Octanoic acid

Biocide for Use as insecticide

Dossier According to Directive 98/8/EC

Document III-A

Data on the Active Substance

Section A1 Applicant

Annex Point IIA1

1.1 Applicant

Name:
FATTY ACIDS Consortium
p.a. SOPURA N.V.
Attention: [redacted]

Address:
Rue de Trazegnies 199
B-6180 Courcelles
Belgium

CONFIDENTIAL
[redacted]

1.2 Manufacturer of Active Substance (if different)

See A2 Point 2.3

CONFIDENTIAL
[redacted]

1.3 Manufacturer of Product(s) (if different)

1) Product 1

2) Product n

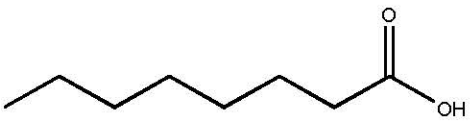
Name: SolNova s.r.l.
Attention: Mr. [redacted]

Address:
Via Sandro Gallo, 12
I-30126 Venezia Lido
Italy

CONFIDENTIAL
[redacted]

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	February 2010
Materials and methods	n.a.
Conclusion	Adopt applicant´s version
Reliability	n.a.
Acceptability	Acceptable
Remarks	-

Section A2 Identity of Active Substance

Subsection (Annex Point)							Official use only
2.1	Common name (IIA2.1)	Caprylic Acid					
2.2	Chemical name (IIA2.2)	n-octanic acid					x
2.3	Manufacturer´s development code number(s) (IIA2.3)	[redacted]					
2.4	CAS No and EC numbers (IIA2.4)						
2.4.1	CAS-No	124-07-2					
	Isomer 1	No isomers					
2.4.2	EC-No	204-677-5					
	Isomer 1	No isomers					
2.4.3	Other	None					
2.5	Molecular and structural formula, molecular mass (IIA2.5)						
2.5.1	Molecular formula	$C_8H_{16}O_2$					
2.5.2	Structural formula						
2.5.3	Molecular mass	144.21 g/mol					
2.6	Method of manufacture of the active substance (IIA2.1)	[redacted]					
2.7	Specification of the purity of the active substance, as appropriate (IIA2.7)	g/kg >996	g/l	% w/w	% v/v		x
2.8	Identity of impurities and additives, as appropriate (IIA2.8)	[redacted]					x
2.8.1	Isomeric composition	No isomers					

Section A2 Identity of Active Substance

2.9	**The origin of the natural active substance or the precursor(s) of the active substance (IIA2.9)**	Oil of coconut; *Cocos nucifera* a member of the Family Arecacea. Coconut oil is produced by extraction of coconuts according to food law.

Evaluation by Competent Authorities	
Date	[redacted]
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A2.8 Identity of impurities and additives (active substance)

Annex Point IIA2.8

Subsection			Official use only
2.8.1.1	Common name	[redacted]	
2.8.1.2	Function	[redacted]	
2.8.2	IUPAC name	[redacted]	
2.8.3	CAS-No	[redacted]	
2.8.4	EC-No	[redacted]	
2.8.5	Other CIPAC	[redacted]	
2.8.6	Molecular formula	[redacted]	
2.8.7	Structural formula	[redacted]	
2.8.8	Molecular mass	[redacted]	
2.8.9	Concentration of the impurity or additive (Ref. A2/01)	g/kg: [redacted] / g/l / % w/w / % v/v	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	February 2010
Materials and methods	n.a.
Conclusion	Agree with the applicant's version with the amendments given below.
Reliability	n.a.
Acceptability	Acceptable
Remarks	Please see confidential section of the CAR. (Doc. III-A2.8d)

Section A2.10

Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Subsection			Official use only
2.10.1	**Human exposure towards active substance**	[redacted]	x
2.10.1.1	**Production of the active substance**		
	i) Description of process		
π	ii) Workplace description		
	iii) Inhalation exposure		
	iv) Dermal exposure		

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Subsection		Official use only
2.10.1.2 Production of the formulated product		
i) Description of process	[redacted]	
ii) Workplace description	[redacted]	
iii) Inhalation exposure		
iv) Dermal exposure		

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Subsection		Official use only
2.10.1.3	**Intended use(s) of the formulated product**	
	1. Professional Users	
	(i) Description of application process	
	(ii) Workplace description	
	(iii) Inhalation exposure	
	(iv) Dermal exposure	
	2. Non-professional Users including the general public	
	(i) via inhalational contact	
	(ii) via skin contact	
	(iii) via drinking water	

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Subsection		Official use only
(iv) via food	[redacted]	
(v) indirect via environment		
2.10.1.4 Secondary Exposure		
(i) acute or chronic inhalation		
(ii) acute or chronic dermal uptake		
(iii) acute or chronic oral ingestion		
2.10.2 Environmental exposure towards active substance		x
2.10.2.1 Production		
(i) Releases into water		
(ii) Releases into air	[redacted]	

Section A2.10
Annex Point IIA2.10

Exposure data in conformity with Annex VIIA to Council Directive 92/32/EEC (OJ No L, 05.06.1992, p. 1) amending Council Directive 67/548/EEC

Subsection		**Official use only**
(iii) Waste disposal	[redacted]	
2.10.2.2 Intended use(s)		
Affected compartments:		
- air		
- surface water		
- sediment		
- soil		
- groundwater		
Predicted concentration in the affected compartment(s)		

Evaluation by Competent Authorities	
Date	[redacted]
Materials and methods	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A2.10: Workplace exposure / Inhalation exposure (based on the TNsGs on Human exposure, European Commission 2002)

Exposure scenario	**Workplace operation**	**PPE**	**Year(s) of measurement**	**Number of measurements**	**Type of measurements**	**Exposure concentration mg a.s./kg bw/day**
Production of active substance	Large-scale industrial operation; closed system.			Not reported		Inhalation: See example calculation point 2.10.1.2 0.000131 mg/kg bw/day
Production of the formulated product	Connection of transfer lines, addition of a small ingredient directly into the mixing vessel, maintenance	Gloves, googles, overall, boots				Inhalation: See example calculation point 2.10.2.1 0.000164 mg/kg bw/day Dermal: accidental 0.25 mg/kg bw
Application of the product: by consumer Direct spraying on insects	n.a.	Not used				The results of the CONSEXPO calculation: - Acute (internal) dose = 6.21 mg/kg - Chronic (internal dose) = 2.14 mg/kg bw/day Integrated (point estimates) - Total acute dose (internal) = 6.21 mg/kg - Total chronic dose (internal) = 2.14 mg/kg bw/day
Indirect exposure of children	n.a.	n.a.				The results of the CONSEXPO calculation: - Acute (internal) dose = 6.21 mg/kg - Chronic (internal dose) = 2.14 mg/kg bw/day Integrated (point estimates) - Total acute dose (internal) = 6.21 mg/kg - Total chronic dose (internal) = 2.14 mg/kg bw/day

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.1 Melting point, boiling point, relative density (IIA3.1)		99.7 %	16.6 °C	-	N	1	SGS – H. Dedeken 2006; A.3/17	x
3.1.1 Melting point			Liquid at room temperature			1	Merck 1989; A.3/03	x
Melting pt. 1	Reference literature		16.7 °C	Reference literature	n.a.			
Melting pt. 2								
3.1.2 Boiling point	The boiling point of the test substance was determined under atmospheric pressure with the distillation method as described in Test Guideline A.2 of EC Directive 92/69/EEC, and TNO-PML S.O.P. Q 213-W-028 'Determination of the Boiling Point Range.	100 %	237.0± 0.5 °C at atmospheric pressure		Y	1	Cordia et al. 1999; A.3/01	x
Boiling pt. 1			result: 237.0± 0.5 °°C pressure: 100.748 kPA					
Boiling pt. 2			result: 236.0 °C pressure: 100.748 kPA					
3.1.3 Relative density	EU A.6: Hydrostatic balance against water.		0.900 kg/L		N	1	Servais 2008; A3/11	x
Rel. density 1		99.7%	0.892 kg/L					
Rel. density 2		99.5%	0.908 kg/L					

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.2 Vapour pressure (IIA3.2)	The vapour pressure of the test substance was measured with the effusion method by loss of weight, as described in Test Guideline A.4 of EC Directive 92169lEEC.	100 %	Temperature: 25 °C result: $1.35*10^{-2}$ Pa Temperature: 20 °C result: $8.90*10^{-3}$ Pa		Y	1	Cordia et al. 1999; A.3/01	x
Vapour pressure 1								
Vapour pressure 2								
3.2.1 Henry´s Law Constant (Pt. I-A3.2)	Calculation with HENRYWIN		Calculated: 25 °C result: $9.55*10^{-5}$	Statement	N	1	Gaisser 2006; A3/05	x
3.3 Appearance (IIA3.3)								
3.3.1 Physical state	Visual inspection	100 %	Liquid		Y	1	Cordia et al. 1999; A.3/01	x
3.3.2 Colour	Visual inspection	100 %	Colourless liquid		Y	1	Cordia et al. 1999; A.3/01	x
3.3.3 Odour	Reference literature		Slightly unpleasant rancid	Reference literature	Y	1	Merck 1989; A.3/03	x
3.4 Absorption spectra (IIA3.4)								
UV/VIS	OECD Guideline A80/2 was applied for recording the UV/Vis absorption spectra of the test substance.	100 %	Absorption spectra different in acidic and alkaline solution. The undissiociated acid is only present in acidic solution: Max		Y	1	Cordia et al. 1999; A.3/01	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
			absorbance E208.0 = 0.3814 ? 0.0282* l.g-l.cm-l,					
IR		100 %	IR, spectra in agreement with proposed structure		Y	1	Cordia et al. 1999; A.3/01	x
NMR		100 %	^{1}H, ^{13}C-NMR spectra in agreement with proposed structure		Y	1	Cordia et al. 1999; A.3/01	x
MS		100 %	mass spectra in agreement with proposed structure		Y	1	Cordia et al. 1999; A.3/01	x
3.5 Solubility in water (IIA3.5)								
Water solubility 1	OECD 105; EU A.6	99.8%	Water: 0.88 g/L without a buffer (20 °C) pH 4: 0.92 g/L (50 °C) 0.75 g/L (20 °C) pH 7: 3.18 g/L (50 °C) 2.97 g/L (20 °C) pH 9: 3.68 g/L (50 °C) 3.35 g/L (20 °C)		Y	1	Garofani 2006; A3/16	x
Water solubility 2	Reference literature		0.68 g/L at 20 °C	Reference literature		1	Merck 1989; A.3/03	
3.6 Dissociation constant (-)	Expert statement		The dissociation constant of n-octanoic acid in water (expressed as the pK, value at 25 ^{0}C) is 4.89	Expert statement	N	1	Van de Beld 1999; A3/04	x
3.7 Solubility in organic	CIPAC method MT181	99.6%	> 1kg/L n-hexane (22 °C)		Y	1	Garofani 2009; A3/19	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
solvents, including the effect of temperature on solubility (IIIA3.1)			> 1kg/L ethanol (22 °C)					
3.8 Stability in organic solvents used in b.p. and identity of relevant breakdown products (IIIA3.2)	Expert statement		Octanoic acid is stable in water and the components of the b.p.. However, as an acid it will dissociate depending on the PH	Expert statement		1	Gaisser 2006; A3/06	x
3.9 Partition coefficient n-octanol/water (IIA3.6)	QSAR		Log Kow = 3.03 For the undissociate acid	Calculated with KOWWIN v1.67 Reference literature		1	Gaisser 2006; A3/05	x
log Pow 1			result: temperature: pH:					
log Pow 2								
3.10 Thermal stability, identity of relevant breakdown products (IIA3.7)	Expert statement		Octanoic acid is stable	Expert statement		1	Gaisser 2006; A3/07	x
3.11 Flammability, including auto-flammability and identity of combustion products (IIA3.8)	Expert statement		Octanoic acid is stable	Expert statement		1	Gaisser 2006; A3/08	x

