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

Annex Point IIA7.6.2.1

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2001) OS 157340: Determination of General Physico-chemical Properties, [redacted] (unpublished)
1.2	**Data protection**	Yes
1.2.1	Data owner	[redacted]
1.2.2	Criteria for data protection	Data submitted to the MS before 14 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**	Yes, Method C7 of Commission Directive 92/69/EEC and Method 835.2110 OPPTS Guidelines
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Test material**	N,N-Methylenebismorpholine
3.1.1	Lot/Batch number	OS 257340 Batch number: N/A
3.1.2	Specification	Extremely pale yellow liquid
3.1.3	Purity	93.5 – 96.4% (cf. Doc IVB 2.1.1)
3.1.4	Further relevant properties	No data
3.2	**Reference substance**	No
3.2.1	Initial concentration of reference substance	Not applicable

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

Annex Point IIA7.6.2.1

3.3 Test solution

Tests were carried out in buffered solutions

Type and composition of buffer solutions

pH	Type of buffer (final molarity) [mol/L]	Composition
1.2	0.065 0.05	Hydrochloric acid Potassium chloride
4	0.01	Potassium hydrogen phthalate
7	0.006 0.004 0.004	Disodium hydrogen phosphate (anhydrous) Potassium dihydrogen orthophosphate Sodium chloride
9	0.002 0.004	Disodium tetraborate Sodium chloride

Description of test solution

Criteria	Details
Purity of water	No data
Preparation of test medium	Sample solutions were prepared in stoppered glass flasks in the 4 buffered solutions. Buffer solutions were filtered through a 0.2 µm membrane filter to ensure they were sterile ans subjected to ultrasonification and degassing with nitrogen to minimise dissolved oxygen content. The solutions were shielded from ligth whilst maintained at the test temperature.
Test concentrations (mg a.i./L)	0.5 g/L (nominal)
Temperature (°C)	50±0.5 °C
Controls	Standards were prepared in pure solvent acetonitrile to avoid degradation. Duplicate standard solutions were prepared at nominal concentrations of 25 mg/L
Identity and concentration of co-solvent	Not applicable
Replicates	2 per pH

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

Annex Point IIA7.6.2.1

3.4 Testing procedure

3.4.1 Test system

Glassware	stoppered gas flasks
Other equipment	No data
Method of sterilization	Buffer solutions were filtered through a 0.2 µm membrane filter to ensure they were sterile.

The solutions were shielded from light whilst maintained at the test temperature. Standards were prepared in pure solvent (acetonitrile) to avoid degradation.

3.4.2 Temperature: 50.0 ± 0.5 °C (pH 4, 7, 9)
37.0 ± 0.5°C (pH 1.2)

3.4.3 pH: 1.2, 4, 7, 9.

3.4.4 Duration of the test: 2.4 hours

3.4.5 Number of replicates: 2 per pH

3.4.6 Sampling: Aliquots of sample solutions were taken from the flasks at various times and the pH of each solution was determined. The concentration of the sample was determined by gas chromatography. Duplicate sample solutions were diluted by a factor of 20 using acetonitrile.

3.4.7 Analytical methods: [redacted]

3.5 Preliminary test

Yes

Buffer systems for pH 4, 7 and 9 were used in the prelinimary test. Sample solutions were maintained at 50±0.5 °C for 2.4 hours. Results from the preliminary tests showed it was necessary to undertake further testing at pH 1.2 at 37.0 ± 0.5 °C for 2.4 hours.

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

Annex Point IIA7.6.2.1

4 RESULTS

4.1 Concentration and hydrolysis values

Transformation compounds were not monitored during the test due to the fast hydrolysis. Test with reference compound was not performed.

Compound	Sampling time pH 1.2 at 37 °C	
	0	2.4 hours
Parent compound	<3.18 mg/L (LOQ[1])	<3.18 mg/L (LOQ[1])
Total % recovery	not applicable	not applicable
Compound	**Sampling time pH 4 at 50 °C**	
	0	2.4 hours
Parent compound	<3.18 mg/L [1]	<3.18 mg/L [1]
Total % recovery	not applicable	not applicable
Compound	**Sampling time pH 7 at 50 °C**	
	0	2.4 hours
Parent compound	<3.18 mg/L [1]	<3.18 mg/L [1]
Total % recovery	not applicable	not applicable
Compound	**Sampling time pH 9 at 50 °C**	
	0	2.4 hours
Parent compound	<3.18 mg/L [1]	<3.18 mg/L [1]
Total % recovery	not applicable	not applicable

[1] limit of quantification

Due to the fast rate of hydrolysis at all pH's investigated no test material was detected at any of the time points.

4.2 Hydrolysis rate constant (k_h)

k_h could not be determined due to the fast hydrolysis.

4.3 Dissipation time

	pH 1.2		pH 5		pH 7		pH 9	
	DT_{50}	DT_{90}	DT_{50}	DT_{90}	DT_{50}	DT_{90}	DT_{50}	DT_{90}
Parent compound	<1 day	no data	<1 day	no data	<1 day	no data	<1 day	no data

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

Annex Point IIA7.6.2.1

4.4	**Concentration – time data**	Not applicable due to the fast hydrolysis.
4.5	**Specification of the transformation products**	[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Samples of N,N-Methylenebismorpholine at a concentration of 0.5 g/L (nominal) were incubed in 4 buffered aqueous solutions for 2.4 hours at 37°C for pH 1.2, at 50 °C or pH 4, 7 and 9 for 2.4 hours. The tests were performded according to Method C7 of Commission Directive 92/69/EEC and Method 835.2110 OPPTS Guidelines. [redacted]
5.2	**Results and discussion**	[redacted]
5.2.1	k_H	not determined
5.2.2	DT_{50}	< 1 day at 25 °C
5.2.3	r^2	not applicable
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

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

Annex Point IIA7.6.2.1

[redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	October 2010
	[redacted]
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

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

Annex Point IIA7.6.2.1

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2005a) Produktcharkterisierung des Biozids ST-1, [redacted], June 2005 (unpublished) [redacted] (2005b) Chargenvergleich des Biozids ST-1, [redacted], 30.8.2005 (unpublished) [redacted] (2007) Hydrolysis study in dependance of pH, temperature and concentration, [redacted] (in German; Hydrolysestude bei verschiedenen pH-Werten, Konzentrationen und Temperaturen ([redacted], 22.3.2007, 1.Nachtrag 22.5.2007, 2.Nachtrag 11.6.2007) (unpublished)
1.2	**Data protection**	Yes
1.2.1	Data owner	[redacted]
1.2.2	Criteria for data protection	Data submitted to the MS before 14 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**	No, but contains elements of OECD Guideline 111
2.2	**GLP**	[redacted]
2.3	**Deviations**	Not applicable

3 MATERIALS AND METHODS

3.1	**Test material**	N,N-Methylenebismorpholine
3.1.1	Lot/Batch number	[redacted] Charge 100376054 [redacted] Chargen 100412062, 100412438, 100413895, 100415125, 100415127 no Charge No. given in BASF study
3.1.2	Specification	Biozid ST-1, CAS No.: 5625-90-1
3.1.3	Purity	93.5 – 96.4% (cf. Doc IVB 2.1.1)
3.1.4	Further relevant properties	No data
3.2	**Reference substance**	No
3.2.1	Initial concentration of reference substance	Not applicable

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

Annex Point IIA7.6.2.1

3.3 Test solution

Tests on product characterisation and chregn control were unbufferd.

[redacted] the pH values were set by using concentrated sulphuric acid or hydrochloric acid

Criteria	Details
Purity of water	No data
Preparation of test medium	[redacted] ST-1 and Acetonitril are diluted in DMSO-D_6 and transfered in NMR tubes [redacted]: dilution of ST-1 with water or sulphuric acid
Test concentrations (mg a.i./L)	100%, 10%, 3%, 0.15%
Temperature (°C)	room temperature or 60 °C (see below)
Controls	[redacted]Acetonitril as internal standard
Identity and concentration of co-solvent	Not applicable
Replicates	no data

3.4 Testing procedure

3.4.1 Test system

Glassware	NMR tubes
Other equipment	No data
Method of sterilization	Not applicable, no sterilization

The 60 °C samples are stored between the measurements in tempered heating cabines.

3.4.2 Temperature: room temperature or 60°C

3.4.3 pH: 2, 5, 8, 11

3.4.4 Duration of the test: up to 30 hours

3.4.5 Number of replicates: no data

3.4.6 Sampling: [redacted]study measurements were done immediately after preparation of the solution. In the following studies samples were taken in the equilibrium of the solution (> 4 hours).

3.4.7 Analytical methods: ^{1}H-NMR and ^{13}C-NMR

3.5 Preliminary test: Not applicable

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

Annex Point IIA7.6.2.1

4 RESULTS

4.1 Concentration and hydrolysis values

The 10% solutions were only qualitative analyzed:

[redacted]

Quantitative NMR analysis were compiled by the applicant:

Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

4.2 Hydrolysis rate constant (k_h)

k_h could not be determined for the active substance due to the fast adjustment of the dynamic equilibrium.

4.3 Dissipation time

For concentrations in the preserved product (< 0.15%), and for environmental relevant concentrations, a half-life time of < 1 day can be estimated from the data above.

4.4 Concentration – time data

Not applicable due to the fast adjustment of the dynamic equilibrium.

4.5 Specification of the transformation products

Following hydrolysis products were identified by NMR signals:

[redacted]

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Samples of N,N-Methylenebismorpholine were characterized and the constituents quantified using the ^{1}H-and ^{13}C-NMR technique. Thereby, the dependance of pH, concentration and temperature has been investigated.

[redacted]

Samples were taken immediately after prepareteion of the solution or after adjustment of the equilibrium (> 4 hours).

5.2 Results and discussion

[redacted]

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

Annex Point IIA7.6.2.1

[redacted]

5.2.1	k_H	not determined
5.2.2	DT_{50}	< 1 day at 25 °C
5.2.3	r^2	not applicable
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

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

Annex Point IIA7.6.2.1

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date October 2010

[redacted]

Materials and Methods

[redacted]

Results and discussion

[redacted]

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

Annex Point IIA7.6.2.1

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

Section A7.1.1.1.2 Annex Point IIA7.6.2.2	Phototransformation in water including identity of transformation products	
	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]	
References	[redacted]	
Undertaking of intended data submission [ ]	Not applicable, no study is planned.	

