### **CLH** report

### **Proposal for Harmonised Classification and Labelling**

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

# International Chemical Identification: Trichlorosilane

**EC Number:** 233-042-5

**CAS Number:** 10025-78-2

**Index Number:** 014-001-00-9

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Version number: 2.0

**Date:** April 2019

### **CONTENTS**

1	IDE	NTITY OF THE SUBSTANCE	1
		AME AND OTHER IDENTIFIERS OF THE SUBSTANCE	
2		POSED HARMONISED CLASSIFICATION AND LABELLING	
_		ROPOSED HARMONISED CLASSIFICATION AND LABELLING ACCORDING TO THE CLP CRITERIA	
_			
3		TORY OF THE PREVIOUS CLASSIFICATION AND LABELLING	
4	JUST	FIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL	6
5	IDE	NTIFIED USES	6
6	DAT	'A SOURCES	7
7	PHY	SICOCHEMICAL PROPERTIES	7
8		LUATION OF PHYSICAL HAZARDS	
		YROPHORIC LIQUIDS	
	8.1.1		
	8.1.2		
	8.1.3	3	
		JBSTANCES WHICH IN CONTACT WITH WATER EMIT FLAMMABLE GASES	
	8.2.1	$\mathcal{L}$	
	8.2.2	r emit flammable gases	
	8.2.3		
	gases		
9	TOX	ICOKINETICS (ABSORPTION, METABOLISM, DISTRIBUTION AND ELIMINATION)	12
10		LUATION OF HEALTH HAZARDS	
		ACUTE TOXICITY - ORAL ROUTE	
	10.1 <i>10.1</i> .		
	10.1.		13
	10.1.	•	
	10.2	ACUTE TOXICITY - DERMAL ROUTE	
	10.3	ACUTE TOXICITY - INHALATION ROUTE	
	10.3.	$\mathcal{J}$	
	10.3. 10.3.	- · · · · · · · · · · · · · · · · · · ·	
	10.3.	SKIN IRRITATION/CORROSION	
	10.4.		
	10.4.	2 Comparison with the CLP criteria	16
	10.4.	3	
	10.5	EYE IRRITATION	
	10.5. 10.5.		
	10.5.	1	
	10.6	RESPIRATORY SENSITISATION	
	10.7	SKIN SENSITISATION	
	10.8	GERM CELL MUTAGENICITY	
	10.9	CARCINOGENICITY	
	10.10	REPRODUCTIVE TOXICITY	
	10.11 10.12	SPECIFIC TARGET ORGAN TOXICITY-SINGLE EXPOSURE  SPECIFIC TARGET ORGAN TOXICITY-REPEATED EXPOSURE	
	10.12	ASPIRATION HAZARD	
			-
11		LUATION OF ENVIRONMENTAL HAZARDS	
12	2 EVA	LUATION OF ADDITIONAL HAZARDS	19

#### CLH REPORT FOR TRICHLOROSILANE

13	ADDITIONAL LABELLING	. 19
14	REFERENCES	. 20
15	ANNEX	. 20

#### 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)	trichlorosilane
Other names (usual name, trade name, abbreviation)	-
ISO common name (if available and appropriate)	-
EC number (if available and appropriate)	233-042-5
EC name (if available and appropriate)	trichlorosilane
CAS number (if available)	10025-78-2
Other identity code (if available)	-
Molecular formula	Cl <sub>3</sub> HSi
Structural formula	CI 
SMILES notation (if available)	Cl[SiH](Cl)Cl
Molecular weight or molecular weight range	135,4524
Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)	no optical activity

#### 1.2 Composition of the substance

Table 2: Constituents (non-confidential information)

Constituent	Concentration range	Current CLH in Annex VI	Current self- classification and
	. 00.5 % ( / )	Table 3.1 (CLP)	labelling (CLP)
trichlorosilane	> 99.5 % (w/w)	<u>Classification</u>	Classification
EC no.: 233-042-5		Flam. Liq. 1 H224	Flam. Liq. 1 H224
		Pyr. Liq. 1 H250	Pyr. Liq. 1 H250
		Acute Tox. 4 (oral)* H302	Water-react 1 H260
		Acute Tox. 4 (inhal)* H332	Acute Tox. 4 (oral) H302
		Skin Corr. 1A H314	Acute Tox. 3 (inhal) H331
			Skin Corr. 1A H314
		Labelling	
		Signal word: Danger	<u>Labelling</u>
			Signal word: Danger
		Pictograms:	
		GHS02	Pictograms:
		GHS05	GHS02
		GHS07	GHS05
			GHS06
		Hazard statements:	
		H224	Hazard statements:
		H250	H224
		H302	H260
		H314	H302
		H332	H314
		EUH014	H331
		EUH029	EUH014
		2011029	EUH029
		Specific Conc. Limits:	EUH071
		*	2011071
		STOT SE 3; H335: C ≥ 1 %	Specific Conc. Limits:
		Notes: Note T	STOT SE 3; H335: C ≥ 1 %

Table 3: Impurities (non-confidential information) if relevant for the classification of the substance

Concentration range	Current CLH in Annex VI Table 3.1 (CLP)	Current self- classification and labelling (CLP)	The impurity contributes to the classification and labelling
> 0 - < 0.5 % (w/w)	-	-	no
	range	Concentration range Annex VI Table 3.1 (CLP)	Concentration range  Annex VI Table 3.1 classification and labelling (CLP)

