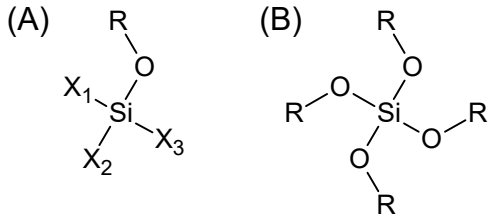
# Assessment of regulatory needs

**Authority: European Chemicals Agency (ECHA)**

## Group Name: Alkoxysilanes and alkoxy aliphatic non-vinylic silanes

## General structure:

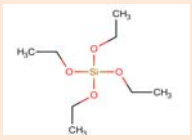
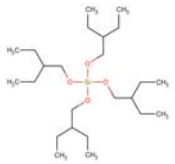
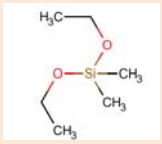
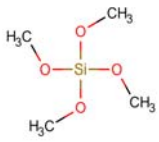
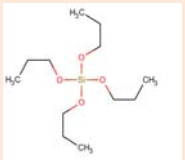
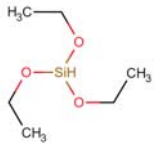
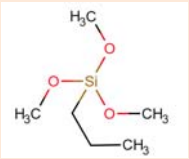



(A) generic structure where at least one of the groups attached to the Si is an alkoxy group (-OR), and Xn is an alkoxy group (-OR), hydrogen (H) or an aliphatic alkyl (or alkenyl) group (R'); (B) example structure for a generic tetraalkoxysilane.

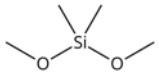
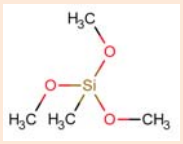
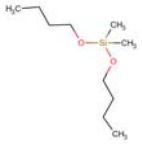
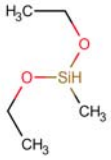
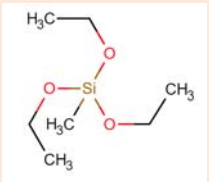
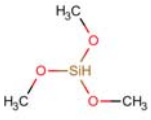
**Revision history**

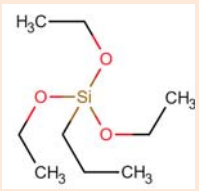
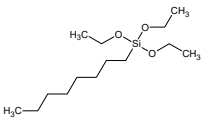
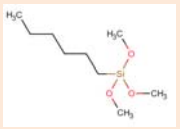
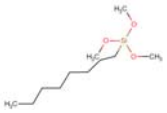
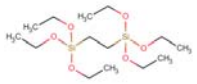
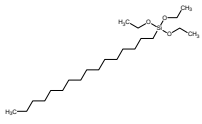
| *Version* | *Date* | *Description* |
|---|---|---|
| **1.0** | 20 March 2024 | |
| | | |
| | | |

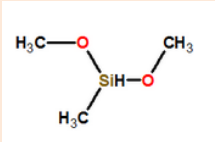
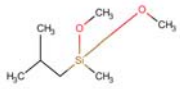
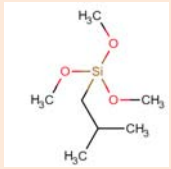
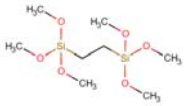
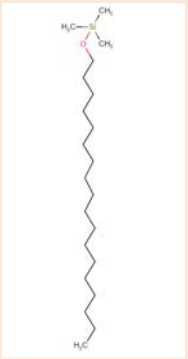
**Substances within this group:**

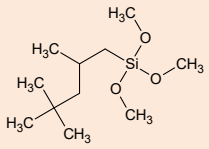
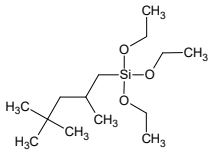
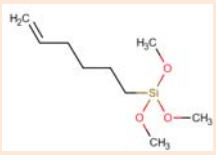
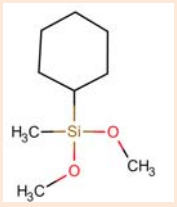
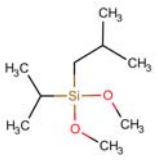
| EC / List no | CAS no | Substance name | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1] |
|---|---|---|---|---|
| **201-083-8** | 78-10-4 | Tetraethyl orthosilicate |  | Full, >1000 |
| **201-085-9** | 78-13-7 | Tetrakis(2-ethylbutyl) orthosilicate |  | Full, not (publicly) available |
| **201-127-6** | 78-62-6 | Diethoxy(dimethyl)silane |  | Full, not (publicly) available |
| **211-656-4** | 681-84-5 | Tetramethyl orthosilicate |  | Full, 100-1000 |
| **211-659-0** | 682-01-9 | Tetrapropyl orthosilicate |  | Full, 100-1000 |
| **213-650-7** | 998-30-1 | Triethoxysilane |  | Full, not (publicly) available |
| **213-926-7** | 1067-25-0 | Trimethoxypropyl silane |  | Full, 100-1000 |

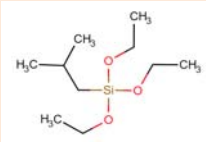
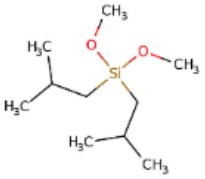
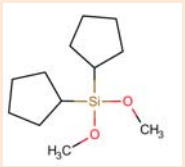
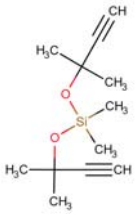
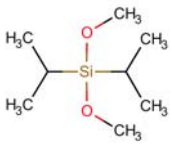
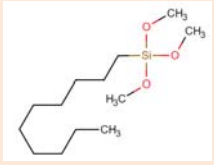
[1] Note that the total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

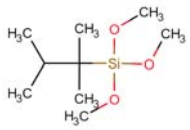
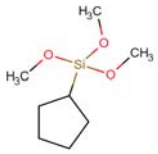
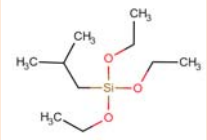
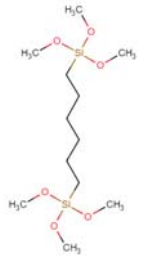
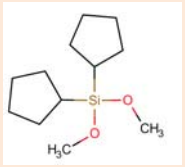
| EC/List no | CAS no | Substance name | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1] |
|---|---|---|---|---|
| **214-189-4** | 1112-39-6 | Dimethoxydimethylsilane |  | Full, >1000 |
| **214-685-0** | 1185-55-3 | Trimethoxy(methyl)silane |  | Full, >1000 |
| **216-467-0** | 1591-02-2 | Dibutoxy(dimethyl)silane |  | Full, not (publicly) available |
| **217-370-6** | 1825-62-3 | Ethoxytrimethylsilane |  | Full, not (publicly) available |
| **217-982-3** | 2031-62-1 | Diethoxy(methyl)silane |  | Full, 10-100 |
| **217-983-9** | 2031-67-6 | Triethoxy(methyl)silane |  | Full, 100-1000 |
| **219-637-2** | 2487-90-3 | Trimethoxysilane |  | OSII or TII |

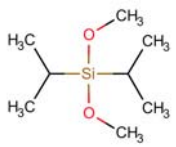
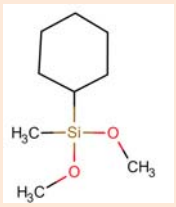
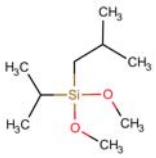
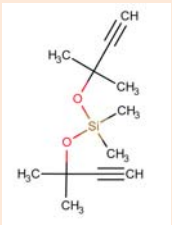
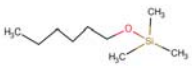
| EC/List no | CAS no | Substance name | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1] |
|---|---|---|---|---|
| **219-842-7** | 2550-02-9 | Triethoxypropylsilane |  | Full, not (publicly) available |
| **220-941-2** | 2943-75-1 | Triethoxyoctylsilane |  | Full, >1000 |
| **221-331-9** | 3069-19-0 | Hexyltrimethoxysilane |  | Full, not (publicly) available |
| **221-338-7** | 3069-40-7 | Trimethoxyoctylsilane |  | Full, not (publicly) available |
| **221-339-2** | 3069-42-9 | Trimethoxyoctadecylsilane |  | Full, not (publicly) available |
| **240-212-2** | 16068-37-4 | 4,4,7,7-tetraethoxy-3,8-dioxa-4,7-disiladecane |  | Full, 100-1000 |
| **240-464-3** | 16415-12-6 | Hexadecyltrimethoxysilane |  | Full, >1000 |
| **240-465-9** | 16415-13-7 | Triethoxyhexadecylsilane |  | Full, not (publicly) available |

