

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Complex inorganics from non-metallurgy

General structure: -

Revision history

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Substances within this group:

	EC/List no	CAS no	Substance name	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) ¹
Ashes and other residues from thermal processes	282-208-3	84144-87-6	Ashes (residues), vanadium-contg.	OSII or TII
	297-049-5	93333-79-0	Ashes (residues), plant	Full, >1000
	297-648-1	93685-99-5	Oil shale, thermal processing waste	Full, >1000
	300-212-6	93924-19-7	Ashes (residues), cenospheres	Full, >1000
	931-257-5	-	Ashes from fluidized Bed combustion coal fired Power stations with and without co-combustion of secondary fuels (biomass; other fuels - to be verified in view of ecotoxicological and toxicological tests)	Full, >1000
	931-322-8	-	Ashes (residues), coal	Full, >1000
	931-597-4	-	The product from the burning of a combination of carbonaceous materials.	Full, >1000
	939-997-0	-	Reaction products of metal-free bottom ash from municipal solid wastes incineration with water and with or without lime	Full, not (publicly) available
	954-402-4	-	Amorphous carbon and silicon dioxide recovered from two-stage pyrolysis of spent tyres	Full, not (publicly) available
Mineral like substance	954-915-3	-	Anatase, rutile, disodium hexatitanate and sodium tetratitanate	Full, not (publicly) available
	274-324-8	70131-50-9	Bentonite, acid-leached	Full, >1000
	285-561-1	85117-09-5	Lime (chemical), hydraulic	Full, >1000
	296-473-8	92704-41-1	Kaolin, calcined	Full, >1000

¹ The total aggregated tonnage band may be available on ECHA's webpage at <https://echa.europa.eu/information-on-chemicals/registered-substances>

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	EC/List no	CAS no	Substance name	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) ¹
	931-259-6	-	Product of Semi-Dry Absorption method of Flue Gas Desulphurization (SDA Product)	Full, >1000
	946-103-2	-	Calcium hydrosilicate, reaction product of natural quartz sand and technical lime by a hydrothermal and tribochemical process	Full, not (publicly) available
Glasses, ceramics and frits	266-046-0	65997-17-3	Glass, oxide, chemicals	Full, not (publicly) available
	266-047-6	65997-18-4	Frits, chemicals	Full, >1000
	266-340-9	66402-68-4	Ceramic materials and wares, chemicals	Full, >1000
	Not (publicly) available	-	Substance 1 (name not (publicly) available)	Full, not (publicly) available
Substances from pulping processes	268-612-2	68131-30-6	Sulfite liquors and Cooking liquors, green	Full, >1000
	268-615-9	68131-33-9	Sulfite liquors and Cooking liquors, white	OSII or TII
	923-511-9	-	Inorganic residual from kraft or soda pulping separated from green liquor in the chemical recovery cycle.	Full, >1000
	931-583-8	-	Spent liquor from semi-chemical pulping containing spent inorganic process chemicals and dissolved organic substances originating from the wood raw material	OSII or TII
	931-584-3	-	Spent liquor from alkaline pulping and bleaching containing spent inorganic process chemicals and dissolved organic substances originating from the cellulosic raw material.	OSII or TII
Cementitious	266-045-5	65997-16-2	Cement, alumina, chemicals	Full, not (publicly) available

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	EC/List no	CAS no	Substance name	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) ¹
	270-659-9	68475-76-3	Flue dust, portland cement	Full, >1000
Pigments	701-090-0	-	Feldspar minerals, hematite and quartz, calcination products of copper mining residues	Full, not (publicly) available
	701-304-2	-	High-temperature calcination products of diiron trioxide and amorphous silica resulting in a glassy silica matrix	Full, >1000
	909-981-8	-	Reaction mass of Fumes, silica and diiron trioxide	C&L notification
	910-670-4	-	Reaction mass of Hematite (Fe ₂ O ₃) and Quartz (SiO ₂)	Not registered
	944-188-0	-	Feldspar minerals, magnetite and quartz, calcination products of copper mining residues.	Full, not (publicly) available

This table contains also a group member that is only notified under the CLP Regulation, however, the list is not necessarily exhaustive.

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Foreword

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

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

The focus of the assessment is largely based on information available in the registration dossiers and on properties requiring regulatory risk management action at EU level³. The information reported on uses is from the registration dossiers (IUCLID) and is used as a proxy for assessing how widespread uses are and whether potential for exposure to humans and releases to the environment can be expected. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

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

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

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

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

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

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

For more information on assessments of regulatory needs please consult ECHA's website⁴.

