Section A6.15.1/03 **Annex Point IIIA, XI.1.1, 1.3, 1.6**		**Metabolism studies in mammals**	
		1 Reference	**Official use only**
1.1		[redacted]	
1.2	**Data protection**	Yes	
1.2.1	**Data owner**	Sumitomo Chemical Co., Ltd.	
1.2.2	**Criteria for data protection**	Data submitted to the MS after 13 May 2000 on existing a.s for the purpose of entry into Annex I	
		2 Guidelines and Quality Assurance	
2.1	**Guideline study**	Yes EPA Guidelines specified in Residue Chemistry, Section 171-4: Nature of the residues, Animals equivalent to Appendix F to Commission Document 1607/VI/97	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 Materials and Methods	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch No	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	

	[redacted]	
3.1.5 Stability	[redacted]	
3.4 Test animals		
3.2.1 Species	Goat (*Capra hircus*)	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	Female	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control animals	[redacted]	
3.3 Administration/ Exposure		
3.3.1 Administration	[redacted]	
3.3.2 Dose level	The test substance was administered in capsules to give an administration rate equivalent to 10 ppm in the feed	
3.4 Examinations		
3.4.1 Observations	[redacted]	
3.4.2 Extraction and analysis	[redacted]	

	[redacted]	
	4 Results and Discussion	
4.1 Results of test	[redacted]	

	[redacted]	
	5 Applicant's Summary and conclusion	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	**The study indicated that ingested pyriproxyfen was extensively degraded in goats, the primary routes of degradation being hydroxylation and cleavage of ether bonds. Pyriproxyfen and its metabolites were readily eliminated through the excreta and the concentration of residues in both milk and edible tissues was very low**	
5.3.1 Reliability	[redacted]	

5.3.2 Deficiencies	[redacted]	

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Section A6.15.1/04 **Annex Point IIIA, XI.1.1, 1.3, 1.6**		**Metabolism studies in mammals**	
		1 Reference	**Official use only**
1.1		[redacted]	
1.2	**Data protection**	Yes	
1.2.1	**Data owner**	Sumitomo Chemical Co., Ltd.	
1.2.2	**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 EPA Guidelines specified in Residue Chemistry, Section 171-4: Nature of the residues, Animals equivalent to Appendix F to Commission Document 1607/VI/97	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 Materials and Methods	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch No	[redacted]	
3.1.2	Specification	[redacted]	
3.1.3	Description	[redacted]	
3.1.4	Purity	[redacted]	

3.1.5 Stability	[redacted]	
3.5 Test animals		
3.2.1 Species	Goat (*Capra hircus*)	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	Female	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	
3.2.7 Control animals	[redacted]	
3.3 Administration/ Exposure		
3.3.1 Administration	[redacted]	
3.3.2 Dose level	The test substance was administered in capsules to give an administration rate equivalent to 10 ppm in the feed	
3.4 Examinations		
3.4.1 Observations	[redacted]	
3.4.2 Extraction and analysis	[redacted]	

	[redacted]	
	4 Results and Discussion	
4.1 Results of test	[redacted]	

	[redacted]	
	5 Applicant's Summary and conclusion	
5.1 Materials and methods	[redacted]	
5.2 Results and discussion	[redacted]	
5.3 Conclusion	**The study indicated that ingested pyriproxyfen was extensively degraded in the goats, the primary routes of degradation being hydroxylation and cleavage of ether bonds. It is clear from the study that pyriproxyfen and its metabolites were readily eliminated in excreta and that retention of residues in both milk and tissues of the animals was very low** [redacted]	

5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[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]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	Comments From

Date
Evaluation of applicant's justification
Conclusion
Remarks

6.16 Any other tests related to the exposure of the active substance to humans, in its proposed biocidal products, that are considered necessary may be required

(An additional data requirement. See Chapter 3, part A.)

None

	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]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	Comments From
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

6.17 If the active substance is to be used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required

(An additional data requirement. See Chapter 3, part A.)

