4.1.2 Number/ percentage of animals showing adverse effects

[redacted]

4.1.3 Nature of adverse effects

[redacted]

4.2 Results test substance

4.2.1 Applied concentrations 0, 28.13, 56.25, 112.5, 225 and 450 g a.i./ha test item

4.2.2 Effect data (Mortality)

[redacted]

4.2.3 Concentration / effect curve

[redacted]

4.2.4 Effect Data (Reproduction)

[redacted]

4.2.5 Other effects

[redacted]

4.3 Results of controls

4.3.1 Mortality

[redacted]

4.3.2 Number/ percentage of animals showing adverse effects

[redacted]

4.3.3 Nature of adverse effects

[redacted]

4.4 Test with reference substance	Performed
4.4.1 Concentrations	[redacted]
4.4.2 Results	[redacted]

5 Applicant's Summary and conclusion

5.1 Materials and methods	[redacted]
5.2 Results and discussion	[redacted]
5.2.1 NOEC	Not determined
5.2.2 LOEC	Not determined
5.2.3 LC_{50}	> 450 g a.i./ha
5.2.4 LC_{100}	Not determined
5.3 Conclusion	This study met the required validity criteria [redacted] Less than 20% mortality was seen in the 7-day exposure phase for the control group and 97% mortality was seen in the toxic standard. The control group produced greater than 4 eggs/female in the reproduction phase of the study
5.3.1 Other Conclusions	None
5.3.2 Reliability	[redacted]
5.3.3 Deficiencies	[redacted]

Evaluation by Competent Authorities
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
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A7.5.4.1/08 Non Target Arthropod, acute toxicity and reproduction test

Official use only

1 Reference

1.1 Reference

[redacted]

1.2 Data protection Yes

1.2.1 Data owner: Sumitomo Chemical Company Ltd.

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 Yes

[redacted]

2.2 GLP [redacted]

2.3 Deviations [redacted]

[redacted]

3 Method

3.1 Test material	[redacted]
3.1.1 Lot/Batch number	[redacted]
3.1.2 Specification	[redacted]
3.1.3 Purity	[redacted]
3.1.4 Composition of Product	[redacted]
3.1.5 Further relevant properties	Not applicable
3.1.6 Method of analysis	[redacted]
3.2 Reference substance	[redacted]
3.2.1 Method of analysis for reference substance	[redacted]
3.3 Testing procedure	
3.3.1 Preparation of the test substance	A[redacted]
3.3.2 Application of the test substance	[redacted]
3.3.3 Test organisms	[redacted]
3.3.4 Test system	[redacted]
3.3.5 Test conditions	[redacted]
3.3.6 Test duration	14 days
3.3.7 Test parameter	Mortality and reproduction
3.3.8 Examination	On days 7, 9, 11, and 14 of each bioassay the number of dead, alive and missing mites and mites stuck in the tangle foot barrier was recorded On days 7, 9 11 and 14 the sex of the mites and the number of eggs and if present, hatched larvae was determined

3.3.9 Monitoring of test substance concentration	No
3.3.10 Statistics	[redacted]

4 Results

4.1 1 Limit Test / Range finding test	Not performed
4.1.1 Concentration	Not applicable
4.1.2 Number/ percentage of animals showing adverse effects	Not applicable
4.1.3 Nature of adverse effects	Not applicable

4.2 Results test substance

4.2.1 Applied concentrations	75, 191.3, 225 g a.i./ha
4.2.2 Effect data (Mortality)	[redacted]
4.2.3 Concentration / effect curve	[redacted]
4.2.4 Effect Data (Reproduction)	[redacted]
4.2.5 Other effects	[redacted]

4.3 Results of controls

4.3.1 Mortality	[redacted]

4.3.2 Number/ percentage of animals showing adverse effects	[redacted]
4.3.3 Nature of adverse effects	[redacted]
4.4 Test with reference substance	[redacted]
4.4.1 Concentrations	[redacted]
4.4.2 Results	[redacted]

5 Applicant's Summary and conclusion

5.1 Materials and methods	[redacted]
5.2 Results and discussion	[redacted]
5.2.1 NOEC	Not reported
5.2.2 LOEC	75 g a.i./ha
5.2.3 LC_{50}	Not reported
5.2.4 LC_{100}	Not reported
5.3 Conclusion	This study met the required validity criteria. Less than 20% mortality was seen in the 7-day exposure phase for the control group and 100% mortality was seen in the toxic standard. The control group produced greater than 4 eggs/female in the reproduction phase of the study