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

Glossary

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

1 Overview of the group

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

The scope of this specific ARN is limited as the assessment of regulatory needs has been defined solely based on the presence of metal compounds, and in one case based on fibre morphology, which are known or potential CMRs based on harmonised classifications or previous assessments.

ECHA has grouped together for this assessment complex inorganic substances originating from other than metallurgical processes. ECHA has assessed the complex inorganic substances from metallurgical processes in two other ARNs^{5,6}. This group consists of ashes and other residues from thermal processes, mineral like solids, glasses, ceramics and frits, substances from pulping processes, cementitious materials as well as pigments.

There are 32 substances in the group of which 26 with full registrations, four with intermediate registrations, one with C&L notification and one without registrations or notifications. 28 substances are UVCB and three are well-defined multi-constituent substances. EC 266-340-9 is registered both as a multi-constituent substance and as an UVCB.

Five of the substances are self-classified for carcinogenicity and/or reproductive toxicity due to presence of lead, cadmium, boron or nickel compounds in the substance. One substance is self-classified as carcinogenic due to the fibre morphology. The rest of the substances in the group are not (self-)classified as category 1 carcinogenic, mutagenic or toxic to reproduction.

Based on information reported in the REACH registration dossiers, the ashes and other residues from thermal processes and cementitious materials are used as fillers, stabilisers, pH regulators, binders and flame retardants in consumer, professional and industrial uses in coatings and paints, construction materials, adsorbents and fertilisers. The mineral like substances have a very wide variety of uses for example as binding, pH regulating, bleaching, oxidising, conductive, adsorbing, absorbing, lubricating, flotation and anti-scaling agents, food and feed additives and fillers in consumer, professional and industrial uses in coatings and paints, fillers, putties and plasters, water treatment, fertilisers and cosmetics. The substances from pulping processes are used mainly as industrial intermediates but one substance is used also as fertiliser by professional workers and another one as chelating agent and pH regulator in industrial water treatment. Glasses, ceramics and frits are used as intermediates and in insulation and filtration applications, refractory products and optical materials in industrial settings and in glazes and enamels used by consumers and industrial and professional workers. Pigments have consumer, professional and industrial uses mainly in coatings and paints.

⁵ <https://echa.europa.eu/documents/10162/5e8a767a-68de-d6ec-6c49-d3a0e41b8200>

⁶ Link to metallurgy ARN to be added later

2 Conclusions and proposed actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (e.g., strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g., on hazards through evaluation processes, or on uses) will become available, the document may be updated, and conclusions and actions revisited.

Table 1: Conclusions and proposed actions

Subgroup name, EC/List no, substance name	Hazard driving regulatory action ⁷	Relevant use(s) & exposure potential	Suggested regulatory actions
Glasses, ceramics and frits 266-047-6 Frits, chemicals	Known or potential hazard for carcinogenicity <i>266-047-6</i> for reproductive toxicity <i>266-047-6</i>	Widespread professional and consumer uses in coatings and paints (266-047-6, 701-090-0, 944-188-0) and in fertilisers (923-511-9).	Potential last action: Restriction <u>Justification:</u> The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the
Substances from pulping 923-511-9 Inorganic residual from kraft or soda pulping separated from green liquor in the chemical recovery cycle.	<i>923-511-9</i> 701-090-0 <i>944-188-0</i>	Potential for exposure to consumers and workers and release to environment	
Pigments 701-090-0 Feldspar minerals, hematite and			

⁷ The scope of this specific ARN is limited. The assessment of regulatory needs has been defined solely based on the presence of metal compounds, and in one case based on fibre morphology, which are known or potential CMRs based on harmonised classifications or previous assessments and therefore the hazards indicated here are not necessarily exhaustive.

