Section 7.4.3.4 Annex Point IIIA XIII 2.4		Effects on reproduction and growth rate with an invertebrate species		
4.1.2	Number/ percentage of animals showing adverse effects	-		
4.1.3	Nature of adverse effects	Main adverse effect of bromoacetic acid was reported as parent animal mortality.	x	
4.2	**Results test substance**			
4.2.1	Initial concentrations of test substance	0.032-100 mg/L		x
4.2.2	Actual concentrations of test substance	Measured, but not reported in detail.		
4.2.3	Effect data	Not reported is detail. However, the followed procedure gives high confidence that the values are correct. LOEC: 3.2 mg/L NOEC: 1.6 mg/L	x	
4.2.4	Concentration / response curve	Not reported in detail.		
4.2.5	Other effects	None		
4.3	**Results of controls**			
4.4	**Test with reference substance**	Not performed		
4.4.1	Concentrations	-		
4.4.2	Results	-		
		5 APPLICANT'S SUMMARY AND CONCLUSION		
5.1	**Materials and methods**	The followed procedure is close to the actual guidelines. In fact this large study laid the basis for development of today's guideline. From that perspective it is assured that the quality of the study is more than sufficient and the followed procedures are adequate.		
5.2	**Results and discussion**	Bromoacetic acid is completely soluble in water at the used concentration. No vehicle was needed. At the conditions of the test bromoacetic acid is stable, does not absorb or is volatile. The results of the reported large study were used to develop and validate the future OECD guideline.		
5.2.1	NOEC	1.6 mg/L		
5.2.2	LOEC	3.2 mg/L		
5.2.3	EC_{50}	65 mg/L		
5.3	**Conclusion**	As all validity criteria are met the EC_{50} is 65 mg/L. This value is close to the value (42 mg/L) of the test reported in A7.4.1.2. The LOEC is 3.2		

Section 7.4.3.4 Annex Point IIIA XIII 2.4	Effects on reproduction and growth rate with an invertebrate species	
	mg/L and the NOEC is 1.6 mg/L. As bromoacetic acid is not bioaccumulation, has a log P <3.0 and is readily biodegradable no classification of bromoacetic acid for the environment is required.	
5.3.1 Reliability	1	x
5.3.2 Deficiencies	No	

Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	August 2008
Materials and Methods	**3.1.3**: The specifications of the test substance must be included **3.4.2**: The OECD Guideline (#211) recommends living algal cells as Daphnia's food **3.4.5**: The OECD Guideline (#211) recommends a photoperiod of 16 hours light and an intensity of 15-20 µE/m^2 s **3.4.9**: The analytical method was not included in the report
Results and discussion	**4.2.1**: The test concentrations used were not detailed in the report
Conclusion	NOEC: 1.6 mg/L (measured) and 3.2 mg/L (nominal)
Reliability	2~~3~~
Acceptability	-Acceptable The report is incomplete especially regarding Bromoacetic acid identity and quantification. No method of detection was described and no data on measured concentrations are provided excepting that corresponding to the measured NOEC. As data is from a peer reviewed scientific article that served as we should deem it as true data and scientifically supported. The reported results were extracted from the reported article where investigations were carried out in order to determine the "no observed effect concentration" (NOEC) of 73 environmentally relevant substances in the 21 d Daphnia reproduction test. The test was conducted in line with the provisional procedure proposed by the Federal Environmental Agency (Umweltbundesamt) (as of 1 January 1984).However, this information can only be regarded as supporting of other toxicity to invertebrates generated according GLP.
Remarks	

Table A7_4_3_4-1: Preparation of TS solution for poorly soluble or volatile test substances

Criteria	Details
Dispersion	No
Vehicle	No
Concentration of vehicle	-
Vehicle control performed	No
Other procedures	-

●

Table A7_4_3_4-1: Dilution water

Criteria	Details
Source	In the interests of national and international standardization, an artificial medium (synthetic fresh water) (DIN-- German Institute of Standardization, 1982a, b) of the following composition was used in the test and control preparations: 11 .76 g $CaCl_2$. $2H_2O$ (A.R.)/L deionized water 4.93 g $MgSO_4$. $7H_2O$ (A.R.)/L deionized water 2.59 g $NaHCO_3$ (A.R.)/L deionized water 0.23 g KCl (A.R.)/L deionized water. Twenty-five millilitres of each solution was pipetted into a graduated flask and completed to 1 litre with deionized water. The amount of calcium and magnesium ions in this solution was 2.5mmol/L. The molar relationship of sodium to potassium ions was 10:1. This water was aerated up to the water saturation level and the pH value was measured (8.0 ± 0.2). When using deionized water with a conductivity of < 1 µS /cm, the dilution water was diluted with 10% tap water.
Salinity	-
Hardness	-
pH	**8.0±0.2**
Ca / Mg ratio	2.38
Na / K ratio	11.3
Oxygen content	Not reported in detail, but never reached a critical level.
Conductance	**< 1 µS /cm**
TOC	**Not reported**
Holding water different from dilution water	No

