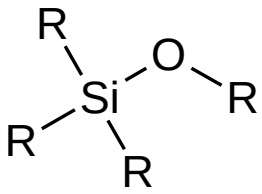
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 13 July 2022

Group Name: Hydrocarbyl siloxanes

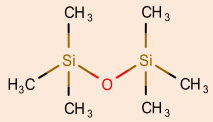
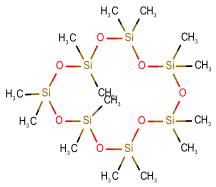
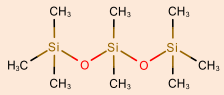
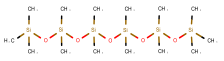
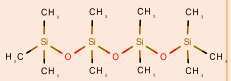
General structure:



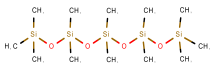
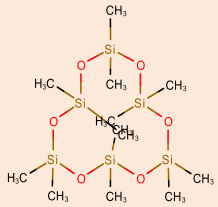
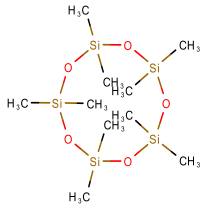
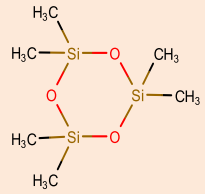
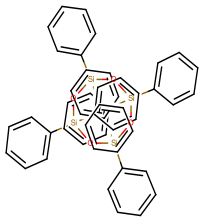
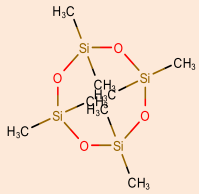
Revision history

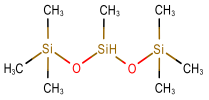
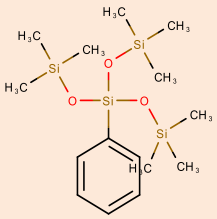
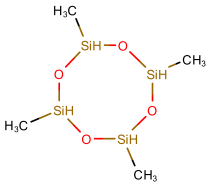
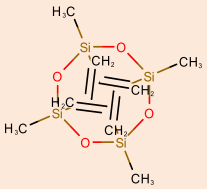
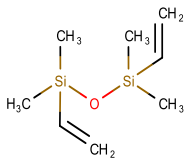
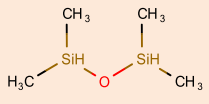
Version	*Date*	*Description*
1.0	1 November 2022	

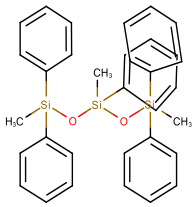
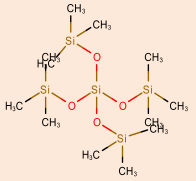
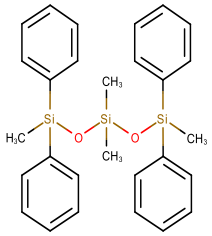
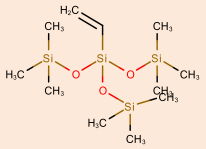
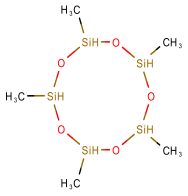
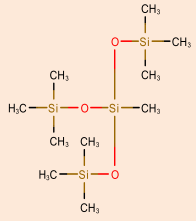
Substances within this group:

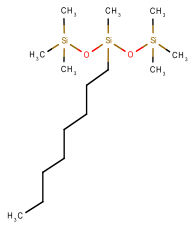
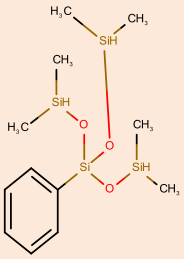
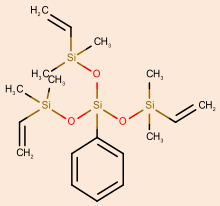
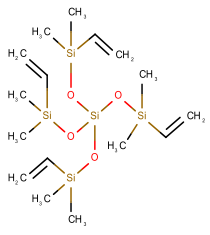
EC/List number	CAS number	Substance name and Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
203-492-7	107-46-0	Hexamethyldisiloxane (L2)		Full, >1000
203-496-9	107-50-6	Tetradecamethylcycloheptasiloxane		Not registered
203-497-4	107-51-7	Octamethyltrisiloxane (L3)		Full, 100-1000
203-499-5	107-52-8	Tetradecamethylhexasiloxane (L6)		Full, not (publicly) available
205-491-7	141-62-8	Decamethyltetrasiloxane (L4)		Full, 100-1000

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

EC/List number	CAS number	Substance name and Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
205-492-2	141-63-9	Dodecamethylpentasiloxane (L5)		Full, >1000
208-762-8	540-97-6	Dodecamethylcyclohexasiloxane (D6)		Full, >1000
208-764-9	541-02-6	Decamethylcyclopentasiloxane (D5)		Full, >1000
208-765-4	541-05-9	Hexamethylcyclotrisiloxane (D3)		Full, >1000
208-904-9	546-56-5	Octaphenylcyclotetrasiloxane		Full, 10-100
209-136-7	556-67-2	Octamethylcyclotetrasiloxane (D4)		Full, >1000

EC/List number	CAS number	Substance name and Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
217-496-1	1873-88-7	1,1,1,3,5,5,5-heptamethyltrisiloxane (H-L3)		Full, 100-1000
218-320-6	2116-84-9	1,1,5,5,5-hexamethyl-3-phenyl-3-[(trimethylsilyl)oxy]trisiloxane (PhM3T)		Full, not (publicly) available
219-137-4	2370-88-9	2,4,6,8-tetramethylcyclotetrasiloxane (H4-D4)		Full, >1000
219-863-1	2554-06-5	2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane (Vi4-D4)		Full, 100-1000
220-099-6	2627-95-4	1,1,3,3-tetramethyl-1,3-divinyldisiloxane (Vi2-L2 (dvTMDS))		Full, 100-1000
221-906-4	3277-26-7	1,1,3,3-tetramethyldisiloxane (H2-L2)		Full, 100-1000

