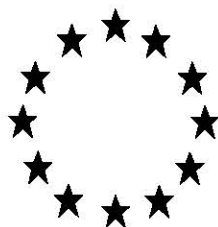


# Competent Authority Report

Work Programme for Review of Active Substances in Biocidal Products  
Pursuant to Council Directive 98/8/EC



## d-Phenothrin (PT18)

Sumitomo Chemical (UK) PLC

Applicant, Identity and Physical and Chemical Properties

Document A1-A3

Rapporteur Member State: Ireland

August 2010 June 2011

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**Section A1 Applicant**

Annex Point IIA1  
IUCLID 1.0.1

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**1.1 Applicant**

Name:- Sumitomo Chemical (UK) PLC

[Redacted]

[Redacted]

[Redacted]

**1.2 Manufacturer of Active Substance (if different)**

[Redacted]

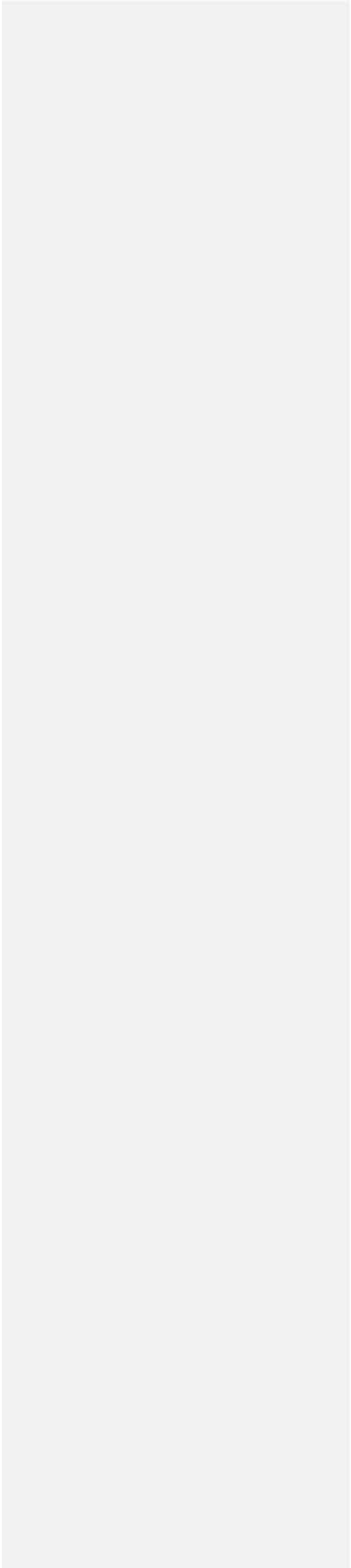
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Telephone: Not available  
Fax number: Not available

**1.3 Manufacturer of Product(s) (if different)**

As above

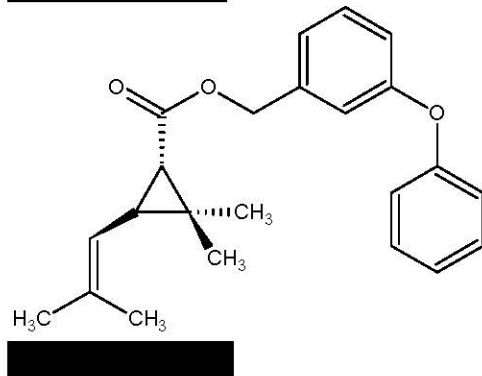
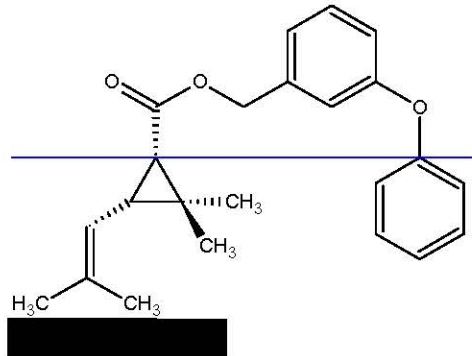
**1) Product –  
Sumithrin® 10 SEC**



Section A2 Identity of  
Active Substance

| Subsection<br>(Annex Point)   |   | Official<br>use<br>only |                       |
|---|---|-------------------------|-----------------------|
| 2.1 Common name<br>(IIA2.1)   | d-Phenothrin<br>also known as [REDACTED] Sumithrin®   | X                       | Formatted: Font: Bold |
| 2.2 Chemical name<br>(IIA2.2)   | CAS: (3-phenoxyphenyl)methyl (1R)-cis-trans-2,2-<br>dimethyl- 3-(2-methyl-1-propenyl)<br>cyclopropanecarboxylate<br>IUPAC: 3-phenoxybenzyl (1R)-cis, trans-chrysanthemate | X                       | Formatted: Font: Bold |
| 2.3 Manufacturer's<br>development code<br>number(s)<br>(IIA2.3)           | Not available   |                         |                       |
| 2.4 CAS No and EC<br>numbers (IIA2.4)                                     | Non-entry field   | X                       | Formatted: Font: Bold |
| 2.4.1 CAS-No<br>Isomer 1  | 188023-86-1<br>Not applicable   |                         |                       |
| 2.4.2 EC-No<br>Isomer 1<br>Isomer n                                       | None-plant protection product<br>Not applicable   |                         |                       |
| 2.4.3 Other   | CIPAC No. 356   |                         |                       |
| 2.5 Molecular and<br>structural<br>formula,<br>molecular mass<br>(IIA2.5) | Non-entry field   |                         |                       |
| 2.5.1 Molecular<br>formula  | C <sub>23</sub> H <sub>26</sub> O <sub>3</sub>  |                         |                       |

2.5.2 Structural formula



2.5.3 Molecular mass

350.46 g/mol

2.6 Method of manufacture of the active substance (IIA2.1)

Refer to Confidential Appendix for File IIIA TNG Section 2.6

2.7 Specification of the purity of the active substance, as appropriate (IIA2.7)

g/kg  
[Redacted]

g/l

% w/w  
[Redacted]

% v/v

X1

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**Chemical (UK) PLC**

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**2.8 Identity of impurities and additives, as appropriate (IIA2.8)**

Refer to Confidential Appendix File IIIA TNG Section 2.8 (1) to (7)

**2.8.1 Isomeric composition**

[Redacted]

X2

**2.9 The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)**

Not Applicable

Refer to Justification for Non-Submission of Data TNG Section A2.9

**2.10 Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC**

**Annex Point IIA,  
II.2.10**

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This information is considered confidential and is presented in the Annex Confidential Data and Information

| Evaluation by Competent Authorities  |   |
|--|---|
| Use separate "evaluation boxes" to provide transparency as to the comments and views submitted |   |
|  | <b>EVALUATION BY RAPPORTEUR MEMBER STATE <del>(X1 &amp; X2)</del></b> |
| <b>Identity of the Active Substance (Section A2)</b>   |   |
| <b>Date</b>  | [REDACTED]  |
| <b>Results and discussion</b>  | [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] | [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] | [REDACTED] | [REDACTED] |

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Applicant : Sumitomo  
Chemical (UK) PLC

d-Phenothrin

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|                               |   |
|-------------------------------|---|
| <b>Reliability</b>            |   |
|                               |   |
|                               |   |
|                               |   |
| <b>COMMENTS FROM ...</b>      |   |
| <b>Date</b>                   | <i>Give date of comments submitted</i>  |
| <b>Results and discussion</b> | <i>Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.<br/>Discuss if deviating from view of rapporteur member state</i> |
| <b>Conclusion</b>             | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Reliability</b>            | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Acceptability</b>          | <i>Discuss if deviating from view of rapporteur member state</i>  |
| <b>Remarks</b>                |   |

