**Figure A7.5.1.1/01-2: Representative ion chromatogram of the measurement of nitrate in a day 28 control sample**

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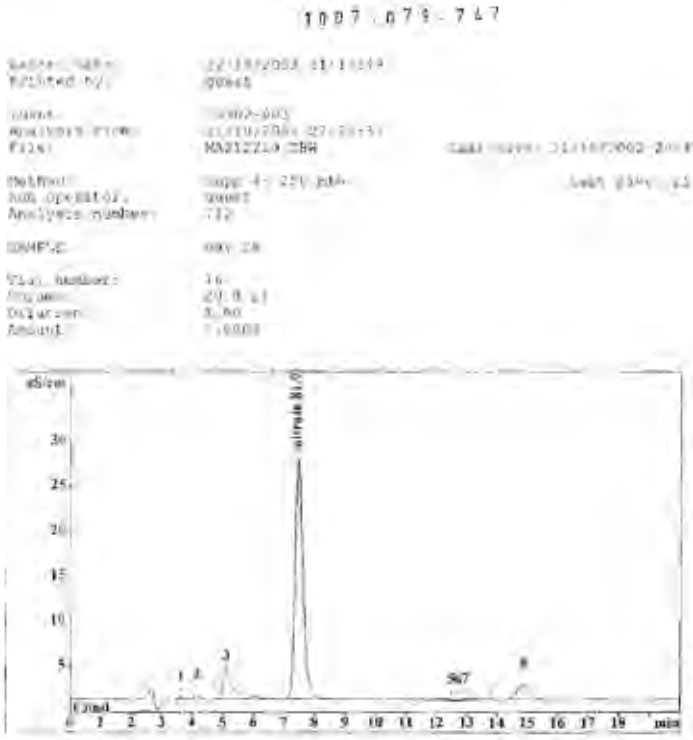
**Figure 2. Representative Ion Chromatogram of the measurement of nitrate in a day 28 control sample.**




Quantitation method: Custom

| No | Retention time | Height | Area | Conc | Name |
|---|---|---|---|---|---|
| | min | uS/cm | uS/cm*sec | mg/L | |
| 4 | 7.48 | 28.73 | 478.092 | 81.900 | Nitrate |

This report has been created by 761 Compact IC

**Figure A7.5.1.1/01-3: Representative ion chromatogram of the measurement of nitrate in a day 28 treated sample at 100 mg DCOIT/kg**

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Figure 3. **Representative Ion Chromatogram of the measurement of nitrate in a day 28 treated sample at 100 mg a.i. of RH-287 Technical/kg.**

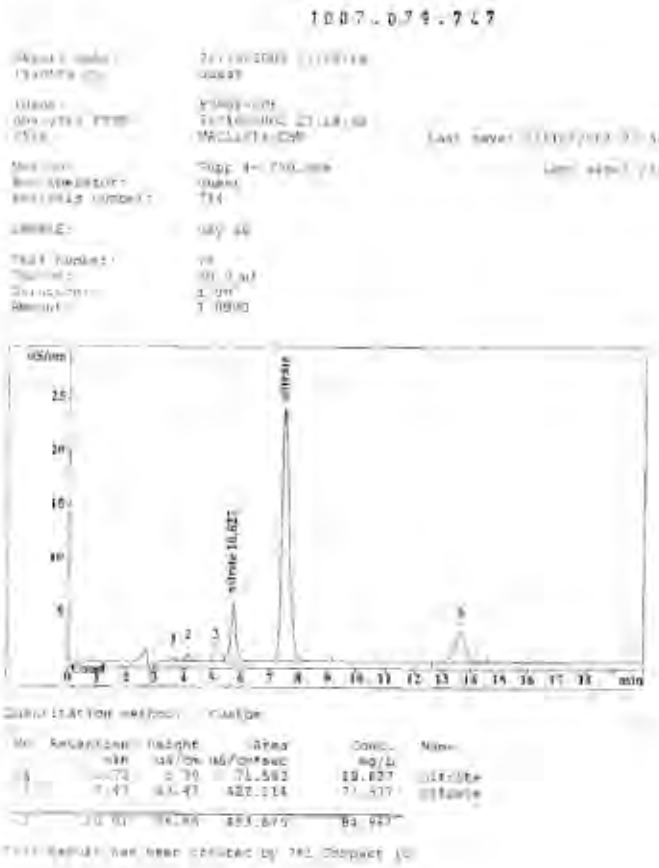

**Figure A7.5.1.1/01-4: Representative ion chromatogram of the measurement of nitrate in a day 28 treated sample at 1000 mg DCOIT/kg**

