Table A7.5.1.3/01-5: Test conditions

Criteria	Details
Test type	Greenhouse
Method of application	soil incorporation
Application levels	not applicable
Dose rates	not applicable
Substrate characteristics	sandy loam, 1.3% organic carbon (2.2% org. matter)
Watering of the plants	Plants were irrigated using 200 mg/L Peters 20-20-20. Approximately 100 ml was provided to all pots by sub-irrigation twice weekly. All subsequent watering was provided using town well water.
Temperature	18 to 40 °C
Thermoperiod	Not applicable
Light regime	800 to 4500 footcandles and 8600 to 48,000 lux; natural sunlight supplemented with sodium vapor light; 16 hr light and 8 hr dark
Relative humidity	37 to 79%
Wind volatility	Not applicable
Observation periods and duration of test	Observation periods: 7, 14 and 21 days after 50% emergence as determined in the controls, the number of emerged plants, individual shoot length and visual phototoxicity was recorded. Duration: 21 days after 50% emergence was observed in the controls, *i.e.* 25 days
Pest control	Seeds were not pretreated with insecticides or fungicides.
Any other treatments and procedures	not applicable

Table A7.5.1.3/01-6: Effective phytotoxicity after test termination

Test Substance Concentration (nominal)[1] [mg DCOIT/kg dwt]	Absolute Numbers, Canola				Percent relative to control, Canola			
	Plant height (cm)	Plant dry weight (g)	Percent emergence	Dead plants	Plant height inhibition	Plant dry weights	Percent emergence inhibition	Dead plants
control	22.2	0.4955	80	0/40	--	--	--	--
solvent control	22.8	0.3854	98	0/40	--	--	--	--
5.0	23.7	0.4413	98	0/40	-5	-14	0	--
10	18.6	0.4272	93	0/40	17 *	-11	5	--
20	4.8	0.1827	98	0/40	79 *	53 *	0	--
40	2.1	0.0563	95	1/40	91 *	85 *	3	2.5
80	0.44	0.0100	80	14/40	98 *	97 *	18	35
Temperature [°C]	18-40 °C over 26 days							
Relative humidity	37-79 % over 26 days							

[1] specify, if TS concentrations were nominal or measured
* statistically different compared to the solvent control

Test Substance Concentration (nominal)[1] [mg DCOIT/kg dwt]	Absolute Numbers, Red clover				Percent relative to control, Red clover			
	Plant height (cm)	Plant dry weight (g)	Percent emergence	Dead plants	Plant height inhibi-tion	Plant dry weights	Percent emergence inhibition	Dead plants
control	12.2	0.0848	78	0/40	--	--	--	--
solvent control	9.8	0.0563	85	1/40	--	--	--	--
2.5	8.9	0.0518	93	0/40	10	8	-14	--
5.0	9.5	0.0660	93	0/40	4	-17	-14	--
10	6.8	0.0396	98	0/40	39 *	30 *	-20	--
20	2.1	0.0079	95	0/40	78 *	86 *	-17	--
40	0.67	0.0048	83	0/40	93 *	92 *	-2	--
80	0.0	0.0000	43	17/40	100 +	100 *	48 *	42.5
Temperature [°C]	18-40 °C over 26 days							
Relative humidity	37-79 % over 26 days							

[1] specify, if TS concentrations were nominal or measured
* statistically different compared to the solvent control
+ excluded from analysis due to emergence effect

Test Substance Concentration (nominal)[1] [mg DCOIT/kg dwt]	Absolute Numbers, Rice				Percent relative to control, Rice			
	Plant height (cm)	Plant dry weight (g)	Percent emergence	Dead plants	Plant height inhibi-tion	Plant dry weights	Percent emergence inhibition	Dead plants
control	32.5	0.1309	98	0/40	--	--	--	--
solvent control	35.1	0.1620	85	0/40	--	--	--	--
5.0	31.3	0.1763	75	0/40	11 *	-9	12	--
10	31.0	0.1360	93	0/40	12 *	16	-9	--
20	18.8	0.0452	95	0/40	44 *	72 *	-12	--
40	9.7	0.0113	85	0/40	72 *	93 *	0	--
80	7.5	0.0071	85	1/40	79 *	96 *	0	2.5
Temperature [°C]	18-40 °C over 26 days							
Relative humidity	37-79 % over 26 days							

[1] specify, if TS concentrations were nominal or measured
* statistically different compared to the solvent control

Table A7.5.1.3/01-7: Morphological abnormalities, plant effect and mortalities

Test Substance Concentration (nominal)[1] [mg DCOIT/kg dwt]	Canola Morphological abnormalities[a]			Plant Effect(%)[b]		
	Necrosis	Chlorosis	Leaf curl	Flowers	Mean	Mortality[c]
control	0	0	0	23	0	0
solvent control	0	0	0	34	0	0
5.0	0	0	0	30	0	0
10	0	1	0	21	2	0
20	1	38	0	0	10	0
40	36	37	0	0	45	1
80	18	18	18	0	88	14

a Number of plants exhibiting the effect.
b An effect of 0 indicates a normal plant while an effect of 100 indicates a total plant effect.
c Number of plants that died throughout the test period.

Test Substance Concentration (nominal)[1] [mg DCOIT/kg dwt]	Red Clover Morphological abnormalities[a]				Plant Effect(%)[b]	
	Necrosis	Chlorosis	Leaf curl	Flowers	Mean	Mortality[c]
control	0	0	0	0	0	0
solvent control	0	0	0	0	3	1
2.5	0	0	0	0	0	0
5.0	0	5	0	0	1	0
10	1	39	0	0	10	0
20	38	38	0	0	40	0
40	0	33	0	0	90	0
80	all plants died				100	17

a Number of plants exhibiting the effect.
b An effect of 0 indicates a normal plant while an effect of 100 indicates a total plant effect.
c Number of plants that died throughout the test period.

Test Substance Concentration (nominal)[1] [mg DCOIT/kg dwt]	Rice Morphological abnormalities[a]				Plant Effect(%)[b]	
	Necrosis	Chlorosis	Leaf curl	Flowers	Mean	Mortality[c]
control	0	0	0	0	0	0
solvent control	0	0	0	0	0	0
5.0	0	20	0	0	7	0
10	0	37	0	0	10	0
20	11	38	1	0	26	0
40	31	33	2	0	45	0
80	33	30	1	0	49	1

a Number of plants exhibiting the effect.
b An effect of 0 indicates a normal plant while an effect of 100 indicates a total plant effect.
c Number of plants that died throughout the test period.

