Acceptability

Remarks

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7.5 Effects on terrestrial organisms

7.5.1 Terrestrial toxicity, initial tests

7.5.1.1 Inhibition to microbiological activity

Section A7.5.1.1/01 Inhibition to microbial activity (terrestrial)

Annex Point IIA7.4

		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	Yes	
	No OECD guidelines available then, but methods used comparable to Dutch guidelines for registering pesticides (Formulier A, H4.1: Invloed op bodemademhaling en stikstofomzettingen), modified May 1983	

2.2 GLP [redacted]

2.3 Deviations [redacted]

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 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 Soil sample / inoculum / test organism [redacted]

3.3.2 Test system [redacted]

3.3.3 Application of TS [redacted]

3.3.4 Test conditions [redacted]

3.3.5 Test parameter Soil respiration was measured as carbon dioxide evolution (absolute method) in the dark at 20 ±2°C

3.3.6 Analytical parameter [redacted]

3.3.7 Duration of the test 30 days

3.3.8 Sampling The CO_2-evolution was analyzed every second hour. The reported table lists values measured every 24 hours over a period of 30 days

3.3.9 Monitoring of TS concentration [redacted]

3.3.10 Controls The test included 12 treatment groups: [redacted]

[redacted]

3.3.11 Statistics	Not applicable

4 Results

4.1 Range finding test	Not performed
4.1.1 Concentration	Not applicable
4.1.2 Effect data	Not applicable
4.2 Results test substance	Non-entry field
4.2 1 Initial concentrations of test substance	0.0, 1.4 and 14.0 mg/ kg soil
4.2.2 Actual concentrations of test substance	Not applicable
4.2.3 Growth curves	Not applicable
4.2.4 Cell concentration data	Not applicable
4.2.5 Concentration/ response curve	Not applicable
4.2.6 Effect data	[redacted]
4.2.7 Other observed effects	[redacted]
4.3 Results of controls	[redacted]
4.4 Test with reference substance	Not performed
4.4.1 Concentrations	Not applicable
4.4.2 Results	Not applicable

5 Applicant's Summary and conclusion

5.1 Materials and methods	Soil respiration was measured as carbon dioxide evolution (absolute method) in the dark at 20 ±2°C. [redacted] The test included 12 treatment groups: [redacted]

The test was conducted according to the Dutch guidelines for registering pesticides (Formulier A, H4.1: Invloed op bodemademhaling en

	stikstofomzettingen), modified May 1983. Deviations were not reported
5.2 Results and discussion	The measured CO_2 production did not indicate any effect on the soil respiration up to and including 14.0 mg/kg soil., this applied to all four soil types.
5.2.1 NOEC	≥14.0 mg/kg soil
5.2.2 EC_{10}	Not determined
5.2.3 EC_{50}	>14.0 mg/kg soil
5.3 Conclusion	The approach to assess the microbial soil respiration by monitoring CO_2-evolution was adopted by the recent guideline (OECD 217) as well, allowing an up-to date assessment. The OECD guideline proposes enrichment with glucose, whereas the study discussed here used soil enriched with lucerne meal. Both approaches allow assessing the possible impact of a test substance on an increased soil respiration. The test was performed with two different soil types, each with and with out enrichment. The current guideline requires only one enriched soil type. The results of controls indicate concentrations in the expected range of soil amended with lucerne meal, and the differences between controls and treatment rates reflect natural variability. A significant impact of pyriproxyfen on the soil respiration can be ruled out
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]	[redacted]

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Comments from ...

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

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Section A7.5.1.1/02 **Inhibition to microbial activity (terrestrial)**

Annex Point IIA7.4

Official use only

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 No OECD guidelines available then, but methods used compliant with Dutch guidelines for registering pesticides (Formulier A, H4.1: Invloed op bodemademhaling en stikstofomzettingen), modified May 1983
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 Composition of Product	[redacted]
3.1.5 Further relevant properties	[redacted]
3.1.6 Method of analysis	[redacted]

