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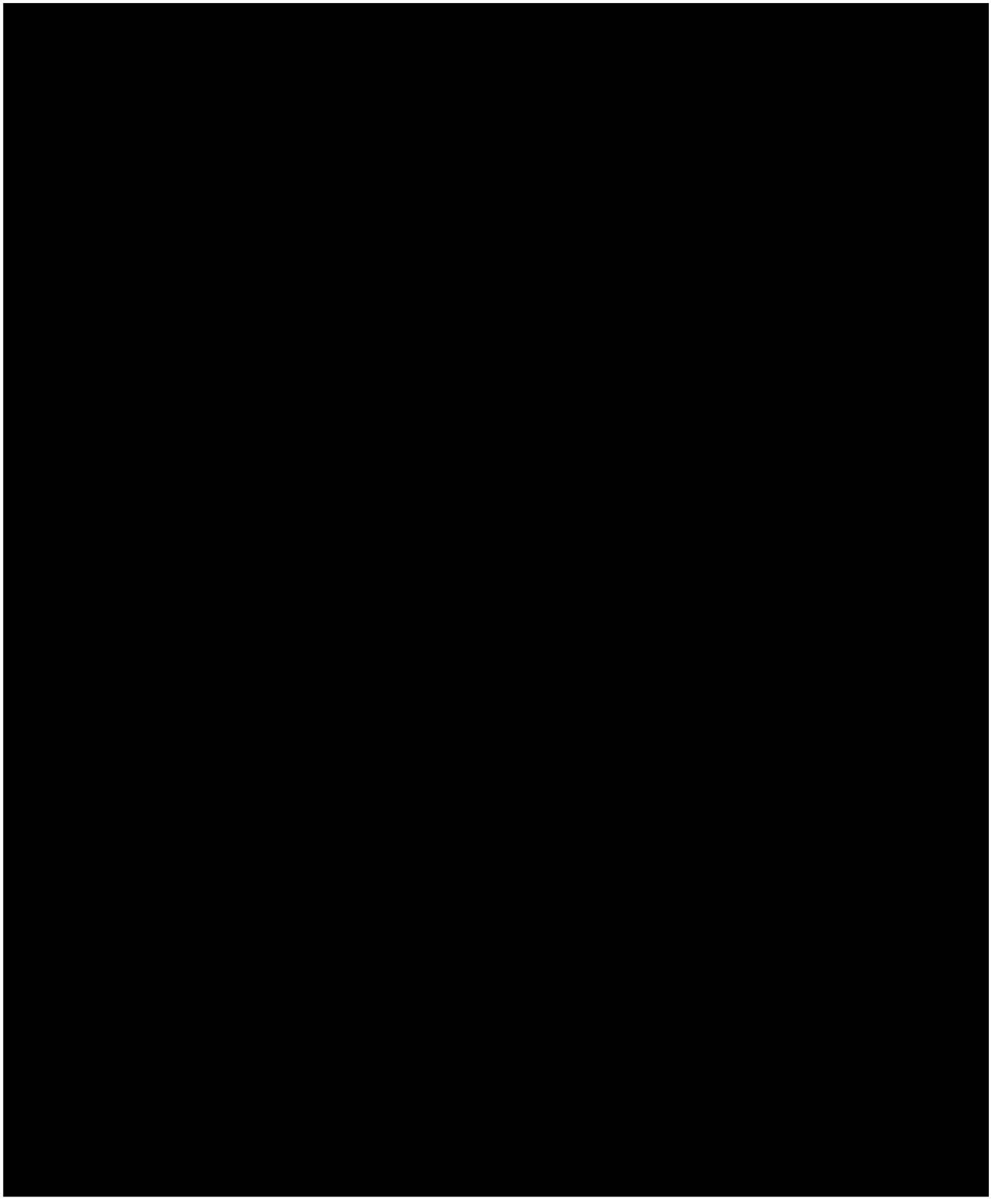