Table A7.5.1.3/01-8: Conclusions

	Percent Emergence (mg DCOIT/kg dwt soil)			Shoot Length (mg DCOIT/kg dwt soil)			Shoot Dry Weight (mg DCOIT/kg dwt soil)		
Species	**NOEC**	**EC_{25}**	**EC_{50}**	**NOEC**	**EC_{25}**	**EC_{50}**	**NOEC**	**EC_{25}**	**EC_{50}**
Canola	80	>80	>80	5.0	13	19	10	14	19
Lower CL	--	NA	NA	--	12	18	--	13	18
Upper CL	--	NA	NA	--	14	20	--	15	20
Red clover	40	54	74	5.0	8.4	14	5.0	8.7	13
Lower CL	--	39	65	--	4.4	12	--	6.7	12
Upper CL	--	63	80	--	11	15	--	10	14
Rice	80	>80	>80	6.1 [a]	14	23	10	11	16
Lower CL	--	NA	NA	3.2	13	20	--	9.0	14
Upper CL	--	NA	NA	11	15	25	--	13	17

CL = confidence limit
[a] An EC10 was calculated as a conservative estimate of the NOEC.

Table A7.5.1.3/01-9: Validity criteria for terrestrial plant toxicity according to OECD Draft Guideline 208

	fulfilled	**Not fullfilled**
The seedling emergence is at least 70%;	**yes**	
The seedlings do not exhibit visible phytotoxic effects (e.g. chlorosis, necrosis, wilting, leaf and stem deformations) and the plants exhibit only normal variation in growth and morphology for that particular species;	**yes**	
The mean survival of emerged control seedlings is at least 90% for the duration of the study;	**yes**	
Environmental conditions for a particular species are identical and growing media contain the same amount of soil matrix, support media, or substrate from the same source.	**yes**	

Section A7.5.1.3/02 Terrestrial plant toxicity – vegetative vigor

Annex Point IIIA XIII 3.4

Official use only

1 REFERENCE

1.1 Reference

Reference Type: test repoprt

Year: 2002

Report date: 25 November 2002

[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 Draft Guideline 208, Part B and US EPA OPPTS Draft Guidelines 850.4150 and 850.4250

2.2 GLP Yes

2.3 Deviations No

3 METHOD

3.1 Test material DCOIT (RH-287 technical)

3.1.1. Lot/Batch number [redacted]

3.1.2 Specification As given in section 2

3.1.3. Purity 99.3%

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]

3.2.1 TS Concentrations Nominal (mg DCOIT/ml): 0(control), 0 (solvent control), 74 (red clover) and 101 (canola and rice)

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Annex Point IIIA XIII 3.4

	Nominal applied by spray: Canola: 2.6, 5.1, 10, 21, 41 mg DCOIT/kg; Red clover: 0.12, 0.36, 1.1, 3.3, 9.9, 30 mg DCOIT/kg; Rice: 0.65, 1.3, 2.6, 5.1, 10, 21, 41 mg DCOIT/kg Analytically Measured (mg DCOIT/ml): 0, 0, 67 (red clover), 89 (canola) and 108 (rice) Percent of nominal: not applicable for controls, 90% (red clover), 88% (canola) and 107% (rice)
3.3 Reference substance	[redacted]
3.3.1Method of analysis for reference substance	[redacted]
3.4 Testing procedure	
3.4.1 Dilution water	[redacted]
3.4.2 Test plants	[redacted]
3.4.3 Test system	[redacted]
3.4.4 Test conditions	see table A7.5.1.3/02-5
3.4.5 Test duration	25 days
3.4.6 Test parameter	[redacted]
3.4.7 Sampling	[redacted]
3.4.8 Method of analysis of the plant material	[redacted]
3.4. 9 Quality control	[redacted]
3.4.10 Statistics	[redacted]

4 RESULTS

4.1 Results test substance	
4.1.1 Applied initial	the TS application volume was 468 L/ha equivalent to the application of

Section A7.5.1.3/02 Terrestrial plant toxicity – vegetative vigor
Annex Point IIIA XIII 3.4

concentration	17.39 mL/spray tray.	
4.1.2 Phytotoxicity rating	Not applicable	
4.1.3 Plant height	see table A7.5.1.3/02-6	
4.1.4 Plant dry weights	see table A7.5.1.3/02-6	
4.1.5 Root dry weights	Not applicable	
4.1.6 Root length	Not applicable	
4.1.7 Number of dead plants	see table A7.5.1.3/02-7	
4.1.8 Effect data	see table A7.5.1.3/02-7	
4.1.9 Concentration / response curve	Graph of the concentration-response curve at test termination not described in report	
4.1.10 Other effects	Canola: necrosis, chlorosis, decreased numbers of seed pods, decreased number of flowers and dead plants were noted.	
	Red clover: necrosis and dead plants were noted.	
	Rice: necrosis and chlorosis were noted.	
	see table A7.5.1.3/02-7	
4.2 Results of controls		
4.2.1 Number/ percentage of plants showing adverse effects	Canola: no effects	x
	Red clover: no effects	
	Rice: no effects	
4.2.2 Nature of adverse effects	Not applicable	
4.3 Test with reference substance	Not performed	
4.3.1 Concentrations	Not applicable	
4.3.2 Results	Not applicable	
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1 Materials and methods	OECD Draft Guideline 208, Part B and OPPTS Draft Guidelines 850.4150 and 850.4250, vegetative vigor in terrestrial plants with analytical confirmation of dosing solutions.	
5.2 Results and discussion		
5.2.1 NOEC	see table A7.5.1.3/02-8	x
5.2.2 EC_{25}	see table A7.5.1.3/02-8	
5.2.3 EC_{50}	see table A7.5.1.3/02-8	
5.3 Conclusion	see table A7.5.1.3/02-8	
5.3.1 Reliability	(1), reliable without restriction	x
5.3.2 Deficiencies	No	x

