Section A7.2.3.1 — **Adsorption / Desorption in soils : Aged Column Leaching Study**

Annex Point III, XII.1.2

4 RESULTS

4.1 Radiochemical purity

Prior to dosing the soils for the half-life determination the radiopurity of ^{14}C-DCOIT was determined by HPLC and found to be greater than 99%.

4.2 Half-life determination

Due to the incongruity of the low dose data (0.5 ppm) it was necessary to use the results from the high dose for half-life determination.

For soils dosed at 5 ppm, the extractable ^{14}C residues decreased from about 94% on Day 0 to 45% on Day 30. The amount of ^{14}C-DCOIT oxidized to $^{14}CO_2$ increased throughout the study to over 17% by Day 30. Recovery of ^{14}C-activity averaged 118.9% and 96.4% for 0.5 ppm and 5.0 ppm dose levels, respectively. At 5 ppm dosing, quantitation of parent by HPLC in soluble residues decreased from 94.4% of applied radioactivity on Day 0 to 45.3% on Day 30.

From these results, the half-life was initially determined by linear regression and calculated to be 21.2 days. After an audit of the data, the half-life was calculated to be 34.9 days (Figure A7.2.3.1-1).

Section A7.2.3.1

Annex Point III, XII.1.2

Adsorption / Desorption in soils : Aged Column Leaching Study

4.3 Column leaching

4.3.1 Rate of leachate movement

The times required for 1030 ml of 0.01M $CaCl_2$ to pass through the columns is tabulated below

Soil Type	Total Volume Added (ml)	Time (hours)	
		Replicate 1	Replicate 2
Agricultural Sand	1030	2.8	2.8
Sandy Loam	1030	17.0	17.0
Silt Loam	1030	55.0	49.0
Silty Clay Loam	1030	8.0	7.8

4.3.2 Distribution of Radiocarbon and material balance

Tables A7.2.3.1-3 and A7.2.3.1-4 provide a distribution of radioactivity in the 6 cm soil fractions, in the leachate, and the volatile traps. The material balance is also presented.

Only the 0-6 cm fraction from each soil column was extracted for residue characterization since no other fraction contained detectable quantities of ^{14}C residues. Soil was initially extracted with methylene chloride:methanol. A subsequent methanol extraction solubilized less than 7%. The Day 0 samples demonstrated that methylene chloride:methanol effectively extracted parent. Subsequent extraction with NaOH extracted an additional14.5 to 32.7% of the applied radioactivity. A summary of the solvent extractions in the 0-6 cm fraction appears in Table A7.2.3.1-5.

4.3.3 Chromatography

The methylene chloride:methanol extracts from the 0-6 cm segments were analyzed and quantitated by HPLC. The only ^{14}C peak present at greater than the limit of quantification was parent compound.

Tabulated below is the percent of applied radiocarbon detected as RH-5287 in the 0-6 cm section

Soil Type	DCOIT as Percent of Applied	
	Replicate 1	Replicate 2
Sand	64.6	54.7
Sandy Loam	52.7	63.2
Silt Loam	47.0	56.4
Silty Clay Loam	54.4	51.9

4.3.4 Metabolites

Only DCOIT and $^{14}CO_2$ were identified. The products that resulted from metabolism of DCOIT in the soil were not identified. The presence of $^{14}CO_2$ demonstrates that the metabolites are ring cleaved and oxidized. At the time of the experiment, this was not a requirement of the guideline. None of the ^{14}C-activity, parent or metabolites, were mobile.

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The test guideline followed were U.S. Environmental Protection Agency, 40 CFR § 158, Subdivision N, Chemistry, Environmental Fate 163-1. There were no deviations from this test guideline.

Initially a half-life determination study was conducted in sandy loam soil to determine the necessary aging time of parent compound in soil prior to its placement on top of the soil columns.

Leaching columns were prepared by placing air dried and sieved sand, sandy loam, silt loam or silty clay loam soil into duplicate polyvinyl chloride tubes. The soils were wetted with 0.01M $CaCl_2$ (from the bottom up) and after removing the excess of water, sandy loam dosed 21 days earlier with ^{14}C DCOIT was placed atop the columns. The final column length was 30 cm. The equivalent of 20 inches of rain (=50.8 cm, on a cross sectional area bases; 1030 ml of 0.01M $CaCl_2$) was added to each column and the leachate collected. At the conclusion, the soil column was removed intact and divided into five 6 cm sections. The leachate and the soils sections were radioassayed.

5.2 Results and discussion

The measured half-life in soil (air dried, sieved and then moistened to 75% of field capacity) was 34.9 days. This half-life is not representative of the half-life in the environment since the soil was air dried which strongly inhibits microbial activity.

Neither parent nor its metabolites were mobile as virtually no radioactivity was detected in the leachate or in the soil columns below the 0-6 cm section (the dosing section). Mobility coefficients could not be calculated due to the lack of mobility. However, it can be stated that the coefficient for both parent and metabolites is greater than 5000.

5.3 Conclusion

The study provided satisfactorily describes the lack of mobility for DCOIT and its soil metabolites per U.S. Environmental Protection Agency, 40 CFR § 158, Subdivision N, Chemistry, Environmental Fate 163-1. While no mobility coefficient could be calculated, it can be stated that the coefficient is greater than 5000.

5.3.1 Reliability

1-valid without restrictions

5.3.2 Deficiencies

There are no deficiencies to the study guidelines, U.S. Environmental Protection Agency, 40 CFR § 158, Subdivision N, Chemistry, Environmental Fate 163-1.

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	23 August 2007
Materials and Methods	Agree with applicant's version
Results and discussion	Agree with applicant's version
Conclusion	Agree with applicant's conclusion
Reliability	1, valid without restrictions
Acceptability	Acceptable
Remarks	The conducted according to USEPA 163-1, Mobility studies: Leaching and Adsorption/Desorption Studies (1982) . The study is in reasonably good agreement with OECD Guideline 312 and shows that neither DCOIT nor its metabolites are mobile in soil.

Section A7.2.3.1	Adsorption / Desorption in soils : Aged Column Leaching Study
	TABLES AND FIGURES

Table A7.2.3.1-1: Classification and Physicochemical Characterization of Soils Used in This Study

Parameter	5.3.3 Soil Type				
	Soil Metabolism	5.3.4 Column Leaching			
	Sandy Loam	**Agricultural Sand**	**Sandy Loam**	**Silt Loam**	**Silty Clay Loam**
pH	7.4	7.9	7.6	6.5	6.9
Percent Sand	66	88	60	17	15
Percent Silt	25	11	30	66	51
Percent Clay	9	1	10	17	34
Field Capacity[1]	24.0	8.7	20.0	38.0	42.9
Organic Mater	2.2	0.6	3.2	3.0	1.2
CEC (meq/100g)[2]	11	3	13	16	30

[1] Field Capacity based on g water/100 g dry soil
[2] CEC = Cation Exchange Capacity

Table A7.2.3.1-2: Half-life and Aging Test Conditions

Parameter	**Half-Life Determination**	**Aging Prior to Leach Study**
Temperature	24.9 ± 0.2°C	24.8 ± 1.0°C
Initial Nominal Concentration (µg DCOIT/g soil)	0.5 and 5.0 µg/g	0.5 µg/g
Soil Type	Sandy loam	Sandy Loam
Sampling Days	0, 1, 3, 7, 10, 14, 21, 30	21

Table A7.2.3.1-3: Distribution of Radioactivity in Sand and Sandy Loam Soils

Fraction	Percent of Radiocarbon Applied			
	Sand		Sandy Loam	
	Replicate 1	Replicate 2	Replicate 1	Replicate 2
Soil Fractions				
0 - 6 cm	80.6	100.4	87.0	90.2
6 – 12 cm	ND[1]	ND	ND	ND
12 – 18 cm	ND	ND	ND	ND
18 –24 cm	ND	ND	ND	ND
24 – 30 cm	ND	ND	ND	ND
Leachate (total)	0.9	0.9	0.8	ND
Ethylene Glycol Trap	2.2	ND	ND	ND
KOH Trap	17.7	14.2	14.4	16.2
Total Recovery	101.3	115.5	102.2	106.4

