

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Hydrocarbylhalosilanes

General structure:

$$R^{1}$$
 R^{1} R^{1} R^{1} R^{2} R^{3} R^{4} R^{4

Revision history

| Version | Date | Description |
|---------|-----------------|-------------|
| 1.0 | 11 January 2024 | |
| | | |

Substances within this group:

| EC/List no | CAS no | Substance name | name Chemical structure | |
|------------|---------|--------------------------|--|--------------------------------------|
| 200-877-1 | 75-54-7 | Dichloro(methyl)silane | CI—SiH | Full, >1000 |
| 200-900-5 | 75-77-4 | Chlorotrimethylsilane | CH ₃ CI—Si H ₃ C CH ₃ | Full, >1000 |
| 200-901-0 | 75-78-5 | Dichloro(dimethyl)silane | CI—Si H ₃ C CI | Full, >1000 |
| 200-902-6 | 75-79-6 | Trichloro(methyl)silane | CI—Si H ₃ C CI | Full, >1000 |
| 200-917-8 | 75-94-5 | Trichloro(vinyl)silane | CI—Si CI CH ₂ | Full, not (publicly) available |

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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 structure | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) 1 |
|------------|----------|-----------------------------------|--|---|
| 201-251-0 | 80-10-4 | Dichloro(diphenyl)silane | CI—Si | Full, 100-1000 |
| 202-640-8 | 98-13-5 | Trichloro(phenyl)silane | c(phenyl)silane | |
| 203-930-7 | 112-04-9 | Trichloro(octadecyl)silane | 0 m o m o m o m o m o m o m o m o m o m | Full, not (publicly) available |
| 204-072-6 | 115-21-9 | Trichloro(ethyl)silane | | Full, not (publicly) available |
| 204-710-3 | 124-70-9 | Dichloro(methyl)(vinyl) silane | CH ₃ CI—Si CI CH ₂ | Full, 100-1000 |
| 205-489-6 | 141-57-1 | Trichloro(propyl)silane | CI CI CH ₃ | Full, 100-1000 |

| EC/List no | CAS no | Substance name Chemical structure | | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) 1 |
|------------|-----------|---|--|---|
| 205-746-2 | 149-74-6 | Dichloro(methyl) (phenyl) silane | CI—Si CI | Full, 100-1000 |
| 211-854-0 | 701-35-9 | Trichloro-p-tolylsilane | Trichloro-p-tolylsilane | |
| 212-193-0 | 768-33-2 | CH ₃ Cl—Si CH ₃ CH ₃ | | OSII or TII |
| 213-600-4 | 993-00-0 | Chloro(methyl)silane | CI—SiH ₂ CH ₃ | |
| 213-615-6 | 994-30-9 | Chlorotriethylsilane | CI—Si CH ₃ CH ₃ | OSII or TII |
| 213-912-0 | 1066-35-9 | Chlorodimethylsilane | CH ₃ CI—SiH CH ₃ | Full, >1000 |

| EC/List no | CAS no | Substance name Chemical structure | | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) 1 |
|------------|-----------|--|---|---|
| 217-007-1 | 1719-58-0 | Chlorodimethylvinylsilane | CH ₃ CH ₃ CH ₂ | Full, >1000 |
| 220-672-0 | 2857-97-8 | Bromotrimethylsilane Br Si CH ₃ H ₃ C CH ₃ | | OSII or TII |
| 222-123-0 | 3353-69-3 | Ethane-1,2- diylbis[dichloromethylsilane] | CH ₃ Cl—Si Cl Cl H ₃ C | Full, not (publicly) available |
| 224-844-6 | 4518-98-3 | 1,1,2,2-tetrachloro-1,2-dimethyldisilane | | C&L notification |
| 225-931-1 | 5157-75-5 | Dichloromethyloctadecyl silane | Card Va | OSII or TII |
| 226-112-1 | 5283-66-9 | Octyltrichlorosilane | Octyltrichlorosilane H,c | |

| EC/List no | CAS no | Substance name | Chemical structure | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹ |
|------------|------------|---|--|--|
| 226-956-0 | 5578-42-7 | Dichlorocyclohexylmethyl silane | H,C | Full, not (publicly) available |
| 227-575-2 | 5894-60-0 | Trichloro(hexadecyl)silane | CI CI—Si—CH ₃ | Full, not (publicly) available |
| 236-870-5 | 13528-88-6 | 1,1,2-trichloro-1,2,2- trimethyldisilane | | C&L notification |
| 238-863-2 | 14799-93-0 | Dichloromethyloctylsilane | N/A | C&L notification |
| 240-171-0 | 16029-98-4 | Iodotrimethylsilane | CH ₃ | |
| 242-042-4 | 18162-48-6 | tert-butylchlorodimethyl silane | H ₃ C CH ₃ CH ₃ CH ₃ CH ₃ | Full, 10-100 |
| 242-044-5 | 18162-84-0 | Chlorodimethyloctylsilane | CH ₃ | Full, 1-10 |