## Section A3 Physical and Chemical Properties of Active Substance

| Subsection<br>(Annex Point)  | Method   | Purity/<br>Specification | Results<br>Give also data on test<br>pressure, temperature,<br>pH and concentration<br>range if necessary | Remarks/<br>Justification | GLP<br>(Y/N) | Reliability | Reference  | Official<br>use<br>only |
|--|--|--------------------------|---|---------------------------|--------------|-------------|------------|-------------------------|
| 3.1 Melting<br>point, boiling point,<br>relative density<br>(IIA3.1) |  |                          |   |                           |              |             |            | X                       |
| 3.1.1 Melting point  |  |                          |   |                           |              |             |            |                         |
| Melting pt. 1 IUCLID<br>2.1/1  | EC A1 OECD 102<br>(Differential Scanning<br>Calorimetry) | [REDACTED]               | <i>result:</i> -41.38 °C<br><i>pressure:</i> performed at<br>atmospheric pressure                         | [REDACTED]                | -            | -           | [REDACTED] |                         |
| Melting pt. 1<br>IUCLID 2.1/2  | Method A1<br>Commission Directive<br>92/69/EEC.          | [REDACTED]               | <i>result:</i> -20.16 °C (<253<br>± 0.5 K)<br><i>pressure:</i> performed at<br>atmospheric pressure       | [REDACTED]                | -            | -           | [REDACTED] |                         |

## Section A3 Physical and Chemical Properties of Active Substance

| Subsection<br>(Annex Point)   | Method              | Purity/<br>Specification | Results<br>Give also data on test<br>pressure, temperature,<br>pH and concentration<br>range if necessary | Remarks/<br>Justification | GLP<br>(Y/N) | Reliability | Reference | Official<br>use<br>only |
|-------------------------------|---------------------|--------------------------|---|---------------------------|--------------|-------------|-----------|-------------------------|
|                               |                     |                          |   |                           |              |             |           |                         |
| Boiling pt. 1<br>IUCLID 2.2/1 | OECD Guideline 103  |                          | result: >301°C<br>pressure: 99.8 kPa  |                           |              |             |           |                         |
| Boiling pt. 2<br>IUCLID 2.2/2 | OECD Guide-line 103 |                          | result: >290°C<br>pressure: 1030 hPa  |                           |              |             |           |                         |

## Section A3 Physical and Chemical Properties of Active Substance

| Subsection<br>(Annex Point)  | Method           | Purity/<br>Specification | Results<br>Give also data on test<br>pressure, temperature,<br>pH and concentration<br>range if necessary | Remarks/<br>Justification | GLP<br>(Y/N) | Reliability | Reference     | Official<br>use<br>only |
|--|------------------|--------------------------|---|---------------------------|--------------|-------------|---------------|-------------------------|
|  |                  |                          |   | [REDACTED]                |              |             | February 1989 |                         |
| <b>3.1.3 Bulk<br/>density/<br/>relative<br/>density</b><br>Bulk/rel. density 1<br>IUCLID 2.3/1 | CIPAC Method MT3 | [REDACTED]               | 1.06 g/ml at 20°C   | [REDACTED]                | [REDACTED]   | [REDACTED]  | [REDACTED]    | [REDACTED]              |
| Bulk/rel. density 2<br>IUCLID 2.3/2  | CIPAC MT 3.2     | [REDACTED]               | 1.06 g/ml at 20°C   | [REDACTED]                | [REDACTED]   | [REDACTED]  | [REDACTED]    | [REDACTED]              |

## Section A3 Physical and Chemical Properties of Active Substance




| Subsection<br>(Annex Point)                            | Method  | Purity/<br>Specification | Results<br>Give also data on test<br>pressure, temperature,<br>pH and concentration<br>range if necessary              | Remarks/<br>Justification | GLP<br>(Y/N) | Reliability | Reference  | Official<br>use<br>only |
|--|---|--------------------------|--|---------------------------|--------------|-------------|------------|-------------------------|
|  |   |                          |  |                           |              |             | [REDACTED] |                         |
| <b>3.2 Vapour<br/>pressure<br/>(IIA3.2)</b>            |   |                          |  |                           |              |             |            |                         |
| Vapour pressure 1<br>IUCLID 2.4/1                      | EEC A4<br>OECD 104 (Knudsen<br>effusion method) | [REDACTED]               | temperature: 20°C and<br>25°C<br>result: $2.372 \times 10^{-5}$ Pa<br>at 20°C and $4.165 \times 10^{-5}$<br>Pa at 25°C | [REDACTED]                |              |             | [REDACTED] |                         |
| <b>3.2.1 Henry's Law<br/>Constant<br/>(Pt. I-A3.2)</b> | Not applicable                                  | [REDACTED]               | Measured/calculated:<br>calculated<br>result: $>6.75 \times 10^{-1}$ Pa<br>$\text{m}^3 \text{mol}^{-1}$                | [REDACTED]                |              |             | [REDACTED] |                         |
| IUCLID 2.14/1  |   |                          |  |                           |              |             | [REDACTED] |                         |



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**Section A3 Physical and Chemical Properties of Active Substance**

| <b>Subsection<br/>(Annex Point)</b> | <b>Method</b> | <b>Purity/<br/>Specification</b> | <b>Results</b><br>Give also data on test<br>pressure, temperature,<br>pH and concentration<br>range if necessary | <b>Remarks/<br/>Justification</b> | <b>GLP<br/>(Y/N)</b> | <b>Reliability</b> | <b>Reference</b> | <b>Official<br/>use<br/>only</b> |
|-------------------------------------|---------------|----------------------------------|--|-----------------------------------|----------------------|--------------------|------------------|----------------------------------|
|                                     |               |                                  |  |                                   |                      |                    |                  |                                  |

|  |   |   |                            |             |   |   |   |                          |
|--|---|---|----------------------------|-------------|---|---|---|--------------------------|
| <p><b>3.3 Appearance (IIA3.3)</b><br/> <b>3.3.1 Physical state</b><br/>                 Visual<br/>                 OPPTS 830.6302<br/>                 IUCLID 1.1.1/1</p> | <p>Visual<br/>                 OPPTS 830.6302</p> |    | <p>Liquid, oily</p>        | <p>None</p> |    |    |    | <p><a href="#">X</a></p> |
| <p><b>3.3.2 Colour</b><br/>                 Visual<br/>                 OPPTS 830.6303<br/>                 IUCLID 1.1.1/1</p>   | <p>Visual<br/>                 OPPTS 830.6303</p> |    | <p>Pale yellow</p>         | <p>None</p> |    |    |   |                          |
| <p><b>3.3.3 Odour</b><br/>                 OPPTS 830.6304<br/>                 IUCLID 1.1.1/1</p>  | <p>OPPTS 830.6304</p>                             |  | <p>Slight petrol odour</p> | <p>None</p> |  |  |  |                          |

|  |                |            |  |  |  |  |  |  |
|--|----------------|------------|--|--|--|--|--|--|
|  |                |            |  |  |  |  | Report No.<br>SYN/2201, 13 April<br>2006 |  |
| <b>3.4 Absorption spectra (IIA3.4)</b> |                |            |  |  |  |  |  |  |
| UV/VIS<br>IUCLID 1.1.2/1               | Not applicable | [REDACTED] | The uv/vis absorbance maxima were observed at 202.96, 202.37 and 217.27 nm at acidic, neutral and alkaline pH.<br>[REDACTED] |  |  |  | [REDACTED]                               |  |
| IR<br>IUCLID 1.1.2/2                   | Not applicable | [REDACTED] | [REDACTED]   |  |  |  | [REDACTED]                               |  |