None

Not applicable the active substance is not to be used in products for action against plants

	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]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]
	Comments From
Date	
Evaluation of applicant's justification	
Conclusion	
Remarks	

6.18 Summary of mammalian toxicology and conclusions

This is included in Document IIA

European Commission

PYRIPROXYFEN

CAS number 95737-68-1

Document III-A Section 7
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.

7.1 Fate and Behaviour in Water

7.1.1 Degradation, initial studies

7.1.1.1 Abiotic

7.1.1.1.1 Hydrolysis as a function of pH and identification of breakdown products

Section A7.1.1.1.1/01 **Hydrolysis as a function of pH and identification of breakdown products**

Annex Point IIA7.6.2.1

		Official use only
	1 Reference	
1.1 Reference	[redacted] (1989) [redacted]	
1.2 Data protection	Yes	
1.2.1 Data owner	Sumitomo Chemical Co., 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	Guideline not specified	
2.2 GLP	Yes	
2.3 Deviations	Not applicable	
	3 Materials and Methods	
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 Further relevant	Not applicable	

properties

3.2 Reference substance	No
3.2.1 Initial concentration of reference substance	Not applicable
3.3 Test solution	[redacted]
3.4 Testing procedure	
3.4.1 Test system	[redacted]
3.4.2 Temperature	50 ± 0.1°C
3.4.3 pH	4, 7 and 9
3.4.4 Duration of the test	7 days
3.4.5 Number of replicates	2 per treatment
3.4.6 Sampling	Samples were taken at 0, 1, 2, 3, 4 and 7 days after incubation for immediate extraction and analysis
3.4.7 Analytical methods	[redacted]
3.5 Preliminary test	No

4 Results

4.1 Concentration and hydrolysis values	[redacted]
4.2 Hydrolysis rate constant (k_h)	No degradation of pyriproxyfen was observed during the 7-day period
4.3 Dissipation time	No degradation of pyriproxyfen was observed during the 7-day period. It can therefore be concluded that pyriproxyfen is hydrolytically stable under the conditions tested. [redacted]

4.4 Concentration – time data	No degradation of pyriproxyfen was observed during the 7-day period
4.5 Specification of the transformation products	No degradation of pyriproxyfen was observed during the 7-day period. Unidentified hydrolysis products did not exceed 3% of applied radioactivity during the study

5 Applicant's Summary and Conclusion

5.1 Materials and methods	The hydrolysis of pyriproxyfen was determined at pH 4, 7 and 9 at 50 ± 0.1°C
5.2 Results and discussion	[redacted]
5.2.1 k_H	No degradation of pyriproxyfen was observed during the 7-day period. It can therefore be concluded that pyriproxyfen is hydrolytically stable under the test conditions
5.2.2 DT_{50}	No degradation of pyriproxyfen was observed during the 7-day period. It can therefore be concluded that pyriproxyfen is hydrolytically stable under the test conditions
5.2.3 r^2	Not applicable
5.3 Conclusion	The hydrolysis of pyriproxyfen was determined at pH 4, 7 and 9 at 50 ± 0.1°C. No degradation of pyriproxyfen was observed during the 7-day period. It can therefore be concluded that pyriproxyfen is hydrolytically stable under the test conditions. The identity of hydrolysis products cannot be determined as no degradation of pyriproxyfen was observed. A rate constant and an estimated DT_{50} value cannot therefore be calculated as no significant degradation of pyriproxyfen was observed
5.3.1 Reliability	[redacted]
5.3.2 Deficiencies	[redacted]

Evaluation by Competent Authorities	
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
Evaluation by Rapporteur Member State	
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Comments from ...	
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Results and discussion	
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Reliability	
Acceptability	
Remarks	

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7.1.1.1.2 Phototransformation in water including identity of the products of transformation

Section A7.1.1.1.2/01 Phototransformation in water including identity of transformation products

Annex Point IIA7.6.2.2

Official use only

1 Reference

1.1 Reference

[redacted]1995a[redacted]

1.2 Data protection Yes

1.2.1 Data owner: Sumitomo Chemical Co., 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

Environmental Protection Agency Pesticide Assessment Guidelines, Subdivision N, Section 161-2

