Section A5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)			Official use only
5.1	**Function (IIA5.1)**	Insecticide, PT18	
5.2	**Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**		
5.2.1	**Organism(s) to be controlled (IIA5.2)**	Pyriproxyfen is a juvenile hormone mimic and insect growth regulator used to control a broad spectrum of insects. It is used in farm applications (animal houses) and waste treatment sites to control flies and to running and standing water to control mosquitoes Pyriproxyfen is used to control flies [redacted] and mosquitoes [redacted]	
5.2.2	**Products, organisms or objects to be protected (IIA5.2)**	The products based on pyriproxyfen are designed to control fly and mosquito populations and provide both a nuisance and public health benefit	
5.3	**Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**		

5.3.1	**Effects on target organisms (IIA5.3)**	Pyriproxyfen is a juvenile hormone mimic and insect growth regulator. [redacted]	X
5.3.2	**Likely concentrations at which the A.S. will be used (IIA5.3)**		
	PT18	[redacted]	X

5.4	**Mode of action (including time delay) (IIA5.4)**		
5.4.1	**Mode of action**	Pyriproxyfen is a juvenile hormone mimic and insect growth regulator used to control a broad spectrum of insects. [redacted]	X
5.4.2	**Time delay**	[redacted]	
5.5	**Field of use envisaged (IIA5.5)**		
	MG01: Disinfectants, general biocidal products	Not applicable	
	MG02: Preservatives	Not applicable	
	MG03: Pest control	Product types PT18, Insecticide	
	MG04: Other biocidal products	Not applicable	
	Further specification	Pyriproxyfen is a juvenile hormone mimic and insect growth regulator used to control a broad spectrum of insects. It is used in products to control flies and mosquitoes	
5.6	**User (IIA5.6)**		
	Industrial	Not applicable	
	Professional	Pyriproxyfen is intended for use in professional products used in controlling flies in farm applications such as cattle pens, pig houses and poultry houses and also in waste treatment facilities. It is used to control mosquitoes in both running and standing water	
	General public	Not applicable	

5.7	**Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)**	
5.7.1	**Development of resistance**	[redacted] There is no evidence of resistance development in biocide applications
5.7.2	**Management strategies**	As with all biocides an alternating regimen is recommended to minimise the potential for resistance development
5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**	Considered to be commercially sensitive information. [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]

[redacted]

[redacted]

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

[redacted]

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)

References:

[redacted]

Table A5.3.1-02 Laboratory efficacy of Pyriproxyfen against mosquito larvae [a,b] (Taken from WHO WHOPES Report) Table 3.

Species	*LC_{50}/EI_{50} [c]*	*LC_{95}/EI_{95} [c]*	*Reference*
Ae aegypti	0.33	2.6	[redacted]
Ae aegypti	0.023	-	
Ae aegypti	0.056	-	
Ae aegypti	0.0039	-	
Ae albopictus	0.11	0.38	
Ae taeniorhynchus	0.01	0.052	
An albimanus	0.016	-	
An balabacensis	0.04	-	
An farauti	0.0017	-	
An gambiae	0.025	-	
An stephensi	0.043	-	
An quadrimaculatus	1.3	17	
Cx pipiens pallens	0.0046	-	
Cx pipiens molestus	0.029	-	
Cx quinquefasciatus	0.04	0.3[d]	
Cx quinquefasciatus	0.018	0.16	
Cx quinquefasciatus	0.29	1.1[d]	

Species	LC_{50}/EI_{50}[c]	LC_{95}/EI_{95}[c]	Reference
Cx tarsalis	0.085	0.32	[redacted]
Cx tarsalis	0.021	0.25	

[a] mostly 4th instar larvae
[b] all toxicity values are in ppb
[c] lethal concentration to inhibit 50% or 95% adult emergence
[d] LC_{90}/EI_{90} values

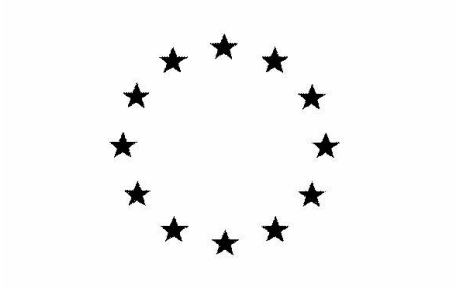
Table A5.3.1-03 Field efficacy of pyriproxyfen against mosquitoes in different habitats (Taken from WHO WHOPES Report) Table 4

Species	Formu-lation[a]	Dosage (a.i.)[b]	%IE[c] (range)	Control Duration	Reference
Ae aegypti	GR	25-50 ppb	98-100	>3 wks	[redacted]
Ae melanimom	GR	0.0028-0.011 kg/ha	20-100	4 days	
Ae nigromaculis	GR	0.0028-0.11 kg/ha	69-100	4 days	
Ae nigromaculis & Ae melanimom	EC	0.0028-0.0056 kg/ha	39-100	3 days	
An albimanus	GR	25-50 ppb	95-100	>3 wks	
An farauti	EC	0.1ppm	>70-100	>2 months	
An punctuans	GR	0.02-0.1ppm	100	20 days -> 2 months	
An minimus & An maculatus	GR	5 ppb	70-100	4 wks	
Cx spp	EC	0.11 kg/ha	100	>51 days	
Cx pipiens pallens	GR	1-100 ppb	91-100	3-6 weeks	
Cx quinquefasciatus	EC	0.0056-0.045kg/ha	100	2-14 days	
Cx quinquefasciatus	EC	0.11 kg/ha	100	2 months	
Cx quinquefasciatus	GR	25-50 ppb	100	>3 wks	