|   |  |                   |  |                   |                   |                   |                   |                   |
|---|--|-------------------|--|-------------------|-------------------|-------------------|-------------------|-------------------|
| <p>NMR<br/>IUCLID 1.1.2/3</p>   | <p>Not applicable</p>  | <p>[REDACTED]</p> | <p>The <sup>1</sup>H and <sup>13</sup>C NMR spectra are consistent with the accepted structure.<br/>[REDACTED]</p> | <p>-</p>          | <p>[REDACTED]</p> | <p>[REDACTED]</p> | <p>[REDACTED]</p> | <p>[REDACTED]</p> |
| <p>MS<br/>IUCLID 1.1.2/4</p>  | <p>Not applicable</p>  | <p>[REDACTED]</p> | <p>[REDACTED]</p>  | <p>[REDACTED]</p> | <p>[REDACTED]</p> | <p>[REDACTED]</p> | <p>[REDACTED]</p> | <p>[REDACTED]</p> |
| <p>3.5 Solubility in water (IIA3.5)<br/>Water solubility 1<br/>IUCLID 2.6.1/1</p> | <p><i>including effects of pH (5-9)</i><br/>CIPAC Method MT157</p> | <p>[REDACTED]</p> | <p>result: 2 µg/l<br/>temperature: 21°C<br/>pH: 5, 7 and 9</p>   | <p>[REDACTED]</p> | <p>[REDACTED]</p> | <p>[REDACTED]</p> | <p>[REDACTED]</p> | <p>[REDACTED]</p> |

|   |  |  |   |      |  |  |  |  |
|---|--|--|---|------|--|--|--|--|
|   |  |  |   |      |  |  |  |  |
| Water solubility 2<br>IUCLID 2.6.1/3  | EPA Chemical Fate Testing Guideline CG-1500. |  | result: <9.7 µg/l<br>temperature: 25±1°C<br>pH:5.80 to 6.02                                   |      |  |  |  |  |
| 3.6 Dissociation constant (-)   |  |  |   |      |  |  |  |  |
| 3.7 Solubility in organic solvents, including the effect of temperature on solubility (IIIA3.1) |  |  |   |      |  |  |  |  |
| Organic solvent Solubility 1<br>IUCLID 2.6.1/2  | CIPAC Method MT181                           |  | Result: The solubility of d-Phenothrin was:-<br>Methanol >250 g/l;<br>Acetone >250 g/l; Ethyl | None |  |  |  |  |

|  |                     |  |  |  |  |  |  |
|--|---------------------|--|--|--|--|--|--|
|  |                     |  | acetate>250 g/l; 1,2-dichloroethane>250 g/l; m-xylene>250 g/l; heptane>250 g/l<br><b>temperature:25°C</b>                                  |  |  |  |  |
| Organic solvent Solubility 2<br><br>IUCLID 2.6.1/4   | OECD Guide-line 105 |  | <b>Result:</b> The solubility of Sumithrin was determined to be >4.96 g/mL in hexane and >5.0 g/mL in methanol.<br><b>temperature:25°C</b> | Shake flask method used.   |  |  |  |
| 3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2) |                     |  | Not applicable.  | Only if additional data are required (see BPD, TNsG)<br><br>Refer to TNG Justification for Non-submission of Data A3.8 |  |  |  |

|   |  |                   |   |                   |                   |                   |                   |                   |
|---|--|-------------------|---|-------------------|-------------------|-------------------|-------------------|-------------------|
| <p>3.9 Partition coefficient n-octanol/water (IIA3.6)</p> <p>log Pow 1</p> <p>IUCLID2.5/1</p> | <p><i>including effects of pH (5-9)</i></p> <p>EEC Method A8</p> | <p>[REDACTED]</p> | <p><b>result:</b> Log Pow = 6.8</p> <p><b>temperature:</b> not stated</p> <p><b>pH:</b> pH7</p> | <p>None</p>       | <p>[REDACTED]</p> | <p>[REDACTED]</p> | <p>[REDACTED]</p> | <p>[REDACTED]</p> |
| <p>log Pow 2</p> <p>IUCLID2.5/2</p>   | <p>OECD Guide-line 107</p>                                       | <p>[REDACTED]</p> | <p><b>result:</b> Log Pow = 6.01</p> <p><b>temperature:</b> 20°C ±1°C</p> <p><b>pH:</b> pH7</p> | <p>[REDACTED]</p> | <p>[REDACTED]</p> | <p>[REDACTED]</p> | <p>[REDACTED]</p> | <p>[REDACTED]</p> |

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| <p>3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)</p> <p>IUCLID 2.14/2</p>  | <p>OECD Guidelines No.113</p> |  | <p>Thermally stable</p>   | <p>The test substance was exposed to 54°C for 14 days.</p> |  |  |  |  |
| <p>3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)</p> <p>Auto-flammability 1</p> <p>IUCLID 2.8/1</p> | <p>EEC Method A15</p>         |  | <p>385°C at 102.2 kPa</p> | <p>Auto-ignition</p>                                       |  |  |  |  |



|                               |               |  |                   |                                     |  |  |  |  |
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|                               |               |  |                   |                                     |  |  |  |  |
| 3.12 Flash-point (IIA3.9)     |               |  |                   |                                     |  |  |  |  |
| Flash point 1<br>IUCLID 2.7/1 | EEC Method A9 |  | 130°C at 101.2kPa | Pensky-Martens closed cup apparatus |  |  |  |  |
| Flash point 2<br>IUCLID 2.7/2 | CIPAC MT12.3  |  | 107°C             | Pensky-Martens closed cup apparatus |  |  |  |  |

|      |  |                    |  |   |  |  |                  |  |
|------|--|--------------------|--|---|--|--|------------------|--|
|      |  |                    |  |   |  |  | 22 November 1988 |  |
| 3.13 | Surface tension (IIA3.10)<br>Surface tension 1 |                    |  | result: Not applicable<br>temperature:                  |  |  |                  |  |
| 3.14 | Viscosity (-)<br><br>IUCLID 2.13/1             | OECD Guideline 114 |  | result:<br>75.9 mPa.s at 25°C<br>and 23.1 mPa.s at 45°C |  |  |                  |  |
| 3.15 | Explosive properties (IIA3.11)                 |                    |  |   | Refer to TNG<br>Justification for<br>Non-submission<br>of Data A3.15 |  |                  |  |
| 3.16 | Oxidizing properties                           |                    |  |   | Refer to TNG   |  |                  |  |

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| (IIA3.12)   |  |  |   |  |  |  |  |  |
| 3.17<br>Reactivity towards container material (IIA3.13)<br><br>IUCLID 1_6_3/1 and 8.8/1 |  |  | No reactivity against container after storage for 6 months at 40°C. |  |  |  |  |  |

**Table 1 Ultraviolet-Visible Spectral Characteristics, Sumithrin ( d -phenothrin)**

| Conditions | Concentration (mg/L) | Molar concentration (mole/L) | Maximum absorbance wavelength (nm) | Extinction coefficient ( $\epsilon$ ) (L/mole) |
|------------|----------------------|------------------------------|------------------------------------|--|
| Acidic     | 5.645                | $1.611 \times 10^{-5}$       | 202.96                             | 43327.29                                       |
| Unadjusted | 6.1916               | $1.767 \times 10^{-5}$       | 202.37                             | 46718.57                                       |
| Alkaline   | 5.996                | $1.711 \times 10^{-5}$       | 217.17                             | 20455.97                                       |

**Table 2 Ultraviolet-Visible Spectral Characteristics, Sumithrin ( d -phenothrin)**

As the spectrum in alkaline methanol differed from that in both neutral and acidic methanol, an additional experiment was performed. A sample of the test substance was prepared in alkaline methanol at a nominal concentration of 6  $\mu\text{g/ml}$  and the spectrum recorded. The solution was then neutralised using 0.1M hydrochloric acid (checked using pH indicator paper), as was the blank alkaline methanol. The spectrum of the neutralised solution was then recorded against the neutralised blank.