Table 4: Additives (non-confidential information) if relevant for the classification of the substance

Additive	Function	Concentration range	Current CLH in Annex VI Table 3.1 (CLP)	Current self- classification and labelling (CLP)	The additive contributes to the classification and labelling
no additive					

#### CLH REPORT FOR TRICHLOROSILANE

Table 5: Test substances (non-confidential information)

Identification of test substance	Purity	The study(ies) in which the test substance is used
Trichlorosilane	≥98 % (w/w)	Key study: Flammability in contact with water 4.13.392-394 BAM 2014 Report on testing of the substance "trichlorosilane" and Expert's Opinion on transport and GHS classification Report no. 2.2-120/13  Key study: Pyrophoricity 4.13.391 BAM 2014 Report on testing of the substance "trichlorosilane" and Expert's Opinion on transport and GHS classification Report no. 2.2-120/13  Supporting study: Pyrophoricity 4.13.382 Mekelburger 2012  Trichlorosilane: UN test N.3: test method for pyrophoric liquids Report no. A120018062  Supporting study: Pyrophoricity 4.13.376 Mekelburger 2012  Test report number A120001617 according to DIN EN ISO/IEC 17025, EEC A.13 Report no. A120001617  DISREGARDED study: Flammability in contact with water 4.13.383 Mekelburger 2012  Trichlorosilane: UN test N.5: test method for substances which in contact with water emit flammable gases Report no. A120018062  Acute toxicity: inhalation 7.2.2.018; Dow Corning 1987  Acute Inhalation Toxicity Report no. 1987-I0005-1665  Acute toxicity: oral; 7.2.1.009; Mellon 1948  Range Finding Tests on Trichlorosilane. Report no. 11-70

#### 2 PROPOSED HARMONISED CLASSIFICATION AND LABELLING

#### 2.1 Proposed harmonised classification and labelling according to the CLP criteria

Table 6: Proposed harmonised classification and labelling

		International			Classification		Labelling			Specific Conc. Limits, M-factors and ATE		
	Index No	Index No	Chemical Identification	EC No	CAS No	Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		Notes
Current Annex VI entry					Flam. Liq. 1 Pyr. Liq. 1 Acute Tox. 4* Acute Tox. 4* Skin Corr. 1A	H224 H250 H302 H332 H314	Danger GHS02 GHS05 GHS07	H224 H250 H302 H332 H314	EUH014 EUH029	STOT SE 3; H335: C ≥ 1 %	Note T	
					retain: Flam. Liq. 1 Acute Tox. 4	retain: H224 H302	retain: Danger GHS02 GHS05	retain: H224 H314 H302	retain: EUH014 EUH029	remove: STOT SE 3; H335: C ≥ 1 %		
Dossier submitters proposal	014-001- 00-9	trichlorosilane	233-042-5	10025-78-2	remove: Pyr. Liq. 1 Skin Corr. 1A Acute Tox. 4	remove: H250 H332	remove: GHS07	remove: H250 H332			remove: Note T	
					add: Water-react 1 Skin Corr. 1B Eye Dam. 1 Acute Tox. 3	add: H260 H314 H318 H331	add: GHS06	add: H260 H331	add: EUH071	add: inhalation: ATE =7.65 mg/L (vapour) oral: 1030 mg/kg bw		
Resulting Annex VI entry if agreed by RAC and COM					Flam. Liq. 1 Water-react 1 Acute Tox. 4 Acute Tox. 3 Skin Corr. 1B Eye Dam. 1	H224 H260 H302 H331 H314 H318	Danger GHS02 GHS05 GHS06	H224 H260 H302 H331 H314	EUH014 EUH029 EUH071	inhalation: ATE =7.65 mg/L (vapour) oral: 1030 mg/kg bw		

Table 7: Reason for not proposing harmonised classification and status under public consultation

Hazard class	Reason for no classification	Within the scope of public consultation
Explosives Flammable gases (including chemically unstable gases)	hazard class not applicable	No
Oxidising gases Gases under pressure		
Flammable liquids	hazard class not assessed in this dossier	No
Flammable solids	nazaru crass not assessed in this dossier	110
Self-reactive substances	hazard class not applicable	No
Pyrophoric liquids	data conclusive but not sufficient for classification	Yes
Pyrophoric solids		
Self-heating substances	hazard class not applicable	No
Substances which in contact with water emit flammable gases	harmonised classification proposed	Yes
Oxidising liquids		
Oxidising solids	hazard class not applicable	No
Organic peroxides		
Corrosive to metals	hazard class not assessed in this dossier	No
Acute toxicity via oral route	harmonised classification proposed	Yes
Acute toxicity via dermal route	data lacking	No
Acute toxicity via inhalation route		Yes
Skin corrosion/irritation	harmonised classification proposed	100
Serious eye damage/eye irritation		
Respiratory sensitisation		
Skin sensitisation		
Germ cell mutagenicity		
Carcinogenicity		
Reproductive toxicity		
Specific target organ toxicity- single exposure	hazard class not assessed in this dossier	No
Specific target organ toxicity- repeated exposure		
Aspiration hazard		
Hazardous to the aquatic environment		
Hazardous to the ozone layer		

#### 3 HISTORY OF THE PREVIOUS CLASSIFICATION AND LABELLING

The substance trichlorosilane with EC Number 233-042-5, CAS Number 10025-78-2 and Index Number 014-001-00-9 has been included in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation) from

16<sup>th</sup> December 2008. Trichlorosilane has been transferred and re-classified from the former Annex I (under Directive 67/548/EEC, inserted by 19<sup>th</sup> ATP) into Annex VI of the CLP Regulation. Due to the circumstance that the classification differs in regards to pyrophoric properties and that Trichlorosilane is classified in Class 4.3 under UN 1295<sup>1</sup> (listed by name in the Dangerous Goods List in Chapter 3.2) the ECB Ad-hoc WG experts on physico chemical properties had decided at that time to assign Note T to this entry.