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	October 2010
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]

Section A7.1.1.2.1 Biodegradability (ready)

Annex Point IIA7.6.1.1

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2001) OS 157340: Assessment of ready biodegradability; CO2 Evolution Test, [redacted] (unpublished)	
1.2	**Data protection**	Yes	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	Data submitted to the MS before 14 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**	OECD 301B "Ready Biodegradability; CO_2 Evolution Test" 92/69/EEC C.4-C OPPTS 835.3110 (m)	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	No	
		3 MATERIALS AND METHODS	
3.1	**Test material**	OS 157340	x
3.1.1	Lot/Batch number	No data	
3.1.2	Specification	Extremely pale yellow liquid	x
3.1.3	Purity	No data	x
3.1.4	Further relevant properties	Stability not specified in the study	
3.1.5	Composition of Product	No data	x
3.1.6	TS inhibitory to microorganisms	Not specified in the study. However, a study according to OECD 209 resulted in a 3 h-NOEC of 32 mg/L (**cf. Doc III A7.4.1.4**).	
3.1.7	Specific chemical analysis	Not analysed	
3.2	**Reference substance**	Sodium benzoate (Sigma Lot No. 77H05005)	
3.2.1	Initial concentration of reference substance	17.1 mg/L	
3.3	**Test ing procedure**		

Section A7.1.1.2.1 Biodegradability (ready)

Annex Point IIA7.6.1.1

3.3.1 Inoculum / test species

Criteria	Details
Nature	activated sewage sludge micro-organisms
Species	not applicable
Strain	not applicable
Source	aeration stage of a sewage treatment plant, predominantly domestic sewage
Sampling site	Severn Trent Water Plc sewage treatment plant at Belper, Derbyshire, UK
Laboratory culture	The sample was maintained on continuous aeration upon receipt.
Method of cultivation	Not applicable
Preparation of inoculum for exposure	washing by settlement and resuspension in culture medium for three times to remove excessive amounts of dissolved organic carbon
Pretreatment	No
Initial cell concentration	30 mg suspended solids/L

Section A7.1.1.2.1 Biodegradability (ready)

Annex Point IIA7.6.1.1

3.3.2 Test system

Criteria	Details
Culturing apparatus	sealed culture vessels, 3 L
Number of culture flasks/concentration	2
Aeration device	Aeration with CO_2-free air, rate of aeration : 40 mL/minute under continuous stirring
Measuring equipment	produced CO_2 was collected in Dreschel bottles containing 350 mL 0.05 M NaOH CO_2 was analysed using a Tekmar-Dohrmann Apollo 9000 analyser and an Ionics 1555B TOC analyser. Samples were injected into the IC (Inorganic Carbon) channel of the TOC analyser. Each analysis was carried out in triplicate. DOC (dissolved organic carbon) analysis was carried out on day 0 and 28. Samples were filtered through Gelman 0.45 Acropap filters and analysed using a Shimadsu TOC-5050A TOC analyser. Samples were injected into the TC (Total Carbon) and IC channels. Analysis was carried out in triplicate.
Test performed in closed vessels due to significant volatility of TS	Yes, however the test substance is not volatile

x

3.3.3 Test conditions

Criteria	Details
Composition of medium	as recommended in the OECD Guideline
Additional substrate	No
Test temperature	21°C
pH	7.4
Aeration of dilution water	Yes, aeration overnight
Suspended solids concentration	30 mg suspended solids/L
Other relevant citeria	stirring of test solution

3.3.4 Method of preparation of test solution

1000 mg of the test material was dissolved in culture medium followed by ultrasonification for 10 min and the volume adjusted to give 100 mL stock solution. An aliquot was dispersed in inoculated culture medium to give a final nominal concentration of 17.2 mg/L.

3.3.5 Initial TS concentration

Test material in inoculated culture medium to give a final nominal concentration of 10 mg carbon/L, coreresponding to 17.2 mg test

Section A7.1.1.2.1 Biodegradability (ready)

Annex Point IIA7.6.1.1

		substance/L
3.3.6	Duration of test	29 days
3.3.7	Analytical parameter	CO_2 evolution
3.3.8	Sampling	Sampling (2 mL) from the first absorber vessel was performed on days 0, 1, 2, 3, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 27, 28 and 29, from the second absorber vessel on days 0 and 29. Samples were analysed immediately. Samples on day 18 were deep frozen prior to analysis. Samples from day 12 were not analysed. On day 28 1 mL of concentrated hydrochloric acid was added to drive off any inorganic carbonates formed., vessels resealed and aerated. On day 29 final samples from the absorber vessels were analysed.
3.3.9	Intermediates/ degradation products	Not identified
3.3.10	Nitrate/nitrite measurement	No
3.3.11	Controls	Controls consisted of inoculated culture medium. Controls were performed in duplicate. Toxicity control consisted of test material (17.2 mg/L) plus reference substance (17.1 mg/L) in inoculated culture medium to give final concentration of 20 mg carbon/L (one vessel only).
3.3.12	Statistics	Calculation were performed according to OECD 301B.
		4 RESULTS
4.1	**Degradation of test substance**	
4.1.1	Graph	Graph by applicant representing degradation results tabulated in the study report: [redacted]
4.1.2	Degradation	[redacted]
4.1.3	Other observations	No further observations are reported
4.1.4	Degradation of TS in abiotic control	Abiotic control was not performed.
4.1.5	Degradation of reference substance	cf. 4.1.1
4.1.6	Intermediates/ degradation products	Degradation products were not monitored.

Section A7.1.1.2.1 Biodegradability (ready)

Annex Point IIA7.6.1.1

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

17.2 mg of N,N-methylenbismorpholine/L, corresponding to 10 mg C/L were exposed in duplicate at 21°C in the dark in an inoculated culture medium. Activated sewage sludge from the aerations stage of a predominantly domestic sewage treatment plant was used as inoculum. The suspended solids concentration was 30 mg/L. The culture vessels were sealed and aerated with CO_2-free air at a rate of 40 mL/min and stirred. The culture vessels were equipped with two subsequent absorber vessels. CO_2 analysis was done daily. At day 29, 1 mL of concentrated hydrochloric acid was added to drive out any inorganic carbonates, vessels resealed, aerated overnight and CO_2 analysed. Controls with inoculated culture medium and standard material (sodium benzoate, 17.7 mg/L, corresponding to 10 mg C /L) were incubated in duplicate. One toxicity control with 17.2 mg N,N-methylenbismorpholine /L and 17.1 mg sodiumbenzoate /L, resulting 20 mg C/L, was performed.

5.2 Results and discussion

In the incubations 93% of the test substance degraded after 28 days. The pass-level was reached within 10 days.

	fulfilled	not fulfilled
Pass levels		
70% removal of DOC resp. 60% removal of ThOD or $ThCO_2$	X	
Pass values reached within 10-d window (within 28-d test period) - not applicable to MITI-I-Test - 14-d window acceptable for Closed-Bottle-Test	X	
Criteria for validity		
Difference of extremes of replicate values of TS removal at plateau (at the end of test or end of 10-d window) < 20%	X	
Percentage of removal of reference substance reaches pass level by day 14	X	

The inorganic carbon content of the in the mineral medium was below 5%. The total CO_2 evolution of the inoculum blank was below 40 mg/L, actually 32.5 mg/L. Therefore; the validity critera can be considered as fulfilled.

[redacted]

5.3 Conclusion

N,N-methylenebismorpholine is readily biodegradable, including the 10 days window criterion. x

5.3.1 Reliability [redacted]

5.3.2 Deficiencies [redacted]

Section A7.1.1.2.1 Biodegradability (ready)

Annex Point IIA7.6.1.1

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	May 2011
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A7.1.1.2.2 Annex Point VII.7.6.1.2	Inherent biodegradability	
	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]	x
Reference:	[redacted]	
Undertaking of intended data submission [ ]	Not applicable, no study is planned.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	July 2011	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	

Section A7.1.3 Adsorption / Desorption screening test

Annex Point IIA7.7

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2001) OS 157340: Determination of General Physico-chemical Properties, [redacted] (unpublished) [redacted] (2005) Estimation of the adsorptions coefficient of N,N-Methylenebismorpholine using KOWWIN v1.67 (published)
1.2	**Data protection**	Yes
1.2.1	Data owner	[redacted]
1.2.2	Criteria for data protection	Data submitted to the MS before 14 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**	OECD draft document (August 1999): Estimation of the Adsorption Coefficient (K_{oc}) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)
2.2	**GLP**	[redacted]
2.3	**Deviations**	Yes The test was conducted only with the ionized form of the test substance.

3 MATERIALS AND METHODS

3.1	**Test material**	N,N-Methylenebismorpholine
3.1.1	Lot/Batch number	OS 257340 Batch number: N/A
3.1.2	Specification	No data
3.1.3	Purity	93.5 – 96.4% (cf. Doc IVB 2.1.1)
3.1.4	Further relevant properties	Rapid hydrolysis of the test substance in aqueous solution: DT50 < 1 day
3.1.5	Method of analysis	No data
3.2	**Degradation products**	[redacted] Hydrolysis DT50 was < 1 day at 25 °C (**cf. Doc. 7.1.1.1.1**).
3.2.1	Method of analysis for degradation products	No degradation products were determined within this study
3.3	**Reference substance**	Yes, several solutions of reference standards were prepared in methanol:water (55:45 v/v) dead time was determined with formamide. Reference standards: Acetanilide, Phenol, Atrazin, Isoproturon, Triadimenol, Naphthalene, endosulfan-alcohol, Fenthion, α-Endosulfan, Diclofop-methyl, Phenanthrene, DDT
3.3.1	Method of analysis for reference substance	Not applicable

Section A7.1.3 Adsorption / Desorption screening test

Annex Point IIA7.7

3.4	**Soil types**	Not applicable, HPLC-Method
3.5	**Testing procedure**	
3.5.1	Test system	HPLC-Method
3.5.2	Test solution and Test conditions	0.5166 g of test material were diluted with 100 mL methanol
3.6	**Test performance**	
3.6.1	Preliminary test	Not applicable
3.6.2	Screening test: Adsorption	Not applicable
3.6.3	Screening test: Desorption	Not applicable
3.6.4	HPLC-method	According to (a)" OECD-HPLC-method"[1]: Yes HPLC System: Hewlett-Packard 1050, incorporating autosampler and workstation Column: Luna CN 5µm (250 X 4.6 mm id) Column temperature: 30°C Mobile phase: methanol/water (55:45 v/v) adjusted to neutral pH using 0.1 M sodium hydroxide Measured pH of mobile phase: 7.0 UV detector wavelength: 210 nm Injection volume: 10µl Calibration curve was determined with reference standards (cf. 3.3) The capacity factor was calculated using following equation: $k= (t_r - t_0) / t_0$ k = capacity factor, t_r = retention time (min), t_0 = dead time (min) $\log_{10}Kd_{oc}$ was determined with reference to the calibration curve
3.6.5	Other test	Not applicable
	4 RESULTS	
4.1	**Preliminary test**	Not applicable
4.2	**Screening test: Adsorption**	Not applicable
4.3	**Screening test: Desorption**	Not applicable
4.4	**Calculations**	
4.4.1	Ka , Kd	Not determined
4.4.2	Ka_{oc} , Kd_{oc}	$\log K_{oc}$ <1.25 K_{oc} < 17.8

[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 Adsorption / Desorption screening test

Annex Point IIA7.7

4.5	**Degradation product(s)**	Degradation products were not determined within the study

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	The adsorption coefficient of N,N-Methylenebismorpholine was determined by the HPLC method following the Draft OECD Guideline. [redacted]
5.2	**Results and discussion**	The adsorption coefficient K_{oc} was determined to be <17.8. [redacted]
5.2.1	Adsorbed a.s. [%]	not applicable
5.2.2	K_a	not determined
5.2.3	K_d	not determined
5.2.4	Ka_{oc}	<17.8 L/kg
5.2.5	Ka/Kd	not applicable
5.2.6	Degradation products (% of a.s.)	not applicable
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Section A7.1.3 Adsorption / Desorption screening test

Annex Point IIA7.7

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	October 2011
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A7.3.1 Phototransformation in air (estimation method)

Annex Point IIIA7.5

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2005) [redacted] estimation for N,N-Methylene-bismorpholine (published)
1.2	**Data protection**	No
1.2.1	Data owner	[redacted]
1.2.2	Criteria for data protection	No data protection claimed

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	No, however generally accepted estimation method
2.2	**GLP**	[redacted]
2.3	**Deviations**	Not applicable

3 MATERIALS AND METHODS

3.1	**Test material**	N,N-Methylenebismorpholine
3.1.1	Lot/Batch number	Not applicable
3.1.2	Specification	Not applicable
3.1.3	Purity	Not applicable
3.1.4	Radiolabelling	Not applicable
3.1.5	Further relevant properties	Not applicable
3.2	**Reference substances**	Not applicable
3.3	**Testing procedure**	
3.3.1	Estimation method	The degradation rate constant with OH radicals for photochemical oxidative reaction of N,N-Methylenebismorpholine is estimated [redacted] The calculation is based on $0.5 \cdot 10^6$ OH radicals per cm^3 for a 24-hours-day according to the TGD (EC 2003, part II chapter 3, 2.3.6.3, p. 51).
3.3.2	Analytical methods	Not applicable
3.4	**Transformation products**	The formation of breakdown products is not considered [redacted].
3.4.1	Method of analysis for transformation products	Not applicable

4 RESULTS

4.1	**Phototransformation data**	
4.1.1	Rate constants	OH rate constant: $3.62 \cdot 10^{-10}$ cm^3 $molecule^{-1}$ s^{-1}
4.1.2	Half-lives	DT50 = 1.06 hours

Section A7.3.1 Phototransformation in air (estimation method)

Annex Point IIIA7.5

4.2	**Specification of the transformation products**	Transformation products are not given [redacted].

