

CLH report

Proposal for Harmonised Classification and Labelling

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

International Chemical Identification:

Toluene-4-sulphonohydrazide; [TSH]

EC Number: 216-407-3

CAS Number: 1576-35-8

Index Number: -

Contact details for dossier submitter:

BAuA

Federal Institute for Occupational Safety and Health
Federal Office for Chemicals
Friedrich-Henkel-Weg 1-25
44149 Dortmund, Germany

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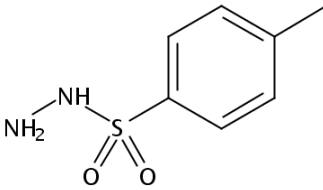
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1 IDENTITY OF THE SUBSTANCE

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)	Toluene-4-sulphonohydrazide
Other names (usual name, trade name, abbreviation)	4-methylbenzene-1-sulphonohydrazide, TSH, Benzenesulfonic acid, 4-methyl-, hydrazide
EC number (if available and appropriate)	216-407-3
EC name (if available and appropriate)	Toluene-4-sulphonohydrazide
CAS number (if available)	1576-35-8
Molecular formula	C ₇ H ₁₀ N ₂ O ₂ S
Structural formula	
SMILES notation (if available)	<chem>Cc1ccc(cc1)[S](=O)(=O)NN</chem>
Molecular weight or molecular weight range	InChI=1S/C7H10N2O2S/c1-6-2-4-7(5-3-6)12(10,11)9-8/h2-5,9H,8H2,1H3
Degree of purity (%) (if relevant for the entry in Annex VI)	100 %

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)
Toluene-4-sulphonohydrazide (CAS No:1576-35-8, EC No:216-407-3)			

2 PROPOSED HARMONISED CLASSIFICATION AND LABELLING

2.1 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	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	-										
Dossier submitters proposal	tbd	Toluene-4-sulphonohydrazide	216-407-3	1576-35-8	Add: Aquatic Chronic 1	Add: H410	Add: GHS09 Wng	Add: H410		Add: M = 1	
Resulting Annex VI entry if agreed by RAC and COM					Aquatic Chronic 1	H410	GHS09 Wng	H410		M = 1	

Table 3: 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>	No
Flammable gases (including chemically unstable gases)	<i>hazard class not applicable (solid)</i>	
Oxidising gases		
Gases under pressure		
Flammable liquids		
Flammable solids	<i>data conclusive but not sufficient for classification</i>	
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>	
Self-heating substances		
Substances which in contact with water emit flammable gases		
Oxidising liquids	<i>hazard class not applicable (solid)</i>	
Oxidising solids	<i>data conclusive but not sufficient for classification</i>	
Organic peroxides		
Corrosive to metals	<i>hazard class not applicable (solid)</i>	
Acute toxicity via oral route	<i>hazard class not assessed in this dossier</i>	
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	<i>harmonised classification proposed</i>	Yes
Hazardous to the ozone layer	<i>hazard class not assessed in this dossier</i>	No

3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

Reasons for a need for action at Community level:

Change in existing entry due to new data

Differences in self-classification

Disagreement by DS with current self-classification

4 IDENTIFIED USES

This substance is used for the manufacture of rubber products, plastic products and chemicals.

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

transfer of chemicals, mixing in open batch processes, production of mixtures or articles by tableting, compression, extrusion or pelletisation, laboratory work and manual maintenance (cleaning and repair) of machinery.

Release to the environment of this substance can occur from industrial use: as processing aid.

5 DATA SOURCES

Registration dossier

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.

