

## **Annex XV report**

# **PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57**

**Substance Name:** Tris(2-methoxyethoxy)vinylsilane

**EC Number:** 213-934-0

**CAS Number:** 1067-53-4

**Submitted by:** Austria

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## ABBREVIATIONS

ATP:	Adaptation to Technical Progress
ATE:	Acute Toxicity Estimate
CA:	Competent Authority
CCH:	Compliance Check
CSR:	Chemical Safety Report
C&L:	Classification & Labelling
CLH:	Harmonised Classification and Labelling
CLP:	Classification, Labelling and Packaging Regulation (EC) No 1272/2008
EC:	European Commission
EOGRTS:	Extended One Generation Reproductive Toxicity Study
MSC:	Member State Committee
MSCA:	Member State Competent Authority
OECD:	Organisation for Economic Co-operation and Development
PC:	Product Category
PNDT:	Prenatal Developmental Toxicity Test
PROC:	Process Category
RAC:	Risk Assessment Committee
RMOA:	Regulatory Management Option Analysis
SU:	Sector of Use
SVHC:	Substance of Very High Concern
tpa:	tons per annum
TPE:	Testing Proposal Examination

## **PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57**

**Substance name:** Tris(2-methoxyethoxy)vinylsilane

**EC number:** 213-934-0

**CAS number:** 1067-53-4

- The substance is proposed to be identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class toxic for reproduction category 1B, H360FD (May damage fertility. May damage the unborn child).

### **Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation**

Tris(2-methoxyethoxy)vinylsilane is covered by index number 014-050-00-6 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1B (H360FD: "May damage fertility. May damage the unborn child") (EU, 2020).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

- Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

**Registration dossiers submitted for the substance:** Yes

## PART I

### Justification

#### 1. Identity of the substance and physical and chemical properties

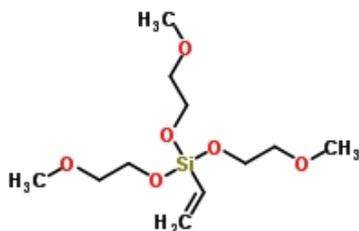
##### 1.1 Name and other identifiers of the substance

**Table 1: Substance identity**

<b>EC number:</b>	213-934-0
<b>EC name:</b>	tris(2-methoxyethoxy)vinylsilane
<b>CAS number (in the EC inventory):</b>	1067-53-4
<b>CAS number:</b>	1067-53-4
<b>IUPAC name:</b>	6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane
<b>Index number in Annex VI of the CLP Regulation</b>	014-050-00-6
<b>Molecular formula:</b>	C <sub>11</sub> H <sub>24</sub> O <sub>6</sub> Si
<b>Molecular weight:</b>	280.39 g/mol
<b>Synonyms:</b>	6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane 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

**Structural formula:**

(Source: European Chemicals Agency, <http://echa.europa.eu/>)



**1.2 Composition of the substance**

**Name:** tris(2-methoxyethoxy)vinylsilane

**Description:** liquid

**Substance type:** mono-constituent

This substance potentially includes an impurity, which has SVHC properties.

**1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment**

**Table 2: Degradation (transformation) product/metabolite**

<b>EC number:</b>	203-713-7
<b>EC name:</b>	2-methoxyethanol
<b>SMILES:</b>	COCCO
<b>CAS number (in the EC inventory):</b>	109-86-4
<b>CAS number:</b>	109-86-4
<b>IUPAC name:</b>	2-methoxyethanol
<b>Index number in Annex VI of the CLP Regulation</b>	603-011-00-4
<b>Molecular formula:</b>	C3H8O2
<b>Molecular weight range:</b>	76.09 g/mol
<b>Synonyms:</b>	EGME Ethylene glycol methyl ether MGE Methyl glycol ether Ethylene glycol methyl ether

**Structural formula:**

(Source: European Chemicals Agency, <http://echa.europa.eu/>)



**Indication of the process, organism and/or organ in which the transformation takes place:**

Tris(2-methoxyethoxy)vinylsilane is a volatile liquid which hydrolyses rapidly when in contact with water or air moisture due to its reactive nature (half-life: 1h at pH 7, 1.6 min at pH 4 and 0.9 min at pH 9 and 25°C)<sup>1</sup>. When hydrolysing, three moles of 2-methoxyethanol (EC 203-713-7, CAS 109-86-4) and one mole of vinyltrisilanol (CAS 143-48-6) are produced (OECD, 2006). In many uses, tris(2-methoxyethoxy)vinylsilane may therefore hydrolyse and release 2-methoxyethanol (ECHA, 2016).