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	For N,N-Methylenebismorpholine the rate constant for indirect photolysis with OH radicals was estimated [redacted] v1.91. Ozone reaction was not estimated by the model. The calculation was based on $0.5 \cdot 10^6$ OH radicals per cm^3 for a 24-hours-day according to the TGD (EC 2003, part II chapter 3, 2.3.6.3, p. 51).
5.2	**Results and discussion**	For N,N-Methylenebismorpholine a specific degradation rate constant of $3.62 \cdot 10^{-10}$ cm^3 $molecule^{-1}$ s^{-1} was calculated. The corresponding half-live was 1.06 hours. [redacted]
5.2.1	Half-life	$\tau_{1/2}$ (•OH) = 1.06 h
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date October 2010

Section A7.3.1 Phototransformation in air (estimation method)

Annex Point IIIA7.5

Materials and Methods

[redacted]

Results and discussion

[redacted]

Conclusion

[redacted]

Reliability

[redacted]

Acceptability

[redacted]

Remarks

[redacted]

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1 *Oncorhynchus mykiss*

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2001) OS 157340: Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*), [redacted] (unpublished)	
1.2	**Data protection**	Yes	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	Data submitted to the MS before 14 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**	OECD Guideline No 203, Fish, Acute Toxicity test 92/69/EEC C.1 US CFR Title 40, part 797, Section 1400 US EPA Pesticide Assessment Guidelines, Sub-Division E, Section 72-4 OPPTS 850.1075	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
3.1	**Test material**	OS 157340, [redacted]	x
3.1.1	Lot/Batch number	No data	
3.1.2	Specification	No data	
3.1.3	Purity	No data	x
3.1.4	Composition of Product	[redacted]	
3.1.5	Further relevant properties	[redacted] Hydrolysis [redacted] DT50 < 1 day at 25°C (**cf. Doc. 7.1.1.1.1**). [redacted]	
3.1.6	Method of analysis	[redacted]	

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1 *Oncorhynchus mykiss*

3.2 Preparation of TS solution for poorly soluble or volatile test substances

Test material (2.0 g) was dissolved in 1 L of dechlorinated tap water with the aid of ultrasonification for approximately 30 minutes to give 2.0 g/L stock solution. The whole was dispersed in 20 L dechlorinated water to give 100 mg/L test solution. [redacted] Concentration and stability of the test material was verified by chemical analysis at 0, 24 and 96 hours. x

Criteria	Details
Dispersion	No
Vehicle	No
Concentration of vehicle	Not applicable
Vehicle control performed	Not applicable
Other procedures	exposure vessels were covered to reduce evaporation

3.3 Reference substance

No

3.3.1 Method of analysis for reference substance

Not applicable

3.4 Testing procedure

3.4.1 Dilution water

Criteria	Details
Source	dechlorinated tap water
Alkalinity	84 mg/L $CaCO_3$
Hardness	97 mg/L $CaCO_3$
pH	8.8 – 8.9
Oxygen content	8.8 – 10.0 mg/L
Conductance	No data
Holding water different from dilution water	No

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1 *Oncorhynchus mykiss*

3.4.2 Test organisms

Criteria	Details
Species/strain	Rainbow trout (*Oncorhynchus mykiss*)
Source	[redacted]
Wild caught	No
Age/size	juvenile rainbow trout (*Oncorhynchus mykiss*) size at the end of the definitive study: mean standard length: 4.4 cm (sd = 0.4) mean weight: 0.78 g (sd = 0.23)
Kind of food	commercial trout pellets
Amount of food	No data
Feeding frequency	No data
Pretreatment	acclimation to test conditions for 14 days
Feeding of animals during test	No, feeding of stock fish discontinued 48 hours before start of the test

3.4.3 Test system x

Criteria	Details
Test type	Semistatic
Renewal of test solution	daily renewal
Volume of test vessels	20 litre exposure vessel
Volume/animal	2 L/ animal
Number of animals/vessel	10
Number of vessels/ concentration	3
Test performed in closed vessels due to significant volatility of TS	Yes, exposure vessels were covered to reduce evaporation

3.4.4 Test conditions

Criteria	Details
Test temperature	14 ±1 °C, recorded daily
Dissolved oxygen	> 9.3 mg/L, recorded daily
pH	recorded daily, 7.7 – 10.0 during the test
Adjustment of pH	No
Aeration of dilution water	No
Intensity of irradiation	No data
Photoperiod	Photoperiod 16 hours, 8 hours darkness, 20 minute dawn and dusk transition period

3.4.5 Duration of the test 96 hours

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1 *Oncorhynchus mykiss*

3.4.6	Test parameter	Mortality	
3.4.7	Sampling	sampling at 3, 6, 42, 48, and 96 hours	
3.4.8	Monitoring of TS concentration	Yes, water samples from the two controls and the 3 replicate test vessels were taken at 0, 24 and 96 hours for quantitative analysis.	
3.4.9	Statistics	Not applied	
		4 RESULTS	
4.1	**Limit Test**	Range-finding test was performed, static conditions	
4.1.1	Concentration	1.0, 10, 100 mg/L (nominal concentrations)	
4.1.2	Number/ percentage of animals showing adverse effects	3 fish were exposed to 3 nominal concentrations [redacted]. After 24, 48 and 96 hours any mortalities or sub-lethal effects were observed by visual inspection.	
4.1.3	Nature of adverse effects	Not applicable	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	As a result from the range-finding test only one concentration was tested in triplicate: 100 mg/L nominal concentration	x

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1 *Oncorhynchus mykiss*

4.2.2 Actual concentrations of test substance

Actual concentrations during the test:

Sample	Nominal concentration [mg/L]	[redacted]	Expressed as a Percent of the Nominal Concentration of Test Material [%]
0 hours	Control R_1 [1)] Control R_2 [1)] 100 R_1 100 R_2 100 R_3	[redacted]	- - 102 103 103
24 hours	Control R_1 Control R_2 100 R_1 100 R_2 100 R_3	[redacted]	- - 102 103 104
96 hours	Control R_1 Control R_2 100 R_1 100 R_2 100 R_3 [1)]	[redacted]	- - 104 103 106

[1)] $R_1 - R_3$ = replicates
[2)] LOQ = limit of quantification

[redacted]

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1 *Oncorhynchus mykiss*

4.2.3 Effect data (Mortality)

Results of the main study:

Test substance Concentration (nominal) [mg/l]	**Mortality**							
	Number				**Percentage**			
	24 h	**48 h**	**72 h**	**96 h**	**24 h**	**48 h**	**72 h**	**96 h**
100 mg/L (n)	>100	>100	>100	>100	0%	0%	0%	0%
Temp. [°C]	14	14	14	14				
pH	8.8	8.8 - 8.9	8.7- 8.9	8.8				
Oxygen [mg/l]	8.8- 10.0	9.0- 9.9	8.8- 10.0	9.0				

	48 h [mg/l][1]	**95 % c l.**	**96 h [mg/l]**	**95 % c.l.**
LC_0	not determined			
LC_{50}	>100	-	>100	-
LC_{100}	not determined			

nominal concentrations

[redacted]

x

4.2.4 Concentration / response curve — Not applicable

4.2.5 Other effects — No other effects were observed

4.3 Results of controls

4.3.1 Number/ percentage of animals showing adverse effects — No adverse effects were observed

4.3.2 Nature of adverse effects — Not applicable

4.4 Test with reference substance — Not performed

4.4.1 Concentrations — Not applicable

4.4.2 Results — Not applicable

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1 *Oncorhynchus mykiss*

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Individuals of juvenile rainbow trout (*Onchorhynchus mykiss*) were exposed to the hydrolysis products of N,N-methylenebismorpholine in dechlorinated tap water. 10 animals per vessel were exposed to 100 mg/L (nominal concentration) for 96 hours at 14 °C, the test was run in triplicate. Dissolved oxygen was 8.8 – 10 mg/L, pH was 7.7 – 8.9 during the test. Controls were performed in duplicate. The test media were renewed daily. Sampling was done at 3, 6, 24, 48 and 96 hours. x

[redacted]

5.2 Results and discussion

[redacted] x

All validity criteria can be considered as fulfilled. The test was performed thoroughly according to Guidelines and national/international standards, as outlined in the study.

	fulfilled	Not fullfilled
Mortality of control animals <10%	X	
Concentration of dissolved oxygen in all test vessels > 60% saturation	X	
Concentration of test substance ≥80% of initial concentration during test	X	

Only one concentration was tested. None of the fish showed adverse effects, therefore no conentration-response curve could be established.

[redacted]

5.2.1 LC_0 No data

5.2.2 LC_{50} > 100 mg/L (nominal concentrations)

5.2.3 LC_{100} No data x

5.3 Conclusion

5.3.1 Other Conclusions [redacted] x

5.3.2 Reliability [redacted]

5.3.3 Deficiencies [redacted]

Section A7.4.1.1 Acute toxicity to fish

Annex Point IIA7.1 *Oncorhynchus mykiss*

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2011
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2001) OS 157340: Acute Toxicity to *Daphnia Magna*, [redacted] (unpublished)	
1.2	**Data protection**	Yes	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	Data submitted to the MS before 14 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**	Yes, OECD Guideline No. 202, Daphnia Sp, Acute Immobilisation Test and Reproduction Test 92/69/EEC C.2 US CFR Title 40, part 797, Section 1300 US EPA Pesticide Assessment Guidelines, Sub-Division E, Section 72-2 OPPTS 850.1010	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
3.1	**Test material**	OS 157340, [redacted]	x
3.1.1	Lot/Batch number	No data	
3.1.2	Specification	No data	
3.1.3	Purity	No data	x
3.1.4	Composition of Product	[redacted]	
3.1.5	Further relevant properties	[redacted] Hydrolysis [redacted] DT50 < 1 day at 25°C (**cf. Doc. 7.1.1.1.1**).	
3.1.6	Method of analysis	[redacted]	

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

3.2 Preparation of TS solution for poorly soluble or volatile test substances

Test material (500 mg) was dissolved in 1 L of dechlorinated tap water with the aid of ultrasonification for approximately 15 minutes to give a 100 mg/L stock solution. [redacted]
Concentration and stability of the test material was verified by chemical analysis at 0 and 48 hours.