6 PHYSICOCHEMICAL PROPERTIES

Table 4: Summary of physicochemical properties

Property	Value	Reference	Comment (e.g. measured or estimated)
Physical state at 20°C and 101,3 kPa	solid	REACH registration Dossier 2018	visual and olfactory assessment
Melting/freezing point	110 °C at 101.3 kPa	REACH registration Dossier 2018	OECD Guideline 102 with differential scanning calorimeter
Boiling point	No boiling was observed at 150oC and 101.3 KPa. Thus, the boiling point of the test item could not be determined. The sample degraded above 150oC.	REACH registration Dossier 2018	OECD TG 103 by distillation at the temperature 0-150oC
Relative density	1298 kg/m ³ at 20 °C	REACH registration Dossier 2018	Estimated with ACD/ChemSketch tool
Vapour pressure	2.9E-8 mmHg and 1.0E-7 mmHg at 20°C and 25°C	REACH registration Dossier 2018	OECD 104 by isothermal thermogravimetric effusion method
Surface tension		REACH registration Dossier	Data Waiving: The surface tension (mN/m) of a 0.1% (~1 g/L), 0.5%, 1.0%, 5.0%, 10% is calculated and found to: 72.4, 69.4, 67.2, 61.8, 61.8 mN/m. These values are all about the cut-off value of 60mN/m.
Water solubility	7.9 g/L at 20 °C and pH= 6.2	REACH registration Dossier 2018	OECD 105
Partition coefficient n-octanol/water	0.55 at 25°C and pH= 7	REACH registration Dossier 2018	Estimated with EpiSuite v. 4.11
Granulometry	The median size of the test substance was 25.60242 (µm) and the mean size 28.74505 (µm).	REACH registration Dossier 2018	ISO 13320 (2009) with a Laser Scattering Particle Size Distribution Analyzer LA-960
Stability in organic solvents and identity of relevant degradation products			Not determined
Dissociation constant			
Viscosity			

7 EVALUATION OF PHYSICAL HAZARDS

7.1 Explosives

Table 5: 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 "TRACEL TSH 75 k Paste" is sensitive to impact using an impact energy of 40 J.	BAM (1992)
84/449/EEC, Method A.14 (equivalent to Annex I of the German Explosive Act (SprengG), 17.04.1986, BGBl, p. 577)	Not explosive in the sense of EEC Method A.14	The test substance "TRACEL TSH 110 NER" is not sensitive to impact or friction and not explosive when heated under defined confinement	BAM (1994) from REACH registration Dossier 2018
Calculated Oxygen Balance C7H10N2O2S 186.23 g/mol	-146,2	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 "TRACEL TSH 75 k Paste" showed explosive properties as it was found to be sensitive to impact (test of mechanical sensitivity with respect to shock).

In a standard A.14 study, the substance "TRACEL TSH 110 NER" is not explosive in the sense of EEC Method A.14, as "TRACEL TSH 110 NER" did not exhibit any thermal or mechanical (impact and friction) sensitivity.

Firstly, TSH 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 (-146) 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).

7.4 Gases under pressure

Hazard class not applicable (solid).

7.5 Flammable liquids

Hazard class not applicable (solid).

7.6 Flammable solids

Table 6: Summary table of studies on flammable solids

Method	Results	Remarks	Reference
84/449/EEC, Method A.10	50.7 s (100 mm): not highly flammable in the sense of EEC Method A.10.	TRACEL TSH 75 k Paste	BAM (1992)
Regulation (EC) No 440/2008, EU Method A.10	The test substance "CELLCOM-H" was determined as being not flammable.	burning rate test: preliminary screening test burning time: 4 min: CELLCOM-H did not ignite and propagate combustion either by burning with flame or smouldering along 200 mm of the train.	Korea Testing & Research Institute (2017) from REACH registration Dossier 2018

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

In a standard A.10 study, the substance "TRACEL TSH 75 k Paste" could be ignited and a flameless combustion along 100 mm in more than 45 seconds was measured.

In a study according to EU Method A.10, the substance "CELLCOM-H" did not ignite in the preliminary screening test and is thus not regarded as highly flammable in the sense of the test method.

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 studies 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 7: Summary table of studies on self-reactivity

Method	Results	Remarks	Reference
Differential scanning calorimetry (DSC)	Exothermic Decomposition energy: 917 J/g	T _{onset} : 117 °C	BAM (1992)
UN Test Series A to H, Part II of the UN-MTC	SELF-REACTIVE SOLID TYPE D	“TRACEL TSH 75 k Paste”	BAM (1992)
Information on transport classification	4-Methylbenzensulfonylhydrazid, 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	4-Methylbenzensulfonylhydrazid, conc. = 100 % is assigned to Division 4.1 as a SELF-REACTIVE SOLID TYPE D	UN 3226, OP7	UN RTDG Model Regulations, (2017)

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

Self-reactive properties of “TRACEL TSH 75 k Paste” 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 of “TRACEL TSH 75 k Paste” showed an exothermic decomposition reaction with an energy release of 917 J/g starting at 117 °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;

