Section A4.1(3) Annex Point IIA4.1 Analytical Methods for Detection and Identification Enforcement Analytical Method for Sumithrin® Technical Grade - Determination of Optical Isomer Ratios

Official use only

1 REFERENCE

1.1	**Reference**	[redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Sumitomo Chemical Co., Ltd.
4.2.3		
4.2.4	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

5 GUIDELINES AND QUALITY ASSURANCE

5.1	**Guideline study**	U.S. EPA Product Properties Test Guidelines OPPTS 830.1800
5.2	**GLP**	[redacted]
5.3	**Deviations**	

6 MATERIALS AND METHODS

6.1	**Preliminary treatment**	*Non-entry field*
6.1.1	Enrichment	Determination of Optical Isomer Ratios Dissolve 0.025 g Sumithrin® T.G. in 100 mL of hexane to prepare a sample solution. Perform the test with 3 µL of the sample solution by HPLC.
6.1.2	Cleanup	No clean-up is required as there are no potentially interfering materials, as standard solutions prepared in solvent are being quantified.
6.2	**Detection**	*Non-entry field*
6.2.1	Separation method	High Performance Liquid Chromatography for the determination of the ratio of optical isomers. Detector: An ultraviolet absorption photometer (wavelength: 230 nm). Column: A stainless steel column (4 mm id. x 25 cm), packed with SUMICHIRAL OA-2000 (5 µm). Connect two columns serially for the analysis. Column temperature: Ambient. Mobile phase: Hexane. Flow rate: Adjust the flow rate so that the retention time of (1*R*)-*trans*-isomer is about 50-60 minutes. Refer to Figure A4_1(3)-1 for a typical chromatogram.
6.2.2	Detector	High Performance Liquid Chromatography (HPLC) employed an ultraviolet absorption photometer (wavelength: 230 nm).
6.2.3	Standard(s)	Approximately 80, 90, 100, 110 and 120 mg of Sumithrin® standard was accurately weighed and dissolved in exactly l0 mL of the internal standard solution (di-(2-ethylhexyl) phthalate) to make calibration

Section A4.1(3) Annex Point IIA4.1 Analytical Methods for Detection and Identification Enforcement Analytical Method for Sumithrin® Technical Grade - Determination of Optical Isomer Ratios

solutions (80- 120 mg/10 mL). The ratio of peak area of Sumithrin® to that of the internal standard was plotted against the amount of Sumithrin® in the solution to make a calibration curve.

The peak areas of *cis*- and *trans*- isomers in the sample solution were measured and calculated using the following equation:-

$$C = \frac{A_{rc} + A_{rt} \times 100}{A_{rc} + A_{sc} + A_{rt} + A_{st}}$$

where, C; (1*R*)-isomer ratio (%).

A_{rc}: peak area of (1*R*)-*cis*-isomer.

A_{sc}: peak area of (1*S*)-*cis*-isomer.

A_{rt}: peak area of (1*R*)-*trans*-isomer.

A_{st}: peak area of (1*S*)-*trans*-isomer.

6.2.4 Interfering substance(s)

No substances are expected to interfere as the standard is prepared in analytical reagent grade hexane. The method developed, adequately separates the active substance from its impurities.

6.3 Linearity

Non-entry field

6.3.1 Calibration range

A calibration curve was not required as this method was developed to compare the ratios of the different isomers and not to quantify the isomers.

6.3.2 Number of measurements

Not applicable. Refer to Section 3.3.1.

6.3.3 Linearity

Not applicable. Refer to Section 3.3.1.

6.4 Specifity: interfering substances

No other substances were found to interfere.

6.5 Recovery rates at different levels

Results for the determination of isomer ratios in the standard mixtures. Refer to Table A4_1(3)-1.

6.5.1 Relative standard deviation

Six separate sub-samples from a sample of Sumithrin® T.G. (250 µg/ml) were analysed according to the analytical method. The results are shown below:-

Analytical Data (%)	Mean (%)	RSD (%)
96.5, 96.5, 96.6 96.6, 96.5, 96.5	96.5	0.1

6.6 Limit of determination

Not applicable, as this method has been developed to determine the optical isomer ratios using a single concentration (250 µg/ml) of Sumithrin® T.G.

6.7 Precision

Non-entry field

6.7.1 Repeatability

Two different analysts analysed the standards and good precision between the results was found, as shown below:-

Analyst	Found Value (%)	Mean (%)	Overall Mean (%)	RSD (%)

Section A4.1(3) Annex Point IIA4.1 Analytical Methods for Detection and Identification Enforcement Analytical Method for Sumithrin® Technical Grade - Determination of Optical Isomer Ratios

A	96.5, 96.5, 96.6 96.6, 96.5, 96.5	96.5	96.6	0.1
B	96.7, 96.6, 96.5	96.6		

6.7.2	Independent laboratory validation	An independent laboratory validation is not required for this type of method.

7 APPLICANT'S SUMMARY AND CONCLUSION

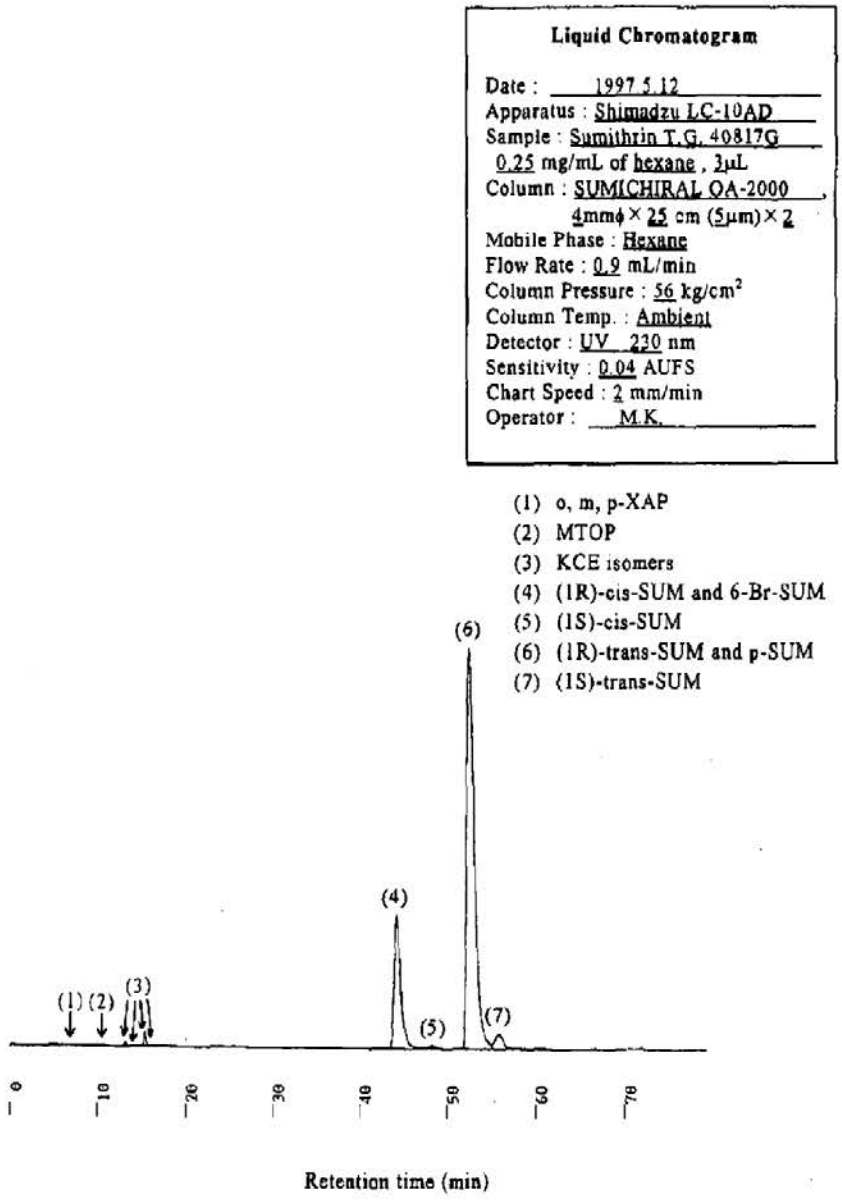
7.1	**Materials and methods**	The method of analysis involves dissolving 0.025 g Sumithrin® T.G. in 100 mL of hexane and determining the ratio of the optical isomers by HPLC-uv.
7.2	**Conclusion**	The method is considered to be acceptable in terms of accuracy, precision and specificity.
7.2.1	Reliability	1
7.2.2	Deficiencies	No

