

**Committee for Risk Assessment
RAC**

Annex 1
Background document
to the Opinion proposing harmonised classification
and labelling at EU level of

trichlorosilane

EC Number: 233-042-5
CAS Number: 10025-78-2

CLH-O-0000006809-60-01/F

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

Adopted
11 June 2020

CLH report

Proposal for Harmonised Classification and Labelling

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

International Chemical Identification:

Trichlorosilane

EC Number: 233-042-5
CAS Number: 10025-78-2
Index Number: 014-001-00-9

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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)	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 ₃ HSi
Structural formula	$ \begin{array}{c} \text{Cl} \\ \\ \text{H} - \text{Si} - \text{Cl} \\ \\ \text{Cl} \end{array} $
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 Table 3.1 (CLP)	Current self- classification and labelling (CLP)
trichlorosilane EC no.: 233-042-5	> 99.5 % (w/w)	<u>Classification</u> Flam. Liq. 1 H224 Pyr. Liq. 1 H250 Acute Tox. 4 (oral)* H302 Acute Tox. 4 (inhal)* H332 Skin Corr. 1A H314 <u>Labelling</u> Signal word: Danger Pictograms: GHS02 GHS05 GHS07 Hazard statements: H224 H250 H302 H314 H332 EUH014 EUH029 Specific Conc. Limits: * STOT SE 3; H335: C ≥ 1 % Notes: Note T	<u>Classification</u> Flam. Liq. 1 H224 Pyr. Liq. 1 H250 Water-react 1 H260 Acute Tox. 4 (oral) H302 Acute Tox. 3 (inhal) H331 Skin Corr. 1A H314 <u>Labelling</u> Signal word: Danger Pictograms: GHS02 GHS05 GHS06 Hazard statements: H224 H260 H302 H314 H331 EUH014 EUH029 EUH071 Specific Conc. Limits: * STOT SE 3; H335: C ≥ 1 %

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

Impurity	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
"Unknown impurities"	> 0 - < 0.5 % (w/w)	-	-	no

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					

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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

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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

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

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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	hazard class not applicable	No
Flammable gases (including chemically unstable gases)		
Oxidising gases		
Gases under pressure		
Flammable liquids	hazard class not assessed in this dossier	No
Flammable solids	hazard class not applicable	No
Self-reactive substances		
Pyrophoric liquids	data conclusive but not sufficient for classification	Yes
Pyrophoric solids	hazard class not applicable	No
Self-heating substances		
Substances which in contact with water emit flammable gases	harmonised classification proposed	Yes
Oxidising liquids	hazard class not applicable	No
Oxidising solids		
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	harmonised classification proposed	Yes
Skin corrosion/irritation		
Serious eye damage/eye irritation		
Respiratory sensitisation	hazard class not assessed in this dossier	No
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 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 16th December 2008. Trichlorosilane has been transferred and re-classified from the former Annex I (under Directive 67/548/EEC, inserted by 19th 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 1295¹ (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 been 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 pyrophoric 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:

¹ UN 1295 TRICHLOROSILANE listed in UN Recommendations on the Transport of Dangerous Goods - Model Regulations, Rev. 19 (2015), see also http://www.unece.org/fileadmin/DAM/trans/danger/publi/unrec/rev19/Rev19e_Vol_I.pdf

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- 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,
- 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/cm ³ 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.	

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Property	Value	Reference	Comment (e.g. measured or estimated)
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): 786,000 mg/L at 20°C	HYDROLYSIS PRODUCT Water solubility 4.8.236 Reconsile 2009 QSAR	The requirement to test the substance for water solubility is waived because in contact with water the substance rapidly 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 n-octanol/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	

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Property	Value	Reference	Comment (e.g. measured or estimated)
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, 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.

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Property	Value	Reference	Comment (e.g. measured or estimated)
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 mm ² /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”, 101st edition, 1995, p. 897, to silanetriol and HCl. Silanetriol is instable and reacts to siloxanes releasing water.