Criteria	Details
Dispersion	No
Vehicle	No
Concentration of vehicle	Not applicable
Vehicle control performed	Not applicable
Other procedures	Yes, test vessels were covered to reduce evaporation.

x

3.3 Reference substance

No

3.3.1 Method of analysis for reference substance

Not applicable

3.4 Testing procedure

3.4.1 Dilution water

Criteria	Details
Source	dechlorinated tap water
Alkalinity	82 mg/L $CaCO_3$
Hardness	144 mg/L $CaCO_3$
pH	7.8 – 8.5
Ca / Mg ratio	No data
Na / K ratio	No data
Oxygen content	8.1 – 8.2 mg/L
Conductance	No data
Holding water different from dilution water	No

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

3.4.2 Test organisms

Criteria	Details
Strain	1st instar *Daphnia magna*
Source	in-house laboratory cultures
Age	<24 hours
Breeding method	reproduction was by parthogenesis
Kind of food	suspension of algae (*Chlorella sp.*)
Amount of food	No data
Feeding frequency	daily
Pretreatment	holding conditions were the same as test conditions
Feeding of animals during test	No

3.4.3 Test system

Criteria	Details
Renewal of test solution	No
Volume of test vessels	200 ml
Volume/animal	20 ml
Number of animals/vessel	10
Number of vessels/ concentration	2
Test performed in closed vessels due to significant volatility of TS	Yes, test vessels were covered to reduce evaporation

x

3.4.4 Test conditions

Criteria	Details
Test temperature	21°C, recorded daily
Dissolved oxygen	at start: 8.4 – 8.5 mg/L at the end: 8.0 – 8.2 mg/L
pH	at start: 7.6 – 8.9 at the end: 7.8 – 8.5
Adjustment of pH	No
Aeration of dilution water	No
Quality/Intensity of irradiation	No data
Photoperiod	Photoperiod 16 hours, 8 hours darkness, 20 minute dawn and dusk transition period

3.4.5 Duration of the test: 48 hours

3.4.6 Test parameter: immobility

3.4.7 Sampling: sampling after 24 and 48 hours

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

3.4.8	Monitoring of TS concentration	Yes	
3.4.9	Statistics	Maximum-likelyhood probit method using ToxCalc computer software package	

4 RESULTS

4.1	**Limit Test**	Range-finding study was performed under static conditions.	
4.1.1	Concentration	0.010, 0.10, 1.0, 10 and 100 mg/L (nominal concentrations)	
4.1.2	Number/ percentage of animals showing adverse effects	No immobilisation was observed at 0.010, 0.10 and 1.0 mg/L.	

Nominal concentration (mg/L)	Cumulative Immobilised *Daphnia* (Initial Population 10 per replicate)	
	24 hours	48 hours
10	0	3
100	9	10

4.1.3	Nature of adverse effects	immobility	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	1.0, 1.8, 3.2, 5.6, 10, 18, 32, 56, 100 mg/L (nominal concentrations)	x

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

4.2.2 Actual concentrations of test substance

Water samples were taken from the 1.0, 3.2, 10, 32 and 100 mg/L test groups for verification of the test concentrations at 0 and 48 hours.

Actual concentrations during the test: x

Sample	Nominal concentration [mg/L]	[redacted]	Expressed as a Percent of the Nominal Concentration of Test Material [%]
0 hours	Control R_1 [1)]	[redacted]	-
	Control R_2 [1)]		-
	1.0 R_1		86
	1.0 R_2		87
	3.2 R_1		95
	3.2 R_2		95
	10 R_1		100
	10 R_2		100
	32 R_1		100
	32 R_2		100
	100 R_1		100
	100 R_2		100
48 hours	Control R_1	[redacted]	-
	Control R_2		-
	1.0 R_1		84
	1.0 R_2		87
	3.2 R_1		95
	3.2 R_2		94
	10 R_1		98
	10 R_2		100
	32 R_1		98
	32 R_2		99
	100 R_1		98
	100 R_2		99

[1)] R_1, R_2 = replicates 1 and 2

[2)] LOQ = limit of quantification

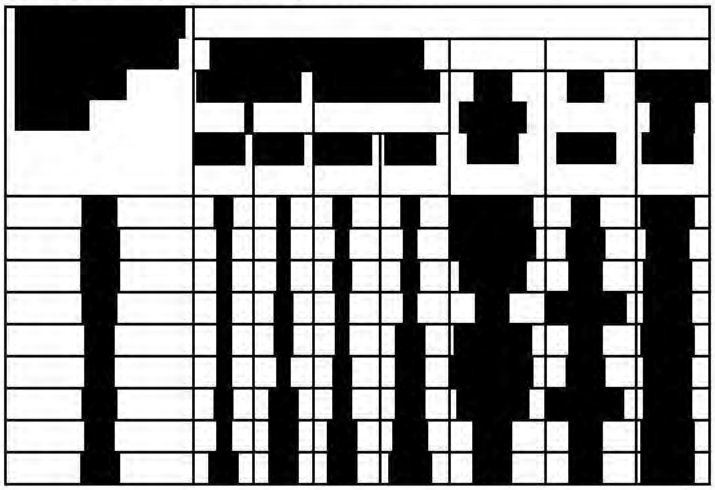
[redacted]

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

4.2.3 Effect data (Immobilisation)

Immobilisation data as absolute numbers of immobile daphnia as a total from $R_1 + R_2$ and as percent of exposed animals:



	EC_{50}	95 % c l.	EC_0	EC_{100}
24 h [mg/l]	71	61 - 83	32	n.d.
48 h [mg/l]	24	20 - 30	5.6	100

(nominal concentrations)

X

4.2.4 Concentration / response curve

Graph by applicant representing degradation results tabulated in the study report:

4.2.5 Other effects

No further data are reported

4.3 Results of controls

In the controls no effects were observed,.

4.4 Test with reference substance

Not performed

4.4.1 Concentrations

Not applicable

4.4.2 Results

Not applicable

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

Individuals of juvenile *Daphnia magna,* less than 24 hours old, were exposed to the hydrolysis products of N,N-methylenebismorpholine in dechlorinated tap water. 10 animals per vessel were exposed to 9 nominal concentrations in the range of 1.0 – 100 mg/L for 48 hours at 21 °C, the test was run in duplicate. Dissolved oxygen was 8.0 – 8.2 mg/L, pH was 7.8 – 8.5 during the test. Controls were also performed in duplicate. Sampling was done at 24 and

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

48 hours.

[redacted]

5.2 Results and discussion

[redacted] X

Validity criteria	fulfilled	Not fullfilled
Immobilisation of control animals <10%	X	
Control animals not staying at the surface	X	
Concentration of dissolved oxygen in all test vessels >3 mg/l	X	
Concentration of test substance ≥80% of initial concentration during test	X	

X

All validity criteria can be considered as fulfilled. The test was performed thoroughly according to Guidelines and national/international standards, as outlined in the study.

[redacted] X

5.2.1 EC_0 5.6 mg/L (24 hours, nominal concentration) X

5.2.2 EC_{50} 71 mg/L (24 hours, nominal concentration) X

5.2.3 EC_{100} 100 mg/L (24 hours, nominal concentration) X

5.3 Conclusion

[redacted]

5.3.1 Reliability [redacted]

5.3.2 Deficiencies [redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2011

Section A7.4.1.2 Acute toxicity to invertebrates

Annex Point IIA7.2 *Daphnia magna*

Materials and Methods

[redacted]

Results and discussion

[redacted]

Conclusion

[redacted]

Reliability

[redacted]

Acceptability

[redacted]

Remarks

[redacted]

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 *Pseudokirchneriella subcapitata*

			Official use only
		1 REFERENCE	
1.1	**Reference**	[redacted] (2001) OS 157340: Algal Inhibition Test, [redacted] (unpublished)	
1.2	**Data protection**	Yes	
1.2.1	Data owner	[redacted]	
1.2.2	Criteria for data protection	Data submitted to the MS before 14 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**	OECD Guideline No 201, Alga, Growth Inhibition Test (1984) 92/69/EEC C.3 US CFR Title 40, part 797, Section 1050 US EPA Pesticide Assessment Guidelines, Sub-Division J, Section 122-2 OPPTS 850.5400 (draft)	
2.2	**GLP**	[redacted]	
2.3	**Deviations**	[redacted]	
		3 MATERIALS AND METHODS	
3.1	**Test material**	N,N'-Methylenebismorpholine	x
3.1.1	Lot/Batch number	No data (batch # 21676 according to applicants statement)	
3.1.2	Specification	OS 157340	
3.1.3	Purity	Purity of the active substance 93.5-96.4% (cf. Doc IVB 2.1.1)	
3.1.4	Composition of Product	No data	
3.1.5	Further relevant properties	[redacted] Hydrolysis [redacted] DT50 < 1 day at 25°C (**cf. Doc. 7.1.1.1.1**). [redacted]	
3.1.6	Method of analysis	[redacted]	

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 *Pseudokirchneriella subcapitata*

3.2 Preparation of TS solution for poorly soluble or volatile test substances

Test material (64 mg) was dissolved in culture medium to give 64 mg/L stock solution. A series of dilutions gave further stock solutions. [redacted] concentration [redacted] was verified by chemical analysis at 0 and 96 hours.

Criteria	Details
Dispersion	No
Vehicle	No
Concentration of vehicle	Not applicable
Vehicle control performed	Not applicable
Other procedures	Yes, flasks were plugged with polyurethan foam bungs

3.3 Reference substance

No

3.3.1 Method of analysis for reference substance

Not applicable

3.4 Testing procedure

3.4.1 Culture medium

The culture medium was prepared using reverse osmosis purified water (Elga Optoma 15+) and the pH was adjusted to 7.5± 0.1 with 0.1 N NaOH or HCl. The prepared media was sterilised by 0.2 µm membrane filtration and stored in darkness.

Composition of the culture medium was als follows:

$NaNO_3$(25.5 mg/L), $MgCl_2.6H_2O$ (12.164 mg/L), $CaCl_2$ 2 H_2O (4.41 mg/L), $MgSO_4.7H_20$ (14.7 mg/l), K_2HPO_4 (1.044 mg/l), $NaHCO_3$ (15.0 mg/l), H_3BO_3 (0.1855 mg/1), $MnCl_2.4H_20$ (0.415 mg/l), $ZnC1_2$ (0.00327 mg/1), $FeCl_3.6H_2O$ (0.159 mg/l), $CoCl_2.6H_2O$ (0.00143 mg/l), $Na_2MoO_4.2H_2O$ (0.00726 mg/l), $CuCl_2.2H_2O$ (0.000012 mg/l), $Na_2EDTA.2H_2$ 0 (0.30 mg/l), $Na_2SeO_3.5H_2O$ (0.000010 mg/l)

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 *Pseudokirchneriella subcapitata*

3.4.2 Test organisms

Criteria	Details
Species	*Pseudokirchneriella subcapitata*
Strain	CCAP 278/4
Source	Cuture Collection of Algae and Proptozoa (CCAP), Institute of Freshwater Ecology, The Ferry House, Far Sawrey, Ambleside, Cumbria
Laboratory culture	Yes
Method of cultivation	Maintained in the laboratory by the periodic replenishment of culture medium at 21 ± 1 °C under continuous illumination (approx. 7000 lux) and constant aeration.
Pretreatment	No
Initial cell concentration	10^4 cells /mL

3.4.3 Test system

Criteria	Details
Volume of culture flasks	250 mL glass conical flask
Culturing apparatus	incubation apparatus: Gallenkamp INR-401-010W
Light quality	Gallenkamp INR-401-010W)
Procedure for suspending algae	Flasks were constantly shaken at approx. 100 rpm during the test.
Number of vessels/ concentration	3
Test performed in closed vessels due to significant volatility of TS	Yes, flasks were plugged with polyurethan foam bungs

3.4.4 Test conditions

Criteria	Details
Test temperature	24 ± 1, recorded hourly
pH	at start: 7.5 – 8.7 at end of test: 7.4 –10.1
Aeration of dilution water	No
Light intensity	7000 lux
Photoperiod	continuous illumination

x

3.4.5 Duration of the test: 96 hours
followed by a re-growth experiment, duration 216 hours

3.4.6 Test parameter: cell multiplication inhibition

3.4.7 Sampling: daily

3.4.8 Monitoring of TS concentration: Yes, at 0 and 96 hours

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 *Pseudokirchneriella subcapitata*

