Section A6.7/04/05/06/07/08/09 Carcinogenicity Feeding Study in Mice

Annex Point IIA, VI.6.7

3.4 Examinations

3.4.1 Clinical signs

3.4.2 Palpable masses

3.4.3 Mortality

3.4.4 Body weight

3.4.5 Food consumption

3.4.6 Water consumption

3.4.7 Ophthalmoscopic examination

3.4.8 Haematology

3.4.9 Clinical Chemistry

3.4.10 Urinalysis

3.4.11 Pathology

3.4.11.1 Organ Weights

3.4.12 Histopathology

3.4.13 Other examinations

3.5 Statistics

3.6 Further remarks none

4 RESULTS AND DISCUSSION.

4.1 Clinical signs *

Section A6.7/04/05/06/07/08/09
Annex Point IIA, VI.6.7

Carcinogenicity
Feeding Study in Mice

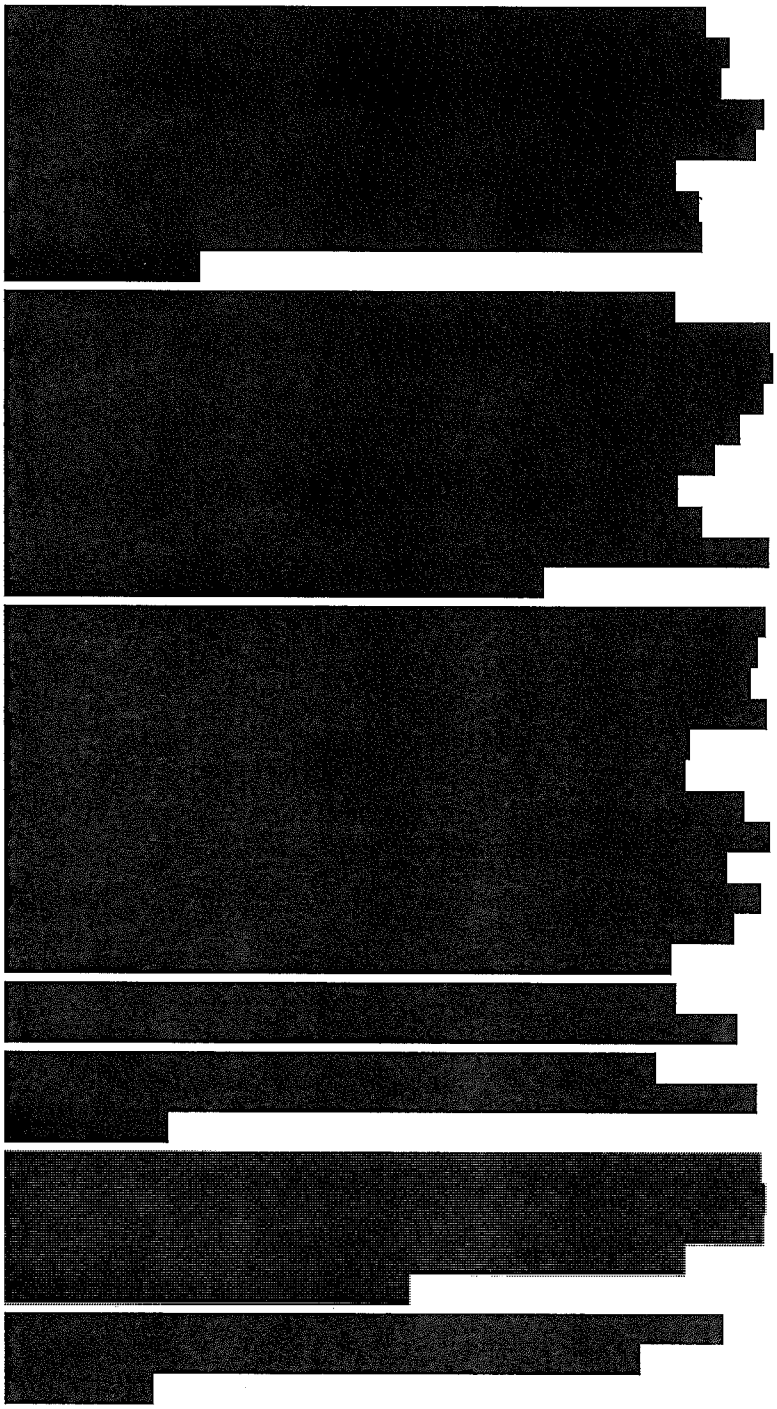
4.2	Mortality	
4.3	Body weight	
4.4	Food consumption	
4.5	Water consumption	
4.6	Ophthalmoscopic examination	
4.7	Haematology	
4.8	Clinical Chemistry	
4.9	Urinalysis	
4.10	Gross pathology	
4.11	Organ Weights	

Section A6.7/04/05/06/07/08/09

Annex Point IIA, VI.6.7

Carcinogenicity Feeding Study in Mice

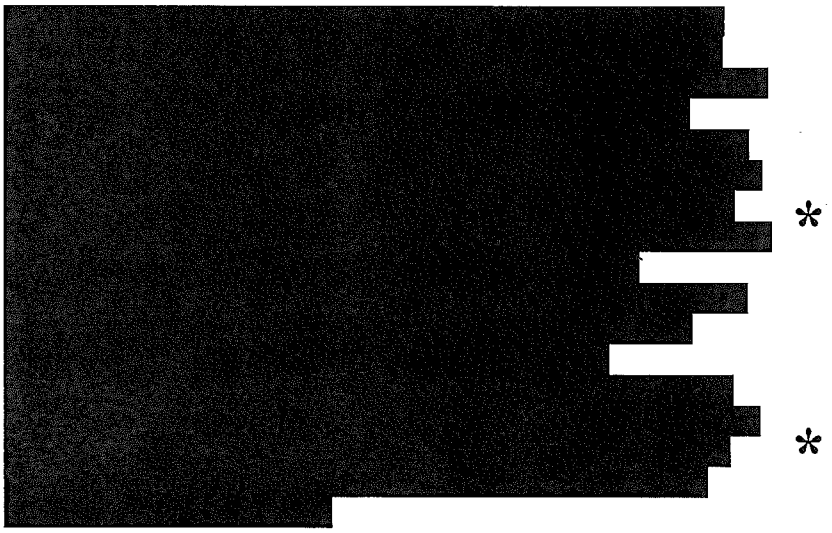
4.12 Histopathology – non-neoplastic findings



Section A6.7/04/05/06/07/08/09
Annex Point IIA, VI.6.7

Carcinogenicity
Feeding Study in Mice

4.13 Histopathology-neoplastic findings



Section A6.7/04/05/06/07/08/09
Annex Point IIA, VI.6.7

Carcinogenicity Feeding Study in Mice

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[redacted]

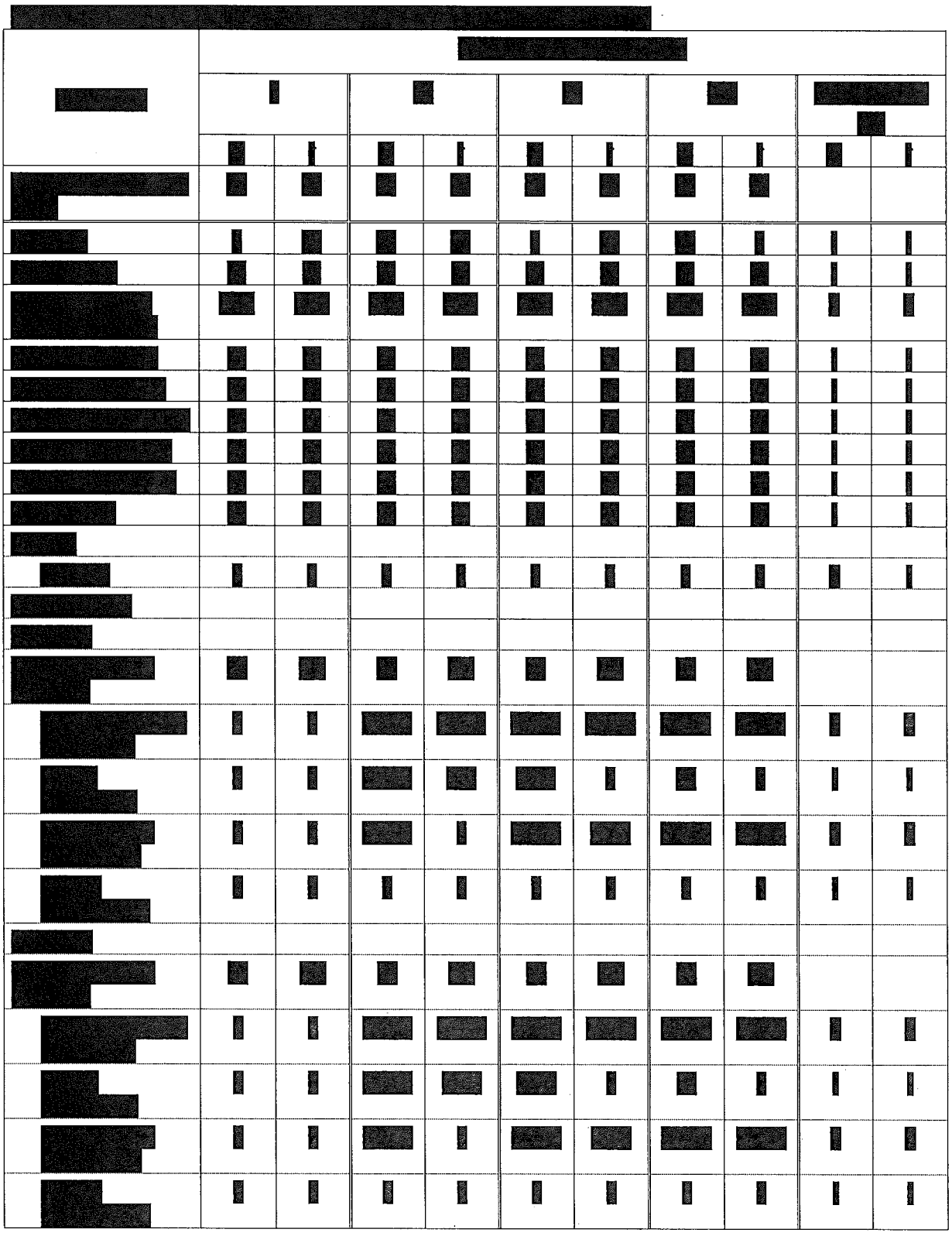
5.2 Results and discussion

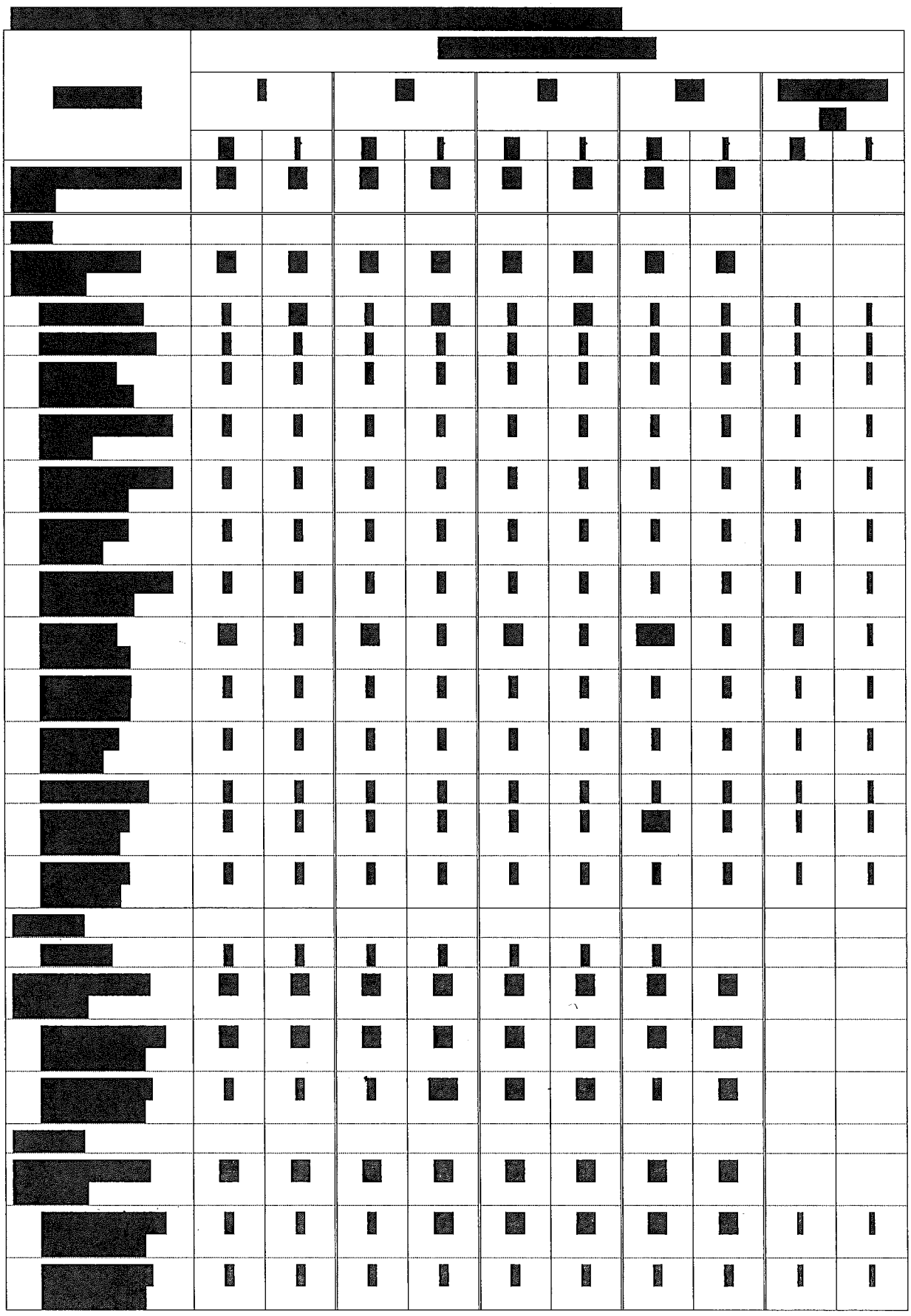
[redacted]

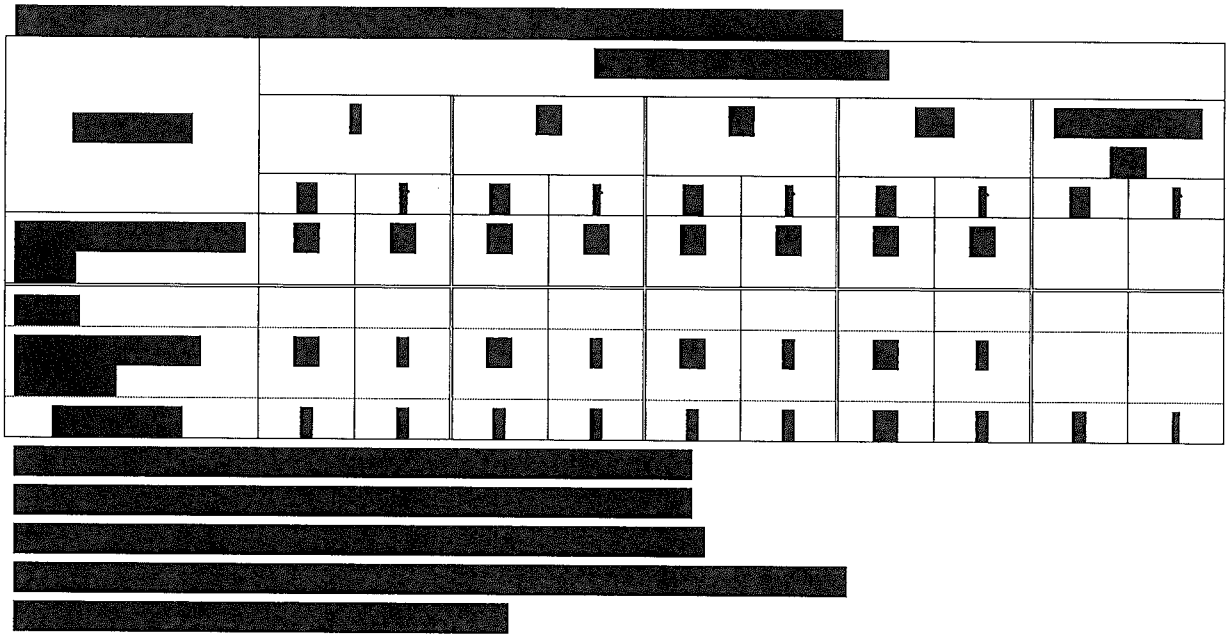
*

Section A6.7/04/05/06/07/08/09	Carcinogenicity Feeding Study in Mice
Annex Point IIA, VI.6.7	
5.3 Conclusion	LOEL 20 mg/kg bw/day, based on histopathological changes in thyroids. IPBC was not carcinogenic under the conditions described in the original report.
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
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]







Section A6.8.1/01 Teratogenicity Study

Annex Point IIA, VI.6.8.1 **Gavage Rabbit- Rangefinder**

[redacted]

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1994): Omacide® (IPBC) Oral (Gavage) Rabbit Developmental Toxicity Dose Ranging Study [redacted] 09.08.1994 [redacted])	[redacted]
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No, not necessary, rangefinding study	
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	The purity of the test substance was slightly lower than the specification given in section 2. This does not influence the integrity of the study.	
3.1.3	Purity	[redacted]	
3.1.4	Description	[redacted]	
3.1.5	Stability	[redacted]	

Section A6.8.1/01 Teratogenicity Study

Annex Point IIA, VI.6.8.1 **Gavage Rabbit- Rangefinder**

[redacted]

3.2	**Test Animals**	
3.2.1	Species	rabbit
3.2.2	Strain	New Zealand White
3.2.3	Source	[redacted]
3.2.4	Sex	female
3.2.5	Age/weight at study initiation	[redacted]
3.2.6	Number of animals per group	[redacted]
3.2.7	Control animals	[redacted]
3.2.8	Mating period	[redacted]
3.3	**Administration/ Exposure**	Oral
3.3.1	Duration of exposure	[redacted] *
3.3.2	Postexposure period	[redacted]
3.3.3	Type	[redacted]

Section A6.8.1/01 Teratogenicity Study

Annex Point IIA, VI.6.8.1 **Gavage Rabbit- Rangefinder**

3.3.4 Concentration

3.3.5 Vehicle

3.3.6 Concentration in vehicle

3.3.7 Total volume applied

3.3.8 Controls

3.4 Examinations

3.4.1 Clinical signs

3.4.2 Body weight

3.4.3 Food consumption

3.4.4 Necropsy

3.4.5 Examination of uterine content

3.4.6 Examination of foetuses

3.4.6.1 General

3.4.6.2 Skelet

3.4.6.3 Soft tissue

3.5 Statistics

*

Section A6.8.1/01 **Teratogenicity Study**
Annex Point IIA, VI.6.8.1 **Gavage Rabbit- Rangefinder**

4 RESULTS AND DISCUSSION

4.1 Effects observed in MTD phase

[redacted]

4.2 Maternal toxic Effects

[redacted]

4.3 Maternal body weight

[redacted]

4.4 Food consumption

[redacted]

4.5 Maternal necropsy

[redacted]

4.6 Organ weights

[redacted]

Section A6.8.1/01 Teratogenicity Study
Annex Point IIA, VI.6.8.1 Gavage Rabbit- Rangefinder

4.7 Pregnancy data

4.8 Foetal and Gravid Uterus Weights

4.9 Teratogenic / embryotoxic effects

4.10 Other effects

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

In this range-finding study for a subsequent teratogenicity study in New Zealand White rabbits, the MTD was assessed in 5 non-mated females which were treated for 20 days via gavage with IPBC

Section A6.8.1/01 Teratogenicity Study

Annex Point IIA, VI.6.8.1 Gavage Rabbit- Rangefinder

5.2 Results and discussion

[redacted]

Section A6.8.1/01 Teratogenicity Study
Annex Point IIA, VI.6.8.1 Gavage Rabbit- Rangefinder

5.3	**Conclusion**	[redacted]
5.3.1	LO(A)EL maternal toxic effects	not applicable, dose range-finder
5.3.2	NO(A)EL maternal toxic effects	not applicable, dose range-finder
5.3.3	LO(A)EL embryotoxic / teratogenic effects	not applicable, dose range-finder
5.3.4	NO(A)EL embryotoxic / teratogenic effects	not applicable, dose range-finder
5.3.5	Reliability	[redacted]
5.3.6	Deficiencies	No

Section A6.8.1/01 Teratogenicity Study

Annex Point IIA, VI.6.8.1 **Gavage Rabbit- Rangefinder**

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

[redacted]

Section A6.8.1/01 Teratogenicity Study

Annex Point IIA, VI.6.8.1 **Gavage Rabbit- Rangefinder**

[redacted]

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

[redacted]

Section A6.8.1/02 Teratogenicity Study
Annex Point IIA, VI.6.8.1 Gavage Rabbit

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1994) [redacted] Omacide® (IPBC) Oral (Gavage) Rabbit Developmental Toxicity Study; [redacted] 16.11.1994;	[redacted]
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, US EPA guideline 83-3 (1984) and OECD 414 (1981)	[redacted]
2.2	**GLP**	[redacted]	
2.3	**Deviations**	no	
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	The purity of the test substance was slightly lower that the specification given in section 2. This does not influence the integrity of the study.	
3.1.3	Purity	[redacted]	
3.1.4	Description	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Test Animals**		
3.2.1	Species	rabbit	
3.2.2	Strain	New Zealand White	
3.2.3	Source	[redacted]	
3.2.4	Sex	female	
3.2.5	Age/weight at study initiation	[redacted]	
3.2.6	Number of animals per group	[redacted]	
3.2.7	Control animals	[redacted]	
3.2.8	Mating period	[redacted]	
3.3	**Administration/ Exposure**	Oral	

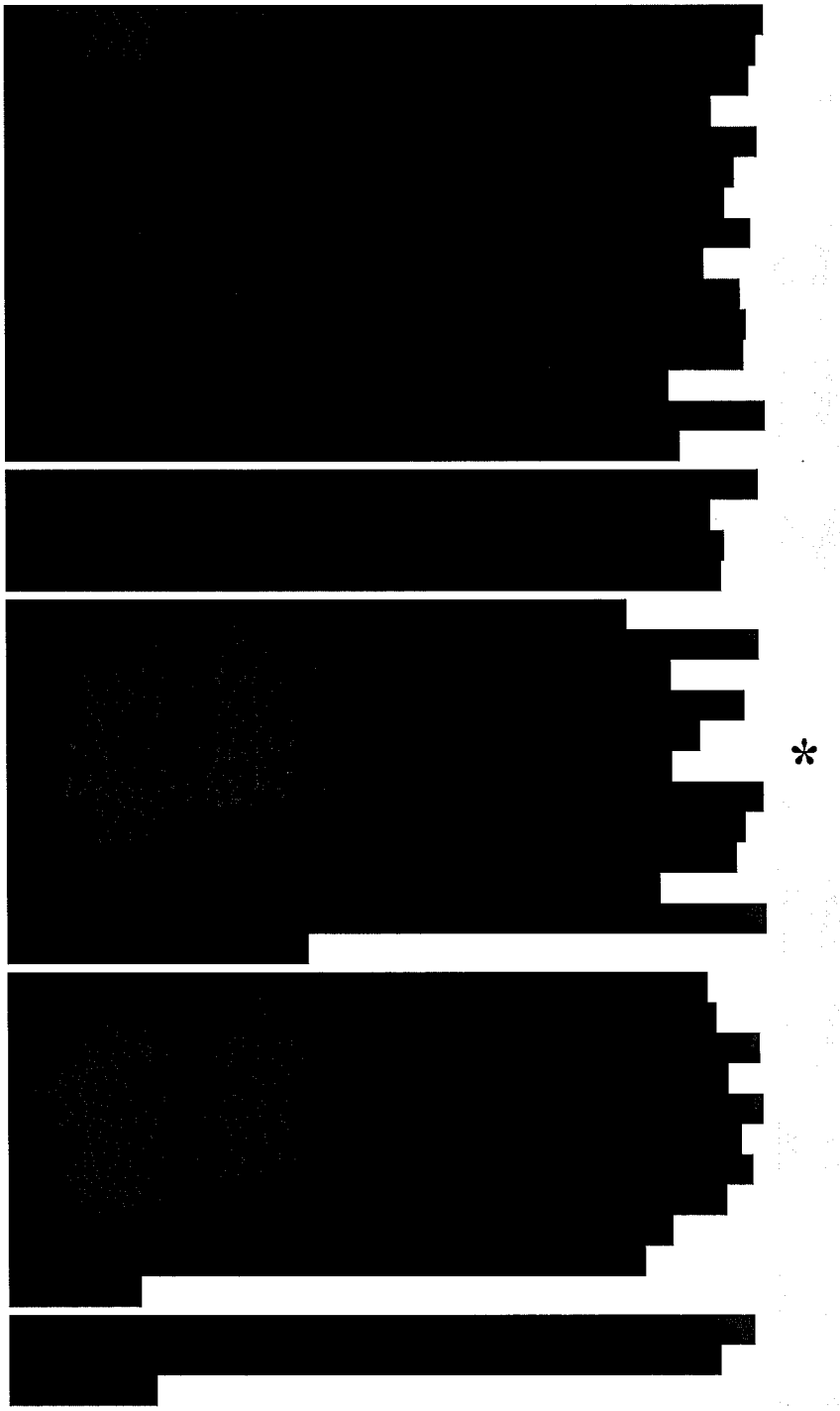
Section A6.8.1/02 Teratogenicity Study
Annex Point IIA, VI.6.8.1 Gavage Rabbit

3.3.1	Duration of exposure	[redacted]
3.3.2	Postexposure period	[redacted]
3.3.3	Type	Gavage
3.3.4	Concentration	[redacted]
3.3.5	Vehicle	[redacted]
3.3.6	Concentration in vehicle	[redacted]
3.3.7	Total volume applied	[redacted]
3.3.8	Controls	[redacted]
3.4	**Examinations**	
3.4.1	Clinical signs	[redacted]
3.4.2	Body weight	[redacted]
3.4.3	Food consumption	[redacted]
3.4.4	Examination of uterine content	[redacted]
3.4.5	Examination of foetuses	
3.4.5.1	General	[redacted]
3.4.5.2	Skelet	[redacted]
3.4.5.3	Soft tissue	[redacted]
3.5	**Further remarks**	[redacted]
3.6	**Statistics**	[redacted]

Section A6.8.1/02 Teratogenicity Study
Annex Point IIA, VI.6.8.1 Gavage Rabbit

4 RESULTS AND DISCUSSION

4.1 Maternal toxic Effects



Section A6.8.1/02 Teratogenicity Study
Annex Point IIA, VI.6.8.1 Gavage Rabbit

4.2 Pregnancy data

[redacted]

4.3 Teratogenic / embryotoxic effects

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[redacted] The study was conducted in accordance to OECD 414 (adopted 1981) and to US EPA guideline 83-3 (adopted 1984).

5.2 Results and discussion

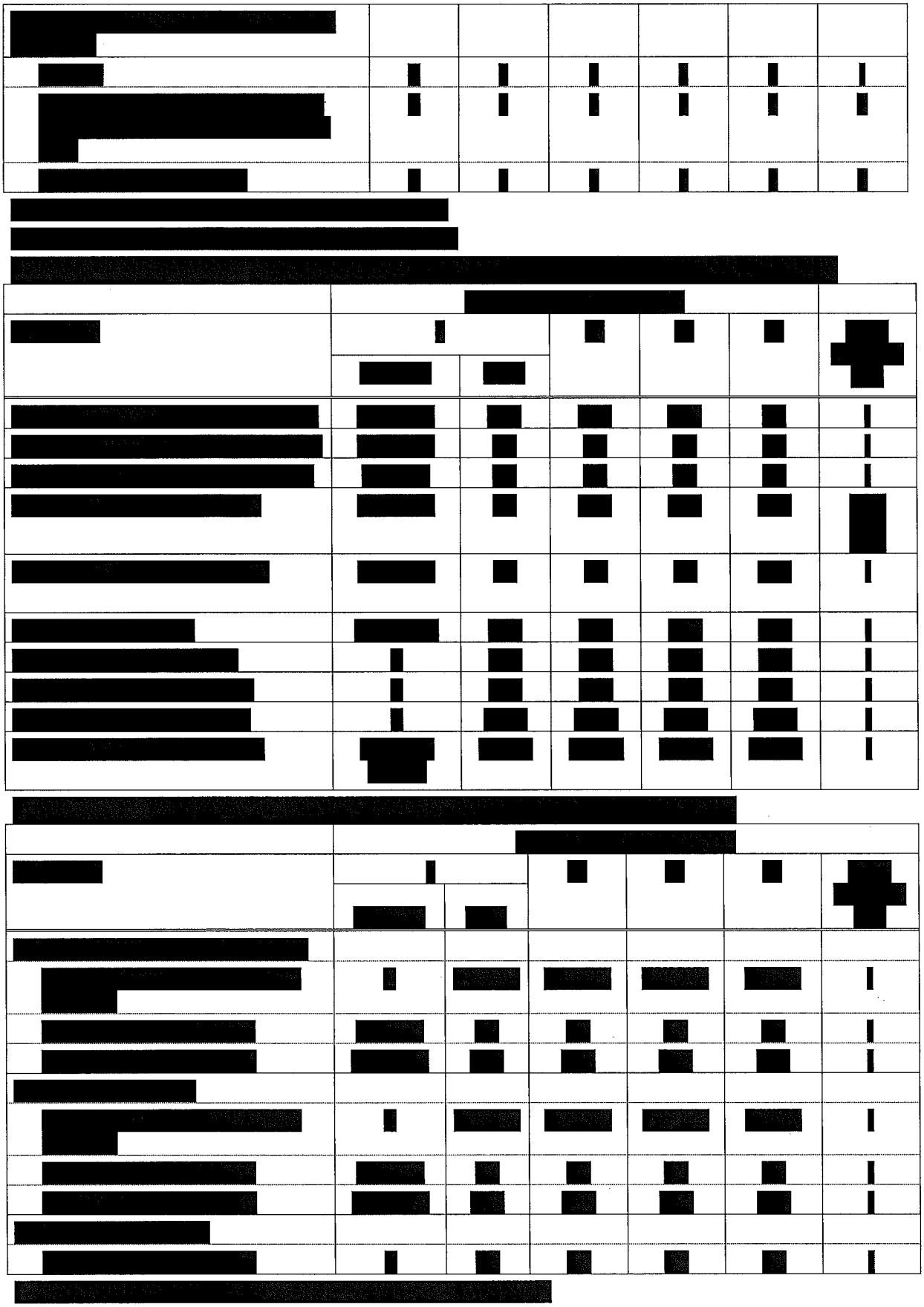
[redacted]

Section A6.8.1/02 Teratogenicity Study
Annex Point IIA, VI.6.8.1 Gavage Rabbit

5.3	**Conclusion**	
5.3.1	LO(A)EL maternal toxic effects	20 mg/kg bw/day, one death at 20 mg/kg bw/day and 4 at 40 mg/kg bw/day due to local stomach irritation which resulted in refusal to eat and consequently body weight loss
5.3.2	NO(A)EL maternal toxic effects	10 mg/kg bw/day
5.3.3	LO(A)EL embryotoxic / teratogenic effects	>40 mg/kg bw/day
5.3.4	NO(A)EL embryotoxic / teratogenic effects	40 mg/kg bw/day
5.3.5	Reliability	[redacted]
5.3.6	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
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
	[redacted]
	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

[redacted]



Section A6.8.1/03 Teratogenicity Study
Annex Point IIA, VI.6.8.1 Gavage Rat dose-rangefinder

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1994): Omacide® (IPBC) Oral (Gavage) Rat Developmental Toxicity Dose Ranging Study; [redacted] 09.08.1994	[redacted]
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No, not necessary range-finder	
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	The purity of the test substance was slightly lower than the specification given in section 2. This does not influence the integrity of the study.	
3.1.3	Purity	[redacted]	
3.1.4	Description	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Test Animals**		
3.2.1	Species	rat	
3.2.2	Strain	Sprague-Dawley (Crl:CD(SD)BR strain (VAF plus)	
3.2.3	Source	[redacted]	
3.2.4	Sex	female	
3.2.5	Age/weight at study initiation	[redacted]	
3.2.6	Number of animals per group	[redacted]	
3.2.7	Control animals	[redacted]	
3.2.8	Mating period	[redacted]	
3.3	**Administration/ Exposure**	[redacted]	
3.3.1	Duration of exposure	[redacted]	
3.3.2	Postexposure period	[redacted]	
3.3.3	Type	Gavage	
3.3.4	Concentration	[redacted]	
3.3.5	Vehicle	[redacted]	

Section A6.8.1/03 Teratogenicity Study

Annex Point IIA, VI.6.8.1 **Gavage Rat dose-rangefinder**

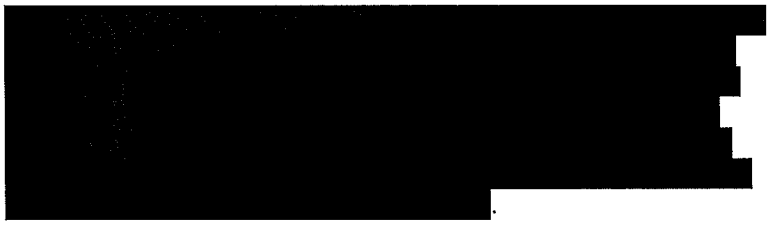
3.3.6	Concentration in vehicle	[redacted]
3.3.7	Total volume applied	[redacted]
3.3.8	Controls	[redacted]
3.4	**Examinations**	
3.4.1	Clinical signs	[redacted]
3.4.2	Body weight	[redacted]
3.4.3	Food consumption	[redacted] *
3.4.4	Examination of uterine content	[redacted]
3.4.5	Examination of foetuses	
3.4.5.1	General	[redacted]
3.4.5.2	Skelet	[redacted]
3.4.5.3	Soft tissue	[redacted]
3.5	**Further remarks**	[redacted]
3.6	**Statistics**	[redacted]

Section A6.8.1/03 Teratogenicity Study
Annex Point IIA, VI.6.8.1 Gavage Rat dose-rangefinder

4 RESULTS AND DISCUSSION

4.1 Maternal toxic Effects

4.2 Pregnancy data



4.3 Teratogenic / embryotoxic effects

Section A6.8.1/03 Teratogenicity Study

Annex Point IIA, VI.6.8.1 **Gavage Rat dose-rangefinder**

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

In this teratogenicity range-finding study, group of 5 females were treated via gavage with IPBC [redacted]

5.2 Results and discussion

[redacted]

5.3 Conclusion

[redacted]

5.3.1	LO(A)EL maternal toxic effects	not applicable, dose range-finder
5.3.2	NO(A)EL maternal toxic effects	not applicable, dose range-finder
5.3.3	LO(A)EL embryotoxic / teratogenic effects	not applicable, dose range-finder
5.3.4	NO(A)EL embryotoxic / teratogenic effects	not applicable, dose range-finder
5.3.5	Reliability	[redacted]
5.3.6	Deficiencies	No

Section A6.8.1/03 Teratogenicity Study
Annex Point IIA, VI.6.8.1 **Gavage Rat dose-rangefinder**