Species	***Formu-lation[a]***	***Dosage (a.i.)[b]***	***%IE[c] (range)***	***Control Duration***	***Reference***
Cx quinquefasciatus	EC& GR	0.1ppm	100	4-11 wks	[redacted]
Cx quinquefasciatus & Cx tarsalis, Cx peus	EC	0.1 kg/ha (single & multiple)	17-100	7-68 days	
Cx quinquefasciatus & Cx peus	GR	0.028-0.056 kg/ha	26-66	7 days	[redacted]
Cx tarsalis	MC &GR	0.011-0.056 kg/ha 0.0056-0.028 kg/ha	78-100 85-100	7 days 7 days	
Cx tritaeniorhynchus	GR	0.01 ppm	43-100	> 3 wks	[redacted]
Psorophora columbiae	GR	0.0056-0.011kg/ha	100	4 days	

[a] GR=granula; EC= emulsifiable concentrate; MC= microencapsulated
[b] a.i. =active ingredient
[c] %IE= % inhibition of adult emergence

European Commission



Pyriproxyfen

Document III-A
Section 6 – Mammalian toxicology
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.

6.1 Acute toxicity

6.1.1 Oral

Section A6.1.1/01 Acute toxicity - oral rat

Annex Point IIA6.1.1

Official use only

1 REFERENCE

1.1 Reference	[redacted]
1.2 Data protection	Yes
1.2.1 Data owner	Sumitomo Chemical Co., Ltd.
1.2.2 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	In-house method equivalent to US EPA FIFRA § 81-1, OECD 401, EEC B.1
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]
3.1.2.1 Description	[redacted]
3.1.2.2 Purity	[redacted]
3.1.2.3 Stability	[redacted]
3.2 Test Animals	
3.2.1 Species	Rat
3.2.2 Strain	[redacted]
3.2.3 Source	[redacted]
3.2.4 Sex	Male and female
3.2.5 Age/weight at study initiation	[redacted]

3.2.6 Number of animals per group	[redacted]
3.2.7 Control animals	Yes
3.3 Administration/ Exposure	Oral
3.3.1 Post exposure period	14 days
3.3.2 Type	[redacted]
3.3.3 Concentration	[redacted] and 5000 mg/kg bw
3.3.4 Vehicle	[redacted]
3.3.5 Concentration in vehicle	[redacted]
3.3.6 Total volume applied	[redacted]
3.3.7 Controls	[redacted]
3.4Examinations	[redacted]
3.5 Method of determination of LD_{50}	[redacted]
3.6 Further remarks	None

4 Results and Discussion

4.1 Clinical signs	[redacted]
4.2 Pathology	[redacted]
4.3 Other	[redacted]
4.4 LD_{50}	[redacted]

5 Applicant's Summary and Conclusion

5.1 Materials and methods	[redacted]

5.2 Results and discussion	[redacted]
5.3 Conclusion	The acute oral LD50 was greater than 5000 mg/kg in males and females
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 ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A6.1.1/02 Acute toxicity - oral mouse

Annex Point IIA6.1.1

Official use only

1 REFERENCE

1.1 Reference [redacted]

1.2 Data protection Yes

1.2.1 Data owner Sumitomo Chemical Co., Ltd.

1.2.2 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 In-house method equivalent to US EPA FIFRA § 81-1, OECD 401, EEC B.1

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]

3.1.2.1 Description [redacted]

3.1.2.2 Purity [redacted]

3.1.2.3 Stability [redacted]

3.2 Test Animals

3.2.1 Species Mice

3.2.2 Strain [redacted]

3.2.3 Source [redacted]

3.2.4 Sex Male and female

3.2.5 Age/weight at study initiation	[redacted]
3.2.6 Number of animals per group	[redacted]
3.2.7 Control animals	Yes
3.3 Administration/ Exposure	Oral
3.3.1 Post exposure period	14 days
3.3.2 Type	[redacted]
3.3.3 Concentration	0, [redacted] 5000 mg/kg bw
3.3.4 Vehicle	[redacted]
3.3.5 Concentration in vehicle	[redacted]
3.3.6 Total volume applied	[redacted]
3.3.7 Controls	[redacted]
3.4 Examinations	[redacted]
3.5 Method of determination of LD_{50}	[redacted]
3.6 Further remarks	None

4 RESULTS AND DISCUSSION

4.1 Clinical signs	[redacted]
4.2 Pathology	[redacted]
4.3 Other	[redacted]

change

4.4 LD_{50} [redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods [redacted]

5.2 Results and discussion [redacted]

5.3 Conclusion The acute oral LD_{50} in mice was >1000 mg/kg in males and >2000 mg/kg in females

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

[redacted]	[redacted]
Comments from ...	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	

[redacted]

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

Section A6.1.1/03 Acute toxicity - oral dog

Annex Point IIA6.1.1

Official use only

1 REFERENCE

1.1 Reference	[redacted]
1.2 Data protection	Yes
1.2.1 Data owner	Sumitomo Chemical Co., Ltd.
1.2.2 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	In-house method equivalent to US EPA FIFRA § 81-1, OECD 401, EEC B.1
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]
3.1.2.1 Description	[redacted]
3.1.2.2 Purity	[redacted]
3.1.2.3 Stability	[redacted]
3.2 Test Animals	
3.2.1 Species	Dog
3.2.2 Strain	[redacted]
3.2.3 Source	[redacted]
3.2.4 Sex	Male and female
3.2.5 Age/weight at study initiation	[redacted]
3.2.6 Number of animals per	[redacted]

group

3.2.7 Control animals	Yes
3.3 Administration/ Exposure	Oral
3.3.1 Post exposure period	14 days
3.3.2 Type	[redacted]
3.3.3 Concentration	0, [redacted] 5000 mg/kg bw
3.3.4 Vehicle	[redacted]
3.3.5 Concentration in vehicle	[redacted]
3.3.6 Total volume applied	[redacted]
3.3.7 Controls	[redacted]
3.4 Examinations	[redacted]
3.5 Method of determination of LD_{50}	[redacted]
3.6 Further remarks	[redacted]