EC/List number	CAS number	Substance name and Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
222-222-9	3390-61-2	1,3,5-trimethyl-1,1,3,5,5-pentaphenyltrisiloxane		Full, 10-100
222-613-4	3555-47-3	1,1,5,5,5-hexamethyl-3,3-bis[(trimethylsilyl)oxy]trisiloxane (M4Q)		Full, not (publicly) available
223-620-5	3982-82-9	1,3,3,5-tetramethyl-1,1,5,5-tetraphenyltrisiloxane		Full, not (publicly) available
226-342-2	5356-84-3	1,1,1,5,5,5-hexamethyl-3-[(trimethylsilyl)oxy)-3-vinyltrisiloxane		OSII or TII
228-204-7	6166-86-5	2,4,6,8,10-pentamethylcyclopentasiloxane (H5-D5)		Full, >1000
241-867-7	17928-28-8	1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane (M3T)		Full, not (publicly) available

EC/List number	CAS number	Substance name and Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
241-881-3	17955-88-3	1,1,1,3,5,5,5-heptamethyl-3-octyltrisiloxane		Full, 100-1000
241-940-3	18027-45-7	3-[(dimethylsilyl) oxy]-1,1,5,5-tetramethyl-3-phenyltrisiloxane		OSII or TII
248-418-4	27342-69-4	Tetramethyltetravinylcyclotetrasiloxane		Not registered
262-056-4	60111-47-9	3-[(dimethylvinylsilyl)oxy]-1,1,5,5-tetramethyl-3-phenyl-1,5-divinyltrisiloxane		Not registered
262-061-1	60111-54-8	3,3-bis[(dimethylvinylsilyl)oxy]-1,1,5,5-tetramethyl-1,5-divinyltrisiloxane (ViM4Q)		Full, not (publicly) available
404-040-3	-	DOW CORNING X2-7551		NONS
406-490-6	-	A mixture of: 1,3-dihex-5-en-1-yl-1,1,3,3-		NONS

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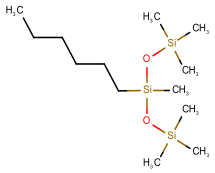
		tetramethyldisiloxane; 1,3-dihex-x-en-1-yl-1,1,3,3-tetramethyldisiloxane x= 1,2,3 or 4		
417-190-1	-	SLM 50524 1,1,3,3-tetramethyl-1,3-dioctadecyldisiloxane		NONS
417-240-0	-	DOW CORNING(R) 2-7935		NONS
417-830-8	-	DVS-BIS-BCB-PREPOLYMER		NONS
421-970-5	-	SYL-OFF(R) 7690 (LIS)		NONS
427-410-6	-	SILATRIPHEN		NONS
428-700-5	1873-90-1	3-hexylheptamethyltrisiloxane		NONS
433-150-4	-	DOW CORNING(R) 2-5647		NONS
435-770-0	-	TRIACONTYLMETHYL DIMETHYLSILOXANE COPOLYMER WITH STABILISERS		NONS
441-110-2	-	DOW CORNING (R) MATERIAL # 04020021		NONS
444-870-3	-	[No public or meaningful		NONS

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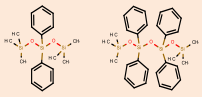
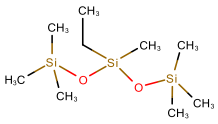
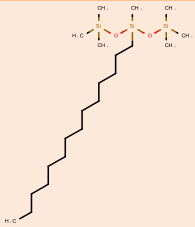
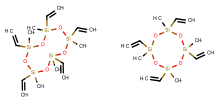
		name is available]		
451-620-7	352230-22-9	KF-56A		Full, not (publicly) available
469-070-1	17861-60-8	3-Ethylheptamethyltrisiloxane		Full, 1-10
476-490-9	-	Trisiloxane, 1,1,1,3,5,5,5-heptamethyl-3-tetradecyl-		Full, not (publicly) available
911-381-6	-	Reaction mass of 2,4,6,8,10-pentamethyl-2,4,6,8,10-pentavinylcyclopentasiloxane and 2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane		Cease manufacture
906-378-1	-	Reaction mass of decamethyltetrasiloxane and dodecamethylpentasiloxane and hexamethyldisiloxane and octamethyltrisiloxane and		OSII or TII

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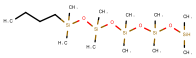
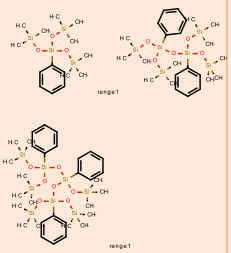
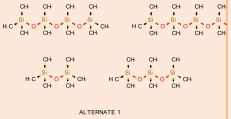
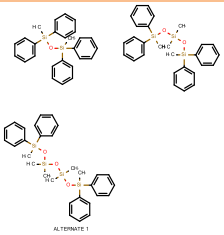
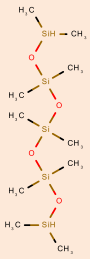
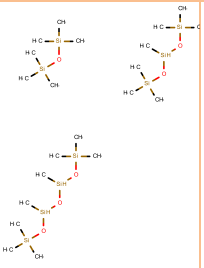
		tetradecamethylhexasiloxane		
696-005-6	121263-53-4	1-butyl-1,1,3,3,5,5,7,7,9,9-decamethylpentasiloxane		OSII or TII
939-487-8	-	Reaction mass of 1,1,1,5,5,5-hexamethyl-3-phenyl-3-((trimethylsilyl)oxy)trisiloxane and 1,1,1,7,7,7-hexamethyl-3,5-diphenyl-3,5-bis[(trimethylsilyl)oxy]tetrasiloxane and 1,1,1,9,9,9-hexamethyl-3,5,7-triphenyl-3,5,7-tris((trimethylsilyl)oxy)pentasiloxane		Full, 100-1000
946-132-0	-	Silicone rubber base compounds, manufacture of, by-product from, thermally separated fraction		OSII or TII
946-797-7	-	Reaction mass of decamethyltetrasiloxane; dodecamethylpentasiloxane; hexamethyldisiloxane;		Full, not (publicly) available