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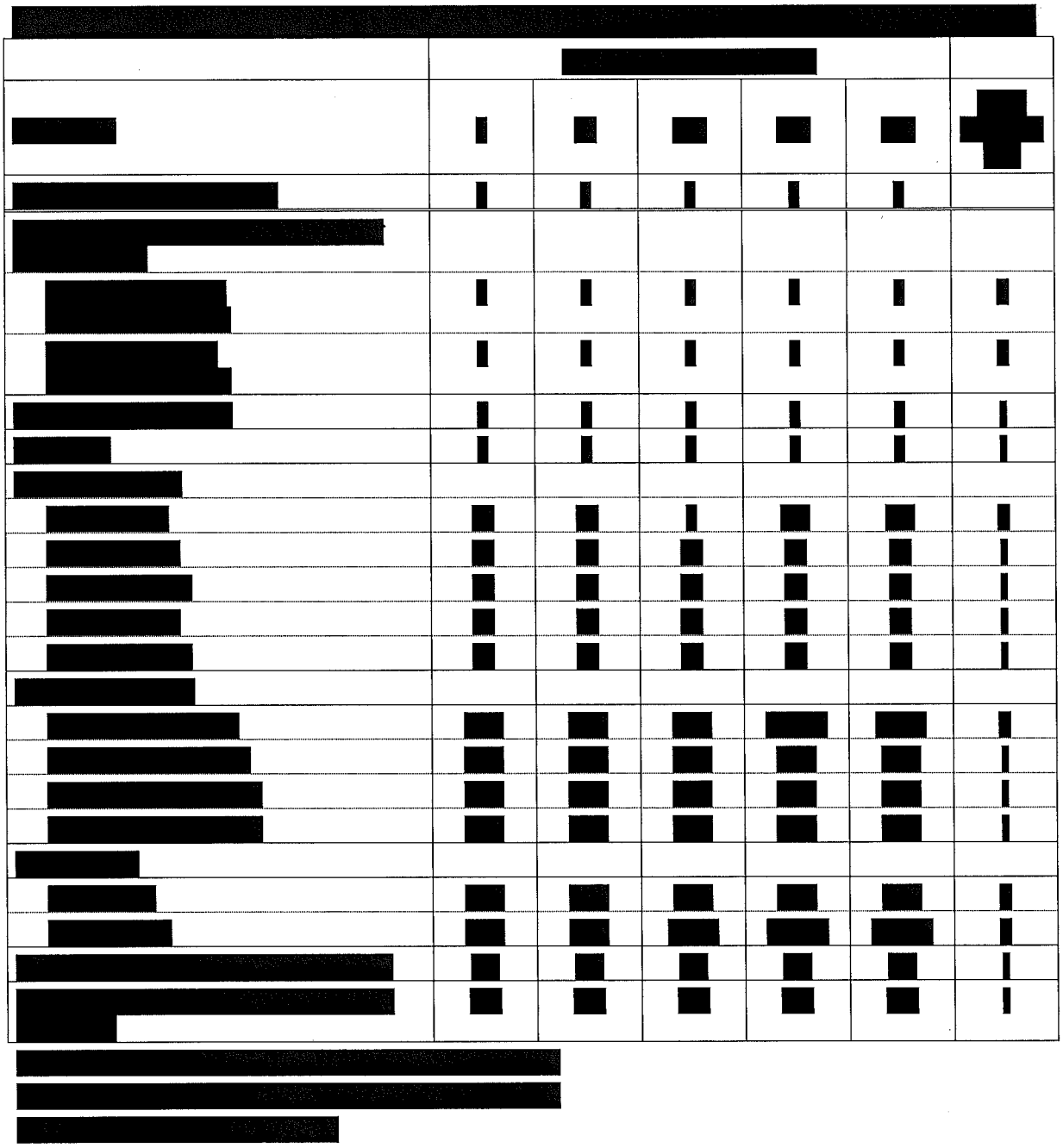
Date	[redacted]
Materials and Methods	[redacted]
	[redacted]
	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Section A6.8.1/03 Teratogenicity Study

Annex Point IIA, VI.6.8.1 Gavage Rat dose-rangefinder



Section A6.8.1/03 Teratogenicity Study

Annex Point IIA, VI.6.8.1 Gavage Rat dose-rangefinder

[redacted]

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

Section A6.8.1/04 Teratogenicity Study
Annex Point IIA, VI.6.8.1 Gavage Rat

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1994): Omacide® (IPBC) Oral (gavage) Rat Developmental Toxicity (Teratogenicity) Study; [redacted] 09.08.1994; [redacted]	[redacted]
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, US EPA guideline Subdivision F: 83-3 (1984) OECD 414 (1981)	[redacted]
2.2	**GLP**	[redacted]	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	*
3.1.2	Specification	The purity of the test substance was slightly lower than the specification given in section 2. This does not influence the integrity of the study.	
3.1.3	Purity	[redacted]	
3.1.4	Description	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Test Animals**		
3.2.1	Species	rat	
3.2.2	Strain	Sprague-Dawley Crl:CD(SD)BR strain (VAF plus)	
3.2.3	Source	[redacted]	
3.2.4	Sex	female	
3.2.5	Age/weight at study initiation	[redacted]	

Section A6.8.1/04 Teratogenicity Study

Annex Point IIA, VI.6.8.1 **Gavage Rat**

3.2.6	Number of animals per group	[redacted]
3.2.7	Control animals	[redacted]
3.2.8	Mating period	[redacted]
3.3	**Administration/ Exposure**	Oral
3.3.1	Duration of exposure	[redacted]
3.3.2	Postexposure period	[redacted]
3.3.3	Type	[redacted]
3.3.4	Concentration	[redacted]
3.3.5	Vehicle	[redacted]
3.3.6	Concentration in vehicle	[redacted]
3.3.7	Total volume applied	[redacted]
3.3.8	Controls	[redacted]
3.4	**Examinations**	
3.4.1	Clinical signs	[redacted]
3.4.2	Body weight	[redacted]
3.4.3	Food consumption	[redacted]
3.4.4	Examination of uterine content	[redacted]
3.4.5	Examination of foetuses	
3.4.5.1	General	[redacted]
3.4.5.2	Skelet	[redacted]
3.4.5.3	Soft tissue	[redacted]
3.5	**Statistics**	[redacted]

Section A6.8.1/04 Teratogenicity Study
Annex Point IIA, VI.6.8.1 Gavage Rat

4 RESULTS AND DISCUSSION

4.1 Maternal toxic Effects

[redacted]

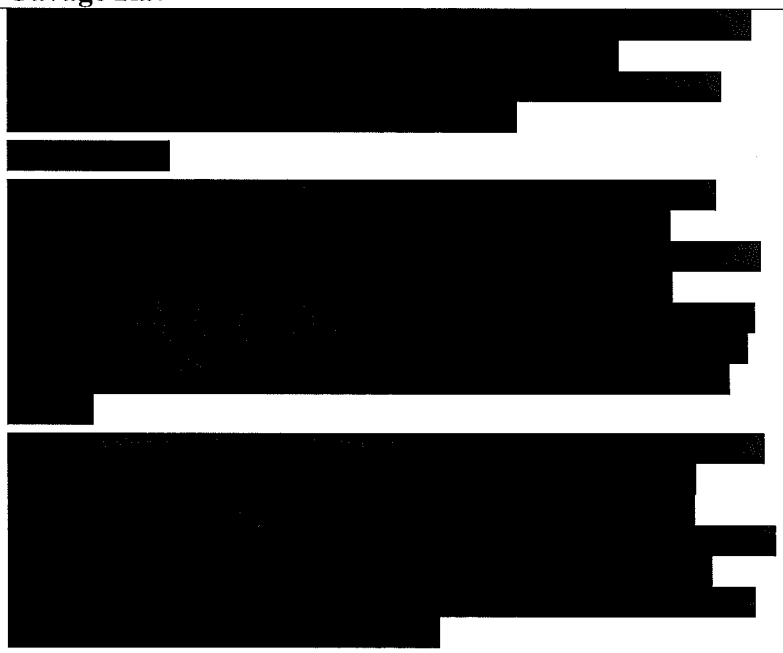
4.2 Pregnancy data

[redacted]

4.3 Teratogenic / embryotoxic effects

[redacted]

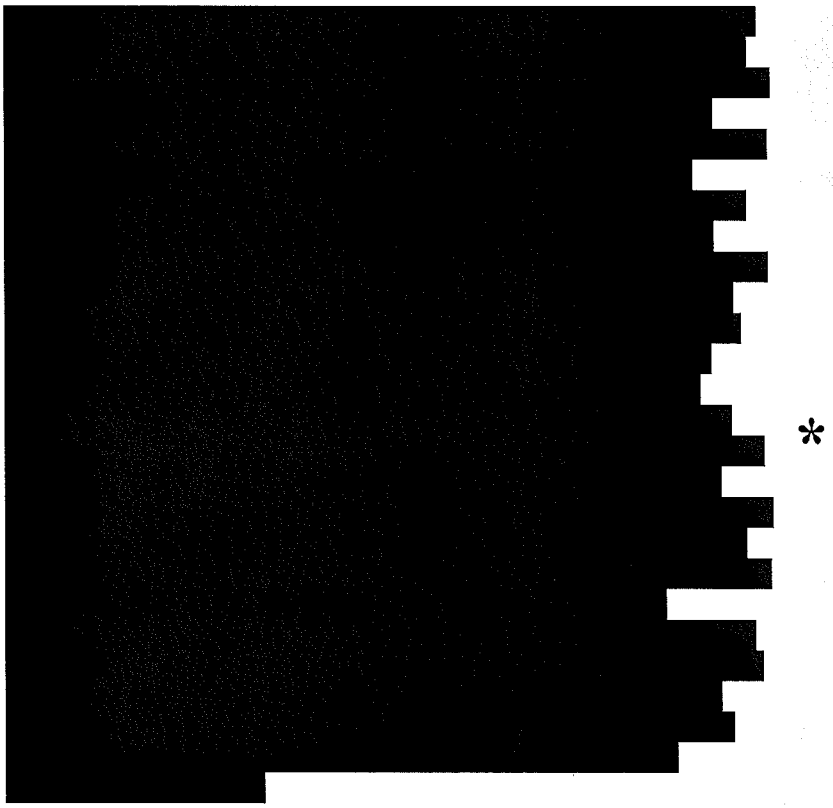
Section A6.8.1/04 Teratogenicity Study
Annex Point IIA, VI.6.8.1 Gavage Rat



5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

5.2 Results and discussion



*

5.3 Conclusion

5.3.1 LO(A)EL maternal toxic effects: 75 mg/kg bw/day, reduced body weight gain and food consumption

Section A6.8.1/04		Teratogenicity Study
Annex Point IIA, VI.6.8.1		Gavage Rat
5.3.2	NO(A)EL maternal toxic effects	25 mg/kg bw/day
5.3.3	LO(A)EL embryotoxic / teratogenic effects	250 mg/kg bw/day, reduced female foetal weight, increased incidence in minor skeletal anomalies and not ossified 5th sternebrae
5.3.4	NO(A)EL embryotoxic / teratogenic effects	75 mg/kg bw/day
5.3.5	Reliability	[redacted]
5.3.6	Deficiencies	No

Section A6.8.1/04 Teratogenicity Study

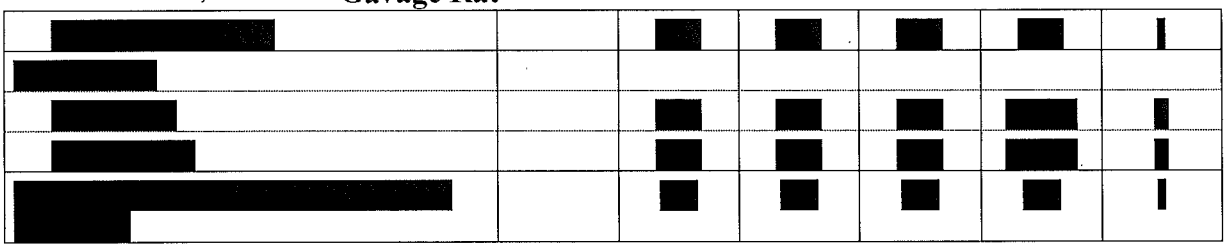
Annex Point IIA, VI.6.8.1 **Gavage Rat**

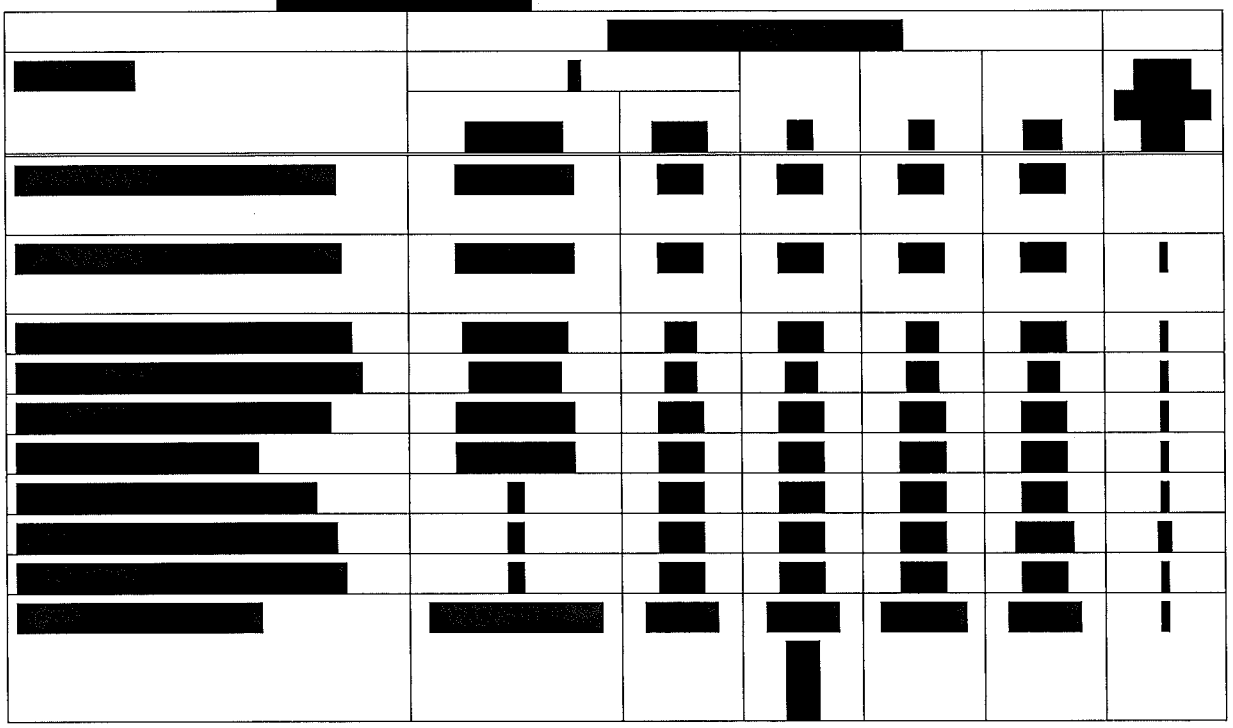
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

[redacted]

Section A6.8.1/04 Teratogenicity Study

Annex Point IIA, VI.6.8.1 **Gavage Rat**





[redacted]

Section A6.8.2/01/02 Multigeneration Reproduction Toxicity Study
Annex Point IIA, VI.6.8.2 Gavage Rat

[redacted]

1 REFERENCE

Official use only

1.1 Reference

A6.8.2/01:

[redacted] (1996): Omacide® (IPBC) Oral (Gavage) Rat One-Generation (Expanded to Two-Generation) Reproductive Toxicity Study; [redacted] 30.07.1996 [redacted]

A6.8.2/02:

[redacted] (2003): Historical control data - Reprotoxicity study in rats (Background Pregnancy Data from Multigeneration, Fertility and Pre- and Post Natal Studies on the Sprague-Dawley rat [redacted] 31.09.2003 [redacted]

1.2 Data protection

[redacted]

1.2.1 Data owner

[redacted]

1.2.2 Companies with letter of access

[redacted]

1.2.3 Criteria for data protection

[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1 Guideline study

A6.8.2/01:

Yes,

US EPA guideline Subdivision F 83-4 (1982)

OECD 415 (1983)

The method described in the report are comparable to current OECD 416 (adopted 2001) because the study was expanded to a second generation.

A6.8.2/02:

No, not applicable, historical control data

[redacted]

2.2 GLP

[redacted]

2.3 Deviations

None

3 MATERIALS AND METHODS

3.1 Test material

[redacted]

3.1.1 Lot/Batch number

[redacted]

3.1.2 Specification

The purity of the test substance was slightly lower than the specification given in section 2. This dose not influence the integrity of the study.

3.1.3 Purity

[redacted]

3.1.4 Description

[redacted]

3.1.5 Stability

[redacted]

Section A6.8.2/01/02 Multigeneration Reproduction Toxicity Study
Annex Point IIA, VI.6.8.2 Gavage Rat

3.2	**Test Animals**	
3.2.1	Species	rat
3.2.2	Strain	Sprague-Dawley Crl:CD(SD)BR VAF plus strain
3.2.3	Source	[redacted]
3.2.4	Sex	male, female
3.2.5	Age/weight at study initiation	[redacted]
3.2.6	Number of animals per group	[redacted]
3.2.7	Mating	[redacted]
3.2.8	Duration of mating	[redacted]
3.2.9	Deviations from standard protocol	[redacted]
3.2.10	Control animals	[redacted]
3.3	**Administration/ Exposure**	Oral, gavage
3.3.1	Animal assignment to dosage groups	[redacted]
3.3.2	Duration of exposure before mating	F_0 animals: 10 weeks F_1 animals: about 13 weeks
3.3.3	Duration of exposure in general P, F1, F2 males, females	[redacted]
3.3.4	Type	[redacted]
3.3.5	Concentration	[redacted]
3.3.6	Vehicle	[redacted]
3.3.7	Concentration in vehicle	[redacted]
3.3.8	Total volume applied	[redacted]
3.3.9	Controls	[redacted]
3.4	**Examinations**	
3.4.1	Clinical signs	[redacted]
3.4.2	Mortality	[redacted]

Section A6.8.2/01/02 Multigeneration Reproduction Toxicity Study

Annex Point IIA, VI.6.8.2 **Gavage Rat**

3.4.3 Body weight

3.4.4 Food consumption

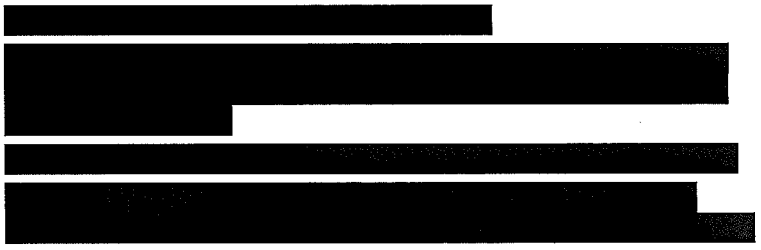
3.4.5 Oestrus cycle

3.4.6 Sperm parameters

3.4.7 Offspring

3.4.8 Organ weights F_0 and F_1

3.4.9 Histopathology F1



3.4.10 Histopathology F1 not selected for mating, F2

Section A6.8.2/01/02 Multigeneration Reproduction Toxicity Study
Annex Point IIA, VI.6.8.2 Gavage Rat

3.5 Further investigations

[redacted]

3.6 Statistics

[redacted]

Section A6.8.2/01/02 Multigeneration Reproduction Toxicity Study
Annex Point IIA, VI.6.8.2 Gavage Rat

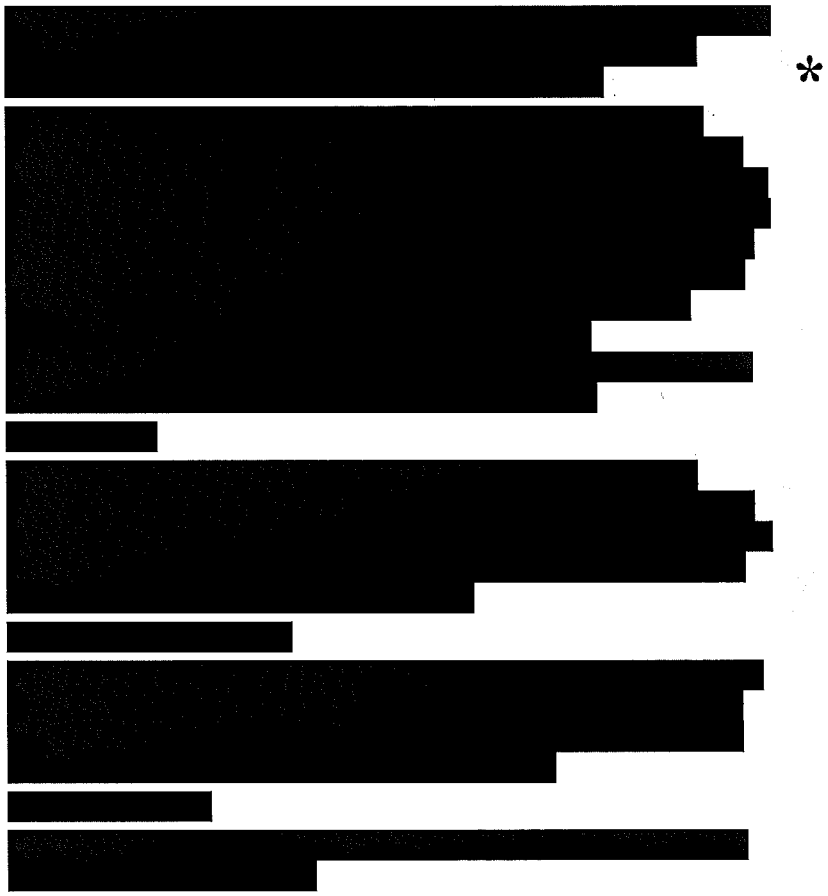
4 RESULTS AND DISCUSSION

4.1 Parental effects

4.1.1 F_0 animals

Section A6.8.2/01/02 **Multigeneration Reproduction Toxicity Study**
Annex Point IIA, VI.6.8.2 **Gavage Rat**

4.1.2 F1 parents

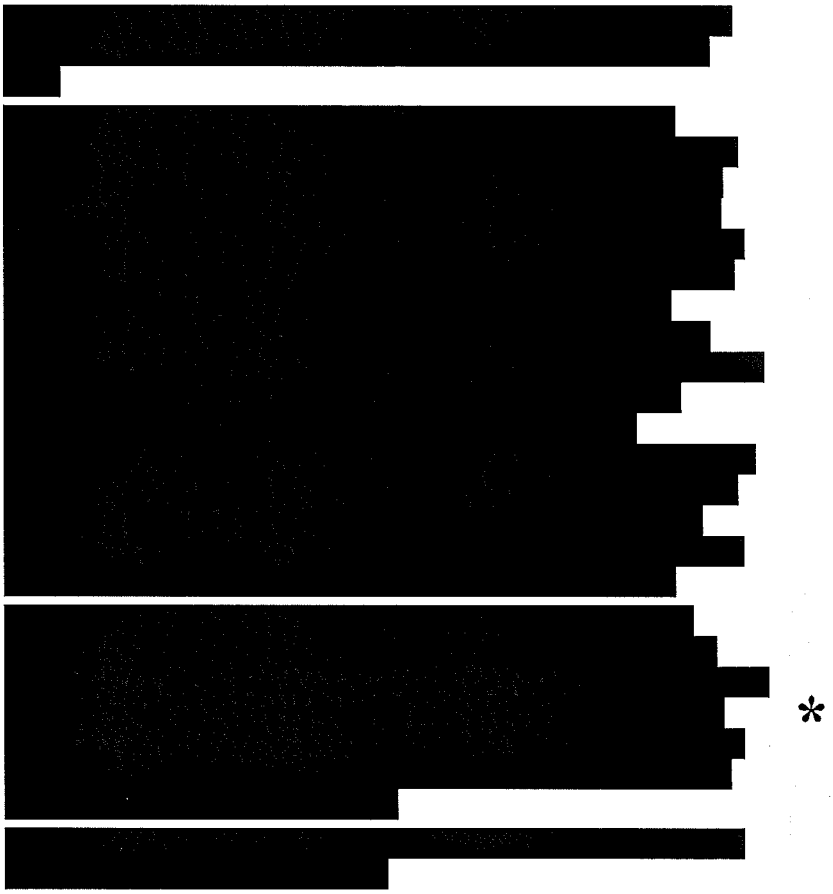


4.2 Oestrus cycle

Section A6.8.2/01/02 Multigeneration Reproduction Toxicity Study

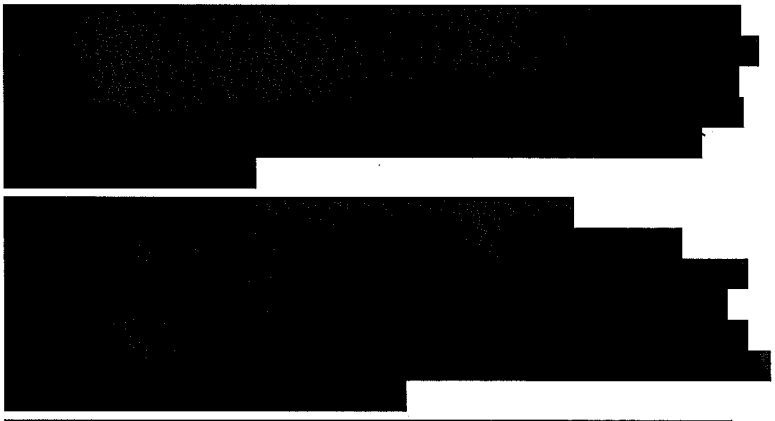
Annex Point IIA, VI.6.8.2 **Gavage Rat**

4.3 Fertility and mating performance



*

4.4 Gestation, parturition and lactation

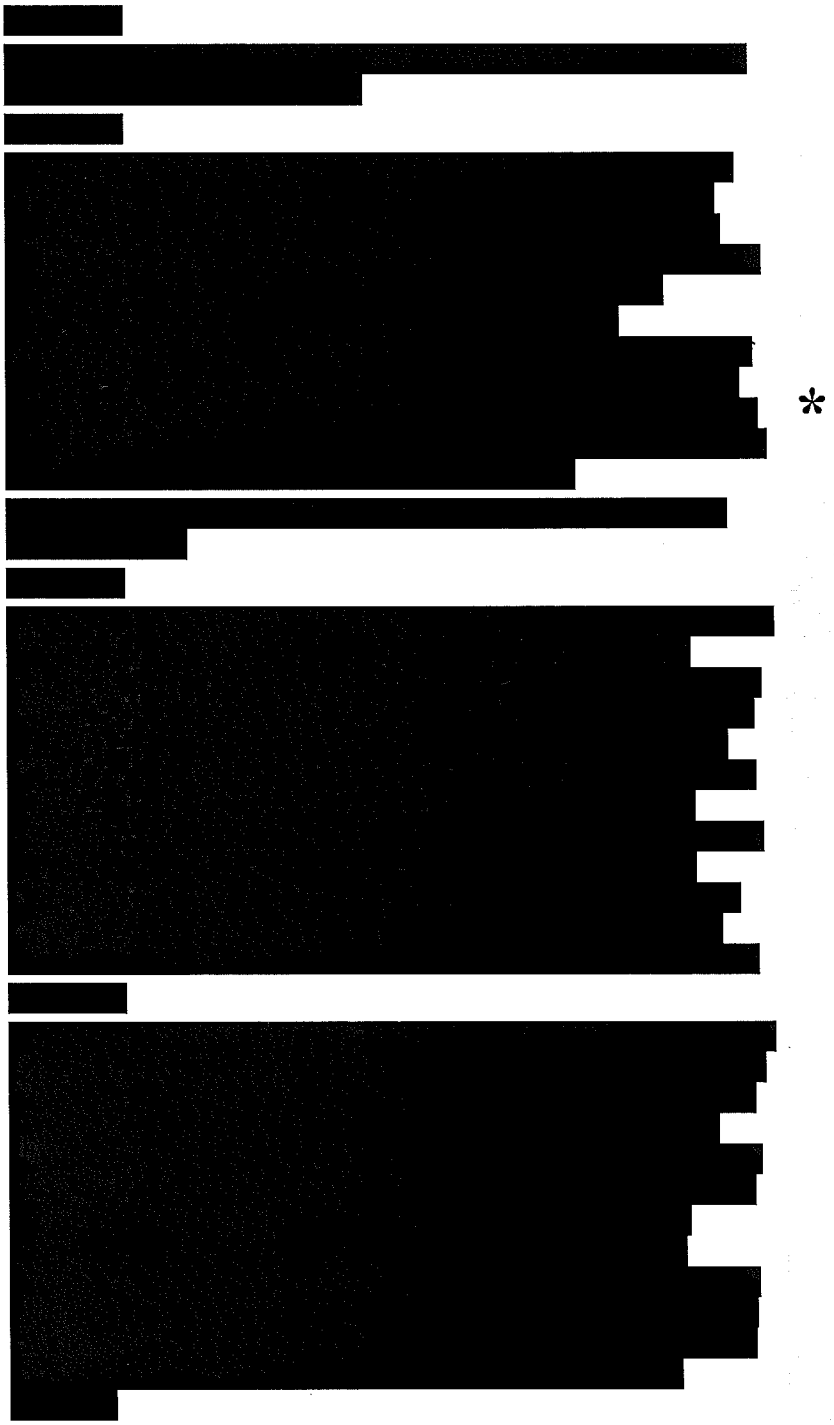


4.5 Pregnancy data

Section A6.8.2/01/02 Multigeneration Reproduction Toxicity Study
Annex Point IIA, VI.6.8.2 Gavage Rat

4.6 Pathology

4.6.1 Gross and histopathology



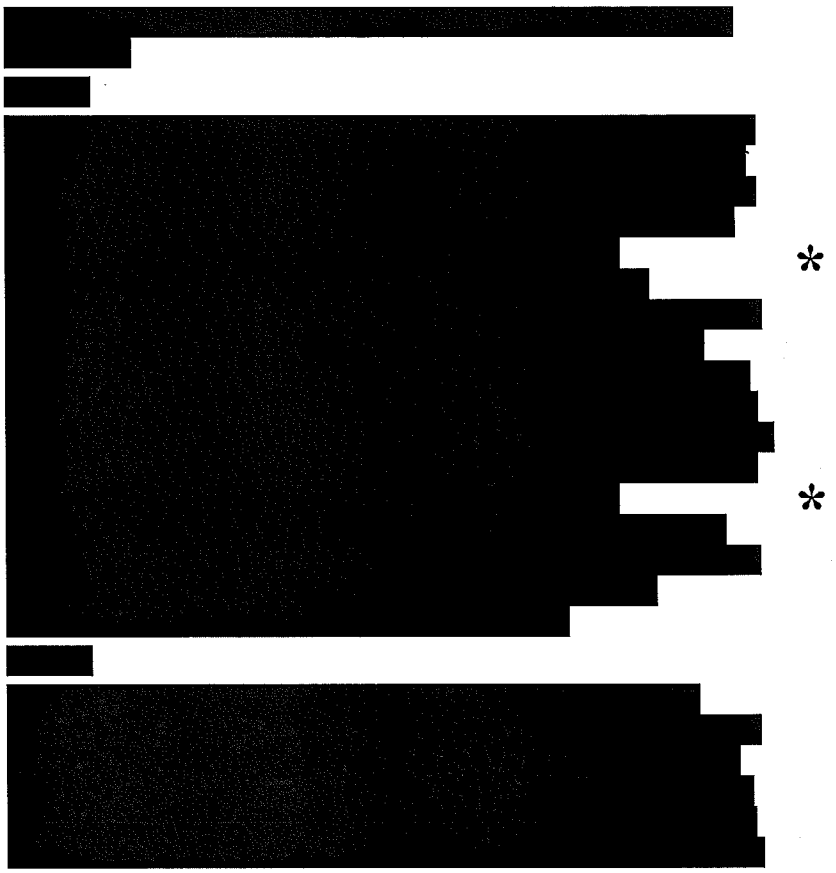
4.6.2 Sperm parameters

4.6.3 Organ weights

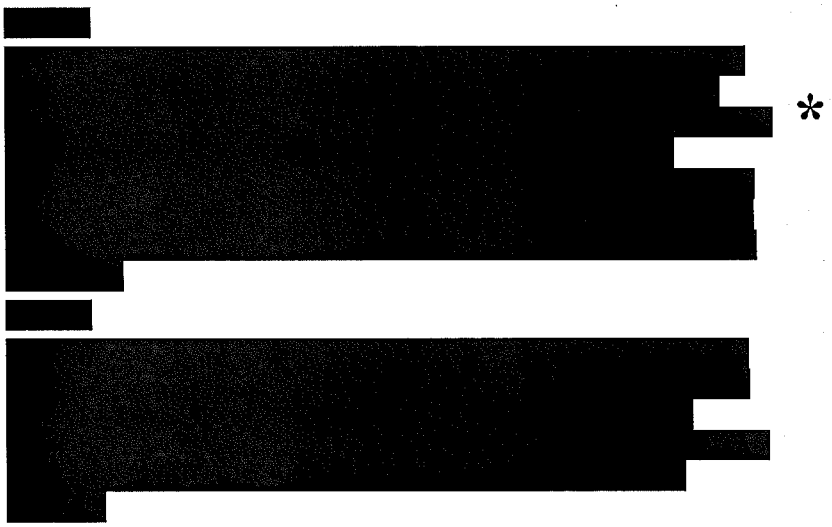
Section A6.8.2/01/02 Multigeneration Reproduction Toxicity Study
Annex Point IIA, VI.6.8.2 Gavage Rat

4.7 Litter observations

4.7.1 Number and sexes of pups born



4.7.2 Pup body weight



Section A6.8.2/01/02 Multigeneration Reproduction Toxicity Study
Annex Point IIA, VI.6.8.2 Gavage Rat

4.7.3 Litter development observations

[redacted]

4.7.4 Pup clinical observation and necropsy findings during lactation

[redacted]

