

**Committee for Risk Assessment
RAC**

Annex 1

Background document

to the Opinion proposing harmonised classification
and labelling at EU level of

4,4'-oxydi(benzenesulphonohydrazide)

EC Number: 201-286-1

CAS Number: 80-51-3

CLH-O-0000006843-68-01/F

The background document is a compilation of information considered relevant by the dossier submitter or by RAC for the proposed classification. It includes the proposal of the dossier submitter and the conclusion of RAC. It is based on the official CLH report submitted to public consultation. RAC has not changed the text of this CLH report but inserted text which is specifically marked as 'RAC evaluation'. Only the RAC text reflects the view of RAC.

Adopted

17 September 2020

CLH report

Proposal for Harmonised Classification and Labelling

Based on Regulation (EC) No 1272/2008 (CLP Regulation),
Annex VI, Part 2

International Chemical Identification:

4,4'-Oxydi(benzenesulphonohydrazide)

EC Number: 201-286-1

CAS Number: 80-51-3

Index Number: -

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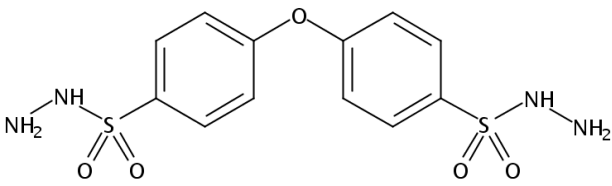
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OXYDI(BENZENESULPHONOHYDRAZIDE)

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity and information related to molecular and structural formula of the substance

Name(s) in the IUPAC nomenclature or other international chemical name(s)	4,4'-oxydi(benzenesulphonohydrazide)
Other names (usual name, trade name, abbreviation)	OBSH, benzenesulfonic acid, 4,4'-oxybis-, 1,1'-dihydrazide diphenyloxide-4-4'-disulfonyl hydrazide 4,4'-oxybis(benzenesulfonyl hydrazide) 4-[4-(hydrazinesulfonyl)phenoxy]benzene-1-sulphonohydrazide
EC number (if available and appropriate)	201-286-1
EC name (if available and appropriate)	4,4'-oxydi(benzenesulphonohydrazide)
CAS number (if available)	80-51-3
Molecular formula	C ₁₂ H ₁₄ N ₄ O ₅ S ₂
Structural formula	
SMILES notation (if available)	<chem>NN[S](=O)(=O)C1=CC=C(C=C1)OC2=CC=C(C=C2)[S](=O)(=O)NN</chem>
Molecular weight or molecular weight range	358.39 g/mol
Degree of purity (%) (if relevant for the entry in Annex VI)	100 0%

1.2 Composition of the substance

Table 2: Constituents (non-confidential information)

Constituent (Name and numerical identifier)	Concentration range (% w/w minimum and maximum in multi- constituent substances)	Current CLH in Annex VI Table 3.1 (CLP)	Current self- classification and labelling (CLP)
4,4'- oxydi(benzenesulphonohydrazide) (CAS-No: 80-51-3, EC-No: 201- 286-1)			

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2 PROPOSED HARMONISED CLASSIFICATION AND LABELLING

2.1 Proposed harmonised classification and labelling according to the CLP criteria

Table 3: 1.1 Proposed harmonised classification and labelling according to the CLP criteria

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors and ATE	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No current Annex VI entry										
Dossier submitters proposal	tbd	4,4'-oxydi(benzenesulfphonohydrazide)	201-286-1	80-51-3	Add: Self-react. D Aquatic Chronic 1	Add: H242 H410	Add: GHS02 GHS09 Dgr	Add: H242 H410		Add: M = 1	
Resulting Annex VI entry if agreed by RAC and COM					Self-react. D Aquatic Chronic 1	H242 H410	GHS02 GHS09 Dgr	H242 H410		M = 1	

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Table 4: Reason for not proposing harmonised classification and status under public consultation

Hazard class	Reason for no classification	Within the scope of public consultation
Explosives	<i>data conclusive but not sufficient for classification</i>	Yes
Flammable gases (including chemically unstable gases)	<i>hazard class not applicable (solid)</i>	No
Oxidising gases		
Gases under pressure		
Flammable liquids		
Flammable solids	<i>data conclusive but not sufficient for classification</i>	Yes
Self-reactive substances	<i>harmonised classification proposed</i>	Yes
Pyrophoric liquids	<i>hazard class not applicable (solid)</i>	No
Pyrophoric solids	<i>data conclusive but not sufficient for classification</i>	Yes
Self-heating substances		
Substances which in contact with water emit flammable gases		
Oxidising liquids	<i>hazard class not applicable (solid)</i>	No
Oxidising solids	<i>data conclusive but not sufficient for classification</i>	Yes
Organic peroxides		
Corrosive to metals	<i>hazard class not applicable (solid)</i>	No
Acute toxicity via oral route	<i>hazard class not assessed in this dossier</i>	No
Acute toxicity via dermal route		
Acute toxicity via inhalation route		
Skin corrosion/irritation		
Serious eye damage/eye irritation		
Respiratory sensitisation		
Skin sensitisation		
Germ cell mutagenicity		
Carcinogenicity		
Reproductive toxicity		
Specific target organ toxicity-single exposure		
Specific target organ toxicity-repeated exposure		
Aspiration hazard		
Hazardous to the aquatic environment		
Hazardous to the ozone layer	<i>hazard class not assessed in this dossier</i>	No

3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

Reason for a need for action at Community level:

Differences in self-classification

Disagreement by DS with current self-classification

4 IDENTIFIED USES

This substance is used in polymers and for the manufacture of plastic products and rubber products.

This substance is used in the following activities or processes at workplace:

transfer of chemicals, blowing agents in manufacture of foam, laboratory work, closed batch processing in synthesis or formulation, calendaring operations, closed processes with no likelihood of exposure, closed, continuous processes with occasional controlled exposure, mixing in open batch processes, transfer of substance into small containers and production of mixtures or articles by tableting, compression, extrusion or pelletisation.

Release to the environment of this substance can occur from industrial use: in the production of articles.

5 DATA SOURCES

Registration dossiers

No studies according to UN Test Series A to H in Part II of the UN RTDG, Manual of Tests and Criteria were made available in any of the registration dossiers. Therefore, unpublished studies have been provided by the competent authority in Germany.

Additional information of classified self-reactive substances and mixtures, which are listed in the UN RTDG Model Regulations has been taken into account.

OECD Screening Information Dataset, 2006

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6 PHYSICOCHEMICAL PROPERTIES

Table 5: Summary of physicochemical properties

Property	Value	Reference	Comment (e.g. measured or estimated)
Physical state at 20°C and 101,3 kPa	odourless fine white crystalline powder	OECD Screening Information Dataset, 2006	visual and olfactory assessment
Melting/freezing point	The test substance decomposed at 155°C and above	OECD Screening Information Dataset, 2006 (Study available in Attached background material of REACH registration Dossier)	According to OECD Guideline 102(capillary method)
Boiling point		REACH registration Dossier	Waiver, Adaption to column 2, Annex VII. OBSH decomposes at 155°C and above, hence no boiling point will be identified.
Relative density	1.52 g/cm ³	OECD Screening Information Dataset, 2006	Data from HSDB with no indication of type of method used
Vapour pressure	≤ 0.00000543 hPa at 80 °C	OECD Screening Information Dataset, 2006	According to OECD Guideline 104 (gas saturation method)
Surface tension		REACH registration Dossier	Waiver, Adaption to column 2, Annex VII. The study does not need to be conducted based on structure i.e. surface activity is not expected and no surface-active properties would be predicted for this compound. Surface activity is not a desired property of the material.
Water solubility	62.5 mg/L, at 20°C and pH 3.8	OECD Screening Information Dataset, 2006	According to OECD Guideline 105 (flask method)
Partition coefficient n-octanol/water	LogKow = 0.08	OECD Screening Information Dataset, 2006	Estimated by KOWWIN v1.67
Granulometry	Average particle size measured by coulter to 14 -17 µm.	Cellcom OBSH SPEC (Study in Attached background material of REACH registration Dossier)	Measured with Coulter Principle (Electrical Sensing Zone Method)
Stability in organic solvents and identity of relevant degradation products		REACH registration Dossier	Waiver, Stability of substance is not considered to be critical
Dissociation constant		REACH registration Dossier	Waiver, Adaption to Column 2, Annex IX. OBSH is hydrolytically unstable as identified in endpoint 5.1.1. i.e. the half-life is less than 12 hours (9.2 h at pH 4; 7.9 h at pH 7 and 5.8 h at pH 9).
Viscosity		REACH registration Dossier	Waiver, Adaption to column 2, Annex IX. This study cannot be conducted on solid materials.

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Property	Value	Reference	Comment (e.g. measured or estimated)
			According to ECHA Chapter 7 guidance, viscosity measurement is only relevant to liquids.

7 EVALUATION OF PHYSICAL HAZARDS

7.1 Explosives

Table 6: Summary table of studies on explosive properties

Method	Results	Remarks	Reference
84/449/EEC, Method A.14	explosive in the sense of EEC Method A.14	The test substance is sensitive to impact using an impact energy of 40 J.	BAM (1992)
Calculated Oxygen Balance C ₁₂ H ₁₄ N ₄ O ₅ S ₂ 358.39 g/mol	-116,2	The Oxygen Balance is greater than -200 The substance should be treated as a potential high risk.	BAM (2018)

7.1.1 Short summary and overall relevance of the information provided on explosive properties

In a standard A.14 study, the substance showed explosive properties as it was found to be sensitive to impact (test of mechanical sensitivity with respect to shock).