EC/List number	CAS number	Substance name and Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
		octamethyltrisiloxane		
946-850-4	-	Reaction mass of 1,3-dimethyl-1,1,3,3-tetraphenyldisiloxane and 1,3,3,5-tetramethyl-1,1,5,5-tetraphenyltrisiloxane and 1,3,3,5,5,7-hexamethyl-1,1,7,7-tetraphenyltetrasiloxane		Full, not (publicly) available
836-576-2	995-83-5	1,1,3,3,5,5,7,7,9,9-decamethylpentasiloxane		OSII or TII
953-427-8	-	Reaction mass of 1,1,1,3,5,5,5-heptamethyltrisiloxane and 1,1,1,3,5,7,7,7-octamethyltetrasiloxane and hexamethyldisiloxane		OSII or TII

This table contains also group members that are only notified under the CLP Regulation. However, the list is currently non-exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

Contents

DISCLAIMER

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Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website[2].

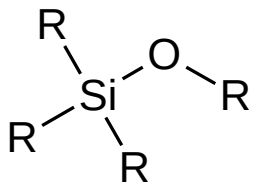
[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

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
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

ECHA has grouped together structurally similar substances based on the presence of the siloxy moiety shown in the figure below.



The substances included in the group cover linear and branched aliphatic and aromatic siloxanes as well as cyclic siloxanes. In addition polymeric siloxanes notified under previous legislation (NONS) have been included in the group.

The present group includes 52 substances of which 30 have full registrations, 7 are intermediates, and 12 are unclaimed NONS. 3 substances have not been registered under REACH, though there are C&L notifications available.

Based on information reported in the REACH registration dossiers, approximately half of the substances with full registrations have widespread uses by consumers and professional workers leading to significant potential for environmental release and human exposure. The main wide dispersive uses cover uses in cosmetics and personal care products, in washing and cleaning products, coatings and paints, thinners and paint removers, inks and toners, adhesives and sealants. The main industrial use types are uses in polymer preparations and compounds and uses as intermediates. Other industrial applications cover uses in washing and cleaning products, pharmaceuticals, lubricants and greases, coatings and paints, thinners, paint removers and ink and toners.

Many substances are used as monomers in polymer preparations and compounds. These are of concern if there is potential for release of the unreacted monomers from the polymers. Together with the high volatility of many of these substances, this may lead to potential for exposure also for these type of uses generally considered of low concern.

Similar types of uses are described for the substances currently with industrial uses only and those with professional and consumer uses. Therefore the potential for substitution among substances cannot be excluded. There is also a risk of regrettable substitution already at this stage as some of the substances and/or some of their uses are already regulated:

- D4 (EC 209-136-7), D5 (EC 208-764-9) and D6 (EC 208-762-8) are included in the Candidate List.
- The placing on the market of D4 and D5 in wash-off cosmetic products (above 0.1 %) is restricted (entry 70 of Annex XVII to REACH[3]).
- ECHA (at the request of the European Commission) submitted in 2019 a proposal to restrict consumer uses and professional uses of D4, D5 and D6

[3] Entry 70 of Annex XVII to REACH (Substances restricted under REACH) at https://echa.europa.eu/substances-restricted-under-reach/-/dislist/details/0b0236e182463cd3

(with some derogations). This restriction[4] is currently under decision making by the Commission.
- ECHA recommended D4, D5 and D6 in its 10th recommendation[5] for their inclusion in Annex XIV (Authorisation List).
- D4 is considered for POPs identification[6].
- One substance is under Substance Evaluation for its PBT/vPvB and/or CMR properties (EC 203-492-7),
- Substance evaluation has been concluded for EC 205-492-2, EC 203-497-4 and EC 205-491-7

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is 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 table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

2 Justification for the need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for potential vPvB and/or PBT hazard due to the potential for release/exposure of all substances in the group. For some substances in the group, there is also a potential for reproductive toxicity (development and/or fertility), ED or STOT RE.

Based on ECHA's assessment of hazard information currently available in registration dossiers, considerations of structural similarity and presence of

[4] The status of this restriction proposal can be followed at https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e181a55ade .

[5] https://echa.europa.eu/recommendations-for-inclusion-in-the-authorisation-list

[6] List of substances proposed as POPs - ECHA (europa.eu)

common functional moiety all the substances in the whole group are (potentially) *vPvB or PBT*:

- these substances are (potentially) very persistent (vP) as they meet the criteria set out in Annex XIII *i.e.,* degradation half-life >180 days in marine, fresh or estuarine sediment (up to several years of half-life), shown via OECD 308 studies or read-across;
- these substances show no or little ready biodegradation in biodegradability tests and therefore screen as potentially persistent (P) or very persistent (vP)
- these substances are (potentially) bioaccumulative (B) or very bioaccumulative vB as
    - they meet the criteria vB as set out in Annex XIII (*i.e.* BCF > 5 000);
    - they have a high potential to partition to lipid storage (e.g., log Kow > 4.5)
- these substances contain constituents and/or impurities (≥0.1%) that have known PBT/vPvB properties and should therefore be considered themselves as PBT/vPvB

Therefore, all the substances are considered as potential vPvB/PBT substances.

Furthermore, a few substances in the group may also be persistent, mobile and toxic (if such property exists after generation of data, these properties will need to be considered as well).

For some substances, for which there is not sufficient hazard information, or where existing hazard information does not allow an extrapolation of the hazard and/or data generation is not already initiated via ongoing Testing Proposal Evaluation (TPE), Compliance Check (CCH) and/or Substance Evaluation (SEv), representative CCHs and/or SEv will be proposed to clarify their environmental hazard properties.

