–

[1] based on mean nominal concentrations

Table A7.4.1.1/01-9: Validity criteria for acute fish test according to OECD Guideline 203

	Fulfilled	**Not fulfilled**
Mortality of control animals <10%	yes	
Concentration of dissolved oxygen in all test vessels > 60% saturation	yes	
Concentration of test substance ≥80% of initial concentration during test	yes	

Criteria for poorly soluble test substances	n.a.	n.a.

Section A7.4.1.2/01 Acute toxicity to invertebrates

Annex Point IIA, VII.7.2 *Daphnia magna*

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2000): Art. 111887 (IR3535) – Acute immobilisation test in *Daphnia magna*; [redacted] Doc. No. 822-001 (unpublished)	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Merck KGaA	
1.2.2	Companies with letter of access	No	
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, EU Commission Directive 92/96/EEC, C.2 OECD 202	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	Insect Repellent IR3535®	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in section A2.	
3.1.3	Purity	[redacted]%	
3.1.4	Description of test substance	[redacted]	
3.1.5	Composition of Product	[redacted]	
3.1.6	Further relevant properties	[redacted]	
3.1.7	Method of analysis	HPLC: LiChrosorb® RP-18 column, 5 µm film thickness Mobile phase: Acetonitrile/water (31:69), flow rate 1.0 ml/min Gradient Program: isocratic Detection: UV; 220 nm	

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Details are given in Table A7.4.1.2/01-1
3.3	**Reference substance**	No reference substance was tested
3.3.1	Method of analysis for reference substance	Not applicable
3.4	**Testing procedure**	
3.4.1	Dilution water	Details are given in table A7.4.1.2/01-2
3.4.2	Test organisms	*Daphnia magna,* details are given in table A7.4.1.2/01-3
3.4.3	Test system	Details are given in table A7.4.1.2/01-4
3.4.4	Test conditions	Details are given in table A7.4.1.2/01-5
3.4.5	Duration of the test	48 hours
3.4.6	Test parameter	Immobilisation
3.4.7	Sampling	Water samples were taken at the beginning (0 hours) and at the end of the test (48 hours)
3.4.8	Monitoring of TS concentration	Concentration of the test substance was measured at the beginning (0 hours) and at the end of the test (48 hours)
3.4.9	Statistics	Not applicable, because EC_{50} was higher than the highest test concentration

4 RESULTS

4.1	**Limit Test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Number/ percentage of animals showing adverse effects	[redacted]
4.1.3	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]

4.2.3	Effect data (Mortality)	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Other effects	[redacted]
4.3	**Results of controls**	[redacted]
4.3.1	Number/ percentage of animals showing adverse effects	[redacted]
4.3.2	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to EU Commission Directive 92/96/EEC, C.2 and OECD 202. It was a static test-system and *Daphnia magna* was used as test organism.
5.2	**Results and discussion**	The analysis of test media indicated a sufficient stability of the test substance during the course of the test. Therefore, toxicity data are based on nominal concentrations.
5.2.1	EC_0	0.0669 g/L
5.2.2	EC_{50}	> 0.1000 g/L
5.2.3	EC_{100}	Not applicable
5.3	**Conclusion**	No mortalities were observed in the control. Also the dissolved oxygen was > 60 % of the air saturation at the temperature used. Therefore, the validity criteria can be considered as fulfilled. For details please refer to table A7.4.1/01-9.
5.3.1	Other Conclusions	Not applicable
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Materials and Methods	[redacted].
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
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 A7.4.1.2/01-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	No, test substance was dissolved in test water
Concentration of vehicle	Not applicable
Vehicle control performed	Not applicable
Other procedures	No

Table A7.4.1.2/01-2: Dilution water

Criteria	Details
Source	Fully demineralized water
Alkalinity	Not applicable
Hardness	250 mg/L, expressed as $CaCO_3$
pH	7.94
Ca / Mg ratio	Not applicable
Na / K ratio	Not applicable
Oxygen content	96.4 % at the start of the test
Conductance	Not given
Holding water different from dilution water	No