3.2 Reference substance	None
3.2.1 Method of analysis for reference substance	Not applicable
3.3 Testing procedure	
3.3.1 Soil sample / inoculum / test organism	[redacted]
3.3.2 Test system	[redacted]
3.3.3 Application of TS	[redacted]
3.3.4 Test conditions	[redacted]
3.3.5 Test parameter	Inhibition of microbial nitrogen transformation
3.3.6 Analytical parameter	NH_4 and NO_3 measurement
3.3.7 Duration of the test	42 days (6 weeks)
3.3.8 Sampling	Weekly / bi-weekly (Days 0, 7, 14, 28, 42)
3.3.9 Monitoring of TS concentration	[redacted]
3.3.10 Controls	Two controls without test substance for each test soil (sandy soil or loamy soil)
3.3.11 Statistics	Not applicable

4 Results

4.1 Range finding test	Not performed
4.1.1 Concentration	Not applicable
4.1.2 Effect data	Not applicable
4.2 Results test substance	Non-entry field
4.2 1 Initial concentrations of test substance	0.0, 1.4 and 14.0 mg/ kg soil
4.2.2 Actual concentrations of test substance	Not applicable
4.2.3 Growth curves	Not applicable
4.2.4 Cell concentration data	Not applicable
4.2.5 Concentration/ response curve	Not applicable
4.2.6 Effect data	[redacted]

[redacted]

4.2.7 Other observed 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 effect of pyriproxyfen on nitrogen transformations in soil was studied using two soil types according to the Dutch guideline H4.1, see below. Ammonification and nitrification as parts of the soil nitrogen transformation process were evaluated by measuring the amounts of ammonium, nitrite and nitrate in soil that previously had been enriched by adding lucerne meal. Two treatment rates (1.4 and 14.0 mg/kg soil) and a control were tested

The test was conducted according to the Dutch guidelines for registering pesticides (Formulier A, H4.1: Invloed op bodemademhaling en stikstofomzettingen), modified May 1983. Deviations were not reported

5.2 Results and discussion

NH_4, NO_2 and NO_3 measurement data did not indicate any effect on the release of ammonium from Lucerne meal and the transformation into nitrate up to and including 14.0 mg/kg soil

5.2.1 NOEC

≥14.0 mg/kg soil

5.2.2 EC_{10}

Not determined

5.2.3 EC_{50}

>14.0 mg/kg soil

5.3 Conclusion

The approach to enrich soil with lucerne meal and to monitor NH_4, NO_2 and NO_3 was adopted by the recent guideline (OECD 216) as well, allowing an up-to date assessment. The test was performed with two different soil types, the current guideline requires only one soil. The results of controls indicate concentrations in the expected range of soil amended with lucerne meal, and the differences between controls and treatment rates reflect natural variability; a significant impact of pyriproxyfen on the nitrogen transformation processes can be ruled out

5.3.1 Reliability [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

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Comments from ...

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

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Section A7.5.1.1/03 **Annex Point IIA 7.4**	**Inhibition to microbial activity (terrestrial)**	
	1 Reference	**Official use only**
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. OECD 216 and OECD 217	
2.2 GLP	[redacted]	
2.3 Deviations	[redacted]	
	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 Composition of Product	[redacted]	
3.1.5 Further relevant properties	[redacted]	
3.1.6 Method of analysis	[redacted]	
3.2 Reference substance	Yes, Dinoseb acetate	
3.2.1 Method of analysis for reference substance	[redacted]	
3.3 Testing procedure		
3.3.1 Soil sample	[redacted]	
3.3.2 Test system	[redacted]	
3.3.3 Application of TS	[redacted]	
3.3.4 Test conditions	[redacted]	
3.3.5 Test parameter	Inhibition of carbon transformation (respiration) and inhibition of nitrogen transformation (nitrification)	
3.3.6 Analytical parameter	Carbon transformation test: CO_2 production rate (based on oxygen consumption) Nitrogen transformation test: ammonium, nitrite and nitrate concentrations	
3.3.7 Duration of the test	Carbon transformation test : 28 days Nitrogen transformation test: 46 days	
3.3.8 Sampling	Carbon transformation test: Soil was sampled on days 0, 7, 14 and 28 Nitrogen transformation test: Soil was sampled on days 0, 7, 14, 28 and 46	
3.3.9 Monitoring of TS concentration	[redacted]	
3.3.10 Controls	Yes. Control soil that contained no test item was prepared.	
3.3.11 Statistics	[redacted]	