Section A3 Physical and Chemical Properties of Active Substance

Subsection (Annex Point)	Method	Purity/ Specification	Results Give also data on test pressure, temperature, pH and concentration range if necessary	Remarks/ Justification	GLP (Y/N)	Reliability	Reference	Official use only
3.12 Flash-point (IIA3.9)	Pensky Martens Closed cup	99.6 %	133.0 °C at 1005 mbar		Y	1	Garofani 2009; A.3/17a	x
Flash-point 1								
Flash point 2								
3.13 Surface tension (IIA3.10)	OECD 115; EU A.5	99.5 - 99.8 %	mean 53.2 mN/M (20°C) at 0.61 g/L		N	1	D. Servais 2008 A3/10	x
Surface tension 1		99.7%	48.4 mN/M (20 °C)					
Surface tension 2		99.5%	58.8 mN/M (20 °C)					
Surface tension 3		99.8%	52.4 mN/M (20 °C)					
3.14 Viscosity (-)	OECD 114	99.5-99.7%	result: 7.7 mPa.s (cP) temperature: 20 °C		N	1	D. Servais 2008 A3/18	
3.15 Explosive properties (IIA3.11)	Expert statement		Octanoic acid is stable	Expert statement		1	Gaisser 2006; A3/12	x
3.16 Oxidizing properties (IIA3.12)	Expert statement		Octanoic acid is stable	Expert statement		1	Gaisser 2006; A3/13	x
3.17 Reactivity towards container material (IIA3.13)	Expert statement		Octanoic acid is stable	Expert statement		1	Gaisser 2006; A3/14; Verschaeve 2006; A3/15	x

