Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Simple inorganic Silicon (Si) compounds

Revision history

Version	*Date*	*Description*
1.0	6 January 2023	
1.1	4 September 2024	Revision of hazards for different forms and corresponding RRM conclusions

Disclaimer: For some group members (e.g Silicon Dioxide) that exist in different forms generic identifiers (EC and CAS number) are used, in the following tables and individual CAS numbers for specific forms are not presented separately.

Table 1. Substances of the group - Subgroup 1 Elemental Si and simple compounds

EC / List number	CAS number	Substance name	Molecular formula	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
206-991-8	409-21-2	Silicon carbide	SiC	Full, >1000
231-130-8	7440-21-3	Silicon	Si	Full, >1000
234-796-8	12033-89-5	Trisilicon tetranitride	Si_3N_4	Full, 100-1000
680-457-6	90337-93-2	Not (publicly)available	Not (publicly) available	C&L notification
915-037-6	-	Reaction mass of calcium disilicide and calcium silicide	$CaSi_2$, CaSi	Full, >1000

Table 2. Substances of the group - Subgroup 2 Inorganic silanes

EC / List number	CAS number	Substance name	Molecular formula	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
223-888-3	4109-96-0	Dichlorosilane	SiH_2Cl_2	Full, 100-1000
232-263-4	7803-62-5	Silane	SiH_4	Full, 100-1000
233-042-5	10025-78-2	Trichlorosilane	$SiHCl_3$	Full, >1000
233-054-0	10026-04-7	Silicon tetrachloride	$SiCl_4$	Full, >1000
233-477-0	10193-36-9	Tetrahydroxysilane	$Si(OH)_4$	Full, not (publicly) available
236-704-1	13465-77-5	Hexachlorodisilane	Si_2Cl_6	Full, 10-100
237-041-0	13596-23-1	Octachlorotrisilane	Si_3Cl_8	Full, not (publicly) available
680-408-9	13862-16-3	Trisilylamine	$N(SiH_3)_3$	Full, not (publicly) available
921-774-4	13763-19-4	Decachlorotetrasilane	Si_4Cl_{10}	Full, not (publicly) available

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

Table 3. Substances of the group - Subgroup 3 Crystalline silicon dioxide and silicates

EC / List number	CAS number	Substance name	Molecular formula	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
233-250-6	10101-39-0	Calcium silicate	$CaSiO_3$	C&L notification
237-413-2	13776-74-4	Magnesium silicate	$MgSiO_3$	C&L notification
237-623-4	13870-28-5	Disodium disilicate	$Na_2Si_2O_5$	Full, not (publicly) available
238-455-4	14464-46-1	Cristobalite	SiO_2	C&L notification
238-878-4	14808-60-7	Quartz (SiO_2)	SiO_2	Cease manufacture
239-487-1	15468-32-3	Tridymite	SiO_2	C&L notification
272-489-0	68855-54-9	Kieselguhr, soda ash flux-calcined	Not (publicly) available	Full, >1000
701-085-3	-	Hydrothermal synthesis product of calcium oxide, quartz and water	Not (publicly) available	Full, not (publicly) available
935-756-9	-	crystalline Silicic acid, calcium salt	Not (publicly) available	Full, not (publicly) available
948-606-2	-	Reaction mass of crystalline magnesium silicate and crystalline silicon and synthetic amorphous silicon dioxide	Not (publicly) available	Full, not (publicly) available

Table 4. Substances of the group - Subgroup 4 Phyllosilicates

EC / List number	CAS number	Substance name	Molecular formula	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
238-877-9	14807-96-6	Talc (Mg3H2(SiO3)4) [2]	$Mg_3H_2(SiO_3)_4$	Full, >1000
258-476-2	53320-86-8	Silicic acid, lithium magnesium sodium salt	Not (publicly) available	Full, >1000
285-349-9	85085-18-3	Silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate	Not (publicly) available	Full, not (publicly) available
442-650-1	56450-90-9	magnesium sodium fluoride silicate	Not (publicly) available	Full, not (publicly) available

[2] Not all production of talc is registered, as talc is exempt from registration according to REACH (natural product)

949-694-5	-	Magnesium potassium fluoride silicate (Mg2.7K0.7Si4O10F2)	$Mg_{2.7}K_{0.7}Si_4O_{10}F_2$	Full, not (publicly) available

Table 5. Substances of the group - Subgroup 5 Amorphous silicon dioxide and silicates

EC / List number	CAS number	Substance name	Molecular formula	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
215-710-8	1344-95-2	Silicic acid, calcium salt	Not (publicly) available	Full, >1000
231-545-4	7631-86-9	Silicon dioxide	SiO_2	Full, >1000
262-373-8	60676-86-0	Silica, vitreous	Not (publicly) available	C&L notification
273-761-1	69012-64-2	Fumes, silica	SiO_2	Full, >1000
275-735-5	71630-92-7	Ashes (residues), rice husk	SiO_2	Full, >1000
701-065-4	-	Synthetic amorphous magnesium silicate, with molar ratio (SiO2:MgO) range of 1.4-4	Not (publicly) available	Full, >1000
945-327-8	-	Calcium magnesium silicate	Not (publicly) available	Full, not (publicly) available
946-073-0	-	Amorphous hydrothermal synthesis product of water, calcium oxide and quartz	Not (publicly) available	Full, not (publicly) available
612-383-7	61790-53-2	Silicium dioxide (Silicium dioxide/Kieselguhr)	Not (publicly) available	BPR active substance Review Programme
272-697-1	68909-20-6	Pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide	Not (publicly) available	BPR active substance Review Programme

Table 6. Substances of the group - Subgroup 6 Soluble silicates and silicon phosphate

EC / List number	CAS number	Substance name	Representative molecular formula	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
215-199-1	1312-76-1	Silicic acid, potassium salt	Not (publicly) available	Full, >1000
215-683-2	1343-98-2	Silicic acid	Not (publicly) available	C&L notification
215-687-4	1344-09-8	Silicic acid, sodium salt	Not (publicly) available	Full, >1000
229-912-9	6834-92-0	Disodium metasilicate	Na_2SiO_3	Full, >1000
231-716-3	7699-41-4	Metasilicic acid	H_2SiO_3	C&L notification
234-858-4	12037-47-7	Silicon orthophosphate	$Si_3(PO_4)_4$	Full, 100-1000

910-245-3	-	Reaction mass of disodium metasilicate and sodium hydroxide	Not (publicly) available	Full, not (publicly) available

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 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[3].