Screening procedures have been used which shows that OBSH has chemical groups present in the molecule which are associated with explosive or self-reactive properties with reference to the screening procedures in Appendix 6 of the UN-MTC, see Tables A6.1 and A6.3. Secondly, the oxygen balance (-116) identifies the material to be a potential explosive, as it is greater than the limit value of -200.

7.1.2 Comparison with the CLP criteria

The traditional aspects of explosive properties, such as detonation, deflagration and thermal explosion, are incorporated in the decision logic Figure 2.8.1 of CLP. Consequently, the determination of explosive properties as prescribed in the hazard class explosives needs not to be conducted for self-reactive substances and mixtures.

7.1.3 Conclusion on classification and labelling for explosive properties

Not classified – conclusive but not sufficient for classification.

7.2 Flammable gases (including chemically unstable gases)

Hazard class not applicable (solid).

7.3 Oxidising gases

Hazard class not applicable (solid).

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7.4 Gases under pressure

Hazard class not applicable (solid).

7.5 Flammable liquids

Hazard class not applicable (solid).

7.6 Flammable solids

Table 7: Summary table of studies on flammable solids

Method	Results	Remarks	Reference
84/449/EEC, Method A.10	highly flammable in the sense of EEC Method A.10		BAM (1992)

7.6.1 Short summary and overall relevance of the provided information on flammable solids

In a standard A.10 study, the substance could be ignited and a flameless combustion along 100 mm in less than 45 seconds was measured.

7.6.2 Comparison with the CLP criteria

A substance (non-metal powder) is classified as a flammable solid when the burning time is less than 45 seconds or the burning rate is more than 2.2 mm/s, by using UN Test N.1 of the UN RTDG, Manual of Tests and Criteria.

The description of the methods A.10 and UN Test N.1 and the determination of the burning time are comparable, therefore the study should be considered to be valid. However, explosives, organic peroxides, self-reactive substances and mixtures as well as pyrophoric or oxidising solids should not be considered for classification as flammable solids since flammability is an intrinsic hazard in these classes. Consequently, the classification criteria of flammable solids need not to be applied for self-reactive substances and mixtures.

7.6.3 Conclusion on classification and labelling for flammable solids

Not classified – conclusive but not sufficient for classification.

7.7 Self-reactive substances

Table 8: Summary table of studies on self-reactivity

Method	Results	Remarks	Reference
Differential scanning calorimetry (DSC)	Exothermic Decomposition energy: 1042 J/g	T _{onset} : 132 °C	BAM (1992)
UN Test Series A to H, Part II of the UN-MTC	SELF-REACTIVE SOLID TYPE D		BAM (1992)
Information on transport classification	Diphenyloxide-4,4'-disulfonyl hydrazide, conc. = 100 % is assigned to Division 4.1 as a SELF-REACTIVE SOLID TYPE D	UN 3226, OP7B	UN RTDG Model Regulations, (1991)
Information on transport classification	Diphenyloxide-4,4'-disulfonyl hydrazide, conc. = 100 % is assigned to Division 4.1 as a SELF-REACTIVE SOLID TYPE D	UN 3226, OP7	UN RTDG Model Regulations, (2017)

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7.7.1 Short summary and overall relevance of the provided information on self-reactive substances

Self-reactive properties of 4,4'-oxydi(benzenesulphonohydrazide) have been tested according to UN Test Series A to H in Part II of the UN RTDG, Manual of Tests and Criteria (see conf. Annex).

DSC showed an exothermic decomposition reaction with an energy release of 1042 J/g starting at 132 °C. In addition, the substance is explosive in the sense of EEC Method A.14, due to six positive results using BAM Fallhammer (mass 10 kg, drop height 40 cm).

7.7.2 Comparison with the CLP criteria

Self-reactive substances or mixtures are classified in one of the seven categories of 'types A to G' according to the classification criteria given in Section 2.8.2.3 of Annex I, CLP.

Annex I: 2.8.2.3. Self-reactive substances and mixtures shall be classified in one of the seven categories of 'types A to G' for this class, according to the following principles:

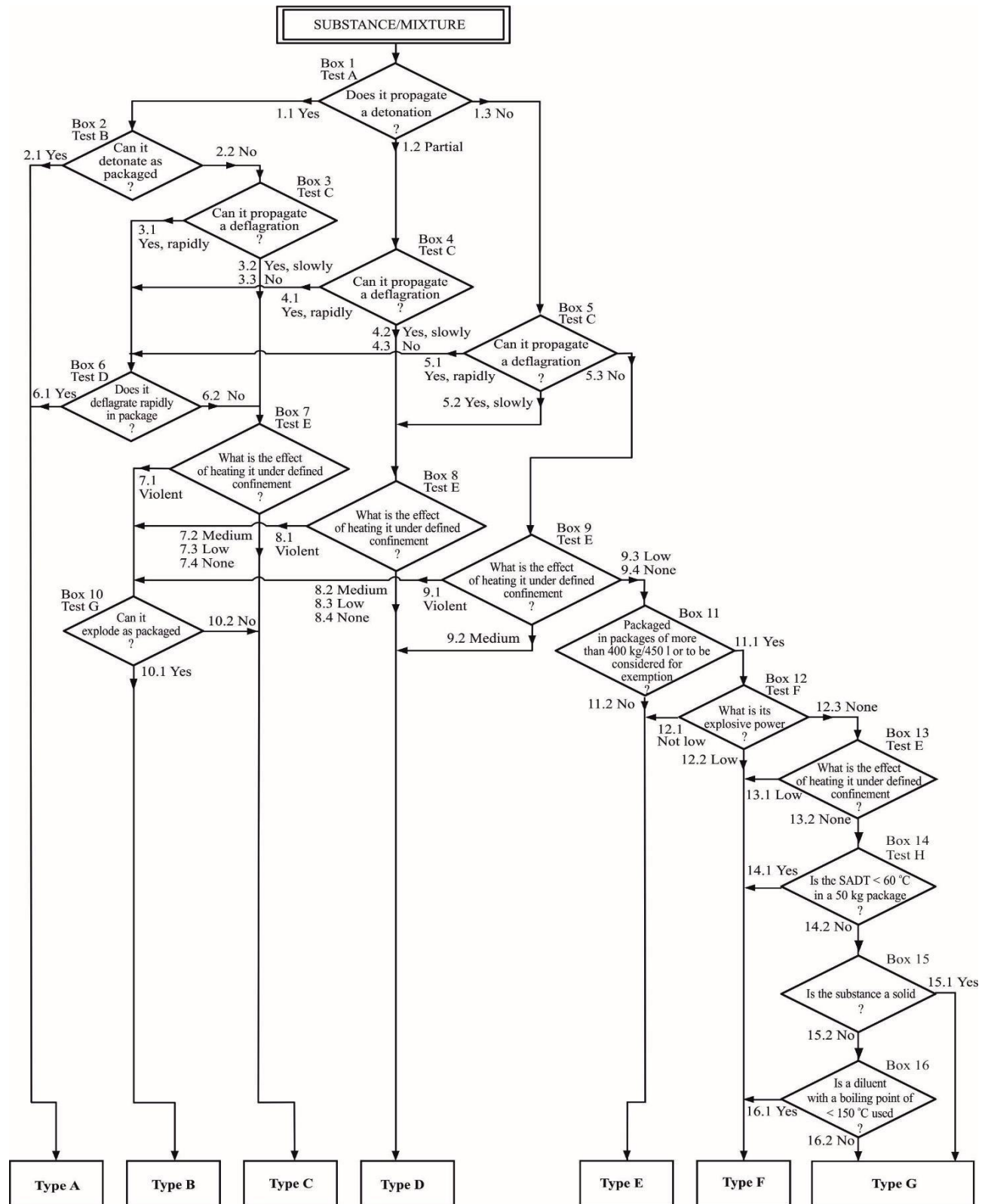
- (a) any self-reactive substance or mixture which can detonate or deflagrate rapidly, as packaged, shall be defined as self-reactive substance TYPE A;
- (b) any self-reactive substance or mixture possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package shall be defined as self-reactive substance TYPE B;
- (c) any self-reactive substance or mixture possessing explosive properties when the substance or mixture as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion shall be defined as self-reactive substance TYPE C;
- (d) any self-reactive substance or mixture which in laboratory testing:
 - (i) detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or
 - (ii) does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or
 - (iii) does not detonate or deflagrate at all and shows a medium effect when heated under confinement;shall be defined as self-reactive substance TYPE D;
- (e) any self-reactive substance or mixture which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement shall be defined as self-reactive substance TYPE E;
- (f) any self-reactive substance or mixture which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power shall be defined as self-reactive substance TYPE F;
- (g) any self-reactive substance or mixture which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (SADT is 60 °C to 75 °C for a 50 kg package), and, for liquid mixtures, a diluent having a boiling point not less than 150 °C is used for desensitisation shall be defined as self-reactive substance TYPE G. If the mixture is not thermally stable or a diluent having a boiling point less than 150 °C is used for desensitisation, the mixture shall be defined as self-reactive substance TYPE F.