4 RESULTS AND DISCUSSION

4.1 Clinical signs	[redacted]
	[redacted]
	[redacted]
4.2 Pathology	[redacted]
	[redacted]

[redacted]

4.3 Other [redacted]

4.4 LD_{50} [redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1Materials and methods [redacted]

5.2 Results and discussion [redacted]

5.3 Conclusion The approximate lethal dose of pyriproxyfen was > 5000mg/kg bw. in dogs

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]

6.1.2 Dermal

Section A6.1.2/01 Acute toxicity - dermal rat

Annex Point IIA 6.1.2

Official use only

1 REFERENCE

1.1 Reference	[redacted]
1.2 Data protection	Yes
1.2.1 Data owner	Sumitomo Chemical Co., Ltd.
1.2.2 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	In-house method equivalent to US EPA FIFRA§ 81-2, OECD 402, EEC B.3
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]
3.1.2.1 Description	[redacted]
3.1.2.2 Purity	[redacted]
3.1.2.3 Stability	[redacted]
3.2 Test Animals	
3.2.1 Species	Rat
3.2.2 Strain	[redacted]
3.2.3 Source	[redacted]
3.2.4 Sex	Male and female
3.2.5 Age/weight at study initiation	[redacted]
3.2.6 Number of animals per	[redacted]

group	
3.2.7 Control animals	Yes
3.3 Administration/ Exposure	Dermal
3.3.1 Post exposure period	14 days
3.3.2 Area covered	[redacted]
3.3.3 Occlusion	[redacted]
3.3.4 Vehicle	[redacted]
3.3.5 Concentration in vehicle	[redacted]
3.3.6 Total volume applied	[redacted]
3.3.7 Duration of exposure	[redacted]
3.3.8 Removal of test substance	[redacted]
3.3.9 Controls	[redacted]
3.4 Examinations	[redacted]
3.5 Method of determination of LD_{50}	[redacted]
3.6 Further remarks	None

4 RESULTS AND DISCUSSION

4.1 Clinical signs	[redacted]
4.2 Pathology	[redacted]
4.3 Bodyweight	[redacted]
4.4 LD_{50}	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1Materials and methods

[redacted]

5.2 Results and discussion

[redacted]

5.3 Conclusion

The acute dermal LD_{50} of pyriproxyfen in rats was > 2000 mg/kg bw

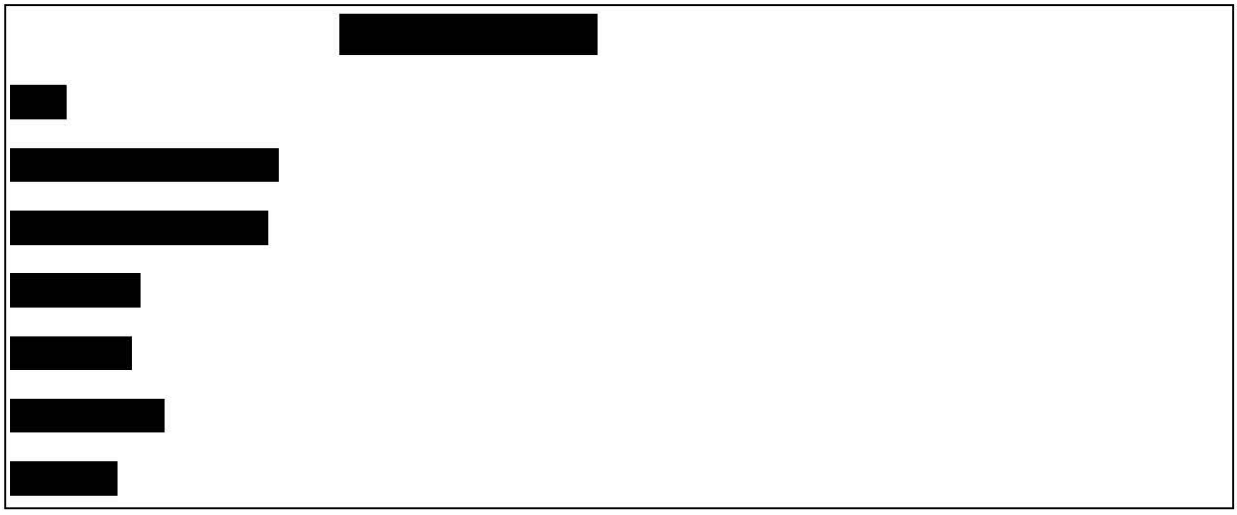
5.3.1 Reliability

[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]



Section A6.1.2/02 Acute toxicity – dermal mouse

Annex Point IIA 6.1.2

Official use only

1 REFERENCE

1.1 Reference [redacted]

1.2 Data protection Yes

1.2.1 Data owner Sumitomo Chemical Co., Ltd.

1.2.2 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 In-house method equivalent to US EPA FIFRA§ 81-2, OECD 402, EEC B.3

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]

3.1.2.1 Description [redacted]

3.1.2.2 Purity [redacted]

3.1.2.3 Stability [redacted]

3.2 Test Animals

3.2.1 Species Mice

3.2.2 Strain [redacted]

3.2.3 Source [redacted]

3.2.4 Sex Male and female

3.2.5 Age/weight at study initiation	[redacted]
3.2.6 Number of animals per group	[redacted]
3.2.7 Control animals	Yes
3.3 Administration/ Exposure	Dermal
3.3.1 Postexposure period	14 days
3.3.2 Area covered	[redacted]
3.3.3 Occlusion	[redacted]
3.3.4 Vehicle	[redacted]
3.3.5 Concentration in vehicle	[redacted]
3.3.6 Total volume applied	[redacted]
3.3.7 Duration of exposure	[redacted]
3.3.8 Removal of test substance	[redacted]
3.3.9 Controls	[redacted]
3.4 Examinations	[redacted]
3.5 Method of determination of LD_{50}	[redacted]
3.6 Further remarks	None