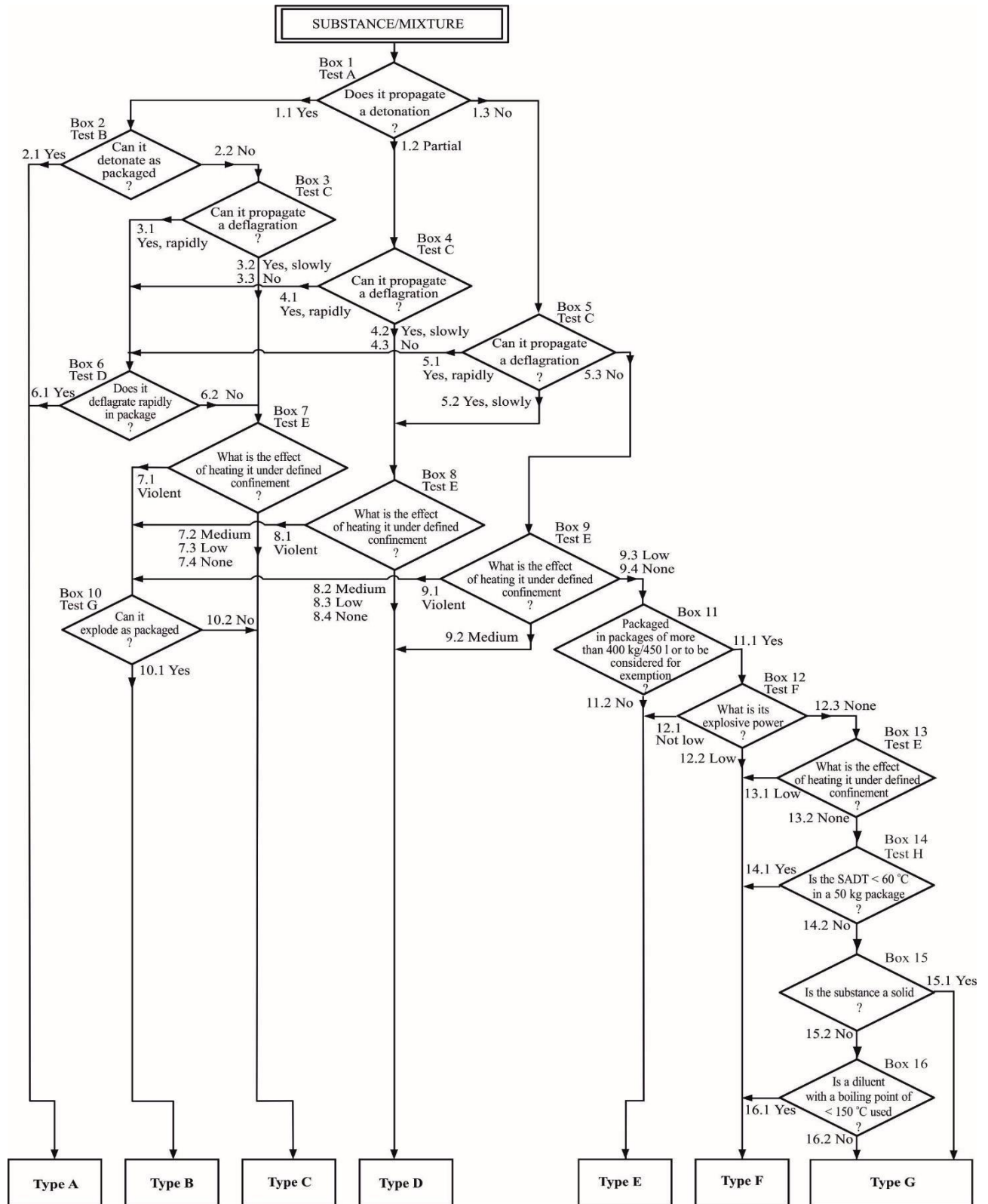
(f) any self-reactive substance or mixture which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power shall be defined as self-reactive substance TYPE F;

(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.

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, Toluene-4-sulphonohydrazide 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
- (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

No studies are available. However, for self-reactive substances no additional classification as oxidizing is required.