[3] 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

1 Overview of the group

For the purpose of this document, it is noted that inorganic silicon compounds exist in different forms, therefore their properties even for the same EC number can differ. In such cases, the current assessment indicates for which form a specific hazard and/or regulatory risk management needs to be considered.

ECHA has grouped together silicon and simple inorganic silicon containing compounds. The group consists of 36 REACH registered substances (two of which are biocidal active substances under the BPR review programme), 8 substances which have been only notified to the C&L inventory and one substance of which the registrant has ceased manufacture.

The substances were further grouped to six subgroups:

1. Elemental Si and simple compounds
2. Inorganic silanes
3. Crystalline silicon dioxide and silicates
4. Phyllosilicates
5. Synthetic amorphous silicon dioxide and silicates
6. Soluble silicates and silicon phosphate

Silicon fluorides are not part of the current group and they will be assessed in a separate ARN.

The chemistry and morphology between the substances in different subgroups vary significantly. Subgroups 1, 3, 4, and 5 consist of substances in solid powder form. Subgroup 6 consists of substances which are either water solutions or when dried amorphous powders. The substances in subgroup 2 are gases or liquids and readily reactive in contact with humidity/water.

There are 46 substances in the group of which 35 have a full registration under REACH, 1 has an inactive registration, 8 are only notified under the CLP Regulation and 2 are regarded as being registered under REACH since they are existing biocidal active substances under the review programme according to the Biocidal Products Regulation.

Eight substances[4] are registered as nanoforms (by 1 April 2022). Furthermore, via the EU Observatory for nanomaterials, it is noted that two substances (EC 206-991-8 silicon carbide; EC 231-130-8 silicon) are listed in the French nano inventory. This information is not reflected in the registration dossiers of these substances**Error!**

[4] EC 215-710-8 silicic acid, calcium salt; EC 231-545-4 Silicon dioxide; EC 258-476-2 Silicic acid, lithium magnesium sodium salt; EC 273-761-1 Fumes, silica; EC 285-349-9 Silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate; EC 442-650-1 magnesium sodium fluoride silicate, EC 945-327-8 Calcium magnesium silicate; EC 946-073-0 Amorphous hydrothermal synthesis product of water, calcium oxide and quartz

Bookmark not defined.. Consequently, there is uncertainty whether these substances are manufactured or imported in the European Union as nanoforms. The REACH Regulation (as amended by Commission Regulation (EU) 2018/1881) sets out explicit information requirements for nanoforms of substances. Manufacturers and importers of nanoforms should meet these specific information requirements as of 1 January 2020. However, as the registration dossiers currently submitted on these two substances do not cover any nanoforms, the present assessment relates only to non-nanoforms.

Based on information reported in the REACH registration dossiers, the members of this group collectively have a very wide range of applications; the most common applications across the group are in adhesives, coatings, fillers, (non-)metal surface treatment agents, inks and toners, lubricants and greases, pH and process regulators, polymers, textile dyes and impregnating products, washing and cleaning products, cosmetics, and use as intermediates. Almost all applications are accompanied by widespread industrial and professional uses, consumer uses and/or article service lifecycle stages (such as stone, cement, glass and ceramic articles, fabrics and textile apparel, powders (adhesives and sealants), etc.).

The following regulatory processes have been completed or are ongoing for the corresponding substances or their forms:

- RAC opinion on CLH proposal for **silicon carbide fibres**[5] (with diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1) as Carc. 1B (inhalation).

- RMOA by NL on Manufacturing and high-energy operations on artificial stone[6] addressing Quartz (EC 238-878-4), cristobalite (EC 238-455-4), tridymite (EC 239-487-1).

- RMOA by NL[7] for Kieselguhr, soda ash flux-calcined (EC 272-489-0).

- CLH intention by FR for Carc. 1B for respirable crystalline silica (quartz, tridymite and cristobalite) withdrawn due to “work involving exposure to respirable crystalline silica dust”, which are now included in the Directive 2017/2398/CE (CMRD)[8] and substances are considered Carc. 1B under this Directive.

- RMOA for Talc (EC 238-877-9) by NL[9] and CLH intention by NL for Talc (EC 238-877-9) proposing its classification as Carc. 2 and STOT RE 1 (lung)(inhalation) as a consequence of the RMOA conclusion. **NOTE from CLH Intention that is not relevant for all registered forms of talc**: for Carcinogenicity: If the substance is to be placed on the market as **fibres (with diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1) or particles of the substance fulfilling the WHO fibre criteria or as particles with modified surface chemistry**, their hazardous properties must be evaluated in accordance with Title II of this Regulation, to assess

[5] https://echa.europa.eu/documents/10162/a2d4abcf-6171-ab2d-933d-c6e63c0ff5df

[6] https://echa.europa.eu/documents/10162/5fcc0b79-a976-4b8a-7b6f-d697b0247722

[7] https://echa.europa.eu/documents/10162/80310414-37a2-5874-bddc-96faaae02845

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017L2398

[9] https://echa.europa.eu/documents/10162/7bacc7ac-1373-7bdf-083f-c4123db3a580

whether a higher category (Carc. 1B or 1A) and/or specification of routes of exposure should be applied.

- Silicon dioxide, EC 231-545-4 (CAS 112945-52-5 and CAS 11296-00-8), a substance evaluation has been performed and an intention for harmonised classification has been submitted proposing classification as STOT RE (lungs, inhalation) **only for synthetic amorphous silica (SAS)**, **without surface modification.**

- Silicon dioxide (EC 231-545-4) is an approved biocidal active substance under the BPR; the approved substance in this case is a synthetic amorphous silica gel obtained by wet-process, with CAS 112926-00-8 (which includes both “precipitated silica” and “silica gel”).

- Synthetic amorphous silica (EC 231-545-4, CAS 7631-86-9) is also approved under Regulation (EC) No 1107/2009 as repellent in plant protection products under the condition that a maximum of 0,1 % of particles of Crystalline Silica have a diameter below 50 µm.

- Several national OELs already exist for respirable crystalline silica, vitreous silica (EC 262-373-8), silica fumes (EC 273-761-1), metasilicic acid (EC 231-716-3), silicic acid, calcium salt (EC 215-710-8), amorphous silica (silicon dioxide, EC 231-545-4), silicon carbide (EC 206-991-8) and for talc (EC 238-877-9)[10] as well as an EU-wide BOEL for respirable crystalline silica dust[11]. For talc an RMOA concluded to set an indicative OEL, also including a limit for fibre concentration for respirable talc when setting the OEL.