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	30 August 2006
Materials and Methods	Agree with applicant's version
Results and discussion	**Comment (4.2.1):** The result is presented as "no effects" for Canola. However, in table A7.5.1.3/02-7 it says that 39 of 40 plants in control and solvent control showed leaf curls. This is normally a sign of some kind of stress in plants.
Conclusion	**Comment (5.2.1):** An EC10 was calculated as a concervative estimate for NOEC for shoot length and shoot weight in rice. However, it should be noted that the 95 % confidence interval for this NOEC is relatively wide.
Reliability	Due to the restrictions described, reliability is changed from 1 to 2, valid with restrictions.
Acceptability	Acceptable with the restrictions noted above
Remarks	-

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Section A7.5.1.3/02	Terrestrial plant toxicity – vegetative vigor – **TABLES AND FIGURES**

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

Table A7.5.1.3/02-5: Test conditions

Criteria	Details
Test type	Greenhouse
Method of application	Foliar spray
Application levels	468 L/ha, equivalent to 17.39 mL/spray tray
Dose rates	not applicable
Substrate characteristics	sandy loam, 1.3% organic carbon (2.2% organic matter)
Watering of the plants	Plants were irrigated using 200 mg/L Peters 20-20-20. Approximately 100 ml was provided to all pots by sub-irrigation twice weekly. All subsequent watering was provided using town well water.
Temperature	18 to 40 °C
Thermoperiod	Not applicable
Light regime	410 to 4300 footcandles and 4400 to 46,000 lux; natural sunlight supplemented with sodium vapor light; 16 hr light and 8 hr dark
Relative humidity	35 to 83%
Wind volatility	Not applicable
Observation periods and duration of test	Observation periods: 7, 14 and 21 days, shoot length

	Duration: 21 days after treatment, *i.e.* 25 days
Pest control	Seeds were not pretreated with insecticides or fungicides.
Any other treatments and procedures	not applicable

Table A7.5.1.3/02-6: Effective phytotoxicity after test termination

Test Substance Concentration (nominal)[1] [mg DCOIT/kg]	Absolute Numbers, Canola		Percent relative to control, Canola	
	Shoot length (cm)	Shoot dry weight (g)	Shoot length inhibition	Shoot dry weight inhibition
control	72.5	1.4362	--	--
solvent control	74.2	1.5268	--	--
2.6	75.0	1.2964	-2	12
5.1	63.5	0.8422	13 *	43 *
10	56.6	0.6823	23 *	54 *
21	41.7	0.5466	43 *	63 *
41	40.7	0.4562	45 *	69 *
Temperature [°C]	18-40 °C over 22 days			
Relative humidity	35-82 % over 22 days			

[1] specify, if TS concentrations were nominal or measured
* statistically different compared to the pooled control

Test Substance Concentration (nominal)[1] [mg DCOIT/kg]	Absolute Numbers, Red clover		Percent relative to control, Red clover	
	Shoot length (cm)	Shoot dry weight (g)	Shoot length inhibition	Shoot dry weight inhibition
control	17.1	0.1133	--	--
solvent control	17.4	0.1273	--	--
0.12	15.6	0.1078	10	10
0.36	17.3	0.0911	0	24 *
1.1	14.8	0.0934	14 *	22 *
3.3	11.0	0.0558	36 *	54 *
9.9	8.1	0.0330	53 *	73 *
30	0.30	0.0031	98 *	97 *
Temperature [°C]	18-40 °C over 22 days			
Relative humidity	37-83 % over 22 days			

[1] specify, if TS concentrations were nominal or measured
* statistically different compared to the pooled control

Test Substance Concentration (nominal)[1] [mg DCOIT/kg]	Absolute Numbers, Rice		Percent relative to control, Rice	
	Shoot length (cm)	Shoot dry weight (g)	Shoot length inhibition	Shoot dry weight inhibition
control	40.9	0.2278	--	--
solvent control	39.4	0.2443	--	--
0.65	36.8	0.1894	8 *	20 *
1.3	36.2	0.1845	10 *	22 *
2.6	37.1	0.2144	7 *	9 *
5.1	33.2	0.1481	17 *	37 *
10	32.8	0.1836	18 *	22 *
21	32.4	0.1407	19 *	40 *
41	30.9	0.1320	23 *	44 *
Temperature [°C]	18-40 °C over 22 days			
Relative humidity	35-82 % over 22 days			

[1] specify, if TS concentrations were nominal or measured
* statistically different compared to the pooled control

Table A7.5.1.3/02-7: Morphological abnormalities, plant condition and mortalities

Test Substance Concentration (nominal)[1] [mg DCOIT/kg]	Canola Morphological abnormalities[a]				Plant Effect(%)[b]	
	Necrosis	Chlorosis	Leaf Curl	Flowers	Mean	Mortality[c]
control	0	0	39	40	0	0
solvent control	0	0	39	40	0	0
2.6	0	0	40	40	0	0
5.1	0	0	35	39	0	0
10	0	40	40	40	14	0
21	0	38	30	36	18	2
41	2	40	29	36	21	0

[a] Number of plants exhibiting the effect.
[b] An effect of 0 indicates a normal plant while an effect of 100 indicates a total plant effect.
[c] Number of plants that died throughout the test period.

Test Substance Concentration (nominal)[1] [mg DCOIT/kg]	Red clover Morphological abnormalities[a]				Plant Effect(%)[b]	
	Necrosis	Chlorosis	Leaf Curl	Flowers	Mean	Mortality[c]
control	0	0	0	6	0	0
solvent control	0	0	0	4	0	0
0.12	0	0	0	2	0	0
0.36	0	0	0	7	0	0
1.1	40	0	0	0	12	0
3.3	40	0	0	0	29	0
9.9	38	0	0	0	44	2
30	5	0	0	0	96	35

[a] Number of plants exhibiting the effect.
[b] An effect of 0 indicates a normal plant while an effect of 100 indicates a total plant effect.
[c] Number of plants that died throughout the test period.

Test Substance Concentration (nominal)[1] [mg DCOIT/kg]	Rice Morphological abnormalities[a]				Plant Effect(%)[b]	
	Necrosis	Chlorosis	Leaf Curl	Flowers	Mean	Mortality[c]
control	0	0	0	0	0	0
solvent control	0	0	0	0	0	0
0.65	0	0	0	0	0	0
1.3	0	40	0	0	10	0
2.6	0	40	0	0	10	0
5.1	40	40	0	0	10	0
10	40	40	0	0	20	0
21	40	40	0	0	30	0
41	40	40	0	0	40	0

[a] Number of plants exhibiting the effect.
[b] An effect of 0 indicates a normal plant while an effect of 100 indicates a total plant effect.
[c] Number of plants that died throughout the test period.

