

**SUBSTANCE EVALUATION
CONCLUSION DOCUMENT**
as required by REACH Article 48
for

Dichloro(dimethyl)silane

EC No 200-901-0

CAS No 75-78-5

Evaluating Member State(s): Czech Republic

Dated: November 2015

DISCLAIMER

The Conclusion document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Evaluating Member State Competent Authority

Ministry of Environment of the Czech Republic

Vršovická 1442/65

Praha 10, 100 10

Tel: +420 2 6712 2129

Fax: +420-2-6731-0308

Email: Jarmila.Sladkova(at)mzp.cz

Year of evaluation in CoRAP: 2014

Member State concluded the evaluation without the need to ask further information from the registrants under Article 46(1) decision.

Please find (search for) further information on registered substances here:

<http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work.

In order to ensure a harmonised approach, ECHA in cooperation with the Member States developed risk-based criteria for prioritising substances for substance evaluation. The list of substances subject to evaluation, the Community rolling action plan (CoRAP), is updated and published annually on the ECHA web site¹.

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by the Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. In this conclusion document, the evaluating Member State shall consider how the information on the substance can be used for the purposes of identification of substances of very high concern (SVHC), restriction and/or classification and labelling. With this Conclusion document the substance evaluation process is finished and the Commission, the registrants of the substance and the competent authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes.

¹ <http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan>

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1. CONCERN(S) SUBJECT TO EVALUATION

Dichloro(dimethyl)silane was originally selected for substance evaluation in order to clarify suspected risks about:

- Assessment of PBT/vPvB properties.
- Aggregated tonnage (exposure assessment, release factors from different uses).
- Environmental fate and ecotoxicological properties (adsorption/desorption, long-term toxicity to aquatic species, terrestrial toxicity).

During the evaluation no further concerns to be clarified under substance evaluation process were identified.

2. CONCLUSION OF SUBSTANCE EVALUATION

The available information on the substance and the evaluation conducted has led the evaluating Member State to the following conclusions, as summarised in the table below.

Conclusions	Tick box
Need for follow up regulatory action at EU level	
<i>Need for Harmonised classification and labelling</i>	
<i>Need for Identification as SVHC (authorisation)</i>	
<i>Need for Restrictions</i>	
<i>Need for other Community-wide measures</i>	
No need for regulatory follow-up action	x

3. JUSTIFICATION FOR THE CONCLUSION ON THE NEED OF REGULATORY RISK MANAGEMENT

3.1. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

3.1.1. Need for harmonised classification and labelling

Not required.

3.1.2. Need for Identification as a substance of very high concern, SVHC (first step towards authorisation)

Not required.

3.1.3. Need for restrictions

Not required.

3.1.4. Proposal for other Community-wide regulatory risk management measures

Not required.

3.2. NO FOLLOW-UP ACTION NEEDED

The concern could be removed because	Tick box
<i>Hazard and /or exposure was verified to be not relevant and/or</i>	
<i>Hazard and /or exposure was verified to be under appropriate control and/or</i>	x
<i>The registrant modified the applied risk management measures.</i>	
<i>other:</i>	

All available information (registration dossiers, Chemical Safety Report(s) and literature data and review) was used to clarify the concerns. The available information is sufficient and reliable to conclude the substance evaluation. There is no need for new studies and information under substance evaluation process.

The following conclusions were reached on this substance evaluation:

PBT/vPvB properties

Pursuant to Regulation (EC) No. 1907/2006, Annex XIII, a substance is identified as a PBT substance if it fulfils the criteria P, B and T; a substance is identified as a vPvB substance if it fulfils the criteria vP and vB. Dichloro(dimethyl)silane and its first hydrolytic product dimethylsilanediol respectively fulfil criteria P/vP, but they do not fulfil criteria B/vB and T. Therefore dichloro(dimethyl)silane cannot be considered as PBT/vPvB substance.

Aggregated tonnage (exposure assessment, release factors from different uses)

According to RCR values calculated by CHESAR software, almost all risks are under control (RCR < 1).

The total releases to the environment from all the exposure scenarios and regional predicted environmental concentration including related risk characterisation ratios were calculated using the same software. Any risk to the environment was not found.

Environmental fate and ecotoxicological properties

The adsorption/desorption potential to soil and sediment, bioaccumulation potential, long-term toxicity to aquatic species, terrestrial toxicity and environmental fate were assessed. With respect to the properties of both substances (dichloro(dimethyl)silane and dimethylsilanediol) and taking into account the literature data and results of the studies there is no significant concern.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Not required.