All of the chlorosilanes react vigorously with water, producing hydrogen chloride and, in the case of trichlorosilane and methylchlorosilane, 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)₃. 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)₄. Hydrogen is produced as the by-product according to the equation:



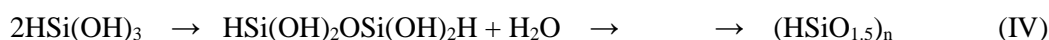
Monosilicic acid condenses readily in water to form polysilicic acid.

2. The HSi(OH)₃ 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)₄, concentrations of silanetriol above about 100-150 mg/l as SiO₂ would condense to form insoluble polymeric species.



Trichlorosilane + water silanetriol + hydrochloric acid

Then almost immediately



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 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)).	Pyrophoricity 4.13.391 BAM 2014 Report on testing of the substance "trichlorosilane" and Expert's Opinion on 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 L/(kg min) was determined.

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

RAC evaluation of physical hazards			
Summary of the Dossier Submitter's proposal			
Trichlorosilane is liquid at 20 °C and 101.3 kPa.			
Summary for relevant physico-chemical studies submitted by Dossier submitter (DS):			
Method	Results	Remarks	Reference
<u>Pyrophoric liquids</u> UN Test Method N.3	not pyrophoric	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)).	Pyrophoricity 4.13.391 BAM 2014 Report on testing of the substance "trichlorosilane" and Expert's Opinion on Transport and GHS
<u>Substances which in contact with water emit flammable gases</u> 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
The result of the new experimental guideline study shows that trichlorosilane is not a pyrophoric liquid, but rather water reactive. Therefore, removal of the current harmonised classification Pyr. Liq. 1; H250 and adding of Water-react. 1; H260 according to regulation			

(EC) 1272/2008 (CLP regulation) was proposed by the DS. As consequence of the re-assessment of the physical hazard, note T is no longer appropriate.

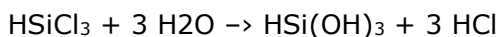
Comments received during public consultation

One company/manufacturer supported the proposal by the DS to remove the classification as Pyrophoric Liquid Cat. 1 and add Water-react. 1.

Additional key elements

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

Trichlorosilane reacts with water to form silanetriol and HCl:

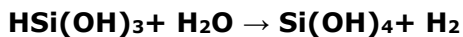


Silanetriol is instable and reacts further into siloxanes releasing water and forming hydrogen gas.

Overall, trichlorosilane contains two reactive groups, [Si-Cl] that produces hydrogen chloride (HCl) which then dissolves in water to form hydrochloric acid, and [Si-H], producing hydrogen.

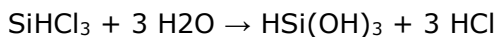
Si-Cl bonds hydrolyse more rapidly than Si-H resulting in the theoretical intermediate hydrolysis product of silanetriol: HSi(OH)_3 . This species has so far not been isolated due to a combination of the following:

1. The reactivity of the Si-H bond results in the production of monosilicic acid Si(OH)_4 . Hydrogen is produced as the by-product according to the equation:



Monosilicic acid condenses readily in water to form polysilicic acid.

2. The HSi(OH)_3 monomer rapidly condenses. Holleman-Wiberg (1995) 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)_4 , concentrations of silanetriol above about 100-150 mg/L as SiO_2 would condense to form insoluble polymeric species.



Trichlorosilane + water → silanetriol + hydrochloric acid

Assessment and comparison with the classification criteria

Pyrophoric liquids

According to section 2.9. of Annex I to CLP Regulation, a pyrophoric liquid shall be classified in a single category for this class using test N.3 in Part III, sub-section 33.3.1.5 of the UN RTDG, Manual of Tests and Criteria according to the following criterion: The liquid ignites within 5 min. when added to an inert carrier and exposed to air, or it ignites or chars a filter paper on contact with air within 5 min.

Trichlorosilane tested with UN Test Method N.3 does not ignite within 5 minutes when added to an inert carrier and exposed to air, nor does it ignite or char a filter paper on contact with air within 5 min.