[redacted]

Table A4_1(3)-1 Results for the determination of isomer ratios in the standard mixtures (250 µg/ml)

	Calculated value (%)					Found value %)				
	(1R)-cis	*(1R)-trans*	*(1S)-cis*	*(1S)-trans*	*(1R)* *	*(1R)-cis*	*(1R)-trans*	*(1S)-cis*	*(1S)-trans*	*(1R)* *
1	25.1	73.8	0.6	0.5	98.9	26.1	72.5	0.6	0.8	98.6
2	28.1	67.0	1.0	3.8	95.1	29.2	65.7	1.1	4.1	94.8
3	10.2	80.1	2.0	7.7	90.3	10.6	79.3	2.1	8.1	89.9

Figure A4_1(3)-1 Typical liquid chromatogram for the determination of optical isomer ratio of Sumithrin® T.G.



Section A4.1(6) Analytical Methods for Detection and Identification CIPAC Method 356 - d-Phenothrin

			Official use only
		2 REFERENCE	
7.3	**Reference**	CIPAC (2002), CIPAC Method 356 - d-Phenothrin, CIPAC/4271/m d-Phenothrin Furuta R.(2002), CIPAC Method 356 - d-Phenothrin Small Scale Collaborative Study on the Determination of d-Phenothrin in d-Phenothrin Technical by Gas Chromatography, Environmental Health Science Laboratory, Sumitomo Chemical Co., Ltd, CIPAC/4272/R d-Phenothrin	
7.4	**Data protection**	No	
7.4.1	**Data owner**	CIPAC	
7.4.2			
7.4.3	**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	
		8 GUIDELINES AND QUALITY ASSURANCE	
8.1	**Guideline study**	This method is a CIPAC (Collaborative International Pesticides Analytical Council) method and as such will be tested in many different laboratories to ensure robustness. There is no requirement to perform this study to a guideline.	
8.2	**GLP**	No. Not required for this type of study.	
8.3	**Deviations**	None	
		9 MATERIALS AND METHODS	
9.1	**Preliminary treatment**	Non-entry field	
9.1.1	**Enrichment**	Prepare sample solutions in duplicate for each sample. Weigh (to the nearest 0.1 mg) 90 to 110 mg (*w* mg) of *d*-phenothrin into a vial or stoppered flask (20 ml). Add by pipette internal standard solution (exactly 5 ml) and dissolve completely. Pipet 1 ml of this solution into another vial or stoppered flask (20 ml). Add by measuring cylinder acetone (19 ml) and mix well. Inject in duplicate 1 µl portions of each sample solution bracketing them by injections of the calibration solutions as follows; calibration solution A, sample solution A, sample solution A, calibration solution B, sample solution B, sample solution B, calibration solution A, and so on. Measure the relevant peak areas.	
9.1.2	**Cleanup**	No clean-up is required as the samples are standard solutions.	
9.2	**Detection**	Non-entry field	
9.2.1	**Separation method**	*Give type and conditions* Gas Chromatography is used. Equipment:- Gas chromatograph equipped with a split/splitless injection and a flame ionisation detector.	

Section A4.1(6) Analytical Methods for Detection and Identification CIPAC Method 356 - d-Phenothrin

Capillary column fused silica, length: 30 m x internal diameter: 0.25 mm and film thickness: 0.25 µm, coated with crosslinked 50% phenyl 50% dimethyl polysiloxane (DB-17 or equivalent)
Electric integrator or data system

Gas chromatographic conditions (typical):

Column	fused silica, length: 30 m x internal diameter: 0.25 mm and film thickness: 0.25 µm, coated with crosslinked 50% phenyl 50% dimethyl polysiloxane (DB-17 or equivalent)
Injection system	
Injector	split injection
Sprit flow	approximately 100 ml/min
Injection volume	1 µl
Temperatures	
Column oven	230°C
Injection port	255°C
Carrier gas	helium, 35 cm/sec
Retention times	m-terphenyl : about 8.7 min d-phenothrin : about 21.3 min

9.2.2 Detector

Detector	flame ionisation detection
Detector	255°C

Refer to Figure A4.1(6)-1 for a typical chromatogram.

9.2.3 Standard(s)

Internal standard calibration was employed. The area response ratio versus the standard concentration was used to construct a calibration line.

Calibration Solution Preparation
Prepare calibration solutions in duplicate. Weigh (to the nearest 0.1 mg) 90 to 110 mg (s mg) of d-phenothrin working standard into a vial or stoppered flask (20 ml). Add by pipette internal standard solution (5 ml) and dissolve completely. Pipet 1 ml of this solution into another vial or stoppered flask (20 ml). Add by measuring cylinder acetone (19 ml) and mix well.
Internal standard solution Preparation
Dissolve m-terphenyl (1.7 g) in acetone (100 ml).

9.2.4 Interfering substance(s)

There are no substances expected to interfere.

9.3 Linearity

Non-entry field

9.3.1 Calibration range

Give concentrations which were used for the calibration of the method

Linearity check
Check the linearity of the detector response by injecting 1 µl of solutions with d-phenothrin concentrations 0.5, 1 and 2 times that of the calibration solution before conducting analysis *i.e.* solutions containing 0.5, 1 and 2 mg/ml.

System equilibration
Prepare two calibration solutions. Inject 1 µl portions of the first one

Section A4.1(6) Analytical Methods for Detection and Identification CIPAC Method 356 - d-Phenothrin

until the response factors obtained for two consecutive injections differ by less than 1.0%. Then inject a 1 µl portion of the second solution. The response factor for this solution should not deviate by more than 1.0% from that for the first calibration solution, otherwise prepare new calibration solutions.

9.3.2 Number of measurements

Each standard was injected at least once.

9.3.3 Linearity

The correlation coefficient has not been reported. The method states that linearity must be achieved and that the difference between two injections should be no more than 1%. From this fact it can be deduced that the r^2 value must be approaching 1.000.

9.4 Specifity: interfering substances

There was a small impurity in the internal standard but it did not interfere with the analysis. No other interferences were noted.

9.5 Recovery rates at different levels

Two technical ingredients were analysed by 5 different Laboratories on two separate days with 4 replicates being tested on each occasion.

Different levels were not tested as this is not required for the determination of the active ingredient content.

