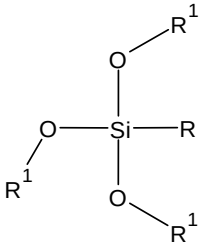
Assessment of regulatory needs

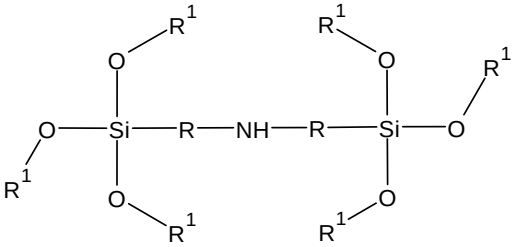
Authority: European Chemicals Agency (ECHA)

Group Name: Amino alkoxysilanes and amino siloxanes

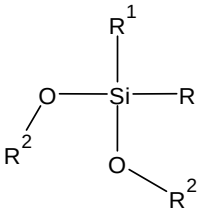
General structures:



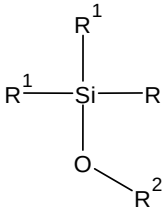
R = aminoalkyl, alkyl-, cyclohexyl- or phenyl-aminoalkyl, polyalkylamino
R^1 = methyl or ethyl



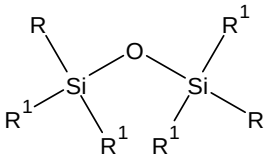
R = alkyl
R^1 = methyl or ethyl



R = aminoalkyl, cyclohexyl- or phenyl-aminoalkyl, polyalkylamino
R^1 = alkyl
R^2 = methyl or ethyl



R = aminoalkyl or polyalkylamino
R^1 = alkyl
R^2 = methyl

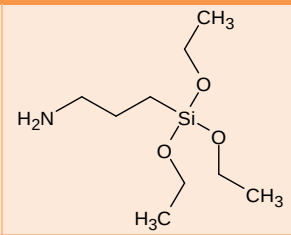
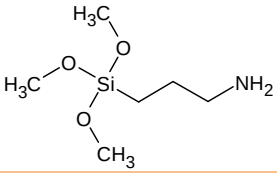
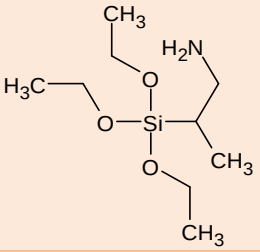
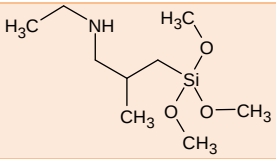
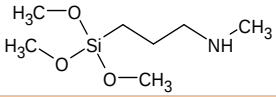
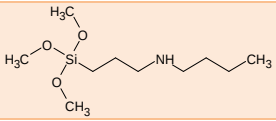
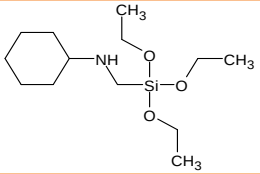


R = aminoalkyl
R^1 = methyl

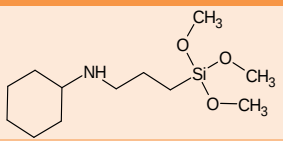
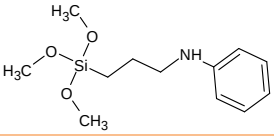
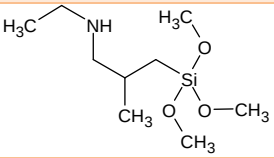
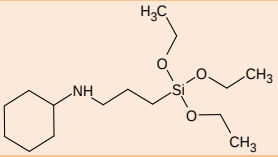
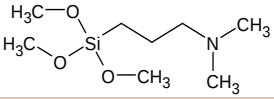
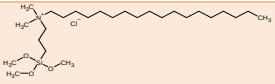
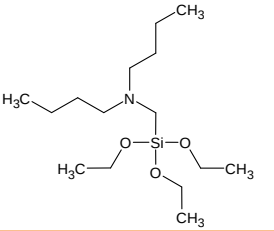
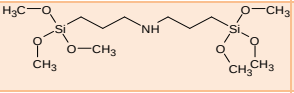
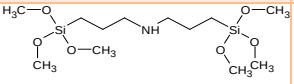
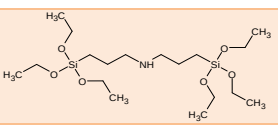
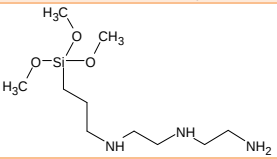
Revision history