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**Figure 4. Representative Ion Chromatogram of the measurement of nitrate in a day 28 treated sample at 1000 mg a.i. of RH-287 Technical/kg.**

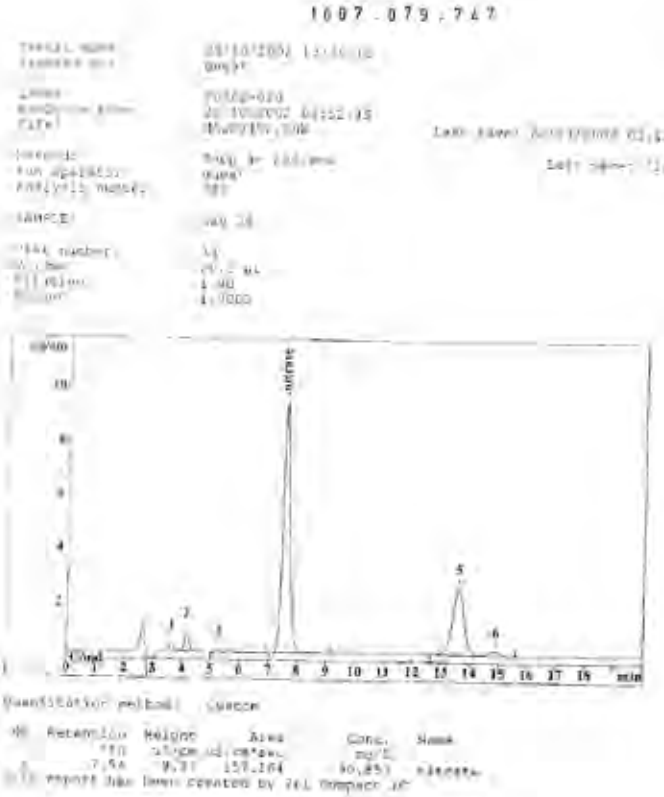

**Figure A7.5.1.1/01-5: Nitrate transformation**

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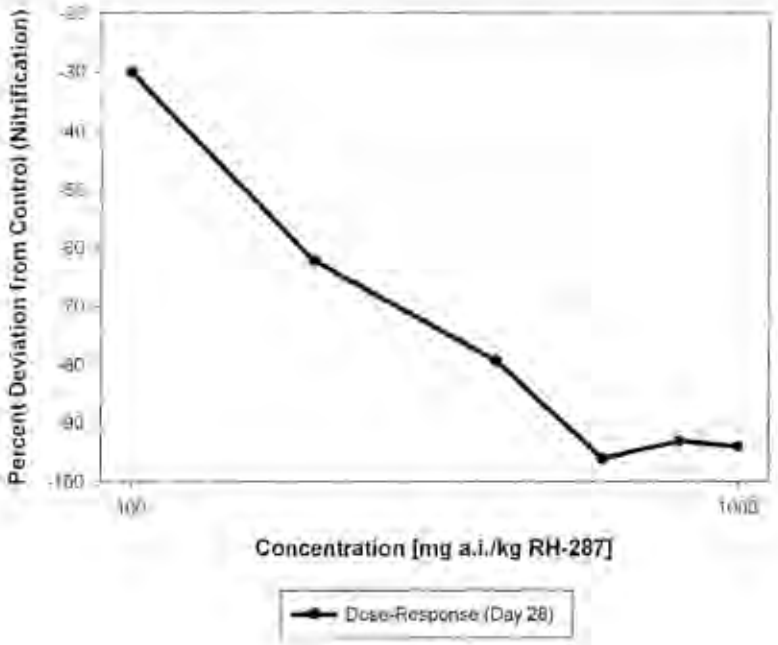
Figure 5. Nitrate transformation: Percent deviation of the RH-287 Technical treated samples from the control represented as dose-response.