[1] ND = not detectable (less than 2X background)

Table A7.2.3.1-4: Distribution of Radioactivity in Silt Loam and Silty Clay Loam Soils

Fraction	Percent of Radiocarbon Applied			
	Silt Loam		Silty Clay Loam	
	Replicate 1	Replicate 2	Replicate 1	Replicate 2
Soil Fractions				
0 - 6 cm	80.2	94.4	81.5	85.4
6 – 12 cm	ND[1]	ND	ND	ND
12 – 18	ND	ND	ND	ND
18 –24 cm	ND	ND	ND	ND
24 – 30 cm	ND	ND	ND	ND
Leachate (total)	ND	ND	ND	ND
Ethylene Glycol Trap	ND	ND	0.1	0.1
KOH Trap	12.7	13.9	12.1	11.5
Total Recovery	93.0	108.3	93.7	96.9

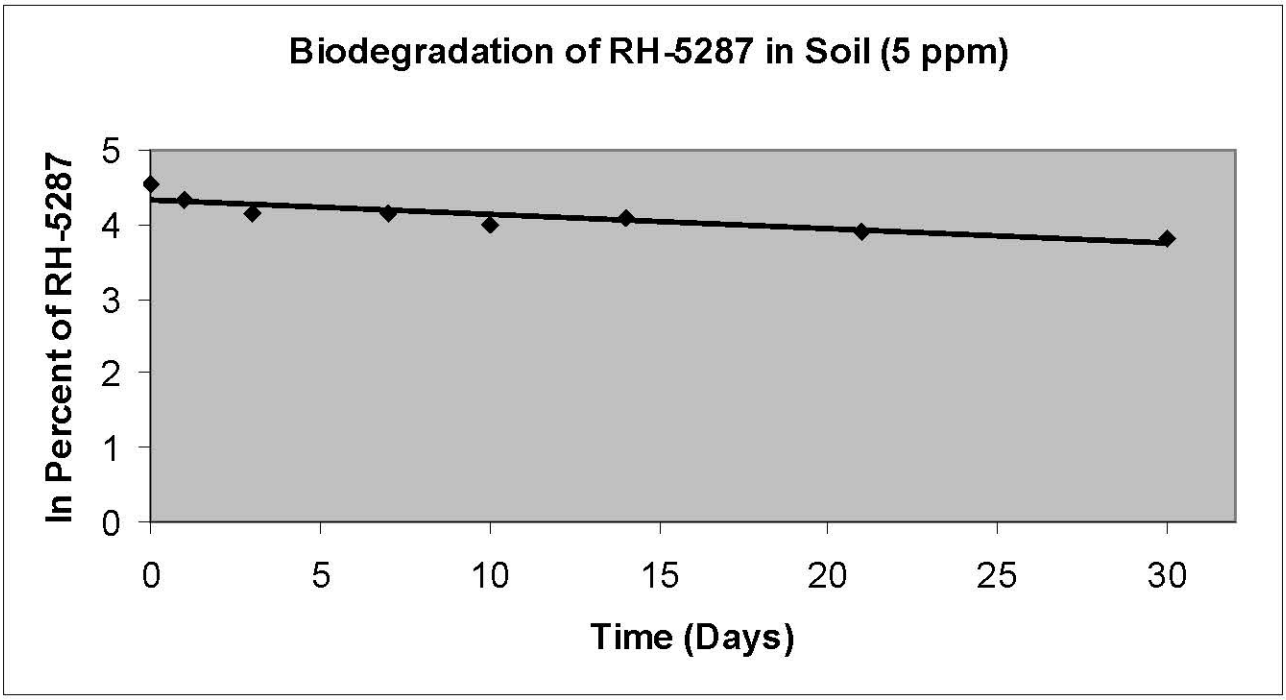
1 ND = not detectable (less than 2X background)

Table A7.2.3.1-5: Extraction of 0 – 6 cm Soil Sections

Soil (0-6 cm)	Percent applied ^{14}C-activity Extracted by Various Solvents			
	Methylene chloride: Methanol (1:1)	Methanol	NaOH	Remaining on Soil
Agricultural Sand				
Replicate 1	64.6	ND[1]	24.1	42.6
Replicate 2	54.7	ND	16.1	28.3
Sandy Loam				
Replicate 1	52.7	ND	32.7	30.3
Replicate 2	63.2	6.1	19.3	26.1
Silt Loam				
Replicate 1	47.0	1.9	18.5	41.8
Replicate 2	56.4	ND	19.3	30.4
Silty Clay Loam				
Replicate 1	65.9	ND	20.3	37.3
Replicate 2	51.9	ND	14.5	21.5

[1] ND= not detectable (at 2X background)

Figure A7.2.3.1-1: Half-Life Determination of ^{14}C DCOIT in Sandy Loam Soil



Linear Regression Analysis	
Correlation Coefficient (R^2)	0.881
Intercept	4.335
Slope (-k)	-0.0198
Half-life	34.9 days

Section A7.2.3.2 Annex Point IIIA, XII.1.3	Mobility	
	Justification for non-submission of data	Official use only
Other existing data [ ] **Limited exposure** [x]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [x]	
Detailed justification:	Detailed justification is considered as confidential information. [redacted]	
Undertaking of intended data submission [ ]	*No*	
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	21 August 2007	
Evaluation of applicant's justification	Agree with applicant's justification	
Conclusion	No further testing considered necessary	
Remarks	-	

Section A7.3.1 Phototransformation in air

Annex Point IIIA, VII.5

Official use only

		1 REFERENCE
1.1	**Reference**	Reference type: Study report Year: 2003 Report date: 15 May 2003 [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Rohm and Haas Company
1.2.2		
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes-Technical Guidance Document, Chapter 3, Section 7.3.1
2.2	**GLP**	Not Applicable
2.3	**Deviations**	None
		3 MATERIALS AND METHODS
3.1	**Test material**	DCOIT (RH-5287)
3.1.1	Lot/Batch number	Not applicable
3.1.2	Specification	Not applicable
3.1.3	Purity	Not applicable
3.1.4	Radiolabeling	Not applicable
3.1.5	UV/VIS absorption spectra and value	Not applicable
3.1.6	Futher relevant properties	[redacted]
3.2	**Reference**	[redacted]

Section A7.3.1 Phototransformation in air

Annex Point IIIA, VII.5

3.3 Test solution

3.4 Testing procedure

3.4.1	Test system	Not applicable
3.4.2	Properties of light source	Not applicable
3.4.3	Determination of irradiance	Not applicable
3.4.4	Temperature	Not applicable
3.4.5	pH	Not applicable
3.4.6	Duration of test	Not applicable
3.4.7	Number of replicate	Not applicable
3.4.8	Sampling	Not applicable
3.4.9	Analytical method	Not applicable

Section A7.3.1 Phototransformation in air

Annex Point IIIA, VII.5

3.5 Transformation products

3.5.1 Method of analysis for transformation procedure

4 RESULTS

4.1 DCOIT

4.1.1 K_{OH}

The first order degradation rate constant (k_{OH}) from OH^- radicals is calculated as the sum of bond k_{OH}'s. This is presented in Table A7.3.1-1. The k_{OH} for DCOIT is 239.3 x 10^{-13} cm^3. $molecule^{-1}$. sec^{-1}.

4.1.2 Half-life ($OH^•$)

The half-life due to the hydroxyl radical is determined as follows:

$t_{½}$ = ln2/(k_{OH}) x [OH]
= 0.693/239.3 x 10^{-13} cm^3-$molec.^{-1}$-sec^{-1} x 6.5 x 10^5 $molecule.cm^{-3}$
= 4.46 x 10^4 sec
= 12.4 hours

4.1.3 K_{NO3}

The first order degradation rate constant (k_{NO3}) from $NO_3^•$ radicals is determined as follows:

$-\log k_{NO3} = -18.86 + 3.05 \times (-\log k_{OH})$
$= -18.86 + 3.05 \times (-\log 239.3 \times 10^{-13})$
$= -18,86 + 3.05 \times (10.621)$
$= 13.534$

k_{NO3} = antilog (-13.534)
= 0.292 x 10^{-13} cm^3.$molecule^{-1}$.sec^{-1}

4.1.4 Half-life ($NO_3^•$)

The half-life due to the nitrate radical is calculated similarly to the hydroxyl (described above) and is 27.5 hours.

