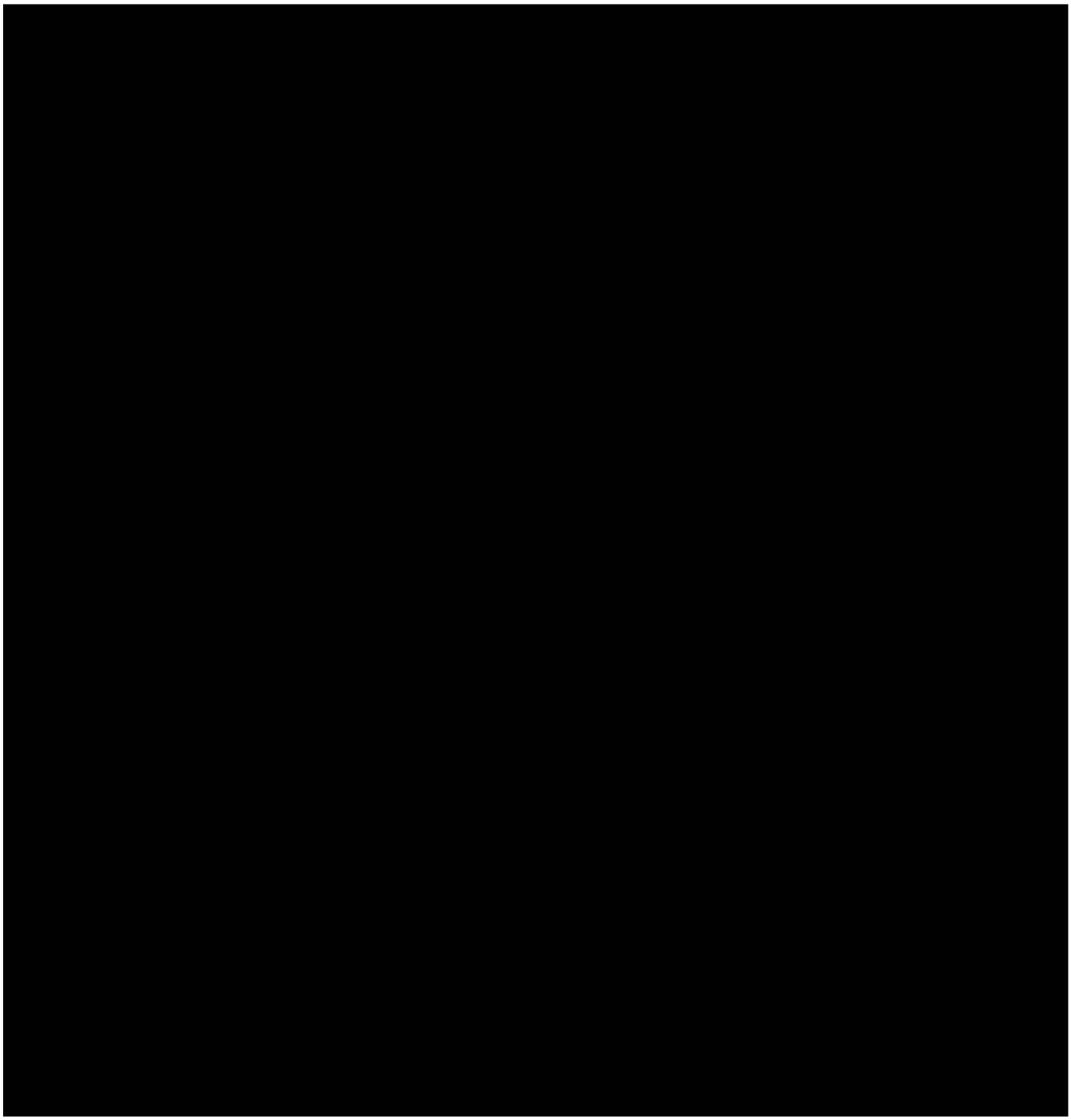
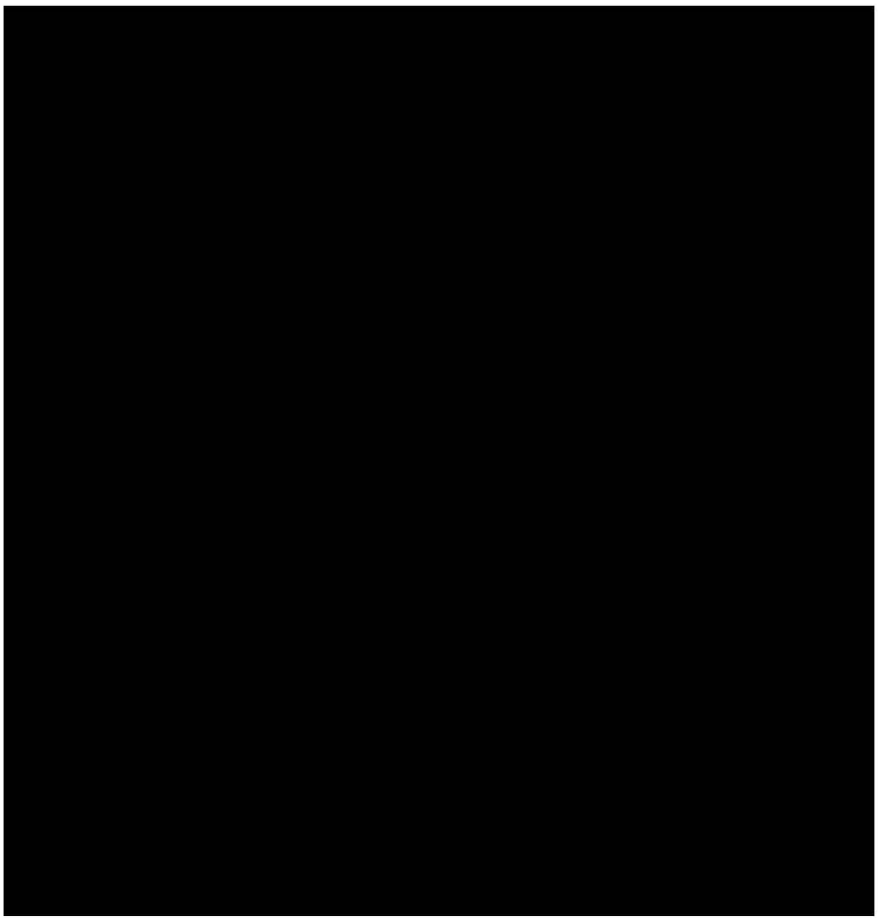
Section 6.7(2)
Carcinogenicity -Mice

Annex Point IIA6.7	**2 year dietary combined toxicity/ carcinogenicity study in mice**
IUCLID 5.7/2	

	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 6.8.1(1)
Teratogenicity study -Rat

Annex Point IIA6.8.1

IUCLID 5.8.2/1

Teratogenicity study in the rat

			Official use only
		31 REFERENCE	
1.1	**Reference**	[redacted]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Sumitomo Chemicals Co., Ltd.	
1.2.2	Companies with letter of access	Sumitomo Chemical (UK) PLC.	
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	[redacted] OECD Test Guideline 414 (adopted 22 January 2001).	
2.2	**GLP**	[redacted]	[redacted]
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted] d-Phenothrin [redacted]	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	

Section 6.8.1(1)
Teratogenicity study -Rat

Annex Point IIA6.8.1

IUCLID 5.8.2/1

		Teratogenicity study in the rat
3.1.2.1	Description	[redacted]
3.1.2.2	Purity	
3.1.2.3	Stability	
3.2	**Test Animals**	
3.2.1	Species	Rat
3.2.2	Strain	[redacted]
3.2.3	Source	
3.2.4	Sex	
3.2.5	Age/weight at study initiation	[redacted] Age not specified. Animals described as adult.
3.2.6	Number of animals per group	[redacted]
3.2.7	Control animals	Yes
3.2.8	Mating period	Not specified.
3.3	**Administration/ Exposure**	Oral
3.3.1	Duration of exposure	From day 6 to 15 of gestation.
3.3.2	Postexposure period	All females were killed on Day 21 post-coitum.
3.3.3	Type	[redacted]
3.3.4	Concentration	
3.3.5	Vehicle	
3.3.6	Concentration in vehicle	Not reported.
3.3.7	Total volume applied	[redacted]
3.3.8	Controls	Vehicle controls.

Section 6.8.1(1)
Teratogenicity study -Rat

Annex Point IIA6.8.1

IUCLID 5.8.2/1

[redacted]

3.4	**Examinations**
3.4.1	Body weight
3.4.2	Food consumption
3.4.3	Clinical signs
3.4.4	Examination of uterine content
3.4.5	Examination of foetuses
3.4.5.1	General
3.4.5.2	Skelet
3.4.5.3	Soft tissue
3.5	**Further remarks**
3.6	**Maternal toxic Effects**

Section 6.8.1(1)
Teratogenicity study -Rat

Annex Point IIA6.8.1

IUCLID 5.8.2/1

[redacted]

3.7 Teratogenic / embryotoxic effects

Section 6.8.1(1)
Teratogenicity study -Rat

Annex Point IIA6.8.1

IUCLID 5.8.2/1

[redacted]

3.8 Other effects

4.1 Materials and methods

4.2 Results and discussion

Section 6.8.1(1)
Teratogenicity study -Rat

Annex Point IIA6.8.1

IUCLID 5.8.2/1

[redacted]

4.3 Conclusion

4.3.1	LO(A)EL maternal toxic effects	[redacted]
4.3.2	NO(A)EL maternal toxic effects	NOEL = 300 mg/kg bw/day.
[redacted]		
4.3.4	NO(A)EL embryotoxic / teratogenic effects	NOEL = 300 mg/kg bw/day
[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	5 January 2007
Materials and Methods	Applicants version is acceptable. It is noted that the active ingredient was 92.6% purity and 80% trans isomer instead of 98% trans isomer.

Section 6.8.1(1)
Teratogenicity study -Rat

Annex Point IIA6.8.1 **IUCLID 5.8.2/1**	[redacted]
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

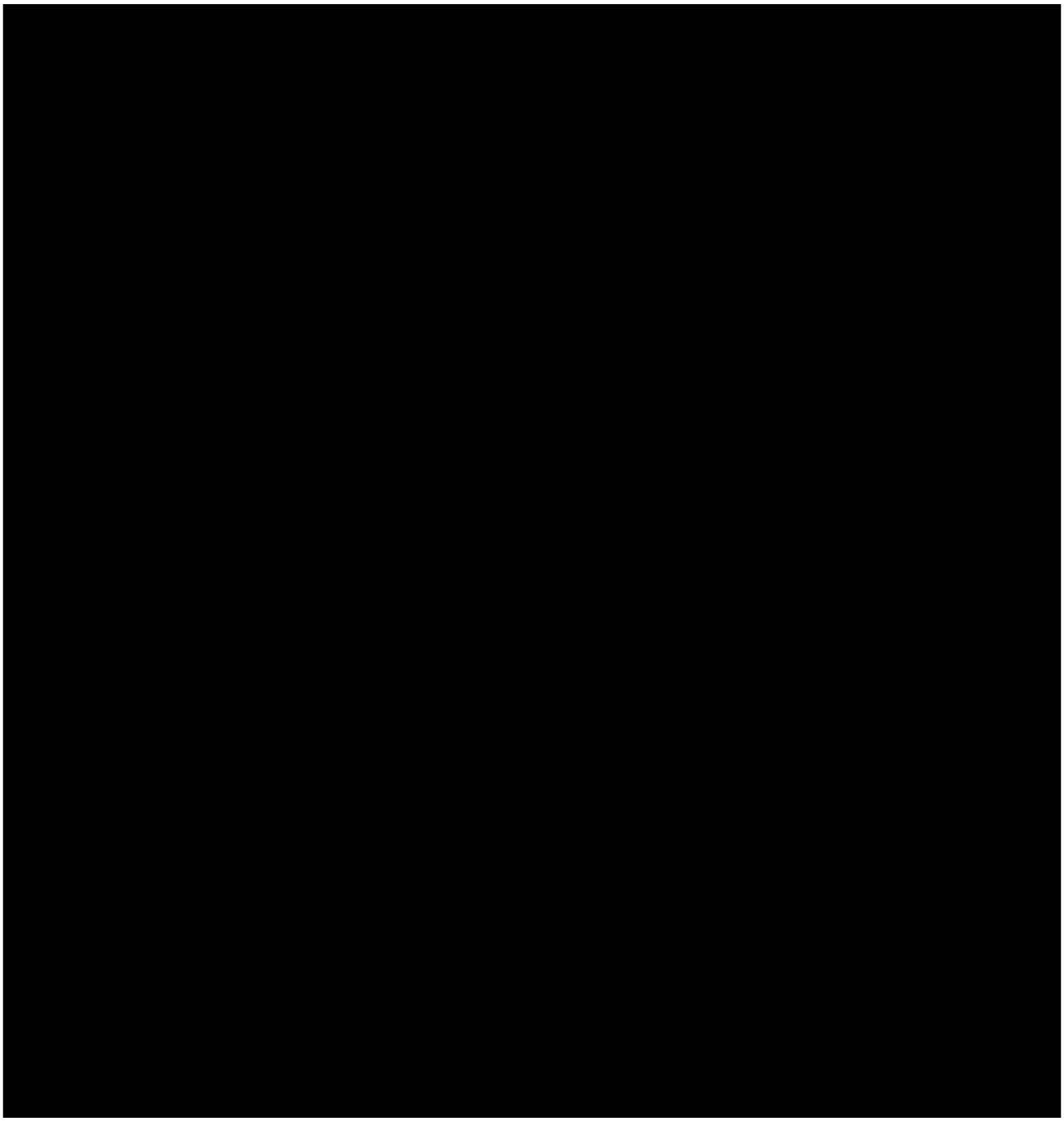
Section 6.8.1(1)
Teratogenicity study -Rat