A CLH Dossier was drafted by an industry representative. The Dossier Submitter (DE CA) re-assessed the endpoints acute oral toxicity, acute inhalation toxicity, skin irritation/corrosion and eye irritation/corrosion.

#### 4 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

Justification that action is needed at Community level is required.

Reason for a need for action at Community level:

Differences in classification with regard to physical hazards have be avoided according to the harmonized criteria of the legislations CLP and the United Nations Recommendations on the Transport of Dangerous Goods (UN RTDG).

- Pyrophoricity and water reactivity: change in existing entry due to new data
- New test data from experimental guideline study for pyrophoricity and water reactivity are available.
- Acute toxicity data: change in existing entry due to new evaluation of existing data

#### Further detail on need of action at Community level

Pyrophoricity and water reactivity:

New test data from experimental guideline study for pyrophoricity and water reactivity are available. The result of the new experimental guideline study data shows that the substance is not phyrophoric but water reactive. The Annex VI classification and labelling needs to be updated.

Acute toxicity data:

The existing entry of Acute Tox 4 \*, H332 was re-evaluated. In an acute inhalation study an LC50 (male/female) value of 2767 ppm with 95 % confidence limits of 2388-3374 ppm was determined. This ATE value justifies classification into Acute Tox 3, H331.

In the respiratory tract the formation of hydrogen chloride during contact with skin or mucosal or lung tissues causes severe local corrosive effects. Therefore the additional labelling EUH071: Corrosive to the respiratory tract is proposed by the dossier submitter.

#### 5 IDENTIFIED USES

The following uses of trichlorosilane are of commercial significance:

- use as an intermediate in the production of other silicon-based substances,
- use as a monomer in the production of silicone polymers and resins, usually in combination with other chlorosilanes,
- use in the semiconductor industry, including photovoltaics,

 $http://www.unece.org/fileadmin/DAM/trans/danger/publi/unrec/rev19/Rev19e\_Vol\_I.pdf$ 

 $<sup>^1</sup>$  UN 1295 TRICHLOROSILANE listed in UN Recommendations on the Transport of Dangerous Goods - Model Regulations, Rev. 19 (2015), see also

- use as a laboratory reagent in research and development activities.

#### 6 DATA SOURCES

REACH registration dossiers

#### 7 PHYSICOCHEMICAL PROPERTIES

Table 8: Summary of physicochemical properties

Property	Value	Reference	Comment (e.g. measured or estimated)
Physical state at 20°C and 101,3 kPa	liquid at 20°C and 101.3 kPa		
Melting/freezing point	-126.5°C at 1013 hPa	Key study Melting point/freezing point 4.2.343 Budavari 1989 The Merck Index - Encyclopedia of Chemicals, Drugs and Biologicals.	
Boiling point	31.5 - 33°C at 101.4 kPa	Key study Boiling point 4.3.590 Gmelin 1959 Gmelin - Handbuch der anorg. Chemie	
Relative density	1.33 - 1.35 g/cm3 at 20°C	Key study Density 4.4.470 Gmelin 1959 Gmelin - Handbuch der anorg. Chemie	
Vapour pressure	72000 Pa at 22.5°C	Key study Vapour pressure 4.6.415 Wiltec 2003 Critical Point and Vapor Pressure Measurements on Trichlorosilane by Means of a Flow Method with Ultra- low Residence Times.	
Surface tension	not surface active		In accordance with column 2 of REACH Annex VII, the Surface tension study (required in section 7.6) does not need to be conducted as, based on structure, neither the substance or its hydrolysis products are expected to be surface active.
Water solubility	Water solubility (substance): Not relevant Water solubility	HYDROLYSIS PRODUCT Water solubility 4.8.236	The requirement to test the substance for water solubility is waived because in contact with water the substance rapidly

Property	Value	Reference	Comment (e.g. measured or estimated)
	(hydrolysis product): 786,000 mg/L at 20°C	Reconsile 2009 QSAR	hydrolyses to form silanetriol and hydrogen chloride.  A water solubility of 786,000 mg/L for the hydrolysis product silanetriol has been determined using an appropriate QSAR. In practice, the solubility of silanols is limited by their tendency to undergo condensation reactions to form siloxane dimers, oligomers and polymers. A highly cross-linked gel may form. Significant condensation is not expected at concentrations below
Partition coefficient noctanol/water	Log Kow (substance): Not relevant Log Kow (Silanol Hydrolysis product): -2.9 at 20°C	HYDROLYSIS PRODUCT Partition coefficient 4.7.159 EPA 2009 QSAR	The requirement to test the substance for n-octanol-water partition coefficient is waived because in contact with water the substance hydrolyses rapidly to form silanetriol and hydrogen chloride. A Log Kow value of -2.9 has been determined for the silanol hydrolysis product, silanetriol using an appropriate QSAR.
Flash point	-27°C at 101.3 kPa	Flash point 4.11.285 Degussa 2002 Degussa Safety Data Sheet (91/155/EWG) Trichlorosilane.	
Flammability	not pyrophoric	Pyrophoricity 4.13.391 BAM 2014 Report on testing of the substance "trichlorosilane" and Expert's Opinion on Transport and GHS classification	
Flammability	in contact with water liberates highly flammable gases	Flammability in contact with water 4.13.392-394 BAM 2014 Report on testing of the substance "trichlorosilane" and Expert's Opinion on transport and GHS classification	
Explosive properties	not explosive		As there are no chemical groups associated with explosive properties present in the molecule, in accordance with column 2 of REACH Annex VII,