Where the test is conducted in the package form and the packaging is changed, a further test shall be conducted where it is considered that the change in packaging will affect the outcome of the test.

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7.7.3 Conclusion on classification and labelling for self-reactive substances

According to the classification principles given in the decision logic in Figure 2.8.1 of CLP, 4,4'-oxydi(benzenesulphonohydrazide) has to be classified as self-reactive substance of Type D.



7.8 Pyrophoric liquids

Hazard class not applicable (solid).

7.9 Pyrophoric solids

7.9.1 Short summary and overall relevance of the provided information on pyrophoric solids

The study does not need to be conducted because the substance is known to be stable in contact with air at room temperature for prolonged periods of time (days) and hence, the classification procedure does not need to be applied.

7.9.2 Comparison with the CLP criteria

Data waiving is acceptable: The classification procedure for pyrophoric solids need not be applied in accordance with section 2.10.4 of Annex I to Regulation (EC) No 1272/2008, when experience in manufacture or handling shows that the substance or mixture does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the substance is known to be stable at room temperature for prolonged periods of time (days)).

7.9.3 Conclusion on classification and labelling for pyrophoric solids

Not classified – conclusive but not sufficient for classification.

7.10 Self-heating substances

7.10.1 Short summary and overall relevance of the provided information on self-heating substances

The study does not need to be conducted because the substance undergoes exothermic decomposition at a temperature below or equal to 140°C.

7.10.2 Comparison with the CLP criteria

Data waiving is acceptable: The classification procedure for this class need not be applied for self-reactive and explosive substances.

7.10.3 Conclusion on classification and labelling for self-heating substances

Not classified – conclusive but not sufficient for classification.

7.11 Substances which in contact with water emit flammable gases

7.11.1 Short summary and overall relevance of the provided information on substances which in contact with water emit flammable gases

The study does not need to be conducted because the organic substance does not contain metals or metalloids and hence, the classification procedure does not need to be applied.

7.11.2 Comparison with the CLP criteria

Data waiving is acceptable: The classification procedure for this class need not be applied in accordance with section 2.12.4 of Annex I to Regulation (EC) No 1272/2008, if:

- (a) the chemical structure of the substance or mixture does not contain metals or metalloids; or
- (b) experience in production or handling shows that the substance or mixture does not react with water, e.g. the substance is manufactured with water or washed with water; or

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(c) the substance or mixture is known to be soluble in water to form a stable mixture.

7.11.3 Conclusion on classification and labelling for substances which in contact with water emit flammable gases

Not classified – conclusive but not sufficient for classification.

7.12 Oxidising liquids

Hazard class not applicable (solid).

7.13 Oxidising solids

7.13.1 Short summary and overall relevance of the provided information on oxidising solids

The study does not need to be conducted because the substance is flammable and has explosive properties.

7.13.2 Comparison with the CLP criteria

Data waiving is acceptable: The UN Test O.3 is not applicable for substances which are explosive or flammable and also not for organic peroxides.

7.13.3 Conclusion on classification and labelling for oxidising solids

Not classified – conclusive but not sufficient for classification.

7.14 Organic peroxides

7.14.1 Short summary and overall relevance of the provided information on organic peroxides

The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.

7.14.2 Comparison with the CLP criteria

Data waiving is acceptable in accordance with the given definition of organic peroxides in section 2.15.1.1 of Annex I to Regulation (EC) No 1272/2008:

Organic peroxides mean liquid or solid organic substances which contain the bivalent -O-O- structure and may be considered derivatives of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term organic peroxide includes organic peroxide mixtures (formulations) containing at least one organic peroxide. Organic peroxides are thermally unstable substances or mixtures, which can undergo exothermic self-accelerating decomposition. In addition, they can have one or more of the following properties:

- (i) be liable to explosive decomposition;
- (ii) burn rapidly;
- (iii) be sensitive to impact or friction;
- (iv) react dangerously with other substances.

7.14.3 Conclusion on classification and labelling for organic peroxides

Not classified – conclusive but not sufficient for classification.

7.15 Corrosive to metals

Hazard class not applicable (solid).

RAC evaluation of physical hazards

Summary of the Dossier Submitter's (DS) proposal

4,4'-oxydi(benzenesulphonohydrazide) (OBSh) is an odourless fine white crystalline powder at 20°C and 101.3 kPa. The substance decomposes at 155°C and above, therefore the melting/freezing point nor boiling point have been identified.

Explosivity

In a standard EEC A.14 study (BAM, 1992), the substance showed explosive properties as it was found to be sensitive to impact (test of mechanical sensitivity with respect to shock).

Screening procedures have been used which shows that OBSh has chemical groups present in the molecule which are associated with explosive or self-reactive properties with reference to the screening procedures in Appendix 6 of the UN-MTC (Tables A6.1 and A6.3) Secondly, the oxygen balance (-116) identifies the material to be a potential explosive, as it is greater than the limit value of -200.

The traditional aspects of explosive properties, such as detonation, deflagration and thermal explosion, are incorporated in the decision logic in Figure 2.8.1 of the CLP Regulation. Consequently, the determination of explosive properties as prescribed in the hazard class explosives needs not to be conducted for self-reactive substances and mixtures (See below).

Flammable solids

In a standard A.10 study (BAM, 1992), the substance could be ignited and a flameless combustion along 100 mm in less than 45 seconds was measured.

A substance (non-metal powder) is classified as a flammable solid when the burning time is less than 45 seconds or the burning rate is more than 2.2 mm/s, by using UN Test N.1 of the UN RTDG, Manual of Tests and Criteria.

The description of the methods A.10 and UN Test N.1 and the determination of the burning time are comparable, therefore the study should be considered to be valid. However, explosives, organic peroxides, self-reactive substances and mixtures as well as pyrophoric or oxidising solids should not be considered for classification as flammable solids since flammability is an intrinsic hazard in these classes. Consequently, the classification criteria of flammable solids need not be applied for self-reactive substances and mixtures (see below).

Self-reactive substances

Self-reactive properties of 4,4'-oxydi(benzenesulphonohydrazide) have been tested according to UN Test Series A to H in Part II of the UN RTDG, Manual of Tests and

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Criteria (BAM, 1992).

DSC showed an exothermic decomposition reaction with an energy release of 1042 J/g starting at 132 °C. In addition, the substance is explosive in the sense of EEC Method A.14, due to six positive results using BAM Fallhammer (mass 10 kg, drop height 40 cm).

The DS concluded that according to the classification principles given in the decision logic in Figure 2.8.1 of CLP, 4,4'-oxydi(benzenesulphonohydrazide) warrants classification as a self-reactive substance of Type D.

Pyrophoric solids

OBSH is known to be stable in contact with air at room temperature for prolonged periods of time (days) and hence, the classification procedure does not need to be applied.

Self-heating substances

The study does not need to be conducted because the substance undergoes exothermic decomposition at a temperature below or equal to 140°C.

Substances which in contact with water emit flammable gases

The study does not need to be conducted because the organic substance does not contain metals or metalloids and hence, the classification procedure does not need to be applied.

Oxidising solids

The study does not need to be conducted, no additional classification as oxidizing is required for explosive substances.

Organic peroxides

The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.

In conclusion, the classification of 4,4'-oxydi(benzenesulphonohydrazide) as self-reactive substance Type D is proposed by the DS. The DS do not propose to classify 4,4'-oxydi(benzenesulphonohydrazide) for the hazard classes of explosives, flammable solids, pyrophoric solids, self-heating substances, substances which in contact with water emit flammable gases, oxidising solids, organic peroxides.

Comments received during consultation

No comments received.

Assessment and comparison with the classification criteria

4,4'-oxydi(benzenesulphonohydrazide) is a compound of the type of aromatic sulfohydrazides (-SO₂-NH-NH₂) known as self-reactive substances (according to section 2.8.1 of the Guidance on the Application of the CLP Criteria, Version 5.0 – July 2017).

Based on the result of differential scanning calorimetry (DSC) an exothermic decomposition reaction with an energy release of 1042 J/g, 4,4'-

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oxydi(benzenesulphonohydrazide) meets the definition of self-reactive substances (according to CLP Regulation, Annex I, 2.8.1.1) as thermally unstable solid substance liable to undergo a strongly exothermic decomposition.

The self-reactive properties of 4,4'-oxydi(benzenesulphonohydrazide) tested (BAM, 1992, results provided in confidential Annex of CLH report) according to UN Test Series A to H described in Part II of the UN RTDG, Manual of Tests and Criteria, fulfil the criteria for classification given in the decision logic in Figure 2.8.1 of CLP Regulation as follows:

- propagation of detonation - a test of UN Test Series A was not performed what was justified by the result "No" obtained from the explosive power test (F.3 BAM Trauzl test) and "Low" result obtained from test E.2 (Dutch pressure vessel test (DPVT)) and "No" result obtained from test E.1 (Koenen test) – exit 1.3;
- propagation of deflagration – result "Yes, slowly" was obtained from the C.1 Time/pressure test – exit 5.2
- Effect of heating under defined confinement - result "No" was obtained from the E.1 Koenen test and result "Low" was obtained from the E.2 Dutch pressure vessel test (DPVT) – exit – 8.3/8.4.

