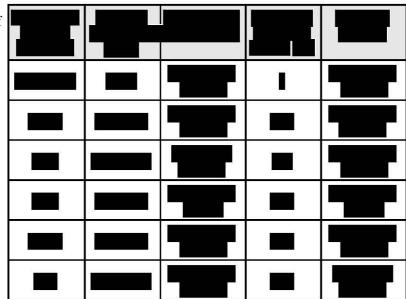
4.1.2 Number/ percentage of animals showing adverse effects



4.1.3 Nature of adverse effects

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)

4.2.3 Concentration / effect curve

4.2.4 Effect Data (Reproduction)



4.2.5 Other effects

4.3 Results of controls

4.3.1 Mortality

4.3.2 Number/ percentage of animals showing adverse effects

4.3.3 Nature of adverse effects



Pyriproxyfen; CAS number: 95737-68-1 January 2012 Doc IIIA RMS: NL 492 / 514 4.4 Test with reference Performed substance 4.4.1 Concentrations 4.4.2 Results 5 Applicant's Summary and conclusion 5.1 Materials and methods

5.2 Results and discussion



5.2.1 NOEC Not determined

5.2.2 LOEC Not determined

5.2.3 LC₅₀ > 450 g a.i./ha

 $5.2.4 \, LC_{100}$ Not determined

This study met the required validity criteria 5.3 Conclusion

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

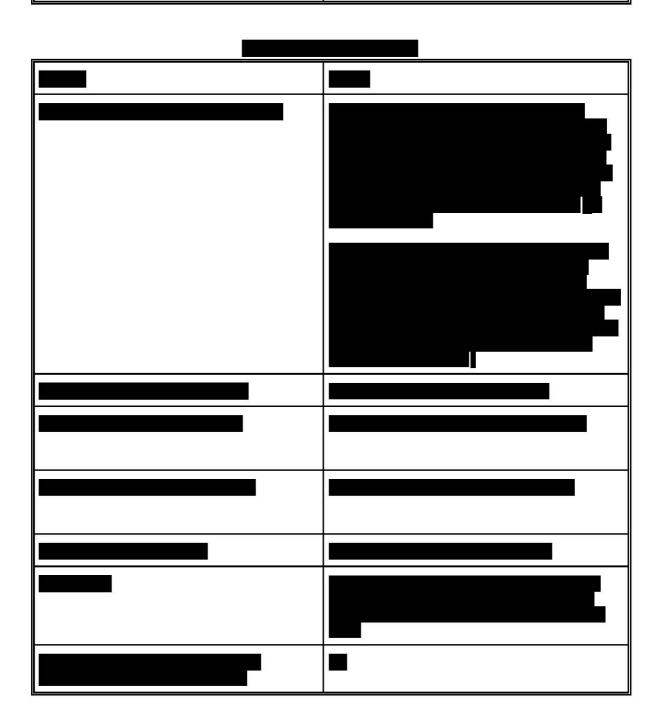
5.3.1 Other Conclusions None

5.3.2 Reliability

5.3.3 Deficiencies

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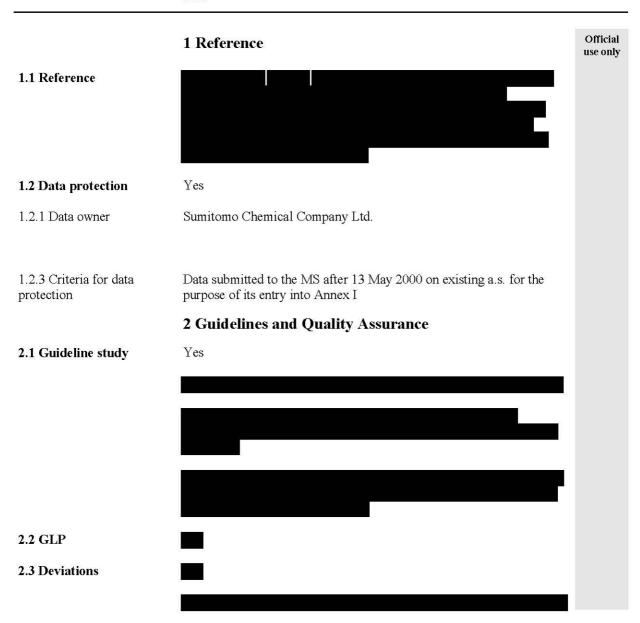
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A7.5.4.1/08 Non Target Arthropod, acute toxicity and reproduction test