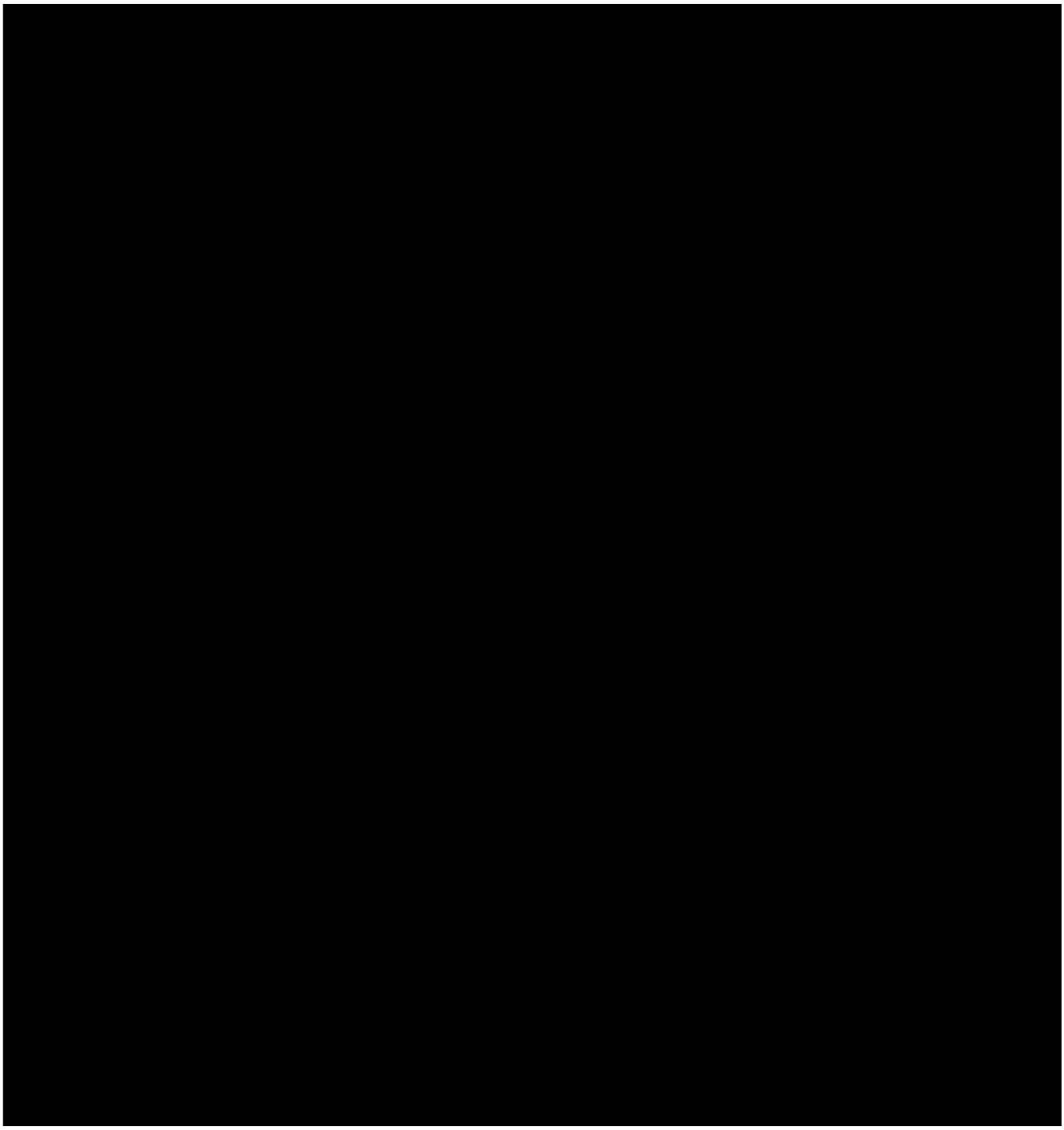
Annex Point IIA6.8.1

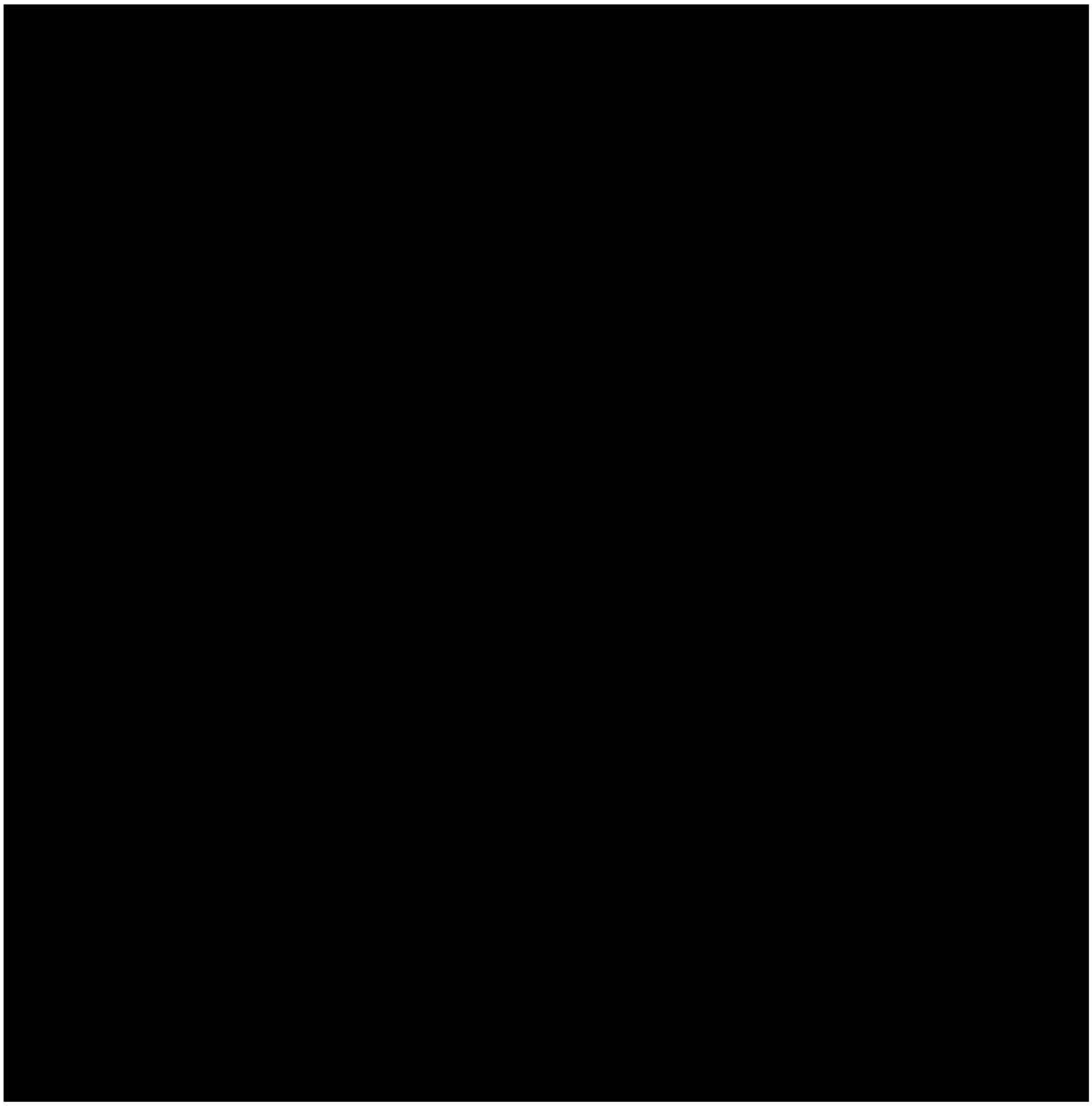
IUCLID 5.8.2/1

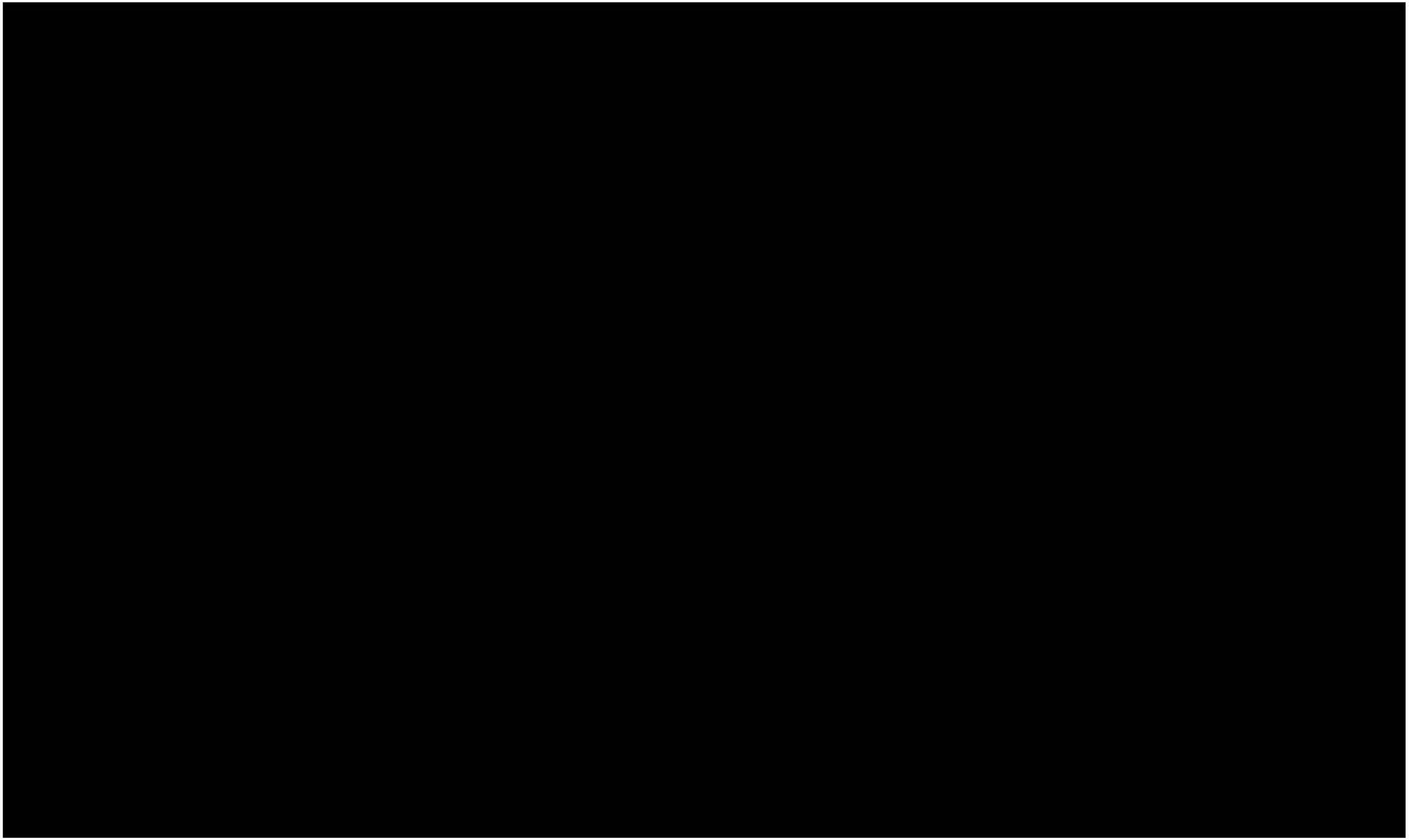
Teratogenicity study in the rat

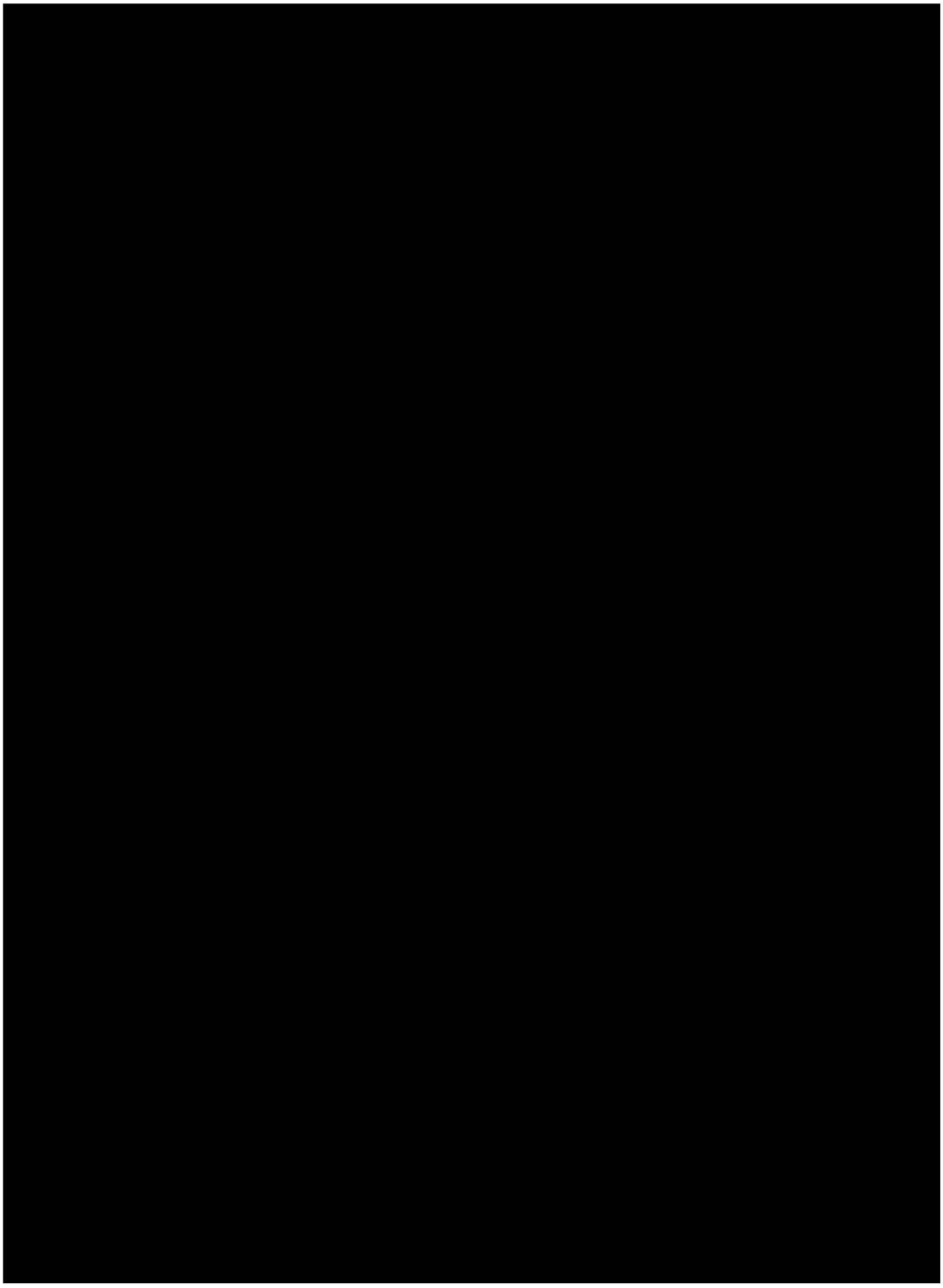
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating 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 6.8.1(2)
Teratogenicity study - Rabbit

Annex Point IIA6.8.1

IUCLID 5.8.2/1 **Teratogenicity study in the rabbit**

			Official use only
		33 REFERENCE	
1.1	**Reference**	[redacted]	
1.2	**Data protection**		
1.2.1	Data owner	Sumitomo Chemicals Co., Ltd.	
1.2.2	Companies with letter of access	Sumitomo Chemical (UK) PLC.	
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	The study was performed to US EPA Pesticide assessment Guidelines, Subdivision F, 83-3. The requirements under the above guideline are essentially equivalent to OECD Test Guideline 414 (adopted 22 January 2001).	
2.2	**GLP**	Yes	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted] d-Phenothrin.	
3.1.1	Lot/Batch number	[redacted]	
3.1.2	Specification	[redacted]	
3.1.2.1	Description	[redacted]	
3.1.2.2	Purity		
3.1.2.3	Stability		
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		

Section 6.8.1(2)
Teratogenicity study - Rabbit

Annex Point IIA6.8.1

IUCLID 5.8.2/1		**Teratogenicity study in the rabbit**
3.2.5	Age/weight at study initiation	[redacted]
3.2.6	Number of animals per group	20
3.2.7	Control animals	Yes
3.2.8	Mating period	Not specified.
3.3	**Administration/ Exposure**	Oral
3.3.1	Duration of exposure	From day 7 to 19 of gestation.
3.3.2	Postexposure period	All females were killed on Day 29 post-coitum.
3.3.3	Type	Oral Gavage
3.3.4	Concentration	[redacted]
3.3.5	Vehicle	[redacted]
3.3.6	Concentration in vehicle	See point 3.3.4.
3.3.7	Total volume applied	5 ml/kg.
3.3.8	Controls	Vehicle only.
3.4	**Examinations**	
3.4.1	Body weight	Individual maternal body weights were recorded individually on gestation days 0, 7, 8, 10, 13, 16, 19, 20, 23, 26 and 29.
3.4.2	Food consumption	Individual food consumption was recorded daily from days 0 through 29 of gestation.

Group No	Dose Level (mg/kg bw/d)	Dose Conc. (mg/ml)	Dosage Volume (ml/kg)
1	0	0	5.0
2	30	6	5.0
3	100	20	5.0
4	300	60	5.0
5	500	100	5.0

Section 6.8.1(2)
Teratogenicity study - Rabbit

Annex Point IIA6.8.1

IUCLID 5.8.2/1

[redacted]

3.4.3 Clinical signs

3.4.4 Examination of uterine content

3.4.5 Examination of foetuses

3.4.5.1 General

3.4.5.2 Skelet

3.4.5.3 Soft tissue

3.5 Further remarks

3.6 Maternal toxic Effects

Section 6.8.1(2)
Teratogenicity study - Rabbit

Annex Point IIA6.8.1

IUCLID 5.8.2/1

[redacted]

Section 6.8.1(2)
Teratogenicity study - Rabbit

Annex Point IIA6.8.1

IUCLID 5.8.2/1

[redacted]

Section 6.8.1(2)
Teratogenicity study - Rabbit

Annex Point IIA6.8.1

IUCLID 5.8.2/1

[redacted]

3.7 Teratogenic / embryotoxic effects

Section 6.8.1(2)
Teratogenicity study - Rabbit

Annex Point IIA6.8.1

IUCLID 5.8.2/1

[redacted]

3.8 Other effects

4.1 Materials and methods

4.2 Results and discussion

Section 6.8.1(2)
Teratogenicity study - Rabbit

Annex Point IIA6.8.1

IUCLID 5.8.2/1

[redacted]

Section 6.8.1(2)
Teratogenicity study - Rabbit

Annex Point IIA6.8.1

IUCLID 5.8.2/1

[redacted]

4.3 Conclusion

4.3.1	LO(A)EL maternal toxic effects	[redacted]
4.3.2	NO(A)EL maternal toxic effects	NOEL = 100 mg/kg bw/day.
4.3.3	[redacted]	
4.3.4	NO(A)EL embryotoxic / teratogenic effects	NOEL = 300 mg/kg bw/day

[redacted]

Section 6.8.1(2)
Teratogenicity study - Rabbit

Annex Point IIA6.8.1 **IUCLID 5.8.2/1**	[redacted]
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section 6.8.1(2)
Teratogenicity study - Rabbit

Annex Point IIA6.8.1

IUCLID 5.8.2/1

[redacted]

Section 6.8.1(2)
Teratogenicity study - Rabbit

Annex Point IIA6.8.1

IUCLID 5.8.2/1 **Teratogenicity study in the rabbit**

	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 A6.8.1(3) **Teratogenicity study**
Annex Point IIA6.8.1 **Developmental Toxicity Study in the Rabbit**