| EC/List no | CAS no | Substance name | Chemical structure | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) 1 |
|------------|------------|------------------------------------|-----------------------|---|
| 242-053-4 | 18169-57-8 | Trichloroisobutylsilane | CI CI CH ₃ | Full, not (publicly) available |
| 242-262-0 | 18379-25-4 | trimethylpentyl)silane | | Full, not (publicly) available |
| 242-286-1 | 18407-07-3 | Dichlorododecylmethylsilane | | Full, not (publicly) available |
| 242-472-2 | 18643-08-8 | Chlorodimethyloctadecyl silane | | Full, 1-10 |
| 261-596-8 | 59086-80-5 | Dichloromethyltetradecyl silane | 0 | Full, not (publicly) available |
| 266-421-9 | 66604-31-7 | Chlorododecyldimethylsilane | n.c. ori | C&L notification |

| EC/List no | CAS no | structure | | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) 1 |
|------------|--------------------------------|---|--|---|
| 273-054-8 | 68937-17-7 | Disilane, chloro Me derivs. | CH, | Cease manufacture |
| 423-700-1 | 1000-50-6 | Butylchlorodimethylsilane | H ₃ C SI CH ₃ | NONS |
| 442-590-6 | Not (publicly) available | Not (publicly) available | Not (publicly) available | NONS |
| 454-150-0 | 13154-25-1 | Triisobutylchlorosilane | H ₃ C — CH ₃ CH ₃ CH ₃ | NONS |
| 600-021-0 | 1000-50-6 | chloro-dimethyl-n-butyl silane | Not (publicly) available | Not registered |
| 603-492-0 | 13154-24-0 | Chlorotriisopropylsilane | H ₃ C CH ₃ | |
| 604-112-6 | 139147-73-2 | Cyclopentane, 1,1'- (dichlorosilylene)bis- | | |
| 627-295-4 | 13154-25-1 | Chlorotriisobutylsilane | N/A | C&L notification |

| EC/List no | CAS no | Substance name | Chemical structure | Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) 1 |
|------------|--------------------------------|--|--|---|
| 678-409-4 | 18402-22-7 | Silane, trichlorotetradecyl- | , o o o o o o o o o o o o o o o o o o o | OSII or TII |
| 700-717-5 | Not (publicly) available | Chloro(methyl)(mono and di)silanes and dichloro(ethyl)methylsilane and hexamethyldisilane from fractionated distillation of the reaction products of silicon and chloromethane | OA 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | Cease manufacture |
| 700-790-3 | Not (publicly) available | chloro(methyl)silanes and tetramethylsilane and trichlorosilane from the fractionated distillation of the reaction products of silicon and chloromethane | CH, CL, SH H,C CH, NA CH, NA CH, NA CH, NA CH, NA | Cease manufacture |
| 935-540-4 | Not (publicly) available | Reaction mass of silane, 1,2-ethanediylbis(trichloro- and silane, 1,1'-(1,2- ethenediyl)bis[1,1,1- trichloro- isomer | 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | OSII or TII |

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

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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 level³. 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 website⁴.

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

Glossary

| ARN | Assessment of Regulatory Needs | | |
|-------------|--|--|--|
| ССН | 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 halosilane moiety shown in the figure below.

$$R^{1}$$
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The group consists of 48 substances out of which 26 have full registrations, nine are registered as intermediates, three are NONS, five have been C&L notified and five have inactive/revoked registrations. All except one of the registered substances are well-defined mono-constituent substances.

The registered substances are mainly used as intermediates, as monomer in polymers (plastic and rubber) preparation and as laboratory agent in industrial setting. Few other industrial uses (e.g. coating; adhesives; surface agent for surface treatments) are mentioned in the registration dossier for a limited number of substances. Few dossiers also report professional uses (adhesives, coatings, etc.), while for only one substance consumer uses have been mentioned; finally, for 2 substances article service is also mentioned (linked to PC1 - adhesive, PC9 coatings, PC32 - polymers). Potential for exposure is particularly relevant for industrial and professional uses of coatings, adhesives and surface treatments and for the limited number of uses where consumers and article service life are mentioned; for the latter, besides the 2 substances where service life is explicitly reported, we have identified few uses and 1 substance where, from combination of PC and technical function, the articles service seems to be likely. In most of cases, the articles involved are rubber and plastics, although other type are possible (e.g. textile in one case). Since the main function of the substances is as monomer in polymers, the article service life is not relevant anyway in most of cases.

2 Conclusions and proposed 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.

Table: Conclusions and proposed actions

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|--|---|---|---|
| 200-877-1 200-901-0 200-902-6 201-251-0 202-640-8 205-746-2 213-912-0 226-112-1 227-575-2 242-042-4 242-262-0 | Known or potential hazard for ED for reproductive toxicity (except for 227-575-2) for mutagenicity For 200-901-0, 201-251-0, 202-640-8 | Known or potential hazard for ED (except for 227-575-2) for PBT/vPvB For 226-112-1, 227-575-2 | Professional uses, including for adhesive, coatings, surface treatments (200-877-1, 200-901-0, 226-112-1) Use in articles (200-901-0, 226-112-1) after adhesive, coatings application or surface treatment and consumer uses in textile (200-901-0) Use in industrial setting, especially as monomer in polymer preparation, intermediate and lab | First step: CCH Potential next steps (if hazard confirmed after data generation): SVHC identification For ED and/or PBT properties CLH For reproductive toxicity Potential last action: Restriction Justification: Releases to the environment from consumer and widespread professional uses cannot be avoided. Widespread professional uses are typically non- |