2-methoxyethanol has a harmonised classification as toxic for reproduction (Repr. 1B, H360FD) in CLP and is included in the Candidate List as an SVHC (MSC, 2010).

**1.4 Identity and composition of structurally related substances (used in a grouping or read-across approach)**

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

**1.5 Physicochemical properties**

Not relevant for the identification of the substance(s) as SVHC in accordance with Article 57 (c) of the REACH Regulation.

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<sup>1</sup> ECHA dissemination site [Registration Dossier - ECHA \(europa.eu\)](https://echa.europa.eu/registration-dossier) [accessed 08/2021]

## 2. Harmonised classification and labelling

Tris(2-methoxyethoxy)vinylsilane is covered by Index number 014-050-00-6 in part 3 of Annex VI to the CLP Regulation as follows:

**Table 3: Classification according to Annex VI, Table 3 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 (EU, 2020)**

Index No	Chemical name	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors and ATEs	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)		
014-050-00-6	tris(2-methoxyethoxy)vinylsilane;  6-(2-methoxyethoxy)-6-vinyl-2,5,7,10-tetraoxa-6-silaundecane	213-934-0	1067-53-4	Repr. 1B	H360FD	GHS08 Dgr	H360FD			

In the RAC opinion (RAC, 2018) it is noted that the “*classification is further supported by the fact that 2-methoxyethanol, a product of tris(2-methoxyethoxy)vinylsilane hydrolysis, and a presumed metabolite of tris(2-methoxyethoxy)vinylsilane in mammals is a known reproductive toxicant with harmonised classification as Repr. 1B; H360FD.*”

## 3. Environmental fate properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

## 4. Human health hazard assessment

The RAC opinion on the proposed harmonised classification and labelling as Repr. 1B (H360FD) was adopted on 8 June 2018 by consensus. The substance was added to Table 3, Annex VI of CLP via Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 (EU, 2020).

## 5. Environmental hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (c) of the REACH Regulation.

## **6. Conclusions on the SVHC Properties**

### **6.1 CMR assessment**

Tris(2-methoxyethoxy)vinylsilane is covered by index number 014-050-00-6 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1B (H360FD: “May damage fertility. May damage the unborn child”) (EU, 2020).

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

- toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

## Part II

### 7. Registration and C&L notification status

#### 7.1 Registration status

**Table 4: Registration status**

From the ECHA dissemination site <sup>2</sup>	
Registrations	<input checked="" type="checkbox"/> Full registration(s) (Art. 10) <input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)

#### 7.2 CLP notification status

**Table 5: CLP notifications**

	CLP Notifications <sup>3</sup>
Number of aggregated notifications	12
Total number of notifiers	234

### 8. Total tonnage of the substance

**Table 6: Tonnage status**

Total tonnage band for the registered substance (excluding the volume registered under Art. 17 or Art. 18) <sup>4</sup>	1,000-10,000 t/pa
Tonnage information from public sources other than registration dossiers (if available)	-

<sup>2</sup> [Tris\(2-methoxyethoxy\)vinylsilane - Registration Dossier - ECHA \(europa.eu\)](#) (accessed 07/2021)

<sup>3</sup> C&L Inventory database, <http://echa.europa.eu/web/quest/information-on-chemicals/cl-inventory-database> (accessed 07/2021)

<sup>4</sup> [Tris\(2-methoxyethoxy\)vinylsilane - Substance Information - ECHA \(europa.eu\)](#)