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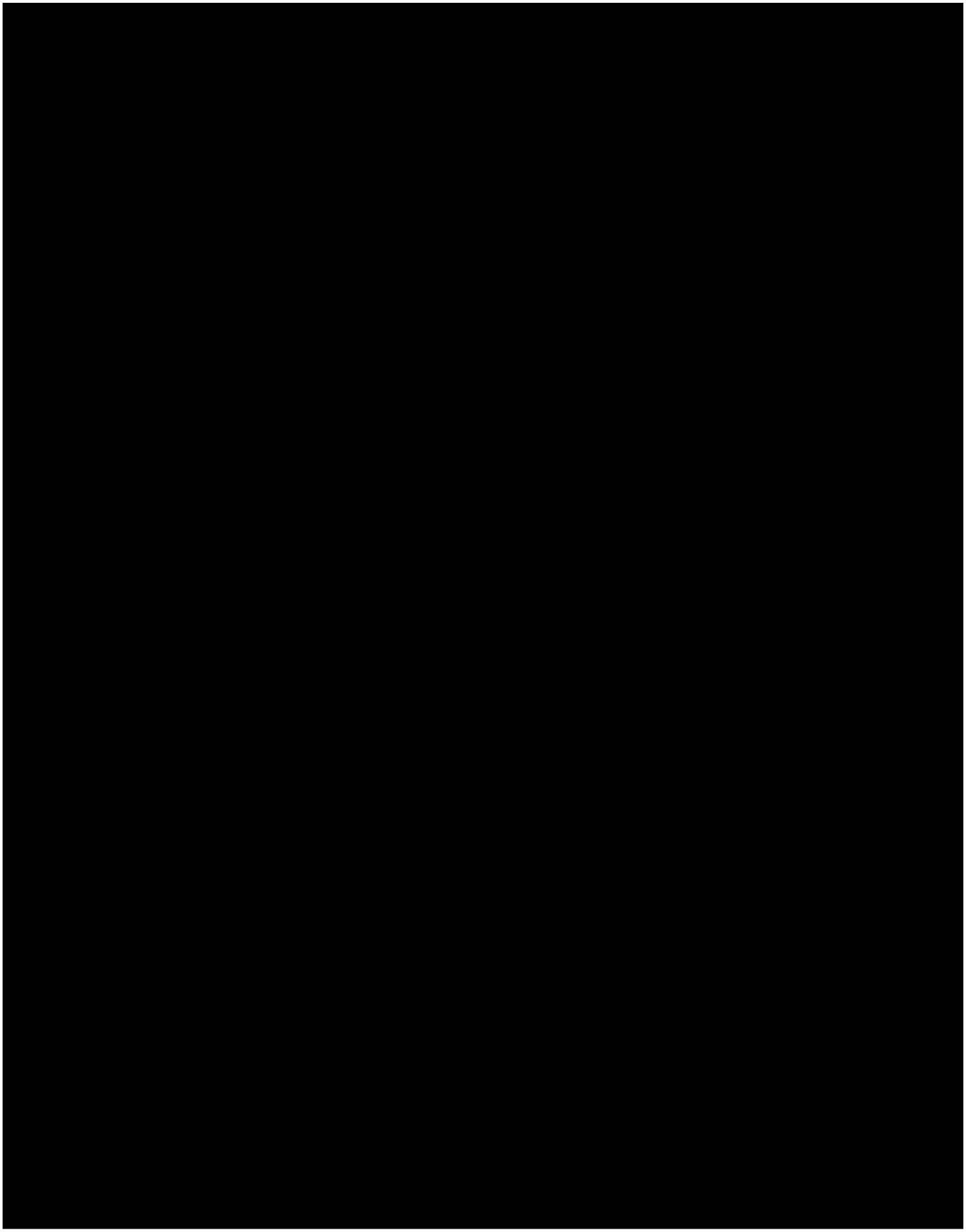