- According to the RMOA by NL for Kieselguhr, soda ash flux-calcined (EC 272-489-0): *“SCOEL[12] has provided recommendations in 2003 for respirable crystalline silica (Quartz, Tridymite and Cristobalite) setting an OEL of 0.05 mg/m³ for crystalline silica dust (cristobalite, CAS 14464-46-1; Quartz, CAS 14808-60-7; Tridymite, CAS 15468-32-3; not Kieselguhr, soda ash flux-calcined). In June 2015, SCOEL has been asked by the European Commission to review SCOEL/SUM/094; This review resulted recently in a proposal by the COM for a BOEL of 0.1 mg/m3 for each of these forms of silica. To note, the currently proposed BOEL is higher that the NL-OEL of 0.075mg/m³ implemented for respirable crystalline silica (RCS). RCS can be a process generated substance.”*

[10] https://echa.europa.eu/documents/10162/7bacc7ac-1373-7bdf-083f-c4123db3a580

[11] EUR-Lex - 32017L2398 - EN - EUR-Lex (europa.eu)

[12] https://echa.europa.eu/documents/10162/35144386/162_silica_crystalline_oel_en.pdf/1f8c415c-0238-d11d-6cf8-df26ad927131?t=1691407199215

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

Silicon compounds can vary from their morphology (spherical but also as fibre [e.g. silicon carbide]) and size (nano and micro). These properties can have impacts on their behaviour and toxicity and are taken into account in the ARN.

The current ARN identifies - based on the available experimental data, the harmonised or self-classifications, information on uses and compositions as well as past and ongoing regulatory processes by ECHA and MS - that

- respirable crystalline silica (Quartz (EC 238-878-4), Tridymite (EC 239-487-1) and cristobalite (EC 238-455-4)) and substances containing them at concentrations defined in CLP for mixtures are known carcinogens (Carc. 1B, inhalation);

- Synthetic amorphous silica with no surface modification and substances containing them at concentrations defined in CLP for mixtures are known STOT RE (inhalation route).

Exposure to amorphous silicon compounds is not associated with cancer. Only the crystalline forms of silica are associated with carcinogenic properties and silicosis.

IARC[13] associates exposure of crystalline silica from occupational sources with cancer while no such association is made for amorphous silica.

A potential concern for lung effects due to inhalation of particles/dust other than amorphous silica or respirable crystalline silica, especially in occupational settings, has not been assessed in detail in this ARN. At this stage no further recommendations are made in this respect; further work is needed with authorities to assess the regulatory needs for such exposure situations (e.g. CLH versus OELs), and the need or not for further information on hazard and exposure.

The main hazard of chronic inflammation of lung tissue is driven by particles that are deposited locally in the lung tissue. Systemic toxicity is not expected for solid particles, therefore unlikely hazard for mutagenicity and reproductive toxicity is concluded.

Based on currently available information, there is a need for (further) EU regulatory risk management – harmonised classification for synthetic amorphous silica (SAS), without surface modification (EC 231-545-4, referring to CAS 112945-52-5 and CAS 11296-00-8); talc specific forms (EC 238-877-9); respirable crystalline silica (Quartz (EC 238-878-4), Tridymite (EC 239-487-1) and cristobalite (EC 238-455-4)) and pending actions for EC/List 272-489-0, 946-073-0, 701-085-3.

For synthetic amorphous silica (SAS), without surface modification (covered under EC 231-545-4 for CAS 112945-52-5 and CAS 11296-00-8) an intention for harmonised classification has been submitted proposing classification as STOT RE (lungs)(inhalation) only. The CLH proposal does not cover any other types of silicon dioxide. In addition, the conclusion of the Substance evaluation (SEv) for synthetic amorphous silica was to consider the possibility to conduct an RMOA on (SAS),

[13] https://inchem.org/documents/iarc/vol68/silica.html

without surface modification after the CLH process is completed. The present ARN does not propose RRM actions beyond those identified in the SEV

In addition, EC 231-545-4 is an approved biocidal active substance under the BPR; the approved substance in this case is silicon dioxide is a synthetic amorphous silica gel obtained by wet-process, with CAS 112926-00-8 (which includes both "precipitated silica" and "silica gel"). The BPR assessment concluded the need for classification as STOT RE 2. The other types and forms of SAS are not covered by the biocidal product assessment. Synthetic amorphous silica (EC 231-545-4, CAS 7631-86-9) is also approved under Regulation (EC) No 1107/2009 as repellent in plant protection products under the condition that a maximum of 0,1 % of particles of Crystalline Silica have a diameter below 50 µm.

For Talc (**EC 238-877-9**), an RMOA[14] by NL is available and an intention from NL for harmonised classification was submitted proposing its classification as Carc. 2 and STOT RE 1 (lung)(inhalation) as a consequence of the RMOA conclusion. Furthermore, the setting of an indicative OEL was also proposed in the RMOA. Due to the ongoing CLH and the need to clarify/define on which forms the resulting classification would apply (fibre concentration in respirable talc), no further RRM is currently proposed in this ARN.

Respirable crystalline silica (Quartz (**EC 238-878-4**), Tridymite (**EC 239-487-1**) and cristobalite (**EC 238-455-4**)):

Cristobalite and Tridymite are not registered, whereas Quartz has ceased manufacture, therefore no exposure potential from registered uses is expected and no need for EU RRM due to low exposure.

There was an initial CLH intention from FR to address this hazard for respirable crystalline silica, however, it was withdrawn reasoning *"work involving exposure to respirable crystalline silica dust" is now included in the Directive 2017/2398/CE, French MSCA considers that the need to propose a classification as carcinogen for crystalline silica has an added-value for human health protection mostly if consumer uses is identified. However, no consumer use leading to a significant exposure to crystalline silica by inhalation has been identified. Therefore, French MSCA has decided to withdraw the intention to submit a CLH report for this substance.*[15]

Currently, there is no active registration for crystalline silica forms (i.e. quartz, crystobalite and tridymite) that could contain fractions of respirable crystalline silica (RCS). However different crystalline silica forms are present in compositions of the following substances: **EC/List 272-489-0, 946-073-0, 701-085-3** at concentrations meeting the classification criteria for mixtures for Carc. 1B.

As these substances have professional, and consumer uses, it is considered appropriate instead of proposing CLH for each of these substances to propose CLH for their constituents that are hazardous. Registrants are invited to consider the potential for self-classification for carcinogenicity for the compositions that contain respirable crystalline silica and update the registration dossiers to reflect on the potential of exposure for professional and consumer users.