Therefore, 4,4'-oxydi(benzenesulphonohydrazide) meets criterion "does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement" (section 2.8.2.3 (d) (ii) for classification as **self-reactive substance TYPE D**. In conclusion, RAC supports the DS's proposal to classify 4,4'-oxydi(benzenesulphonohydrazide) as **Self-react. D, (H242: Heating may cause a fire)**.

Self-reactive substances and mixtures need to be subjected to temperature control when the SADT is $\leq 55^{\circ}\text{C}$. The SADT is defined as the lowest temperature at which self-accelerating decomposition of a substance or mixture may occur in the packaging as used in transport, handling and storage.

Temperature control is not needed based on SADT of 4,4'-oxydi(benzenesulphonohydrazide) which is above 60°C (for a package up to 50 kg).

The traditional aspects of explosive properties, such as detonation, deflagration and thermal explosion, are incorporated in the decision logic Figure 2.8.1 of CLP. Consequently, the determination of explosive properties as prescribed in the hazard class explosives needs not to be conducted for self-reactive substances and mixtures (according to section 2.8.4.1 of Guidance on the Application of the CLP Criteria Version 5.0 – July 2017).

Self-reactive substances and mixtures should not be considered for classification as flammable solids since flammability is an intrinsic hazard in this class (according to section 2.7.3 of Guidance on the Application of the CLP Criteria Version 5.0 – July 2017).

According to CLP Annex I, 2.10.4, the classification procedure for pyrophoric solids need not be applied when experience in manufacture or handling shows that the substance or mixture does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the substance or mixture is known to be stable at room temperature for prolonged periods of time (days)).

OBSH is known to be stable in contact with air at room temperature for prolonged periods of time (days) and hence, the classification procedure for pyrophoricity does not need to

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be applied.

A study for self-heating substances does not need to be conducted because the substance undergoes exothermic decomposition at a temperature below or equal to 140°C.

A study for substances which emit flammable gases in contact with water does not need to be conducted because the organic substance does not contain metals or metalloids and hence, the classification procedure does not need to be applied.

According to screening procedures and waiving of testing (section 2.14.4.1.1 of Guidance on the Application of the CLP Criteria Version 5.0 – July 2017) solids that are classified as explosives should not be subjected to the testing procedures for oxidising solids. Since the screening procedure identifies 4,4'-oxydi(benzenesulphonohydrazide) to be a potential explosive (the substance contains chemical groups associated with explosive and the oxygen balance (-116) is greater than the limit value of -200) the test for oxidising solids does not need to be conducted.

According to the definition in CLP Regulation Annex I: 2.15.1 organic peroxides means liquid or solid organic substance which contain the bivalent -O-O- structure and may be considered derivatives of hydrogen peroxide. Therefore, study for organic peroxides does not need to be conducted because the substance does not fall under the definition of organic peroxides.

In conclusion, RAC agrees with DS's proposal to classify 4,4'-oxydi(benzenesulphonohydrazide) as **self-reactive substance TYPE D (Self-react. D, H242: Heating may cause a fire)** and **not to classify the substance for the hazard classes:**

- **explosives,**
- **flammable solids,**
- **pyrophoric solids,**
- **self-heating substances,**
- **substances which in contact with water emit flammable gases,**
- **oxidising solids, and**
- **organic peroxides.**

8 TOXICOKINETICS (ABSORPTION, METABOLISM, DISTRIBUTION AND ELIMINATION)

Not addressed in this dossier.

9 EVALUATION OF HEALTH HAZARDS

Not addressed in this dossier.

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10 EVALUATION OF ENVIRONMENTAL HAZARDS

10.1 Rapid degradability of organic substances

Table 9: Summary of relevant information on rapid degradability

Method	Results	Remarks	Reference
OECD 111	Half-lives (25°C): pH4: 9.2 h pH7: 7.9 h pH9: 5.8 h degradation products: not measured	Rel. 2	(ECHA, 2018; OECD, 2006)
OECD 301C	10.9 % degradation (based on BOD) after 28 days	Rel. 1	(ECHA, 2018; OECD, 2006)

10.1.1 Ready biodegradability

The ready biodegradability of OBSH was evaluated in an OECD 301C study at 25 ± 2 °C. OBSH (purity > 99 %) with an initial concentration of 100 mg/L and 30 mg/L inoculum (activated sludge, adoption not specified) was used. Inoculum was collected from 15 sites such as river, domestic and industrial wastewater treatment plants. After 28 days 10.9 % degradation (BOD) was observed. The result of the conducted reference control is not mentioned in the OECD SIDS Initial Assessment Report.

A further biodegradation study (without details on method) was cited in the registration dossier as well the OECD SIDS Initial Assessment Report (Rel. 2). 100 mg/L of OBSH (purity 93.3 %) was used as initial concentration (concentration of the non-adapted inoculum was not mentioned). After 14 days 2 % degradation (BOD) was measured.

10.1.2 BOD₅/COD

No data available.

10.1.3 Hydrolysis

Rapid hydrolysis of OBSH was shown in a study according to OECD guideline 111 (ECHA, 2018; OECD, 2006). The study was conducted at 25 °C and the half-lives ranged between 5.8 and 9.2 hours for all three pH-values (pH = 4, 7 and 9). Transformation products were not identified. Therefore, it could not be demonstrated that the transformation products do not fulfil the criteria for classification as hazardous to the aquatic environment and OBSH should not be considered as rapidly degradable according to CLP regulation (section 4.1.2.9.4) and ECHA Guidance ((ECHA, 2017) Annex II.4).

Based on chemical structure, hydrazine and 4,4'-oxybis(benzenesulfonic acid) are expected degradation products from hydrolysis. Hydrazine is harmonised classified as Aquatic Acute 1 and Aquatic Chronic 1 (Index number 007-008-00-3).

10.1.4 Other convincing scientific evidence

No data available.

10.1.4.1 Field investigations and monitoring data (if relevant for C&L)

Not relevant.

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10.1.4.2 Inherent and enhanced ready biodegradability tests

No data available.

10.1.4.3 Water, water-sediment and soil degradation data (including simulation studies)

No data available.

10.1.4.4 Photochemical degradation

An atmospheric half-life of 5.1 days was calculated (AOPWIN v1.92) for the reaction of OBSH with OH-radicals.

10.2 Environmental fate and other relevant information

Based on the low log Kow (0.08), a low log Koc of 1.34 (KOCWIN v2.0) and consequently a low adsorption potential is expected.

Volatilisation is not considered to be a significant removal mechanism for OBSH from water systems (Henry's Law constant = 1.28×10^{-12} Pa·m³·mol⁻¹; HENRYWIN v3.20)

10.3 Bioaccumulation

Table 10: Summary of relevant information on bioaccumulation

Method	Results	Remarks	Reference
KOWWIN	Log Kow = 0.08	Rel. 2	(ECHA, 2018; OECD, 2006)
OECD 305	0.1 mg/L test concentration: BCF = 0.3 1 mg/L test concentration: OBSH: BCF= 3	Rel. 2	(ECHA, 2018; OECD, 2006)

10.3.1 Estimated bioaccumulation

A log Kow of 0.08 was estimated using KOWWIN v1.67 (ECHA, 2018; OECD, 2006)

10.3.2 Measured partition coefficient and bioaccumulation test data

Bioaccumulation of OBSH was evaluated according to OECD guideline 305 (ECHA, 2018; OECD, 2006). *Cyprinus sp* were exposed to 0.1 and 1 mg/L of OBSH for 42 days at 25 °C. All measured concentration values were below the detection limit, thus no BCF could be determined. Therefore, BCF values were calculated based on the detection limit of HPLC. For 0.1 mg/L test concentration a BCF of 0.3 and for 1 mg/L a BCF of 3 were calculated, respectively.

Furthermore, a QSAR calculated BCF value was stated in the OECD SIDS Initial Assessment Report (OECD,2006). Based on the estimated log Kow of 0.08 a BCF value of 3.162 was calculated (BCFWIN v 2.15).

10.4 Acute aquatic hazard

Table 11: Summary of relevant information on acute aquatic toxicity

Method	Species	Test material	Results	Remarks	Reference
OECD 203	<i>Oryzias latipes</i>	OBSH CAS 80-51-3	96h-LC ₅₀ = 74 mg/L (nominal)	Semi-static; solvent used (DMSO); Rel.1	(ECHA, 2018)
OECD 203	<i>Oryzias latipes</i>	OBSH CAS 80-51-3	96h-LC ₅₀ > 20 mg/L (nominal) 96h-LC ₅₀ > 6.6 mg/L (mean measured)	Semi-static; solvent used (DMF, 0.1 mL/L); Limit- test; Rel.1	(ECHA, 2018)

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OECD 202	<i>Daphnia magna</i>	OBSH CAS 80-51-3	48h-E _{immobilisation} C ₅₀ = 15 mg/L (nominal) 48h-E _{immobilisation} C ₅₀ = 0.69 mg/L (measured)	Static, recovery rate: 3.43 to 16.7 % OBSH; Rel.1 EC ₅₀ based on measured concentration not used because low recovery rate due to very fast hydrolysis (high tox. of one expected hydrolysis product)	(ECHA, 2018)
OECD 202	<i>Daphnia magna</i>	OBSH CAS 80-51-3	48h-E _{immobilisation} C ₅₀ = 2.9 mg/L (measured)	Semi-static; solvent used (DMF; 0.1 mL/L); Rel.1	(ECHA, 2018)
OECD 201	<i>Pseudokirchneriella subcapitata</i>	OBSH CAS 80-51-3	72h-E _r C ₅₀ = 6.7 mg/L (nominal)	Static; stability test: 50% after 3h of initial level; Rel.1	(ECHA, 2018)
OECD 201	<i>Pseudokirchneriella subcapitata</i>	OBSH CAS 80-51-3	72h-E _r C ₅₀ = 3 mg/L (initial measured)	Static; solvent used, Rel.1	(ECHA, 2018)

10.4.1 Acute (short-term) toxicity to fish

The acute toxicity of OBSH to fish was evaluated in two tests according to OECD Guideline 203 (ECHA, 2018; OECD, 2006) using a solvent. They were conducted with *Oryzias latipes* over 96 hours under semi-static conditions. The first test used the nominal concentrations: control, solvent control, 6.3, 12.5, 25.0, 50.0, and 100.0 mg/L and resulted in a LC₅₀ of 74 mg/L (based on nominal concentrations). The second test – a limit-test – resulted in a LC₅₀ of higher than 6.6 mg/L (based on mean measured concentrations; the corresponding nominal concentration is 20 mg/L). Both tests are reliable (1; according to Klimish et al. (1997)) and suitable to be used for classification purposes.