Property	Value	Reference	Comment (e.g. measured or estimated)
			the Explosive properties study (required in section 7.11) does not need to be conducted.
Self-ignition temperature	Auto flammability temperature: 224°C	Auto flammability 4.12.199 SEHSC 2000 Southwest Research Institute Company study no. SSBJALLO	
Oxidising properties	not oxidising		The study does not need to be conducted because the substance is flammable.
Granulometry	not relevant		In accordance with Column 2 of REACH Annex VII, the granulometry study (required in Section 7.14) does not need to be conducted as the substance is used and marketed in a non-solid form.
Stability in organic solvents and identity of relevant degradation products	not critical		As the stability of the substance in organic solvents is not deemed to be critical for the performance or interpretation of any other studies, the stability in organic solvents and the identity of relevant degradation products study (required in section 7.15) is not needed.
Dissociation constant	Dissociation constant (substance): Not relevant Dissociation constant (silanol hydrolysis product): ca. 10	RA Dissociation constant 4.21.007 CES 2008 Phenylsilanetriol: Determination of partition coefficient and dissociation constant	The requirement to test the substance for dissociation constant is waived because in contact with water the substance rapidly hydrolyses to form silanetriol and hydrogen chloride. The first dissociation constant of silanetriol is estimated to be ca. 10, based on read-across from the related substance phenylsilanetriol.
Viscosity	0.33 mPa·s (dynamic), 0.24 mm2/s (static) at 20°C	Key study Viscosity 4.22.135 Budavari 1989 The Merck Index - Encyclopedia of Chemicals, Drugs and Biologicals.	

Trichlorosilane reacts with water according to the Chemistry textbook "Holleman-Wiberg, Lehrbuch der anorganischen Chemie",  $101^{st}$  edition, 1995, p. 897, to silanetriol and HCl. Silanetriol is instable and reacts to siloxanes releasing water.

$$HSiCl_3 + 3 H_2O \rightarrow HSi(OH)_3 + 3 HCl$$
 (I)

All of the chlorosilanes react vigorously with water, producing hydrogen chloride and, in the case of trichlorosilane and methyldichlorosilane, flammable hydrogen gas and hazardous residues. Hydrogen gas is extremely flammable.

Trichlorosilane contains two reactive groups, [Si-Cl] (producing hydrogen chloride (HCl) which then dissolves in water to give hydrochloric acid), and [Si-H], producing hydrogen.

Si-Cl bonds hydrolyse more rapidly than Si-H resulting in the theoretical intermediate hydrolysis product of silanetriol: HSi(OH)<sub>3</sub>. This species has so far not been isolated due to combination of the following:

1. The reactivity of the Si-H bond results in the production of monosilicic acid Si(OH)<sub>4</sub>. Hydrogen is produced as the by-product according to the equation:

$$HSi(OH)_3 + H_2O \rightarrow Si(OH)_4 + H_2$$
 (II)

Monosilicic acid condenses readily in water to form polysilicic acid.

2. The HSi(OH)<sub>3</sub>monomer rapidly condenses. Holleman-Wiberg suggests that the product of trichlorosilane hydrolysis would be initially silanetriol and followed immediately by elimination of water. In a similar manner to monosilicic acid, Si(OH)<sub>4</sub>, concentrations of silanetriol above about 100-150 mg/l as SiO<sub>2</sub> would condense to form insoluble polymeric species.

$$SiHCl_3 + 3H_2O \rightarrow HSi(OH)_3 + 3HCl$$
 (III)

Trichlorosilane + water silanetriol + hydrochloric acid

Then almost immediately

$$2HSi(OH)_3 \rightarrow HSi(OH)_2OSi(OH)_2H + H_2O \rightarrow (HSiO_{1.5})_n$$
 (IV)

#### 8 EVALUATION OF PHYSICAL HAZARDS

#### 8.1 Pyrophoric liquids

Table 9: Summary table of studies on pyrophoric liquids

Method	Results	Remarks	Reference
UN Test Method N.3	not pyrophoric	In a study performed in accordance with	Pyrophoricity 4.13.391
		UN Test Method N.3, trichlorosilane was	BAM 2014
		demonstrated to be not pyrophoric because	Report on testing of
		it could not be ignited in the first part of	the substance "tri-
		the test, and did not ignite or char the filter	chlorosilane" and
		paper in the second part of the test (BAM	Expert's Opinion on
		(2014b)).	Transport and GHS

### 8.1.1 Short summary and overall relevance of the provided information on pyrophoric liquids

In a study performed in accordance with UN Test Method N.3, trichlorosilane was demonstrated to be not pyrophoric because it could not be ignited in the first part of the test, and did not ignite or char the filter paper in the second part of the test (BAM (2014b)).