Table A7_4_3_4-2: Test organisms

Criteria	Details
Strain / Clone	*Daphnia magna* (IRCHA strain)
Source	The *Daphnia magna* have been maintained in accordance with the procedure practised since 1978. In each case, 20-30 specimens were placed in forty 2-L beakers, which had been filled with at least 1.6 L. Berlin tap water. They provided 24 h-old animals when the offspring were removed daily from the cultures.
Age	24 h
Breeding method	For all Daphnia strain cultures, temperature-controlled, dechlorinated and oxygen-saturated tap water (German hardness 16 °, pH value 7.6-7.7) was used which had been left to stand for 24 h. Before collecting the water, the tap was turned on fully and left to run for at least I h. All beakers were covered with watch glasses and placed on a white supporting surface. Feeding with dry algae of the *Scenedesmus* genus took place daily. Nine g of feed were suspended in 1000 ml tap water and 2 ml of the suspension were added to each beaker. The temperature of the culture area was regulated thermostatically at 20°C. Under exclusion of daylight, the area was lit by fluorescent lamps (Philips TL 65/33W) for 9 hours.
Kind of food	Dry algae of the *Scenedesmus* genus
Amount of food	9 g in 1000 mL
Feeding frequency	Daily
Pretreatment	Continuous culture to have fresh daphnia 24 h old
Feeding of animals during test	Yes, daily at the time oberserving th appearance of the offspring.

Table A7_4_3_4-3: Test system

Criteria	Details
Test type	Semistatic renewal on Mondays, Wednesdays and Fridays
Renewal of test solution	The semi-static procedure adopted applied the following procedure: The parent animals in the test and control vessels were pipetted 3 times a week (Mondays, Wednesdays and Fridays) into freshly prepared test and control media - in each case at the corresponding concentration level. During this process, dead parent animals or those incapable of swimming were removed. The offspring were counted and the total number for each test vessel was recorded. Then, the pH value and the oxygen concentration were measured in two test vessels per concentration level.
Volume of test vessels	250 mL
Volume/animal	1/ 50 mL
Number of animals/vessel	5
Number of vessels/ concentration	4
Test performed in closed vessels due to significant volatility of TS	No

Table A7_4_3_4-4: Test conditions

Criteria	Details
Test temperature	20°C
Dissolved oxygen	> 69%
pH	> 7.0
Adjustment of pH	No
Aeration of dilution water	No
Quality/Intensity of irradiation	Fluorescent lamps (Philips TL 65/33W)
Photoperiod	9 h between 7:00 and 16:00

Table A7_4_3_4-5: Validity criteria for invertebrate reproduction test according to OECD Guideline 211

	fulfilled	Not fulfilled
Mortality of parent animals < 20% at test termination	X	
Mean number of live offspring produced per parent animal surviving at test termination ≥ 60	X	
Criteria for poorly soluble test substances		X

Section A7.5.1.1 **Annex Point IIA7.4**	**Inhibition to microbial activity (terrestrial)**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	Not intended	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	October 2009	
Evaluation of applicant's justification	The justification is accepted. This study is not core data for the active substance. No emission to the terrestrial compartment is expected.	
Conclusion	Id.	
Remarks		

Section A7.5.1.2 **Annex Point IIIA XIII 3.2**	**Earthworm, acute toxicity test**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	Not intended	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	October 2009	
Evaluation of applicant's justification	The justification is accepted. This study is not core data for the active substance. No emission to the terrestrial compartment is expected.	
Conclusion	Id.	
Remarks		

Section 7.5.1.3 **Annex Point IIIA XIII 3.4**	**Terrestrial plant toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	Not intended	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	October 2009	
Evaluation of applicant's justification	For the preliminary Risk Assessment the justification is accepted. This study is not core data for the active substance. No emission to the terrestrial compartment is expected.	
Conclusion	Id.	
Remarks		

Section 7.5.3.1.1 **Annex Point**	**Acute oral toxicity on birds**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	Not intended	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	October 2009	
Evaluation of applicant's justification	For the preliminary Risk Assessment the justification is accepted. This study is not core data for the active substance. No emission to the terrestrial compartment is expected.	
Conclusion	Id.	
Remarks		

Section 7.5.3.1.2 **Annex Point IIIA XIII 1.2**	**Short-term toxicity on birds**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	Not intended	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	October 2009	
Evaluation of applicant's justification	For the preliminary Risk Assessment the justification is accepted. This study is not core data for the active substance. No emission to the terrestrial compartment is expected.	
Conclusion	Id.	
Remarks		