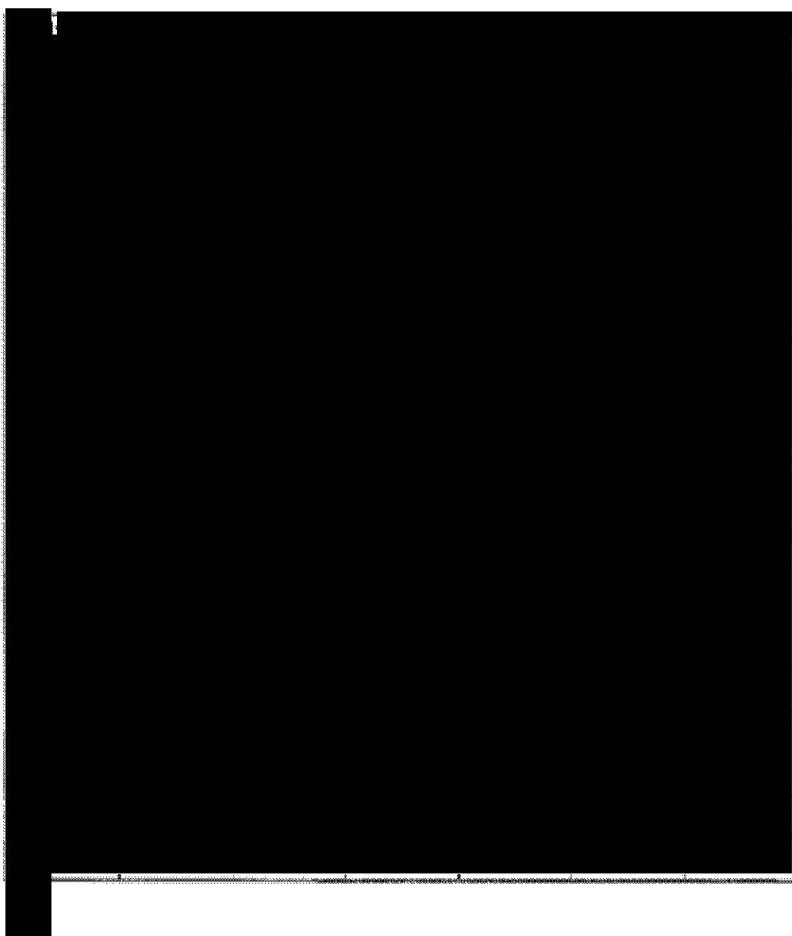
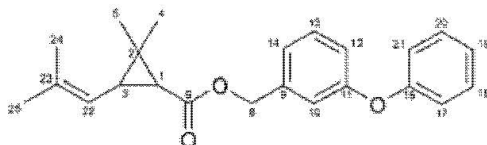
| Conditions | Concentration (mg/L) | Molar concentration (mole/L) | Maximum absorbance wavelength (nm) | Extinction coefficient ( $\epsilon$ ) (L/mole) |
|------------|----------------------|------------------------------|------------------------------------|--|
| Acidic     | 7.6846               | $2.193 \times 10^{-5}$       | 202.01                             | 55739.04                                       |
| Unadjusted | 6.8962               | $1.968 \times 10^{-5}$       | 203.16                             | 44794.16                                       |
| Alkaline   | 13.1636              | $3.756 \times 10^{-5}$       | 217.18                             | 16713.12                                       |

**Table 3 Infrared Spectral Details**

| Functional Group                        | Mode                        | Wavenumber (cm <sup>-1</sup> ) |
|---|-----------------------------|--------------------------------|
| Vinyl and Aryl C-H                      | C-H stretch                 | 3062.84 to 3038.65             |
| Aliphatic C-H                           | C-H stretch                 | 2969.29 to 2872.97             |
| Ester                                   | C=O stretch                 | 1724.99                        |
| Aryl C=C                                | C=C stretch                 | 1585.30 to 1489.7              |
| Aliphatic C-H                           | C-H deformations            | 1447.45 to 1421.25             |
| Methyl                                  | C-H symmetrical deformation | 1378.83                        |
| Ester and Ether                         | C-O-C stretch               | 1257.33 to 1070.37             |
| Vinyl                                   | C-H bend                    | 855.25                         |
| Aryl C-H (meta di and mono-substituted) | C-H bend                    | 755.48                         |
| Aryl C-H (mono-substituted)             | C-H bend                    | 692.24                         |

**Table 4** Assignment of the signals ( $^1\text{H}$ -NMR spectrum and  $^{13}\text{C}$  spectrum)

The  $^1\text{H}$  and  $^{13}\text{C}/\text{Dept}135$  NMR spectra of the Test Material may be assigned as:



**Table 5** MS Spectra

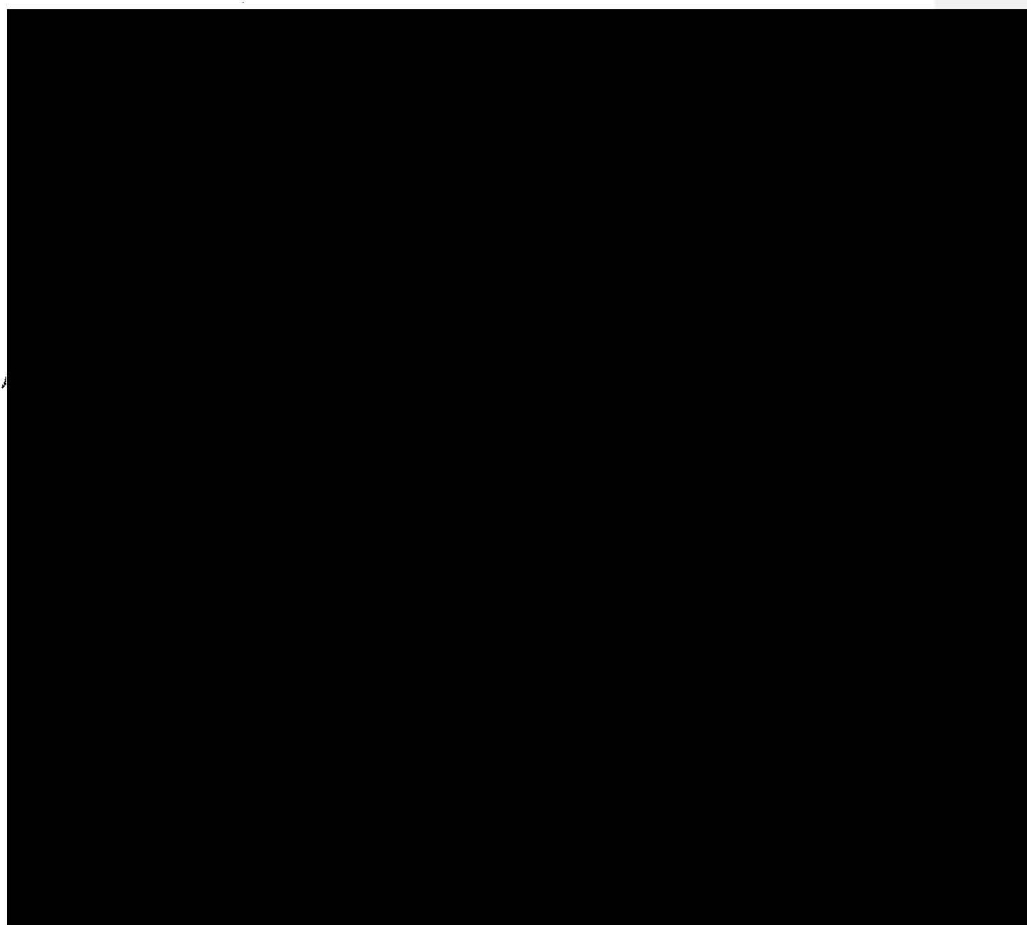
| Sumithrin       | Observed $m/z$ | Elemental composition* | $\Delta m$ (ppm) |
|-----------------|----------------|------------------------|------------------|
| Full scan       | 351.1955       | $C_{23}H_{27}O_3$      | +0.1             |
| MS <sup>2</sup> | 305.1900       | $C_{22}H_{25}O$        | +0.0             |
|                 | 333.1846       | $C_{23}H_{25}O_2$      | -0.9             |