Table A7.5.1.3/02-8: Conclusions

	Shoot Length (mg DCOIT/kg)			Shoot Dry Weight (mg DCOIT/kg)		
Species	**NOEC**	**EC_{25}**	**EC_{50}**	**NOEC**	**EC_{25}**	**EC_{50}**
Canola	2.6	11	>41	2.6	3.7	8.6
Lower CL	--	7.9	--	--	2.8	4.9
Upper CL	--	14	--	--	4.4	14
Red clover	0.36	2.2	8.8	0.12	0.94	3.1
Lower CL	--	1.2	6.4	--	0.27	2.5
Upper CL	--	2.8	11	--	1.8	4.6
Rice	2.9 [a]	>41	>41	0.64 [a]	4.7	>41
Lower CL	0.91	--	--	0.25	2.6	--
Upper CL	3.9	--	--	2.8	12	--

CL = confidence limit
[a] An EC_{10} was calculated as a conservative estimate of the NOEC.

Table A7.5.1.3/02-9: Validity criteria for terrestrial plant toxicity according to EPA OPPTS 850.4150 (vegetative vigor test)

	Fulfilled	Not fulfilled
Adverse effect > 25 % on one or more plant species (EPA)	**yes**	

Section A7.5.2.1 Earthworm, chronic toxicity test
Annex Point IIIA XIII.3.2

Official use only

1 REFERENCE

1.1 Reference

Reference Type: test repoprt

Year: 2005

Report date: 10 May 2005

[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 Method 222

2.2 GLP Yes

2.3 Deviations No

3 METHOD

3.1 Test material DCOIT supplied as RH-287 Technical

3.1.1 Lot/Batch number [redacted]

3.1.2 Specification As given in section 2

3.1.3 Purity 98.5 %

3.1.4 Composition of Product [redacted]

3.1.5 Further relevant properties [redacted]

3.1.6 Method of analysis [redacted]

3.2 Reference substance [redacted]

3.3 Testing procedure

3.3.1 Preparation of the test substance [redacted]

3.3.2 Application of the test substance [redacted]

Section A7.5.2.1 Earthworm, chronic toxicity test
Annex Point IIIA XIII.3.2

[redacted]

3.3.3 Test organisms	[redacted]
3.3.4 Test system	[redacted]
3.3.5 Test conditions	see table A7.5.2.1/01-4
3.3.6 Test duration	56 days
3.3.7 Test parameter	[redacted]
3.3.8 Examination	[redacted]
3.3.9 Monitoring of test substance concentration	[redacted]
3.3.10 Statistics	[redacted]

4 RESULTS

4.1	**Filter paper test**	Not performed
4.2	**Soil test**	
4.2.1	Initial concentrations of test substance	0 (control), 0 (vehicle control), 5.0, 10, 20, 40, 80 and 160 mg DCOIT/kg dry soil, nominal. The low and high dosing solution mean measured concentrations of TS were 3030 and 92,500 mg /L, representing 111 and 105% recovery, respectively.
4.2.2	Effect data (Mortality)	see table A7.5.2.1/01-5
4.2.3	Concentration / effect curve	None
4.2.4	Other effects	Not applicable
4.3	**Results of controls**	
4.3.1	Mortality	1% in deionized water control; 0% in acetone control
4.3.2	Number/ percentage of earthworms showing adverse	see table A7.5.2.1/01-6

	effects	
4.3.3	Nature of adverse effects	None
4.4	**Test with reference substance**	Performed
4.4.1	Concentrations	0.13, 0.26, 0.51, 1, 2, and 4 mg carbendazim/kg dry soil
4.4.2	Results	NOEC <1.3 mg carbendazim/kg dry soil LOEC = 1.3 mg carbendazim/kg dry soil
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	OECD Method 222, Earthworm reproduction test
5.2	**Results and discussion**	DCOIT did not affect mortality and growth (percent weight change) at 28 days but did produce statistically significant reproduction effects at 10, 20, 40, 80 and 160 mg DCOIT/kg treatments at 56 days.
5.2.1	NOEC	160 mg DCOIT/kg dry soil (28-day survival and 28-day growth) 5.0 mg DCOIT/kg dry soil (56-day reproduction)
5.2.2	LC_{10}	>160 mg DCOIT/kg dry soil (28-day survival and 28-day growth) <5.0 mg DCOIT/kg dry soil (56-day reproduction)
5.2.3	LC_{50}	>160 mg DCOIT./kg dry soil (28-day survival and 28-day growth) 25.9 mg DCOIT/kg dry soil (56-day reproduction)
5.2.4	LC_{100}	no concentration caused 100% mortality
5.3	**Conclusion**	see table A7.5.2.1/01-7 and see table A7.5.2.1/01-8
5.3.1	Other Conclusions	
5.3.2	Reliability	(1), reliable without restriction
5.3.3	Deficiencies	No

Document III-A / Section A7.5

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	12 September 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, valid without restrictions
Acceptability	Acceptable
Remarks	-

Section A7.5.2.1	Earthworm, chronic toxicity test – **TABLES AND FIGURES**

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Table A7.5.2.1/01-4: Test conditions

Criteria	Details
Test temperature	19.6 to 20.5 °C
Moisture content	Day 0 = 21.4 to 24.1 % Day 28: 28.0 to 34.7 % Day 56: 30.0 to 35.6 %
pH	Day 0 = 6.3 to 6.5; Day 28 = 6.6 to 7.0; Day 56: 5.6 to 6.6
Adjustment of pH	Not applicable
Light intensity / photoperiod	456.3 to 670.6 lux, 16 h light and 8 h dark
Relevant degradation products	Not applicable

Table A7.5.2.1/01-5: Mortality data

Test Substance Concentration (nominal)[1] [mg DCOIT/kg artificial soil]	Mortality	
	Number Dead or Missing Day 28	Percentage Day 28
0 (control)	1	1
0 (acetone control)	0	0
5.0	0	0
10	0	0
20	0	0
40	0	0
80	0	0
160	0	0
Temperature [°C]	19.6 to 20.5 °C	
pH	6.6 to 7.0	
Moisture content	28.0 to 34.7%	