Section 7.5.3.1.3 Annex Point IIIA XIII 1.3	Effects on reproduction of birds	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	[redacted]	
Undertaking of intended data submission [ ]	Not intended	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	October 2009	
Evaluation of applicant's justification	For the preliminary Risk Assessment the justification is accepted. This is not core data for the active substance. No emission to the terrestrial compartment is expected.	
Conclusion	Please see above.	
Remarks		

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**	On the basis of available information bromoacetic acid (toxic, corrosive very toxic to aquatic organisms) will cause significant health or environmental effects when not used according to instructions provided by the supplier. When handling bromoacetic acid personal protection equipment (PPE) is mandatory.	
8.1.1	**Methods and precautions concerning production, handling and use of the active substance**	Technical Measures: • Local exhaust and general ventilation must be adequate to meet exposure standards. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. • Wear suitable protecting clothing resistant to acids. Use neoprene or rubber gloves (EN 374). Taking into account the diversity of the types, it is necessary to respect the instructions of the manufacturers. • Chemical goggles or face shield with safety glasses. • Trained cleaning personnel properly equipped with eye protection should handle spills. • Prevent entry to sewers and public waters. • After spillage / leakage: Clean up any spills as soon as possible, using an absorbent material (earth, sand,...) to collect the spill. Use suitable disposal containers.	
8.1.2	**Methods and precautions concerning storage of the active substance**	Storage conditions: • Store on a clean area allowing recuperation of leaks and effusion. • Protect from freezing. Provide local exhaust or general room ventilation to minimize dust and/or vapour concentrations. Keep container closed when not in use. • Handle in accordance with good industrial hygiene and safety procedures. Ensure prompt removal from eyes, skin and clothing. Wash hands and other exposed areas with mild soap and water before eating, drinking, smoking and when leaving work. Packaging material: Use containers made of polyethylene or polypropylene, certified for use with acid.	
8.1.3	**Methods and precautions concerning transport of the active substance**	Transport information: Corrosive liquid, toxic Proper shipping name: Corrosive liquid, toxic, N.O.S. (Bromoacetic acid) UN Nr.: 2922 H.I. Nr.: 886 Class: 8 (6.1) Packing group: I EMS: F-A, S-B Hazard Label(s): 8. Marine pollutant	

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

			Official use only
8.1.4	**Methods and precautions concerning fire of the active substance**	Fire – fighting measures • Extinguishing media: Use extinguishing media appropriate for surrounding fire. • Special exposure hazards: May release heat and harmful fumes. • Protection against fire: Wear proper protective equipment. • Special procedures: Exercise caution when fighting any chemical fire.	
8.2		**In case of fire, nature of reaction products, combustion gases, etc. (IIA8.2)** • Contains organically bound halogen (bromine).	
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**	• Inhalation: Remove to fresh air. Allow the affected person to rest. Not expected to require first aid measures. • Skin contact: Remove contaminated clothing and shoes. Flush with plenty of water. Obtain medical attention. Eye contact: Rinse immediately with plenty of water during 15 minutes and keep the eyelids open. (Keep a bottle of water at hand). Seek medical attention immediately. Ingestion: Rinse mouth. DO NOT INDUCE VOMITING Take to hospital.	
8.3.2	**Emergency measures to protect the environment**	• Prevent entry into sewers and public waters. • Clean up any spills as soon as possible, using an absorbent material (earth, sand,...) to collect the spill. Use suitable disposal containers.	
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**	Bromoacetic acid has a vapour pressure, which could by accidental release into air lead to hazardous vapour concentrations. Clean up any spills as soon as possible, using an absorbent material (earth, sand ...) to collect the spill.	
8.4.2	**Possibility of destruction or decontamination following release in water, including drinking water**	Bromoacetic acid is readily biodegradable but is very toxic to aquatic organisms. Collection the liquid into container for chemical waste is recommended. Small spills may be diluted with plenty of water to neutralise the low pH and to lower the concentration.	
8.4.3	**Possibility of destruction or decontamination following release in or on soil**	Dilution with plenty of water to neutralise the low pH and dilution is recommended.	
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)**	

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

		Official use only
8.5.1	**Possibility of re-use or recycling** Reuse is not intended. Unused material may be returned to the manufacturer.	
8.5.2	**Possibility of neutralisation of effects** Dilute with copious of water to lower the acidity.	
8.5.3	**Conditions for controlled discharge including leachate qualities on disposal** Diluted solution can be released after neutralisation to a STP.	
8.5.4	**Conditions for controlled incineration** Bromoacetic acid could be safely incinerated in a licensed facility.	
8.6	**Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (IIA8.6)** Bromoacetic acid is a substance with a high toxicity in invertebrate animals and is very toxic to aquatic organisms.	
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*)*** Bromoacetic acid falls under List II of the Annex to Directive 80/98/EEC	