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Reference list by Author

A	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
	IIIA6.3.1	1983	Sumithrin®: Five Week Range-Finding Toxicity Study in Mice [redacted]	Y	Sumitomo Chemical C
	IIIA6.7/2	1987	Sumithrin®: Oncogenicity and Toxicity Study in Mice. [redacted]	Y	Sumitomo Chemical C
	A8	2004	Safety Data Sheet SUMITHRIN TG; Issued: 19/03/2004 Revision 1	N	Sumitomo Chemical C
	IIIA6.5	1987	Chronic Toxicity Study in Dogs with Sumithrin®, T.G. [redacted]	Y	Sumitomo Chemical C
	IIIA6.2/02	2006	Sumithrin: In Vitro Absorption from a 1% Sumithrin Formulation through Human Epidermis Draft Report [redacted]	Y	Sumitomo Chemical C
	IIIA6.1.3	1995	An Acute (4-hour) Inhalation Toxicity Study of Sumithrin® in the Rat via Whole-Body Exposure. [redacted]	Y	Sumitomo Chemical C
C .,	IIIA6.4.3	1989	Sumithrin T.G. 90 Day Inhalation Toxicity Study in the Rat [redacted]	Y	Sumitomo Chemical C
	IIIA6.3.3	1973	Acute and Subacute Inhalation Toxicity Studies of S-2539 and S-2539 Forte in Rats and Mice. [redacted]	Y	Sumitomo Chemical C

IIIA6.6.4/2	1981a	Mutagenicity Test of Sumithrin® in Host-Mediated Assay. [redacted]	Y	Sumitomo Chemical C
IIIA6.6.1	1981b	Gene Mutation Test of Sumithrin® in Bacterial System. [redacted]	Y	Sumitomo Chemical C
IIIA6.7/1	1987	Sumithrin®: Combined Toxicity and Oncogenicity Study in rats. [redacted]	Y	Sumitomo Chemical C
IIIA6.1.1	1997	Acute Oral Toxicity Study [redacted]	[redacted]	[redacted]
IIIA6.1.2	1996	Acute Dermal Toxicity Study of Sumithrin® in Rats. [redacted]	Y	Sumitomo Chemical C
IIIA6.4.1/2	1981	Six Month Oral Toxicity Study of [redacted] Rats [redacted]	Y	Sumitomo Chemical C
IIIA6.6.2	1989	Mutagenicity Test on Sumithrin® T.G.in an In Vitro Cytogenetic Assay Measuring Chromosomal Aberration Frequencies in Chinese Hamster Ovary (CHO) Cells [redacted]	Y	Sumitomo Chemical C
IIIA6.1.4/ 1	1988	Primary Eye and Skin Irritation Tests with Sumithrin® in Rabbits.	Y	Sumitomo Chemical C

[redacted]			[redacted]		
[redacted]	1.4/ 2	1988	Primary Eye and Skin Irritation Tests with Sumithrin® in Rabbits. [redacted]	Y	Sumitomo Chemical C
[redacted]	IIIA6.1.5	1988	Skin Sensitization Test with Sumithrin® in Guinea pigs. [redacted]	Y	Sumitomo Chemical Co.,
[redacted]	IIIA6.8.1/2	1989	A Teratology Study in Rabbits with Sumithrin® [redacted]	Y	Sumitomo Chemical Co.,
[redacted]	IIIA6.9	1978	Neurotoxicity Study of d-Phenothri [redacted] Rats Administration. [redacted] (Unpublished).	Y	Sumitomo Chemical Co.,
[redacted]	IIIA6.4.1/3	1981	Subchronic Toxicity Study in Dogs [redacted]	Y	Sumitomo Chemical Co.,

[redacted]

IIIA6.12.1	2005	Review on Medical Examination of Factory Workers Exposed to oids [redacted], (Unpublished).	N	Sumitomo Chemical Co.,
IIIA6.6.4/1	1981	In Vivo Chromosomal Aberration Test of Sumithrin® on Bone Marrow Cells of Mice. [redacted]	Y	Sumitomo Chemical Co.,
IIIA6.8.2	1986	Sumithrin®: Effects Upon Reproductive Performance of Rats Treated Continuously Throughout Two Successive Generations. [redacted]	Y	Sumitomo Chemical Co.,
IIIA6.8.1/1	1983	Sumithrin®: Effects of Oral Administration Upon Pregnancy in the Rat (2.) Main Study. [redacted]	Y	Sumitomo Chemical Co.,

[redacted]	IIIA6.4.1/1	1983	Sumithrin®:Toxicity in Dietary Administration over 13 Weeks. [redacted] (Unpublished).	Y	Sumitomo Chemical Co.,
	IIIA6.2/01	1987	Metabolism of (1R, trans)- and (1R, cis)- Isomers of Phenothrin in Rats. [redacted]	Y	Sumitomo Chemical Co.,

Refernece List by Data Point.