For respirable crystalline silica (Quartz (EC 238-878-4), Tridymite (EC 239-487-1) and cristobalite (EC 238-455-4)) the first step of the regulatory risk management

[14] https://echa.europa.eu/documents/10162/7bacc7ac-1373-7bdf-083f-c4123db3a580

[15] Registry of CLH intentions until outcome - ECHA (europa.eu)

action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as Carc. 1A/1B and/or STOT RE (inhalation exposure)). The substances are included in Directive 2017/2398/CE (CMRD), but this does not cover consumer uses and some professional uses might also not fall under this Directive.

For Kieselguhr, soda ash flux-calcined (**EC 272-489-0**) according to the information provided in the registration dossiers, registrants self-classified different compositions depending on the content of respirable cristobalite as STOT RE 1 or STOT RE 2. EC 272-489-0, is a mixture of EC 231-545-4 (silicon dioxide (amorphous), EC 238-455-4 (cristobalite), EC 238-878-4 (Silicon dioxide (quartz), EC 239-487-1 (Tridymite). It has consumers uses in coatings and professional uses in coatings, adhesives. The substance has been assessed in an RMOA by NL where it was concluded that: "*Repeated inhalation of Kieselguhr, soda ash flux-calcined can cause silicosis, a form of occupational lung disease, which eventually can lead to lung cancer. There are several reports that show, both in experimental animals as well as in humans that were occupationally exposed to the substance, that it is detrimental to the lungs through inhalation. For four constituents of kieselguhr, soda ash flux-calcined, three of which are on the Dutch SZW-list of Cat.1 carcinogens, intentions for harmonized classification for carcinogenicity are expressed. Once one or more of these constituents will be classified as Carc.Cat.1 it is expected that most, if not all Kieselguhr, soda ash flux calcined compositions will also need to be self-classified as carcinogen Cat. 1 (mixture ≥ 0.1% for a category 1A or 1B carcinogen, ≥ 1.0% for a category 2 carcinogen)".*

EC 272-489-0 has professional and consumer uses mostly in application of coatings and article service life in rubber and plastic articles.

EC 946-073-0 contains as constituent Quartz, is used by professional workers in fillers, putties, plasters, modelling clay, paper and board treatment products and has article service life (active ingredient in mixtures for Stone, plaster, cement, glass and ceramic articles). The registrant uses read-across from EC 231-545-4 for the inhalation route, with this substance being considered as STOT RE but no classification for this route is applied by the registrant. There is potential for exposure from the uses via the inhalation route. There are no consumer uses for this substance.

EC 701-085-3 has professional, and consumer uses in fillers, plasters, modelling clay. It contains quartz in its composition therefore inhalation exposure potential cannot be excluded from its use or from exposure situations that can arise from article service life.

CLH for Carc. 1A/1B i) is needed or highly recommended for further regulatory processes under REACH and ii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 28 (Carc. 1A/1B).

The need to consider potential restriction as a next step for any professional uses that might not be covered by Directive 2017/2398/CE can be examined after the completion of the CLH process.

For these substances at this stage, for occupational settings the provisions by Directive 2017/2398/CE and the setting of occupational exposure levels by SCOEL are considered sufficient and no further EU RRM is proposed.

Based on currently available information, there is no need for (further) EU regulatory risk management of all group members except for EC/List 231-545-4 (*Silicon dioxide, amorphous silica form without surface modification*), 238-877-9 (*Talc, only specific forms*), 272-489-0 (Kieselguhr soda ash flux calcinated), 946-073-0 (Amorphous hydrothermal synthesis product of water, calcium oxide and quartz), 701-085-3 (Hydrothermal synthesis product of calcium oxide, quartz and water).

No CMR/ED properties are expected via the oral and dermal route for any group members; this is based on the available information in the registration dossiers and information from the public domain. An overview of the toxicological profile of silica compounds by the US Agency for Toxic Substances and Disease Registry[16] (2019) also supports absence of CMR/ED properties via the oral and dermal routes, summarising also previous assessments under the OECD SIDS programme (synthetic amorphous silica and silicates[17] , Soluble silicates[18]).

There are no hazards identified neither for PBT/vPvB nor for aquatic toxicity for any of the substances. This is based on the hypothesis that all substances are reacting rapidly with water and release Si which will then be instantly oxidised. There is no aquatic toxicity hazard for SiO_2 or $Si(OH)_4$. There are two exceptions for which this hypothesis cannot be readily applied: EC 206-991-8 and EC 234-796-8. All substances are inorganic and thus the concept of persistency (and hence PBT/vPvB) does not apply. Finally, no bioaccumulation is expected as silicate is a trace nutrient and thus physiological homeostasis can be anticipated.

Silicon dioxide is reported in some of the compositions in registration dossiers (often identified by a generic EC 231-545-4): EC 206-991-8 (SG1), EC 272-489-0 (SG3), EC 701-085-3 (contains also Quartz, SG3), EC 948-606-2 (SG3),

Further assessment for the need of self-classification might be needed for these substances, depending on the outcome of the CLH process for of synthetic amorphous silica (SAS), in order to verify if the reported SiO_2 is present in the form of SAS.

At this stage there is no specific information in the registration dossiers regarding particle size and/or fraction regarding the presence of amorphous silica without surface modification. The substances are not currently flagged as potential or known STOT RE. Following the outcome of the CLH process for amorphous silica without surface modification, these substances will need to be further assessed if they fall under the classification for the proposed STOT RE 1 to decide the next potential RRM steps. Registrants are advised to specify the form of such constituents in their registration dossiers and indicate if these are the synthetic amorphous silica without surface modification.

EC 275-735-5 (SG5), Ashes rice husk is self-classified either as STOT RE 1 or as STOT RE 2 depending on the content of respirable crystalline silica; registrants are invited to reflect the carcinogenic potential of respirable crystalline silica (as per CMRD (Directive 2017/2398/CE) by means of self-classification if relevant although the substance has only industrial uses and the occupational hazards from respirable crystalline silica are covered by CMRD. It is also noted that the substance is used in construction material. The available information does not allow to conclude if

[16] https://www.atsdr.cdc.gov/ToxProfiles/tp211.pdf

[17] https://hpvchemicals.oecd.org/ui/handler.axd?id=1db41a5f-cce0-4e6c-bd75-806a9e88a20b

[18] https://hpvchemicals.oecd.org/ui/handler.axd?id=3cb4f34b-2afa-4004-b447-521188909235

during the life cycle of the material there will be opportunities for exposure to respirable crystalline silica via specific tasks for professional workers or bystanders. No assumptions are made regarding this for the purpose of this ARN but it is highlighted for MS in case further work on this topic is needed.