Note that some substances contain constituents and/or impurities above 0.1% that have known PBT/vPvB properties. In some cases the main constituents of the substances are themselves potentially PBT/vPvB. Therefore, on a case by case basis, depending on the amount of impurities/constituents present data generation might be needed to clarify hazard properties of the main constituents.

Furthermore, based on ECHA's assessment of hazard information in the registration dossiers, for some substances (see table in section 3) potential hazards were also identified for human health in repeated dose toxicity (RDT), pre-natal developmental (PNDT), and/or extended one-generation reproductive toxicity (EOGRTS) studies:

- STOT RE (liver, kidney, thyroid),and/or
- reproductive toxicity (development, and/or fertility), and/or
- endocrine disrupting properties (thyroid weight, and thyroid hormones levels).

Only D4 (EC 209-136-7) has a harmonised classification as Repr. 2. However, the findings observed indicate that D4 and H2-L2 (EC 221-906-4) could be classified as Repr. 1 B. Regarding repeated dose toxicity, M3T (EC 241-867-7) is self-classified as STOT RE 2 (liver). L2 (EC 203-492-7) has a C&L notification for STOT RE 1 (lungs). The available data suggests that several other substances could be classified as STOT RE 2 (EC 208-764-9 [D5], EC 209-136-7 [D4], EC 469-070-1). For further substances with human health hazard potential, please consult the table in section 3.

Data generation via TPE, CCH and/or SEV is currently ongoing or will be proposed for several substances to clarify the potential human health hazards. Unlike for the environment, no general pattern or structural dependency could be identified for the group regarding human health hazards. Therefore, a case by case assessment and/or data generation is required to clarify the potential human health hazards. Nevertheless, the same regulatory needs (i.e. restriction) applies, including additional steps in the strategy compared to environmental endpoints (see table in section 3). Any additional hazards identified should also be taken into account in the restriction proposal.

Restriction is considered as the most appropriate regulatory risk management option to minimise releases of these substances to the environment and to limit exposure.

Where there is enough hazard information available, the first step of the regulatory risk management action proposed is the confirmation of the hazard via SVHC identification and inclusion on the Candidate List as PBT/vPvB and ED (where relevant). In addition, should any Repr. 1B and/or STOT RE 1 or 2 hazards exist, confirmation of hazards via harmonised classification (CLH) will have to be initiated.

CLH i) will require company level risk management measures (RMM) for workers, to be in place, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 30.

CLH will also support regulatory action under other regulations. For instance, in this specific case:

- Harmonised classification as CMR cat. 1 will trigger regulatory action under the Cosmetic products regulation (EC) No 1223/2009 for uses within its scope, since CMR cat. 1 are restricted by this regulation.
- Harmonised classification as CMR cat. 1 will trigger regulatory action under the biocidal product regulation (EU) 528/2012, which does not allow the use by the general public of a product containing substances above the concentration limit leading to classification of the mixture as CMR cat 1.

Confirmation of hazard via SVHC identification is highly recommended for further regulatory processes under REACH (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 a regulatory threshold.

However, 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 releases and exposure is expected from consumer uses, professional uses, article service life and industrial uses.

Releases to the environment from consumer uses cannot be avoided, in particular for uses such as washing, cleaning and personal care products, cosmetics[7], air care products, coatings and paints or other products or similar uses. Furthermore, exposure of vulnerable groups (e.g. babies) for D4, D5 and D6 has been confirmed from consumer products like mattresses[8].

[7] See also: Kortlægning og risikovurdering af siloxaner i kosmetiske produkter (mst.dk)

[8] See Ministry of Environment of Denmark, *Survey and risk assessment of VOCs in PU foam products* (Rapport (mst.dk))

Widespread professional uses (similar to the above described consumer uses) are expected to be widespread (at many sites and by many users) and typically non-contained and non-automated leading to low levels of operational controls and risk management measures leading to exposure to professional workers and releases to the environment.

Furthermore, potential for exposure and releases to the environment from articles is likely, based on available information. This includes articles where the substances are used in adhesives, sealants, coatings and paints.

It should be noted that polymer preparations (in mixtures or articles) produced from these monomer substances, can also lead to releases of the monomers to the environment. For some substances in the group (e.g. D4 (EC 209-136-7), D5 (EC 208-764-9) and D6 (EC 208-762-8)) it is known that unreacted monomers remain in polymers at considerable amounts[9] and/or can be released from polymer articles[10]. Additionally, a report analysing linear and cyclic siloxanes in food contact materials, also showed the release potential from silicon polymers[11].

Therefore, a **restriction of the substances as such, as a constituent in other substance, as unreacted monomers in polymers and/or in mixtures (>0.1 %) used by consumers, professional workers and industrial workers** is suggested after SVHC identification and/or CLH, with the aim to minimise exposures and emissions to humans and the environment.

The use of PBT/vPvB substances by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[12].

Moreover, **restricting substances in articles** used by professionals or consumers is proposed as potential for exposure from articles is likely.

It is suggested to cover possibly also industrial uses as part of the restriction.

It seems that some substances in the group are used by professional workers in uses where substitution is difficult and/or considerable socio-economic impact could be expected, e.g. in certain polymer preparations, dry cleaning or in uses as medical devices. For such uses, derogations might be considered, similar to the ones granted in the proposed restriction on D4, D5 and D6[13].

It should be noted that the substances of this group are at very different regulatory stages, some are already identified as SVHC and some of their uses (proposed to be) restricted, some have sufficient information to be identified as SVHC, some are under ongoing data generation and others have not yet been identified for data generation. To avoid unnecessary delay of regulatory action, the hazards of the

[9] Information available from Restriction process: Registry of restriction intentions until outcome - ECHA (europa.eu) or the Recommendation of the substances for inclusion in the Authorisation list, example D4: Recommendations for inclusion in the Authorisation List - ECHA (europa.eu)

[10] See Ministry of Environment of Denmark, *Survey of selected endocrine disruptors* (978-87-7038-242-7.pdf (mst.dk))

[11] Rapport: Siloxanes in silicone products intended for food contact (mattilsynet.no)

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

[13] Registry of restriction intentions until outcome - ECHA (europa.eu)

substances in this group should be clarified and confirmed as early as possible and where feasible read-across should be considered.