The results from the analysis of standard 1on Day 1 were as follows:-

Reference	g/kg	Mean	SD
Lab 1	957.5; 960.3	958.9	1.98
Lab 2	964.3; 955.2	959.8	6.43
Lab 3	960.4; 959.7	960.1	0.49
Lab 4	958.1; 957.7	957.9	0.28
Lab 5	957.1; 958.9	958.0	1.27

9.5.1 Relative standard deviation

Refer to table above

9.6 Limit of determination

The limit of determination has not been defined in this study as it is not appropriate.

9.7 Precision

Non-entry field

9.7.1 Repeatability

Refer to Table A4.1(6)-1

9.7.2 Independent laboratory validation

Refer to Table A4.1(6)-1

10 APPLICANT'S SUMMARY AND CONCLUSION

10.1 Materials and methods

Give a short description and discussion of the method (all analytical methods should be summarized in tabular form in the hazard and effects assessment document (see sample table there)

Samples of technical material (d-phenothrin) were dissolved in internal standard solution (m-terphenyl) in acetone. The samples were quantified using gas chromatography (GC) with flame ionisation detection (FID).

Section A4.1(6) Analytical Methods for Detection and Identification CIPAC Method 356 - d-Phenothrin

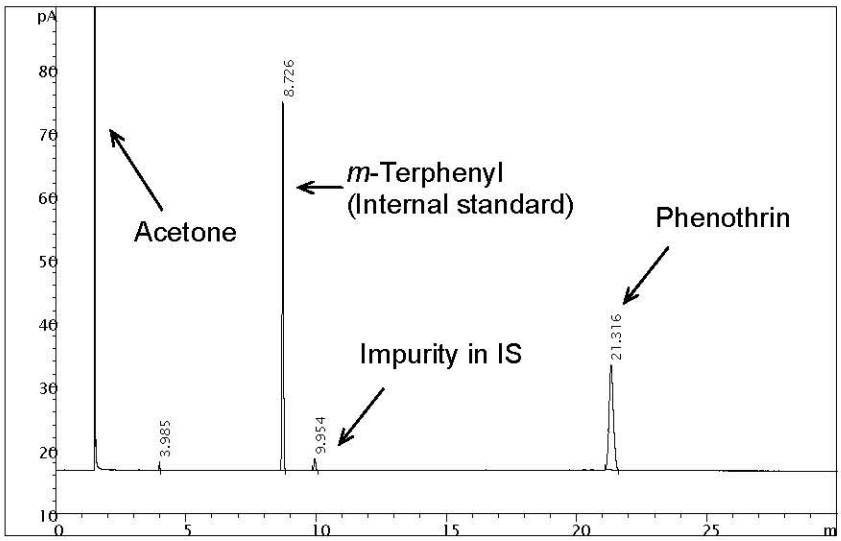
10.2 Conclusion	The method was considered to be acceptable in terms of accuracy and precision, repeatability, linearity and specificity.
10.2.1 Reliability	[redacted]
10.2.2 Deficiencies	[redacted]

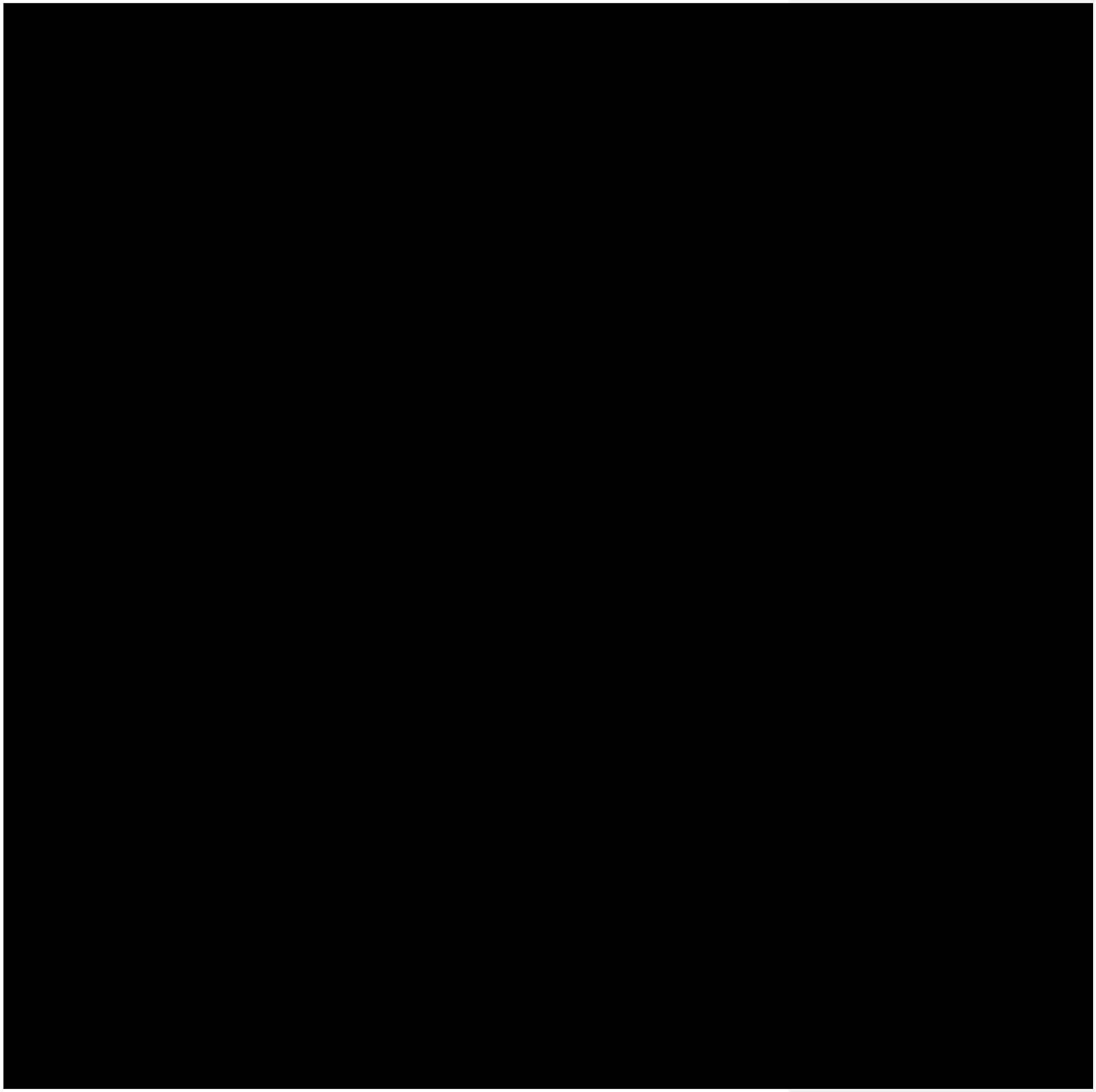
[redacted]

Table A4.1(6)-1 Results of Interlaboratory Trial

Lab.	Day	Technical 1 (g/kg)		Technical 2 (g/kg)		Mean (g/kg)	CV (%)
1	1	957.5	960.3	963.2	964.3	961.3	0.3
	2	960.3	957.0	957.8	957.9	958.3	0.1
2	1	964.3	955.2	963.0	957.6	960.0	0.5
	2	954.8	962.9	960.1	958.1	959.0	0.4
3	1	960.4	959.7	962.1	962.8	961.3	0.2
	2	961.0	959.1	962.3	959.8	960.6	0.1
4	1	958.1	957.7	961.1	959.8	959.2	0.2
	2	960.7	963.4	960.5	962.2	961.7	0.1
5	1	957.1	958.9	961.6	960.6	959.6	0.2
	2	959.9	953.5	956.9	960.9	957.8	0.3