Evaluation by Competent Authorities

Date

Materials and methods

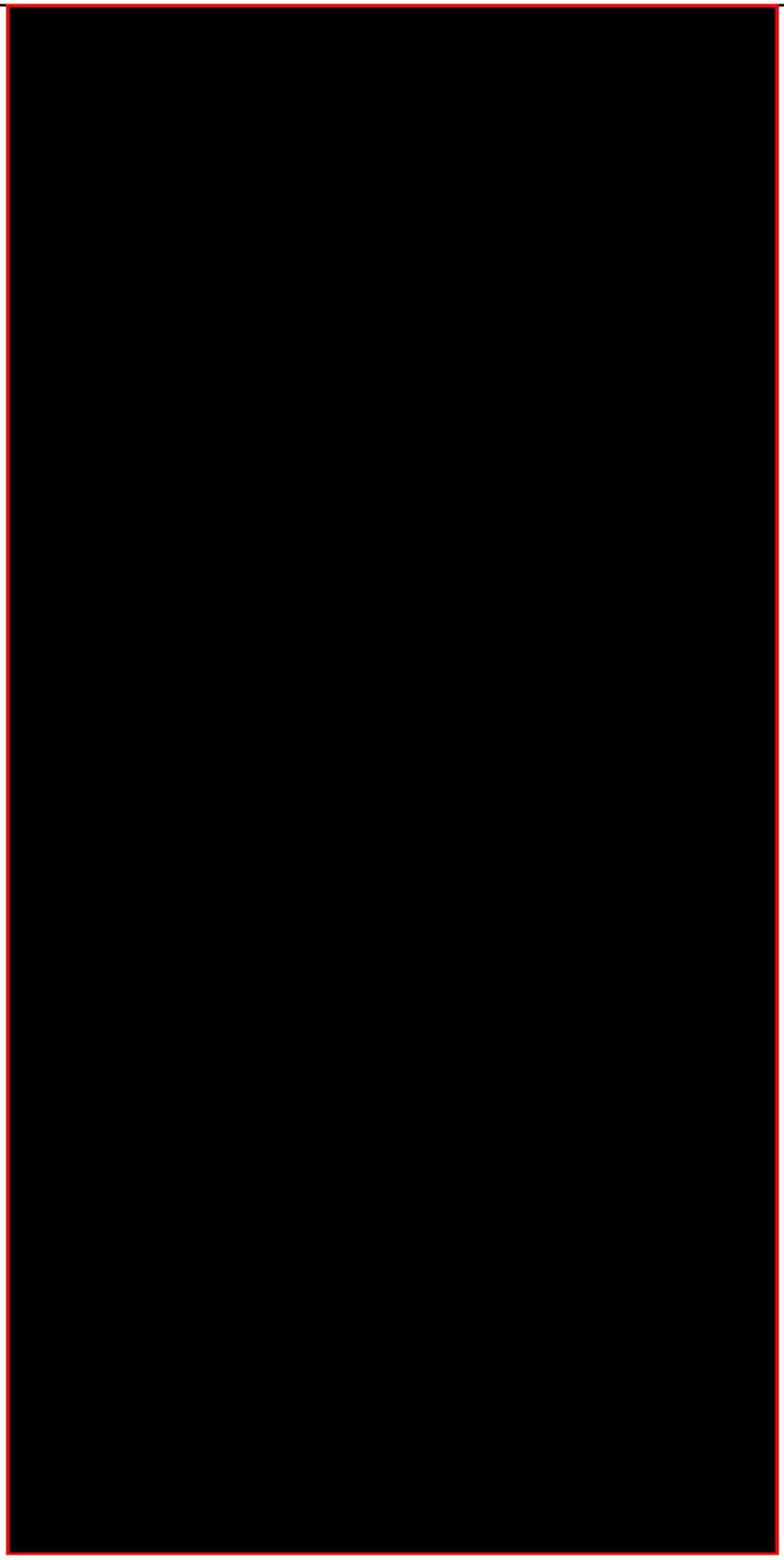
Conclusion

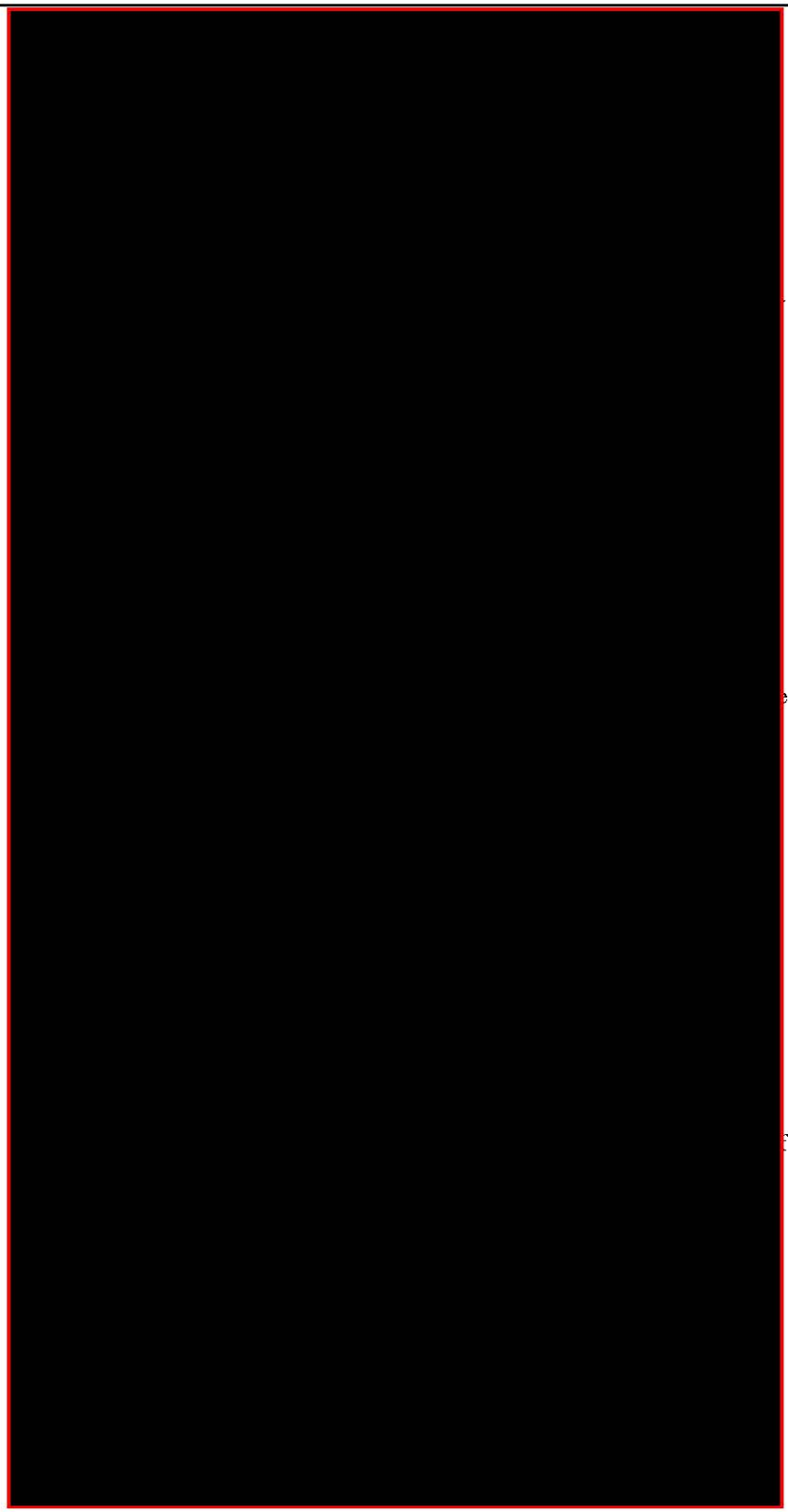
Reliability

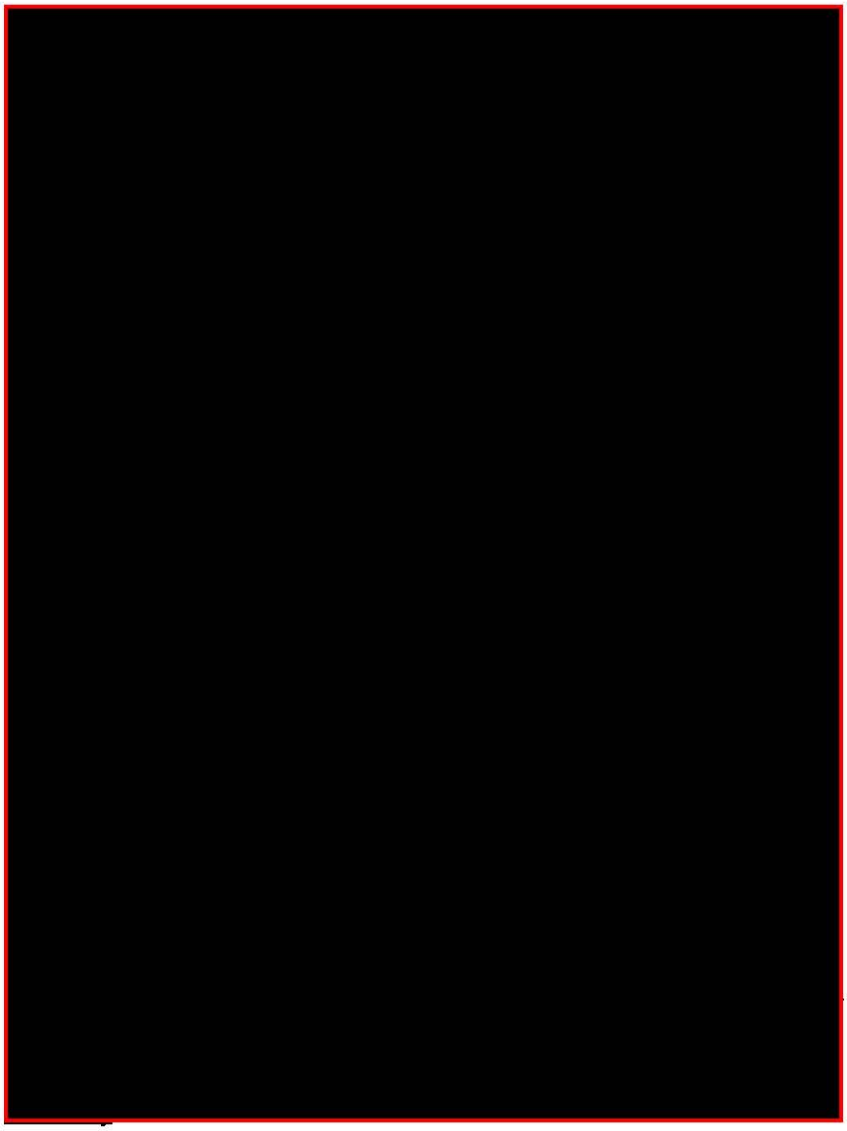
Acceptability

Remarks

[redacted]







Section A4 (4.1)

Annex Point IIA4.1a

Analytical Methods for Detection and Identification

For pure substance

Official use only

[redacted]

1.1 Reference

1.2 Data protection

1.2.1 Data owner

1.2.2

1.2.3 Criteria for data protection

2.1 Guideline study

2.2 GLP

2.3 Deviations

3.1 Preliminary treatment

3.1.1 Enrichment

3.1.2 Cleanup

3.2 Detection

3.2.1 Separation method

3.2.2 Detector

3.2.3 Standard(s)

3.2.4 Interfering substance(s)

3.3 Linearity

3.3.1 Calibration range

3.3.2 Number of measurements

3.3.3 Linearity

3.4 Specifity: interfering substances

3.5 Recovery rates at different levels

3.5.1 Relative standard deviation

[redacted]

3.6 Limit of determination

3.7 Precision

3.7.1 Repeatability

3.7.2 Independent laboratory validation

4.1 Materials and methods

[redacted]

4.2 Conclusion

4.2.1 Reliability

4.2.2 Deficiencies

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	November 2009
Materials and methods	Acceptable
Conclusion	Agree with applicant's version
Reliability	1
Acceptability	Acceptable
Remarks	-

Section A4 (4.2) Annex Point IIA-IV.4.2	Analytical Methods for Detection and Identification *(a) Soil*	
	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]	X
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
Date Evaluation of applicant's justification Conclusion Remarks	[redacted]	

Section A4 (4.2) Annex Point IIA-IV.4.2	Analytical Methods for Detection and Identification (b) Air	
	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]	X X
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
Date Evaluation of applicant's justification Conclusion Remarks	[redacted]	

Section A4 (4.2) Analytical Methods for Detection and Identification
Annex Point IIA4.2 **(c) Water**

			Official use only
		1 REFERENCE	
1.1	**Reference**	Peter L. Neitzel, W. Walther, W. Nestler In-situ methylation of strongly polar organic acids in natural waters supported by ion-pairing agents for headspace GC-MSD analysis; Dresden University of technology; Fresenius J Anal Chem (1998) 361:318-323. (A4.2/01)	
1.2	**Data protection**	[redacted]	X
1.2.1	Data owner		
1.2.2			
1.2.3	Criteria for data protection		
2.1	**Guideline study**		
2.2	**GLP**		
2.3	**Deviations**		
3.1	**Preliminary treatment**		
3.1.1	Enrichment		
3.1.2	Cleanup		
3.2	**Detection**		
3.2.1	Separation method		
3.2.2	Detector		
3.2.3	Standard(s)		
3.2.4	Interfering substance(s)		
3.3	**Linearity**		
3.3.1	Calibration range		
3.3.2	Number of measurements		

Section A4 (4.2) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 **(c) Water**

3.3.3 Linearity

3.4 Specifity: interfering substances

3.5 Recovery rates at different levels

3.5.1 Relative standard deviation

3.6 Limit of determination

3.7 Precision

3.7.1 Repeatability

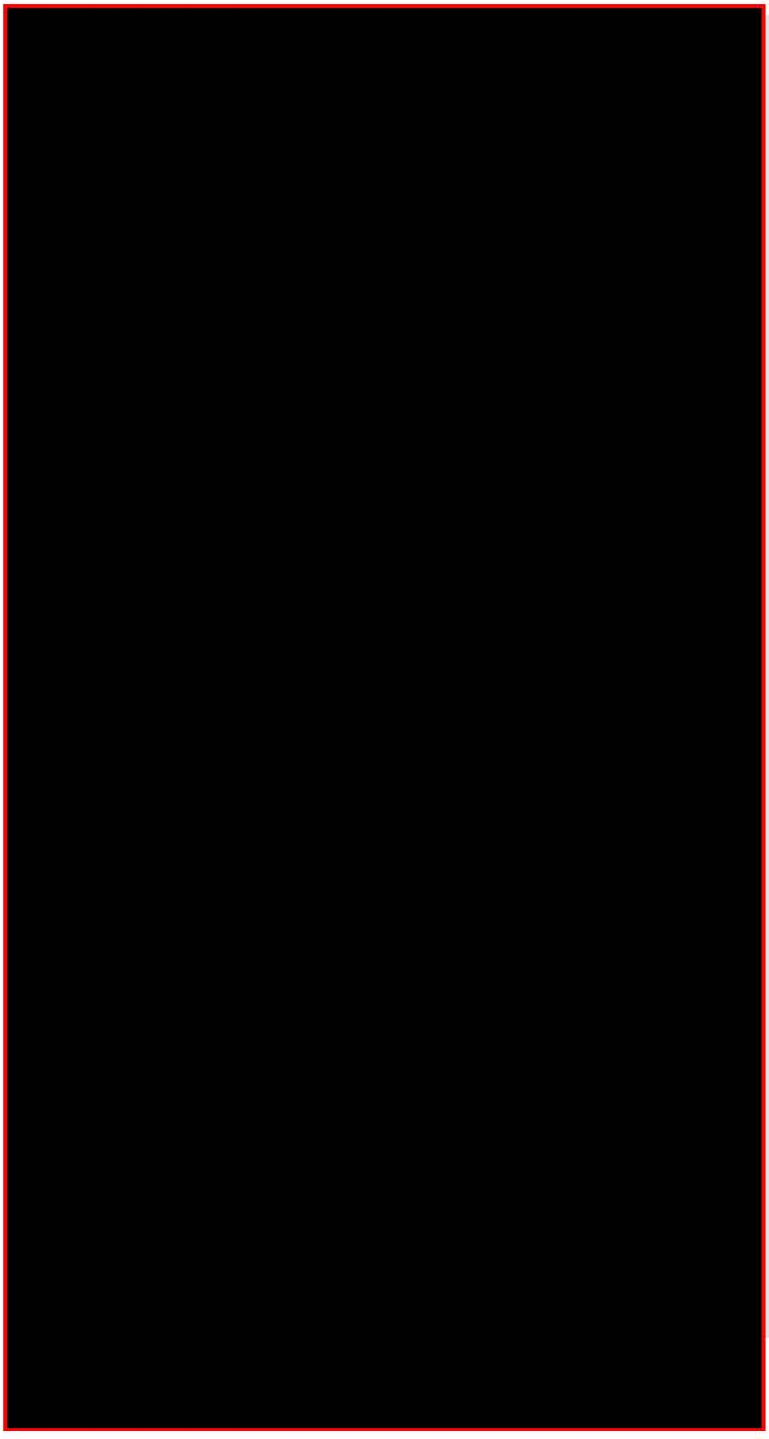
3.7.2 Independent laboratory validation

4.1 Materials and methods

4.2 Conclusion

4.2.1 Reliability

4.2.2 Deficiencies



Section A4 (4.2) **Analytical Methods for Detection and Identification**

Annex Point IIA4.2 **(c) Water**

Evaluation by Competent Authorities	
Date	[redacted]
Materials and methods	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A4 (4.2) Annex Point IIA-IV.4.2	Analytical Methods for Detection and Identification (d) Animal body fluids and tissues	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [ ]	Technically not feasible [X] Scientifically unjustified [X] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
Date Evaluation of applicant's justification Conclusion Remarks	[redacted] -	