Therefore, ECHA subdivides the group into:

- substances that appear to have already sufficient information to be identified as SVHC based on their vPvB/PBT properties,
- substances that contain constituents with confirmed vPvB/PBT properties at relevant amounts. Those would not need to be identified as SVHC, but regulatory action (e.g. restriction) can be undertaken via the constituents,
- substances for which read-across could be applied to identify them as vPvB/PBT SVHCs, and
- substances for which further data generation is needed to confirm their vPvB/PBT properties.

As some substances could be regulated already whereas for others generation of data and confirmation of hazards will need to be awaited, it is suggested to formulate the restriction in a way that allows for easy future inclusion of additional hydrocarbyl siloxanes (or similar siloxane substances) identified as vPvB/vPvBT or PBT. As soon as further data generation allows, the remaining substances of this group (or other siloxane substances), if hazard exist, should be identified as SVHC and included in the restriction.

As explained above some substances are not only vPvB but also toxic to human health. This should be considered when developing the restriction proposal further.

It should be noted, that at this stage it cannot yet be concluded that D4, D5 and D6 are sufficiently regulated. It seems that the substances are not adequately classified based on available hazard information. Data generation for reproductive toxicity is ongoing for D6 (EC 208-762-8). For D4 (EC 209-136-7) a more severe classification than the current Repr. 2 is suggested by the existing data (see above). Additionally, even though these substances are (proposed to be) restricted[14] and recommended to be included into the Authorisation List[15], during both processes it has been highlighted that in particular the polymer preparations containing these substances as unreacted monomers pose an unacceptable risk to human health and the environment. The use as monomer in polymers is exempted from the authorisation requirement and derogated from the restriction based on scope considerations (no risk assessment performed by RAC).

Furthermore, D4 (EC 209-136-7)[16] has been identified as a potential POP candidate by the Commission and the Competent Authorities expert group for the Regulation (EU) 2019/1021 on POPs. The listing of a substance as a persistent organic pollutant (POP) under the Stockholm Convention leads to wider global regulatory risk management actions. To meet the criteria of a POP substance, the substance needs to have vPvB properties, as well as adverse effects to human health and/or the environment, and a potential for long-range environmental transport. Other substances in the group (e.g. D5 (EC 208-764-9) and D6 (EC 208-762-8)) may also fulfil the screening criteria for POPs identification as laid out in Annex D to the Convention[17].

[14] Registry of restriction intentions until outcome - ECHA (europa.eu)

[15] Recommendations for inclusion in the Authorisation List - ECHA (europa.eu)

[16] List of substances proposed as POPs - ECHA (europa.eu)

[17] Text of the Convention (pops.int)

Some substances in the group, are at this stage not registered or are only used at industrial sites, e.g. as monomers or functional fluids. Nevertheless, these substances should be included in the restriction. This would ensure that releases from polymer preparations are minimised and regrettable substitution is prevented.

Based on currently available information, there is no need for EU regulatory risk management for potential vPvB hazard of the remaining substances in the group for which the available information does not allow confirmation of the hazard and data generation is not possible (see table in section 3).

The available information and structural similarity indicate that these substances may have a similar environmental hazard profile as the other substances in the group, i.e. potential PBT/vPvB. However, from a human health perspective it is not possible to conclude on the hazards based on the information available.

However, due to intermediate registration, not registered substance or NONS, it is not possible to clarify the potential 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.

Furthermore, whenever new information would become available on the substance or a constituent, or structural similarity (read-across) allows, regulatory action as proposed above (i.e. restriction) should be initiated to avoid regrettable substitution. This is already proposed for EC 906-378-1, 911-381-6, 946-132-0 and 953-427-8 based on constituents, and for 428-700-5 based on read-across.

3 Conclusions and actions

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

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
209-136-7* (D4) **208-764-9* (D5)** **208-762-8* (D6)** **203-492-7 (L2)** **203-497-4 (L3)** **205-491-7 (L4)** **205-492-2 (L5)**	Known or potential hazard for reproductive toxicity, for ED and/or for STOT RE	Known or potential hazard for PBT/vPvB Known or potential hazard for persistency and mobility for EC 203-492-7 Known or potential hazard for aquatic toxicity for EC 209-136-7	High potential for exposure to the environment, professional workers and consumers from widespread uses, e.g. in cosmetics, personal care products, washing and cleaning, or in polymers. Exposure from articles is also likely, where the substances are used in adhesives, sealants, coatings, paints or in polymers.	**Need for EU RRM: Restriction** <u>Justification:</u> Releases to the environment from consumer and widespread professional uses cannot be avoided. Widespread professional uses are typically non-contained and non-automated leading to releases to the environment. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective	**First step:** SVHC identification (of vPvB hazard). Substances with * are already identified as SVHC. CCH (to generate data on HH hazard): L4 **Next steps:** CLH (for Repr. and/or STOT RE) Restriction
906-378-1 **911-381-6** **946-132-0**	Known or potential hazard for reproductive toxicity,	Known or potential hazard for PBT/vPvB	Some substances in the group have high potential for exposure to the environment, professional workers		**Restriction** (based on constituents once their PBT/vPvB, Repr and/or ED properties are confirmed)