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Subgroup name, EC/List no, substance name	Hazard driving regulatory action ⁷	Relevant use(s) & exposure potential	Suggested regulatory actions
quartz, calcination products of copper mining residues 944-188-0 Feldspar minerals, magnetite and quartz, calcination products of copper mining residues.			level of placing on the market rather than at the level of uses.
<p>Glasses, ceramics and frits</p> 266-046-0 Glass, oxide, chemicals Substance 1 (name and identifier not (publicly) available)	Known or potential hazard for carcinogenicity <i>266-046-0</i> <i>282-208-3</i> for reproductive toxicity <i>Substance 1</i> <i>282-208-3</i>	<p><i>266-046-0</i> Industrial use and article service life in filtration media</p> <p><i>Substance 1</i> Industrial use and article service life</p> <p><i>282-208-3</i> Industrial intermediate use</p> <p>Low potential for exposure and for releases to environment for all substances</p>	<p>Potential last action: Currently no need for EU RRM</p> <p><u>Justification:</u> <i>266-046-0</i> Restriction already proposed by German competent authority</p> <p><i>282-208-3 and Substance 1</i> According to the reported uses, low potential for exposure to both human health and environment is expected. Actions may be re-considered if there is a change in the registration status and/or reported uses, when the assessment will be revisited.</p>
<p>Glasses, ceramics and frits</p>	Not assessed. Hazards in the scope of this assessment are unlikely. For	Industrial uses as processing aid and in refractory bricks	<p>Potential last action: Currently no need for EU RRM</p>

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Subgroup name, EC/List no, substance name	Hazard driving regulatory action ⁷	Relevant use(s) & exposure potential	Suggested regulatory actions
266-340-9 Ceramic materials and wares, chemicals	further information see Annex I	Low potential for exposure and for releases to environment	<u>Justification:</u> Overall, no or unlikely hazard in the scope of this assessment that would lead to concern for the reported uses.
Ashes and other residues from thermal processes		Widespread professional and consumer uses as well as industrial uses in construction materials, coating and paints, adsorbents and fertilisers	
297-049-5 Ashes (residues), plant		Article service life in construction materials	
297-648-1 Oil shale, thermal processing waste		Potential for exposure to consumers and workers and for release to environment	
300-212-6 Ashes (residues), cenospheres			
931-257-5 Ashes from fluidized Bed combustion coal fired Power stations with and without co-combustion of secondary fuels (biomass; other fuels - to be verified in view of ecotoxicological and toxicological tests)			
931-322-8 Ashes (residues), coal			
931-597-4 The product from the burning of			

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Subgroup name, EC/List no, substance name	Hazard driving regulatory action ⁷	Relevant use(s) & exposure potential	Suggested regulatory actions
<p>a combination of carbonaceous materials.</p> <p>939-997-0 Reaction products of metal-free bottom ash from municipal solid wastes incineration with water and with or without lime</p> <p>954-402-4 Amorphous carbon and silicon dioxide recovered from two-stage pyrolysis of spent tyres</p> <p>954-915-3 Anatase, rutile, disodium hexatitanate and sodium tetratitanate</p> <p>Cementitious materials</p> <p>266-045-5 Cement, alumina, chemicals</p> <p>270-659-9 Flue dust, portland cement</p>			
<p>Mineral like substances</p> <p>274-324-8 Bentonite, acid-leached</p>		<p>Widespread professional and consumer uses as well as industrial uses in coatings and paints, fillers, putties and plasters, water treatment, fertilisers and cosmetics</p>	

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Subgroup name, EC/List no, substance name	Hazard driving regulatory action ⁷	Relevant use(s) & exposure potential	Suggested regulatory actions
<p>285-561-1 Lime (chemical), hydraulic</p> <p>296-473-8 Kaolin, calcined</p> <p>931-259-6 Product of Semi-Dry Absorption method of Flue Gas Desulphurization (SDA Product)</p> <p>946-103-2 Calcium hydrosilicate, reaction product of natural quartz sand and technical lime by a hydrothermal and tribochemical process</p>		<p>Potential for exposure to consumers and workers and for release to environment</p>	
<p>Substances from pulping</p> <p>268-612-2 Sulfite liquors and Cooking liquors, green</p> <p>268-615-9 Sulfite liquors and Cooking liquors, white</p> <p>931-583-8 Spent liquor from semi-chemical pulping containing spent inorganic process chemicals and dissolved organic substances</p>		<p>Industrial use in water treatment and as intermediate</p> <p>Low potential for exposure and for releases to environment</p>	

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Subgroup name, EC/List no, substance name	Hazard driving regulatory action ⁷	Relevant use(s) & exposure potential	Suggested regulatory actions
<p>originating from the wood raw material</p> <p>931-584-3 Spent liquor from alkaline pulping and bleaching containing spent inorganic process chemicals and dissolved organic substances originating from the cellulosic raw material.</p>			
<p>Pigments</p> <p>701-304-2 High-temperature calcination products of diiron trioxide and amorphous silica resulting in a glassy silica matrix</p> <p>909-981-8 Reaction mass of Fumes, silica and diiron trioxide</p> <p>910-670-4 Reaction mass of Hematite (Fe₂O₃) and Quartz (SiO₂)</p>		<p>701-304-2 Consumer, professional and industrial uses in coatings and paints</p> <p>Potential for exposure to consumers and workers and for release to environment</p> <p>909-981-8 910-670-4 No registration</p>	