5.3.1 Other Conclusions	Not applicable
5.3.2 Reliability	[redacted]
5.3.3 Deficiencies	[redacted]

Evaluation by Competent Authorities	
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[redacted]	[redacted]	

A7.5.4.1/09 Non Target Arthropod, acute toxicity and reproduction test

1 Reference

Official use only

1.1 Reference

[redacted]

1.2 Data protection Yes

1.2.1 Data owner Sumitomo Chemical Company Ltd.

1.2.3 Criteria for data Data submitted to the MS after 13 May 2000 on existing a.s. for the

protection	purpose of its entry into Annex I
	2 Guidelines and Quality Assurance
2.1 Guideline study	Yes
	[redacted]
2.2 GLP	[redacted]
2.3 Deviations	[redacted]
	[redacted]
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	[redacted]
	3 Method
3.1 Test material	[redacted]
3.1.1 Lot/Batch number	[redacted]
3.1.2 Specification	[redacted]
3.1.3 Purity	[redacted]
3.1.4 Composition of Product	[redacted]
3.1.5 Further relevant properties	[redacted]
3.1.6 Method of analysis	[redacted]
3.2 Reference substance	[redacted]
3.2.1 Method of analysis for reference substance	[redacted]
3.3 Testing procedure	
3.3.1 Preparation of the test substance	[redacted]
3.3.2 Application of the test substance	[redacted]

[redacted]

3.3.3 Test organisms [redacted]

3.3.4 Test system [redacted]

3.3.5 Test conditions [redacted]

3.3.6 Test duration 14 days after test item application

3.3.7 Test parameter Mortality and reproduction

3.3.8 Examination Immediately after and 7 and 10 days after test item application

3.3.9 Monitoring of test substance concentration [redacted]

3.3.10 Statistics [redacted]

[redacted]

4 Results

4.1 1 Limit Test / Range finding test Not performed

4.1.1 Concentration Not applicable

4.1.2 Number/ percentage of animals showing adverse effects Not applicable

4.1.3 Nature of adverse effects Not applicable

4.2 Results test substance

4.2.1 Applied concentrations 75, 191.3, 225 g a.i./ha

4.2.2 Effect data (Mortality) [redacted]

[redacted]

[redacted]

4.2.3 Concentration / effect curve [redacted]

4.2.4 Effect Data (Reproduction) [redacted]

4.2.5 Other effects [redacted]

4.3 Results of controls

4.3.1 Mortality [redacted]

4.3.2 Number/ percentage of animals showing adverse effects [redacted]

4.3.3 Nature of adverse effects [redacted]

4.4 Test with reference substance [redacted]

4.4.1 Concentrations [redacted]

4.4.2 Results [redacted]

5 Applicant's Summary and conclusion

5.1 Materials and methods [redacted]

5.2 Results and discussion [redacted]

	[redacted]
5.2.1 NOEC	75 g a.i./ha
5.2.2 LOEC	191.3 g a.i./ha
5.2.3 LC_{50}	Not reported
5.2.4 LC_{100}	Not reported
5.3 Conclusion	This study met the required validity criteria ([redacted] Less than 20% mortality was seen in the 7-day exposure phase for the control group and 100% mortality was seen in the toxic standard. The control group produced greater than 4 eggs/female in the reproduction phase of the study
5.3.1 Other Conclusions	None
5.3.2 Reliability	[redacted]
5.3.3 Deficiencies	[redacted]

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7.5.5 Bioconcentration, terrestrial

7.5.5.1 Bioconcentration, further studies

Pyriproxyfen has a Log Pow of 5.37, which may give concerns with regard to possible bioaccumulation and subsequent secondary poisoning. However, information included within the dossier clearly indicates that this is not a concern. The aquatic bioconcentration study does not give a very high BCF (Whole fish 1379 to 1495) and pyriproxyfen is rapidly depurated from the fish (DT_{50} 0.86 to 1.63 days). Pyriproxyfen is also not persistent within the environment with a mean DT_{50} in aquatic systems of 6.6 days and DT_{50}s in soil below 17 days. The mammalian metabolism studies summarised in Document IIIA Point 6 also indicate that pyriproxyfen is extensively and rapidly metabolised and excreted in mammals. The risk of secondary poisoning can therefore be considered low and further studies are unnecessary.

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7.5.6 Effects on other terrestrial non-target organisms

The risk assessment with the submitted data demonstrates an acceptable risk to terrestrial non-target organisms, further tests are therefore not required.

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7.5.7 Effects on mammals

The risk assessment with the submitted data demonstrates an acceptable risk to mammals, further tests are therefore not required.