Table A7.4.1.2/01-3: Test organisms

Criteria	Details
Strain	*Daphnia magna* Straus
Source	[redacted]
Age	Not older than 24 hours
Breeding method	The strain with the parent generation was bred and maintained in vessels containing a lot of *Daphnia magna* in different ages. From this vessel, young Daphnids were separated in 100 mL of reconstituted water. Newborn animals were separated and assigned to the different groups.
Kind of food	Daphnids were fed with a suspension of algae
Amount of food	Not given
Feeding frequency	Once a week
Pre-treatment	No
Feeding of animals during test	No

Table A7.4.1.2/01-4: Test system

Criteria	Details
Renewal of test solution	No
Volume of test vessels	25 mL glass vessels containing 10 mL test solution
Volume/animal/day	2 mL/animal
Number of animals/vessel	5
Number of vessels/ concentration	4
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.2/01-5: Test conditions

Criteria	Details
Test temperature	19 to 21 °C
Dissolved oxygen	94.7 – 97.3 %
pH	7.82 – 7.94
Adjustment of pH	No
Aeration of dilution water	No
Quality/Intensity of irradiation	Not given
Photoperiod	16 hours light, 8 hours dark

Table A7.4.1.2/01-6: Actual concentrations of test substance

Nominal concentrations of test substance (g/L)	Measured concentration (g/L)			
	0 hour	48 hour	Mean	Percent of Nominal
0.0200	0.0192	0.0203	0.0198	98.8
0.0447	0.0433	0.0445	0.0439	98.2
0.1000	0.0968	0.0990	0.0979	97.9

Table A7.4.1.2/01-7: Immobilisation data

[redacted]	[redacted]				[redacted]		
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							
[redacted]							

[redacted]

Table A7.4.1.2/01-8: Effect data

	EC_{50}[1]	95 % C.I.	EC_0[1]	EC_{100}[1]
24 h [g/L]	> 0.1000	–	> 0.1000	–
48 h [g/L]	> 0.1000	–	0.0669	–

[1]data are based on nominal concentrations

Table A7.4.1.2/01-9: Validity criteria for acute daphnia immobilisation test according to OECD Guideline 202

	Fulfilled	Not fulfilled
Immobilisation of control animals <10%	yes	
Control animals not staying at the surface	yes	
Concentration of dissolved oxygen in all test vessels >3 mg/L	yes	
Concentration of test substance ≥80% of initial concentration during test	yes	

Criteria for poorly soluble test substances	n.a.	

Section A7.4.1.3/01 Growth inhibition test on algae

Annex Point IIA, VII.7.3 *Desmodesmus subspicatus*

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2001): Art. 111887 (IR3535) – Algae growth inhibition test in *Desmodesmus subspicatus*; [redacted] Doc. No. 823-001 (unpublished)	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Merck KGaA	
1.2.2	Companies with letter of access	No	
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, OECD No. 201 (1984) and European Commission Directive 92/69/EEC, C.3 (1992)	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	Insect repellent IR3535®	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in Section A2.	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Composition of Product	[redacted]	
3.1.6	Further relevant properties	[redacted]	
3.1.7	Method of analysis	HPLC: LiChrosorb® RP-18 column, 5 µm film thickness Mobile phase: Acetonitrile/water (31:69), flow rate 1.0 ml/min Gradient Program: isocratic Detection: UV; 220 nm	

3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Details are given in Table A7.4.1.2/01-1
3.3	**Reference substance**	No reference substance was tested
3.3.1	Method of analysis for reference substance	Not applicable
3.4	**Testing procedure**	
3.4.1	Culture medium	Details are given in table A7.4.1.3/01-2
3.4.2	Test organisms	*Desmodesmus subspicatus*, details are given in table A7.4.1.3/01-3
3.4.3	Test system	Details are given in table A7.4.1.3/01-4
3.4.4	Test conditions	Details are given in table A7.4.1.3/01-5
3.4.5	Duration of the test	72 hours
3.4.6	Test parameter	Growth inhibition
3.4.7	Sampling	For determination of cell density, samples were taken after 24, 48 and 72 hours.
3.4.8	Monitoring of TS concentration	Samples for analysis were taken directly after preparation and at the end of the exposure period.
3.4.9	Statistics	Not reported