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
946-797-7 **953-427-8**	for ED and/or for STOT RE based on constituents.		and consumers from widespread uses, e.g. in cosmetics, personal care products, washing and cleaning, or in polymers. Exposure from articles is also likely, where the substances are used in adhesives, sealants, coatings, paints or in polymers. For the other substances in this group there seem to be potential for substitution in (some of) the uses described above.	to introduce controls at the level of placing on the market rather than at the level of uses. Specific restriction for use in articles is proposed as potential exposure from articles is likely Industrial uses to be considered as part of the restriction	
217-496-1 (H-L3) **241-867-7 (M3T)** **222-613-4 (M4Q)** **203-499-5 (L6)** **241-881-3**	Known or potential hazard for reproductive toxicity, for ED and/or for STOT RE (for all but 222-222-9, 262-061-1, 262-056-4,	Known or potential hazard for PBT/vPvB Known or potential hazard for persistency and mobility EC 217-496-1	Some substances in the group have high potential for exposure to the environment, professional workers and consumers from widespread uses, e.g. in cosmetics, personal care products, washing		**First step:** PBT EG consultation for possibility of read across CCH (if not possible to read across) CCH/SEV (to generate data on HH hazard)

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
262-061-1 (ViM4Q) **469-070-1** **218-320-6 (PhM3T)** **222-222-9** **223-620-5** **451-620-7 (KF-56A)** **476-490-9** **203-496-9** **226-342-2** **262-056-4428-700-5** **939-487-8** **946-850-4**	428-700-5, 451-620-7, 939-487-8)		and cleaning, or in polymers. Exposure from articles is also likely, where the substances are used in adhesives, sealants, coatings, paints or in polymers. For the other substances in this group there seem to be potential for substitution in (some of) the uses described above.		**Next steps (if hazard confirmed)** SVHC identification (confirming vPvB hazard) CLH (for Repr. and/or STOT RE) Restriction

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
208-765-4 (D3) **219-137-4 (H4-D4)** **219-863-1 (Vi4-D4)** **220-099-6 (Vi2-L2 (dvTMDS))** **221-906-4 (H2-L2)** **228-204-7 (H5-D5)** **208-904-9**	Known or potential hazard for reproductive toxicity, for ED and/or for STOT RE (for all but 208-904-9)	Known or potential hazard for PBT/vPvB Known or potential hazard for persistency and mobility for EC 221-906-4	Some substances in the group have high potential for exposure to the environment, professional workers and consumers from widespread uses, e.g. in cosmetics, personal care products, washing and cleaning, or in polymers. Exposure from articles is also likely, where the substances are used in adhesives, sealants, coatings, paints or in polymers. For the other substances in this group there seem to be potential for substitution in (some of) the uses described above.		**First step:** CCH/SEV (to generate data on vPvB and HH hazard) **Next steps:** SVHC identification (to confirm vPvB and ED where relevant) CLH (for Repr. and/or STOT RE) Restriction
241-940-3	Inconclusive hazard for reproductive toxicity	Potential hazard for PBT/vPvB	Only intermediate/monomer uses registered, or	**Currently no need for EU RRM**	**First step:** No action

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
248-418-4 **404-040-3** **406-490-6** **417-190-1** **417-240-0** **417-830-8** **421-970-5** **427-410-6** **433-150-4** **435-770-0** **441-110-2** **444-870-3** **696-005-6** **836-576-2**	for ED, for STOT RE		substance not registered.	<u>Justification:</u> Due to intermediate registration, NONs, not-registered, 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. Whenever, a hazard could be confirmed based on existing information, constituents or read-across, regulatory action should be initiated to avoid regrettable substitution.	

Annex 1: Overview of classifications

Data extracted on 7 February 2022

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
203-492-7	107-46-0	Hexamethyldisiloxane (L2)	-	Carc. 2 H351 [intermediate (inactive)] Flam. Liquid 2 H225 Aquatic Acute 1 H400 Aquatic Chronic 2 H411
203-496-9	107-50-6	tetradecamethylcycloheptasiloxane	-	-
203-497-4	107-51-7	Octamethyltrisiloxane (L3)	-	Flam. Liquid 3 H226
203-499-5	107-52-8	Tetradecamethylhexasiloxane (L6)	-	-
205-491-7	141-62-8	Decamethyltetrasiloxane (L4)	-	Flam. Liquid 3 H226
205-492-2	141-63-9	Dodecamethylpentasiloxane (L5)	-	-
208-762-8	540-97-6	Dodecamethylcyclohexasiloxane (D6)	-	-
208-764-9	541-02-6	Decamethylcyclopentasiloxane (D5)	-	-
208-765-4	541-05-9	Hexamethylcyclotrisiloxane (D3)	-	Flam. Solid 1 H228
208-904-9	546-56-5	octaphenylcyclotetrasiloxane	-	-
209-136-7	556-67-2	Octamethylcyclotetrasiloxane (D4)	*Aquatic Chronic 1 H410, very toxic to aquatic life with long lasting effects.* *Repr. 2 H361f***, suspected of damaging fertility*	Repr. 2 H361, specific effect:effect on fertility Flam. Liquid 3 H226 Aquatic Chronic 4 H413
217-496-1	1873-88-7	1,1,1,3,5,5,5-heptamethyltrisiloxane	-	Flam. Liquid 3 H226 Skin Irrit. 2 H315 [intermediate

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
		(H-L3)		(active)] STOT Single Exp. 3 H335, affected organs: Respiratory system [intermediate (active)] Flam. Liquid 3 H225 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)]
218-320-6	2116-84-9	1,1,5,5,5-hexamethyl-3-phenyl-3-[(trimethylsilyl)oxy]trisiloxane (PhM3T)	-	-
219-137-4	2370-88-9	2,4,6,8-tetramethylcyclotetrasiloxane (H4-D4)	-	Flam. Liquid 3 H226
219-863-1	2554-06-5	2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane (Vi4-D4)	-	-
220-099-6	2627-95-4	1,1,3,3-tetramethyl-1,3-divinyldisiloxane (Vi2-L2 (dvTMDS))	-	Repr. 2 H361, specific effect:lower fetal weights Flam. Liquid 2 H225 Flam. Liquid 3 H226 Repr. 2 H361 [intermediate (active)]
221-906-4	3277-26-7	1,1,3,3-tetramethyldisiloxane (H2-L2)	-	Flam. Liquid 2 H225
222-222-9	3390-61-2	1,3,5-trimethyl-1,1,3,5,5-pentaphenyltrisiloxane	-	-
222-613-4	3555-47-3	1,1,5,5,5-hexamethyl-3,3-bis[(trimethylsilyl)oxy]trisiloxane (M4Q)	-	-
223-620-5	3982-82-9	1,3,3,5-tetramethyl-1,1,5,5-	-	-