*

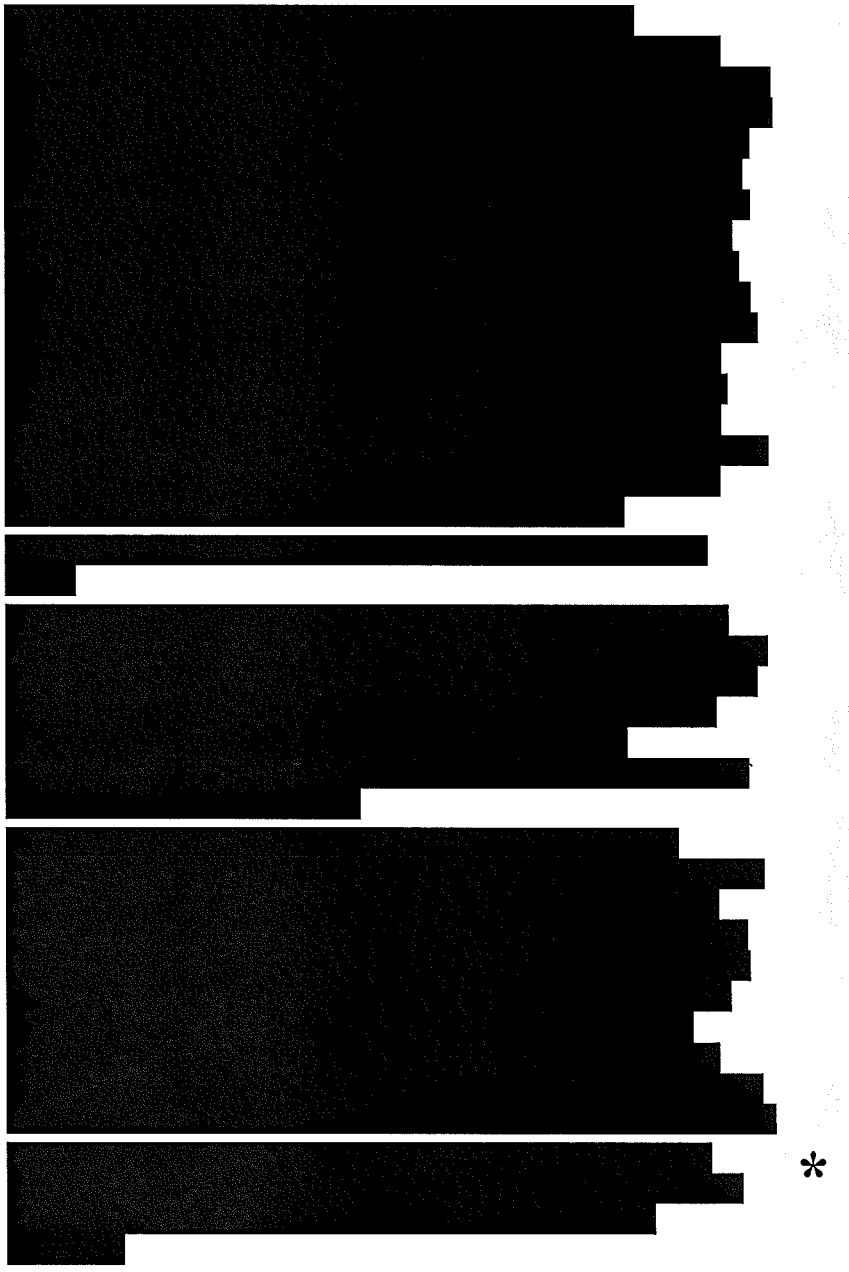
4.7.5 Necropsy findings of weaned pups

[redacted]

Section A6.8.2/01/02 Multigeneration Reproduction Toxicity Study
Annex Point IIA, VI.6.8.2 Gavage Rat

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods



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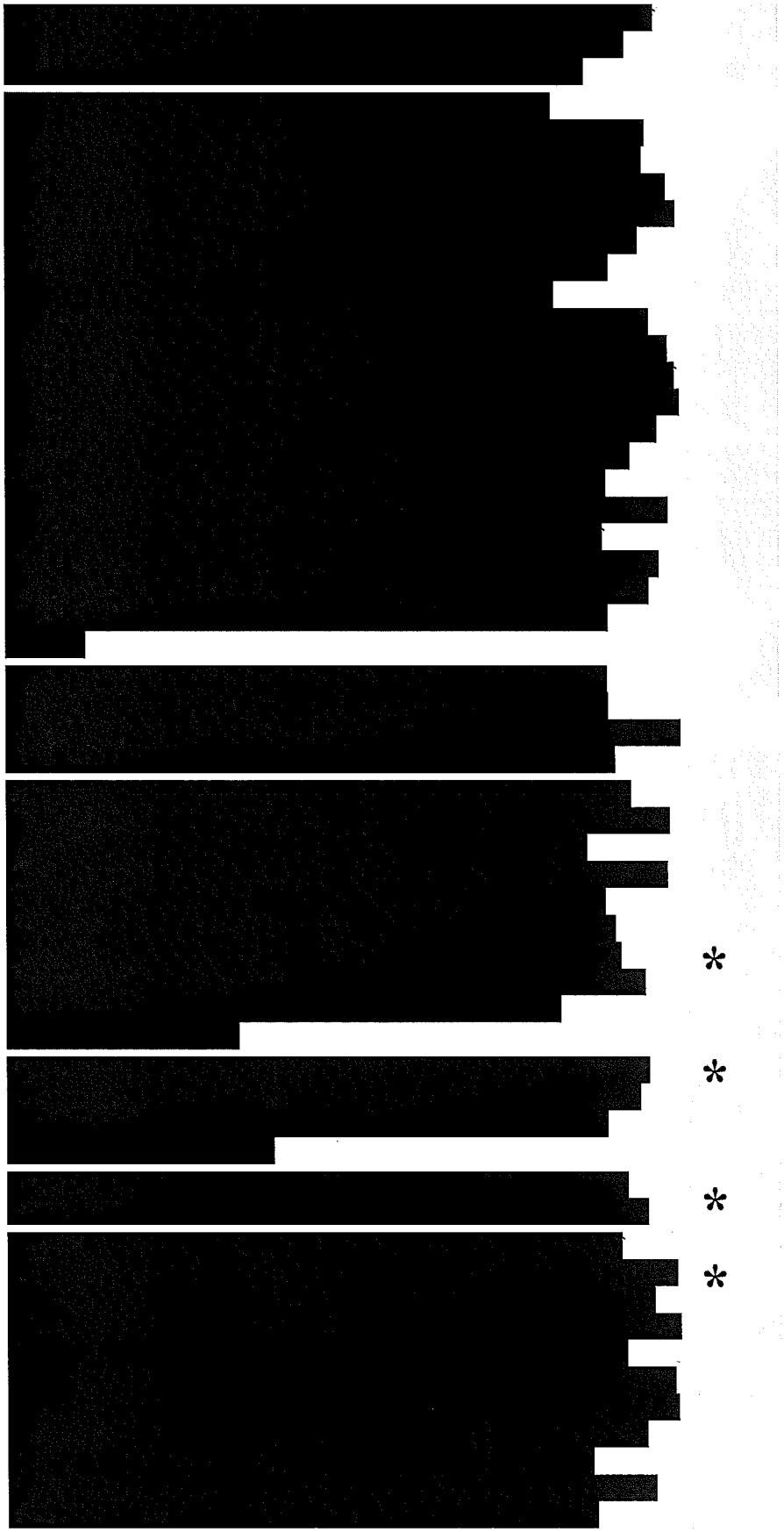
Section A6.8.2/01/02 **Multigeneration Reproduction Toxicity Study**
Annex Point IIA, VI.6.8.2 **Gavage Rat**

5.2 Results and discussion



Section A6.8.2/01/02 Multigeneration Reproduction Toxicity Study
Annex Point IIA, VI.6.8.2 **Gavage Rat**

[redacted] *

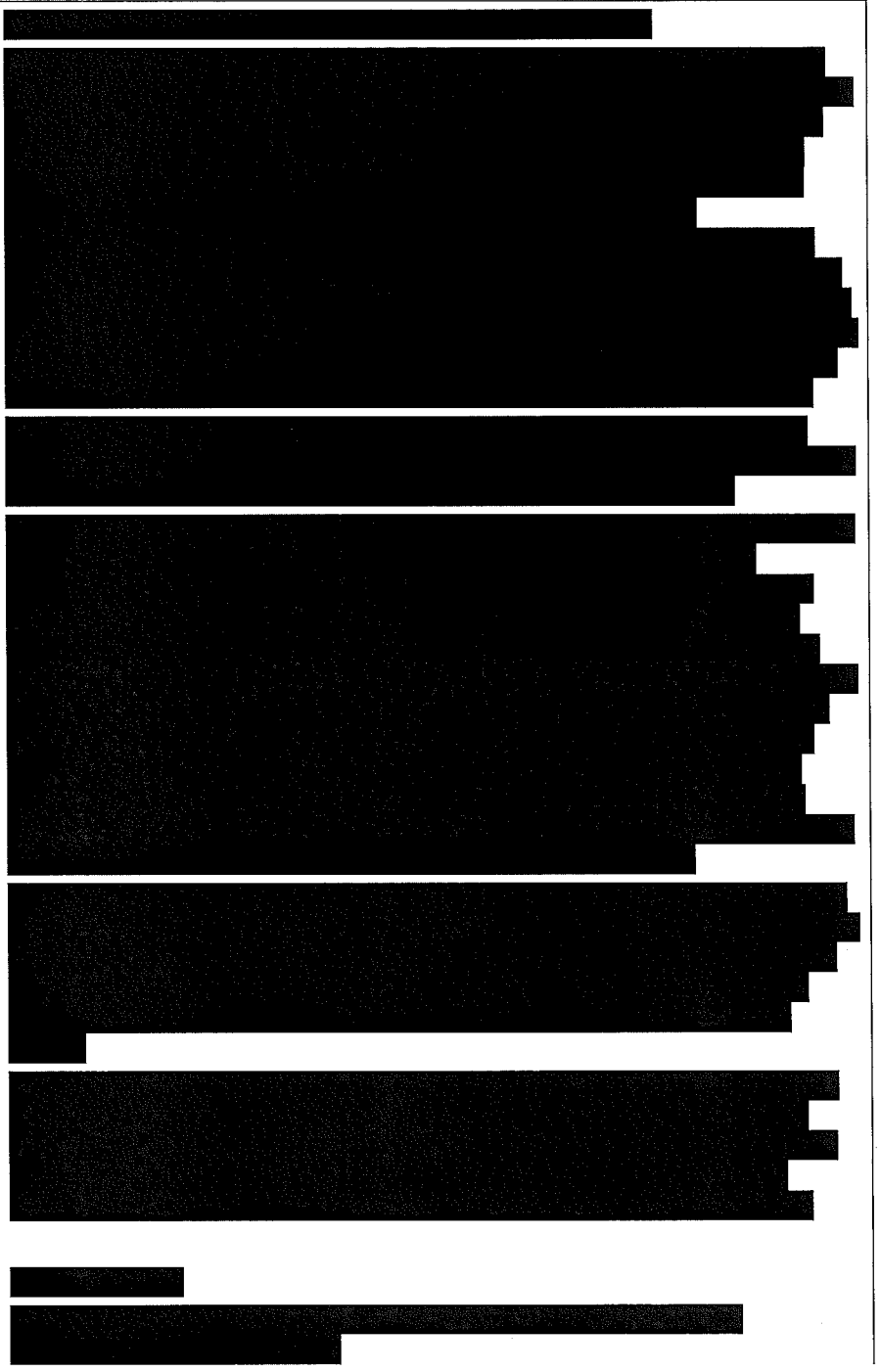
5.3	**Conclusion**		
5.3.1	$LO(A)EL_{parental}$		
5.3.1.1	F_0 males	30 mg/kg bw/day, clinical signs	
5.3.1.2	F_0 females	30 mg/kg bw/day, clinical signs	
5.3.1.3	F_1 males	30 mg/kg bw/day, clinical signs	
5.3.1.4	F_1 females	30 mg/kg bw/day, clinical signs	
5.3.2	$NO(A)EL_{parental}$		
5.3.2.1	F_0 males	10 mg/kg bw/day	
5.3.2.2	F_0 females	10 mg/kg bw/day	
5.3.2.3	F_1 males	10 mg/kg bw/day	
5.3.2.4	F_1 females	10 mg/kg bw/day	
5.3.3	$LO(A)EL_{developmental}$	100 mg/kg bw/day, reduced live birth index, reduced pup survival during the first 4 days of lactation, increased incidence of missing pups	*
5.3.4	$NO(A)EL_{developmental}$	30 mg/kg bw/day	*
5.3.5	$LO(A)EL_{reproduction}$	> 100 mg/kg bw/day, no effects on reproductive parameters	*
5.3.6	$NO(A)EL_{reproduction}$	100 mg/kg bw/day	*
5.3.7	Reliability	[redacted]	
5.3.8	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
Date	[redacted]
Materials and Methods	[redacted]

Section A6.8.2/01/02 **Multigeneration Reproduction Toxicity Study**

Annex Point IIA, VI.6.8.2 **Gavage Rat**

Results and discussion

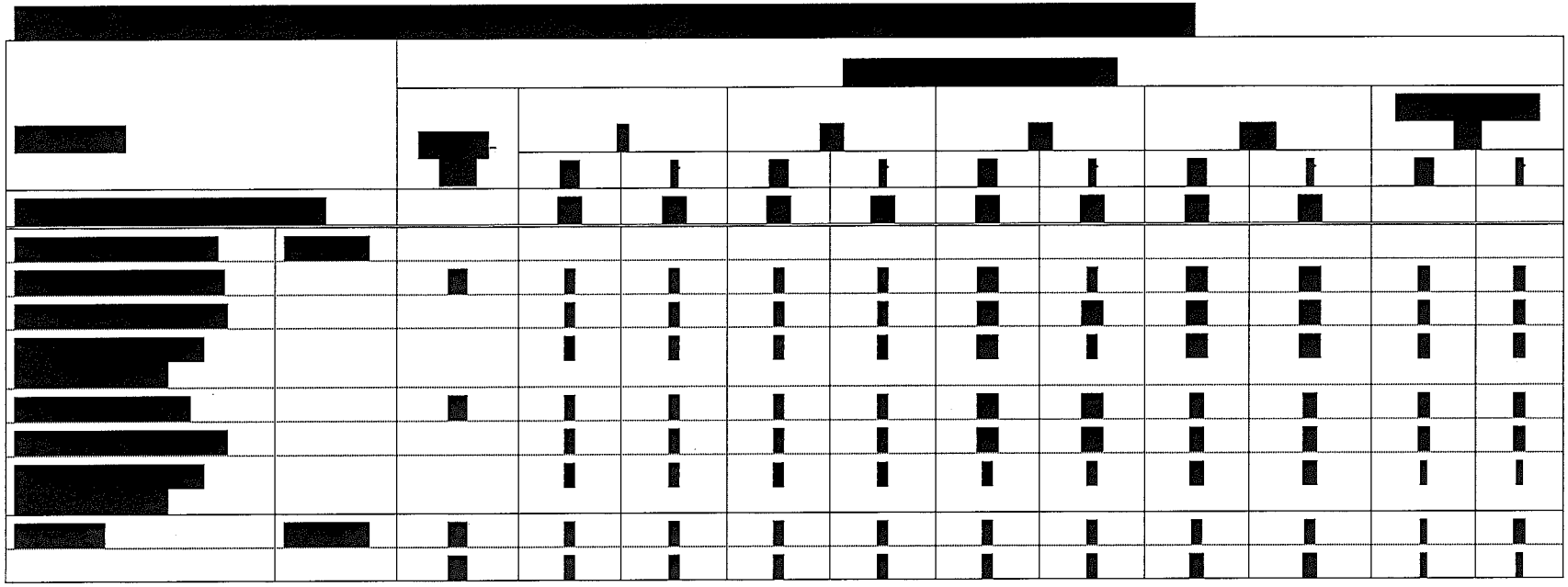


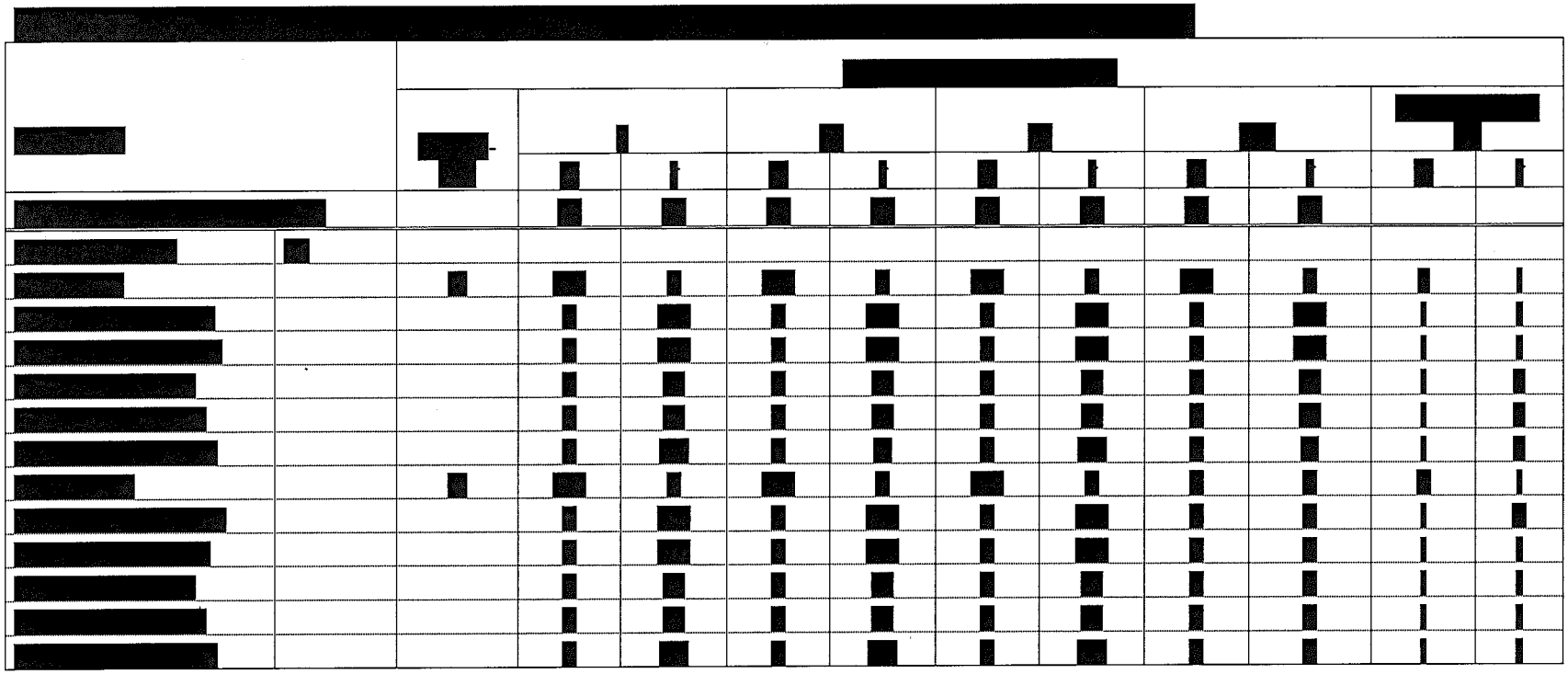
Section A6.8.2/01/02 Multigeneration Reproduction Toxicity Study

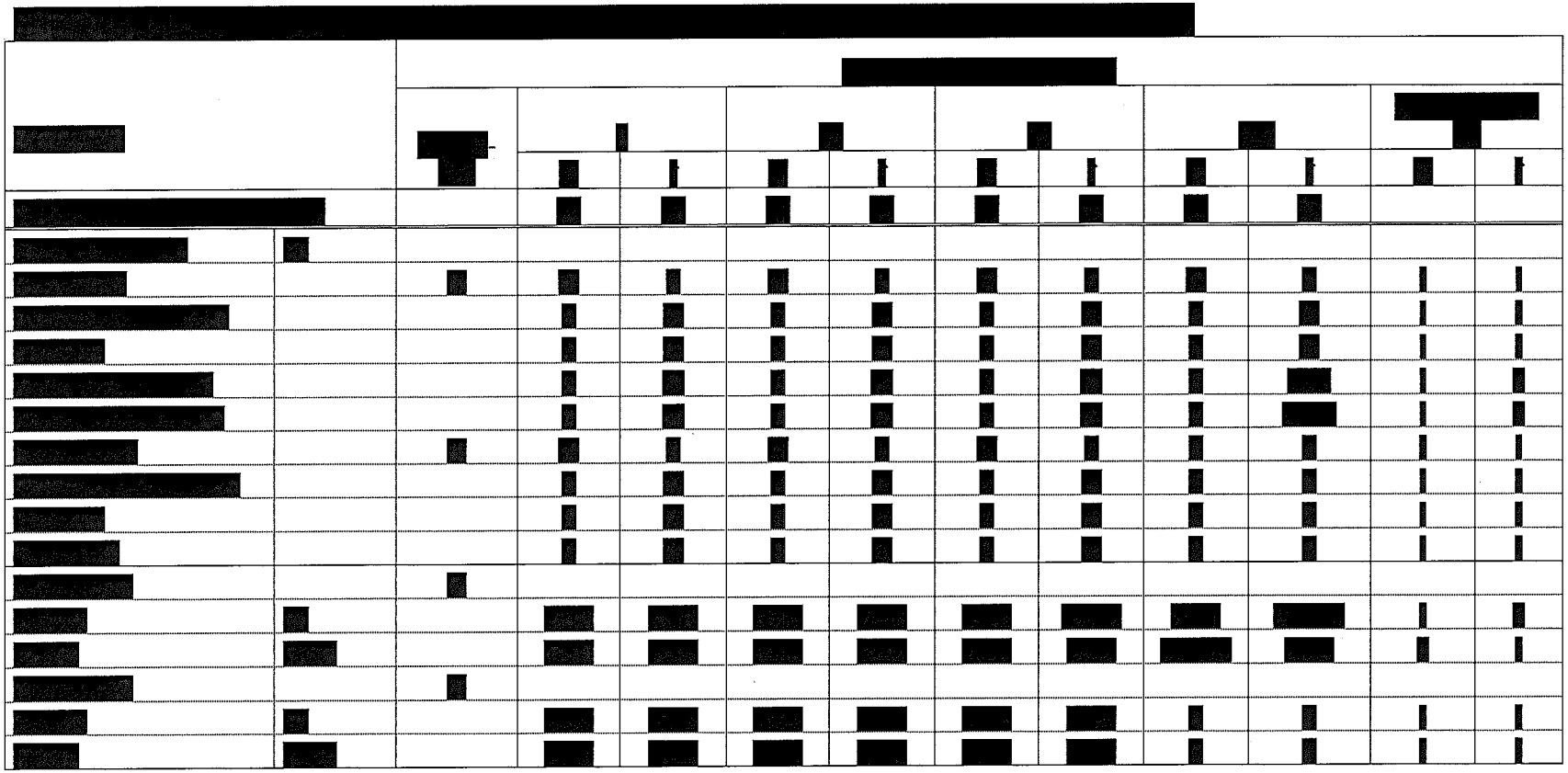
Annex Point IIA, VI.6.8.2 **Gavage Rat**

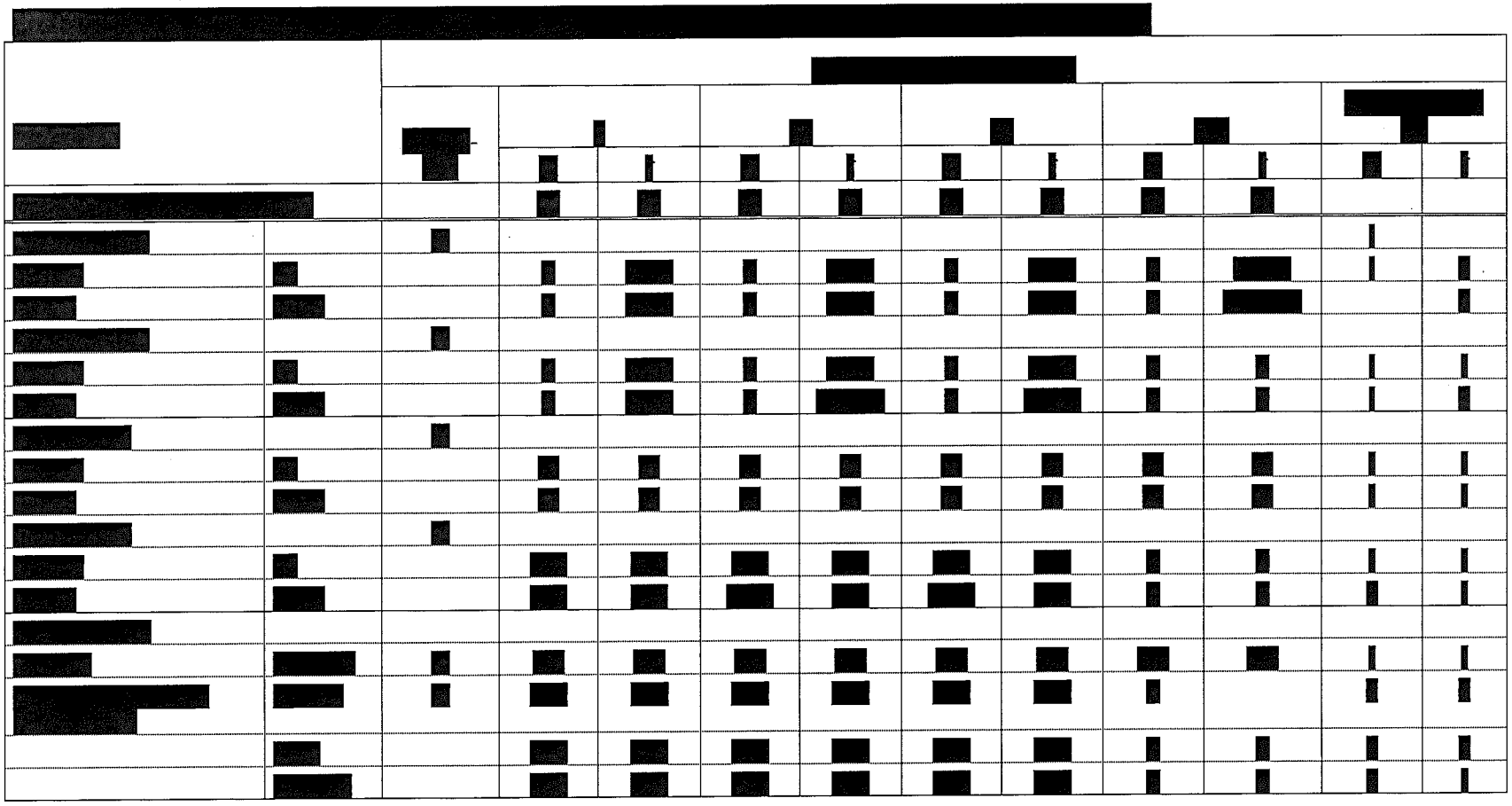
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

[redacted]

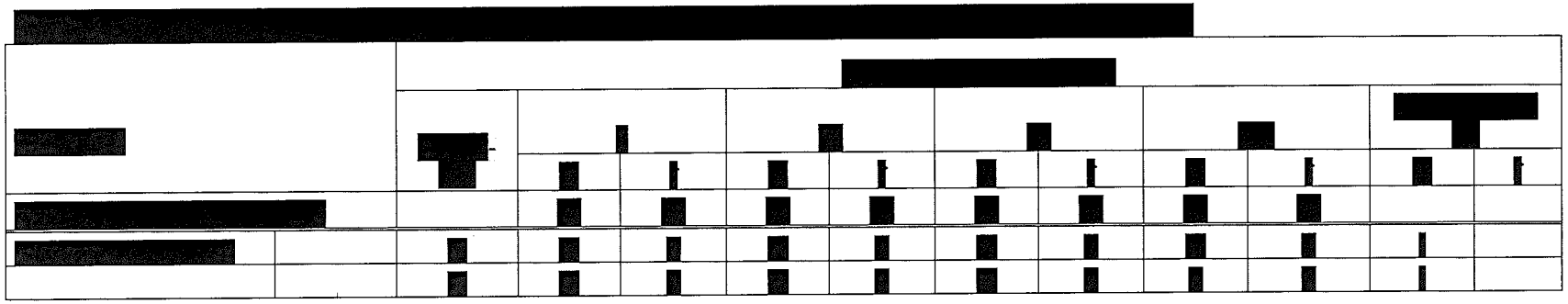






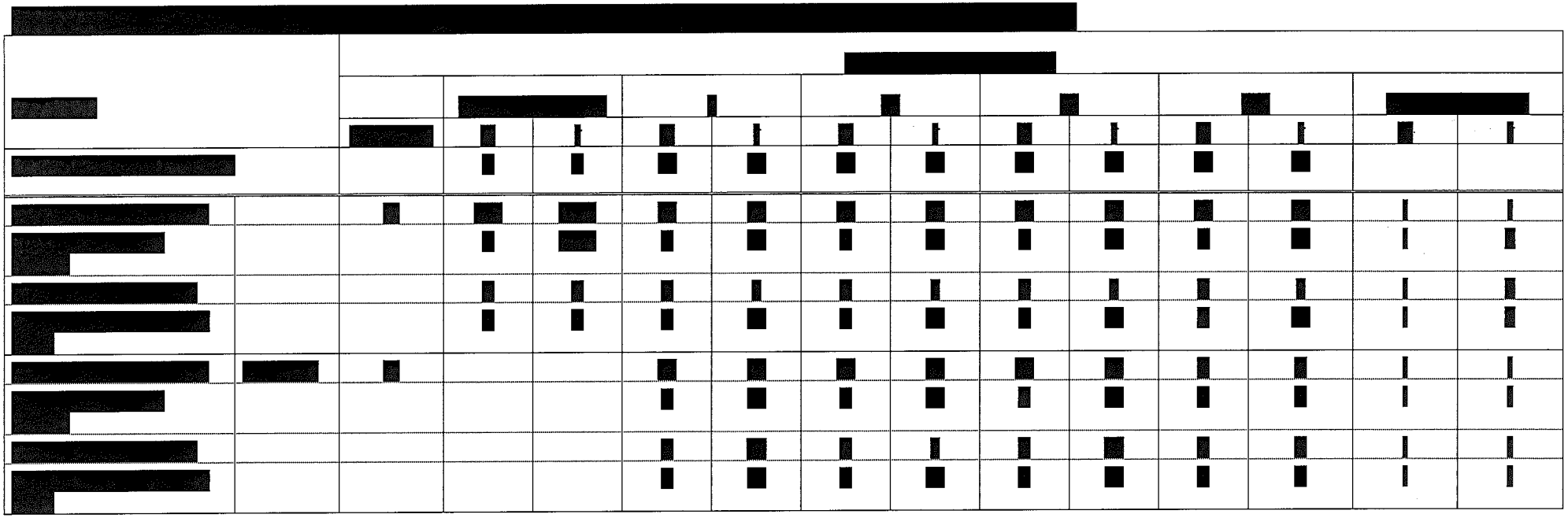


[redacted]

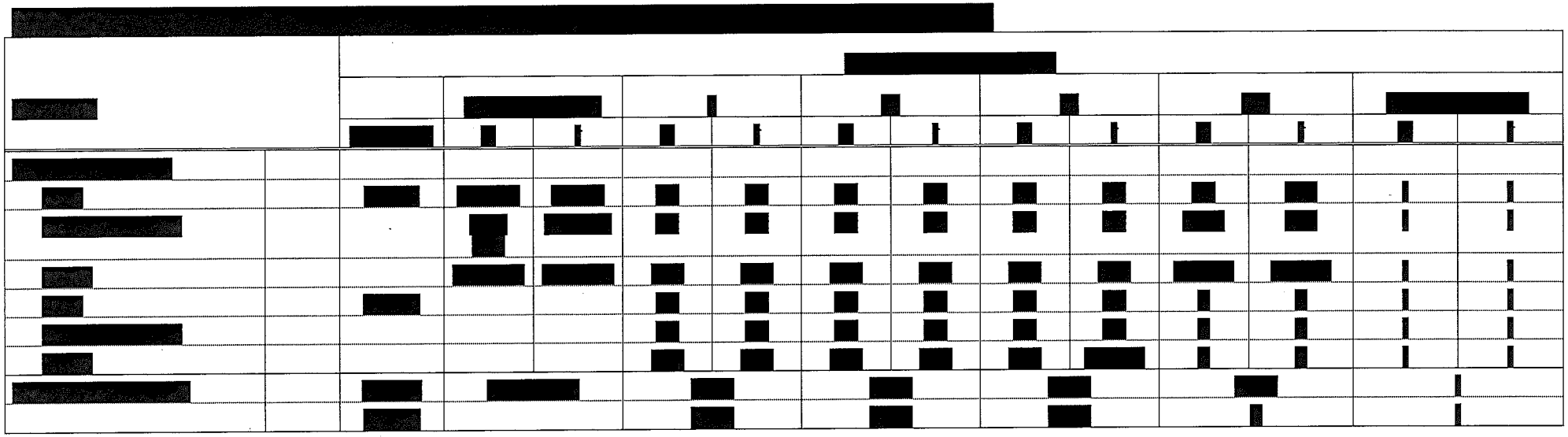


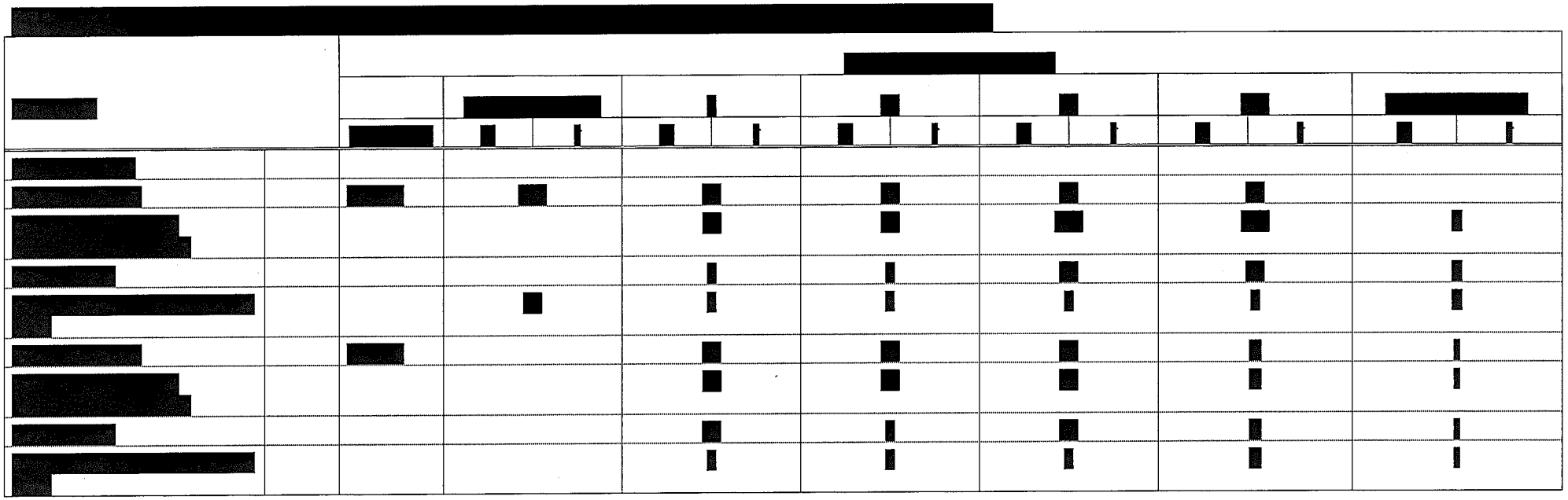
[redacted]

nd not determined



[redacted]





Section A6.8.2/03 Multigeneration Reproduction Toxicity Study
Annex Point IIA, VI.6.8.2 Feeding Rat Rangefinder

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1986): Troysan Polyphase – Preliminary Study for a 2 Generation Oral Reproduction Study in the Male Sprague Dawley Rat; [redacted] 18.12.86	[redacted]
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No, this study is only a rangefinder	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	Not applicable	
2.4	**Further remarks**		
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	The purity of the test substance was slightly lower than the specification given in section 2. This does not influence the integrity of the study.	
3.1.3	Purity	[redacted]	
3.1.4	Description	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Test Animals**		
3.2.1	Species	rat	
3.2.2	Strain	Sprague-Dawley Crl:CD(SD)BR	
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	[redacted]	
3.3	**Administration/ Exposure**	Oral	
3.3.7	Duration of treatment	[redacted]	
3.3.8	Frequency of exposure	[redacted]	
3.3.9	Type	In food	
3.3.10	Vehicle	[redacted]	

Section A6.8.2/03 Multigeneration Reproduction Toxicity Study
Annex Point IIA, VI.6.8.2 Feeding Rat Rangefinder