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

Suggested regulatory risk management action for 'Frits, chemicals' (EC 266-047-6) due to carcinogenicity and reproductive toxicity, for 'Feldspar minerals, hematite and quartz, calcination products of copper mining residues' (List 701-090-0) and 'Feldspar minerals, magnetite and quartz, calcination products of copper mining residues' (List 944-188-0) due to reproductive toxicity as well as for 'Inorganic residual from kraft or soda pulping separated from green liquor in the chemical recovery cycle' (List 923-511-9) if reproductive toxicity hazard for manganese compounds is confirmed.

Based on currently available information, there is a potential hazard for carcinogenicity and/or reproductive toxicity for four substances (EC/List 266-047-6, 701-090-0, 923-511-9 and 944-188-0) in the group which have professional and consumer uses.

EC 266-047-6 is self-classified for carcinogenicity and reproductive toxicity as well as acute and chronic aquatic toxicity (Category 1) due to presence of lead, cadmium, boron or nickel compounds in the substance. The substance is also part of a CLH group entry (Index number 082-001-00-6) with Repr. 1A classification. List 701-090-0 and 944-188-0 are self-classified for reproductive toxicity and chronic aquatic toxicity (Category 2) due to presence of lead compounds in the substances. Based on reported information on uses, compositions self-classified as carcinogenic and/or toxic to reproduction are used by both consumers and professional workers in coatings and paints.

The restriction of the substances in consumer mixtures by means of restriction entries 28 and 30 apply and consumer mixtures should not contain components which are carcinogenic or toxic to reproduction above concentration of specific or generic limit defined in CLP Regulation.

The existing restrictions under REACH on lead and its compounds (entry 63), cadmium (entry 23) as well as nickel and its compounds (entry 27) do not cover the reported uses for the substances. Lead carbonates and lead sulphates are restricted in paints under REACH entries 16 and 17 (previously Directive 89/677/EEC) and therefore assumed not to be present in the substances used in paints other than for restoration and maintenance of works of art and historic buildings, which are uses exempted from the restrictions.

List 923-511-9 contains manganese compounds and it is used by professional workers in fertilisers. ECHA has assessed the regulatory needs of simple manganese compounds⁸. There are multiple studies with evidence of reproductive toxicity, neurotoxicity and aquatic toxicity of manganese compounds. Many of the observed effects in animals are severe, e.g., offspring mortality, resorptions and impaired spermatogenesis. The ECHA's assessment of regulatory needs for manganese compounds suggests as a first step the confirmation of the hazards via CLH. Thus, any regulatory action proposed for List 923-511-9 is pending for that confirmation.

⁸ <https://echa.europa.eu/documents/10162/99534c29-54e2-8fb3-f974-e6e84cbe6359>

The professional uses in coatings and paints and in fertilisers are expected to be widespread (at many sites and by many users). Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation.

Consumers may be co-exposed to the substances used by professionals in coatings and paints.

Therefore, a **restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals** is suggested after CLH.

Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability **Error! Bookmark not defined.** which aims to extend to professional users under REACH the level of protection granted to consumers.

The fertiliser regulation (EU 2019/1009⁹) provides a harmonised approach for assessing hazardous substances in fertilisers under the CE marking within the context of the EU single market. The fertiliser regulation includes limit values for manganese in specific fertiliser, however, as compliance with harmonised rules remain optional it does not alone seem to be sufficient to address the reproductive toxicity concern of List 923-511-9 in fertilisers used by professional workers.

Some of the substances may be used in paints that are used to restore/maintain historic buildings. The restriction process is expected to clarify such uses and if they should be included in the scope of the restriction.

Currently no need to suggest (further) regulatory risk management actions for the other substances in the group.

Based on currently available information, there is no need for (further) EU regulatory risk management for the other substances in the group.