4.2 Transformations products

4.2.1 K_{OH}

The first order degradation rate constant (k_{OH}) from $OH^•$ radicals for the 5 transformation products is presented in Table A7.3.1-2

4.2.2 Half-life ($OH^•$)

The half-life of the 5 potential transformation products due to the hydroxyl radical is presented in Table A7.3.1-2. The half-life ranges from 18.6-24.4 hours.

Section A7.3.1 Phototransformation in air

Annex Point IIIA, VII.5

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The guideline followed is that described in the Technical Guidance Document, Chapter 3, Section 7.3.1

The phototransformation rate constant of DCOIT is calculated using SAR method.

Global average OH and NO_3 radical concentrations in daylight and night hours are used.

Potential phototransformation products of DCOIT are hypothesized based on information from previous studies.

The estimation is demonstrated to be accurate by comparing the rate constant of DCOIT with that of six compounds which have similar bond types.

5.2 Results and discussion

Due to relative low vapor pressure and high water solubility, the concentration of DCOIT in the troposphere is expected to be low. This ensures that the photodegradation of the radicals with DCOIT follows a pseudo first-order kinetics required by SAR calculation method.

Due to the presence of nitrogen and sulfur bonds, DCOIT has a large phototransformation rate constant. The parent compound quickly photodegrades during the daylight with half-life of 12.4 hours.

Due to the presence of nitrogen and sulfur bonds, all potential photodegradation products are expected to be very reactive to photodegradation with half-lives in a range of 18.6-24.4 hours.

5.3 Conclusion

Daylight photolysis is the dominant phototransformation procedure for DCOIT and its potential metabolites.

DCOIT photodegrades quickly with half-life of 12.4 hours and the half-life of its metabolites range from18.6-24.1 hours.

Due to very low production and usage volume, the effect from DCOIT and its potential photodegradation products towards global warming is minimal. Therefore, DCOIT and its photodegradation metabolites impose no effect to global warming.

5.3.1 Reliability

1-valid without restrictions

5.3.2 Deficiencies

There are no deficiencies.

Document III-A / Section A7.1.3, A7.1.4, A7.2 and A7.3

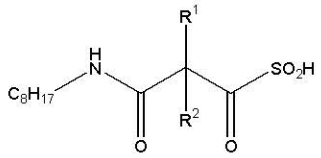
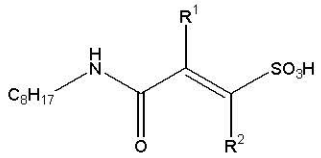
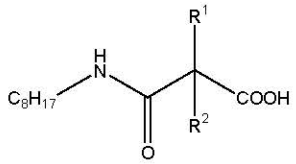
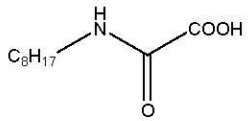
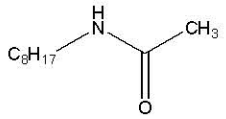
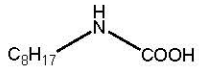
Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	29 August 2006, revised 31 July 2009
Materials and Methods	Agree with applicants version
Results and discussion	Adopt applicant's version
Conclusion	Adopt applicant's version
Reliability	1, reliable without restrictions
Acceptability	Acceptable
Remarks	These are theoretical estimates, performed using verified models and are therefore reliable enough for the present use. The TGD prescribes a $5*10^5$ concentration of OH-radicals in atmosphere [molec.cm^{-3}] and a 24 hour time frame. With this approach, the calculated half-life for OH radical reactions for DCOIT is 16.1 hours. This calculation considers the photolysis by radical [OH] as the dominated factor for a 24 hour period and does not consider the one by [NO_3] during the night.

Section A7.3.1	Phototransformation in air **TABLES AND FIGURES**

Table A7.3.1-1: Hydroxyl Rate Constants of Different Types of Reactions for DCOIT

Bond Type	k_{OH} (10^{-13} cm^3.$molecule^{-1}$.sec^{-1})	Number of Bonds	Total (10^{-13} cm^3.$molecule^{-1}$.sec^{-1})
C-H	0.14	17	2.38
>C=C<	11.0	1	11.0
>C=O	0.31	2	0.62
>N-	60.2	3	180.6
-S-	20.0	2	40.0
C-Cl	2.36	2	4.72
			239.3

Table A7.3.1-2: Reaction Rate Constant k_{OH} and Half-Life of Transformation Products

Compound	k_{OH} (10^{-13} cm^3.$molecule^{-1}$.sec^{-1})	$t_{½}$ (hours)
	152 – 159	18.6 – 19.4
	142 – 148	19.8 – 20.9
	122 – 128	23.1 – 24.3
	121 – 123	24.0 – 24.4
	122 – 124	23.9 – 24.3
	121 - 123	24.1 – 24.4

Section A7.3.2 Annex Point IIIA, VII.5	Fate and behaviour in air, further studies	
	Justification for non-submission of data	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [x]**	
Detailed justification:	Due to the rapid decline of parent and metabolites calculated in Section A7.3.1, DCOIT does not trigger the need for additional fate and behavior in air studies.	
Undertaking of intended data submission [ ]	-	
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	17 August 2007	
Evaluation of applicant's justification	Agree with applicant's justification	
Conclusion	No further testing is required.	
Remarks	-	

Directive 98/8/EC on the placing of biocidal products on the market.

Dossier for the inclusion of an active substance in the Annex 1

4,5-Dichloro-2-octyl-2H-isothiazol-3-one (DCOIT)

Product type 21: Antifouling products

Document III-A (A7)
Study summaries – Active substance
Ecotoxicological profile including environmental fate and behaviour

Part IV

Fate and behaviour in the environment

Section A7.4.1: Aquatic toxicity initial (acute) tests

Section A7.4.2: Estimation of bioconcentration

Document III-A / Section A7.4.1 and A7.4.2

TABLE OF CONTENTS

Document III-A / Section A7.4.1 and A7.4.2

Section A7.4.1.1a/01 Acute toxicity of DCOIT to fish-Fresh water, Rainbow trout

Annex Point IIA VII.7.1

Official use only

		1 REFERENCE
1.1	**Reference**	Reference type: Study report Year: 1990 Report date: 8 March 1990 [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Rohm and Haas Company
1.2.2		
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes, US EPA Guideline 72-1
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 MATERIALS AND METHODS
3.1	**Test material**	RH-287 Technical
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2
3.1.3	Purity	96.9%
3.1.4	Composition of Product	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]

Section A7.4.1.1a/01 Acute toxicity of DCOIT to fish-Fresh water, Rainbow trout

Annex Point IIA VII.7.1

3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	[redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	see table A7.4.1.1.a/01-5
3.4.5	Duration of the test	96 h
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]

4 RESULTS

4.1	**Limit Test**	Not performed
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	Nominal (µg DCOIT/L) 0.50, 1.0, 2.0, 4.0, 8.0
4.2.2	Actual concentrations of test substance	Measured concentrations (µg DCOIT/L)
4.2.3	Effect data (Mortality)	see table A7.4.1.1.a/01-6; see table A7.4.1.1.a/01-7

0 hr	96 hr	mean
0.50	0.38	0.44
0.96	0.90	0.93
1.9	1.6	1.8
3.3	3.3	3.3
6.4	6.2	6.3

Document III-A / Section A7.4.1 and A7.4.2

Section A7.4.1.1a/01 — Acute toxicity of DCOIT to fish-Fresh water, Rainbow trout