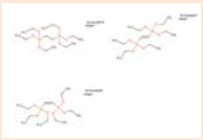
| EC/List no | CAS no | Substance name | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1] |
|---|---|---|---|---|
| **240-914-9** | 16881-77-9 | Dimethoxymethylsilane |  | Full, not (publicly) available |
| **242-171-6** | 18293-82-8 | Isobutyldimethoxymethylsilane |  | Full, not (publicly) available |
| **242-272-5** | 18395-30-7 | Trimethoxy(2-methylpropyl)silane |  | Full, 100-1000 |
| **242-285-6** | 18406-41-2 | 3,3,6,6-tetramethoxy-2,7-dioxa-3,6-disilaoctane |  | Cease manufacture |
| **242-554-8** | 18748-98-6 | Trimethyl(octadecyloxy)silane |  | Full, not (publicly) available |
| **249-385-9** | 29043-70-7 | Dimethylbis(octadecyloxy)silane |  | Full, not (publicly) available |

| EC/List no | CAS no | Substance name | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1] |
|---|---|---|---|---|
| **251-995-5** | 34396-03-7 | Trimethoxy(2,4,4-trimethylpentyl)silane |  | Full, not (publicly) available |
| **252-558-1** | 35435-21-3 | Triethoxy(2,4,4-trimethylpentyl)silane |  | Full, not (publicly) available |
| **261-419-4** | 58751-56-7 | 5-hexenyltrimethoxysilane |  | OSII or TII |
| **274-936-5** | 70851-50-2 | Dimethoxymethyloctadecylsilane |  | Full, not (publicly) available |
| **402-140-1**<br>(629-092-6*) | 17865-32-6 | Cyclohexyldimethoxymethylsilane |  | Full, not (publicly) available |
| **402-580-4**<br>(682-466-0*) | 111439-76-0 | Isobutylisopropyldimethoxysilane |  | Full, not (publicly) available |

| EC/List no | CAS no | Substance name | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1] |
|---|---|---|---|---|
| **402-810-3**<br><br>(605-871-6*) | 17980-47-1 | Triethoxyisobutyl silane |  | Full, not (publicly) available |
| **404-020-4** | - | Bis(2-methylpropyl)di methoxysilane |  | Full, not (publicly) available |
| **404-370-8**<br><br>(620-337-2*) | 126990-35-0 | Dicyclopentyldim ethoxysilane |  | Full, not (publicly) available |
| **414-960-7**<br><br>(691-550-6*) | 53863-99-3 | Bis(1,1-dimethyl-2-propynyloxy)dim ethylsilane |  | NONS |
| **Not (publicly) available**<br><br>**“Substance 1”** | - | Not (publicly) available | Not (publicly) available | NONS |
| **421-540-7**<br><br>(620-530-1*) | 18230-61-0 | Bis(1-methylethyl)-dimethoxysilane |  | Full, not (publicly) available |
| **422-350-7** | 5575-48-4 | Decyltrimethoxys ilane |  | Full, not (publicly) available |

| EC/List no | CAS no | Substance name | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1] |
|---|---|---|---|---|
| **439-360-2** | 142877-45-0 | (2,3-dimethylbut-2-yl)-trimethoxysilane |  | Full, not (publicly) available |
| **Not (publicly) available**<br><br>**"Substance 2"** | - | [No public or meaningful name is available] | Not (publicly) available | NONS |
| **604-361-0** | 143487-47-2 | cyclopentyl(trimethoxy)silane |  | OSII or TII |
| **605-871-6***<br><br>(duplicate List entry for 402-810-3) | 17980-47-1 | Triethoxy(isobutyl)silane |  | C&L notification |
| **617-969-6** | 87135-01-1 | 2,11-Dioxa-3,10-disiladodecane, 3,3,10,10-tetramethoxy- |  | Full, not (publicly) available |
| **620-337-2***<br><br>(duplicate List entry for 404-370-8) | 126990-35-0 | Cyclopentane,1,1'-(dimethoxysilylene)bis- |  | C&L notification |

| EC/List no | CAS no | Substance name | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1] |
|---|---|---|---|---|
| **620-530-1*** (duplicate List entry for 421-540-7) | 18230-61-0 | bis(1-methylethyl)-dimethoxysilane |  | C&L notification |
| **629-092-6*** (duplicate List entry for 402-140-1) | 17865-32-6 | Cyclohexane, (dimethoxymethylsilyl)- |  | C&L notification |
| **682-466-0*** (duplicate List entry for 402-580-4) | 111439-76-0 | Isobutylisopropyl dimethoxy-dimethoxysilan |  | C&L notification |
| **691-550-6*** (duplicate List entry for 414-960-7) | 53863-99-3 | Bisdimethylpropynyl(oxy)dimesilane |  | C&L notification |
| **823-658-8** | 17888-62-9 | 1-(trimethylsilyloxy)-hexane |  | OSII or TII |

| EC / List no | CAS no | Substance name | Chemical structures | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1] |
|---|---|---|---|---|
| **935-539-9** | - | [No public or meaningful name is available] |  | OSII or TII |

*Duplicate List no for a substance with also an EC no corresponding to the same CAS no (only C&L notifications under the List no)

This table contains also group members that are only notified under the CLP Regulation. However, the list is not necessarily exhaustive.

# Contents

# DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

# Foreword

The assessment of regulatory needs of a group of substances is an iterative, informal process to help authorities consider the most appropriate way to address an identified concern for a group of substances or a single substance and decide whether further regulatory risk management activities are necessary.

The grouping is mainly based on structural similarity and associations made by the registrants between substances through read-across and category approaches as well as category associations from external sources (e.g. OECD categories)[2]. These methods are different from grouping as defined in Section 1.5 of Annex XI to REACH because the scope and intended use of ECHA's grouping is different. Thus, in this context, grouping does not aim to validate read-across and category approaches according to the Annex XI requirements but rather to support a faster and more consistent approach for regulating chemicals and avoid regrettable substitution.

The focus of the assessment is largely based on information available in the registration dossiers and on properties requiring regulatory risk management action at EU level[3]. The information reported on uses is from the registration dossiers (IUCLID) and is used as a proxy for assessing how widespread uses are and whether potential for exposure to humans and releases to the environment can be expected. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

The outcome of these assessments are proposals for immediate (the first action) and subsequent regulatory action(s), including the foreseen ultimate regulatory action (last foreseen regulatory action) to address the identified concern(s) in case the potential hazards are confirmed. For example, further data generation through compliance check is suggested as a first action, to confirm the identified hazard.

Where hazards are confirmed, regulatory risk management actions could be considered for the whole group, for a subgroup or for individual substances within the group. The robustness of the group depends on the stage of assessment and the level of certainty this stage requires. For example, the needs for grouping under restriction may differ from the needs for grouping for the purpose of harmonised classification. Group membership is reconsidered accordingly throughout the iterative assessment of regulatory needs, for example, after further information is generated and the hazard has been clarified or when new insights on uses and risks are available.

The assessment of regulatory needs in itself does not represent a regulatory action, but rather a preparatory step to consider further possible regulatory actions at the level of individual substances or groups/subgroups of substances.

[2] Working with Groups - ECHA (europa.eu)

[3] Regarding hazard properties the focus is for instance on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the report. This does not mean that the substances do not have other known or potential hazards. In some specific cases, ECHA may consider additional hazards (e.g. neurotoxicity, STOT RE).

Publication of ARNs makes it easier for companies to follow the latest status of their substances of interest, anticipate potential regulatory actions and make strategic choices in their chemicals portfolio.

For more information on assessments of regulatory needs please consult ECHA's website[4].

[4] https://echa.europa.eu/understanding-assessment-regulatory-needs

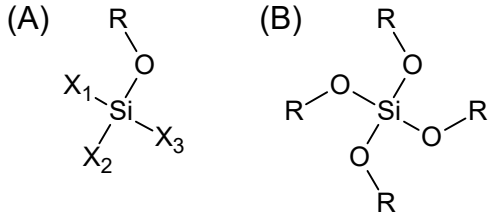
## Glossary

| | |
|---|---|
| ARN | Assessment of Regulatory Needs |
| CCH | Compliance Check |
| CLH | Harmonised classification and labelling |
| CMR | Carcinogenic, mutagenic and/or toxic to reproduction |
| DEv | Dossier evaluation |
| ED | Endocrine disruptor |
| NONS | Notified new substances |
| OEL | Occupational exposure limit |
| OSII or TII | On-site isolated intermediate or transported isolated intermediate |
| PBT/vPvB | Persistent, bioaccumulative and toxic / very persistent and very bioaccumulative |
| PMT/vPvM | Persistent, mobile, and toxic / very persistent and very mobile |
| RDT | Repeated dose toxicity |
| RMOA | Regulatory management options analysis |
| RRM | Regulatory risk management |
| SEv | Substance evaluation |
| STOT RE | Specific target organ toxicity, repeated exposure |
| SVHC | Substance of very high concern |
| TPE | Testing proposal evaluation |

# 1 Overview of the group

*Explanations on the scope of this assessment is available in the foreword to this document. Please read it carefully before going through the report.*

ECHA has grouped together structurally similar substances based on the presence of the "alkoxysilane" moiety shown in the figures below.




(A) is a generic structure where at least one of the groups attached to the Si is an alkoxy group (-OR), and Xn is an alkoxy group (-OR), hydrogen (H) or an aliphatic alkyl (or alkenyl) group (R'); (B) is an example structure for a generic tetraalkoxysilane

The group includes 53 substances, mostly mono-constituent substances, and a few multi-constituent ones. There are 1–4 alkoxy groups attached to the Si, and the substances are either "alkoxysilanes" with only alkoxy groups attached to the Si, or "alkoxy aliphatic non-vinylic silanes" where there are also other groups present. The alkoxy groups -OR include as the R moiety linear saturated alkyl groups with carbon numbers between C1–C18 and branched groups with carbon numbers C5 (unsaturated) and C6 (saturated). Majority of the substances have methoxy or ethoxy as the alkoxy groups. The R' groups include linear, branched and cyclic alkyl groups, with carbon numbers between C1–C18. The R' groups are mainly saturated alkyl groups; two substances include unsaturations in R'. All substances are non-vinylic. Four substances in the group deviate from the generic figure above in the sense that they have "bridged" structures where two alkoxysilane moieties are connected by a hydrocarbon bridge between the two Si.