10.4.2 Acute (short-term) toxicity to aquatic invertebrates

The acute toxicity of OBSH to aquatic invertebrates was evaluated in two tests according to OECD Guideline 202 (ECHA, 2018; OECD, 2006). In the first test, *Daphnia magna* was exposed over 48 hours under static conditions using the nominal concentrations: control; 0.3, 0.6, 1, 3, 5, 10, 20, and 40 mg/L (corresponding to the mean measured concentrations: 0.05, 0.07, 0.10, 0.20, 0.38, 0.52, 0.81, and 1.37 mg/L) The exposure with OBSH resulted in a EC₅₀ of 15 mg/L (based on nominal concentrations) for *Daphnia magna*. As the recovery rate was only 3.43 to 16.7 % of the nominal concentrations, the EC₅₀ based on measured concentrations was significantly lower (0.69 mg/L). The very low recovery rate is most likely the result of the very fast hydrolysis. The high toxicity of one of the expected hydrolysis products fits to this assumption. Therefore it is not justified in this case to refer the results to the measured concentrations. Therefore, the resulting EC₅₀ based on nominal concentrations is used.

In the second test, *Daphnia magna* was exposed over 48 hours under semi-static conditions using the solvent DMF (0.1 mL/L). The nominal test concentrations were: control, solvent control, 2.0, 3.6, 6.4, 11.2, and 20 mg/L (corresponding to the geometric mean measured concentrations: 1.16, 1.91, 3.39, 5.89, and 10.3 mg/L). This resulted in an EC₅₀ of 2.9 mg/L (based on mean measured concentrations).

Both tests are reliable (1; according to Klimish et al. (1997)) and suitable to be used for classification purposes.

10.4.3 Acute (short-term) toxicity to algae or other aquatic plants

There are two test on the toxicity of OBSH to algae available (ECHA, 2018; OECD, 2006). Both were conducted with *Pseudokirchneriella subcapitata* under static conditions over 72 hours. In the first test, no solvent was used and the stability examination revealed a concentration decline of 50 % within the first three

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hours. The nominal concentrations used in the first test were: control, 0.4, 0.9, 1.9, 4.2, and 9.3 mg/L. The result of the test was an E_rC_{50} of 6.7 mg/L (based on nominal concentrations).

In the second test, a solvent was used (DMF; 0.1 mL/L). The nominal concentrations used in this second algae test were: control, solvent control, 0.50, 0.82, 1.40, 2.20, 3.70, 6.10, and 10.0 mg/L (corresponds to: 0.45, 0.70, 1.17, 1.83, 3.11, 5.20, and 8.21 mg/L initially measured concentrations). The exposure of *Pseudokirchperiella sp.* with OBSH over 72 hours resulted in an E_rC_{50} of 3 mg/L (based on initial measured concentrations as at the end of the test no test material could be determined analytically).

Both tests are reliable (1; according to Klimish et al. (1997)) and suitable to be used for classification purposes.

10.4.4 Acute (short-term) toxicity to other aquatic organisms

No data available.

10.5 Long-term aquatic hazard

Table 12: Summary of relevant information on chronic aquatic toxicity

Method	Species	Test material	Results	Remarks	Reference
OECD 210	<i>Oryzias latipes</i>	OBSH CAS 80-51-3	45d-NOEC mortality = 0.09 mg/L (arithmetic mean measured) 45d-NOEC mortality = 0.10 mg/L (nominal)	Flow-through, Rel.1	(ECHA, 2018)
OECD 211	<i>Daphnia magna</i>	OBSH CAS 80-51-3	21d-NOEC _{reproduction} = 2.13 mg/L (mean measured) 21d-NOEC _{reproduction} = 3.80 mg/L (nominal) 21d-EC _{50, reproduction} = 2.48 mg/L (measured) 21d-LC ₅₀ = 2.13 mg/L (measured)	Semi-static; solvent used (DMF; 0.1 mL/L); Rel.1	(ECHA, 2018)
OECD 201	<i>Pseudokirchneriella subcapitata</i>	OBSH CAS 80-51-3	72h-NOE _{r,C} = 0.9 mg/L (nominal)	Static; stability test: 50 % after 3h of initial level; Rel.1	(ECHA, 2018)
OECD 201	<i>Pseudokirchneriella subcapitata</i>	OBSH CAS 80-51-3	72h-NOE _{r,C} = 0.82 mg/L (nominal) 72h-NOE _{r,C} = 0.7 mg/L (initial measured)	Static; solvent used, Rel.1	(ECHA, 2018)

10.5.1 Chronic toxicity to fish

There is one chronic toxicity test available, evaluating the effects of OBSH on *Oryzias latipes*. This test followed the OECD Guideline 210. The test duration was 45 days, it used flow-through conditions. Dimethylformamide (DMF) was used as a solvent in a concentration of 0.1 mL/L. The arithmetic mean was used to calculate the overall concentration during the test period (although all measured concentrations were within 80-120 % of nominal concentration). The arithmetic mean measured concentrations were 0.09, 0.30, 1.01, 3.28 and 10.22 mg/L for 0.1, 0.31, 0.98, 3.13, 10 mg/L of nominal concentrations during the test period. The water hardness was 31 to 38 mg/L. The test temperature ranged from 24.0 to 25.1 °C and the pH from 7.25 to 7.88. The dissolved oxygen ranged from 7.51 to 8.80 mg/L (91-105 % of air saturation value). Teflon aquaria were used as test vessels (6.0 × 7.0 × 9.0 cm length, width, height). At the start of the study, each test vessel contained one egg container. Twenty fertilised eggs were placed in to each egg container. For each test concentration four replicates were established. The egg containers were removed from the test vessels, when all eggs had hatched. The no observed effect concentration based on mortality (post hatch survival and overall survival) was 0.09 mg/L (based on the arithmetic mean of the measured concentrations).

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The 45d-NOEC for hatching rate success was 1.01 mg/L (arithmetic mean measured). The test is reliable (1; according to Klimish et al. (1997)) and suitable to be used for classification purposes.

10.5.2 Chronic toxicity to aquatic invertebrates

One long-term toxicity test on aquatic invertebrates is available, evaluating the effects of OBSH on *Daphnia magna* according to OECD 211. This test used a solvent (0.1 mL/L DMF) and semi-static conditions. The nominal concentrations used were: control, solvent control, 0.4, 0.85, 1.80, 3.80, and 8.00 mg/L (corresponding to the time weighted mean measured concentrations: 0.229, 0.495, 1.07, 2.13, and 4.47 mg/L). The in the aged test solutions measured concentrations were 32 ~ 39 % and the concentration recovered to 81 ~ 93 % after renewal of test solutions. The peaks of the hydrolysis product were observed but not identified. It resulted in a no observed effect concentration for reproduction of 2.13 mg/L (based on measured concentrations - twa). The test is reliable (1; according to Klimish et al. (1997)) and suitable to be used for classification purposes.

10.5.3 Chronic toxicity to algae or other aquatic plants

There are two tests on the toxicity of OBSH to algae available (ECHA, 2018; OECD, 2006). Both were conducted with *Pseudokirchneriella subcapitata* under static conditions over 72 hours. In the first test, no solvent was used and the stability examination using 1 mg OBSH/L revealed a concentration decline of 50 % within the first three hours in algae medium (HPLC with C18 column and DAD G1315B detector). The nominal concentrations used in the first test were: control, 0.4, 0.9, 1.9, 4.2, and 9.3 mg/L. The result of the test was a NOEC of 0.9 mg/L (based on nominal concentrations).

In the second test, a solvent was used (DMF; 0.1 mL/L). The nominal concentrations used in this second algae test were: control, solvent control, 0.50, 0.82, 1.40, 2.20, 3.70, 6.10, and 10.0 mg/L (corresponds to: 0.45, 0.70, 1.17, 1.83, 3.11, 5.20, and 8.21 mg/L initially measured concentrations). The exposure of *Pseudokirchneriella sp.* with OBSH over 72 hours resulted in a NOEC of 0.7 mg/L (based on initial measured concentrations as at the end of the test no test material could be determined analytically).

Both tests are reliable (1; according to Klimish et al. (1997)) and suitable to be used for classification purposes.