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European Commission

Pyriproxyfen

Document III-A

Section 8 - Measures
Study Summaries
Active Substance

Rapporteur Member State: The Netherlands

January 2012

Draft CA-report and Proposed Decision of The Netherlands in the context of the
Possible inclusion of Pyriproxyfen in Annex I of Council Directive 98/8/EC

Table of contents

Please refer to "Technical Notes for Guidance on Dossier Preparation including preparation and evaluation of study summaries under Directive 98/8 EC Concerning the Placing of Biocidal Products on the Market (Appendix 7.1 and 7.2)" for a list of the Standard Terms and Abbreviations used in this document.

Section A8	Measures necessary to protect man, animals and the environment	Official use only
	Refer to Safety Data Sheet for pyriproxyfen technical grade as generated according to EC-directive 2001/58/EC	

8.1 Recommended methods and precautions concerning handling, use, storage, transport or fire

8.1.0 Methods and precautions concerning placing on the market	No information available, manufacturing occurs outside the EU
8.1.1 Methods and precautions concerning production, handling and use of the active substance and its formulations	**Handling** - The usual precautions for handling chemicals should be observed **Engineering controls** - Provide adequate ventilation **Exposure limits** – No exposure limits have been set for this material **Personal protection (also applicable for accidental release)** **Respiratory** - In case of dust formation use dust mask **Hand** - Wear protective gloves **Eye** - Wear safety goggles or face shield **Skin and body** - Wear suitable protective clothing **Other information** - Launder clothes before reuse
8.1.2 Methods and precautions concerning storage of the active substance and its formulations	**Warehouse storage** - Store in a dry and cool place. Keep container in a well-ventilated place. Keep away from heat **User level storage** - Store in a dry and cool place. Keep container in a well-ventilated place. Keep away from heat. Keep out of the reach of children. Keep away from food, drink and animal feedingstuffs. Keep only in original container
8.1.3 Methods and precautions concerning transport of the active substance and its formulations	**Land transport** ADR/RID: Class 9 Warning sign, Hazard No.90, Substance No.3077 UN No.: 3077 Packing group: III Trem-Card: CEFIC TEC(R)-90GM7-III Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Pyriproxyfen) **Sea transport** IMO/IMDG: Class 9 UN No.: 3077 Packing group: III EMS: F-A, S-T Marine pollutant: Yes Proper shipping name: Environmentally hazardous substance, solid,

	n.o.s. (Pyriproxyfen)
	Air transport ICAO/IATA: Class 9 UN No.: 3077 Packing group: III Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Pyriproxyfen)
8.1.4 Methods and precautions concerning fire of the active substance and its formulations	**Extinguish media** - Dry chemical powder, carbon dioxide, foam **Unsuitable extinguishing media** – None known **Special exposure hazards** – None known **Protective equipment** - Wear self contained breathing apparatus. Wear suitable protective clothing and eye/face protection **Other information** – Water used to extinguish a fire should not be allowed to enter the drainage system or water courses

8.2 In case of fire, nature of reaction products, combustion gases, etc.

	Hazardous decomposition/combustion products – May emit toxic and irritating fumes under fire conditions (Carbon monoxide (CO) and nitrous gases (Nox))

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	**Symptoms and effects** – No typical symptoms and effects known **First aid** **General** - In case of doubt, seek medical attention **Inhalation** - Move to fresh air. If symptoms persist, seek medical advice. **Skin contact** - Remove contaminated clothing. Wash off with a plenty of soap and water. Launder clothes before reuse **Eye contact** - Rinse thoroughly with plenty of water. Eyelids should be held away from the eyeball to ensure thorough rinsing. Seek medical advice if irritation develops **Ingestion** - Rinse mouth. Never induce vomiting in unconscious or confused persons. Seek medical advice **Advice to physicians** – No specific recommendations
8.3.2 Emergency measures to protect the environment	**Procedures for the decontamination of water in case of an accident:** There is no readily available method for decontamination

	of water. Precaution must be taken to avoid contamination. Do not allow spills to escape into sewage system or water courses. A spill contaminated water is to be contained and decontaminated in a suitable sewage plant or incinerated **Containment of spillages:** Clean up spills immediately. Sweep up and place into sealable containers. Dig up heavily contaminated soil and place into drums. Use a damp cloth to clean floors and other objects after removal of spills and also place in sealable container. Dispose of all waste and contaminated clothing in the same manner as waste chemicals (i.e. via an authorized disposal facility) **Decontamination of areas, vehicles and buildings:** Clean up spills immediately. Sweep up and dispose as waste following local regulations. Do not wash residues into drains or other waterways **Disposal of damaged packaging, adsorbents and other materials:** Dispose in the same manner as waste chemicals according to local regulations (i.e. via authorized disposal facility)