## Section A7.5.1.2 Earthworm, acute toxicity test
**Annex Point IIIA XIII 3.2**

Official use only

| | | |
|---|---|---|
| | | **1 REFERENCE** |
| **1.1** | **Reference** | [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 207 |
| **2.2** | **GLP** | Yes |
| **2.3** | **Deviations** | No |
| | | **3 METHOD** |
| **3.1** | **Test material** | DCOIT [redacted] |
| [redacted] | [redacted] | [redacted] |
| 3.1.2 | Specification | As given in section 2 |
| 3.1.3 | Purity | 99.3 % [redacted] |
| 3.1.4 | Composition of Product | [redacted] |
| 3.1.5 | Further relevant properties | |
| 3.1.6 | Method of analysis | |
| **3.2** | **Reference substance** | |
| **3.3** | **Testing procedure** | |
| 3.3.1 | Preparation of the test substance | |
| 3.3.2 | Application of the | |

## Section A7.5.1.2 Earthworm, acute toxicity test
**Annex Point IIIA XIII 3.2**

| | | | |
|---|---|---|---|
| | test substance | [redacted] | |
| 3.3.3 | Test organisms | [redacted] | x |
| 3.3.4 | Test system | [redacted] | |
| 3.3.5 | Test conditions | see table A7.5.1.2/01-4 | x |
| 3.3.6 | Test duration | 14 days | |
| 3.3.7 | Test parameter | [redacted] | |
| 3.3.8 | Examination | | |
| 3.3.9 | Monitoring of test substance concentration | | |
| 3.3.10 | Statistics | | |

**4 RESULTS**

| | | |
|---|---|---|
| **4.1** | **Filter paper test** | Not performed |
| **4.2** | **Soil test** | |
| 4.2.1 | Initial concentrations of test substance | 17, 33, 65, 130, 250 and 500 [mg DCOIT/kg wet weight artificial soil] |
| 4.2.2 | Effect data (Mortality) | see table A7.5.1.2/01-5 |
| 4.2.3 | Concentration / effect curve | See Figure A7.5.1.2/01-1 |
| 4.2.4 | Other effects | Not applicable |
| **4.3** | **Results of controls** | |
| 4.3.1 | Mortality | 90% survival and no sublethal effects in control and acetone control, although one control worm was observed to be slightly lethargic on day 7. |
| 4.3.2 | Number/ percentage of earthworms showing adverse effects | see table A7.5.1.2/01-6 |

## Section A7.5.1.2 Earthworm, acute toxicity test
**Annex Point IIIA XIII 3.2**

| | | |
|---|---|---|
| 4.3.3 | Nature of adverse effects | lethargy and increased time to burrow |
| **4.4** | **Test with reference substance** | Performed |
| 4.4.1 | Concentrations | 2-chloracetamide |
| 4.4.2 | Results | $LC_{50}$ = 17 mg/kg, wet weight |
| | | **5 APPLICANT'S SUMMARY AND CONCLUSION** |
| **5.1** | **Materials and methods** | OECD Method 207, Acute toxicity to the earthworm |
| **5.2** | **Results and discussion** | All surviving worms exposed to the control, solvent control and 17, 33 and 65 mg DCOIT/kg burrowed into the soil within 10 minutes on days 0, 7 and 14. Worms exposed to 130, 250 and 500 mg DCOIT/kg required more than 30 minutes to burrow on day 0. Worms exposed to 250 mg DCOIT/kg required more than 30 minutes to burrow on day 7 and worms exposed to 500 mg DCOIT/kg, replicate 4, required more than 30 minutes to burrow on day 14. |
| 5.2.1 | NOEC | 14 d NOEC = 130 mg DCOIT/kg (soil) based on survival and sublethal (behavioral) effects and 500 mg DCOIT/kg based on weight change data |
| 5.2.2 | $LC_{50}$ | 14 d $LC_{50}$ = 250 mg DCOIT/kg (soil) |
| 5.2.3 | $LC_{0\ or}\ LC_{100}$ | no concentration caused 0% or 100% mortality |
| **5.3** | **Conclusion** | see table A7.5.1.2/01-7 and see table A7.5.1.2/01-8 |
| 5.3.1 | Other Conclusions | |
| 5.3.2 | Reliability | (1), reliable without restriction |
| 5.3.3 | Deficiencies | No |

