Response to CLH report

The members of the Reconsile REACH Consortium and the Lead Registrant, hereinafter referred to as "the Reconsile REACH Consortium", have considered the proposed classification in the Proposal for Harmonised Classification and Labelling for trichlorosilane (EC No: 233-042-5; CAS No: 10025-78-2). The proposed classification is shown below in Table 1 for reference.

The Reconsile REACH Consortium agrees with addition of the following:

- Retention of Flammable Cat. 1
- Addition of Water React 1
- Removal of Pyrophoric Liquid Cat. 1
- Additional labelling EUH071: Corrosive to the respiratory tract

The Reconsile REACH Consortium does not consider that the following are justified:

- Change of Skin Corr. 1A to Skin Corr. 1B
- Retention of Acute Tox. 4 H 302
- Replacement of Acute Tox. 4 H332 by Acute Tox. 3 H331

Table 1 Proposed harmonised classification and labelling according to the CLP criteria in CLH Report

	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)	Hazard Class and Category Code(s)	
Current Annex VI entry	014-001-00-9	trichlorosilane	233-042-5	10025-78-2	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					retain: Flam. Liq. 1 Acute Tox. 4 remove: Pyr. Liq. 1 Skin Corr. 1A Acute Tox. 4 add: Water-react 1 Skin Corr. 1B Eye Dam. 1 Acute Tox. 3	retain: H224 H302 remove: H250 H332 add: H260 H314 H318 H331	retain: Danger GHS02 GHS05 remove: GHS07 add: GHS06	retain: H224 H314 H302 remove: H250 H332 add: H260 H331	retain: EUH014 EUH029 add: EUH071	remove: STOT SE 3; H335: C ≥ 1 % add: inhalation: ATE =7.65 mg/L (vapour) oral: 1030 mg/kg bw	Remove: 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	

The published CLH proposal does not match the Reconsile REACH Consortium's agreed classification for this substance, in particular the skin corrosion category.

Reconsile measured data do support:

- Flammable Cat. 1
- Water React 1
- Removal of Pyrophoric Liquid Cat. 1
- Additional labelling EUH071: Corrosive to the respiratory tract
- Acute Tox. 4 (oral) and Acute Tox. 3 (inhalation), but see below

Acute toxicity

The classification proposed in the CLH report would replace the existing Acute Tox. 4 (inhalation), H332 classification and labelling with Acute Tox. 3 H331 and the additional labelling EUH071: Corrosive to the respiratory tract.

The classification proposed in the CLH report retains the existing Acute Tox. 4 (oral) classification.

The measured data are in agreement with the proposed acute toxicity categories, however, it is considered by the Reconsile REACH Consortium that the mortalities observed in the acute studies were linked to the local corrosive effects and therefore the Skin Corr. 1A classification was sufficient, and this was discussed with BAuA and BfR in September 2018. Although the CLH Report acknowledges that the acute toxicity and deaths are secondary to the local effects, acute oral classification is proposed. For acute oral toxicity the Report states: *"Observations from necropsy indicated that direct injury to the gastrointestinal tract was the cause of death."* For acute inhalation toxicity the Report states: *"The clinical signs and the necropsy findings in the mentioned acute inhalation study are consistent with local corrosive effects…"* but continues *"…are covered by classification for acute inhalation toxicity and by applying EUH071."* It is the Reconsile REACH Consortium's opinion that the effects observed are covered by the classification for skin corrosion and by applying EUH071, and therefore classification for acute oral and inhalation toxicity is not required. Owing to the corrosive nature of trichlorosilane, testing for acute toxicity would not be carried out according to Column 2 of the REACH Annex VII and VIII requirements; data exist only because testing was carried out before animal welfare considerations precluded the testing of corrosive substances for acute toxicity.

Skin corrosion

The classification proposed in the CLH report would replace the existing Skin Corr. 1A classification with Skin Corr. 1B, retaining the H314 hazard phrase.

The CLH report states: *"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 Corr. 1B may be considered."*

The Reconsile REACH Consortium observes that the classification of hydrogen chloride in Annex VI of Regulation (EC) No 1273/2008 is Skin Corrosion 1A. On hydrolysis under humid conditions, trichlorosilane produces hydrogen chloride, not hydrochloric acid which is classified Skin Corr. 1B at concentrations of ≥25%. A theoretical estimate of the amount of hydrogen chloride that trichlorosilane produces is 80.7 g HCl per 100 g of substance (please see Table 2 for more information).

Measured data which support the conclusion that chlorosilanes belong to category 1A rather than 1B for skin corrosion are available for three chlorosilanes:

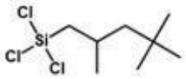
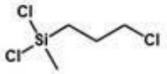
Trichloro(methyl)silane – not according to any guideline

Trichloro(2,4,4-trimethylpentyl)silane – according to OECD 404

Dichloro(3-chloropropyl)methylsilane – according to OECD 404

The theoretical masses of hydrogen chloride produced by these chlorosilanes (given in brackets above) are considerably lower than the 80.7 g per 100 g substance for trichlorosilane. Therefore the Reconsile REACH Consortium considers that the classification Skin Corr. 1A should be retained.

Table 2 Theoretical mass of HCl produced by chlorosilanes

CAS Number	EC Number	Substance	Mr	Moles of Cl	Cl	% w/w of Cl	HCl	HCl produced from 100g of substance
10025-78-2	233-042-5	Trichlorosilane Cl[SiH](Cl)Cl 	135.45	3 moles	106.35	78.5% w/w	109.38	80.7g per 100g
75-79-6	200-902-6	Trichloro(methyl)silane C[Si](Cl)(Cl)Cl 	149.48	3 moles	106.35	47.4% w/w	109.38	48.8g per 100g
18379-25-4	242-262-0	Trichloro(2,4,4-trimethylpentyl)silane CC(C[Si](Cl)(Cl)Cl)CC(C)(C)C 	247.67	3 moles	106.35	42.9% w/w	109.38	44.1g per 100g
7787-93-1	232-136-3	Dichloro(3-chloropropyl)methylsilane ClCCC[Si](Cl)(Cl)C 	191.56	2 moles	70.9	37.0% w/w	72.92	38.1g per 100g