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
		tetraphenyltrisiloxane		
226-342-2	5356-84-3	1,1,1,5,5,5-hexamethyl-3-[(trimethylsilyl)oxy)-3-vinyltrisiloxane	-	-
228-204-7	6166-86-5	2,4,6,8,10-pentamethylcyclopentasiloxane (H5-D5)	-	Flam. Liquid 3 H226
241-867-7	17928-28-8	1,1,1,3,5,5,5-heptamethyl-3-[(trimethylsilyl)oxy]trisiloxane (M3T)	-	Flam. Liquid 3 H226 STOT Rep. Exp. 2 H373, affected organs: liver
241-881-3	17955-88-3	1,1,1,3,5,5,5-heptamethyl-3-octyltrisiloxane	-	-
241-940-3	18027-45-7	3-[(dimethylsilyl)oxy]-1,1,5,5-tetramethyl-3-phenyltrisiloxane	-	Flam. Liquid 3 H226 [intermediate (active)]
248-418-4	27342-69-4	tetramethyltetravinylcyclotetrasiloxane	-	-
262-056-4	60111-47-9	3-[(dimethylvinylsilyl)oxy]-1,1,5,5-tetramethyl-3-phenyl-1,5-divinyltrisiloxane	-	-
262-061-1	60111-54-8	3,3-bis[(dimethylvinylsilyl)oxy]-1,1,5,5-tetramethyl-1,5-divinyltrisiloxane (ViM4Q)	-	-
451-620-7	-	451-620-7	-	-
469-070-1	17861-60-8	469-070-1	-	Flam. Liquid 3 H226

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
476-490-9	-	476-490-9	-	-
696-005-6	121263-53-4	1-butyl-1,1,3,3,5,5,7,7,9,9-decamethylpentasiloxane	-	Eye Irrit. 2 H319 [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: respiratory tract [intermediate (active)]
836-576-2	995-83-5	1,1,3,3,5,5,7,7,9,9-decamethylpentasiloxane	-	Skin Irrit. 2 H315 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: respiratory tract [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)]
906-378-1	-	Reaction mass of decamethyltetrasiloxane and dodecamethylpentasiloxane and hexamethyldisiloxane and octamethyltrisiloxane and tetradecamethylhexasiloxane	-	Skin Irrit. 2 H315 [intermediate (active)] Aquatic Chronic 1 H410 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: Respiratory tract [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Flam. Liquid 2 H225 [intermediate (active)]
911-381-6	-	Reaction mass of 2,4,6,8,10-pentamethyl-2,4,6,8,10-pentavinylcyclopentasiloxane and 2,4,6,8-tetramethyl-2,4,6,8-tetravinylcyclotetrasiloxane	-	-
939-487-8	-	Reaction mass of 1,1,1,5,5,5-	-	Acute Tox. 2 H330

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
		hexamethyl-3-phenyl-3-((trimethylsilyl)oxy)trisiloxane and 1,1,1,7,7,7-hexamethyl-3,5-diphenyl-3,5-bis[(trimethylsilyl)oxy]tetrasiloxane and 1,1,1,9,9,9-hexamethyl-3,5,7-triphenyl-3,5,7-tris((trimethylsilyl)oxy)pentasiloxane		
946-132-0	-	Silicone rubber base compounds, manufacture of, by-product from, thermally separated fraction	-	Flam. Liquid 2 H225 [intermediate (active)] Aquatic Acute 1 H400 [intermediate (active)] Aquatic Chronic 2 H411 [intermediate (active)]
946-797-7	-	Reaction mass of decamethyltetrasiloxane and dodecamethylpentasiloxane and hexamethyldisiloxane and octamethyltrisiloxane	-	Flam. Liquid 3 H226 Aquatic Chronic 3 H412
946-850-4	-	Reaction mass of 1,3-dimethyl-1,1,3,3-tetraphenyldisiloxane and 1,3,3,5-tetramethyl-1,1,5,5-tetraphenyltrisiloxane and 1,3,3,5,5,7-hexamethyl-1,1,7,7-tetraphenyltetrasiloxane	-	-

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
953-427-8	-	Reaction mass of 1,1,1,3,5,5,5-heptamethyltrisiloxane and hexamethyldisiloxane and 1,1,1,3,5,7,7,7-octamethyltetrasiloxane	-	Aquatic Acute 1 H400 [intermediate (active)] Aquatic Chronic 2 H411 [intermediate (active)] Flam. Liquid 2 H225 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] STOT Single Exp. 3 H335, affected organs: Respiratory system [intermediate (active)] Skin Irrit. 2 H315 [intermediate (active)]

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

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

Data extracted on 07 February 2022

Substances with only polymer, intermediate and other industrial uses:

EC/List number	208-765-4	220-099-6	221-906-4	222-613-4	946-850-4	208-904-9	217-496-1	219-137-4	228-204-7	262-061-1	241-940-3	696-005-6	836-576-2	906-378-1	946-132-0	226-342-2	476-490-9	953-427-8
Washing and cleaning products		**F, I**	**F**															
Biocidal products (e.g. disinfectants, pest control)		**F, I**																
Cosmetics, personal care products	**I**																	
Pharmaceuticals		**I**	**I**															
Non-metal-surface treatment products		**I**			**I**													
Lubricants, greases, release products	**I**	**F, I**																
Heat transfer fluids				**I**														
Polymer preparations and compounds	**I**	**F, I,**	**F, I,**	**I**		**I**	**I**	**I**	**I**	**I**								
Adhesives, sealants	**I**	**F, I,**	**F**															
Fillers, putties, plasters, modelling clay		**F, I**																
Coatings and paints, thinners, paint removes	**I**	**F, I,**	**F**															
Ink and toners		**F, I**	**F**															
Paper and board treatment products	**I**	**F, I,**			**I**													