\* positive species

**Figure 1** Ultraviolet-Visible Spectrum Between 200 and 750 nm of Solutions of Sumithrin (d -phenothrin)

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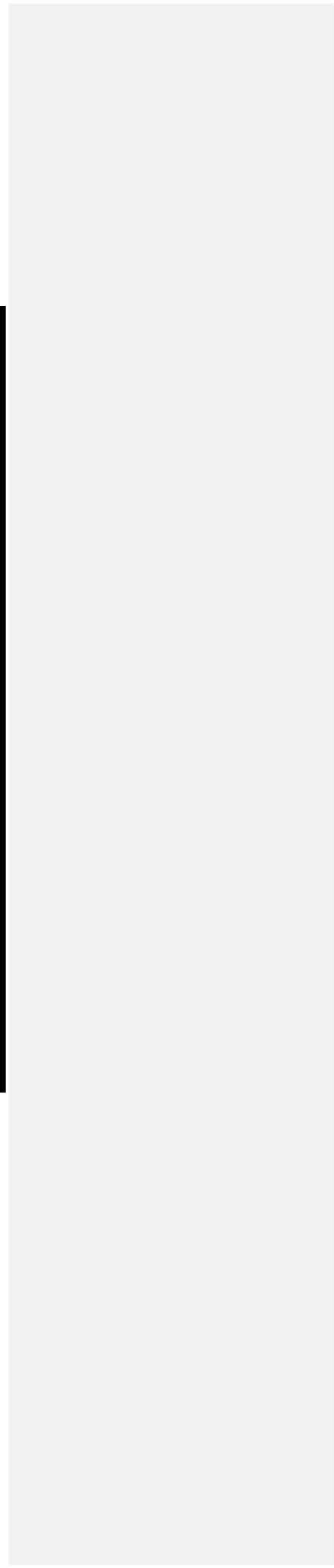
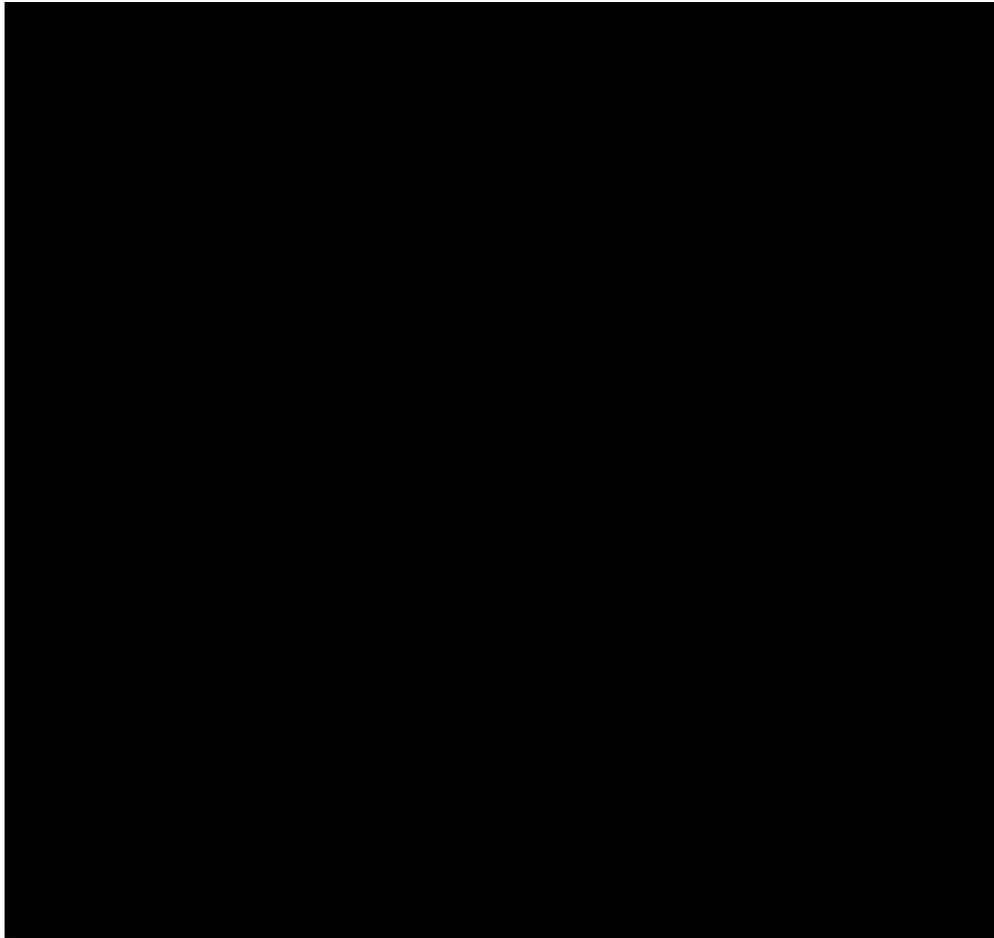






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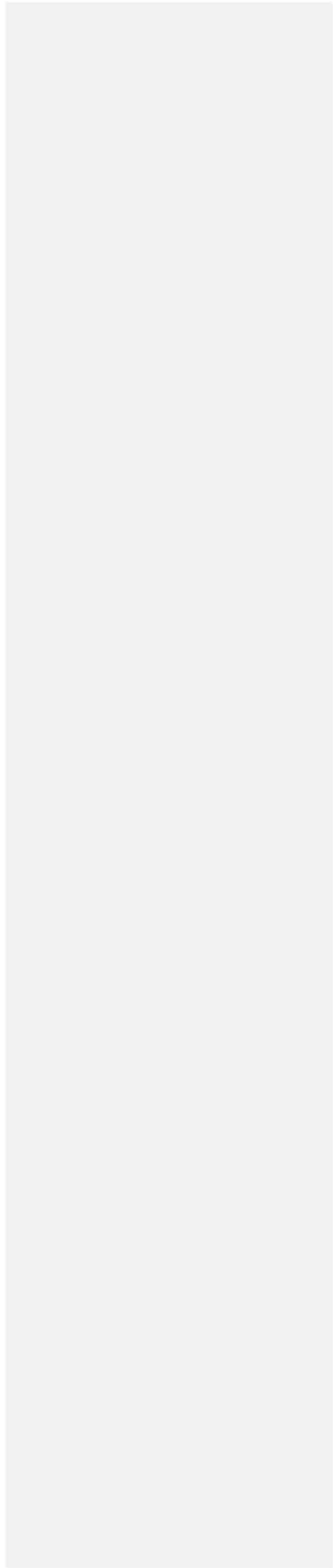
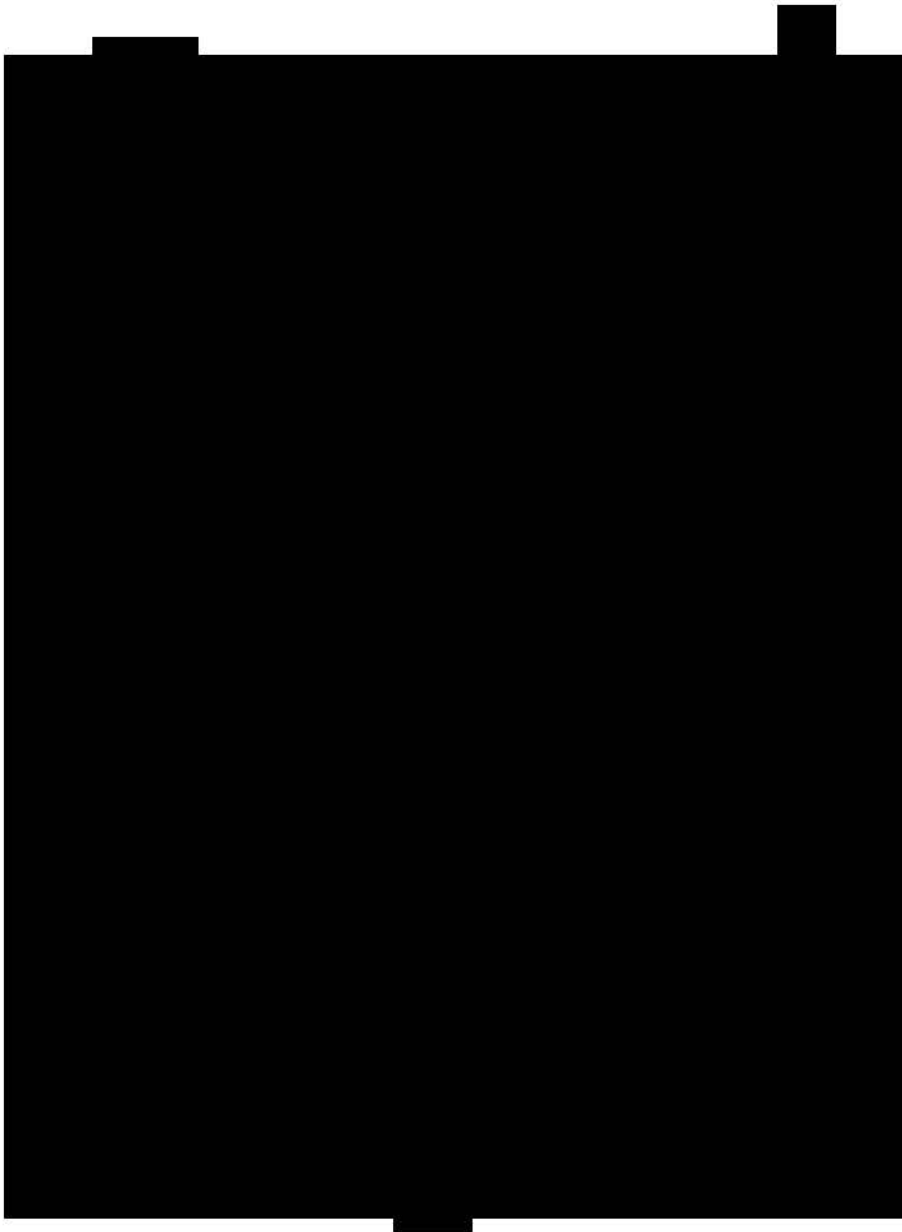