3.3.11	Concentration in vehicle	[redacted]
3.4	**Examinations**	
3.4.7	Observations	[redacted]
3.4.7.1	Clinical signs	[redacted]
3.4.7.2	Mortality	[redacted]
3.4.8	Body weight	[redacted]
3.4.9	Food consumption	[redacted]
3.4.10	Water consumption	[redacted]
3.5	**Further remarks**	[redacted]
	4 RESULTS AND DISCUSSION	
4.1	**Observations**	
4.1.7	Clinical signs	[redacted]
4.1.8	Mortality	[redacted]
4.2	**Body weight gain**	[redacted]
4.3	**Food consumption**	[redacted]
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	
5.3.7	LOEL	not applicable, dose-rangefinder
5.3.8	NOAEL	not applicable, dose-rangefinder
5.3.9	Other	
5.3.10	Reliability	[redacted]
5.3.11	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
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]

Section A6.8.2/03 Multigeneration Reproduction Toxicity Study

Annex Point IIA, VI.6.8.2 **Feeding Rat Rangefinder**

Acceptability	[redacted]
Remarks	[redacted]

Section A6.8.2/04 Multigeneration Reproduction Toxicity Study

Annex Point IIA, VI.6.8.2 Gavage Rat Rangefinder

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (1986): Troysan Polyphase – Preliminary Study for a 2 Generation Oral Reproduction Study in the Female Sprague Dawley Rat; [redacted] 18.12.86 [redacted]	[redacted]
1.2	**Data protection**	[redacted]	
1.2.9	Data owner	[redacted]	
1.2.10	Companies with letter of access	[redacted]	
1.2.11	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	[redacted] a rangefinding study	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	Not applicable	
2.4	**Further remarks**		
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	The purity of the test substance was slightly lower than the specification given in section 2. This does not influence the integrity of the study.	
3.1.3	Purity	[redacted]	
3.1.4	Description	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Test Animals**		
3.2.1	Species	rat	
3.2.2	Strain	Sprague-Dawley Crl:CD(SD)BR	
3.2.3	Source	[redacted]	
3.2.4	Sex	Female	
3.2.5	Age/weight at study initiation	[redacted]	*
3.2.6	Number of animals per group	[redacted]	
3.2.7	Mating	[redacted]	
3.2.8	Control animals	[redacted]	

Section A6.8.2/04 Multigeneration Reproduction Toxicity Study

Annex Point IIA, VI.6.8.2 **Gavage Rat Rangefinder**

3.3	**Administration/ Exposure**	Oral
3.3.1	Duration of exposure	[redacted]
3.3.2	Type	[redacted]
3.3.3	Vehicle	[redacted]
3.3.4	Concentration in vehicle	[redacted]
3.3.5	Concentration in vehicle	[redacted]
3.3.6	Total volume applied	[redacted] *
3.4	**Examinations**	
3.4.1	Clinical signs	[redacted]
3.4.2	Mortality	[redacted]
3.4.3	Body weight	[redacted]
3.4.4	Terminal examination	[redacted]
3.5	**Statistics**	[redacted]
		4 RESULTS AND DISCUSSION
4.1	**Clinical signs**	[redacted]
4.2	**Mortality**	[redacted]
4.3	**Body weight**	[redacted]
4.4	**Terminal examinations**	[redacted]

Section A6.8.2/04 Multigeneration Reproduction Toxicity Study

Annex Point IIA, VI.6.8.2 Gavage Rat Rangefinder

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]
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
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

Section A6.8.2/05/06/07

Annex Point IIA, VI.6.8.2

Multigeneration Reproduction Toxicity Study
Feeding study in rats

		1 REFERENCE	Official use only
1.1	**Reference**	A6.8.2/05: [redacted] (1987): Troysan Polyphase – Two Generation Oral (Dietary Administration) Reproduction Toxicity Study in the Rat (one Litter per Generation) [redacted] 16.10.1987 [redacted] A6.8.2/06: [redacted] (2004): Historical Control Data of Two/One Generation Oral (Dietary Administration) Reproduction Toxicity Studies 1984 to 1990; [redacted]; 26.03.2004 [redacted] A6.8.2/07: [redacted] (2004): To Whom It May Concern – IPBC purity [redacted] 26.03.2004 [redacted]	[redacted]
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	A6.8.2/05: Yes, US EPA guideline Subdivision F 83-4 (1982) The method described in the report is comparable to current OECD 416 (adopted 2001)* A6.8.2/06 and A6.8.2/07: No, not applicable	[redacted]
2.2	**GLP**	[redacted]	*
2.3	**Deviations**	A6.8.2/05: No A6.8.2/06 and A6.8.2/07: Not applicable	*
2.4	**Further remarks**	[redacted]	
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	The purity of the test substance was slightly lower than the specification	

Section A6.8.2/05/06/07
Annex Point IIA, VI.6.8.2

Multigeneration Reproduction Toxicity Study
Feeding study in rats

		given in section 2. This does not influence the integrity of the study.
3.1.3	Purity	[redacted]
3.1.4	Description	[redacted]
3.1.5	Stability	[redacted] *
3.2	**Test Animals**	
3.2.1	Species	rat
3.2.2	Strain	Sprague-Dawley Crl:CD(SD)BR
3.2.3	Source	[redacted]
3.2.4	Sex	male, female
3.2.5	Age/weight at study initiation	[redacted]
3.2.6	Number of animals per group	[redacted]
3.2.7	Mating	[redacted]
3.2.8	Duration of mating	[redacted]
3.2.9	Control animals	[redacted]
3.3	**Administration/ Exposure**	Oral
3.3.1	Duration of exposure before mating	[redacted]
3.3.2	Duration of exposure in general P, F1, F2 males, females	[redacted]
3.3.3	Type	In food
3.3.4	Vehicle	[redacted]
3.3.5	Concentration in vehicle	[redacted]
3.3.6	Controls	[redacted]
3.4	**Examinations**	
3.4.1	Clinical signs	[redacted]
3.4.2	Mortality	[redacted]

Section A6.8.2/05/06/07
Annex Point IIA, VI.6.8.2

Multigeneration Reproduction Toxicity Study
Feeding study in rats

3.4.3	Body weight	
3.4.4	Food consumption	
3.4.5	Oestrus cycle	
3.4.6	Sperm parameters	
3.4.7	Offspring	
3.4.8	Organ weights F_0 and F_1	
3.4.9	Histopathology F_1	*
3.4.10	Histopathology F1 not selected for mating, F2	
3.5	**Further investigations**	
3.6	**Statistics**	

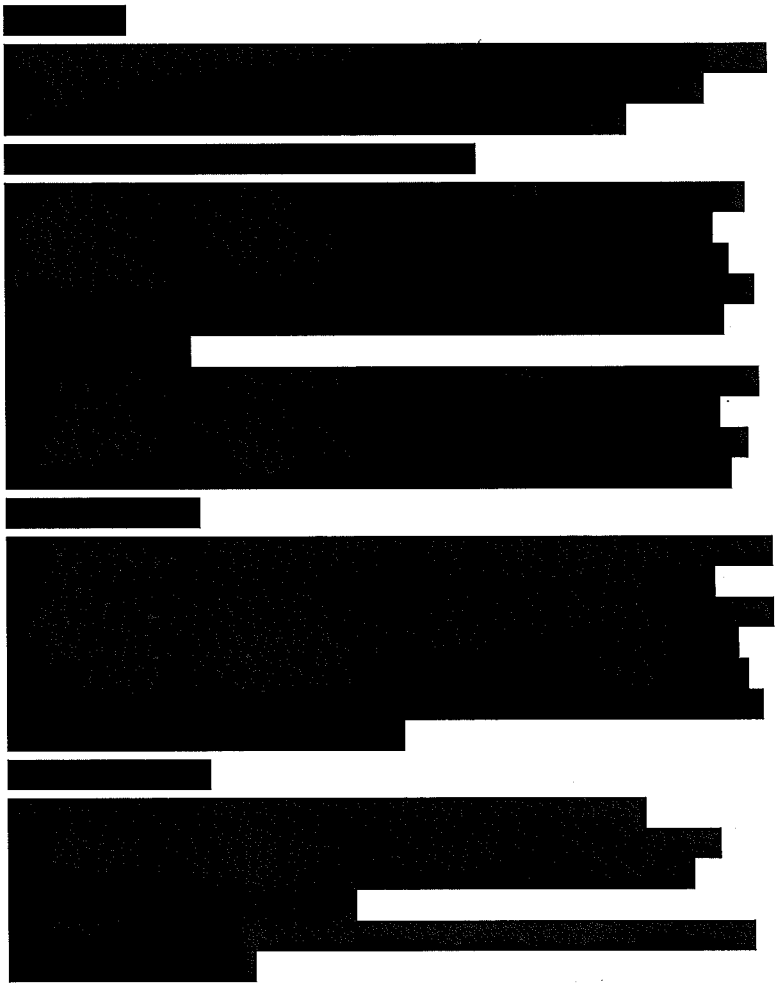
Section A6.8.2/05/06/07
Annex Point IIA, VI.6.8.2

Multigeneration Reproduction Toxicity Study
Feeding study in rats

4 RESULTS AND DISCUSSION

4.1 Parental effects

4.1.1 F_0 animals



Section A6.8.2/05/06/07
Annex Point IIA, VI.6.8.2

Multigeneration Reproduction Toxicity Study
Feeding study in rats

4.1.2 F_1 parents

[redacted]

4.2 Fertility and mating performance

[redacted]

4.3 Gestation, parturition and lactation

[redacted]

Section A6.8.2/05/06/07
Annex Point IIA, VI.6.8.2

Multigeneration Reproduction Toxicity Study
Feeding study in rats

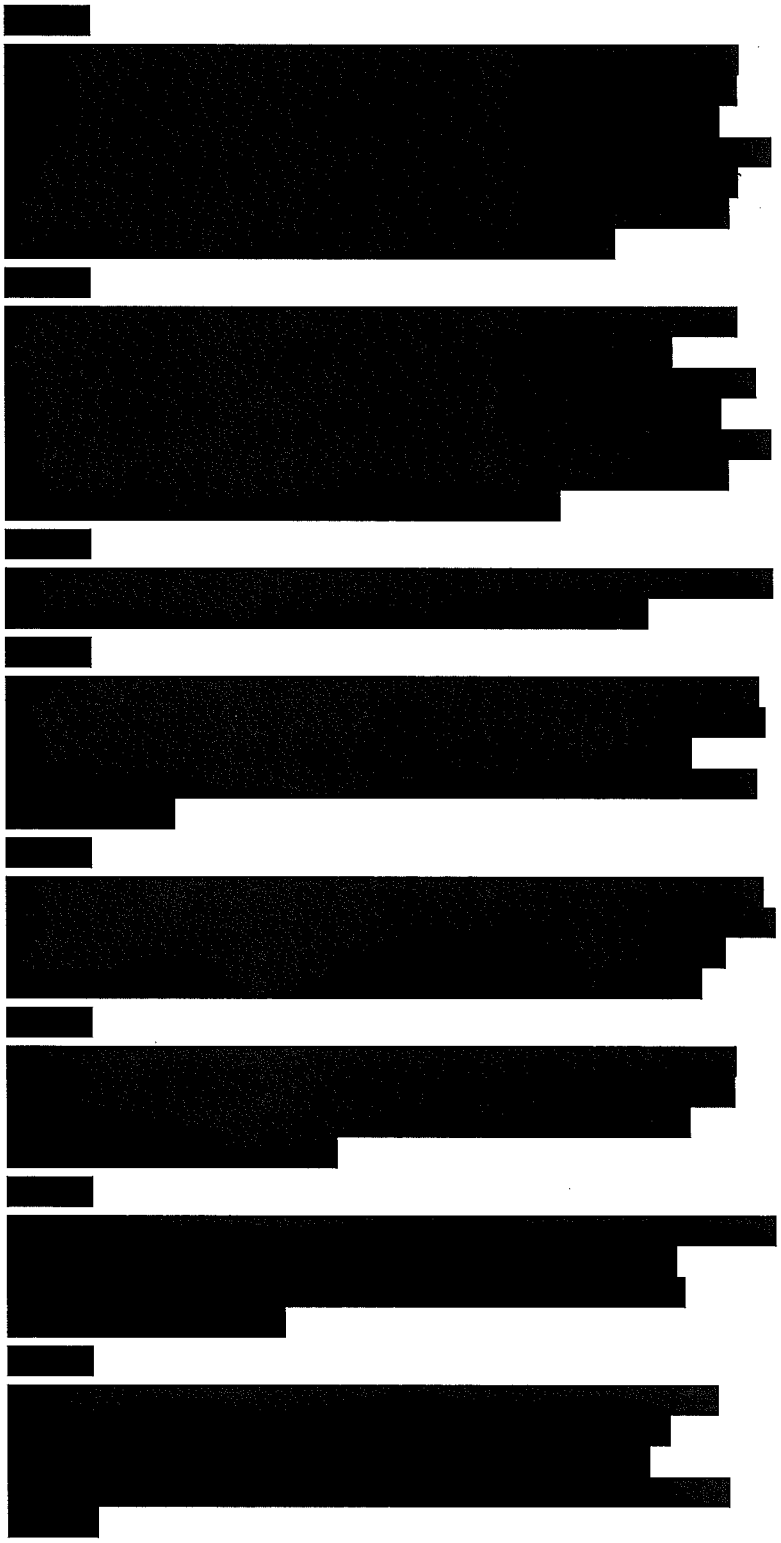
4.4 Litter observations

4.4.1 Number and sexes of pups born

4.4.2 Pup body weight

4.4.3 Litter development observations

4.4.4 Pup clinical observation and necropsy findings



Section A6.8.2/05/06/07
Annex Point IIA, VI.6.8.2

Multigeneration Reproduction Toxicity Study
Feeding study in rats

4.4.5 Histopathological examinations

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 **Materials and methods**

In an 2-generation reprotoxicity study Sprague-Dawley rats (25/sex/group) were treated via food with IPBC [redacted] *

[redacted] *

The study conduction was comparable to OECD 414 (2-generation reprotoxicity study).

Section A6.8.2/05/06/07
Annex Point IIA, VI.6.8.2

Multigeneration Reproduction Toxicity Study
Feeding study in rats

5.2 Results and discussion

5.3 Conclusion

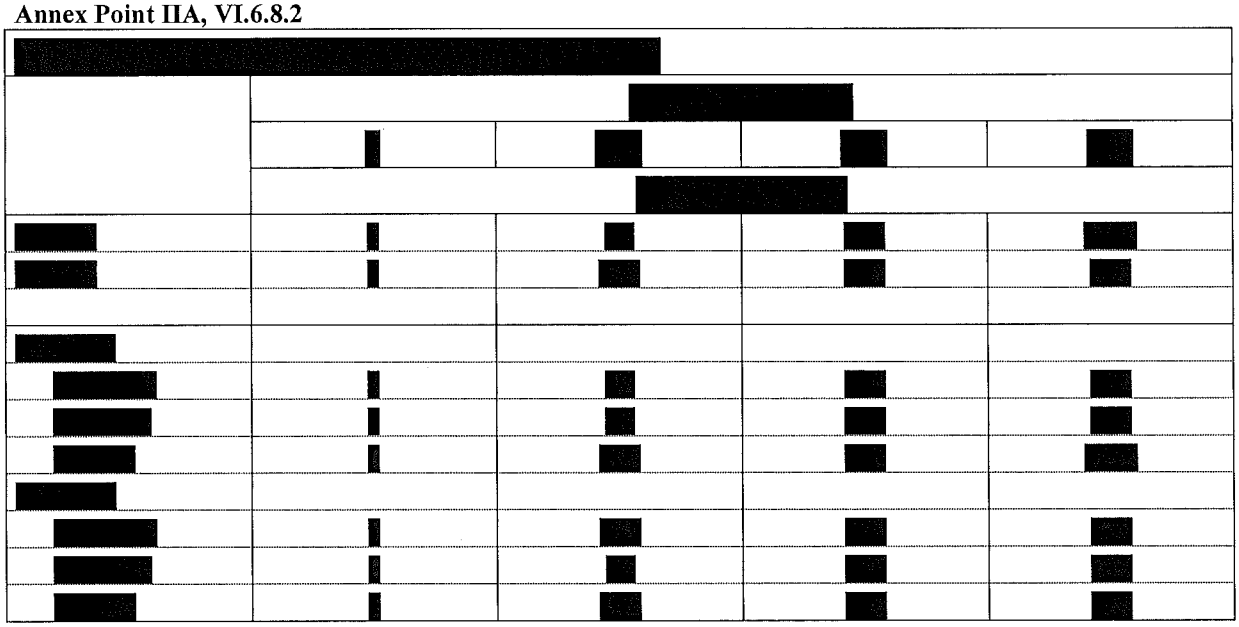
5.3.1	$LO(A)EL_{parental}$		
5.3.1.1	F_0 males	300 ppm (equivalent to 50.5 mg/kg bw/day), based on reduced body weight gain and food consumption	*
5.3.1.2	F_0 females	300 ppm (equivalent to 49.8 to 101.2 mg/kg bw/day), based on reduced body weight gain	*
5.3.1.3	F_1 males	300 ppm (equivalent to 62.8 mg/kg bw/day), based on reduced body weight gain and food consumption	*
5.3.1.4	F_1 females	300 ppm (equivalent to 52.7 to 90.4 mg/kg bw/day), based on reduced body weight gain	*
5.3.2	$NO(A)EL_{parental}$		
5.3.2.1	F_0 males	120 ppm (equivalent to 20.7 mg/kg bw/day)	*
5.3.2.2	F_0 females	120 ppm (equivalent to 20.2 to 39.6 mg/kg bw/day)	*
5.3.2.3	F_1 males	120 ppm (equivalent to 26.1 mg/kg bw/day)	*
5.3.2.4	F_1 females	120 ppm (equivalent to 20.3 to 34.0 mg/kg bw/day)	*
5.3.3	$LO(A)EL_{developmental}$	>750 ppm (equivalent to 49.8 to 101.2 mg/kg bw/day)	*
5.3.4	$NO(A)EL_{developmental}$	> 750 ppm (equivalent to 49.8 to 101.2 mg/kg bw/day)	*
5.3.5	$LO(A)EL_{reproduction}$	>750 ppm (equivalent to 49.8 to 101.2 mg/kg bw/day)	*

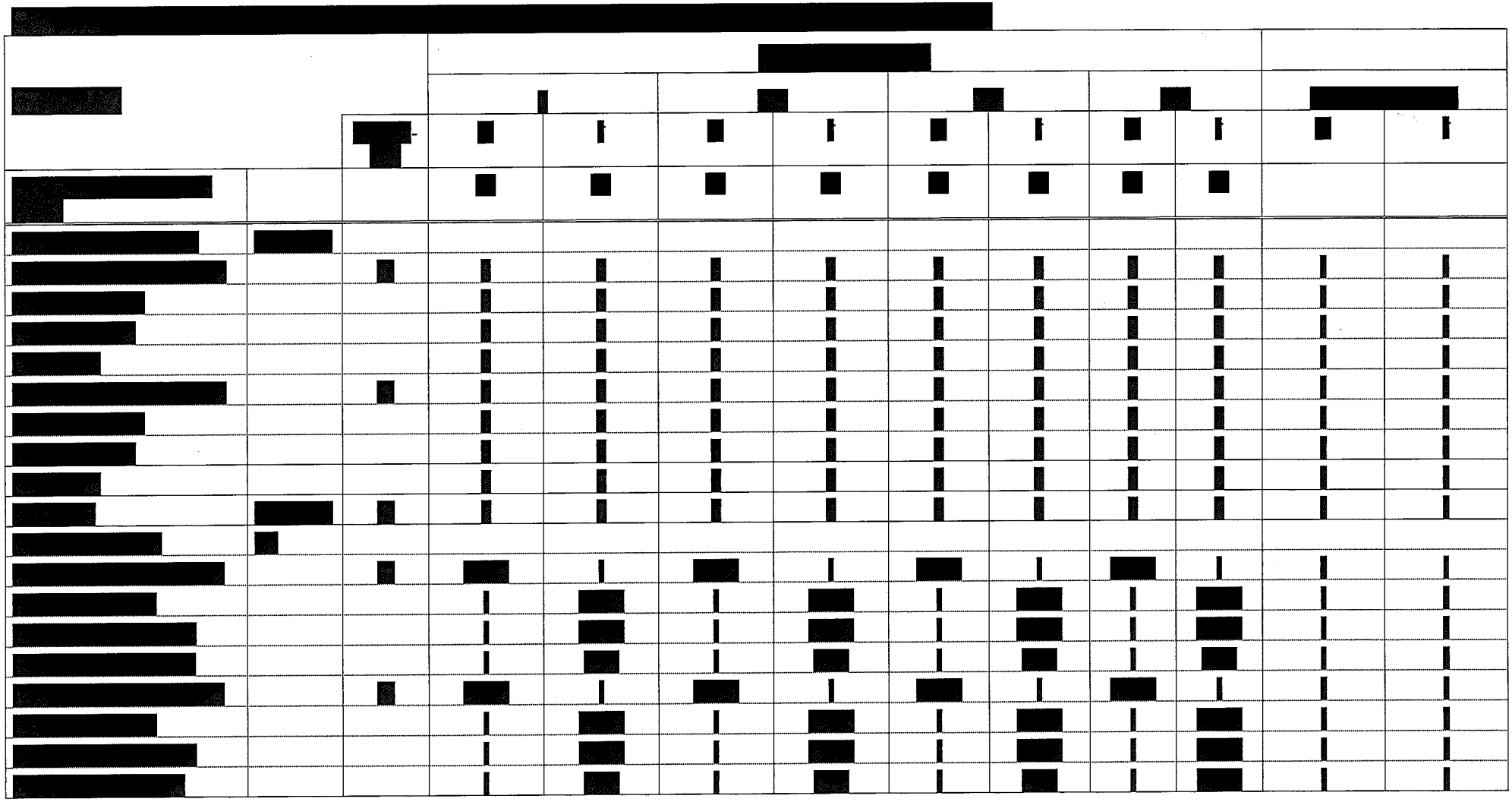
Section A6.8.2/05/06/07	Multigeneration Reproduction Toxicity Study Feeding study in rats	
Annex Point IIA, VI.6.8.2		
5.3.6 $NO(A)EL_{reproduction}$	> 750 ppm (equivalent to 49.8 to 101.2 mg/kg bw/day)	*
5.3.7 Reliability	[redacted]	*
5.3.8 Deficiencies	No	*

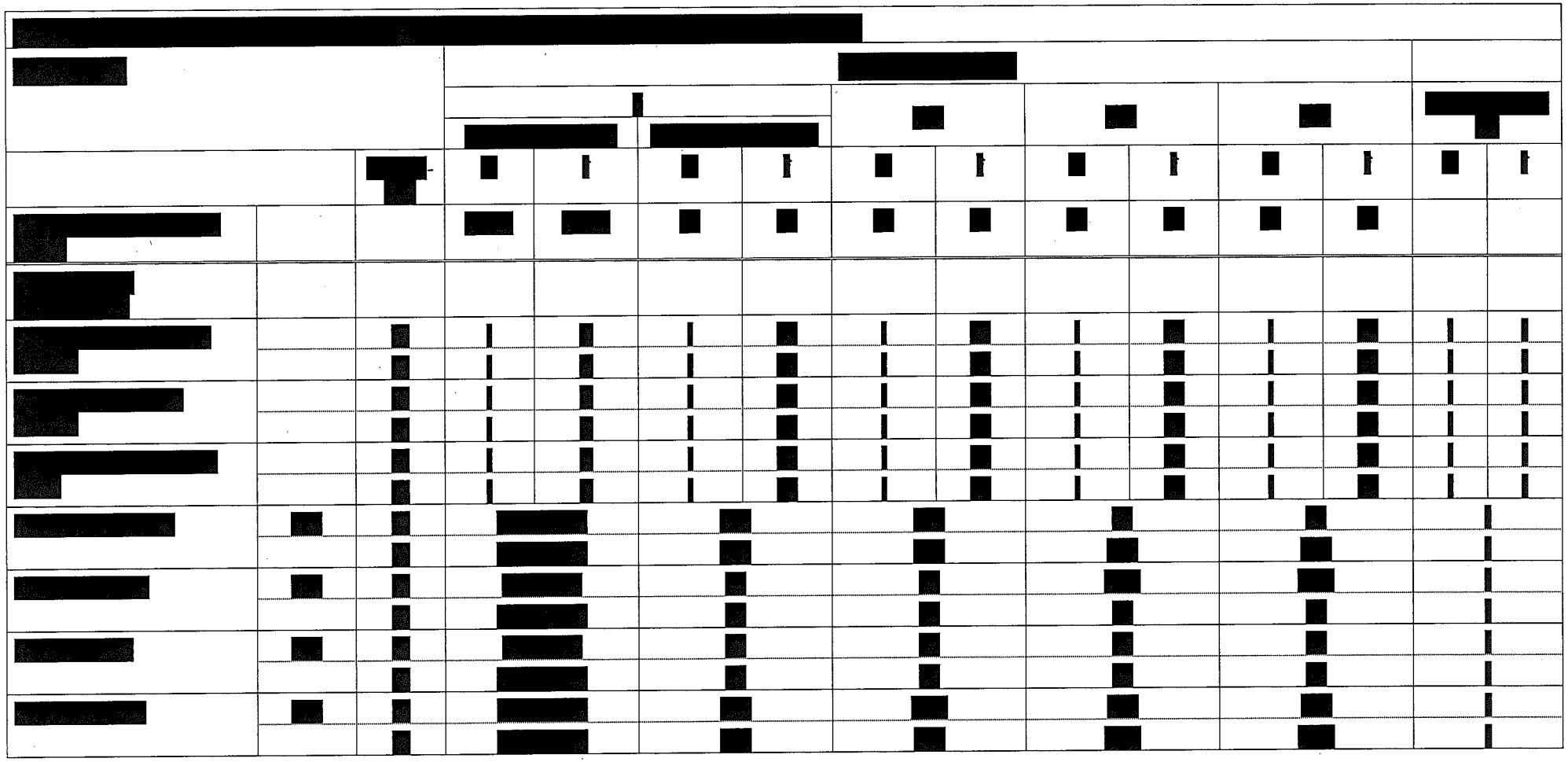
Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

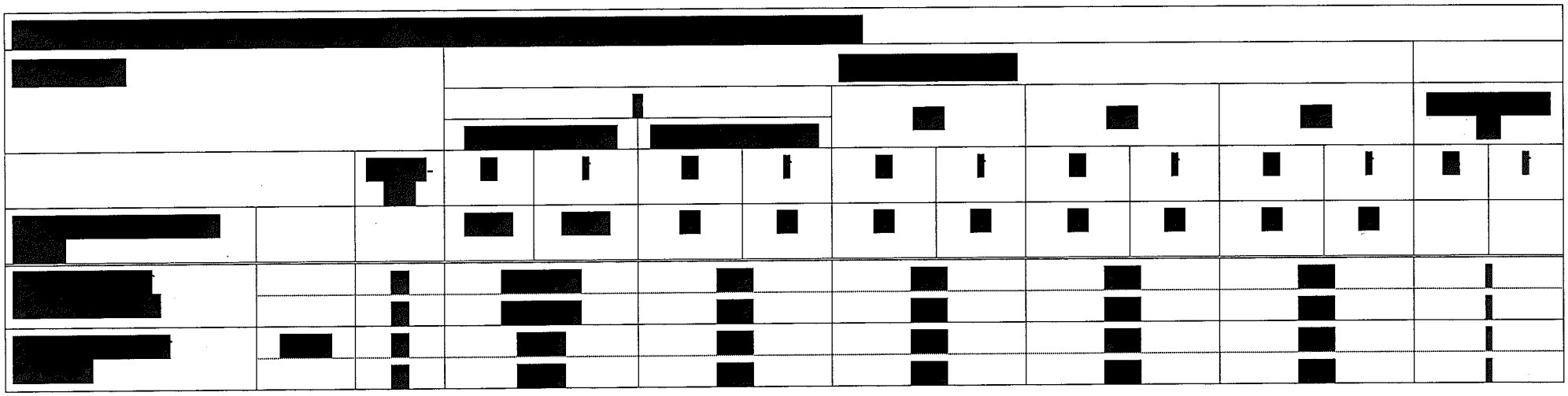
Section A6.8.2/05/06/07
Annex Point IIA, VI.6.8.2

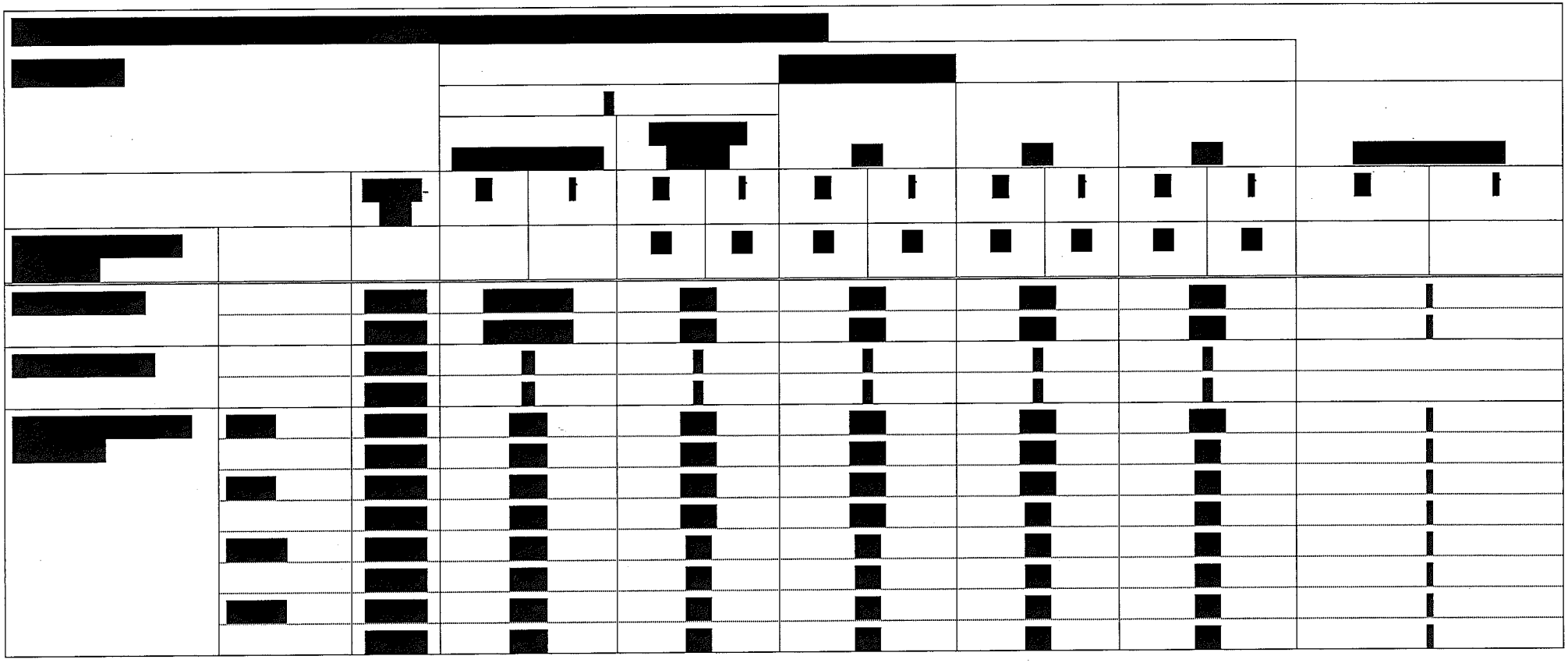
Multigeneration Reproduction Toxicity Study
Feeding study in rats

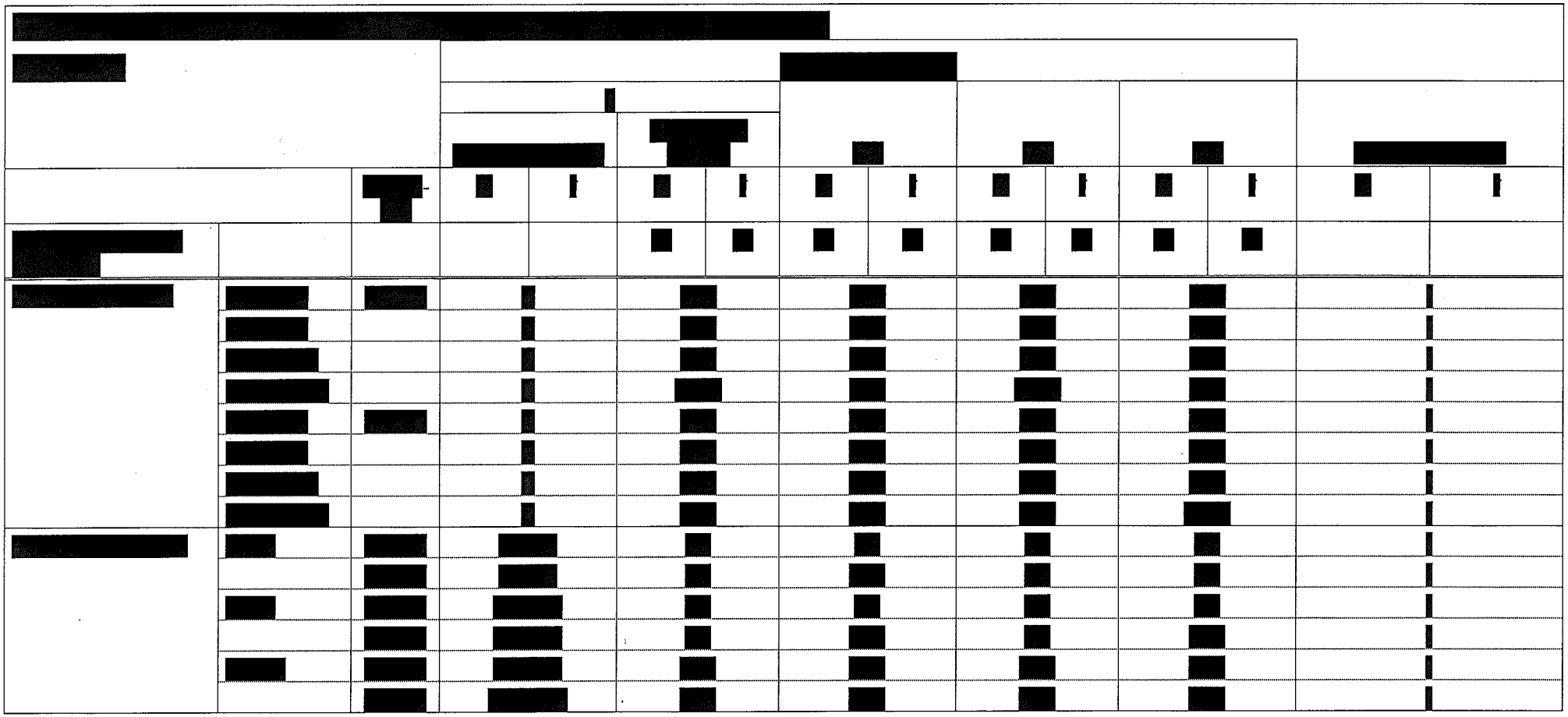












Section A6.9/01 Neurotoxicity

Annex Point IIIA, VI.1

Acute, Gavage, Rats, Range-finding study

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted]	[redacted]
		[redacted] (2002): Acute Oral Dose Range-Finding Study with 3-Iodopropynylbutyl Carbamate (IPBC) Administered by Gavage in CD® Rats. [redacted] 12.04.2002	[redacted]
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	n.a., range finding study	
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	As given in section 2	
3.1.3	Purity	[redacted]	
3.1.4	Description	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Reference Substance (positive control)**	[redacted]	