Annex Point IIA VII.7.1

4.2.4	Concentration / response curve	The slope of the 96-hour dose-response line was 8.5 as calculated by the least squares regression analysis. See Figure A7.41.1.a/01-1.	
4.2.5	Other effects	surfacing, loss of equilibrium	
4.3	**Results of controls**		
4.3.1	Number/ percentage of animals showing adverse effects	no adverse effects	
4.3.2	Nature of adverse effects	not applicable	
4.4	**Test with reference substance**	Not performed	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	US EPA Guideline 72-1, Acute flow-through 96h fish study with analytical confirmation of test solution concentrations.	
5.2	**Results and discussion**	96 h NOEC = 1.8 µg DCOIT/L	
5.2.1	LC_0	96 h = 1.8 µg DCOIT/L	
5.2.2	LC_{50}	96 h = 2.7 µg DCOIT/L	
5.2.3	LC_{100}	96 h = 6.3 µg DCOIT/L	
5.3	**Conclusion**	see validity criteria summarized in table A7.4.1.1.a/01-8	x
5.3.1	Other Conclusions	none	
5.3.2	Reliability	(1), valid without restriction	
5.3.3	Deficiencies	No	

Evaluation by Competent Authorities

Evaluation by Rapporteur Member State

Date	29 September 2007
Materials and Methods	Agree with applicant's version
Results and discussion	Agree with applicant's version
Conclusion	**Comment (5.3):** The validity criteria in table A7.4.1.1.a/01-8 are not quite fulfilled. At the lowest tested concentration, the measured value at 96 hours was only 76 % of the value measured at at the beginning of the test. However, as the LC50, based on mean measured concentration, is above this concentration level, this finding is not considered to have influenced the outcome of the test.
Reliability	1, valid without restrictions

Document III-A / Section A7.4.1 and A7.4.2

Section A7.4.1.1a/01 **Annex Point IIA VII.7.1**	**Acute toxicity of DCOIT to fish-Fresh water, Rainbow trout**

Acceptability	Acceptable
Remarks	-

Document III-A / Section A7.4.1 and A7.4.2

Section A7.4.1.1a/01	Acute toxicity of DCOIT to fish-Fresh water, Rainbow trout
	TABLES AND FIGURES

[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
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Table A7.4.1.1.a/01-5: Test conditions

Criteria	Details		
Test temperature (degree C)	0 h: 12.2-12.4	48 h: 11.8	96 h: 12.1-12.4
Dissolved oxygen (mg/L)	0 h: 9.2-9.4	48 h: 9.0-9.2	96 h: 8.7-9.0
pH	0 h: 8.0	48 h: 7.9	96 h: 8.0
Adjustment of pH	Yes		
Aeration of dilution water	Yes, flow-through		
Intensity of irradiation	not described		
Photoperiod	16 h daylight		

Table A7.4.1.1.a/01-6: Mortality data

Test-Substance Concentration (mean measured) [µg DCOIT/l]	Mortality							
	Number				Percentage			
	24 h	48 h	72 h	96 h	24 h	48 h	72 h	96 h
Control	0	0	0	0	0	0	0	0
Solvent control	0	0	0	0	0	0	0	0
0.44	0	0	0	0	0	0	0	0
0.93	0	0	0	0	0	0	0	0
1.8	0	0	0	0	0	0	0	0
3.3	0	0	11/20	17/20	0	0	55	85
6.3	0	20/20	20/20	20/20	0	100	100	100
Temperature [°C]	--	11.8	--	12.1-12.4				
pH	--	7.9	--	8.0				
Oxygen [mg/l]	--	9.0-9.2	--	8.7-9.0				

Table A7.4.1.1.a/01-7: Effect data

	48 h [µg DCOIT/l][1]	95 % c.l.	96 h [µg DCOIT/l][1]	95 % c.l.
LC_{50}	4.6 (m)	3.3-6.3	2.7 (m)	1.8-3.3

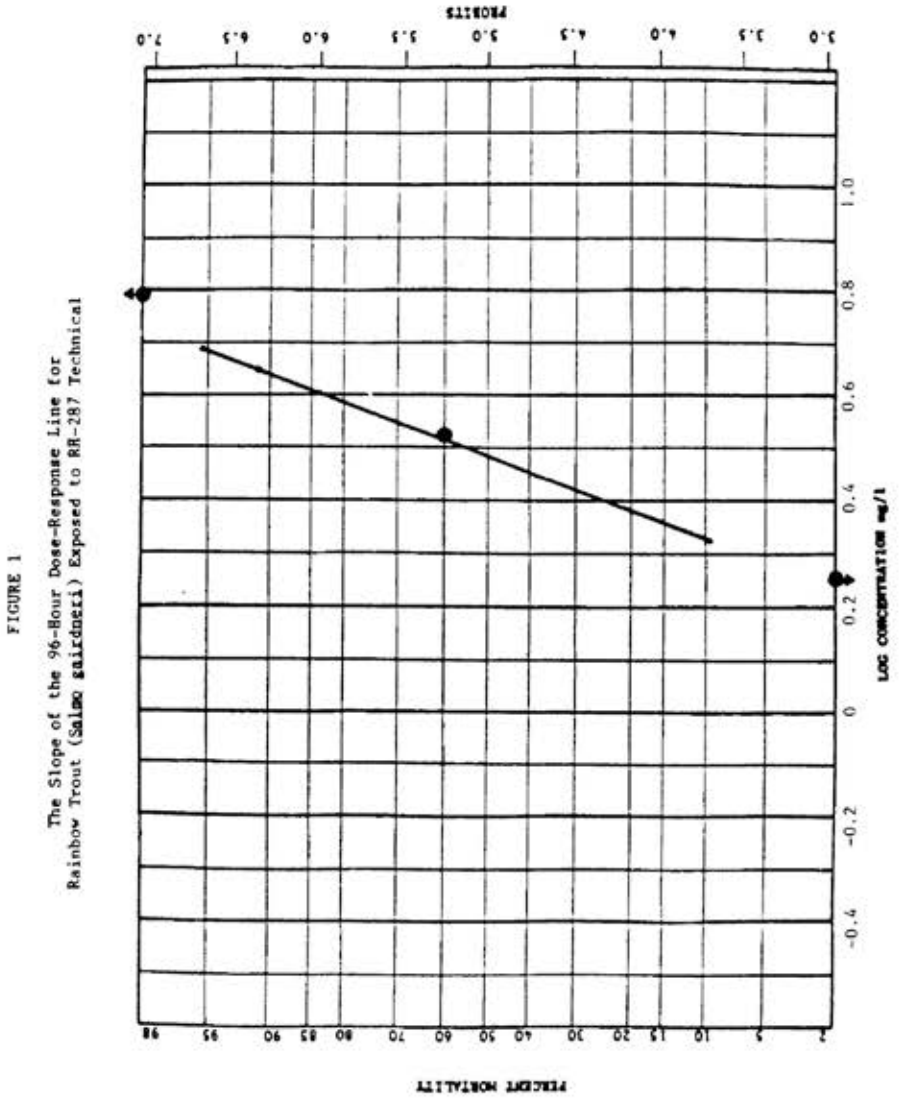
[1] indicate if effect data are based on nominal (n) or measured (m) concentrations

Table A7.4.1.1.a/01-8: Validity criteria for acute fish test according to OECD Guideline 203

	fulfilled	Not fullfilled
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	

Figure A7.4.1.1.a/01-1: **Slope of the 96-hour dose-response line for Rainbow trout (*Salmo gairdneri*) exposed to DCOIT**

Rohm and Haas Report No. 89RC-0015



ABC LABS NO. 37737-22

Document III-A / Section A7.4.1 and A7.4.2

Section A7.4.1.1.a/02 Acute toxicity of DCOIT to fish-Fresh water, Bluegill Sunfish

Annex Point IIA VII.7.1

Official use only

		1 REFERENCE
1.1	**Reference**	Reference type: Study report Year: 1990 Report date: 8 MArch 1990 [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Rohm and Haas Company
1.2.2		
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes, US EPA Guideline 72-1
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 MATERIALS AND METHODS
3.1	**Test material**	RH-287 Technical
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2
3.1.3	Purity	96.9%
3.1.4	Composition of Product	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]

Section A7.4.1.1.a/02 Acute toxicity of DCOIT to fish-Fresh water, Bluegill Sunfish

Annex Point IIA VII.7.1

3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	[redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	see table A7.4.1.1.a/02-5
3.4.5	Duration of the test	96 h
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]

4 RESULTS

4.1	**Limit Test**	Not performed
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	Nominal (µg DCOIT/L) 1.9, 3.8, 7.5, 15, 30
4.2.2	Actual concentrations of test substance	measured concentration (µg DCOIT/L)