7.13.2 Comparison with the CLP criteria

Data waiving is acceptable: The classification procedure for this class need not be applied in accordance with the definition given in section 2.8.1.1. of Annex I to Regulation (EC) No 1272/2008: Self-reactive substances or mixtures are thermally unstable liquid or solid substances or mixtures liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes substances and mixtures classified according to this Part as explosives, organic peroxides or as oxidising. The reverse principle should apply: If a substance meets the criteria for classification as self-reactive, no additional classification as oxidizing should be required.

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).

8 TOXICOKINETICS (ABSORPTION, METABOLISM, DISTRIBUTION AND ELIMINATION)

Not assessed in this dossier.

9 EVALUATION OF HEALTH HAZARDS

Not assessed in this dossier.

10 EVALUATION OF ENVIRONMENTAL HAZARDS

10.1 Rapid degradability of organic substances

Table 8: Summary of relevant information on rapid degradability

Method	Results	Remarks	Reference
OECD 111	Half-lives (20°C): pH 4: 139 h pH 7: 39 h pH 9: 41 h Half-lives (50°C): pH 4: 36 h pH 7: 1.9 h pH 9: 1.8 h Half-lives (60°C): pH 4: 12 h pH 7: 0.84 h pH 9: 0.81 h	Rel. 1	(Bioconvergence Technology Laboratory, 2017; ECHA, 2018b)
OECD 301 F	0 % degradation (based on BOD) after 28 days	Rel. 2	(ECHA, 2018b; KIT, 2017)

10.1.1 Ready biodegradability

The ready biodegradability of TSH was evaluated in an OECD 301F study. 50 mg/L TSH was used as initial concentration. Inoculum was collected from a secondary effluent of a treatment plant (adaption and concentration not specified). After 28 days 0% degradation (oxygen consumption) was observed. Degradation for the reference substance was 74.4% after 14 days. In conclusion, TSH is not readily biodegradable.

10.1.2 BOD5/COD

No data available.

10.1.3 Hydrolysis

Rapid hydrolysis of TSH was shown in a study according to OECD guideline 111 (Bioconvergence Technology Laboratory, 2017; ECHA, 2018b). The study was conducted at 20°C, 50°C and 60°C at pH 4, 7 and 9 with an initial concentration of 0.01 mol/L. The half-lives ranged between 39 and 139 hours at 20°C for all three pH-values. The transformation product p-toluenesulfonic acid monohydrate was identified at all three temperatures and pH-values. Hydrazine was not detected. But based on read-across to 4,4'-oxydi(benzenesulphonohydrazide) (OBSh; CAS 80-51-3) and due to chemical structure formation of hydrazine is expected. Hydrazine is harmonised classified as Aquatic Acute 1 and Aquatic Chronic 1 (Index number 007-008-00-3). Therefore, TSH should not be considered as rapidly degradable according to ECHA Guidance ((ECHA, 2017) Annex II.4).

10.1.4 Other convincing scientific evidence

No data available.

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

No data available.

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 8.7 days was calculated (AOPWIN v1.91) for the reaction of TSH with OH-radicals.

10.2 Environmental fate and other relevant information

Based on the low log Kow (0.55), a low log Koc and consequently a low adsorption potential is expected.

10.3 Bioaccumulation

Table 9: Summary of relevant information on bioaccumulation

Method	Results	Remarks	Reference
EpiSuite	Log Kow = 0.55 (25°C)		(ECHA, 2018b)

10.3.1 Estimated bioaccumulation

A log Kow of 0.55 was estimated using EpiSuite v. 4.11 (ECHA, 2018b).

10.3.2 Measured partition coefficient and bioaccumulation test data

No data available.

10.4 Acute aquatic hazard

In the registration dossier, no data on the ecotoxicological effects of Toluene-4-sulphonohydrazide is available as the registrant has used a read-across to 4,4'-oxydi(benzenesulphonohydrazide) (OBSH; CAS 80-51-3) (see Annex read-across justification).

Table 10: 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)
OECD 202	<i>Daphnia magna</i>	OBSH CAS 80-51-3	48h-EC ₅₀ = 15 mg/L (nominal) 48h-EC ₅₀ = 0.69 mg/L (measured)	Static, recovery rate: 3.43 to 16.7%; Rel.1	(ECHA, 2018)
OECD 202	<i>Daphnia magna</i>	OBSH CAS 80-51-3	48h-EC 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, 2018a; 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).

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, 2018a; 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 known 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 a EC₅₀ of 2.9 mg/L (based on mean measured concentrations).