Section A6.9/01 Neurotoxicity

Annex Point IIIA, VI.1 Acute, Gavage, Rats, Range-finding study

3.3	**Test Animals**	
3.3.1	Species	CD® rats
3.3.2	Strain	Crl:CD® (SD) IGS BR
3.3.3	Source	[redacted]
3.3.4	Sex	male and female
3.3.5	Rearing conditions	[redacted]
3.3.6	Age/weight at study initiation	[redacted]
3.3.7	Number of animals per group	[redacted]
3.3.8	Control animals	[redacted]
3.4	**Administration**	Oral by gavage
3.4.1	Exposure	Single oral administration
3.4.2	Dose Levels	[redacted]
3.4.3	Vehicle	[redacted]
3.4.4	Concentration in vehicle	[redacted]
3.4.5	Total volume applied	[redacted]
3.4.6	Postexposure period	[redacted]
3.4.7	Anticholinergic substances used	[redacted]
3.4.8	Controls	[redacted]
3.5	**Examinations**	
3.5.1	Body Weight	[redacted]

Section A6.9/01 Neurotoxicity

Annex Point IIIA, VI.1 Acute, Gavage, Rats, Range-finding study

3.5.2 Signs of Toxicity

[redacted]

3.5.3 Observation schedule

[redacted]

3.5.4 Clinical Chemistry

[redacted]

3.5.5 Pathology

[redacted]

3.5.6 Histopathology

[redacted]

3.6 Further remarks

[redacted]

4 RESULTS AND DISCUSSION

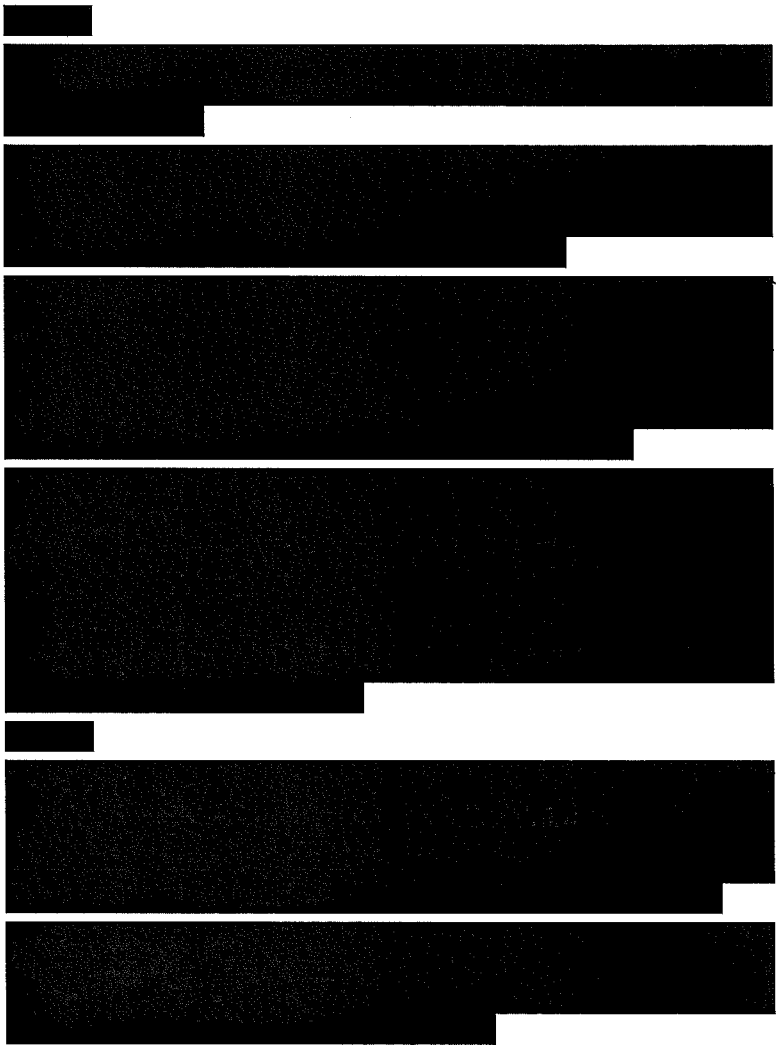
4.1 Body Weight

[redacted]

Section A6.9/01 Neurotoxicity

Annex Point IIIA, VI.1 **Acute, Gavage, Rats, Range-finding study**

4.2 Clinical signs of toxicity

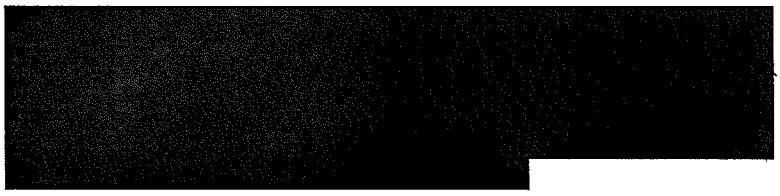


4.3 Clinical Chemistry

4.4 Pathology

4.5 Histopathology

4.6 Other



Section A6.9/01 Neurotoxicity
Annex Point IIIA, VI.1 Acute, Gavage, Rats, Range-finding study

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[redacted]

The study was designed as a range-finding study and followed in principle OPPTS 870.6200 (Neurotoxicity Screening Battery). [redacted]

5.2 Results and discussion

[redacted]

Section A6.9/01 Neurotoxicity

Annex Point IIIA, VI.1 **Acute, Gavage, Rats, Range-finding study**

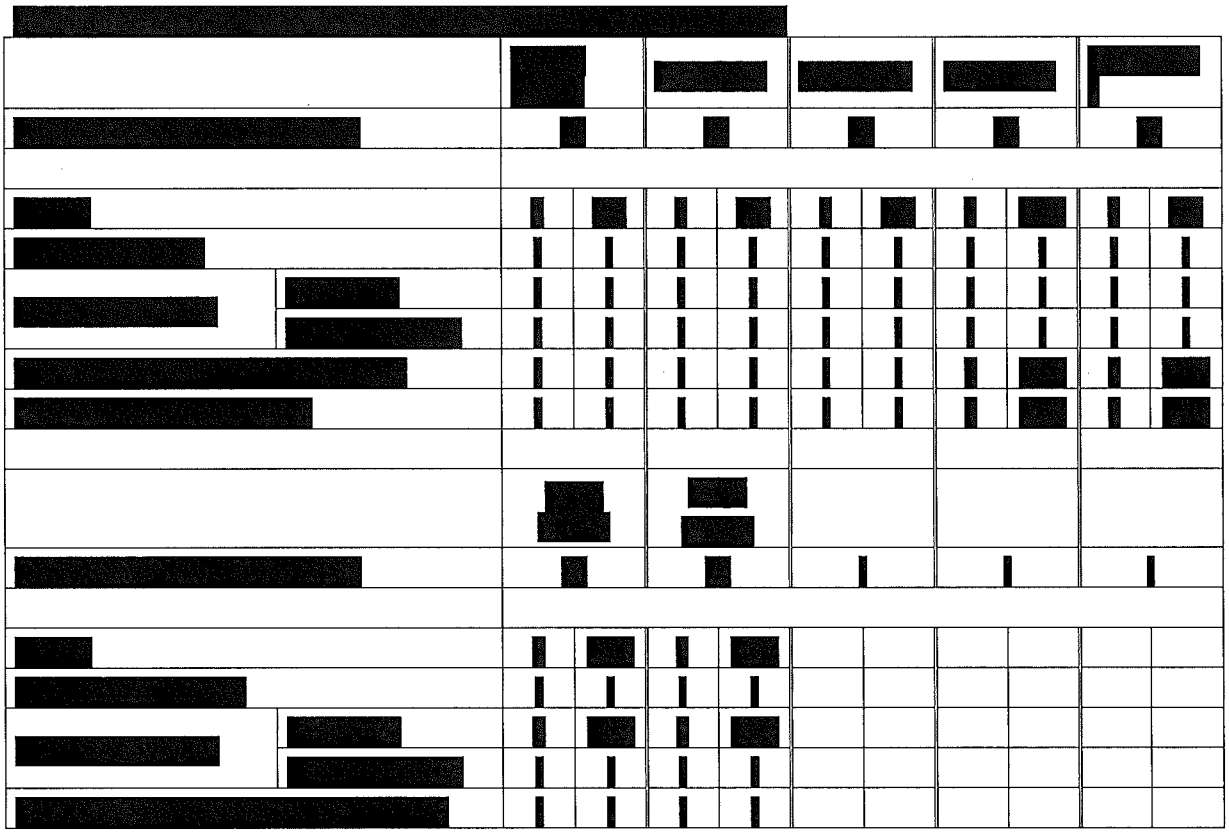
5.3	Conclusion	[redacted] Therefore, for the estimation of the time to peak effect the metabolic profile of IPBC has to be considered.
5.3.1	LOAEL	n.a., dose-range-finding study
5.3.2	NOAEL	n.a., dose-range-finding study
5.3.3	Reliability	[redacted]
5.3.4	Deficiencies	No (range-finding study)

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A6.9/01 Neurotoxicity

Annex Point IIIA, VI.1 **Acute, Gavage, Rats, Range-finding study**

[redacted]



[redacted]

Section A6.9/02/03/04 Neurotoxicity
Annex Point IIIA, VI.1 Acute, Gavage, Rats

			Official use only
		1 REFERENCE	
1.1	**Reference**	A6.9/02: [redacted] (2001): Acute Oral Neurotoxicity Study with 3-Iodopropynylbutyl Carbamate (IPBC) Administered by Gavage in CD® Rats. Volume I of III. [redacted] 31.08.2001 [redacted] A6.9/03: [redacted] (2001): Acute Oral Neurotoxicity Study with 3-Iodopropynylbutyl Carbamate (IPBC) Administered by Gavage in CD® Rats. Volume II of III. [redacted] 31.08.2001 [redacted] A6.9/04: [redacted] (2001): Acute Oral Neurotoxicity Study with 3-Iodopropynylbutyl Carbamate (IPBC) Administered by Gavage in CD® Rats. Volume III of III. [redacted] 31.08.2001 [redacted]	[redacted]
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	A6.9/02 to A6.9/04, Yes: US EPA OPPTS Guidelines 870.6200 which is comparable to OECD 424	[redacted]
2.2	**GLP**	[redacted]	
2.3	**Deviations**	No neuropathologic evaluation was performed; no positive control data were included to provide evidence for the reliability and sensitivity for the observational methods employed	
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in section 2	
3.1.3	Purity	[redacted]	
3.1.4	Description	[redacted]	

Section A6.9/02/03/04 Neurotoxicity

Annex Point IIIA, VI.1 **Acute, Gavage, Rats**

3.1.5	Stability	[redacted]
3.2	**Reference Substance (positive control)**	[redacted]
3.3	**Test Animals**	
3.3.1	Species	CD® rats
3.3.2	Strain	Crl:CD® (SD) IGS BR
3.3.3	Source	[redacted]
3.3.4	Sex	male and female
3.3.5	Rearing conditions	[redacted]
3.3.6	Age/weight at study initiation	[redacted]
3.3.7	Number of animals per group	[redacted]
3.3.8	Control animals	[redacted]
3.4	**Administration**	Oral by gavage
3.4.1	Exposure	Single oral administration
3.4.2	Dose Levels	[redacted]
3.4.3	Vehicle	[redacted]
3.4.4	Concentration in vehicle	[redacted]
3.4.5	Total volume applied	[redacted]
3.4.6	Postexposure period	[redacted]

Section A6.9/02/03/04 Neurotoxicity

Annex Point IIIA, VI.1 **Acute, Gavage, Rats**

3.4.7	Anticholinergic substances used	[redacted]
3.4.8	Controls	[redacted]
3.5	**Examinations**	
3.5.1	Body Weight	[redacted]
3.5.2	Signs of Toxicity	[redacted]
3.5.3	Observation schedule	[redacted]
3.5.4	Clinical Chemistry	[redacted]
3.5.5	Pathology	[redacted] -
3.5.6	Histopathology	[redacted] -

Section A6.9/02/03/04 Neurotoxicity
Annex Point IIIA, VI.1 Acute, Gavage, Rats

3.6 Further remarks

[redacted]

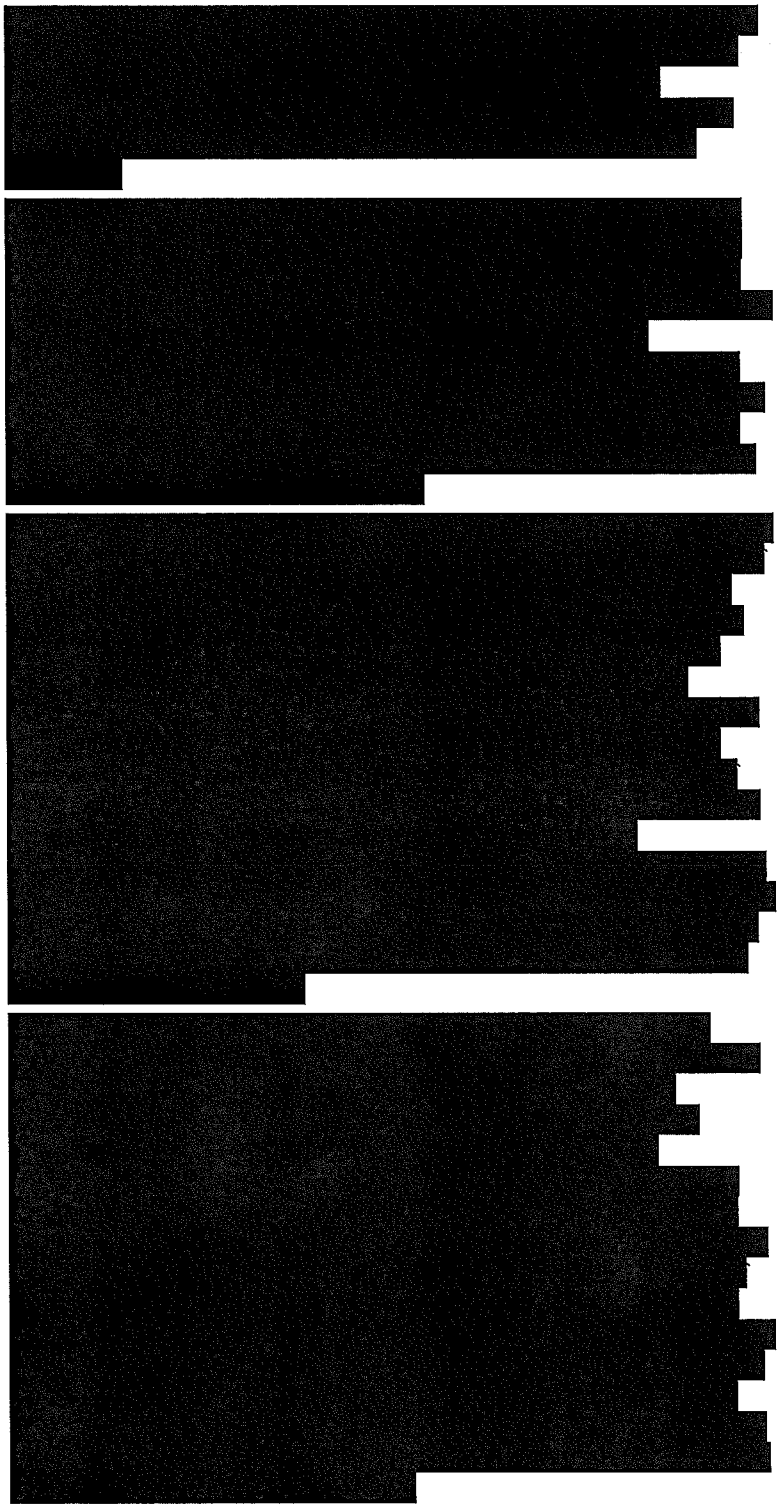
4 RESULTS AND DISCUSSION

4.1 Body Weight

[redacted]

Section A6.9/02/03/04 Neurotoxicity
Annex Point IIIA, VI.1 Acute, Gavage, Rats

4.2 Clinical signs of toxicity



Section A6.9/02/03/04 Neurotoxicity

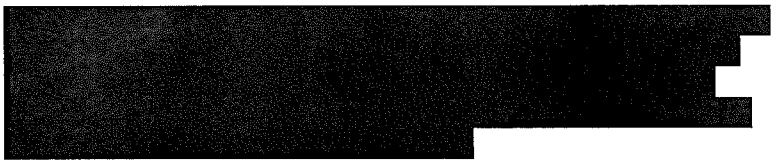
Annex Point IIIA, VI.1 **Acute, Gavage, Rats**

4.2 Clinical signs of toxicity (continued)

4.3 Clinical Chemistry

4.4 Pathology

4.5 Histopathology



4.6 Other

Section A6.9/02/03/04 Neurotoxicity

Annex Point IIIA, VI.1 **Acute, Gavage, Rats**

5 APPLICANT'S SUMMARY AND CONCLUSION

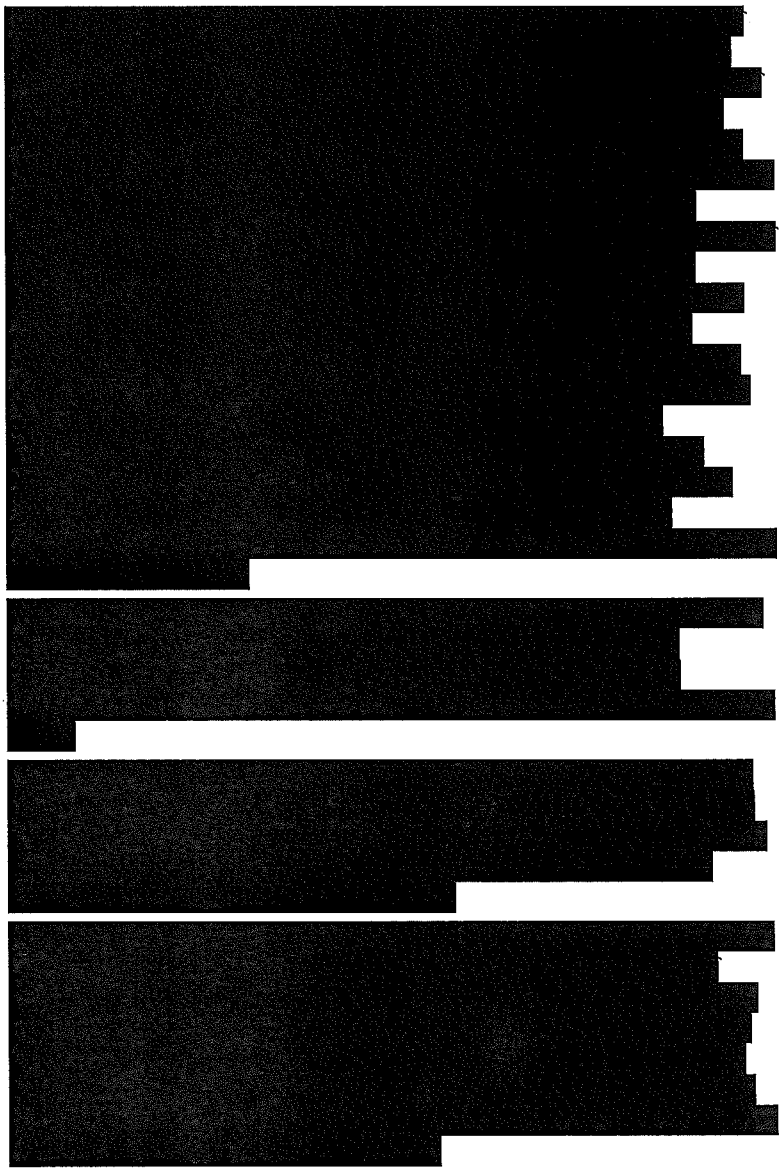
5.1 Materials and methods

[redacted]

The study was performed according to OPPTS 870.6200 (Neurotoxicity Screening Battery). No neuropathological examination of nervous tissue was performed in this acute rat neurotoxicity study since no significant neuropathologic changes were noted in the nervous system examined in a companion 90-day study in rats with this material [redacted]

Section A6.9/02/03/04 Neurotoxicity
Annex Point IIIA, VI.1 **Acute, Gavage, Rats**

5.2 Results and discussion



Section A6.9/02/03/04 Neurotoxicity

Annex Point IIIA, VI.1 **Acute, Gavage, Rats**

5.3	**Conclusion**	[redacted]
5.3.1	NOEL	100 mg/kg bw for systemic toxicity based on statistically significantly reduced body weight reductions in males of sets 2 + 3 at 300 and 1,000 mg/kg bw and statistically significant effects on motor activity in males at 300 mg/kg bw.
5.3.2	NOAEL	1,000 mg/kg bw (neurotoxicity)
5.3.3	Reliability	[redacted] *
5.3.4	Deficiencies	None *

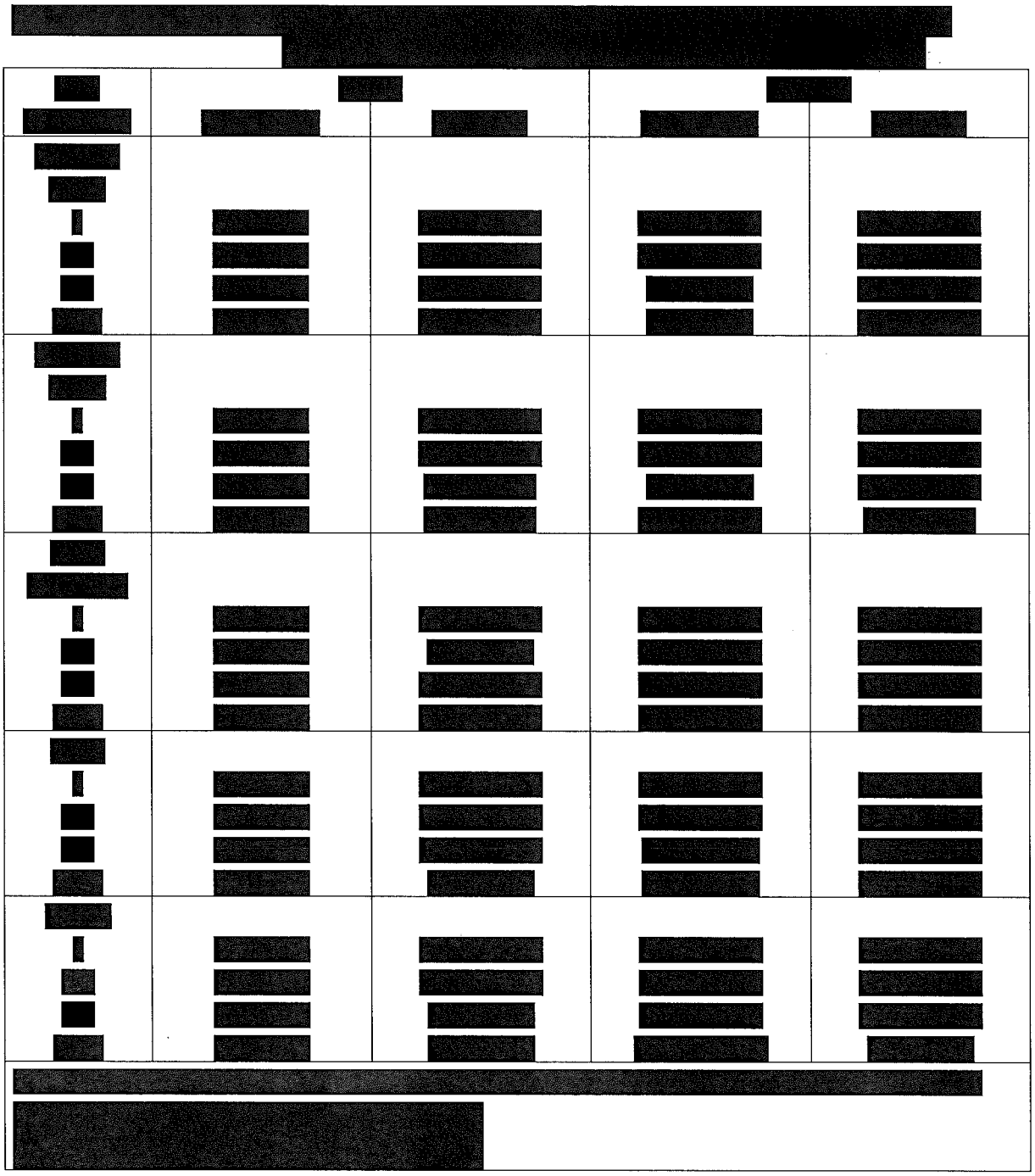
Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section A6.9/02/03/04 Neurotoxicity

Annex Point IIIA, VI.1 **Acute, Gavage, Rats**

Remarks	[redacted]

[redacted]



Section A6.9/05 Neurotoxicity

Annex Point IIIA, VI.1 Feeding, Rat, Rangefinder for subchronic study

			Official use only
		1 REFERENCE	
1.1	**Reference**	A6.9/05: [redacted] (2002): 2-Week Dietary Range-Finding and Palatability Study with 3-Iodopropynylbutyl Carbamate (IPBC) in CD® Rats. [redacted] 25.04.2002	[redacted]
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	n.a., range finding study	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	n.a., range-finding study	
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	*
3.1.2	Specification	As given in section 2	
3.1.3	Purity	[redacted]	*
3.1.4	Description	[redacted]	
3.1.5	Stability	[redacted]	
3.2	**Reference Substance (positive control)**	[redacted]	
3.3	**Test Animals**		
3.3.1	Species	CD® rats	
3.3.2	Strain	Crl:CD® (SD) IGS BR	
3.3.3	Source	[redacted]	
3.3.4	Sex	Male and female	
3.3.5	Rearing conditions	[redacted]	

Section A6.9/05 Neurotoxicity

Annex Point IIIA, VI.1 **Feeding, Rat, Rangefinder for subchronic study**

3.3.6	Age/weight at study initiation	[redacted]
3.3.7	Number of animals per group	[redacted]
3.3.8	Control animals	[redacted]
3.4	**Administration**	Oral with the diet
3.4.1	Exposure	14 consecutive days
3.4.2	Dose Levels	[redacted] *
3.4.3	Vehicle	[redacted]
3.4.4	Concentration in vehicle	[redacted]
3.4.5	Total volume applied	[redacted]
3.4.6	Postexposure period	[redacted]
3.4.7	Anticholinergic substances used	[redacted]
3.4.8	Controls	[redacted]
3.5	**Examinations**	
3.5.1	Body Weight	[redacted]
3.5.2	Signs of Toxicity	[redacted]
3.5.3	Observation schedule	[redacted]

Section A6.9/05 Neurotoxicity

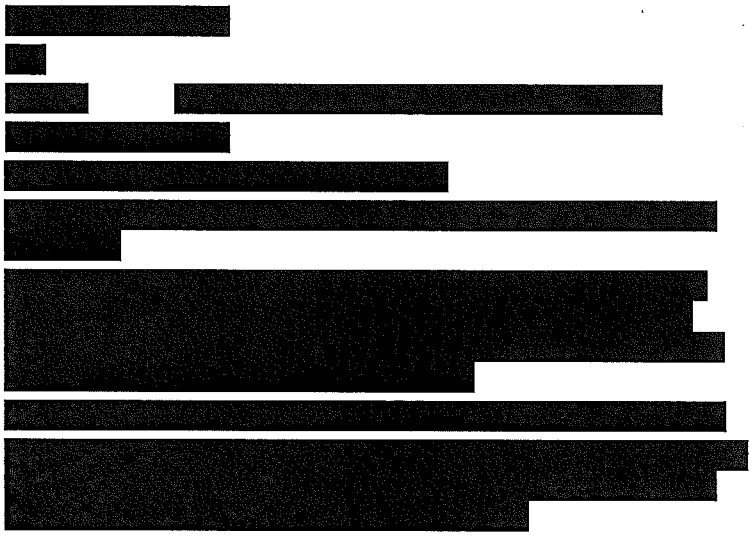
Annex Point IIIA, VI.1 **Feeding, Rat, Rangefinder for subchronic study**

3.5.4 Clinical Chemistry

3.5.5 Pathology

3.5.6 Histopathology

3.6 Further remarks



4 RESULTS AND DISCUSSION

4.1 Body Weight

[redacted]

4.2 Clinical signs of toxicity

[redacted]

4.3 Clinical Chemistry

[redacted]

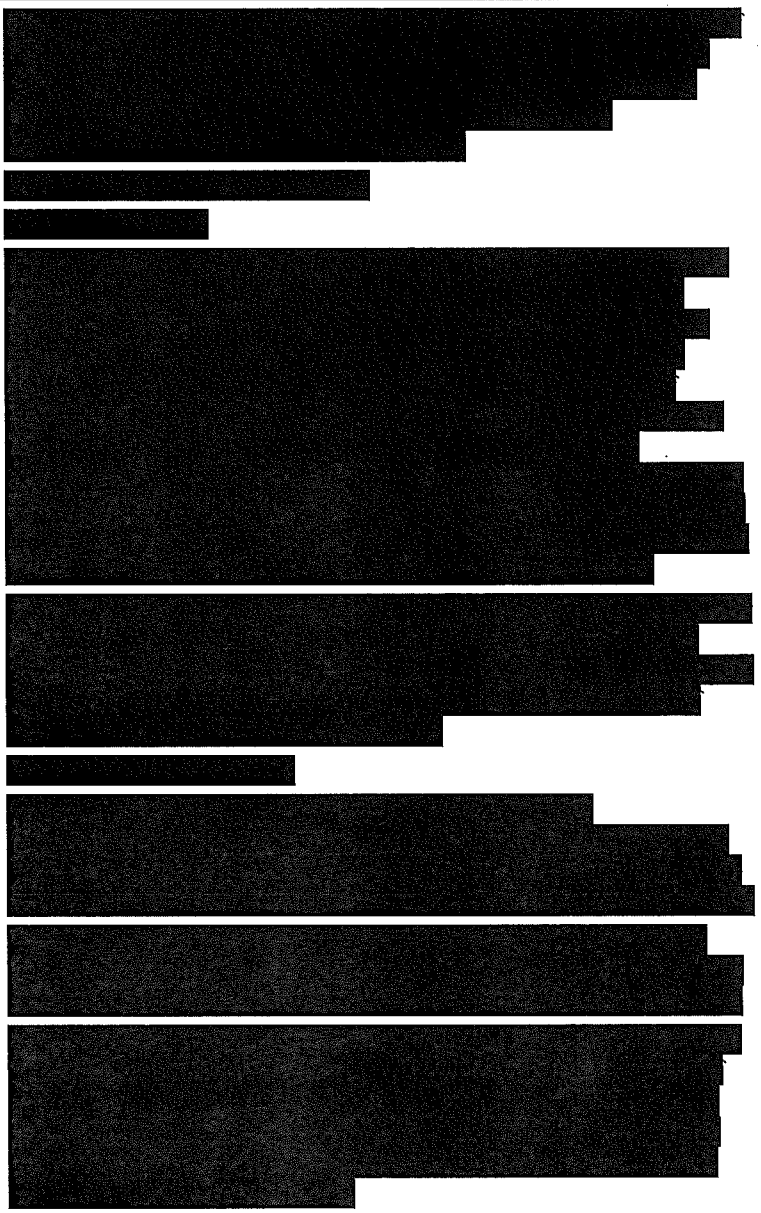
Section A6.9/05 Neurotoxicity

Annex Point IIIA, VI.1 **Feeding, Rat, Rangefinder for subchronic study**

4.4 Pathology

4.5 Histopathology

4.6 Other



Section A6.9/05 Neurotoxicity

Annex Point IIIA, VI.1 **Feeding, Rat, Rangefinder for subchronic study**

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

IPBC was administered to male and female CD® rats with the diet in a range-finding-study during 14 consecutive days.