0 hr	96 hr	mean
1.8	1.4	1.6
3.5	3.1	3.3
6.9	6.0	6.5
14	12	13
27	25	26

4.2.3	Effect data (Mortality)	see table A7.4.1.1.a/02-6; see table A7.4.1.1.a/02-7
4.2.4	Concentration / response curve	The slope of the 96-hour dose-response line was 7.7 as calculated by the least squares regression analysis. See Figure A7.4.1.1.a/02-1.
4.2.5	Other effects	quiescence, fish on the chamber bottom, loss of equilibrium

Section A7.4.1.1.a/02 Acute toxicity of DCOIT to fish-Fresh water, Bluegill Sunfish

Annex Point IIA VII.7.1

4.3	**Results of controls**	
4.3.1	Nr/ percentage of animals showing adverse effects	no adverse effects
4.3.2	Nature of adverse effects	not applicable
4.4	**Test with reference substance**	Not performed
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	US EPA Guideline 72-1, Acute flow-through 96h fish study with analytical confirmation of test solution concentrations.
5.2	**Results and discussion**	96 h NOEC = 6.5 µg DCOIT/L
5.2.1	LC_0	96 h = 6.5 µg DCOIT/L
5.2.2	LC_{50}	96 h = 14 µg DCOIT/L
5.2.3	LC_{100}	96 h = 26 µg DCOIT/L
5.3	**Conclusion**	see validity criteria summarized in table table A7.4.1.1.a/02-8
5.3.1	Other Conclusions	none
5.3.2	Reliability	(1), valid without restriction
5.3.3	Deficiencies	No

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	29 September 2007
Materials and Methods	Agree with applicant's version
Results and discussion	Agree with applicant's version
Conclusion	Agree with applicant's version
Reliability	1, valid without restrictions
Acceptability	Acceptable
Remarks	-

Document III-A / Section A7.4.1 and A7.4.2

Section A7.4.1.1.a/02	Acute toxicity of DCOIT to fish-Fresh water, Bluegill Sunfish
	TABLES AND FIGURES

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Table A7.4.1.1.a/02-5: Test conditions

Criteria	Details		
Test temperature (degree C)	0 h: 22.6	48 h: 22.3	96 h: 22.3-22.4
Dissolved oxygen (mg/L)	0 h: 8.5-8.7	48 h: 8.4	96 h: 8.0-8.4
pH	0 h: 7.9	48 h: 7.7	96 h: 7.7-7.8
Adjustment of pH	Yes		
Aeration of dilution water	Yes, flow-through		
Intensity of irradiation	not described		
Photoperiod	16 h daylight		

Table A7.4.1.1.a/02-6: Mortality data

Test-Substance Concentration (mean measured) [µg DCOIT/l]	Mortality							
	Number				Percentage			
	24 h	48 h	72 h	96 h	24 h	48 h	72 h	96 h
Control	0	0	0	0	0	0	0	0
Solvent control	0	0	0	0	0	0	0	0
1.6	0	0	0	0	0	0	0	0
3.3	0	0	0	0	0	0	0	0
6.5	0	0	0	0	0	0	0	0
13	0	0	3/19	8/19	0	0	16 %	42 %
26	16/20	20/20	20/20	20/20	80 %	100 %	100 %	100 %
Temperature [°C]	--	22.3	--	22.3-22.4				
Ph	--	7.7	--	7.7-7.8				
Oxygen [mg/l]	--	8.4	--	8.0-8.4				

Table A7.4.1.1.a/02-7: Effect data

	48 h [ug ai/l][1]	95 % c.l.	96 h [ug ai/l][1]	95 % c.l.
LC_{50}	18 (m)	13-26	14 (m)	6.5-26

[1] indicate if effect data are based on nominal (n) or measured (m) concentrations

Table A7.4.1.1.a/02-8: Validity criteria for acute fish test according to OECD Guideline 203

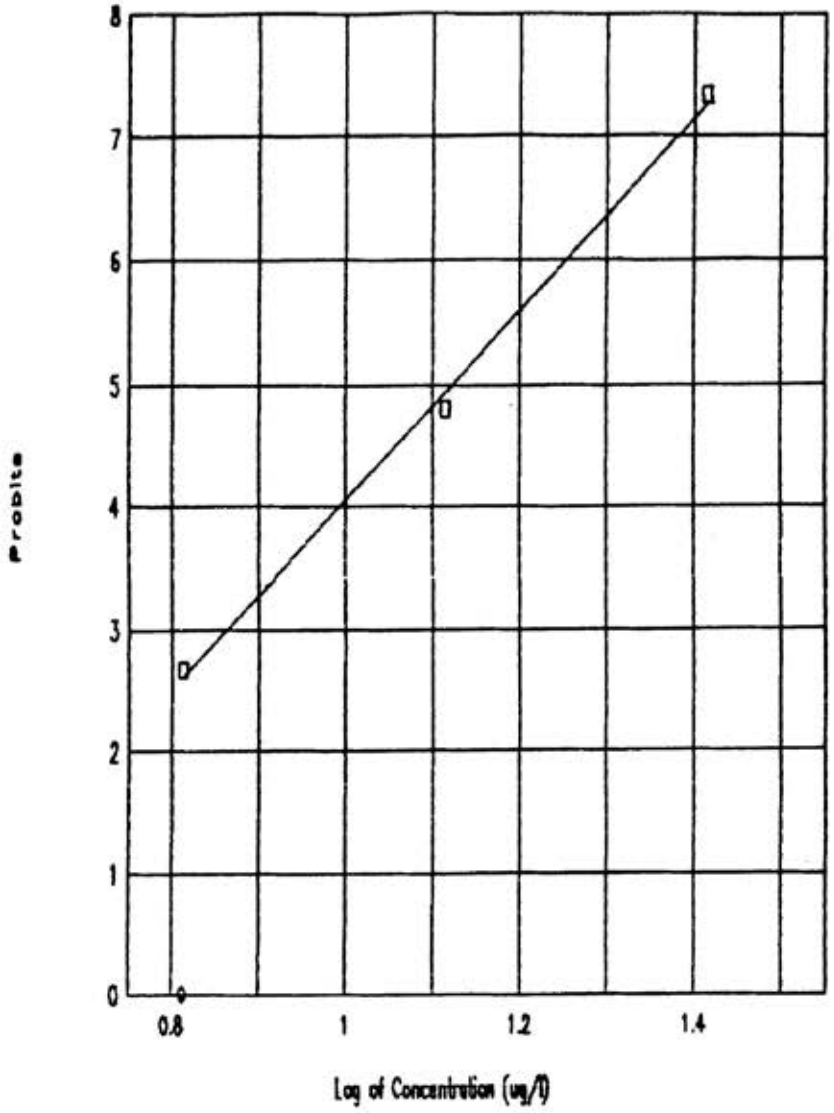
	fulfilled	Not fullfilled
Mortality of control animals <10%	yes	
Concentration of dissolved oxygen in all test vessels > 60% saturation	yes	
Concentration of test substance ≥80% of initial concentration during test	yes	

Figure A7.4.1.1.a/02-1: The 96-hour Dose-response line for Bluegill Sunfish (*Lepomis macrochirus*) exposed to DCOIT

Rohm and Haas Report No. 89RC-0016

FIGURE 1

The 96-Hour Dose-Response Line for Bluegill Sunfish
(Lepomis macrochirus) Exposed to RH-287 Technical



ABC LABS NO. 37736-22

Document III-A / Section A7.4.1 and A7.4.2

Section A7.4.1.1b/01 — Acute toxicity of DCOITto fish-Marine water, Sheepshead Minnow

Annex Point IIA VII.7.1

Official use only

		1 REFERENCE
1.1	**Reference**	Reference type: Study report Year: 1990 Report date: 28 November 1990 [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Rohm and Haas Company
1.2.2		
1.2.3	Criteria for data protection	[redacted]
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	Yes, US-EPA FIFRA Guideline 72-3
2.2	**GLP**	Yes
2.3	**Deviations**	No
		3 MATERIALS AND METHODS
3.1	**Test material**	RH-287 Technical
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2
3.1.3	Purity	96.9% DCOIT
3.1.4	Composition of Product	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis	[redacted]