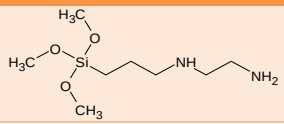
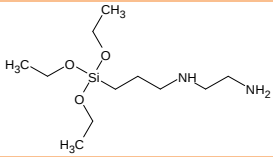
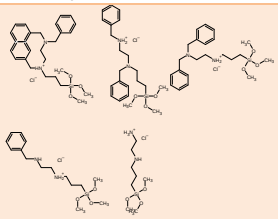
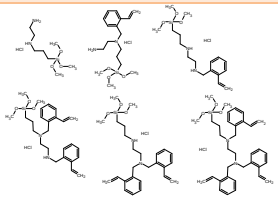
Version	*Date*	*Description*
1.0	11 March 2024	

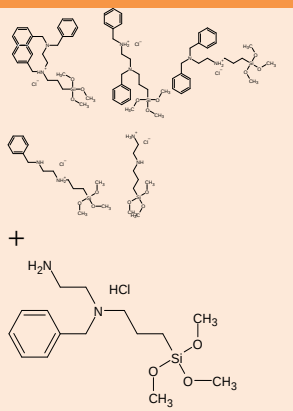
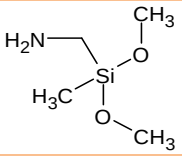
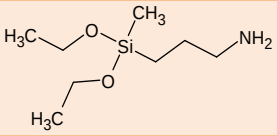
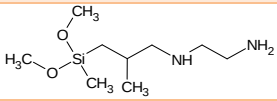
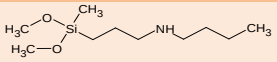
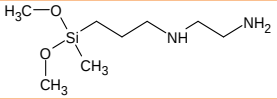
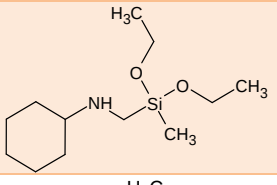
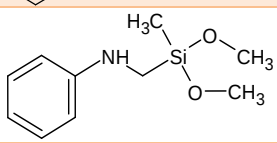
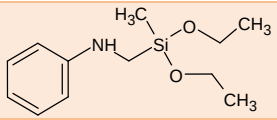
Substances within this group:

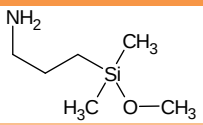
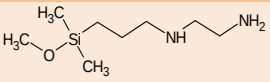
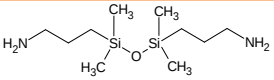
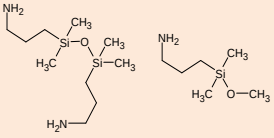
EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
213-048-4	919-30-2	3-aminopropyltriethoxysilane		Full, >1000
237-511-5	13822-56-5	3-(trimethoxysilyl)propylamine		Full, >1000
253-288-7	36957-84-3	2-(triethoxysilyl)propylamine		Not registered
436-680-4	-	Y-11637	-	NONS
607-140-7	227085-51-0	*N*-ethyl-3-trimethoxysilyl-2-methyl-propanamine		Not registered
221-334-5	3069-25-8	*N*-methyl-3-(trimethoxysilyl)propylamine		Full, not (publicly) available
250-437-8	31024-56-3	*N*-[3-(trimethoxysilyl)propyl]butylamine		Full, 100-1000
247-744-4	26495-91-0	*N*-[(triethoxysilyl)methyl]cyclohexylamine		Full, not (publicly) available

[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 number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
221-329-8	3068-78-8	*N*-[3-(trimethoxysilyl)propyl]cyclohexanamine		Full, not (publicly) available
221-328-2	3068-76-6	*N*-[3-(trimethoxysilyl)propyl]aniline		Full, not (publicly) available
480-000-9	-	GENIOSIL XL 973	-	NONS
437-720-3	227085-51-0	*N*-ethyl-3-trimethoxysilyl-2-methyl-propanamine Y-15167		NONS
601-682-8	120218-26-0	*N*-[3-(triethoxysilyl)propyl]cyclohexanamine		Not registered
219-786-3	2530-86-1	*N*,*N*-dimethyl-3-(trimethoxysilyl)propylamine		Full, not (publicly) available
248-595-8	27668-52-6	dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride		Full, not (publicly) available
810-490-5	35501-23-6	*N*-butyl-*N*-[(triethoxysilyl)methyl]butan-1-amine		Full, not (publicly) available
280-084-5(*)	82985-35-1	3-(trimethoxysilyl)-*N*-[3-(trimethoxysilyl)propyl]propan-1-amine		Full, 100-1000
403-480-3(*)	-	3-(trimethoxysilyl)-*N*-[3-(trimethoxysilyl)propyl]propan-1-amine		NONS
236-818-1	13497-18-2	3-(triethoxysilyl)-*N*-[3-(triethoxysilyl)propyl]propan-1-amine		Full, 100-1000
252-390-9	35141-30-1	*N*-(2-aminoethyl)-*N*′-[3-(trimethoxysilyl)propyl]ethylenediamine		Full, not (publicly) available