EC 442-650-1 has a harmonised classification as STOT RE 2; it has industrial uses and article service life in construction materials, resins and paints. There is no toxicological data in the registration dossiers to explain the basis of the existing classification; it is noted that some compositions in the joint submission contain impurities that are known Carc. 1B as per Directive 2017/2398/CE (CMRD) with reference to respirable crystalline silica. Registrants are advised to take this into consideration and reflect the carcinogenic properties by self-classification where relevant. The available information does not allow to conclude if such compositions are also used in construction material that during its life cycle there will be opportunities for exposure via specific tasks to respirable crystalline silica for professional workers or bystanders. For the purpose of this ARN, no assumptions are made regarding such exposure scenarios but this is highlighted for MS in case further work on this topic is needed.

EC 285-349-9 (SG5) contains in some composition(s) Quartz (EC 238-878-4) as an impurity that has carcinogenic properties. There is limited information on the relevance of this for hazard and risk assessment and there is remaining uncertainty if such compositions are used in applications that might lead to inhalation. Currently no further action is proposed for this substance due to these uncertainties.

Silicon carbide fibres (SiC) fibres (EC 206-991-8) with this specific definition (diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1) are carcinogenic (Carc. 1B) based on RAC Opinion[19]. However, these are not placed in the market by registrants under REACH and therefore for these registrations no carcinogenic property is identified.

EC 258-476-2 and 285-349-9 contain Lithium as part of the substance which is toxic for reproduction. However, based on experimental data available release of lithium from the substance is unlikely, therefore these two substances are not considered potential reproductive toxicants.

[19] https://echa.europa.eu/documents/10162/a2d4abcf-6171-ab2d-933d-c6e63c0ff5df

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/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
238-878-4 **238-455-4** **239-487-1**	Known or potential hazard for carcinogenicity for STOT RE	No hazard or unlikely hazard	Substances are not registered or ceased manufacture, no exposure potential	CLH Justification: Proposal for CLH although substances are not registered to ensure correct classification of mixtures containing them that have professional and/or consumer uses not covered by the CMRD where these substances are included.
272-489-0 **946-073-0** **701-085-3**	Known or potential hazard for carcinogenicity for STOT RE	No hazard or unlikely hazard	Professional and consumers uses in fillers, plasters, modelling clay. Potential for exposure can be anticipated.	Pending action Justification: Due to presence of crystalline silica, after CLH of EC 238-878-4, 238-455-4 and 239-487-1, the need for additional EU RRM for professional uses if not covered under CMRD will be examined.

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
275-735-5 **442-650-1**	Known or potential hazard for carcinogenicity for STOT RE	No hazard or unlikely hazard	Industrial uses. Limited potential for exposure can be assumed.	No action Justification: The identified hazard is due to presence of respirable crystalline silica; for industrial settings occupational measures covered under CMRD
231-545-4 (Synthetic amorphous silica without surface modification form only CAS 112945-52-5 and CAS 11296-00-8)	Known or potential hazard for STOT RE	No hazard or unlikely hazard	Not assessed for the specific form	Pending action Justification: Following ongoing CLH, further analysis to determine if additional RRM like OEL/Restriction might need to be considered.
238-877-9 (potentially for specific forms)	Known or potential hazard for carcinogenicity for STOT RE	No hazard or unlikely hazard	Industrial, professional and consumer uses in various product types. Potential for exposure can be anticipated.	Pending action Justification: Following CLH, further analysis to determine if additional RRM like OEL/Restriction might need to be considered for specific forms and/or uses
231-545-4 (except SAS without surface modification)	No hazard or unlikely hazard	No hazard or unlikely hazard	Widespread industrial and professional uses, consumer uses and/or article service life and thus potential	No action Justification: No hazard and/or no exposure/release potential

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
206-991-8[20] **231-130-8** **234-796-8** **915-037-6** **223-888-3** **232-263-4** **233-042-5** **233-054-0** **233-477-0** **236-704-1** **237-041-0** **680-408-9** **921-774-4** **237-623-4** **935-756-9**			for exposure except for: 234-796-8, 915-037-6, 223-888-3, 232-263-4, 233-042-5, 233-054-0, 236-704-1, 237-041-0, 680-408-9, 921-774-4, 948-606-2, 701-065-4, 945-327-8, 215-683-2, 234-858-4, 680-457-6, 231-716-3, 262-373-8, 233-250-6, 237-413-2 that have low exposure/release potential due to industrial uses only or not registered.	

[20] Note: Silicon carbide fibres (with diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1) are harmonised classified as Carc. 1B, but these forms are not covered by the Registrations under REACH

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
948-606-2 258-476-2 285-349-9 949-694-5 215-710-8 273-761-1 701-065-4 945-327-8 612-383-7 272-697-1 215-199-1 215-683-2 215-687-4 229-912-9 234-858-4 910-245-3 680-457-6				

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
231-716-3 **262-373-8** **233-250-6** **237-413-2**				

Annex 1: Overview of classifications

Data extracted on 21 January 2022.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
206-991-8	409-21-2	silicon carbide[21]	Carc. 1B, H350i	-
215-199-1	1312-76-1	Silicic acid, potassium salt	-	Met. Corr. 1 H290 Skin Irrit. 2 H315 Skin Corr. 1B H314 Eye Damage 1 H318, specific concentration: 38-<50 Eye Irrit. 2A H319 Eye Damage 1 H318 STOT Single Exp. 3 H335, affected organs: respiratory organs
215-687-4	1344-09-8	Silicic acid, sodium salt	-	Met. Corr. 1 H290 Skin Corr. 1B H314 Skin Irrit. 2 H315 Eye Damage 1 H318, specific concentration: 28-<39 Eye Irrit. 2 H319 Eye Damage 1 H318 STOT Single Exp. 3 H335, affected organs: respiratory organs
215-710-8	1344-95-2	Silicic acid, calcium salt	-	-
223-888-3	4109-96-0	dichlorosilane	-	Flam. Gas 1A H220 Liquefied gas H280 Acute Tox. 2 H330 Skin Corr. 1A H314 Eye Damage 1 H318

[21] Only for Silicon carbide fibres (with diameter < 3 µm, length > 5 µm and aspect ratio ≥ 3:1)