Evaluation by Competent Authorities

Evaluation by Rapporteur Member State

Date	August 2010
Materials and methods	
Results and discussion	
Conclusion	Acceptable
Reliability	
Acceptability	
Remarks	

Section A9	Proposals including Justification for the Proposals for the Classification and Labelling of the Active Substance according to Council Directive 67/548/EEC	

Classification and Labelling			Official use only
Hazard symbol	T, C, N		
Indication of danger	Toxic, Corrosive, Dangerous for the environment		
Labelling symbol			
Risk phrases	R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.	
	R35	Causes severe burns.	
	R43	May cause sensitization by skin contact	
	R50	Very toxic to aquatic organisms.	
Safety phrases	S1/2	Keep locked up and out of the reach of children.	
	S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.	
	S36/37/39	Wear suitable protective clothing, gloves and eye/face protection.	
	S45	In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).	
	S61	Avoid release to the environment. Refer to special instructions/Safety data sheets.	

Justification for the proposal		
T	Substances and preparations shall be classified as toxic and assigned the symbol 'T' and the indication of danger 'toxic' in accordance with the criteria given in ANNEX VI - GENERAL CLASSIFICATION AND LABELLING REQUIREMENTS FOR DANGEROUS SUBSTANCES AND PREPARATIONS	
C	The substance or preparation shall be classified as corrosive and assigned the symbol 'C' and the indication of danger 'corrosive' in accordance with the criteria given in ANNEX VI - GENERAL CLASSIFICATION AND LABELLING REQUIREMENTS FOR DANGEROUS SUBSTANCES AND PREPARATIONS	
N	Substances shall be classified as dangerous for the environment and assigned the symbol 'N' and the appropriate indication of danger, and assigned risk phrases in accordance with the criteria given in ANNEX VI - GENERAL CLASSIFICATION AND LABELLING REQUIREMENTS FOR DANGEROUS SUBSTANCES AND PREPARATIONS	
R23/24/25	Risk phrases shall be assigned in accordance with the following criteria. R25 Toxic if swallowed Acute toxicity results: - LD_{50} oral, rat: 25 < LD50 ≤ 200 mg/kg, - discriminating dose, oral, rat, 5 mg/kg: 100 % survival but evident toxicity, or - high mortality in the dose range > 25 to ≤ 200 mg/kg oral, rat, by the acute toxic class method (for R24 Toxic in contact with skin Acute toxicity results: - LD_{50} dermal, rat or rabbit: 50 ≤ LD50 ≤ 400 mg/kg R23 Toxic by inhalation Acute toxicity results: - LC_{50} inhalation, rat, for aerosols or particulates: 0,25 ≤ LC_{50} ≤ 1 mg/litre/4h, - LC_{50} inhalation, rat, for gases and vapours: 0,5 ≤ LC_50 ≤ 2 mg/litre/4h.	
R35	Risk phrases shall be assigned in accordance with the following criteria: R35 Causes severe burns - if, when applied to healthy intact animal skin, full thickness destruction of skin tissue occurs as a result of up to three minutes exposure, or if this result can be predicted.	
R43	May cause sensitization by skin contact	
R50	Substances shall be assigned risk phrases in accordance with the following criteria: R50 Very toxic to aquatic organisms Acute toxicity: 72 h IC_{50} (for algae) < 1 mg/l	
	No other risk phrases are applicable since the available data would not	

	lead to classification (see also DOC IIA).	
S1/2	Applicable for all dangerous substances and preparations and obligatory for all dangerous substances and preparations sold to the general public, except for those only classified as dangerous for the environment.	
S26	Applicable for corrosive or irritant substances and preparations and obligatory for corrosive substances and preparations and those to which R41 has already been ascribed, recommended for irritant substances and preparations to which the risk phrase R36 has already been ascribed.	
S36/37/39	Recommended for substances and preparation irritating to skin and eyes.	
S45	Applicable for toxic and corrosive substances and preparations.	
S61	Applicable for substances and preparations dangerous for the environment.	
	Evaluation by Competent Authorities	

EVALUATION BY RAPPORTEUR MEMBER STATE

Date	August 2010
Materials and Methods	
Results and discussion	We have included the classification according to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures *(please see below)*
Conclusion	Accepted
Reliability	
Acceptability	
Remarks	

Hazard Class and Category Code(s)		**Hazard Statement Code(s)**	
Acute Tox. 3	H331: Toxic if inhaled	**Pictogram, Signal Word Code(s)**	**Hazard Statement Code(s)**
Acute Tox. 3	H311: Toxic in contact with skin	GHS06	
Acute Tox. 3	H301: Toxic if swallowed	GHS05	
Skin Corr. 1A	H314: Causes severe skin burns and eye damage	GHS09	
Skin Sens. 1	H317: May cause an allergic skin reaction	Dgr	