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
217-164-6	1760-24-3	*N*-(3-(trimethoxysilyl)propyl)ethylenediamine		Full, 100-1000
225-806-1	5089-72-5	*N*-[3-(triethoxysilyl)propyl]ethylenediamine		Full, 10-100
700-961-2	-	Reaction mass of 2-{[3-(trimethoxysilyl)propyl]amino}ethanaminium chloride and N-[2-(benzylamino)ethyl]-3-(trimethoxysilyl)propan-1-aminium chloride and N-[2-(dibenzylamino)ethyl]-3-(trimethoxysilyl)propan-1-aminium chloride and N-benzyl-2-{benzyl[3-(trimethoxysilyl)propyl]amino}ethanaminium chloride and N-benzyl-N-[2-(dibenzylamino)ethyl]-3-(trimethoxysilyl)propan-1-aminium chloride		Full, not (publicly) available
605-620-0	171869-89-9	1,2-Ethanediamine, N-{3-(trimethoxysilyl)propyl}-,N-{(ethenylphenyl)methyl}derivate,hydrochlorides Reaction Mass of 3-(2-aminoethylamino)propyltrimethoxysilane hydrochloride and (2-aminoethyl)[(vinylphenyl)methyl][3- (trimethoxysilyl)propyl] amine hydrochloride and N-[3-(trimethoxysilyl)propyl]-N'-(vinylbenzyl)-1,2-ethanediamine hydrochloride and N-[3-(trimethoxysilyl)propyl]-N,N'-di(vinylbenzyl)-1,2-ethanediamine hydrochloride and N-[3- (trimethoxysilyl)propyl]-N',N'-di(vinylbenzyl)-1,2-ethanediamine hydrochloride and N-[3-(trimethoxysilyl)propyl]-N,N',N'-tri(vinylbenzyl)-1,2-ethanediamine hydrochloride		Full, not (publicly) available

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
414-340-6		**ELINCS:** reaction mass of: N-(3-(trimethoxysilyl)propyl)ethylenediamine; N-benzyl-N-(3-trimethoxysilyl)propyl)ethylenediamine; N-benzyl-N'-[3-(trimethoxysilyl)propyl]ethylenediamine; N,N'-bis-benzyl-N'-[3-(trimethoxysilyl)propyl]ethylenediamine; N,N,N'-tris-benzyl-N'-[3-(trimethoxysilyl)propyl]ethylenediamine; N,N-bis-benzyl-N'-[3-(trimethoxysilyl)propyl]ethylenediamine		NONS
812-377-6	343926-26-1	1-[dimethoxy(methyl)silyl]methanamine		OSII or TII
221-660-8	3179-76-8	3-(diethoxymethylsilyl)propylamine		Full, 100-1000
245-642-4	23410-40-4	N-[3-(dimethoxymethylsilyl)-2-methylpropyl]ethylenediamine		Full, not (publicly) available
601-747-0	120939-52-8	N-{3-[dimethoxy(methyl)silyl]propyl}butan-1-amine		Full, not (publicly) available
221-336-6	3069-29-2	N-{3-[dimethoxy(methyl)silyl]propyl}ethane-1,2-diamine		Full, 100-1000
608-099-8	27445-54-1	N-{[diethoxy(methyl)silyl]methyl}cyclohexanamine		C&L notification
457-680-0	17890-10-7	N-{[dimethoxy(methyl)silyl]methyl}aniline		OSII or TII
454-780-6	27445-54-1	N-{[diethoxy(methyl)silyl]methyl}aniline		Full, not (publicly) available

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
608-570-8	31024-26-7	3-[methoxy(dimethyl)silyl]propan-1-amine		OSII or TII
221-337-1	3069-33-8	N-[3-(methoxydimethylsilyl)propyl]ethylenediamine		Full, not (publicly) available
219-588-7	2469-55-8	EINECS name: 3,3'-(1,1,3,3-tetramethyldisiloxane-1,3-diyl)bispropylamine		Full, not (publicly) available
938-245-9	-	Reaction mass of 3-[methoxy(dimethyl)silyl]propan-1-amine and 3,3'-(1,1,3,3-tetramethyldisiloxane-1,3-diyl)dipropan-1-amine		OSII or TII

(*) When a dossier is submitted without EC/List number, a new or existing EC/List number will be assigned to the substance. Sometimes, due to IT technical limitations, duplicate EC/List numbers are created during this submission process. In this Group the following are considered duplicate entries: EC 280-084-5 is a duplicate of NONS with EC 403-480-3.