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
229-912-9	6834-92-0	disodium metasilicate	Skin Corr. 1B, H314 STOT SE 3, H335	Met. Corr. 1 H290 Skin Corr. 1B H314 Eye Damage 1 H318 STOT Single Exp. 3 H335, affected organs: respiratory organs
231-130-8	7440-21-3	Silicon	-	-
231-545-4	7631-86-9	silicon dioxide	-	-
232-263-4	7803-62-5	Silane	-	Flam. Gas 1A H220 Liquefied gas H280
233-042-5	10025-78-2	trichlorosilane	Flam. Liq. 1, H224 Pyr. Liq. 1, H250 Acute Tox. 4, H302 Skin Corr. 1A, H314 Acute Tox. 4, H332	Flam. Liquid 1 H224 Pyr. Liquid 1 H250 Water React. Flam. Gas 1 H260 Acute Tox. 4 H302 Acute Tox. 4 H332 Acute Tox. 3 H331 Skin Corr. 1A H314 Eye Damage 1 H318
233-054-0	10026-04-7	silicon tetrachloride	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	Acute Tox. 3 H301 Acute Tox. 3 H331 Skin Irrit. 2 H315 Skin Corr. 1A H314 Eye Damage 1 H318 Eye Irrit. 2 H319 STOT Single Exp. 3 H335
233-477-0	10193-36-9	tetrahydroxysilane	-	Skin Corr. 1 H314 Eye Damage 1 H318
234-796-8	12033-89-5	trisilicon tetranitride	-	-

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
234-858-4	12037-47-7	silicon orthophosphate	-	Eye Damage 1 H318
236-704-1	13465-77-5	hexachlorodisilane	-	Skin Corr. 1A H314
237-041-0	13596-23-1	octachlorotrisilane	-	Skin Corr. 1A H314
237-623-4	13870-28-5	disodium disilicate	-	Eye Damage 1 H318, specific concentration: >=10
238-877-9	14807-96-6	Talc (Mg3H2(SiO3)4)	-	-
238-878-4	14808-60-7	Quartz (SiO2)	-	-
258-476-2	53320-86-8	Silicic acid, lithium magnesium sodium salt	-	-
272-489-0	68855-54-9	Kieselguhr, soda ash flux-calcined	-	STOT Rep. Exp. 2 H373, affected organs: lungs STOT Rep. Exp. 1 H372, affected organs: lungs
273-761-1	69012-64-2	Fumes, silica	-	-
275-735-5	71630-92-7	Ashes (residues), rice husk	-	STOT Rep. Exp. 1 H372, affected organs: lung STOT Rep. Exp. 2 H373, affected organs: lung
285-349-9	85085-18-3	Silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate	-	-
442-650-1	56450-90-9	442-650-1	STOT RE 2, H373	STOT Rep. Exp. 2 H373, affected organs: organs
680-408-9	13862-16-3	680-408-9	-	Flam. Liquid 2 H225 Water React. Flam. Gas 1 H260 Acute Tox. 4 H302 Acute Tox. 4 H312

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
				Acute Tox. 1 H330 Skin Corr. 1A H314 Eye Damage 1 H318
701-065-4		Synthetic amorphous magnesium silicate, with molar ratio (SiO2:MgO) range of 1.4-4	-	-
701-085-3		Hydrothermal synthesis product of calcium oxide, quartz and water	-	-
910-245-3		Reaction mass of disodium metasilicate and sodium hydroxide	-	Met. Corr. 1 H290 Acute Tox. 4 H302 Skin Corr. 1A H314 Eye Damage 1 H318 STOT Single Exp. 3 H335, affected organs: Lungs, respiratory tract
915-037-6		Reaction mass of calcium disilicide and calcium silicide	-	-
921-774-4		Decachlortetrasilan	-	Skin Corr. 1A H314
935-756-9		crystalline Silicic acid, calcium salt	-	Eye Irrit. 2 H319
945-327-8		Reaction mass of Silicic acid, magnesium salt and Silicic acid, calcium salt	-	-
946-073-0		Amorphous hydrothermal synthesis product of water, calcium oxide and quartz	-	-

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
948-606-2		Reaction mass of crystalline magnesium silicate and crystalline silicon and synthetic amorphous silicon dioxide	-	-
949-694-5		Magnesium potassium fluoride silicate (Mg2.7K0.7Si4O10F2)	-	-

(*) 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 20 January 2022.

Subgroup 1: Elemental Si and simple compounds

Main types of applications structured by product or article types	EC 206-991-8	List 915-037-6	EC 231-130-8	EC 234-796-8
PC 1: Adhesives, sealants	F, I, **P**		I	I, **P**
PC 7: Base metals and alloys	F, I, **P**, **C**, **A**	F, I, **A**	F, I, **P**, **C**, **A**	F, I
PC 9a: Coatings and paints, thinners, paint removes	F, I, **P**, **A**		F, I, **A**	F, I, **A**
PC 9b: Fillers, putties, plasters, modelling clay	F, I, **P**, **C**, **A**		F, I, **P**, **A**	I
PC 9c: Finger paint	F, I, **P**			I
PC 11: Explosives		F, I, **A**	F, I, **P**, **A**	
PC 13: Fuels			I, **A**	
PC 14: Metal surface treatment products	F, I, **P**, **C**		F, I, **P**, **C**, **A**	I
PC 15: Non-metal-surface treatment products	F, I, **P**, **C**		F, I, **P**	I
PC 16: Heat transfer fluids	I			
PC 17: Hydraulic fluids	I		F, I	
PC 18: Ink and toners	F, I		I, **A**	I
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	I, **P**		I	
PC 23: Leather treatment products	I, **P**		F, I	
PC 24: Lubricants, greases, release products			F	F
PC 25: Metal working fluids	I		I, **P**	I
PC 26: Paper and board treatment products	I, **P**			I
PC 27: Plant protection products			F, I	

Main types of applications structured by product or article types	EC 206-991-8	List 915-037-6	EC 231-130-8	EC 234-796-8
PC 28: Perfumes, fragrances		I		
PC 29: Pharmaceuticals	F, I		F	
PC 31: Polishes and wax blends	F, I, **P**, **A**		F	
PC 32: Polymer preparations and compounds	F, I, **A**		F, I, **A**	I
PC 33: Semiconductors	I, **P**		F, I, **P**	
PC 34: Textile dyes, and impregnating products	F, I		F, I	
PC 35: Washing and cleaning products	F, I, **P**, **C**		F, I	
PC 37: Water treatment chemicals			F	
PC 38: Welding and soldering products, flux products	F, I, **P**, **C**	I, **A**	F, I, **P**, **C**, **A**,	I
PC 39: Cosmetics, personal care products	F, I		F	
PC 19: Intermediate	F, I, **P**		F, I	I
PC 21: Laboratory chemicals	I	I	F, I, **P**	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