#### 8.1.2 Comparison with the CLP criteria

The liquid does not ignite within 5 min when added to an inert carrier and exposed to air, or it does not ignite or char a filter paper on contact with air within 5 min.

#### 8.1.3 Conclusion on classification and labelling for pyrophoric liquids

Not classified based on GHS/CLP criteria.

#### 8.2 Substances which in contact with water emit flammable gases

Table 10: Summary table of studies on substances which in contact with water emit flammable gases

Method	Results	Remarks	Reference
UN Test Method N.5	in contact with water liberates highly flammable gases	Trichlorosilane produces a flammable gas in contact with water at a maximum rate of gas of more than 10 L/(kg min), determined by UN Test Method N.5 (BAM (2014a)). It was not possible to determine the relative amounts of hydrogen and hydrogen chloride gas produced. this represents a worst-case scenario for classification independent on the chemical identity of the gas evolved.	Flammability in contact with water 4.13.392-394 BAM 2014 Report on testing of the substance "trichlorosilane" and Expert's Opinion on transport and GHS classification

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

Trichlorosilane produces a flammable gas in contact with water at a maximum rate of gas of 68.0 L/(kg min), determined by UN Test Method N.5 (BAM (2014a)).

The composition of the evolved gas in the UN Test N.5 was not analysed at BAM. But in the additional autoclave experiment it was shown that the gas which was evolved during the reaction of "trichlorosilane" with water is flammable.

this represents a worst-case scenario for classification independent on the chemical identity of the gas evolved.

#### 8.2.2 Comparison with the CLP criteria

Classification criteria for this class in category 1: Any substance which reacts vigorously with water at ambient temperatures and demonstrates generally a tendency for the gas produced to ignite spontaneously, or which reacts readily with water at ambient temperatures such that the rate of evolution of flammable gas is equal to or greater than 10 litres per kilogram of substance over any one minute.

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

Trichlorosilane fulfils the criteria of Division 4.3 "Substance which in contact with water emit flammable gases" packing group I of the UN Recommendation on the Transport of Dangerous Good and the Hazard Class "Substance or Mixtures which in contact with water, emit flammable gases", Category 1 of the Regulatory EC 1272/2008 (CLP/GHS Regulations) because the maximum rate of gas of more than  $10 \, \text{L/(kg min)}$  was determined.

This represents a worst-case scenario for classification independent on the chemical identity of the gas evolved.

# 9 TOXICOKINETICS (ABSORPTION, METABOLISM, DISTRIBUTION AND ELIMINATION)

Not assessed in this dossier.

#### 10 EVALUATION OF HEALTH HAZARDS

#### 10.1 Acute toxicity - oral route

Table 11: Summary table of animal studies on acute oral toxicity

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels, duration of exposure	Value LD <sub>50</sub>	Reference
Similar to an appropriate test guideline	Rat, strain not specified, male, 10 males/dose	Trichlorosilane, CAS 10025-78-2	795, 1000, 1260, and 1580 mg/kg (as a 10 % dilution in corn oil), 14-day post observation period	1030 mg/kg bw	(Mellon Institute, 1948)

Table 12: Summary table of human data on acute oral toxicity

Type of data/report	Test substance,	Relevant information about the study (as applicable)	Observations	Reference
		No human data available.		

Table 13: Summary table of other studies relevant for acute oral toxicity

Type of study/data	Test substance,	Relevant information about the study (as applicable)	Observations	Reference		
	No other study data available.					

### 10.1.1 Short summary and overall relevance of the provided information on acute oral toxicity

The only available oral LD50 value (1030 mg/kg bw dose at 10 % v/v in corn oil) is derived from a gavage study (Mellon Institute, 1948) in male rats (no information on strain) comparable to the meanwhile deleted OECD 401. Ten animals per dose were treated, the substance was diluted in corn oil (10%). The following doses were applied: 0.795, 1.0, 1.26 and 1.58 g/kg. There was a 14-day post observation period.

In males 2/10 (0.795 g/kg bw), 5/10 (1.0 g/kg bw), 7/10 (1.26 g/kg bw), 9/10 (1.58 g/kg bw) animals died. A LD50 of 1.03 g/kg bw was calculated according to the method of Thompson. No information is available on clinical signs. Observations from necropsy indicated that direct injury to the gastrointestinal tract was the cause of death. The stomach and intestines haemorrhaged and where the stomach contacted the liver and kidney the latter organs had a cooked appearance.

#### 10.1.2 Comparison with the CLP criteria

Trichlorosilane is formally classified in Annex VI of Regulation 1272/2008 as Acute Tox 4 for oral exposure. Trichlorosilane has an ATE of 1030 mg/kg bw and therefore qualifies for category 4 (300 < ATE < 2000).

#### 10.1.3 Conclusion on classification and labelling for acute oral toxicity

The available data indicate the classification for acute toxicity as Acute toxic 4 by oral exposure with an ATE of 1030 mg/kg bw. (Acute Tox 4, H302).

#### 10.2 Acute toxicity - dermal route

Not assessed in this dossier.