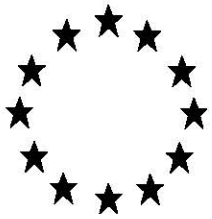
Figure A4.1(6)-1 Typical Chromatogram





Competent Authority Report

Programme for Inclusion of Active Substances in Annex I to Council Directive 98/8/EC



d-Phenothrin (PT 18)

DOCUMENT IIIA (A5)

Evaluation Report

Sumitomo Chemical (UK) Plc

Rapporteur: Ireland

August 2010

Table of contents Doc III, section A5

Section A5 Effectiveness against target organisms and intended uses

5.1 Function

5.1	**Function (IIA5.1)**	Main Group:- 3 Pest Control Product Type:- 18 Insecticide	

5.2 Organism(s) to be controlled and products, organisms or objects to be protected

5.2	**Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**		
5.2.1	**Organism(s) to be controlled (IIA5.2)**	The formulation is intended to be used for the control of crawling insects e.g. cockroaches [redacted] Crawling insects e.g. Blattodea = Code I.3.4 *Blattellidae* - Blattellid cockroaches *(e.g.* German Cockroach *(Blattella germanica)* = Code I.3.4.1 *Blattidae* - Blattid cockroaches *(e.g.* American Cockroach *(Periplaneta Americana)* = Code I.3.4.2 Oriental Cockroaches - *Blatta Orientalis* Flying Insects e.g. house fly – *Musca domestica* Code I.3.12.6 [redacted]	
5.2.2	**Products, organisms or objects to be protected (IIA5.2)**	Method of application Spraying = Code VI.1 Application Aim Health protection = Code VII.2	

5.3 Effects on target organisms, and likely concentration at which the active substance will be used

5.3	**Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**		
5.3.1	**Effects on target organisms (IIA5.3)**	Refer to the Table for section 5.3 at the end of this document.	X

Section A5 Effectiveness against target organisms and intended uses

5.3.2	**Likely concentrations at which the A.S. will be used (IIA5.3)**		
	PT18	PT18 Insecticide Crawling Insects For the control of cockroaches use 1 part of Sumithrin® 10 SEC diluted with 150-250 parts of water and applied by knapsack or power sprayer at the rate of 50 ml/square metre to give a maximum of 33 mg a.i. per square metre (0.07% a.i.). For the ultra low volume (ULV) application, Sumithrin 10 SEC should be diluted with an equal quantity of water and applied at the rate of 20 ml per 100 square metres or 0.08 ml/cubic metre via microgen E2, G2, 67 or 69 ULV equipment to give a maximum of 10 mg a.i. per square metre (5.25% a.i.). Flying Insects For the control of flying insects (flies, mosquitoes) use 1 part of sumithrin 10 SEC diluted with 250-500 parts of water and apply by knapsack or power sprayer at a rate of 50 ml/square metre to give a maximum of 20 mg a.i. per square metre for flying insects (0.04% a.i.).	

5.4 Mode of action (including time delay)

5.4	**Mode of action (including time delay) (IIA5.4)**		
5.4.1	**Mode of action**	d-Phenothrin is an acute toxin = Code III.1 It has the following effects:- • Contact Toxin = III 1.3 • lethal effect = III 1.4 • Knockdown effect = III 1.5 • Flushing effect = III 1.6 Pyrethroids modify the gating characteristics of voltage-sensitive sodium channels in mammalian and invertebrate neuronal membranes ([redacted] 1989) to delay their closure. This results in severe disturbances of synaptic transmission ([redacted] 1989). These effects on sodium channels are common to all pyrethroids although specific effects of type I pyrethroids such as d-Phenothrin have been clarified in experimental studies. These show that type I compounds keep sodium channels open ([redacted] 1989)	x
5.4.2	**Time delay**	There is no significant time delay in the action of d-Phenothrin. Pyrethroids are *ca* 2250 times more toxic to insects than mammals. This can be explained in terms of differences in their potency as neuronal toxins and differences in rates of detoxification between invertebrates and vertebrates ([redacted] 1996). The sensitivity of invertebrate neuronal sodium channels to pyrethroids is ten times greater than in mammals ([redacted], 1996). Furthermore, invertebrates typically have body temperatures some 10°C lower than mammals and *in vitro* studies	

Section A5 Effectiveness against target organisms and intended uses

show tetramethrin to be more potent at evoking repetitive neuronal discharges at lower temperatures ([redacted] 1996). In these experiments it was noted that the recovery of sodium channels from tetramethrin intoxication after washing was some five times faster in mammals than invertebrates. In addition pyrethroid hepatic metabolism (detoxification) is faster in mammals. Finally small insect size increases the likelihood of end-organ (neuronal) toxicity prior to detoxification ([redacted] 1996).

5.5 Field of use envisaged

5.5 Field of use envisaged (IIA5.5)	
[redacted]	[redacted]
MG03: Pest control	The product is intended to be used indoors = Code IV.1 There is no potential for contamination outdoors – Code IV.1.1.2 There is no potential for contamination of food = Code IV.1.2.2. The product is intended to be used in the following sites:- Industrial/commercial premises = Code IV 1.3.1 Households/private area = Code IV 1.3.2 Public areas (e.g Clinics, Nursery Houses, Kindergarten,) = Code IV 1.3.3
MG04: Other biocidal products	Not supported
Further specification	The product is a liquid formulation (Code VIII.3). It will be sold as a concentrate (Code VIII.3.1). The concentrate is an emulsion/ microemulsion (Code VIII.3.1.2).

5.6 User

5.6 User (IIA5.6)	
Industrial	*[The inclusion of further exposure information is possible, see e.g. EASE (LEV, Full containment etc.)]* Not applicable.
Professional	Code = V.2 Sumithrin 10 SEC is to be used by professional pest control operators in kitchens, food processing factories, trains, trucks, hospitals, restaurants, food shops, hotels and other public buildings.
General public	Professional use only, therefore not applicable.

5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies

Section A5 Effectiveness against target organisms and intended uses

5.7 Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)		
5.7.1 Development of resistance	There are no reported cases of resistance developing.	[redacted]
5.7.2 Management strategies	The product should only be used when there is a cockroach infestation and should be used in areas where cockroaches are sighted. These conditions should limit resistance occurring. In addition for flying insects the spray should only be used where flying insects are considered a pest.	[redacted]

5.8 Likely tonnage to be placed on the market per year

5.8 Likely tonnage to be placed on the market per year (IIA5.8)	The information is in Annex Confidential Data and Information.

