[redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

µg/kg

[redacted]

The whole-fish depuration half-lives were 0.9 and 1.6 days for the [redacted] labels, respectively. The percentage of ^{14}C eliminated from test fish (whole body after 14 days was 98.1% and 89.6% for the [redacted] and [redacted] labels, respectively

4.1.4 Bioconcentration factors (BCF)

BCF	Whole fish	Edible tissue	Non-edible tissue
[redacted]	1379	465	2482
[redacted]	1495	478	2390

4.1.5 Uptake and depuration

[redacted]

rate constants [redacted]

4.1.6 Depuration time [redacted]

4.1.7 Metabolites [redacted]

4.1.8 Other Observations [redacted]

4.2 Estimation of bioconcentration [redacted]

5 Applicant's Summary and conclusion

5.1 Materials and methods

The objective of the study was to delineate the uptake, depuration and bioconcentration behaviour of [redacted] in whole fish, edible and non-edible tissues of bluegill sunfish (*Lepomis macrochirus*). The study was done in accordance with the US-EPA guidelines for assessment of pesticide accumulation in fish (Subdivision N, 165-4, Reference 1)

The study consisted of a 28-day uptake phase and a 14-day depuration phase. During the uptake phase, two different radiolabels, [redacted] were administered in two separate chambers using a flow-trough system. A third chamber served as control

Exposure initiation date: 06 June [redacted]
Depuration completion date: 18 July [redacted]

[redacted]

5.2 Results and discussion

The mean [redacted] pyriproxyfen concentrations in the test water were 19.1 ±2.3 µg/L and 20.0 ±2.7 µg/L, respectively (days 0-28 average)

[redacted]

5.3 Conclusion

The validity criterion can be considered as fulfilled (no mortality exceeding 10%)

At expositions levels of *ca* 20 µg/L test water, the ^{14}C concentrations in whole fish remained at *ca* 30 mg/kg fish during the uptake period. The radiocarbon was depurated rapidly from the fish body during the depuration period. After 14 days, 98 % of the [redacted] and 89.6 % of the [redacted] residues had been depurated from the fish tissues (whole fish). Consequently, the potential for bioaccumulation in fish is considered to be fairly low

5.3.1Reliability [redacted]

5.3.2 Deficiencies [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	
[redacted]	[redacted]
Comments from ...	
Date	
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Reliability	
Findings	
Conclusion	
Remarks	

7.4.3 Effects on aquatic organisms, further studies

7.4.3.1 Prolonged toxicity to an appropriate species of fish

This test is not necessary as a fish reproduction study is submitted at Point 7.4.3.2.

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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Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

7.4.3.2 Effects on reproduction and growth rate of fish

Section A7.4.3.2 **Effects on reproduction and growth rate of fish**
Annex Point IIIA XIII 2.2

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 No

Method used comparable to U.S. EPA, Proposed recommended bioassay procedure for egg and fry stages of freshwater fish, Unpublished manuscript, (1972)

2.2 GLP [redacted]

2.3 Deviations

3 Method

3.1 Test material [redacted]

3.1.1 Lot/Batch number [redacted]

3.1.2 Specification [redacted]

3.1.3 Purity [redacted]

[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 Preparation of TS solution for poorly soluble or volatile test substances [redacted]

[redacted]

3.3 Reference substance	No
3.3.1 Method of analysis for reference substance	Not applicable
3.4 Testing procedure	
3.4.1 Dilution water	[redacted]
3.4.2 Test organisms	[redacted]
3.4.3 Handling of embryos and larvae (OECD 210/212)	[redacted]
3.4.4 Test system	[redacted]
3.4.5 Test conditions	[redacted]
3.4.6 Duration of the test	95 Days
3.4.7 Test parameter(s)	Egg Hatchability, Fry Survival, Fry Growth
3.4.8 Examination / Sampling	Day 0, 1, 7 and then weekly thereafter
3.4.9 Monitoring of TS concentration	[redacted]
3.4.10 Statistics	[redacted]

4 Results

4.1 Range finding test	Not performed
4.1.1 Concentrations	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 Initial concentrations of test substance	[redacted]
4.2.2 Actual concentrations of test substance	[redacted]
4.2.3 Effect data	[redacted]