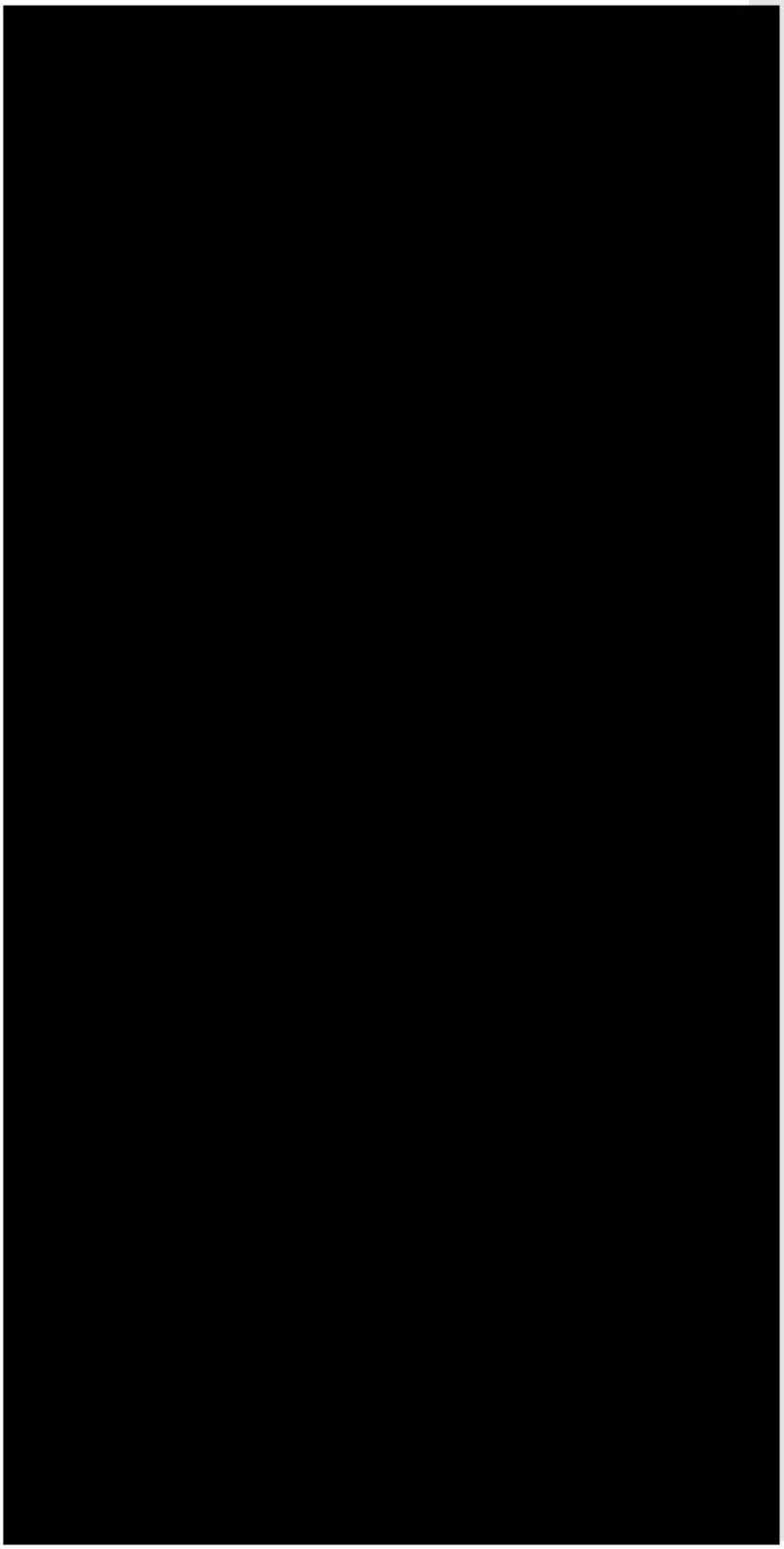
			Official use only
		35 REFERENCE	
35.1	**Reference**	[redacted]	
35.2	**Data protection**	Yes	
35.2.1	Data owner	Sumitomo Chemicals Co., Ltd.	
35.2.2	Companies with letter of access	Sumitomo Chemical (UK) PLC.	
35.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I.	
		36 GUIDELINES AND QUALITY ASSURANCE	
36.1	**Guideline study**	OECD Test Guideline 414 (adopted 22 January 2001).	
36.2	**GLP**	[redacted]	[redacted]
36.3	**Deviations**		
		37 MATERIALS AND METHODS	
37.1	**Test material**	[redacted]d-Phenothrin.	
37.1.1	Lot/Batch number	[redacted]	
37.1.2	Specification		

Section A6.8.1(3)		**Teratogenicity study**
Annex Point IIA6.8.1		**Developmental Toxicity Study in the Rabbit**
37.1.2.1	Description	[redacted]
37.1.2.2	Purity	
37.1.2.3	Stability	
37.2	**Test Animals**	
37.2.1	Species	Rabbit
37.2.2	Strain	[redacted]
37.2.3	Source	
37.2.4	Sex	
37.2.5	Age/weight at study initiation	[redacted]
37.2.6	Number of animals per group	[redacted]
37.2.7	Control animals	Yes
37.2.8	Mating period	The rabbits were mated on four consecutive days.
37.3	**Administration/ Exposure**	Oral
37.3.1	Duration of exposure	From day 6 to 28 of (presumed) gestation.
37.3.2	Postexposure period	Caesarean-Sectioning: day 29 of (presumed) gestation.
37.3.3	Type	[redacted]
37.3.4	Concentration	
37.3.5	Vehicle	
37.3.6	Concentration in vehicle	
37.3.7	Total volume applied	
37.3.8	Controls	

Section A6.8.1(3) **Teratogenicity study**
Annex Point IIA6.8.1 **Developmental Toxicity Study in the Rabbit**

37.4	**Examinations**	[redacted]
37.4.1	Body weight	
37.4.2	Food consumption	
37.4.3	Clinical signs	
37.4.4	Examination of uterine content	
37.4.5	Examination of foetuses	
37.4.5.1	General	
37.4.5.2	Skelet	
37.4.5.3	Soft tissue	
37.5	**Further remarks**	
38.1	**Maternal toxic Effects**	

Section A6.8.1(3) Teratogenicity study
Annex Point IIA6.8.1 Developmental Toxicity Study in the Rabbit

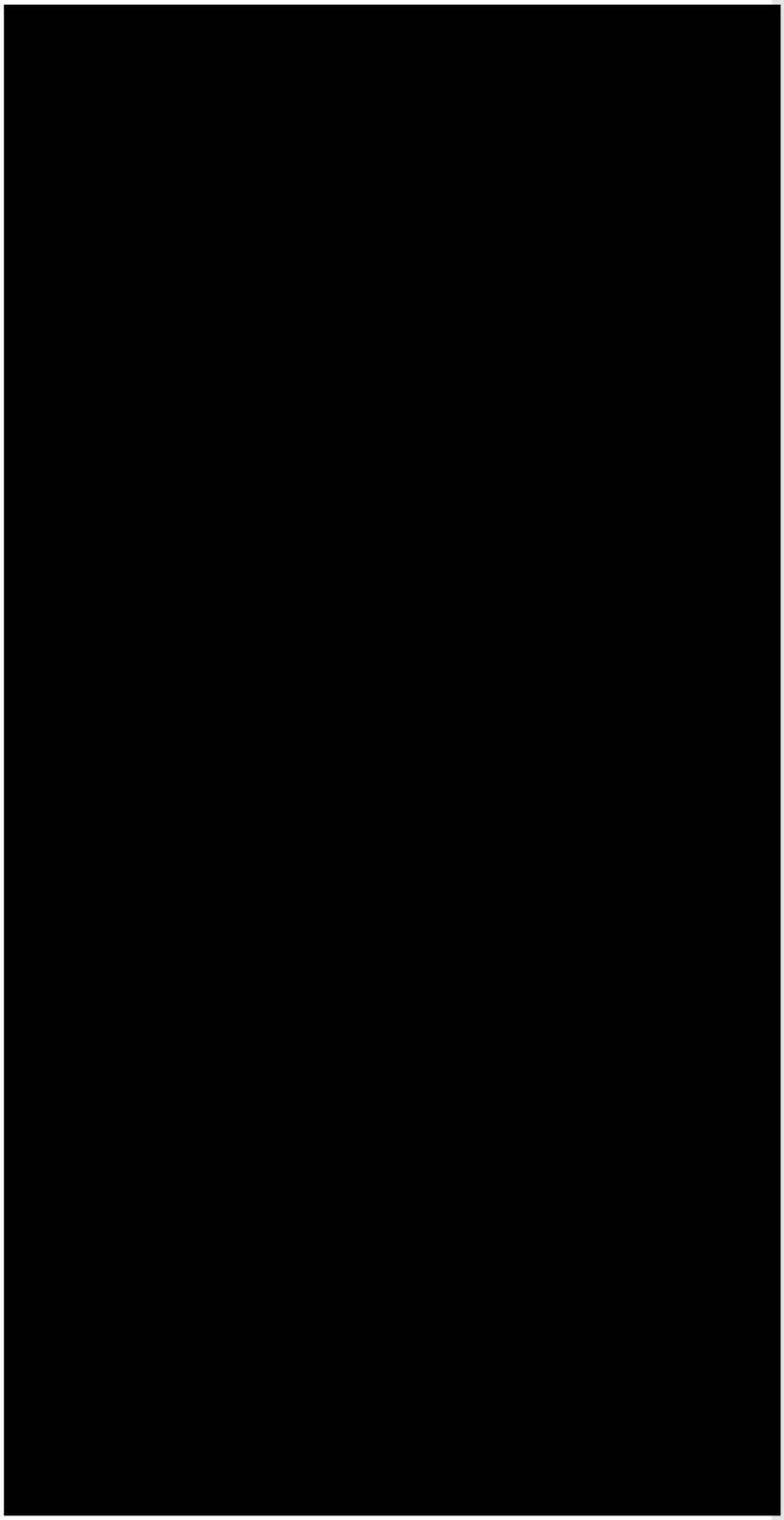


Section A6.8.1(3)	**Teratogenicity study**
Annex Point IIA6.8.1	**Developmental Toxicity Study in the Rabbit**

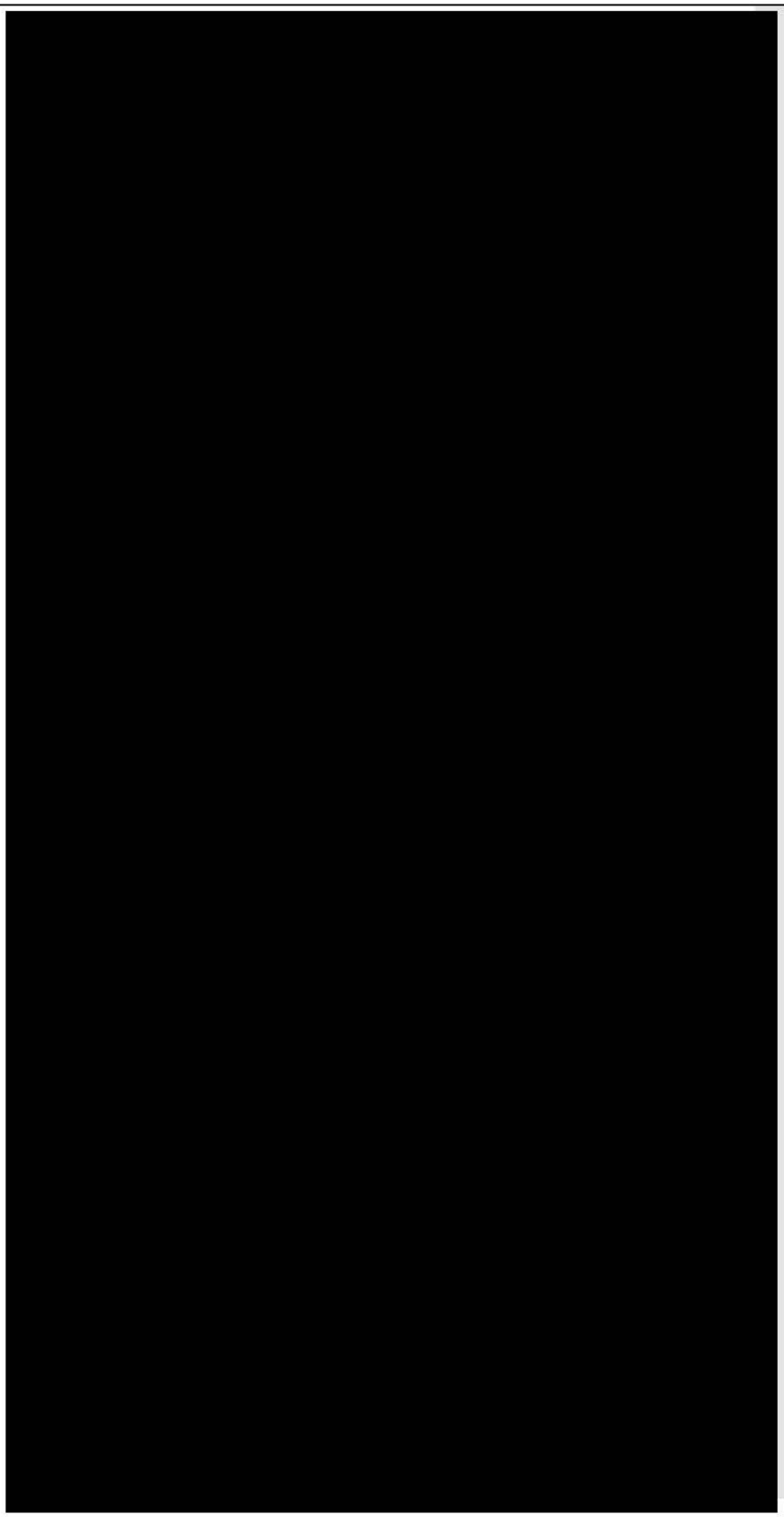
[redacted]

38.2 Teratogenic / embryotoxic effects

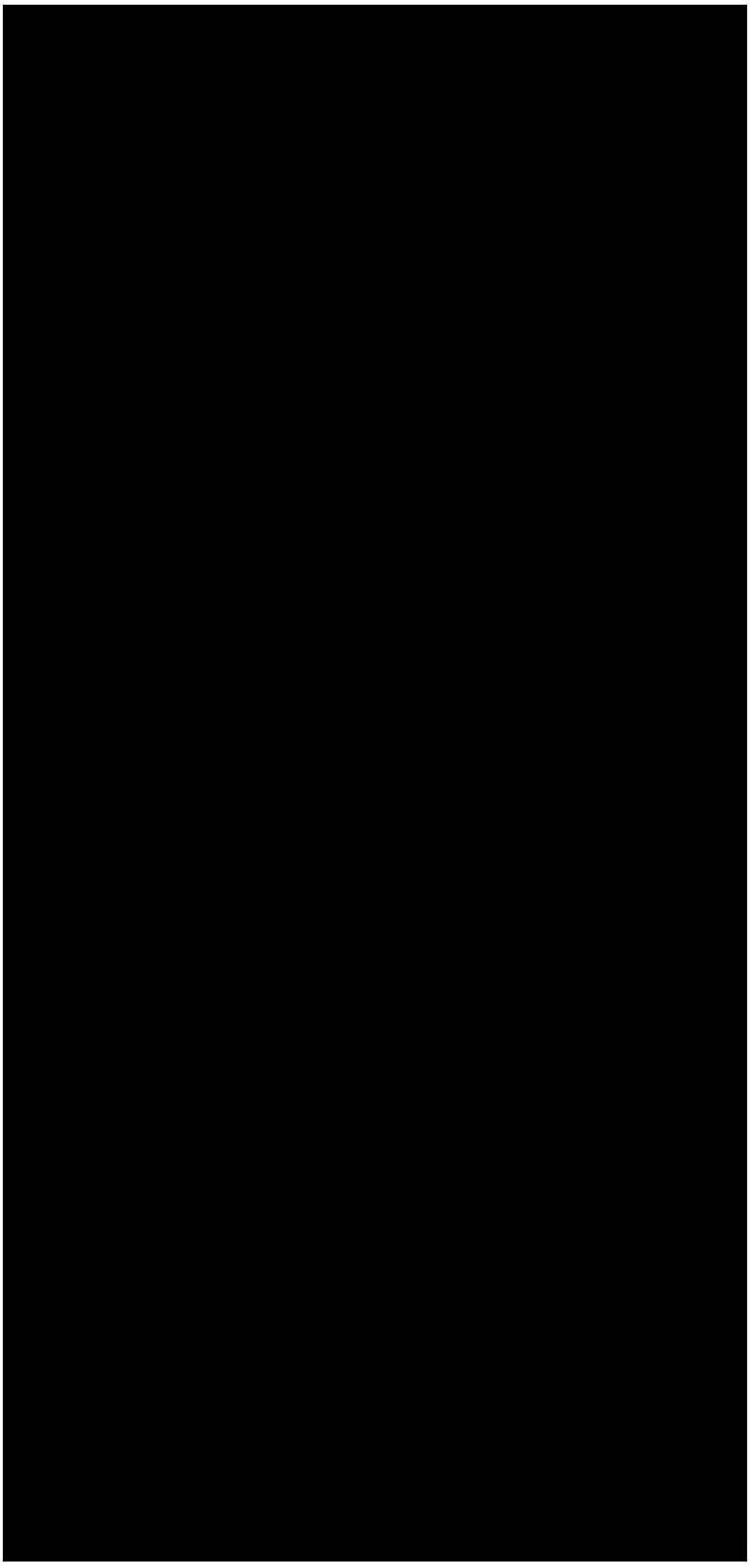
Section A6.8.1(3)	Teratogenicity study
Annex Point IIA6.8.1	Developmental Toxicity Study in the Rabbit



Section A6.8.1(3) Teratogenicity study
Annex Point IIA6.8.1 Developmental Toxicity Study in the Rabbit



Section A6.8.1(3)	Teratogenicity study
Annex Point IIA6.8.1	Developmental Toxicity Study in the Rabbit



Section A6.8.1(3) **Teratogenicity study**

Annex Point IIA6.8.1 **Developmental Toxicity Study in the Rabbit**

[redacted]

38.3 **Other effects**

39.1 **Materials and methods**

39.2 **Results and discussion**

Section A6.8.1(3) **Teratogenicity study**

Annex Point IIA6.8.1 **Developmental Toxicity Study in the Rabbit**

[redacted]