#### 10.3 Acute toxicity - inhalation route

Table 14: Summary table of animal studies on acute inhalation toxicity

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance, form and particle size (MMAD)	Dose levels, duration of exposure	Value LC <sub>50</sub>	Reference
Acute Inhalation Toxicity, OECD Guideline 403	Rat, Sprague- Dawley, male/female, 5/sex/dose	Trichlorosilane, CAS 10025-78-2, vapour	1687, 2287, 2683, and 3770 ppm, exposure 1 h	2767 ppm (7.65 mg/L)	(Dow Corning, 1987)
Acute Inhalation Toxicity, comparable to the appropriate OECD test guideline.	Rat, Sprague- Dawley, male/female, 5/sex/dose	Trichlorosilane, CAS 10025-78-2, vapour	995, 962, and 703 ppm, exposure 1 h	No rats died during the exposure or during the 14-day postexposure period.	(Nachreiner and Dodd, 1986)
Acute Inhalation Toxicity, but not consistent with current test guidelines	Rat, strain not specified, sex not specified, 6 rats/dose group	Trichlorosilane, CAS 10025-78-2, vapour	1000 and 500 ppm, exposure 5 minutes	A concentration of 1000 ppm killed 3 of 6 rats in 4 hours, while 500 ppm killed 1 of 6 in a similar period of time.	(Mellon Institute, 1948)
Acute Inhalation Toxicity, no guideline followed	Rat, no further data	Trichlorosilane, CAS 10025-78-2	Dose levels: no data, exposure 4 h	LCLo: 1000 ppm	(Carpenter et al., 1949)
Acute Inhalation Toxicity, no guideline followed	Mouse, no further data	Trichlorosilane, CAS 10025-78-2	Dose levels: no data, exposure 2 h	1.5 mg/L	(Izmerov, 1982)
Acute Inhalation Toxicity, no guideline followed	Rat, Sherman, male/female, 6 rats/dose group	Trichlorosilane, CAS 10025-78-2	1000 and 500 ppm, exposure 4 h	The vapour pressure values 500 ppm and 1000 ppm were found to lead to 1/6 and 3/6 mortalities respectively	(Mellon Institute, 1951) (assumed to be the same data as in Mellon Institute (1948)

Table 15: Summary table of human data on acute inhalation toxicity

Type of data/report substance,		Relevant information about the study (as applicable)	Observations	Reference
		No human data available.		

Table 16: Summary table of other studies relevant for acute inhalation toxicity

Type of study/data	Test substance,	Relevant information about the study (as applicable)	Observations	Reference		
	No other study data available.					

### 10.3.1 Short summary and overall relevance of the provided information on acute inhalation toxicity

The available study with the highest reliability (Dow Corning, 1987) was chosen as the key study. The DS considers the reliability as high and the exposure via nose-only as adequate.

The study was performed according to OECD 403, however the exposure period was modified from four hours to one hour. The test compound was applied via nose-only administration. The study was performed with young adult rats (Sprague-Dawley), body weight of 147 g (males) and 129 g (females), five animals per sex and dose. The following concentrations were tested: 1687, 2287, 2683 and 3770 ppm (as measured by IR spectroscopy). The study was performed in compliance with GLP.

In males 1/5 (1687 ppm), 2/5 (2287 ppm), 1/5 (2683 ppm), 5/5 (3770 ppm) animals died. In females 1/5 (1687 ppm), 0/5 (2287 ppm), 4/5 (2683 ppm), 4/5 (3770 ppm) animals died. An  $LC_{50}$  of 2767 ppm was calculated, however no details of the procedure were given.

When this value is adjusted for the exposure of one hour according to CLP, section 3.1.2.1 and notes to table 3.1.1, item c) by dividing by a factor of 2 for gases and vapours, the  $LC_{50}$  becomes approximately 7650 mg/m<sup>3</sup>.

Clinical signs seen in all groups included nasal crust, rough coat, sores on the face and corneal opacity. Mouth breathing was seen in all groups except 3770 ppm. Other less frequently observed signs included rales, ocular discharge and an absent nasal septum for one male rat of the 3770 ppm group.

There were no data available on body weights during the post treatment period.

Necropsy findings noted in all groups were changes in the external nares (N = 15), corneal opacity (N = 11) and dark areas on the lungs (N = 5), not 2287 ppm group). Exudate on the nasal turbinates (N = 5) and gas in the stomach (N = 11) were seen in a number of animals but not in all groups. There were no other necropsy findings. The clinical signs and the necropsy findings in the mentioned acute inhalation study are consistent with local corrosive effects that are covered by classification for acute inhalation toxicity and by applying EUH071.

Another study on acute toxicity after inhalation was performed by (Nachreiner and Dodd, 1986). Male and female Sprague-Dawley rats were exposed for one hour in a whole body chamber. Three different chamber concentrations were used with different amounts of relative humidity: 703 ppm (29% relative humidity), 962 ppm (78%) and 995 ppm (29%). The trichlorosilane concentrations were verified by gas chromatographic analysis. Five animals were used per sex and per concentration. The study was not compliant with GLP.

No rats died during the exposure or during the 14-day post exposure period.

Clinical signs were observed in all exposure groups and included lacrimation, periocular, perioral, and perinasal wetness (and/or audible respiration), and eye opacity. Clinical signs were partially attributed to hydrogen chloride since trichlorosilane per se was not detected during animal exposures.