10.5.4 Chronic toxicity to other aquatic organisms

No data available.

10.6 Comparison with the CLP criteria

10.6.1 Acute aquatic hazard

Table 13: Comparison with criteria for acute aquatic hazards for OBSH

	Criteria for environmental hazards	OBSH	Conclusion
Acute Aquatic Toxicity	Cat. 1: LC ₅₀ /EC ₅₀ /ErC ₅₀ ≤ 1 mg/L	Fish: 96h-LC ₅₀ = 74 mg/L (nominal) Invertebrates: 48h-EC ₅₀ = 15 mg/L (nominal) Algae: 72h-ErC ₅₀ = 3 mg/L (initial measured)	No classification

According to CLP Guidance chapter 4.1.3.1.1 (ECHA, 2017b), “for substances where the degradation half-life (DT₅₀) is less than 12 hours, environmental effects are likely to be attributed to the hydrolysis products rather than to the parent substance itself (IR&CSA, Chapter R7.8)”. In ECHA Guidance R.7b (ECHA, 2017a), Table 7.8-3 it is described that:

“Classification should account for the loss of the substance during the test, if relevant and possible. For example, if degradation occurs, it is necessary to determine whether it is the substance or the degradate that

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has been tested, and whether the data produced are relevant to the classification of the parent substance. Measured concentrations of the parent material and all significant toxic degradates are desirable.

Where degradation is rapid (e.g. half-life < 1 hour), the available test data will frequently define the hazard of the degradation products since it will be these that have been tested. These data may be used to classify the parent substance in the normal way.

Where degradation is slower (e.g. half-life > 3 days), it may be possible to test the parent substance and thus generate hazard data in the normal manner using a suitable renewal regime. The subsequent degradation may then be considered in determining whether an acute or chronic hazard class should apply.

Where degradation rates fall between these two, testing of either parent and/or degradates should be considered on a case-by- case basis. “

“There may be occasions when a substance may degrade to give rise to a more hazardous or persistent product (this may be determined from preliminary tests or non-testing methods). [...]In these circumstances, the classification of the parent should take due account of the hazard of the degradation product, and the rate at which it can be formed under normal environmental conditions.”

Taking these guidances into account with respect to the hydrolysis-DT₅₀ of OBSH of 7.9 hours at pH7 and 20 °C, it would be necessary to classify the parent substance (OBSH) based on the most hazardous hydrolysis product. As described in ECHA Guidance R.7b (ECHA, 2017a), Table 7.8-3, the classification of the parent should take due account of the hazard and rate at which the degradate can be formed. Nevertheless, as in the hydrolysis test (chapter 10.1.3) no degradation products were identified and no rate for transformation could be derived, the classification of OBSH is based on data of OBSH itself.

Table 14: Comparison with criteria for acute aquatic hazards for OBSH

	Criteria for environmental hazards	OBSH	Conclusion
Acute Aquatic Toxicity	Cat. 1: LC ₅₀ /EC ₅₀ /ErC ₅₀ ≤ 1 mg/L	Fish: 96h-LC ₅₀ = 74 mg/L (nominal) Invertebrates: 48h-EC ₅₀ = 15 mg/L (nominal) Algae: 72h-E _r C ₅₀ = 3 mg/L (initial measured)	No classification

10.6.2 Long-term aquatic hazard (including bioaccumulation potential and degradation)

Table 15: Comparison with criteria for long-term aquatic hazards for OBSH

	Criteria for environmental hazards	OBSH	Conclusion
Rapid Degradation	Half-life hydrolysis < 16 days Readily biodegradable in a 28-day test for ready biodegradability (> 70 % DOC removal or > 60% theoretical oxygen demand, theoretical carbon dioxide)	Rapid hydrolysis (≤9.2 hours at 25°C), but degradation products not identified 10.9 % degradation after 28 days (BOD)	Not rapidly degradable
Bioaccumulation	Log Kow ≥ 4 BCF ≥ 500	Log Kow = 0.08 BCF ≤ 3	Low potential for bioaccumulation
Aquatic Toxicity	Non-rapidly degradable substances: Cat. 1: NOEC ≤ 0.1 mg/L Cat. 2: NOEC ≤ 1 mg/L	Fish: 45d-NOEC _{mortality} = 0.09 mg/L (arithmetic mean measured)	Aquatic chronic 1, H410, M= 1 (based on <i>Oryzias latipes</i> NOEC= 0.09)

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		Invertebrates: 21d- NOEC _{reproduction} = 3.80 mg/L (nominal) Algae: 72h-NOE _{r,C} = 0.82 mg/L (nominal)	mg/L)
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10.7 CONCLUSION ON CLASSIFICATION AND LABELLING FOR ENVIRONMENTAL HAZARDS

OBSH hydrolysis with a hydrolysis-DT₅₀ of OBSH of 7.9 hours at pH7 and 20 °C. As the transformation products are not identified, the classification and labelling of OBSH is based on data of OBSH itself.

OBSH is not rapidly degradable and has a low potential for bioaccumulation. The most sensitive valid long-term toxicity no effect concentration is 0.09 mg/L (flow-through test; based on arithmetic mean measured concentrations). This results in a classification of OBSH as Aquatic Chronic 1 (M-factor of 1) and a labelling with H410.

RAC evaluation of aquatic hazards (acute and chronic)

Summary of the Dossier Submitter's proposal

Summary

The Dossier Submitter (DS) proposed to classify OBSH as Aquatic Chronic 1, M=1 based on a NOEC of 0.09 mg/L for the fish *Oryzias latipes*, with an M-factor of 1 (0.01 mg/L < NOEC ≤ 1.0 mg/L). The substance was not considered rapidly degradable and to have a low potential for bioaccumulation. After the consultation comments, the DS agreed to add Aquatic Acute category 1, M=1 to their proposal based on the E_rC₅₀ of 0.35 mg/L for algae.

Degradation

There was one ready biodegradability study available (OECD TG 301C, GLP). The initial test substance concentration was 100 mg/L and 30 mg/L inoculum was used. After 28 days 10.9 % degradation was observed.

Rapid hydrolysis was shown in a study according to OECD TG 111 (GLP). The study was conducted at 25 °C and the half-lives were 5.8, 7.9 and 9.2 hours for pH values 4, 7 and 9, respectively. Transformation products were not identified. Therefore, it could not be demonstrated that the transformation products do not fulfil the criteria for classification as hazardous to the aquatic environment. Based on chemical structure, potential degradation products from hydrolysis were hydrazine and 4,4'-oxybis(benzenesulfonic acid). Hydrazine has a harmonised classification as Aquatic Acute 1 and Aquatic Chronic 1 (Index number 007-008-00-3). In the response to the consultation comments, the DS also gave the half-lives at 20 and 30 °C presented in the study.

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Table: Hydrolysis half-lives of OBSH

	pH 4	pH 7	pH 9
20 °C	23.1 h	17.2 h	13.9 h
25 °C	9.2 h	7.9 h	5.8 h
30 °C	3.76 h	3.72 h	2.46 h

The DS concluded that OBSH should be considered as not rapidly degradable for classification.

Bioaccumulation

Bioaccumulation of OBSH was evaluated according to OECD TG 305 (GLP). *Cyprinus* sp. were exposed to 0.1 and 1 mg/L of OBSH for 42 days at 25 °C. All measured concentration values were below the detection limit and no BCF could be determined. Therefore, BCF values were calculated based on the detection limit of HPLC. For 0.1 mg/L test concentration a BCF of 0.3 and for 1 mg/L a BCF of 3 were calculated, respectively.

Furthermore, a QSAR calculated BCF value was stated in the OECD SIDS Initial Assessment Report (OECD 2006). Based on the estimated log Kow of 0.08, a BCF value of 3.162 was calculated (BCFWIN v 2.15).

Acute Aquatic toxicity

Table: Summary of relevant information on acute aquatic toxicity of OBSH (**the results used for classification proposal in bold**)

Method	Species	Results	Remarks	Reference
OECD TG 203	<i>Oryzias latipes</i>	96h-LC₅₀ = 74 mg/L (nominal)	Semi-static; solvent used (DMSO); Rel.1	ECHA 2018
OECD TG 203	<i>Oryzias latipes</i>	96h-LC ₅₀ > 20 mg/L (nominal) 96h-LC ₅₀ > 6.6 mg/L (mean measured)	Semi-static; solvent used (DMF, 0.1 mL/L); Limit-test; Rel.1	ECHA 2018
OECD TG 202	<i>Daphnia magna</i>	48h- E_{immobilisation}C₅₀ = 15 mg/L (nominal) 48h- E _{immobilisation} C ₅₀ = 0.69 mg/L (measured)	Static, recovery rate: 3.43 to 16.7 % OBSH; Rel.1 EC50 based on measured concentration not used because low recovery rate due to very fast hydrolysis (high tox. of one expected hydrolysis product)	ECHA 2018

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OECD TG 202	<i>Daphnia magna</i>	48h- E _{immobilisation} C ₅₀ = 2.9 mg/L (measured)	Semi-static; solvent used (DMF; 0.1 mL/L); Rel.1	ECHA 2018
OECD TG 201	<i>Pseudokirchneriella subcapitata</i>	72h-ErC ₅₀ = 6.7 mg/L (nominal)	Static; stability test: 50% after 3h of initial level; Rel.1	ECHA 2018
OECD TG 201	<i>Pseudokirchneriella subcapitata</i>	72h-ErC₅₀= 3 mg/L (initial measured)	Static; solvent used, Rel.1	ECHA 2018

ECHA 2018: Registration dossier 4,4'-oxydi(benzenesulphonohydrazide) (last accessed July 2018)

DMSO = dimethyl sulfoxide

DMF = dimethylformamide

There were two acute toxicity studies for fish (OECD TG 203) available. The tests were performed with *Oryzias latipes* for 96 hours under semi-static conditions. In the first test, nominal concentrations were: control, solvent (DMSO) control, 6.3, 12.5, 25.0, 50.0, and 100.0 mg/L. The 96-hour LC₅₀ was 74 mg/L based on nominal concentrations. No analytical monitoring was performed.