3.4.9	Statistics	One way analysis of variance incorporating Bartlett's test for homogeneity of variance Dunnett's multiple comparison procedure for comparing several treatments with a control SAS computer software package 95% confidence limits are determined using the method of Litchfield and Wilcoxon (1949)

4 RESULTS

4.1	**Limit Test**	Range finding study performed
4.1.1	Concentration	1.0, 10 and 100 mg/L (nominal concentrations)
4.1.2	Number/ percentage of animals showing adverse effects	[redacted] No effect was observed at 1.0 mg/L. Growth was observed to be reduced at 10 and 100 mg/L. In addition a slight precipitate was observed at 100 mg/L. Cell Densities and Percentage Inhibition of Growth from the Range-finding Study:

[1] Cell densities represent the mean number of cells per ml calculated from the mean of the cell counts from 3 counts or fields of view for each of the replicate flasks.
[2] Nominal concentration [redacted]
[3] replicates R_1-R_2
[4] [Increase to growth compared to controls]

4.2	**Results test substance**	
4.2.1	Initial concentrations of test substance	2.0, 4.0, 8.0, 16 and 32 mg/L (nominal concentrations)

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 *Pseudokirchneriella subcapitata*

4.2.2 Actual concentrations of test substance

Actual concentrations [redacted] during the test:

Sample	Nominal concentration [mg/L]	[redacted]	Expressed as a Percent of the Nominal Concenbtration of Test Material [%]
0 hours	Control R_1 [1)]	[redacted]	-
	Control R_2 [1)]		-
	Control R_3 [1]		-
	2.0 R_1		103
	2.0 R_2		104
	2.0 R_3		104
	4.0 R_1		106
	4.0 R_2		107
	4.0 R_3		107
	8.0 R_1		112
	8.0 R_2		113
	8.0 R_3		112
	16 R_1		108
	16 R_2		109
	16 R_3		109
	32 R_1		105
	32 R_2		105
	32 R_3		105
96 hours	Control R_1 [1)]	[redacted]	-
	Control R_2 [1)]		-
	Control R_3 [1]		-
	2.0 R_1		104
	2.0 R_2		105
	2.0 R_3		103
	4.0 R_1		107
	4.0 R_2		108
	4.0 R_3		107
	8.0 R_1		112
	8.0 R_2		112
	8.0 R_3		112
	16 R_1		108
	16 R_2		108
	16 R_3		107
	32 R_1		107
	32 R_2		106
	32 R_3		106

[1)] $R_1 - R_3$ = replicates 1 – 3
[2)] LOQ = limit of quantification

[redacted]

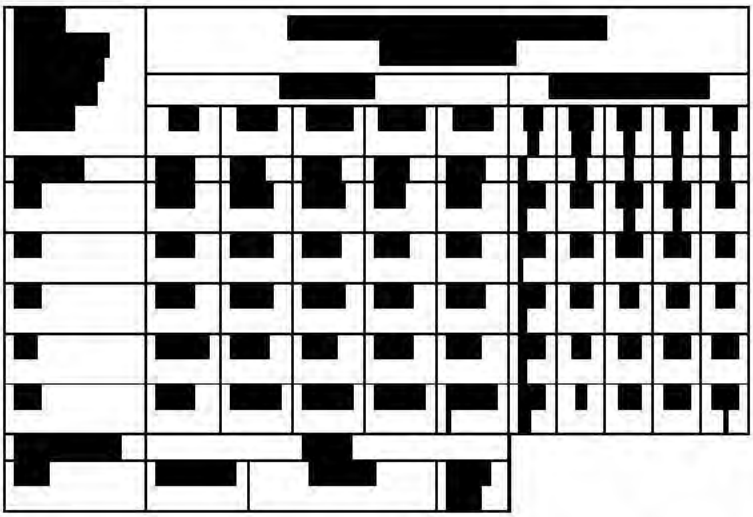
Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 *Pseudokirchneriella subcapitata*

4.2.3 Growth curves

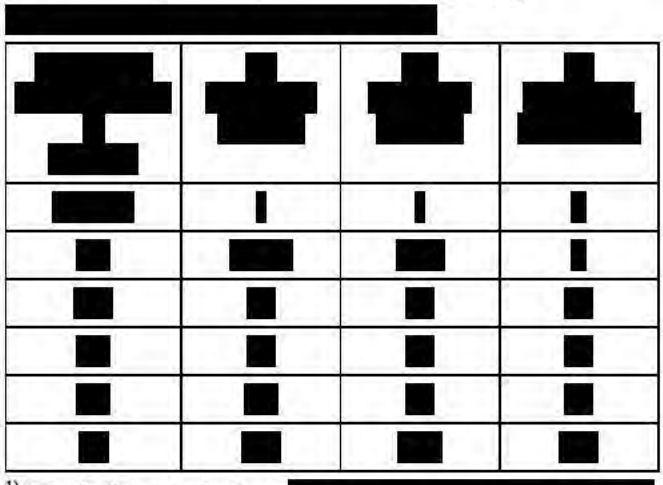
4.2.4 Concentration / response curve

4.2.5 Cell concentration data



x

4.2.6 Effect data (cell multiplication inhibition)



x

[1] Nominal concentrations

[2] Increase in growth as compared to the controls

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 *Pseudokirchneriella subcapitata*

		Effect data, based on nominal concentrations: [redacted] NOE_rC = 2.0 mg/L	
4.2.7	Other observed effects	All test and control cultures were inspected microscopically at 96 hours. There were no abnormalities in any of the cultures. [redacted]	x
4.3	**Results of controls**	cf. 4.2.5	
4.4	**Test with reference substance**	Not performed	
4.4.1	Concentrations	Not applicable	
4.4.2	Results	Not applicable	
		5 APPLICANT'S SUMMARY AND CONCLUSION	
5.1	**Materials and methods**	Green algae *Pseudokirchneriella subcapitata* CCAP 278/4 were exposed to the hydrolysis products of N,N-methylenebismorpholine in culture medium. Algae at initial cell concentration of 10^4 cells /mL were exposed to 5 nominal concentrations in the range of 2.0 - 32 mg/L for 96 hours at 24 °C. Three flasks per concentrations and 3 controls were used. At start pH was 7.5 – 8.7, at the end 7.4 – 10.1. Sampling was done at 0, 24, 48 72 and 96 hours. [redacted]	x

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 *Pseudokirchneriella subcapitata*

5.2 Results and discussion

[redacted] x

x

All validity criteria can be considered as fulfilled. The tests were performed thoroughly according to Guidelines and national/international standards, as outlined in the study.

	fulfilled	Not fullfilled
Cell concentration in control cultures increased at least by a factor of 16 within 3 days	X	
Concentration of test substance ≥80% of initial concentration during test	X	

A clear dose-response relationship was determined.

[redacted]

5.2.1 NOE_rC NOE_rC = 2.0 mg/L (nominal concentration) x

5.2.2 E_{r50} [redacted] x

5.2.3 E_bC_{50} [redacted] x

[redacted] x

5.3 Conclusion

[redacted]

5.3.1 Reliability [redacted]

5.3.2 Deficiencies [redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	June 2011
Materials and Methods	[redacted]

Section A7.4.1.3 Growth inhibition test on algae

Annex Point IIA7.3 *Pseudokirchneriella subcapitata*

Results and discussion

[redacted]

Conclusion

[redacted]

Reliability

[redacted]

Acceptability

[redacted]

Remarks

[redacted]

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA7.4

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2001) OS 157340: Assessment of the Inhbitory Effect on the Respiratipon of Activated Sewage Sludge, [redacted] (unpublished)
1.2	**Data protection**	Yes
1.2.1	Data owner	[redacted]
1.2.2	Criteria for data protection	Data submitted to the MS before 14 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**	OECD 209, Activated sludge, respiration inhibition test (1984) 87/302/EEC OPPTS 850.6800 (draft)
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 MATERIALS AND METHODS

3.1	**Test material**	OS 157340
3.1.1	Lot/Batch number	No data
3.1.2	Specification	No data
3.1.3	Purity	No data
3.1.4	Composition of Product	No data
3.1.5	Further relevant properties	[redacted] Hydrolysis [redacted] DT50 < 1 day at 25°C (**cf. Doc. 7.1.1.1.1**).
3.1.6	Method of analysis	No, not required by the Guideline

3.2 Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	No
Concentration of vehicle	Not applicable
Vehicle control performed	Not applicable
Other procedures	No

3.3	**Reference substance**	Yes 3,5-dichlorophenol
3.3.1	Method of analysis for reference substance	Not analysed

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA7.4

3.4 Testing procedure

3.4.1 Culture medium

16 g peptone, 11g meat extract, 3 g urea, 0.7 g NaCl, 0.4 g $CaCl_2.2H_2O$, 0.2 g $MgSO_4$, 2.8 g K_2HPO_4 dissolved in 1 L dechlorinated water. Water was softened with Elga Nimbus 1248D Duplex Water Softener. Hardness: 100 mg/L $CaCO_3$

3.4.2 Inoculum / test organism

Criteria	Details
Nature	activated sludge
Species	mixed population
Strain	Not applicable
Source	aeration stage of a sewage treatment plant, predominantly domestic sewage
Sampling site	Severn Trent Water Plc sewage treatment plant at Belper, Derbyshire, UK
Laboratory culture	No, activated sewage sludge was used on the day of collection
Method of cultivation	activated sludge was maintained unter aeration and used at the day of collection
Preparation of inoculum for exposure	No further praparation
Pretreatment	No
Initial cell concentration	4000 mg suspended solids/L

3.4.3 Test system

Criteria	Details
Culturing apparatus	500 ml conical flask, after 30 min and 3h darkened glass BOD bottles (measuring vessel)
Number of culture flasks/concentration	1
Aeration device	Mixture was aerated by narrow bore glass tubes with compressed air
Measuring equipment	Yellow springs dissolved oxygen meter fitted with a BOS probe
Test performed in closed vessels due to significant volatility of TS	No

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA7.4

3.4.4 Test conditions

Criteria	Details
Test temperature	21°C
pH	7.6 at start of the test pH ranges between 7.7 at the lowest test substance concentration to 8.7 at the highest
Aeration of dilution water	Yes, compressed air at a rate of 0.5-1 L/min
Suspended solids concentration	4.0 g/L

3.4.5 Duration of the test: 3 hours

3.4.6 Test parameter: respiration inhibition

3.4.7 Analytical parameter: oxygen measurement

3.4.8 Sampling: Sampling after 30 min and 3 hours

3.4.9 Monitoring of TS concentration: No

3.4.10 Controls: Control without test substance.

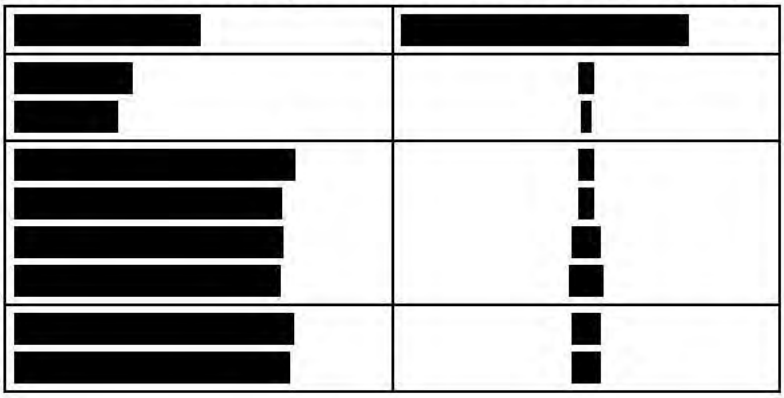
3.4.11 Statistics: Percent inhibition was calculated as the percentage of the two control respiration rates. Percentage inhibition was plotted against the concentration, and the EC50 was determined by inspection of the graph. NOEC value was determined by inspection of the inhibition of respiration rate data.