[redacted]

5.2 Results and discussion

[redacted]

*

Section A6.9/05 Neurotoxicity

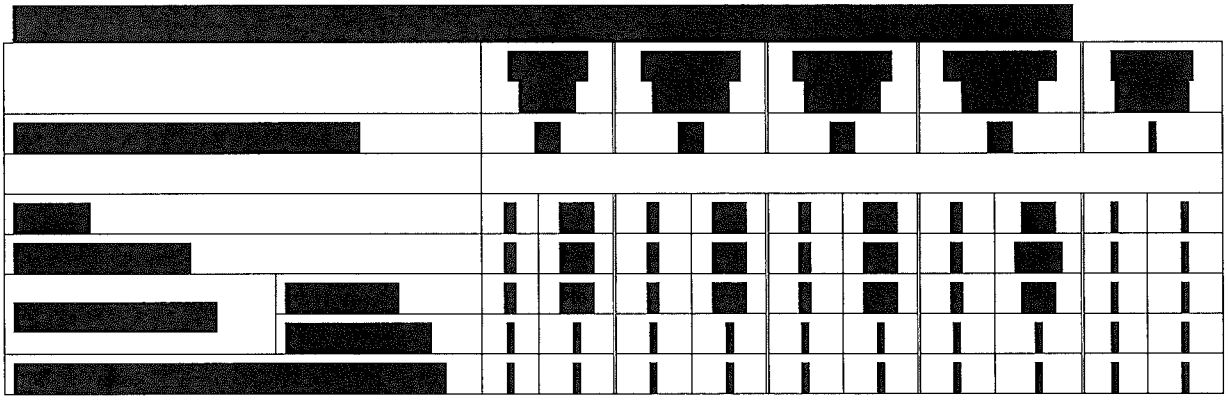
Annex Point IIIA, VI.1 **Feeding, Rat, Rangefinder for subchronic study**

5.3	Conclusion	[redacted]
5.3.1	LOAEL	n.a., dose-range-finding study
5.3.2	NOAEL	n.a., dose-range-finding study
5.3.3	Reliability	[redacted]
5.3.4	Deficiencies	n.a., dose-range-finding study

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A6.9/05 Neurotoxicity

Annex Point IIIA, VI.1 **Feeding, Rat, Rangefinder for subchronic study**



Section A6.9/06/07/08/09 Neurotoxicity Subchronic, Feeding, Rat

Annex Point IIIA, VI.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	A6.9/06: [redacted] (2001): 13-Week Dietary Neurotoxicity Study with 3-Iodopropynylbutyl Carbamate (IPBC) in CD® Rats. [redacted] 20.09.2001 [redacted] A6.9/07: [redacted] (2001): 13-Week Dietary Neurotoxicity Study with 3-Iodopropynylbutyl Carbamate (IPBC) in CD® Rats. [redacted] 20.09.2001 [redacted] A6.9/08: [redacted], (2001): 13-Week Dietary Neurotoxicity Study with 3-Iodopropynylbutyl Carbamate (IPBC) in CD® Rats. [redacted] 20.09.2001; [redacted] A6.9/09: [redacted] 13-Week Dietary Neurotoxicity Study with 3-Iodopropynylbutyl Carbamate (IPBC) in CD® Rats. [redacted] 20.09.2001; [redacted]	[redacted] [redacted]
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	A6.9/06 to A6.9/09, Yes: US EPA OPPTS Guidelines 870.6200 which is comparable to OECD 424	[redacted]
2.2	**GLP**	[redacted]	
2.3	**Deviations**	Initial body weight of male and female rats at the time of randomisation exceeded the range of 20% of the mean body weight of each sex; no positive control data were included to provide evidence for the reliability and sensitivity for the observational methods employed. None of these deviations affected the quality or integrity of the study results.	*

Section A6.9/06/07/08/09
Annex Point IIIA, VI.1

Neurotoxicity
Subchronic, Feeding, Rat

3 MATERIALS AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted] *
3.1.2	Specification	As given in section 2
3.1.2.1	Description	[redacted]
3.1.2.2	Purity	[redacted] *
3.1.2.3	Stability	[redacted]
3.2	**Reference Substance (positive control)**	[redacted]
3.3	**Test Animals**	
3.3.1	Species	CD® rats
3.3.2	Strain	Crl:CD® (SD) IGS BR
3.3.3	Source	[redacted]
3.3.4	Sex	Male and female
3.3.5	Rearing conditions	[redacted]
3.3.6	Age/weight at study initiation	[redacted]
3.3.7	Number of animals per group	[redacted]
3.3.8	Control animals	[redacted]

Section A6.9/06/07/08/09
Annex Point IIIA, VI.1

Neurotoxicity
Subchronic, Feeding, Rat

3.4	**Administration**	Oral (*ad lib* with the diet)
3.4.1	Exposure	13 consecutive weeks
3.4.2	Dose Levels	[redacted]
3.4.3	Vehicle	[redacted]
3.4.4	Concentration in vehicle	[redacted]
3.4.5	Total volume applied	[redacted]
3.4.6	Postexposure period	[redacted]
3.4.7	Anticholinergic substances used	[redacted]
3.4.8	Controls	[redacted]
3.5	**Examinations**	
3.5.1	Body Weight	[redacted]
3.5.2	Signs of Toxicity	[redacted]
3.5.3	Observation schedule	[redacted]

Section A6.9/06/07/08/09
Annex Point IIIA, VI.1

Neurotoxicity
Subchronic, Feeding, Rat

3.5.4 Clinical Chemistry

[redacted]

3.5.5 Pathology

[redacted]

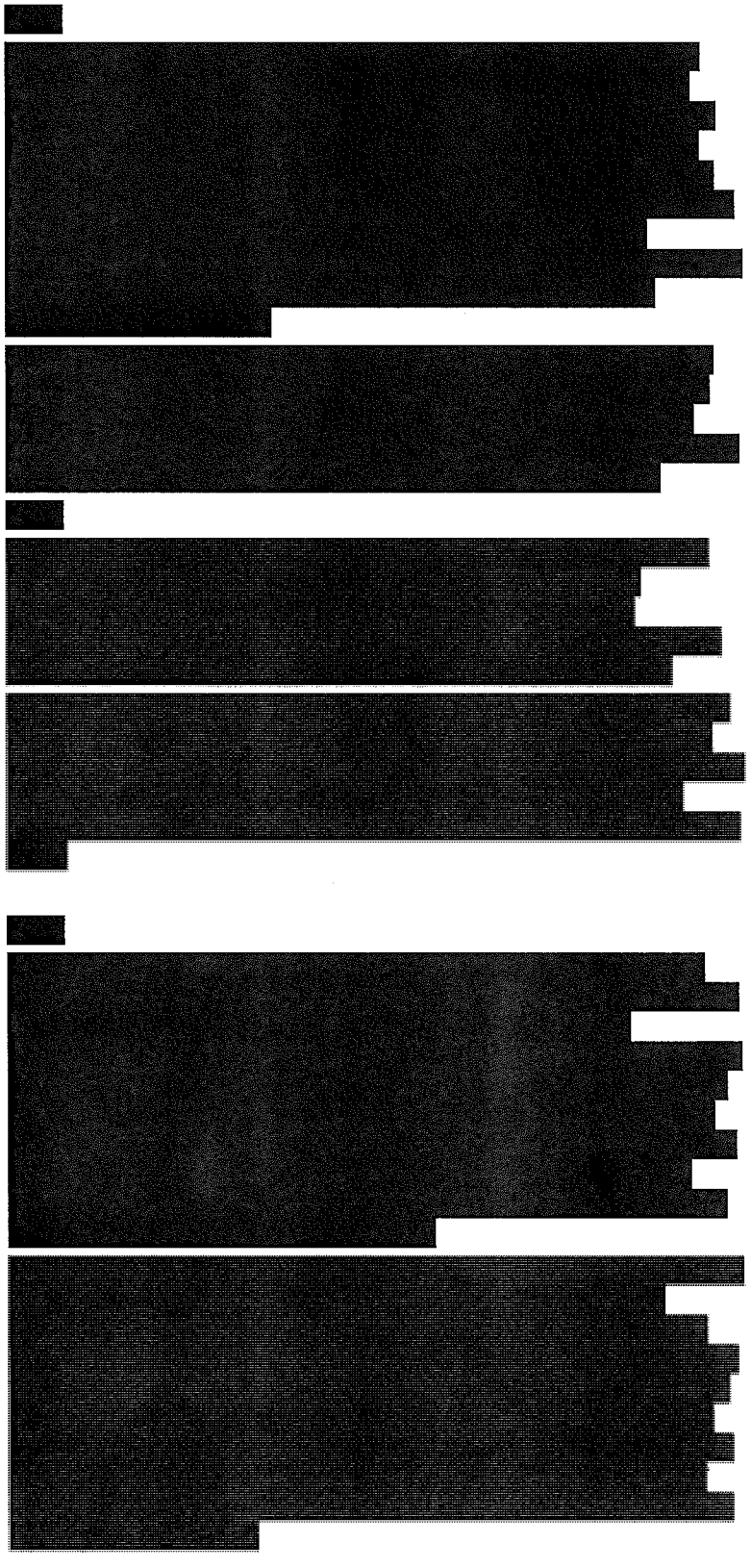
3.5.6 Histopathology

[redacted]

Section A6.9/06/07/08/09	Neurotoxicity Subchronic, Feeding, Rat
Annex Point IIIA, VI.1	
3.6 Further remarks	[redacted]

4 RESULTS AND DISCUSSION

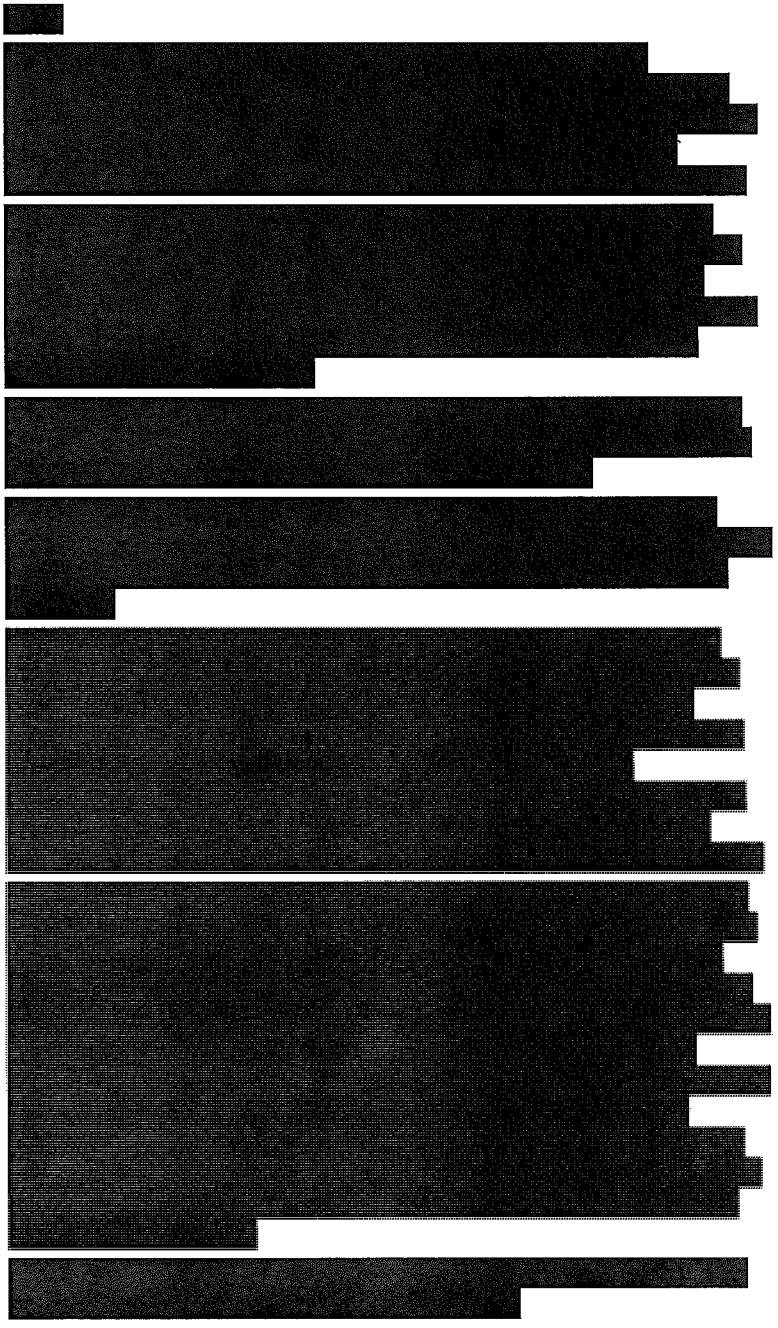
4.1 Body Weight



Section A6.9/06/07/08/09
Annex Point IIIA, VI.1

Neurotoxicity
Subchronic, Feeding, Rat

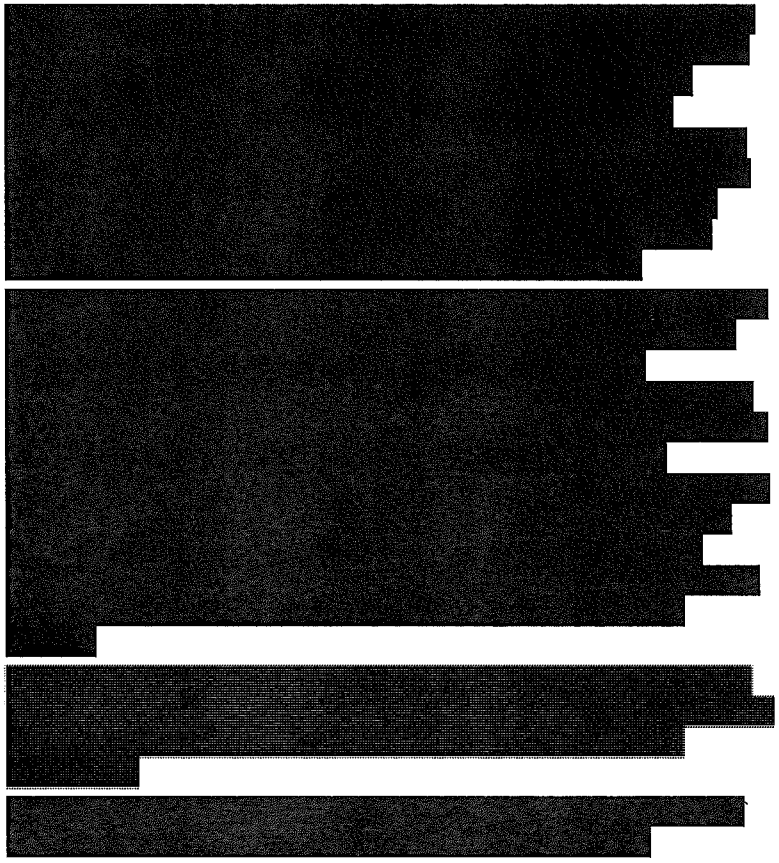
4.2 Clinical signs of toxicity



Section A6.9/06/07/08/09
Annex Point IIIA, VI.1

Neurotoxicity
Subchronic, Feeding, Rat

4.3 Clinical Chemistry

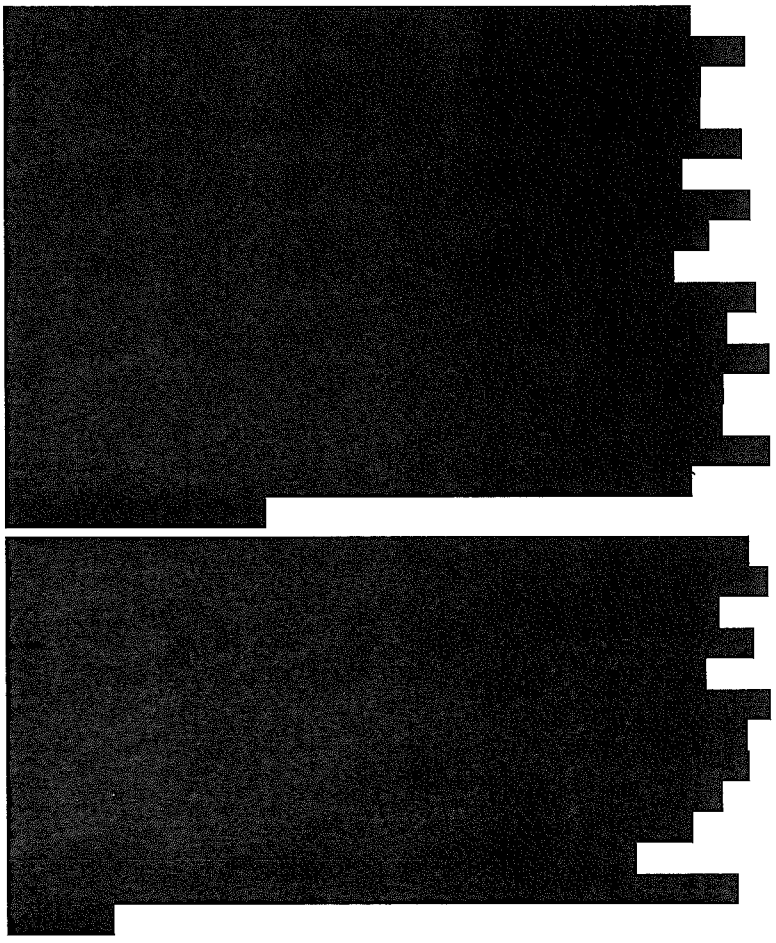


4.4 Pathology

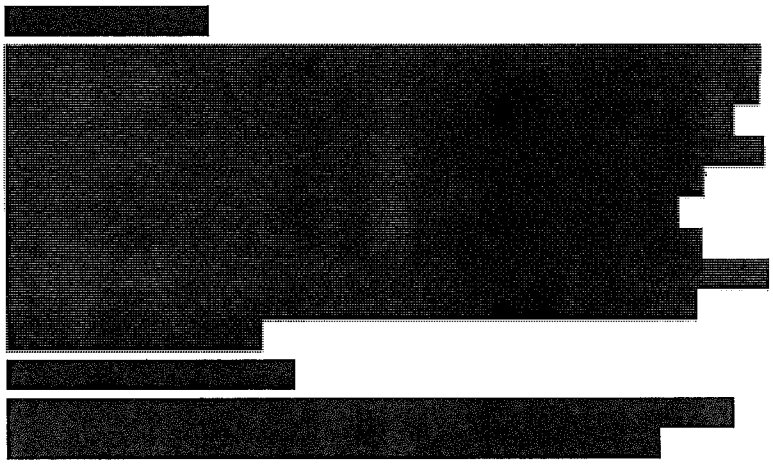
Section A6.9/06/07/08/09
Annex Point IIIA, VI.1

Neurotoxicity
Subchronic, Feeding, Rat

4.5 Histopathology



4.6 Other



Section A6.9/06/07/08/09
Annex Point IIIA, VI.1

Neurotoxicity
Subchronic, Feeding, Rat

5 APPLICANT'S SUMMARY AND CONCLUSION

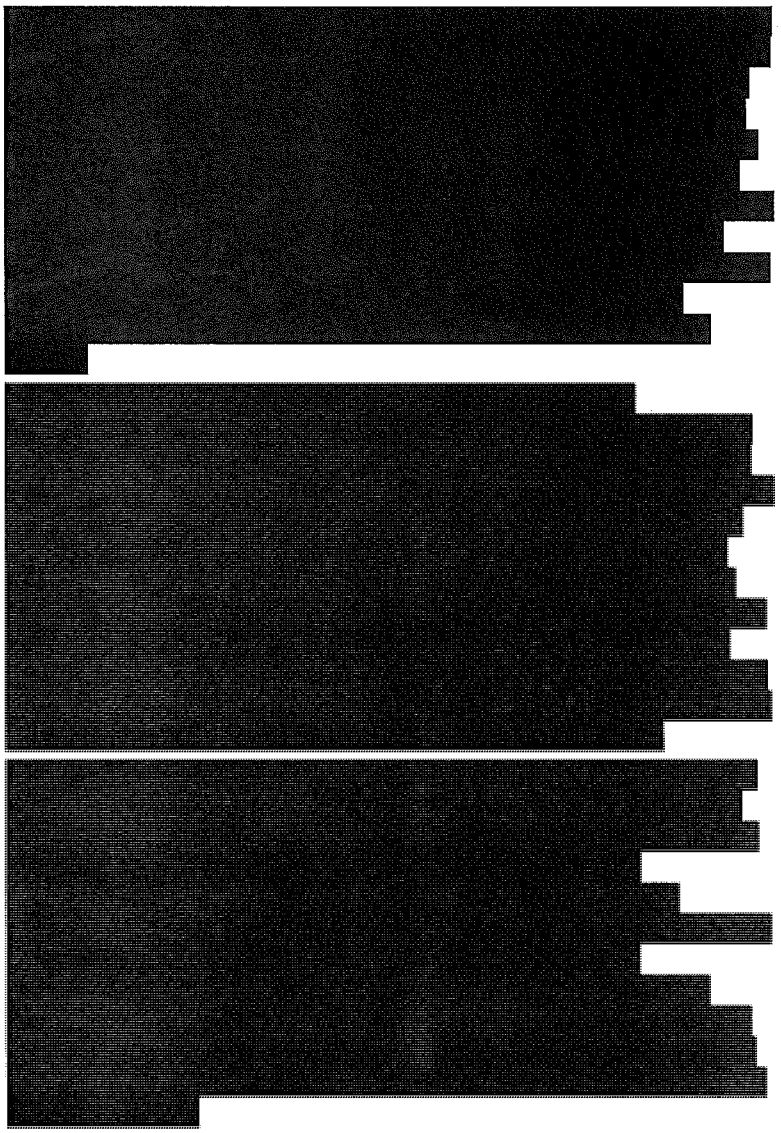
5.1 Materials and methods

IPBC was administered to male and female CD® rats with the diet in a neurotoxicity study during 13 weeks followed by a 4-week recovery period [redacted] *

Section A6.9/06/07/08/09
Annex Point IIIA, VI.1

Neurotoxicity
Subchronic, Feeding, Rat

5.2 Results and discussion



*

5.3 Conclusion

5.3.1 NOEL

NOEL for systemic toxicity: 10 mg/kg bw/day based on statistically significant reductions in absolute body weight and food consumption in males and females at 50 and 120 mg/kg bw/day as well as statistically significant reductions in plasma ChE activity exceeding 20% in females at the 50 and 120 mg/kg bw/day dosage levels, respectively.

*

Section A6.9/06/07/08/09 Annex Point IIIA, VI.1	Neurotoxicity Subchronic, Feeding, Rat	
5.3.2 NOAEL	NOAEL for systemic toxicity: 50 mg/kg bw/day based on statistically significant reductions in absolute body weight (males) and body weight gain (males and females) at 120 mg/kg bw/day. NOAEL for neurotoxicity: 120 mg/kg bw/day based on the absence of treatment-related neurohistologic findings.	*
5.3.3 Reliability	[redacted]	*
5.3.4 Deficiencies	None	*

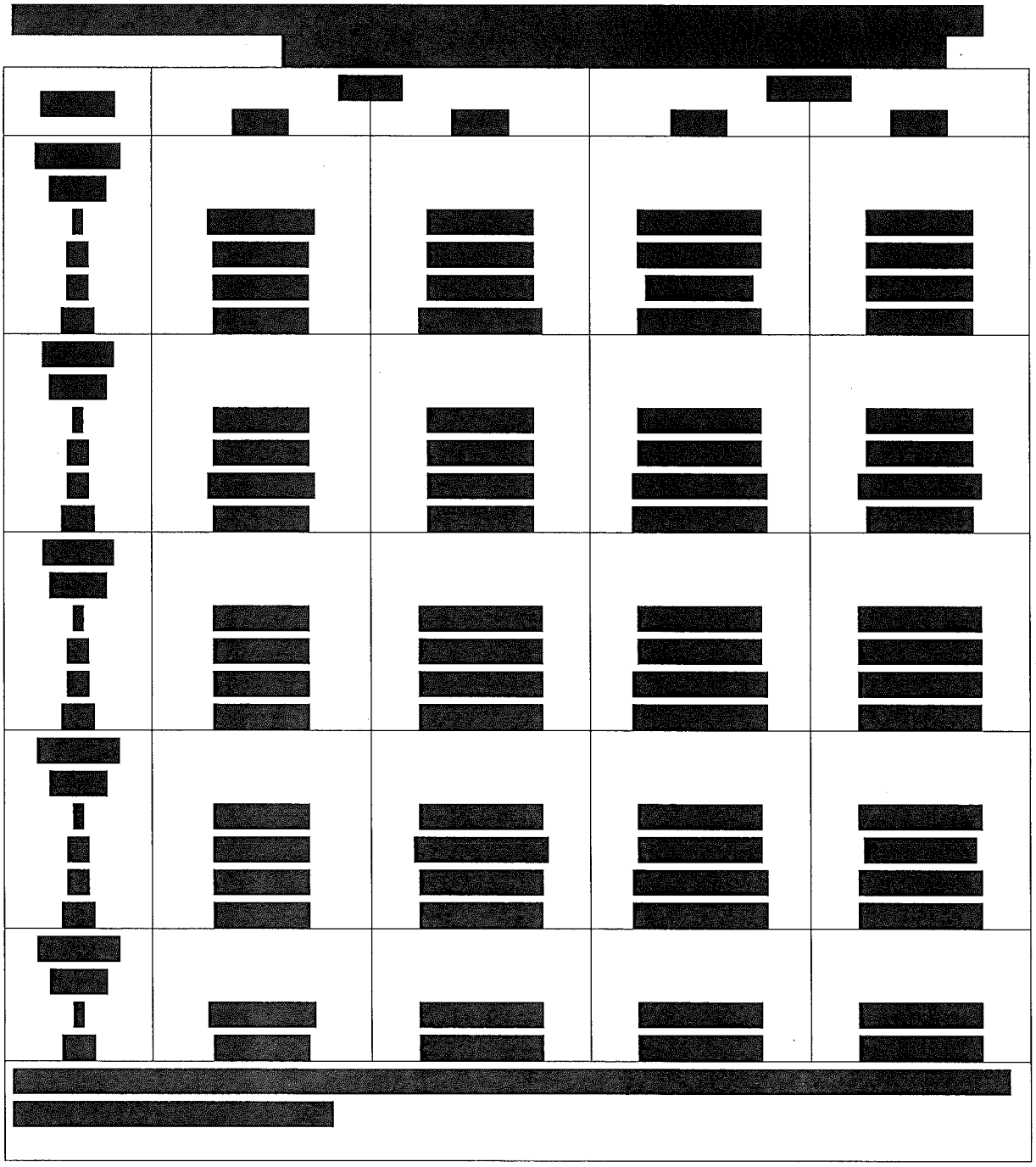
Evaluation by Competent Authorities

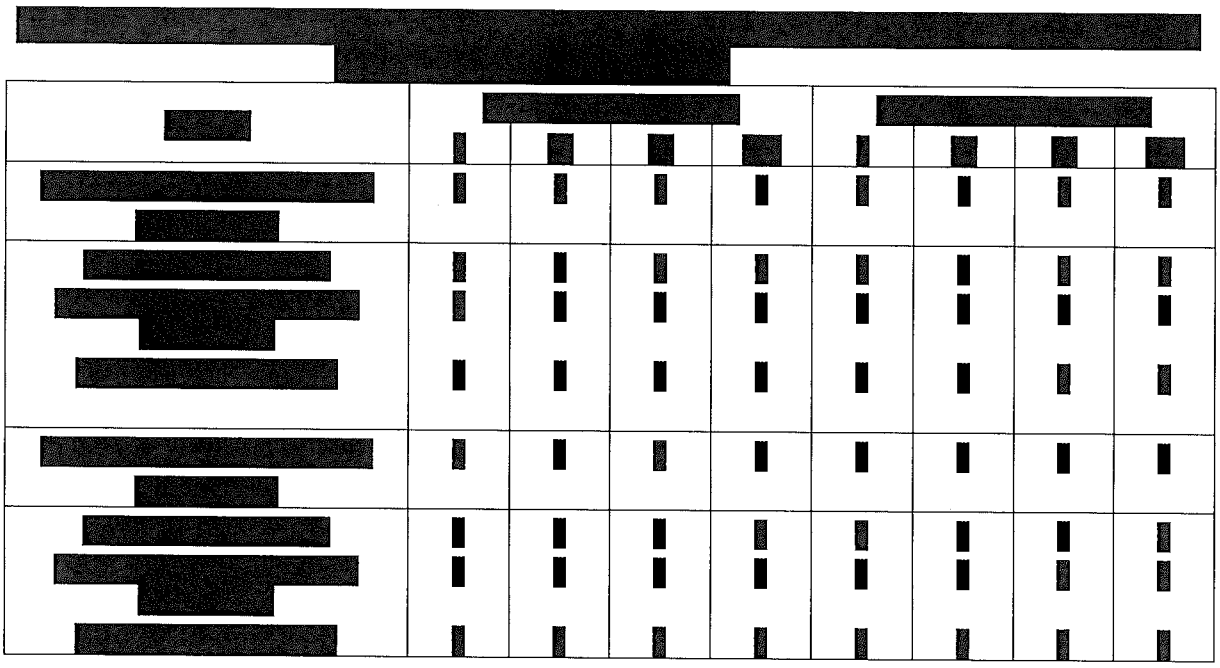
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

Date

Materials and Methods





Section A6.12.1/01/02 Medical surveillance on manufacturing plant personal

Annex Point IIA, VI.6.9.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	A6.12.1/01 [redacted] (2003): Arch Letter to SCC – Health Data (Cholinesterase levels – Rochester); [redacted] A6.12.1/02 Anonymous (2001): Medical Surveillance Program – Carbamate- IPBC (3-iodo-2-propynylbutyl carbamate), [redacted]	[redacted]
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE (NOT APPLICABLE)	
		3 MATERIALS AND METHODS	
3.1	**Substance**	Technical IPBC	
3.2	**Persons tested**		
3.2.1	Sex	not indicated	
3.2.2	Age/weight	[redacted]	
3.2.3	Known Diseases	[redacted]	
3.2.4	Number of persons	[redacted]	
3.2.5	Other information	[redacted]	
3.3	**Exposure**	not indicated, most likely dermal and inhalation	
3.3.1	Reason of exposure	[redacted]	
3.3.2	Frequency of exposure	[redacted]	
3.3.3	Overall time period of exposure	[redacted]	
3.3.4	Duration of single exposure	[redacted]	
3.3.5	Exposure concentration/dose	[redacted]	

Section A6.12.1/01/02 Medical surveillance on manufacturing plant personal

Annex Point IIA, VI.6.9.1

3.4	Examinations	[redacted] *
3.5	Treatment	[redacted]
3.6	Remarks	[redacted]

4 RESULTS

4.1	Results of examinations	[redacted]. There weren't any adverse health effects related to IPBC in workers who work with this material.
4.2	Effectivity of medical treatment	[redacted]
4.3	Outcome	[redacted]
4.4	Other	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	Materials and methods	[redacted]. RBC and plasma cholinesterase activity were determined in regular intervals.
5.2	Results and discussion	[redacted]
5.3	Conclusion	Occupational contact with IPBC did not result in adverse health effects or unacceptable reductions of cholinesterase activity.

Section A6.12.1/01/02 Medical surveillance on manufacturing plant personal

Annex Point IIA, VI.6.9.1

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Remarks	[redacted]

Section A6.12.2 Annex Point IIA, VI.6.9.2	Direct observations, e.g. clinical cases, poisoning incidents	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [X]	
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A6.12.3/01 Health records

Annex Point IIA, VI.6.9.3

			Official use only
		1 REFERENCE	
1.1	**Reference**	Ulfvarson, U.; Alexandersson, R.; Dahlqvist, M.; Ekholm, U.; Bergström, B.; Scullman, J. (1992): Temporary health effects from exposure to water-borne paints; Scand J Work Environ Health, Volume 18, page 376 – 387; [redacted] (published)	
1.2	**Data Protection**	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE (NOT APPLICABLE)	
		3 MATERIALS AND METHODS	
3.1	**Substance**	Several water-borne paints (a total of 8 paints were used, one having IPBC as active ingredient) [redacted]	*
3.2	**Persons tested**		
3.2.1	Sex	male	
3.2.2	Age/weight	[redacted]	
3.2.3	Known Diseases	[redacted]	
3.2.4	Number of persons	[redacted]	
3.2.5	Other information		
3.3	**Exposure**	not indicated	
3.3.1	Reason of exposure	[redacted]	
3.3.2	Frequency of exposure	[redacted]	
3.3.3	Overall time period of exposure	[redacted]	
3.3.4	Duration of single exposure	[redacted]	
3.3.5	Exposure concentration/dose	[redacted]	
3.3.6	Other information	[redacted]	

Section A6.12.3/01 Health records

Annex Point IIA, VI.6.9.3

3.4	Examinations	[redacted]
3.5	Treatment	not applicable
3.6	Remarks	none

4 RESULTS

4.1	Results of examinations	[redacted]
4.2	Effectivity of medical treatment	[redacted]
4.3	Outcome	[redacted]
4.4	Other	[redacted]

Section A6.12.3/01 Health records

Annex Point IIA, VI.6.9.3

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

A total of 18 workers applied a IPBC containing paint (900 ppm IPBC) during a normal working day for professional painters.

[redacted] *

5.2 Results and discussion

[redacted]

5.3 Conclusion

Reports on health complaints in workers applying a IPBC containing paint are not indicative for a adverse health effect. Findings may be attributable to organic solvents.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Remarks	

Section A6.12.4 Annex Point IIA, VI.6.9.4	Epidemiological studies on the general population	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure** [ ]	**Technically not feasible** [ ] **Scientifically unjustified** [ ] **Other justification** [X]	
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A6.12.5/01
Annex Point IIA, VI.6.9.5

Diagnosis of poisoning including specific signs of poisoning and clinical tests

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2003): Material Safety Data Sheet According to 91/155 EC; [redacted]	[redacted]
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letters of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE (NOT APPLICABLE)	
		3 MATERIALS AND METHODS (NOT APPLICABLE)	
3.1	**Substance**	Technical active substance IPBC [redacted]	
		4 RESULTS	
4.1	**Clinical Signs of oisoning**	Contact with the eyes would be expected to cause moderate to severe irritation consisting of reversible redness, swelling and mucous membrane discharge to the conjunctiva, corneal damage with visual impairment may occur if this product is not washed out immediately. Acute and chronic exposure would be expected to produce moderate to severe reversible irritation characterised by well defined but reversible swelling and redness. No other significant effect to health would be expected. Because of the physical form of this substance, inhalation is not likely. Moderate irritation of the nose, throat, mucous membranes, upper respiratory tract and lungs may occur. Exposure to highly exaggerated concentrations via inhalation of this product may result in inhibition of acetylcholinesterase. Symptoms may include blurred vision, nausea, vomiting, abdominal cramps, salivation, profuse sweating, laboured breathing, tremors, muscle twitching, staggered gait and headache. Penetration into the Central Nervous System by carbamates is generally insignificant and therefore few Central Nervous System symptoms would be expected to occur. There is a rapid disappearance of symptoms after the cessation of the exposure. Acute exposure may result in gastrointestinal irritation with any or all of the following symptoms, nausea, vomiting, lethargy or diarrhoea. Other symptoms same as inhalation.	
4.2	**Clinical Tests**	Determination of plasma and cholinesterase activity.	[redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]

Section A6.12.5/01
Annex Point IIA, VI.6.9.5

Diagnosis of poisoning including specific signs of poisoning and clinical tests

Results and discussion	[redacted]
Conclusion	[redacted]
Remarks	

Section A6.12.7
Annex Point IIA, VI.6.9.7

Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment

			Official use only
		1 REFERENCE	
1.1	**Reference**	A6.12.5/01 [redacted] (2003): Material Safety Data Sheet According to 91/155 EC; [redacted] A6.12.1/02 [redacted] (2001): Medical Surveillance Program – Carbamate- IPBC (3-iodo-2-propynylbutyl carbamate), [redacted]	[redacted]
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE (NOT APPLICABLE)	
		3 MATERIALS AND METHODS (NOT APPLICABLE)	
3.1	**Substance**	Technical active substance IPBC [redacted]	
		4 RESULTS	
4.1	**First aid measures**	Eyes: Immediately flush with large amounts of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Seek medical attention immediately. Impairment of vision is possible. Skin: Immediately wash with water and soap and rinse thoroughly. If irritation develops, seek medial attention. Remove contaminated clothing immediately and launder before re-use. Acute exposure may cause transient redness and irritation. Ingestion: Immediately drink large amounts of water. Seek medial advice. Do not give anything by mouth if the person is unconscious or is having convulsions. If swallowed, gastro-enteritis may occur with nausea, vomiting, lethargy and diarrhoea. Inhalation: Because of the physical form of this substance, inhalation is not likely. Symptoms may include tremors, ataxia and convulsions. Seek immediate medial advice. Acute exposure may cause mild and transient irritation of the respiratory tract.	
4.2	**Clinical Tests**	Determination of plasma and cholinesterase activity.	
4.3	**Antidotes**	Atropine, symptomatic treatment	

Section A6.12.7
Annex Point IIA, VI.6.9.7

Specific treatment in case of an accident or poisoning: first aid measures, antidotes and medical treatment

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Remarks	

Section A6.12.8
Annex Point IIA, VI.6.9.8

Prognosis following poisoning (expected effects and the duration of these effects must be described)

Please refer to Document IIIA, Section A6.12.5/01.

Section A6.13 Annex Point IIIA, VI.2	Toxic effects on livestock and pets	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [X]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [ ]	
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A6.14 Annex Point IIIA, VI.3	Other tests related to the exposure of humans	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [X] Other justification [ ]	
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A6.15 Annex Point IIIA, VI.4	Food and feeding stuffs	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [X]	
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A6.16 Annex Point IIIA, VI.5	Any other tests related to the exposure of the active substance of humans, in its proposed biocidal products	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [ ] Other justification [X]	
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A6.17 **Annex Point IIIA, VI.6**	**If the active substance is to be used in products for action against plants then tests to assess toxic effects of metabolites from treated plants, if any, where different from those identified in animals shall be required**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		

Section A6.18 Annex Point IIA, VI.6.10	Summary of toxicology
	The toxicological properties of IPBC are summarised in Document IIA, Chapter 3.