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|--|---|--|---|--|
| | | | agent (all substances) | contained and non-automated leading to releases to the environment. 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 |
| 200-917-8 203-930-7 204-710-3 211-854-0 217-007-1 222-123-0 242-044-5 242-286-1 242-472-2 261-596-8 | Inconclusive hazard for reproductive toxicity for ED for mutagenicity | Known or potential hazard for PBT/vPvB For 242-044-5, 203-930-7, 242-286-1, 242-472-2, 261-596-8 (all Annex VII substances, no info possible from CCH) Inconclusive hazard for ED | Article service life in polymer and adhesives for 242-472-2 Use in industrial setting, especially as monomer in polymer preparation, intermediate and lab agent (all substances) | First step: CCH Potential last action: Currently not possible to assess the regulatory needs Justification: It is not possible to assess the needs for regulatory risk management as information on hazard is not sufficient to conclude on ED/R and M. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH). |

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|--|---|--|--|
| 212-193-0 213-615-6 220-672-0 225-931-1 240-171-0 603-492-0 604-112-6 678-409-4 935-540-4 | for reproductive toxicity for ED for mutagenicity | Inconclusive hazard for ED Known or potential hazard for PBT/vPvB For 604-112-6, 678-409-4 | Used as intermediate under strictly controlled conditions (registration ex art 17/18) | First step: No action Potential last action: Currently no need for EU RRM Justification: According to the reported uses, low potential for exposure to both human health and environment is expected. Actions (including data generation) will be re-considered when the assessment will be revisited if the registration status and/or uses change. |
| 213-600-4 224-844-6 236-870-5 238-863-2 266-421-9 273-054-8 600-021-0 627-295-4 700-717-5 700-790-3 423-700-1 442-590-6 454-150-0 | Inconclusive hazard Except for 213-600-4 for reproductive toxicity for ED | Inconclusive hazard Except for 213-600-4 for ED | No Uses Not registered substance or inactive registration NONs a with no uses reported (423-700-1, 442-590-6, 454-150- 0) | First step: No action Potential last action: Currently no need for EU RRM Justification: Due to NONs, not registered substance, 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. |
| 200-900-5 204-072-6 205-489-6 | No hazard or unlikely hazard | No hazard or unlikely hazard | Industrial uses as Intermediate or laboratory agent | First step: No action |

| Subgroup name, EC/List no, substance name | Human Health Hazard | Environmental Hazard | Relevant use(s) & exposure potential | Suggested regulatory actions |
|---|------------------------|-------------------------|--|--|
| 226-956-0 242-053-4 | | | 200-900-5 several uses, including by consumers | Potential last action: Currently no need for EU RRM Justification: Overall, no or unlikely hazard that would lead to concern for the reported uses. |

3 Justification for the (no) need for regulatory risk management action 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. However, this approach also has its disadvantages. One of the uncertainties identified relates to the potential interchangeability of the substances for some of their uses within but also between groups. The potential for substitution can impact the regulatory actions proposed in this assessment of regulatory needs. Therefore, ECHA may modify the assessment once all individual assessment for regulatory needs have been finalised. This should help ensure a coherent approach throughout the silane groups on the proposed regulatory actions.

It should be noted that based primarily on experimental hydrolysis studies, the hydrocarbylhalosilanes hydrolyse rapidly, but all ultimately release alkylsilanol hydrolysis products, which are not readily biodegradable, hydrocarbylsilanols and hydrogen chloride (HCl). Corrosive properties deriving from HCl have been addressed in REACH registrations with self-classifications. The hazards related to the alkylsilanol hydrolysis products is further discussed in this report. For this group, the silanol-containing hydrolysis products include EC/CAS 213-915-7, 219-489-9, 5651-16-1, 213-427-4, 221-257-7, 223-562-0, 219-903-6, 213-915-7. The alkylsilanol hydrolysis products, ECs 213-914-1, 213-915-7 and 219-489-9 are also common to other silanes/siloxanes groups.

For the environment, due to the rapid rate of hydrolysis of hydrocarbylhalosilane, the potential hazards identified can be generally associated with the alkylsilanol hydrolysis products. Where there is no/limited hydrolysis information, the potential hazards identified may be generally associated with either the parent and/or the alkylsilanol hydrolysis products.

Whilst CCH is proposed for this group, the final proposed selection of substances for which to conduct a CCH will consider commonalities to other silane groups, the intrinsic properties of the substances (e.g. corrosivity), tonnages and uses.

Based on currently available information, suggested regulatory management action – restriction for ED (both human health and environment) and/or reprotoxic toxicity for EC 200-877-1, 200-901-0, 200-902-6, 201-251-0, 202-640-8, 205-746-2, 213-912-0, 242-042-4, 242-262-0, and, in few cases, PBT hazard 226-112-1, and 227-575-2 due to the potential for release/ exposure.