4 RESULTS AND DISCUSSION

4.1 Clinical signs	[redacted]
4.2 Pathology	[redacted]
4.3 Bodyweight	[redacted]
4.4 LD_{50}	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

5.2 Results and discussion

5.3 Conclusion

The acute dermal LD_{50} values of pyriproxyfen were >2000 mg/kg bw. for both sexes in mice

5.3.1 Reliability

5.3.2 Deficiencies

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

[redacted]

6.1.3 Inhalation

Section A6.1.3/01 Acute toxicity - inhalation rat

Annex Point IIA 6.1.3

		Official use only
	1 REFERENCE	
1.1 Reference	[redacted]	
1.2 Data protection	Yes	
1.2.1 Data owner	Sumitomo Chemical Co., Ltd.	
1.2.2 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	In-house method equivalent to OECD 403, EEC B.2	
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]	
3.1.2.1 Description	[redacted]	
3.1.2.2 Purity	[redacted]	
3.1.2.3 Stability	[redacted]	
3.2 Test Animals		
3.2.1 Species	Rat	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	Male and female	
3.2.5 Age/weight at study initiation	[redacted]	
3.2.6 Number of animals per group	[redacted]	

3.2.7 Control animals	Yes, vehicle and negative control	
3.3 Administration/ Exposure	Inhalation	
3.3.1 Post exposure period	14 days	
3.3.2 Concentrations	Nominal concentration	Not included in the report
	Analytical concentration	600 and 1300 mg/m³
3.3.3 Particle size of mists generated	[redacted]	
3.3.4 Type or preparation of particles	[redacted]	
3.3.5 Type of exposure	[redacted]	
3.3.6 Vehicle	[redacted]	
3.3.7 Concentration in vehicle	[redacted]	
3.3.8 Duration of exposure	4 hours	
3.3.9 Controls	[redacted]	
3.4 Examinations	[redacted]	
3.5 Method of determination of LD_{50}	[redacted]	
3.6 Further remarks	None	

4 Results and Discussion

4.1 Clinical signs	[redacted]
4.2 Pathology	[redacted]
4.3 Body weight	[redacted]
4.4 LD_{50}	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1Materials and methods

[redacted]

5.2 Results and discussion

[redacted]

In accordance with the provisions of Council Directive 67/548/EEC, classification is not required.

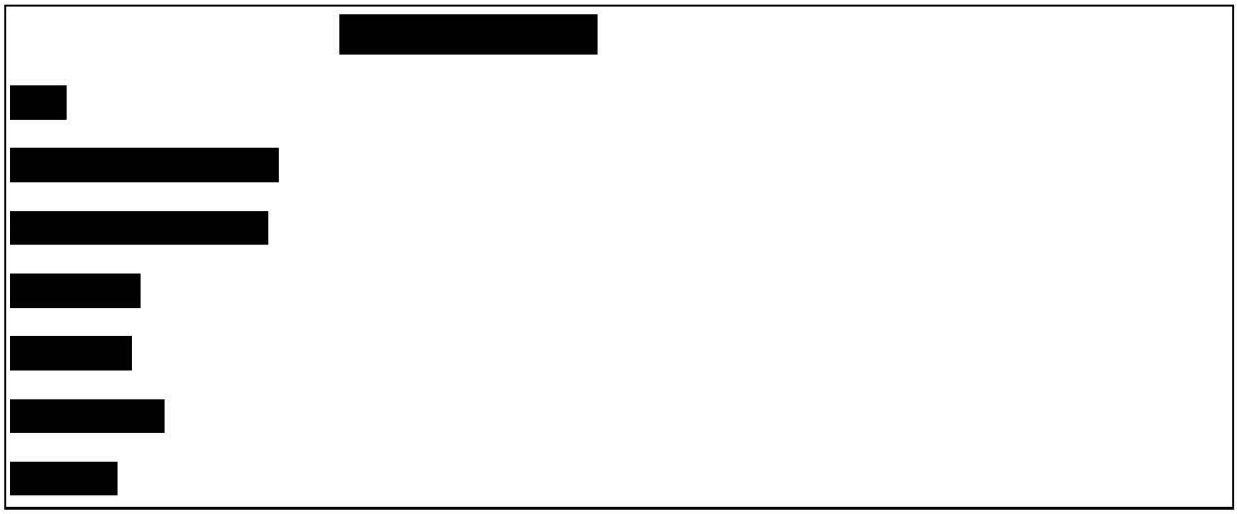
5.3 Conclusion

The acute LC_{50} by inhalation of pyriproxyfen in rats was determined to be greater than 1300 mg/m^3 (1.30 mg/l), the maximum concentration which could be tested

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]



Section A6.1.3/02 Acute toxicity – inhalation mouse

Annex Point IIA 6.1.3

Official use only

1 REFERENCE

1.1 Reference [redacted]

1.2 Data protection Yes

1.2.1 Data owner Sumitomo Chemical Co., Ltd.

1.2.2 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 In-house method equivalent to OECD 403, EEC B.2

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]