The substances were divided to the following further subgroups considering the types of the functional groups other than the alkoxy groups:

- tetraalkoxysilanes: include only alkoxy groups
- hydro-trialkoxy-silanes: include only H in addition to three alkoxy groups
- alkyl-alkoxy-silanes: include saturated alkyl groups in addition to alkoxy groups
    - "Short" linear alkyl group (up to 4 C)
    - "Long" linear alkyl groups
    - Branched/cyclic alkyl groups
- alkenyl-alkoxy-silanes: includes unsaturated alkenyl group in addition to alkoxy groups
- alkoxy-di-silanes: include two Si in the structure.

Based on the information reported in the REACH registration dossiers, the substances in the group are commonly used in applications such as adhesives, sealants; coatings and paints, thinners, paint removers; polymer preparations and compounds; and fillers, putties, plasters, modelling clay as precursors, sealants, surface modifiers etc. In these applications, uses by professional worker and consumers are often reported and therefore these uses can be considered widespread with a potential for exposure and releases.

Other less common applications reported for some substances in the group include uses by professional workers or consumers in inks and toners; cosmetics, personal care products; textile dyes, and impregnating products, etc. Although these uses are less frequently reported, they can be considered widespread with a potential for exposure and releases.

Many substances in the group are also used as intermediates or as laboratory chemicals, mostly in industrial setting and sometimes in professional setting for the laboratory chemicals. In these cases, the potential for exposure and releases is much lower.

Silanes are commonly used as precursors, crosslinking agent or water repellents for mineral surfaces. According to the information screened, the substances in this group react and hydrolyse very rapidly (in some cases at the formulation stage). This means that in most use situations, the parent substance is very unlikely to end-up in articles manufactured or treated with the substance. However, if it is possible that the reaction or hydrolysis products end-up in articles, the registrant should report article service life in their dossier.

In the dossiers screened, article service life was identified by registrants for some substances, but not consistently. The light analysis conducted during the screening exercise did not allow to confirm or exclude the presence of hydrolysis products of the substances in the group in articles. Therefore, a worst-case approach was taken, and article service life was added (where not reported by the registrant) to substances used in relevant product categories (see Annex 2 for more details).

It should however be noted that this cannot directly be understood as an indication for potential exposure or releases to the environment. This potential will depend on factors such as the presence of the substance on the surface of the article or its concentration and migration rate in the matrix. Information available in the registration dossier of some substances of this group seems to indicate that this potential for exposure or releases from articles is low. However, this type of information was not available for all substances and therefore the topic should be further assessed in conjunction with actions taken on the substances or if/when the registrants update their dossiers with additional information (see also annex 2).

## 2 Conclusions and proposed actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited.

**Table 1: Conclusions and proposed actions**

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|---|---|---|---|
| 214-189-4<br>214-685-0<br>220-941-2<br>221-338-7<br>240-212-2<br>240-464-3<br>240-465-9<br>240-914-9<br>249-385-9<br>252-558-1<br>402-580-4<br>404-370-8 | Known or potential hazard for mutagenicity for EC 214-189-4, 240-212-2<br><br>Known or potential hazard for reproductive toxicity for EC 214-189-4, 214-685-0, EC 220-941-2, 249-385-9, 252-558-1<br><br>Known or potential hazard for ED for EC 214-189-4, 214-685-0, 249-385-9 | Known or potential hazard for PBT/vPvB for EC 220-941-2, 221-338-7 (Si-hydrolysis product), 240-464-3, 240-465-9, 249-385-9 (parent), 252-558-1 (parent), 402-580-4 (parent), 404-370-8 (parent).<br><br>Known or potential hazard for PMT for EC 214-189-4, 214-685-0, 221-338-7 (parent), 240-212-2, 240-914-9, 252-558-1 (Si-hydrolysis product), | For most substances IND, PROF and CONS uses where potential for exposure is likely (non-metal surface treatment, adhesive and sealants, coatings and paints)<br><br>For 249-385-9 CONS uses where potential for exposure is likely (cosmetics). | **First step:**<br>CCH for all substances, except for EC: 214-189-4 (for 249-385-9 for aquatic toxicity only)<br><br>**Potential next steps (if hazard confirmed after data generation):**<br>CLH for all substances<br><br>**Potential last action:**<br>Restriction<br>for all substances<br><br>Justification:<br>Releases to the environment from consumer and widespread professional uses cannot be avoided. Widespread professional uses are typically non-contained and non-automated leading to releases to the environment. |

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|---|---|---|---|
| | Known or potential hazard for STOT RE for EC 240-212-2<br><br>Known or potential hazard for skin sensitisation for EC 214-685-0<br><br>No hazard or unlikely hazard for EC 240-464-3, 240-465-9 | 404-370-8 (Si-hydrolysis product).<br><br>Known or potential hazard for ED for EC 214-189-4, 214-685-0, 249-385-9<br><br>Known or potential hazard for aquatic toxicity for all substances except EC 220-941-2 | | Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses. Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses. Industrial uses to be considered as part of the restriction.<br><br>For 249-385-9, CLH for reproductive toxicity would ensure appropriate action is taken under the Cosmetics Regulation. |
| 201-083-8<br>211-656-4<br>211-659-0<br>213-650-7<br>213-926-7<br>217-983-9<br>219-842-7<br>242-272-5 | No hazard or unlikely hazard | Known or potential hazard for aquatic toxicity for all substances<br><br>Known or potential hazard for PMT for EC 213-926-7, 217-983-9, 219-842-7, 242-272-5, 251-995-5, 402-140-1, 402-810-3 | For most substances IND, PROF and CONS uses where potential for exposure is likely (non-metal surface treatment, adhesive and sealants) | **First step:**<br><br>CCH for all substances (except EC 422-350-7)<br><br>**Potential last action:**<br>**Currently no need for EU RRM**<br><br>Justification:<br>Self-classification for aquatic toxicity followed by implementation of necessary RRMs should be sufficient to ensure safe use of the substances from that perspective. |

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|---|---|---|---|
| 251-995-5<br><br>402-140-1<br><br>402-810-3 | | | | For PMT hazard, the need for EU RRM will be further investigated once the hazard properties will be clarified after data generation and once there is clarity on the approach to persistent and mobile substances. |
| 201-085-9<br><br>242-554-8 | No hazard or unlikely hazard<br>for EC 242-554-8<br><br>Known or potential hazard<br>for skin sensitisation<br>for EC 201-085-9 | Known or potential hazard<br>for aquatic toxicity<br>for all substances<br><br>Known or potential hazard<br>for PMT for 242-554-8 | EC 242-554-8 CONS uses where potential for exposure is likely (cosmetics)<br><br>EC 201-085-9 PROF uses where potential for exposure is possible (lubricants, hydraulic fluids) | **First step:**<br>CCH for aquatic toxicity<br>for all substances<br><br>**Potential last action:**<br>**Currently no need for EU RRM**<br><br><u>Justification</u>:<br>Self-classification for aquatic toxicity followed by implementation of necessary RRMs should be sufficient to ensure safe use of the substances from that perspective.<br><br>For 201-085-9, self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace.<br><br>For EC 242-554-8, further data to clarify the persistency and mobility cannot be generated due to low tonnage. Therefore, |

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|---|---|---|---|
| | | | | currently no follow-up actions are proposed for the PMT hazard. |
| 421-540-7<br><br>439-360-2<br><br>617-969-6 | Known or potential hazard<br>for skin sensitisation<br>for EC 421-540-7<br><br>Known or potential hazard<br>for STOT RE<br>for EC 617-969-6 | Known or potential hazard<br>for PMT for all substances<br><br>Known or potential hazard<br>for aquatic toxicity<br>for all substances except 617-969-6 | EC 421-540-7 and 439-360-2 IND uses where potential for exposure is limited (polymer preparations and compounds, laboratory chemicals<br><br>For 617-969-6 IND, PROF uses where potential for exposure is likely (adhesive and sealants) | No action<br>for all substances<br><br>**Potential last action:**<br>**Currently no need for EU RRM**<br><br><u>Justification</u>:<br><br>Further data to clarify the persistency and mobility cannot be generated due to low tonnage. Therefore, currently no follow-up actions are proposed for the PMT hazard.<br><br>For EC 421-540-7, existing harmonised classification for skin sensitisation and aquatic toxicity should be sufficient to ensure safe use at the workplace. |
| 217-370-6<br><br>217-982-3<br><br>242-171-6 | No hazard or unlikely hazard | No hazard or unlikely hazard | For EC 217-370-6 and 217-982-3 mostly IND uses where potential for exposure is likely (non-metal surface treatment, coatings and paints) | **First step:**<br>CCH for aquatic toxicity<br>for EC 217-982-3<br><br>**Potential last action:**<br>**Currently no need for EU RRM**<br><br><u>Justification:</u> |