Section A4 (4.3) Annex Point IIIA-IV.1	Analytical Methods for Detection and Identification For food/feedstuffs	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] Limited exposure [X]	Technically not feasible [X] Scientifically unjustified [X] Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended		

Section A4 (4.3) Annex Point IIIA-IV.1	Analytical Methods for Detection and Identification For food/feedstuffs
data submission [ ]	

Evaluation by Competent Authorities	
Date	[redacted]
Evaluation of applicant's justification	
Conclusion	
Remarks	

Section A5 Effectiveness against target organisms and intended uses

Subsection (Annex Point)		[redacted]	Official use only
5.1	Function (IIA5.1)		X
5.2	Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)		X
5.2.1	Organism(s) to be controlled (IIA5.2)		X
5.2.2	Products, organisms or objects to be protected (IIA5.2)		X
5.3	Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)		
5.3.1	Effects on target organisms (IIA5.3)		X
5.3.2	Likely concentrations at which the A.S. will be used (IIA5.3)		X
5.4	Mode of action (including time delay) (IIA5.4)		

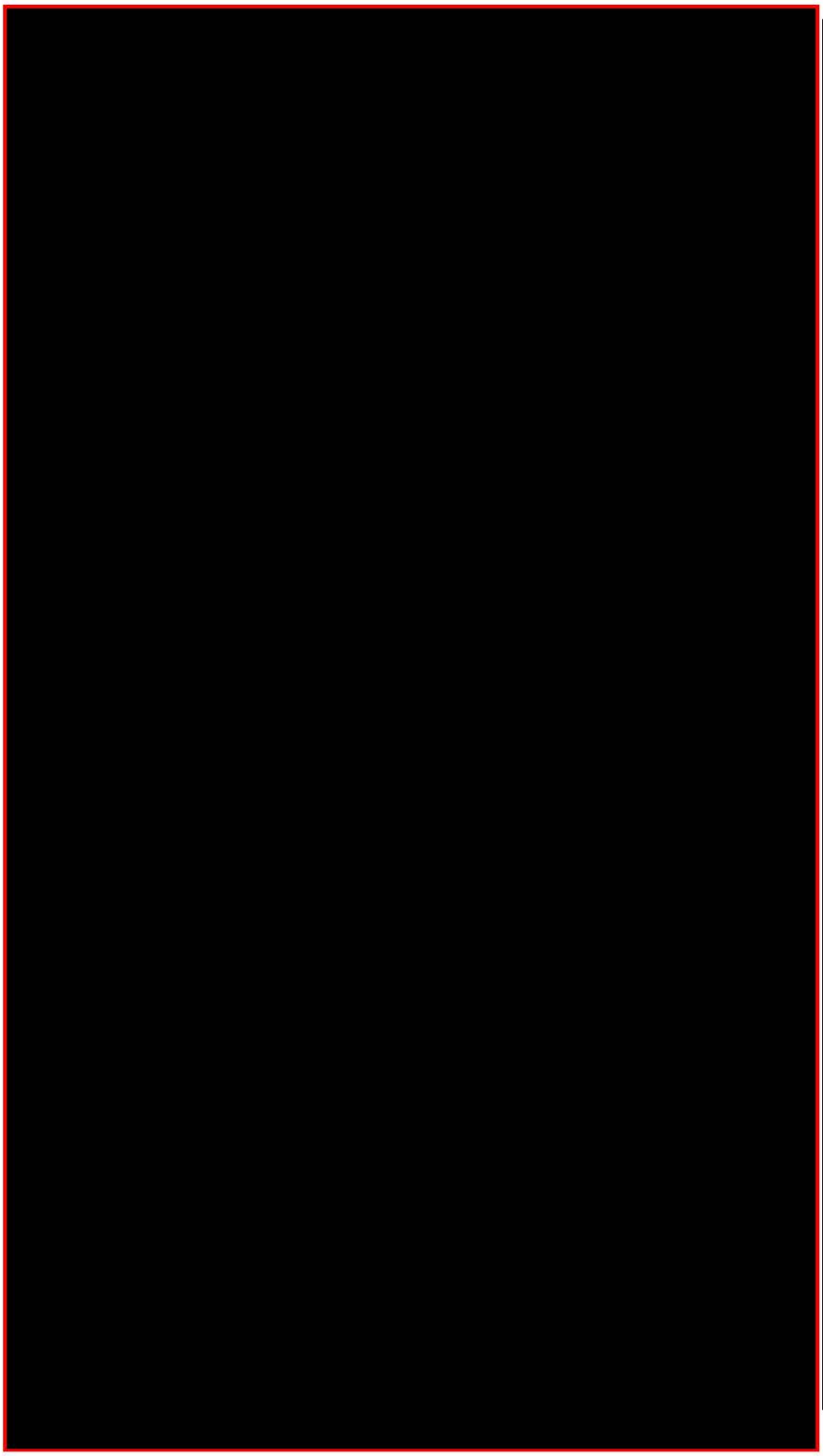
Section A5 Effectiveness against target organisms and intended uses

5.4.1	**Mode of action**	[redacted]	
5.4.2	**Time delay**		
5.5	**Field of use envisaged (IIA5.5)**		
	MG03: Pest control		
	Further specification		X
5.6	**User (IIA5.6)**		X
5.7	**Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)**		
5.7.1	**Development of resistance**		X
5.7.2	**Management strategies**		
5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**		

Section A5 Effectiveness against target organisms and intended uses

Evaluation by Competent Authorities	
Date	[redacted]
Materials and methods	

Section A5 Effectiveness against target organisms and intended uses



Section A5 Effectiveness against target organisms and intended uses

Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	-

Section A5.3 **Efficacy Data**
Annex Point IIA5.3_1 laboratory study (weight of evidence only)

			Official use only
1.1	**Reference**	[redacted]	
1.2	**Data protection**		
1.2.1	Data owner		
1.2.2	Criteria for data protection		
1.3	**Guideline study**		
1.4	**Deviations**		
2.1	**Test Substance**		
2.1.1	Trade name/ proposed trade name		
2.1.2	Lot/Batch number		
2.1.3	Physical state and nature		
2.1.4	Monitoring of active substance concentration		
2.1.5	Method of analysis		
2.2	**Reference substance**		
2.2.1	Method of analysis for reference substance		
2.3	**Testing procedure**		
2.3.1	Test population / inoculum / test organism		
2.3.2	Test system		

2.3.3	Application of TS	[redacted]
2.3.4	Test conditions	
2.3.5	Duration of the test / Exposure time	
2.3.6	Number of replicates performed	
2.3.7	Controls	
2.4	**Examination**	
2.4.1	Effect investigated	
2.4.2	Method for recording / scoring of the effect	
2.4.3	Intervals of examination	
2.4.4	Statistics	
2.4.5	Post monitoring of the test organism	
3.1	**Efficacy**	
3.1.1	Dose/Efficacy curve	
3.1.2	Begin and duration of effects	
3.1.3	Observed effects in the post monitoring phase	
3.2	**Effects against organisms or objects to be protected**	
3.3	**Other effects**	

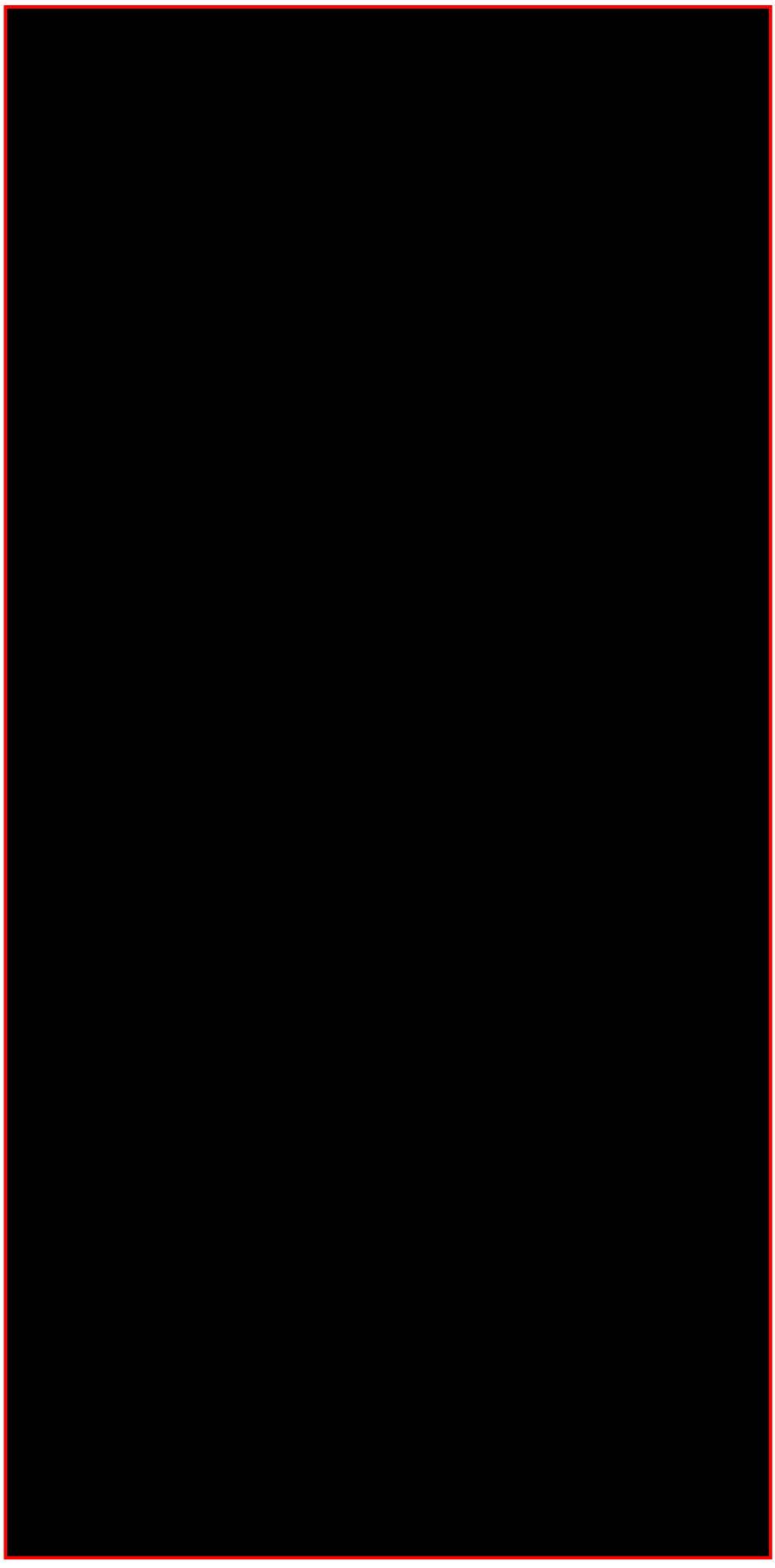
3.4	**Efficacy of the reference substance**	[redacted]
3.5	**Tabular and/or graphical presentation of the summarised results**	
3.6	**Efficacy limiting factors**	
3.6.1	Occurrences of resistances	
3.6.2	Other limiting factors	
4.1	**Reasons for laboratory testing**	
5.2	**Intended actual scale of biocide application**	
5.3	**Relevance compared to field conditions**	
4.1.1	Application method	
4.1.2	Test organism	
4.1.3	Observed effect	
5.4	**Relevance for read-across**	
5.1	**Materials and methods**	
5.2	**Reliability**	
5.3	**Assessment of efficacy, data analysis and interpretation**	