39.3 Conclusion

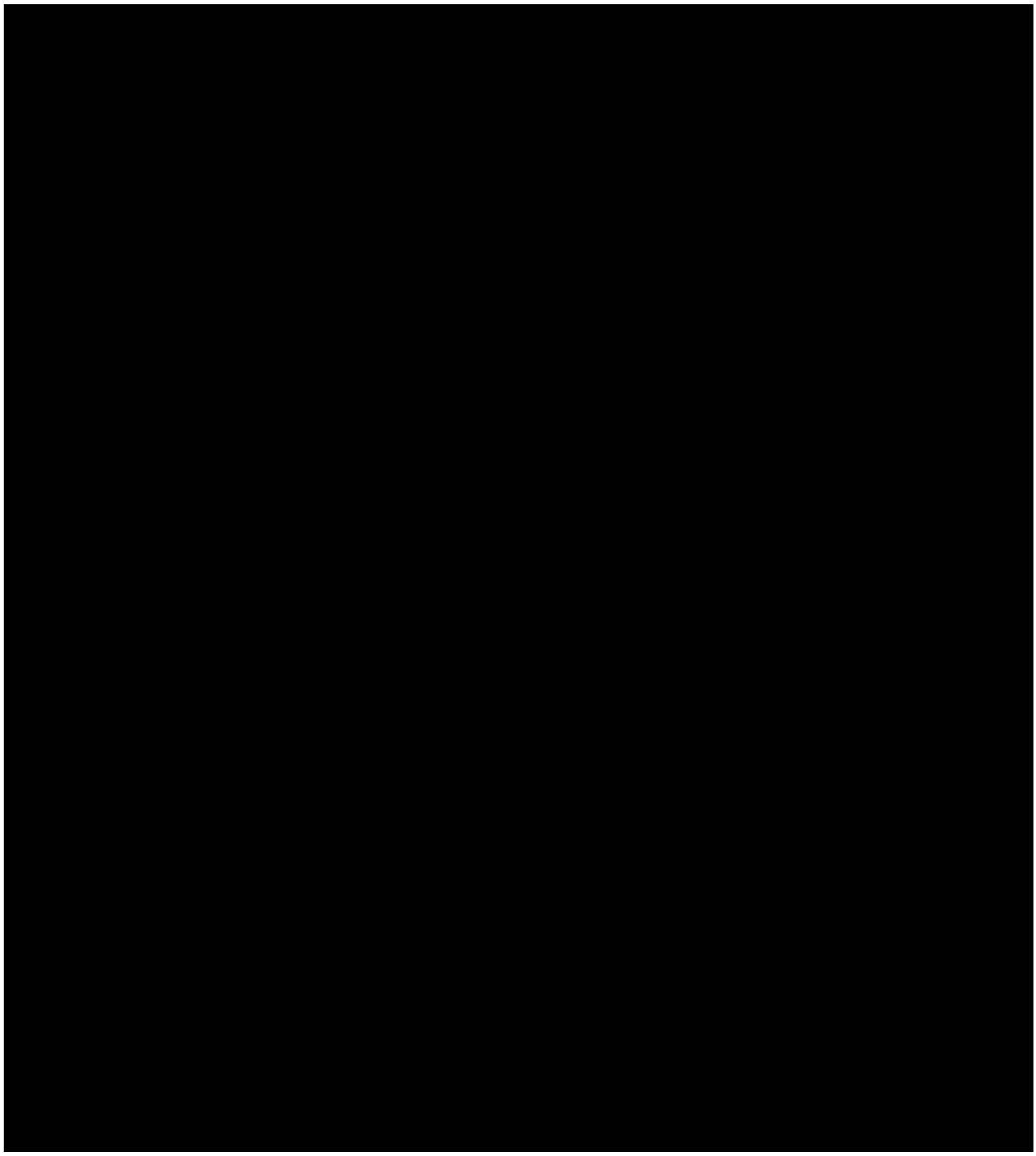
39.3.1	LO(A)EL maternal toxic effects	[redacted]
39.3.2	NO(A)EL maternal toxic effects	[redacted]
39.3.3	LO(A)EL embryotoxic / teratogenic effects	LOAEL = 750 mg/kg bw/day [redacted]
39.3.4	NO(A)EL embryotoxic / teratogenic effects	[redacted]
39.3.5	Reliability	[redacted]
39.3.6	Deficiencies	[redacted]

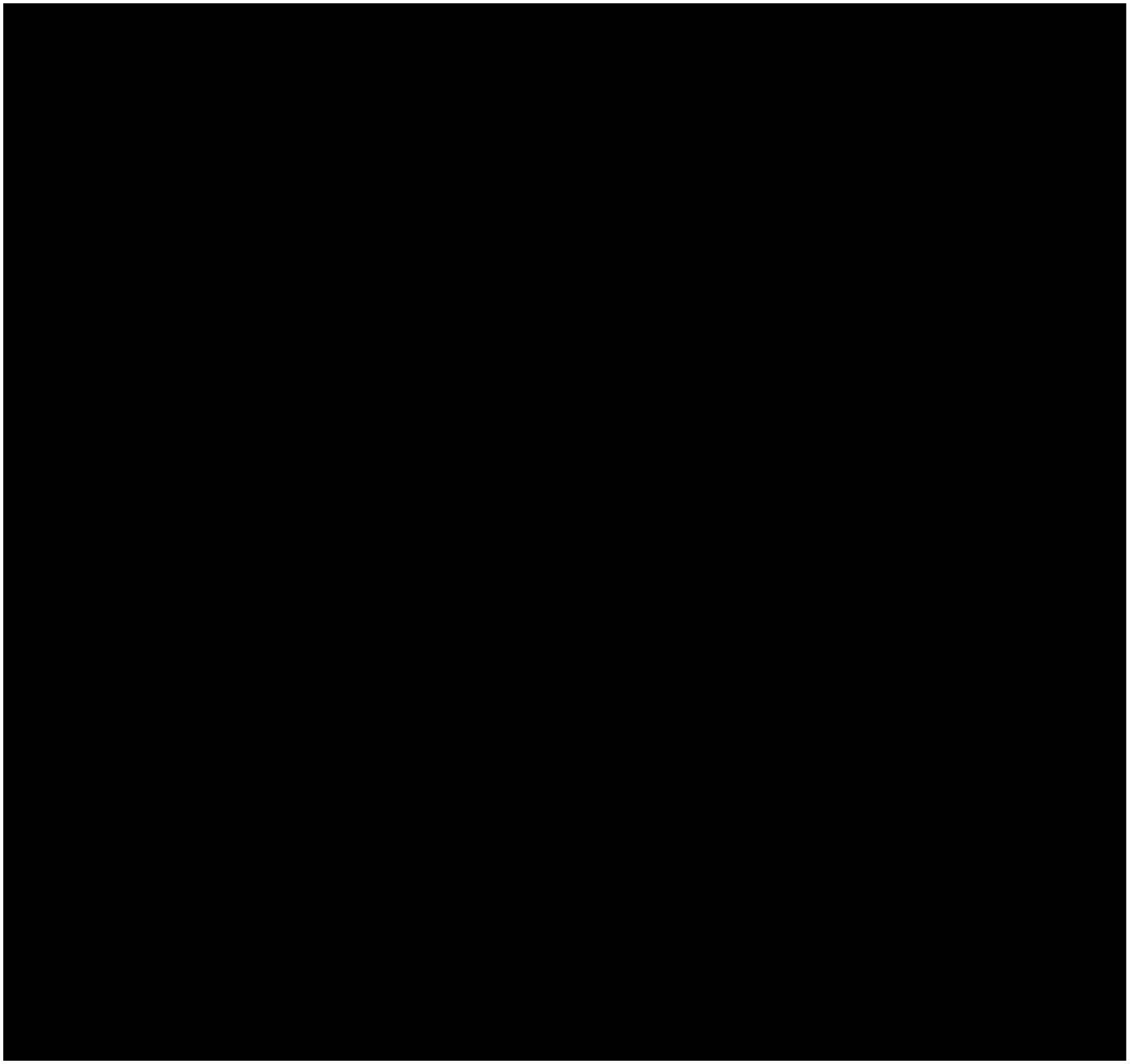
Section A6.8.1(3) **Teratogenicity study**
Annex Point IIA6.8.1 **Developmental Toxicity Study in the Rabbit**

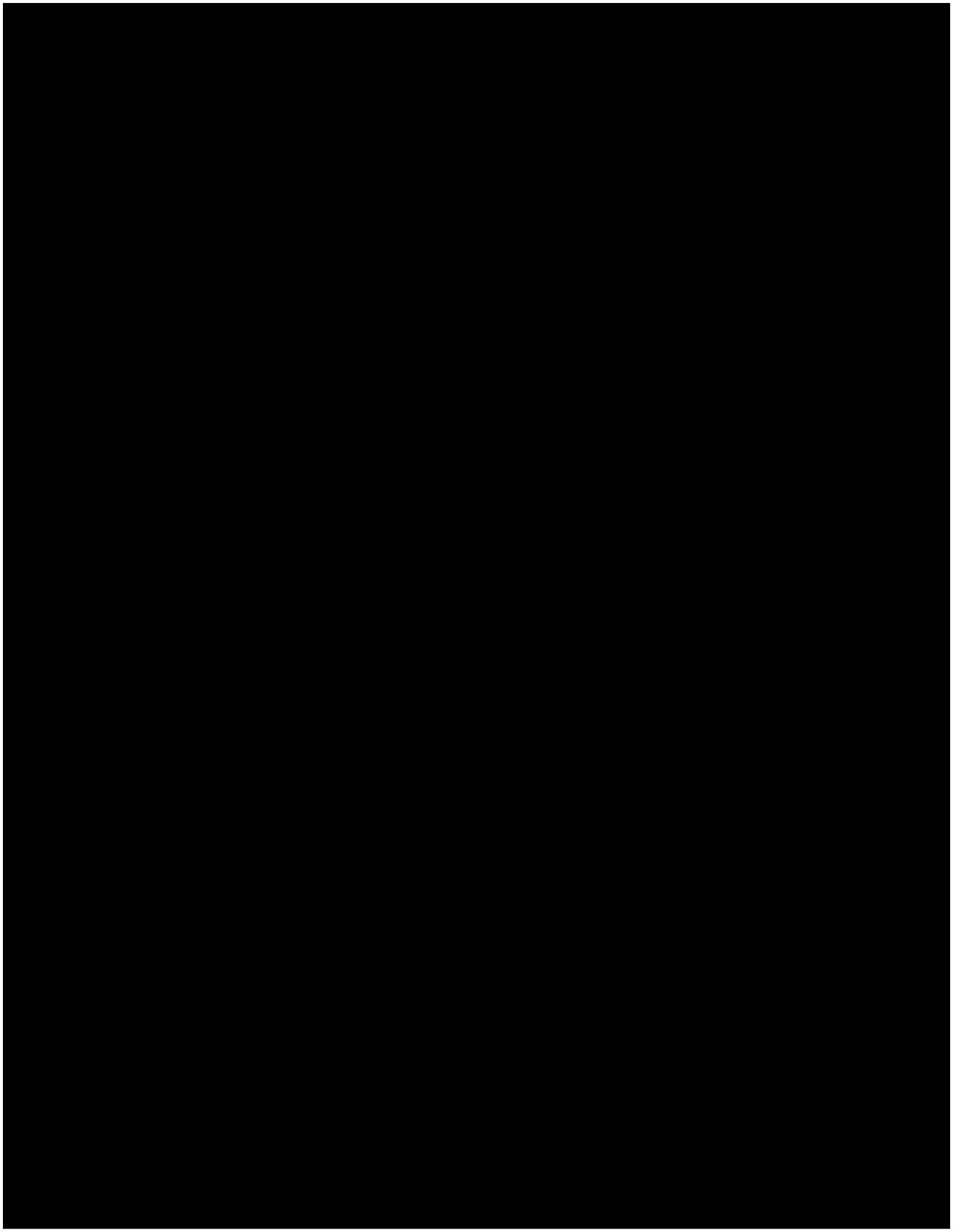
	[redacted]
	[redacted]ion boxes" to provide transparency as to the [redacted]omments and views submitted
Date	[redacted]
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	No additional remarks
	COMMENTS FROM ...
Date	*Give date of comments submitted*

Section A6.8.1(3)	**Teratogenicity study**
Annex Point IIA6.8.1	**Developmental Toxicity Study in the Rabbit**