3.1.2.1 Description [redacted]

3.1.2.2 Purity [redacted]

3.1.2.3 Stability [redacted]

3.2 Test Animals

3.2.1 Species Mouse

3.2.2 Strain [redacted]

3.2.3 Source [redacted]

3.2.4 Sex Male and female

3.2.5 Age/weight at study initiation	[redacted]
3.2.6 Number of animals per group	[redacted]
3.2.7 Control animals	Yes, vehicle and negative control
3.3 Administration/ Exposure	Inhalation
3.3.1 Post exposure period	14 days
3.3.2 Concentrations	Nominal concentration Not reported Analytical concentration 600 and 1300 mg/m³
3.3.3 Particle size of mists generated	[redacted]
3.3.4 Type or preparation of particles	[redacted]
3.3.5 Type of exposure	[redacted]
3.3.6 Vehicle	[redacted]
3.3.7 Concentration in vehicle	[redacted]
3.3.8 Duration of exposure	4 h
3.3.9 Controls	[redacted]
3.4 Examinations	[redacted]
3.5 Method of determination of LD_{50}	[redacted]
3.6 Further remarks	None

4 RESULTS AND DISCUSSION

4.1 Clinical signs	[redacted]
4.2 Pathology	[redacted]

[redacted]

4.3 Body weight [redacted]

4.4 LD_{50} [redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1Materials and methods [redacted]

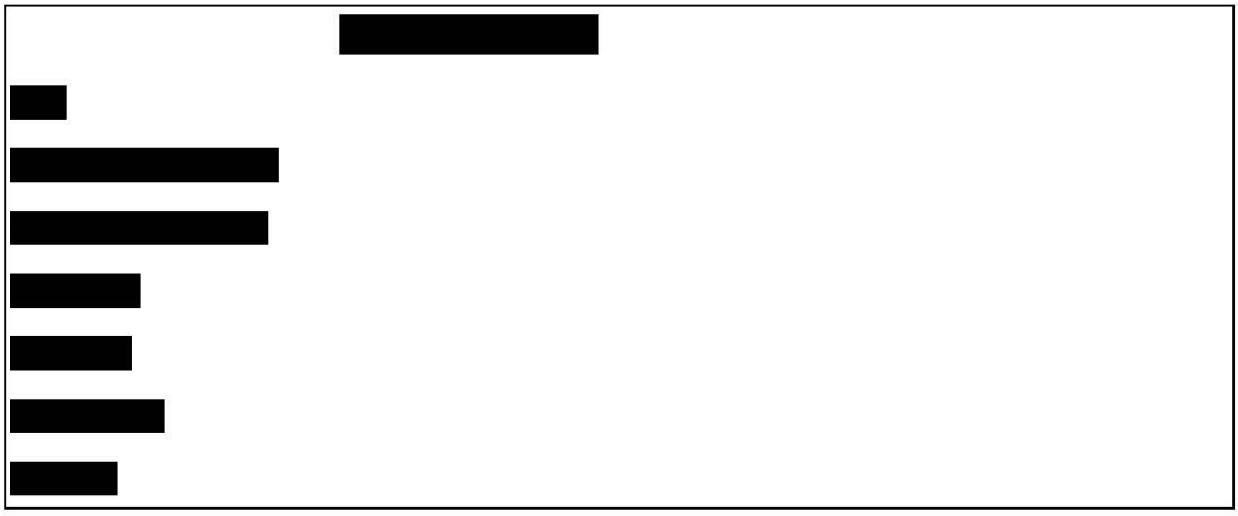
5.2 Results and discussion [redacted]

5.3 Conclusion The acute LC50 by inhalation of pyriproxyfen in mice was > 1.30 mg/l (Maximum concentration which could be tested)

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]



6.1.4 Skin and eye irritation

Section A6.1.4/01 Acute skin irritation - rabbit

Annex Point IIA.6.1.4

		Official use only
	1 REFERENCE	
1.1 Reference	[redacted]	
1.2 Data protection	Yes	
1.2.1 Data owner	Sumitomo Chemical Co., Ltd	
1.2.2 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose for its entry into Annex I	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	Yes Ministry of Agriculture, Forestry and Fisheries (1985): Primary dermal irritation test, equivalent to US EPA FIFRA § 81-5, OECD 404, EEC B.4	
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]	
3.1.2.1 Description	[redacted]	
3.1.2.2 Purity	[redacted]	
3.1.2.3 Stability	[redacted]	
3.2 Test Animals	[redacted]	
3.2.1 Species	Rabbit	
3.2.2 Strain	[redacted]	
3.2.3 Source	[redacted]	
3.2.4 Sex	Male and female	

3.2.5 Age/weight at study initiation	[redacted]
3.2.6 Number of animals per group	[redacted]
3.2.7 Control animals	No
3.3 Administration/ Exposure	Dermal
3.3.1 Application	
3.3.1.1 Preparation of test substance	[redacted]
3.3.1.2 Site and Preparation of Test Site	[redacted]
3.3.2 Occlusion	[redacted]
3.3.3 Vehicle	[redacted]
3.3.4 Concentration in vehicle	[redacted]
3.3.5 Total volume applied	[redacted]
3.3.6 Removal of test substance	[redacted]
3.3.7 Duration of exposure	4 hours
3.3.8 Post exposure period	72 hours
3.3.9 Controls	None
3.4 Examinations	
3.4.1 Clinical signs	No
3.4.2 Dermal examination	Yes
3.4.2.1 Scoring system	[redacted]
3.4.2.2 Examination time points	[redacted]
3.4.3 Other examinations	None
3.5 Further remarks	

4 RESULTS AND DISCUSSION

4.1 Average score

4.1.1 Erythema [redacted]

4.1.2 Edema [redacted]

4.2 Reversibility [redacted]

4.3 Other examinations None

4.4 Overall result [redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods [redacted]

5.2 Results and discussion [redacted]

5.3 Conclusion Pyriproxyfen was non irritant to the skin of rabbits

In accordance with the criteria specified in Council Directive 67/548/EEC, pyriproxyfen is not classified as a skin irritant

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]