5.4 Conclusion

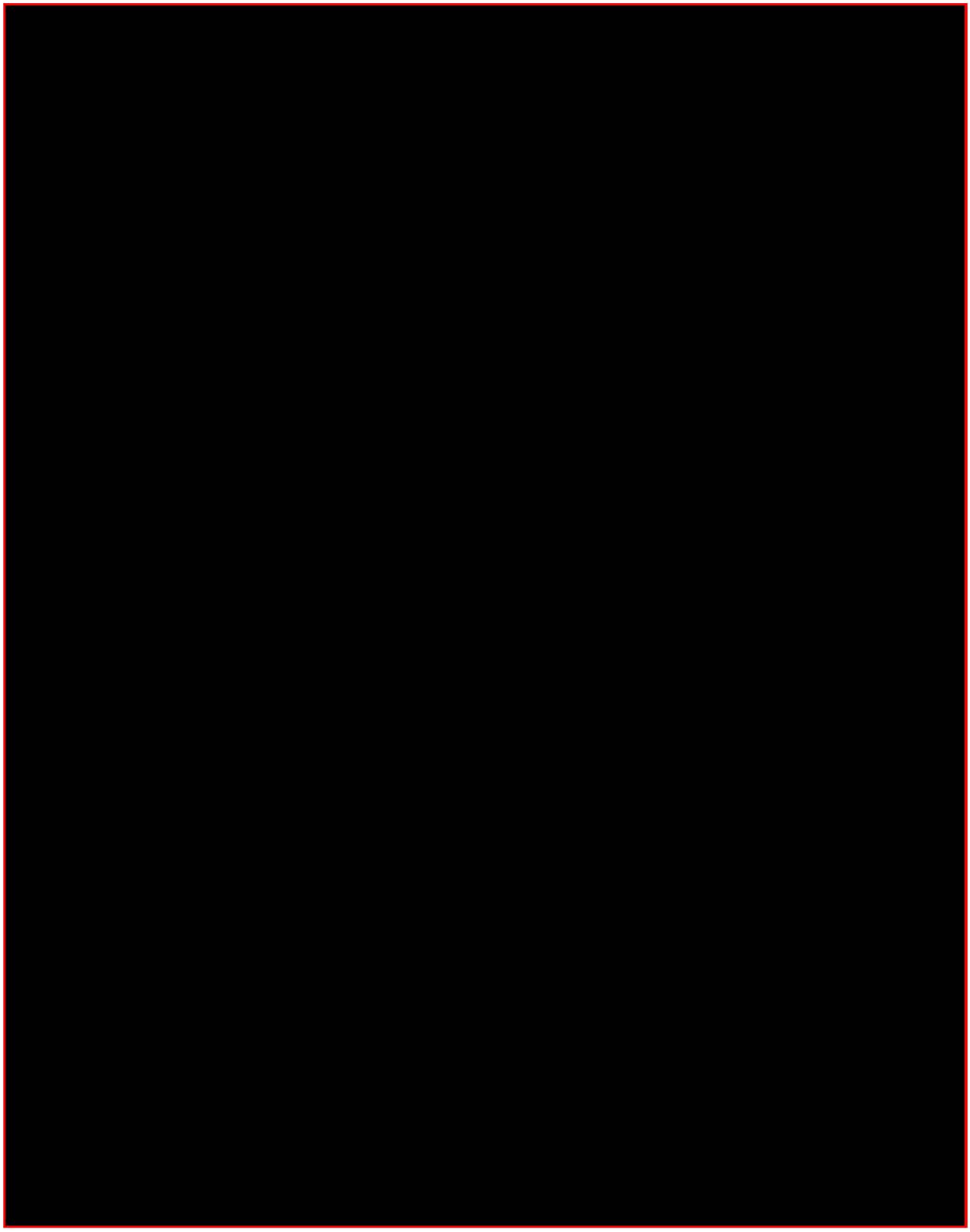
[redacted]

5.5 Proposed efficacy specification

Evaluation by Competent Authorities	
Date	[redacted]
Materials and Methods	
Results and discussion	



Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	



Section A5.3 **Efficacy Data**
Annex Point IIA5.3_1 laboratory study

			Official use only
1.1	**Reference**	[redacted]	
1.2	**Data protection**		
1.2.1	Data owner		
1.2.2	Criteria for data protection		
1.3	**Guideline study**		
1.4	**Deviations**		
2.1	**Test Substance**		
2.1.1	Trade name/ proposed trade name		
2.1.2	Lot/Batch number		
2.1.3	Physical state and nature		x
2.1.4	Monitoring of active substance concentration		x
2.1.5	Method of analysis		x
2.2	**Reference substance**		
2.2.1	Method of analysis for reference substance		
2.3	**Testing procedure**		
2.3.1	Test population / inoculum / test organism		x
2.3.2	Test system		x

2.3.3	Application of TS	[redacted]	x
2.3.4	Test conditions		
2.3.5	Duration of the test / Exposure time		x
2.3.6	Number of replicates performed		x
2.3.7	Controls		
2.4	**Examination**		
2.4.1	Effect investigated		
2.4.2	Method for recording / scoring of the effect		
2.4.3	Intervals of examination		

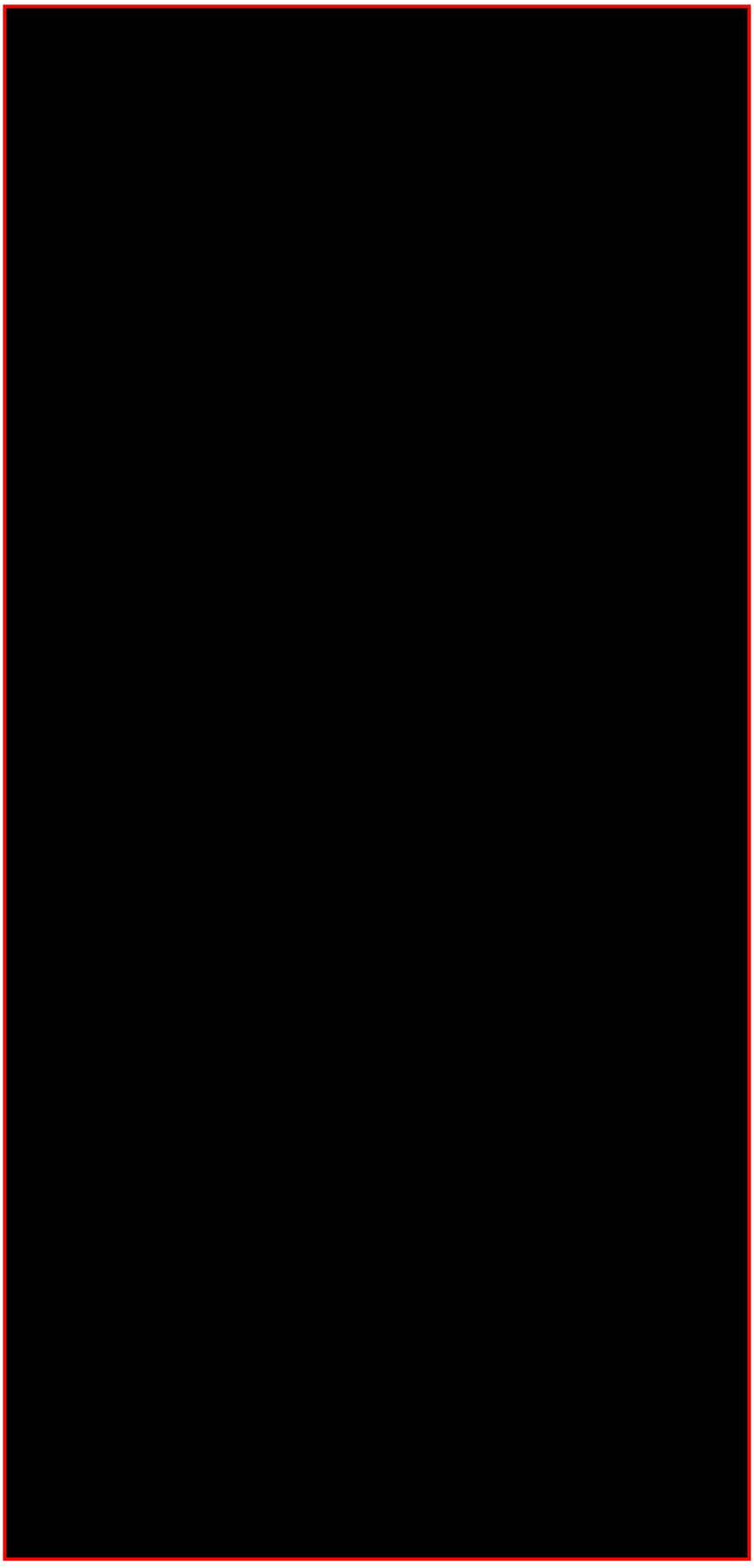
2.4.4	Statistics	[redacted]	x
2.4.5	Post monitoring of the test organism		
3.1	**Efficacy**		
3.1.1	Dose/Efficacy curve		x
3.1.2	Begin and duration of effects		x
3.1.3	Observed effects in the post monitoring phase		