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

Table A7.5.2.1/01-6: Number affected data

Test Substance Concentration (nominal)[1] [mg DCOIT/kg artificial soil]	Number Affected		
	Worm weights (grams/replicate) Day 28		Mean Replicate Reproduction Day 56
	Mean change	% change	Number of juvenil worms
0 (control)	3.383	63	221
0 (acetone control)	3.318	59	234
5	3.382	60	218
10	3.204	61	177 *
20	3.468	67	114 *
40	3.178	59	89 *
80	2.882	54	63 *
160	2.643	50	7 *
	Day 28	**Day 56**	
Temperature [°C]	19.6 to 20.5 °C		
pH	6.6 to 7.0	5.6 to 6.6	
Moisture content	28.0 to 34.7%	30.0 to 35.6%	

[1] specify, if TS concentrations were nominal or measured
* Statistically significant ($p \leq 0.05$) reduction in the number of juvenile worms produced as compared to control.

Table A7.5.2.1/01-7: Effect data

NOEC (survival)	160 mg DCOIT/kg dry soil (n)
28-day EC_{10} (survival)	>160 mg DCOIT/kg dry soil (n)
28-day EC_{50} (survival)	>160 mg DCOIT/kg dry soil (n)
NOEC (reproduction)	5.0 mg DCOIT/kg dry soil (n)
56-day EC_{10} (reproduction)	<5.0 mg DCOIT/kg dry soil (n)
56-day EC_{50} (reproduction)	25.9 mg DCOIT/kg dry soil (n) 95% C.L.: 16 to 36 mg DCOIT/kg dry soil
NOEC (growth)	160 mg DCOIT/kg dry soil (n)
28-day EC_{10} (growth)	>160 mg DCOIT/kg dry soil (n)
28-day EC_{50} (growth)	>160 mg DCOIT/kg dry soil (n)

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

Table A7.5.2.1/01-8: Validity criteria for acute earthworm test according to OECD 222

	fulfilled	Not fulfilled
Mortality of control animals < 10%	**yes**	

Section A7.5.2.2	Long term toxicity to terrestrial plants	
	Justification for non-submission of data	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [X]	**Other justification [ ]**	
Detailed justification:	Due to the rapid biodegradation of DCOIT in soil and to its low mobility, for the product type 8, long term exposure of terrestrial plants to significant concentrations of DCOIT is unlikely.	
Undertaking of intended data submission [ ]	No	
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	19 September 2006	
Evaluation of applicant's justification	Applicant's justification is acceptable.	
Conclusion	Applicant's justification is acceptable	
Remarks	-	

Section A7.5.3.1.1/01 Acute oral toxicity on birds - Mallard duck
Annex Point IIIA XIII.1.1

		Official use only
	1. REFERENCE	
1.1 Reference	Reference Type: test repoprt Year: 1976 Report date: 23 September 1976 [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	No, no guidelines available at the time the study was conducted	
2.2 GLP	No, GLP was not compulsory at the time the study was performed	
2.3 Deviations	Yes, TS not analysed in dosing solutions and housing conditions were not described.	
	3 METHOD	
3.1 Test material	DCOIT (RH-287)	
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Specification	Test substance was a dilution of DCOIT in xylene.	x
3.1.3 Purity	77.2% DCOIT in xylene	x
3.1.4 Composition of Product	[redacted]	
3.1.5 Further relevant properties	[redacted]	
3.1.6 Method of analysis	[redacted]	
3.2 Reference substance	[redacted]	
3.3 Testing procedure	[redacted]	
3.3.1 Preparation of the test substance	[redacted]	
3.3.2 Application of the	[redacted]	

Section A7.5.3.1.1/01 Acute oral toxicity on birds - Mallard duck
Annex Point IIIA XIII.1.1

test substance	[redacted]
3.3.3 Test organisms	[redacted]
3.3.4 Test system	[redacted]
3.3.5 Test conditions	Birds were maintained in a brooder with the temperature maintained at 37°C upon hatching through the completion of the study. See table A7.5.3.1.1/01-4.
3.3.6 Test duration	8 days
3.3.7 Test parameter	[redacted]
3.3.8 Examination	[redacted]
3.3.9 Monitoring of test substance concentration	[redacted]
3.3.10 Statistics	[redacted]

4 RESULTS

4.1	**Filter paper test**	Not performed
4.2	**Soil test**	
4.2.1	Initial concentrations of test substance	215, 464, 1000, 2150, 4640 (mg technical/kg bw)
4.2.2	Effect data (Mortality)	see table A7.5.3.1.1/01-5
4.2.3	Concentration / effect curve	

TS mg technical/kg	Body weight Day 0 (g)	Body weight Day 8 (g)
215	216	390
464	208	412
1000	198	390
2150	189	352
4640	175	275

Section A7.5.3.1.1/01 Acute oral toxicity on birds - Mallard duck
Annex Point IIIA XIII.1.1

4.2.4 Other effects

TS mg technical/kg	Total estimated feed consumption (g)
215	4075
464	4375
1000	3525
2150	3550
4640	3400

4.3 Results of controls Day 0 and Day 8 body weight (g) and total estimated food consumption (g) for the control:

Dosage (mg/kg)	Day 0	Day 8	Total Estimated Food Consumption (g)
0	192	387	3875
0	204	420	3900
0	230	415	3775
0	217	395	3800
0	216	425	3850

4.3.1 Mortality: No

4.3.2 Number/ percentage of earthworms showing adverse effects: None. All birds appeared normal and healthy.

4.3.3 Nature of adverse effects: Not relevant.

4.4 Test with reference substance

4.4.1 Concentrations: Dieldrin: 14.7, 21.5, 31.6, 46.6, and 68.2 mg/kg.

4.4.2 Results: Day 0 and Day 8 body weight (g) and total estimated food consumption (g) following dosage with dieldrin:

Section A7.5.3.1.1/01 **Acute oral toxicity on birds - Mallard duck**
Annex Point IIIA XIII.1.1

Dosage (mg/kg)	Day 0	Day 8	Total Estimated Food Consumption (g)
Dieldrin			
14.7	198	412	3825
21.5	200	380	3450
31.6	235	365	2100
46.6	212	315	2200
68.2	217	*	0

* Data not available due to mortality

LD_{50} = 35.8 mg/kg (C.I. = 28.0 - 45.7).

