



Analysis of the most appropriate risk management option (RMOA)

Substance Name: Tris(2-methoxyethoxy)vinylsilane

EC Number: 213-934-0

CAS Number: 1067-53-4

Authority: European Chemicals Agency on behalf of the European Commission

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1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Other Substance identifiers

EC name (public):	Tris(2-methoxyethoxy)vinylsilane
IUPAC name (public):	6-(2-Methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	C ₁₁ H ₂₄ O ₆ Si
Molecular weight or molecular weight range:	280.39 g/mol
Synonyms:¹	2,5,7,10-Tetraoxa-6-silaundecane, 6-ethenyl-6-(2-methoxyethoxy)- 6-ethenyl-6-(2-methoxyethoxy)-2,5,7,10-Tetraoxa-6-silaundecane Vinyltris(2-methoxyethoxy)silane Ethenyl-tris(2-methoxyethoxy)silane

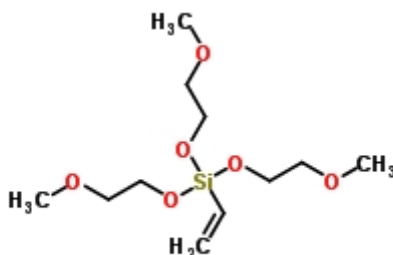
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



Other relevant information about substance composition

This substance is potentially of relevance for regulatory risk management due to its impurity which has SVHC properties. It should be noted that the impurity is not identified in all registrations of tris(2-methoxyethoxy)vinylsilane.

¹ Please note this is a non-exhaustive list.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table 2: Completed or ongoing processes for the substance tris(2-methoxyethoxy)vinylsilane

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA) other than this RMOA	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check, Final decision
		<input checked="" type="checkbox"/> Testing proposal ECHA has issued a testing proposal decision for the Tris(2-methoxyethoxy)vinylsilane (see below).
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
	Restriction	<input type="checkbox"/> Annex XVII
Harmonised C&L	<input type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	

(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment
	<input type="checkbox"/> In relevant Annex
Other processes/ EU legislation	<input type="checkbox"/> Other (provide further details below) Other legislation applies to the impurity.

ECHA has issued a testing proposal decision for tris(2-methoxyethoxy)vinylsilane, requiring to carry out a pre-natal developmental toxicity study in rats, oral route (Annex IX, 8.7.2., test method EU B.31/OECD 414) or to classify the substance as toxic for reproduction category 1B.² Following this decision, the lead registrant updated their dossier in August 2014, in which the substance tris(2-methoxyethoxy)vinylsilane itself was self classified as reproductive toxicant category 1B (Repr. 1B, H360Df).

There appears to be no EU legislation in place that imposes risk management measures where the substance, tris(2-methoxyethoxy)vinylsilane, is specifically identified by name (and numerical identifiers).

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table 3: Harmonised classification for the substance tris(2-methoxyethoxy)vinylsilane and its impurity

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
Substance							
--	tris(2-methoxyethoxy)vinylsilane	213-934-0	1067-53-4	--	--	--	--

² Testing proposal decision is available at http://echa.europa.eu/documents/10162/6986752/final_reg_public_tpe-d-0000002236-79-05_en.pdf

3.1.2 Self classification

- In the registrations (updated in August 2014)³ the substance tris(2-methoxyethoxy)vinylsilane is self classified, independently of the presence of impurity, as follows:

Repr. 1B, H360Df

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory for the substance tris(2-methoxyethoxy)vinylsilane:

Acute Tox 4, H302

Acute Tox 4, H312

Acute Tox 4, H332

Repr. 2, H361(f)

Eye Irrit. 2, H319

Aquatic Chronic 4, H413

3.1.3

3.1.4 CLP Notification Status

Table 4: CLP Notifications

	CLP Notifications ⁴
Number of aggregated notifications	11
Total number of notifiers	200

3.2 Additional hazard information

The substance tris(2-methoxyethoxy)vinylsilane appears to fulfil Article 57 criteria where its impurity, which has been identified as an SVHC fulfilling the criteria of Article 57, is equal to or above the concentration limit for classification.

The substance tris(2-methoxyethoxy)vinylsilane itself was self classified by the registrants as reproductive toxicant category 1B (Repr. 1B, H360Df) in the update of the lead registration dossier made in August 2014. Therefore, this substance (i.e. irrespective of the presence of the impurity) may meet the criteria for classification in the hazard class reproductive toxicity category 1B.

Additionally, it should be noted that tris(2-methoxyethoxy)vinylsilane during use may hydrolyse rapidly due to its reactive nature, in particular in contact with water or air moisture.⁵ One of the hydrolysis products is 2-methoxyethanol,⁵ which is a substance included in the Candidate List.⁶

³ No co-registrants have submitted a different classification and labelling, in accordance to Article 11 of REACH.

⁴ C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed 07 December 2015)

⁵ See Ref. 1 in Section 5.4.