3.2	**Effects against organisms or objects to be protected**	[redacted]	x
3.3	**Other effects**		
3.4	**Efficacy of the reference substance**		x
3.5	**Tabular presentation of the summarised results**		
3.6	**Efficacy limiting factors**		
3.6.1	Occurrences of resistances		x
3.6.2	Other limiting factors		x
4.1	**Reasons for laboratory testing**		x
5.2	**Intended actual scale of biocide application**		x
5.3	**Relevance compared to field conditions**		
4.1.1	Application method		
4.1.2	Test organism		x
4.1.3	Observed effect		x
5.4	**Relevance for read-across**		x

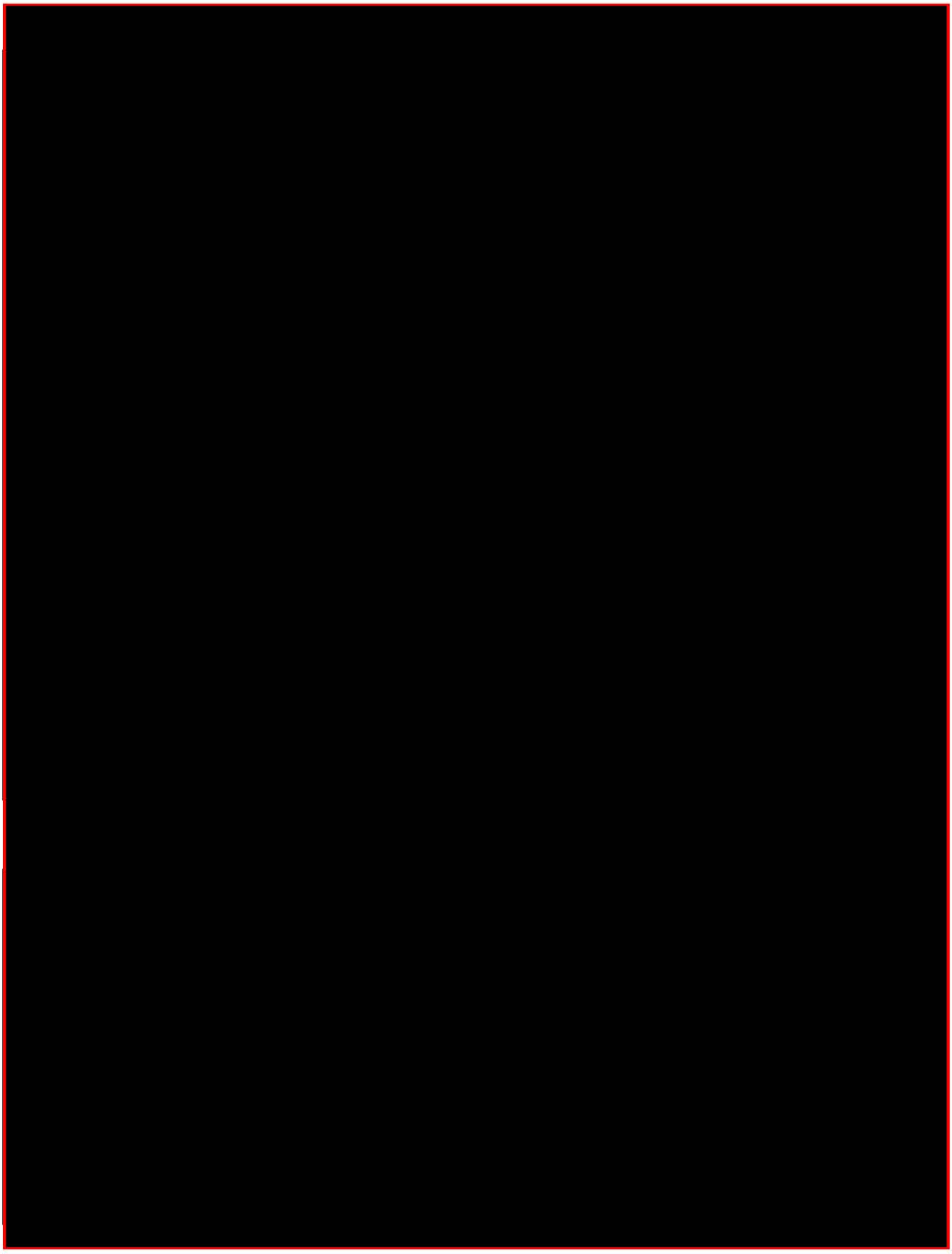
5.1	Materials and methods	[redacted]	x
5.2	Reliability		
5.3	Assessment of efficacy, data analysis and interpretation		
5.4	Conclusion		
5.5	Proposed efficacy specification		

Evaluation by Competent Authorities	
Date	[redacted]
Materials and Methods	

Results and discussion	[redacted]



Conclusion	[redacted]
Reliability	
Acceptability	
Remarks	



Section A6.1.1. Acute Toxicity

Annex Point IIA6.1.1. **Oral,** acute toxicity study in rats (LD50)

			Official use only
	1 REFERENCE		
1.1	**Reference**	[redacted]	
1.2	**Data protection**		
1.2.1	Data owner		
1.2.2			
1.2.3	Criteria for data protection		
2.1	**Guideline study**		
2.2	**GLP**		X
2.3	**Deviations**		
3.1	**Test material**		
3.1.1	Lot/Batch number		
3.1.2	Specification		
3.1.2.1	**Description**		
3.1.2.2	**Purity**		X
3.1.2.3	**Stability**		X
3.2	**Test Animals**		
3.2.1	Species		
3.2.2	Strain		
3.2.3	Source		
3.2.4	Sex		
3.2.5	Age/weight at study initiation		
3.2.6	Number of animals per group		
3.2.7	Control animals		
3.3	**Administration/ Exposure**		
3.3.1	Postexposure period		
3.3.2	Type		
3.3.3	Concentration		

3.3.4	Vehicle	[redacted]	
3.3.5	Concentration in vehicle		
3.3.6	Total volume applied		
3.3.7	Controls		
3.4	**Method of determination of LD_{50}**		
3.5	**Further remarks**		
4.1	**Clinical signs**		X
4.2	**Pathology**		
4.3	**Other**		
4.4	**LD_{50}**		
5.1	**Materials and methods**		
5.2	**Results and discussion**		
5.3	**Conclusion**		
5.3.1	Reliability		
5.3.2	Deficiencies		

Evaluation by Competent Authorities	
Date	[redacted]
Materials and Methods	
Results and discussion	
Conclusion	

Reliability	1
Acceptability	acceptable
Remarks	

Section A6.1.1. **Annex Point IIA6.1.1.**	**Acute Toxicity** **Oral**, acute toxicity study in rats (LD50)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	No additional animal studies are planned	
	Evaluation by Competent Authorities	
Date **Evaluation of applicant's justification** **Conclusion** **Remarks**	[redacted]	

Section A6.1.2 Acute Toxicity

Annex Point IIA6.1.2.

Dermal; *Specify heading and species as appropriate*
Specify type of test (Limit Test, LD_{50}, special investigation)

[redacted]

Official use only

1.1 Reference

1.2 Data protection

1.2.1 Data owner

1.2.2

1.2.3 Criteria for data protection

2.1 Guideline study

2.2 GLP

2.3 Deviations

3.1 Test material

3.1.1 Lot/Batch number

3.1.2 Specification

3.1.2.1 Description

3.1.2.2 Purity

3.1.2.3 Stability

Section A6.1.2 Acute Toxicity

Annex Point IIA6.1.2. ***Dermal;*** *Specify heading and species as appropriate*
Specify type of test (Limit Test, LD_{50}, special investigation)

3.2 Test Animals

3.2.1 Species

3.2.2 Strain

3.2.3 Source

3.2.4 Sex

3.2.5 Age/weight at study initiation

3.2.6 Number of animals per group

3.2.7 Control animals

3.3 Administration/ Exposure

3.3.1 Postexposure period

3.3.2 Area covered

3.3.3 Occlusion

3.3.4 Vehicle

3.3.5 Concentration in vehicle

3.3.6 Total volume applied

3.3.7 Duration of exposure

3.3.8 Removal of test substance

3.3.9 Controls

3.4 Examinations

3.5 Method of determination of LD_{50}

3.6 Further remarks

4.1 Clinical signs

[redacted]

Section A6.1.2 Acute Toxicity

Annex Point IIA6.1.2.