Therefore, it does not meet the criterion for classification as pyrophoric liquid, and thus, **removal of the current harmonised classification as Pyr. Liq. 1; H250 is justified according to the CLP Regulation, as well as the removal of Note T.**

Substances which in contact with water emit flammable gases

According to section 2.12. of Annex I to CLP Regulation, a substance or mixture which, in contact with water, emits flammable gases shall be classified as 'substances or mixtures which in contact with water emit flammable gases' category 1, using test N.5 in Part III, sub-section 33.4.1.4 of the UN RTDG, Manual of Tests and Criteria, in accordance with the following criterion. Any substance or mixture 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.

Trichlorosilane tested with UN Test Method N.5 (BAM, 2014a) produces a flammable gas in contact with water at a maximum rate of gas of 68.0 L/(kg min). The composition of the evolved gas in the UN Test N.5 was not analysed at BAM. According to procedure of UN Test Method N.5, if the chemical identity of the gas is unknown, the gas should be tested for flammability. Therefore, 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.

Thus, trichlorosilane fulfils the criterion for Category 1 of 'substances or mixtures which in contact with water emit flammable gases' and addition of classification as Water-react. 1 and hazard statement H260 (In contact with water releases flammable gases, which may ignite spontaneously) is warranted according to the CLP Regulation.

In conclusion, **RAC supports the DS's proposal classify Trichlorosilane as Water-react. 1; H260.**

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 ₅₀	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 ₅₀	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	Test 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 LC₅₀ 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 LC₅₀ becomes approximately 7650 mg/m³.

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/m³) 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 mg/m³) 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.

RAC evaluation of acute toxicity
<p>Summary of the Dossier Submitter’s proposal</p> <p>Oral route</p> <p>For the oral LD₅₀, only one study was available and reported for trichlorosilane (Mellon Institute, 1948). The study is comparable to the meanwhile deleted OECD TG 401 and pre-dating GLP requirements. Ten male rats (no information on strain) per dose were administered oral doses of 795, 1000, 1260 and 1580 mg/kg of trichlorosilane diluted in corn oil (10%). There was a 14-day post observation period.</p> <p>The death rate per dose was 2/10 (795 mg/kg bw), 5/10 (1000 mg/kg bw), 7/10 (1260 mg/kg bw), and 9/10 (1580 mg/kg bw). An LD₅₀ of 1030 mg/kg bw was calculated according to the method of Thompson. No clinical signs were reported. 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.</p>

Classification of trichlorosilane for acute oral toxicity as Acute Tox. 4; H302 (Harmful if swallowed), oral: ATE = 1030 mg/kg bw was proposed by the DS.

Inhalation route

Six inhalation acute toxicity studies were considered by the DS.

The DS considers the study from (Dow Corning, 1987) as having high reliability and the exposure via nose-only as adequate. This was also chosen as the key study.

The study was performed according to OECD TG 403 in compliance with GLP; however, the exposure period was modified from four hours to one hour. Sprague-Dawley rats (5/sex/dose) were exposed to trichlorosilane via nose-only administration. The following concentrations were tested: 1687, 2287, 2683 and 3770 ppm (as measured by IR spectroscopy).

In males, 1/5 (1687 ppm), 2/5 (2287 ppm), 1/5 (2683 ppm), and 5/5 (3770 ppm) animals died. In females, 1/5 (1687 ppm), 0/5 (2287 ppm), 4/5 (2683 ppm), and 4/5 (3770 ppm) animals died. An LC₅₀ of 2767 ppm was calculated; however, no details on 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 LC₅₀ becomes approximately 7.65 mg/L.

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 in the 3770 ppm dose group. Other less frequently observed signs included rales, ocular discharge and an absent nasal septum for one male rat of the 3770 ppm group.

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 seen on the 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 dose 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 (Nachreiner and Dodd, 1986), also following OECD guideline (non-GLP). Male and female Sprague-Dawley rats (5/sex/dose) were exposed for one hour in a whole body chamber. Three different chamber concentrations were used with different amounts of relative humidity (RH): 703 ppm (29% RH), 962 ppm (78% RH) and 995 ppm (29% RH). The trichlorosilane concentrations were verified by gas chromatographic analysis.