A loss of body weight was observed on post-exposure day 7 in the majority of animals from the 995 and 962 ppm groups and for one female rat from the 703 ppm group. However, body weight gains were observed for all males and the majority of female rats during the second post-exposure week.

No test material was detected in the exposure chambers presumably due to decomposition in the presence of water vapour. The results of analysis for hydrogen chloride gas, a product of the hydrolysis of trichlorosilane, were highly variable and ranged from < 250 (the minimum limit of detection by gas chromatography) to 1850 ppm for the three exposure groups.

Another study was performed by the (Mellon Institute, 1948) on rats (no information on strain and sex available). Three groups of six rats/group were exposed to substantially saturated vapour produced at room temperature (concentration not determined), 1000, or 500 ppm.

The inhalation of substantially saturated vapour produced at room temperature was lethal to 6 rats within an exposure of five minutes. A concentration of 1000 ppm killed 3 of 6 rats in 4 hours, while 500 ppm killed 1 of 6 rats in a similar period of time.

Concentrations of 500 ppm and 1000 ppm were found to lead to 1/6 and 3/6 mortalities respectively in a study which did not meet current guideline requirements due to lack of detail on exposure, test animals, test substance and test conditions. However, it does add weight of evidence for inhalation toxicity.

For all other studies mentioned in table 14 no information is available about the experimental details.

#### 10.3.2 Comparison with the CLP criteria

Trichlorosilane is formally classified in Annex VI of Regulation 1272/2008 as Acute Tox 4 for vapour exposure. After adjustment an ATE of 7.65 mg/L (or 7650 mg/m $^3$ ) can be derived. Trichlorosilane therefore qualifies for category 3 (2.0 < ATE < 10.0 mg/L).

#### 10.3.3 Conclusion on classification and labelling for acute inhalation toxicity

After adjustment an ATE of 7.65 mg/L (or  $7650 \text{ mg/m}^3$ ) can be derived. Trichlorosilane therefore qualifies for category 3 (2.0 < ATE < 10.0 mg/L), Acute toxic 3, H331. Since the results of the key study clearly indicate the corrosive properties of the compound, it should be additionally labelled as EUH071: Corrosive to the respiratory tract.

#### 10.4 Skin irritation/corrosion

Table 17: Summary table of animal studies on skin irritation/corrosion

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels, duration of exposure	Results -Observations and time point of onset -Mean scores/animal -Reversibility	Reference
No details on the study are available	Rabbit, no further data	Trichlorosilane, CAS 10025- 78-2	24 hour exposure in rabbit belly vesicant test	An erythema/oedema score of 2 out of a maximum of 5 was reported.	(Mellon Institute, 1951)
Rabbit belly vesicant test	Rabbit, no further data	Trichlorosilane, CAS 10025- 78-2	Exposure in rabbit belly vesicant test, duration unknown	This compound falls in activity Grade 2 in the rabbit belly vesicant test, indicating a mild skin reaction.	(Mellon Institute, 1948)

Table 18: Summary table of human data on skin irritation/corrosion

Type of data/report	Test substance,	Relevant information about the study (as applicable)	Observations	Reference		
	No human data available.					

Table 19: Summary table of other studies relevant for skin irritation/corrosion

Type of study/data	Test substance,	Relevant information about the study (as applicable)	Observations	Reference		
No other study data available.						

### 10.4.1 Short summary and overall relevance of the provided information on skin irritation/corrosion

A non-guideline study was performed by the (Mellon Institute, 1951). Trichlorosilane had been investigated for 24 exposure in the rabbit belly vesicant test. No information was given on the strain or sex or numbers of animals or on the test system at all. An erythema/oedema score of 2 out of a maximum of 5 was reported.

Another non-guideline study was performed by the (Mellon Institute, 1948). Trichlorosilane had been investigated in the rabbit belly vesicant test. No information was given on the strain or sex or numbers of animals or on the test system at all. An activity grade of 2 was reported. Since the value of 2 is identical in the two studies of the Mellon Institute it could be possible, that both studies base on the same data set.

No data from guideline-conform *in vitro* or *in vivo* studies on skin irritation/corrosion are available. The available studies have been performed in 1948 and 1951 and indicate mild skin reaction and formation of erythema/oedema but they do not allow to decide on the need for classification as neither the numbers of affected/tested animals nor the mean scores for 24, 48 and 72 h and recovery were documented.

However, a concern can be identified based on the fact that this substance is a chlorosilane that generates hydrogen chloride in the presence of moisture. Trichlorosilane hydrolyses in contact with water, releasing 3 moles of hydrogen chloride (HCl) for each mole of parent material (see chapter 7). Based on the hydrolysis to hydrogen chloride under humid conditions (here after contact with sweating skin) the same classification as for hydrogen chloride as Skin corrosive 1B may be considered.

#### 10.4.2 Comparison with the CLP criteria

Trichlorosilane is at present formally classified in Annex VI of Regulation 1272/2008 as Skin Corr. 1A. The justification and underlying data for Category 1A is not known. Due to limitations of the available studies, however, a conclusion is not possible. A proprosal on classification as skin corrosive should therefore be based on the hydrolysis product hydrogen chloride.

Trichlorosilane is proposed to be classified as Skin Corr. 1B, H314 (Causes severe skin burns and eye damage).

