

**Committee for Risk Assessment**

**RAC**

Annex 2

**Response to comments document (RCOM)**

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

**Adopted**

**11 June 2020**

## ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON TRICHLOROSILANE

### COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during public consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the public consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the public consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties.

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**Substance name: trichlorosilane**

**EC number: 233-042-5**

**CAS number: 10025-78-2**

**Dossier submitter: Germany**

#### GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
29.08.2019	Belgium	ReconSile REACH Consortium	Company-Manufacturer	1

#### Comment received

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

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

The attached document provides detailed information including tables.

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ECHA note – An attachment was submitted with the comment above. Refer to public attachment Response to CLH report 20190829.pdf
<b>Dossier Submitter’s Response</b>
The DS considered the available information, including the acute inhalation toxicity study, performed according to the OECD guideline 403, from Dow Corning, 1987. On the basis of this study it possible to conclude on acute toxicity and to derive an ATE value.
The DS note that reference is made in the attached document to hydrogen chloride in gaseous phase (Classification Skin Corr. 1A). The reason for the proposal on Skin Corr 1B is the concept of the hydrolysis of trichlorosilane in water to hydrogen chloride. Therefore, hydrogen chloride would be dissolved in water. It is the point of view of the DS that for classification and labelling the appropriate reference would be index no. 017-002-01-X (hydrochloric acid ...%) hydrochloric acid solution with a classification Skin Corr. 1B.
<b>RAC’s response</b>
Thank you for your comment. RAC agrees with the DS’s response.

**OTHER HAZARDS AND ENDPOINTS – Acute Toxicity**

Date	Country	Organisation	Type of Organisation	Comment number
21.08.2019	France		MemberState	2
<b>Comment received</b>				
FR agrees with categories of classification proposed for oral and inhalation toxicity. However, considering the weakness of the data available for both endpoint, we wonder if generic ATE would have not be more appropriate.				
<b>Dossier Submitter’s Response</b>				
The support of the FR CA is acknowledged. The DS agrees in the assessment of the acute oral toxicity. The data are weak. However, the proposal was made with an ATE value derived from this data set to start the scientific discussion. The DS considers the data on the acute inhalative toxicity as sufficient to develop an ATE value.				
<b>RAC’s response</b>				
Thank you for your comment. RAC agrees with the DS’s response.				

Date	Country	Organisation	Type of Organisation	Comment number
27.08.2019	Finland		MemberState	3
<b>Comment received</b>				
In the only available in vivo study (similar to an appropriate test guideline) investigating acute oral toxicity of trichlorosilane, male rats were administered the substance by gavage. An LD50 value of 1030 mg/kg bw was derived from the study. Direct injury to gastrointestinal tract was the cause of death. Category 4 for acute oral toxicity under the CLP regulation is assigned for substances with an ATE > 300 and ≤ 2000 mg/kg. FI CA supports the proposed classification of Acute Tox. 4; H302 for trichlorosilane.				
In an acute inhalation toxicity study conducted in accordance with OECD TG 403 and GLP, trichlorosilane was applied via nose-only administration to rats for one hour (instead of the recommended four). An LC50 value of 7.65 mg/l was derived from the study. Clinical signs included nasal crust, rough coat, sores on the face and corneal opacity; the nasal septum was also missing in one rat at the highest dose level. Necropsy findings included				

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changes in the external nares, corneal opacity and dark areas on the lungs. Category 3 for acute inhalation toxicity under the CLP regulation is assigned for substances with an ATE > 2.0 and ≤ 10.0 mg/l for vapours. FI CA supports the proposed classification of Acute Tox. 3; H331 for trichlorosilane. Based on the clinical signs and necropsy findings, the supplemental labelling phrase EUH071 `Corrosive to the respiratory tract` is justified.
Dossier Submitter's Response
The support of the FI CA is acknowledged.
RAC's response
Thank you for your comment.

Date	Country	Organisation	Type of Organisation	Comment number
29.08.2019	Belgium	ReconSile REACH Consortium	Company-Manufacturer	4

Comment received
<p>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.</p> <p>The classification proposed in the CLH report retains the existing Acute Tox. 4 (oral) classification.</p> <p>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.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Response to CLH report 20190829.pdf</p>
Dossier Submitter's Response
The DS disagrees with the view of the Reconsile REACH consortium and upholds acute toxicity classification for oral and inhalative toxicity.
RAC's response
Please, see DS's response to your comment no.1

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**OTHER HAZARDS AND ENDPOINTS – Skin Hazard**

Date	Country	Organisation	Type of Organisation	Comment number
21.08.2019	France		MemberState	5
Comment received				
FR agrees with the proposed classification				
Dossier Submitter's Response				
The support of the FR CA is acknowledged.				
RAC's response				
Thank you for your comment.				