Abbreviations

ROAT	Repeated Open Application Test
MWF	Metal Working Fluid
PBC	2-Propargyl Butyl Carbamate
PEG 400	Polyethyleneglycol 400
TSH	Thyroid Stimulating Hormone

Section A6.12.6/01 Sensitisation/Allergenicity Observations

Annex Point IIA, VI.6.9.6

			Official use only
		1 REFERENCE	
1.1	**Reference**	Bryld, L.E.; Agner, T.; Rastogi, S.C. Menné, T. (1997): Iodopropynyl butylcarbamate: a new contact allergen; Contact Dermatitis, Volume 36, page 156 – 158; [redacted]	
1.2	**Data protection**	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE (NOT APPLICABLE)	
		3 MATERIALS AND METHODS	
3.1	**Substance**	IPBC formulated in Glycasil-S™ was used for patch testing. [redacted]	
3.2	**Persons tested**		
3.2.1	Sex	Patients from allergenicity hospitals (106 men, 205 women) were patch tested.	
3.2.2	Age/weight	[redacted]	
3.2.3	Known Diseases	[redacted]	
3.2.4	Number of persons	[redacted]	
3.2.5	Other information	[redacted]	
3.3	**Exposure**	Dermal	
3.3.1	Reason of exposure	patch test	
3.3.2	Frequency of exposure	[redacted]	
3.3.3	Overall time period of exposure	[redacted]	
3.3.4	Duration of single exposure	[redacted]	
3.3.5	Exposure concentration/dose	[redacted]	
3.3.6	Other information	[redacted]	
3.4	**Examinations**	[redacted]	
3.5	**Treatment**	[redacted]	
3.6	**Remarks**		

Section A6.12.6/01 Sensitisation/Allergenicity Observations

Annex Point IIA, VI.6.9.6

4 RESULTS

4.1 Results of examinations

[redacted]

4.2 Effectivity of medical treatment

[redacted]

4.3 Outcome

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[redacted]

Section A6.12.6/01 Sensitisation/Allergenicity Observations

Annex Point IIA, VI.6.9.6

5.2	**Results and discussion**	The authors reported about 3 positive patch tests and 3 irritant patch tests. Thus, the concentration used (0.1%) might have been far the tolerable concentration. Sodium bicarbonate did not produce positive patch tests. A cross reactivity to thiuram could be excluded. All 3 positive tested persons had dermatitis on hand/and or trunk which lasted for about 6 months before being patch tested. A previous contact to IPBC before the positive patch tests for 2 of the 3 persons could not be demonstrated. The 3rd persons had occupationally contact with IPBC (about 30% concentration) and was further tested in a double-blind study using IPBC diluted in Essex Cream™ or in alcohol (up to 0.1% IPBC). There was no reaction until day 4 (itching and redness). After 3 days this developed to a eczematous reaction. The persons had no symptoms when IPBC contact was avoided.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Remarks	

Section A6.12.6/02 Sensitisation/Allergenicity Observations

Annex Point IIA, VI.6.9.6

			Official use only
		1 REFERENCE	
1.1	**Reference**	Pazzaglia, M., Tosti, A. (1999): Allergic contact dermatitis from 3-Iodo-2-propynyl butylcarbamate in a cosmetic cream; Contact Dermatitis, Volume 41, page 290-304; [redacted]	*
1.2	**Data protection**	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE (NOT APPLICABLE)	
		3 MATERIALS AND METHODS	
3.1	**Substance**	IPBC formulated in Glycacil-L was used for patch testing. [redacted]	
3.2	**Persons tested**		
3.2.1	Sex	140 men, 172 women	
3.2.2	Age/weight	[redacted]	
3.2.3	Known Diseases	[redacted]	
3.2.4	Number of persons	[redacted]	
3.2.5	Other information	[redacted]	
3.3	**Exposure**	Dermal	
5.2.1	Reason of exposure	patch test	
3.3.1	Frequency of exposure	[redacted]	
3.3.2	Overall time period of exposure	[redacted]	
3.3.3	Duration of single exposure	[redacted]	
3.3.4	Exposure concentration/dose	[redacted]	
3.3.5	Other information	[redacted]	
3.4	**Examinations**	[redacted]	
3.5	**Treatment**	[redacted]	

Section A6.12.6/02 Sensitisation/Allergenicity Observations

Annex Point IIA, VI.6.9.6

4 RESULTS

4.1	Results of examinations	[redacted]
4.2	Effectivity of medical treatment	[redacted]
4.3	Outcome	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	Materials and methods	A total of 312 persons was patch tested to investigate sensitisation/allergenicity potential of IPBC [redacted]
5.2	Results and discussion	The authors reported about 3 persons showing reactions to the patch tests. The reactions of 2 persons were considered irritant. Only 1 person reactions were interpreted as allergic.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Remarks	[redacted]

Section A6.12.6/03 Sensitisation/Allergenicity Observations

Annex Point IIA, VI.6.9.6

			Official use only
		1 REFERENCE	
1.1	**Reference**	Majoie, I.M.L; van Ginkel, C.J.W. (2000): The biocide iodopropynyl butylcarbamate (IPBC) as an allergen in cutting oils; Contact Dermatitis, Volume 43, page 238-240; [redacted] (published)	
1.2	**Data protection**	No, publication	
		2 GUIDELINES AND QUALITY ASSURANCE (NOT APPLICABLE)	
		3 MATERIALS AND METHODS	
3.1	**Substance**	Metal working fluid (MWF) series were provided by Trolab Hermal and Chemotechnique [redacted]	
3.2	**Persons tested**		
3.2.1	Sex	[redacted]	
3.2.2	Age/weight	[redacted]	
3.2.3	Known Diseases	[redacted]	
3.2.4	Number of persons	23 metalworkers	
3.2.5	Other information	[redacted]	
3.3	**Exposure**	Dermal	
5.2.2	Reason of exposure	patch test, ROAT	
3.3.1	Frequency of exposure	[redacted]	
3.3.2	Overall time period of exposure	[redacted]	
3.3.3	Duration of single exposure	[redacted]	
3.3.4	Exposure concentration/dose	[redacted]	
3.3.5	Other information	[redacted]	
3.4	**Examinations**	[redacted]	
3.5	**Treatment**	[redacted]	

Section A6.12.6/03 Sensitisation/Allergenicity Observations

Annex Point IIA, VI.6.9.6

4 RESULTS

4.1 Results of examinations

Five of 23 metalworkers (with a history of dermatitis) patch-tested were positive for IPBC.

[redacted]

4.2 Effectivity of medical treatment

[redacted]

4.3 Outcome

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

A total of 23 metalwokers were patch tested to investigate sensitisation/allergenicity potential of IPBC [redacted]

5.2 Results and discussion

The authors reported about 5 persons positively patch tested out of 23 persons when IPBC at 0.5 to 2.5% was applied. [redacted]

Section A6.12.6/03 Sensitisation/Allergenicity Observations

Annex Point IIA, VI.6.9.6

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Remarks	

Section A6.12.6/04 Sensitisation/Allergenicity Observations

Annex Point IIA, VI.6.9.6

			Official use only
		1 REFERENCE	
1.1	**Reference**	Bryld, L.E.; Agner, T.; Menné, T. (2001): Allergic contact dermatitis from 3-iodo-2-propynyl-butylcarbamate (IPBC) – an update; Contact Dermatitis, Volume 44, page 276 – 278; [redacted] (published)	
1.2	**Data protection**	No, publication	
		2 GUIDELINES AND QUALITY ASSURANCE (NOT APPLICABLE)	
		3 MATERIALS AND METHODS	
3.1	**Substance**	The initially used material for patch test was a preparation of IPBC in sodium bicarbonate (Glycasil-S™). Subsequently, Biodocarb and Troysan was used. [redacted]	
3.2	**Persons tested**		
3.2.1	Sex	1070 men, 2077 women	
3.2.2	Age/weight	[redacted]	
3.2.3	Known Diseases	[redacted]	
3.2.4	Number of persons	[redacted]	
3.2.5	Other information	[redacted]	
3.3	**Exposure**	Dermal	
5.2.3	Reason of exposure	patch test	
3.3.1	Frequency of exposure	[redacted]	
3.3.2	Overall time period of exposure	[redacted]	
3.3.3	Duration of single exposure	[redacted]	
3.3.4	Exposure concentration/dose	[redacted]	
3.3.5	Other information	[redacted]	
3.4	**Examinations**		
3.5	**Treatment**	[redacted]	

Section A6.12.6/04 Sensitisation/Allergenicity Observations

Annex Point IIA, VI.6.9.6

4 RESULTS

4.1	Results of examinations	[redacted]
4.2	Effectivity of medical treatment	[redacted]
4.3	Outcome	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	Materials and methods	[redacted]
5.2	Results and discussion	The authors reported about 4 new persons (all women) reacting positive to patch tests. In 2 cases sensitisation from cosmetics was identified, and in 2 cases sensitisation was suspected. [redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Remarks	

Section A6.12.6/05 Sensitisation/Allergenicity Observations

Annex Point IIA, VI.6.9.6

			Official use only
		1 REFERENCE	
1.1	**Reference**	Schnuch, A., Geier, J., Brasch, J., Uter, W. (2002): The preservative iodopropynyl butylcarbamtate: frequency of allergic reactions and diagnostic considerations; Contact Dermatitis, Volume 46, page 153 – 156; [redacted] (published)	
1.2	**Data protection**	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE (NOT APPLICABLE)	
		3 MATERIALS AND METHODS	
3.1	**Substance**	IPBC [redacted]	
3.2	**Persons tested**		
3.2.1	Sex	Male and female	
3.2.2	Age/weight	[redacted]	
3.2.3	Known Diseases	[redacted]	
3.2.4	Number of persons	[redacted]	
3.2.5	Other information	[redacted]	
3.3	**Exposure**	Dermal	
5.2.4	Reason of exposure	patch test	
3.3.1	Frequency of exposure	[redacted]	
3.3.2	Overall time period of exposure	[redacted]	
3.3.3	Duration of single exposure	[redacted]	
3.3.4	Exposure concentration/dose	[redacted]	
3.3.5	Other information	[redacted]	
3.4	**Examinations**	[redacted]	
3.5	**Treatment**	[redacted]	
		4 RESULTS	
4.1	**Results of examinations**	[redacted]	
4.2	**Effectivity of medical treatment**	[redacted]	

Section A6.12.6/05 Sensitisation/Allergenicity Observations

Annex Point IIA, VI.6.9.6

4.3	Outcome	[redacted]
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	Materials and methods	[redacted]
5.2	Results and discussion	Patch testing of 4883 persons with IPBC yielded a proportion of 0.3 % with positive skin reactions and 0.5 % with a doubtful skin reaction on day 3.

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Remarks	

Section A6.12.6/06 Sensitisation/Allergenicity Observations

Annex Point IIA, VI.6.9.6

			Official use only
		1 REFERENCE	
1.1	**Reference**	Jensen, C. D., Thormann, J., Andersen, K. E. (2003): Airborne allergic contact dermatitis from 3-iodo-2-propynyl-butylcarbamtate at a paint factory; Contact Dermatitis, Volume 48, page 155 – 157; [redacted] (published)	
1.2	**Data protection**	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE (NOT APPLICABLE)	
		3 MATERIALS AND METHODS	
3.1	**Substance**	IPBC unspecified	
3.2	**Persons tested**		
3.2.1	Sex	female	
3.2.2	Age/weight	[redacted]	
3.2.3	Known Diseases	[redacted]	
3.2.4	Number of persons	[redacted]	
3.2.5	Other information	[redacted]	
3.3	**Exposure**	Dermal	
5.2.5	Reason of exposure	Occupational, patch test	
3.3.1	Frequency of exposure	[redacted]	
3.3.2	Overall time period of exposure	[redacted]	
3.3.3	Duration of single exposure	[redacted]	
3.3.4	Exposure concentration/dose	[redacted]	
3.3.5	Other information	[redacted]	
3.4	**Examinations**	[redacted]	
3.5	**Treatment**	[redacted]	

Section A6.12.6/06 Sensitisation/Allergenicity Observations

Annex Point IIA, VI.6.9.6

4 RESULTS

4.1	Results of examinations	The patient showed strong reactions to all 3 concentrations tested.
4.2	Effectivity of medical treatment	[redacted]
4.3	Outcome	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	Materials and methods	This publication is a case report of a woman with an occupational exposure to IPBC.
5.2	Results and discussion	The woman was positively patch tested with 0.01, 0.03, and 0.1% IPBC in petrolatum.

Evaluation by Competent Authorities

Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

EVALUATION BY RAPPORTEUR MEMBER STATE

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

Document III-A.7

DOCUMENTATION SUMMARIES

IPBC

CAS No. 55406-53-6

from European Union IPBC Task Force

for use in wood preservatives (Product type 8)

Section A7.1.1.1.1/01

Annex Point IIA, VII.7.6.2.1

Hydrolysis as a function of pH and identification of breakdown products

[redacted]

Official use only

1 REFERENCE

1.1	**Reference**	Jungheim (2001): Preventol MP 100 – Abiotic degradation; Bayer AG, ZF-Zentrale Analytik, Leverkusen, Germany; Study No.: N00/0070/05 LEV; [redacted]; 29.06.2001; [redacted]
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes. EG guideline C7. 92/69
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Further relevant properties	[redacted]
3.2	**Reference substance**	[redacted]
3.2.1	Initial concentration of reference substance	[redacted]

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

Annex Point IIA, VII.7.6.2.1

3.3	**Test solution**	[redacted]
3.4	**Testing procedure**	
3.4.1	Test system	[redacted]
3.4.2	Temperature	[redacted]
3.4.3	pH	[redacted]
3.4.4	Duration of the test	[redacted]
3.4.5	Number of replicates	[redacted]
3.4.6	Sampling	[redacted]
3.4.7	Analytical methods	[redacted]
3.5	**Preliminary test**	[redacted]
	4 RESULTS	
4.1	**Concentration and hydrolysis values**	[redacted]
4.2	**Hydrolysis rate constant (k_h)**	[redacted]
4.3	**Dissipation time**	[redacted]
4.4	**Concentration – time data**	[redacted]
4.5	**Specification of**	[redacted]

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

Annex Point IIA, VII.7.6.2.1

	the transformation products	
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The aqueous hydrolysis test was conducted according to test method C.7 for determination of abiotic degradation, EG guideline 92/69. [redacted].
5.2	**Results and discussion**	[redacted]
5.2.1	k_H	The test substance IPBC is not degradable at pH 4 and pH 7. At pH 9 the hydrolysis rate constants k_H are 0.0025 h^{-1} at 50°C, 0.0224 h^{-1} at 65°C and 0.125 h^{-1} at 80°C. The hydrolysis rate constant at 25°C was extrapolated according to the Arrhenius equation and calculated to be 5.36 x 10^{-5} h^{-1}.
5.2.2	DT_{50}	The test substance IPBC is not degradable at pH 4 and pH 7. DT_{50} values at pH 9: 5.6 h = 0.2 days (80°C) 31 h = 1.3 days (65°C) 282 h = 11.8 days (50°C) 12942 h = 539 days (25°C)
5.3	**Conclusion**	[redacted] IPBC was found to be stable under acidic and neutral conditions. Under alkaline conditions IPBC degraded slowly at ambient temperatures with a DT_{50} of 539 days.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	Yes Formation of degradation products was not investigated. However, the study is acceptable to predict the hydrolysis rate constant and dissipation times of the parent substance IPBC.

Section A7.1.1.1.1/01

Annex Point IIA, VII.7.6.2.1

Hydrolysis as a function of pH and identification of breakdown products

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

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

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[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]

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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]

Section A7.1.1.1.1/02 Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA, VII.7.6.2.1

[redacted]

Official use only

1 REFERENCE

1.1	**Reference**	Reynolds, J.L. (1994): Hydrolysis of ^{14}C-3-Iodo-2-propynyl-n-butylcarbamate (^{14}C-IPBC); XenoBiotic Laboratories, Inc., Plainsboro, NJ, U.S.A.; Study No.: XBL 94051; Lab.-Report No.: RPT00201; Doc. No. 711-003; 13.12.1994; (unpublished)
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes, U.S. EPA Pesticide Assessment Guidelines, Subdivision N, § 161-1, Chemistry: Environmental Fate
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	^{14}C-IPBC, labelled in the n-butyl-1-position of the molecule
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Further relevant properties	[redacted]
3.2	**Reference substance**	[redacted]

Section A7.1.1.1.1/02 Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA, VII.7.6.2.1

3.2.1	Initial concentration of reference substance	[redacted]
3.3	**Test solution**	[redacted]
3.4	**Testing procedure**	
3.4.1	Test system	[redacted]
3.4.2	Temperature	[redacted]
3.4.3	pH	[redacted]
3.4.4	Duration of the test	[redacted]
3.4.5	Number of replicates	[redacted]
3.4.6	Sampling	[redacted]
3.4.7	Analytical methods	[redacted]
3.5	**Preliminary test**	[redacted]

4 RESULTS

4.1	**Concentration and hydrolysis values**	[redacted]
4.2	**Hydrolysis rate constant (k_h)**	[redacted]
4.3	**Dissipation time**	[redacted]

Section A7.1.1.1.1/02 Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA, VII.7.6.2.1

[redacted]

4.4 Concentration – time data

[redacted]

4.5 Specification of the transformation products

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The aqueous hydrolysis test was conducted according to U.S. EPA Pesticide Assessment Guidelines, Subdivision N, § 161-1, Chemistry: Environmental Fate.

[redacted]

5.2 Results and discussion

[redacted]

5.2.1 k_H

pH 5: 0.0026 d^{-1}

pH 7: 0.00279 d^{-1}

pH 9: 0.00302 d^{-1}

5.2.2 DT_{50}

pH 5: 267 days (25°C)

pH 7: 248 days (25°C)

pH 9: 229 days (25°C)

5.2.3 r^2

Correlation coefficients ranged from 0.657 to 0.796.

5.3 Conclusion

Validity criteria can be considered as fulfilled.

IPBC was found to be hydrolytically stable in sterile aqueous solutions at ambient temperatures.

5.3.1 Reliability

[redacted]

5.3.2 Deficiencies

No

Section A7.1.1.1.1/02 Hydrolysis as a function of pH and identification of breakdown products

Annex Point IIA, VII.7.6.2.1

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

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

Section A7.1.1.1.2/01/02

Annex Point IIA, VII.7.6.2.1

Phototransformation in water including identity of transformation products

			Official use only
		1 REFERENCE	
1.1	**Reference**	A7.1.1.1.2/01: Lee, D. et al. (1991): Photostability of organoiodine wood preservatives I, Progressive degradation and loss in fungal inhibition rate through photoirradiation; Mokuzai Gakkaishi Vol. 37, No. 1, p. 76 – 81; Doc. No. 792-005, (published). A7.1.1.1.2/02: Lee, D. et al. (1991): Photostability of organoiodine wood preservatives II, The photolytic process of preservatives; Mokuzai Gakkaishi Vol. 37, No. 3, p. 261 – 265; Doc. No. 792-004, (published).	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	No, publication	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	Not applicable	
		3 MATERIAL AND METHODS	
3.1	**Test material**	IPBC	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	Not indicated	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Radiolabelling	[redacted]	
3.1.6	UV/VIS absorption spectra and absorbance value	[redacted]	
3.1.7	Further relevant properties	[redacted]	

Section A7.1.1.1.2/01/02

Annex Point IIA, VII.7.6.2.1

Phototransformation in water including identity of transformation products

3.2 Reference substance

[redacted]

3.3 Test solution

[redacted]

b) [redacted]

3.4 Testing procedure

3.4.1 Test system

[redacted]

3.4.2 Properties of light source

[redacted]

3.4.3 Determination of irradiance

[redacted]

3.4.4 Temperature

[redacted]

3.4.5 pH

[redacted]

3.4.6 Duration of the test

[redacted]

3.4.7 Number of replicates

[redacted]

3.4.8 Sampling

[redacted]

3.4.9 Analytical methods

[redacted]

Section A7.1.1.1.2/01/02

Annex Point IIA, VII.7.6.2.1

Phototransformation in water including identity of transformation products

[redacted]

3.4.10 Calculations

[redacted]

3.5 Transformation products

[redacted]

3.5.1 Method of analysis for transformation products

[redacted]

4 RESULTS

4.1 Screening test

[redacted]

4.2 Actinometer data

[redacted]

4.3 Controls

[redacted]

4.4 Photolysis data

4.4.1 Concentration values

[redacted]

4.4.2 Mass balance

[redacted]

4.4.3 k^c_p

[redacted]

4.4.4 Kinetic order

[redacted]

4.4.5 k^c_p / k^a_p

[redacted]

4.4.6 Reaction quantum yield (ϕ^c_E)

[redacted]

4.4.7 k_{pE}

[redacted]

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

[redacted]

4.5 Specification of the transformation products

[redacted]

Section A7.1.1.1.2/01/02

Annex Point IIA, VII.7.6.2.1

Phototransformation in water including identity of transformation products

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	IPBC was dissolved in ethanol and exposed to sunlight lamps and UV lamps for up to 50 days. In addition, wood slices were dipped in an IPBC solution and irradiated for up to 50 days. Extracts were analysed by GC-MS.
5.2	**Results and discussion**	In irradiated ethanol solutions approximately 25 % of the initial IPBC was degraded within 17 days of exposure. Results on the decomposition of IPBC in wood suggest that photodegradation will also occur in a thin layer of the wood surface. After 25 to 50 days of irradiation the recovery rate of IPBC decreased to approximately 40 to 50 %. IPBC was converted to propargyl butyl carbamate (PBC) by photolytic cleavage of the carbon-iodine bond and release of the iodine.
5.2.1	k^c_p	Not indicated
5.2.2	K_{pE}	Not indicated
5.2.3	ϕ^c_E	Not indicated
5.2.4	$t_{1/2E}$	Not indicated
5.3	**Conclusion**	The test results show that IPBC may be subject to photolytical degradation.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	Yes The publication shows methodological and reporting deficiencies. However, the test results show that IPBC may be subject to photolytical degradation.

Section A7.1.1.1.2/01/02

Annex Point IIA, VII.7.6.2.1

Phototransformation in water including identity of transformation products

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section A7.1.1.1.2/01/02 Annex Point IIA, VII.7.6.2.1	Phototransformation in water including identity of transformation products

Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.1.1.2/03

Annex Point IIA, VII.7.6.2.2

Addendum 2 to Dossier

Phototransformation in water including identity of transformation products

			Official use only
		1 REFERENCE	
1.1	**Reference**	Phaff, R. (2005): Aqueous photolysis of IPBC and determination of the quantum yield; RCC, Itingen Switzerland; Doc. No. 712-001 (unpublished).	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, OECD Guideline for Testing of Chemicals, draft document, August 2000	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in section 2	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Radiolabelling	[redacted]	
3.1.6	UV/VIS absorption spectra and absorbance value	[redacted]	
3.1.7	Further relevant properties	[redacted]	

Section A7.1.1.1.2/03

Annex Point IIA, VII.7.6.2.2

Addendum 2 to Dossier

Phototransformation in water including identity of transformation products

---

3.2 Reference substance

[redacted]

3.3 Test solution

[redacted]

3.4 Testing procedure

[redacted]

3.4.1 Test system

[redacted]

3.4.2 Properties of light source

[redacted]

3.4.3 Determination of irradiance

[redacted]

3.4.4 Temperature

[redacted]

3.4.5 pH

[redacted]

3.4.6 Duration of the test

[redacted]

3.4.7 Number of replicates

[redacted]

3.4.8 Sampling

[redacted]

Section A7.1.1.1.2/03

Annex Point IIA, VII.7.6.2.2

Addendum 2 to Dossier

Phototransformation in water including identity of transformation products

3.4.9 Analytical methods [redacted]

3.4.10 Calculations [redacted]

3.5 Transformation products [redacted]

3.5.1 Method of analysis for transformation products [redacted]

4 RESULTS

4.1 Screening test [redacted]

4.2 Actinometer data [redacted]

4.3 Controls [redacted]

4.4 Photolysis data [redacted]

4.4.1 Concentration values [redacted]

Section A7.1.1.1.2/03 Phototransformation in water including identity of transformation products

Annex Point IIA, VII.7.6.2.2

Addendum 2 to Dossier

4.4.2	Mass balance	[redacted]
4.4.3	k^c_p	[redacted]
4.4.4	Kinetic order	[redacted]
4.4.5	k^c_p / k^a_p	[redacted]
4.4.6	Reaction quantum yield (ϕ^c_E)	[redacted]
4.4.7	k_{pE}	[redacted]
4.4.8	Half-life ($t_{1/2E}$)	[redacted]
4.5	**Specification of the transformation products**	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The rate of photochemical degradation of IPBC was determined under simulated sunlight in sterilised aqueous buffer solution at pH 7 and natural pond water at a pH value of about 8.5. [redacted]
5.2	**Results and discussion**	The results show that IPBC was stable within 3 days of continuous irradiation (corresponding to 6.1 days natural summer sunlight at latitude 50° N). Since IPBC was stable during the incubation period no half-lives and no quantum yield could be calculated.
5.2.1	k^c_p	Not indicated
5.2.2	K_{pE}	Not indicated
5.2.3	ϕ^c_E	Not indicated
5.2.4	$t_{1/2E}$	Not indicated
5.3	**Conclusion**	The results of the study demonstrate that IPBC is stable to direct and indirect photolysis in the aquatic environment.
5.3.1	Reliability	[redacted]

Section A7.1.1.1.2/03

Annex Point IIA, VII.7.6.2.2

Addendum 2 to Dossier

Phototransformation in water including identity of transformation products

5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

[redacted]

Official use only

1 REFERENCE

1.1	**Reference**	Grützner, I. (2002): Ready biodegradability of IPBC in a Manometric Respirometry Test; RCC Ltd, Environmental Chemistry & Pharmanalytics Division; Itingen, Switzerland; Lab.-Study No.: 831172; 11.03.2002; Doc. No. 713-002; unpublished
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes, OECD guideline 301 F
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Composition of Product	[redacted]
3.1.7	TS inhibitory to microorganisms	[redacted]

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

3.1.8	Specific chemical analysis	[redacted]
3.2	**Reference substance**	[redacted]
3.2.1	Initial concentration of reference substance	[redacted]
3.3	**Testing procedure**	
3.3.1	Inoculum / test species	[redacted]
3.3.2	Test system	[redacted]
3.3.3	Test conditions	[redacted]
3.3.4	Method of preparation of test solution	[redacted]
3.3.5	Initial TS concentration	[redacted]
3.3.6	Duration of test	[redacted]
3.3.7	Analytical parameter	[redacted]
3.3.8	Sampling	[redacted]
3.3.9	Intermediates/ degradation products	[redacted]
3.3.10	Nitrate/nitrite measurement	[redacted]
3.3.11	Controls	[redacted]
3.3.12	Statistics	[redacted]

4 RESULTS

4.1	**Degradation of test substance**

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

4.1.1	Graph	[redacted]
4.1.2	Degradation	-24 to –26 % after 28 days based on $ThOD_{NH4}$ -20 to –22 % after 28 days based on $ThOD_{NO3}$ The biochemical oxygen demand (BOD) of the test item IPBC in the test media was lower than in the inoculum controls. Consequently, IPBC was found to be not biodegradable under the test conditions within 28 days.
4.1.3	Other observations	[redacted]
4.1.4	Degradation of TS in abiotic control	[redacted]
4.1.5	Degradation of reference substance	[redacted]
4.1.6	Intermediates/ degradation products	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	A manometric respirometry test was conducted according to OECD Guideline 301 F over a period of 28 days.
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	According to the guideline all validity criteria were fulfilled. IPBC was not ready biodegradable under the test conditions within 28 days.
5.3.1	Reliability	[redacted]
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
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]

Section A7.1.1.2.1/01 Biodegradability (ready)

Annex Point IIA, VII.7.6.1.1

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	

	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

[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]

[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 A7.1.1.2.2/01 Biodegradability (inherent)

Annex Point IIA, VII.7.6.1.2

			Official use only
		1 REFERENCE	
1.1	**Reference**	Seyfried, B. (2004): Inherent biodegradability of IPBC in a modified "Zahn-Wellens / EMPA Test"; RCC Ltd, Environmental Chemistry & Pharmanalytics Division; Itingen, Switzerland; Lab.-Study No.: 851399; 12.08.2004; Doc. No. 713-007; unpublished	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, OECD guideline 302 B	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	Yes: instead of DOC (COD) measurement, biodegradation was monitored with specific analysis of IPBC and of its degradation product PBC in the aqueous phase and in the activated sludge	
		3 MATERIAL AND METHODS	
3.1.1	**Test material**	[redacted]	
3.1.1.1	Lot/Batch number	[redacted]	
3.1.1.2	Specification	As given in section 2	
3.1.1.3	Purity	[redacted]	
3.1.1.4	Description of test substance	[redacted]	
3.1.1.5	Further relevant properties	[redacted]	
3.1.1.6	Composition of Product	[redacted]	
3.1.1.7	TS inhibitory to micro-organisms	[redacted]	

Section A7.1.1.2.2/01 Biodegradability (inherent)

Annex Point IIA, VII.7.6.1.2

3.1.1.8	Specific chemical analysis	[redacted]
3.1.2	**Test material used as analytical reference item**	[redacted]
3.1.2.1	Lot/Batch number	[redacted]
3.1.2.2	Specification	[redacted]
3.1.2.3	Purity	[redacted]
3.1.2.4	Description of test substance	[redacted]
3.1.2.5	Further relevant properties	[redacted]
3.1.2.6	Composition of Product	[redacted]
3.1.2.7	TS inhibitory to micro-organisms	[redacted]
3.1.2.8	Specific chemical analysis	[redacted]
3.2	**Reference substance**	[redacted]
3.2.1	Initial concentration of reference substance	[redacted]
3.3	**Testing procedure**	
3.3.1	Inoculum / test species	[redacted]
3.3.2	Test system	[redacted]
3.3.3	Test conditions	[redacted]
3.3.4	Method of preparation of test solution	[redacted]
3.3.5	Initial TS concentration	[redacted]
3.3.6	Duration of test	[redacted]

Section A7.1.1.2.2/01 Biodegradability (inherent)

Annex Point IIA, VII.7.6.1.2

3.3.7	Analytical parameter	[redacted]
3.3.8	Sampling	[redacted]
3.3.9	Intermediates/ degradation products	[redacted]
3.3.10	Nitrate/nitrite measurement	[redacted]
3.3.11	Controls	[redacted]
3.3.12	Statistics	[redacted]

4 RESULTS

4.1 Degradation of test substance

4.1.1	Graph	[redacted]

Section A7.1.1.2.2/01 Biodegradability (inherent)

Annex Point IIA, VII.7.6.1.2

4.1.2 Degradation

[redacted]

4.1.3 Other observations

[redacted]

4.1.4 Degradation of procedure control

[redacted]

4.1.5 Degradation of toxicity control

[redacted]

Section A7.1.1.2.2/01 Biodegradability (inherent)

Annex Point IIA, VII.7.6.1.2

4.1.6	Intermediates/ degradation products	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	A modified Zahn Wellens / EMPS test was conducted according to OECD Guideline 302 B. The biodegradation process was monitored by specific analysis of the test item IPBC and the degradation product PBC in the aqueous phase and in the activated sludge
5.2	**Results and discussion**	[redacted]
5.3	**Conclusion**	Based on the measured concentrations of IPBC and PBC, rapid biodegradation of IPBC to PBC and further biodegradation of PBC was shown.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]

Section A7.1.1.2.2/01 Biodegradability (inherent)

Annex Point IIA, VII.7.6.1.2

Remarks	[redacted]
	Comments from ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A7.1.1.2/01-1: Inoculum / Test organism

[redacted]	[redacted]
Nature	Aerobic activated sludge
Species	Not specified
Strain	Not applicable
Source	Sewage treatment plant treating predominantly domestic sewage
[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]	[redacted]
[redacted]	[redacted]

[redacted]

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

[redacted]

Section A7.1.1.2.3 Annex Point IIIA, XII.2.1	Biodegradation in seawater	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	According to the TNsG on data requirements a seawater biodegradation test is required if a substance is to be used or released in marine environments in considerable amounts (e.g. it is known to be repeatedly used or continuously released in marine environments). [redacted] Therefore, a study on biodegradation in seawater is not regarded to be warranted.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.1.2.1.1 Annex Point IIIA, XI.-2.1	Aerobic biodegradation
	JUSTIFICATION FOR NON-SUBMISSION OF DATA (Official use only)
	Other justification
Detailed justification:	[redacted] Therefore, a study on aerobic biodegradation is not regarded to be warranted.
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section A7.1.2.1.2 Annex Point IIIA, XII.2.1	Anaerobic biodegradation	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	According to the TNsG on data requirements, an anaerobic biodegradation study is not required for product type PT 8 (wood preservatives). Therefore, a study on anaerobic biodegradation is not regarded to be warranted for IPBC.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section A7.1.2.2.1 Annex Point IIIA, XII.2.1	Aerobic aquatic degradation study	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Detailed justification:	According to the TNsG on data requirements, an aerobic aquatic degradation study is required with non-adapted inoculum. [redacted]	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.1.2.2.2/01 Water/sediment study under anaerobic conditions

Annex Point IIIA, XII.2.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	Blumhorst, M. R. (1992): Anaerobic aquatic metabolism study of P-100; EPL Bio-Analytical Services Inc., Harristown, IL, U.S.A.; Study No.: 147-003; Doc. No. 715-001; 24.08.1992; (unpublished)	
1.2	**Data protection**	[redacted]	
1.2.1	Data owner	[redacted]	
1.2.2	Companies with letter of access	[redacted]	
1.2.3	Criteria for data protection	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Yes, U.S. EPA Pesticide Assessment Guidelines, Subdivision N, § 162-3, Chemistry: Environmental Fate	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	No	
		3 MATERIAL AND METHODS	
3.1	**Test material**	[redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	As given in section 2	
3.1.3	Purity	[redacted]	
3.1.4	Description of test substance	[redacted]	
3.1.5	Further relevant properties	[redacted]	
3.1.6	Composition of Product	[redacted]	
3.1.7	TS inhibitory to microorganisms	[redacted]	
3.1.8	Specific chemical analysis	[redacted]	

Section 7.1.2.2.2/01 Water/sediment study under anaerobic conditions

Annex Point IIIA, XII.2.1

3.2	**Reference substance**	[redacted]
3.2.1	Initial concentration of reference substance	[redacted]
3.3	**Test solution**	[redacted]
3.3	**Testing procedure**	
3.3.1	Water/sediment systems	[redacted]
3.3.2	Test system	[redacted]
3.3.3	Temperature	[redacted]
3.3.4	Initial TS concentration	[redacted]
3.3.5	Duration of test	[redacted]
3.3.6	Analytical parameter	[redacted]

Section 7.1.2.2.2/01 Water/sediment study under anaerobic conditions

Annex Point IIIA, XII.2.1

3.3.7 Sampling

[redacted]

3.3.8 Sampling and Analytical methods

[redacted]

3.3.9 Statistics

[redacted]

Section 7.1.2.2.2/01 Water/sediment study under anaerobic conditions

Annex Point IIIA, XII.2.1

4 RESULTS

4.1 Material balance

[redacted]

4.2 Distribution of radioactivity between water and sediment

[redacted]

4.3 Concentration – time data

[redacted]

Section 7.1.2.2.2/01 Water/sediment study under anaerobic conditions

Annex Point IIIA, XII.2.1

4.4 Dissipation time

[redacted]

4.5 Specification of the transformation products

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The anaerobic biodegradation test was conducted according to U.S. EPA Pesticide Assessment Guidelines, Subdivision N, § 162-3, Chemistry: Environmental Fate.

^{14}C-IPBC was applied to a natural water/sediment system and incubated under anaerobic conditions at 22 ± 2°C in the dark. Water and sediment samples were taken up to 244 days after treatment.