Section A7.4.1.1b/01 **Acute toxicity of DCOITto fish-Marine water, Sheepshead Minnow**

Annex Point IIA VII.7.1

for reference substance

3.4 Testing procedure

3.4.1 Dilution water [redacted]

3.4.2 Test organisms [redacted]

3.4.3 Test system [redacted]

3.4.4 Test conditions see table A7.4.1.1.b/01-5

3.4.5 Duration of the test 96 hr

3.4.6 Test parameter [redacted]

3.4.7 Sampling [redacted]

3.4.8 Monitoring of TS concentration [redacted]

3.4.9 Statistics [redacted]

4 RESULTS

4.1 Limit Test Not performed

4.2 Results test substance

4.2.1 Initial concentrations of test substance

Nominal (µg DCOIT/L)

9.9, 14.9, 24.8, 39.7, 62.0

4.2.2 Actual concentrations of test substance

measured concentrations (µg DCOIT/L)

0 hr-rep1	0 hr-rep2	96 hr-rep1	96hr-rep2	mean
6.2	7.0	8.7	8.5	7.6
11	10	13	12	11.5
16	22	23	24	21.5
36	31	35[a]	36[a]	35
54	62	84[b]	80[b]	70

[a] samples collected after 48 h due to complete mortality of exposed test organisms.

[b] samples collected after 24 h due to complete mortality of exposed test organisms.

x

Section A7.4.1.1b/01 **Acute toxicity of DCOITto fish-Marine water, Sheepshead Minnow**

Annex Point IIA VII.7.1

4.2.3	Effect data (Mortality)	see table A7.4.1.1.b/01-6; see table A7.4.1.1.b/01-7	
4.2.4	Concentration / response curve	The slope of the 96-hour dose-response line was 8.0. See Figure A7.4.1.1.b/01-1.	
4.2.5	Other effects	lethargy and a loss of equilibrium	
4.3	**Results of controls**		
4.3.1	Number/ percentage of animals showing adverse effects	no adverse effects	
4.3.2	Nature of adverse effects	not applicable	
4.4	**Test with reference substance**	Not performed	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	US EPA Guideline 72-3, Acute flow-through 96h fish study with analytical confirmation of test solution concentrations.	
5.2	**Results and discussion**	96 h NOEC = 11.5 µg DCOIT/L based on survival	
5.2.1	LC_0	96 h = 7.6 µg DCOIT/L	
5.2.2	LC_{50}	96 h = 20.5 µg DCOIT/L	
5.2.3	LC_{100}	96 h = 34.5 µg DCOIT/L	
5.3	**Conclusion**	see validity criteria summarized in table A7.4.1.1.b/01-8	x
5.3.1	Other Conclusions	none	
5.3.2	Reliability	(1) reliable without restriction	
5.3.3	Deficiencies	No	

Document III-A / Section A7.4.1 and A7.4.2

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	29 September 2007
Materials and Methods	Agree with applicant's version
Results and discussion	**Comment (4.2.2):** At the highest tested concentration the values measured at 96 hours are more than 120% of the initial measured concentrations. Considering the fact that DCOIT is rapidly degradable in the aquatic environment, no explanation for this finding could be found.
Conclusion	**Comment (5.3):** Test substance concentrations were above 80%, but at the highest tested concentration the values measured at 96 hours are more than120% of the initial measured concentration. However, the LC50, based on mean measured concentrations, is below this concentration level, and therefore this finding is not considered to have influenced the outcome of the test.
Reliability	1, reliable without restrictions
Acceptability	Acceptable
Remarks	-

Document III-A / Section A7.4.1 and A7.4.2

Section A7.4.1.1b/01	Acute toxicity of DCOITto fish-Marine water, Sheepshead Minnow

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Table A7.4.1.1.b/01-5: Test conditions

Criteria	Details
Test temperature	22 ± 1 C
Dissolved oxygen	6.4-8.0 mg/L
pH	7.7-7.9
Adjustment of pH	not described
Salinity	16-17 parts per thousand
Aeration of dilution water	Yes
Intensity of irradiation	cool-white fluorescent lights, light intensity of 10 uEs-1m-2
Photoperiod	16 hr daylight, 8 hr dark

Table A7.4.1.1.b/01-6: Mortality data

Test-Substance Concentration (mean measured)[1] [µg DCOIT/l]	Mortality							
	Number				Percentage			
	24 h	48 h	72 h	96 h	24 h	48 h	72 h	96 h
0 (control)	0	0	0	0	0	0	0	0
0 (solvent control)	0	0	0	0	0	0	0	0
7.6	0	0	0	0	0	0	0	0
11.5	0	0	1/20	1/20	0	0	5	5
21.2	0	1/20	8/20	9/20	0	5	40	45
34.5	2/20	20/20	20/20	20/20	10	100	100	100
70.0	20/20	20/20	20/20	20/20	100	100	100	100
Temperature [°C]	22 ± 1 °C							
pH	7.7-7.9							
Oxygen [mg/l]	6.4-8.0 mg/L							

[1] specify, if TS concentrations were nominal or measured

Table A7.4.1.1.b/01-7: Effect data

	48 h [µg DCOIT/l][1]	95 % c.l.	96 h [µg DCOIT/l][1]	95 % c.l.
LC_0	11.5 (m)	--	7.6 (m)	--
LC_{50}	26.2 (m)	21.2-34.5	20.5 (m)	17.7-23.5
LC_{100}	34.5 (m)	--	34.5 (m)	--

[1] effect data are based on measured (m) concentrations

Table A7.4.1.1.b/01-8: Validity criteria for acute fish test according to OECD Guideline 203

	fulfilled	Not fullfilled
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**	

Figure A7.4.1.1 b/01-1: Survival of organisms exposed to DCOIT for 96 hours

Amended 11/28/90

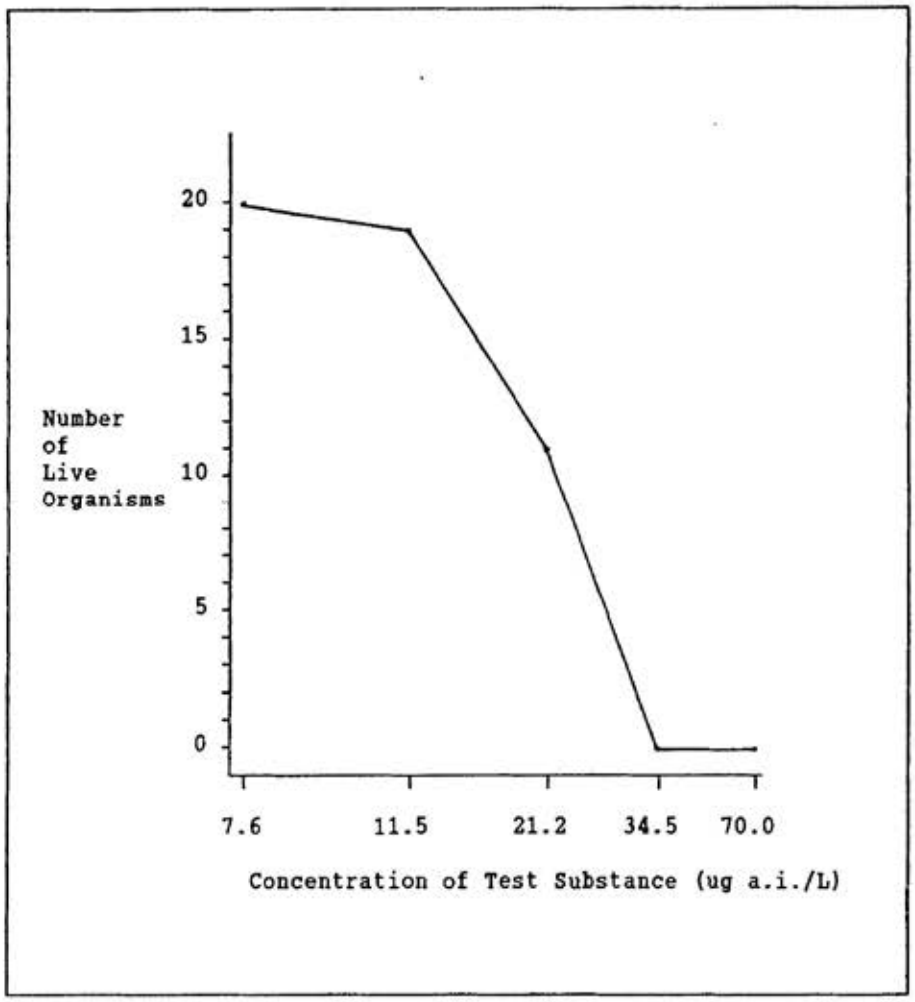

Figure 1. Survival of organisms exposed to the test substance for 96 hours

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Rohm and Haas Report No. 89RC-0262
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Section A7.4.1.1b/02 Acute toxicity of DCOIT to fish-Marine water, Japanese blowfish