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. Assessments 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

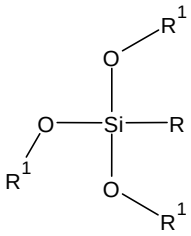
Glossary

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
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

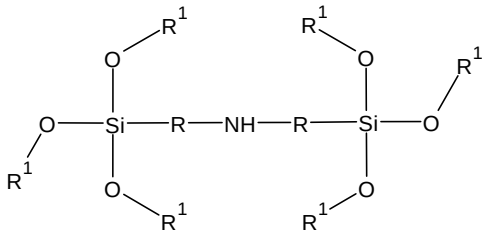
1 Overview of the group

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

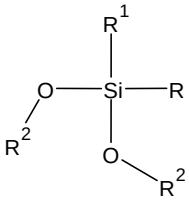
ECHA has grouped together **37** structurally similar substances based on the presence of silicone tetrasubstituted with various substituents, all containing an "*aminoalkyl*" (or *N*-substituted aminoalkyl) moiety, as shown in the figure below:



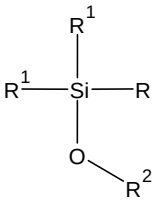
R = aminoalkyl, alkyl-, cyclohexyl- or phenyl-aminoalkyl, polyalkylamino
R^1 = methyl or ethyl



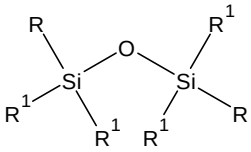
R = alkyl
R^1 = methyl or ethyl



R = aminoalkyl, cyclohexyl- or phenyl-aminoalkyl, polyalkylamino
R^1 = alkyl
R^2 = methyl or ethyl



R = aminoalkyl or polyalkylamino
R^1 = alkyl
R^2 = methyl



R = aminoalkyl
R^1 = methyl

The registration status of the substances is the following: **24** with full (Article 10) registrations, **4** intermediate registrations and **5** NONS. Additionally, **3** substances are not registered and **1** is only notified under the CLP Regulation.

Based on information reported in the REACH registration dossiers, **10** substances have only industrial uses with limited potential for exposure and releases, mainly used as intermediates or as laboratory chemicals. For the majority of substances in the group the registrants indicate professional, consumer and article uses across several product categories, mainly uses in cosmetics, washing and cleaning products, polymer preparations, adhesives, sealants, fillers and putties, coatings and paints. Substances are used mainly as cross-linking agents, adhesion promotors or stabilisers. These uses are considered widespread with potential for exposure for humans and the environment.

2 Conclusions and actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (*e.g.*, strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). 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 may be updated, and conclusions and actions revisited.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
213-048-4 217-164-6 219-588-7 219-786-3 221-328-2 221-329-8 221-334-5 221-336-6 221-337-1 221-660-8 225-806-1 236-818-1	Known or potential hazard for mutagenicity 457-680-0 480-000-9 for STOT RE 2 217-164-6 457-680-0 480-000-9 for skin sensitisation for all substances Inconclusive hazard for Repro and ED 213-048-4 237-511-5 812-377-6	Known or potential hazard for aquatic toxicity 219-588-7 248-595-8 280-084-5 605-620-0 700-961-2 Inconclusive hazard for aquatic toxicity (the remaining substances) for PBT/vPvB (all substances) for PMT/vPvM (all substances)	Wide dispersive uses with potential for exposure and release for most substances (professional, consumer uses and ASL reported across multiple product categories). Low exposure and release potential for substances used only in laboratory settings and/or as intermediates: 247-744-4 248-595-8 454-780-6 457-680-0 812-377-6 221-337-1 608-570-8 219-588-7 938-245-9	**First step:** CCH or pending ongoing data generation **Potential next steps (if hazard confirmed after data generation):** No action Currently not possible to assess the regulatory needs Justification: For inconclusive hazards (Repro, ED, PBT/vPvB and PMT/vPvM), the need for EU RRM will be further investigated once the hazard

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
237-511-5 245-642-4 247-744-4 248-595-8 250-437-8 252-390-9 253-288-7* 280-084-5 403-480-3** 414-340-6** 436-680-4** 437-720-3** 454-780-6** 457-680-0 480-000-9** 601-682-8* 601-747-0				properties will be clarified after data generation. For substance 217-164-6, the need for EU RRM will be further investigated once the hazard properties will be clarified when the classification process is completed. Currently no need for EU RRM Justification: Due to intermediate (EC 457-680-0, List 812-377-6) and inactive registration (EC 480-000-9), no data generation is possible to clarify the hazards currently. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change. In case of skin sensitisation hazard, self-classification

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
605-620-0 607-140-7* 608-099-8* 608-570-8*** 700-961-2 810-490-5 812-377-6*** 938-245-9***				followed by implementation of necessary RRMs 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. For aquatic toxicity, self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use for environment.

* C&L notified substance

** NONS

*** intermediate registration

3 Justification for the (no) need for regulatory risk management action at EU level

ECHA is working on the assessment of regulatory needs for various groups of silanes. The silanes have been split in several 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.

Based on ECHA's assessment of hazard information currently available in the registration dossiers and considerations of structural similarity and presence of common functional moiety, the following human health/environmental hazards have been identified for the substances in this group. It should be noted that the substances in this group hydrolyse to the corresponding Si-containing hydrolysis products and the potential hazards identified are sometimes related to the parent substance and sometimes to the hydrolysis products, as specified below where possible.