| Evaluation by Competent Authorities | |
|---|---|
| | |
| | **Evaluation by Rapporteur Member State** |
| **Date** | 23 August.2006 |
| **Materials and Methods** | **Comment (3.3.3):** The age of the earthworms are not reported, only weight and sexual status (developed clitella).<br><br>**Comment (3.3.5):** In Table A7.5.1.2701-4 it is stated that the temperature was 20 ± 2 °C. However, in the study report (XIII. Protocol deviations) it is stated that the temperature was not continuously recorded during the first 7 days of the definite toxicity test. During days 8 to 14 the continuously recorded temperature was not always 20 ± 2 °C (individually recorded daily temperatures in each vessel were always within the specified range). These deviations did not affect the outcome of the study according to the study report. It is not possible to control these deviations in temperature in the report, as all temperatures given in table A.1 are within the given range. |
| **Results and discussion** | Agree with applicant's version |
| **Conclusion** | Agree with applicant's version |
| **Reliability** | 1, reliable without restrictions |
| **Acceptability** | Acceptable |
| **Remarks** | - |

| Section A7.5.1.2 | Earthworm, acute toxicity test – **TABLES AND FIGURES** |
|---|---|

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**Table A7.5.1.2/01-4: Test conditions**

| Criteria | Details |
|---|---|
| Test temperature | 20 ± 2 °C |
| Moisture content | The initial and final moisture content was approximately 26%. |
| pH | Day 0 = 5.6; Day 14 = 5.5 |
| Adjustment of pH | Yes, pH was adjusted to 6.0 ± 0.5 by the addition of calcium carbonate. |
| Light intensity / photoperiod | approximately 400 to 800 lux, 24 h light and 0 h dark |
| Relevant degradation products | Not applicable |

**Table A7.5.1.2/01-5: Mortality data**

| Test Substance Concentration (nominal)[1] [mg DCOIT/kg artificial soil] | Mortality | | | |
|---|---|---|---|---|
| | Number Dead or Missing | | Percentage | |
| | 7 d | 14 d | 7 d | 14 d |
| 0 (control) | 3 | 4 | 8 | 10 |
| 0 (solvent control) | 4 | 4 | 10 | 10 |
| 17 | 5 | 5 | 13 | 13 |
| 33 | 7 | 8 | 18 | 20 |
| 65 | 4 | 5 | 10 | 13 |
| 130 | 6 | 6 | 15 | 15 |
| 250 | 12 | 20 | 30 | 50 |
| 500 | 23 | 26 | 58 | 65 |
| **Temperature [°C]** | 20.8-21.6 | 20.9-21.9 | | |
| **pH** | 5.5-5.6 | 5.5-5.6 | | |
| **Moisture content** | 26 % | 26 % | | |

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

**Table A7.5.1.2/01-6: Number affected data**

| Test Substance Concentration (nominal)[1] [mg DCOIT/kg artificial soil] | Number Affected | | | |
|---|---|---|---|---|
| | Number affected | | Percentage | |
| | 7 d | 14 d | 7 d | 14 d |
| 0 (control) | 1 | 0 | 3 | -- |
| 0 (solvent control) | 0 | 0 | -- | -- |
| 17 | 1 | 0 | 3 | -- |
| 33 | 0 | 0 | -- | -- |
| 65 | 0 | 0 | -- | -- |
| 130 | 0 | 0 | -- | -- |
| 250 | 7 | 0 | 25 | -- |
| 500 | 8 | 6 | 47 | 43 |
| **Temperature [°C]** | 20.8-21.6 | 20.9-21.9 | | |
| **pH** | 5.5-5.6 | 5.5-5.6 | | |
| **Moisture content** | 26 % | 26 % | | |