Annex Point IIA VII.7.1

Official use only

1 REFERENCE

1.1	**Reference**	Reference type: Study report Year: 1997 Report date: 27 September 1997 [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Rohm and Haas Company
1.2.2		
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes, OECD Guideline 203
2.2	**GLP**	Not described in report
2.3	**Deviations**	Yes, test substance was not analytically determined in test solutions

3 MATERIALS AND METHODS

3.1	**Test material**	RH-287T
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2
3.1.3	Purity	100% DCOIT
3.1.4	Composition of Product	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference**	[redacted]

Section A7.4.1.1b/02 **Acute toxicity of DCOIT to fish-Marine water, Japanese blowfish**

Annex Point IIA VII.7.1

	substance	
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	[redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	see table A7.4.1.1.b/02-5
3.4.5	Duration of the test	96 h
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]

4 RESULTS

4.1	**Limit Test**	Not performed
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	0.25, 0.5, 1.0, 2.0, 4.0, 8.0 and 16.0 µg/L
4.2.2	Actual concentrations of test substance	Not performed
4.2.3	Effect data (Mortality)	see table A7.4.1.1.b/02-6; see table A7.4.1.1.b/02-7
4.2.4	Concentration / response curve	See Figures A7.4.1.1.b/02-1 and A7.4.1.1.b/02-2.
4.2.5	Other effects	abnormal behaviour
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	no effects
4.3.2	Nature of adverse effects	not applicable
4.4	**Test with reference**	Not performed

Document III-A / Section A7.4.1 and A7.4.2

Section A7.4.1.1b/02 **Acute toxicity of DCOIT to fish-Marine water, Japanese blowfish**

Annex Point IIA VII.7.1

	substance		
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	96 hr semi-static fish study conducted in accordance with OECD Guideline 203	
5.2	**Results and discussion**		x
5.2.1	LC0	96 h = 3.67 µg/L	
5.2.2	LC50	96 h = 5.66 µg/L	
5.2.3	LC100	96 h = 8.72 µg/L	
5.3	**Conclusion**	see validity criteria summarized in table A7.4.1.1.b/02-8	
5.3.1	Other Conclusions	not applicable	
5.3.2	Reliability	(2), reliable with restrictions	
5.3.3	Deficiencies	Yes, test substance was not analytically determined in test solutions	

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	04 December 2007
Materials and Methods	Agree with applicant's version
Results and discussion	**Comment (5.2):** Test concentrations have not been measured and that the species tested is not one recommended by OECD. However, the test is a semi-static OECD test from 1997, renewal of medium every 24 hours, gives a clear dose-response-relationship and is fairly well documented. Therefore, the results of this test are nevertheless considered valid.
Conclusion	Agree with applicant's version
Reliability	2, reliable with restrictions
Acceptability	Acceptable with the restrictions noted above
Remarks	-

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Table A7.4.1.1.b/02-5: Test conditions

Criteria	Details
Test temperature	20 ± 1 °C
Dissolved oxygen	90.8 – 100.1% of saturation
pH	7.95 – 8.19
Adjustment of pH	not described
Aeration of dilution water	not described
Salinity	30.1 – 30.2 % at test initiation
Intensity of irradiation	not described
Photoperiod	16 h photoperiod daily

Table A7.4.1.1.b/02-6: Mortality data

Test-Substance Concentration (nominal)[1] [µg/l]	Mortality							
	Number				Percentage			
	24 h	48 h	72 h	96 h	24 h	48 h	72 h	96 h
0 (control)	0	0	0	0	0	0	0	0
0 (DMSO solvent control)	0	0	0	0	0	0	0	0
0.25	0	0	0	0	0	0	0	0
0.5	0	0	0	0	0	0	0	0
1.0	0	0	0	0	0	0	0	0
2.0	0	0	0	0	0	0	0	0
4.0	0	1/10	1/10	1/10	0	10	10	10
8.0	0	2/10	8/10	9/10	0	20	80	90
16.0	0	10/10	10/10	10/10	0	100	100	100
Temperature [°C]	19.6-20.2	19.5-20.3	19.7-20.2	19.6-20.5				
pH	7.95-8.11	7.98-8.15	7.98-8.17	8.03-8.19				
Oxygen [mg/L]	93.4-97.0	91.6-99.9	93.1-96.3	94.6-100.1				

[1] specify, if TS concentrations were nominal or measured

Table A7.4.1.1.b/02-7: Effect data

	48 h [µg/L][1]	95 % C.I.	96 h [µg/L][1] calculated	95 % C.I.
LC_0	2.0 (n)	--	3.67 (n)	--
LC_{50}	not described in report	--	5.66 (n)	--
LC_{100}	16.0 (n)	--	8.72 (n)	--

[1] indicate if effect data are based on nominal (n) or measured (m) concentrations

Table A7.4.1.1.b/02-8: Validity criteria for acute fish test according to OECD Guideline 203

	fulfilled	Not fullfilled
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	**not described**	

Figure A7.4.1.1b/02-1: Correlation between mortality and logarithmic concentration of test solution

97Rc-1028
Japanese Blowfish

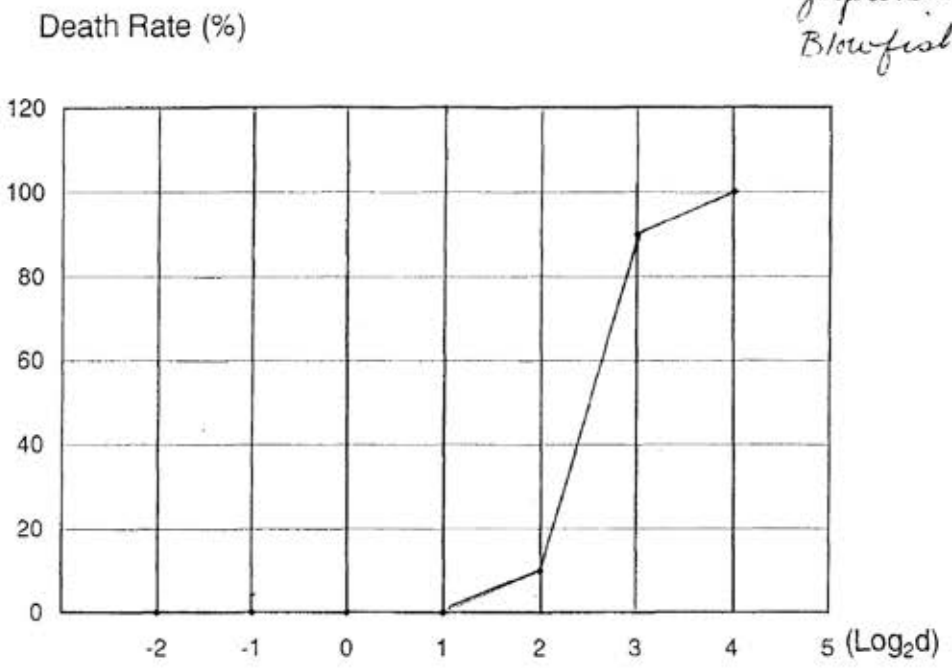

Fig. 1. Correlation between mortality and logarithmic concentration of test solution

