

**Risk Management Option Analysis Conclusion Document**

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

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

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

**Authority:** Austria

**Date:** June, 2021

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# Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[[1]](#footnote-1).

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

### OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

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| RMOA |  | [x]  Risk Management Option Analysis (RMOA) other than this RMOAPerformed by ECHA on behalf of the European Commission, based on an SVHC impurity (ECHA, 2016) |
| REACH Processes | Evaluation | [ ]  Compliance check, Final decision |
| [x]  Testing proposalECHA has issued a testing proposal decision for tris(2-methoxyethoxy)vinylsilane (see below). |
| [ ]  CoRAP and Substance Evaluation |
| Authorisation | [ ]  Candidate List |
| [ ]  Annex XIV  |
| Restriction | [ ]  Annex XVII |
| Harmonised C&L  |  | [x]  Annex VI (CLP) (see section 3.1)CLH-dossier for tris(2-methoxyethoxy)vinylsilane submitted by Austria, 2017; 15th ATP to CLP |
| Processes under other EU legislation |  | [ ]  Plant Protection Products Regulation Regulation (EC) No 1107/2009  |
|  | [ ]  Biocidal Product RegulationRegulation (EU) 528/2012 and amendments  |
| Previous legislation |  | [ ]  Dangerous substances Directive Directive 67/548/EEC (NONS) |
|  | [ ]  Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)  |
| (UNEP) Stockholm convention (POPs Protocol) |  | [ ]  Assessment  |
|  | [ ]  In relevant Annex  |
| Other processes/ EU legislation |  | [ ]  Other (provide further details below) |

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]](#footnote-2) Following this decision, the lead registrant updated its dossier in August 2014, in which the substance tris(2-methoxyethoxy)vinylsilane was self-classified as reproductive toxicant category 1B (Repr. 1B, H360Df).

### CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

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| **Conclusions** | **Tick box** |
| Need for follow-up regulatory action at EU level: |  |
| *Harmonised classification and labelling* |  |
| *Identification as SVHC (authorisation)* | x |
| *Restriction under REACH* |  |
| *Other EU-wide regulatory measures* |  |
| Need for action other than EU regulatory action |  |
| No action needed at this time |  |

### Need for follow-up regulatory action at EU level

The substance tris(2-methoxyethoxy)vinylsilane shows reproductive toxicity and has a harmonized classification as reproductive toxicant category 1B (H360FD).

It 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). It is produced/imported at high tonnage (> 1,000 t/a). Industrial and professional uses have been registered and include the professional use of sealants containing the substance (mixtures).

There are several uses with high potential for exposure. The Austrian CA does not fully agree with the DNEL derivation by registrants, with the consequence that their might occur certain uses with RCRs close to one or even somewhat higher.

Based on its harmonized classification as Repr 1B, inclusion of tris(2-methoxyethoxy)vinylsilane into Group 30 of Annex XVII, REACH, is anticipated. Therefore, consumer uses of sealants containing tris(2-methoxyethoxy)vinylsilane should not be possible in the future.

However, tris(2-methoxyethoxy)vinylsilane hydrolises 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 hydrolise 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[[3]](#footnote-3).

### Identification as a substance of very high concern, SVHC (first step towards authorisation)

The substance tris(2-methoxyethoxy)vinylsilane fulfils the Article 57(c) criteria of REACH based on the harmonized classification as reproductive toxicant category 1B (H360FD). It further fulfils the SVHC Roadmap 2020 criteria that have been defined for selecting substances that are relevant for identification as SVHC and thus it is in principle desirable to substitute these substances on a long term perspective.

The authorisation process provides incentives for the development of safer alternatives. Until substitution is achieved, the authorisation process aims at ensuring the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable (REACH Article 55).

For tris(2-methoxyethoxy)vinylsilane potential alternative substances seem to be already available for a significant number of uses. Depending on the mechanical, thermal and electrical properties needed, specific alternatives will have to be determined use by use. The inclusion of the substance in the Candidate List for eventual inclusion in Annex XIV will put further pressure on substitution and is therefore regarded as the most appropriate and efficient measure to control the risks arising from the substance until substitution has been achieved.

### TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

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| **Follow-up action** | **Date for follow-up**  | **Actor** |
| Annex XV SVHC dossier | August / 2021  | Austria |

1. For more information on the SVHC Roadmap: <http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation> [↑](#footnote-ref-1)
2. Testing proposal decision is available at <https://echa.europa.eu/documents/10162/62a741f6-6183-8f70-431d-ea4f8794377b> [↑](#footnote-ref-2)
3. ECHA (2016). RMOA Tris(2-methoxyethoxy)vinylsilane <https://echa.europa.eu/documents/10162/f5d36f70-e0f3-95ba-b9b7-69a9582c3839> [↑](#footnote-ref-3)