Section A5 Effectiveness against target organisms and intended uses

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
[redacted]	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*

Formatted: Font: 10 pt
Formatted: Font: Not Italic
Formatted: Font: 10 pt
Formatted: Font: Not Italic
Formatted: Font: 10 pt
Formatted: Font: Not Italic
Formatted: Font: 10 pt
Formatted: Font: Not Italic
Formatted: Font: 10 pt
Formatted: Font: Not Italic
Formatted: Font: 10 pt
Formatted: PCS Normal
Formatted: Font: 10 pt, Font color: Auto, English (Ireland)

Section A5 Effectiveness against target organisms and intended uses

Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 5.3: Summary table of experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged, where applicable

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
Include respective code(s) for function type(s) given in section 5.1	*Include respective code(s) for product type(s) given in section 5.5*	*Describe specification if deviating from that given in section 2*	*Specify species, strain, sex, weight, growth stage etc. as appropriate*	*Shortly describe test system and application method used in the tests*	*Shortly describe test conditions including concentrations applied and exposure time*	*Describe relevant results; quantify the effects on target organisms; indicate the dependence on the concentrations of the A.S. and the possible existence of a threshold concentration.* *Also describe if results indicate the mode of action and/or the development of resistance.*	*Only author(s) and year of publication / report; full bibliographic data in footnote*
PT18	EC	As per Section 2	German cockroaches *(Blattella germanica)*	A flushing out and knockdown test were performed. 10 cockroaches were released into the shelter and allowed to acclimatise for 3 days. [redacted]	A water based aerosol was tested containing Sumithrin 2% w/v. [redacted]	[redacted] This shows that Sumithrin 2% w/v aerosol is effective in killing cockroaches.	[redacted]
PT18	EC	As per Section 2	American and German cockroaches (*Periplaneta americana* and *Blattella Germanica*)	A field test was performed to assess mortality rates in cockroaches by comparing d-Phenothrin permethrin and phenothrin/ allerthrin. 4 test areas were identified and the houses were	0.5% d-Phenothrin was used. [redacted]	207 german cockroaches died on day 1 and 1 died on day 2. For the American cockroaches all of them died on day 1 [redacted]	[redacted]

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
				sprayed. The traps were placed in the houses and the number of dead cockroaches present was monitored over a 3 day period.		[redacted]	
PT18	EC	As per Section 2	German cockroaches *(Blattella germanica)*	An LD_{50} test was performed using Sumithrin [redacted] Knock down and flushing out ability were also assessed.	The knock down and flushing out ability of Sumithrin was assessed over a range of concentrations; 0.2, 0.25 and 0.5 %.	The LD [redacted] was 0.98ug/cockroach. [redacted]	[redacted]
PT18	EC	As per Section 2	German cockroaches *(Blattella germanica)*	The test item was assessed on a glass surface, a filter paper surface and a glass surface with an opening in it to simulate cracks and crevices.	The knockdown and mortality were assessed following an application of 20 g (2.8 g a.i.) sumithrin. [redacted]	Knockdown KT50 was reached at 16.0, 48.0 and 59.0 min for the glass surface, filter paper surface and glass surface with opening, respectively. [redacted]	[redacted]
PT18	EC	As per Section 2	Housefly (*Musca domestica*) and	The Peet grady chamber method was used.	The knockdown time and percentage mortality determined. The effect of	Sumithrin 0.2% was comparable to [redacted] for the housefly and exceeded [redacted]	[redacted]

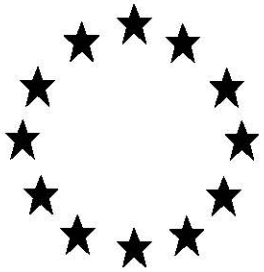
Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference
			Mosquito (*Culex pipiens pallens*)		Sumithrin 0.1% and 0.2% [redacted]	[redacted] for mosquitoes. No resistance was observed.	
PT18	EC	As per Section 2	Housefly (*Musca domestica*)	Three replicates each containing 100 flies were tested using Sumithrin 10 SEC 0.4 ml/m^3. [redacted]	Test performed in a room 36 m^3; temperature 26°C; relative humidity 70-80%.	Total efficacy (100% mortality) was established for all replicates. [redacted]	

References:

- [redacted]

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

DOCUMENT III-A6

Toxicological and Metabolic Studies

Rapporteur Member State: Ireland

August 2010

Table of contents Doc III, section A6

Section A6.1.1 Acute oral toxicity

Annex Point IIA6.1 **Acute oral toxicity in the rat (Limit Test)**

IUCLID 5.1.1/1

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Sumitomo Chemicals Co., Ltd.	
1.2.2	Companies with letter of access	Sumitomo Chemical (UK) PLC.	
1.2.3	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.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	The study report claims compliance with EPA Pesticide Assessment Guidelines, Subdivision F, 81-1 (1984). See point 2.3.	
2.2	**GLP**	Yes	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted] d-Phenothrin	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification		
3.1.2.1	Description	Not described.	
3.1.2.2	Purity	[redacted]	
3.1.2.3	Stability	Not reported.	

Section A6.1.1 Acute oral toxicity

Annex Point IIA6.1 **Acute oral toxicity in the rat (Limit Test)**

IUCLID 5.1.1/1

3.2	**Test Animals**	Non-entry field
3.2.1	Species	Rat
3.2.2	Strain	[redacted]
3.2.3	Source	[redacted]
3.2.4	Sex	[redacted]
3.2.5	Age/weight at study initiation	The body weight of animals at dosing ranged from 211 to 230 g for males and from 162 to 182 g for females. [redacted]
3.2.6	Number of animals per group	[redacted]
3.2.7	Control animals	Yes
3.3	**Administration/ Exposure**	Oral
3.3.1	Postexposure period	14 days
3.3.2	Type	[redacted]
3.3.3	Concentration	0 or 5000 mg/kg bw.
3.3.4	Vehicle	None
3.3.5	Concentration in vehicle	Not applicable.
3.3.6	Total volume applied	[redacted]
3.3.7	Controls	No treatment control.
3.4	**Examinations**	[redacted]
3.5	**Method of determination of LD_{50}**	Not applicable (Limit Test).
3.6	**Further remarks**	None

Section A6.1.1 Acute oral toxicity

Annex Point IIA6.1 **Acute oral toxicity in the rat (Limit Test)**

IUCLID 5.1.1/1

RESULTS AND DISCUSSION

3.7	**Clinical signs**	There were no test material related deaths or clinical signs.
3.8	**Pathology**	No treatment-related findings were observed by gross pathological examination.
3.9	**Other**	Bodyweight [redacted]
3.10	**LD_{50}**	The LD_{50} of the test material was greater than 5000 mg/kg bw. [redacted]

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	[redacted]
4.2	**Results and discussion**	[redacted]
4.3	**Conclusion**	The acute oral LD_{50} of the test material in the rat was greater than 5000 mg/kg bw. In this study [redacted] does not meet the criteria for classification for acute oral toxicity according to Annex VI of Commission Directive 2001/59/EC.
4.3.1	Reliability	[redacted]
4.3.2	Deficiencies	[redacted]

Section A6.1.1 Acute oral toxicity

Annex Point IIA6.1 **Acute oral toxicity in the rat (Limit Test)**

IUCLID 5.1.1/1

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
[redacted]	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

[redacted]

Section A6.1.2 Acute dermal toxicity

Annex Point IIA6.1.2 **Acute dermal toxicity study in the rat (Limit Test)**

IUCLID 5.1.3/1

			Official use only
		1 REFERENCE	
Reference		[redacted]	
1.1	**Data protection**	Yes	
1.1.1	Data owner	Sumitomo Chemicals Co., Ltd.	
1.1.2	Companies with letter of access	Sumitomo Chemical (UK) PLC.	
1.1.3	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.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	[redacted] A review of the study report revealed that this study also meets the requirements of OECD test Guideline 402 (adopted 24 February 1987). [redacted]	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted] d-Phenothrin	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	X
3.1.2.1	Description	Not provided.	
3.1.2.2	Purity	[redacted]	
3.1.2.3	Stability	Not reported.	