2.2 GLP Yes

2.3 Deviations No

3 Materials and Methods

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 Radiolabelling

[redacted]

3.1.5 UV/VIS absorption

[redacted]

spectra and absorbance value	[redacted]
3.1.6 Further relevant properties	Not applicable

3.2 Reference substances [redacted]

[redacted]

3.3 Test solution

[redacted]

3.4 Testing procedure

3.4.1 Test system

The photolysis of pyriproxyfen in water was investigated using a xenon lamp in which light of <290 nm was excluded. Samples were irradiated continuously for up to 14 days using a xenon lamp at 25 ± 1°C. Control vessels were maintained in darkness. Samples were taken immediately after dosing and at specified intervals after treatment up to 14 days. At each sampling interval, the headspaces of the dark control and irradiated sample containers were purged with nitrogen to trap any existing volatiles before the sample containers were opened. The nitrogen stream was purged [redacted] Materials and equipment used during sample preparation were sterilised in an autoclave or in methanol. [redacted]

3.4.2 Properties of light source

The light intensity of the xenon lamp was similar to that of natural sunlight in July at latitude 43°N and longitude 89°W. The intensity of the xenon light source was measured before and/or at the end of the test and found to be 72.5% of the natural sunlight intensity measured at noon at 43°N on June 24. The continuous irradiation by the xenon lamp over 14 days produced approximately 107% of the total exposure that would have been produced by 30 days of irradiation by natural sunlight [redacted]

3.4.3 Determination of irradiance

The spectral energy distribution and intensity of the artificial sunlight source (xenon lamp) was measured with and without a Pyrex glass plate before the definitive study [redacted] It was also measured with and without a Pyrex glass plate after the definitive study [redacted] Measurements of the natural sunlight intensity were conducted in [redacted] (43°N latitude and

	89°W longitude) on July 15, 1991 at approximately 1 pm. The light intensity of artificial and natural sunlight was compared and it was concluded that the xenon lamp had light intensity similar to that of natural sunlight. Electronic light measurements were conducted under conditions simulating actual test conditions. This includes the passage of light through Pyrex glass with a UV filter. Comparison between natural sunlight and artificial light from a xenon lamp (with and without Pyrex glass) showed similar light intensities
3.4.4 Temperature	25 ± 1°C
3.4.5 pH	pH 7.0
3.4.6 Duration of the test	14 days
3.4.7 Number of replicates	2
3.4.8 Sampling	Samples were taken at 0, 1, 2, 3, 4, 7, 10 and 14 days [redacted] and 0, 2, 4, 6, 8, 10 and 14 days [redacted] after treatment for immediate analysis
3.4.9 Analytical methods	[redacted]
3.5 Transformation products	Transformation products tested: Yes. [redacted]
3.5.1 Method of analysis for transformation products	[redacted]

4 Results

4.1 Screening test	Not performed
4.2 Actinometer data	Not applicable
4.3 Controls	[redacted]
4.4 Photolysis data	
4.4.1 Concentration values	[redacted]
4.4.2 Mass balance	Recoveries from both irradiated and non-irradiated samples were in the range of 91.6-106.8% of applied radioactivity

4.4.3 k^{e}_{p} [redacted]

4.4.4 Kinetic order [redacted]

4.4.5 k^{e}_{p} / k^{a}_{p} [redacted]

4.4.6 Reaction quantum yield (ϕ^{e}_{E}) [redacted]

4.4.7 k_{pE} [redacted]

4.4.8 Half-life ($t_{1/2E}$) [redacted]

4.5 Specification of the transformation products [redacted]

5 Applicant's Summary and Conclusion

5.1 Materials and methods

The photolysis of pyriproxyfen in water was investigated using a xenon lamp in which light of <290 nm was excluded

The Environmental Protection Agency Pesticide Assessment Guidelines, Subdivision N, Section 161-2 were followed without significant deviations

5.2 Results and discussion

Recoveries from both irradiated and non-irradiated samples were in the range of 91.6-106.8% of applied radioactivity

Irradiated samples degraded in buffer pH 7. [redacted]

No significant degradation was observed in the dark control samples. The photochemical half-lives [redacted] in pH 7 buffer calculated using first order kinetics were 6.36 days (r^2 = 0.98) and 3.72 days (r^2 = 0.98), respectively.