[redacted]

4.2.4 Concentration / response curve	[redacted]
4.2.5 Other effects	[redacted]
4.3 Results of controls	[redacted]
4.3.1 Number/ percentage of animals showing adverse effects	[redacted]
4.3.2 Nature of adverse effects	Not applicable
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	The study was conducted following a method comparable to U.S. EPA, Proposed recommended bioassay procedure for egg and fry stages of freshwater fish, Unpublished manuscript, (1972). The test system was flow through and rainbow trout was the test organism
5.2 Results and discussion	Based on the most sensitive endpoint (growth) evaluated during this 61-day post hatch rainbow trout early life stage study the maximum acceptable toxicant concentration (MATC) limits for Sumilarv [redacted] are estimated to be the mean measured concentrations of 4.3 µg/L (NOEC) and 6.7µg/L (LOEC) with the point estimate MATC value being 5.4 µg /L
5.2.1 NOEC	4.3 µg/L
5.2.2 LOEC	6.7µg/L
Conclusion	The evaluation criteria for OECD guidelines 210/11 and 215 were all met by this study. Based on the most sensitive endpoint (growth), the NOEC was 4.3 µg/L and the LOEC was 6.7 µg/L
Other Conclusions	

Reliability [redacted]

Deficiencies [redacted]

Evaluation by Competent Authorities	
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Evaluation by Rapporteur Member State	
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[redacted]		

7.4.3.3 Bioaccumulation in an aquatic organism

7.4.3.3.1 Bioaccumulation in an appropriate species of fish

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. A fish bioconcentration study is submitted under Point 7.4.2. This 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).

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
[redacted]	[redacted]
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Reliability	
Acceptability	
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7.4.3.3.2 Bioaccumulation in an appropriate invertebrate species

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 summarised at Point 7.4.2 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. The risk of bioaccumulation can therefore be considered low and a bioaccumulation study in an aquatic invertebrate species is not necessary.

Evaluation by Competent Authorities	
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Evaluation by Rapporteur Member State	
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Comments from ...	

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Results and discussion	
Conclusion	
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Acceptability	
Remarks	

7.4.3.4 Effects on reproduction and growth rate with an invertebrate species

Section A7.4.3.4/01
Annex Point IIIA XIII 2.4

Effects on reproduction and growth rate with an invertebrate species

		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 ASTM E-47.01 (Draft, May 1981); EPA-660/3-75-009, April 1975; OECD 202, May 1981	
2.2 GLP	[redacted]	
2.3 Deviations	[redacted]	
	3 Method	
3.1 Test material	[redacted]	
3.1.1Lot/Batch number	[redacted]	

[redacted]

[redacted]1

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 Preparation of TS solution for poorly soluble or volatile test substances

[redacted]

3.3 Reference substance

No

3.3.1 Method of analysis for reference substance

Not applicable

3.4 Testing procedure

3.4.1 Dilution water

[redacted]

3.4.2 Test organisms

[redacted]

3.4.3 Handling of offspring

[redacted]

3.4.4 Test system

[redacted]

[redacted]

3.4.5 Test conditions [redacted]

3.4.6 Duration of the test 21 days

3.4.7 Test parameter Mortality, immobilisation, sub-lethal effects, time to first brood, reproductive success, body length of P_0

3.4.8 Examination / Sampling Survival, abnormal effects and observance of first brood of the organisms were recorded every day throughout the 21 day study. Reproductive success was assessed on Mondays, Wednesdays and Fridays. The body length of the P_0-generation was determined at the end of the study.