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

**Table A7.5.1.2/01-7: Effect data**

| | 14 d [mg/kg soil][1] | 95 % c.l. |
|---|---|---|
| $LC_0$ | not applicable | |
| $LC_{50}$ | 250 mg (n) | 130 to >500 mg DCOIT/kg (n) |
| $LC_{100}$ | not applicable | |

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

**Table A7.5.1.2/01-8: Validity criteria for acute earthworm test according to OECD 207**

| | fulfilled | Not fulfilled |
|---|---|---|
| Mortality of control animals < 10% | yes | |

**Figure A7.5.1.2/01-1: Survival of earthworms, *Eisenia foetida*, exposed to DCOIT for 14 days**

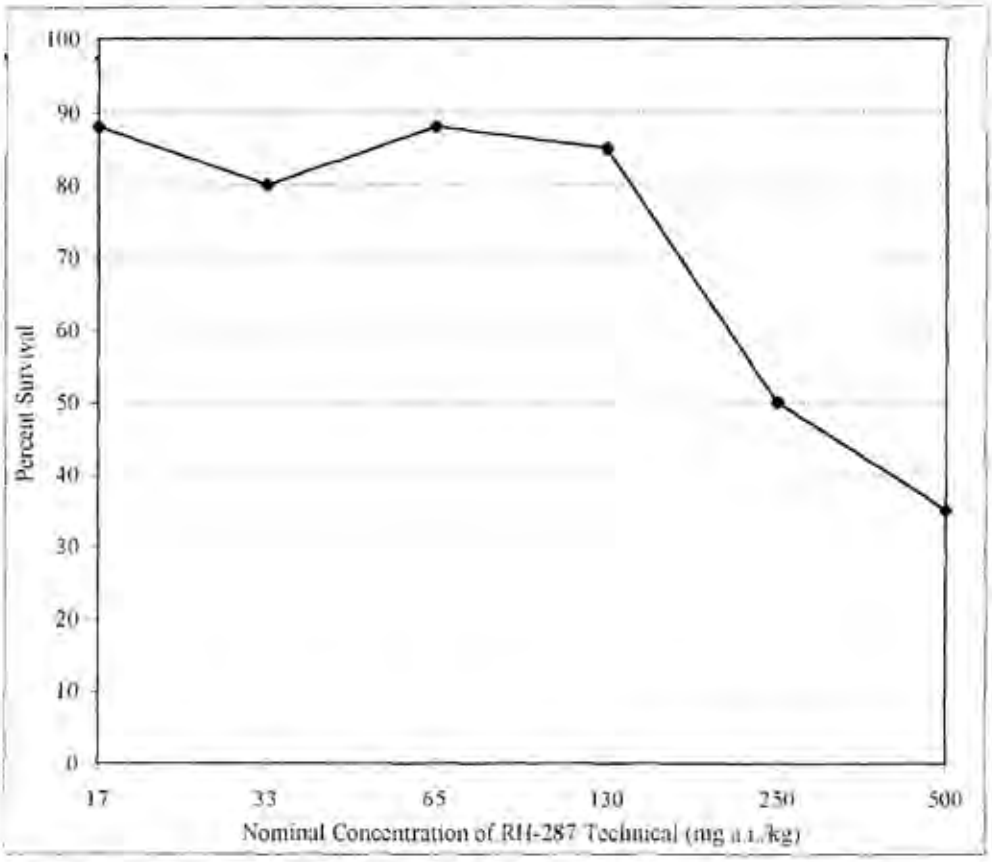


Figure 1 Survival of earthworms, *Eisenia foetida*, exposed to RH-287 Technical for 14 days.

## Section A7.5.1.3/01 Terrestrial plant toxicity – seedling emergence and growth

Annex Point IIIA XIII 3.4

Official use only

| | | |
|---|---|---|
| | | **1 REFERENCE** |
| **1.1** | **Reference** | [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 A and US EPA OPPTS Draft Guidelines 850.4100 and 850.4225 |
| **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** | |
| 3.2.1 | TS Concentrations | |