Based on ECHA's assessment of currently available hazard information, potential hazards were identified for human health. The available information indicates potential for reproductive toxicity and/or ED. EC 200-877-1, 200-901-0, 200-902-6, 201-251-0, 202-640-8, 213-600-4, 213-912-0, 226-112-1 and 242-262-0 have extrapolated reproductive toxicity hazards from tested analogue substances in a related silane group. EC 242-042-4, 201-251-0, 205-746-2 and 200-901-1 have potential reproductive toxicity and ED hazards based on AGD, NR and thyroid developmental effects reported in prenatal developmental toxicity studies, screening studies and a repeated dose toxicity study studies (no extrapolation, group member substances tested). The reported effects are fetal variations and malformations, and AGD and/or NR.

The available data on EC 200-901-0 warrants already harmonised classification

(CLH) as Repr. 1B H360D (based on fetal variations and malformations including small thyroid, and lower fetal weight).

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via **SVHC** identification and inclusion on the Candidate List as ED and/or PBT. SVHC identification is highly recommended as a step prior to restriction. In addition, SVHC identification brings immediate obligations for suppliers of the substances such as (i) supplying a safety data sheet and communicating on the safe use of the substances, (ii) responding to consumer requests within 45 days and (iii) notifying ECHA if the article they produce contains the substance above regulatory threshold. CLH for reprotoxic effects (e.g. for EC 200-901-0 it is already possible to proceed with CLH as Repro 1B) can also be considered.

Confirmation of the hazard properties via SVHC identification is not considered sufficient to minimise potential releases of the substances in the environment. A **restriction is seen as the most appropriate option** as potential for exposure is expected from professional uses, article service and cannot be excluded for industrial uses.

Few of these substances (EC 200-877-1, 200-901-0, 226-112-1) have reported widespread uses (**professional**, **article service life**). Widespread professional uses are typically non-contained and non-automated leading to releases to the environment (e.g. when used in coating, adhesives or for textile treatments). Furthermore, potential for exposure and releases to the environment from articles cannot be excluded based on available information. Restricting substances in articles used by professionals or consumers (EC 200-901-0, 226-112-1) should be considered in the context of the restriction of consumer/professional uses as potential exposure from articles needs further investigation first.

Other substances (EC 200-902-6, 201-251-0, 202-640-8, 205-746-2, 213-912-0, 227-575-2, 242-042-4, 242-262-0) report only **industrial uses**, especially as intermediate, as monomer in polymer production and as laboratory agent; emissions to environment and exposure towards workers cannot be excluded (e.g. polymer production) also for the abovementioned industrial uses. It is therefore suggested to cover possibly also industrial uses as part of the restriction, also in light to the fact that authorisation might not be applicable in most of the cases (use as intermediate or as monomer in polymer production). EU-wide exposure limit for workers under OSH or REACH might also be considered as an alternative to control the risk for human health in industrial setting; however, this would not cover potential emission to the environment, which needs to be covered by a specific restriction.

Based on currently available information, it is not possible to regulatory risk management actions since information is not sufficient to conclude on reproductive toxicity and/or ED and/or PBT/vPvB hazards for many substances in the group (EC 200-917-8, 203-930-7, 204-710-3, 211-854-0, 217-007-1, 222-123-0, 242-044-5, 242-286-1, 242-472-2, 261-596-8). In this respect, available hazard information on the substance(s) (including any relevant data on structurally related substances in the group or from other GMTs) is insufficient to get a holistic view

Compliance checks are preliminary suggested for the substances in this group to clarify mutagenic, reproductive toxic, ED and target organ toxicity hazards.

Based on currently available information, there is no need to suggest (further) regulatory risk management actions for some substances in the group.

In particular for 5 substances, namely EC 200-900-5 (the only substance for which consumer uses are reported), 204-072-6, 205-489-6, 226-956-0 and 242-053-4, the reproductive toxicity, ED and PBT-vPvB hazards are unlikely based on the information available in the dossier or from structurally related substances in other GMTs.

Other substances are only used as intermediate under strictly controlled conditions (namely, EC 212-193-0, 213-615-6, 220-672-0, 225-931-1, 240-171-0, 603-492-0, 604-112-6, 678-409-4 and 935-540-4), are not registered or have invalid/revoked registrations (namely, EC 213-600-4, 224-844-6, 236-870-5, 238-863-2, 266-421-9, 273-054-8, 600-021-0, 627-295-4, 700-717-5, 700-790-3) or are low tonnage NONS registration with no uses reported (namely, EC 423-700-1, 442-590-6, 454-150-0). For these substances, should the registration status change, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

Compliance checks are preliminary suggested for the following substances to clarify

- mutagenic hazard: EC 200-877-1, 200-900-5, 200-902-6, 200-917-8, 201-251-0, 202-640-8, 203-930-7, 204-072-6, 204-710-3, 205-489-6, 205-746-2, 213-912-0, 217-007-1, 226-112-1, 226-956-0, 242-262-0, 242-286-1, 261-596-8
- reproductive toxicity and ED: EC 200-877-1, 200-900-5, 200-902-6, 200-917-8, 201-251-0, 202-640-8, 204-072-6, 204-710-3, 205-489-6, 205-746-2, 213-912-0, 217-007-1, 222-123-0, 226-112-1, 242-053-4, 242-262-0
- STOT RE: 200-877-1, 200-900-5, 202-640-8, 204-072-6, 204-710-3, 205-489-6, 205-746-2, 213-912-0, 217-007-1, 222-123-0, 226-956-0, 242-053-4, 242-262-0

Annex 1: Overview of classifications

Data extracted on 11 March 2022.