4 RESULTS

4.1 Preliminary test: Range-finding was performed

4.1.1 Concentration: 1.0, 10, 100 and 1000 mg/L (nominal concentrations)

4.1.2 Effect data: Significant inhibiton of respiration was observed at 100 and 1000 mg/L.



4.2 Results test substance

4.2.1 Initial concentrations of test substance: 10, 32, 100, 320, and 1000 mg/L (nominal concentrations)

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA7.4

4.2.2	Actual concentrations of test substance	[redacted]
4.2.3	Growth curves	No data
4.2.4	Cell concentration data	Not determined during the test
4.2.5	Concentration/ response curve	Graph by applicant representing degradation results tabulated in the study report: [redacted]
4.2.6	Effect data	[redacted]
4.2.7	Other observed effects	No
4.3	**Results of controls**	Variation of controls (2 replicates) after 30 min was ± 3%,, after 3 hours 1 %.
4.4	**Test with reference substance**	Performed
4.4.1	Concentrations	3.2, 10, and 32 mg/L
4.4.2	Results	3,5-dichlororphenol 30 min EC50 = 11 mg/L 3,5-dichlororphenol 3 hours EC50 = 7.3 mg/L

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1	**Materials and methods**	Following the preliminary range-finding study, activated sludge was exposed to an aqueous solution of the test material at concentrations of 10, 32, 100, 320 and 1000 mg/L for a period of 3 hours at 21°C with synthetic sewage as a respiratory substrate. The rate of respiration was determined after 30 min and 3 hours and compared to data for control and 3,5-dichlorophenol as reference material.
5.2	**Results and discussion**	Inhibition of respiration after 3 hours was determined for 3h EC_{50} = 340 mg/L. The No Effect Concentration was determined for 3h NOEC = 32 mg/L. Validity criteria for control respiration rates (within 15%) and EC_{50} of 3,5-dichlororphenole (within 5-30 mg/L) are fulfilled. The tests were performed according to Guidelines and national/international standards, as outlined in the study. [redacted]

Section A7.4.1.4 Inhibition to microbial activity (aquatic)

Annex Point IIA7.4

[redacted]

5.2.1	EC_{20}	No data
5.2.2	EC_{50}	340 mg/L (3h)
5.2.3	EC_{80}	No data
5.3	**Conclusion**	[redacted]
5.3.1	Reliability	[redacted]
5.3.2	Deficiencies	[redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	September 2011
Materials and Methods	[redacted]
Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A7.4.2 Annex Point IIA 7.5	Bioconcentration in aquatic and terrestrial organisms	
	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]	
Reference:	EC (2003) Technical Guidance Document on Risk Assessment in support of Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No. 1488/94 on risk assessment for existing substances (Parts I, II, III and IV) and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocidal products on the market. European Commission 2003	
Undertaking of intended data submission [ ]	Not applicable, no study is planned.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	August 2011	

Section A7.4.2 Annex Point IIA 7.5	Bioconcentration in aquatic and terrestrial organisms
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]

Section A7.4.3.2 Annex Point IIIA XIII 2.2	Effects on reproduction and growth rate of fish	
	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]	
References:	No	
Undertaking of intended data submission [ ]	Not applicable, no study is planned.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	August 2011	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	-	

Section 7.4.3.4 Annex Point IIIA XIII 2.4 — Effects on reproduction and growth rate with an invertebrate species

Official use only

1 REFERENCE

1.1	**Reference**	[redacted] (2007) Study on the Chronic Toxicity towards Daphnia of „ST-1" according OECD-Guideline No. 211 *(Daphnia magna* Reproduction Test). [redacted], July 12th 2007 (draft) [redacted] (2009) Purity of N,N-Methylenebismorpholine (CONTRAM™ ST-1). [redacted], November 2009, 18p.
1.2	**Data protection**	Yes
1.2.1	Data owner	[redacted]
1.2.2	Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I

2 GUIDELINES AND QUALITY ASSURANCE

2.1	**Guideline study**	Yes, according to the OECD guideline 211 for testing of chemicals – Daphnia magna Reproduction Test. (21.09.1998)
2.2	**GLP**	[redacted]
2.3	**Deviations**	No

3 METHOD

3.1	**Test material**	N,N-methylenebismorpholine
3.1.1	Lot/Batch number	0100529283
3.1.2	Specification	N,N-methylenebismorpholine (CONTRAM™ST-1); yellowish liquid with a strong odour
3.1.3	Purity	[redacted]
3.1.4	Composition of Product	Not applicable
3.1.5	Further relevant properties	density at 20°C: 1.051 g/cm^3
3.1.6	Method of analysis	[redacted]
3.2	**Preparation of TS solution for poorly soluble or volatile test substances**	Not applicable
3.3	**Reference substance**	No, not required by guideline OECD 211.
3.3.1	Method of	Not applicable

Section 7.4.3.4 Effects on reproduction and growth rate with an invertebrate species
Annex Point IIIA XIII 2.4

analysis for reference substance

3.4 Testing procedure

3.4.1 Dilution water

Table A7_4_3_4-2: Dilution water

Criteria	Details
Source	ultrapure water, Seral, Purelab Plus
Salinity	No data
Hardness	No data
pH	7.11 – 9,38
Ca / Mg ratio	No data
Na / K ratio	No data
Oxygen content	7.17 – 9.05 mg/L
Conductance	No data
TOC	No data
Holding water different from dilution water	No

Test medium according Elendt M4 given in the test guideline OECD 211

3.4.2 Test organisms

Table A7_4_3_4-3: Test organisms

Criteria	Details
Strain / Clone	Daphnia magna STRAUS (clone 5)
Source	laboratory bred [redacted]
Age	<24 hours
Breeding method	The cultivation of the daphnia is performed in a way that the animals are transferred in new test medium at an interval of 1 to 3 days followed by feeding with *Desmodesmus subspicatus*- and/or *Chlorella*-cells. Daphnia were transferred into fresh medium one day before starting of the daphnia test in order to get daphnia for the test younger than 24h.
Kind of food	*Desmodesmus subspicatus*- and/or *Chlorella*-cells

Section 7.4.3.4 Effects on reproduction and growth rate with an invertebrate species
Annex Point IIIA XIII 2.4

Amount of food	calculated to refer to a content of 0.1-0.2 mg C / Daphnia (corresponding to 1-2 mg C/L)
Feeding frequency	daily
Pretreatment	Prior to start of the test, the daphnia (parent animals) were adapted to the test medium (M4 according Elendt).
Feeding of animals during test	Yes, The daphnids were fed during the test with suspensions of unicellular alga *Desmodesmus subspicatus*.

3.4.3 Handling of offspring

Daily the test solutions were investigated for appearance of offspring animals, and the numbers were recorded. The newborn offspring animals were eliminated daily from the treatments.

3.4.4 Test system

Table A7_4_3_4-4: Test system

Criteria	Details
Test type	semistatic
Renewal of test solution	daily
Volume of test vessels	100 mL
Volume/animal	100 mL/animal at start of the test
Number of animals/vessel	1 daphnid (individual exposure)
Number of vessels/ concentration	13
Test performed in closed vessels due to significant volatility of TS	Yes, carboys with glass stoppers .

3.4.5 Test conditions

Table A7_4_3_4-5: Test conditions

Criteria	Details
Test temperature	18.8 – 21.4 °C
Dissolved oxygen	7.17 – 9.05 mg/L
pH	7.11 – 9,38
Adjustment of pH	No
Aeration of dilution water	No
Quality/Intensity of irradiation	0.73 µmol*m^2*s^{-1} (0.73 klx) corresponding to ≈ 11.0 µE/m^2s
Photoperiod	light/dark cycle 16/8 hours

3.4.6 Duration of the test

21 days

Section 7.4.3.4 Effects on reproduction and growth rate with an invertebrate species
Annex Point IIIA XIII 2.4

3.4.7	Test parameter	**mortality:** offspring survival **reproduction:** number of living offspring **growth:** adult size (length and width) at test termination on day 21 mobility	x
3.4.8	Examination / Sampling	daily	
3.4.9	Monitoring of TS concentration	[redacted] The recoveries were in the range 70-110% being set in the study plan.	
3.4.10	Statistics	For each endpoint, the NOEC, LOEC, and, if possible, the EC_{50}, EC_{20} and EC_{10} were determined. Random generator in EXCEL, following ten vessels were chosen for routine statistical analysis with the ToxRat Program MATC was calculated.	

4 RESULTS

4.1	**Range finding test**	Not performed (acute test available, **c.f. Doc III A7.4.1.2**)	
4.1.1	Concentrations	Not applicable	
4.1.2	Number/ percentage of animals showing adverse effects	Not applicable	
4.1.3	Nature of adverse effects	Not applicable	
4.2	**Results test substance**		
4.2.1	Initial concentrations of test substance	Nominal concentrations: The test was performed using concentrations of 0.625, 1.25, 2.50, 5.00, 10.00, and 20.00 mg/L (geometric series with a separation factor of 2.0). Controls were test medium without test item.	x
4.2.2	Actual concentrations of test substance	During chemical monitoring [redacted], it could be shown that the test item remained stable in the aqueous phase. The recoveries, calculated on the basis of the measured concentrations at test start, were in the range of 82.5 - 102.9%. For this reason, the results of this test are based on the nominal concentrations	

Section 7.4.3.4
Annex Point IIIA XIII 2.4

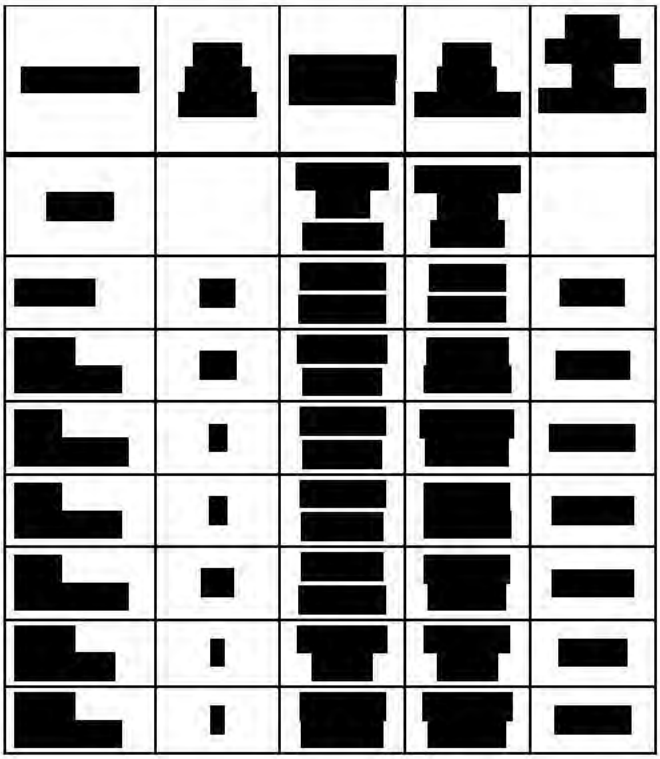
Effects on reproduction and growth rate with an invertebrate species

tested.