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, 2018a; 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 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_rC₅₀ 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_rC₅₀ of 3 mg/L (based on initial measured concentrations as at the end of the test no test material could be determined analytically).

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

No data available.

10.5 Long-term aquatic hazard

Table 11: 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 and no solvent. 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 no observed Effect concentration based on mortality was 0.09 mg/L (based on the arithmetic mean of the measured concentrations).

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).

10.5.3 Chronic toxicity to algae or other aquatic plants

There are two tests on the toxicity of OBSH to algae available (ECHA, 2018a; 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 NOE_rC 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 NOE_rC of 0.7 mg/L (based on initial measured concentrations as at the end of the test no test material could be determined analytically).

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 12: Comparison with criteria for acute aquatic hazards

	Criteria for environmental hazards	TSH	Conclusion
Acute Aquatic Toxicity	Cat. 1: LC ₅₀ /EC ₅₀ /ErC ₅₀ ≤ 1 mg/L	(based on data from OBSH) 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 13: Comparison with criteria for long-term aquatic hazards

	Criteria for environmental hazards	TSH	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 (≤ 139 hours at 20°C), but degradation product classified as hazardous to the environment 0 % degradation after 28 days (oxygen consumption)	Not rapidly degradable
Bioaccumulation	Log Kow ≥ 4 BCF ≥ 500	Log Kow = 0.55	Low potential for bioaccumulation
Aquatic Toxicity	Non-rapidly degradable substances: Cat. 1: NOEC ≤ 0.1 mg/L Cat. 2: NOEC ≤ 1 mg/L	(based on data from OBSH) Fish: 45d-NOEC _{mortality} = 0.09 mg/L (arithmetic mean measured) Invertebrates: 21d-NOEC _{reproduction} = 3.80 mg/L (nominal) Algae: 72h-NOE _{r,C} = 0.82 mg/L (nominal)	Aquatic chronic 1, H410, M= 1 (based on <i>Oryzias latipes</i> NOEC = 0.09 mg/L)

10.7 CONCLUSION ON CLASSIFICATION AND LABELLING FOR ENVIRONMENTAL HAZARDS

TSH 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 (based on data from OBSH; flow-through test; based on arithmetic mean measured concentrations). This results in a classification of TSH as Aquatic Chronic 1 (M-factor of 1) and a labelling with H410.

11 REFERENCES

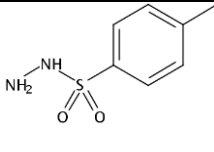
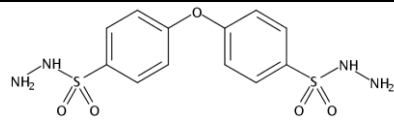
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12 ANNEXES

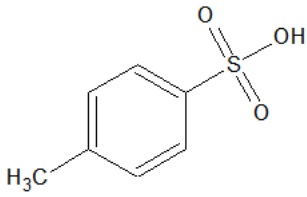
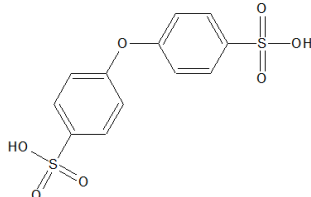
- Confidential Annex I to the CLH report
- Read-across justification

Read-across for missing ecotoxicological data of TSH is based on structural similarities to 4,4'-oxydi(benzenesulphonohydrazide (OBSH)). This approach is also used and described by the registrant in his registration dossier. Both substances are based on benzylsulfonylhydrazide. The main difference is that OBSH has two benzylsulfonylhydrazide groups bridged by another oxygen, whereas TSH has only one benzylsulfonylhydrazide with a methyl group bound to the benzene ring in para position. It is assumed that the main activity (toxicity) of both substances is allocated to the hydrazide group forming hydrazine when hydrolysed in aquatic media. The read-across based on (bio)transformation to common compound(s) corresponds to scenario 3 of the ECHA Read-Across Assessment Framework (RAAF¹). More information on physicochemical properties, stability, ecotoxicological information and chemical structures is shown in the following table.