## 9. Information on uses of the substance

**Table 7: Uses**

	<b>Use(s)</b>	<b>Registered use</b>	<b>Use <u>likely</u> to be in the scope of Authorisation</b>
<b>Manufacture</b>	<p>Manufacture of the substance</p> <p><i>PROC 2, 3, 8b, 9</i></p>	Yes	No
<b>Uses as intermediate</b>	-	No	No
<b>Formulation or repacking</b>	<p>Use in the manufacture of rubber and plastic</p> <p><i>PROC 5, 8b; PC15: Non-metal-surface treatment products, PC 32 Polymer preparations and compounds</i></p> <p>Use in sealants</p> <p><i>PROC 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 19, 21; PC 1: Adhesives, sealants, PC 32: Polymer preparations and compounds</i></p>	Yes	Yes
<b>Uses at industrial sites</b>	<p>Non-metal surface treatment</p> <p><i>PROC 4, 5, 7, 8a, 8b, 13; PC 15: Non-metal-surface treatment products, SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement</i></p> <p>Use in the manufacture of rubber and plastic</p> <p><i>PROC 5, 7, 8b; PC15: Non-metal-surface treatment products, PC 32 Polymer preparations and compounds, SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys), SU 11: Manufacture of rubber products, SU 12: Manufacture of plastics products, including compounding and conversion</i></p> <p>Use in sealants</p> <p><i>PROC 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 19, 21; PC 1: Adhesives, sealants, PC 32: Polymer preparations and compounds; SU 5: Manufacture of textiles, leather, fur, SU 6a: Manufacture of wood and wood products, SU 6b: Manufacture of pulp, paper and paper products, SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys), SU 11: Manufacture of rubber products, SU 12: Manufacture of plastics</i></p>	Yes	Yes

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	<p><i>products, including compounding and conversion, SU 15: Manufacture of fabricated metal products, except machinery and equipment, SU 16: Manufacture of computer, electronic and optical products, electrical equipment, SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment, SU 19: Building and construction work</i></p> <p>Use as a monomer (production of silicone polymers, silicone resins)</p> <p><i>PROC 1, 8b, PC 19: Intermediate, SU 8: Manufacture of bulk, large scale chemicals (including petroleum products), SU 9: Manufacture of fine chemicals</i></p> <p>Use as laboratory chemical</p> <p><i>PROC 15, PC 21: Laboratory chemicals, SU 24: Scientific research and development</i></p>		
<b>Uses by professional workers</b>	<p>Use in sealants</p> <p><i>PROC 2, 3, 4, 5, 7, 8a, 8b, 9, 10, 13, 14, 19, 21, PC 1: Adhesives, sealants, PC 32: Polymer preparations and compounds, SU 5: Manufacture of textiles, leather, fur, SU 6a: Manufacture of wood and wood products, SU 6b: Manufacture of pulp, paper and paper products, SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys), SU 11: Manufacture of rubber products, SU 12: Manufacture of plastics products, including compounding and conversion, SU 15: Manufacture of fabricated metal products, except machinery and equipment, SU 16: Manufacture of computer, electronic and optical products, electrical equipment, SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment, SU 19: Building and construction work</i></p>	Yes	Yes
<b>Consumer uses</b>	-	No	-
<b>Article service life</b>	-	No	-

PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions  
 PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions  
 PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions  
 PROC 4: Chemical production where opportunity for exposure arises  
 PROC 5: Mixing or blending in batch processes  
 PROC 7: Industrial spraying  
 PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities  
 PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities

PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)  
PROC 10: Roller application or brushing  
PROC 13: Treatment of articles by dipping and pouring  
PROC 14: Tableting, compression, extrusion, pelletisation, granulation  
PROC 19: Hand-mixing with intimate contact and only PPE available  
PROC 21: Low energy manipulation of substances bound in materials and/or articles

The technical function of the substance can be described as crosslinking, binding and coupling agent and surface modifier (ECHA, 2016).

The SPIN-database<sup>5</sup> summarises information on substances in different products on the national markets of Norway, Sweden, Finland and Denmark. Table 8 gives an overview on the number of preparations containing tris(2-methoxyethoxy)vinylsilane. Specific information on use in consumer preparations is not available.

**Table 8: SPIN database – Total use 2019** (accessed 08/2021)

Country	No. of preparations	Tonnes
Sweden	5	1.1
Finland	0	Conf
Norway	-	-
Denmark	0	Conf

Conf: data are not available for reasons of confidentiality. Generally, data are kept confidential if the substance is a component in less than 4 preparations from less than 3 producers.

## 10. Information on structure of the supply chain

According to ECHA dissemination site<sup>6</sup>, tris(2-methoxyethoxy)vinylsilane is registered in high quantities (>1000 tpa); it has 4 active registrations under REACH, 1 joint submission. The geographical localisation of active registrants is limited to three Member States.

The substance has 12 aggregated C&L notifications with high number of notifiers (total of 234) listed at ECHA's C&L inventory (accessed 07/2021).