4 RESULTS

4.1	**Limit Test**	
4.1.1	Concentration	[redacted]
4.1.2	Nature of adverse effects	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Growth curves	[redacted]
4.2.4	Concentration / response curve	[redacted]
4.2.5	Cell concentration data	[redacted]
4.2.6	Effect data (cell multiplication	[redacted]

	inhibition)	
4.2.7	Other observed effects	[redacted]
4.3	**Results of controls**	[redacted]
4.3.1	Nature of adverse effects	[redacted]
4.4	**Test with reference substance**	[redacted]
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Test was conducted according to OECD No. 201 (1984) and European Commission Directive 92/69/EEC, C.3 (1992). It was a static test system and *Desmodesmus subspicatus* was used as the test organism
5.2	**Results and discussion**	The analysis of test media indicated a sufficient stability of the test substance during the course of the test. Therefore, toxicity data are based on nominal concentrations.
5.2.1	NOEC (biomass)	> = 0.1 g/L
5.2.2	NOEC (growth rate)	> = 0.1 g/L
5.2.3	E_bC_{50}	> 0.1 g/L
5.2.4	E_rC_{50}	> 0.1 g/L
5.3	**Conclusion**	The 72 hour exposure of *Desmodesmus subspicatus* to IR3535® at a test concentration of 0.1 g/L revealed no inhibition of algal growth in this test system. Also the validity criteria can be considered as fulfilled. For details please refer to table A7.4.1.3/01-9.
5.3.1	Other Conclusions	Not applicable
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	No explanation is given for the deviation of the pH-value by more than one unit during the course of the test.

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]

Reliability	[redacted]
Acceptability	[redacted]
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 A7.4.1.3/01-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	No, test substance was dissolved in test water
Concentration of vehicle	Not applicable
Vehicle control performed	Not applicable
Other procedures	No

Table A7.4.1.3/01-2: Culture medium (according to OECD 201)

Nutrient	Concentration
$NaHCO_3$	50.0 mg/L
$CaCl_2$ x 2 H_2O	18.0 mg/L
NH_4Cl	15.0 mg/L
$MgSO_4$ x 7 H_2O	15.0 mg/L
$MgCl_2$ x 6 H_2O	12.0 mg/L
KH_2PO_4	1.6 mg/L
Na_2EDTA x 2 H_2O	100 µg/L
$FeCl_3$ x 6 H_2O	80.0 µg/L
$MnCl_2$ x 4 H_2O	415.0 µg/L
H_3BO_3	185.0 µg/L
Na_2MoO_4 x 2 H_2O	7.0 µg/L
$ZnCl_2$	3.0 µg/L
$CoCl_2$ x 6 H_2O	1.5 µg/L
$CuCl_2$ x 2 H_2O	0.01µg/L

Table A7.4.1.3/01-3: Test organism

Criteria	Details
Species	*Desmodesmus subspicatus*
Strain	SAG 86.81
Source	Sammlung von Algenkulturen, Pflanzenphysiologisches Institut der Universität Göttingen
Laboratory culture	Yes
Method of cultivation	Culture was cultivated under standardised conditions
Pre-treatment	An exponentially growing preculture had been set up 3 days prior to the experimental part under the same conditions as in the main study
Initial cell concentration	10^4 cells/mL

Table A7.4.1.3/01-4: Test system

Criteria	Details
Volume of culture flasks	300 mL, containing 100 mL test medium
Culturing apparatus	Erlenmeyer flasks
Light quality	Achieved by fluorescent tubes
Procedure for suspending algae	Flask were continuously shaken by a pulsating panel
Number of vessels/ concentration	3
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.3/01-5: Test conditions

Criteria	Details
Test temperature	22 to 23 °C
pH	7.39 to 7.99 in test flasks without algae 7.71 to 9.96 in test flasks with algae
Aeration of dilution water	No
Light intensity	7300 to 9000 Lux
Photoperiod	Continuous illumination

Table A7.4.1.3/01-6: Concentrations of test substance in test medium

Nominal concentrations of test substance (g/L)	Measured concentration (g/L)			
	Day 0	Day 3	Mean	Percent of Nominal
0.100	0.0989	0.0965	0.0977	97.7