TNG Section No.	[redacted]	Year	Title Source Report No,	Data Protection Claimed	Owner
IIIA6.1.1		1997	Acute Oral Toxicity Study of [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.1.2		1996	Acute Dermal Toxicity Study of Sumithrin® in Rats. [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.1.3		1995	An Acute (4-hour) Inhalation Toxicity Study of Sumithrin® in the Rat via Whole-Body Exposure. [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.1.4/1		1988	Primary Eye and Skin Irritation Tests with Sumithrin® in Rabbits. [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.1.4/2		1988	Primary Eye and Skin Irritation Tests with Sumithrin® in Rabbits. [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.1.5		1988	Skin Sensitization Test with Sumithrin® in Guinea pigs. [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.2/01		1987	Metabolism of (1R, trans)- and (1R, cis)- Isomers of Phenothrin in Rats. [redacted]	Y	Sumitomo Chemical Co., Ltd.

IIIA6.2/02	[redacted]	2006	Sumithrin: In Vitro Absorption from a 1% Sumithrin Formulation through Human Epidermis [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.3.1	[redacted]	1983	Sumithrin®: Five Week Range-Finding Toxicity Study in Mice [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.3.3	[redacted]	1973	Acute and Subacute Inhalation Toxicity Studies of [redacted] in Rats and Mice. [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.4.1/1	[redacted]	1983	Sumithrin®:Toxicity in Dietary Administration over 13 Weeks. Life [redacted]	Y	Sumitomo [redacted]hemical Co., Ltd.
[redacted]	[redacted]	19	Six Month Oral Toxicity Study of [redacted] Forte (Sumithrin®) in Rats Laboratory of Biochemistry and Toxicology, Research Department, [redacted]n. , [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.4.1/3	H [redacted] L.,	1981	Subchronic Toxicity Study in Dogs [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.4.3	[redacted]	1989	Sumithrin T.G. 90 Day Inhalation Toxicity Study in the Rat [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.5	[redacted]	1987	Chronic Toxicity Study in Dogs with Sumithrin®, T.G. [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.6.1	[redacted]	1981b	Gene Mutation Test of Sumithrin® in Bacterial System. [redacted] Pes [redacted]	Y	Sumitomo Chemical Co., Ltd.

IIIA6.6.2	[redacted]	1989	Mutagenicity Test on Sumithrin® T.G.in an In Vitro Cytogenetic Assay Measuring Chromosomal Aberration Frequencies in Chinese Hamster Ovary (CHO) Cells [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.6.4/1		1981	In Vivo Chromosomal Aberration Test of Sumithrin® on Bone Marrow Cells of Mice. [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.6.4/2		1981a	Mutagenicity Test of Sumithrin® in Host-Mediated Assay. Laboratory of Biochemist[redacted] Research Department, P[redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.7/1		1987	Sumithrin®: Combined Toxicity and Oncogenicity Study in rats. [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.7/2		1987	Sumithrin®: Oncogenicity and Toxicity Study in Mice. [redacted]	Y	Sumitomo Chemical Co., Ltd.
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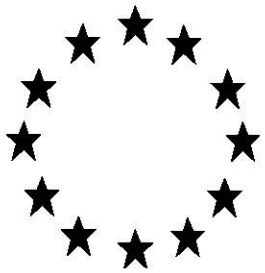
IIIA6.8.2		1986	Sumithrin®: Effects Upon Reproductive Performance of Rats Treated Continuously Throughout Two Successive Generations. [redacted]	Y	Sumitomo Chemical Co., Ltd.
IIIA6.9		1978	Neurotoxicity Study of d-Phenothrin[redacted] in Rats by Repeated Oral Administration. [redacted]	Y	Sumitomo Chemical Co., Ltd.

IIIA6.12.1	[redacted]	2005	Review on Medical Examination of Factory Workers Exposed to Pyrethroids [redacted]	N	Sumitomo Chemical Co., Ltd.