No harmonised classifications (CLH) in the group

| EC/ List No | CAS No | Substance name | Classification in registrations |
|----------------|-----------------|--|--|
| | | l | |
| 604- 112-6 | 13914 7-73-2 | 604-112-6 | - |
| 226- 956-0 | 5578- 42-7 | dichlorocyclohexy Imethylsilane | Skin Corr. 1A H314 Eye Damage 1 H318 Aquatic Chronic 3 H412 |
| 200- 902-6 | 75-79- 6 | trichloro(methyl)s ilane | Flam. Liquid 2 H225 Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 3 H331 Skin Irrit. 2 H315, specific concentration: >=1 Skin Corr. 1A H314 Eye Irrit. 2 H319, specific concentration: >=1 STOT Single Exp. 3 H335, affected organs: Respiratory tractus, specific concentration: >=1 |
| 203- 930-7 | 112- 04-9 | trichloro(octadec yl)silane | Skin Corr. 1A H314 Eye Damage 1 H318 |
| 200- 877-1 | 75-54- 7 | dichloro(methyl)s ilane | Flam. Liquid 2 H225 Water React. Flam. Gas 3 H261 Acute Tox. 3 H301 Acute Tox. 3 H331 Skin Corr. 1A H314 |
| 222- 123-0 | 3353- 69-3 | ethane-1,2- diylbis[dichlorom ethylsilane] | Skin Corr. 1A H314 Eye Damage 1 H318 STOT Single Exp. 3 H335, affected organs: Respiratory tract |
| 242- 053-4 | 18169- 57-8 | trichloroisobutylsi lane | Flam. Liquid 2 H225 Acute Tox. 3 H301 Skin Corr. 1A H314 |
| 213- 600-4 | 993- 00-0 | chloro(methyl)sila ne | Water React. Flam. Gas 3 H261 [intermediate (inactive)] Skin Corr. 1A H314 [intermediate (inactive)] Compressed gas H280 [intermediate (inactive)] Flam. Gas 1A H220 [intermediate (inactive)] |

| EC/ | CAS | Substance | Classification in registrations |
|---------------|----------------|---|---|
| List No | No | name | |
| 201- 251-0 | 80-10- 4 | dichloro(diphenyl)silane | Skin Corr. 1A H314 Eye Damage 1 H318 Aquatic Chronic 2 H411 |
| 220- | 2857- | bromotrimethylsil | Eye Damage 1 H318 [intermediate (active)] STOT Single Exp. 3 H335, affected system: respiratory system, affected organs: respiratory tract [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] Flam. Liquid 2 H225 [intermediate (active)] |
| 672-0 | 97-8 | ane | |
| 226- | 5283- | octyltrichlorosilan | Skin Corr. 1A H314 |
| 112-1 | 66-9 | e | Eye Damage 1 H318 |
| 627- 295-4 | 13154- 25-1 | 627-295-4 | - |
| 266- | 66604- | chlorododecyldim | - |
| 421-9 | 31-7 | ethylsilane | |
| 205- 489-6 | 141- 57-1 | trichloro(propyl)si lane | Flam. Liquid 3 H226 Acute Tox. 4 H302 Acute Tox. 3 H331 Skin Corr. 1A H314 Eye Damage 1 H318 |
| 236- 870-5 | 13528- 88-6 | 1,1,2-trichloro- 1,2,2- trimethyldisilane | - |
| 225- 931-1 | 5157- 75-5 | dichloromethyloc tadecylsilane | Skin Corr. 1A H314 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] |
| 238- | 14799- | dichloromethyloc | - |
| 863-2 | 93-0 | tylsilane | |

| EC/ List No | CAS No | Substance name | Classification in registrations |
|----------------|----------------|------------------------------------|--|
| 200- 917-8 | 75-94- 5 | trichloro(vinyl)sila ne | Flam. Liquid 2 H225 Acute Tox. 4 H302 Acute Tox. 3 H311 Acute Tox. 3 H331 Skin Corr. 1A H314 |
| 205- 746-2 | 149- 74-6 | dichloro(methyl)(phenyl)silane | Acute Tox. 4 H302 Skin Corr. 1A H314 Eye Damage 1 H318 |
| 213- 615-6 | 994- 30-9 | chlorotriethylsilan e | Skin Corr. 1A H314 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] Flam. Liquid 3 H226 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] |
| 678- 409-4 | 18402- 22-7 | 678-409-4 | Eye Damage 1 H318 [intermediate (active)] Skin Corr. 1A H314 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Flam. Liquid 3 H226 [intermediate (active)] |
| 213- 912-0 | 1066- 35-9 | chlorodimethylsil ane | Flam. Liquid 1 H224 Water React. Flam. Gas 3 H261 Acute Tox. 3 H331 Skin Corr. 1A H314 Eye Damage 1 H318 |
| 204- 710-3 | 124- 70-9 | dichloro(methyl)(vinyl)silane | Flam. Liquid 2 H225 Acute Tox. 4 H302 Acute Tox. 3 H331 Skin Corr. 1A H314 Eye Damage 1 H318 |
| 242- 472-2 | 18643- 08-8 | chlorodimethyloc tadecylsilane | Skin Corr. 1A H314 Eye Damage 1 H318 |
| 242- 286-1 | 18407- 07-3 | dichlorododecylm ethylsilane | Skin Corr. 1A H314 Eye Damage 1 H318 |