The substance is manufactured/imported in the EU, formulated and used at industrial sites and by professional workers. The technical function of the substance can be described as crosslinking, binding and coupling agent and surface modifier (ECHA, 2016).

According to information from ECHA's dissemination webpage, tris(2-methoxyethoxy)vinylsilane is used in a high number of product categories and sectors of use (PC 1, 15, 19, 21, 31; SU 5, 6a, 6b, 8, 9, 10, 11, 12, 13, 15, 16, 17, 19, 24) indicating a high complexity of the supply chain. However, the number of industrial and professional sites using the substance is unknown.

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<sup>5</sup> Substances in Preparations in the Nordic countries <https://eng.mst.dk/chemicals/chemicals-in-products/assessment-of-chemicals/spin-database/> (accessed 08/2021)

<sup>6</sup> [Tris\(2-methoxyethoxy\)vinylsilane - Brief Profile - ECHA \(europa.eu\)](#) (accessed 07/2021)



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vinyl/alkyl	Dynasylan® 6598	oligomeric siloxane containing vinyl, propyl and ethoxy groups	x	x	x	x
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Further possible alternatives are other **closely related alkoxysilanes** like triethoxy(vinyl)silane (EC 201-081-7) or trimethoxyvinylsilane (EC 220-449-8). Although these substances do not hydrolyse to 2-methoxyethanol their reproductive toxicity remains to be clarified.

For trimethoxyvinylsilane a pre-natal developmental toxicity study (PNDT, OECD Test Guideline 414) in rabbits and an extended one-generation reproductive toxicity study (EOGRTS, OECD Test Guideline 443) in rats have been requested following a Compliance Check (CCH) (ECHA, 2018). Results from the PNDT study in rabbits are already available showing, according to the registrants, no developmental toxicity up to a dose level of 75 mg/kg bw<sup>9</sup>. Results from the EOGRT study are not available at ECHA’s dissemination website yet.

For triethoxy(vinyl)silane a PNDT study in a first and second species and an EOGRT study have to be conducted following a Testing Proposal decision. Results are expected for end of 2021.

**Silane** coupling agents usually consist of three hydrolysable groups such as chloride, oxime, enoxy, alkoxy and acyloxy groups and one non-hydrolysable organic group such as vinyl, allyl, acryl, methacryl, unsaturated polyesters, alkylamines, epoxyalkyls linked to the silicium atom, according to a manufacturer<sup>10</sup>. Depending on the function and properties needed, different silane-products are commercially available and may serve as substitutes for the reprotoxic tris(2-methoxyethoxy)vinylsilane. Possible alternatives may be triacetoxymethylsilane (EC 223-943-1), tri(isopropoxy) vinylsilane (EC 241-931-4) or tris(isopropenyloxy)vinylsilane (EC 239-362-1).

For information, registered uses and self-classification of possible alternatives are compiled in Table 10.

Oxime silanes, which may also serve as alternatives are currently under assessment<sup>11</sup> due to their release of (possible) toxic oximes.

Another type of coupling agents are so-called **dipodal silanes**, which consist of two silicium atoms and six hydrolysable groups. According to literature they offer a distinctive advantage over conventional silanes in terms of maintaining the integrity of surface coatings, adhesive primers and composites in aqueous and aggressive environments (Singh *et al.*, 2014). One representative is 4,4,7,7-tetraethoxy-3,8-dioxo-4,7-disiladecane (EC 240-212-2); data generation will clarify the toxicity of the substance (TPE for repeated dose, genetic toxicity, developmental toxicity, long-term toxicity currently ongoing). Bis[3-(trimethoxysilyl)-propyl]amine (EC 280-084-5) may be another alternative out of the huge group of silanes possible for replacing each other depending on the required properties.

<sup>9</sup> ECHA dissemination site [Registration Dossier - ECHA \(europa.eu\)](https://echa.europa.eu/registration-dossier) [accessed 08/2021]

<sup>10</sup> <https://www.dynasylan.com/product/dynasylan/de/produkte/chemische-funktionalitaeten/pages/default.aspx>

<sup>11</sup> [Regulatory management option analysis - ECHA \(europa.eu\)](https://echa.europa.eu/regulatory-management-option-analysis)

**Table 10: Tris(2-methoxyethoxy)vinylsilane, possible alternative substances and their current classification and uses (ECHA dissemination site, accessed 04/2021)**