Pyriproxyfen was stable in the dark solution (no half-lives calculated). The calculated half-lives for the irradiated solution are therefore effective photolytic half-lives. The 14-day irradiation period was equivalent to ~32 days natural sunlight at 43°N, summer

5.2.1 k^{c}_{p} [redacted]

5.2.2 K_{pE} [redacted]

5.2.3 ϕ^{c}_{E} [redacted]

5.2.4 $t_{1/2E}$ [redacted]

5.3 Conclusion The effective photolytic half-lives of [redacted] n pH 7 buffer calculated using first order kinetics were 6.36 and 3.72 days, respectively. The 14 day irradiation period was equivalent to ~32 days natural sunlight in July at latitude 43°N and longitude 89°W. No significant degradation was observed in the dark control samples. [redacted]

5.3.1 Reliability 1

5.3.2 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
[redacted]

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Comments from ...
Date
Materials and Methods
Results and discussion
Conclusion
Reliability
Acceptability
Remarks

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Section A7.1.1.1.2/02 Phototransformation in water including identity of transformation products

Annex Point IIA7.6.2.2

Official use only

1 Reference

1.1 Reference	[redacted] 1988) [redacted]
1.2 Data protection	Yes
1.2.1 Data owner	Sumitomo Chemical Co., 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	No. In-house method The study was initiated before the adoption of the modification of Point 7 of Part A of Annex II of Directive 91/414/EEC (the modification was published 14 July 1995 as Directive 95/36/EC)
2.2 GLP	No GLP was not compulsory at the time the study was performed
2.3 Deviations	Not applicable

3 Materials and Methods

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 Radiolabelling	[redacted]
3.1.5 UV/VIS absorption spectra and absorbance value	[redacted]

[redacted]

3.1.6 Further relevant properties	Not applicable

3.2 Reference substances

[redacted]

3.3 Test solution

[redacted]

3.4 Testing procedure

3.4.1 Test system	5 mL aliquots of each suspension or solution were poured into cylindrical quartz tubes (15 mm i.d. x 120 mm). The quartz tubes were capped with Teflon septum, placed in a merry-go-round type photochemical apparatus and irradiated for up to 30 hours at 313 nm.

	During the photolysis experiment samples were taken at appropriate intervals. The PNA solution was analysed by HPLC-UV and pyriproxyfen by LSC and 2D-TLC analysis. Rate constants for pyriproxyfen and *p*-nitroanisole were obtained by log linear regression analysis (first order). The quantum yield for pyriproxyfen was calculated from the rate constants, the molar extinction coefficients and the known quantum yield of the actinometer [redacted]
3.4.2 Properties of light source	To attain monochromatic light at 313 nm, the light emitted from a 400-W high-pressure mercury vapour lamp was filtered through a 1 cm thick solution of 0.001 M potassium chromate in 3% aqueous potassium carbonate, followed by a UV-D35 glass filter. [redacted]
3.4.3 Determination of irradiance	Refer to section 3.4.2
3.4.4 Temperature	[redacted]
3.4.5 pH	[redacted]
3.4.6 Duration of the test	30 hours
3.4.7 Number of replicates	3
3.4.8 Sampling	Samples were taken at 6, 12, 18, 24 and 30 hours after treatment for immediate analysis
3.4.9 Analytical methods	[redacted]
3.5 Transformation products	[redacted]
3.5.1 Method of analysis for transformation products	[redacted]

4 Results

4.1 Screening test	[redacted]
4.2 Actinometer data	[redacted]
4.3 Controls	[redacted]
4.4 Photolysis data	

4.4.1 Concentration values [redacted]

[redacted]

4.4.2 Mass balance [redacted]

4.4.3 k^{c}_{p} [redacted]