Subgroup 2: Inorganic silanes

Main types of applications structured by product or article types	EC 233-042-5	EC 232-263-4	List 680-408-9	List 921-774-4	EC 236-704-1	EC 233-477-0	EC 233-054-0	EC 223-888-3	EC 237-041-0
PC 8: Biocidal products (e.g. disinfectants, pest control)						F, I, **P**			
PC 9a: Coatings and paints, thinners, paint removes		I							
PC 12: Fertilisers						F, I, **P**, **C**			
PC 14: Metal surface treatment products					I				
PC 15: Non-metal-surface treatment products		I			I				
PC 27: Plant protection products						F, I, **P**, **C**			

Main types of applications structured by product or article types	EC 233-042-5	EC 232-263-4	List 680-408-9	List 921-774-4	EC 236-704-1	EC 233-477-0	EC 233-054-0	EC 223-888-3	EC 237-041-0
PC 28: Perfumes, fragrances						F			
PC 29: Pharmaceuticals						F, **C**			
PC 32: Polymer preparations and compounds	I			I	I		F, I		
PC 33: Semiconductors	F, I	F, I	I		I		F, I	F, I	I
PC 35: Washing and cleaning products	I						I		
PC 39: Cosmetics, personal care products						F, **C**			
PC x1: Food and feed additives						F			
PC 19: Intermediate	I	I					I	I	I
PC 21: Laboratory chemicals	F, I	F, I, **P**		I	I		F, I	F, I, **P**	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

Subgroup 3: Crystalline silicon dioxide and silicates

Main types of applications structured by product or article types	EC 238-878-4	List 948-606-2	EC 237-623-4	EC 272-489-0	List 701-085-3	EC 935-756-9
PC 1: Adhesives, sealants				I, **P**		F, I, **P**, **C**, **A**
PC 2: Adsorbents				F, I, **P**	I, **P**, **C**	
PC 7: Base metals and alloys						F, I
PC 9a: Coatings and paints, thinners, paint removes				F, I, **P**, **C**		**C**
PC 9b: Fillers, putties, plasters, modelling clay				F, I, **P**, **C**	I, **P**, **C**	F, I, **C**
PC 9c: Finger paint				F, I, **P**, **C**		
PC 14: Metal surface treatment products				F, I, **P**		
PC 16: Heat transfer fluids				**P**		
PC 17: Hydraulic fluids				**P**		
PC 18: Ink and toners				F, I, **P**		

Main types of applications structured by product or article types	EC 238-878-4	List 948-606-2	EC 237-623-4	EC 272-489-0	List 701-085-3	EC 935-756-9
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents				F, I, **P**		
PC 24: Lubricants, greases, release products				**P**		
PC 25: Metal working fluids				F, I, **P**		
PC 26: Paper and board treatment products					**P**	
PC 29: Pharmaceuticals				**P**		
PC 32: Polymer preparations and compounds				I, **P**		F, I
PC 35: Washing and cleaning products			**C**	F, I, **P**, **C**		
PC 36: Water softeners			**C**			
PC 37: Water treatment chemicals				**P**, **C**	I, **P**, **C**	
PC 39: Cosmetics, personal care products				**C**		
PC 0: Other: Anode material for secondary batteries		I, A				
PC 19: Intermediate	I			F, I, **P**		
PC 21: Laboratory chemicals				F, I, **P**		

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

Subgroup 4: Phyllosilicates

Main types of applications structured by product or article types	EC 238-877-9	EC 258-476-2	EC 442-650-1	List 949-694-5	EC 285-349-9
PC 1: Adhesives, sealants	P	F, I, P, C			F, P, C
PC 2: Adsorbents	F, I, P, C, A	F, I, P, C			
PC 3: Air care products		F, I, P, C			
PC 4: Anti-freeze and de-icing products		F, I, P, C			
PC 8: Biocidal products (e.g. disinfectants, pest control)	I, P, C	F, I, P			
PC 9a: Coatings and paints, thinners, paint removes	F, I, P, C, A	F, I, P, C	I, A	I	F, I, P, C
PC 9b: Fillers, putties, plasters, modelling clay	F, I, P, C	F, I, P, C	I	F, I	
PC 9c: Finger paint	C	F, I, P, C			
PC 14: Metal surface treatment products		F, I, P, C			P
PC 15: Non-metal-surface treatment products		F, I, P, C			P
PC 17: Hydraulic fluids		F, I			
PC 18: Ink and toners	F, I, P	F, I, P, C			F, P, C
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents		F, I, P			
PC 23: Leather treatment products	I, P, C				
PC 24: Lubricants, greases, release products	F, I, P, C, A	F, I, C		I	
PC 25: Metal working fluids		C			
PC 26: Paper and board treatment products	F, I, P, C, A	F, I, P			F, I, P, C
PC 27: Plant protection products	C	F, I, P, C			
PC 28: Perfumes, fragrances	C	F, I, P, C			
PC 31: Polishes and wax blends		F, I, P, C			

Main types of applications structured by product or article types	EC 238-877-9	EC 258-476-2	EC 442-650-1	List 949-694-5	EC 285-349-9
PC 32: Polymer preparations and compounds	F, I, **P**, **C**, **A**				
PC 35: Washing and cleaning products		F, I, **P**, **C**			F, **P**, **C**
PC 39: Cosmetics, personal care products	F, **P**, **C**, **A**	F, I, **P**, **C**		F, I, **C**	F, **P**, **C**
PC 19: Intermediate	F, I, **P**, **C**	F, I, **P**			
PC 21: Laboratory chemicals	**C**	F, I, **P**			

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

Subgroup 5: Synthetic amorphous silicon dioxide and silicates

Main types of applications structured by product or article types	EC 215-710-8	List 701-065-4	List 945-327-8	List 946-073-0	EC 273-761-1	EC 275-735-5	EC 231-545-4
PC 1: Adhesives, sealants	F	I	F, I		F, I, **P**, **C**, **A**		F, I, **P**, **C**, **A**
PC 2: Adsorbents	F, I, **P**	F, **P**	F, I	I, **P**		I	F, I, **P**, **C**
PC 3: Air care products							F, I, **P**, **C**
PC 7: Base metals and alloys					F, I, **P**, **C**, **A**		I, **P**, **C**, **A**
PC 8: Biocidal products (e.g. disinfectants, pest control)			F, I				F, I, **P**, **C**
PC 9a: Coatings and paints, thinners, paint removes	F, I, **P**, **C**	F, I, **P**, **C**			F, I, **P**, **A**		F, I, **P**, **C**, **A**
PC 9b: Fillers, putties, plasters, modelling clay	F, I, **P**, **C**	F, I, **P**, **C**		I, **P**	F, I, **P**, **A**	I	F, I, **P**, **C**, **A**
PC 9c: Finger paint		F, I, **P**, **C**					F, I, **P**, **C**
PC 12: Fertilisers		F, I, **P**			F, I, **P**, **C**, **A**		F, I, **P**, **C**
PC 13: Fuels							I
PC 14: Metal surface treatment products					**C**		F, I, **P**, **C**
PC 15: Non-metal-surface treatment products							F, I, **P**, **C**
PC 16: Heat transfer fluids							I, **P**, **C**
PC 17: Hydraulic fluids							I, **P**, **C**