Table A7.4.1.3/01-7: Cell concentration data

[redacted]

Table A7.4.1.3/01-8: Effect data

	EC_{50}[1]	95 % C.L.	NOEC[1]
24 h [g/L]	ND	ND	ND
48 h [g/L]	ND	ND	ND
72 h [g/L] (biomass)	> 0.1	ND	> = 0.1
72 h [g/L] (growth rate)	> 0.1	ND	> = 0.1

[1] data are based on nominal concentrations
ND = not determined

Table A7.4.1.3/01-9: Validity criteria for algal growth inhibition test according to OECD Guideline 201

	Fulfilled	Not fulfilled
Cell concentration in control cultures increased at least by a factor of 16 within 3 days	yes	
Concentration of test substance ≥80% of initial concentration during test[1]	yes	

Criteria for poorly soluble test substances	n.a.	

Section A7.4.1.4/01 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 *Activated sludge*

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2001): Toxicity of Art. 111887 (IR3535) to Activated Sludge in a Respiration Inhibition Test; [redacted] Doc. No. 842-001 (unpublished)	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Merck KGaA	
1.2.2	Companies with letter of access	No	
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes EU Commission Directive 88/302/EEC, Part C11 OECD Guideline No. 209 (1984)	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	Technical active substance IR3535®	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in section A2.	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Composition of Product	[redacted]	
3.1.6	Further relevant properties	[redacted]	
3.1.7	Method of analysis	GC	
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Details are given in table A7.4.1.4/01-1	
3.3	**Reference substance**	3,5-Dichlorophenol	
3.3.1	Method of analysis for reference substance	Not given	

Section A7.4.1.4/01 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 *Activated sludge*

3.4	**Testing procedure**	
3.4.1	Culture medium	Not applicable
3.4.2	Inoculum / test organism	Details on test organisms are given in table A7.4.1.4/01-2.
3.4.3	Test system	Details on test type, laboratory equipment etc. are given in table A7.4.1.4/01-3
3.4.4	Test conditions	Relevant test conditions are given in table A7.4.1.4/01-4.
3.4.5	Duration of the test	3 hours
3.4.6	Test parameter	Inhibition of respiration rate
3.4.7	Analytical parameter	Oxygen measurement
3.4.8	Sampling	Not applicable
3.4.9	Monitoring of TS concentration	No
3.4.10	Controls	Two inoculum controls were prepared
3.4.11	Statistics	Not performed, because EC_{20} and EC_{50} values were clearly higher than the highest test concentration
	4 RESULTS	
4.1	**Preliminary test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Effect data	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Growth curves	[redacted]
4.2.4	Cell concentration data	[redacted]
4.2.5	Concentration/ response curve	[redacted]
4.2.6	Effect data	[redacted]
4.2.7	Other observed effects	[redacted]

Section A7.4.1.4/01 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 *Activated sludge*

4.3	**Results of controls**	[redacted]
4.4	**Test with reference substance**	
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	The test was conducted according to EU Commission Directive 88/302/EEC, Part C11 and OECD Guideline 209. The test organisms were activated sludge-microorganisms from a domestic waste water treatment plant.
5.2	**Results and discussion**	
5.2.1	EC_{20}	> 1000 mg test item/L
5.2.2	EC_{50}	> 1000 mg test item/L
5.2.3	EC_{80}	> 1000 mg test item/L
5.3	**Conclusion**	
5.3.1	Other Conclusions	Not applicable
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	None

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
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 A7.4.1.4/01-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	No, test substance was dissolved in test water
Concentration of vehicle	Not applicable
Vehicle control performed	Not applicable
Other procedures	No

Table A7.4.1.4/01-2: Inoculum / Test organism

Criteria	Details
Nature	Activated sludge
Species	A mixture of aquatic micro organisms
Strain	Not applicable
Source	Domestic waste water treatment plant
Sampling site	Sewage plant [redacted]
Laboratory culture	Not applicable
Method of cultivation	Details are not provided.
Preparation of inoculum for exposure	According to guideline. Details are not provided.
Pre-treatment	Sludge was conditioned before use
Initial cell concentration	4 g/L