Competent Authority Report

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



d-Phenothrin (PT 18)

Sumitomo Chemical (UK) Plc

DOCUMENT IIIA (A8)

Evaluation Report

Rapporteur: Ireland

August 2010

Table of contents Doc III, section A8

Section A8	Measures necessary to protect man, animals and the environment	Official use only
	The information supplied in Annex A/8 should at least meet the requirements of the Safety Data Sheets Directive. The Safety Data Sheets should reflect the contents of Annex B where applicable. *If different measures are necessary for the active substance and its formulations this should be stated in different dossiers.*	
Subsection (Annex Point)		
8.1Recommended methods and precautions concerning handling, use, storage, transport or fire		
8.1.0 Methods and precautions concerning placing on the market	The active substance is not produced in the EU and is therefore not covered by this dossier.	
8.1.1 Methods and precautions concerning production, handling and use of the active substance and its formulations	• *engineering controls, e.g. LEV, contained use, closed system* **Engineering measures:** Ensure there is sufficient ventilation of the area. The floor of the storage room must be impermeable to prevent the escape of liquids. • *hygiene measures like segregation of working areas, barriers against splashes* None specified. • *protective gloves (tested by a certified institution, protection factor), respiratory protective equipment (type and where applicable dependent on the level of exposure), further PPE if necessary (work clothing)* **Respiratory protection:** Respiratory protection not required. **Hand protection:** Rubber gloves. Protective gloves. **Eye protection:** Safety glasses. **Skin protection:** Protective clothing. • *the protection of bystanders, the protection in case of secondary exposure* **Personal precautions:**. Turn leaking containers leak-side up to prevent the escape of liquid. Mark out the contaminated area with signs and prevent access to unauthorised personnel. • *precautionary measures against environmental exposure, e.g. appropriate use of control systems to avoid contamination of the surrounding environment, for example, via ventilation systems or drains*	

Section A8	Measures necessary to protect man, animals and the environment	Official use only
	Environmental precautions: Do not discharge into drains or rivers. Contain the spillage using bunding.	
8.1.2 Methods and precautions concerning storage of the active substance and its formulations	**Handling requirements:** Ensure there is sufficient ventilation of the area. **Storage conditions:** Store in cool, well ventilated area. Keep container tightly closed. The floor of the storage room must be impermeable to prevent the escape of liquids. Keep away from direct sunlight.	
8.1.3 Methods and precautions concerning transport of the active substance and its formulations	**ADR/RID** UN No: 3082 ADR Class: 9 Packing group: Ill Classification code: M6 [redacted] Labelling: 9 Hazard ID No: 90 **IMDG/IMO** UN No: 3082 Class: 9 Packing group: III EmS: F-A,S-F Marine pollutant: Yes. Labelling: 9 **IATA/ICAO** UN No: 3082 Class: 9 Packing group: III Packing instructions: 914 Labelling: 9	
8.1.4 Methods and precautions concerning fire of the active substance and its formulations	**Extinguishing media:** Suitable extinguishing media for the surrounding fire should be used. Use water spray to cool containers. Use water for large fires. Avoid contamination of waterways from runoff. **Exposure hazards:** In combustion emits toxic fumes. **Protection of fire-fighters:** Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.	
8.2 In case of fire, nature of reaction products,		

Section A8	Measures necessary to protect man, animals and the environment	Official use only
combustion gases, etc.	Hazard decomposition products: In combustion emits toxic fumes.	
8.3 Emergency measures in case of an accident		
8.3.1 Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available	**FIRST AID MEASURES (SYMPTOMS)** **Skin contact:** May cause a transient itching and/or burning sensation in exposed human skin. Synthetic pyrethroids can produce parasthesias. Typically, symptoms begin several hours after cutaneous exposure, peaks within 12 hours and resolves within about 24 hours. **Eye contact:** There may be irritation and redness. **Ingestion:** High systemic doses may cause tremor, hyperexcitability, uncoordinated movements, salivation, nausea, vomiting and/or diarrhoea. **Inhalation:** No symptoms. **FIRST AID MEASURES (ACTION)** **Skin contact:** Wash immediately with plenty of soap and water. If symptoms persist, seek medical advice. **Eye contact:** Bathe the eye with running water for 15 minutes. If symptoms persist, seek medical attention. **Ingestion:** Wash out mouth with water. Seek medical advice. Do not induce vomiting in unconscious or confused persons. **Inhalation:** Remove casualty from exposure ensuring one's own safety whilst doing so. Seek medical advice.	
8.3.2 Emergency measures to protect the environment	**Environmental precautions**: Do not discharge into drains or rivers. Contain the spillage using bunding. **Clean-up procedures:** Absorb into dry earth or sand. Transfer to a closable, labelled salvage container for disposal by an appropriate method.	
8.4 Possibility of destruction or decontamination following release in or on the following: (a) Air; (b) Water, including drinking water; (c) Soil (IIA8.4)		
8.4.1 Possibility of destruction or	In view of the very low vapour pressure of the active substance, release into the air compartment is very unlikely. There is no	