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.

Based on currently available information, it is not possible to assess the need for regulatory risk management as information on hazard is not sufficient to conclude on

- Reproductive and developmental toxicity and ED hazards for substance EC/List 213-048-4, 237-511-5 and 812-377-6;
- all substances in this group for the PBT/vPvB and PMT/vPvM hazards;

The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH).

Higher-tier toxicity data are missing for EC/List 213-048-4, 237-511-5 and 812-377-6 to conclude on their reproductive and developmental as well as ED potential.

Substance EC 237-511-5 is the only substance from this group for which changes on oestrous cycle were observed, more specifically, an increased incidence in irregular oestrous cycle and/or acyclic oestrous cycles were reported at exposure doses of 300 mg/kg bw/day and above in the available repeated dose toxicity study (OECD TG 408). The substance has high potential for exposure for workers and consumers based on uses in polymer preparations, adhesives, sealants, coatings, paints and explosives.

List 812-377-6 shares the same hydrolysis products with one substance in another group of substances on 'Alkoxysilyl_carbamates' (EC 457-690-5), which is self-classified for reproductive and developmental effects as Repr. 2 H361fd and potentially has endocrine disrupting properties. However, List 812-377-6 is only used as intermediate and cannot be investigated further.

To clarify the reproductive and developmental toxicity and ED hazards of the substances in this subgroup, it is proposed to wait for the outcome of the data generation already ongoing for EC 213-048-4 and 237-511-5. The needs for regulatory risk management actions will be assessed once the follow-up process is completed.

Hydrolysis products (including amines) of concern for repro/ED have been considered. Extrapolating the repro concern for primary aliphatic amines from other groups of substances does not seem justified as there are structural differences with members of this group, *i.e.*, the covalent bond with CH_2-Si and presence of 3 -OH groups.

Skin sensitisation

Thirteen substances in this group are self-classified as Skin sens. 1/1A/1B. Due to the identified trend within the group for skin sensitisation and the structural similarity, the skin sensitisation hazard is extrapolated to all substances in the group.

For industrial and professional uses, sufficient and consistent self-classification by registrants should require adequate risk management measures to be in place according to workplace legislation.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing substances in this group.

For the use of the substance(s) in cosmetics, sufficient and consistent self-classification by registrants would inform on the need or not for classification of the final product and safety assessment to be done according to Cosmetic product regulation (EC) No 1223/2009.

However, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern.

Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

Mutagenicity, STOT RE 2

Substances EC 457-680-0 and 480-000-9 are potentially mutagenic and STOT RE 2. Both are positive in in vitro mutagenicity tests and EC 457-680-0 is self-classified as Muta 2, however, the hazards could be related to the reported impurity (aniline), for which further testing would be needed to clarify the hazard. For this reason,

and due to impurity not being reported for other substances in the group, the mutagenicity hazard is not extrapolated further. Substance 457-680-0 (used as intermediate and in laboratory settings) is also self-classified as STOT RE 2. The STOT RE 2 hazard effects are most likely caused by the presence of impurity aniline. Similar effects are therefore expected based on the presence of aniline to similar levels as for EC 457-680-0.

Due to intermediate registration (EC 457-680-0) and inactive registration (EC 480-000-9) it is not possible to clarify the potential mutagenicity and STOT RE hazards of these substances. 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.

Substance EC 217-164-6 (widespread dispersive uses) is self-classified as STOT RE 2. Due to diverging classifications of EC 217-164-6, the substance has been flagged for harmonised classification. The hazard is not extrapolated to other substances in the group due to absence of sufficient data.

It is not possible to assess the needs for regulatory risk management for substance EC 217-164-6. It is recommended to wait for the outcome of the harmonised classification. The needs for regulatory risk management actions will be assessed once the process is completed.

Currently, data generation is ongoing for substances EC 236-818-1, 221-336-6, 250-437-8, 280-084-5 and 213-048-4. The outcome of this data generation should provide further clarification of repeated dose and reproductive and developmental toxicity potentials.

All the substances in the group are unlikely to be carcinogenic. All substances in the group, except EC/List 213-048-4, 237-511-5 and 812-377-6 (inconclusive), are unlikely to be reproductive and developmental toxic, and endocrine disruptors. However, it should be noted that experimental data on the group members themselves are very limited.