4.5	**Materials and methods**	**5 APPLICANT'S SUMMARY AND CONCLUSION**
5.1	**Results and discussion**	Not a guideline study. Dosing solutions were administered by intubation directly into the crop of each bird via stainless steel catheter. The dosing solutions were administered based on kg body weight. The negative control birds received corn oil.
5.1.1	NOAEL	2150 mg technical/kg bw (1660 mg DCOIT/kg bw)
5.1.2	LD_{10}	ND
5.1.3	LD_{50}	> 4640 mg technical/kg bw (>3580 mg DCOIT/kg bw)
5.1.4	LD_{100}	
5.2	**Conclusion**	(2), reliable with restrictions
5.2.1	Other Conclusions	Yes, TS not analysed in dosing solutions and housing conditions were not described.

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	16 September 2006
Materials and Methods	**Comment (3.1.2):** The only solvent mentioned in the study report was corn oil before dosing of the animals. It is not mentioned thet the test compound was dissolved in xylene anywhere in the report. **Comment (3.1.3):** Purity of the test compound is not given in the study report.
Results and discussion	Agree with applicant's version
Conclusion	Agree with applicant's version
Reliability	2, valid with restrictions
Acceptability	Acceptable with the restrictions mentioned above
Remarks	-

Section A7.5.3.1.1/01	Acute oral toxicity on birds - Mallard duck – **TABLES AND FIGURES**

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Table A7.5.3.1.1/01-4: Test conditions (housing)

Criteria	Details
Test temperature	37°C
Shielding of the animals	Not described
Ventilation	Not described
Relative humidity	Not described
Photoperiod and lighting	Not described

Table A7.5.3.1.1/01-5: Mortality data after test termination

Test substance dosage level [mg technical/kg bw]	Mortality after test termination (8 days)									
	Total number per dose level					Percentage per dose level				
	Pen 1	Pen 2	Pen 3	Pen 4	Pen 5	Pen 1	Pen 2	Pen 3	Pen 4	Pen 5
0 (control)	0/10	--	--	--	--	--	--	--	--	--
215	0/10	--	--	--	--	0	--	--	--	--
464	0/10	--	--	--	--	0	--	--	--	--
1000	0/10	--	--	--	--	0	--	--	--	--
2150	0/10	--	--	--	--	0	--	--	--	--
4640	3/10	--	--	--	--	30	--	--	--	--

Table A7.5.3.1.1/01-6: Validity criteria for avian acute oral toxicity test according to EPA OPPTS 850.2100

	Fulfilled	Not fulfilled
Mortality of control animals <10%	Yes	

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Section A7.5.3.1.2/01 Short-term toxicity on birds- Bobwhite Quail
Annex Point IIIA XIII.1.2

			Official use only
		1 REFERENCE	
1.1	**Reference**	Reference Type: test repoprt Year: 1992 Report date: 7 January 1992 [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 71-2	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 METHOD	
3.1	**Test material**	DCOIT (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	**Administration of the test substance**	[redacted]	
3.3	**Reference substance**	[redacted]	
3.4	**Testing procedure**		
3.4.1	Test organisms	[redacted]	x

Section A7.5.3.1.2/01 Short-term toxicity on birds- Bobwhite Quail
Annex Point IIIA XIII.1.2

3.4.2	Test system	[redacted]
3.4.3	Diet	[redacted]
3.4.4	Test conditions	see table A7.5.3.1.2/01-4
3.4.5	Duration of the test	8 days (5 days dosing and 3 days observation)
3.4.6	Test parameter	[redacted]
3.4.7	Examination / Observation	[redacted]
3.4.8	Statistics	[redacted]

4 RESULTS

4.1	**Limit Test / Range finding test**	Not performed
4.2	**Results test substance**	
4.2.1	Applied concentrations	312, 625, 1250, 2500, 5000 ppm DCOIT
4.2.2	Effect data (Mortality)	see table A7.5.3.1.2/01-5
4.2.3	Body weight	Body weight change (g)

nominal concentration (mg/kg food)	0 h-day 5	days 6-8
control - I	+13	+8
control - II	+13	+8
control - III	+11	+8
control - IV	+15	+8
control -V	+16	+8
312	+13	+8
625	+14	+8
1250	+11	+8
2500	+7	+8
5000	-3	+8

4.2.4	Food consumption	food consumption/bird/day (g)	

Nominal concentration (mg/kg food)	0 h-day 5	days 6-8
control - I	5	8
control - II	5	7
control - III	5	6
control - IV	5	6
control - V	6	9
312	5	7
625	5	8
1250	5	7
2500	4	7
5000	2	6

4.2.5	Concentration / response curve	Not described	
4.2.6	Other effects	Reduced bw, reduced feed consumption, lethargy, anorexia were evident in the 5000 ppm DCOIT group. There were no abnormal gross necropsy findings. Complete remission of clinical signs was achieved in survivors by the first day of observation (day 6).	x
4.3	**Results of controls**		
4.3.1	Number/ percentage of animals showing adverse effects	No mortality, no symptoms of toxicity in the 5 groups of 10 control birds	
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 FIFRA 71-2, Acute dietary toxicity test to birds with analytical confirmation of TS concentration in feed.
5.2	**Results and discussion**	The TS in the feed stored in the freezer for up to 5 days is stable; however, the TS partially degrades at elevated temperatures in the animal room for one day. The analyses displayed that the lower the initial test concentration, the greater the degradation.
5.2.1	NOEC	1250 mg DCOIT/kg food
5.2.2	LC_0	2500 mg DCOIT/kg food

5.2.3	LC_{50}	>4640 mg DCOIT/kg food
5.2.4	LC_{100}	Not applicable
5.3	**Conclusion**	see table A7.5.3.1.2/01-6
5.3.1	Reliability	(1), reliable without restriction
5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	16 September 2006
Materials and Methods	**Comment (3.4.1):** The initial body weights reported in this form disagree with the study report. According to table 2 in the study report the average weight of the birds was 23-25 g at study start.
Results and discussion	**Comment (4.2.6):** A weak body weight reduction and reduced feed consumption was registered in group IV (2500 ppm) in addition to the stronger effects seen in group V (5000 ppm).
Conclusion	Agree with applicant's version
Reliability	1, valid without restrictions
Acceptability	Acceptable
Remarks	-