3.4.9 Monitoring of TS concentration [redacted]

3.4.10 Statistics [redacted]

4 Results

4.1 Range finding test [redacted]

4.1.1 Concentrations 1.2, 2.4, 5.0, 10 and 20 ng/L

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 Initial concentrations of test substance [redacted]

4.2.2 Actual concentrations of test substance [redacted]

[redacted]

4.2.3 Effect data

[redacted]

4.2.4 Concentration / response curve

[redacted]

4.2.5 Other effects [redacted]

4.3 Results of controls [redacted]

4.4 Test with reference substance [redacted]

4.4.1 Concentrations

4.4.2 Results

5 Applicant's Summary and conclusion

5.1 Materials and methods

Two 21-day flow-through chronic toxicity dose-response tests were performed in order to evaluate the effects of [redacted] on the immobilisation (mortality) and reproduction rate of Daphnia magna. The tests were following the procedures outlined in the guidelines ASTM E-47.01 (Draft, May 1981); EPA-660/3-75-009, April 1975 and OECD 202, May 1981. the study was conducted with radio-labelled test material in order to verify the exposition concentrations

There were slight deviations from the guideline regarding food supply and turnover rate (see 2.3.). These deviations were considered not to have affected the study outcome.

5.2 Results and discussion

Summarize relevant results; discuss relevant test material-specific properties (e.g. solubility, stability, adsorption behaviour, volatility)

In the first test (with lower test concentrations), mean measured test concentrations (analysed at six dates throughout the study) ranged from 71% to 93% of nominal, indicating that the nominal concentrations were generally achieved. In the second test (with lower test concentrations), mean measured test concentrations (analysed at six dates throughout the study) ranged from 75% to 111% of nominal, indicating that the nominal concentrations were achieved.
In both studies, the mortality of the adult Daphnia was not affected in any of the treated groups. No clear effects on the reproductive success and body length were observed in test 1. During Test 2, statistically significant effects (α=0.05) were recorded regarding time to first brood, reproductive success and body length of P_0-generation.

5.2.1 NOEC

15 ng/L (at p = 0.05) for reproduction and body length
≥240 ng/L (at p = 0.05) for mortality and immobilisation

5.2.2 LOEC

27 ng/L (at p = 0.05) for reproduction and body length
>240 ng/L (at p = 0.05) for mortality and immobilisation

5.2.3 EC_{50} (EC_x)

EC_{50}: >240 ng/L (mortality and immobilisation)

5.3 Conclusion	The validity criteria can be considered as fulfilled. A clear dose-response relationship was observed for the reproductive success (see validity criteria summarized in table A7.4.3.4-08)
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
[redacted]
Comments from ... *(SPECIFY)*
Date
Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

[redacted]	[redacted]

[redacted]

[redacted]	[redacted]
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[redacted]

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	Test 1 and Test 2: 164-188 mg/L as $CaCO_3$
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

Table A7.4.3.4-03: Test organisms

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]

[redacted]

Section A7.4.3.4/02 Annex Point IIIA XIII 2.4 — Effects on reproduction and growth rate with an invertebrate species

Official use only

1 Reference

1.1 Reference

[redacted]

1.2 Data protection

Yes

1.2.1 Data owner

Sumitomo Chemical Company Ltd.

1.2.2

-

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

European Commission, Health & Consumer Protection Directorate-General, 2002. Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC, Working Document SANCO/3268/2001 rev4 (final), 2002

2.2 GLP

[redacted]

2.3 Deviations

[redacted]

3 Method

3.1 Test material	[redacted]
3.1.1Lot/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 Preparation of TS solution for poorly soluble or volatile test substances	Not applicable
3.3 Reference substance	No
3.3.1 Method of analysis for reference substance	Not applicable
3.4 Testing procedure	
3.4.1 Test water	[redacted]
3.4.2 Test organisms	[redacted]
3.4.3 Test system	[redacted]
3.4.4 Test conditions	[redacted]
3.4.5 Duration of the test	36 days acclimation, 57 days after dosing
3.4.6 Test parameter	Community effects
3.4.7 Examination / Sampling (Zooplankton)	Samples were taken at 8 and 1 days before application, and at 3, 7, 14, 21, 28, 35, 42, 49 and 56 days after application to assess effects on zooplankton (species composition and abundance). On each occasion, water was sampled in each microcosm from several points by means of a perspex tube to obtain a total sample volume of approximately 1 litre. The water was filtered through a 55-µm mesh plankton net and the plankton preserved in formalin. The filtered water was poured back into microcosm from which it had originally been taken
3.4.8 Examination / Sampling (Phytoplankton)	Effects on phytoplankton (chlorophyll-a) were carried out at the same time as for the zooplankton, in order to avoid a dilution effect on the chlorophyll-a. An integral water sample of about 250 mL was collected from each microcosm, at three random locations. Water samples of *ca.* 100 mL were concentrated over a glass-fibre filter, using a vacuum pump and surplus water and filtrates were returned to the appropriate microcosms