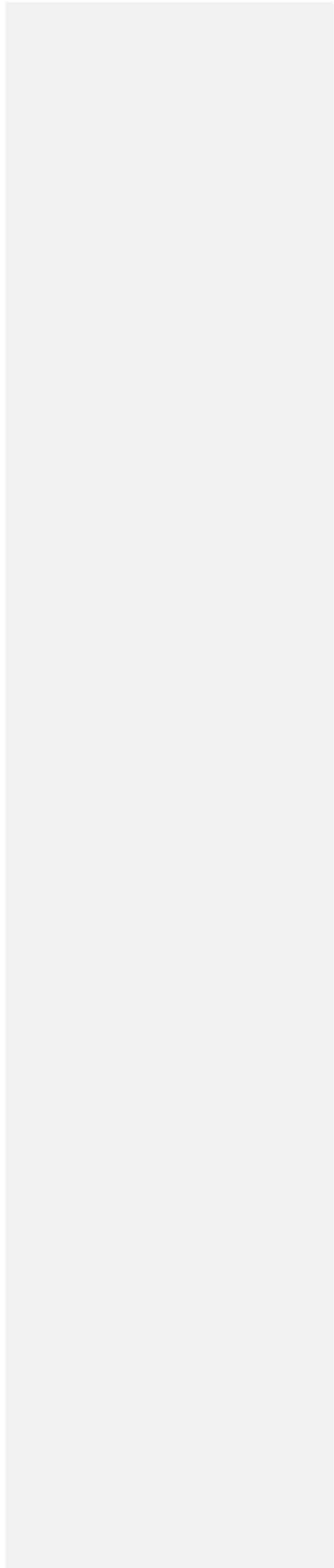
Figure 4 Infrared Spectrum between 2000 and 500  $\text{cm}^{-1}$



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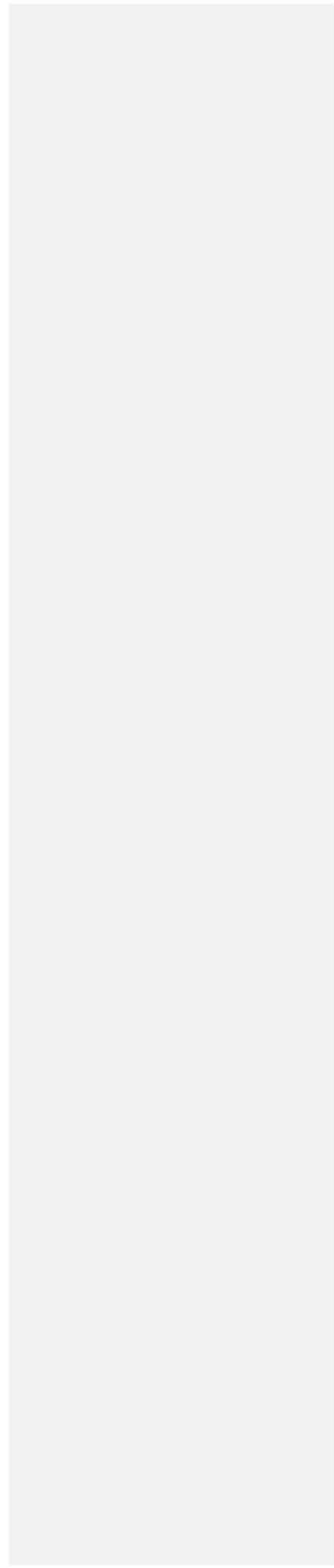
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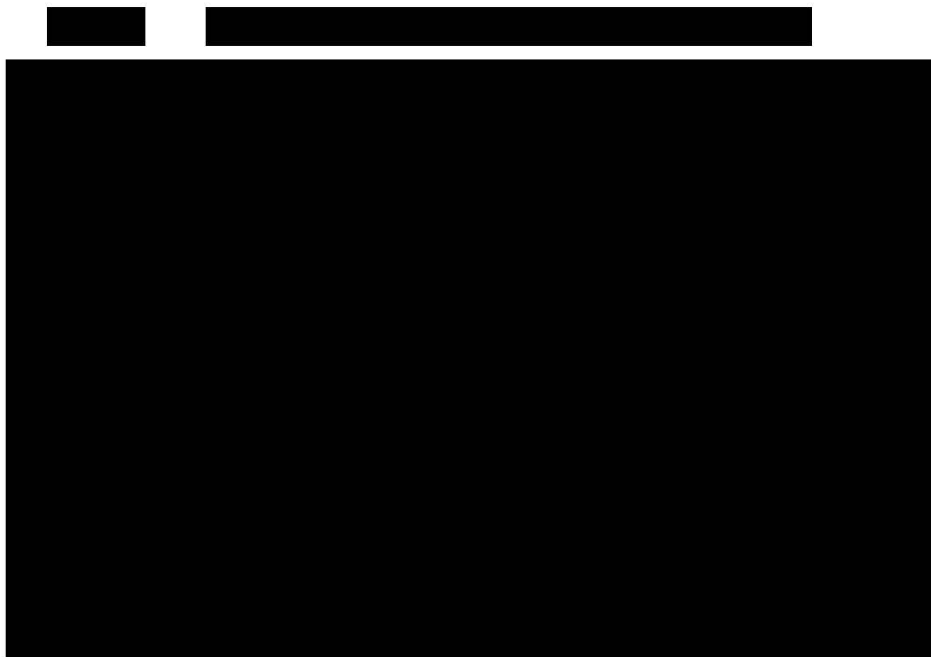
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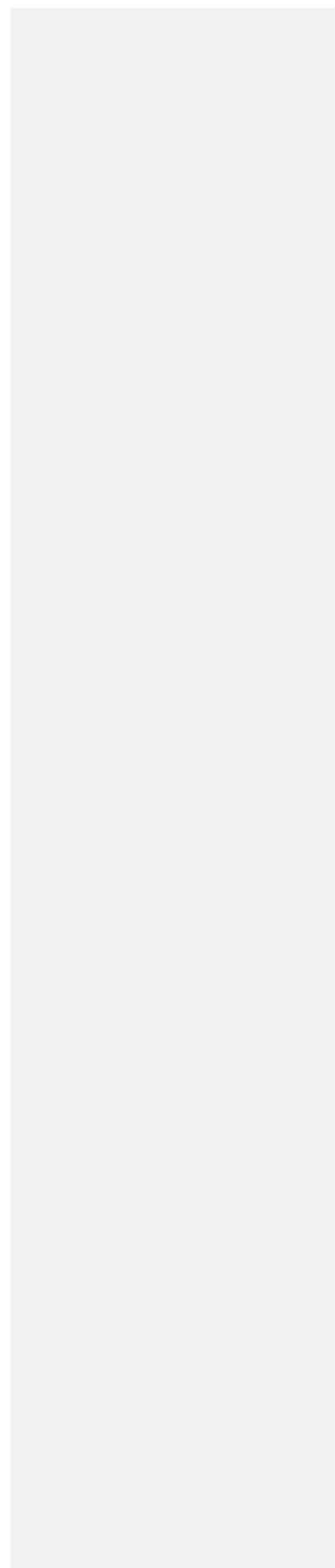
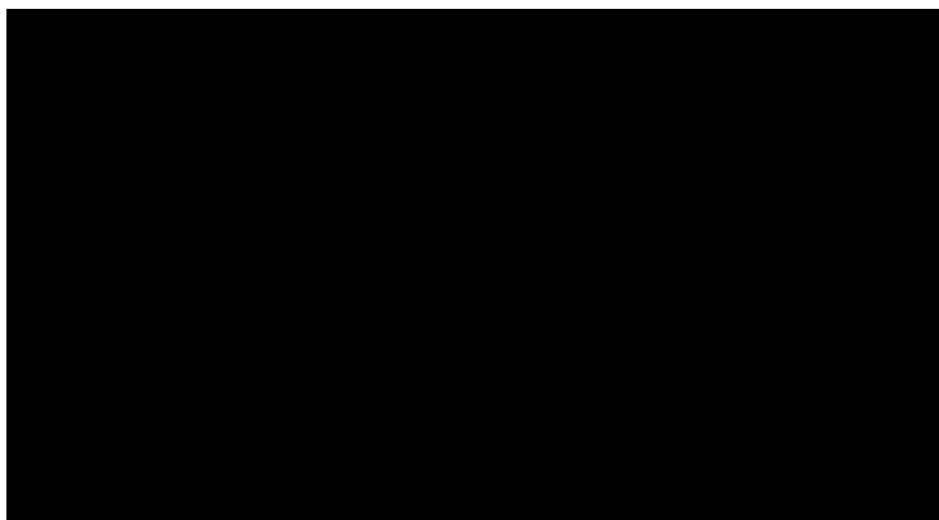
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**Figure 8** Product ion spectrum of Sumithrin (d-phenothrin)