EC No CAS No	Substance name	Current classification (bold: harmonized C&L)	Hydrolysis product <sup>12</sup>	Additional Information	Registered uses			Article service life
					Consumer	Professional	Industrial	
213-934-0 1067-53-4	tris(2-methoxyethoxy)vinylsilane	<b>Repr. 1B, H360FD</b>	2-methoxy ethanol, vinylsilanetriol	-	-	<ul style="list-style-type: none"> <li>• Use in sealants (PC1, 32)</li> </ul>	<ul style="list-style-type: none"> <li>• Use in rubber and plastic manufacture (PC 15, 31)</li> <li>• Use in sealants (PC1, 32)</li> <li>• Use as monomer (PC 19)</li> <li>• Non-metal surface treatment (PC 15)</li> <li>• Laboratory reagent (PC 21)</li> </ul>	-
220-449-8 2768-02-7	trimethoxyvinylsilane	<b>Skin Sens. 1B, H317</b>	methanol, vinylsilanetriol	<p>CCH: PNDT study in a second species, EOGRTS (data received and under evaluation by ECHA)</p> <p>Reproductive toxicity to be evaluated</p>	<ul style="list-style-type: none"> <li>• Use of coatings (PC 9a)</li> <li>• Use of sealants (PC 1)</li> <li>• Laboratory reagent (PC 21)</li> </ul>	<ul style="list-style-type: none"> <li>• Use of coatings (PC 9a)</li> <li>• Use of sealants (PC 1)</li> <li>• Use as monomer (PC 19)</li> <li>• Non-metal-surface treatment products (PC 15)</li> <li>• Intermediate (PC32)</li> </ul>	<ul style="list-style-type: none"> <li>• Use of sealants (PC 1)</li> <li>• Use as monomer (PC 19)</li> <li>• Use of coatings (PC 9a) (e.g. beverage can coating, automotive refinishing)</li> <li>• Non-metal-surface treatment products (PC 15) and/or mass hydrophobation</li> <li>• Intermediate – on site use</li> <li>• In situ treatment/polymer modification (PC 15, 20, 32)</li> </ul>	-

<sup>12</sup> Silanetriol (hydrolysis product) reacts further under formation of water (condensation reaction) and builds a siloxane network (-Si-O-Si-).

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201-081-7 78-08-0	triethoxy(vinyl)silane	Flam. Liquid 3, H226 Eye Irrit. 2, H319 STOT SE 3, H335	ethanol, vinylsilanetriol	TPE: PNDT study in a first and second species, EOGRTS (data end of 2021)  Reproductive toxicity to be evaluated	• Use of coatings (PC 9a) Use of sealants (PC 1)	• Use of coatings (PC 9a) Use of sealants (PC 1)	• Use of coatings (PC 9a) • Use of sealants (PC 1) • Use as monomer (PC 32) • Chemical intermediate • Production of articles using fire retardant additives • Non-metal-surface treatment products (PC 15) Laboratory reagent (PC 21)	• Use of articles containing retardant additives • Consumer use of sealants
223-943-1 4130-08-9	triacetoxyvinylsilane	Skin Corr. 1B, H314 Eye Dam. 1, H318	acetic acid, vinylsilanetriol	-	• Use of sealants (PC 1)	Use of sealants/adhesives (PC 1)	• Use of sealants (PC1) • Use of coatings (PC 9a)	-
241-931-4 18023-33-1	tri(isopropoxy)vinylsilane	Flam. Liquid 3, H226	2-propanol, vinylsilanetriol	-	-	-	• Use of coatings (PC 9a) • Use of sealants/adhesives (PC 1) Laboratory chemical (PC 21)	-
239-362-1 1533299-7	tris(isopropenyloxy)vinylsilane	Flam. Liquid 3, H226 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	propen-2-ol - > acetone vinylsilanetriol	-	-	-	• Use of sealants/adhesives (PC1) • Laboratory chemical (PC 21)	-
240-212-2 16068-37-4	4,4,7,7-tetraethoxy-3,8-dioxa-4,7-disiladecane	Acute Tox. 3, H301 Acute Tox. 4, H312 STOT RE 1, H372	ethanol, 1,2-bis(trihydroxysilyl)ethane	TPE ongoing (long-term aquatic, repeated dose, genotox developmental	-	• Sealants/adhesives (PC1) • Use in coatings (PC9a)	• Use of coatings (PC 9a, 14, 33) • Sealants/adhesives (PC1) • Polymerization	-