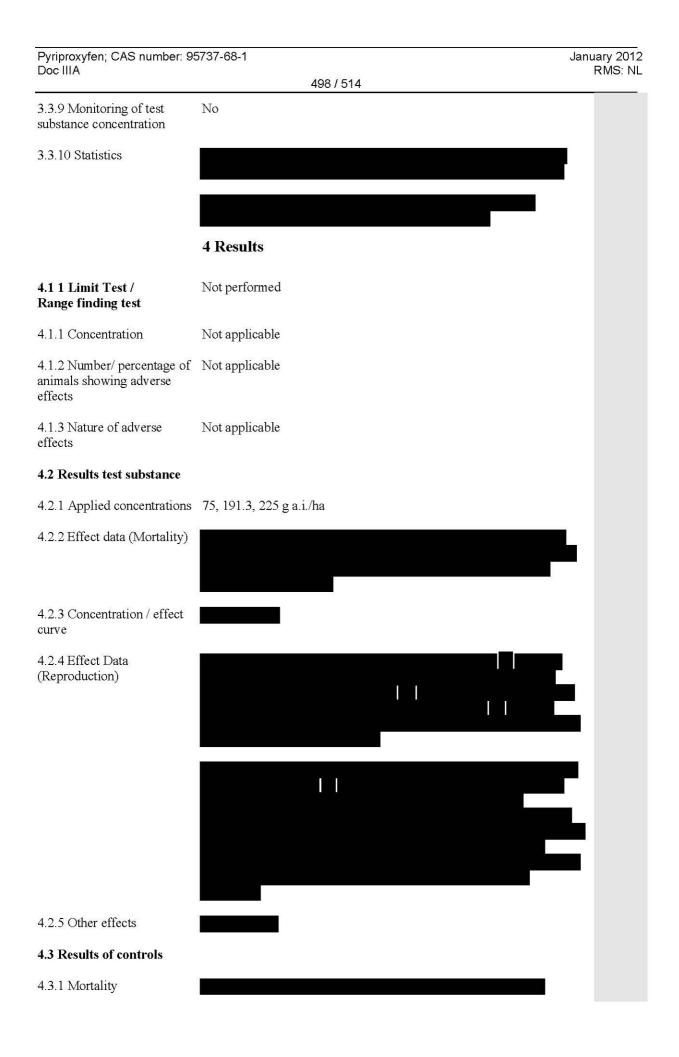


On days 7, 9, 11, and 14 of each bioassay the number of dead, alive and missing mites and mites stuck in the tangle foot barrier was recorded

On days 7, 9 11 and 14 the sex of the mites and the number of eggs and

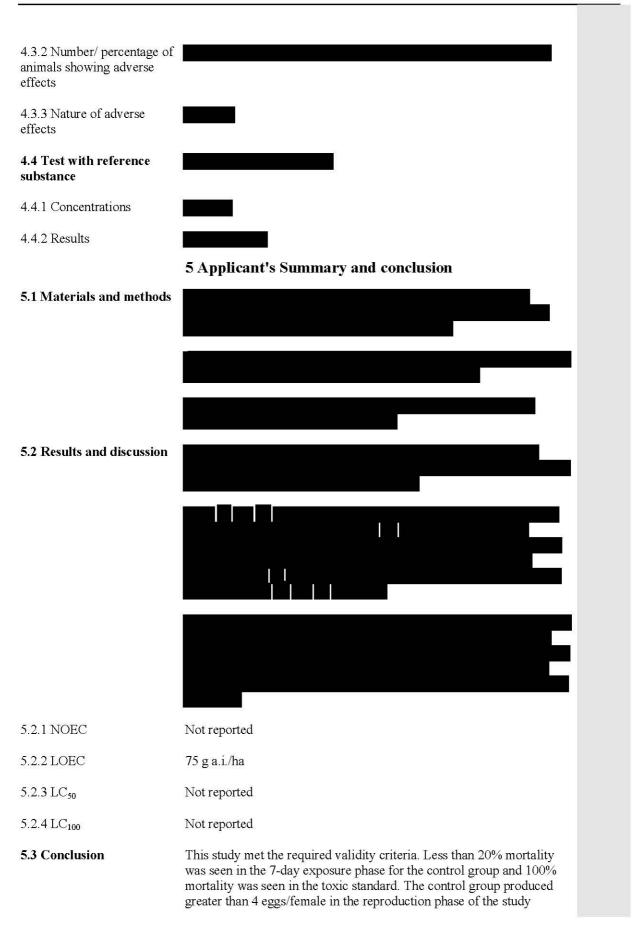
if present, hatched larvae was determined