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| <u>Reliability</u>            | <i>Discuss if deviating from view of rapporteur member state</i>  |
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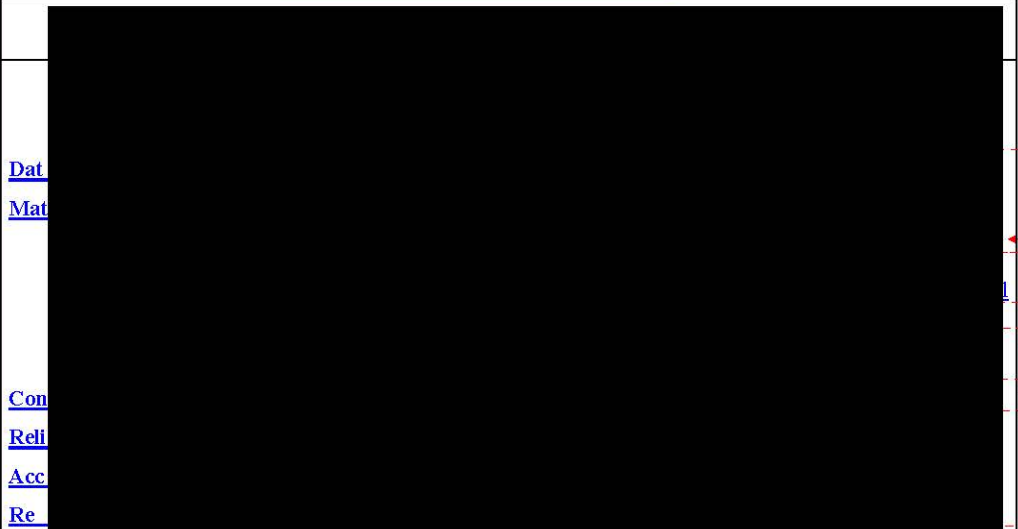
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| Conclusion  | <i>Discuss if deviating from view of rapporteur member state</i> |            |



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| <b>Remarks</b>   | <i>Discuss if deviating from view of rapporteur member state</i> |





## Section A1-A3 Reference list by section number

| Section No./Reference No. | Author(s)  | Year | Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published | Data Protection Claimed (Yes/No) | Owner                       |
|---------------------------|------------|------|--|----------------------------------|-----------------------------|
| A2                        | [REDACTED] | 2001 | Analysis Results of Recent Batches of [REDACTED] (d-Phenothrin)<br>[REDACTED]                          | Y                                | Sumitomo Chemical Co., Ltd. |
| A3 1 1                    | [REDACTED] | 2009 | Sumithrin (d-phenothrin): Evaluation of Selected Physical Chemistry Properties                         | Y                                | [REDACTED]                  |
| A3_1_2                    | [REDACTED] | 2006 | Determination of Physical and Chemical Properties of d-Phenothrin<br>[REDACTED]                        | Y                                | Sumitomo Chemical Co., Ltd. |
| A3_1_3                    | [REDACTED] | 2006 | Determination of Physical and Chemical Properties of d-Phenothrin<br>[REDACTED]                        | Y                                | Sumitomo Chemical Co., Ltd. |
| A3_1_3                    | [REDACTED] | 1988 | Specific Gravity of Sumithrin®<br>[REDACTED]   | Y                                | Sumitomo Chemical Co., Ltd. |

| Section No./Reference No. | Author(s)  | Year | Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published | Data Protection Claimed (Yes/No) | Owner                       |
|---------------------------|------------|------|--|----------------------------------|-----------------------------|
| A3_2                      | [REDACTED] | 2009 | Phenothrin: Evaluation of Vapour Pressure  | Y                                | [REDACTED]                  |
| A3_2_1                    | [REDACTED] | 2000 | Henry's Law Constant for d-Phenothrin (Sumithrin®)<br>[REDACTED]                                       | Y                                | Sumitomo Chemical Co., Ltd. |
| A3_3_1                    | [REDACTED] | 2006 | Determination of Physical and Chemical Properties of d-Phenothrin<br>[REDACTED]                        | Y                                | Sumitomo Chemical Co., Ltd  |
| A3_3_2                    | [REDACTED] | 2006 | Determination of Physical and Chemical Properties of d-Phenothrin<br>[REDACTED]                        | Y                                | Sumitomo Chemical Co., Ltd. |
| A3_3_3                    | [REDACTED] | 2006 | Determination of Physical and Chemical Properties of d-Phenothrin<br>[REDACTED]                        | Y                                | Sumitomo Chemical Co., Ltd  |
| A3_4                      | [REDACTED] | 2009 | Sumithrin (d-phenothrin): Evaluation of Selected Physical Chemistry Properties                         | Y                                | [REDACTED]                  |