Table A7.4.1.4/01-3: Test system

Criteria	Details
Culturing apparatus	Glass flasks
Number of culture flasks/concentration	One
Aeration device	Details are not provided
Measuring equipment	Oxygen was measured with an oxygen electrode
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.4/01-4: Test conditions

Criteria	Details
Test temperature	Not given
pH	7.6 – 8.4
Aeration of dilution water	With compressed air (approx. 0.6 L/min)
Suspended solids concentration	4 g/L

Table A7.4.1.4/01-5: O_2 concentrations and inhibition rates of the TS

[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				

Section A7.4.2 Annex Point IIA, VII.7.5	Bioconcentration in aquatic organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Detailed justification:	Bioconcentration has been calculated on the basis of EUSES: Based on the P_{ow} (K_{ow}) value of 1.7, no risk of bioaccumulation is to be expected. The resulting value (5.6) for the estimation of the bioaccumulation factor in fish is much lower than 100, the limit-value for not readily biodegradable substances. Also for terrestrial organisms the value is very low: 1.44. For fish-eating birds no estimate could be made as no studies on the toxicity in birds are available. However, based on the estimations above also here no bioaccumulation is to be expected.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.4.1.4/01 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 *Activated sludge*

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2001): Toxicity of Art. 111887 (IR3535) to Activated Sludge in a Respiration Inhibition Test; [redacted], Doc. No. 842-001 (unpublished)	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Merck KGaA	
1.2.2	Companies with letter of access	No	
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes EU Commission Directive 88/302/EEC, Part C11 OECD Guideline No. 209 (1984)	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	Technical active substance IR3535®	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in section A2.	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Composition of Product	[redacted]	
3.1.6	Further relevant properties	[redacted]	
3.1.7	Method of analysis	GC	
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Details are given in table A7.4.1.4/01-1	
3.3	**Reference substance**	3,5-Dichlorophenol	
3.3.1	Method of analysis for reference substance	Not given	
3.4	**Testing procedure**		

Section A7.4.1.4/01 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 *Activated sludge*

3.4.1	Culture medium	Not applicable
3.4.2	Inoculum / test organism	Details on test organisms are given in table A7.4.1.4/01-2.
3.4.3	Test system	Details on test type, laboratory equipment etc. are given in table A7.4.1.4/01-3
3.4.4	Test conditions	Relevant test conditions are given in table A7.4.1.4/01-4.
3.4.5	Duration of the test	3 hours
3.4.6	Test parameter	Inhibition of respiration rate
3.4.7	Analytical parameter	Oxygen measurement
3.4.8	Sampling	Not applicable
3.4.9	Monitoring of TS concentration	No
3.4.10	Controls	Two inoculum controls were prepared
3.4.11	Statistics	Not performed, because EC_{20} and EC_{50} values were clearly higher than the highest test concentration
		4 RESULTS
4.1	**Preliminary test**	[redacted]
4.1.1	Concentration	[redacted]
4.1.2	Effect data	[redacted]
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	[redacted]
4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Growth curves	[redacted]
4.2.4	Cell concentration data	[redacted]
4.2.5	Concentration/ response curve	[redacted]
4.2.6	Effect data	[redacted]
4.2.7	Other observed effects	[redacted]
4.3	**Results of controls**	[redacted]

Section A7.4.1.4/01 Inhibition to microbial activity (aquatic)

Annex Point IIA, VII.7.4 *Activated sludge*

4.4	**Test with reference substance**	
4.4.1	Concentrations	[redacted]
4.4.2	Results	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The test was conducted according to EU Commission Directive 88/302/EEC, Part C11 and OECD Guideline 209. The test organisms were activated sludge-microorganisms from a domestic waste water treatment plant.
5.2	**Results and discussion**	
5.2.1	EC_{20}	> 1000 mg test item/L
5.2.2	EC_{50}	> 1000 mg test item/L
5.2.3	EC_{80}	> 1000 mg test item/L
5.3	**Conclusion**	
5.3.1	Other Conclusions	Not applicable
5.3.2	Reliability	[redacted]
5.3.3	Deficiencies	None

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
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 A7.4.1.4/01-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	No, test substance was dissolved in test water
Concentration of vehicle	Not applicable
Vehicle control performed	Not applicable
Other procedures	No