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|---|---|---|---|
| | | | EC 242-171-6 is directly exported | no potential hazards were identified for human health or the environment. |
| 201-127-6<br><br>216-467-0<br><br>221-331-9<br><br>221-339-2<br><br>274-936-5<br><br>404-020-4<br><br>422-350-7 | Known or potential hazard<br>for ED<br>for reproductive toxicity<br>for EC 201-127-6, 216-467-0<br><br>Known or potential hazard<br>for skin sensitisation<br>For EC 221-331-9<br><br>No hazard or unlikely hazard<br>For EC 221-339-2, 274-936-5, 404-020-4 | Known or potential hazard<br>for ED for<br>EC 201-127-6, 216-467-0<br><br>Known or potential hazard<br>for PMT for<br>EC 201-127-6, 216-467-0 (Si-hydrolysis product),404-020-4; Si-hydrolysis product)<br><br>Known or potential hazard<br>for PBT/vPvB<br>for EC 216-467-0 (parent), 221-331-9 (Si-hydrolysis product), 221-339-2, 274-936-5, 404-020-4 (parent), 422-350- | For EC 201-127-6, 221-339-2, 274-936-5, 404-020-4 mostly IND uses where potential for exposure is limited (polymer preparations and/or compounds, laboratory chemicals)<br><br>For EC 216-467-0, 221-331-9 and 422-350-7 IND (and PROF and/or CONS for 221-331-9 and 422-350-7) uses where potential for exposure is likely (coatings and paints, inks and toners) | **First Step:**<br>No action<br><br>**Potential last action:**<br>**Currently no need for EU RRM**<br><br><u>Justification</u>:<br>Due to low tonnage, NONs no data generation is possible to clarify the PBT/PMT/Repr./ED hazards currently. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change.<br><br>For EC 221-331-9 the existing self-classification for skin sensitisation should be sufficient to ensure safe use at the workplace. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation. |

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|---|---|---|---|
| | | 7 (Si-hydrolysis product)<br><br>Known or potential hazard<br>for aquatic toxicity<br>for EC 221-331-9, 221-339-2, 274-936-5, 404-020-4, 422-350-7 | | |
| 219-637-2<br><br>242-285-6<br><br>261-419-4<br><br>414-960-7<br><br>Substance 1<br><br>Substance 2<br><br>604-361-0<br><br>823-658-8<br><br>935-539-9 | Known or potential hazard<br>for reproductive toxicity<br>for ED<br>for EC: 414-960-7<br><br>for mutagenicity<br>242-285-6 (inactive)<br><br>No hazard or unlikely hazard<br>for the rest of the group members | Known or potential hazard<br>for aquatic toxicity and for PMT for EC 242-285-6, 261-419-4, 414-960-7, Substance 1, Substance 2 (Si-hydrolysis product), 604-361-0, 823-658-8 and 935-539-9.<br><br>Known or potential hazard<br>for aquatic toxicity and for PBT/vPvB for Substance 2 (parent) | IND uses where potential for exposure is low (intermediates) | No action<br><br>**Potential last action:**<br>**Currently no need for EU RRM**<br><br><u>Justification</u>:<br>The substances are either NONs, inactive registration or intermediate registration. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change |

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|---|---|---|---|
| | | Known or potential hazard<br>for ED for 414-960-7<br><br>No hazard or unlikely hazard for EC 219-637-2 | | |

# 3 Justification for the (no) need for regulatory risk management action at EU level (if hazard confirmed)

**Regulatory risk management at EU level**

ECHA is currently working on the assessment of regulatory needs for various groups of silanes. The silanes have been split in groups to facilitate the assessment of this large group of substances. Therefore, it was not possible to assess the potential interchangeability of the substances for some of their uses between groups. ECHA may need in the future to revisit the assessment considering all groups of silanes in order to account for the potential for substitution as this can impact the regulatory actions proposed in this assessment of regulatory needs.

**Based on currently available information, suggested regulatory risk management action** for mutagenicity and/or reproductive toxicity and/or ED HH/ENV and/or PBT/vPvB hazards due to the potential for release/ exposure of substances EC 214-189-4, 214-685-0, 220-941-2, 221-338-7, 240-212-2, 240-464-3, 240-465-9, 240-914-9, 249-385-9, 252-558-1, 402-580-4, 404-370-8 if these hazards are confirmed.

*Reproductive toxicity and ED properties*

Based on ECHA's assessment of hazard information currently available in the registration dossiers the following substances have (potentially) reproductive toxicity hazards: EC: 214-189-4, EC: 240-914-9, 214-685-0. EC: 220-941-2, EC: 252-558-1.

For EC: 214-189-4, the available information (OECD TG 421, OECD TG 422, OECD TG 408, OECD TG 414) reveals effects on fertility and development (i.e. prolonged gestation period, effects on sperm quality, histopathological and gross pathological effects on reproductive organs, fertility index, post-implantation loss, post-natal loss, decreased number of live pups, skeletal malformations), as well as effects on thyroid (follicular cell hypertrophy (dose-dependent; observed in the control with same severity), changes in T3 and TSH, and effects on testosterone levels and several testosterone-sensitive organs, that can be regarded as indications for possible endocrine-disrupting modes of action. The registrants have self-classified the substance as Repr. 1B for fertility. ECHA has assessed this information and considers, that taken together those effects raise also a concern for developmental toxicity and ED potential and may warrant a classification as Repr. 1B for both fertility and development and for ED Cat. 1.

For four group members: EC: 240-914-9, 214-685-0, the available data reveal changes in sperm morphology and motility, together with thyroid changes (follicular cell hypertrophy accompanied with thyroid hormone changes) and for EC: 220-941-2, EC: 252-558-1 potential for developmental neurotoxicity (effects on brain, spinal cord, peripheral nerves) have been indicated.
However, it has to be noted that, currently, there is a data generation ongoing (TPE for EOGRTS with DNT and DIT cohorts) for EC: 214-685-0, EC: 220-941-2 and EC: 252-558-1 and EC: 240-914-9 (TPE for 90-day repeated dose toxicity study), therefore, the hazards are not yet confirmed.

It has been hypothesised that the hazards exerted by EC: 214-189-4 are driven by the hydrolysis product - dimethylsilanediol (EC: 213-915-7), a substance with reproductive toxicity potential. The same hydrolysis product is formed by EC: 249-

385-9. Therefore, if the reproductive toxicity/ED potential of EC: 214-189-4 is confirmed by CLH, the hazard can be extrapolated to EC: 249-385-9.

Group members EC: 214-685-0 and EC: 240-914-9 release common hydrolysis product methylsilanetriol, EC: 219-489-9. Based on the lack of information on the toxicity of the hydrolysis product, as well as on the different toxicological behaviour of the substances, observed from the available data, it is highly uncertain to hypothesise that toxicity is carried only by the hydrolysis product. Therefore, currently, no extrapolation to other group members that form methylsilanetriol as a hydrolysis product (for details see Annex 4 Overview of potential hydrolysis products) is possible.

*Mutagenicity*

Based on ECHA's assessment of hazard information currently available in the registration dossiers the following substances have (potentially) mutagenicity hazards: EC: 214-189-4 and EC: 240-212-2. The substances were tested positive in *in vitro* gene mutation in mammalian cells test (TG 476). The potential hazard is still to be confirmed (TPEs for OECD TG 489).

In addition, group member EC: 240-212-2 has identified *known systemic toxicity hazard*, addressed by self-classification as STOT RE 1 (target organ: olfactory epithelium) and group member EC: 214-685-0) has a known hazard for skin sensitisation (self-classified as Skin sens. 1B, H317).

*PBT/vPvB*

Few substances in this group (i.e. 8 substances) have **potential PBT/vPvB hazards**, because the parent and/or the Si-containing hydrolysis products are potentially P/vP, potentially B/vB. More specifically:

- Among the short-chain alkoxysilanes, there is potential PBT/vPvB concern with the parent substance for EC 249-385-9.
- For the long-chain alkoxysilanes (C6-C18), there is potential PBT/vPvB concern for all substances i.e. EC 220-941-2, 221-338-7, 240-464-3, 240-465-9. The potential concern is with all Si-containing hydrolysis products of these substances, as well as with most of the parent substances (i.e. EC 220-941-2, 240-464-3 and 240-465-9).
- Among the branched and cyclic alkoxysilanes, there is potential PBT/vPvB concern with the parent substance for the following substances (i.e. EC 252-558-1, 402-580-4, 404-370-8).

*Persistency, mobility and toxicity*

The following 4 substances EC 214-189-4, 214-685-0, 240-212-2 and 240-914-9 have **potential persistency, mobility and toxicity hazards,** since the parent and/or the Si-containing hydrolysis products are potentially P/vP and potentially mobile based on screening information, as well as likely T (mostly with uncertainty due to data gaps for aquatic toxicity and/or human health). More specifically:

- Among the short-chain alkoxysilanes (C1-C4), there is potential persistency, mobility and toxicity hazard for EC 214-189-4, 214-685-0, 216-467-0 and 240-914-9. The potential concern is with all Si-containing hydrolysis products of these substances, as well as with the parent substances.
- For the alkoxy di-silanes i.e. EC 240-212-, there is potential persistency, mobility and toxicity hazard with the Si-containing hydrolysis products, as well as with all of the parent substance.