4.4.4 Kinetic order [redacted]

4.4.5 k^{c}_{p} / k^{a}_{p} [redacted]

4.4.6 Reaction quantum yield (ϕ^{c}_{E}) [redacted]

4.4.7 k_{pE} [redacted]

4.4.8 Half-life ($t_{1/2E}$) [redacted]

4.5 Specification of the transformation products [redacted]

5 Applicant's Summary and Conclusion

5.1 Materials and methods

The rate and half-life of direct phototransformation in distilled water was theoretically estimated for pyriproxyfen based on its measured quantum yield and absorption spectrum

5.2 Results and discussion

The quantum yield was experimentally determined to be 0.08661 at 313 nm in distilled water and the estimated half-lives at 40°N were 7.9 days (spring), 4.4 days (summer) and 15.8 days (fall)

5.2.1 k^{c}_{p}

8.83×10^{-7}, 8.83×10^{-7} and 1.01×10^{-6} s^{-1} (triplicate determination)

5.2.2 K_{pE}

The estimated photolytic rate constant of pyriproxyfen at 0 to 60°N was found to vary with season from 0.257 $days^{-1}$ (0°N, fall) to 1.947×10^{-4} $days^{-1}$ (60°N, winter)

5.2.3 ϕ^{c}_{E}

0.08661 ± 0.002333

5.2.4 $t_{1/2E}$

The estimated photolytic half-life of pyriproxyfen at 0 to 60°N was found to vary with season from 2.7 days (0°N, fall) to 3560 days (60°N, winter)

5.3 Conclusion

The quantum yield of direct phototransformation of pyriproxyfen in distilled water was calculated to be 0.08661 ± 0.002333 at 313 nm. The half-life of pyriproxyfen in distilled water, calculated from the quantum yield was 4.4 days by sunlight irradiation in summer at latitude 40°N. This is in good agreement with the calculated photolysis half-lives for

pyriproxyfen at similar latitude that are reported in the study by [redacted] (1995) [redacted]

5.3.1 Reliability [redacted]

5.3.2 Deficiencies [redacted]

Evaluation by Competent Authorities
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
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7.1.1.2 Biotic

7.1.1.2.1 Ready biodegradability

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA7.6.1.1

		Official use only
	1 Reference	
1.1 Reference	[redacted] 1988) [redacted]	
1.2 Data protection	Yes	
1.2.1 Data owner	Sumitomo Chemical Co., 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 "Ready biodegradability of chemical substance by microbe" (EHWD No.5, PAB No.615, BIB No.392 [74]) equivalent to OECD Guideline for Testing of Chemicals, No. 301C Modified MITI Test (I)	
2.2 GLP	[redacted] [redacted]	
2.3 Deviations	[redacted]	
	3 Materials and Methods	
3.1 Test material	Pyriproxyfen	
3.1.1 Lot/Batch number	[redacted]	
3.1.2 Specification	[redacted]	
3.1.3 Purity	[redacted]	
3.1.4 Further relevant properties	Not applicable	
3.1.5 Composition of Product	Not applicable. The test substance was prepared as test sample not as commercial product	
3.1.6 TS inhibitory to microorganisms	No	

3.1.7 Specific chemical analysis	Not applicable
3.2 Reference substance	Aniline
3.2.1 Initial concentration of reference substance	100 mg/L
3.3 Testing procedure	
3.3.1 Inoculum / test species	Activated sludge. [redacted]
3.3.2 Test system	Test solutions (300 mL, triplicate) containing pyriproxyfen (100 mg/L) and activated sludge inoculum (30 mg/L) were kept in bottles in the dark for 28 days at 24 – 25.5°C. Single flasks for the inoculum blank control (inoculum, no test substance), sterile control (test substance, no inoculum) and the reference substance (aniline, 100 mg/L) were included. The test solution was stirred continuously. Oxygen consumption was continuously monitored using a coulometer. The residual (28 days) pyriproxyfen concentration was determined by HPLC-UV (analysis of concentrated dichlormethane extract). [redacted]
3.3.3 Test conditions	Bottles were kept in the dark at 24.0-25.5°C for a period of 28 days. [redacted]
3.3.4 Method of preparation of test solution	Not reported
3.3.5 Initial TS concentration	100 mg TS/L
3.3.6 Duration of test	28 days
3.3.7 Analytical parameter	Oxygen consumption
3.3.8 Sampling	Oxygen consumption was measured continuously throughout the incubation period
3.3.9 Intermediates/ degradation products	[redacted]
3.3.10 Nitrate/nitrite measurement	[redacted]
3.3.11 Controls	Single flasks for the inoculum blank control (inoculum, no test substance), sterile control (test substance, no inoculum) and the reference substance (aniline, 100 mg/L) were included
3.3.12 Statistics	[redacted]