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	

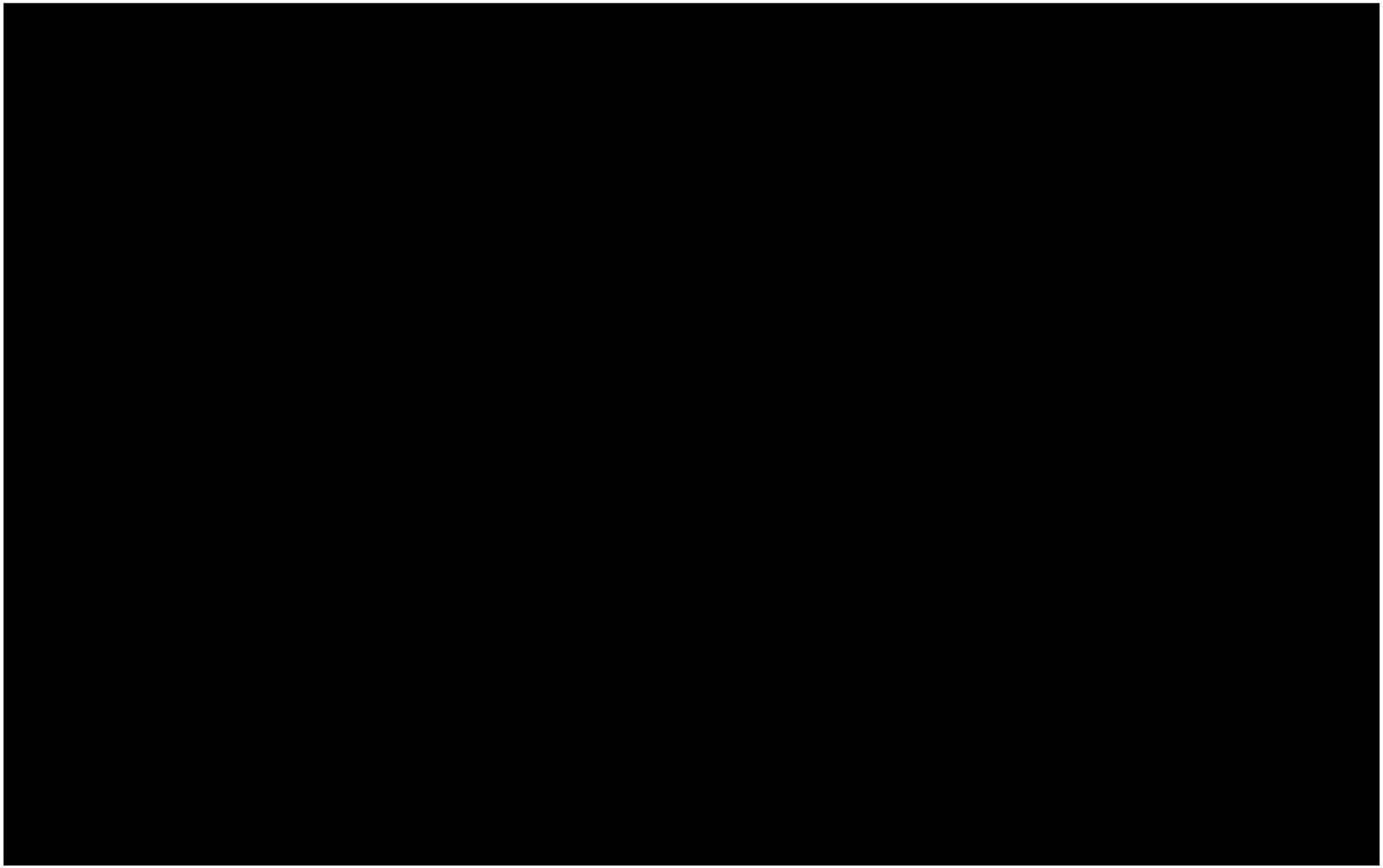


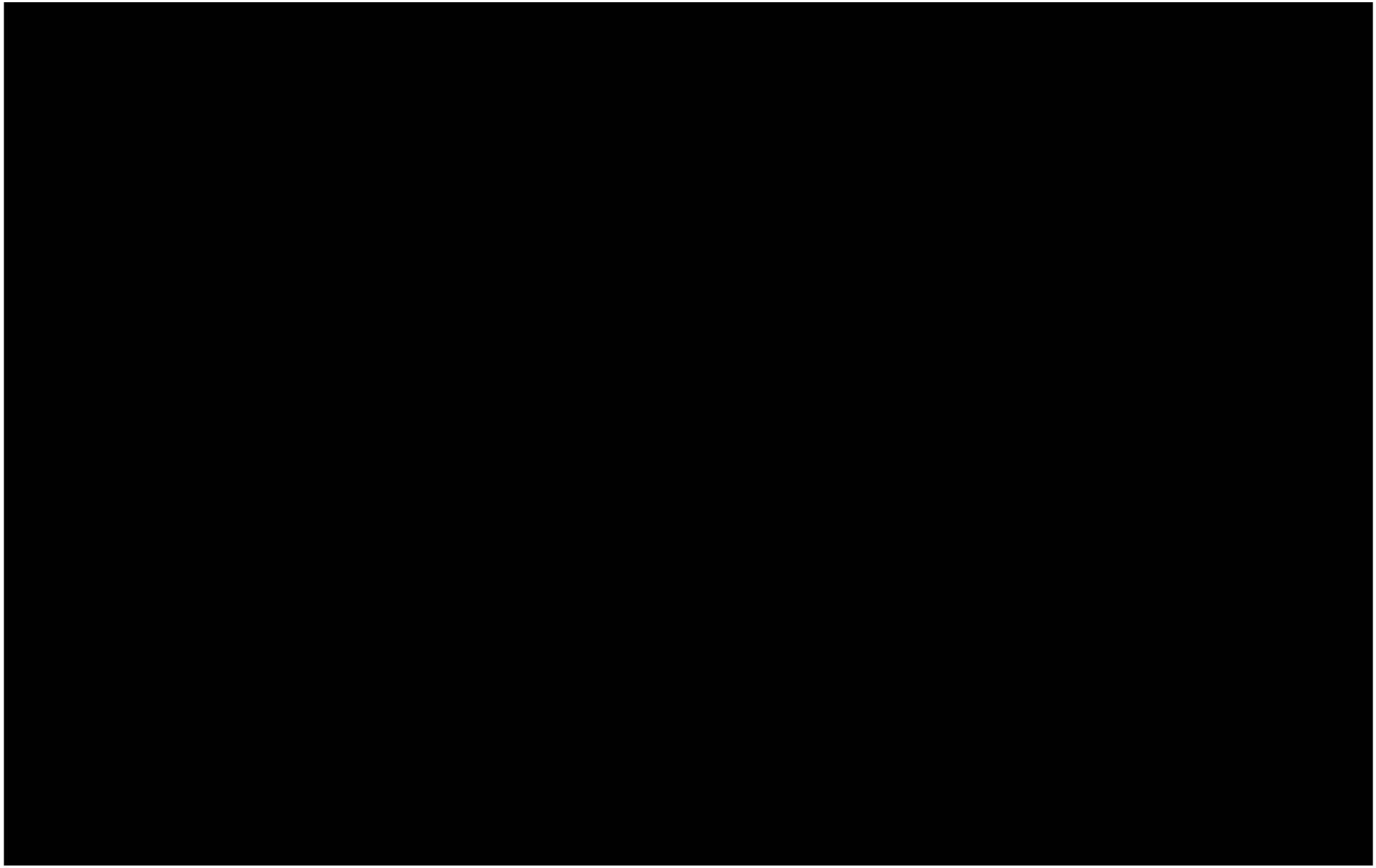


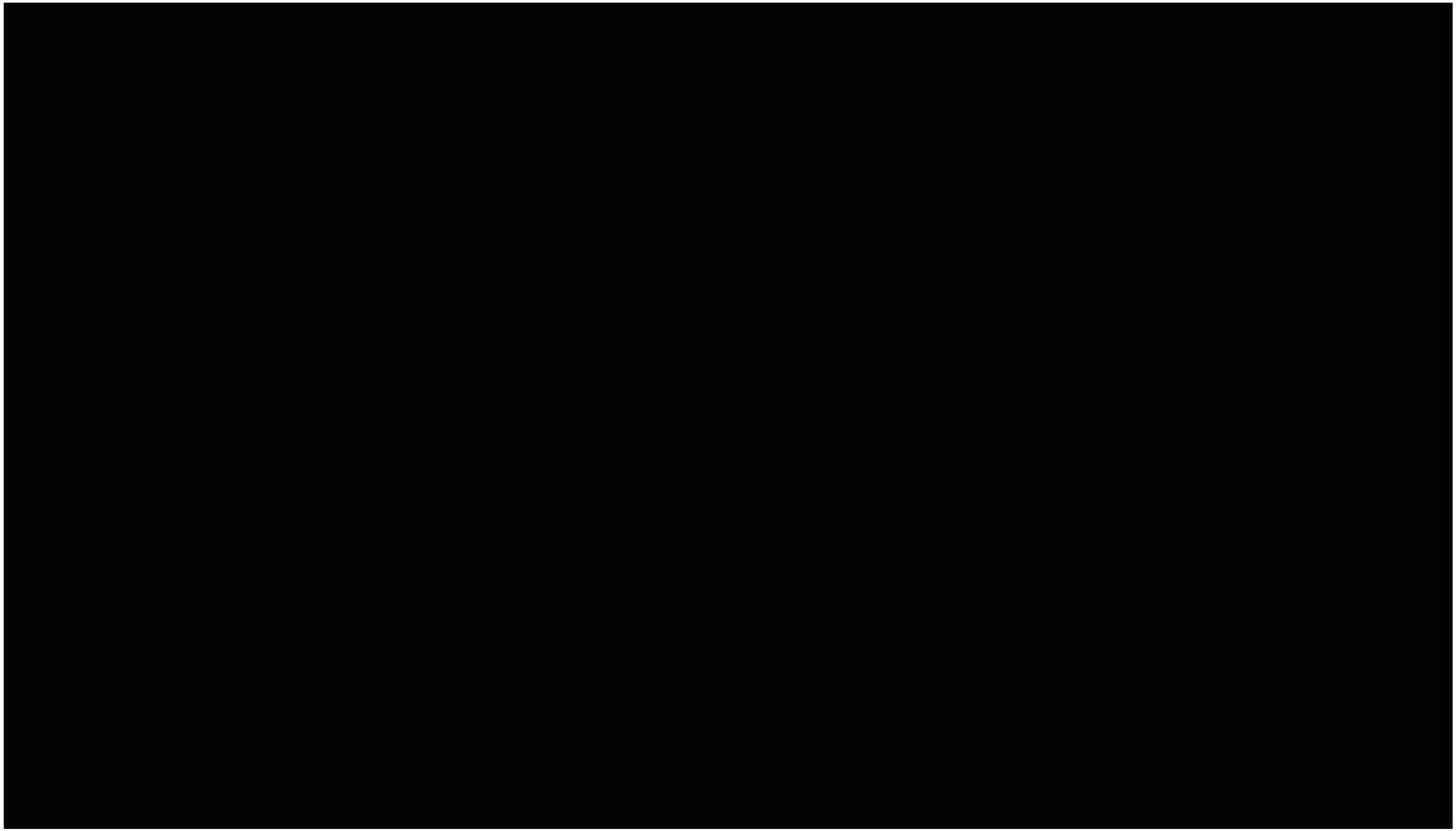


[redacted]

[redacted]







6.8.2 Multigeneration reproduction toxicity

Annex Point IIA6.8.2

IUCLID 5.8.1/1

Two generation dietary reproduction study in rats

			Official use only
		40 REFERENCE	
1.1	**Reference**	[redacted]	
1.2	**Data protection**	Yes	
1.2.1	Data owner	Sumitomo Chemical Co., Ltd.	
1.2.2	Companies with letter of access	Sumitomo Chemical (UK) PLC.	
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	[redacted] OECD Test Guideline 416 (adopted 22 January 2001) [redacted]	
2.2	**GLP**	[redacted]	
2.3	**Deviations**		
		3 MATERIALS AND METHODS	
3.1	**Test material**	[redacted] d-Phenothrin [redacted]	
3.1.1	Lot/Batch number		
3.1.2	Specification	[redacted]	
3.1.2.1	Description		
3.1.2.2	Purity		
3.1.2.3	Stability		
3.2	**Test Animals**	*Non-entry field*	

6.8.2 Multigeneration reproduction toxicity

Annex Point IIA6.8.2

IUCLID 5.8.1/1

Two generation dietary reproduction study in rats

3.2.1	Species	Rat
3.2.2	Strain	[redacted]
3.2.3	Source	
3.2.4	Sex	
3.2.5	Age/weight at study initiation	[redacted]
3.2.6	Number of animals per group	[redacted]. See Table A.6.8.2-1.
3.2.7	Mating	[redacted]
3.2.8	Duration of matin	
3.2.9	Deviations from standard protocol	
3.2.10	Control animals	
3.3	**Administration/ Exposure**	
3.3.1	Animal assignme to dosage groups	
3.3.2	Duration of exposure before mating	
3.3.3	Duration of exposure in gener P, F1, F2 males, females	
3.3.4	Type	Oral Via the diet.

6.8.2 Multigeneration reproduction toxicity

Annex Point IIA6.8.2

IUCLID 5.8.1/1

Two generation dietary reproduction study in rats

3.3.5	Concentration	[redacted]
3.3.6	Vehicle	
3.3.7	Concentration in vehicle	
3.3.8	Total volume applied	
3.3.9	Controls	
3.4	**Examinations**	
3.4.1	Clinical signs	
3.4.2	Body weight	
3.4.3	Food/water consumption	
3.4.4	Oestrus cycle	
3.4.5	Sperm parameters	
3.4.6	Offspring	

of

rs

6.8.2 Multigeneration reproduction toxicity

Annex Point IIA6.8.2

IUCLID 5.8.1/1

Two generation dietary reproduction study in rats

[redacted]

3.4.7 Organ weights P and F1

3.4.8 Histopathology P and F1

6.8.2 Multigeneration reproduction toxicity	
Annex Point IIA6.8.2	
IUCLID 5.8.1/1	**Two generation dietary reproduction study in rats**

[redacted]

3.4.9 Histopathology F1 not selected f mating, F2

3.5 Further remark

3.6 Effects

3.6.1 Parent males

6.8.2 Multigeneration reproduction toxicity

Annex Point IIA6.8.2

IUCLID 5.8.1/1

Two generation dietary reproduction study in rats

[redacted]

3.6.2 Parent females

3.6.3 F1 males

6.8.2 Multigeneration reproduction toxicity	
Annex Point IIA6.8.2	
IUCLID 5.8.1/1	**Two generation dietary reproduction study in rats**

[redacted]

3.6.4 F1 females

3.6.5 F2 males

3.6.6 F2 females

3.7 Other

4.1 Materials and methods

6.8.2 Multigeneration reproduction toxicity

Annex Point IIA6.8.2

IUCLID 5.8.1/1

[redacted]

4.2 Results and discussion

4.3 Conclusion

4.3.1	LO(A)EL	
4.3.1.1	Parent males	> 3000 ppm No reproductive toxicity was seen at any concentration.
4.3.1.2	Parent females	3000 ppm (increased absolute and relative liver weight). No reproductive toxicity was seen at any concentration.
4.3.1.3	F1 males	> 3000 ppm No reproductive toxicity was seen at any concentration.
4.3.1.4	F1 females	3000 ppm ([redacted] No reproductive toxicity was seen at any concentration.
4.3.1.5	F2 males	3000 ppm (increased relative liver weight in F2B weanlings).
4.3.1.6	F2 females	3000 ppm (increased relative liver weight in F2B weanlings).

6.8.2 Multigeneration reproduction toxicity

Annex Point IIA6.8.2

IUCLID 5.8.1/1 **Two generation dietary reproduction study in rats**

4.3.2	NO(A)EL	*Non-entry field*
4.3.2.1	Parent males	3000 ppm
4.3.2.2	Parent females	1000 ppm (the lowest equivalent intake was seen in F0 females at first paring and was ca. 60 mg/kg bw/day).
4.3.2.3	F1 males	3000 ppm
4.3.2.4	F1 females	1000 ppm
4.3.2.5	F2 males	1000 ppm
4.3.2.6	F2 females	1000 ppm

[redacted]

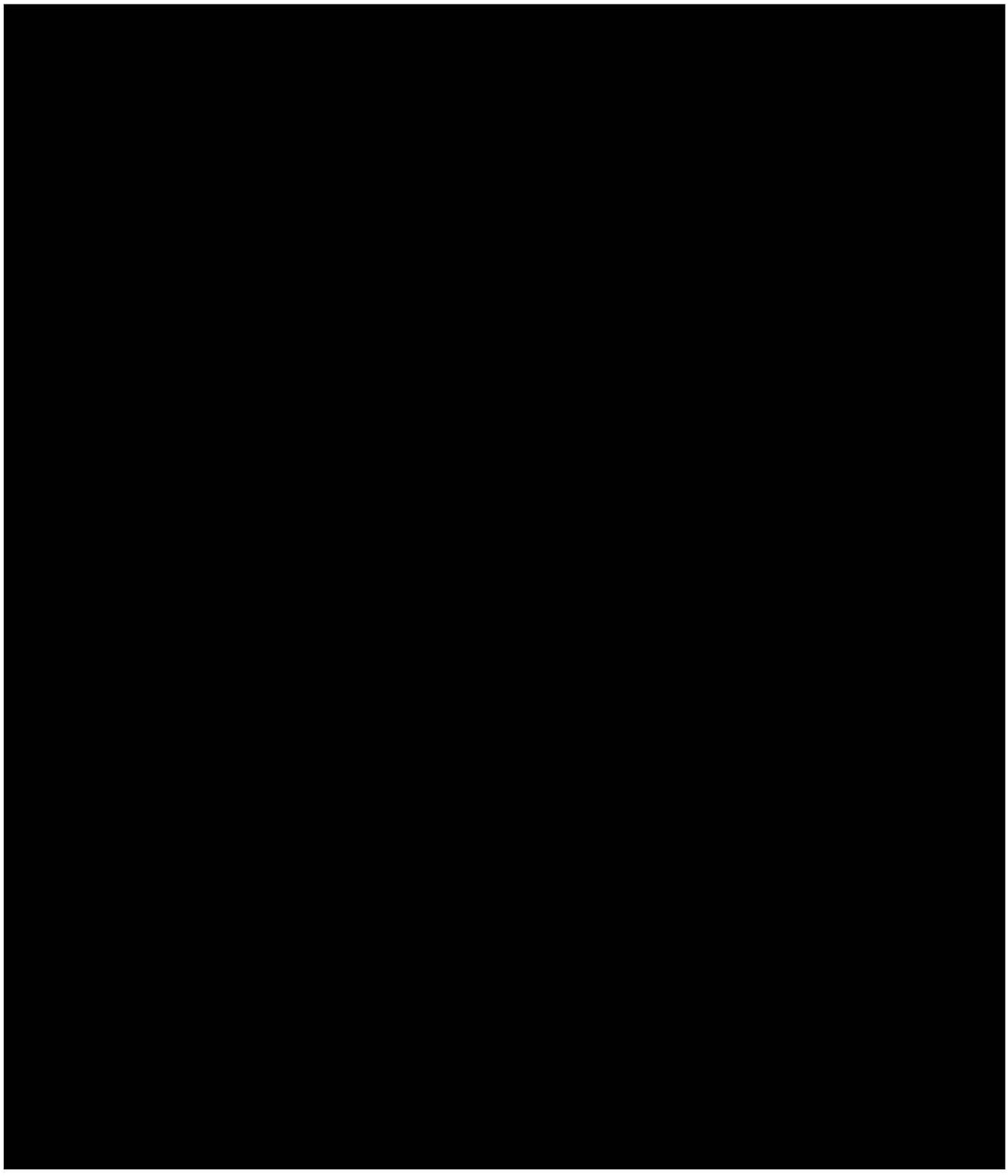
6.8.2 Multigeneration reproduction toxicity