Table A7.4.1.4/01-2: Inoculum / Test organism

Criteria	Details
Nature	Activated sludge
Species	A mixture of aquatic micro organisms
Strain	Not applicable
Source	Domestic waste water treatment plant
Sampling site	Sewage plant [redacted]
Laboratory culture	Not applicable
Method of cultivation	Details are not provided.
Preparation of inoculum for exposure	According to guideline. Details are not provided.
Pre-treatment	Sludge was conditioned before use
Initial cell concentration	4 g/L

Table A7.4.1.4/01-3: Test system

Criteria	Details
Culturing apparatus	Glass flasks
Number of culture flasks/concentration	One
Aeration device	Details are not provided
Measuring equipment	Oxygen was measured with an oxygen electrode
Test performed in closed vessels due to significant volatility of TS	No

Table A7.4.1.4/01-4: Test conditions

Criteria	Details
Test temperature	Not given
pH	7.6 – 8.4
Aeration of dilution water	With compressed air (approx. 0.6 L/min)
Suspended solids concentration	4 g/L

Table A7.4.1.4/01-5: O_2 concentrations and inhibition rates of the TS

[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				

Section A7.4.2 Annex Point IIA, VII.7.5	Bioconcentration in aquatic organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Detailed justification:	Bioconcentration has been calculated on the basis of EUSES: Based on the P_{ow} (K_{ow}) value of 1.7, no risk of bioaccumulation is to be expected. The resulting value (5.6) for the estimation of the bioaccumulation factor in fish is much lower than 100, the limit-value for not readily biodegradable substances. Also for terrestrial organisms the value is very low: 1.44. For fish-eating birds no estimate could be made as no studies on the toxicity in birds are available. However, based on the estimations above also here no bioaccumulation is to be expected.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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 A7.4.3.1 Annex Point IIIA, XIII.2.1	Prolonged toxicity to an appropriate species of fish	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 19.01 (repellents).	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification		
Conclusion		
Remarks	[redacted]	
	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*	

Section A7.4.3.2 Effects on reproduction and growth rate of fish

Annex Point IIIA, XIII.2.2

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 19.01 (repellents).	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	
Conclusion	
Remarks	[redacted]
	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*

Section A7.4.3.3.1 Annex Point IIIA, XIII.2.3	Bio-accumulation in an appropriate species of fish	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Scientifically unjustified	
Detailed justification:	Not required for Product type 19.01 (repellents).	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification		
Conclusion		
Remarks	[redacted]	
	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*	

Section A7.4.3.3.2 Annex Point IIIA, XIII.2.3	Bio-accumulation in an appropriate invertebrate species	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 19.01 (repellents).	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification		
Conclusion		
Remarks	[redacted]	
	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*	

Section A7.4.3.4 Effects on reproduction and growth rate with an invertebrate species

Annex Point IIIA, XIII.2.4 *Daphnia magna*

	Other justification	Official use only
Detailed justification:	Not required for Product type 19.01 (repellents).	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	
Conclusion	
Remarks	[redacted]
	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*

Section A7.4.3.5.1 Annex Point IIIA, XIII.3.4	Effects on sediment dwelling organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 19.01 (repellents).	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification		
Conclusion		
Remarks	[redacted]	
	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*	

Section A7.4.3.5.2 Annex Point IIIA, XIII.3.4	Aquatic plant toxicity	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 19.01 (repellents).	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification		
Conclusion		
Remarks	[redacted]	
	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*	

Section A7.5.1.1 Inhibition to microbial activity (terrestrial)

Annex Point IIA, VII.7.4

Nitrogen Transformation Test

Carbon Transformation Test

Official use only

JUSTIFICATION FOR NON-SUBMISSION OF DATA

Detailed justification:

A PEC_{soil} of 0.00068 mg/kg soil was calculated for IR3535® in the in-door scenario. In the outdoor scenario, a PEC_{soil} of 0.0159 mg/kg for the upper 5 cm of soil was calculated (please refer to Doc. IIB, chapter 8.3).