⁶ See Ref. 2 and 3 in Section 5.4.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES⁷

4.1 Tonnage and registration status

Table 5: Tonnage and registration status

From ECHA dissemination site	
Registrations	<input checked="" type="checkbox"/> Full registration(s) (Art. 10) <input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)
Total tonnage band for substance (excluding volume registered under Art 17 or Art 18, or directly exported)	1,000-10,000 tpa

4.2 Overview of uses

According to the registrations, tris(2-methoxyethoxy)vinylsilane is used in a variety of applications which include the use in the manufacture of rubber and plastics, in the formulation and use of non-metal surface treatment solutions/dispersions, and in the formulation of sealants and their use at industrial sites and by professional workers. In relation to these uses, the substance has various technical functions, including its use as crosslinking, binding and coupling agent and surface modifier⁸. These uses appear to be in the scope of authorisation under REACH.

This substance is also used as a monomer in the production of silicone polymers (use as intermediate) and as a laboratory reagent in research and development activities. These uses appear to be out of the scope of authorisation.

4.3 Additional information

Based on information provided in the registrations, it appears that there is potential for exposure to workers (in industrial sites and by professionals) from the uses of this substance, falling in the scope of authorisation, and thus also to the impurity. The registrants recommend to address exposure through specified conditions of use including various risk management measures (e.g. engineering or technical measures, requirements for storage containers, adequate local ventilation and personal protective equipment).

⁷ Information obtained from ECHA's dissemination website, <http://echa.europa.eu/information-on-chemicals/registered-substances> (accessed 07 December 2015).

⁸ See Ref. 1 and 4 in Section 5.4.

2-methoxyethanol is a hydrolysis product of tris(2-methoxyethoxy)vinylsilane when in contact with (moisture in) air and water.⁵

Sealants containing tris(2-methoxyethoxy)vinylsilane may be used by professionals in buildings (private homes and public buildings). In sealants, tris(2-methoxyethoxy)vinylsilane hydrolyses to 2-methoxyethanol during the curing process. Therefore, tris(2-methoxyethoxy)vinylsilane and its hydrolysis product 2-methoxyethanol can be released from sealants to the indoor air, both at the time when sealants are applied by professionals and during the subsequent service life stages. Thus, general public may be exposed to these substances released into the indoor air.

Information on alternatives and socio-economic consequences has not been gathered for this RMOA.

5 JUSTIFICATION FOR THE RISK MANAGEMENT OPTION

5.1 Need for (further) risk management

The substance tris(2-methoxyethoxy)vinylsilane is considered to be of potential relevance under the SVHC Roadmap (Table 6) due to the impurity, which has SVHC properties.

Moreover, the substance tris(2-methoxyethoxy)vinylsilane, in itself, may fulfil Article 57(c) criteria based on the lead registrant's self classification as reproductive toxicant category 1B (H360Df).

Table 6: SVHC Roadmap 2020 criteria

	Yes	No
a) Art 57 criteria fulfilled? <ul style="list-style-type: none"> • Tris(2-methoxyethoxy)vinylsilane • Tris(2-methoxyethoxy)vinylsilane with impurity at concentration equal to or above the concentration limit for classification 	<p>Maybe (Self classified by registrants as Repr. Cat. 1B; there is no harmonised classification)</p> <p>✓</p>	
b) Registrations in accordance with Article 10?	✓	
c) Registrations include uses within scope of authorisation?	✓	
d) Known uses <u>not</u> already regulated by specific EU legislation that provides a pressure for substitution?	✓	

5.2 Identification and assessment of risk management options

The substance tris(2-methoxyethoxy)vinylsilane is registered for uses within the scope of authorisation (i.e. manufacture of rubber and plastic, in the formulation and use of non-metal surface treatment solutions/dispersions, and in the formulation of sealants and their use). This substance is produced/imported at high tonnage (> 1,000 t/a). The (share of the total) volume used for uses in the scope of authorisation is high and includes the professional use of sealants containing the substance (mixtures).

The substance meets the relevancy criteria in the SVHC Roadmap, where its hazardous impurity, is equal to or above the concentration limit (Table 6) for classification. Therefore, the inclusion of the substance in the Candidate List for eventual inclusion in Annex XIV could be considered. It should be noted however that the impurity is not identified in all registrations of tris(2-methoxyethoxy)vinylsilane. Where it is identified as an impurity, the concentration may be equal to, or above, the concentration limit for classification. However, there is no information on the tonnage of the substance that is on the market, which contains the impurity at or above the relevant concentration limit. Due to uncertainty regarding the tonnage of the substance containing the impurity at or above this concentration limit on the market and the (relatively low) concentration of the impurity that exceeds the concentration limit, it could result in low priority of the substance for inclusion in Annex XIV.