Main types of applications structured by product or article types	EC 215-710-8	List 701-065-4	List 945-327-8	List 946-073-0	EC 273-761-1	EC 275-735-5	EC 231-545-4
PC 18: Ink and toners	I, **P**, **C**	F, I, **P**			F, I, **P**, **A**		F, I, **P**, **C**, **A**
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents		I, **P**	F, I		F, I		F, I
PC 23: Leather treatment products	I, **P**, **C**						F, I, **P**, **C**, **A**
PC 24: Lubricants, greases, release products	F						F, I, **P**, **C**
PC 25: Metal working fluids							F, I, **P**, **C**
PC 26: Paper and board treatment products	I, **P**, **C**			**P**			F, I, **P**,**C**, **A**
PC 27: Plant protection products	F, **P**						F, I, **P**, **C**
PC 28: Perfumes, fragrances	F	F, I, **P**, **C**					F, I, **P**, **C**
PC 29: Pharmaceuticals	I, **P**, **C**	F, I, **P**, **C**					F, I, **P**, **C**
PC 30: Photo-chemicals							F, I
PC 31: Polishes and wax blends							F, I, **P**, **C**
PC 32: Polymer preparations and compounds	F, I, **P**, **C**, **A**	F, I	F, I		F, I, **P**, **A**		F, I, **P**, **C**, **A**
PC 33: Semiconductors							F, I, **P**
PC 34: Textile dyes, and impregnating products	I, **P**, **C**						F, I, **P**, **C**, **A**
PC 35: Washing and cleaning products		F, I, **P**, **C**			F, **P**		F, I, **P**, **C**, **A**
PC 37: Water treatment chemicals	I, **P**, **C**		F, I	I, **P**			F, I, **P**, **C**
PC 38: Welding and soldering products, flux products							I, **P**, **C**
PC 39: Cosmetics, personal care products	F, I, **P**, **C**	F, I, **P**, **C**			**A**		F, I, **P**, **C**, **A**
PC 40: Extraction agents			F, I				F, I, **P**, **C**
PC42: Electrolytes for batteries							I, **P**
PC x1: Food and feed additives	I, **P**, **C**	F, I, **C**, **A**					F, I, **P**, **C**
PC 19: Intermediate	I, **P**				I		F, I, **P**
PC 21: Laboratory chemicals	I, **P**	F, I, **P**			F		F, I, **P**, **C**

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

Subgroup 6: Soluble silicates and silicon phosphate

Main types of applications structured by product or article types	List 910-245-3	EC 215-199-1	EC 215-687-4	EC 229-912-9	EC 234-858-4
PC 1: Adhesives, sealants		F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	
PC 2: Adsorbents			F, I		
PC 3: Air care products		F, I, **C**	F, I, **P**, **C**	I, **C**	
PC 4: Anti-freeze and de-icing products			F, I	F, I, **P**, **C**	
PC 7: Base metals and alloys		F, I, **P**, **C**	F, I, **P**, **C**		
PC 8: Biocidal products (e.g. disinfectants, pest control)		F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	
PC 9a: Coatings and paints, thinners, paint removes		F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	
PC 9b: Fillers, putties, plasters, modelling clay		F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	
PC 9c: Finger paint			**P**	**P**, **C**	
PC 12: Fertilisers		F, I, **P**	I, **P**		
PC 13: Fuels				I, **P**	
PC 14: Metal surface treatment products		F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	
PC 15: Non-metal-surface treatment products		F, I, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	
PC 16: Heat transfer fluids			I, **P**, **A**	I, **P**, **C**, **A**	
PC 17: Hydraulic fluids			**P**	I, **P**, **C**	
PC 18: Ink and toners		F, I, **P**, **C**	F, I, **P**	F, I, **P**, **C**	
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	I, **P**	F, I	F, I	F, I, **P**	
PC 23: Leather treatment products		F, I, **A**	F, I, **P**, **C**, **A**	F, I, **A**	
PC 24: Lubricants, greases, release products		F, I	F, I, **P**	F, I	

Main types of applications structured by product or article types	List 910-245-3	EC 215-199-1	EC 215-687-4	EC 229-912-9	EC 234-858-4
PC 25: Metal working fluids		I	I	I	
PC 26: Paper and board treatment products		F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**	
PC 27: Plant protection products	I, **P**				
PC 28: Perfumes, fragrances			I, **P**, **C**	**C**	
PC 29: Pharmaceuticals		I, **P**	I, **P**	I, **P**	
PC 30: Photo-chemicals		F, I	F, I	F, I	
PC 31: Polishes and wax blends		**P**, **C**	F, I, **P**, **C**	**P**, **C**	
PC 32: Polymer preparations and compounds		F, I, **P**, **C**	F, I, **P**, **A**	F, I, **P**, **C**	
PC 33: Semiconductors			I		
PC 34: Textile dyes, and impregnating products		F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	F, I, **P**, **C**, **A**	
PC 35: Washing and cleaning products		F, I, **P**, **C**	F, I, **P**, **C**, **A**	F, I, **P**, **C**	I
PC 37: Water treatment chemicals		I	F, I, **P**, **C**	I, **P**	
PC 38: Welding and soldering products, flux products		F, I, **P**, **C**	F, I, **P**, **C**, **A**		
PC 39: Cosmetics, personal care products		F, **P**, **C**	F, I, **P**, **C**	F, I, **P**, **C**	
PC 19: Intermediate	I, **P**		F, I, **P**	**P**	
PC 21: Laboratory chemicals		F, I, **P**	F, I, **P**	F, I, **P**	

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 28 January 2022.

EC / List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
206-991-8					Yes	
231-545-4					Yes[1]	
233-042-5					Yes	
238-455-4					Yes[2]	
238-877-9	Yes				Yes[1]	
238-878-4					Yes[2]	
240-968-3				Yes		
272-489-0	Yes					
442-650-1						NONS

*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).

[1] CLH intention

[2] CLH intention withdrawal

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