

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

EC Number: 216-407-3

CAS Number: 1576-35-8

Index Number: -

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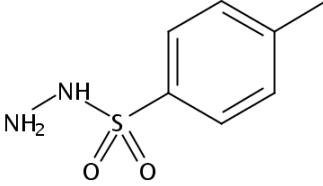
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1 IDENTITY OF THE SUBSTANCE

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	No current Annex VI entry										
Dossier submitters proposal	tbd	Toluene-4-sulphonohydrazide	216-407-3	1576-35-8	Add: Self-react. D	Add: H242	Add: GHS02 Dgr	Add: H242			
Resulting Annex VI entry if agreed by RAC and COM					Self-react. D	H242	GHS02 Dgr	H242			

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>	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>	
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		

3 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

Reasons 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 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;

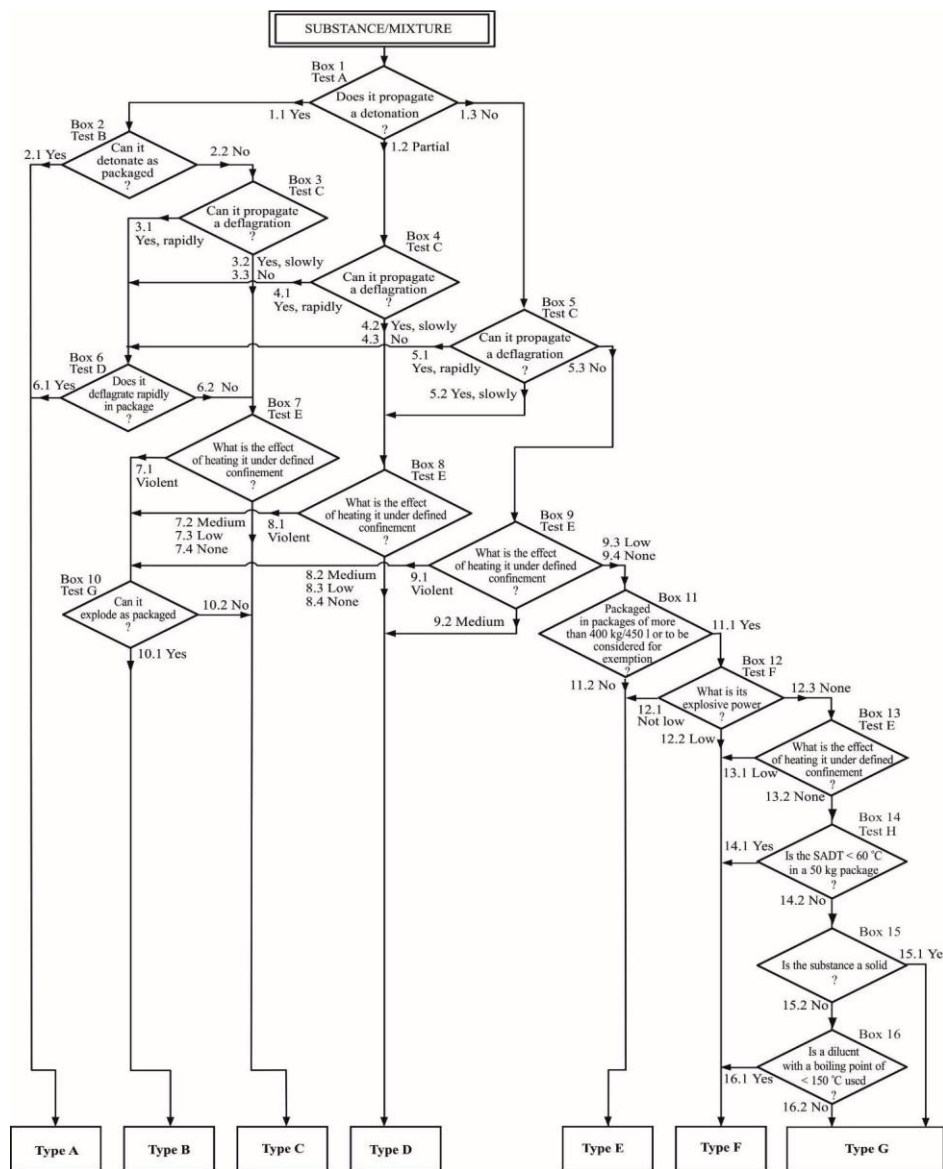
(f) any self-reactive substance or mixture which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power shall be defined as self-reactive substance TYPE F;

(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

Not assessed in this dossier.

11 REFERENCES

BAM (1992): Lemke, Prüfung der explosiven Eigenschaften und der thermischen Beständigkeit einer selbstzersetzlichen Substanz (self-reactive substance), Tgb.-Nr. 4-2570/92, 1992.

BAM (1994): Lemke, Bericht über die Prüfung des Produktes "TRACEL TSH 110 NER" auf Explosionsgefährlichkeit gemäß der Anlage I zum Sprengstoffgesetz (SprengG), Tgb.-Nr. 10177/93; 4-5718, 1994.

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12 ANNEXES