8.4 Possibility of destruction or decontamination following release in or on the following:

8.4.1 Possibility of destruction or decontamination following release in the air	Not relevant as the technical material is a solid
8.4.2 Possibility of destruction or decontamination following release in water, including drinking water	There is no readily available method for decontamination of water. Precaution must be taken to avoid contamination. Do not allow spills to escape into sewage system or water courses. A spill contaminated water is to be contained and decontaminated in a suitable sewage plant or incinerated
8.4.3 Possibility of destruction or decontamination following release in or on soil	There is no readily available method for decontamination of soil. Clean up spills immediately. Sweep up and place into sealable containers. Dig up heavily contaminated soil and place into drums. Dispose of all waste and contaminated clothing in the same manner as waste chemicals (i.e. via an authorized disposal facility)

8.5 Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration

8.5.1 Possibility of re-use or recycling	The recommended means of safe disposal is by controlled incineration at an approved chemical waste facility
8.5.2 Possibility of neutralisation of effects	Not applicable. The recommended means of safe disposal is by controlled incineration at an approved chemical waste facility
8.5.3 Conditions for	Not applicable. The recommended means of safe disposal is by

controlled discharge including leachate qualities on disposal	controlled incineration at an approved chemical waste facility
8.5.4 Conditions for controlled incineration	In order to continue perfect combustion, it is desirable that combustion temperature is kept over 800 °C. This is a standard process and no further detailed instructions are required

8.6 Observations on undesirable or unintended side-effects, for example, on beneficial and other non-target organisms

No information available

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 ground water against pollution caused by certain dangerous substances.

Not relevant

Evaluation by Competent Authorities
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European Commission

Pyriproxyfen

Document III-A

Section 9 - Classification
Study Summaries
Active Substance

Rapporteur Member State: The Netherlands

January 2012

Draft CA-report and Proposed Decision of The Netherlands in the context of the Possible inclusion of Pyriproxyfen in Annex I of Council Directive 98/8/EC

Classification and labelling

Hazard symbol(s):

N

Indications of danger:	Dangerous for the Environment	
Risk phrases:	R50	Very toxic to aquatic organisms
	R53	May cause long-term adverse effects in the environment
Safety phrases:	S60	This material and its container must be disposed of as hazardous waste
	S61	Avoid release to the environment. Refer to special instructions/Safety data sheets

Justifications for the proposal

Chemistry classification criteria

Explosive properties	Pyriproxyfen has no explosive properties
	No classification required
Oxidising properties	Pyriproxyfen has no oxidising properties
	No classification required
Flammability	Not highly flammable
	No classification required

Health classification criteria

Acute oral toxicity	Rat LD_{50}: > 5000 mg/kg
	No classification required
Acute dermal toxicity	Rat LD_{50}: > 2000 mg/kg
	No classification required
Acute inhalation toxicity	Rat (4 h) LC_{50}: >1.3 mg/L (whole body; maximum attainable concentration
	No classification required
Skin irritation	Non irritant
	No classification required
Eye irritation	Mild irritant
	No classification required
Skin sensitisation	Non sensitiser
	No classification required

Environmental classification criteria

96 hour LC_{50}, fish	96 h LC_{50} (*Oncorhynchus mykiss*) : > 0.325 mg/L 96 h LC_{50} (*Lepomis macrochirus*) : > 0.270 mg/L Classified: Very toxic to aquatic organisms
48 hours EC_{50}, *Daphnia magna*	48 h EC_{50} (*Daphnia magna*) : 0.4 mg/L Classified: Very toxic to aquatic organisms
72 hour EC_{50}, algae	72 h E_rC_{50} (*Selenastrum capricornutum*) : 0.15 mg/L Classified: Very toxic to aquatic organisms CLP (Regulation No. 1272/2008, 16 December 2008) M-factor: 1
48 hour LD_{50}, honey bee	Acute oral and contact 48 h LD_{50} (*Apis mellifera*) : >100 µg/bee
Ready biodegradability	Not readily biodegradable Classified: May cause long term adverse effects in the environment (linked to very toxic to aquatic organisms classification)
Log P_{ow}	Log P_{ow} = 4.86
Bioconcentration factor (BCF)	Exposure 28 days (*Lepomis macrochirus*) : 1379 – 1495 (whole fish); depuration time: rapid ($t_{1/2}$ = approximately 1 day)

Evaluation by Competent Authorities
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Evaluation by Rapporteur Member State

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