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

Clinical signs were observed in all exposure groups. These 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.

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 ppm (the

minimum limit of detection by gas chromatography) to 1850 ppm for the three exposure groups.

Another study (Mellon Institute, 1948) did not meet current guideline requirements due to lack of detail on exposure, test animals, test substance and test conditions. In this study, 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 out of 6 rats in 4 hours, while 500 ppm killed 1 out of 6 rats.

For all other studies considered by the DS, no information is available about the experimental details.

The classification of trichlorosilane for acute inhalation toxicity as Acute Tox. 3; H331 (Toxic if inhaled), inhalation: ATE = 7.65 mg/L (vapour) was proposed by the DS.

To avoid double classification, in line with CLP guidance 3.1.6.1.7, the DS proposed to remove the classification as STOT SE 3 when the concentration is $\geq 1\%$.

Comments received during public consultation

Two Member State Competent Authorities (MSCA) agreed with the classification proposed by the DS for oral and inhalation acute toxicity. The first MSCA was of the opinion that, considering the weakness of the data available for the endpoint, a generic ATE would be more appropriate. The second MSCA agreed with the supplemental labelling with phrase EUH071.

One Company-Manufacturer was of the opinion that the mortalities observed in the acute studies were linked to the local corrosive effects and are covered by the classification for skin corrosion and by applying EUH071, and therefore classification for acute oral and inhalation toxicity is not required.

Assessment and comparison with the classification criteria

The results of one available acute oral toxicity study for trichlorosilane in rats indicate an LD₅₀ of 1030 mg/kg bw. Therefore, trichlorosilane meets the criteria of the CLP regulation for classification in acute oral toxicity Category 4 ($300 < \text{ATE} \leq 2000$), with an oral ATE of 1000 mg/kg bw (rounded value to 2 significant figures) instead of the ATE value of 1030 mg/kg bw proposed by DS.

Only the Dow Corning (1987) acute inhalation toxicity study (with exposure via nose-only), conducted in rats in accordance with OECD TG 403 and GLP, can be considered for classification purposes.

The concentrations in inhalation acute toxicity studies considered by the DS are expressed as gases (in ppm); however, if the substance is a liquid at room temperature the inhalation exposure is likely to be to vapours.

The LC₅₀ value of 7.65 mg/L (vapour) was derived after correction for the reduced exposure time (one hour only) by dividing by a factor of 2 (for gases and vapours). Comparing the results of this acute inhalation toxicity study (Dow Corning, 1987) with the CLP criteria ($2.0 < \text{LC}_{50} \leq 10.0$ mg/l for vapours) trichlorosilane meets the classification criteria for category 3 of

acute inhalation toxicity, with an ATE of 7.6 mg/L (rounded value to 2 significant figures) instead of the ATE value of 7.65 mg/L proposed by DS.

In the second study performed (Nachreiner and Dodd, 1986) following OECD guidelines (non-GLP), male and female Sprague-Dawley rats (5/sex/dose) were exposed for one hour in a whole body chamber. No rats died during the exposure to three dose levels: 703 (3.90), 962 (5.33), 995 (5.51) ppm (mg/L); or during the 14-day post exposure period. The results of this study are not conclusive due to too low doses tested (between 3.90-5.51 mg/L).

Other studies (Mellon Institute, 1948; Carpenter et al., 1949; Izmerov, 1982; Mellon Institute, 1951) submitted by the DS were of low reliability (no guidelines followed, no data on dose levels, no information on the experimental details). Hence, these studies could not be used for classification purposes.

The clinical signs and the necropsy findings (audible respiration, absent nasal septum, dark areas on the lungs, exudate on the nasal turbinates) in acute inhalation studies (Dow Corning, 1987; Nachreiner and Dodd, 1986) indicate that the mechanism of toxicity is corrosivity. Thus, trichlorosilane should also be labelled as EUH071: 'corrosive to the respiratory tract' in addition to classification for acute inhalation toxicity (according to Note 1 in section 3.1.4.1. of Annex I to CLP Regulation).