4.2.3 Effect data

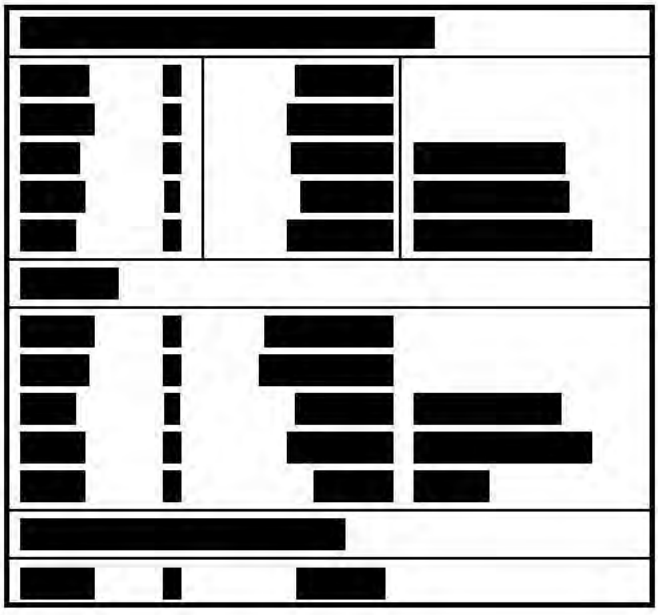
Survival, growth and reproduction data

x

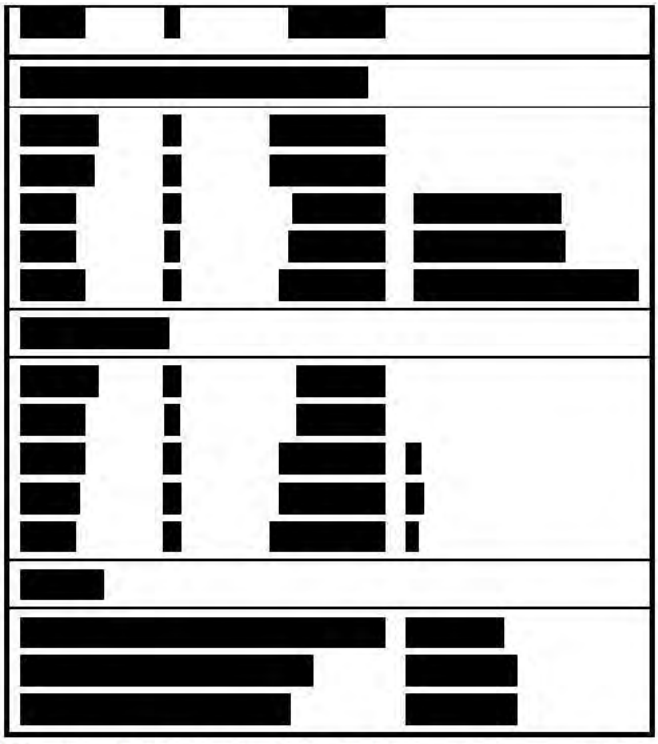


[redacted]

Effect summary table



Section 7.4.3.4 Annex Point IIIA XIII 2.4 — Effects on reproduction and growth rate with an invertebrate species



[redacted]

[1] Numbers in brackets indicate the lower and upper confidence limits at the 95% confidence level.

[2] No values are given due to mathematical reasons.

[3] No confidence limits are given due to mathematical reasons.

Test item related effects were also found for the additional endpoint size (length and width) of animals: A NOEC of 10 mg/L was determined for both parameters.

4.2.4	Concentration / response curve	Not presented	x
4.2.5	Other effects	No further effects were observed	
4.3	**Results of controls**	See 4.2.4	
4.4	**Test with reference substance**	Not performed, according to the guideline OECD 211 no reference item is required (acute test available, **c.f. Doc III A7.4.1.2**)	
4.4.1	Concentrations	Not applicable	
4.4.2	Results	Not applicable	

5 APPLICANT'S SUMMARY AND CONCLUSION

5.1 Materials and methods

The influence of ST-1 on the reproduction of aquatic invertebrates was investigated by a test on *Daphnia magna* according to the OECD guideline 211.

Exposure to six different nominal test concentrations of 0.625, 1.25, 2.50, 5.00, 10.00, and 20.00 mg/L was conducted with 12 replicates per concentration and for the control. Per replicate one daphnid (individual exposure) was exposed. The test was performed in a semistatic system

Section 7.4.3.4 Annex Point IIIA XIII 2.4 — Effects on reproduction and growth rate with an invertebrate species

(daily renewal of test solution) at 18.8-21.4°C and pH 7.11-9.38 in a test medium prepared by addition of several salts to ultrapure water. Effects on growth (adult length and width at test termination), reproductive performance and mobility were investigated. Test item concentrations were measured at representative fresh and aged test solutions [redacted]

5.2 Results and discussion

According to the results of the quantifications [redacted] the test item remained stable at >80% of the initial values, as requested by the OECD guideline.

Test item related effects were also found for the additional endpoint size (length and width) of animals: A NOEC of 10 mg/L was determined for both parameters.

[redacted]

All validity criteria were fulfilled.

Validity criteria for invertebrate reproduction test according to OECD Guideline 211

	fulfilled	Not fullfilled
Mortality of parent animals < 20% at test termination	X	
Mean number of live offspring produced per parent animal surviving at test termination ≥ 60	X	

5.2.1 NOEC

5.0 mg/L (nominal, cumulative offspring survivors)
≥ 20.0 mg/L (nominal, mobility)

5.2.2 LOEC

10.0 mg/L (nominal, cumulative offspring survivors)
> 20.0 mg/L (nominal, mobility)

5.2.3 EC_{50} (EC_x)

EC_{50}: 16.4 mg/L (nominal, cumulative offspring survivors)
EC_{20}: 8.9 mg/L (nominal, cumulative offspring survivors)
EC_{10}: 6.4 mg/L (nominal, cumulative offspring survivors)

EC_{50}: 20.5 mg/L (nominal, mean offspring survivors)
EC_{20}: 7.5 mg/L (nominal, mean offspring survivors)
EC_{10}: 4.4 mg/L (nominal, mean offspring survivors)

EC_{50} : not given for mathematical reasons

Section 7.4.3.4 Effects on reproduction and growth rate with an invertebrate species
Annex Point IIIA XIII 2.4

EC_{20}: 52.8 mg/L (nominal, mobility)
EC_{10}: 6.6 mg/L (nominal, mobility)

5.3 Conclusion [redacted]

5.3.1 Reliability [redacted]

5.3.2 Deficiencies [redacted]

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	October 2011
Materials and Methods	[redacted]

Section 7.4.3.4 Effects on reproduction and growth rate with an invertebrate species
Annex Point IIIA XIII 2.4

Results and discussion	[redacted]
Conclusion	[redacted]
Reliability	[redacted]
Acceptability	[redacted]
Remarks	[redacted]

Section A7.5 Annex Point II A7	Effects on terrestrial organisms	
	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]	
References:	No	
Undertaking of intended data submission [ ]	Not applicable, no study is planned.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	October 2011	
Evaluation of applicant's justification	[redacted]	
Conclusion	[redacted]	
Remarks	[redacted]	

Section A7.5.5 Annex Point IIA 7.5	Bioconcentration in aquatic and terrestrial organisms	
	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]	
Reference:	EC (2003) Technical Guidance Document on Risk Assessment in support of Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No. 1488/94 on risk assessment for existing substances (Parts I, II, III and IV) and Directive 98/8/EC of the European Parliament and the Council concerning the placing of biocidal products on the market. European Commission 2003	
Undertaking of intended data submission [ ]	Not applicable, no study is planned.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	August 2011	

Section A7.5.5 Annex Point IIA 7.5	Bioconcentration in aquatic and terrestrial organisms
Evaluation of applicant's justification	[redacted]
Conclusion	[redacted]
Remarks	[redacted]

Section A8 Measures necessary to protect man, animals and the environment

Subsection (Annex Point)			Official use only
8.1		**Recommended methods and precautions concerning handling, use, storage, transport or fire (IIA8.1)**	
8.1.0	**Methods and precautions concerning placing on the market**	Not applicable.	
8.1.1	**Methods and precautions concerning production, handling and use of the active substance and its formulations**	Handling: Maximum handling temperature: 60 °C Handling procedures: Keep containers closed when not in use. Do not discharge into drains or the environment; dispose to an authorized waste collection point. Use appropriate containment to avoid environment contamination. Do not breathe dust or mist. Wash thoroughly after handling. Launder contaminated clothing before reuse. Empty container product residues which may exhibit hazards of product. Do not eat, drink or smoke when using product.	
8.1.2	**Methods and precautions concerning storage of the active substance and its formulations**	Storage: Maximum storage temperature: 40 °C Storage procedures: No special storage precautions required.	x
8.1.3	**Methods and precautions concerning transport of the active substance and its formulations**	Transport: LAND GGVSE: 8 UN: 1760 PG: III RID/ADR: 8 UN: 1760 PG: III Warning sign: Hazard no. 80 UN No: 1760 Corrosive liquid MARINE Do not transport - additional information required AIR ICAO-TI/IATA-DGR: 8 UN: 1760 Hazard label: 80 PG: III Corrosive liquid	x
8.1.4	**Methods and precautions concerning fire of the active substance and its formulations**	Extinguishing media: CO2, dry chemical, or foam. Water can be used to cool and protect exposed material. Firefighting procedures: Recommended wearing self-contained breathing apparatus. Water may cause splattering. Use water to cool containers exposed to fire.	
8.2		**In case of fire, nature of reaction products, combustion gases, etc. (IIA8.2)**	

Section A8 Measures necessary to protect man, animals and the environment

			Official use only
		Fire may produce carbon monoxide and carbon dioxide. Under combustion conditions, oxides of the following elements will be formed: nitrogen. Formaldehyde vapour may also be released.	
8.3		**Emergency measures in case of an accident (IIA8.3)**	
8.3.1	**Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available**	Engineering controls: Use material in well ventilated area only. Additional ventilation or exhaust may be required to maintain air concentrations below recommended exposure limits. Hand protection: Use nitrile or neoprene gloves. Eye protection: Chemical goggles or faceshield Respiratory protection: Use full face respirator with a combination organic vapour and dust/mist cartridge if the recommended exposure limit is exceeded. Use self-contained breathing apparatus for entry into confined space, for other poorly ventilated areas and for large spill clean-up sites. Clothing recommendation: Long sleeve shirt is recommended. Wear either a chemical protective suit or apron when potential for contact with material exists. Use chemically protective boots when necessary to avoid contaminating shoes. Do not wear rings, watches or similar apparel that could entrap the material and cause burns. Launder contaminated clothing before reuse. Spill procedures: Personal protective equipment must be worn, see above. Ventilate area if spilled in confined space or other poorly ventilated areas.	
8.3.2	**Emergency measures to protect the environment**	Do not discharge into drains or the environment; dispose to an authorized waste collection point. Use appropriate containment to avoid environment contamination. Spill procedures: Prevent entry into sewers and waterways; dispose in accordance with federal, state and local environmental regulation. Do not dispose in landfill. Pick up free liquid for recycle and/or disposal. Residual liquid can be absorbed on inert material.	
8.4		**Possibility of destruction or decontamination following release in or on the following: (a) Air; (b) Water, including drinking water; (c) Soil (IIA8.4)**	
8.4.1	**Possibility of destruction or decontamination following release in the air**	Not applicable (readily biodegradable)	X
8.4.2	**Possibility of destruction or decontamination following release in water, including drinking water**	Not applicable (readily biodegradable)	X
8.4.3	**Possibility of**	Not applicable (readily biodegradable)	X

Section A8 Measures necessary to protect man, animals and the environment

			Official use only
	destruction or decontamination following release in or on soil		
8.5		**Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration (IIA8.5)**	
8.5.1	**Possibility of re-use or recycling**	Pick up free liquid for recycle and/or disposal.	
8.5.2	**Possibility of neutralisation of effects**	Residual liquid can be absorbed on inert material.	
8.5.3	**Conditions for controlled discharge including leachate qualities on disposal**	Dispose in accordance with federal, state and local environmental regulation.	
8.5.4	**Conditions for controlled incineration**	Not stated.	
8.6		**Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIA8.6)**	x
		Not applicable.	
8.7		**Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances (IIA8.7*)***	x
		Not applicable.	