## Section A7.5.1.3/01 Terrestrial plant toxicity – seedling emergence and growth

Annex Point IIIA XIII 3.4

[redacted]

| | | |
|---|---|---|
| **3.3** | **Reference substance** | |
| 3.3.1 | Method of analysis for reference substance | |
| **3.4** | **Testing procedure** | |
| 3.4.1 | Dilution water | |
| 3.4.2 | Test plants | |
| 3.4.3 | Test system | |
| 3.4.4 | Test conditions | see table A7.5.1.3/01-5 |
| 3.4.5 | Test duration | 25 days |
| 3.4.6 | Test parameter | [redacted] |
| 3.4.7 | Sampling | |
| 3.4.8 | Method of analysis of the plant material | |
| 3.4.9 | Quality control | |
| 3.4.10 | Statistics | |

**4 RESULTS**

**4.1 Results test substance**

| | |
|---|---|
| 4.1.1 Applied initial concentration | not applicable |

**Section A7.5.1.3/01** **Terrestrial plant toxicity – seedling emergence and growth**
**Annex Point IIIA XIII 3.4**

| | |
|---|---|
| 4.1.2 Phytotoxicity rating | see table A7.5.1.3/01-6 |
| 4.1.3 Plant height | see table A7.5.1.3/01-6 |
| 4.1.4 Plant dry weights | see table A7.5.1.3/01-6 |
| 4.1.5 Root dry weights | Not applicable |
| 4.1.6 Root length | Not applicable |
| 4.1.7 Number of dead plants | see table A7.5.1.3/01-6 |
| 4.1.8 Effect data | see table A7.5.1.3/01-6 |
| 4.1.9 Concentration / response curve | Graph of the concentration-response curve at test termination not described in report |
| 4.1.10 Percent emergence | see table A7.5.1.3/01-6 |
| 4.1.11 Other effects | Canola: necrosis, chlorosis, leaf curl, absence of flowers and dead plants were noted.<br>Red clover: necrosis, chlorosis and dead plants were noted.<br>Rice: necrosis, chlorosis, leaf curl, and dead plants were noted.<br>see table A7.5.1.3/01-7 |
| **4.2 Results of controls** | |
| 4.2.1 Number/ percentage of plants showing adverse effects | Canola: no effects<br>Rice: no effects<br>Red clover: one dead plant in solvent control |
| 4.2.2 Nature of adverse effects | Red clover: one dead plant in solvent control |
| **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 A and OPPTS Draft Guidelines 850.4100 and 850.4225, growth test in terrestrial plants with analytical confirmation of dosing solutions. |
| **5.2 Results and discussion** | |
| 5.2.1 NOEC | see table A7.5.1.3/01-8 |
| 5.2.2 $EC_{25}$ | see table A7.5.1.3/01-8 |
| 5.2.3 $EC_{50}$ | see table A7.5.1.3/01-8 |
| **5.3 Conclusion** | see table A7.5.1.3/01-8 |
| 5.3.1 Reliability | (1), reliable without restriction |
| 5.3.2 Deficiencies | No |

| Evaluation by Competent Authorities | |
|---|---|
| | |
| | **Evaluation by Rapporteur Member State** |
| **Date** | 30 August 2006 |
| **Materials and Methods** | **Comment (3.2.1):** Only red clover was tested at 2.5 mg/kg dwt soil. In the tests with rice and canola 5 mg/kg dwt soil was the lowest concentration.<br>**Comment (3.4.10):** If a NOEC value was established to be less than the lowest concentration tested, an EC10 could be calculated by linear regression, to provide a concervative NOEC. This is also done, for shoot length in rice. However, in part 2.9 Data Analysis in the study report it is stated that an EC05 should be used as a concervative NOEC in the above mentioned situations. An EC05 will normally have a wider 95 % confidence interval than EC10, so we suggest keeping EC10 as a NOEC. However, extrapolating outside the concentration range in linear regression is certainly not recommended. Moreover, the EC50 is the most relevant endpoint from this acute test. |
| **Results and discussion** | Agree with applicant's version |
| **Conclusion** | Agree with applicant's version |
| **Reliability** | 1, valid without restrictions |
| **Acceptability** | Acceptable |
| **Remarks** | - |

| Section A7.5.1.3/01 | Terrestrial plant toxicity – **TABLES AND FIGURES** |
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**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.<br>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 inhibi-tion | 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 inhibition | 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 inhibition | 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** | [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) |