In conclusion, RAC supports the DS proposal for revising the classification of trichlorosilane after rounding to 2 significant figures the ATE values. Overall, RAC considers the following classification is warranted for trichlorosilane:

- **Acute Tox. 4; H302 (Harmful if swallowed) with an ATE of 1000 mg/kg bw and;**
- **Acute Tox. 3; H331 (Toxic if inhaled) with an ATE of 7.6 mg/L and labelling with;**
- **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 proposal 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).

RAC evaluation of skin corrosion/irritation

Summary of the Dossier Submitter's proposal

In two non-guideline studies (Mellon Institute, 1951, 1948), trichlorosilane was investigated for 24-hour exposure in the rabbit belly vesicant test. In both studies, no information was given on the strain, sex, number of animals or on the test system. An erythema/oedema score of 2/5 was reported in the first test, and an activity grade of 2 in the second test.

No other data from guideline-conform *in vitro* or *in vivo* studies on skin irritation/corrosion are available.

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 ($\text{SiHCl}_3 + 3 \text{H}_2\text{O} \rightarrow \text{HSi(OH)}_3 + 3 \text{HCl}$). Based on the hydrolysis to hydrogen chloride under humid conditions (such as after contact with sweating skin) the same classification as for hydrogen chloride as Skin Corr. 1B was proposed by the DS.

Comments received during public consultation

Two MSCAs supported the proposed classification as Skin Corr. 1B; H314 for trichlorosilane.

One company-manufacturer did not agree with classification as Skin Corr. 1B proposed by the DS and considered that the classification Skin Corr. 1A should be retained. Based on the hydrolysis under humid conditions, trichlorosilane produces hydrogen chloride, which is classified as Skin Corr. 1A in Annex VI of the CLP Regulation², and not hydrochloric acid, which is classified as Skin Corr. 1B. In support of this interpretation, the company-manufacturer also referred to three studies (two of them according to OECD TG 404) for three different chlorosilanes, which support Category 1A rather than 1B.

Assessment and comparison with the classification criteria

The available studies (Mellon Institute) were 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 number of affected/tested animals, nor the mean scores for 24 h, 48 h and 72 h and recovery were documented.

Trichlorosilane currently has a harmonised classification in Annex VI of the CLP Regulation as Skin Corr. 1A. The justification and underlying data for Category 1A is not known. Trichlorosilane is known to vigorously hydrolyse in contact with water, humidity and the potentially in protic solvents (e.g. ethanol) with the release of hydrogen chloride (index no.

017-002-00-2) classified as Skin Corr. 1A in Annex VI of the CLP Regulation. In the presence of moisture (as in contact with sweating skin), hydrogen chloride dissolves in water and forms hydrochloric acid (index no. 017-002-01-X, hydrochloric acid ...%), which is classified as Skin Corr. 1B under the CLP Regulation.

Taking into account results from OECD TG 404 studies with structurally related chlorosilanes (study summaries can be found in Supplemental information, below) and harmonised classification of gaseous HCl as Skin Corr. 1A, RAC supports the read across from other chlorosilanes and gaseous HCl instead of the read across from the hydrolysis product - aqueous HCl, proposed by the DS.

In conclusion, **RAC agreed to retain the classification of trichlorosilane as Skin Corr. 1A; H314 (Causes severe skin burns and eye damage).**

Supplemental information - In depth analyses by RAC

Summary of study results with chlorosilanes structurally related to trichlorosilane (according to 'registered substances factsheets' in the ECHA dissemination website).