Section A6.1.2 Acute dermal toxicity

Annex Point IIA6.1.2 **Acute dermal toxicity study in the rat (Limit Test)**

IUCLID 5.1.3/1

3.2	**Test Animals**	Non-entry field
3.2.1	Species	Rat
3.2.2	Strain	[redacted]
3.2.3	Source	[redacted]
3.2.4	Sex	Males and females.
3.2.5	Age/weight at study initiation	[redacted]
3.2.6	Number of animals per group	[redacted]
3.2.7	Control animals	Yes
3.3	**Administration/ Exposure**	Dermal
3.3.1	Postexposure period	14 days
3.3.2	Area covered	*ca.* 30 cm^2
3.3.3	Occlusion	[redacted]
3.3.4	Vehicle	
3.3.5	Concentration in vehicle	Not applicable.
3.3.6	Total volume applied	4.72 ml/kg bw.
3.3.7	Duration of exposure	24 h
3.3.8	Removal of test substance	The area was cleaned with absorbent cotton dipped in diethyl ether.
3.3.9	Controls	Yes
3.4	**Further remarks**	[redacted]

Section A6.1.2 Acute dermal toxicity

Annex Point IIA6.1.2 **Acute dermal toxicity study in the rat (Limit Test)**

IUCLID 5.1.3/1

RESULTS AND DISCUSSION.

3.5 Clinical signs

[redacted]

3.6 Pathology

[redacted]

3.7 Other

[redacted]

3.8 LD_{50}

The acute dermal LD_{50} of the test material, in [redacted] male and female rat was found to be greater than 5000 mg/kg bw.

[redacted]

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

[redacted]

4.2 Results and discussion

[redacted]

4.3 Conclusion

The acute dermal LD_{50} of the test material in the [redacted] male and female rat was found to be greater than 5000 mg/kg bw.

In this study, Sumithrin® does not meet the criteria for classification for acute dermal toxicity according to Annex VI of Commission Directive 2001/59/EC.

4.3.1 Reliability

[redacted]

4.3.2 Deficiencies

Section A6.1.2 Acute dermal toxicity

Annex Point IIA6.1.2 **Acute dermal toxicity study in the rat (Limit Test)**

IUCLID 5.1.3/1

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.1.3 Acute inhalation toxicity

Annex Point IIA6.1 **Acute inhalation toxicity study in the rat (Limit Test)**

IUCLID 5.1.2/1

			Official use only
		5 REFERENCE	
1.1	**Reference**	[redacted]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Sumitomo Chemicals Co., Ltd.	
1.2.2	Companies with letter of access	Sumitomo Chemical (UK) PLC.	
1.2.3	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.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	[redacted] These guidelines are comparable with OECD Test Guideline 403 "Acute Inhalation Toxicity" (adopted 12 May 1981).	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	X
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted] Phenothrin	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	X
3.1.2.1	Description	[redacted]	
3.1.2.2	Purity	[redacted]	
3.1.2.3	Stability	[redacted]	

Section A6.1.3 Acute inhalation toxicity

Annex Point IIA6.1 **Acute inhalation toxicity study in the rat (Limit Test)**

IUCLID 5.1.2/1

3.2	**Test Animals**	Non-entry field
3.2.1	Species	Rat
3.2.2	Strain	[redacted]
3.2.3	Source	[redacted]
3.2.4	Sex	Male and Female.
3.2.5	Age/weight at study initiation	[redacted]
3.2.6	Number of animals per group	
3.2.7	Control animals	No
3.3	**Administration/ Exposure**	Inhalation
3.3.1	Postexposure period	14 days
3.3.2	Concentrations	[redacted]
3.3.3	Particle size	[redacted]
3.3.4	Type or preparation of particles	The test material was generated into the breathing zone of the animals as a liquid aerosol.
3.3.5	Type of exposure	Whole body.
3.3.6	Vehicle	None
3.3.7	Concentration in vehicle	Not applicable.
3.3.8	Duration of exposure	4 h
3.3.9	Controls	None

Section A6.1.3 Acute inhalation toxicity

Annex Point IIA6.1 **Acute inhalation toxicity study in the rat (Limit Test)**

IUCLID 5.1.2/1

3.4	**Method of determination of LD_{50}**	Not applicable (Limit Test).
3.5	**Examinations**	[redacted]
3.6	**Further remarks**	None

RESULTS AND DISCUSSION

3.7	**Clinical signs**	[redacted]
3.8	**Pathology**	
3.9	**Other**	[redacted]
3.10	**LD_{50}**	The acute inhalation LC_{50} (4 h) in [redacted] rat was found to be greater than 2.1 mg/l.

[redacted]

4 APPLICANT'S SUMMARY AND CONCLUSION

Section A6.1.3 Acute inhalation toxicity

Annex Point IIA6.1 **Acute inhalation toxicity study in the rat (Limit Test)**

IUCLID 5.1.2/1

4.1	**Materials and methods**	[redacted]	
4.2	**Results and discussion**	[redacted]	
4.3	**Conclusion**	The acute inhalation LC_{50} (4 h) in [redacted] rats was found to be greater than 2.1 mg/l. Therefore, Sumithrin does not meet the criteria for classification for acute inhalation toxicity according to Annex VI of Commission Directive 2001/59/EC.	X
4.3.1	Reliability	[redacted]	
4.3.2	Deficiencies		

Evaluation by Competent Authorities
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
EVALUATION BY RAPPORTEUR MEMBER STATE [redacted]

Section A6.1.3 Acute inhalation toxicity

Annex Point IIA6.1 **Acute inhalation toxicity study in the rat (Limit Test)**

IUCLID 5.1.2/1

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	
Remarks	None
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.1.4(1) Acute dermal irritation

Annex Point IIA6.1.4 **Acute dermal irritation study in the rabbit**

IUCLID 5.2.1/1

			Official use only
		6 REFERENCE	
1.1	**Reference**	[redacted]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Sumitomo Chemicals Co., Ltd.	
1.2.2	Companies with letter of access	Sumitomo Chemical (UK) PLC.	
1.2.3	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.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	[redacted] OECD Test Guideline 404 "Acute Dermal Irritation/Corrosion" (adopted 24 April 2002) (see point 2.3).	
2.2	**GLP**	[redacted]	X
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted] d-Phenothrin.	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	X

Section A6.1.4(1) Acute dermal irritation

Annex Point IIA6.1.4 **Acute dermal irritation study in the rabbit**

IUCLID 5.2.1/1

		[redacted]
3.1.2.1	Description	Not available.
3.1.2.2	Purity	[redacted]
3.1.2.3	Stability	Not available.
3.2	**Test Animals**	*Non-entry field*
3.2.1	Species	Rabbit
3.2.2	Strain	[redacted]
3.2.3	Source	[redacted]
3.2.4	Sex	Males and females.
3.2.5	Age/weight at study initiation	[redacted]
3.2.6	Number of animals per group	[redacted]
3.2.7	Control animals	No
3.3	**Administration/ Exposure**	Dermal
3.3.1	Application	*Non entry field*
3.3.1.1	Preparation of test substance	The test material (liquid) was applied without vehicle.
3.3.1.2	Test site and Preparation of Test Site	The dorsal hair of rabbits was clipped by using an electric clipper. Two application sites on the back were prepared, and one of the sites was abraded in the "#" shape by using a 18 G needle. The other site remained untreated. The scratches were deep enough to disturb the stratum corneum, but not the dermis.
3.3.2	Occlusion	[redacted].
3.3.3	Vehicle	None
3.3.4	Concentration in vehicle	Not applicable.
3.3.5	Total volume applied	[redacted].
3.3.6	Removal of test substance	The treated area was wiped with absorbent cotton [redacted]
3.3.7	Duration of exposure	4 h
3.3.8	Postexposure period	72 h
3.3.9	Controls	No
3.4	**Examinations**	
3.4.1	Clinical signs	No