PBT/vPvB and PMT/vPvM

Based on valid OECD 301X degradation tests after 28 d, 8 substances have experimental data (ECs 250-437-8, 810-490-5, 236-818-1, 280-084-5, 454-780-6, 700-961-2, 217-164-6, 221-337-1) which fail to reach the threshold of the criteria, at the end of the tests and are considered as potentially P/vP. Of these 8 substances, concerning B/vB or M/vM hazards, there is no valid experimental data on these substances. There are adaptations (QSARs, read-across, other waivers) which have not been screened for this exercise, however, the QSARs values indicate, low log Kow adaptations. For these 8 substances, all are considered as inconclusive for the B/vB and M/vM. Therefore, overall, these 8 substances are considered as inconclusive for PBT/vPvB and PMT/vPvM. There is no valid experimental degradation, bioaccumulation or mobility data on the remaining substances in the group. The whole group are considered as inconclusive for PBT/vPvB and PMT/vPvM, due to low data density and poor quality data. There is no Env data for "T". There is human health data for "T", as outlined above for ECs 457-680-0, 217-164-6, 457-680-0 and 480-000-9, but no extrapolation is possible to the remaining group substances due to low data density. To clarify the PBT/vPvB and PMT/vPvM hazards, it is proposed to wait for the outcome of the data generation already ongoing. The needs for regulatory risk management actions will be assessed once the follow-up process is completed.

Aquatic toxicity

There are 5 substances in the group with a self-classification or CLH for aquatic toxicity: ECs 280-084-5, 248-595-8, 605-620-0, 700-961-2, 219-588-7. It is expected that based on the harmonised/self-classification registrants have implemented necessary RMMs to ensure safe use. Therefore, it is proposed that there is currently no need for EU-wide regulatory risk management.

Due to limited data and quality of the available data, there is no extrapolation for aquatic toxicity considered currently or for those substances proposed for data generation.

Data generation under CCH is proposed to clarify the above hazards.

In conclusion, to confirm the overall low hazard conclusion for the group, it is proposed to wait for the outcome of the ongoing data generation and to re-assess the need to open CCH on selected substances upon considering all groups of silanes to account for the potential for substitution.

Annex 1: Overview of classifications

Data extracted on 02/09/2022

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations[5]
213-048-4	919-30-2	3-aminopropyltriethoxysilane	*Acute Tox. 4 H302* *Skin Corr. 1B H314*	*Acute Tox. 4 H302* *Skin Corr. 1B H314* *Eye Damage 1 H318* *Skin Sens. 1 H317*
237-511-5	13822-56-5	3-(trimethoxysilyl)propylamine	-	*Skin Irrit. 2 H315* *Eye Damage 1 H318*
253-288-7	36957-84-3	2-(triethoxysilyl)propylamine	-	-
436-680-4	-	Y-11637	-	-
607-140-7	227085-51-0	*N*-ethyl-3-trimethoxysilyl-2-methyl-propanamine	-	-
221-334-5	3069-25-8	*N*-methyl-3-(trimethoxysilyl)propylamine	-	*Eye Damage 1 H318*
250-437-8	31024-56-3	*N*-[3-(trimethoxysilyl)propyl]butylamine	-	*Skin Irrit. 2 H315* *Eye Damage 1 H318*
247-744-4	26495-91-0	*N*-[(triethoxysilyl)methyl]cyclohexylamine	-	*Flam. Liquid 3 H226*
221-329-8	3068-78-8	EINECS: *N*-[3-(trimethoxysilyl)propylcyclohexylamine] Correct IUPAC name: *N*-[3-(trimethoxysilyl)propyl]cyclohexanamine	-	*Eye Damage 1 H318*
221-328-2	3068-76-6	*N*-[3-(trimethoxysilyl)propyl]aniline	-	*Acute Tox. 4 H302*
480-000-9	-	GENIOSIL XL 973	-	-
437-720-3	227085-51-0	*N*-ethyl-3-trimethoxysilyl-2-methyl-propanamine Y-15167	*Eye Dam. 1 H318*	-
601-682-8	120218-26-0	*N*-[3-(triethoxysilyl)propyl]cyclohexanamine	-	-
219-786-3	2530-86-1	*N*,*N*-dimethyl-3-(trimethoxysilyl)propylamine	-	*Skin Sens. 1B H317* *Eye Damage 1 H318*
248-595-8	27668-52-6	dimethyloctadecyl[3-(trimethoxysilyl)propyl]ammonium chloride	-	*Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Aquatic Acute 1 H400*

[5] The column gives the classifications in registrations received under REACH. Additional classifications in intermediate and in inactive registrations (if any) are annotated and displayed last. For each classification the table includes information on the hazard category, the hazard statement, and any available information on specific effects (relevant for reproductive toxicity), specific concentration limits, M-Factors and affected organs. Two classifications differing in any of these aspects are considered different and are repeated in the table. The columns "Classifications in registrations" and "Classifications in C&L notifications" are empty if there are no Registrations/C&L notifications (hazard is unknown). The value '-' is displayed on the same columns when there are (relevant) submissions but they do not contain self-classifications (substance is not hazardous).