3.4.9 Monitoring of TS concentration	Yes Samples were taken from the 5 µg a.s./L microcosm at -1d, < 1 h, 1 d, 3 d, 7 d, 14 d and every 2 weeks, until 2 consecutive time points gave an analysis below the limit of detection (approximately 0.01 µg a.s./L). Additional analysis of water samples taken from all microcosms shortly after application (about 1 hour) was conducted to verify the initial exposure concentrations
3.4.9 Statistics	[redacted]

4 Results

4.1 Range finding test	Not performed
4.1.1 Concentrations	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 Initial concentrations of test substance	[redacted]
4.2.2 Actual concentrations of test substance	[redacted]

4.2.3 Effect data

4.2.3.1 Effect data (Zooplankton)

[redacted]

4.2.3.2 Effect Data (Chlorophyll)

[redacted]

4.2.3.3 Effect Data (Community metabolism)

[redacted]

4.2.3.4 Effect Data (Community interactions)

[redacted]

[redacted]

4.2.4 Concentration / response curve [redacted]

4.2.5 Other effects [redacted]

4.3 Results of controls

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

This test to assess the impact of [redacted] was carried out in indoor laboratory plankton-dominated microcosms. The guidelines followed were:
European Commission, Health & Consumer Protection Directorate-General, 2002. Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC, Working Document SANCO/3268/2001 rev4 (final), 2002.
Nominal concentrations of 0.00, 0.02, 0.08, 0.32, 1.2, 5 and 20 µg a.i./L were applied as a single application to microcosms. Effects on zooplankton, phytoplankton, and community metabolism were measured. The concentration of pyriproxyfen was measured over time for one microcosm in the 5µg a.i./L group

5.2 Results and discussion

The measured concentrations from samples taken showed that the nominal values were achieved. The half-life for pyriproxyfen in the water phase of the fate microcosm (5 µg a.i./L – treatment level) was about 1 day. There were no consistent treatment-related effects in physico-chemical endpoints

There were no consistent treatment related effects on nutrients or chlorophyll-a levels.

The cladoceran *Daphnia* gr.*galeata* was the most sensitive taxon and its $NOEC_{population}$ was 1.2 µg a.i./L. Duration of effects at the 5µg a.i./L was < 7 days. At the 20 µg a.i./L treatment level effects were consistent. Recovery occurred within 35 days
There were no consistent treatment-related effects on copepods.
Some rotifer populations showed a consistent increase in abundance in the 20 µg a.i./L microcosms. However the total rotifer abundance had recovered within 28 days of treatment. The NOEC for rotifers was 5 µ a.i./L

The $NOEC_{community}$ was 5 µg a.i./L Recovery of the community was within 28 days in the 20 µg a.i./L microcosms. The community response was mainly dominated by the increase in rotifers. This can be explained by a reduction in grazing/competition on this group as a result of direct effects caused by pyriproxyfen on sensitive zooplankton at the highest treatment level. Indirect effects (increase in rotifers) were of a longer duration than direct effects (decrease in sensitive cladocerans in the form of *D.*gr. *galeata*)

5.2.1 NOEC

NOEC for most sensitive population (*Daphnia* gr.*galeata*) = 1.2 µg a.i./L

$NOEC_{community}$ = 5.0µg a.i./L

5.2.2 LOEC

Not reported

5.3 Conclusion

Summary of effects:

Treatment (µg a.i./L)	Response
0.02	No treatment-related effects observed
0.08	No treatment-related effects observed
0.32	No treatment-related effects observed
1.2	No treatment-related effects observed. NOEC for cladoceran populations
5.0	Slight transient effect: reduction in 1 cladoceran species, duration < 1 week. No effects at the community level – NOECcommunity
20.0	Clear effects: Reduction in cladocerans but recovery within 35 days after treatment, indirect effects on some rotifers were observed, with an increase in one species up to the end of the experiment. However, most rotifer species, as well as total rotifer abundance had recovered within 42 days. Community recovery occurred within 28 days after treatment.