Date	Country	Organisation	Type of Organisation	Comment number
27.08.2019	Finland		MemberState	6
Comment received				
<p>Trichlorosilane has been classified as Skin Corr. 1A under the CLP Regulation. Two non-guideline rabbit studies (conducted in 1948 and 1951) investigating skin irritation/corrosion properties of the substance are available, but both are lacking vital information and are therefore not suitable for classification purposes. No human or in vitro data are available. Trichlorosilane is known to vigorously hydrolyse in contact with water, releasing hydrogen chloride. In the presence with moisture (as in contact with sweating skin), hydrogen chloride dissolves in water and forms hydrochloric acid, which is classified as Skin Corr. 1B under the CLP Regulation. Since data on corrosive properties of trichlorosilane are not suitable for classification, the substance can be classified based on the hydrolysis product. FI CA supports the proposed classification of Skin Corr. 1B, H314 for trichlorosilane.</p> <p>In this context, FI CA would like to draw attention to the erroneous classification of the hydrolysis product hydrogen chloride, which is Skin Corr. 1A and not 1B, as stated by the DS in the CLH dossier in 10.4.1 (page 16).</p>				
Dossier Submitter's Response				
<p>The DS notes that the FI CA takes reference to hydrogen chloride (Index no 017-002-00-2) in gaseous phase (Classification Skin Corr. 1A). The reason for the proposal on Skin Corr 1B is the concept of the hydrolysis of trichlorosilane in water to hydrogen chloride. Therefore, hydrogen chloride would be dissolved in water. It is the point of view of the DS that for classification and labelling the appropriate reference would be index no. 017-002-01-X (hydrochloric acid ...%) hydrochloric acid solution with a classification Skin Corr. 1B. Therefore, the DS made reference to Skin Corr 1B in the dossier.</p>				
RAC's response				
Thank you for your comment. RAC agrees with the DS's response.				

Date	Country	Organisation	Type of Organisation	Comment number
29.08.2019	Belgium	ReconSile REACH Consortium	Company-Manufacturer	7
Comment received				
<p>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</p>				

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<p>conditions [here after contact with sweating skin] the same classification as for hydrogen chloride as Skin Corr. 1B may be considered.”</p> <p>The Reconcile 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 <math>\geq 25\%</math>. 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).</p> <p>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</p> <p>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 Reconcile REACH Consortium considers that the classification Skin Corr. 1A should be retained.</p> <p>ECHA note – An attachment was submitted with the comment above. Refer to public attachment Response to CLH report 20190829.pdf</p>
<b>Dossier Submitter’s Response</b>
<p>As stated in the dossier, the data available for trichlorosilane were not performed according to guidelines. The results indicated mild skin reactions. However, the DS identified a concern based on the fact that trichlorosilane generates hydrogen chloride in the presence of moisture. Since hydrogen chloride will dissolve in the water, the following considerations base on hydrochloric acid. Therefore, the following classification is proposed: Skin Corr 1B, H314.</p>
<b>RAC’s response</b>
<p>Thank you for your comment. RAC agrees with the DS’s response.</p>

**OTHER HAZARDS AND ENDPOINTS – Eye Hazard**

Date	Country	Organisation	Type of Organisation	Comment number
27.08.2019	Finland		MemberState	8
<b>Comment received</b>				
<p>There are two non-guideline rabbit studies investigating eye irritation of trichlorosilane. In the first study, immediate evident eye injury was seen after three-minute exposure to vapours of trichlorosilane at 500 ppm, and delayed eye damage was observed after three hours at 250 ppm. A 5% trichlorosilane dilution in deodorized kerosene ruined the eyes of the animal in the second study, although the contribution of the solvent could not be excluded. In the presence of moisture (as on the ocular surface) trichlorosilane generates hydrochloric acid, which is a known corrosive agent and classified as Skin Corr. 1B under the CLP Regulation. Effects on the eye are consistent with corrosive effects on other mucosal tissues. FI CA supports the proposed classification of Eye Dam. 1, H318.</p>				
<b>Dossier Submitter’s Response</b>				
<p>The support of the FI CA is acknowledged.</p>				
<b>RAC’s response</b>				
<p>Thank you for your comment.</p>				

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Date	Country	Organisation	Type of Organisation	Comment number
21.08.2019	France		MemberState	9
Comment received				
<p>FR agrees with the conclusion.                      However, the two studies available which are used for this classification are poorly detailed and of questionable quality.                      Considering the fact that a classification for skin corrosion implicitly implies a risk for serious eye damage ("It should be noted that 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"), it seems unnecessary to describe and discuss the studies, and maybe even redundant.</p>				
Dossier Submitter's Response				
<p>The support of the FR CA for the conclusion is acknowledged.                      It was the view of the DS to present all data available, even if the data were of questionable quality.</p>				
RAC's response				
Thank you for your comment.				

**PUBLIC ATTACHMENTS**

1. Response to CLH report 20190829.pdf [Please refer to comment No. 1, 4, 7]