Section 6.1.4/02 Acute eye irritation - rabbit

Annex Point IIA6.1.4

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 entry into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study	Yes Ministry of Agriculture, Forestry and Fisheries (1985): Primary eye irritation test, equivalent to US EPA FIFRA § 81-4, OECD 405, EEC B.5
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]
3.1.2.1 Description	[redacted]
3.1.2.1 Purity	[redacted]
3.1.2.1 Stability	[redacted]
3.2 Test animals	
3.2.1 Species	Rabbit
3.2.2 Strain	[redacted]
3.2.3 Source	[redacted]
3.2.4 Sex	Male and female

3.2.5 Age/ weight at study initiation	[redacted]
3.2.6 Number of animals per group	[redacted]
3.2.7 Control animals	No
3.3 Administration/ Exposure	
3.3.1 Preparation of test substance	[redacted]
3.3.2 Amount of active substance instilled	[redacted]
3.3.3 Exposure period	72 hours
3.3.4 Post exposure period	72 hours
3.4 Examinations	
3.4.1 Ophthalmoscopic examination	[redacted]
3.4.1.1 Scoring system	[redacted]
3.4.1.2 Examination time points	1h, 24h, 48h and 72hours
3.4.2 Other investigations	None
3.5 Further remarks	

4 RESULTS AND DISCUSSION

4.1 Clinical signs	[redacted]
4.2 Average score	
4.2.1 Cornea	[redacted]
4.2.2 Iris	[redacted]
4.2.3 Conjunctuva	
4.2.3.1 Redness	[redacted]
4.2.3.2 Chemosis	[redacted]
4.3 Reversibility	[redacted]

4.4 Other

4.5 Overall Result

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

5.2 Results and discussion

5.3 Conclusion

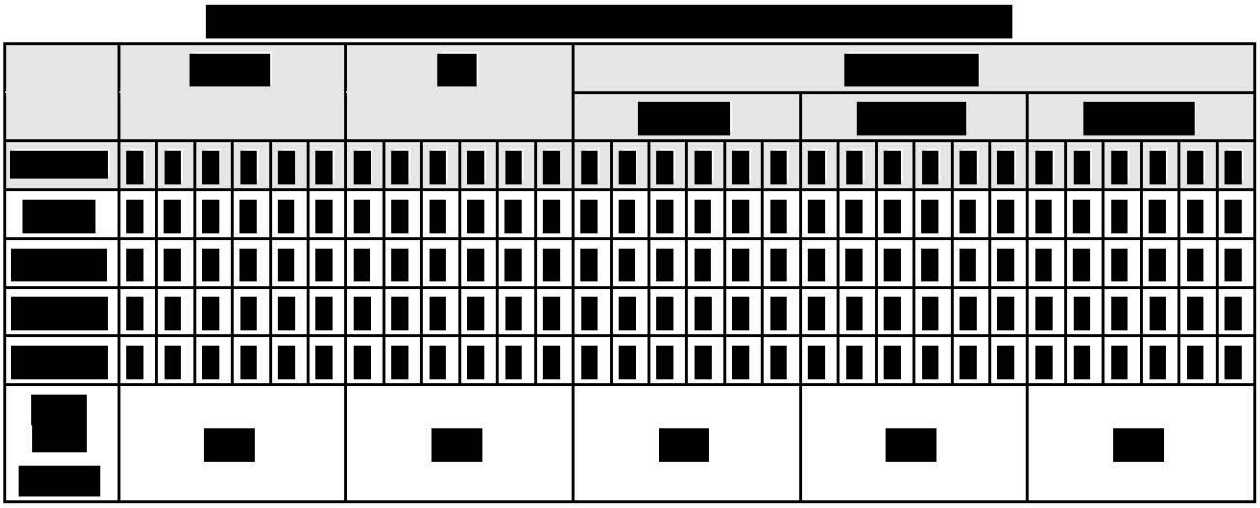
The irritating potency of pyriproxyfen was judged to be minimal

In accordance with the criteria specified in Council Directive 67/548/EEC, pyriproxyfen is not classified as an eye irritant

5.3.1 Reliability

5.3.2 Deficiencies

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



6.1.5 Skin sensitisation

Section 6.1.5/01 Skin sensitisation

Annex Point IIA6.1.5

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 entry into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study Yes

Maximization test: FIFRA 81-6, OECD 406, EEC B.6

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]

3.1.2.1 Description [redacted]

3.1.2.2 Purity [redacted]

3.1.2.3 Stability [redacted]

3.1.2.4 Preparation of test substance for application [redacted]

[redacted]

3.1.2.5 Pre test performed on irritant effects	Yes

3.2 Test animals

3.2.1 Species	Guinea pigs
3.2.2 Strain	[redacted]
3.2.3 Source	[redacted]
3.2.4 Sex	Male
3.2.5 Age/ weight at study initiation	[redacted]
3.2.6 Number of animals per group	[redacted]
3.2.7 Control animals	Yes

3.3 Administration/ Exposure

3.3.1 Induction Schedule	day 0 – day 7, (Table A6.1.5-01)
3.3.2 Way of induction	Intradermal and topical
	[redacted]
3.3.3 Concentrations used for induction	[redacted]
3.3.4 Concentration Freunds Complete Adjuvant (FCA)	[redacted]
3.3.5 Challenge schedule	Day 21; (Table A6.1.5-01)
3.3.6 Concentrations used for challenge	[redacted]
3.3.7 Rechallenge	No
3.3.8 Scoring schedule	[redacted]
3.3.9 Removal of the test substance	[redacted]
3.3.10 Positive control substance	Dinitrochlorobenzene
	[redacted]

3.4 Examinations [redacted]

3.5 Further remarks None

4 RESULTS

4.1 Results of pilot studies [redacted]

4.2 Results of test

4.2.1 24 hr after challenge [redacted]