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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	[redacted]
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Comments from ... *(SPECIFY)*

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

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[redacted]							[redacted]				
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[redacted]

[redacted]

7.4.3.5 Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk

7.4.3.5.1 Effects on sediment dwelling organisms

Section A7.4.3.5.1/01 Effects on sediment dwelling organisms
Annex Point IIIA XIII 2.4

		Official use only
	1 Reference	
1.1 Reference	[redacted]	
1.2 Data protection	Yes	
1.2.1 Data owner	Sumitomo Chemical Company, Ltd.	
1.2.2		
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	OECD 219 (Draft, 2001)	

2.2 GLP [redacted]

2.3 Deviations [redacted]

[redacted]

3 Method

3.1 Test material [redacted]

3.1.1Lot/Batch number [redacted]

[redacted]

3.1.2 Specification [redacted]

3.1.3 Purity [redacted]

[redacted]

3.1.4 Composition of Product [redacted]

3.1.5 Further relevant properties [redacted]

3.1.6 Method of analysis [redacted]

3.2 Preparation of TS solution for poorly soluble or volatile test substances [redacted]

3.3 Reference substance Not applicable

3.3.1 Method of analysis for reference substance Not applicable

3.4 Testing procedure

3.4.1 Dilution water [redacted]

3.4.2 Test organisms Non-biting Midge (*Chironomus riparius*). [redacted]

3.4.3 Handling of offspring [redacted]

3.4.4 Test system Glass beakers containing sediment and water, [redacted]

3.4.5 Test conditions [redacted]

3.4.6 Duration of the test 28 days

3.4.7 Test parameter Emergence/sex ratio

3.4.8 Examination / Sampling	During period of expected emergence, daily check of emerged midges, number and sex of emerged midges was recorded
3.4.9 Monitoring of TS concentration	[redacted]
3.4.10 Statistics	[redacted]

4 Results

4.1 Range finding test	Not performed
4.1.1 Concentrations	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	Non-entry field
4.2.1 Initial concentrations of test substance	2.5, 5, 10, 20 and 40 µg a.i./L
4.2.2 Actual concentrations of test substance	[redacted]
4.2.3 Effect data	[redacted]

[redacted]	Midges emerged [redacted]	
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

[redacted]

4.2.4 Concentration / response curve [redacted]

4.2.5 Other effects [redacted]

4.3 Results of controls [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 The study was conducted following the OECD draft guideline 219 "Sediment Water Chironomid Toxicity test Using Spiked Water

5.2 Results and discussion The test was conducted with radiolabelled test substance in spiked water. Since the test substance disappears rapidly from the water phase, the values measured one hour after application do not reflect the whole amount of applied test substance, but only the proportion that still was in the water phase one hour after application. That is why the results were based on nominal values and not on measured values

No statistically significant deviations from the pooled controls were observed

5.2.1 NOEC ≥40 µg a.s./L

5.2.2 LOEC	>40 µg a.s./L
5.2.3 EC_{50} (EC_x)	>40 µg a.s./L
5.3 Conclusion	The validity criteria can be considered as fulfilled. [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
Evaluation by Rapporteur Member State
[redacted]

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Comments from ... *(SPECIFY)*

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

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7.4.3.5.2 Aquatic plant toxicity

Pyriproxyfen is an insecticide, therefore additional tests with aquatic plants are not necessary.

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

7.4.3.5.3/01 Effects on aquatic insects

1 Reference		Official use only
1.1 Reference	[redacted] (1987)	

[redacted]

1.2 Data protection No

1.2.1 Data owner Published report

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

2.2 GLP No

2.3 Deviations

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 Methoprene (purity 88.2%), diflubenzuron (25% wettable powder), temephos (5% wettable powder)

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]

3.3.3 Test organisms	[redacted]
3.3.4 Test system	[redacted]
3.3.5 Test conditions	[redacted]
3.3.6 Test duration	24 hours
3.3.7 Test parameter	Mortality
3.3.8 Examination	Mosquito: Mortality was assessed at 24 hours. Feed was then added to each cup, the cups were covered with nets and left until adults emerged. Housefly: The overall inhibition of adult emergence from pupae was examined.
3.3.9 Monitoring of test substance concentration	[redacted]
3.3.10 Statistics	[redacted]