| EC/ | CAS | Substance | Classification in registrations |
|---------------|----------------|---|---|
| List No | No | name | |
| 700- 790-3 | - | Chloro(methyl)sil anes and tetramethylsilane and trichlorosilane from the fractionated distillation of the reaction products of silicon and chloromethane | Pyr. Liquid 1 H250 [intermediate (inactive)] Acute Tox. 4 H302 [intermediate (inactive)] Repr. 2 H361, specific effect:suspected damage to fertility and the unborn child. Lesions induced in testes and epididymis, associated effects on reproductive hormones. Heart defects were observed in fetus. [intermediate |
| 242- 042-4 | 18162- 48-6 | tert- butylchlorodimet hylsilane | Flam. Solid 1 H228 Flam. Solid 2 H228 Skin Corr. 1A H314 Eye Damage 1 H318 Aquatic Chronic 2 H411 |
| 200- | 75-78- | dichloro(dimethyl | STOT Single Exp. 3 H335, affected organs: UPPER TRACT [intermediate (active)] Flam. Liquid 2 H225 Acute Tox. 4 H302 Acute Tox. 3 H331 Skin Irrit. 2 H315 Skin Corr. 1A H314 Eye Irrit. 2 H319 Eye Damage 1 H318 STOT Single Exp. 3 H335, affected organs: other: RTI |
| 901-0 | 5 |)silane | |
| 273- | 68937- | Disilane, chloro | Flam. Liquid 2 H225 [intermediate (inactive)] Skin Corr. 1A H314 [intermediate (inactive)] |
| 054-8 | 17-7 | Me derivs. | |
| 217- 007-1 | 1719- 58-0 | chlorodimethylvin ylsilane | Flam. Liquid 2 H225 Acute Tox. 4 H302 Skin Corr. 1A H314 Eye Damage 1 H318 |

| EC/ | CAS | Substance | Classification in registrations |
|---------------|----------------|---------------------------------|--|
| List No | No | name | |
| 935- 540-4 | - | 935-540-4 | Eye Damage 1 H318 [intermediate (active)] Acute Tox. 3 H311 [intermediate (active)] STOT Single Exp. 3 H335 [intermediate (active)] Flam. Liquid 3 H226 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Acute Tox. 3 H331 [intermediate (active)] Skin Corr. 1A H314 [intermediate (active)] |
| 211- | 701- | trichloro-p- | Skin Corr. 1A H314 |
| 854-0 | 35-9 | tolylsilane | |
| 212- | 768- | chlorodimethylph | Skin Corr. 1B H314 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: Respiratory system [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] |
| 193-0 | 33-2 | enylsilane | |
| 242- 044-5 | 18162- 84-0 | chlorodimethyloc tylsilane | Flam. Liquid 3 H226 Skin Corr. 1A H314 Eye Damage 1 H318 Aquatic Chronic 2 H411 |
| 200- | 75-77- | chlorotrimethylsil | Flam. Liquid 2 H225 Acute Tox. 3 H301 Acute Tox. 4 H312 Acute Tox. 3 H331 Skin Corr. 1A H314 Eye Damage 1 H318 |
| 900-5 | 4 | ane | |
| 261- | 59086- | dichloromethyltet radecylsilane | Skin Corr. 1A H314 |
| 596-8 | 80-5 | | Eye Damage 1 H318 |
| 423- | 1000- | butylchlorodimet | <u>-</u> |
| 700-1 | 50-6 | hylsilane | |