Taking into account the $PNEC_{soil}$ of 4.54 mg/kg calculated on the basis of the equilibrium partitioning method as described in the TNsG, a $PEC/PNEC_{soil}$ of 1.5×10^{-4} results for the in-house scenario and a $PEC/PENC_{soil}$ of 0.0035 results for the outdoor scenario. Thus, the calculated $PEC/PNEC_{soil}$ are well below the relevant trigger of 1. A risk for soil micro-organisms by IR3535® can therefore not be assumed

[redacted] It can be excluded that a large area would be contaminated should IR3535® be spilled accidentally. It can furthermore be assumed that a recolonization with soil micro-organisms on contaminated area would take place from the surrounding area, because the contaminated area would be small. A test assessing the effects of IR3535® on soil micro-organisms is therefore not necessary.

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]

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	

Section A7.5.1.2 Earthworm, acute toxicity test

Annex Point IIIA, XIII.3.2 *Eisenia fetida*

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Detailed justification:	A PEC_{soil} of 0.00068 mg/kg soil was calculated for IR3535® in the in-door scenario. In the outdoor scenario, a PEC_{soil} of 0.0159 mg/kg for the upper 5 cm of soil was calculated (please refer to Doc. IIB, chapter 8.3). Taking into account the $PNEC_{soil}$ of 4.54 mg/kg calculated on the basis of the equilibrium partitioning method as described in the TNsG, a $PEC/PNEC_{soil}$ of 1.5 x 10^{-4} results for the in-house scenario and a $PEC/PENC_{soil}$ of 0.0035 results for the outdoor scenario. Thus, the calculated $PEC/PNEC_{soil}$ are well below the relevant trigger of 1. A risk for earthworms by IR3535® can therefore not be assumed [redacted] It can be excluded that a large area would be contaminated should IR3535® be spilled accidentally. It can furthermore be assumed that a recolonization with earthworms on contaminated area would take place from the surrounding area, because the contaminated area would be small. A test assessing the effects of IR3535® on earthworms is therefore not necessary.	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	
Conclusion	
Remarks	

Section 7.5.1.3 Terrestrial plant toxicity

Brassica napus / Glycine max / Avena sativa

	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Detailed justification:	A PEC_{soil} of 0.00068 mg/kg soil was calculated for IR3535® in the in-door scenario. In the outdoor scenario, a PEC_{soil} of 0.0159 mg/kg for the upper 5 cm of soil was calculated (please refer to Doc. IIB, chapter 8.3). Taking into account the $PNEC_{soil}$ of 4.54 mg/kg calculated on the basis of the equilibrium partitioning method as described in the TNsG, a $PEC/PNEC_{soil}$ of 1.5 x 10^{-4} results for the in-house scenario and a $PEC/PENC_{soil}$ of 0.0035 results for the outdoor scenario. Thus, the calculated $PEC/PNEC_{soil}$ are well below the relevant trigger of 1. A risk for terrestrial plants by IR3535® can therefore be not assumed. [redacted] It can be excluded that a large area would be contaminated should IR3535® be spilled accidentally. It can furthermore be assumed that a recolonization with terrestrial plants (seeds) on contaminated area would take place from the surrounding area, because the contaminated area would be small. A test assessing the effects of IR3535® on terrestrial plants is therefore not necessary.	

Evaluation by Competent Authorities	
EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
COMMENTS FROM ... *(specify)*	
Date	*Give date of comments submitted*
Evaluation of applicant's justification	
Conclusion	
Remarks	

Section A7.5.2.1 Annex Point IIIA, XIII.3.2	Reproduction study with earthworm or other soil non-target organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Detailed justification:	According to Fig. 3.2 of the TNsG, long-term tests with terrestrial plants are required when there is an indication of risk for the terrestrial compartment based on the data for aquatic toxicity. The PEC/PNEC for the terrestrial compartment was calculated with EUSES on the basis of the equilibrium partitioning coefficient, resulting in a value of 1.5×10^{-4} for the in-house scenario and a value of 0.0035 results for the outdoor scenario, which is far below the trigger value of 1. Therefore, a risk to terrestrial organisms can not assumed and reproduction tests with earthworms or other soil non-target organisms are not necessary.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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	Long-term test with terrestrial plants	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Detailed justification:	According to Fig. 3.2 of the TNsG, long-term tests with terrestrial plants are required when there is an indication of risk for the terrestrial compartment based on the data for aquatic toxicity. The PEC/PNEC for the terrestrial compartment was calculated with EUSES on the basis of the equilibrium partitioning coefficient, resulting in a value of 1.5×10^{-4} for the in-house scenario and a value of 0.0035 results for the outdoor scenario, which is far below the trigger value of 1. Therefore, a risk to terrestrial organisms can not assumed and a long-term test with terrestrial plants is not necessary.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	
	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*	