4 Results

4.1 1 Limit Test / Range finding test	Not Performed
4.1.1 Concentration	
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	[redacted]
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		
4.4.1 Concentrations	[redacted]	
4.4.2 Results	[redacted]	

5 Applicant's Summary and conclusion

5.1 Materials and methods

The activity [redacted] against the [redacted] larvae of *Culex pipiens pallens, Anopheles stephensi* and *Aedes aegypti* was evaluated by the immersion method. [redacted] Mortality was assessed at 24 hours, then feed was added to the cup which was covered with a cup until adults emerged.

The effects of [redacted] on eggs or 4-day old larvae of *Musca domestica* were evaluated using the artificial and chicken manure medium methods. Eggs deposited within 3 hours or larvae were released into the medium and were reared until pupation. Pupae were transferred into new containers and the adults that emerged normally were counted.

5.2 Results and discussion

[redacted] x

5.2.1 NOEC

Not reported

5.2.2 LOEC	Not reported
5.2.3 IC_{50}	The IC_{50} values [redacted] against the larvae of of *Culex pipiens pallens, Anopheles stephensi* and *Aedes aegyptiwa* were 0.0046, 0.043 and 0.023 ppb respectively. Against WHO and CSMA strain larvae the IC_{50} values were 0.0091 and 0.0031 µg/g medium.
5.2.4 LC_{100}	
5.3 Conclusion	[redacted] is a strong insect growth regulator and should be of practical use for control of these insects.
5.3.1 Other Conclusions	
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
Evaluation by Rapporteur Member State
[redacted]

Comments from ... *(SPECIFY)*

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

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[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

7.4.3.5.3/02 Effects on aquatic insects

Official use only

1 Reference

1.1 Reference [redacted]

1.2 Data protection No

1.2.1 Data owner Published report

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

WHO (1981) Instruction for determining the susceptibility or resistance of mosquito larvae to insect developmental inhibitors. WHO/UBC/91.812

2.2 GLP [redacted]

2.3 Deviations [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 [redacted]

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	6 hour exposure method: 6 hours exposure followed by emergence period in distilled water Continuous exposure method: The larvae were exposed continuously to the test solution until emergence.
3.3.7 Test parameter	Bioefficacy study: mortality including abnormal immatures and adults. The parameters of the sub-lethal effects study were % pupation, % adult emergence and its sex ratio, fecundity of emerging adults and % hatchability of eggs produced by emerging adults.
3.3.8 Examination	The mortality of larvae, pupae and adults were recorded daily in the bioefficacy study. In the sub-lethal effects study, daily observations were made of pupation, adult emergence, sex ratio, fecundity and hatchability of eggs.
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	
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, 0.4, 2.0, 20.0, 40.0, 60.0 and 100 x 10^{-5} mg/l

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 Not applicable

4.4.1 Concentrations

4.4.2 Results

5 Applicant's Summary and conclusion

5.1 Materials and methods Bioefficacy study: Two methods were used for bioefficacy testing. A 6-hour exposure method involved 25 4th instar mosquito larvae being exposed to the prescribed concentrations in 250 ml test solutions in glass beakers for 6 hours. Following this exposure period the larvae were transferred to 250 ml distilled water with mosquito food added. In the continuous exposure method the larvae remained in the test solutions with food added at 6 hours post-treatment. In both cases the mosquito immatures were kept until emergence during which the mortality of larvae, pupae and adult were recorded daily.