## Section A7.5.1.3/02 Terrestrial plant toxicity – vegetative vigor
**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<br>Analytically Measured (mg DCOIT/ml): 0, 0, 67 (red clover), 89 (canola) and 108 (rice)<br>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 | |
| **3.4 Testing procedure** | |
| 3.4.1 Dilution water | |
| 3.4.2 Test plants | |
| 3.4.3 Test system | |
| 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 | |
| 3.4.8 Method of analysis of the plant material | |
| 3.4. 9 Quality control | |
| 3.4.10 Statistics | |

**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.<br>Red clover: necrosis and dead plants were noted.<br>Rice: necrosis and chlorosis were noted.<br>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<br>Red clover: no effects<br>Rice: no effects | x |
| 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** | - |

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

[redacted]

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

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| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [redacted] | [redacted] |
| [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** | [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 | |
| 3.1.6 Method of analysis | |
| **3.2 Reference substance** | |
| **3.3 Testing procedure** | |
| 3.3.1 Preparation of the test substance | |
| 3.3.2 Application of the test substance | |

## 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 | |
| 3.3.9 Monitoring of test substance concentration | |
| 3.3.10 Statistics | |

**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 |

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

| | | |
|---|---|---|
| | 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<br>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)<br>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)<br><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)<br>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** |
|---|---|

[redacted]

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

**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 %<br>Day 28: 28.0 to 34.7 %<br>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)<br>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** | [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 [redacted] | [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 | |
| 3.3.4 Test system | |
| 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.<br>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 | |
| 3.3.9 Monitoring of test substance concentration | |
| 3.3.10 Statistics | |

## 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.<br>**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** |
|---|---|

[redacted]

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| [redacted] | [redacted] |
| [redacted] | [redacted] |

**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 | |

## Document III-A / Section A7.5

### 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** | [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 | |
| 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 | |
| 3.4.8 | Statistics | |

**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). |
| **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**

[redacted]

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

**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** | [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** | - |

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** [ ]<br>**Limited exposure** [ X ] | **Technically not feasible** [ ] **Scientifically unjustified** [ X ]<br>**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<br>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** [ ]<br>**Limited exposure** [ X ] | **Technically not feasible** [ ] **Scientifically unjustified** [ ]<br>**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.<br>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]** | **Technically not feasible [ ]** **Scientifically unjustified [ X ]** | |
| **Limited exposure [ ]** | **Other justification [ ]** | |
| **Detailed justification:** | The potential of DCOIT bioconcentration in earthworms is very low.<br>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).<br>Bioconcentration was studied in aquatic organisms (see section A7.4.3.3) and the results indicated a low bioaccumulation potential for DCOIT.<br>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<br>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** [ ]<br>**Limited exposure** [ X ] | **Technically not feasible** [ ] **Scientifically unjustified** [ X ]<br>**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** | | A6.1.1/02 |
| A7.5.7.1.2 | **Short-term toxicity-Repeated 28-day oral dose toxicity in rats** | | A6.3.1/01 |
| A7.5.7.1.2 | **Short term toxicity-Repeated dermal dose toxicity in rabbits** | | A6.3.2/01 |
| A7.5.7.1.2 | **Subchronic toxicity-Repeated 90-day oral dose toxicity in rats** | | A6.4.1a/01 |
| A7.5.7.1.2 | **Subchronic toxicity-Repeated 90-day oral dose toxicity in dogs** | | A6.4.1b/01 |
| A7.5.7.1.2 | **Subchronic toxicity-Repeated inhalation dose toxicity in rats** | | A6.4.3/01 |
| A7.5.7.1.3 | **Effects on reproduction Teratogenicity - rabbits** | | A6.8.1a/01 |
| A7.5.7.1.3 | **Effects on reproduction Teratogenicity -rats** | | A6.8.1b/01 |
| A7.5.7.1.3 | **Effects on reproduction Teratogenicity - rats** | | A6.8.1b/02 |
| A7.5.7.1.3 | **Effects on reproduction-Multigeneration reproduction toxicity rats** | | A6.8.2 |