Substance 'Glass, oxide, chemicals' (EC 266-046-0) consists of glass microfibres and it is self-classified as carcinogenic due to the fibre morphology. It is also part of two CLH group entries (Index number 650-017-00-8¹⁰ and 650-016-00-2¹¹, which have classification for Carc 1B and Carc 2, respectively. The substance has been assessed by German competent authority in the context of a regulatory management option analysis (RMOA) on substances in fibre form¹². In that context, the human exposure potential from use in filtration media in industrial settings and article service life in filters in manufacture of pulp, paper and paper products was concluded not to be high. However, the substance was proposed to be restricted.

⁹ <https://eur-lex.europa.eu/eli/reg/2019/1009/oj>

¹⁰ Refractory Ceramic Fibres, Special Purpose Fibres, with the exception of those specified elsewhere in this Annex (<https://echa.europa.eu/fi/substance-information/-/substanceinfo/100.240.852>)

¹¹ Mineral wool, with the exception of those specified elsewhere in this Annex (<https://echa.europa.eu/fi/substance-information/-/substanceinfo/100.240.851>)

¹² <https://echa.europa.eu/documents/10162/4d2a0bc5-48ab-d3df-3dbd-daa23375c80e>

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The exemptions for restriction are proposed to be possible based on a five-tiered testing strategy even if fibres fulfil the WHO fibre criterion¹³.

Substance 'Ashes (residues), vanadium-contg.' (EC 282-208-3) is self-classified for carcinogenicity and reproductive toxicity whereas Substance 1 is self-classified for reproductive and chronic aquatic toxicity. However, EC 282-208-3 is used only as an intermediate and all the uses of Substance 1 are such that exposure to humans and releases to environment are expected to be low. Furthermore, the self-classification as C/M/R requires company level risk management (RMM) to be in place and this should be sufficient to ensure safe use for the workers at industrial settings. Therefore, no EU RRM is proposed for either of these substances.

The rest of the substances in the group are not (self-)classified as category 1 carcinogenic, mutagenic or toxic to reproduction. In terms of environmental hazards, only two substances from pulping processes (EC 268-612-2 and 268-615-9) are self-classified for category 1 acute aquatic toxicity.

The ashes and other residues from thermal processes, mineral like substances and cementitious materials have widespread professional and consumer uses as well as industrial uses for example in coatings and paints, construction materials, water treatment, adsorbents and fertilisers. The pigments have consumer, professional and industrial uses in coating and paints. The rest of the substances in group are used in industrial settings in many cases as intermediate.

No EU regulatory risk management action is currently proposed for any of the substances with no or unlikely hazard in the scope of this assessment that would lead to concern and/or with low exposure and release potential. It is worth noting however that the strategy may need to be revisited and need for further regulatory action reconsidered if there is a change in the registration status or reported uses for any of these substances.

One registrant of 'The product from the burning of a combination of carbonaceous materials.' (List 931-597-4) has reported that their substance contains manganese chromate ($MgCrO_4$). Hexavalent chromium is known to be carcinogenic and magnesium chromate is C&L notified also to be mutagenic. As manganese chromate is reported only by one registrant out of 72 registrants, no EU RRM action for the substance List 931-597-4 is proposed. The registrant having manganese chromate as a constituent of their substance is invited to update their registration dossier and revise the classification of the substance based on constituents, as appropriate, or if technically feasible to ensure that the concentration of the constituent is below the relevant concentration limit for carcinogenicity and mutagenicity. The Safety Data Sheet needs to be updated accordingly. The need for further EU RRM may be re-considered if the substance is not classified correctly.

¹³ <https://kohahq.searo.who.int/cgi-bin/koha/opac-detail.pl?biblionumber=8448>

Annex 1: Overview of classifications

Data extracted on 15 December 2023.

Substance EC 266-046-0 is part of two CLH group entries (Index number 650-017-00-8¹⁴ and 650-016-00-2¹⁵, which have classification for Carc 1B and Carc 2, respectively. Substance 266-047-6 is part of a CLH group entry (Index number 082-001-00-6¹⁶) with Repr. 1A, STOT RE 2, Acute tox. 4 and Aquatic acute 1 and Aquatic chronic 1 classification. Other substances in the group do not have a harmonised classification.