	4 Results and Discussion	
4.1 Range finding test	[redacted]	
4.1.1 Concentration	[redacted]	
4.1.2 Effect data	[redacted]	
4.2 Results test substance		
4.2 1 Initial concentrations of test substance	0.30 and 1.5 mg a.i./ kg dry soil	
4.2.2 Actual concentrations of test substance	Not applicable	
4.2.3 Growth curves	Not applicable	
4.2.4 Cell concentration data	Not applicable	
4.2.5 Concentration/ response curve	Not applicable	
4.2.6 Effect data	[redacted]	
4.2.7 Other observed effects	[redacted]	
4.3 Results of controls	[redacted]	

	[redacted]	
4.4 Test with reference substance	Performed with dinoseb acetate	
4.4.1 Concentrations	[redacted]	
4.4.2 Results	[redacted]	
	5 Applicant's Summary and conclusion	
5.1 Materials and methods	The study to determine the effect of pyriproxyfen on soil microflora activity was performed in accordance with OECD guidelines 216 and 217. Loamy sans soil was collected from a meadow site [redacted]	
5.2 Results and discussion	The microbial respiration levels of the treated soil samples were not significantly different when compared to the control soil and showed	

	less than 25% deviation after 28 days incubation. The results of the nitrogen transformation study indicated that the loamy sand microflora transformed Lucerne meal-bound nitrogen into nitrate-bound nitrogen without a significant accumulation of nitrite or ammonium. Nitrate levels showed less than 25% deviation from the control after 46 days incubation. The nitrate transformation rates and the incremental nitrate transformation rates of the treated soils were not significantly different from those of the control soil after 46 days incubation.	
5.2.1 NOEC	>1.5 mg a.i./kg dry soil	
5.2.2 EC_{10}	Not applicable	
5.2.3 EC_{50}	> 1.5 mg a.i./kg dry soil	
5.3 Conclusion	The variation between the replicate control samples was less than 15% at all sampling intervals for both the respiration rate and nitrate concentration tests. The results for the reference study with dinoseb acetate demonstrate that the methods used in this study were appropriate. The deviations in respiration rate and nitrate levels after 28 days were lower than the guideline trigger value of 25%. Changes to the nitrate transformation rates were transient and not dose-dependent. It can be concluded that pyriproxyfen had no lasting effects on the respiration and nitrification processes of soil microflora at the concentrations tested.	
5.3.1 Reliability	[redacted]	
5.3.2 Deficiencies	[redacted]	
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
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Materials and Methods	
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7.5.1.2 Earthworm, acute toxicity test

Section A7.5.1.2 **Earthworm, acute toxicity test**
Annex Point IIIA XIII 3.2

	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
	OECD Guideline 207
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 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	14 days
3.3.7 Test parameter	Mortality

3.3.8 Examination	Examinations at 7 and 14 days
3.3.9 Monitoring of test substance concentration	[redacted]
3.3.10 Statistics	[redacted]

4 Results

4.1 Filter paper 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 Soil test	
4.2.1 Initial concentrations of test substance	0, 62.5, 125, 250, 500, 1000 mg/kg dry weight soil
4.2.2 Effect data (Mortality)	[redacted]
4.2.3 Concentration / effect curve	[redacted]
4.2.4 Other effects	[redacted]
4.3 Results of controls	
4.3.1 Mortality	[redacted]
4.3.2 Number/ percentage of earthworms 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	The study was conducted according to OECD guideline 207. The test was performed in a static medium and the earthworm *Eisenia foetida foetida* was the test organism
5.2 Results and discussion	The study was conducted mixing stock solutions containing Tween 80 and up to 1000mg/kg dry weight soil[redacted]
5.2.1 LC_0	Not applicable
5.2.2 LC_{50}	>1000mg/kg
5.2.3 LC_{100}	>1000mg/kg
5.3 Conclusion	The study meets the validity criteria[redacted] Based on the mortality data[redacted] is not considered to be toxic to earthworms. Reductions in bodyweights in the 250mg/kg and above groups indicate that these concentrations exceeded the no effect level in soil
5.3.1 Other Conclusions	Not applicable
5.3.2 Reliability	[redacted]
5.3.3 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	
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Comments from ...