*ENV ED*

Few substances in this group (6 out of 47) have **potential ENV ED hazard** (with uncertainty) based on indications of ED properties from the available HH data, for which further HH data generation is ongoing or proposed (except from 214-189-4). These substances (from the short-chain alkoxysilanes sub-group) are 214-189-4, 214-685-0 and 249-385-9. For one substance in this group (EC 240-914-9) it is not possible to conclude on potential **ENV ED hazard** based on inconclusive indications of ED properties from the available HH data and for which further HH data generation is ongoing. For these substances, conclusion and further actions on ENV ED (potentially SEV) will be considered when the HH studies will be available.

*Plans for regulatory actions*

Except for EC 240-914-9, 402-580-4, 404-370-8, the substances are commonly used by professional workers and consumers in applications such as non-metal-surface treatment products, adhesives and sealants, coatings, and paints, etc. where there is a potential for exposure and releases to the environment. These uses also occur in industrial settings under conditions where there is a potential for exposure to workers and releases to the environment (industrial spraying, dipping & pouring, roller application and brushing).

Group members: EC 240-914-9, 402-580-4, 404-370-8 are used in industrial applications where the potential for exposure and releases in the environment can generally be considered of low concern (polymer preparations, laboratory or intermediates), however the information screened indicates that these uses do not take place under strictly controlled conditions and therefore releases to the environment cannot be excluded.

Data generation will be conducted first for all substances to clarify the hazards (Muta and/or Repr. and/or ED and/or PBT/vPvB, PMT); for ECs 214-685-0 Data generation will help to clarify the potential persistency and mobility (parent and hydrolysis product), 221-338-7 (parent), 252-558-1 (hydrolysis product) and 404-370-8 (hydrolysis product).

For the substances with potential PBT properties and potential Muta, Repr. or ED properties (all except EC 240-212-2 that only has potential Muta properties identified), the first step of the regulatory risk management action proposed, should the hazards exist, is the confirmation of hazard via harmonised classification (CLH) as mutagenic / toxic to reproduction, PBT, ED. For EC 240-212-2, This will not be necessary as no potential PBT or ED properties have been identified.

CLH is highly recommended as a step prior to restriction.

CLH i) will require company level risk management measures (RMM) under the occupational safety and health (OSH) legislation for workers to be in place, and ii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entries 28, 29 and 30. The CLH would have to consider other substances in the groups for which a potential for toxicity (Muta/Repr.) has been identified. When preparing the proposals, it may be considered what would be the best way to develop them, for instance whether to make a proposal for the group of substances, to submit them individually or jointly.

Confirmation of the hazard properties via CLH is not considered sufficient to minimise potential releases of the substances in the environment. Potential for release and exposure is expected in particular from consumer uses (e.g. adhesives,

sealants, fillers, putties, plasters and coatings) where releases to the environment cannot be avoided. The professional uses in polymer preparations for adhesives, fillers or coatings, ink and toners, textile dyes and impregnating products as well as in non-metal surface treatment products are expected to be widespread (at many sites and by many users) and typically non-contained and non-automated leading to releases to the environment and with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration leading to potential workers' exposure. In addition, professional users may be self-employed and therefore not covered by OSH legislation.

Consumers may be co-exposed to the substances used by professionals (polymer preparations for adhesives, fillers or coatings, ink and toners, textile dyes and impregnating products as well as in non-metal surface treatment products).

Therefore, a restriction of the substances as such or in mixtures (concentration limit in mixtures) used by consumers, professional workers, industrial workers is suggested after CLH, with the aim to minimise exposures and emissions to humans and the environment.

The use of PBT/vPvB and ED substances by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[5].

Moreover, as explained in section 1, potential exposure to the hydrolysis products of the substances via inclusion into articles (e.g. where the substances are used as adhesives, coatings, fillers, inks and surface treatment) needs further investigation. The need for restricting substances in articles used by professionals or consumers should be considered in the context of the restriction.

EC 249-385-9 forms the same hydrolysis product - dimethylsilanediol (EC: 213-915-7), as the group member EC: 214-189-4 that has identified reproductive/ED potential (see above). Therefore, this may warrant a classification as Repr. 1B; H360FD and for ED Cat. 1 also for EC 249-385-9.

EC 249-385-9 is registered only for its use by professional workers and consumers in cosmetic products. If Repr. and/or ED hazard is confirmed, a harmonised classification for reproductive toxicity would ensure appropriate action is taken under the Cosmetics Regulation and that its use in cosmetics is discontinued. This would also ensure that company level risk management measures are implemented to protect workers during the laboratory uses. These company level measures are likely to be sufficient to protect the workers against the ED hazards as well. In addition, while the hydrolysis product dimethylsilanediol is not PBT/vPvB, EC 249-385-9 itself is potentially PBT/vPvB. There is uncertainty on the PBT/vPvB potential and further data to clarify this hazard cannot be generated due to low tonnage. Therefore, currently no follow-up actions are proposed for this hazard. If the registration status changes, data generation and potentially follow up actions will be reconsidered when the assessment will be revisited. Furthermore, this hazard and potentially follow-up actions may be revisited when conclusive PBT/vPvB data will be available for more substances in this group (and in related silane groups), if extrapolation will be possible (currently there is no sufficient data density).

[5] European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

For EC 240-212-2, for which the main hazard is potential mutagenicity, considering its relative high registration tonnage, that mutagenicity is by default assumed to have a non-threshold mode of action and that some of the industrial uses can lead to significant exposure to workers, CLH may not be sufficient to ensure that adequate company level risk management measures are implemented. For this reason, restriction is also proposed to address the industrial uses and ensure workers protection. Compared with authorisation, this would allow for more flexibility in setting conditions and possible derogations for uses where the necessary RMMs to ensure safe use at the workplace are considered to be in place (e.g. semiconductors).

**Based on currently available information, no need to suggest (further) regulatory risk management actions for the rest of the substances in the group.**

As explained in the previous section, some group members form hydrolysis products some of which are hypothesised to be responsible for the observed hazards. The detail of the hydrolysis products and their associated potential hazards is not reported for each substance in this section but is available in Annex 4 Overview of potential hydrolysis products.

ECs: 201-083-8, 211-656-4, 211-659-0, 213-650-7, 213-926-7, 217-983-9, 219-842-7, 242-272-5, 251-995-5, 402-140-1, 402-810-3: these substances have known or potential aquatic toxicity. They have been registered at Annex IX or X and most of them are used in applications where releases to the environment are possible (for example non-metal-surface treatment products; adhesives, sealants; fillers, putties, plasters, modelling clay). In addition, ECs: 213-926-7, 217-983-9, 219-842-7, 242-272-5, 251-995-5, 402-140-1, 402-810-3 have potential PMT hazards. Compliance check is proposed to clarify the potential aquatic toxicity and where relevant persistency and mobility of the substances (i.e. ECs: 201-083-8, 217-983-9, 219-842-7, 251-995-5, 402-140-1, 402-810-3). It is expected that following data generation for aquatic toxicity registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use from that perspective. For the time being no EU regulatory risk management is proposed for these substances until there is clarity on the approach to persistent and mobile substances. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

EC 201-085-9 and EC 242-554-8: these substances have known or potential aquatic toxicity. EC 201-085-9 is also self-classified for skin sensitisation and is used in several applications in industrial and professional settings where, sufficient, and consistent self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation. EC 242-554-8 also has potential PMT hazard. This substance is used by consumers in cosmetic products. Compliance check is proposed to clarify the potential aquatic toxicity of both substances. It is expected that following data generation for aquatic toxicity registrants would adequately self-classify the substances and implement necessary RMMs to ensure safe use from that perspective. Due to low tonnage, further data to clarify the persistency and mobility cannot be generated for EC 242-554-8. Therefore, currently no follow-up actions are proposed for the PMT hazard. If the registration status changes, data generation and potentially follow up actions will be reconsidered when the assessment will be revisited.

EC 421-540-7, EC 439-360-2, EC 617-969-6: these substances have known or potential hazards (aquatic toxicity, STOT RE not related to neurotoxicity or immunotoxicity). In addition, they have potential PMT hazards. Group members: EC 421-540-7 and EC 439-360-2 are currently used in industrial or industrial-like

applications where the potential for exposure and to releases to the environment can be considered of low concern (polymer preparations). EC 421-540-7 also has a harmonised classification for skin sensitisation and aquatic toxicity which should be sufficient to ensure appropriate measures are taken for industrial uses. Group member EC 617-969-6 is used in applications where releases to the environment are possible (adhesives and sealants). Due to low tonnage, further data to clarify the PMT hazard cannot be generated. Therefore, currently no follow-up actions are proposed for the PMT hazard. If the registration status changes, data generation and potentially follow up actions will be reconsidered when the assessment will be revisited.

EC 217-370-6, EC 217-982-3, EC 242-171-6: based on ECHA's assessment of currently available hazard information, no potential hazards were identified for human health or the environment. Therefore, it is proposed that there is currently no need for EU RRM action on these substances. Data generation to confirm no or unlikely hazards for aquatic toxicity is proposed for EC 217-982-3.

EC 201-127-6, EC 216-467-0, EC 221-331-9, EC 221-339-2, EC 274-936-5, EC 404-020-4, EC 422-350-7: the main potential hazard for these substances is PBT and /or PMT hazards and for the first two substances also potential Repr. and ED. However, due to the registration status of these substances no further data generation can be done to clarify the PBT/PMT/Repr/ED of these substances. The hazards will be revisited and the need for EU RMM will be considered when data will be available for other substances in this group/other silane groups. Therefore, it is proposed that there is currently no need for EU RRM action on these substances.