3.3.8 Examination



Pyriproxyfen; CAS number: 95737-68-1 January 2012
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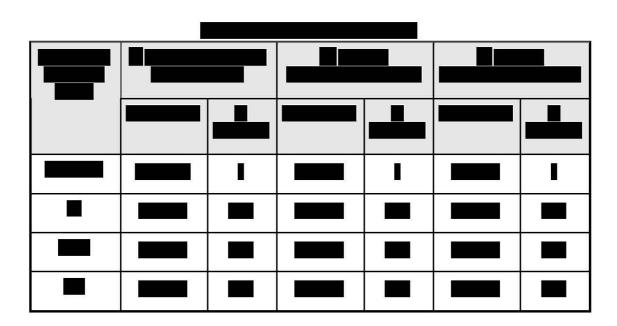
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5.3.1 Other Conclusions	Not applicable	
5.3.2 Reliability	I	
5.3.3 Deficiencies		

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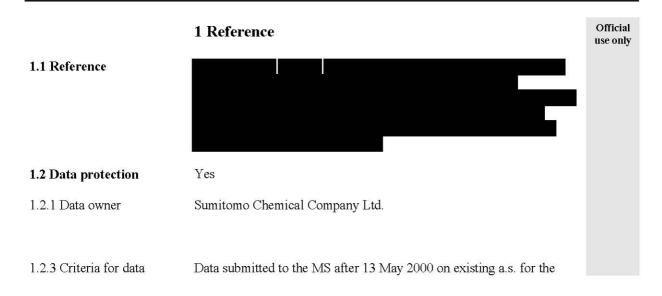
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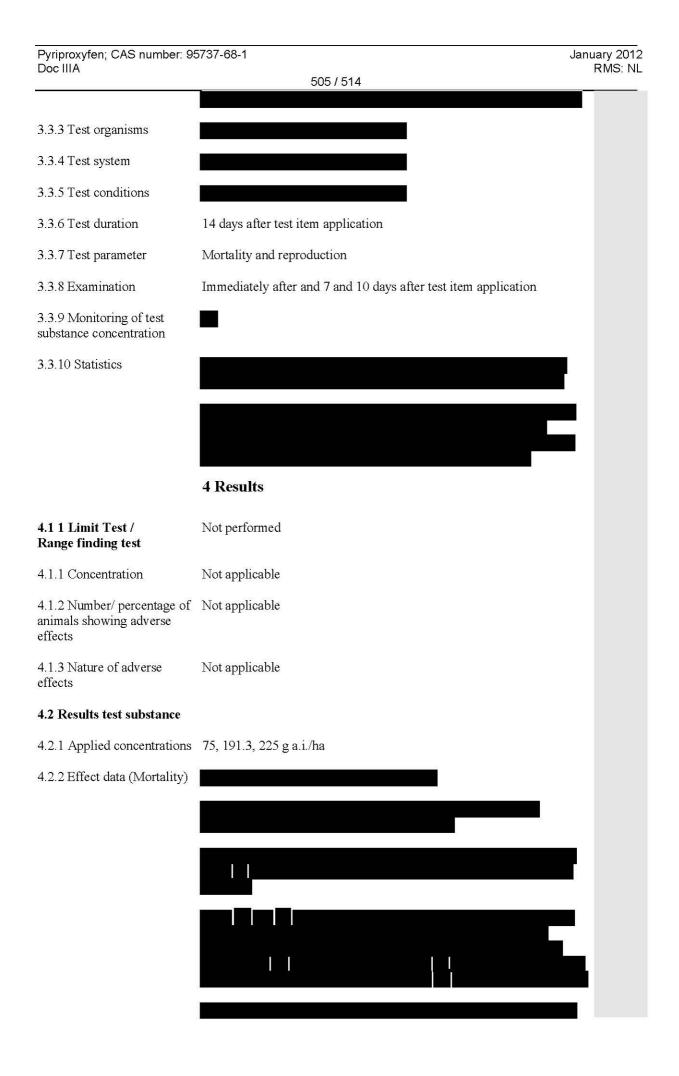
A7.5.4.1/09 Non Target Arthropod, acute toxicity and reproduction test