Section A6.1.4(1) Acute dermal irritation

Annex Point IIA6.1.4	**Acute dermal irritation study in the rabbit**
IUCLID 5.2.1/1	

3.4.2	Dermal examination	Yes
3.4.2.1	scoring system	Skin reactions of erythema and oedema were scored according to the method of Draize.
3.4.2.2	Examination time points	4.5, 24, 48 and 72 hours after application*. *It is not clear if this is the time after the beginning or the end of the 4h application period.
Other examinations		None
3.5	**Further remarks**	None
		RESULTS AND DISCUSSION
3.6	**Average score**	*Non-entry field*
3.6.1	Erythema	[redacted]
3.6.2	Edema	[redacted]
3.7	**Reversibility**	[redacted] No skin irritation seen.
3.8	**Other examinations**	None.
3.9	**Overall result**	No irritation was noted at any time during the study. [redacted]
		4 APPLICANT'S SUMMARY AND CONCLUSION
4.1	**Materials and methods**	[redacted]
4.2	**Results and discussion**	No irritation was noted at any time during the study.
4.3	**Conclusion**	Following a 4 h occlusive exposure, the test material was found to be non-irritant to the rabbit skin. In this study, Sumithrin® does not meet the criteria for classification for dermal irritation according to Annex VI of Commission Directive 2001/59/EC.

Section A6.1.4(1) Acute dermal irritation

Annex Point IIA6.1.4 **Acute dermal irritation study in the rabbit**

IUCLID 5.2.1/1

4.3.1	Reliability	1
4.3.2	Deficiencies	No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
[redacted]	[redacted]
Results and discussion	[redacted]
Conclusion	
Reliability	[redacted]
Acceptability	
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 6.1.4(2) Acute eye irritation

Annex Point IIA6.1.4 **Acute eye irritation study in the rabbit**

IUCLID 5.2.2/1

			Official use only
		7 REFERENCE	
7.1	**Reference**	[redacted]	
7.2	**Data protection**	Yes	
7.2.1	Data owner	Sumitomo Chemicals Co., Ltd.	
7.2.2	Companies with letter of access	Sumitomo Chemical (UK) PLC.	
7.2.3	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.	
		8 GUIDELINES AND QUALITY ASSURANCE	
8.1	**Guideline study**	[redacted] OECD Test Guideline 405: Acute Eye Irritation/Corrosion (adopted 24 April 2002) (see point 2.3).	
8.2	**GLP**	[redacted]	X
8.3	**Deviations**	[redacted]	
		9 MATERIALS AND METHODS	
9.1	**Test material**	[redacted] d-Phenothrin).	
9.1.1	Lot/Batch number	[redacted]	
9.1.2	Specification	[redacted]	X
9.1.2.1	Description	Not available.	
9.1.2.2	Purity	[redacted]	
9.1.2.3	Stability	Not available.	

Section 6.1.4(2) Acute eye irritation

Annex Point IIA6.1.4 **Acute eye irritation study in the rabbit**

IUCLID 5.2.2/1

9.2	**Test Animals**	Non-entry field
9.2.1	Species	Rabbit
9.2.2	Strain	[redacted]
9.2.3	Source	[redacted]
9.2.4	Sex	Male and Female
9.2.5	Age/weight at study initiation	[redacted]
9.2.6	Number of animals per group	[redacted]
9.2.7	Control animals	No
9.3	**Administration/ Exposure**	Ocular
9.3.1	Preparation of test substance	Test substance was used as delivered.
9.3.2	Amount of active substance instilled	[redacted]
9.3.3	Exposure period	The treated eyes remained unwashed.
9.3.4	Postexposure period	72 hrs.
9.4	**Examinations**	
9.4.1	Ophthalmoscopic examination	Yes, however, examination procedure not described.
9.4.1.1	Scoring system	The grading and scoring of irritating reactions were performed in accordance with the scale of Draize.
9.4.1.2	Examination time points	1, 24, 48 and 72 h.
9.4.2	Other investigations	None
9.5	**Further remarks**	None

Section 6.1.4(2) Acute eye irritation

Annex Point IIA6.1.4 **Acute eye irritation study in the rabbit**

IUCLID 5.2.2/1

RESULTS AND DISCUSSION

9.6	**Clinical signs**	Not reported.
9.7	**Average score**	Non-entry field
9.7.1	Cornea	[redacted]
9.7.2	Iris	
9.7.3	Conjunctiva	Non-entry field
9.7.3.1	Redness	[redacted]
9.7.3.2	Chemosis	
9.8	**Reversibility**	
9.9	**Other**	None
9.10	**Overall result**	[redacted]

The irritating potency of the material was judged to be minimal.

10 APPLICANT'S SUMMARY AND CONCLUSION

10.1 Materials and methods

[redacted]

10.2 Results and discussion

[redacted]

Section 6.1.4(2) Acute eye irritation

Annex Point IIA6.1.4 **Acute eye irritation study in the rabbit**

IUCLID 5.2.2/1

		[redacted]
10.3	**Conclusion**	The irritating potency of the test material was judged to be minimal. Sumithrin® does not meet the criteria for classification for eye irritation according to Annex VI of Commission Directive 2001/59/EC.
10.3.1	Reliability	[redacted]
10.3.2	Deficiencies	

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A6.1.5 Skin sensitisation Guinea pig maximisation test (GPMT)

Annex Point IIA6.1.5

IUCLID 5.3/1

			Official use only
		11 REFERENCE	
1.1	**Reference**	[redacted]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Sumitomo Chemicals Co., Ltd.	
1.2.2	Companies with letter of access	Sumitomo Chemical (UK) PLC.	
1.2.3	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.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	[redacted] A review of the study report revealed minor deviations from OECD Test Guideline 406: Skin sensitisation (adopted 17 July 2002) (see point 2.3).	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	X
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted] d-Phenothrin).	
3.1.1	Lot/Batch number	[redacted]	

Section A6.1.5 Skin sensitisation Guinea pig maximisation test (GPMT)

Annex Point IIA6.1.5

IUCLID 5.3/1

3.1.2	Specification	[redacted]	X
3.1.2.1	Description	Not provided.	
3.1.2.2	Purity	[redacted].	
3.1.2.3	Stability	Not provided.	
3.1.2.4	Preparation of test substance for application	Intradermal induction: 5% solution of test material [redacted] Dermal induction and challenge: test material applied undiluted.	
3.1.2.5	Pretest performed on irritant effects	Yes	
3.2	**Test Animals**	Non-entry field	
3.2.1	Species	Guinea Pig	
3.2.2	Strain	[redacted]	
3.2.3	Source	[redacted]	
3.2.4	Sex	[redacted]	
3.2.5	Age/weight at study initiation	[redacted]	
3.2.6	Number of animals per group	[redacted]. DNCB positive control [redacted].	
3.2.7	Control animals	Yes	
3.3	**Administration/ Exposure**	[redacted]	
3.3.1	Induction schedule	Day 0: Intradermal induction Day 6: Topical pre-treatment with irritating substance Day 7: Topical induction [redacted]	
3.3.2	Way of Induction	Intradermal induction followed by a topical (occlusive) induction.	
3.3.3	Concentrations used for induction	Intradermal induction: 5 % w/w in corn oil. Topical induction: 0.4 ml undiluted test material.	
3.3.4	Concentration Freunds Complete Adjuvant (FCA)	Freund's Complete Adjuvant plus distilled water in the ratio of 1:1.	
3.3.5	Challenge schedule	Day 21: Topical challenge. [redacted]	
3.3.6	Concentrations used for challenge	0.2 ml undiluted test material.	
3.3.7	Rechallenge	No	
3.3.8	Scoring schedule	24 and 48h after challenge.	