| Section No./Reference No. | Author(s)   | Year | Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published | Data Protection Claimed (Yes/No) | Owner                       |
|---------------------------|-------------|------|--|----------------------------------|-----------------------------|
|                           | Marshall I. |      |  |                                  | Ltd.                        |
| A3_5                      | [REDACTED]  | 2006 | Determination of Physical and Chemical Properties of d-Phenothrin<br>[REDACTED]                        | Y                                | Sumitomo Chemical Co., Ltd  |
| A3_5                      | [REDACTED]  | 1989 | Water Solubility of Sumithrin®-TGAI.<br>[REDACTED]   | Y                                | Sumitomo Chemical Co., Ltd. |
| A3_7                      | [REDACTED]  | 2006 | Determination of Physical and Chemical Properties of d-Phenothrin<br>[REDACTED]                        | Y                                | Sumitomo Chemical Co., Ltd  |
| A3_7                      | [REDACTED]  | 1989 | Determination of Solubility of Sumithrin® in Organic Solvents<br>[REDACTED]                            | Y                                | Sumitomo Chemical Co., Ltd. |
| A3_9                      | [REDACTED]  | 2006 | Determination of Physical and Chemical Properties of d-Phenothrin<br>[REDACTED]                        | Y                                | Sumitomo Chemical Co., Ltd  |

| Section No./Reference No. | Author(s)  | Year | Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published | Data Protection Claimed (Yes/No) | Owner                       |
|---------------------------|------------|------|--|----------------------------------|-----------------------------|
|                           |            |      | [REDACTED]   |                                  |                             |
| A3_9                      | [REDACTED] | 1989 | Octanol/ Water Partition Coefficient Determination of Sumithrin®<br>[REDACTED]                         | Y                                | Sumitomo Chemical Co., Ltd. |
| A3_10                     | [REDACTED] | 2006 | Determination of Physical and Chemical Properties of d-Phenothrin<br>[REDACTED]                        | Y                                | Sumitomo Chemical Co., Ltd  |
| A3_11                     | [REDACTED] | 2006 | Determination of Physical and Chemical Properties of d-Phenothrin<br>[REDACTED]                        | Y                                | Sumitomo Chemical Co., Ltd. |
| A3_11                     | [REDACTED] | 1988 | Flammability of Sumithrin®<br>[REDACTED]   | Y                                | Sumitomo Chemical Co., Ltd  |
| A3_12                     | [REDACTED] | 2006 | Determination of Physical and Chemical Properties of d-Phenothrin                                      | Y                                | [REDACTED]                  |

| Section No./Reference No. | Author(s)  | Year | Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published | Data Protection Claimed (Yes/No) | Owner                       |
|---------------------------|------------|------|--|----------------------------------|-----------------------------|
|                           |            |      | [REDACTED]   |                                  |                             |
| A3_14                     | [REDACTED] | 2006 | Determination of Physical and Chemical Properties of d-Phenothrin<br>[REDACTED]                        | Y                                | [REDACTED]                  |
| A3_17                     | [REDACTED] | 2005 | Reactivity of Pyrethroids Technical Materials towards Container Materials<br>[REDACTED]                | Y                                | Sumitomo Chemical Co., Ltd. |
| A3_17                     | [REDACTED] | 2005 | Reactivity of Pyrethroids Technical Materials towards Container Materials<br>[REDACTED]                | Y                                | Sumitomo Chemical Co., Ltd  |



## Reference List by Author

| Author(s)  | Section No./Reference No. | Year | Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published | Data Protection Claimed (Yes/No) | Owner                       |
|------------|---------------------------|------|--|----------------------------------|-----------------------------|
| [REDACTED] | A3_17                     | 2005 | Reactivity of Pyrethroids Technical Materials towards Container Materials<br>[REDACTED]                | Y                                | Sumitomo Chemical Co., Ltd  |
| [REDACTED] | A3_1_3                    | 2006 | Determination of Physical and Chemical Properties of d-Phenothrin<br>[REDACTED]                        | Y                                | Sumitomo Chemical Co., Ltd  |
| [REDACTED] | A3_7                      | 1989 | Determination of Solubility of Sumithrin® in Organic Solvents<br>[REDACTED]                            | Y                                | Sumitomo Chemical Co., Ltd. |
| [REDACTED] | A2                        | 2001 | Analysis Results of Recent Batches of [REDACTED] d-Phenothrin)<br>[REDACTED]                           | Y                                | Sumitomo Chemical Co., Ltd. |

|            |         |      |   |   |                                   |
|------------|---------|------|---|---|-----------------------------------|
| [REDACTED] | A3_1_3  | 1988 | Specific Gravity of Sumithrin®<br>[REDACTED]  | Y | Sumitomo<br>Chemical Co.,<br>Ltd. |
| [REDACTED] | A3_11   | 1988 | Flammability of Sumithrin®<br>[REDACTED]  | Y | Sumitomo<br>Chemical Co.,<br>Ltd. |
| [REDACTED] | A3      | 1989 | Determination of Boiling Point/ Boiling Range of<br>Sumithrin®<br>[REDACTED]              | Y | Sumitomo<br>Chemical Co.,<br>Ltd. |
| [REDACTED] | A2      | 2006 | Description of Starting Materials and Manufacturing Process of<br>Sumithrin<br>[REDACTED] | Y | Sumitomo<br>Chemical Co.,<br>Ltd. |
| [REDACTED] | A 3.1.1 | 2009 | Sumithrin (d-phenothrin): Evaluation of Selected Physical<br>Chemistry Properties         | Y | [REDACTED]                        |
| [REDACTED] | A 3.2   | 2009 | Phenothrin: Evaluation of Vapour Pressure   | Y | [REDACTED]                        |

|            |        |      |  |   |                             |
|------------|--------|------|--|---|-----------------------------|
| [REDACTED] | A 3.4  | 2009 | Sumithrin (d-phenothrin): Evaluation of Selected Physical Chemistry Properties | Y | [REDACTED]                  |
| [REDACTED] | A3_9   | 1989 | Octanol/ Water Partition Coefficient Determination of Sumithrin®<br>[REDACTED] | Y | Sumitomo Chemical Co., Ltd. |
| [REDACTED] | A3_5   | 1989 | Water Solubility of Sumithrin®-TGAL<br>[REDACTED]                              | Y | Sumitomo Chemical Co., Ltd. |
| [REDACTED] | A3_2_1 | 2000 | Henry's Law Constant for d-Phenothrin (Sumithrin®)<br>[REDACTED]               | Y | Sumitomo Chemical Co., Ltd. |

Section A4.2(a) Analytical Methods for Detection and Identification

Annex Point IIA4.2

Method Validation for the Analysis of Sumithrin in Soil

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3 REFERENCE

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use only

3.1 Reference

[Redacted text]

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3.2 Data protection

Yes

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3.2.1 Data owner

Sumitomo Chemical Co., Ltd.

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3.2.2

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3.2.3 Criteria for data protection

Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA

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4 GUIDELINES AND QUALITY ASSURANCE

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4.1 Guideline study

No guideline specified.

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The method was originally validated under Report No. ER-MT-8941 and was subsequently modified and revalidated under Report No. 40310 to achieve a lower LOQ of 0.01 mg/kg.

4.2 GLP

[Redacted text]

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4.3 Deviations

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5 MATERIALS AND METHODS

5.1 Preliminary treatment

Non-entry field

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5.1.1 Enrichment

Sumithrin was extracted from soil using methanol. Twenty grams of soil were weighed into a 250-mL polypropylene bottle. Control samples were fortified at this point by application of the appropriate spiking solution directly onto the soil. Forty milliliters of methanol were added to the sample, the jar was capped and placed on a reciprocating shaker for 10 minutes. The sample was then filtered under vacuum through glass-fibre filter paper contained in a Büchner funnel. The liquid portion was collected in a 500-mL separatory funnel. The residue was re-extracted with an additional 40 mL of methanol, filtered, and the extracts combined in the separatory funnel. The sample container and Büchner funnel were rinsed with approximately 30 mL of methanol and the rinse combined with the sample extract.

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5.1.2 Cleanup

The extract was partitioned using 80 mL of a 10% sodium chloride solution and 40 mL of methylene chloride. The methylene chloride was passed through a bed of sodium sulphate to remove water and collected in a 250-mL flat bottom flask. The partitioning was done again using 40 mL of methylene chloride, drained through the sodium sulphate, and collected in the flat bottom flask. The methylene chloride was concentrated to dryness under vacuum with a rotary evaporator and a water bath held at approximately 30 °C.

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