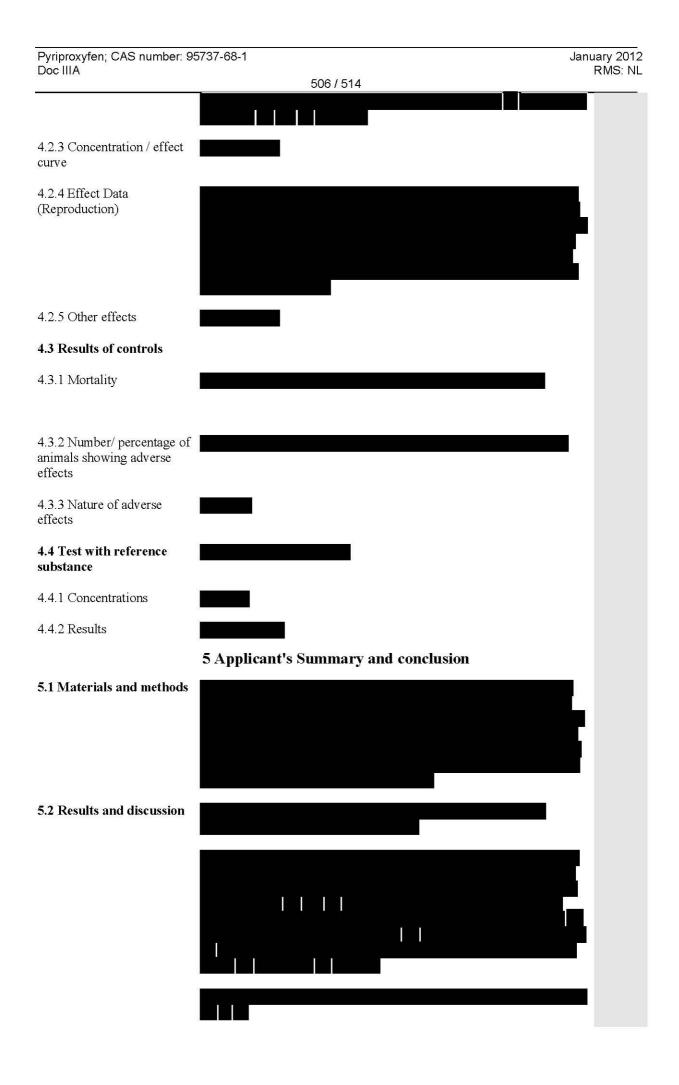


Pyriproxyfen; CAS number: 95737-68-1 January 2012 RMS: NL Doc IIIA 504 / 514 purpose of its entry into Annex I protection 2 Guidelines and Quality Assurance 2.1 Guideline study Yes 2.2 GLP 2.3 Deviations 3 Method 3.1 Test material 3.1.1 Lot/Batch number 3.1.2 Specification 3.1.3 Purity 3.1.4 Composition of Product 3.1.5 Further relevant properties 3.1.6 Method of analysis 3.2 Reference substance 3.2.1 Method of analysis for reference substance 3.3 Testing procedure 3.3.1 Preparation of the test substance