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

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7.5.1.3 Terrestrial plant toxicity

Section A7.5.1.3 Terrestrial plant toxicity
Annex Point IIIA XIII 3.4

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	No (Data requirement: Council Directive 91/414/EC, Annex IIA, Point 8.6)
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 Preparation of TS solution for poorly soluble or volatile test substances [redacted]

3.3 Reference substance [redacted]

3.3.1 Method of analysis for reference substance

3.4 Testing procedure [redacted]

3.4.1Dilution water [redacted]

3.4.2 Test plants [redacted]

3.4.3 Test system [redacted]

3.4.4 Test conditions [redacted]

3.4.5 Test duration 19 days

3.4.6 Test parameter Herbicidal activity

3.4.7 Sampling [redacted]

3.4.8 Method of analysis of the plant material [redacted]

3.4.9 Quality control

3.4.10 Statistics [redacted]

4 Results

4.1 Results test substance

4.1.1 Applied initial concentration [redacted]

4.1.2 Phytotoxicity rating [redacted]

4.1.3 Plant height [redacted]

4.1.4 Plant dry weights [redacted]

4.1.5 Root dry weights [redacted]

4.1.6 Root length [redacted]

4.1.7 Number of dead plants [redacted]

4.1.8 Effect data [redacted]

4.1.9 Concentration / response curve [redacted]

4.1.10 Other effects [redacted]

4.2 Results of controls

4.2.1 Number/ percentage of plants showing adverse effects	[redacted]
4.2.2 Nature of adverse effects	[redacted]
4.3 Test with reference substance	[redacted]
4.3.1 Concentrations	[redacted]
4.3.2 Results	[redacted]

5 Applicant's Summary and conclusion

5.1 Materials and methods	Test plants were cultivated in a greenhouse 30°C (by day) and 25°C (by night). Seeds were sown in plastic pots 10 cm diameter. Pyriproxyfen was applied at a dose rate of 8000g a.i./ha to test plants (one pot per species with no replication) at post emergence (as foliar application 7 days after seeding). Herbicidal activity was visually evaluated on a scale of 0 (no injury) to 10 (complete kill), 19 days after treatment
5.2 Results and discussion	In post-mergence application, pyriproxyfen showed very weak activity on barnyard grass, velvet leaf and radish at 8000 g a.i./ha. No activity was observed on oats
5.2.1 EC_{20}	Not applicable
5.2.2 EC_{50}	Not applicable
5.2.3 EC_{80}	Not applicable
5.3 Conclusion	Pyriproxyfen did not show any remarkable herbicidal activities to the tested plants at 8000 g a.i./ha
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]	[redacted]
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Comments from ...

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Reliability

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Remarks

[redacted]

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[redacted]	[redacted]
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[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]
[redacted]	Green house
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
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[redacted]	[redacted]
[redacted]	[redacted]
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[redacted]	[redacted]

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

[redacted]

7.5.2 Terrestrial tests, long-term tests

7.5.2.1 Reproduction Studies with other soil non-target macro-organisms

The risk assessment to the terrestrial compartment based on the results of the acute toxicity tests demonstrates an acceptable risk to terrestrial non-target organisms. Long term tests on terrestrial organisms are therefore 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]	[redacted]
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Comments from ...	
Date	
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Acceptability	
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7.5.2.2 Long-term tests with terrestrial plants

The risk assessment to the terrestrial compartment based on the results of the acute toxicity tests demonstrates an acceptable risk to terrestrial non-target organisms. Long term tests on terrestrial organisms are therefore 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]

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

	Comments from ...
Date	
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7.5.3 Effect on Birds

7.5.3.1 Acute oral toxicity to birds

Section A7.5.3.1/01 **Acute oral toxicity on birds**
Annex Point IIIA XIII 1.1

		Official use only
	1 Reference	
1.1 Reference	[redacted] (1989) [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	
	US EPA Assessment Guidelines; Series 71- Avian and mammalian	

testing No 71-1 Avian single-dose oral LD_{50} test

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 in the diet [redacted]

3.2 Administration of the test substance [redacted]

3.3 Reference substance [redacted]

3.3.1 Method of analysis for reference substance [redacted]

3.4 Testing procedure

3.4.1 Test organisms [redacted]

3.4.2 Test system [redacted]

3.4.3 Diet [redacted]

[redacted]

3.4.4 Test conditions [redacted]

3.4.5 Duration of the test 14 days from dosing.

3.4.6 Test parameter Mortality

3.4.7 Examination / Observation	Bird health and mortality observed daily Individual bodyweights measured at –14, -7, 0, 7 and 14 days.
3.4.8 Statistics	[redacted]

4 Results

4.1 Limit Test / Range finding test	Performed
4.1.1 Concentration	[redacted]
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	500, 1000 and 2000mg/kg bw
4.2.2 Effect data (Mortality)	[redacted]
4.2.3 Body weight	[redacted]
4.2.4 Feed consumption	[redacted]