#### 10.4.3 Conclusion on classification and labelling for skin irritation/corrosion

Due to limitations of these studies, a conclusion is not possible. Therefore, the conclusion on classification and labelling relies on the properties of the hydrolysis product hydrogen chloride. Due to the severe corrosive nature to skin of its hydrolysis product hydrogen chloride, Trichlorosilane meets the criteria for classification as Skin Corr. 1B (Skin Corr. 1B, H 314).

#### 10.5 Eye irritation

Table 20: Summary table of animal studies on eye irritation

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels, duration of exposure	Results -Observations and time point of onset -Mean scores/animal -Reversibility	Reference
No guideline followed	Rabbit, strain and sex not specified, Number of animals: 7	Trichlorosilane, CAS 10025- 78-2	250, 500 and 1000 ppm exposure to vapour, 3 minute exposure	In a non-guideline study, immediate evident eye injury was seen in rabbits following 3-minutes exposure to vapours of trichlorosilane at a nominal concentration of 500 ppm. Delayed eye damage was observed following exposure to 250 ppm.	(Union Carbide, 1947)
No guideline followed	Rabbit, no futher data	Trichlorosilane, CAS 10025- 78-2	1 % and 5 % dilutions in "Deobase" (deodorized kerosene) were evaluated by instillation into rabbits eyes.  3-minute exposures to 250 and 500 ppm dose levels were evaluated.	A 5 % dilution in "Deobase" (deodorized kerosene) ruined rabbit eyes whereas a 1 % dilution produced minor damage. The compound is relegated to grade 9 in a 10-grade rating system for eye burns and is comparable in activity to acetic anhydride.	(Mellon Institute, 1948)
				A 3-minute exposure of rabbit eyes to 500 ppm of vapour produced immediate opacity of the cornea. A concentration of 250 ppm gave no damage that was immediately detectable, but which because apparent 3 hours later, in other words a reaction which is termed a delayed burn resulted.	

Table 21: Summary table of human data on eye irritation

Type of data/report	Test substance,	Relevant information about the study (as applicable)	Observations	Reference			
No human data available.							

Table 22: Summary table of other studies relevant for eye irritation

Type of study/data	Test substance,	Relevant information about the study (as applicable)	Observations	Reference			
No other study data available.							

#### 10.5.1 Short summary and overall relevance of the provided information on eye irritation

A non-guideline study has been performed by (Union Carbide, 1947) in rabbits. Seven animals were exposed to 250, 500 and 1000 ppm triclorosilane for three minutes. The effects on the eye were evaluated at different time points after exposure for symptoms such as opacity or dullness of the cornea or internal congestion. Immediate evident eye injury was seen in rabbits following 3 minutes exposure to vapours of trichlorosilane at a nominal concentration of 500 ppm. Delayed eye damage was observed following exposure to 250 ppm.

No guideline-conform in vivo studies on eye irritation have been performed. However, the available studies published in 1948 using 5 % dilution in 'deobase' (a solvent based on refined petroleum) indicated severe eye damage ('ruined eyes'). However, it remains unclear whether the solvent 'Deobase' may have contributed to the eye effects<sup>2</sup>.

As pointed out in chapter 7, trichlorosilane generates hydrogen chloride in the presence of moisture, the substance is obviously corrosive.

Corrosive effects on the eye are consistent with corrosive effects at other mucosal tissues which supply the humidity to generate hydrogen chloride. The effects referred to are the gastric lesions in the acute oral study and the lack of nasal septum in the acute inhalation study.

#### 10.5.2 Comparison with the CLP criteria

After exposure to 5% trichlorosilane in a deodorized kerosene ruined rabbit eyes were described. The wording ruined eyes correspond to category 1 "effects on the cornea, iris or conjunctiva that are not expected to reverse ...". This severe eye damage was noted in at least one animal (without data on the total number of affected animals). However, a contribution of the solvent could not be excluded.

Taking into consideration the corrosivity of the hydrolysis product hydrogen chloride (which is labelled with H314: Causes severe skin burns and eye damage) and the evidence from the available study trichlorosilane is considered to damage the eyes.

Trichlorosilane is proposed to be classified as Eye Dam. 1, H318 (Causes serious eye damage).

#### 10.5.3 Conclusion on classification and labelling for eye irritation

Trichlorosilane meets the criteria for classification as Eye Dam. 1, H318.

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<sup>&</sup>lt;sup>2</sup> https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/f?./temp/~tjexHX:3

#### 10.6 Respiratory sensitisation

Not assessed in this dossier.

#### 10.7 Skin sensitisation

Not assessed in this dossier.

#### 10.8 Germ cell mutagenicity

Not assessed in this dossier.

#### 10.9 Carcinogenicity

Not assessed in this dossier.

#### 10.10 Reproductive toxicity

Not assessed in this dossier.

#### 10.11 Specific target organ toxicity-single exposure

Not assessed in this dossier.

#### 10.12 Specific target organ toxicity-repeated exposure

Not assessed in this dossier.

#### 10.13 Aspiration hazard

Not assessed in this dossier.

#### 11 EVALUATION OF ENVIRONMENTAL HAZARDS

Not assessed in this dossier.

#### 12 EVALUATION OF ADDITIONAL HAZARDS

Not assessed in this dossier.

#### 13 ADDITIONAL LABELLING

Not assessed in this dossier.

#### 14 REFERENCES

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#### 15 ANNEX

Technical dossier