4 Results

4.1 Degradation of test substance

4.1.1 Graph

The percentage degradation of pyriproxyfen and aniline was calculated from the oxygen consumption, [redacted]

4.1.2 Degradation

Pyriproxyfen was not readily biodegradable in this test (<1% biodegradation after 7 and 28 days, respectively)

4.1.3 Other observations

[redacted] The study was therefore judged to be valid. S[redacted]

4.1.4 Degradation of TS in abiotic control

[redacted]

4.1.5 Degradation of reference substance

[redacted]

4.1.6 Intermediates/ degradation products

[redacted]

5 Applicant's Summary and Conclusion

5.1 Materials and methods

The ready biodegradability of pyriproxyfen was studied in accordance with the guideline ""Ready biodegradability of chemical substance by microbe" (EHWD No.5, PAB No.615, BIB No.392 ['74]), equivalent to the OECD Guideline for Testing of Chemicals, No. 301C Modified MITI test (I)". There were no significant deviations from the guideline.

5.2 Results and discussion

Pyriproxyfen was not readily biodegradable in this test (<1% biodegradation after 7 and 28 days, respectively). After 7 days, the pass level for the reference substance (aniline) was reached (60% ThOD).

[redacted] Pyriproxyfen can therefore be considered as non-toxic to the micro-organisms in activated sewage sludge.

	The study was therefore judged to be valid
5.3 Conclusion	Pyriproxyfen was not readily biodegradable in a modified MITI-I test
5.3.1 Reliability	[redacted]
5.3.2 Deficiencies	[redacted]

	Evaluation by Competent Authorities
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[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

7.1.1.2.2 Inherent biodegradability, where appropriate

No study available. Sufficient information on the biodegradation of pyriproxyfen in the aquatic environment is provided in the water-sediment degradation studies (section 7.1.2.2.2).

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7.1.1.2.3 Biodegradation in seawater

No study available. A study on the biodegradation of pyriproxyfen in seawater is not required, as the biocidal product is not intended for use or release in marine environments.

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Evaluation by Rapporteur Member State	
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7.1.2 Rate and route of degradation in aquatic systems including identification of metabolites and degradation products

No specific study available. A further study on the rate and route of degradation of pyriproxyfen in aquatic systems is not required, as sufficient information is provided in the water-sediment degradation studies (section 7.1.2.2.2).

Evaluation by Competent Authorities
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Evaluation by Rapporteur Member State
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7.1.2.1 Biological sewage treatment

7.1.2.1.1 Aerobic biodegradation

No study available. An aerobic biodegradation study is not required, as the biocidal product is not expected to enter a sewage treatment plant before release to the environment.

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
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7.1.2.1.2 Anaerobic biodegradation

Section 7.1.2.1.2/01 Anaerobic biodegradation
Annex Point IIIA XII 2.1

Official use only

1 Reference

1.1 Reference [redacted]

1.2 Data protection Yes

1.2.1 Data owner: Sumitomo Chemical Co., 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

Environmental Protection Agency Pesticide Assessment Guidelines, Subdivision N, Section 162-3

2.2 GLP Yes

2.3 Deviations No

3 Materials and Methods

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 Further relevant properties: Not applicable

3.1.5 Composition of Product: Not applicable. The test substance was prepared as test sample not as commercial product

3.1.6 TS inhibitory to microorganisms: No