Dermal; *Specify heading and species as appropriate*
Specify type of test (Limit Test, LD_{50}, special investigation)

[redacted]

4.2 Pathology

4.3 Other

4.4 LD_{50}

5.1 Materials and methods

5.2 Results and discussion

Section A6.1.2 Acute Toxicity

Annex Point IIA6.1.2. *Dermal; Specify heading and species as appropriate*
Specify type of test (Limit Test, LD_{50}, special investigation)

[redacted]

5.3 Conclusion

5.3.1 Reliability

5.3.2 Deficiencies

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	2009-06-09
Materials and Methods	Agree with applicant's version
Results and discussion	Agree with applicant's version
Conclusion	Agree with applicant's version
Reliability	1
Acceptability	acceptable
Remarks	

[redacted]

Section A6.1.2 Annex Point IIA6.1.2.	Acute Toxicity (Dermal)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [X] Limited exposure [ ]	Technically not feasible [ ] Scientifically unjustified [X] Other justification [ ]	
Detailed justification:	[redacted]	X
Undertaking of intended data submission [ ]		
	Evaluation by Competent Authorities	
Date Evaluation of applicant's justification Conclusion Remarks	[redacted]	

Section A6.1.3. Acute Toxicity

Annex Point IIA6.1.3. Inhalation

	Justification for non-submission of data	Official use only
Other existing data [X]	Technically not feasible [ ] Scientifically unjustified [X]	
Limited exposure […]	Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]		

Evaluation by Competent Authorities	
Date	[redacted]
Evaluation of applicant's justification	
Conclusion	
Remarks	

Section A6.1.3. **Annex Point IIA6.1.3.**	**Acute Toxicity** **Inhalation**, acute toxicity study in rats (LD50)	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	[redacted]	X X
Undertaking of intended data submission [ ]	No additional animal studies are planned	
	Evaluation by Competent Authorities	
Date **Evaluation of applicant's justification** **Conclusion** **Remarks**	[redacted]	

Section A6.1.3. **Annex Point IIA6.1.3.**	**Acute Toxicity** **Inhalation**, acute toxicity study in rats (LD50)
	For an overview of the available acute inhalation data please see Doc II-A 3.2.

Section A6.1.3_01 **Acute Toxicity**
Annex Point IIA6.1.3. **Inhalation**

					Official use only
		1 REFERENCE			
1.1	**Reference**	Copping L.G. (1998), The BioPesticide Manual, British Crop Protection Council, 1st edition, p. 25			
1.2	**Data protection**	No			
1.2.1	Data owner	----			
1.2.2	Companies with letter of access	----			
1.2.3	Criteria for data protection	----			
		2 GUIDELINES AND QUALITY ASSURANCE			
2.1	**Guideline study**	No information available			
2.2	**GLP**	No information available			
2.3	**Deviations**	No information available			
		3 MATERIALS AND METHODS			
3.1	**Test material**	No information available			
3.1.1	Lot/Batch number	No information available			
3.1.2	Specification	No information available			
3.1.2.1	Description	No information available			
3.1.2.2	Purity	No information available			
3.1.2.3	Stability	No information available			
3.2	**Test Animals**				
3.2.1	Species	Rat			
3.2.2	Strain	No information available			
3.2.3	Source	No information available			
3.2.4	Sex	No information available			
3.2.5	Age/weight at study initiation	No information available			
3.2.6	Number of animals per group	No information available			
3.2.7	Control animals	No information available			
3.3	**Administration/ Exposure**	**Inhalation**			
3.3.1	Postexposure period	No information available			
3.3.2	Concentrations	Nominal concentration	[mg/m³]	No information available	
		Analytical concentration	[mg/m³]	No information available	
3.3.3	Particle size	No information available			
3.3.4	Type or preparation of particles	No information available			
3.3.5	Type of exposure	No information available			

Section A6.1.3_01 Annex Point IIA6.1.3.		Acute Toxicity Inhalation
3.3.6	Vehicle	No information available
3.3.7	Concentration in vehicle	No information available
3.3.8	Duration of exposure	4 h
3.3.9	Controls	No information available
3.4	**Method of determination of LC_{50}**	No information available
3.5	**Further remarks**	----
		4 RESULTS AND DISCUSSION
4.1	**Clinical signs**	No information available
4.2	**Pathology**	No information available
4.3	**Other**	No information available
4.4	**LC_{50}**	>5.3 mg/L
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	No information available
5.2	**Results and discussion**	The LC_{50} (4 h) in the rat was found to be > 5.3 mg/L.
5.3	**Conclusion**	
5.3.1	Reliability	4 ("studies or data....which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.)." Acceptable as additional information, acute oral and acute dermal data are available.
5.3.2	Deficiencies	Yes As only the end point of the study is given in the reference no information on possible deficiencies regarding methodology is available.

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	March 2008
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	Study summary contributed by RMS

Section A6.1.3_02 **Acute Toxicity**
Annex Point IIA6.1.3. **Inhalation**

					Official use only
		1 REFERENCE			
1.1	**Reference**	Anonymous (date not stated), Toxicological Similarity of Straight Chain Saturated Fatty Acids of Greater Than 8 Carbon Chain Length by Various Routes of Exposure, Safer Inc, Eden Prairie MN 55334-3585, USA			
1.2	**Data protection**	No			
1.2.1	Data owner	----			
1.2.2	Companies with letter of access	----			
1.2.3	Criteria for data protection	----			
		2 GUIDELINES AND QUALITY ASSURANCE			
2.1	**Guideline study**	No information available			
2.2	**GLP**	No information available			
2.3	**Deviations**	No information available			
		3 MATERIALS AND METHODS			
3.1	**Test material**	C9 and C10 fatty acids: 60% a.s. formulation C9 fatty acids: 80% a.s. formulation			
3.1.1	Lot/Batch number	No information available			
3.1.2	Specification	No information available			
3.1.2.1	Description	No information available			
3.1.2.2	Purity	No information available			
3.1.2.3	Stability	No information available			
3.2	**Test Animals**				
3.2.1	Species	No information available			
3.2.2	Strain	No information available			
3.2.3	Source	No information available			
3.2.4	Sex	No information available			
3.2.5	Age/weight at study initiation	No information available			
3.2.6	Number of animals per group	No information available			
3.2.7	Control animals	No information available			
3.3	**Administration/ Exposure**	**Inhalation**			
3.3.1	Postexposure period	No information available			
3.3.2	Concentrations	Nominal concentration	[mg/m³]	No information available	
		Analytical concentration	[mg/m³]	No information available	
3.3.3	Particle size	No information available			

Section A6.1.3_02	**Acute Toxicity**
Annex Point IIA6.1.3.	**Inhalation**

3.3.4	Type or preparation of particles	No information available
3.3.5	Type of exposure	No information available
3.3.6	Vehicle	No information available
3.3.7	Concentration in vehicle	No information available
3.3.8	Duration of exposure	4 h
3.3.9	Controls	No information available
3.4	**Method of determination of LC_{50}**	No information available
3.5	**Further remarks**	----
		4 RESULTS AND DISCUSSION
4.1	**Clinical signs**	No information available
4.2	**Pathology**	No information available
4.3	**Other**	No information available
4.4	**LC_{50}**	C10 fatty acid >4.1 mg/L (2h) C9 and C10 fatty acids 60% formulation >5.53 mg/L (4h) C9 80% formulation >5.9 mg/L (4h)
		5 APPLICANT'S SUMMARY AND CONCLUSION
5.1	**Materials and methods**	No information available
5.2	**Results and discussion**	The LC_{50} (4 h) of a 60% formulation of C9 and C10 fatty acids was found to be > 5.53 mg/L and the LC_{50} (4 h) of a 80% formulation of C9 fatty acids was found to be > 5.53 mg/L.
5.3	**Conclusion**	
5.3.1	Reliability	4 ("studies or data....which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.)." Acceptable as additional information, acute oral and acute dermal data are available.
5.3.2	Deficiencies	Yes As only the end points of the studies are given in the reference no information on possible deficiencies regarding methodology is available.

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	March 2008
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	Study summary contributed by RMS

Section A 6.1.4.e. Acute Eye Irritation

Annex Point IIA6.1.4 Acute eye irritation study in rabbits

		Official use only
1.1	**Reference**	
1.2	**Data protection**	
1.2.1	Data owner	
1.2.2		
1.2.3	Criteria for data protection	
2.1	**Guideline study**	
2.2	**GLP**	
2.3	**Deviations**	
3.1	**Test material**	
3.1.1	Lot/Batch number	
3.1.2	Specification	
3.1.2.1	**Description**	
3.1.2.2	**Purity**	
3.1.2.3	**Stability**	
3.2	**Test Animals**	
3.2.1	Species	
3.2.2	Strain	
3.2.3	Source	
3.2.4	Sex	
3.2.5	Age/weight at study initiation	
3.2.6	Number of animals per group	
3.2.7	Control animals	
3.3	**Administration/ Exposure**	
3.3.1	Preparation of test substance	
3.3.2	Amount of active	

[redacted]

Section A 6.1.4.e. Acute Eye Irritation

Annex Point IIA6.1.4 Acute eye irritation study in rabbits

	substance instilled	[redacted]	
3.3.3	Exposure period		
3.3.4	Postexposure period		
3.4	**Examinations**		
3.4.1	Ophthalmoscopic examination		
3.4.1.1	**Scoring system**		X
3.4.1.2	**Examination time points**		
3.4.2	Other investigations		
3.5	**Further remarks**		
4.1	**Clinical signs**		
4.2	**Average score**		
4.2.1	Cornea		X
4.2.2	Iris		
4.2.3	Conjunctiva		
4.2.3.1	**Redness**		
4.2.3.2	**Chemosis**		
4.3	**Reversibility**		
4.4	**Other**		
4.5	**Overall result**		X
5.1	**Materials and methods**		
5.2	**Results and**		X

Section A 6.1.4.e. Acute Eye Irritation

Annex Point IIA6.1.4 Acute eye irritation study in rabbits

	discussion	[redacted]	
5.3	**Conclusion**		X
5.3.1	Reliability		X
5.3.2	Deficiencies		

Evaluation by Competent Authorities	
Date	[redacted]
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A 6.1.4.e. Acute Eye Irritation

Annex Point IIA6.1.4

	Justification for non-submission of data	Official use only
Other existing data [ ]	Technically not feasible [ ] Scientifically unjustified [X]	
Limited exposure […]	Other justification [ ]	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	[redacted]	

Evaluation by Competent Authorities	
Date	[redacted]
Evaluation of applicant's justification	
Conclusion	

Section A 6.1.4.e. Acute Eye Irritation

Annex Point IIA6.1.4

Remarks

Section A6.1.4.s. Acute Dermal Irritation

Annex Point IIA6.4.