The second fish test was a semi-static limit test with a nominal concentration of 20 mg/L. Analytical monitoring was performed. No mortality was seen in the test. The 96-hour LC₅₀ based on mean measured concentrations was > 6.6 mg/L.

For invertebrates there were two acute *Daphnia* studies (OECD TG 202) available. The first study was a static system using nominal concentrations of 0.3, 0.6, 1, 3, 5, 10, 20 and 40 mg/L. The corresponding measured concentrations were 0.05, 0.07, 0.10, 0.20, 0.38, 0.52, 0.81, and 1.37 mg/L, respectively. The 48-hour EC₅₀ for immobility was 15 mg/L (nominal) and 0.69 mg/L (mean measured).

The second *Daphnia* study was semi-static and solvent DMF was used. Test concentrations were measured at the beginning of the study and 24 hrs after exposure (before renewal of test solution). The nominal concentrations were 2.0, 3.6, 6.0, 11.2, 20.0 mg/L and the corresponding mean measured concentrations in the 24-hour old test solution were 0.78, 1.24, 2.17, 3.80, and 6.50 mg/L, respectively. The geometric mean concentration during 24-hours were 1.16, 1.91, 3.39, 5.89 and 10.3 mg/L, respectively. The 48-hour EC₅₀ for immobility was 2.9 mg/L (mean measured).

There were two tests available on algae. Both tests (OECD TG 201) were conducted with *Pseudokirchneriella subcapitata* under static conditions over 72 hours. In the first test, no solvent was used. The concentrations were measured at the beginning and end of the study. According to the result of analytical monitoring, OBSH was not detected in all samples at the end of the test. The nominal concentrations used in the first test were: control, 0.4, 0.9, 1.9, 4.2, and 9.3 mg/L. The result of the test was an ErC₅₀ of 6.7 mg/L based on nominal concentrations.

In the second test DMF was used as a solvent (0.1 mL/L). The concentrations of the test substance were measured at the beginning and end of the study. The nominal concentrations used were 0.50, 0.82, 1.40, 2.20, 3.70, 6.10, and 10.0 mg/L corresponding to initial measured concentrations of 0.45, 0.70, 1.17, 1.83, 3.11, 5.20, and 8.21 mg/L, respectively. After 72 hours, the measured concentrations were lower than 2% of the nominal. The 72-hour ErC₅₀ was 3 mg/L based on initial measured concentrations.

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Chronic Aquatic Toxicity

Table: Summary of relevant information on chronic aquatic toxicity of OBSH

Method	Species	Results	Remarks	Reference
OECD TG 210	<i>Oryzias latipes</i>	45d- NOEC_{mortality} = 0.09 mg/L (arithmetic mean measured) 45d-NOEC _{mortality} = 0.10 mg/L (nominal)	Flow-through, Rel.1	ECHA 2018
OECD TG 211	<i>Daphnia magna</i>	21d- NOEC _{reproduction} = 2.13 mg/L (mean measured) 21d- NOEC_{reproduction}= 3.80 mg/L (nominal) 21d-EC50 _{reproduction} = 2.48 mg/L (measured) 21d-LC50= 2.13 mg/L (measured)	Semi-static; solvent used (DMF; 0.1 mL/L); Rel.1	ECHA 2018
OECD TG 201	<i>Pseudokirchneriella subcapitata</i>	72h-NOErC= 0.9 mg/L (nominal)	Static; stability test: 50 % after 3h of initial level; Rel.1	ECHA 2018
OECD TG 201	<i>Pseudokirchneriella subcapitata</i>	72h-NOErC= 0.82 mg/L (nominal) 72h-NOErC= 0.7 mg/L (initial measured)	Static; solvent used, Rel.1	ECHA 2018

ECHA 2018: Registration dossier 4,4'-oxydi(benzenesulphonohydrazide) (last accessed July 2018)
DMF = dimethylformamide

There was one flow-through 45-day Early Life-Stage toxicity test available with fish, *Oryzias latipes* (OECD TG 210, GLP). DMF was used as a solvent in a concentration of 0.1 mL/L. The nominal concentrations were 0.1, 0.31, 0.98, 3.13 and 10 mg/L and the respective arithmetic mean measured concentrations were 0.09, 0.30, 1.01, 3.28 and 10.22 mg/L. The NOEC based on mortality (post hatch survival and overall survival) was 0.09 mg/L. The 45-day NOEC for hatching rate success was 1.01 mg/L. The results are based on arithmetic mean of the measured concentrations.

For invertebrates there was one long-term toxicity test on *Daphnia magna* available (OECD TG 211, GLP). This test used a solvent (0.1 mL/L DMF) and semi-static conditions. The nominal concentrations used were: 0.4, 0.85, 1.80, 3.80, and 8.00 mg/L corresponding to the time weighted mean measured concentrations of 0.229, 0.495, 1.07, 2.13, and 4.47 mg/L. Measured concentrations in the new test solutions on days 0, 7 and 14 were 81 - 93 % of the nominal concentrations. In the aged test solutions on days 1, 8 and 15 the measured concentrations were 32 - 39 % of the nominal concentrations. The peaks of the hydrolysis product were observed but not identified. The 21-day NOEC for reproduction was 2.13 mg/L based on time weighted mean measured concentrations.

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The two available algae tests are described under the acute aquatic toxicity above. The two 72-hour NOE_rC values for *Pseudokirchneriella subcapitata* from these tests were 0.9 mg/L based on nominal concentrations and 0.7 mg/L based on initial measured concentrations.

Comments received during consultation

Comments were received from four Member States (MS).

One MS was of the opinion that lack of identification of hydrolysis products does not justify leaving them out of consideration and using nominal/initial measured values when evaluating the aquatic toxicity of OBSH. Consequently, the EC₅₀ of 0.69 mg/L based on measured concentrations would be the lowest acute toxicity value leading to Aquatic Acute 1, M= 1 classification. Another MS supported to add acute classification to the proposed classification.

They also pointed out that when measured concentrations are available, as in for example in algae studies, results should be based on geometric mean measured concentrations, and where concentrations at the end of test are below the analytical detection limit, such concentrations shall be considered to be half that detection limit. In case of semi-static tests, it should be clarified whether the geometric mean for each renewal period has been calculated, and if the mean exposure over the whole exposure period has calculated from these data.

Although the DS in the CLH proposal had based their evaluation on nominal concentrations, they now (after receiving the comments from the consultation) agreed that test concentrations not remaining between 80 and 120% of nominal should be based on measured concentrations. They also agreed that half of the analytical detection limit should be used if the measured concentrations are below this detection limit. They also informed that for the semi-static tests described in the CLH report, the geometric mean measured concentrations included the measured concentrations for the new medium and the aged one for every renewal period. For the first algae study, the limit of quantification was 0.1 mg/L. Using the half of the LOQ the resulting mean measured concentrations would be: 0.68 – 0.46 – 0.31 – 0.21 – 0.14 mg/L (nominal: 9.3 – 4.2 – 1.9 – 0.9 – 0.4 mg/L). The E_rC₅₀ based on mean measured concentrations would be 0.57 mg/L and the NOE_rC would be 0.21 mg/L.

The DS agreed that basing the classification on measured concentrations would result in an EC₅₀ of 0.69 mg/L (*Daphnia magna*). The results from the algae toxicity studies based on mean measured concentrations were in the same order of magnitude (E_rC₅₀ is 0.57 or 0.35 mg/L, first and second test) and therefore they agreed to classify OBSH with Aquatic acute 1 (M=1).

The DS pointed out that the aquatic chronic classification is based on mean measured concentrations. In the relevant fish test a solvent (DMF) was used and the measured concentrations of OBSH were stable (within 80 to 120% of nominal). The 45-day NOEC = 0.09 mg/L results in Aquatic Chronic (M= 1).

One MS had concerns about the hydrolysis rate in different temperatures and its bearing on whether initial/nominal or measured values from the aquatic toxicity tests should be used. The DS presented extrapolated values at 12°C but pointed out that the extrapolation may contain remarkable uncertainties. The MS also pointed out that

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endpoints for length and weight are not included in the summary of the chronic toxicity test. As this is the key chronic study, these should be presented to conclude if they are more sensitive or not. According to the DS this information was not given in the report.

One MS supported the conclusion that OBSH is not rapidly degradable and not meeting the bioaccumulation criterion for classification. They also considered the first fish study with a 96-hour LC₅₀ of 74 mg/L invalid because no analytical monitoring was performed during the study.