| EC/ | CAS | Substance | Classification in registrations |
|---------------|----------------|--|---|
| List No | No | name | |
| 227- | 5894- | trichloro(hexadec | Acute Tox. 4 H302 |
| 575-2 | 60-0 | yl)silane | Skin Corr. 1 H314 |
| 242- 262-0 | 18379- 25-4 | trichloro(2,4,4- trimethylpentyl)si lane | Acute Tox. 3 H301 Skin Corr. 1A H314 Eye Damage 1 H318 |
| 202- 640-8 | 98-13- | trichloro(phenyl)s ilane | Acute Tox. 4 H312 Skin Corr. 1A H314 Eye Damage 1 H318 |
| 700- 717-5 | - | Chloro(methyl)(m ono and di)silanes and dichloro(ethyl)me thylsilane and hexamethyldisilan e from fractionated distillation of the reaction products of silicon and chloromethane | STOT Single Exp. 3 H335, affected organs: Respiratory tract [Article 10 (inactive)] Acute Tox. 3 H331 [Article 10 (inactive)] Eye Damage 1 H318 [Article 10 (inactive)] Acute Tox. 3 H301 [Article 10 (inactive)] Flam. Liquid 2 H225 [Article 10 (inactive)] Skin Corr. 1A H314 [Article 10 (inactive)] |
| 603- | 13154- | chloro(triisopropy | Skin Corr. 1B H314 [intermediate (active)] |
| 492-0 | 24-0 | l)silane | Eye Damage 1 H318 [intermediate (active)] |
| 204- 072-6 | 115- 21-9 | trichloro(ethyl)sil ane | Flam. Liquid 2 H225 Acute Tox. 4 H302 Acute Tox. 3 H331 Skin Corr. 1A H314 |
| 240- | 16029- | iodotrimethylsila | Skin Sens. 1 H317 [intermediate (active)] Eye Damage 1 H318 [intermediate (active)] Skin Corr. 1B H314 [intermediate (active)] STOT Single Exp. 3 H335, affected system: respiratory system, affected organs: respiratory tract [intermediate (active)] STOT Single Exp. 3 H335, affected organs: Respiratory |
| 171-0 | 98-4 | ne | |

| EC/ List No | CAS No | Substance name | Classification in registrations |
|----------------|---------------|--|---|
| | | | system [intermediate (active)] Flam. Liquid 2 H225 [intermediate (active)] |
| 224- 844-6 | 4518- 98-3 | 1,1,2,2- tetrachloro-1,2- dimethyldisilane | - |
| | | | |
| | | | |

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

Data extracted on 23/02/2022

| Main types of applications structured by product or article types | EC/List 200-877-1 | EC/List 200-900-5 | EC/List 200-901-0 | EC/List 200-902-6 | EC/List 200-917-8 | EC/List 201-251-0 | EC/List 202-640-8 | EC/List 203-930-7 | EC/List 204-072-6 | EC/List 204-710-3 | EC/List 205-489-6 | EC/List 205-746-2 | EC/List 211-854-0 | EC/List 212-193-0 | EC/List 213-600-4 | EC/List 213-615-6 | EC/List 213-912-0 | EC/List 217-007-1 | EC/List 220-672-0 | EC/List 222-123-0 |
|--|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| PC 20: Products such as phregulators, flocculants, precipitants, neutralisation agents | | I, P | F, I, P | | | | | | | | | | | | | | | | | |
| PC 37: Water treatment chemicals | | | F, I | | | | | | | | | | | | | | | | | |
| PC 12: Fertilisers | F, I, | | | | | | | | | | | | | | | | | | | |
| PC 4: Anti-freeze and de-icing products | | F, I | | | | | | | | | | | | | | | | | | |

| Main types of applications structured by product or article types | EC/List 200-877-1 | EC/List 200-900-5 | EC/List 200-901-0 | EC/List 200-902-6 | EC/List 200-917-8 | EC/List 201-251-0 | EC/List 202-640-8 | EC/List 203-930-7 | EC/List 204-072-6 | EC/List 204-710-3 | EC/List 205-489-6 | EC/List 205-746-2 | EC/List 211-854-0 | EC/List 212-193-0 | EC/List 213-600-4 | EC/List 213-615-6 | EC/List 213-912-0 | EC/List 217-007-1 | EC/List 220-672-0 | EC/List 222-123-0 |
|---|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| PC 35: Washing and cleaning products | F, I, P | | F, I | | | | | | | | | | | | | | | | | |
| PC 39: Cosmetics, personal care products | F, I, P | | F, I | F | | | | | | | | | | | | | | | | |
| PC 29: Pharmaceuticals | | | F, I | | | | | | | | | | | | | | | | | |
| PC 31: Polishes and wax blends | F, I, P | | F, I | | | | | | | | | | | | | | | | | |
| PC 15: Non- metal-surface treatment products | I | F, I, A * | F, I, A * | I | | | | | | | | | | | | | | | | |
| PC 24: Lubricants, greases, release products | F, I, P | | F, I | | | | | | | | | | | | | | | | | |
| PC 25: Metal working fluids | F, I, P | | | | | | | | | | | | | | | | | | | |

| Main types of applications structured by product or article types | EC/List 200-877-1 | EC/List 200-900-5 | EC/List 200-901-0 | EC/List 200-902-6 | EC/List 200-917-8 | EC/List 201-251-0 | EC/List 202-640-8 | EC/List 203-930-7 | EC/List 204-072-6 | EC/List 204-710-3 | EC/List 205-489-6 | EC/List 205-746-2 | EC/List 211-854-0 | EC/List 212-193-0 | EC/List 213-600-4 | EC/List 213-615-6 | EC/List 213-912-0 | EC/List 217-007-1 | EC/List 220-672-0 | EC/List 222-123-0 |
|---|----------------------|------------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| PC 16: Heat transfer fluids | | | F, I | | | | | | | | | | | | | | | | | |
| PC 32: Polymer preparations and compounds | F, I, P | F, I, P, C | F, I, A * | | | I | I | | | I | | I | | | | | I | F, I | | |
| PC 1: Adhesives, sealants | | F, I, P , C | F, I, A * | | | | | | | | | | | | | | | | | |
| PC 9b: Fillers, putties, plasters, modelling clay | P | F, I, P, C | | | | | | | | | | | | | | | | | | |
| PC 9a: Coatings and paints, thinners, paint removes | F, I, P | F, I, P, C | F, I, A * | | | | | | | | | | | | | | | | | |
| PC 18: Ink and toners | F, I, | | F, I, A* | | | | | | | | | | | | | | | | | |
| PC 34: Textile dyes, and impregnating products | F, I | I, C | F, I, C, A* | | | | | | | | | | | | | | | | | |