Section A6.1.5 Skin sensitisation		Guinea pig maximisation test (GPMT)
Annex Point IIA6.1.5		
IUCLID 5.3/1		
3.3.9	Removal of the test substance	Not described.
3.3.10	Positive control substance	2,4-Dinitrochlorobenzene [redacted]
3.4	**Examinations**	Non-entry field
3.4.1	Pilot study	[redacted]
3.5	**Further remarks**	[redacted]

RESULTS AND DISCUSSION

3.6	**Results of pilot studies**	[redacted]
3.7	**Results of test**	
3.7.1	24h after challenge	[redacted] 0/20 animals with allergic reactions.
3.7.2	48h after challenge	[redacted] 0/20 animals with allergic reactions.
3.7.3	Other findings	None
3.8	**Overall result**	Under the conditions of this test, Sumithrin® produced a 0 % (0/20) sensitisation rate.

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1	**Materials and methods**	[redacted]

Section A6.1.5 Skin sensitisation	Guinea pig maximisation test (GPMT)
Annex Point IIA6.1.5	
IUCLID 5.3/1	

[redacted]

4.2 Results and discussion

Challenge

[redacted]

4.3 Conclusion

Under the conditions of this test the test material produced a 0 % (0/20) sensitisation rate.

Sumithrin® did not meet the criteria for classification as a sensitiser by skin contact according to labelling regulations outlined in Annex VI of Commission Directive 2001/59/EC.

Section A6.1.5 Skin sensitisation	Guinea pig maximisation test (GPMT)
Annex Point IIA6.1.5	
IUCLID 5.3/1	

4.3.1 Reliability [redacted]

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
Reliability	
Acceptability	[redacted]
[redacted]	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section 6.2.1Metabolism studies in mammals

Section A6.2(1) **Metabolism studies in mammals**

Annex Point IIA6.2 **Metabolism study in the rat**

IUCLID 5.0/1

			Official use only
		12 REFERENCE	
1.1	**Reference**	[redacted]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Sumitomo Chemical Co., Ltd.	
1.2.2	Companies with letter of access	Sumitomo Chemical (UK) PLC.	
1.2.3	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.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	[redacted]	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	**Radiolabelled test material 1**		
3.1.1.1	Description	Not provided.	
3.1.1.2	Lot/Batch number	[redacted]	
3.1.1.3	Purity	[redacted]	
3.1.1.4	Stability	[redacted]	
3.1.2	**Radiolabelled test material 2**		
3.1.2.1	Description	Not provided	
3.1.2.2	Lot/Batch number	[redacted]	
3.1.2.3	Purity	[redacted]	

Section A6.2(1) **Metabolism studies in mammals**
Annex Point IIA6.2 **Metabolism study in the rat**
IUCLID 5.0/1

3.1.2.4	Stability	[redacted]
3.1.3	**Non-radiolabelled test material 1**	[redacted]
3.1.3.1	Description	Not provided.
3.1.3.2	Lot/Batch number	[redacted]
3.1.3.3	Purity	[redacted]
3.1.3.4	Stability	[redacted]
3.1.4	**Non-radiolabelled test material 2**	[redacted]phenothrin
3.1.4.1	Description	Not provided
3.1.4.2	Lot/Batch number	[redacted]
3.1.4.3	Purity	[redacted]
3.1.4.4	Stability	[redacted]
3.2	**Test Animals**	*Non-entry field*
3.2.1	Species	Rat
3.2.2	Strain	[redacted]
3.2.3	Source	[redacted]
3.2.4	Sex	[redacted]
3.2.5	Age/weight at study initiation	[redacted]
3.2.6	Number of animals per group	[redacted]
3.2.7	Control animals	None
3.3	**Administration/ Exposure**	Oral
3.3.1	Duration of treatment	Single application Single radioactive dose Repeat application One radioactive dose after 14 consecutive daily non-radioactive doses.
3.3.2	Post-exposure period	7 days
3.3.3	Type	Gavage
3.3.4	Concentration	Single application 4 or 200 mg/kg bw.

		Repeat application 4 mg/kg bw	
3.3.5	Vehicle	[redacted]	
3.3.6	Total volume applied	[redacted]	
3.4	**Examinations**		
3.4.1	Sampling	[redacted]	
3.4.2	Analytics	[redacted]	X

RESULTS AND DISCUSSION

3.5 ^{14}C Excretion

[redacted]

^{14}C-recoveries with [redacted] isomers in male rats were 99.5% (faeces; 61.3% and urine; 38.2%) and 100.2% (faeces; 82.1% and urine; 18.1%) for low dose and 94.4% (faeces; 55.9% and urine; 38.5%) and 98.5% (faeces; 86.5% and urine; 12.0%) for high dose, respectively. In female rats, ^{14}C-recoveries with [redacted] isomers were 100.5% (faeces; 60.3% and urine; 40.1%) and 96.1% (faeces; 80.5% and urine; 15.6%) for low dose and 94.3% (faeces; 69.0% and urine; 25.3%) and 97.4% (faeces; 86.6% and urine; 10.8%) for high dose, respectively. Faecal ^{14}C-excretion with [redacted] isomer was larger than that with [redacted] isomer independently on the sex and dose. There was no remarkable difference in ^{14}C-excretion between males and females.

[redacted]

Section A6.2(1) **Metabolism studies in mammals**
Annex Point IIA6.2 **Metabolism study in the rat**
IUCLID 5.0/1

3.6 Tissue residues

[redacted]

3.7 Amounts of metabolites in excreta

[redacted]

4 APPLICANT'S SUMMARY AND CONCLUSION

4.1 Materials and methods

[redacted]

The purpose of this study was to elucidate the metabolism of [redacted] phenothrin in rats.

Groups of [redacted] rats received a single low (4 mg/kg bw) or high (200 mg/kg bw) radiolabelled dose of [redacted] phenothrin. Further groups of 5 males and 5 females received one radiolabelled low dose after 14 consecutive

non-radiolabelled low doses of phenothrin.

4.2 Results and discussion

Section A6.2(1) **Metabolism studies in mammals**
Annex Point IIA6.2 **Metabolism study in the rat**
IUCLID 5.0/1

[redacted]

4.3 Conclusion

On single oral administration of [redacted]-phenothrin at the rates of 4 or 200 mg/kg to male and female [redacted] rats, nearly 100% of the radiocarbon was eliminated in faeces and urine within 7 days and ^{14}C-tissue residues were generally very low. [redacted]

4.3.1 Reliability [redacted]

4.3.2 Deficiencies

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide *trans*parency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*18 December 2006*
Materials and Methods	[redacted]

Section A6.2(1) **Metabolism studies in mammals**
Annex Point IIA6.2 **Metabolism study in the rat**
IUCLID 5.0/1

Results and discussion	[redacted]
Reliability	[redacted]
Acceptability	
Remarks	[redacted]

	COMMENTS FROM
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

[redacted]