3.3.2 Application of the test

substance





Pyriproxyfen; CAS number: 95737-68-1

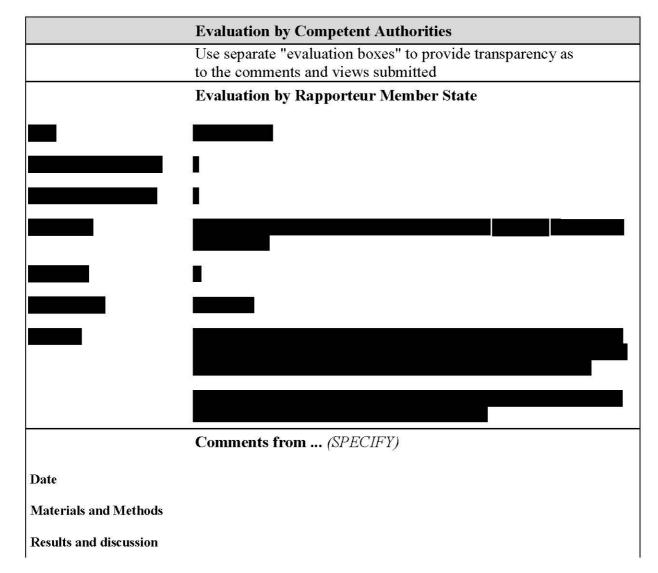
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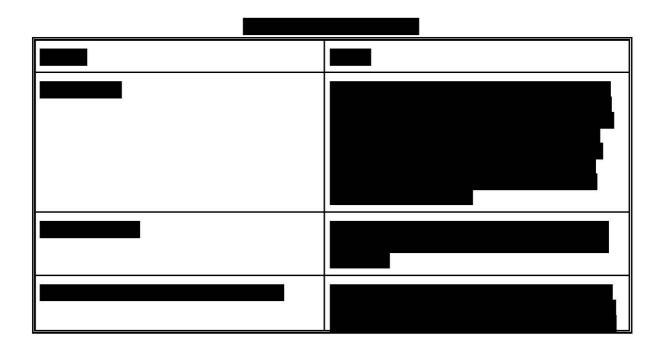
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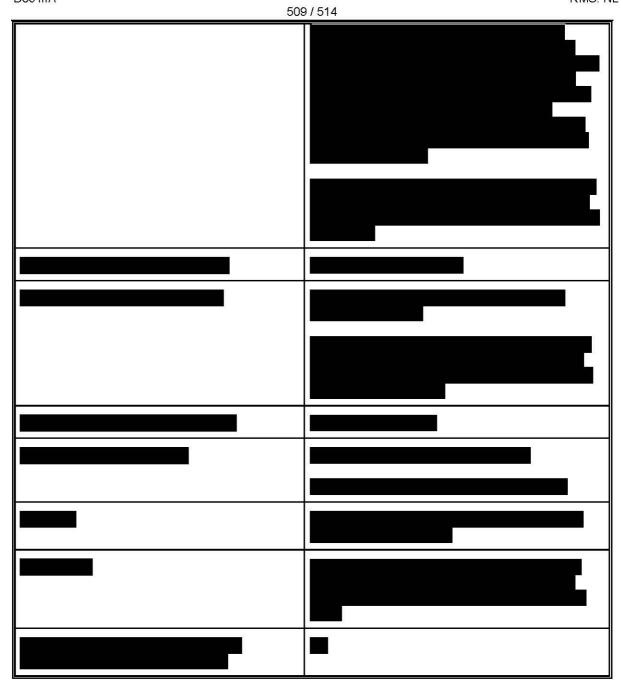
5.2.1 NOEC	75 g a.i./ha
5.2.2 LOEC	191.3 g a.i./ha
$5.2.3~{\rm LC}_{50}$	Not reported
$5.2.4\mathrm{LC_{100}}$	Not reported
5.3 Conclusion	This study met the required validity criteria (Less than 20% mortality was seen in the 7-day exposure phase for the control group and 100% mortality was seen in the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

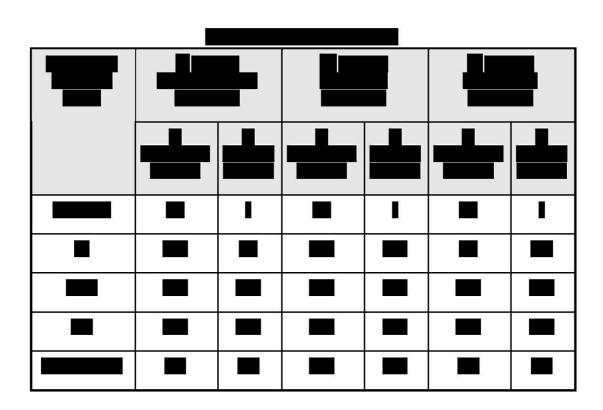


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7.5.5 Bioconcentration, terrestrial