			Official use only
		1 REFERENCE	
1.1	**Reference**	Smyth Jr. H.F. , Carpenter C.P. , Weil C.S. , Pozzani U.C. and Striegel J.A. (1962) Range-finding toxicity data: List VI. American Industrial Hygiene Association Journal (AIHAJ), 23, 95-107; Ref nr A6.1.1/01D.	X
1.2	**Data protection**	No	
1.2.1	Data owner	published	
1.2.2			
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I.	
		2 GUIDELINES AND QUALITY ASSURANCE	
2.1	**Guideline study**	Not reported	
2.2	**GLP**	Not reported	
2.3	**Deviations**	-	
		3 MATERIALS AND METHODS	
3.1	**Test material**	Decanoic acid	
3.1.1	Lot/Batch number	Not reported	
3.1.2	Specification	Not reported	
3.1.2.1	**Description**	Not reported	
3.1.2.2	**Purity**	Not reported	
3.1.2.3	**Stability**	Not reported	
3.2	**Test Animals**		
3.2.1	Species	rabbit	
3.2.2	Strain	albino	
3.2.3	Source	Not reported	
3.2.4	Sex	Not reported	
3.2.5	Age/weight at study initiation	Not reported	
3.2.6	Number of animals per group	5/group	
3.2.7	Control animals	No	
3.3	**Administration/ Exposure**	Dermal	
3.3.1	Application		
3.3.1.1	**Preparation of test**	undiluted or as a solution in water, propylene glycol or acetone.	

Section A6.1.4.s. Acute Dermal Irritation

Annex Point IIA6.4.

	substance	
3.3.1.2	**Test site and Preparation of Test Site**	A 0.01-ml aliquot of the test material was applied to the clipped skin of the animals undiluted or as a solution in water, propylene glycol or acetone
3.3.2	Occlusion	Not reported
3.3.3	Vehicle	Not reported
3.3.4	Concentration in vehicle	Not reported
3.3.5	Total volume applied	0.01-ml aliquots
3.3.6	Removal of test substance	Not reported
3.3.7	Duration of exposure	24 h
3.3.8	Postexposure period	Not reported
3.3.9	Controls	Not reported
3.4	**Examinations**	
3.4.1	Clinical signs	Not reported
3.4.2	Dermal examination	Yes
3.4.2.1	**scoring system**	irritation grades that ranged from 1 to 10 (grade 1 = no irritation; 2 = least visible capillary injection from the undiluted material; 6 = higher necrosis with the undiluted material; and 10 = necrosis from a 0.01% solution)
3.4.2.2	**Examination time points**	24h
3.4.3	Other examinations	Not reported
3.5	**Further remarks**	

4 RESULTS AND DISCUSSION

4.1	**Average score**	100 % irritant effects, score=5
4.2	**Reversibility**	Not reported
4.3	**Other examinations**	-
4.4	**Overall result**	

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Primary skin irritation was determined using groups of 5 albino rabbits. A 0.01-ml aliquot of the test material was applied to the clipped skin of the animals undiluted or as a solution in water, propylene glycol or acetone. Scoring of the reactions was conducted within 24 hours.
5.2	**Results and discussion**	100 % irritant effects

Section A6.1.4.s. Acute Dermal Irritation

Annex Point IIA6.4.

5.3	**Conclusion**	The classification for skin irritation (R38) is considered required for decanoic acid according to Directive 2001/59/EC (adaptation of 67/548/EEC).
5.3.1	Reliability	2
5.3.2	Deficiencies	-

Evaluation by Competent Authorities	
Date	[redacted]
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Section A6.1.4.s. Acute Dermal Irritation

Annex Point IIA6.4. Human

Official use only

1 REFERENCE

1.1	**Reference**	Robinson M.K., Whittle E. and Basketter D.A. (1999) A two-center study of the development of acute irritation responses to fatty acids. American Journal of Contact Dermatitis, 10(3), 136-145; Ref nr A6.1.4/01.
1.2	**Data protection**	No
1.2.1	Data owner	published
1.2.2		
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I.

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No
2.2	**GLP**	No
2.3	**Deviations**	-

3 MATERIALS AND METHODS

3.1	**Test material**	Octanoic acid (Sigma Cat. # C2875) **decanoic acid** (Sigma Cat. # C1875) dodecanoic acid (Sigma Cat. # L4250) sodium dodecyl sulphate/SDS (Sigma Cat. # L45095) (positive control)
3.1.1	Lot/Batch number	Not reported
3.1.2	Specification	Not reported
3.1.2.1	**Description**	Not reported
3.1.2.2	**Purity**	All test chemicals were at least 99% pure
3.1.2.3	**Stability**	Not reported
3.2	**Test Animals**	Human volunteers
3.2.1	Species	-
3.2.2	Strain	-
3.2.3	Source	-
3.2.4	Sex	Male and female
3.2.5	Age/weight at study initiation	24 to 64 years
3.2.6	Number of animals per group	study 1: 18 men, 15 women for study 2: 39 women (2 volunteers dropped from each test)
3.2.7	Control animals	No
3.3	**Administration/ Exposure**	Dermal application, each volunteer had a maximum of 5 patches per substance tested

Section A6.1.4.s. Acute Dermal Irritation

Annex Point IIA6.4. Human

3.3.1	Application	
3.3.1.1	**Preparation of test substance**	Test substances were used as delivered except of SDS SDS was used as 20% solution diluted with water.
3.3.1.2	**Test site and Preparation of Test Site**	1st patch: upper left or right arm 2nd patch: same arm near site of 1st patch 3. and 4. patch: alternate arm in same fashion as 1st and 2nd patch A maximum of 3 sequential patches of each tests material were applied to each arm, and no patch was reapplied to a previous exposed skin site. The test material was patched for a duration up to 4 hours unless a positive skin reaction developed from earlier (shorter) exposure.
3.3.2	Occlusion	occlusive
3.3.3	Vehicle	Destilled water
3.3.4	Concentration in vehicle	0.2 g or 0.2 mL test substance
3.3.5	Total volume applied	-Octanoic acid applied as liquid (2mL) -decanoic acid applied as powder (0.2 g) chamber was wetted with 0.2 mL destilled water -dodecanoic acid applied as powder (0.2 g) to dry chamber
3.3.6	Removal of test substance	All patch removal sites were individually wiped with cotton wool or paper towel moistened with destilled water
3.3.7	Duration of exposure	0 patch : 0.5 hour exposure (only study 2) 1st patch: 1 hour (study 1+2) 2nd patch: 2 hours (study 1+2) 3. patch: 3 hours (study 1+2) 4. patch: 4 hours (study 1+2) (graded duration of chemical exposure)
3.3.8	Postexposure period	
3.3.9	Controls	SDS as positive control destilled water as negative control (only study 2)
3.4	**Examinations**	
3.4.1	Clinical signs	Yes
3.4.2	Dermal examination	Yes
3.4.2.1	**scoring system**	0 – no significant reaction + - weak but unequivocal erythema over most or all of test site. The response may include some edema or other surface effects (glazing, scalling, ect.) ++ - moderate erythema that may spread beyond the edge of the treatment site. The response is usually accompanied by edema and/or surface effects (e.g. glazing, scaling) and possibly other focal injuries (hemorrhage, erosion, scabbing) +++ - strong, usually spreading, erythema usually accompanied by edema and possibly with injuries in depth (vesiculation, scabbing, hemorrhage)
3.4.2.2	**Examination time**	Treatment sites were assessed 24, 48 and 72 hours after patch removal.

Section A6.1.4.s.	**Acute Dermal Irritation**	
Annex Point IIA6.4.	Human	
	points	
3.4.3	Other examinations	none
3.5	**Further remarks**	-
	4 RESULTS AND DISCUSSION	
4.1	**Average score**	
4.1.1	Erythema	Not reported
4.1.2	Edema	Not reported
4.2	**Reversibility**	More than 90% of the skin reactions were mild in severity and resolved quickly.
4.3	**Other examinations**	none
4.4	**Overall result**	Decanoic acid was shown to produce a significantly greater cumulative incidence of positive responses than SDS at all exposure time points. (Table A6_1-4S-1). Both tests showed it to be more irritating after 2 and 3 hours of exposure. Based on the approach described for interpretation of the results (Basketter, et al. 1997), in terms of formal classification in the European Union decanoic acid would be classified as irritant to skin (R38).
	5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	An acute irritation response test was performed with 70 human volunteers. Patches with substance were applied to the upper arms with graded duration of exposure (0.5, 1, 2, 3, 4 hours). The treatment sites were assessed 24, 48 and 72 hours after patch removal.
5.2	**Results and discussion**	More than 90% of the skin reactions were mild in severity and resolved quickly. Decanoic acid was directionally (not statistically) more irritating than SDS at 4 hours.
5.3	**Conclusion**	The classification for skin irritation (R38) is considered required for decanoic acid according to Directive 2001/59/EC (adaptation of 67/548/EEC) based on the approach described for interpretation of the results (Basketter, D.A. et al. 1997), in terms of formal classification in the European Union.
5.3.1	Reliability	1
5.3.2	Deficiencies	No

X

Evaluation by Competent Authorities	
Date	[redacted]
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

[redacted]

Section A6.1.4.s. Acute Dermal Irritation

Annex Point IIA6.4. Human

Official use only

		1 REFERENCE
1.1	**Reference**	Robinson M.K., Whittle E. and Basketter D.A. (1999) A two-center study of the development of acute irritation responses to fatty acids. American Journal of Contact Dermatitis, 10(3), 136-145; Ref nr A6.1.4.5/01.
1.2	**Data protection**	No
1.2.1	Data owner	published
1.2.2		
1.2.3	Criteria for data protection	Data on existing a.s. submitted for the first time for entry into Annex I.
		2 GUIDELINES AND QUALITY ASSURANCE
2.1	**Guideline study**	No
2.2	**GLP**	No
2.3	**Deviations**	-
		3 MATERIALS AND METHODS
3.1	**Test material**	**Octanoic acid** (Sigma Cat. # C2875) decanoic acid (Sigma Cat. # C1875) dodecanoic acid (Sigma Cat. # L4250) sodium dodecyl sulphate/SDS (Sigma Cat. # L45095) (positive control)
3.1.1	Lot/Batch number	Not reported
3.1.2	Specification	Not reported
3.1.2.1	**Description**	Not reported
3.1.2.2	**Purity**	All test chemicals were at least 99% pure
3.1.2.3	**Stability**	Not reported
3.2	**Test Animals**	Human volunteers
3.2.1	Species	-
3.2.2	Strain	-
3.2.3	Source	-
3.2.4	Sex	Male and female
3.2.5	Age/weight at study initiation	24 to 64 years
3.2.6	Number of animals per group	study 1: 18 men, 15 women for study 2: 39 women (2 volunteers dropped from each test)
3.2.7	Control animals	No
3.3	**Administration/**	Dermal application, each volunteer had a maximum of 5 patches per substance tested