Section A7.5.3.1.2/01 Short-term toxicity on birds- Bobwhite Quail – **TABLES AND FIGURES**

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Table A7.5.3.1.2/01-4: Test conditions (housing)

Criteria	Details
Test temperature	102 degrees F (39°C)
Shielding of the animals	Not described
Ventilation	Adequate
Relative humidity	60%
Photoperiod and lighting	full spectrum fluorescent, continuous (24 h/day)

Table A7.5.3.1.2/01-5: Mortality data after test termination

Test substance dosage level [mg/kg food] (nominal)	Mortality after test termination (days 6-8)									
	Total number per dose level					Percentage per dose level				
	Pen 1	Pen 2	Pen 3	Pen 4	Pen 5	Pen 1	Pen 2	Pen 3	Pen 4	Pen 5
0 (control)	0/10	0/10	0/10	0/10	0/10	--	--	--	--	--
312	0/10	--	--	--	--	0	--	--	--	--
625	0/10	--	--	--	--	0	--	--	--	--
1250	0/10	--	--	--	--	0	--	--	--	--
2500	0/10	--	--	--	--	0	--	--	--	--
5000	0/7 *	--	--	--	--	0	--	--	--	--
Temperature [°C]	39	--	--	--	--					
Relative humidity	60 %	--	--	--	--					

* three birds died in the 5000 ppm ai dose group – one each on days 3, 4 and 5.

Table A7.5.3.1.2/01-6: Validity criteria for short-term toxicity test according to OECD 205

	Fulfilled	Not fulfilled
Mortality of control animals <10%	**yes**	
Test substance concentration > 80 % of nominal concentration throughout the dosing period	**yes**	
Lowest treatment level causing no compound-related mortality or other observable toxic effects	**yes**	

Section A7.5.3.1.2/02 Short-term toxicity on birds – Mallard duck
Annex Point IIIA XIII.1.2

Official use only

	1 REFERENCE
1.1 Reference	Reference Type: test repoprt Year: 1992 Report date: 7 January 1992 [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 71-2
2.2 GLP	Yes
2.3 Deviations	No
	3 METHOD
3.1 Test material	DCOIT (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 Administration of the test substance	[redacted]
3.3 Reference substance	[redacted]
3.4 Testing procedure	
3.4.1 Test organisms	[redacted]

Section A7.5.3.1.2/02 Short-term toxicity on birds – Mallard duck
Annex Point IIIA XIII.1.2

3.4.2 Test system [redacted]

3.4.3 Diet [redacted]

3.4.4 Test conditions see table A7.5.3.1.2/02-4

3.4.5 Duration of the test 9 days (5 days dosing and 4 days observation)

3.4.6 Test parameter [redacted]

3.4.7 Examination / Observation [redacted]

3.4.8 Statistics [redacted]

4 RESULTS

4.1 Limit Test / Range finding test Not performed

4.2 Results test substance

4.2.1 Applied concentrations 312, 625, 1250, 2500, 5000 mg DCOIT/kg food

4.2.2 Effect data (Mortality) see table A7.5.3.1.2/02-5

4.2.3 Body weight Body weight change (g)

nominal concentration (mg/kg food)	0 h-day 5	days 6-9
control - I	+114	+119
control - II	+115	+161
control - III	+101	+157
control - IV	+102	+112
control -V	+91	+119
312	+104	+109
625	+99	+121
1250	+93	+124
2500	+43	+134
5000	-23	+133

4.2.4 Food consumption

Food consumption/bird/day (g)

nominal concentration (mg/kg food)	0 h-day 5	days 6-9
control - I	61	73
control - II	58	72
control - III	57	71
control - IV	59	78
control - V	63	84
312	55	61
625	64	65
1250	52	79
2500	35	75
5000	18	61

4.2.5 Concentration / response curve: Not described

4.2.6 Other effects: Clinical signs of toxicity noted during the test period were asthenia and smallness of size in one bird in each of the 1250 and 2500 ppm DCOIT groups, reduced body weight and feed consumption in the 2500 and 5000 ppm DCOIT groups and lethargy in the 5000 ppm ai group. Complete remission of clinical signs was achieved in survivors by test day 6. Gross pathology was revealed no abnormal findings.

4.3 Results of controls

4.3.1 Number/ percentage of animals showing adverse effects: No mortality, no symptoms of toxicity in the 5 groups of 10 control birds

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 FIFRA 71-2, Acute dietary toxicity test to birds with analytical confirmation of TS concentration in feed.
5.2 Results and discussion	The TS in the feed stored in the freezer for up to 5 days is stable; however, the TS partially degrades at elevated temperatures in the animal room for one day. The analyses displayed that the lower the initial test concentration, the greater the degradation.
5.2.1 NOEL	625 ppm (mg/kg food) DCOIT
5.2.2 LC_0	625 ppm (mg/kg food) DCOIT
5.2.3 LC_{50}	> 4640 mg DCOIT/kg food
5.2.4 LC_{100}	Not applicable
5.3 Conclusion	see table A7.5.3.1.2/02-6
5.3.1 Reliability	(1), reliable without restriction
5.3.2 Deficiencies	No

Evaluation by Competent Authorities	
Evaluation by Rapporteur Member State	
Date	18 September 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, valid without restrictions
Acceptability	Acceptable
Remarks	-

Document III-A / Section A7.5

Section A7.5.3.1.2/02 Short-term toxicity on birds – Mallard duck – **TABLES AND FIGURES**

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Table A7.5.3.1.2/02-4: Test conditions (housing)

Criteria	Details
Test temperature	average 82 °F (28 °C)
Shielding of the animals	Not described
Ventilation	adequate
Relative humidity	average 83%
Photoperiod and lighting	full spectrum fluorescent, continuous (24 h/day)

Table A7.5.3.1.2/02-5: Mortality data after test termination

Test substance dosage level [mg/kg food] (nominal)	Mortality after test termination (days 6-9)									
	Total number per dose level					Percentage per dose level				
	Pen 1	Pen 2	Pen 3	Pen 4	Pen 5	Pen 1	Pen 2	Pen 3	Pen 4	Pen 5
0 (control)	0/10	0/10	0/10	0/10	0/10	--	--	--	--	--
312	0/10	--	--	--	--	0	--	--	--	--
625	0/10	--	--	--	--	0	--	--	--	--
1250	0/9 *	--	--	--	--	0	--	--	--	--
2500	0/9 *	--	--	--	--	0	--	--	--	--
5000	1/10 *	--	--	--	--	10	--	--	--	--
Temperature [°C]	28	--	--	--	--					
Relative humidity	83 %	--	--	--	--					

* three birds died in this study - one each in the 1250, 2500 and 5000 ppm DCOIT groups.