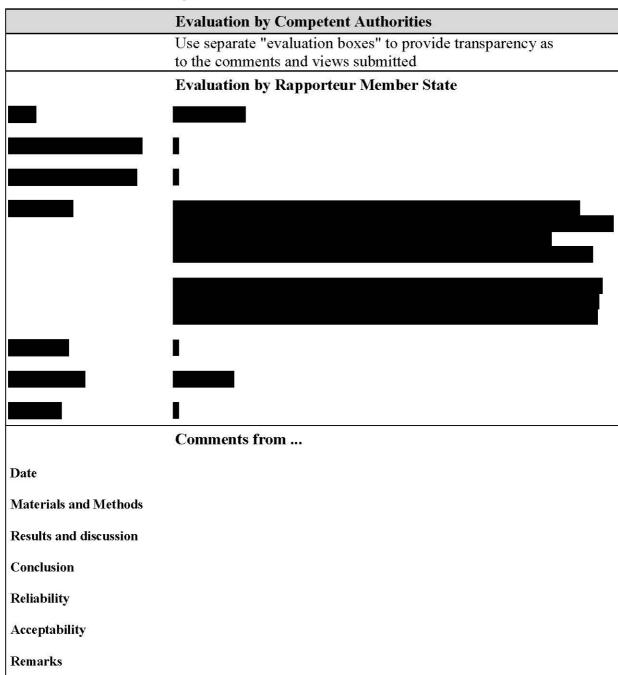
7.5.5.1 Bioconcentration, further studies

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.



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.

Pyriproxyfen; CAS number: 95737-68-1 January 2012
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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

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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

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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

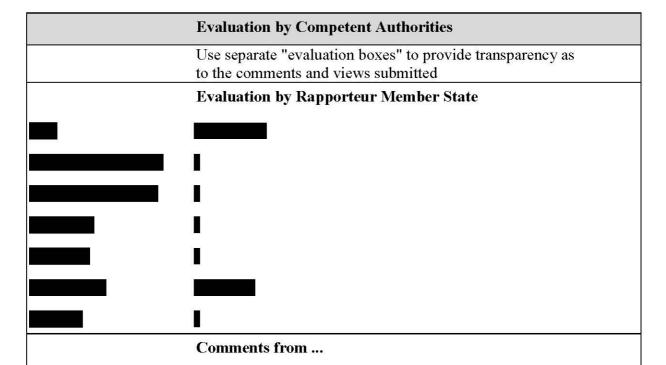
In order to continue perfect combustion, it is desirable that combustion temperature is kept over 800 °C. This is a standard process and no further detailed instructions are required

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



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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

Pyriproxyfen: CAS number 95737-68-1

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Classification and labelling

Hazard symbol(s):



Indications of danger: Dangerous for the Environment

R50 Risk phrases: Very toxic to aquatic organisms

> R53 May cause long-term adverse effects in the environment

S60 Safety phrases: 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

Pyriproxyfen has no explosive properties Explosive properties

No classification required

Oxidising properties Pyriproxyfen has no oxidising properties

No classification required

Not highly flammable Flammability

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) LC₅₀: >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

Pyriproxyfen: CAS number 95737-68-1

96 hour LC₅₀, fish 96 h LC₅₀ (Oncorhynchus mykiss): > 0.325 mg/L

96 h LC_{50} (Lepomis macrochirus) : > 0.270 mg/L

Classified: Very toxic to aquatic organisms

48 hours EC₅₀, *Daphnia*

magna

Doc IIIA

48 h EC₅₀ (Daphnia magna): 0.4 mg/L

Classified: Very toxic to aquatic organisms

72 hour EC₅₀, algae 72 h E_r C₅₀ (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 μ g/bee

Ready biodegradability Not readily biodegradable

Classified: May cause long term adverse effects in the environment (linked to

very toxic to aquatic organisms classification)

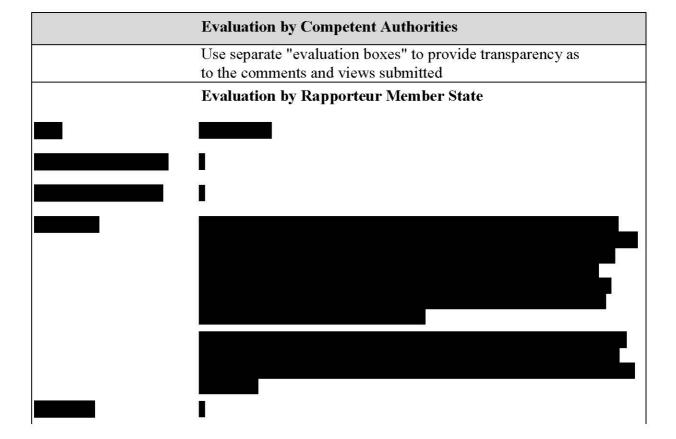
 $Log P_{ow} = 4.86$

Bioconcentration factor

(BCF)

Exposure 28 days (Lepomis macrochirus): 1379 – 1495 (whole fish); depuration

time: rapid ($t_{1/2}$ = approximately 1 day)



January 2012 RMS: NL

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