The DS agreed to consider the first fish study invalid. They also presented new calculations for the second algae study. The nominal concentrations were: 10.0 – 6.10 – 3.7 – 2.2 – 1.4 – 0.82 – 0.50 mg/L, and the mean measured concentrations (using half of the LOQ for concentrations below the LOQ): 0.81 – 0.46 – 0.35 – 0.096 – 0.076 – 0.059 – 0.047 mg/L. This resulted in an E_rC₅₀ of approximately 0.35 mg/L and a NOE_rC of 0.059 mg/L.

More detailed descriptions of the studies in the CLH Report to allow proper assessment of the validity score was expected by two MS.

Assessment and comparison with the classification criteria

RAC agrees with the Dossier Submitter to consider OBSH as not rapidly degradable, based on:

- 10.9% degradation after 28 days in Ready biodegradability test – The substance is not demonstrated to be readily biodegradable
- no surface water simulation test available
- rapid hydrolysis at 25 °C; half-lives of 5.8, 7.9 and 9.2 hours for pH values 4, 7 and 9, respectively. Transformation products were not identified. Therefore, it could no demonstration that the transformation products do not fulfil the criteria for classification as hazardous to the aquatic environment.

RAC agrees with the Dossier Submitter on OBSH not being bioaccumulative:

- Bioconcentration factors 0.3 and 3 for fish are below the bioaccumulation cut-off value ≥ 500
- the estimated (KOWWIN) log K_{ow} was 0.08 and thus smaller than the cut-off log K_{ow} of 4.

Aquatic toxicity

After the consultation comments, the DS agreed that endpoint values where test concentrations have not remaining between 80 and 120% of nominal should be based on measured concentrations. They also agreed that half of the analytical detection limit should be used if the measured concentrations are below the detection limit. Finally, they also agreed, and RAC concurs, that the first fish test with no analytical monitoring during the test was invalid.

A hydrolysis study (REACH Registration Dossier) had been presented in the CLH Report. The hydrolysis products were not identified although this is a requirement in the OECD

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TG 111. The hydrolysis products had not been identified in the aquatic toxicity tests either and it was therefore unclear whether the parent compound or the degradation products were responsible for the toxicity.

RAC, in line with CLP Guidance (I.4.1), agrees with the DS's view presented in the reply to the consultation comments that test concentrations not remaining between 80 and 120% of nominal should be based on measured concentrations and that half of the analytical detection limit should be used if the measured concentrations are below the detection limit. The aquatic toxicity tables below reflect this change.

Acute Aquatic Toxicity

There were relevant acute toxicity data available for fish, *Daphnia* and algae. For fish the lowest 96-hour LC₅₀ based on mean measured concentrations was > 6.6 mg/L for *Oryzias latipes* in a semi-static test (OECD TG 203). For invertebrates there were two acute *Daphnia* studies (OECD TG 202) available. The lowest EC₅₀ was a 48-hour EC₅₀ for immobility of 0.69 mg/L (mean measured concentrations) from the static test. For algae there were two static studies available with *Pseudokirchneriella subcapitata* (OECD TG 201). In response to the consultation comments, the DS recalculated the results based on mean measured concentrations using half of the LOQ when the measured concentration was below the LOQ (CLP Guidance I.4.1). The 72-hour E_rC₅₀ values were 0.57 mg/L and 0.35 mg/L based on mean measured concentrations.

Table: Reliable aquatic acute toxicity data on OBSH relevant for classification

Method	Species	Test material	Results	Remarks	Reference
OECD TG 203, GLP Limit test, semi-static, renewal every 24-h	<i>Oryzias latipes</i>	OBSH	96h-LC ₅₀ > 6.6 mg/L (mean measured)	Solvent used (DMF 0.1 mL/L) No mortality in the test	REACH Registration Dossier
OECD TG 202, GLP Static	<i>Daphnia magna</i>	OBSH 95.3%	48-h EC ₅₀ : 0.69 mg/L (mm) Immobility	Static Mean measured conc. 3.43 to 16.7% of nominal ⁽³⁾	REACH Registration Dossier
OECD TG 202, GLP semi-static, renewal every 24-h	<i>Daphnia magna</i>	OBSH 99.3%	48-h EC ₅₀ : 2.9 mg/L (mm) Immobility	Solvent used (DMF 0.1 mL/L) ⁽³⁾	REACH Registration Dossier
OECD TG 201, GLP Static	<i>Pseudokirchneriella subcapitata</i>	OBSH 95.3%	72h-E _r C ₅₀ : 0.57 mg/L (mm) ⁽¹⁾		REACH Registration Dossier
OECD TG 201, GLP Static	<i>Pseudokirchneriella subcapitata</i>	OBSH 99.3%	72h-E_rC₅₀: 0.35 mg/L (mm) ⁽²⁾ mean measured conc. after 72-h <2% of nominal	Solvent used (DMF 0.1 mL/L)	REACH Registration Dossier

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mm=mean measured

DMF = dimethylformamide

⁽¹⁾ calculated by the DS in the response to the consultation comment using half of the LOQ (mean measured concentrations 0.68, 0.46, 0.31, 0.21 and 0.14 mg/L)

⁽²⁾ calculated by the DS in the response to the consultation comment using half of the LOQ (mean measured concentrations 0.81, 0.46, 0.35, 0.096, 0.076, 0.059 and 0.047 mg/L)

⁽³⁾ precipitation of the test substance and formation of film at the surface were observed in more than 1 mg/L but immobilisation was observed in more than 10 mg/L. Therefore, immobilization of daphnia and film formation are not related to each other (REACH Registration Dossier).

Chronic Aquatic Toxicity

There were relevant chronic toxicity data for fish, *Daphnia* and algae. For fish *Oryzias latipes* the 45-day NOEC based on mortality from the flow-through Early Life-Stage toxicity test (OECD TG 210) was 0.09 mg/L (arithmetic mean of the measured concentrations). For invertebrates there was one semi-static long-term toxicity test on *Daphnia magna* available (OECD TG 211). The 21-day NOEC for reproduction was 2.13 mg/L based on time weighted mean measured concentrations. The 72-hour NOE_rC values for *Pseudokirchneriella subcapitata* from the static studies were 0.21 mg/L and 0.059 mg/L recalculated by the DS based on mean measured concentrations using half of the LOQ when the measured concentration was below the LOQ.

Table: Reliable aquatic chronic toxicity data on OBSH relevant for classification

Method	Species	Test material	Results	Remarks	Reference
OECD TG 210, GLP Flow-through	<i>Oryzias latipes</i>	OBSH, 99.5-100%	45d-NOEC mortality: 0.09 mg/L (arithmetic mm)	Solvent used (DMF 0.1 mL/L) arithmetic mm conc. 80-120% of nominal	REACH Registration Dossier
OECD TG 211, GLP Semi-static, renewal on days 7 and 14	<i>Daphnia magna</i>	OBSH, 99.3%	21-d NOEC: 2.13 mg/L (mm, TWA) reproduction	Solvent used (DMF 0.1 mL/L)	REACH Registration Dossier
OECD 201, GLP Static	<i>Pseudokirchneriella subcapitata</i>	OBSH 95.3%	72-h NOE _r C 0.21 mg/L (mm) ⁽¹⁾		REACH Registration Dossier
OECD TG 201, GLP Static	<i>Pseudokirchneriella subcapitata</i>	OBSH 99.3%	72-h NOE_rC 0.059 mg/L (mm) ⁽²⁾ mean measured conc. after 72 h <2% of nominal	Solvent used (DMF 0.1 mL/L)	REACH Registration Dossier

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mm=mean measured

DMF = dimethylformamide

⁽¹⁾ calculated by the DS in the response to the consultation comment using half of the LOQ (mean measured

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concentrations 0.68, 0.46, 0.31, 0.21 and 0.14 mg/L)

(² calculated by the DS in the response to the consultation comment using half of the LOQ (mean measured concentrations 0.81, 0.46, 0.35, 0.096, 0.076, 0.059 and 0.047 mg/L)

RAC concludes that the lowest value was a 72-hour NOE_rC of 0.059 mg/L (mean measured) for the algae *Pseudokirchneriella subcapitata*.

Comparison with the criteria

Acute Aquatic Toxicity

RAC is of the opinion that OBSH should be classified as Aquatic Acute 1 due to the lowest acute toxicity value 0.35 mg/L being smaller than the cut-off 1 mg/L. An M-factor of 1 is warranted ($0.1 \text{ mg/L} < \text{ErC}_{50} \leq 1 \text{ mg/L}$).

Chronic Aquatic Toxicity

RAC is of the opinion that OBSH should be classified as Aquatic Chronic 1 due to the lowest chronic toxicity value of 0.059 mg/L and the substance being not rapidly degradable (Chronic NOEC $\leq 0.1 \text{ mg/L}$). An M-factor of 1 is warranted ($0.01 \text{ mg/L} < \text{NOEC} \leq 0.1 \text{ mg/L}$).

Overall, RAC agrees with the DS proposal modified after the consultation that OBSH warrants classification as **Aquatic Acute 1; H400 (M=1) and Aquatic Chronic 1; H410 (M=1)**.

There is an ongoing information request (decision on a compliance check, decision date 14/05/2020, <https://www.echa.europa.eu/documents/10162/082d88da-f90c-3dcd-d3da-880d20713d93>) for this substance. The classification might have to be revisited in case relevant data e.g. to identify the hydrolysis degradation products will be available.

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