Section A7.5.3.1.1 **Annex Point IIIA, XIII.1.1**	**Acute oral toxicity to birds**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	This testing is not required because IR3535® is not used as a bait, granulate or powder.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.5.3.1.2 **Annex Point IIIA, XIII.1.2**	**Short-term toxicity to birds**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	This testing is not required because IR3535® is not used as a bait, granulate or powder.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.5.3.1.3 Annex Point IIIA, XIII.1.3	Effects on reproduction of birds	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	This testing is not required because IR3535® is not used as a bait, granulate or powder.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.5.4.1 **Annex Point IIIA, XIII.3.1**	**Acute toxicity to honeybees and other beneficial arthropods**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	In a study assessing the efficacy of IR3535® to bees and wasps (Marchio 1995, Doc.-No. 336-1907, Section point A.5.3.1/07) resulted in a significant repellent effect of IR3535® to both species. It can be assumed that a risk of intoxication by IR3535® is not given and therefore further testing is not required.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.5.5 Annex Point IIA, VII.7.5	Bioconcentration in terrestrial organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Detailed justification:	• According to the BPD 98/8/EC and the TNsG on data requirements, the intrinsic potential for bio-concentration in terrestrial organisms should be estimated on the basis of physical and chemical properties. The most important indicator of the bio-accumulation potential is the octanol/water partition coefficient. According to the TGD on Risk Assessment, the bio-concentration potential of an active substance should be determined, when the log K_{ow} is greater or equal to 3. The log K_{ow} of IR3535® is 1.7, i.e. below the trigger value of 3. • The calculated $BCF_{earthworm}$ is very low (1.44). Although no trigger value for the bio-accumulation in terrestrial organisms exists, this value is considered to be low enough to justify the conclusion that no further tests are needed. • The environmental exposure assessed shows that there is no significant release of IR3535® terrestrial compartment. From the above arguments, it is not necessary to perform a specific study on the bio-concentration potential of IR3535® for terrestrial organisms.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.5.5.1 Annex Point IIA, VII.7.5	Bioconcentration, further studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Detailed justification:	Further studies are not required. For details please refer to Document IIIA, Section 7, Point 7.5.5.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

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 justification	
Detailed justification:	Not required for Product type 19.01 (insect repellents)	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.5.7.1.1 Annex Point IIIA, XIII.3.4	Acute oral toxicity to mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 19.01 (insect repellents)	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.5.7.1.2 Annex Point IIIA, XIII.3.4	Short-term toxicity to mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 19 (insect repellents)	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.5.7.1.3 Annex Point IIIA, XIII.3.4	Effects on reproduction of mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 19 (insect repellents)	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.5.7.1.2 Annex Point IIIA, XIII.3.4	Short term toxicity to mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 19.01 (insect repellents)	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.5.7.1.2 Annex Point IIIA, XIII.3.4	Short-term toxicity to mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 19 (insect repellents)	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.5.7.1.3 Annex Point IIIA, XIII.3.4	Effects on reproduction of mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 19 (insect repellents)	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.5.7.1.3 Annex Point IIIA, XIII.3.4	Reproductive effects to mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 19.01 (insect repellents)	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.5.7.1.2 Annex Point IIIA, XIII.3.4	Short-term toxicity to mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 19 (insect repellents)	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.5.7.1.3 Annex Point IIIA, XIII.3.4	Effects on reproduction of mammals	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	Not required for Product type 19 (insect repellents)	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
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*	

Section A7.6	Summary of ecotoxicological effects and fate and behavior in the environment
	This section number is covered by Document IIA of the dossier.