EC/ List No	CAS No	Substance name	Classification in registrations
266-045-5	65997-16-2	Cement, alumina, chemicals	Eye Irrit. 2 H319
266-046-0	65997-17-3	Glass, oxide, chemicals	Carc. 1B H350
266-047-6	65997-18-4	Frits, chemicals	Carc. 1A H350 Carc. 2 H351 Muta. 2 H341 Repr. 1A H360 Repr. 1A H360Df Repr. 1B H360 Repr. 1B H360FD Repr. 2 H361d Repr. 2 H361 Acute Tox. 4 H302 Acute Tox. 4 H312 Acute Tox. 4 H332 STOT Rep. Exp. 1 H372 STOT Rep. Exp. 2 H373 Eye Damage 1 H318 Resp. Sens. 1A H334 Skin Sens. 1 H317 Effect on or via lactation H362 Aquatic Acute 1 H400 Aquatic Chronic 1 H410 Aquatic Chronic 2 H411 Aquatic Chronic 3 H412
266-340-9	66402-68-4	Ceramic materials and wares, chemicals	Eye Damage 1 H318 Eye Irrit. 2 H319
268-612-2	68131-30-6	Sulfite liquors and Cooking liquors, green	Acute Tox. 3 H301 Acute Tox. 3 H311 Acute Tox. 4 H302 Acute Tox. 4 H312 Met. Corr. 1 H290 Skin Corr. 1A H314

¹⁴ Refractory Ceramic Fibres, Special Purpose Fibres, with the exception of those specified elsewhere in this Annex (<https://echa.europa.eu/fi/substance-information/-/substanceinfo/100.240.852>)

¹⁵ Mineral wool, with the exception of those specified elsewhere in this Annex (<https://echa.europa.eu/fi/substance-information/-/substanceinfo/100.240.851>)

¹⁶ lead compounds with the exception of those specified elsewhere in this Annex (<https://echa.europa.eu/fi/information-on-chemicals/cl-inventory-database/-/discli/details/153460>)

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Classification in registrations
			Skin Corr. 1B H314 Aquatic Acute 1 H400
268-615-9	68131-33-9	Sulfite liquors and Cooking liquors, white	Acute Tox. 3 H311 Acute Tox. 4 H312 Acute Tox. 4 H302 Met. Corr. 1 H290 Skin Corr. 1A H314 Eye Damage 1 H318 Aquatic Acute 1 H400
270-659-9	68475-76-3	Flue dust, portland cement	STOT Single Exp. 3 H335 Eye Damage 1 H318 Skin Irrit. 2 H315 Skin Sens. 1 H317
274-324-8	70131-50-9	Bentonite, acid-leached	-
282-208-3	84144-87-6	Ashes (residues), vanadium-contg.	Carc. 1A H350 Repr. 1B H361 Muta. 2 H341 Acute Tox. 4 Acute Tox. 4 H332 STOT Rep. Exp. 2 H372 Skin Sens. 1 H317 Eye Irrit. 2 H319 Eye Irrit. 2 H320 Resp. Sens. 1 H334 Aquatic Chronic 3 H412
285-561-1	85117-09-5	Lime (chemical), hydraulic	STOT Single Exp. 3 H335 Skin Irrit. 2 H315 Eye Damage 1 H318
296-473-8	92704-41-1	Kaolin, calcined	-
297-049-5	93333-79-0	Ashes (residues), plant	-
297-648-1	93685-99-5	Oil shale, thermal processing waste	STOT Rep. Exp. 1 H372 STOT Rep. Exp. 2 H372 STOT Single Exp. 3 H335 Eye Damage 1 H318
300-212-6	93924-19-7	Ashes (residues), cenospheres	-
701-090-0	-	Feldspar minerals, hematite and quartz, calcination products of copper mining residues	Repr. 1A H360D STOT Rep. Exp. 2 H373 Aquatic Chronic 2 H411
701-304-2	-	High-temperature calcination products of diiron trioxide and amorphous silica resulting in a glassy silica matrix	-
N/A	-	Substance 1	Repr. 1A H360Df Carc. 2 STOT Rep. Exp. 1 H372 Acute Tox. 4 H302 Acute Tox. 4 H332 Aquatic Chronic 1 H410
909-981-8	-	Reaction mass of Fumes, silica and diiron trioxide	-
910-670-4	-	Reaction mass of Hematite (Fe ₂ O ₃) and Quartz (SiO ₂)	-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Classification in registrations
923-511-9	-	Inorganic residual from kraft or soda pulping separated from green liquor in the chemical recovery cycle.	Skin Irrit. 2 H315 Eye Damage 1 H318
931-257-5	-	Ashes from fluidized Bed combustion coal fired Power stations with and without co-combustion of secondary fuels (biomass; other fuels - to be verified in view of ecotoxicological and toxicological tests)	-
931-259-6	-	Product of Semi-Dry Absorption method of Flue Gas Desulphurization (SDA Product)	-
931-322-8	-	Ashes (residues), coal	-
931-583-8	-	Spent liquor from semi-chemical pulping containing spent inorganic process chemicals and dissolved organic substances originating from the wood raw material	Skin Irrit. 2 H315
931-584-3	-	Spent liquor from alkaline pulping and bleaching containing spent inorganic process chemicals and dissolved organic substances originating from the cellulosic raw material.	Met. Corr. 1 H290 Skin Corr. 1B H314 Eye Damage 1 H318 Aquatic Chronic 3 H412
931-597-4	-	The product from the burning of a combination of carbonaceous materials.	STOT Single Exp. 3 H335 Skin Irrit. 2 H315 Eye Damage 1 H318
939-997-0	-	Reaction products of metal-free bottom ash from municipal solid wastes incineration with water and with or without lime	-
944-188-0	-	Feldspar minerals, magnetite and quartz, calcination products of copper mining residues.	Repr. 1A H360D STOT Rep. Exp. 2 H373 Aquatic Chronic 2 H411
946-103-2	-	Calcium hydrosilicate, reaction product of natural quartz sand and technical lime by a hydrothermal and tribochemical process	Eye Irrit. 2 H319
954-402-4	-	Amorphous carbon and silicon dioxide recovered from two-stage pyrolysis of spent tyres	-
954-915-3	-	Anatase, rutile, disodium hexatitanate and sodium tetratitanate	-