4.2.2 48 hr after challenge [redacted]

4.2.3 Other findings [redacted]

4.3 Overall Result [redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods [redacted]

5.2 Results and discussion [redacted]

5.3 Conclusion Pyriproxyfen was not a sensitiser in the Magnusson and Kligmann test

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...	
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	

[redacted]

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

[redacted]

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

6.2 Metabolism studies in mammals. Basic toxicokinetics, including a dermal absorption study

[redacted]

6.2.1 Absorption, distribution, metabolism and excretion in rats (phenoxyphenyl-^{14}C)

Section 6.2.1/01
Annex point IIA 6.2

Absorption, distribution, metabolism and excretion in rats (phenoxyphenyl-^{14}C)

Official use only

1 REFERENCE

1.1 Reference	[redacted]
1.2 Data protection	Yes
1.2.1 Data owner	Sumitomo Chemical Co., Ltd.
1.2.2 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	In house method equivalent to US EPA FIFRA 85-1 General Metabolism, EU Directive 88/302/EEC, Part B Toxicokinetics
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]
3.1.6 Specific activity	[redacted]
3.2 Test animals	
3.2.1 Species	Rat
3.2.2 Strain	[redacted]
3.2.3 Source	[redacted]
3.2.4 Sex	Male and female
3.2.5 Number of animals/group	[redacted]
3.3 Administration	Oral
3.3.1 Duration of treatment	Single and repeated doses
3.3.2 Dose levels	[redacted]
3.3.3 Sample collection	[redacted]
3.3.4 Analysis	[redacted]

4 RESULTS

4.1 Excretion

4.2 Tissue residues

4.3 Identity of metabolites

4.4 Biliary excretion

5 APPLICANT'S SUMMARY AND CONCLUSIONS

5.1 Materials and methods

[redacted]

5.2 Results and discussion

[redacted]

5.3 Conclusion

Pyriproxyfen was rapidly excreted in rats, mainly in the faeces. Tissue residues 7 days after dosing were generally low in all dose groups, except the fat. [redacted]

Absorption was calculated to be 63-69% of the dose [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 ...

[redacted]

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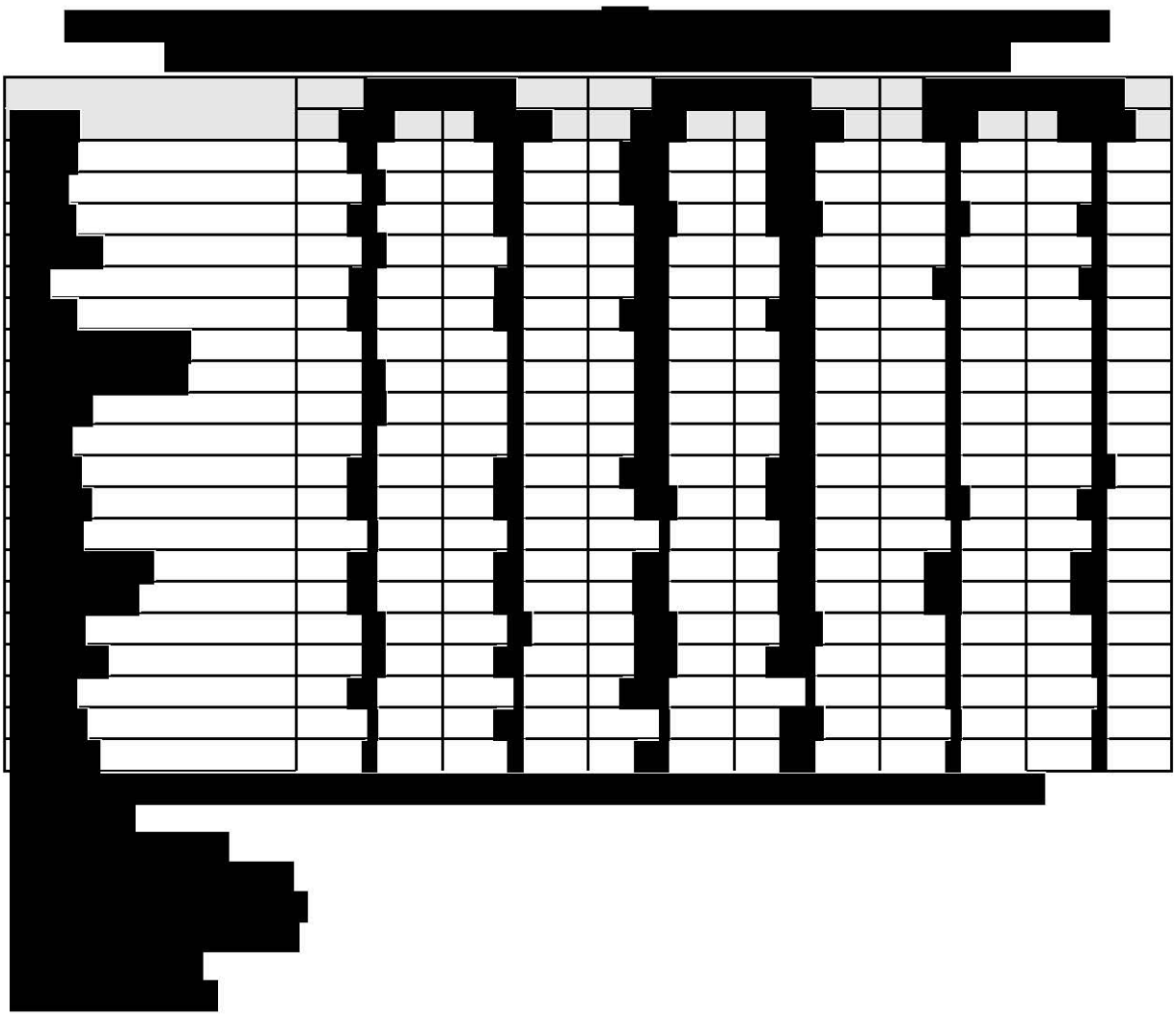
[redacted]