EC/List number	208-765-4	220-099-6	221-906-4	222-613-4	946-850-4	208-904-9	217-496-1	219-137-4	228-204-7	262-061-1	241-940-3	696-005-6	836-576-2	906-378-1	946-132-0	226-342-2	476-490-9	953-427-8
Textile dyes, and impregnating products		**F, I, (A)**																
Leather treatment products		**F, I,**																
Metal surface treatment products					**I**													
Semiconductors		**F, I,**																
Intermediate	**F, I**	**F, I**	**I,**	**I**		**I**	**I**	**I,**	**I**	**I**	**I**	**I**	**I**	**I**	**I**			
Electrolytes for batteries								**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

Susbtances with widespread uses by consumers, professional workers and/or with article service life:

EC/List number	203-492-7	203-497-4	203-499-5	205-491-7	205-492-2	208-762-8	208-764-9	209-136-7	222-222-9	241-867-7	241-881-3	451-620-7	939-487-8	946-797-7	218-320-6	469-070-1	219-863-1	223-620-5
Products such as ph-regulators, flocculants, precipitants, neutralisation agents	**F, I**			**I, P**			**I, P**										**F, I, P**	
Water treatment chemicals	**F, I, P**							**C**										
Adsorbents	**I**			**I**														
Washing and cleaning products	**F, I, P, C**	**F, I, P, C**	**F, I, P**	**F, I, P, C**	**F, P, C**	**F, I, P, C**	**F, I, P, C**	**I, P, C**	**F**			**F**	**F**	**F, P, C**			**F, I**	
Biocidal products (e.g. disinfectants, pest control)	**I**	**F**	**F**	**F, I**	**F**		**I, C**						**F**				**F, I**	
Perfumes, fragrances	**F, C**	**F**		**F**	**F, C**	**F, C**	**F, I, C**		**F**	**F, P**		**F, C**	**F**					
Air care products	**F, P, C**	**F, P, C**	**F**	**F, P, C**	**F, P**	**F, C,**	**F,**					**F**		**F**				
Cosmetics, personal care products	**F, I, P, C**	**F, P, C,**	**F, P, C**	**F, P, C,**	**F, P, C,**	**F, P, C,**	**F, I, P, C**	**F, I, P, C**	**F, C**	**F, P, C**	**F, I, P, C**	**F, P, C**	**F, P, C**	**F, P, C**	**F, C**	**F, C**		
Pharmaceuticals	**F, I**	**F, I**				**F, I, C**	**F, I, C**										**I**	
Polishes and wax blends	**F, I, P, C**	**F, P**		**F, P**		**F, I, P, C**	**F, I, P, C**	**I, P, C**			**F**							
Non-metal-surface	**F, I**	**F, I**		**F, I**	**F, I**		**C**	**I**	**I**								**I**	

EC/List number	203-492-7	203-497-4	203-499-5	205-491-7	205-492-2	208-762-8	208-764-9	209-136-7	222-222-9	241-867-7	241-881-3	451-620-7	939-487-8	946-797-7	218-320-6	469-070-1	219-863-1	223-620-5
treatment products																		
Lubricants, greases, release products	**F, I, C**			**F, I**	**F, I**	**F**	**F, C**	**F, I**	**I**								**F, I**	
Heat transfer fluids	**F, I,**	**I**	**I**	**F, I**	**I**		**C**							**I**				
Hydraulic fluids																		**I, P**
Polymer preparations and compounds	**F, I,**	**F, I, A**	**F**	**F, I, A**	**F, I, A**	**I**	**F, I, P, C, A**	**F, I, C, A**			**F, I, P, C, A**		**F**				**F, I, A**	
Adhesives, sealants	**F, I, P,**	**F, I, A**	**F**	**F, I, A**	**F, A**		**F, I, P, C, A**	**I**					**F**				**F, I, A**	
Fillers, putties, plasters, modelling clay		**F, I**				**C**											**F, I**	
Coatings and paints, thinners, paint removes	**F, I, P, C**	**F, I, A**	**F**	**F, I**	**F, I**	**F**	**F, P, C**	**F, I, P, C**	**F**				**F**				**F, I, A**	
Ink and toners	**F, I, P, C**	**F, I, A**		**A**	**F, A**	**I**	**C**	**P, C, A**									**F, I, A**	
Paper and board treatment products	**A**	**I**						**A**	**I**								**I**	
Textile dyes, and impregnating products	**F, I**						**F, I, P, C**	**F, I**									**F, I, P, C**	
Leather treatment products	**F, I**	**I**					**F, I, C**	**F, I**									**F, I, P, C**	

EC/List number	203-492-7	203-497-4	203-499-5	205-491-7	205-492-2	208-762-8	208-764-9	209-136-7	222-222-9	241-867-7	241-881-3	451-620-7	939-487-8	946-797-7	218-320-6	469-070-1	219-863-1	223-620-5
Metal surface treatment products							**C**		**I**									
Welding and soldering products, flux products	**I**			**I**														
Semiconductors	**I,**			**I**		**P**		**I**									**F, I**	
Intermediate	**I,**	**I**			**I**	**I**	**F, I**	**I**									**F, I**	
Extraction agents							**C**											
Electrolytes for batteries																		
Photo-chemicals	**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

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

Data extracted on 10 Feb 2022

EC/List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
208-762-8 (D6)	YES	YES	YES	YES		
208-764-9 (D5)	YES	YES	YES	YES		
209-136-7 (D4)	YES	YES	YES	YES	YES	POPs (ongoing)

*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.