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

Data extracted on 15 December 2023.

Uses of substances for which EU RRM is proposed.

Main types of applications structured by product or article types	EC / List	266-047-6	701-090-0	923-511-9	944-188-0
PC 12: Fertilisers				F, P	
PC 9b: Fillers, putties, plasters, modelling clay				I	
PC 9a: Coatings and paints, thinners, paint removes		F, I, P, C	F, I, P, C		F, I, P, C
PC 18: Ink and toners		F, I			
PC 19: Intermediate		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

ASSESSMENT OF REGULATORY NEEDS

Uses of ashes and other residues from thermal processes

Main types of applications structured by product or article types	EC / List	282-208-3	297-049-5	297-648-1	300-212-6	931-257-5	931-322-8	931-597-4	939-997-0	954-402-4	954-915-3
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents				P, C	F, I			I, P			
PC 2: Adsorbents				P, C	F, I, P						
PC 11: Explosives					F, I, P						
PC 12: Fertilisers			F, I, P, C	P	F, I	P, A	P, C	F, I, P, C			
PC 4: Anti-freeze and de-icing products					F, I						
PC 35: Washing and cleaning products					F, I, P			I, P			
PC 8: Biocidal products (e.g. disinfectants, pest control)					F, I						
PC 28: Perfumes, fragrances					F, I						
PC 3: Air care products					F, I						
PC 39: Cosmetics, personal care products					F, I					F, I, P, C	
PC 31: Polishes and wax blends					F, I, P					F, I, P	
PC 15: Non-metal-surface treatment products					F, I, P	I, P	F, I, P, C				
PC 24: Lubricants, greases, release products					F, I					F, I, P, C	
PC 25: Metal working fluids					F, I						
PC 17: Hydraulic fluids					F, I						
PC 13: Fuels				I	F, I		I				
PC 32: Polymer preparations and compounds					F, I, P	I	I			F, I, A	
PC 1: Adhesives, sealants					F, I, P		F, I, P			F, I, P, C	

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	EC / List	282-208-3	297-049-5	297-648-1	300-212-6	931-257-5	931-322-8	931-597-4	939-997-0	954-402-4	954-915-3
PC 9c: Finger paint								F		F, I, P, C	
PC 9b: Fillers, putties, plasters, modelling clay				F, C	F, I, P, C	F, I, P, C, A	F, I, P, C, A	F, I, P	F, I, P, A	F, I, P, C, A	
PC 9a: Coatings and paints, thinners, paint removes				F, P, C, A	F, I, P	I, P	I, P, C	P		F, I, P, C	
PC 18: Ink and toners					F, I					F, I, P, C	
PC 26: Paper and board treatment products					F, I			I		F, I, A	
PC 34: Textile dyes, and impregnating products					F, I					F, I, C, A	
PC 23: Leather treatment products					F, I					F, I, P, C, A	
PC 14: Metal surface treatment products					F, I	I, P	I, P				
PC 7: Base metals and alloys					F, I, P			F			
PC 33: Semiconductors					F, I					I	
PC 21: Laboratory chemicals					F, I, P						
PC 19: Intermediate		I			F, I			I			I
PC41: Oil and gas exploration or production products					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