Table A7.5.3.1.2/02-6: Validity criteria for short-term toxicity test according to OECD 205

	Fulfilled	Not fulfilled
Mortality of control animals <10%	**yes**	
Test substance concentration > 80 % of nominal concentration throughout the dosing period	**yes**	
Lowest treatment level causing no compound-related mortality or other observable toxic effects	**yes**	

Section A7.5.3.1.3	Bird reproduction	
	Justification for non-submission of data	Official use only
Other existing data [ ] **Limited exposure** [X]	**Technically not feasible** [ ] **Scientifically unjustified** [X] **Other justification** [ ]	
Detailed justification:	The acute and short term toxicity tests in birds indicate a low toxicity of DCOIT. Besides, due to the rapid biodegradation of DCOIT in the environment and to its low potential for bioaccumulation, the exposure of birds to DCOIT in the wood preservatives application is expected to be very limited As a consequence, the bird reproduction test is not considered to be necessary.	
Undertaking of intended data submission [ ]	No	
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	19 September 2006	
Evaluation of applicant's justification	Applicant's justification is acceptable	
Conclusion	Applicant's justification is acceptable	
Remarks	-	

Section A7.5.4	Effects on honeybees	
	Justification for non-submission of data	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Due to the use pattern of DCOIT in the wood preservation application, honeybees are not expected to be exposed to significant concentration of DCOIT in the environment. As a consequence, toxicity tests on honey bees anot considered to be necessary.	
Undertaking of intended data submission [ ]	No	
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	19 September 2006	
Evaluation of applicant's justification	Applicant's justification is acceptable	
Conclusion	Applicant's justification is acceptable	
Remarks	-	

Section A7.5.5.1	Bioconcentration in earthworms	
	Justification for non-submission of data	Official use only
Other existing data [x] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	The potential of DCOIT bioconcentration in earthworms is very low. Indeed, the log P_{ow} is 2.8, indicates a low potential for bioaccumulation. Besides, DCOIT was shown to be rapidly biodegradaded in soil with half-life less than 2 days (section A7.2.1). Bioconcentration was studied in aquatic organisms (see section A7.4.3.3) and the results indicated a low bioaccumulation potential for DCOIT. As a consequence, the bioconcentration study in earthworms was not performed.	x
Undertaking of intended data submission [ ]	No.	
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	19 September 2006	
Evaluation of applicant's justification	The DT50 from study A7.2.1 is 4.7 days at 12°C. However, biodegradation of DCOIT in soil is still rapid and based on a log Kow of 2.8 DCOIT is expected to have a low potential of bioconcentration in soil organisms and therefore the applicant's justification is acceptable.	
Conclusion	Applicant's justification is acceptable	
Remarks	-	

Section A7.5.6 Annex Point IIIA XIII.2.1	Effects on other terrestrial non-target organisms	
	Justification for non-submission of data	Official use only
Other existing data [ ] **Limited exposure** [X]	**Technically not feasible** [ ] **Scientifically unjustified** [X] **Other justification** [ ]	
Detailed justification:	Further tests on terrestrial organisms are not considered to be necessary.	
Undertaking of intended data submission [ ]	No	
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	19 September 2006	
Evaluation of applicant's justification	Applicant's justification is acceptable	
Conclusion	Applicant's justification is acceptable	
Remarks	-	

Section A7.5.7 Effects on mammals

Tests with mammals are summarised in the Toxicological section (Section A6). The summaries are not repated in the current section, please refer to section A6.

Section A7	End point	Authors	Section A6 cross-reference
A7.5.7.1.1	**Acute Oral LD_{50} Toxicity Rat**	[redacted]	A6.1.1/01
A7.5.7.1.1	**Acute Oral LD_{50} Toxicity Mouse**	[redacted]	A6.1.1/02
A7.5.7.1.2	**Short-term toxicity-Repeated 28-day oral dose toxicity in rats**	[redacted]	A6.3.1/01
A7.5.7.1.2	**Short term toxicity-Repeated dermal dose toxicity in rabbits**	[redacted]	A6.3.2/01
A7.5.7.1.2	**Subchronic toxicity-Repeated 90-day oral dose toxicity in rats**	[redacted]	A6.4.1a/01
A7.5.7.1.2	**Subchronic toxicity-Repeated 90-day oral dose toxicity in dogs**	[redacted]	A6.4.1b/01
A7.5.7.1.2	**Subchronic toxicity-Repeated inhalation dose toxicity in rats**	[redacted]	A6.4.3/01
A7.5.7.1.3	**Effects on reproduction Teratogenicity - rabbits**	[redacted]	A6.8.1a/01
A7.5.7.1.3	**Effects on reproduction Teratogenicity -rats**	[redacted]	A6.8.1b/01
A7.5.7.1.3	**Effects on reproduction Teratogenicity - rats**	[redacted]	A6.8.1b/02
A7.5.7.1.3	**Effects on reproduction-Multigeneration reproduction toxicity rats**	[redacted]	A6.8.2

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 (A8-A9)
Study summaries – Active substance

Section A8: Measures necessary to protect man, animals and the environment
Section A9: Classification and labelling

Section A8 Measures necessary to protect man, animals and the environment

This information for DCOIT as an active substance has already been submitted in the DCOIT dossier for product type 8. Please refer to this dossier, Document IIIA 8-9.

Section A9 Classification and labelling

This information for DCOIT as an active substance has already been submitted in the DCOIT dossier for product type 8. Please refer to this dossier, Document IIIA 8-9.