Figure A7.4.1.1b/02-2: Time course for numbers of death

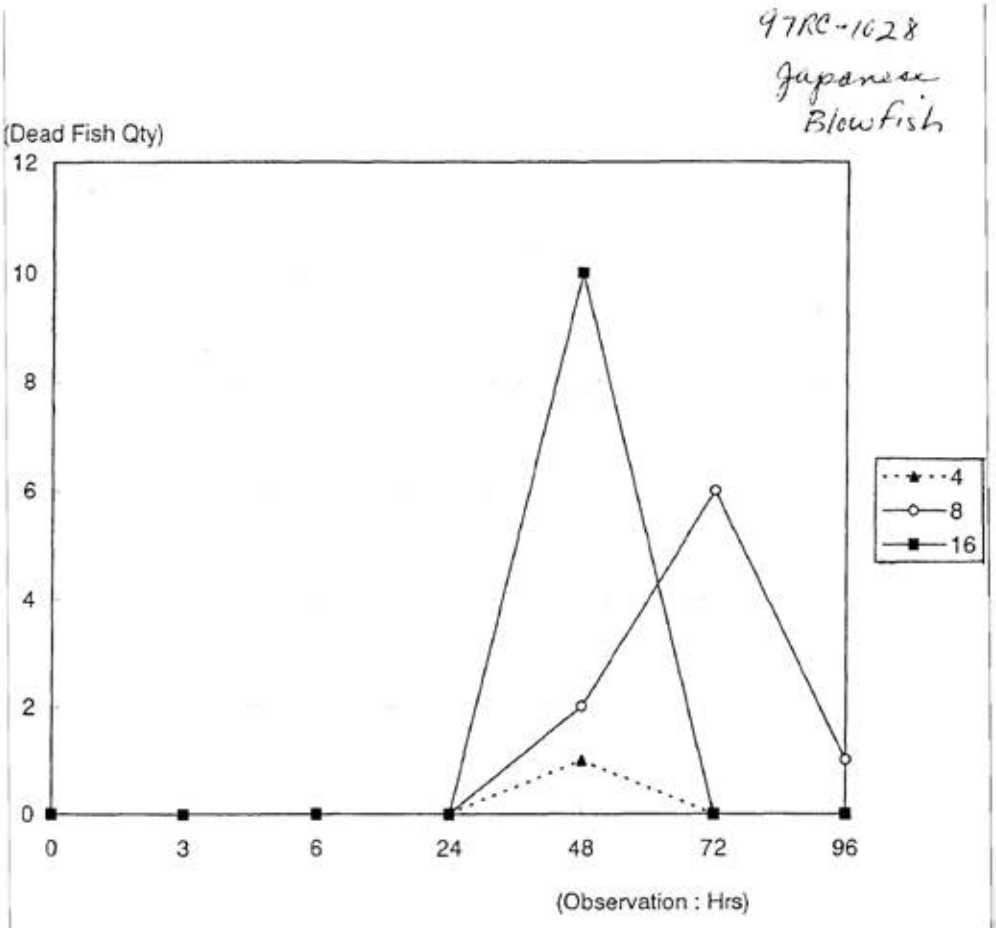

Fig. 2. Time course for numbers of death

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Section A7.4.1.1.c/01 Acute toxicity of N-(n-octyl) malonamic acid to fish- Fresh water, Rainbow trout

Annex Point IIA VII.7.1

Official use only

1 REFERENCE

1.1	**Reference**	Reference type: Study report Year: 1994 Report date: 7 July 1994 [redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Rohm and Haas Company
1.2.2		
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes, US EPA Guideline 72-1
2.2	**GLP**	Yes
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Test material**	N-(n-octyl) malonamic acid (NNOMA), metabolite of DCOIT
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	The test material was a metabolite of DCOIT
3.1.3	Purity	96.9% [redacted] and 96.6% [redacted]
3.1.4	Composition of Product	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis	[redacted]

Section A7.4.1.1.c/01 **Acute toxicity of N-(n-octyl) malonamic acid to fish- Fresh water, Rainbow trout**

Annex Point IIA VII.7.1

	for reference substance	
3.4	**Testing procedure**	
3.4.1	Dilution water	[redacted]
3.4.2	Test organisms	[redacted]
3.4.3	Test system	[redacted]
3.4.4	Test conditions	see table A7.4.1.1.c/01-5
3.4.5	Duration of the test	96 hr
3.4.6	Test parameter	[redacted]
3.4.7	Sampling	[redacted]
3.4.8	Monitoring of TS concentration	[redacted]
3.4.9	Statistics	[redacted]

4 RESULTS

4.1	**Limit Test**	Not performed
4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	15, 27, 48, 86, 150, 270, and 480 mg NNOMA/L
4.2.2	Actual concentrations of test substance	measured concentrations (mg NNOMA/L)

0 hr	96 hr	mean
14.9	16.2	16
29.2	27.9	29
49.3	50.2	50
88.1	87.8	88
163	159	160
276	284	280
428	433	430

4.2.3	Effect data	see table A7.4.1.1.c/01-6; see table A7.4.1.1.c/01-7

Section A7.4.1.1.c/01 Acute toxicity of N-(n-octyl) malonamic acid to fish- Fresh water, Rainbow trout

Annex Point IIA VII.7.1

	(Mortality)	
4.2.4	Concentration / response curve	The slope of the 96- hour dose-response line was 11. See Figure A7.4.1.1.c/01-1.
4.2.5	Other effects	quiescence, fish on the chamber bottom, loss of equilibrium, labored respiration, dark discoloration, surfacing
4.3	**Results of controls**	
4.3.1	Number/ percentage of animals showing adverse effects	no adverse effects
4.3.2	Nature of adverse effects	not applicable
4.4	**Test with reference substance**	Not performed
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	US EPA Guideline 72-1, Acute static 96h fish study with analytical confirmation of test solution concentrations.
5.2	**Results and discussion**	96 h NOEC = 160 mg NNOMA/L based on lack of mortality and abnormal effects at this concentration
5.2.1	LC_0	96 h = 160 mg NNOMA/L
5.2.2	LC_{50}	96 h = 250 mg NNOMA/L
5.2.3	LC_{100}	96 h = 430 mg NNOMA/L
5.3	**Conclusion**	see validity criteria summarized in table table A7.4.1.1.c/01-8
5.3.1	Other Conclusions	none
5.3.2	Reliability	(1), reliable without restriction
5.3.3	Deficiencies	No

Evaluation by Competent Authorities	
Evaluation by Rapporteur Member State	
Date	29 August 2006
Materials and Methods	Agree with applicant's version
Results and discussion	Agree with applicant's version
Conclusion	Agree with applicant's version
Reliability	1, reliable without restrictions
Acceptability	Acceptable

Remarks	-

Document III-A / Section A7.4.1 and A7.4.2

Section A7.4.1.1c/01	Acute toxicity of N-(n-octyl) malonamic acid to fish-Fresh water, Rainbow trout – **TABLES AND FIGURES**

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Table A7.4.1.1.c/01-5: Test conditions

Criteria	Details
Test temperature	12 – 13 °C
Dissolved oxygen	6.4 – 10.4
pH	7.5 – 8.4
Adjustment of pH	Yes
Aeration of dilution water	No
Intensity of irradiation	667 lux
Photoperiod	16 h daylight, 8 h dark

Table A7.4.1.1.c/01-6: Mortality data

Test-Substance Concentration (mean measured)[1] [mg NNOMA/l]	Mortality							
	Number				Percentage			
	24 h	48 h	72 h	96 h	24 h	48 h	72 h	96 h
0 (control)	0	0	0	0	0	0	0	0
0 (NaOH control)	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0
88	0	0	0	0	0	0	0	0
160	0	0	0	0	0	0	0	0
280	6/10	7/10	7/10	7/10	60	70	70	70
430	10/10	10/10	10/10	10/10	100	100	100	100
Temperature [°C]	12 - 13	12 – 13	12 – 13	12 – 13				
pH	7.5 – 8.4	7.5 – 8.4	7.5 – 8.4	7.5 – 8.4				
Oxygen [mg/l]	6.4 – 10.4	6.4 – 10.4	6.4 – 10.4	6.4 – 10.4				

[1] specify, if TS concentrations were nominal or measured