ASSESSMENT OF REGULATORY NEEDS

Uses of mineral like substances

Main types of applications structured by product or article types	EC / List	274-324-8	285-561-1	296-473-8	931-259-6	946-103-2
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents		F, I, P, C	F, I, P, C	I		
PC 36: Water softeners		F, I, P, C	F, I, P			
PC 37: Water treatment chemicals		F, I, P, C	F, I, P, C			
PC 2: Adsorbents		F, I, P, C	F, I, P, C		I, C	
PC 11: Explosives			F, I, P			
PC 12: Fertilisers		F, I, P, C	F, I, P, C		I, P	
PC 27: Plant protection products			F, I, P			
PC 35: Washing and cleaning products		F, I, P, C	F, I, P			
PC 8: Biocidal products (e.g. disinfectants, pest control)			F, I, P			
PC 28: Perfumes, fragrances			F, I, P			
PC 3: Air care products		F, I, P, C	F, I, P			
PC 39: Cosmetics, personal care products		F, I, P, C	F, I, P, C			
PC 29: Pharmaceuticals		F, I, P, C	F, I, P			
PC 31: Polishes and wax blends		P	F, I, P			
PC 15: Non-metal-surface treatment products		F, I	F, I, P			
PC 24: Lubricants, greases, release products		F, I, P, C	F, I, P			
PC 25: Metal working fluids			F, I, P			
PC 16: Heat transfer fluids			F, I, P			
PC 17: Hydraulic fluids			F, I, P			
PC 13: Fuels		F, I, P, C	F, I, P			
PC 32: Polymer preparations and compounds		F, I, A	F, I, P			
PC 1: Adhesives, sealants		F, I, P, C	F, I, P			
PC 9c: Finger paint		F, I, P, C				
PC 9b: Fillers, putties, plasters, modelling clay		F, I, P, C	F, I, P, C		F, I, C	
PC 9a: Coatings and paints, thinners, paint removes		F, I, P, C	F, I, P, C			F, I, P, C, A
PC 18: Ink and toners		F, I, P, C	F, I, P			
PC 26: Paper and board treatment products		F, I, P, C	F, I, P			

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	EC / List	274-324-8	285-561-1	296-473-8	931-259-6	946-103-2
PC 34: Textile dyes, and impregnating products		F, I, P, C	F, I, P			
PC 23: Leather treatment products		F, I, P, C	F, I, P			
PC 14: Metal surface treatment products			F, I, P			
PC 38: Welding and soldering products, flux products			F, I, P			
PC 7: Base metals and alloys			F, I, P			
PC 33: Semiconductors			F, I, P			
PC 21: Laboratory chemicals		F, I, P, C	F, I, P	I		
PC 19: Intermediate		F, I, P, C	F, I, P	I		
PC 40: Extraction agents		F, I, P, C	F, I, P			
PC41: Oil and gas exploration or production products						
PC42: Electrolytes for batteries						
PC 30: Photo-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

ASSESSMENT OF REGULATORY NEEDS

Uses of substances from pulping processes

Main types of applications structured by product or article types	EC / List	268-612-2	268-615-9	931-583-8	931-584-3
PC 37: Water treatment chemicals		I			
PC 19: Intermediate		I	I	I	I

I: industrial use

Uses of glasses, ceramics, cementitious materials and a pigment

Main types of applications structured by product or article types	EC / List	266-046-0	266-340-9	N/A	266-045-5	270-659-9	701-304-2
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents			I			I, P	
PC 2: Adsorbents						I	
PC 12: Fertilisers						P	
PC 32: Polymer preparations and compounds					F, I		A
PC 9b: Fillers, putties, plasters, modelling clay					F, I	F, I, P , C , A	F, I, P
PC 9a: Coatings and paints, thinners, paint removes						F, I, P	F, I
PC 18: Ink and toners							F, I

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

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

Data extracted on 11 January 2024.

EC/List No	RMOA, ARN	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV			
266-046-0					YES	OEL
266-340-9						OEL
270-659-9						OEL
285-561-1						OEL
296-473-8						Food contact material
931-257-5						OEL

*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, 40 and 75).

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