[redacted]

4.2.5 Concentration / response curve [redacted]

4.2.6 Other effects [redacted]

4.3 Results of controls

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

4.3.2 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 The study was conducted according to EPA Guideline series 71- Avian and mammalian testing § 71-1 Avian single dose LD_{50}

[redacted]

5.2 Results and discussion There was no treatment related mortality observed in the study.

5.2.1 LD_{50} >2000mg/kg

5.3 Conclusion The validity criteria for this study were fulfilled. The study indicates that pyriproxyfen [redacted] is not toxic to birds

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]	[redacted]
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[redacted]	[redacted]
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Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
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	[redacted]	[redacted]
[redacted]	[redacted]	

Section A7.5.3.1/02 Acute oral toxicity on birds

Annex Point IIIA XIII 1.1

Official use only

1 Reference

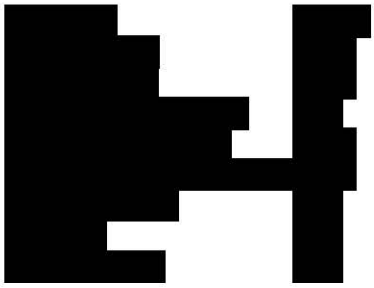
1.1 Reference	[redacted]
1.2 Data protection	Yes
1.2.1 Data owner	Sumitomo Chemical Company Ltd.
1.2.2	-
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

2 Guidelines and Quality Assurance

2.1 Guideline study	Yes US EPA Assessment Guidelines; Series 71- Avian and mammalian testing No 71-1 Avian single-dose oral LD_{50} test
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 in the diet	[redacted]
3.2 Administration of the test substance	[redacted]

3.3 Reference substance	No
3.3.1 Method of analysis for reference substance	Not applicable
3.4 Testing procedure	
3.4.1 Test organisms	[redacted]
3.4.2 Test system	[redacted]
3.4.3 Diet	[redacted]
	
	[redacted]
3.4.4 Test conditions	[redacted]
3.4.5 Duration of the test	14 days pre dosing, 14 days post dosing
3.4.6 Test parameter	Mortality
3.4.7 Examination / Observation	Bird health and mortality observed daily. Individual bodyweights measured at -14, -7, 0, 7 and 14 days.
3.4.8 Statistics	[redacted]

4 Results

4.1 Limit Test / Range finding test	Performed
4.1.1 Concentration	[redacted]
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	500, 1000 and 2000 (mg/kg bw)
4.2.2 Effect data (Mortality)	[redacted].
4.2.3 Body weight	[redacted]

[redacted]

4.2.4 Feed consumption

[redacted]

4.2.5 Concentration / response curve

[redacted]

4.2.6 Other effects

[redacted]

4.3 Results of controls

4.3.1 Number/ percentage of animals showing adverse effects

[redacted]

4.3.2 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 The study was conducted according to EPA Guideline series 71- Avian and mammalian testing § 71-1 Avian single dose LD_{50}

[redacted]

5.2 Results and discussion There was no treatment related mortality observed in the study.

A probable treatment related decrease in bodyweight was seen in the 2000 mg/kg groups. This group showed compensatory bodyweight increase following the treatment period

5.2.1 LD_{50} > 2000 mg/kg

5.3 Conclusion The validity criteria for this study have all been fulfilled. These results indicate that pyriproxyfen [redacted] is not toxic to birds.

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 ...
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Conclusion
Reliability
Acceptability
Remarks

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[redacted]

7.5.3.2 Short-term toxicity on birds

Section A7.5.3.2/01 Short-term toxicity to birds
Annex Point IIIA XIII 1.2

		Official use only
1 Reference		
1.1 Reference	[redacted]	
1.2 Data protection	Yes	
1.2.1 Data owner	Sumitomo Chemical Company Ltd.	