Sub-lethal effect study: Using the LC_{50} value determined under continuous exposure, 4th instar larvae were exposed to 2.14×10^{-5} mg/l [redacted] with 25 larvae per 250 ml solution. After 6 hours exposure food was provided and observations were made of sub-lethal effects until the completion of the experiment. For the fecundity experiment, 30 blood fed females were placed individually in polyethelene cups containing moist filter paper. The egg laying period was limited to 5 days. The filter paper was then dried for 2 days and the eggs were

	counted. All eggs were given a single flooding and the number of larvae hatched within 5 days was taken as an indication of egg hatchability. Sub lethal effects in the F1 generation were determined by looking at the % of pupation, % of adult emergence and its related sex ratio.	
5.2 Results and discussion	The results from both the 6-hour and the continuous exposure methods indicated that [redacted] caused more mortality at pupal than at larval or adult stages. The LC_{50} values and 95% confidence limits for the exposure methods were 25.57×10^{-5} (18.39 – 31.43) and 2.14×10^{-5} (1.49 -2.93mg/l for the 6 hour and continuous exposure methods respectively. The continuous exposure method was able to control *Aedes aegypti* at a much lower dose than the 6-hour method. The sub lethal effects seen all occurred in the treated generation. Adult emergence was reduced by 48.7%, sex ratio for the emerging female versus male ratio was 1.7:1.0 and egg hatchability was reduced by 36.8%. For the F1 generation, all parameters tested showed no significant effect. This suggested that [redacted] did not persist in the subsequent generation.	x
5.2.1 NOEC	Not reported	
5.2.2 LOEC	0.4×10^{-5} mg/l	
5.2.3 LC_{50}	6-hour exposure method: 25.57×10^{-5} mg/l Continuous exposure method: 2.14×10^{-5} mg/l	
5.2.4 LC_{100}	Not applicable	
5.3 Conclusion	The continuous exposure method was able to control *Aedes aegypti* at lower doses. The LC_{50} value of 2.14×10^{-5} mg/l is consistent with previously obtained results. Most of the mortality occurred in the pupal stage and a minimal level occurred at the larval and adult stages. The action of [redacted] was similar to terpenoid and butyl-substituted insect growth regulators. The F1 generation did not show any effects on the percentage of pupae or adult emergence and the sex ratio was similar to that of mosquitoes in the field. This suggested that [redacted] did not persist in the subsequent generation.	
5.3.1 Other Conclusions		
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
Evaluation by Rapporteur Member State
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Comments from ... *(SPECIFY)*

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

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[redacted]

7.4.3.5.3/03 Effects on aquatic insects

		Official use only
	1 Reference	
1.1 Reference	[redacted]	
1.2 Data protection	No	
1.2.1 Data owner	Published report	
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	

2.2 GLP [redacted]

2.3 Deviations [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 Methoprene

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]

3.3.3 Test organisms [redacted]

3.3.4 Test system [redacted]

3.3.5 Test conditions [redacted]

3.3.6 Test duration 10 days

3.3.7 Test parameter Emergence/ mortality

3.3.8 Examination Emergence was determined 10 days after insecticide exposure

3.3.9 Monitoring of test substance concentration [redacted]

3.3.10 Statistics [redacted]

4 Results

4.1 1 Limit Test / Not Performed

Range finding test

4.1.1 Concentration

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 [redacted]

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

4.3 Results of controls [redacted]

4.3.1 Mortality

4.3.2 Number/ percentage of animals showing adverse effects

4.3.3 Nature of adverse effects

4.4 Test with reference substance

4.4.1 Concentrations [redacted]

4.4.2 Results [redacted]

5 Applicant's Summary and conclusion

5.1 Materials and methods As part of an evaluation into the efficacy of novel insecticides in the control of *Aedes aegypti* the toxicity of pyriproxyfen was tested.

[redacted]

5.2 Results and discussion Pyriproxyfen was approximately 28 fold more toxic to *Aedes aegypti* than methoprene. X

5.2.1 NOEC	Not reported
5.2.2 LOEC	Not reported
5.2.3 LC_{50}	The EC_{50} for pyriproxyfen was 0.0017 µg/l.
5.2.4 LC_{100}	Not reported
5.3 Conclusion	Pyriproxyfen is an effective insect growth regulator preventing the emergence of adults from treated larvae and is considered promising for mosquito control. Insect growth regulators are slower acting than other types of insecticide but are highly potent.
5.3.1 Other Conclusions	
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
Evaluation by Rapporteur Member State
[redacted]
Comments from ... *(SPECIFY)*
Date
Materials and Methods
Results and discussion
Conclusion
Reliability