Except for Substance 2 for which the environmental screening information are available (which has allowed to conclude on the environmental hazard), the following substances EC 219-637-2, EC 242-285-6, EC 261-419-4, EC 414-960-7, Substance 1, EC 604-361-0, EC 823-658-8, EC 935-539-9: there is no information on the hazard of these substances due to their registration status (NONs, inactive registration or intermediate registration,) and it is not possible to clarify the potential hazards. Therefore, it is proposed that there is currently no need for EU RRM action on these substances. If the registration status changes, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

# Annex 1: Overview of classifications

Data extracted on 18 February 2022

| EC/ List No | CAS No | Substance name | Harmonised classification | Classification in registrations |
|---|---|---|---|---|
| **201-083-8** | 78-10-4 | Tetraethyl orthosilicate | *Flam. Liquid 3 H226*<br>*Acute Tox. 4 H332*<br>*Eye Irrit. 2 H319*<br>*STOT Single Exp. 3 H335* | Flam. Liquid 3 H226<br>Acute Tox. 4 H332<br>Eye Irrit. 2 H319<br>STOT Single Exp. 3 H335 |
| **201-085-9** | 78-13-7 | Tetrakis(2-ethylbutyl) orthosilicate | | Skin Sens. 1B H317 |
| **201-127-6** | 78-62-6 | Diethoxy(dimethyl)silane | | Eye Irrit. 2 H319 [Article 10 (inactive)]<br>Skin Irrit. 2 H315 [Article 10 (inactive)]<br>Flam. Liquid 2 H225 |
| **211-656-4** | 681-84-5 | Tetramethyl orthosilicate | | Flam. Liquid 3 H226<br>Acute Tox. 1 H330<br>Skin Irrit. 2 H315<br>Eye Damage 1 H318 |
| **211-659-0** | 682-01-9 | Tetrapropyl orthosilicate | | - |
| **213-650-7** | 998-30-1 | Triethoxysilane | | Flam. Liquid 3 H226<br>Acute Tox. 4 H302<br>Acute Tox. 2 H330<br>Skin Irrit. 2 H315<br>Eye Damage 1 H318 |
| **213-926-7** | 1067-25-0 | Trimethoxypropylsilane | | Flam. Liquid 3 H226<br>Skin Irrit. 2 H315 |
| **214-189-4** | 1112-39-6 | Dimethoxydimethylsilane | | Flam. Liquid 2 H225 |
| **214-685-0** | 1185-55-3 | Trimethoxy(methyl)silane | | Flam. Liquid 2 H225 |
| **216-467-0** | 1591-02-2 | Dibutoxy(dimethyl)silane | | - |
| **217-370-6** | 1825-62-3 | Ethoxytrimethylsilane | | Flam. Liquid 2 H225 |
| **217-982-3** | 2031-62-1 | Diethoxy(methyl)silane | | Flam. Liquid 2 H225 |
| **217-983-9** | 2031-67-6 | Triethoxy(methyl)silane | | Flam. Liquid 3 H226 |
| **219-637-2** | 2487-90-3 | Trimethoxysilane | | Water React. Flam. Gas 3 H261 [intermediate (active)]<br>Flam. Liquid 2 H225 [intermediate (active)]<br>Acute Tox. 1 H330 [intermediate (active)]<br>Skin Corr. 1C H314 [intermediate (active)] |

| EC/ List No | CAS No | Substance name | Harmonised classification | Classification in registrations |
|---|---|---|---|---|
| **219-842-7** | 2550-02-9 | Triethoxypropylsilane | | Flam. Liquid 3 H226<br>Skin Irrit. 2 H315 |
| **220-941-2** | 2943-75-1 | Triethoxyoctylsilane | | Flam. Liquid 3 H226<br>Skin Irrit. 2 H315 |
| **221-331-9** | 3069-19-0 | Hexyltrimethoxysilane | | Flam. Liquid 3 H226<br>Skin Irrit. 2 H315<br>Skin Sens. 1B H317 |
| **221-338-7** | 3069-40-7 | Trimethoxyoctylsilane | | Acute Tox. 3 H332<br>Skin Irrit. 2 H315 |
| **221-339-2** | 3069-42-9 | Trimethoxyoctadecylsilane | | - |
| **240-212-2** | 16068-37-4 | 4,4,7,7-tetraethoxy-3,8-dioxa-4,7-disiladecane | | STOT Rep. Exp. 1 H372, affected organs: upper respiratory tract [Article 10 (inactive)]<br>Acute Tox. 3 H301<br>Acute Tox. 4 H312<br>STOT Rep. Exp. 1 H372<br>Aquatic Chronic 3 H412 |
| **240-464-3** | 16415-12-6 | Hexadecyltrimethoxysilane | | - |
| **240-465-9** | 16415-13-7 | Triethoxyhexadecylsilane | | - |
| **240-914-9** | 16881-77-9 | Dimethoxymethylsilane | | Flam. Liquid 2 H225 |
| **242-171-6** | 18293-82-8 | Isobutyldimethoxymethylsilane | | Flam. Liquid 3 H226<br>Skin Irrit. 2 H315 |
| **242-272-5** | 18395-30-7 | Trimethoxy(2-methylpropyl)silane | | Flam. Liquid 3 H226<br>Skin Irrit. 2 H315<br>STOT Single Exp. 3 H336 |
| **242-285-6** | 18406-41-2 | 3,3,6,6-tetramethoxy-2,7-dioxa-3,6-disilaoctane | | Aquatic Chronic 3 H412 [Article 10 (inactive)]<br>Acute Tox. 1 H330 [Article 10 (inactive)]<br>Skin Irrit. 2 H315 [Article 10 (inactive)]<br>Muta. 2 H341 [Article 10 (inactive)] |
| **242-554-8** | 18748-98-6 | Trimethyl(octadecyloxy)silane | | - |
| **249-385-9** | 29043-70-7 | Dimethylbis(octadecyloxy)silane | | - |
| **251-995-5** | 34396-03-7 | Trimethoxy(2,4,4-trimethylpentyl)silane | | Flam. Liquid 3 H226 |
| **252-558-1** | 35435-21-3 | Triethoxy(2,4,4-trimethylpentyl)silane | | Flam. Liquid 3 H226 |
| **261-419-4** | 58751-56-7 | 5-hexenyltrimethoxysilane | | Eye Irrit. 2 H319 [intermediate (active)] |
| **274-936-5** | 70851-50-2 | Dimethoxymethyloctadecylsilane | | - |
| **402-140-1** (629-092-6*) | 17865-32-6 | Cyclohexyldimethoxymethylsilane | *Skin Irrit. 2 H315* | Skin Irrit. 2 H315<br>Aquatic Chronic 2 H411 |

| EC/ List No | CAS No | Substance name | Harmonised classification | Classification in registrations |
|---|---|---|---|---|
| | | | *Aquatic Chronic 2 H411* | |
| **402-580-4** (682-466-0*) | 111439-76-0 | Isobutylisopropyldimethoxysilane | *Flam. Liquid 3 H226*<br>*Acute Tox. 4 H332*<br>*Skin Irrit. 2 H315* | Flam. Liquid 3 H226<br>Acute Tox. 4 H332<br>Skin Irrit. 2 H315 |
| **402-810-3** (605-871-6*) | 17980-47-1 | Triethoxyisobutylsilane | *Skin Irrit. 2 H315* | Skin Irrit. 2 H315 |
| **404-020-4** | - | Bis(2-methylpropyl)dimethoxysilane | | Aquatic Chronic 2 H411 |
| **404-370-8** (620-337-2*) | 126990-35-0 | Dicyclopentyldimethoxysilane | *Skin Irrit. 2 H315*<br>*Eye Damage 1 H318*<br>*Aquatic Acute 1 H400*<br>*Aquatic Chronic 1 H410* | Skin Irrit. 2 H315<br>Eye Damage 1 H318<br>Aquatic Acute 1 H400<br>Aquatic Chronic 1 H410 |
| **414-960-7** (691-550-6*) | 53863-99-3 | Bis(1,1-dimethyl-2-propynyloxy)dimethylsilane | *Acute Tox. 4 H332* | - |
| **Substance 1** | - | Not (publicly) available | | |
| **421-540-7** (620-530-1*) | 18230-61-0 | Bis(1-methylethyl)-dimethoxysilane | *Flam. Liquid 3 H226*<br>*Skin Irrit. 2 H315*<br>*Skin Sens. 1 H317*<br>*Aquatic Chronic 3 H412* | Flam. Liquid 3 H226<br>Skin Irrit. 2 H315<br>Skin Sens. 1 H317<br>Aquatic Chronic 3 H412 |
| **422-350-7** | 5575-48-4 | Decyltrimethoxysilane | | Skin Irrit. 2 H315<br>Eye Irrit. 2 H319<br>Aquatic Chronic 3 H412 |
| **439-360-2** | 142877-45-0 | (2,3-dimethylbut-2-yl)-trimethoxysilane | *Skin Irrit. 2 H315*<br>*Eye Damage 1 H318*<br>*Aquatic Chronic 3 H412* | Flam. Liquid 3 H226<br>Skin Irrit. 2 H315<br>Eye Damage 1 H318<br>Aquatic Chronic 3 H412 |
| **Substance 2** | - | [No public or meaningful name is available] | | |
| **604-361-0** | 143487-47-2 | cyclopentyl(trimethoxy)silane | | Aquatic Chronic 2 H411 [intermediate (active)]<br>Skin Irrit. 2 H315 [intermediate (active)]<br>Flam. Liquid 3 H226 [intermediate (active)]<br>Aquatic Acute 2 H401 [intermediate (active)] |