Trichloro(methyl)silane (CAS no.: 75-79-6)

The skin irritation/corrosion *in vivo* study (1989) was conducted according to a test protocol that is comparable to the appropriate OECD test guideline. It was not compliant with GLP. A 3-minute application of 0.5 mL of the test material, undiluted to occluded rabbit skin, resulted in moderate oedema and full thickness necrosis in 2 out of 2 rabbits within one hour after contact. Erythema was not visible around the necrosed site. Ulceration was observed in both animals at 24 hours, with the tissue of the dose site of one animal apparently completely destroyed.

The available data indicate that the substance should be classified Skin Corr. 1A under the CLP Regulation.

The current entry for trichloro(methyl)silane in Annex VI of the CLP Regulation includes classification as Skin Irrit. 2. However, the available data indicate that this classification is not sufficient.

Trichloro(2,4,4-trimethylpentyl)silane (CAS no.: 18379-25-4)

The skin irritation/corrosion study (1985) is the only available study for that endpoint conducted in accordance with a method equivalent or similar to OECD TG 404 test guideline and according to GLP. Exposure for 3 minutes in one New Zealand White rabbit was associated with severe erythema, moderate oedema and severe blanching (covering more than 50% of the test site). Trichloro(2,4,4-trimethylpentyl)silane was determined to be corrosive to rabbit skin following a three minute exposure to the neat test substance. Trichloro(2,4,4-trimethylpentyl)silane is classified Skin Corr. 1A under the CLP Regulation.

Dichloro(3-chloropropyl)methylsilane (CAS no.: 7787-93-1)

The skin irritation/corrosion study (1997) was conducted according to OECD 404 and GLP. 1.5 minute exposure to neat dichloro(3-chloropropyl)methylsilane in one animal caused severe erythema and oedema with marked necrosis after 2 minutes. The test substance was corrosive to the skin of a rabbit and is classified Skin Corr. 1A; H314 (Causes severe skin burns and eye damage) according to the CLP Regulation.

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 further 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. 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 became apparent 3 hours later, in other words a reaction which is termed a delayed burn resulted.	(Mellon Institute, 1948)

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 trichlorosilane 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 effects².

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.

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

RAC evaluation of serious eye damage/irritation

Summary of the Dossier Submitter's proposal

In a non-guideline study (Union Carbide, 1947), 7 animals were exposed to 250, 500 and 1000 ppm trichlorosilane for 3 minutes. The effects on the eye were evaluated at different time points after exposure for symptoms such as opacity, dullness of the cornea or internal congestion. Immediate and evident eye injury was seen in rabbits following 3-minute 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 by Mellon Institute published in 1948 using 5 % dilution in 'deobase' (a solvent based on refined petroleum) indicated severe eye damage ('ruined eyes'). 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).

Classification of trichlorosilane as Eye Dam. 1; H318 (Causes serious eye damage) was proposed by DS.

Comments received during public consultation

Two MSCAs supported the proposed classification Eye Dam. 1; H318 for trichlorosilane.

Assessment and comparison with the classification criteria

In the presence of moisture (as on the ocular surface), trichlorosilane generates hydrogen chloride, which is a known corrosive agent and classified as Skin Corr. 1A under the CLP Regulation. The eye effects observed in two non-guideline rabbit studies (Union Carbide, 1947, Mellon Institute, 1948) with trichlorosilane are consistent with corrosive/damaging effects.

Trichlorosilane currently has a harmonised classification as Skin Corr. 1A; H314 (Causes severe skin burns and eye damage) in Annex VI of the CLP Regulation. Taking into account section 3.3 of the Guidance on the Application of the CLP Criteria (Version 5.0 – July 2017) – *'if a substance or mixture is classified as Skin corrosion Category 1 then serious damage to eyes is implicit as reflected in the hazard statement for skin corrosion (H314: Causes severe skin burns and eye damage). Thus, the corrosive substance or mixture is also classified, but the corresponding hazard statement (H318: Causes serious eye damage) is not indicated on the label to avoid redundancy'*.

RAC supports the DS's proposal for **classification of trichlorosilane as Eye Dam. 1; H318 (Causes serious eye damage)**; however, to avoid redundancy, only the hazard statement H314 (Causes severe skin burns and eye damage) should be indicated on the label.

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