1.2.2	-
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 US EPA Pesticide Assessment Guideline § 71-2, Avian dietary LC_{50} Test
2.2 GLP	[redacted]
2.3 Deviations	[redacted]

3 Method

3.1Test 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	-
3.1.6 Method of analysis	[redacted]
3.2 Administration of the test substance	[redacted]
3.3 Reference substance	No
3.3.1 Method of analysis for reference substance	Not applicable
3.4 Testing procedure	
3.4.1 Test organisms	[redacted]
3.4.2 Test system	[redacted]
3.4.3 Diet	[redacted]
3.4.4 Test conditions	[redacted] 04

3.4.5 Duration of the test	8 days.
3.4.6 Test parameter	Mortality
3.4.7 Examination / Observation	Mortality and clinical observations were made daily. Group mean body weights were observed on days -3, 0 (immediately prior to the introduction of test diets), 5 and 8. Group mean food consumption was observed between days -3 to 0, daily on days 1 to 5 and between days 6 to 8
3.4.8 Statistics	[redacted]

4 Results

4.1 Limit Test / Range finding test	Performed
4.1.1 Concentration / dose	[redacted]
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 (Control), 650, 1300, 2600, 5200 mg/kg food
4.2.2 Effect data (Mortality)	[redacted]
4.2.3 Body weight	[redacted]

[redacted]

4.2.4 Food consumption

[redacted]

4.2.5 Concentration / response curve

[redacted]

4.2.6 Other effects

[redacted]

4.3 Results of controls

4.3.1 Number/ percentage of animals showing adverse effects

[redacted]

4.3.2 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

This study was conducted according to US EPA Pesticide Assessment Guideline § 71-2, Avian dietary LC_{50} Test. [redacted]

5.2 Results and discussion	No adverse effects were seen in any of the treatment groups
5.2.1 LC_0	5200 mg/kg
5.2.2 LC_{50}	>5200 mg/kg
5.2.3 LC_{100}	>5200 mg/kg
5.3 Conclusion	The validity criteria in Table A7.5.3.2-05 are all met. The result indicates that pyriproxyfen [redacted] is of low toxicity to the Mallard duck
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]	[redacted]
	Comments from ...
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Materials and Methods	
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Conclusion	
Reliability	
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Remarks	

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

Section A7.5.3.2/02 Short-term toxicity on birds
Annex Point IIIA XIII 1.2

Official use only

1 Reference

1.1 Reference	[redacted]
1.2 Data protection	Yes
1.2.1 Data owner	Sumitomo Chemical Company Ltd.
1.2.2	-
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 US EPA Pesticide Assessment Guideline § 71-2, Avian dietary LC_{50} Test.
2.2 GLP	[redacted]
2.3 Deviations	[redacted]

3 Method

3.1Test 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]

[redacted]

3.2 Administration of the test substance	[redacted]
3.3 Reference substance	No
3.3.1Method of analysis for reference substance	Not applicable
3.4 Testing procedure	
3.4.1 Test organisms	[redacted]
3.4.2 Test system	[redacted]
3.4.3 Diet	[redacted]
3.4.4 Test conditions	[redacted]
3.4.5 Duration of the test	11 days
3.4.6 Test parameter	Mortality
3.4.7 Examination / Observation	Mortality and clinical observations were made daily. Group mean body weights were observed on days -3, 0 (immediately prior to the introduction of test diets), 5 and 8. Group mean food consumption was observed between days -3 to 0, daily on days 1 to 5 and between days 6 to 8
3.4.8 Statistics	[redacted]

4 Results

4.1 Limit Test / Range finding test	Performed
4.1.1 Concentration / dose	[redacted]
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, 650, 1300, 2600 and 5200 mg/kg food
4.2.2 Effect data (Mortality)	[redacted]
4.2.3 Body weight	[redacted]

[redacted]

4.2.4 Food consumption

[redacted]

4.2.5 Concentration / response curve

[redacted]

4.2.6 Other effects

[redacted]

4.3 Results of controls

4.3.1 Number/ percentage of animals showing adverse effects	[redacted]
4.3.2 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	This study was conducted according to US EPA Pesticide Assessment Guideline § 71-2, Avian dietary LC_{50} Test. [redacted]
5.2 Results and discussion	No mortality was seen in the treatment groups. Animals in the 5200 ppm group showed a reduced rate of food consumption during the treatment period
5.2.1 LC_0	5200 mg/kg food
5.2.2 LC_{50}	>5200 mg/kg food
5.2.3 LC_{100}	Not applicable
5.3 Conclusion	The validity criteria [redacted] have been met. The result indicates that pyriproxyfen [redacted] is of low toxicity to the bobwhite quail
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
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[redacted]	[redacted]

Comments from ...

Date

Materials and Methods

Results and discussion

Conclusion

Reliability

Acceptability

Remarks

[redacted]

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