Table 14: Information on TSH and OBSH relevant to justify read-across of ecotoxicological data

	TSH	OBSH
IUPAC name	Toluene-4-sulphonohydrazide	4,4'-oxydi(benzenesulphonohydrazide)
CAS No	1576-35-8	80-51-3
Chemical structure		
Molecular formula	C ₇ H ₁₀ N ₂ O ₂ S	C ₁₂ H ₁₄ N ₄ O ₅ S ₂
Molecular weight	186.23 g/mol	358.39 g/mol
Composition		
Partitioning coefficient log Kow	0.55	0.08
Water solubility	7900 mg/L (at 20°C and pH 6.2)	62.5 mg/L (at 20°C and pH 3.8)
Vapour pressure	3.86·10 ⁻⁶ Pa at 20°C 1.33·10 ⁻⁵ Pa at 25°C	< 0.000543 Pa at 80°C
Stability		
Hydrolysis as a function of pH	Half-life at 20°C: 139 h at pH4 39 h at pH 7 41 h at pH 9 identified transformation products: p-toluenesulfonic acid monohydrate	Half-life at 25°C: 9.2 h at pH4 7.9 h at pH 7 5.8 h at pH 9 expected transformation products: 4,4'-oxybis(benzenesulfonic acid)

¹ <http://echa.europa.eu/support/grouping-of-substances-and-read-across>

	 <p>further expected transformation product: hydrazine: H₂N-NH₂</p>	 <p>and hydrazine: H₂N-NH₂</p>
Biodegradation	Not readily biodegradable (0% degradation after 28 days)	Not readily biodegradable (10.9% degradation after 28 days)
Ecotoxicological information		
Acute (short-term) toxicity to fish	-	96h-LC ₅₀ = 74 mg/L (nominal) 96h-LC ₅₀ > 20 mg/L (nominal) 96h-LC ₅₀ > 6.6 mg/L (mean measured)
Acute (short-term) toxicity to aquatic invertebrates	-	48h-EC ₅₀ = 15 mg/L (nominal) 48h-EC ₅₀ = 0.69 mg/L (measured) 48h-EC ₅₀ = 2.9 mg/L (measured)
Acute (short-term) toxicity to algae or other aquatic plants	-	72h-E _r C ₅₀ = 6.7 mg/L (nominal) 72h-E _r C ₅₀ = 3 mg/L (initial measured)
Chronic toxicity to fish	-	45d-NOEC _{mortality} = 0.09 mg/L (arithmetic mean measured) 45d-NOEC _{mortality} = 0.10 mg/L (nominal)
Chronic toxicity to aquatic invertebrates	-	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)
Chronic toxicity to algae or other aquatic plants	-	72h-NOE _r C = 0.9 mg/L (nominal) 72h-NOE _r C = 0.82 mg/L (nominal) 72h-NOE _r C = 0.7 mg/L (initial measured)
Toxicity to microorganisms	Total respiration of activated sludge organisms (OECD 209) EC ₂₀ (30 min)= 244 mg/L EC ₅₀ (30 min)= 911 mg/L EC ₂₀ (180 min)= 186 mg/L EC ₅₀ (180 min)= 641 mg/L	Total respiration of activated sludge organisms (OECD 209) EC ₂₀ (30 min)= 5-10 mg/L EC ₅₀ (30 min) > 20 mg/L EC ₂₀ (180 min)= 5 mg/L EC ₅₀ (180 min)= 177 mg/L

RAAF Scenario 3, category approach: (Bio)transformation to common compound(s): Variations in the strength of effect(s) observed among source substances. Prediction based on regular pattern or on a worst-case approach.

As OBSH as the source substance and TSH as the target substance have similar chemical structures, their hydrolysis results in similar degradation products. For ecotoxicological effects of the target substance TSH, it is expected that the hydrolysis product hydrazine is the toxicity driving component. The hydrolysis half-time for the source substance OBSH is lower (faster) than for the target substance TSH. As the hydrolysis of the source substance OBSH results in two molecules of hydrazine per molecule the target substance TSH yields only one molecule of hydrazine per molecular unit, it is expected that the use of ecotoxicological test data of OBSH is conservative and protective in respect to the evaluation of TSH. The available data on the toxicity of both substances to microorganisms substantiate this assumption. The source substance OBSH appears to be more toxic than the target substance. Neither source nor target substance are readily biodegradable. Both have a low vapour pressure, a low potential for bioaccumulation and adsorption to organic material. They are expected to behave in a similar way in the aquatic environment. Therefore, it is justified to derive the ecotoxicity data for the target substance TSH from a read-across to ecotoxicity data for OBSH.