				Aquatic Chronic 1 H410
810-490-5	35501-23-6	*N*-butyl-*N*-[(triethoxysilyl)methyl]butan-1-amine	-	*Skin Sens. 1B H317*
280-084-5	82985-35-1	EINECS: bis(trimethoxysilylpropyl)amine Correct IUPAC name: 3-(trimethoxysilyl)-*N*-[3-(trimethoxysilyl)propyl]propan-1-amine	*Eye Dam. 1 H318* *Aquatic Chronic 2 H411*	*Eye Damage 1 H318*
236-818-1	13497-18-2	EINECS: bis(triethoxysilylpropyl)amine Correct IUPAC name: 3-(triethoxysilyl)-*N*-[3-(triethoxysilyl)propyl]propan-1-amine	-	*Skin Irrit. 2 H315* *Eye Irrit. 2 H319* *Skin Sens. 1B H317*
252-390-9	35141-30-1	*N*-(2-aminoethyl)-*N'*-[3-(trimethoxysilyl)propyl]ethylenediamine	-	*Acute Tox. 4 H332* *Eye Damage 1 H318* *Skin Sens. 1A H317*
217-164-6	1760-24-3	*N*-(3-(trimethoxysilyl)propyl)ethylenediamine		
225-806-1	5089-72-5	*N*-[3-(triethoxysilyl)propyl]ethylenediamine		
700-961-2	-	Reaction mass of 2-{[3-(trimethoxysilyl)propyl]amino}ethanaminium chloride and N-[2-(benzylamino)ethyl]-3-(trimethoxysilyl)propan-1-aminium chloride and N-[2-(dibenzylamino)ethyl]-3-(trimethoxysilyl)propan-1-aminium chloride and N-benzyl-2-{benzyl[3-(trimethoxysilyl)propyl]amino}ethanaminium chloride and N-benzyl-N-[2-(dibenzylamino)ethyl]-3-(trimethoxysilyl)propan-1-aminium chloride		*Aquatic Chronic 2 H411 &* *Aquatic Chronic 3 H412*
605-620-0	171869-89-9	Reaction Mass of 3-(2-aminoethylamino)propyltrimethoxysilane hydrochloride and (2-aminoethyl)[(vinylphenyl)methyl][3-(trimethoxysilyl)propyl] amine hydrochloride and N-[3-(trimethoxysilyl)propyl]-N'-(vinylbenzyl)-1,2-ethanediamine hydrochloride and N-[3-(trimethoxysilyl)propyl]-N,N'- di(vinylbenzyl)-1,2-ethanediamine hydrochloride and N-[3-(trimethoxysilyl)propyl]-N',N'-di(vinylbenzyl)-1,2-ethanediamine hydrochloride and N-[3-(trimethoxysilyl)propyl]-N,N',N'-tri(vinylbenzyl)-1,2-ethanediamine hydrochloride		*Aquatic Chronic 3 H412*

414-340-6		**ELINCS:** reaction mass of: N-(3-(trimethoxysilyl)propyl)ethylenediamine; N-benzyl-N-(3-trimethoxysilyl)propyl)ethylenediamine; N-benzyl-N'-[3-(trimethoxysilyl)propyl]ethylenediamine; N,N'-bis-benzyl-N'-[3-(trimethoxysilyl)propyl]ethylenediamine; N,N,N'-tris-benzyl-N'-[3-(trimethoxysilyl)propyl]ethylenediamine; N,N-bis-benzyl-N'-[3-(trimethoxysilyl)propyl]ethylenediamine		
812-377-6	343926-26-1	1-[dimethoxy(methyl)silyl]methanamine		
221-660-8	3179-76-8	3-(diethoxymethylsilyl)propylamine		
245-642-4	23410-40-4	N-[3-(dimethoxymethylsilyl)-2-methylpropyl]ethylenediamine		
601-747-0	120939-52-8	N-{3-[dimethoxy(methyl)silyl]propyl}butan-1-amine		
221-336-6	3069-29-2	Wrong name in EINECS: N-[3-(dimethoxymethylsilyl)propyl]ethylenediamine Correct: N-{3-[dimethoxy(methyl)silyl]propyl}ethane-1,2-diamine		
608-099-8	27445-54-1	N-{[diethoxy(methyl)silyl]methyl}cyclohexanamine		
457-680-0	17890-10-7	N-{[dimethoxy(methyl)silyl]methyl}aniline		
454-780-6	27445-54-1	N-{[diethoxy(methyl)silyl]methyl}aniline		
608-570-8	31024-26-7	3-[methoxy(dimethyl)silyl]propan-1-amine		
221-337-1	3069-33-8	N-[3-(methoxydimethylsilyl)propyl]ethylenediamine		
219-588-7	2469-55-8	EINECS name: 3,3'-(1,1,3,3-tetramethyldisiloxane-1,3-diyl)bispropylamine		
938-245-9	-	Reaction mass of 3-[methoxy(dimethyl)silyl]propan-1-amine and 3,3'-(1,1,3,3-tetramethyldisiloxane-1,3-diyl)dipropan-1-amine		