| EC/ List No | CAS No | Substance name | Harmonised classification | Classification in registrations |
|---|---|---|---|---|
| **617-969-6** | 87135-01-1 | 2,11-Dioxa-3,10-disiladodecane, 3,3,10,10-tetramethoxy- | | STOT Rep. Exp. 1 H372, affected organs: bladder |
| **823-658-8** | 17888-62-9 | 1-(trimethylsilyloxy)-hexane | | Eye Irrit. 2 H319 [intermediate (active)]<br>STOT Single Exp. 3 H335, affected organs: repiratory tract [intermediate (active)]<br>Flam. Liquid 3 H226 [intermediate (active)]<br>Skin Irrit. 2 H315 [intermediate (active)] |
| **935-539-9** | - | [No public or meaningful name is available] | | Flam. Liquid 3 H226 [intermediate (active)]<br>STOT Rep. Exp. 1 H372 [intermediate (active)]<br>Acute Tox. 4 H312 [intermediate (active)]<br>Aquatic Chronic 3 H412 [intermediate (active)]<br>Acute Tox. 3 H301 [intermediate (active)] |

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers, therefore the number may differ from the C&L inventory which displays number of notifiers.

# Annex 2: Overview of uses based on information available in registration dossiers

Data extracted on 18 February 2022

From the information available on the substances and/or similar substances within the group, we have assumed that article service life is of relevance to the assessment of the substances within this group. Therefore, the assessment of regulatory needs has considered those uses relevant. Industry should update their registration dossiers and clarify whether or not these uses should be reported for this substance and if not bring sufficient justification for not considering those uses. If no additional information is provided at the next iteration of the assessment those uses will be considered for further regulatory risk management.

Article service life: according to the information provided, the substances in this group react and hydrolyse very rapidly. This means that in most use situations, the parent substance is very unlikely to end-up in articles manufactured or treated with the substance. However, if it is possible that the reaction or hydrolysis products end-up in articles, the registrant should report article service life in their dossier.

This is particularly relevant for substances used in applications/uses such as:

- PC 15: Non-metal-surface treatment products
- PC 32: Polymer preparations and compounds
- PC 1: Adhesives, sealants
- PC 9c: Finger paint
- PC 9b: Fillers, putties, plasters, modelling clay
- PC 9a: Coatings and paints, thinners, paint removes
- PC 18: Ink and toners
- PC 34: Textile dyes, and impregnating products
- PC 14: Metal surface treatment products
- PC 33: Semiconductors

In the dossiers screened, article service life was identified for some substances but not consistently. The level of analysis conducted during the screening exercise did not allow to confirm or exclude the presence of hydrolysis products in articles. Therefore, a worst-case approach was taken, and article service life was added (where not reported by the registrant) to substances used in the product categories (PC) mentioned above. It should however be noted that this cannot directly be understood as an indication for potential exposure or potential releases to the environment. This potential will depend on factors such as the presence of the substance on the surface of the article or its concentration and migration rate in the matrix.

Industry should update their registration dossiers and clarify whether or not these uses should be reported for the substances and if not, bring sufficient justification for not considering those uses. For substances where article service life is justified, the registrants should also clarify its relevance in terms of potential for exposure and releases to the environment and, where necessary, provide an exposure assessment. If no additional information is provided at the next iteration of the assessment, those uses will be considered for further regulatory risk management.

| Main types of applications structured by product or article types | PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents | PC 4: Anti-freeze and de-icing products | PC 28: Perfumes, fragrances | PC 3: Air care products | PC 39: Cosmetics, personal care products | PC 29: Pharmaceuticals | PC 31: Polishes and wax blends | PC 15: Non-metal-surface treatment products | PC 24: Lubricants, greases, release products | PC 16: Heat transfer fluids | PC 17: Hydraulic fluids | PC 32: Polymer preparations and compounds | PC 1: Adhesives, sealants | PC 9c: Finger paint | PC 9b: Fillers, putties, plasters, modelling clay | PC 9a: Coatings and paints, thinners, paint removes | PC 18: Ink and toners | PC 34: Textile dyes, and impregnating products | PC 14: Metal surface treatment products | PC 33: Semiconductors | PC 21: Laboratory chemicals | PC 19: Intermediate |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **201-083-8** | I, **P** | F, I | | | | | | F, I, **A** | | I | | F, I, **P**, **C**, **A** | F, I, **P**, **C**, **A** | I, **A** | F, I, **P**, **C**, **A** | F, I, **P**, **C**, **A** | | | F, I, **A** | I, **A** | I, **P** | F, I |
| **201-085-9** | | | | | | | | | I, **P** | I, **P** | I, **P** | | | | | | | | | | | |
| **201-127-6** | | | | | | | | | | | | F, I, **A** | | | | | | | | | I | F, I |
| **211-656-4** | F, I | | | | | | | | | | | F, I, **A** | F, I, **P**, **C**, **A** | | | F, I, **P**, **C**, **A** | | | | | I, **P** | F, I |
| **211-659-0** | | | | | | | | | | | | I, **P**, **A** | F, I, **P**, **C**, **A** | | | F, I, **P**, **C**, **A** | | | | | I | F, I |
| **213-650-7** | | | | | | | | | | | | | | | | | | | | | I | I |
| **213-926-7** | I | | | | | | | F, I, **A** | | | | I, **A** | F, I, **A** | | F, **P**, **A** | | | | | | I, **P** | F, I |
| **214-189-4** | | | | | | | | F, I, **A** | | | | F, I, **A** | F, I, **A** | | | I, **A** | | | | I, **A** | I | I |
| **214-685-0** | | | | | | | | F, I, **A** | | F, I | | F, I, **P**, **C**, **A** | F, I, **P**, **C**, **A** | | | F, I, **P**, **C**, **A** | | F, I, **P**, **C**, **A** | | F, I, **A** | I, **P** | F, I |
| **216-467-0** | | | | | | | | | | | | | | | | F, I, **A** | | | | | | |
| **217-370-6** | | | | | | | | F, I, **A** | | | | F, I, **A** | F, I, **P**, **C**, **A** | | F, I, **A** | F, I, **A** | F, I, **A** | | | | I, **P** | F, I |

| | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **217-982-3** | | | | | | | | | | | | I, **A** | | | | F, I, **A** | | | | I | I | F, I |
| **217-983-9** | | | | | | | | F, I, **A** | | | | F, I, **P, C, A** | F, I, **P, C, A** | | F, I, **P, C, A** | F, I, **P, C, A** | F, I, **P, A** | | | I, **A** | I, **P** | I |
| **219-637-2** | | | | | | | | | | | | | | | | | | | | | | I |
| **219-842-7** | F, I | | | | | | | F, I, **A** | | | | F, I, **A** | F, I, **P** | | F, I, **P, A** | F, I, **P, A** | | | | | I, **P** | F, I |
| **220-941-2** | | | F, I, **C** | I | F, I, **P, C** | I, **C** | I | F, I, **P, C, A** | | | | F, I, **P, C, A** | F, I, **P, C, A** | I, **A** | F, I, **P, C, A** | F, I, **P, C, A** | F, I, **P, C, A** | | I, **A** | F, I, **A** | I, **P** | I |
| **221-331-9** | | | | | | | | F, I, **A** | | | | | | | | | F, **C, A** | | | | | |
| **221-338-7** | | | | | | | | F, I, **A** | | | | I, **A** | F, I, **A** | | | | | | | | I | I |
| **221-339-2** | | | | | | | | I, **A** | | | | | | | | | | | | | I | I |
| **240-212-2** | | | | | | | | F, I, **A** | | | | F, I, **A** | F, I, **P, A** | | | F, I, **P, A** | | | F, I, **A** | F, I, **A** | I | I |
| **240-464-3** | | | | | F, **P, C** | | | F, I, **P, C, A** | | | | F, I, **A** | F, I, **P, C, A** | | | F, I, **P, C, A** | | | | | I | I |
| **240-465-9** | | | | | | | | I, **A** | | | | F, I, **A** | | | I, **A** | | | | | | | |
| **240-914-9** | | | | | | | | | | | | | | | | | | | | | I, **P** | I |
| **242-171-6 *** | | | | | | | | | | | | | | | | | | | | | | |
| **242-272-5** | | | | | | | | I, **A** | | | | | I, **A** | | | | P, **C, A** | | | | I, **P** | I |
| **242-285-6** | | | | | | | | | | | | I, **A** | | | | | | | | | | |
| **242-554-8** | | | | | F, **C** | | | | | | | | | | | | | | | | | |
| **249-385-9** | | | | | F, **P, C** | | | | | | | | | | | | | | | | I | |
| **251-995-5** | | | | | | | | | | | | | F, I, **P, C, A** | | F, I, **P, C, A** | F, I, **P, C, A** | | | | | I | I |
| **252-558-1** | | | | | | | | | | | | | | | F, I, **P, C, A** | F, **P, A** | | | | | I | |

| | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **261-419-4** | | | | | | | | | | | | | | | | | | | | | I |
| **274-936-5** | | | | | | | | F, I, **A** | | | | | | | | | | | | I | I |
| **402-140-1** | F, I | | | | | | | I, **A** | | | | F, I, **A** | | | | | | | | I | |
| **402-580-4** | | | | | | | | | | | | I, **A** | | | | | | | | | |
| **402-810-3** | | | | | | | | | | | | | | | F, I, **P**, **C**, **A** | | | | | I | I |
| **404-020-4** | | | | | | | | | | | | I, **A** | | | | | | | | | |
| **404-370-8** | F, I | | | | | | | | | | | F, I, **A** | | | | | | | | I | F, I |
| **414-960-7 **** | | | | | | | | | | | | | | | | | | | | | |
| **Substance 1 **** | | | | | | | | | | | | | | | | | | | | | |
| **421-540-7** | | | | | | | | | | | | I, **A** | | | | | | | | | |
| **422-350-7** | | | | | | | | | | | | | | | | | F, I, **P**, **C**, **A** | | | | |
| **439-360-2** | | | | | | | | | | | | I, **A** | | | | | | | | | |
| **Substance 2 **** | | | | | | | | | | | | | | | | | | | | | |
| **604-361-0** | | | | | | | | | | | | | | | | | | | | I | I |
| **617-969-6** | | | | | | | | | | | | | F, I, **P**, **A** | | | | | | | I | |
| **823-658-8** | | | | | | | | | | | | | | | | | | | | | I |
| **935-539-9** | | | | | | | | | | | | | | | | | | | | I | I |

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release
*: substance directly exported.
**: NONs

# Annex 3: Overview of completed or ongoing regulatory risk management activities

Data extracted on 23 June 2022

| EC / List number | RMOA | Authorisation | | Restriction* | CLH | Actions not under REACH / CLP |
|---|---|---|---|---|---|---|
| | | Candidate list | Annex XIV | Annex XVII | Annex VI (CLP) | |
| **201-083-8** | | | | | YES | |
| **214-685-0** | | | | | YES, not added | |
| **402-140-1** (629-092-6*) | | | | | YES | |
| **402-580-4** (682-466-0*) | | | | | YES | |
| **402-810-3** (605-871-6*) | | | | | YES | |
| **404-370-8** (620-337-2*) | | | | | YES | |
| **414-960-7** (691-550-6*) | | | | | YES | |
| **421-540-7** (620-530-1*) | | | | | YES | |
| **439-360-2** | | | | | YES | |

There are no relevant completed or ongoing regulatory risk management activities for the other substances.

# Annex 4: Overview of potential hydrolysis products

Overview of hydrolysis information (rate at pH 7 and Si-containing hydrolysis products), together with the potential PBT/vPvB, PMT and HH/ENV ED hazards identified for the Si-containing hydrolysis products of the substances in this group.

| EC number | Hydrolysis rate at pH 7 | Si-containing hydrolysis product | Potential PBT/vPvB, PMT and/or ED hazards ( Si-hydrolysis prod.) |
|---|---|---|---|
| | | **Tetraalkoxysilanes** | |
| 201-083-8 | **DT50 = 4.4h** (OECD 111) | **silicic acid** | Not PBT/vPvM nor PMT |
| 201-085-9 | No info | | |
| 211-656-4 | **DT50 < 3min** (experiment, no TG) | | |
| 211-659-0 | **DT50 = 6.7h** (OECD 111) | | |
| | | **Hydro-trialkoxy-silanes** | |
| 213-650-7 | **DT50 = 0.7h** (QSAR) | silanetriol further hydrolysing to **silicic acid** | Not PBT/vPvM nor PMT |
| 219-637-2 | **DT50 < 0.3min** (OECD 111) | | |
| | | **Short-chain alkoxy silanes** | |
| 214-685-0 | **DT50 = 2.2h** (OECD 111) | **methylsilanetriol** (C1) | Pot. PMT |
| 217-983-9 | **DT50 = 5.5h** (QSAR) | | |
| 217-982-3 | **DT50 <2min** (EU C.7) | methylsilanediol further hydrolysing to **methylsilanetriol** (C1) (final hydrolysis product, emerging immediately at pH 7 and 9 in study with EC 217-982-3) | Pot. PMT |
| 240-914-9 | **DT50 = 0.3h** (QSAR) | | |
| 201-127-6 | **DT50 = 5.5h** (QSAR) | **dimethylsilanediol** (2xC1) | Pot. PMT, Pot. HH/ENV ED, Repr |
| 214-189-4 | **DT50 < 0.6h** (OECD 111) | | |
| 216-467-0 | **DT50 = 1.4h** (OECD 111) | | |
| 249-385-9 | **DT50 > 15h** (QSAR) | | |
| 414-960-7 | No info | | |
| 217-370-6 | **DT50 = 2.2min** (EU C.7) | **trimethylsilanol** (3xC1) | Pot. PMT |
| 242-554-8 | No info | | |
| 823-658-8 | No info | | |
| 213-926-7 | **DT50 = 2.6h** (QSAR) | **propylsilanetriol** (C3) | Pot. PMT |
| 219-842-7 | **DT50 = 1.4d** (OECD 111) DT50 = 21.8h (QSAR) | | |
| **Substance 1** | No info | not (publicly) available | Pot. PMT |
| | | **Long-chain alkoxy silanes** | |
| 221-331-9 | **DT50 = 3.3h** (QSAR) | **hexylsilanetriol** (C6) | Pot. PBT/vPvB |
| 220-941-2 | **DT50 = 30h** (QSAR) | **octylsilanetriol** (C8) | Pot. PBT/vPvB |
| 221-338-7 | **DT50 = 4h** (QSAR) | | |
| 422-350-7 | No info | **decylsilanetriol** (C10) | Pot. PBT/vPvB |
| 240-464-3 | **DT50 > 14d** (OECD 111) | **hexadecylsilanetriol** (C16) | Pot. PBT/vPvB |
| 240-465-9 | **DT50 = 58.4 h** (QSAR) | | |
| 221-339-2 | **DT50 = 9.3 h** (QSAR) | **octadecylsilanetriol** (C18) | Pot. PBT/vPvB |
| 274-936-5 | **DT50 = 2.6h** (QSAR) | **methyloctadecylsilanediol** (C1 and C18) | Pot. PBT/vPvB |

| EC number | Hydrolysis rate at pH 7 | Si-containing hydrolysis product | Potential PBT/vPvB, PMT and/or ED hazards ( Si-hydrolysis prod.) |
|---|---|---|---|
| | | **Cyclic alkoxy silanes** | |
| 604-361-0 | No info | **cyclopentylsilanetriol** (C5 cyclic) | Pot. PMT |
| 402-140-1 | **DT50 = 19h** (RA from 404-370-8) | **cyclohexylmethylsilanediol** (C6 cyclic) | Pot. PMT |
| 404-370-8 | **DT50 = 19h** (EU C.7) | **dicyclopentylsilanediol** (2xC5 cyclic) | Pot. PMT |
| | | **Branched alkoxy silanes** | |
| 242-272-5 | **DT50 = 4.1h** (QSAR) | **isobutylsilanetriol** (C4 branched) | Pot. PMT |
| 402-810-3 | **DT50 = 21.7h** (QSAR) | | |
| 251-995-5 | **DT50 = 5.7h** (QSAR) | **(2,4,4-trimethylpentyl)silanetriol** (C8 branched) | Pot. PMT |
| 252-558-1 | **DT50 = 43h** (QSAR) | | |
| 439-360-2 | DT50 = 40.9h at pH 4 and 523.2h at pH 9 (experimental, no TG) | **(1,1,2-trimethylpropyl)silanetriol** (C6 branched) | Pot. PMT |
| 421-540-7 | **DT50 = 141.6h** (OECD 111) | **diisoproylsilanediol** (C3 branched) | Pot. PMT |
| 242-171-6 | **DT50 = 1.7h** (QSAR) | **isobutyl(methyl)silanediol** (C1 and C4 branched) | Unlikely PMT (Pot. PM) |
| 402-580-4 | **DT50 = 45.9h** (OECD 111) | **Isobutylisopropylsilanediol** (C3 and C4 branched) | Unlikely PMT (Pot. PM) |
| 404-020-4 | **DT50 = 15.35h** (OECD TG 111) | **di-isobutylsilanediol** (C4 branched) | Pot. PMT |
| Substance 2 | **DT50 =60.8 h** (OECD 111) | Not (publicly) available | Pot. PMT |
| | | **Alkenyl alkoxy silanes** | |
| 261-419-4 | No info | **5-hexenylsilanetriol** (C6 unsaturated) | Pot. PMT |
| | | **Alkoxy di-silanes** | |
| 240-212-2 | **DT50 = 36h** (QSAR) | **1,1,1,4,4,4-hexahydroxy-1,4-silabutane** | Pot. PMT |
| 242-285-6 | No info | | |
| 935-539-9 | No info | No name available | Pot. PMT |
| 617-969-6 | **DT50 = 5.2 h** (OECD 111) | **1,6-bis(trihydroxysilyl)hexane** | Pot. PMT |