5.2 Results and discussion

IPBC was rapidly degraded in anaerobic aquatic systems with a half-life of 1.5 hours. IPBC remained predominantly in the water layer but degradation products were similar between water and sediment. [redacted]

Section 7.1.2.2.2/01 Water/sediment study under anaerobic conditions

Annex Point IIIA, XII.2.1

5.3	**Conclusion**	[redacted] IPBC was rapidly degraded in anaerobic aquatic systems with a half-life of 1.5 hours. The major degradation product was propargyl butyl carbamate (PBC) which degraded itself with a half-life of 11.5 days. The terminal degradation products of IPBC in anaerobic aquatic systems appear to be CO_2 and CH_4. IPBC degradation in anaerobic aquatic systems was primarily microbially mediated but nonbiological mechanisms also contribute to the degradative process.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]

Section 7.1.2.2.2/01 Water/sediment study under anaerobic conditions

Annex Point IIIA, XII.2.1

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

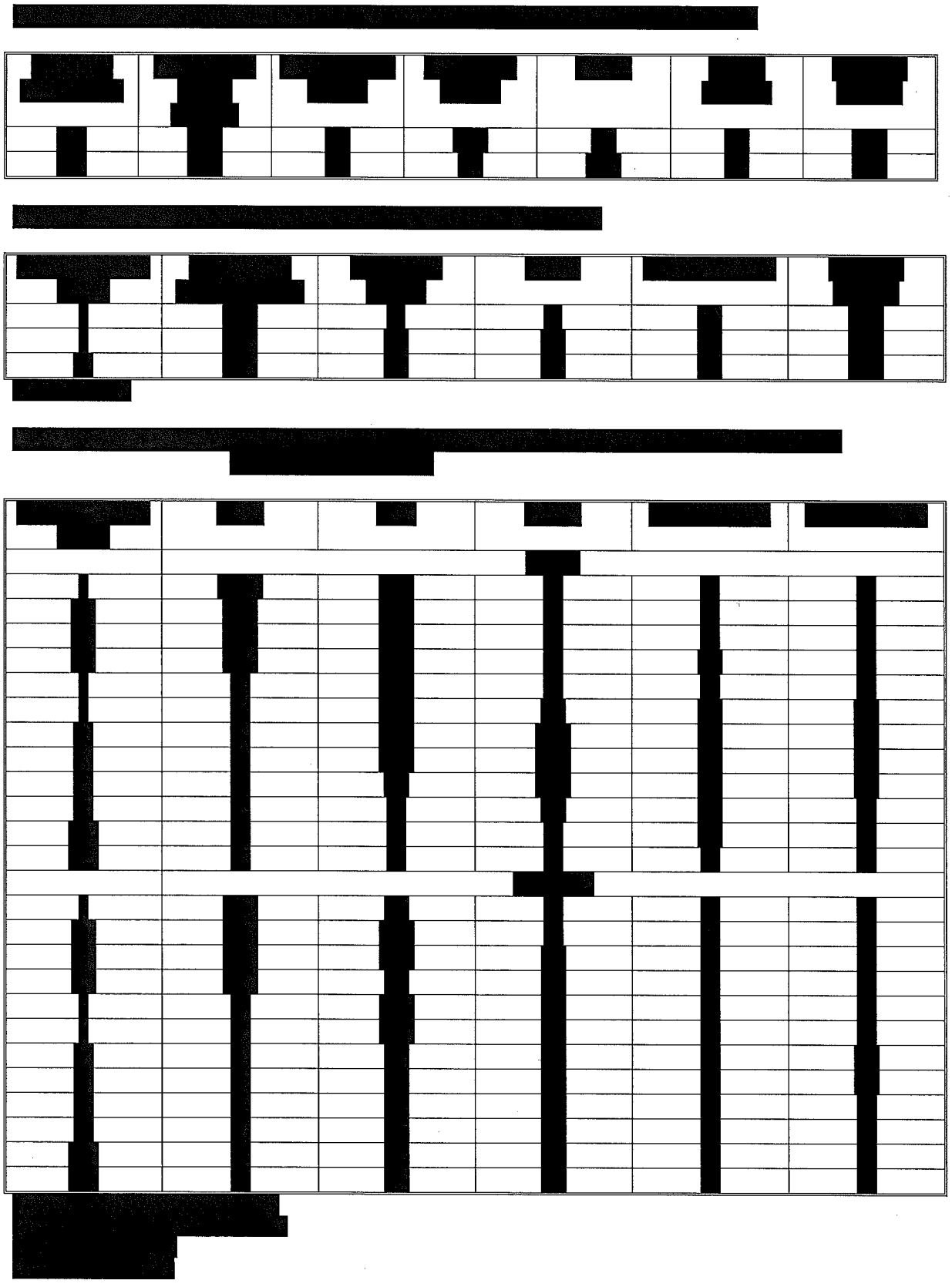
[redacted]

[redacted]

[redacted]

[redacted]

[redacted]



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[redacted]

[redacted]

[redacted]

Section A7.1.3/01 Adsorption / Desorption screening test

Annex Point IIA, VII.7.7

[redacted]

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1 REFERENCE

1.1	**Reference**	Schneider, U. (2002): Estimation of the adsorption coefficient on soil and on sewage sludge using HPLC; Infracor GmbH, Analytisch Technische Services, Marl, Germany; Lab.-Report No.: AN-ASB 0203; Doc. No. 731-003; 02.04.2002; (unpublished)
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes EEC-No. C.19 and OECD Guideline No. 121
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Further relevant properties	[redacted]

Section A7.1.3/01 Adsorption / Desorption screening test

Annex Point IIA, VII.7.7

3.1.6	Method of analysis	[redacted]
3.2	**Degradation products**	[redacted]
3.2.1	Method of analysis for degradation products	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Soil types**	[redacted]
3.5	**Testing procedure**	
3.5.1	Test system	[redacted]
3.5.2	Test solution and Test conditions	[redacted]
3.6	**Test performance**	
3.6.1	Preliminary test	[redacted]
3.6.2	Screening test: Adsorption	[redacted]
3.6.3	Screening test: Desorption	[redacted]
3.6.4	HPLC-method	[redacted]

[1] OECD (1999) OECD-Guidelines for the Testing of Chemicals. Proposal for a new guideline 121: Estimation of the adsorption coefficient (K_{OC}) on soil and on sewage sludge using High Performance Liquid Chromatography (HPLC), Draft Document (August 1999).

Section A7.1.3/01 Adsorption / Desorption screening test

Annex Point IIA, VII.7.7

3.6.5	Other test	[redacted]
		4 RESULTS
4.1	**Preliminary test**	[redacted]
4.2	**Screening test: Adsorption**	The adsorption coefficient of IPBC on soil was found to be Koc = 126 (log Koc = 2.1).
4.3	**Screening test: Desorption**	Not applicable
4.4	**Calculations**	
4.4.1	Ka , Kd	Not determined.
4.4.2	Ka_{oc} , Kd_{oc}	Koc = 126
4.5	**Degradation product(s)**	Not applicable
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	The adsorption coefficient (Koc) of IPBC was determined according to EEC-No. C.19 and OECD Guideline No. 121.
5.2	**Results and discussion**	The adsorption coefficient on soil (Koc) of IPBC was determined using the HPLC method. With the HPLC method the retention of IPBC in a HPLC system was compared with the retention of six calibration substances with known Koc values. The adsorption coefficient of IPBC on soil was found to be Koc = 126 (log Koc = 2.1).
5.2.1	Adsorbed a.s. [%]	Not applicable.
5.2.2	K_a	Not applicable.
5.2.3	K_d	Not applicable.
5.2.4	Ka_{oc}	Koc = 126 (log Koc = 2.1).
5.2.5	Ka/Kd	Not applicable.
5.2.6	Degradation products (% of a.s.)	Not applicable.
5.3	**Conclusion**	[redacted] The adsorption coefficient of IPBC on soil, determined with the HPLC method, was found to be Koc = 126 (log Koc = 2.1).
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	No

Section A7.1.3/01 Adsorption / Desorption screening test

Annex Point IIA, VII.7.7

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

[redacted]

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

[redacted]

Section A7.1.3/02 Adsorption / Desorption screening test

Annex Point IIA, VII.7.7

[redacted]

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1 REFERENCE

1.1	**Reference**	Blumhorst, M. R. (1990): Adsorption/Desorption studies – Batch equilibrium for P-100; EPL Bio-Analytical Services Inc., Harristown, IL, U.S.A.; Study No.: 147-002; Doc. No. 731-001; 29.10.1990 (unpublished)
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes, U.S. EPA Pesticide Assessment Guidelines, Subdivision N, § 163-1, Chemistry: Environmental Fate
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL AND METHODS

3.1	**Test material**	[redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	As given in section 2
3.1.3	Purity	[redacted]
3.1.4	Description of test substance	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Method of analysis	[redacted]

Section A7.1.3/02 Adsorption / Desorption screening test

Annex Point IIA, VII.7.7

3.2	**Degradation products**	[redacted]
3.2.1	Method of analysis for degradation products	[redacted]
3.3	**Reference substance**	[redacted]
3.3.1	Method of analysis for reference substance	[redacted]
3.4	**Soil types**	[redacted]
3.5	**Testing procedure**	
3..5.1	Test system	[redacted]
3.5.2	Test solution and Test conditions	[redacted]
3.6	**Test performance**	
3.6.1	Preliminary test	[redacted]
3.6.2	Screening test: Adsorption	[redacted]

Section A7.1.3/02 Adsorption / Desorption screening test

Annex Point IIA, VII.7.7

[redacted]

3.6.3 Screening test: Desorption

[redacted]

3.6.4 HPLC-method

[redacted]

3.6.5 Other test

[redacted]

4 RESULTS

4.1 Preliminary test

[redacted]

4.2 Screening test: Adsorption

[redacted]

4.3 Screening test:

[redacted]

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2 OECD (1999) OECD-Guidelines for the Testing of Chemicals. Proposal for a new guideline 121: Estimation of the adsorption coefficient (K_{OC}) on soil and on sewage sludge using High Performance Liquid Chromatography (HPLC), Draft Document (August 1999).

Section A7.1.3/02 Adsorption / Desorption screening test

Annex Point IIA, VII.7.7

	Desorption	[redacted]
4.4	**Calculations**	
4.4.1	Kads , Kdes	[redacted]
4.4.2	Ka_{oc} , Kd_{oc}	[redacted]
4.5	**Degradation product(s)**	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The adsorption/desorption test was conducted according to U.S. EPA Pesticide Assessment Guidelines, Subdivision N, § 163-1, Chemistry: Environmental Fate. The adsorption/desorption of IPBC by five different soils was investigated via the batch equilibrium method.
5.2	**Results and discussion**	[redacted]
5.2.1	Adsorbed a.s. [%]	7.99 - 37.9 %
5.2.2	K_{ads}	0.676 – 2.46
5.2.3	K_{des}	3.43 – 31.3
5.2.4	Ka_{oc}	61.0 - 309
5.2.5	Kd_{oc}	457 - 4065
Degradation products (% of a.s.)		Propargyl butyl carbamate (PBC)
5.3	**Conclusion**	[redacted] The adsorption coefficients of IPBC on soil, determined with the batch equilibrium method, were found to range from 61 to 309. IPBC adsorption did not appear to be highly correlated with soil organic matter content, clay content or cation exchange capacity.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	No

Section A7.1.3/02 Adsorption / Desorption screening test

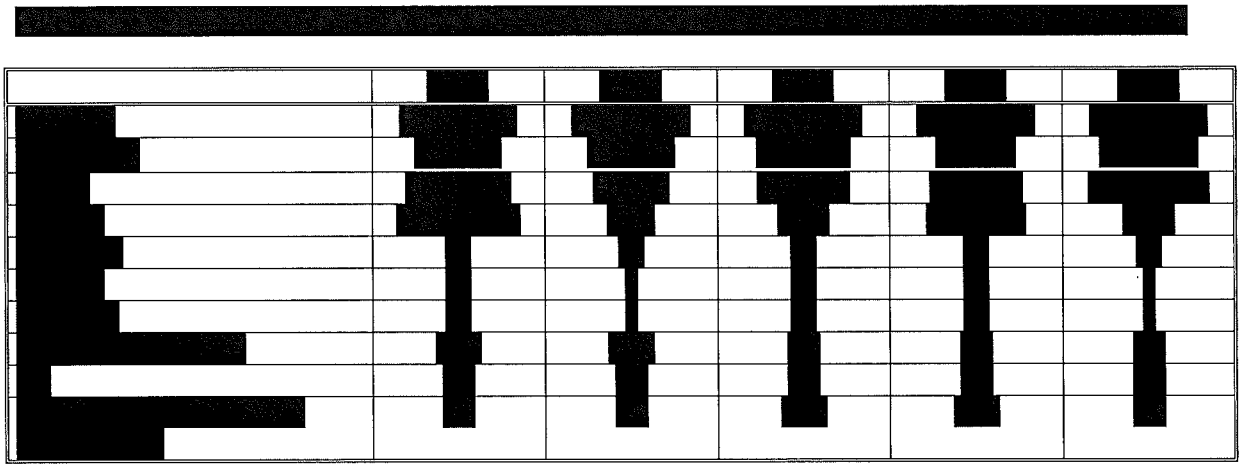
Annex Point IIA, VII.7.7

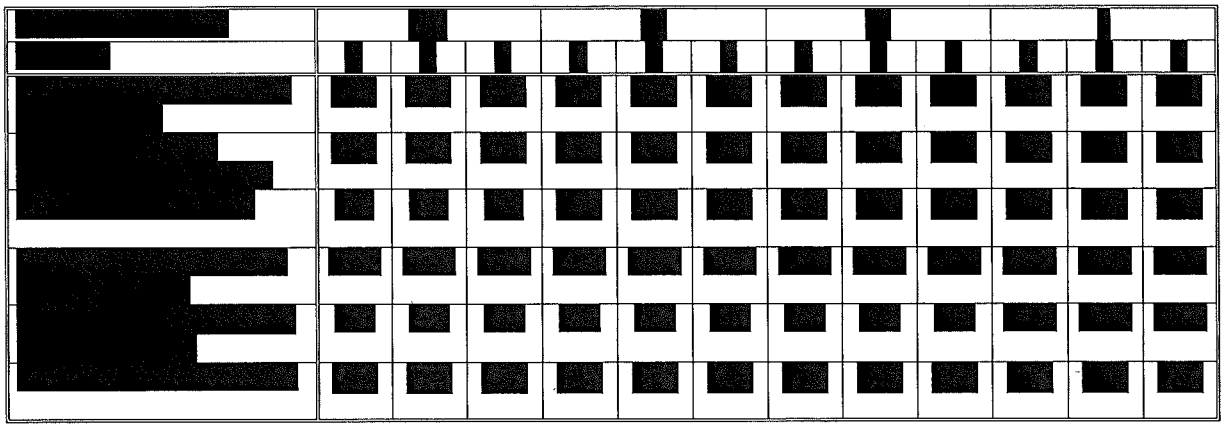
Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ...
Date	*Give date of comments submitted*

Section A7.1.3/02 Adsorption / Desorption screening test

Annex Point IIA, VII.7.7

Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	





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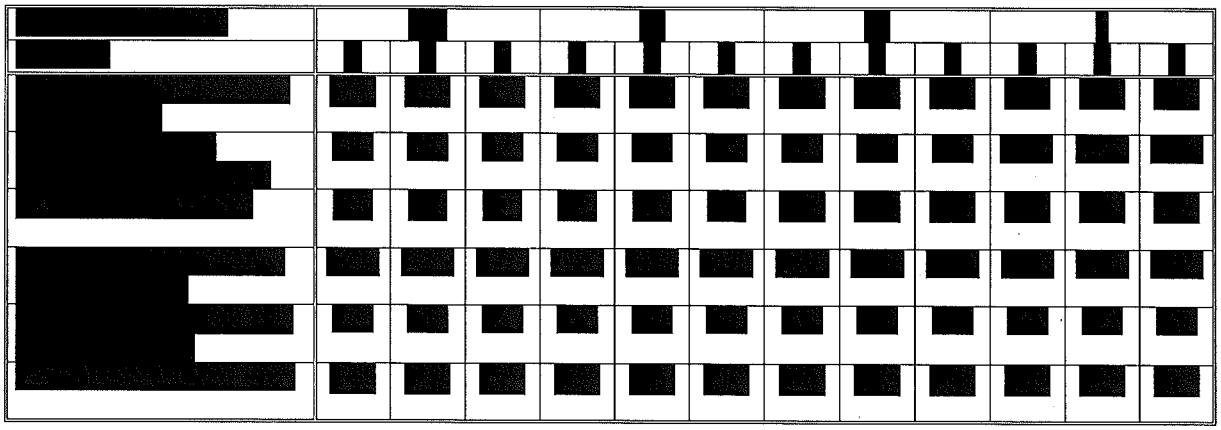

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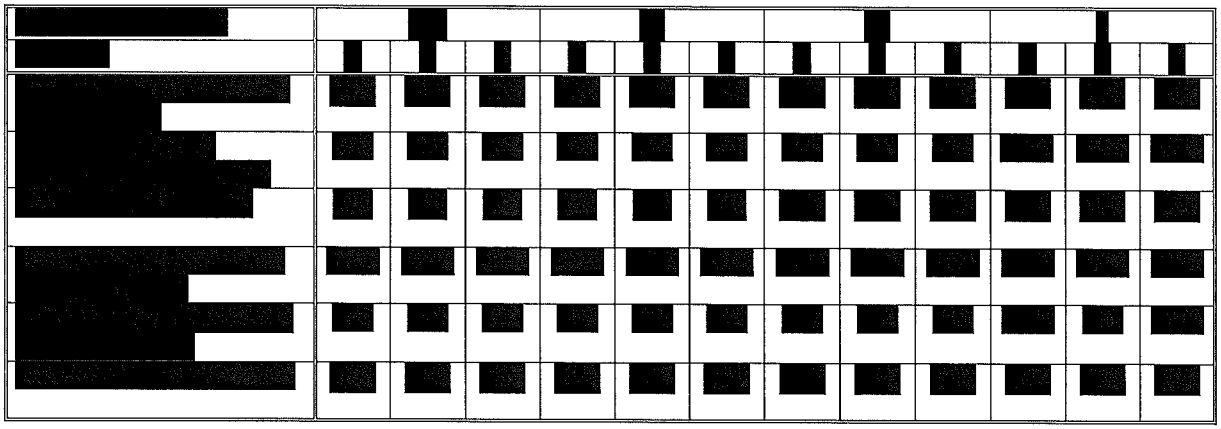

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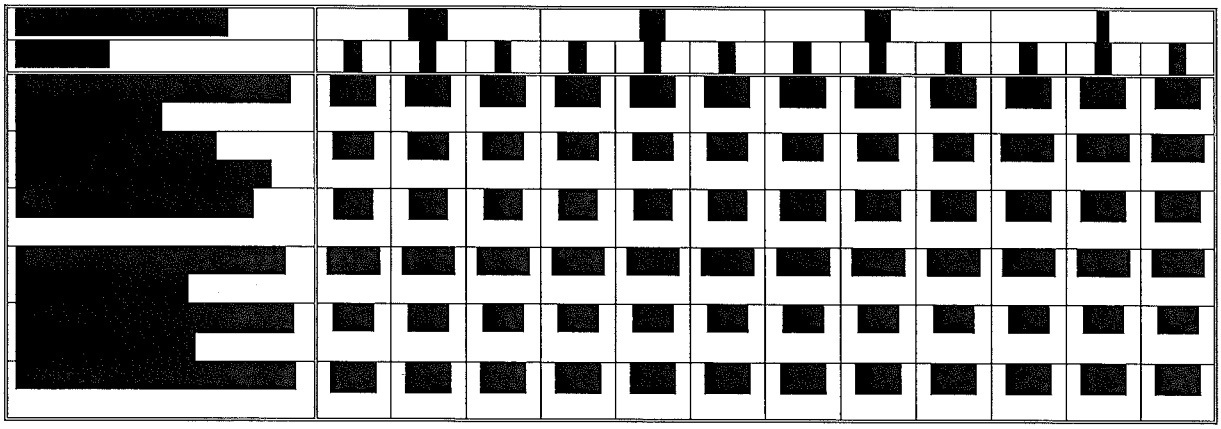

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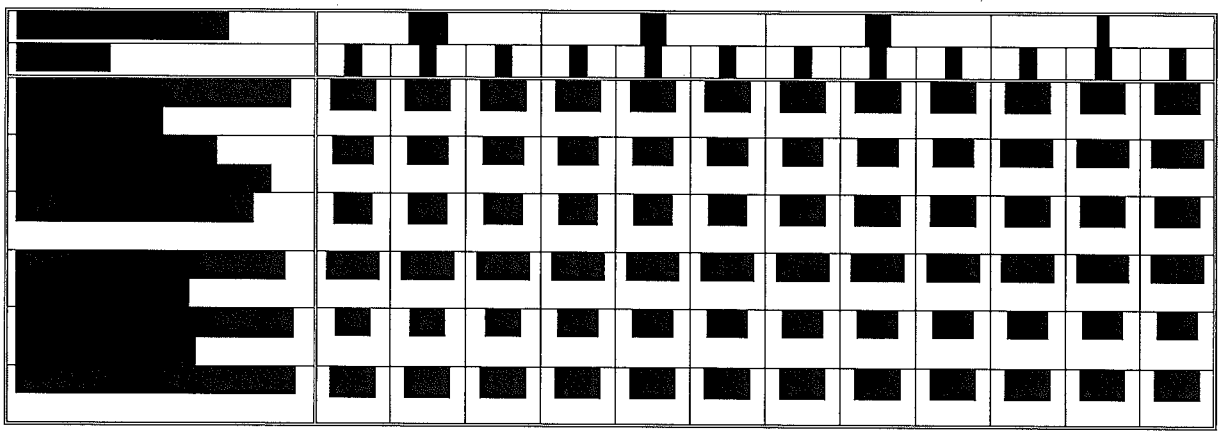

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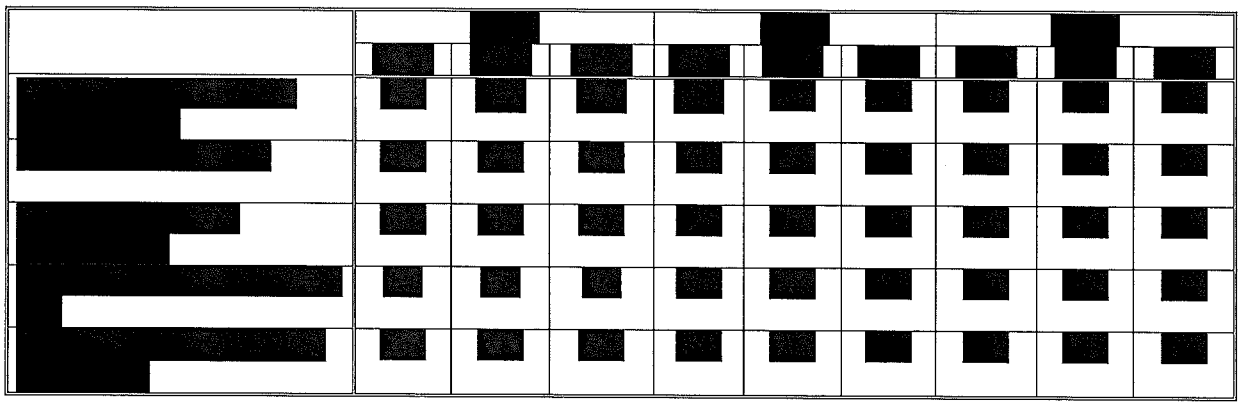

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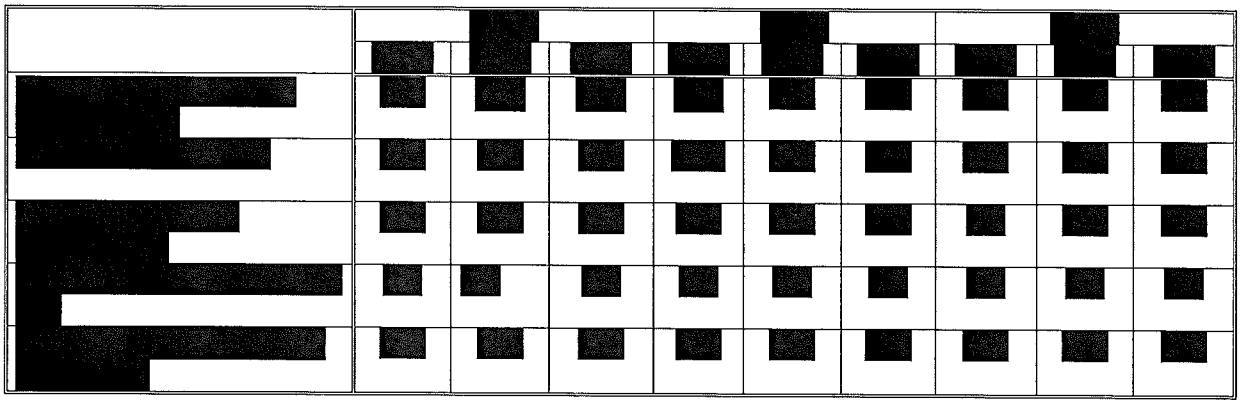

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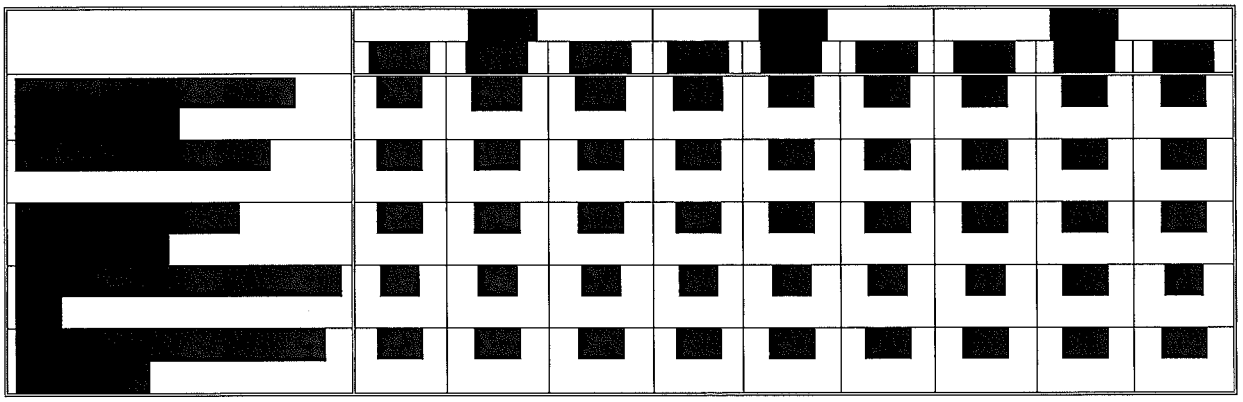

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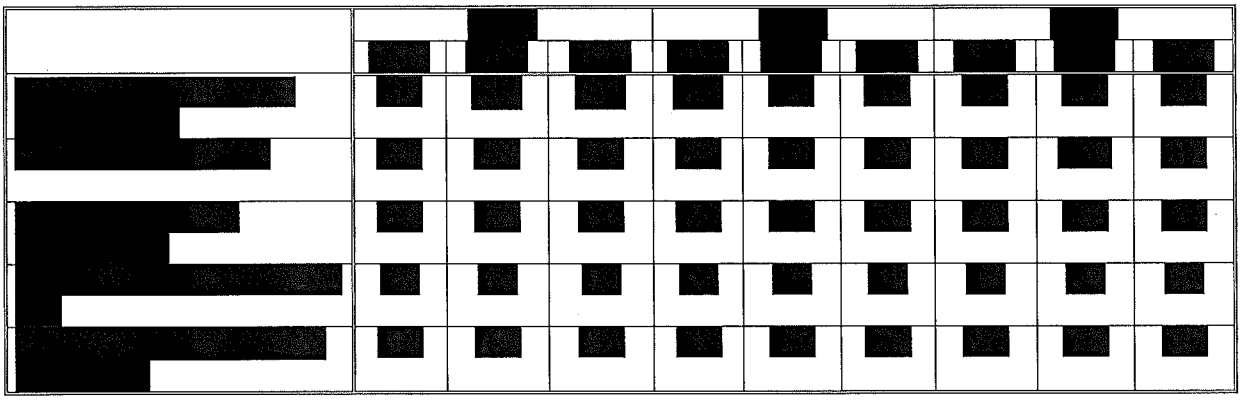

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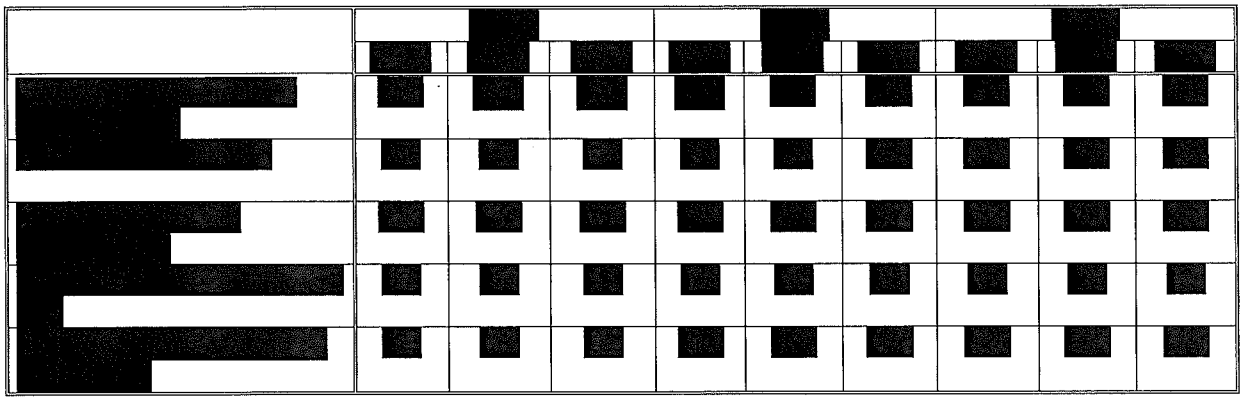

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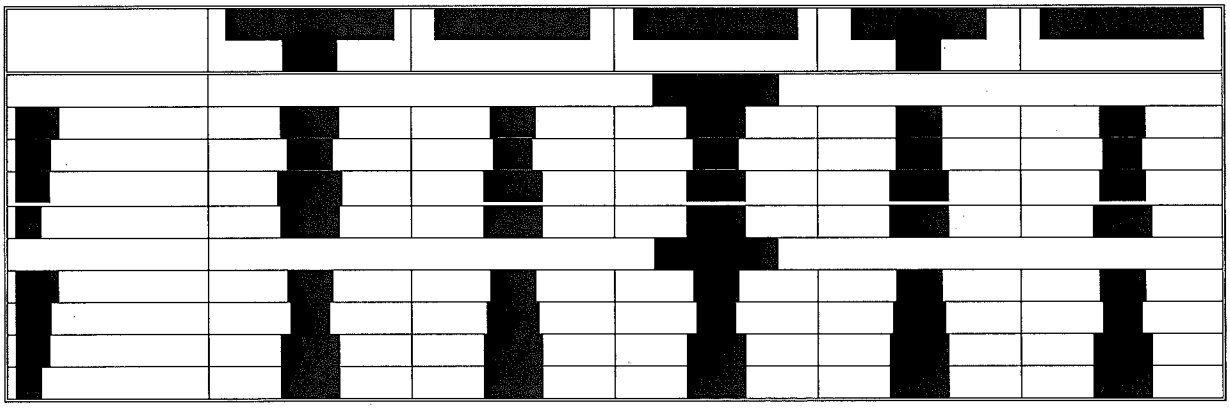

Section A7.1.4.1 Annex Point IIIA, XII.2.1	Field study on accumulation in the sediment	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Other justification	
Detailed justification:	According to the TNsG on data requirements, a field study on accumulation in the sediment is required if non-extractable residues are formed exceeding 70 % of the initial dose in the water/sediment study or if the mineralisation rate in the water/sediment study is less than 5 % in 100 days. [redacted] Therefore, a field study on accumulation in the sediment is not regarded to be warranted.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	[redacted]	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks		
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section 7.2.1/01 Aerobic degradation in soil, initial study

Annex Point IIIA, VII.4, XII.1.1

[redacted]

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1 REFERENCE

1.1	**Reference**	Blumhorst, M. R. (1992): Aerobic soil metabolism of P-100; EPL Bio-Analytical Services Inc., Harristown, IL, U.S.A.; Study No.: 147-004; Doc. No. 722-001; 05.05.1992; (unpublished)
1.2	**Data protection**	[redacted]
1.2.1	Data owner	[redacted]
1.2.2	Companies with letter of access	[redacted]
1.2.3	Criteria for data protection	[redacted]

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes, U.S. EPA Pesticide Assessment Guidelines, Subdivision N, § 162-1, Chemistry: Environmental Fate
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIAL 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	Description of test substance	[redacted]
3.1.5	Further relevant properties	[redacted]
3.1.6	Composition of Product	[redacted]

Section 7.2.1/01 Aerobic degradation in soil, initial study

Annex Point IIIA, VII.4, XII.1.1

3.1.7	TS inhibitory to microorganisms	
3.1.8	Specific chemical analysis	
3.2	**Reference substance**	
3.2.1	Initial concentration of reference substance	
3.3	**Test solution**	
3.4	**Testing procedure**	
3.4.1	Test soil	
3.4.2	Test system	
3.4.3	Temperature	
3.4.4	Initial TS concentration	
3.4.5	Duration of test	
3.4.6	Analytical parameter	
3.4.7	Sampling	

Section 7.2.1/01 **Aerobic degradation in soil, initial study**
Annex Point IIIA, VII.4, XII.1.1

3.4.8 Analytical methods

[redacted]

3.4.9 Calculations

[redacted]

4 RESULTS

4.1 Material balance

[redacted]

4.2 Distribution of radioactivity

[redacted]

Section 7.2.1/01 Aerobic degradation in soil, initial study

Annex Point IIIA, VII.4, XII.1.1

4.3 Concentration – time data

[redacted]

4.4 Specification of the transformation products

[redacted]

4.5 Dissipation time

Soil DT_{50} and DT_{90} values of IPBC and propargyl butyl carbamate were calculated assuming pseudo first-order kinetics (see table A7.2.1/01-8).

DT_{50} of IPBC:

- 2.13 hours (nonsterile, 22°C)
- 8.6 hours (nonsterile, 5°C)

DT_{50} of PBC:

- 4.3 days (nonsterile, 22°C)

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The aerobic biodegradation test was conducted according to U.S. EPA Pesticide Assessment Guidelines, Subdivision N, § 162-1, Chemistry: Environmental Fate.

[redacted]

5.2 Results and discussion

[redacted]

Section 7.2.1/01 Aerobic degradation in soil, initial study

Annex Point IIIA, VII.4, XII.1.1

5.3	**Conclusion**	[redacted] IPBC was rapidly degraded in soil with a half-life of *ca.* 2 hours at 22°C. The degradation of IPBC in soil was primarily microbially mediated but nonbiological mechanisms may contribute to the degradation process. The major degradation product of IPBC was Propargyl butyl carbamate (PBC) which degraded itself with a DT_{50} value of 4.3 days. Due to their fast degradation in soil, neither IPBC nor PBC will accumulate in the soil compartment, but will completely mineralise to CO_2.
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	No

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]

Section 7.2.1/01 Aerobic degradation in soil, initial study

Annex Point IIIA, VII.4, XII.1.1

Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]
	COMMENTS FROM ... *(specify)*
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

[redacted]

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