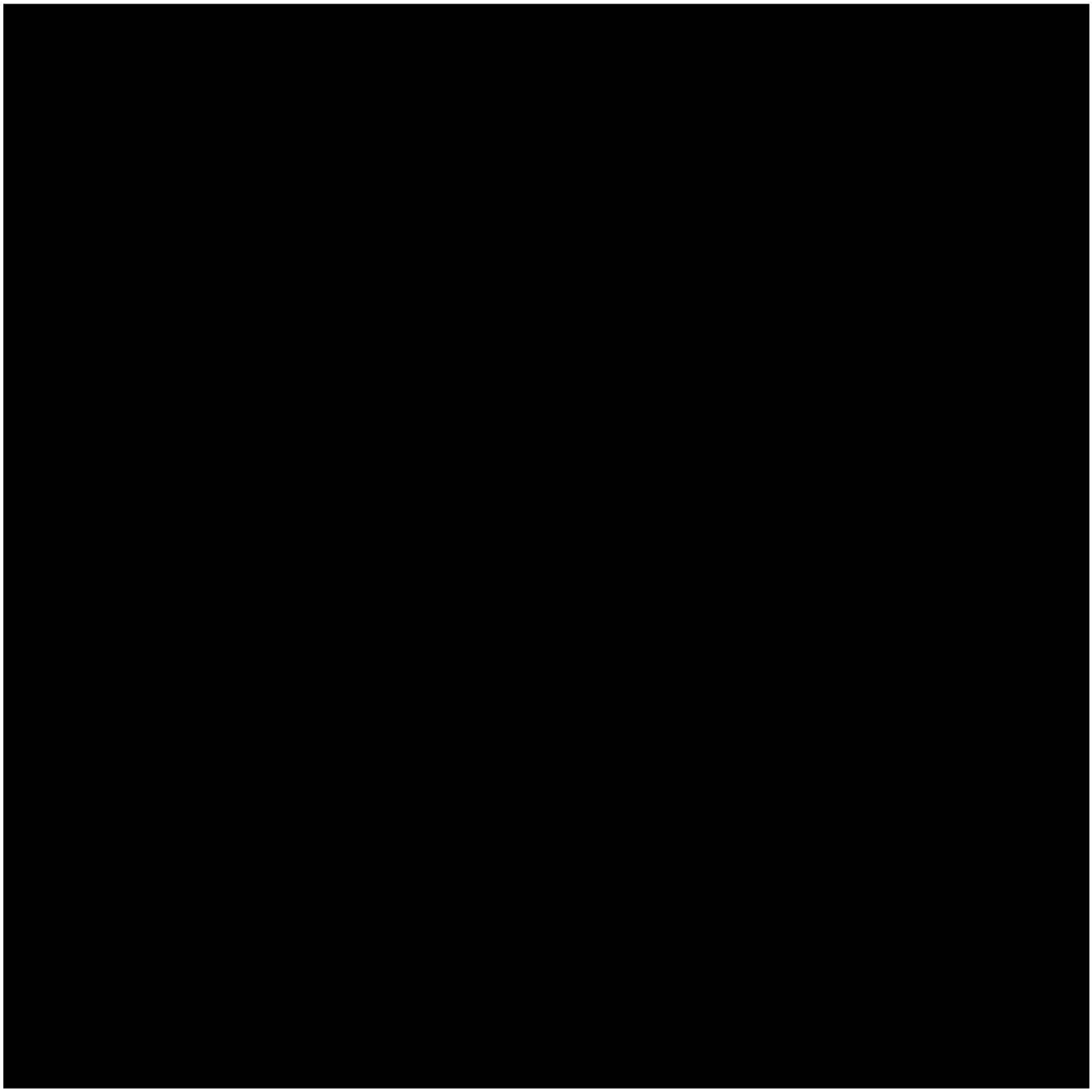
Annex Point IIA6.8.2

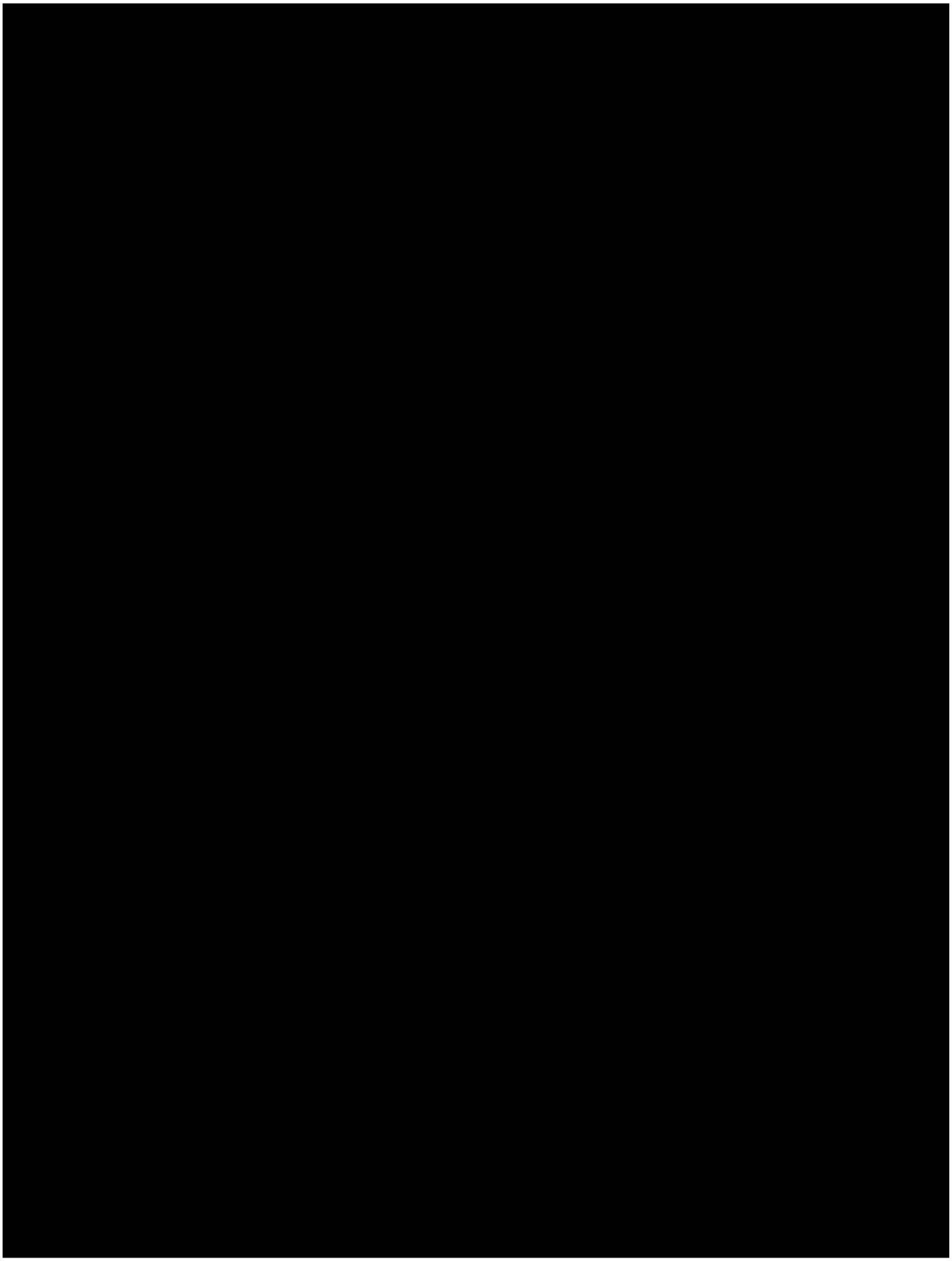
IUCLID 5.8.1/1

Two generation dietary reproduction study in rats

	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 6.9 Repeat dose neurotoxicity

Annex Point IIIA VI.1 **Subacute oral (gavage) neurotoxicity study in rats**

IUCLID 5.9/3

Official use only

42 REFERENCE

1.1	**Reference**	[redacted]
1.2	**Data protection**	Yes
1.2.1	Data owner	Sumitomo Chemical Co., Ltd.
1.2.2	Companies with letter of access	Sumitomo Chemical (UK) PLC.
1.2.3	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I/IA.

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	[redacted]
2.2	**GLP**	
2.3	**Deviations**	

3 MATERIALS AND METHODS

3.1	**Test material**	d-Phenothrin [redacted]
3.1.1	Lot/Batch number	[redacted]
3.1.2	Specification	
3.1.2.1	Description	
3.1.2.2	Purity	
3.1.2.3	Stability	
3.2	**Reference Substance (positive control)**	
3.3	**Test Animals**	*Non-entry field*
3.3.1	Species	Rat
3.3.2	Strain	[redacted]
3.3.3	Source	
3.3.4	Sex	
3.3.5	Rearing conditions	

Section 6.9 Repeat dose neurotoxicity

Annex Point IIIA VI.1 **Subacute oral (gavage) neurotoxicity study in rats**

IUCLID 5.9/3

[redacted]

3.3.6 Age/weight at study initiation

3.3.7 Number of animals per group

3.3.8 Control animals

3.4 Administration

3.4.1 Exposure

3.4.2 Dose Levels

3.4.3 Vehicle

3.4.4 Concentration in vehicle

3.4.5 Total volume applied

3.4.6 Postexposure period

3.4.7 Anticholinergic substances used

3.4.8 Controls

3.5 Examinations

3.5.1 Body Weight

3.5.2 Signs of Toxicity

3.5.3 Observation schedule

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

4.2 Clinical signs of toxicity

[redacted]

Section 6.9 Repeat dose neurotoxicity

Annex Point IIIA VI.1 **Subacute oral (gavage) neurotoxicity study in rats**

IUCLID 5.9/3

[redacted]

4.3 Clinical Chemistry

4.4 Pathology

4.5 Histopathology

[redacted]

4.6 Other None

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

[redacted]

5.2 Results and discussion

5.3 Conclusion

5.3.1 LOAEL

Section 6.9 Repeat dose neurotoxicity

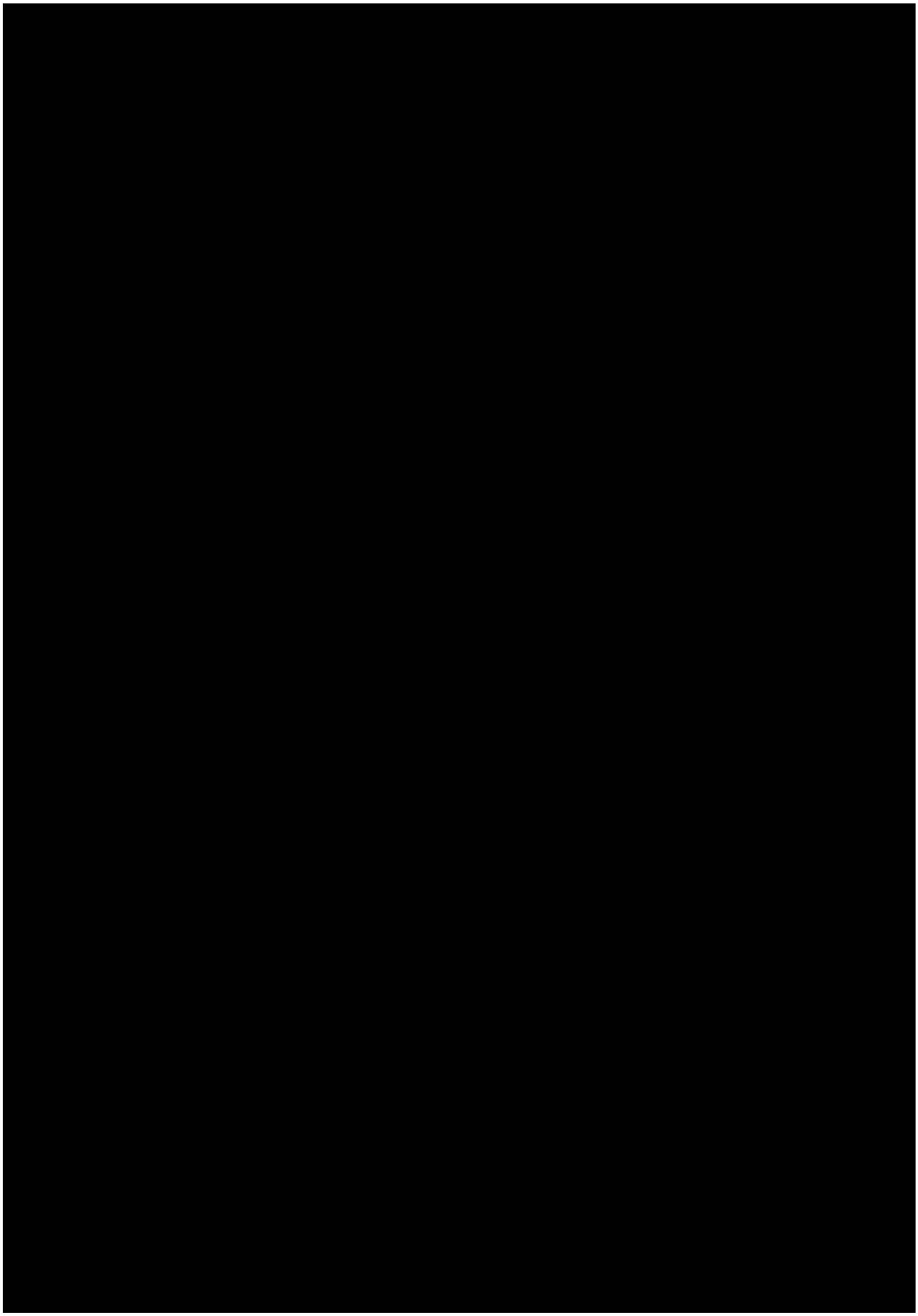
Annex Point IIIA VI.1 **Subacute oral (gavage) neurotoxicity study in rats**

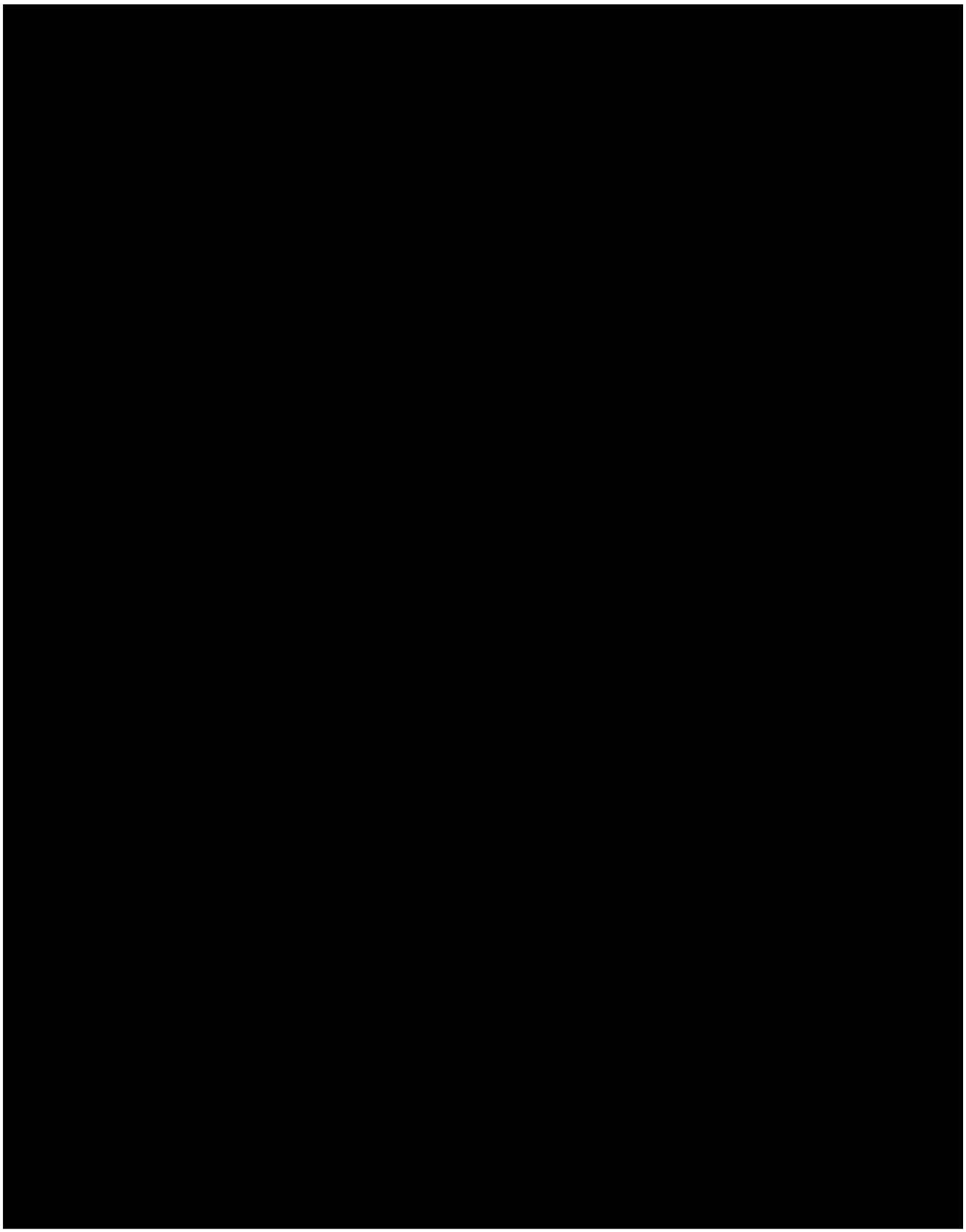
IUCLID 5.9/3

		[redacted]
5.3.2	NOAEL	The NOAEL for neurotoxic effects was 5000 mg/kg bw/day.
5.3.3	Reliability	[redacted]
5.3.4	Deficiencies	[redacted]

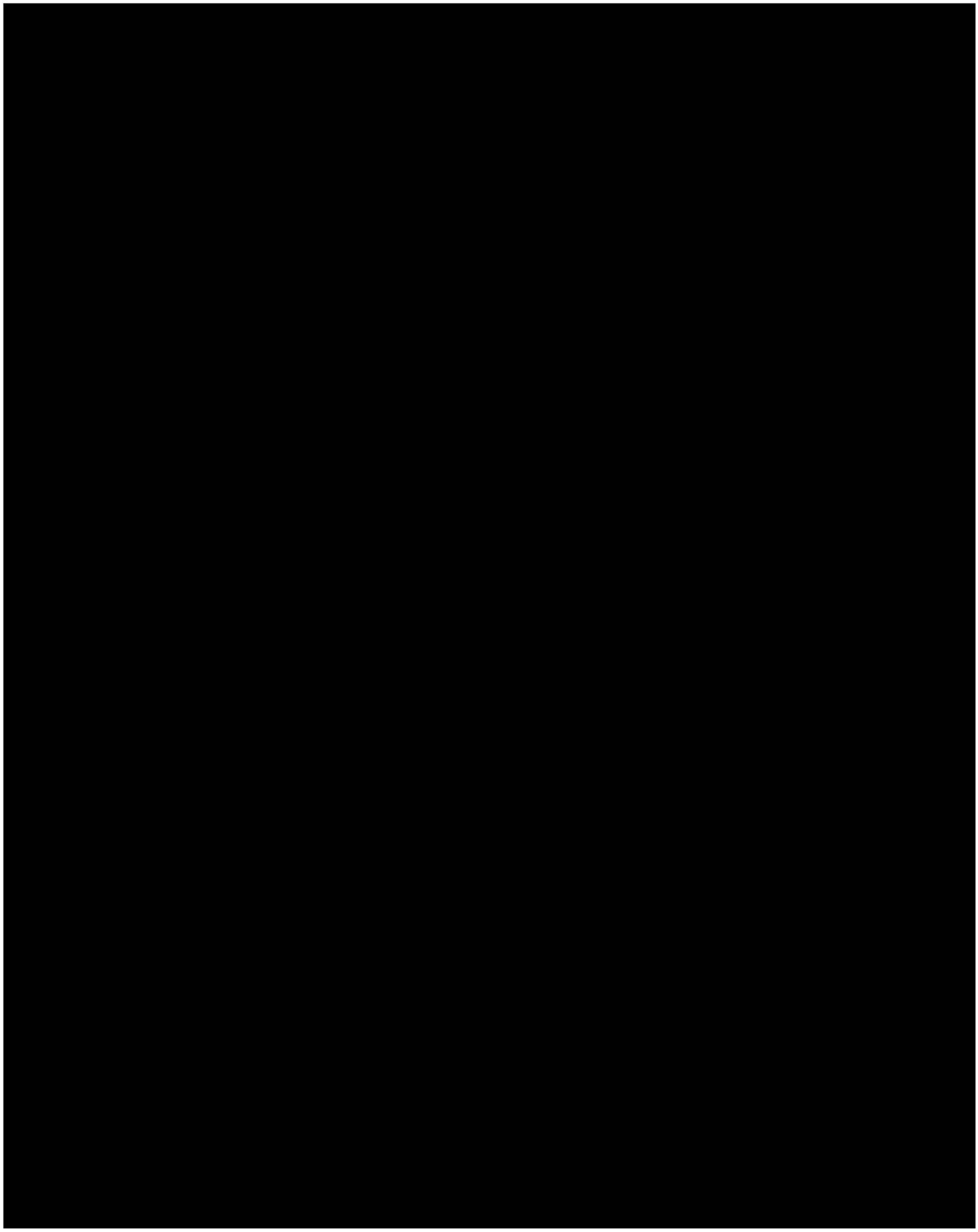
Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
Date	[redacted]
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	
Date	
Materials and Methods	
Results and discussion	
Conclusion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