Furthermore, tris(2-methoxyethoxy)vinylsilane may hydrolyse rapidly into 2-methoxyethanol, when in contact with water or air moisture. 2-methoxyethanol is classified as toxic for reproduction and included in the Candidate List. In many uses, tris(2-methoxyethoxy)vinylsilane may therefore hydrolyse and release 2-methoxyethanol. Thus, exposure to 2-methoxyethanol is possible during use of tris(2-methoxyethoxy)vinylsilane, including "passive" exposure of the general public in indoor air as a result of professional uses of sealants containing it.

In relation to tris(2-methoxyethoxy)vinylsilane as such, i.e. irrespective of the presence of the impurity, this substance is not included in Annex VI to the CLP Regulation. However, in August 2014, the lead registrant of this substance updated their registration dossier due to a change in the self classification (and labelling) from Repr. 2, H361f to Repr. 1B, H360Df. Therefore, tris(2-methoxyethoxy)vinylsilane may fulfil the Article 57(c) criteria of REACH (Table 6) regardless of the impurities. To confirm that, the substance could undergo a CLH procedure according to Article 37 of the CLP Regulation. If the Repr. 1B classification was confirmed, the substance tris(2-methoxyethoxy)vinylsilane, independently of the presence of impurity, would meet the relevancy criteria in the Roadmap, and its inclusion in the Candidate List for potential prioritisation to Annex XIV could be considered. It may warrant high priority for inclusion in Annex XIV due to its uses in the scope of authorisation and respective tonnages. The authorisation requirement would address all the grades of the substance, including those with impurity. The authorisation requirement would also address the uses where the substance may hydrolyse and produce hydrolysis products having SVHC properties.

It has to be noted that, independently of the possible identification of tris(2-methoxyethoxy)vinylsilane as an SVHC and inclusion in the Candidate List, its harmonized classification would already improve risk management at industrial and professional settings. From the 11 aggregated notifications, only one (including 7 out of 200 notifiers) (Table 4), contains the self classification of tris(2-methoxyethoxy)vinylsilane as Repr. 1B. Thus, harmonised classification and labelling as Repr. 1B seems to be needed to ensure that all notifiers classify the

substance correctly. CLH would ensure coherent communication of the hazards in the supply chains and trigger additional risk management actions by companies and professionals. A harmonised classification as Repr. 1B would also allow the substance to be covered by restriction entry 30 of Annex XVII of REACH Regulation.

5.3 Conclusions on the most appropriate (combination of) risk management options

5.3.1 Harmonised classification and labelling

Harmonised classification of tris(2-methoxyethoxy)vinylsilane, regardless of the presence of its hazardous impurity, as Repr. 1B would ensure coherent communication in the supply chains and trigger additional risk management actions by all companies and professional workers dealing with this substance. Furthermore, harmonised classification as Repr. 1B would provide a basis for its possible inclusion in the Candidate List, if deemed necessary. Therefore, it seems to be an appropriate step in further risk management for the substance. While the CLH process as proposed above is running, the registrants and notifiers of tris(2-methoxyethoxy)vinylsilane should be encouraged to make every effort to agree on and apply the proper self classification (Art. 41 of CLP).

5.4 References

1. SIDS Initial Assessment Report for SIAM 22 for Tris(2-methoxyethoxy)vinylsilane (VTMOEOS), OECD, April 2006. Available at <http://webnet.oecd.org/HPV/UI/Search.aspx>.
2. Member State Committee support document for identification of 2-Methoxyethanol as a substance of very high concern because of its CMR properties, ECHA, 25 November 2010. Available at <http://echa.europa.eu/documents/10162/8f31ac1a-9d66-4e7e-81b0-87c37906ca76>;
3. Annex XV dossier – Proposal for identification of a substance as a CMR Cat 1 or 2, PBT, vPvB or a substance of an equivalent level of concern – for 2-Methoxyethanol (ethylene glycol monomethyl ether; EGME), EC Number(s): 203-713-7, CAS Number(s): 109-86-4; Environment Agency Austria on behalf of the Austrian Competent Authority (Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management) in cooperation with the Belgian Federal Public Service (FPS) Health, Food Chain Safety and Environment, Risk Management Service and the Polish Bureau for Chemical Substances and Preparations, August 2010. Available at <http://echa.europa.eu/documents/10162/b6b959c2-14c8-4612-9e91-cf181a867dd2>;
4. (a) Technical Data Sheet - Silquest* A-172NT, Momentive: <https://www.momentive.com/products/showtechnicaldatasheet.aspx?id=10111> (accessed 15 December 2015); (b) Dynasylan® VTMOEO, Vinyltris(2-methoxyethoxy)silane, Evonik Industries: <http://www.dynasylan.com/lpa-productfinder/page/productsbytext/detail.html?pid=213&lang=en> (accessed 15 December 2015); (c) Dynasylan product range, Evonik Industries: [EC no 213-934-0](http://adhesives-</div><div data-bbox=)

sealants.evonik.com/sites/lists/CA/Documents/Dynasylan-product-range-EN.pdf (accessed 15 December 2015).