ANNEX XV – IDENTIFICATION OF TRIS(2-METHOXYETHOXY)VINYLSILANE AS SVHC

		Aquatic chronic 3, H412		tox)			• In-situ treatment (non-metal surface) (PC 15)	
280-084-5 82985-35-1	Bis[3-(trimethoxysilyl)-propyl]amine	Eye Dam. 1, H318 Skin Irrit. 2, H315 Aquatic Chronic 2, H411	methanol, bis[(trihydroxysilyl)-propyl]amine	TPE to fulfil information requirements ongoing (repeated dose toxicity, PNDT)	<ul style="list-style-type: none"> <li>• Use of coatings (PC9a)</li> <li>• Use of sealants/adhesives (PC1)</li> </ul>	<ul style="list-style-type: none"> <li>• Use of sealants/adhesives (PC1)</li> <li>• Use of coatings (PC9a)</li> </ul>	<ul style="list-style-type: none"> <li>• Monomer/intermediate (PC32)</li> <li>• Use of coatings (PC9a)</li> <li>• Use of sealants</li> <li>• Non-metal surface treatment (PC15)</li> </ul>	<ul style="list-style-type: none"> <li>• Non-metal surface treatment</li> <li>• Coatings</li> <li>• Adhesives/sealants</li> </ul>

### 11.3 Existing EU legislation

Except in the CLP Regulation (EU, 2020; EU, 2008), there appears to be no EU legislation in place that imposes risk management measures under which the substance tris(2-methoxyethoxy)vinylsilane is specifically identified by name (and numerical identifiers).

An amendment of Appendix 6 of Annex XVII of the REACH Regulation is currently under preparation. It is anticipated that due to its harmonised classification as Repr 1B the substance tris(2-methoxyethoxy)vinylsilane will be included in this Appendix and consequently shall not be placed on the market, or used, as substances, as constituents of other substances, or, in mixtures, for supply to the general public.

Due to its classification, the substance is covered by the following legislations according to ECHA's database EUCLEF<sup>13</sup>:

- Active Implantable Medical Devices Directive (EU, 1990, as amended)
- CAD - Chemical Agents Directive (EU, 1998a, as amended)
- Construction Product Regulation (EU, 2011, as amended)
- EU Ecolabel Regulation (EU, 2010, as amended)
- End-of-Life Vehicles Directive (EU, 2000, as amended)
- Food Contact Active and Intelligent Materials and Articles Regulation (EU, 2009, as amended)
- General Product Safety Directive (EU, 2002, as amended)
- In Vitro Diagnostic Medical Devices Directive (EU, 1998b, as amended)
- Marine Environmental Policy Framework Directive (EU, 2008a, as amended)
- Medical Device Directive (EU, 1993, as amended)
- Protection of Pregnant and Breastfeeding Workers Directive (EU, 1992a, as amended)
- Protection of Young People Directive (EU, 1994, as amended)
- Safety and Health of Workers at Work Directive (EU, 1989, as amended)
- Safety and/or Health Signs at Work Directive (EU, 1992b, as amended)
- Waste Framework Directive (EU, 2008b, as amended)

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<sup>13</sup> [EU Chemicals Legislation Finder - ECHA \(europa.eu\)](https://eucha.europa.eu)

## **11.4 Previous assessments by other authorities/ongoing regulatory activities**

At OECD level, a sponsored SIDS Initial Assessment Report has been elaborated for tris(2-methoxyethoxy)vinylsilane in 2006 (OECD, 2006).

A Regulatory Management Options Analysis (RMOA) has been performed by ECHA on behalf of the European Commission, based on an SVHC impurity (ECHA, 2016). In this document it was concluded that 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.

Austria submitted a CLH dossier for tris(2-methoxyethoxy)vinylsilane containing a classification proposal together with the justification and background information documented in a CLH report. The CLH report was made publicly available in accordance with the requirements of the CLP Regulation on 20 June 2017. Concerned parties and Member State Competent Authorities (MSCA) were invited to submit comments and contributions by 4 August 2017. The RAC opinion on the proposed harmonised classification and labelling as Repr. 1B (H360FD) was adopted on 8 June 2018 by consensus. The substance was added to Table 3, Annex VI of CLP via Commission Delegated Regulation (EU) 2020/1182 of 19 May 2020 (EU, 2020).

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