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date May 2013

Materials and methods [redacted]

Results and discussion [redacted]

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

Section A9 Classification and labelling of active substance

Official use only

Subsection (Annex Point)	
9.1	Classification & labelling
Class of danger	[redacted]
R phrases	[redacted]
S phrases	[redacted]

Evaluation by Competent Authorities

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	April 2013
Results and discussion	[redacted]

Section No / Reference No	**Author(s)**	**Year**	**Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
A2.7/01	[redacted]	2009	Purity of N,N-Methylenebismorpholine (CONTRAM™ ST-1). [redacted], November 2009, 18p. [redacted], unpublished	Y	Lubrizol
A 2.7/02	[redacted]	2009	Analytical report: Determination of the water content of different batches CONTRAMTM ST-1: 4,4'-Methylenebismorpholine, N, N'-Methylenebismorpholine, Bismorpholinomethane, Methylen-bistetrahydro-1,4-oxazine (CAS# 5625-90-1) [redacted], Document No. 56, July 2009, 5p. [redacted], unpublished	Y	Lubrizol
A2.8	[redacted]	2009a	Determination of "free" formaldehyde in the active substance N,N-Methylenbismorpholine: Evaluation of analytical reports. [redacted], November 2009, 19p [redacted], unpublished	Y	Lubrizol
A2.10_02	[redacted]	2007	Estimation of the Environmental Concentrations and the Preliminary Environmental Risk Assessment of "N,N-Methylene¬bismorpholine" for life-cycle step production as well as biocidal use as in-can preservative in fuels (PT 6) and as preservative of metal-working fluids (PT 13). [redacted], 20.7.2007 [redacted], unpublished	Y	Lubrizol
A2.10_01a	[redacted]	2007	Medical statement for formaldehyde-releasing active ingredients [redacted], unpublished	Y	Lubrizol
A2.10_01b	[redacted]	2007	Statement of compliance to all maximum permissible workplace exposures	Y	Lubrizol
A3.1.1	[redacted]	2001	OS 157340: Determination of General Physico-chemical Properties [redacted]	Y	Lubrizol

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			[redacted], unpublished		
A3.1.3	[redacted]	2007	Determination of the Density of CONTRAM™ ST-1. [redacted] July 4, 2007 [redacted], unpublished	Y	Lubrizol
A3.2a	[redacted]	2001	OS 157340: Determination of Vapour Pressure [redacted] [redacted], unpublished	Y	Lubrizol
A3.2b	[redacted]	2005	Estimation of physical chemical properties of N,N-Methylenebis-morpholine using EpiSuite 3.12 [redacted], published	N	Lubrizol
A3.4/01	[redacted]	2007	UV Spectrum of CONTRAM™ ST-1. [redacted], July 3, 2007 [redacted], unpublished	Y	Lubrizol
A3.4/02	[redacted]	2007	Determination of the Infrared (IR) Spectrum of CONTRAM™ ST-1. [redacted] 17.12.2007 [redacted], unpublished	Y	Lubrizol
A3.4/04	[redacted]	2007	Mass-Spectrum [redacted]. 09.07.2007 [redacted], unpublished	Y	Lubrizol
A3.4/05	Anonymous		1-H Spektren		Lubrizol
A3.4/06	Anonymous		13-C Spektren		Lubrizol
A3.6b	[redacted]	2007	Determination of the pH-Value of CONTRAM™ ST-1. [redacted] July 4, 2007 [redacted], unpublished	Y	Lubrizol
A3.6a	[redacted]	2006	Estimation of the dissociation constants of N,N-Methylolmorpholine by using QSAR ACD/pKa DB, Product Version 10.01, 8.12.2006 [redacted], unpublished	N	Lubrizol

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A3.7a	[redacted]	2006	Determination of the Solubility Range of CONTRAM™ ST-1: N,N'-methylene-bismorpholine (CAS# 5625-90-1) in n-Heptane Using a Turbidimetric Method. [redacted], January 13, 2006 [redacted], unpublished	Y	Lubrizol
A3.7b	[redacted]	2007	Solubility of CONTRAM™ ST-1, N,N'-methylenebismorpholine (CAS# 5625-90-1) in various organic solvents. [redacted], June 29, 2007 [redacted], unpublished	Y	Lubrizol
A3.10	[redacted]	2007	Safety-related evaluation of the thermal stability of "CONTRAM(TM) ST-1 BC 6005 / 100500234". [redacted], unpublished	Y	Lubrizol
A3.12	[redacted]	2008	Determination of the Flash Point (COC) of Contram™ ST-1. [redacted], unpublished	Y	Lubrizol
A3.14	[redacted]	2007	Determination of the Viscosity of Contram™ ST-1 [redacted] July 13, 2007 [redacted], unpublished	Y	Lubrizol
A3.17	[redacted]	2007	Reactivity towards container material: CONTRAMTM ST-1. [redacted], 1907.2007	Y	Lubrizol
A4.1/01	[redacted]	2005b	Chargenvergleich des Biozids ST-1. [redacted], 30.8.2005 Revision 17.11.2009 & elaborated spectra [redacted], unpublished	Y	Lubrizol
A4.1/02	[redacted]	2008	Validation of the method: Determination of the Formaldehyde content of different concentrations of CONTRAM™ ST-1 (N, N'-Methylenebismorpholine) (CAS# 5625-90-1) Internal report, 20.02.2008, [redacted], unpublished	Y	Lubrizol

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A4.1/03	[redacted]	2005a	Produktcharakterisierung des Biozids ST-1. [redacted], 30.6.2005 Revision 16.11.2009 [redacted], unpublished	Y	Lubrizol
A6.1.1	[redacted]	2000	OS157340:Acute oral toxicity in the rat – acute toxic class method. [redacted], unpublished	Y	Lubrizol
A6.1.2	[redacted]	2001	Statement of non performance of dermal toxicity study in the rat. [redacted]., 03 April 2001		
A6.1.4	[redacted]	2001	OS157340: Acute dermal irritation in the rabbit. [redacted], unpublished	Y	LUB
A6.1.5	[redacted]	2001	OS157340, Skin sensitisation to the guinea-pig (Magnusson & Kligman method). [redacted], unpublished	Y	LUB
A6.2_01	[redacted]	2007	The in vitro percutaneous absorption of radiolabelled ST-1 through human skin. [redacted], unpublished	Y	LUB
A6.2_02	[redacted]	2007a	*Toxicokinetics of the formaldehyde donor ST-1 in rats after intratracheal instillation. Interim Report: Results with N,N'-Methylenebis[U-^{14}C]morpholine.* [redacted] *,unpublished*	Y	Lubrizol
A6.2_02	[redacted]	2007b	*Toxicokinetics of the formaldehyde donor ST-1 in rats: Pre-Study with intratracheal instillation.* [redacted] *,unpublished*	Y	Lubrizol
A6.3.1	[redacted]	2002a	*OS 157340: Ninety day repeated dose oral (gavage) toxicity study in the rat.* [redacted]	Y	Lubrizol

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			[redacted] *unpublished*		
A6.4.1	[redacted]	2002b	OS 157340: Ninety day repeated dose oral (gavage) toxicity study in the rat. [redacted], unpublished	Y	Lubrizol
A6.4.1	[redacted]	2002	OS 157340: 90-day oral toxicity study in the rat. Further comments on the histopathological findings [redacted], unpublished	Y	Lubrizol
A6.6.1	[redacted]	2000	OS157340: Reverse mutation assay "Ames test" using Salmonella typhymurium and Escherichia coli. [redacted], unpublished	Y	Lubrizol
A6.6.2	[redacted]	2001	*OS157340: Chromosome aberration test in CHL cells in vitro.* [redacted] *unpublished*	Y	Lubrizol
A6.6.3	[redacted]	2001	OS157340: L5178 TK+/- mouse lymphoma assay. [redacted], unpublished	Y	Lubrizol
A6.6.4	[redacted]	2001	OS157340: Micronucleus test in the mouse. [redacted], unpublished	Y	Lubrizol
A6.6.5	[redacted]	2002	*OS157340: In vivo liver unscheduled DNA synthesis (UDS) assay.* [redacted]*, unpublished*	Y	Lubrizol
A6.8.1	[redacted]	2005	*Oral Prenatal developmental toxicity test with Biozid ST-1 in New Zealand White rabbits.* [redacted]*, unpublished*	Y	Lubrizol

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A6.12	[redacted]	2007	Medical statement for formaldehyde-releasing active ingredients [redacted], unpublished	Y	Lubrizol
A7.1.1.1.1/01	[redacted]	2001	OS 157340: Determination of General Physico-chemical Properties [redacted], unpublished	Y	Lubrizol
A7.1.1.1.1/02	[redacted]	2005a	Produktcharkterisierung des Biozids ST-1 [redacted], June 2005 [redacted], unpublished	Y	Lubrizol
A7.1.1.1.1/02	[redacted]	2005b	Chargenvergleich des Biozids ST-1 [redacted] 30.8.2005 [redacted], unpublished	Y	Lubrizol
A7.1.1.1.1/02	[redacted]	2007	Hydrolysis study in dependance of pH, temperature and concentration, [redacted] 2007 (in German; Hydrolysestude bei verschiedenen pH-Werten, Konzentrationen und Temperaturen) [redacted], 22.3.2007, 1.Nachtrag 22.5.2007, 2.Nachtrag 11.6.2007 [redacted], unpublished	Y	Lubrizol
A7.1.1.1.2	[redacted]	1998	Fate, Transport and Transformation Test Guidelines OPPTS 835.2210 "Direct Photolysis Rate in Water by Sunlight". [redacted], January 1998. [redacted], published	N	Lubrizol
A7.1.1.2.1	[redacted]	2001	OS 157340: Assessment of ready biodegradability; CO_2 Evolution Test [redacted], unpublished	Y	Lubrizol
A7.1.3	[redacted]	2001	OS 157340: Determination of General Physico-chemical Properties [redacted] unpublished	Y	Lubrizol
A7.1.3	[redacted]	2005	Estimation of the adsorptions coefficient of N,N-Methylenebismorpholine using	N	Lubrizol

Section No / Reference No	**Author(s)**	**Year**	**Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
			[redacted], published		
A7.3.1	[redacted]	2005	[redacted] estimation for N,N-Methylenebismorpholine [redacted], published	N	Lubrizol
A7.4.1.1	[redacted]	2001	OS 157340: Acute Toxicity to Rainbow Trout (*Oncorhynchus Mykiss* [redacted] unpublished	Y (Exist./First/)	Lubrizol
A7.4.1.2	[redacted]	2001	OS 157340: Acute Toxicity to *Daphnia Magna* [redacted], unpublished	Y	Lubrizol
A7.4.1.3	[redacted]	2001	OS 157340: Algal Inhibition Test [redacted], unpublished	Y	Lubrizol
A7.4.1.4	[redacted]	2001	OS 157340: Assessment of the Inhbitory Effect on the respiratipon of activated Sewage Sludge [redacted], unpublished	Y	Lubrizol

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A7.4.3.4	[redacted]	2007	Study on the Chronic Toxicity towards Daphnia of „ST-1" according OECD-Guideline No. 211 *(Daphnia magna* Reproduction Test) [redacted], July 12th 2007 (draft) [redacted], unpublished	Y	Lubrizol
A7.4.3.4	[redacted]	2009	Purity of N,N-Methylenebismorpholine (Contram ST-1). [redacted], Nov. 2009 18p.	Y	Lubrizol