| Main types of applications structured by product or article types | EC/List 200-877-1 | EC/List 200-900-5 | EC/List 200-901-0 | EC/List 200-902-6 | EC/List 200-917-8 | EC/List 201-251-0 | EC/List 202-640-8 | EC/List 203-930-7 | EC/List 204-072-6 | EC/List 204-710-3 | EC/List 205-489-6 | EC/List 205-746-2 | EC/List 211-854-0 | EC/List 212-193-0 | EC/List 213-600-4 | EC/List 213-615-6 | EC/List 213-912-0 | EC/List 217-007-1 | EC/List 220-672-0 | EC/List 222-123-0 |
|---|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| PC 23: Leather treatment products | | | F, I, A * | | | | | | | | | | | | | | | | | |
| PC 14: Metal surface treatment products | | F, I, A * | | | | | | | | | | | | | | | | | | |
| PC 33: Semiconductors | I | I | I | I | | | | | | | | | | | | | I | | | |
| PC 21: Laboratory chemicals | | F, I, P | F, I, P | I, P | I | I, P | I | I | I, P | I | I | I | I | | | | I | I | | I |
| PC 19: Intermediate | I | F, I | F, I | F, I | 1 | I | I | I | I | I | I | I | I | I | I | I | I | F, I | 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

| Main types of applications structured by product or article types | EC/List 225-931-1 | EC/List 226-112-1 | EC/List 226-956-0 | EC/List 227-575-2 | EC/List 240-171-0 | EC/List 242-042-4 | EC/List 242-044-5 | EC/List 242-053-4 | EC/List 242-262-0 | EC/List 242-286-1 | EC/List 242-472-2 | EC/List 261-596-8 | EC/List 273-054-8 | EC/List 603-492-0 | EC/List 604-112-6 | EC/List 678-409-4 | EC/List 700-717-5 | EC/List 700-790-3 | EC/List 935-540-4 |
|--|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| PC 20: Products such as phregulators, flocculants, precipitants, neutralisation agents | | | | | | | | | | | | | | | | | | | |
| PC 37: Water treatment chemicals | | | | | | | | | | | | | | | | | | | |
| PC 12: Fertilisers | | | | | | | | | | | | | | | | | | | |
| PC 4: Anti-freeze and de-icing products | | | | | | | | | | | | | | | | | | | |
| PC 35: Washing and cleaning products | | | | | | I | | | | | | | | | | | | | |

| PC 39: Cosmetics, personal care products | | | | | | | | | | | |
|---|------------------|--|--|--|---|-------------|---|--|--|--|--|
| PC 29: Pharmaceuticals | | | | | | | | | | | |
| PC 31: Polishes and wax blends | | | | | | | | | | | |
| PC 15: Non- metal-surface treatment products | I, A * | | | | | F, I | | | | | |
| PC 24: Lubricants, greases, release products | | | | | | | | | | | |
| PC 25: Metal working fluids | | | | | | | | | | | |
| PC 16: Heat transfer fluids | | | | | | | | | | | |
| PC 32: Polymer preparations and compounds | I, A | | | | I | F, A | I | | | | |

| PC 1: Adhesives, sealants | I, A | | I | F, I | | F, A | | | | |
|--|------------------|--|---|------|--|-------------|--|--|--|--|
| PC 9b: Fillers, putties, plasters, modelling clay | | | | | | I | | | | |
| PC 9a: Coatings and paints, thinners, paint removes | | | I | F, I | | I | | | | |
| PC 18: Ink and toners | A | | | | | A | | | | |
| PC 34: Textile dyes, and impregnating products | | | | | | | | | | |
| PC 23: Leather treatment products | | | | | | | | | | |
| PC 14: Metal surface treatment products | I, A * | | | | | | | | | |
| PC 33: Semiconductors | | | I | F, I | | | | | | |

| PC 21: Laboratory chemicals | | I | I | I | | I | I | I | I | I | I | I | | | | I | | I | |
|-----------------------------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|--|---|--|
| PC 19: Intermediate | I | I | I | I | I | I | I | I | I | I | I | I | I | Ι | I | 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; A*: article service not reported in the dossier, but likely due to combination of the use and technical function

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

Data extracted on 25 March 2022

| EC/List number | RMOA | Authorisation | | Restriction* | CLH | Actions not under REACH/ CLP |
|-------------------|-----------------------|----------------|-----------|--------------|-------------------|---------------------------------|
| | | Candidate list | Annex XIV | Annex XVII | Annex VI (CLP) | |
| 200- 901-0 | PBT assess ment | | | | | |

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