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

Data extracted on 02/09/2022

Main types of applications structed by product or article types	EC/List 213-048-4	EC/List 217-164-6	EC/List 219-588-7	EC/List 219-786-3	EC/List 221-328-2	EC/List 221-329-8	EC/List 221-334-5	EC/List 221-336-6	EC/List 221-337-1	EC/List 221-660-8	EC/List 225-806-1	EC/List 236-818-1	EC/List 237-511-5	EC/List 245-642-4	EC/List 247-744-4	EC/List 248-595-8	EC/List 250-437-8	EC/List 252-390-9	EC/List 280-084-5	EC/List 454-780-6	EC/List 457-680-0	EC/List 601-747-0	EC/List 605-620-0	EC/List 608-570-8	EC/List 700-961-2	EC/List 810-490-5	EC/List 812-377-6	EC/List 938-245-9
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	I, **P**																								I			
PC 2: Adsorbents		F																										
PC 11: Explosives													**C**															

PC 35: Washing and cleaning products	F, I	F, I, **P**, **C**					F, I	F, I, **P**, **C**				F, I, **P**		F				F, I	F				F				
PC 8: Biocidal products (e.g. disinfectants, pest control)	F, I	F, I, **P**, **C**				F, I, **P**	F	F, **P**				F, I						F	F				F		F, I, **P**		
PC 39: Cosmetics, personal care products	**C**	F, **P**, **C**			**P**			**P**, **C**				**P**						**C**									
PC 29: Pharmaceuticals	I	I			I		I	I				I		I				I					I				
PC 15: Non-metal-surface treatment products	F, I, **P**	F, I			F, I			F, I		F, I		F, I	F, I					F, I	F, I				F, I		F, I		
PC 24: Lubricants, greases, release products	F, I, **P**	F						I																			

PC 25: Metal working fluids	F, I, **P**																										
PC 13: Fuels	I											F															
PC 32: Polymer preparations and compounds	F, I, **A**	F, I, **P**, **C**, **A**	F	F, I, **A**	F, I	F, I, **P**	F, I, **A**	F, I, **P**, **C**, **A**		F, I		F, I, **P**	F, I, **A**	F, I, **A**	I		F, I, **A**	F, I	F, I, **A**				F, I		F, I, **P**			
PC 1: Adhesives, sealants	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**		F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**	F, I, **P**, **A**	F, I, **P**, **C**, **A**		F, I, **P**	F, I, **P**	F, I, **P**, **A**	F, I, **P**, **C**	F, I, **A**			F, I, **P**, **C**, **A**	F, I, **P**, **C**	F, I, **P**, **C**, **A**			F, I,	F, I		F, I, **P**, **A**			
PC 9c: Finger paint	**C**	**C**																									
PC 9b: Fillers, putties, plasters, modelling clay	F, I, **P**, **C**	F, I, **P**, **C**, **A**			I			F, I, **P**, **C**				F, I, **P**						I	F				F, I		F, I			
PC 9a: Coatings and paints, thinners, paint removes	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**			F, I, **P**, **C**	I	F, I, **P**, **A**	F, I, **P**, **C**, **A**		F, I, **P**, **C**	F, I, **P**	F, I, **P**	F, I, **P**, **C**	I			F, I, **P**, **C**, **A**	F, I, **P**	F, I, **P**, **C**, **A**			F, I	I		I	F, I, **P**		

PC 18: Ink and toners	F, I, **P**, **C**	F, I, **P**, **A**					**A**	F, I, **P**, **A**																			
PC 26: Paper and board treatment products		I, **P**, **C**						I, **P**, **C**				**P**															
PC 34: Textile dyes, and impregnating products					F, I			F, I, **C**																			
PC 23: Leather treatment products		F, I, **C**						F, I, **C**				I															
PC 14: Metal surface treatment products	I	I						I																			
PC 33: Semiconductors					I																	F, I					
PC 21: Laboratory	I, **P**, **A**	I, **P**	I	I	I	I	I	I	I	I	I	I, **P**	I, **P**	I, **P**	I	I	I	I	I	I	I	I	I	I	I	I	I

chemicals																											
PC 19: Intermediate	F, I	I	I			I	F	I	I	I		I	I	I	I	F, I	I	F, I	F, I	I	I	I		I	I		I	I
PC41: Oil and gas exploration or production products	F, I											F, 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

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

Data extracted on 02/09/2022

EC/List number	RM OA	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
213-048-4				YES	YES	
248-595-8						BPR
280-084-5				YES	YES	
437-720-3				YES	YES	

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, *e.g.*, when the scope of the restriction is defined by its classification or the substance identification is broad (*e.g.*, entries 3, 28-30 and 40).

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