[redacted]



[redacted]

[redacted]

[redacted]

6.2.2 Tissue distribution in rats (low dose)

Section 6.2.2/01 Tissue distribution in rats (low dose)

Annex point IIA 6.2

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 entry into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study In-house method equivalent to Directive 88/302/EEC, Part B Toxicokinetics,

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]

3.1.6 Specific activity [redacted]

3.2 Test animals

3.2.1 Species Rats

3.2.2 Strain	[redacted]
3.2.3 Source	[redacted]
3.2.4 Sex	Male and female
3.2.5 Number of animals/groups	[redacted]
3.3 Administration	Oral
3.3.1 Duration of treatment	Single dose
3.3.2 Dose level	2 mg/kg
3.3.3 Sample collection	[redacted]
3.3.4 Analysis	[redacted]

4 RESULTS

4.1 Tissue residues

[redacted]

4.2 Identity of metabolites

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSIONS

5.1 Materials and methods

[redacted]

[redacted]

5.2 Results and discussion

[redacted] The rate of elimination of radioactivity from tissues varied between 8 and 35 hours

The concentration of radioactivity was higher in the blood of males than in females. [redacted]

5.3 Conclusion

Highest concentrations of radioactivity were detected in blood, liver, kidney and fat of male rats and in the liver, kidney and fat of female rats. Radioactivity was rapidly eliminated from all tissues and residues were low 72 hours after dosing

5.3.1 Reliability [redacted]

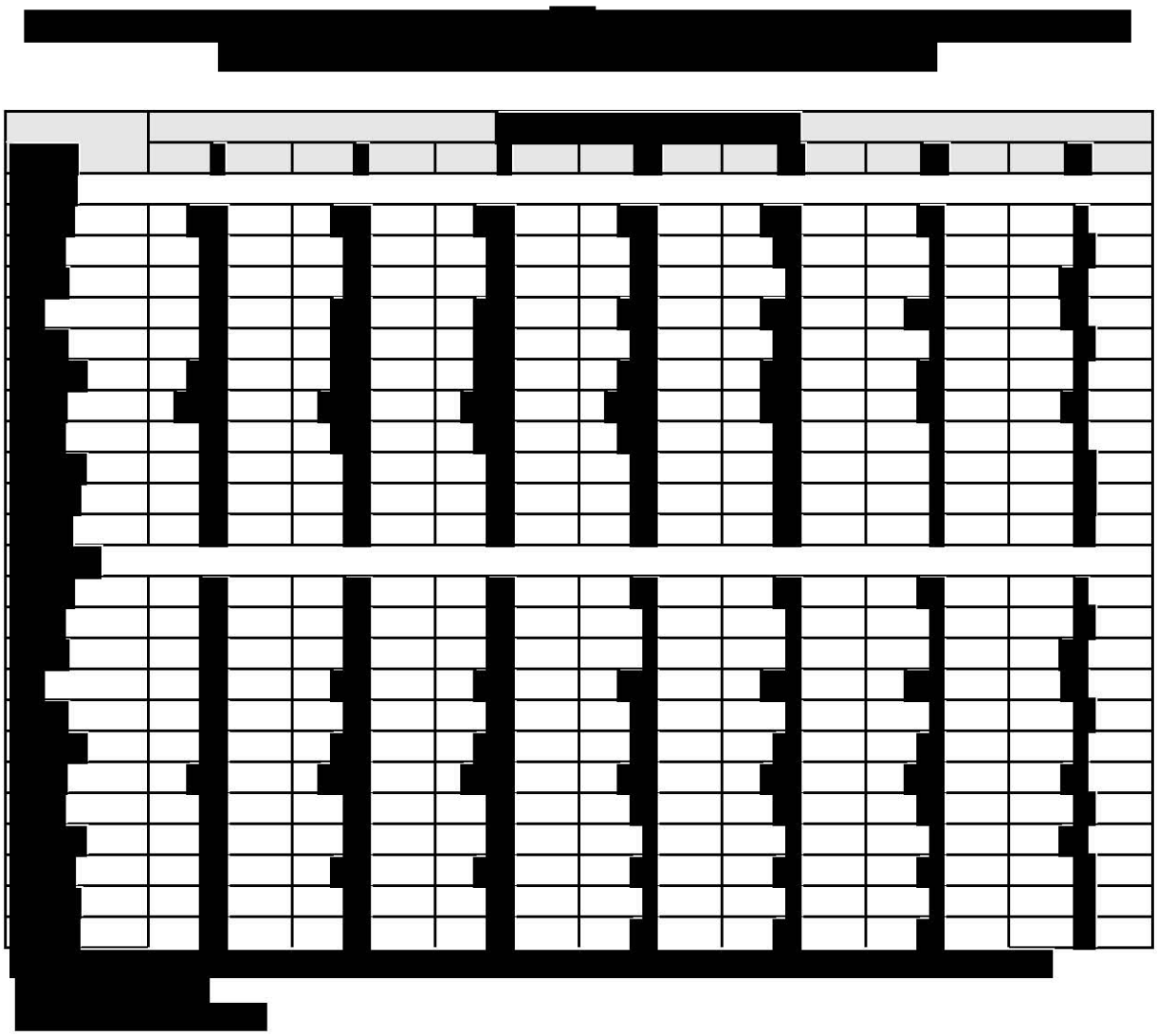
5.3.2 Deficiencies [redacted]

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...

[redacted]



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[redacted]