Section 6.9 Repeat dose neurotoxicity	
Annex Point IIIA VI.1	**Subacute oral (gavage) neurotoxicity study in rats**
IUCLID 5.9/3	
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	





[redacted]



Section A6.12.1 Medical surveillance

Annex Point IIA6.9.1 **Surveillance of factory workers exposed to pyrethroids**

IUCLID 5.10/1

		43 REFERENCE	Official use only
1.1	**Reference**	[redacted]	
3.1	**Substance**		
3.2	**Persons exposed**		
3.2.1	Sex	[redacted]	
3.2.2	Age/weight		
3.2.3	Known Diseases		
3.2.4	Number of persons		
3.2.5	Other information	None	
3.3	**Exposure**	Possible accidental inhalation and/or dermal exposure to workers during packaging operations.	
43.5.1	Reason of exposure	Occupational	
3.3.1	Frequency of exposure	Throughout entire working period.	
3.3.2	Overall time period of exposure	[redacted]	
3.3.3	Duration of single exposure	8h/working day	
3.3.4	Exposure concentration/dose	[redacted]	
3.3.5	Other information		

Section A6.12.1 Medical surveillance

Annex Point IIA6.9.1 **Surveillance of factory workers exposed to pyrethroids**

IUCLID 5.10/1

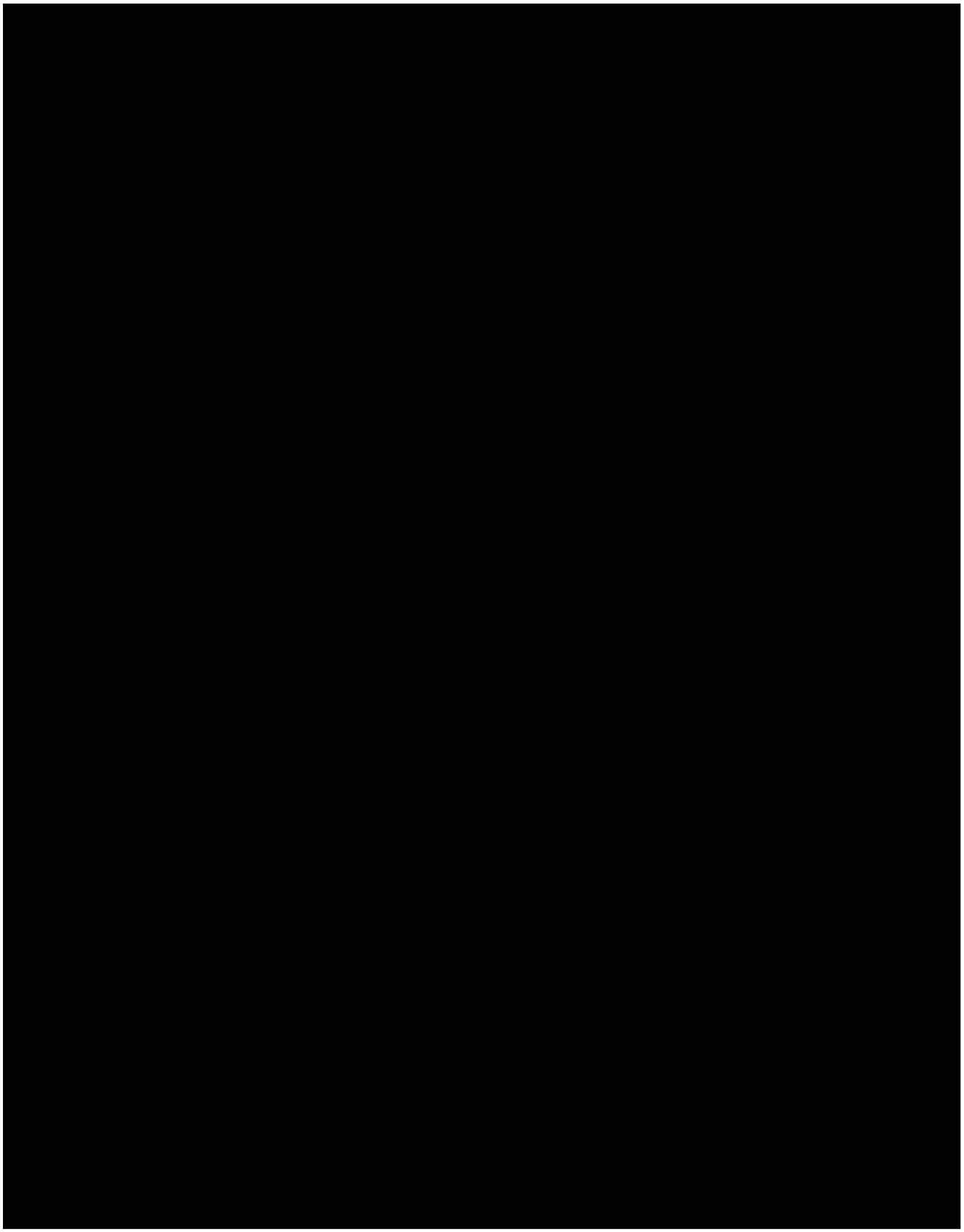
3.4	**Examinations**	[redacted]
3.5	**Treatment**	None
3.6	**Remarks**	None
		4 RESULTS
4.1	**Clinical signs**	Not applicable
4.2	**Results of examinations**	[redacted]

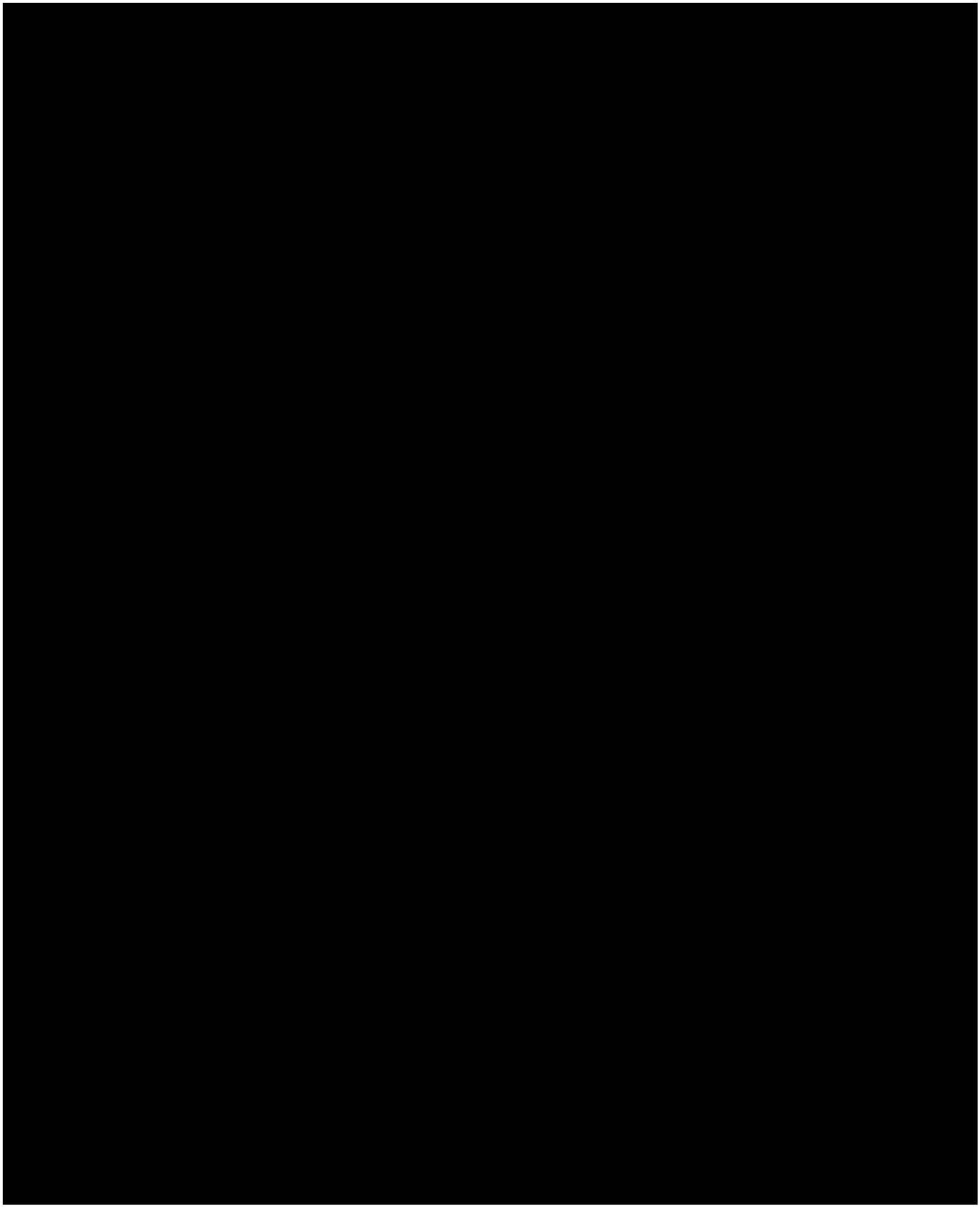
Section A6.12.1 Medical surveillance	
Annex Point IIA6.9.1	**Surveillance of factory workers exposed to pyrethroids**
IUCLID 5.10/1	

4.3	**Effectivity of medical treatment**	[redacted]
4.4	**Outcome**	
4.5	**Other**	
5.1	**Materials and methods**	
5.2	**Results and discussion**	
5.3	**Conclusion**	

Date	
Materials and Methods	
Results and discussion	
Conclusion	

Section A6.12.1 Medical surveillance	[redacted]
Annex Point IIA6.9.1	
IUCLID 5.10/1	
Remarks	
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Remarks	





Section 6.12.1 Medical surveillance

Annex Point IIA6.9.1

IUCLID 5.10/1

Surveillance of factory workers exposed to pyrethroids

			Official use only
		44 REFERENCE	
1.1	**Reference**	[redacted]	
		2 GUIDELINES AND QUALITY ASSURANCE (NOT APPLICABLE)	
3.1	**Substance**	[redacted]	
3.2	**Persons exposed**		
3.2.1	Sex		
3.2.2	Age/weight		
3.2.3	Known Diseases		
3.2.4	Number of persons		
3.2.5	Other information		
3.3	**Exposure**		
44.5.1	Reason of exposure		
3.3.1	Frequency of exposure		
3.3.2	Overall time period of exposure		
3.3.3	Duration of single exposure		
3.3.4	Exposure concentration/dose		
3.3.5	Other information		

Section 6.12.1 Medical surveillance	**Surveillance of factory workers exposed to pyrethroids**
Annex Point IIA6.9.1	
IUCLID 5.10/1	

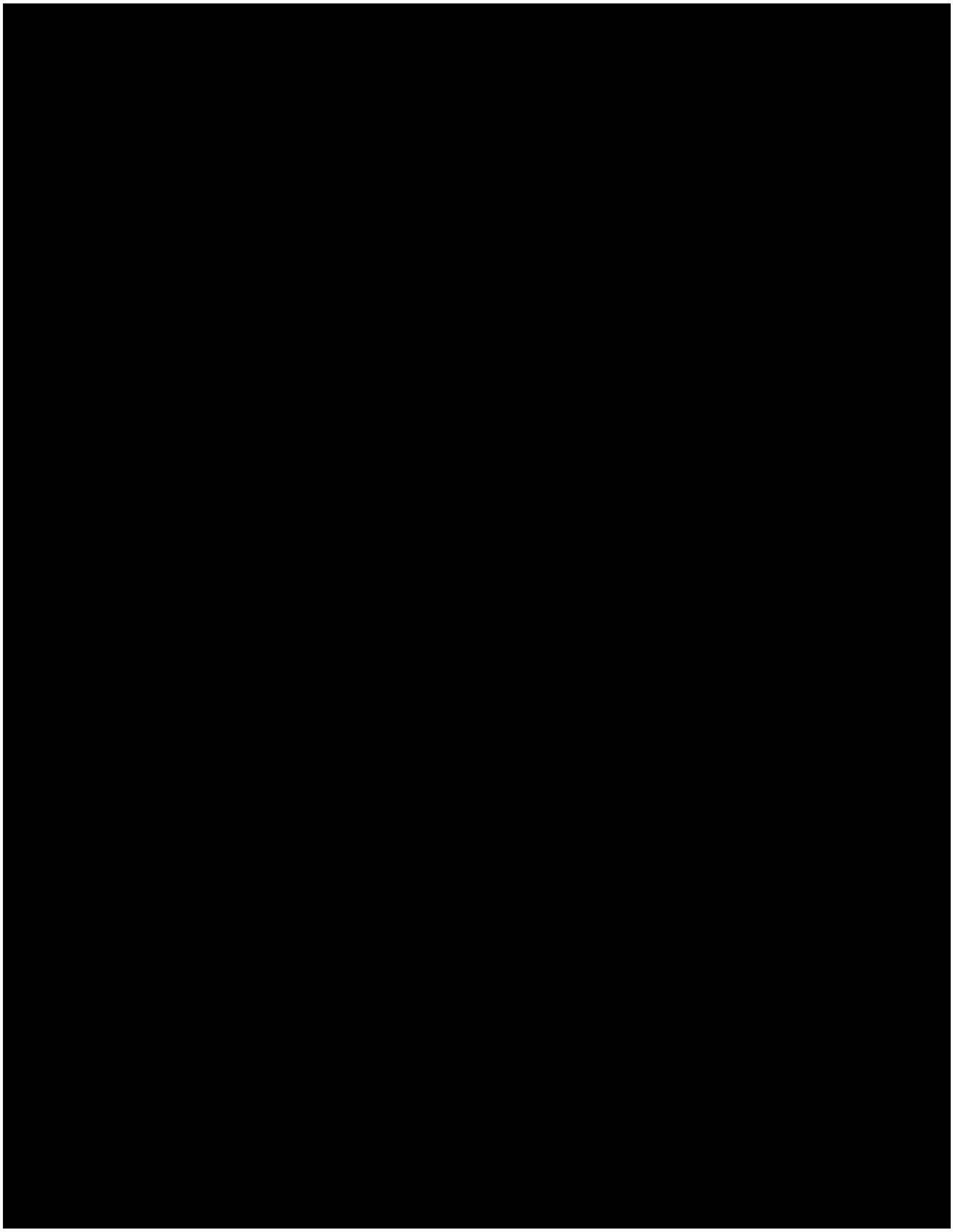
3.4	**Examinations**	[redacted]
3.5	**Treatment**	
3.6	**Remarks**	
		4 RESULTS
4.1	**Clinical signs**	Not applicable
4.2	**Results of examinations**	[redacted]
4.3	**Effectivity of medical treatment**	
4.4	**Outcome**	