Section A8	Measures necessary to protect man, animals and the environment	Official use only
decontamination following release in the air	possibility of decontamination or destruction.	
8.4.2 Possibility of destruction or decontamination following release in water, including drinking water	There are no recommended decontamination procedures. Contact with water should be avoided. Any spillage should be contained by bunding.	
8.4.3 Possibility of destruction or decontamination following release in or on soil	Any spillages onto soil should be contained using bunding, absorbed into dry earth or sand then transferred to a closable, labelled salvage container for disposal by an appropriate method.	
8.5 Procedures for waste management of the active substance for industry or professional users	**Disposal operations:** According to local regulations. For further advice contact manufacturer. **Disposal of packaging:** According to local regulations. NB: The users attention is drawn to the possible existence of regional or national regulations regarding disposal.	
8.5.1 Possibility of re-use or recycling	The test substance cannot be recycled.	
8.5.2 Possibility of neutralisation of effects	The test substance cannot be neutralised.	
8.5.3 Conditions for controlled discharge including leachate qualities on disposal	The test substance should not be allowed to enter ground water systems or contaminate surface water. Contaminated packaging should not be re-used. Ponds, waterways or ditches should not be contaminated with chemical or used containers.	
8.5.4 Conditions for controlled incineration	In accordance with local and national regulations.	
8.6 Observations on undesirable or unintended side-effects	The biocidal product is unlikely to affect beneficials and non-target organisms as it is intended for indoor use only.	

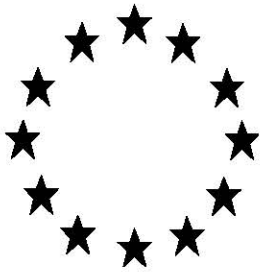
Section A8	Measures necessary to protect man, animals and the environment	
8.7 Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances	There are no substances present that are contained in these lists.	Official use only

	Evaluation by Competent Authorities
Date	*4th July 2008*
Materials and Methods	*Not applicable*
Results and discussion	*Not applicable*
Conclusion	*Not applicable*
Reliability	*Based on the assessment of materials and methods include appropriate reliability indicator Not applicable*
Acceptability	*Not applicable*
Remarks	[redacted]
	Comments from ... *(SPECIFY)*
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*

Section A8	Measures necessary to protect man, animals and the environment	
		Official use only
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Competent Authority Report

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



d-Phenothrin (PT 18)

Sumitomo Chemical (UK) Plc

DOCUMENT IIIA (A9)

Evaluation Report

Rapporteur: Ireland

August 2010

Section A9 Classification and labelling

Annex Point IIA, IX

			Official use only
9.1 Current classification according to Directive 67/548/EEC	*Classification as in Directive 67/548/EEC*	Not classified	
9.2 Proposed classification	Class of danger	N – Harmful for the environment	
	R phrases	R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. [R63] [Possible risk of harm to the unborn child]	
	S phrases	[S36/37] - [Wear suitable protective clothing and gloves.] S57- Use appropriate containment to avoid environmental contamination. S60 – This material and/or its container must be disposed of as hazardous waste. S61 – Avoid release to the environment. Refer to special instructions safety data sheet.	

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*4th July 2008*
Materials and Methods	*Not applicable*
Results and discussion	*Not applicable*
Conclusion	*Not applicable*
Reliability	*Not applicable*
Acceptability	*Acceptable*
Remarks	
	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	