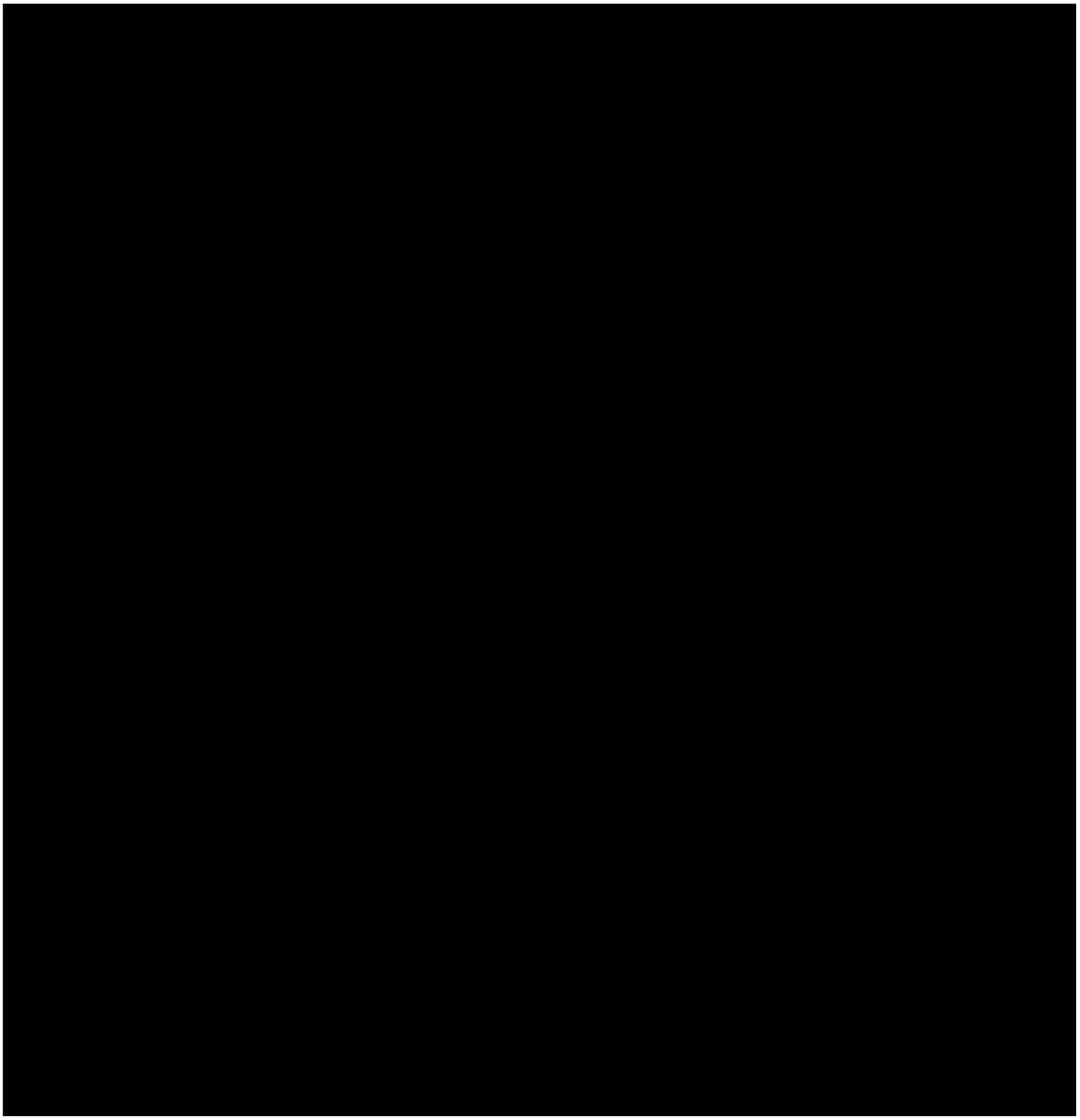
Section 6.12.1 Medical surveillance	**Surveillance of factory workers exposed to pyrethroids**
Annex Point IIA6.9.1	
IUCLID 5.10/1	

4.5	**Other**	None
5.1	**Materials and methods**	[redacted]
5.2	**Results and discussion**	
5.3	**Conclusion**	

Date	
Materials and Methods	
Results and discussion	
Conclusion	

Section 6.12.1 Medical surveillance	**Surveillance of factory workers exposed to pyrethroids**
Annex Point IIA6.9.1	
IUCLID 5.10/1	[redacted]
Remarks	
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Remarks	





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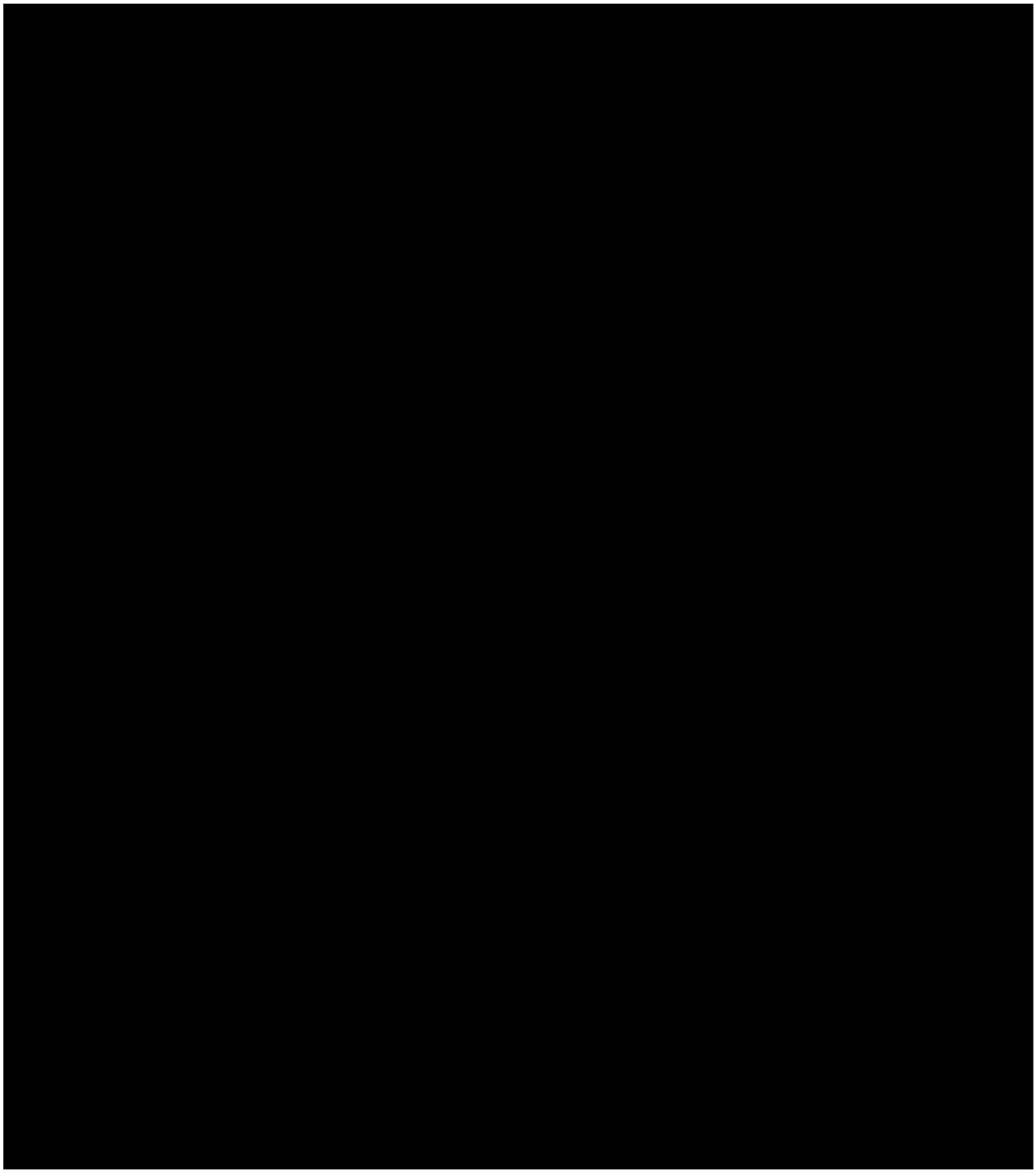

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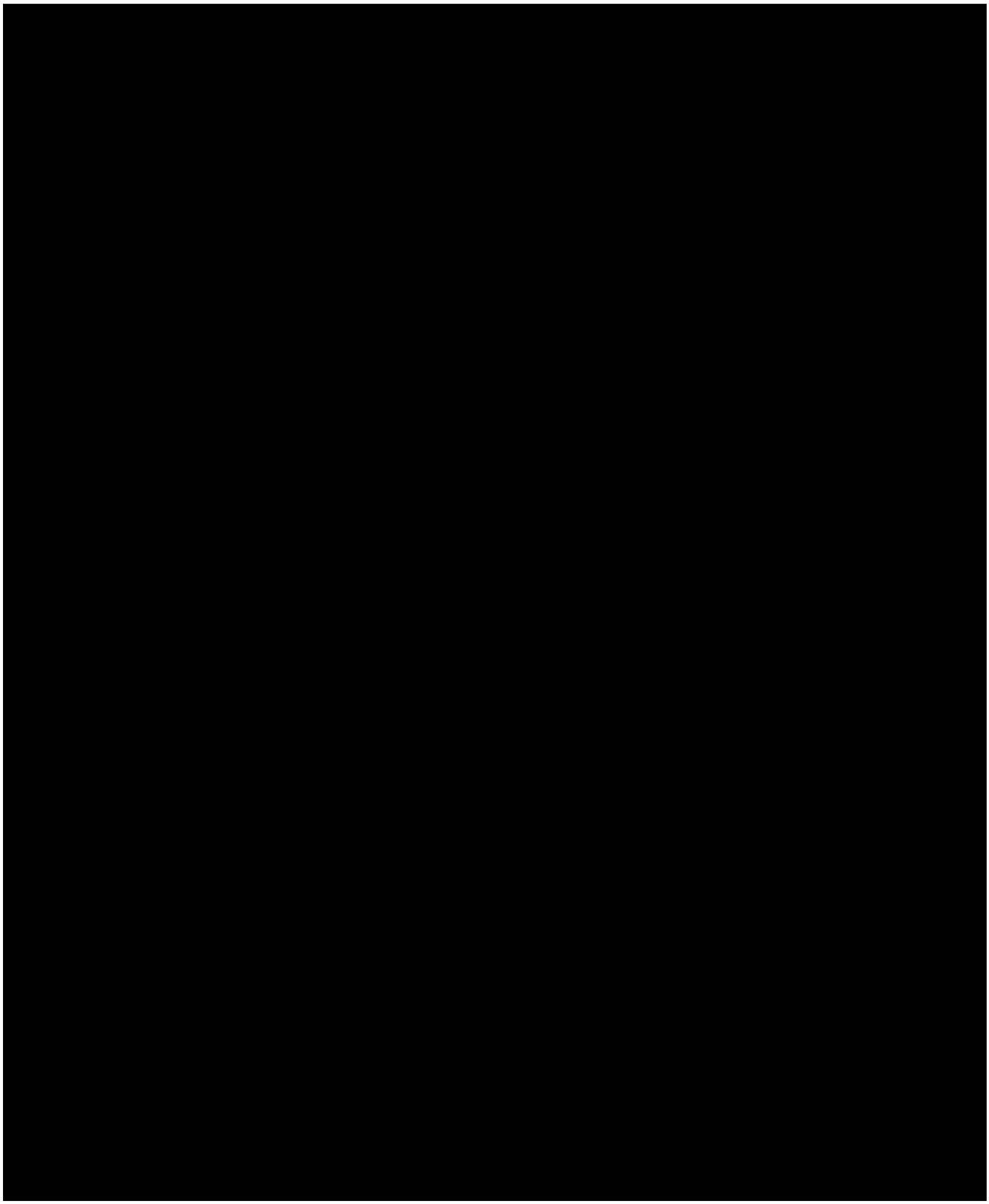

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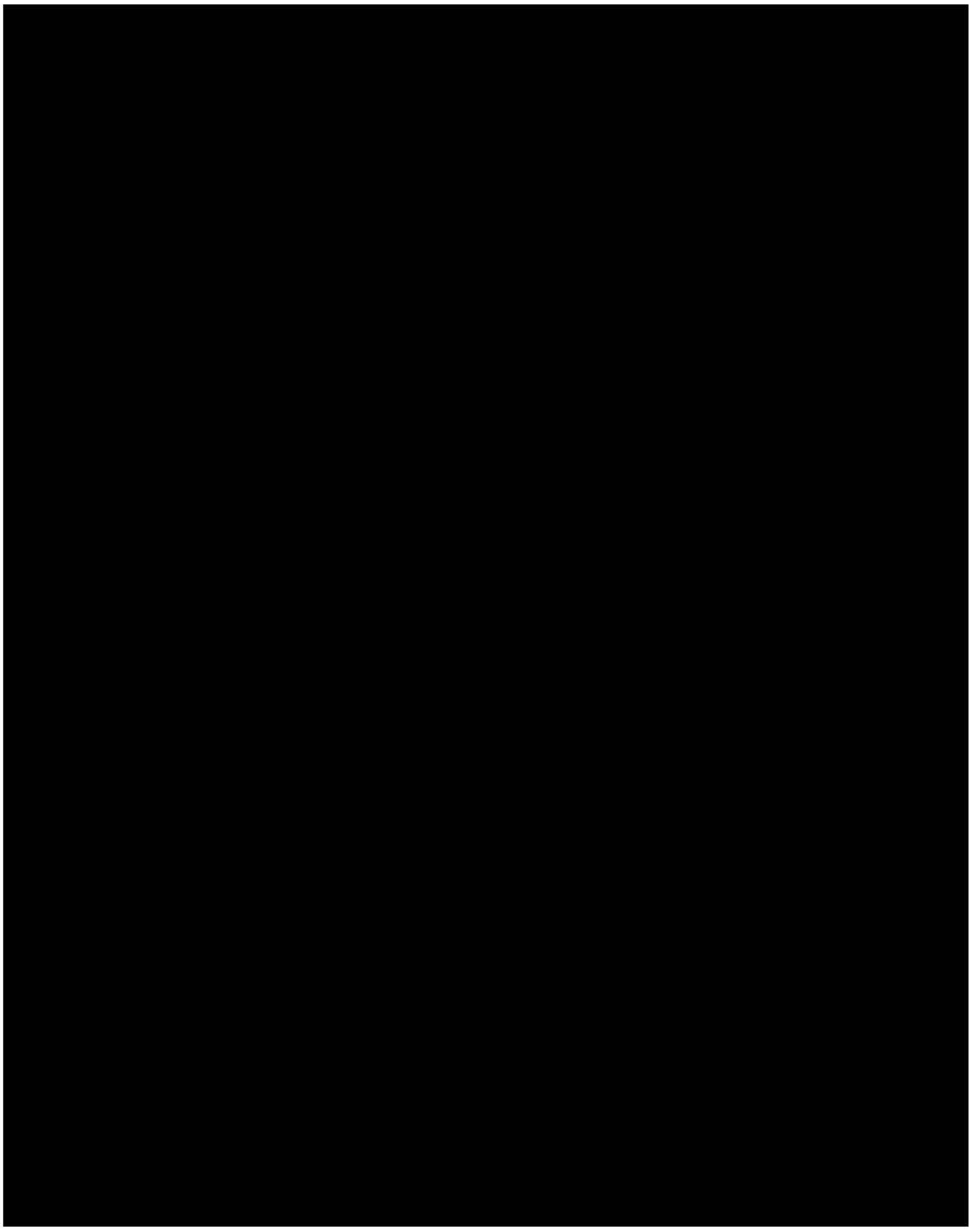

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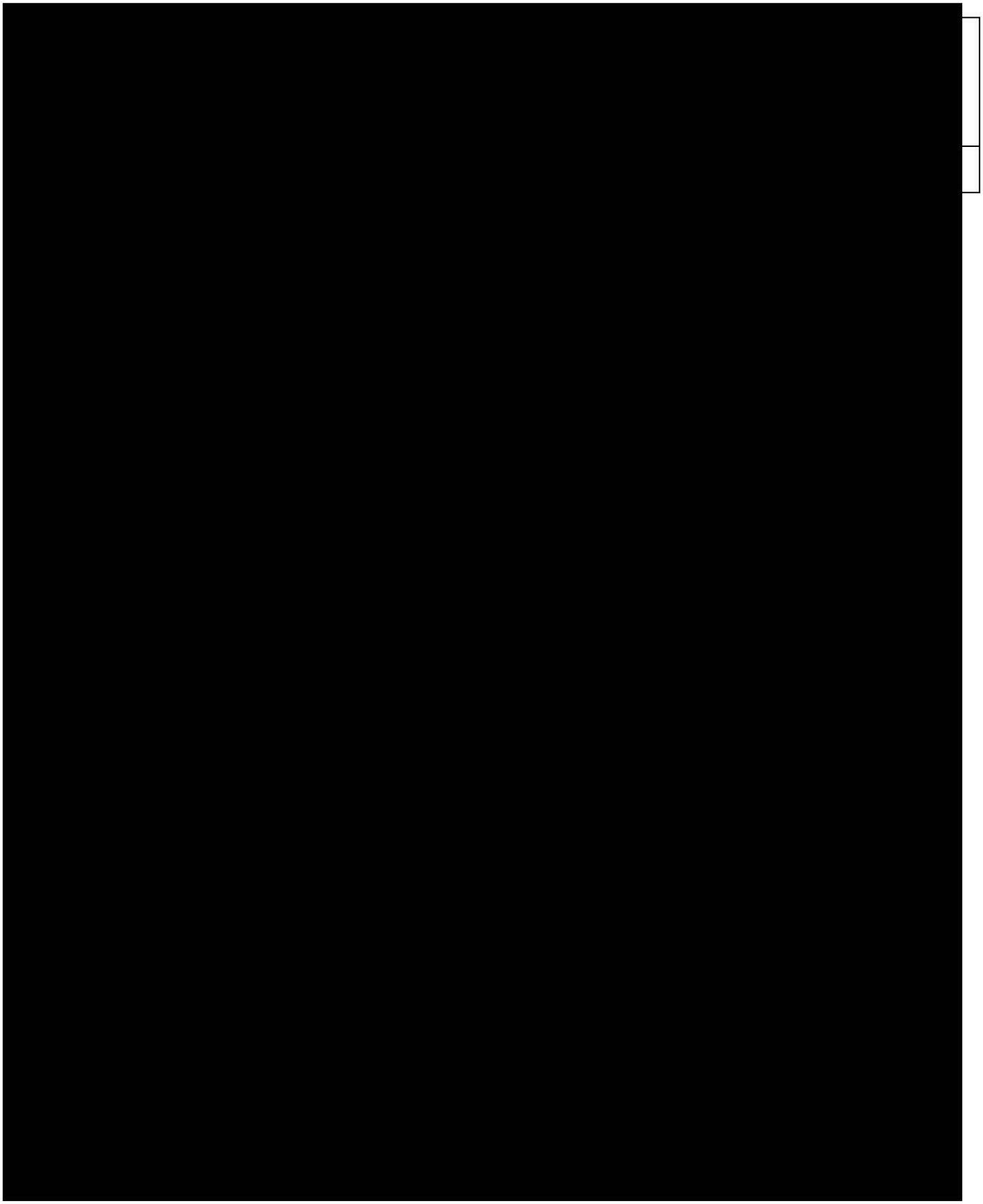

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