

## Assessment of regulatory needs

**Authority:** European Chemicals Agency (ECHA)

**Group Name:** Slag substances (residues from processing of primary and secondary metal sources)

**General structure:** -

**Revision history**

<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	29 November 2023	

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### Substances within this group:<sup>1</sup>

Lead containing substances

EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>2</sup>
266-970-4	67711-94-8	Slags, copper refining	Full, >1000
273-800-2	69029-58-9	Slags, lead reverbatory smelting	Full, not (publicly) available
273-812-8	69029-71-6	Leach residues, lead slag	Not registered
273-824-3	69029-83-0	Residues, zinc smelting	OSII or TII
273-825-9	69029-84-1	Slags, lead smelting	Full, >1000
273-826-4	69029-85-2	Slags, precious metal recovery lead refining	Not registered
273-828-5	69029-86-3	Slags, tellurium	OSII or TII
297-907-9	93763-87-2	Slags, lead-zinc smelting	Full, >1000
308-515-5	98072-60-7	Slags, precious metal refining	Full, >1000

Manganese containing substances

EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>2</sup>
266-002-0	65996-69-2	Slags, ferrous metal, blast furnace	Full, >1000
266-004-1	65996-71-6	Slags, steelmaking	Full, >1000
273-728-1	69012-28-8	Slags, ferromanganese-manufg.	Full, >1000
273-733-9	69012-33-5	Slags, silicomanganese-manufg.	Full, >1000
273-734-4	69012-34-6	Slags, steelmaking, vanadium	Full, not (publicly) available
293-671-6	91081-64-0	Slags, ilmenite electrothermal smelting	Full, >1000
294-409-3	91722-09-7	Slags, steelmaking, converter	Full, >1000
701-265-1	-	Slags from smelting of oxidic stainless-steelmaking residues	Full, not (publicly) available

<sup>1</sup> The substances were sub-grouped based on the presence of metals (lead, manganese, chromium and vanadium) of which some compounds are known or have potential to cause CMR hazard. The substances may contain compounds of several metals and in such cases sub-grouping was done in order of presence of lead, manganese, chromium and vanadium and each substance was allocated to only one of the subgroups.

<sup>2</sup> Note that 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 number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>2</sup>
		containing Chromium, Nickel, Molybdenum, Manganese and Iron.	
922-716-0	-	Products of roasting of "slags, steelmaking, vanadium"	OSII or TII
931-787-7	-	Reaction mass of aluminium oxide and vanadium dioxide	OSII or TII
932-275-6	91722-10-0	Calcium-Iron-Silicium-Magnesium-Manganese-Aluminium oxide equivalent	Full, >1000
932-476-9	91722-10-0	Calcium-Silicium-Magnesium-Aluminium-Iron-Manganese oxide equivalent	Full, >1000

Chromium containing substances

EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>2</sup>
273-727-6	69012-27-7	Slags, ferrochromium-manufg.	Full, not (publicly) available
273-729-7	69012-29-9	Slags, ferronickel-manufg.	Full, not (publicly) available
273-736-5	69012-35-7	Slags, tin-smelting	Full, not (publicly) available
919-559-5	-	Leach of products of roasting of "slags, steelmaking, vanadium"	OSII or TII

Vanadium containing substances

EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>2</sup>
282-220-9	84144-98-9	Slags, ferrovanadium-manufg., aluminothermic	Full, >1000
701-306-3	-	Reaction mass of sodium pyrovanadate and sodium orthovanadate and diiron trioxide and sodium sulfate and sodiumironsulfide	OSII or TII

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EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>2</sup>
909-634-0	-	Reaction mass of calcium oxide and silicon dioxide and vanadium dioxide and aluminium oxide	OSII or TII
931-787-7	-	Reaction mass of aluminium oxide and vanadium dioxide	OSII or TII

Other slag substances not containing compounds known / potential to cause CMR hazard

EC/List number	CAS number	Substance name	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) <sup>2</sup>
266-968-3	67711-92-6	Slags, copper smelting	C&L notified
273-732-3	69012-32-4	Slags, phosphorus-manufg.	Not registered
282-217-2	84144-95-6	Slags, ferromolybdenum-manufg., silicothermic	Full, >1000
310-060-2	102110-59-8	Slags, elec. furnace smelting, iron silicate	Full, >1000
701-258-3	-	Slag, pig iron ladle refining, non-granulated, water-cooled	Full, not (publicly) available
701-480-0	-	Iron silicate, copper smelting and refining	Full, >1000
909-586-0	-	Reaction mass of aluminium and aluminium oxide and calcium oxide and magnesium oxide	Full, not (publicly) available
920-632-9	-	Slags, nickel smelting	Full, not (publicly) available
940-591-0	-	Slags, granulated, resulting from plasma-enhanced gasification of non-hazardous municipal waste	Not registered
940-884-3	-	Slags, sponge iron production by coal reduction in retort	Full, not (publicly) available
953-903-5	-	aluminium, magnesium and silicon oxides and hydroxides from refinement of aluminium salt slag residues	Full, >1000

The tables contain 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)<sup>3</sup>. These methods are different from grouping as defined in Section 1.5 of Annex XI to REACH because the scope and intended use of ECHA's grouping is different. Thus, in this context, grouping does not aim to validate read-across and category approaches according to the Annex XI requirements but rather to support a faster and more consistent approach for regulating chemicals and avoid regrettable substitution.

The focus of the assessment is largely based on information available in the registration dossiers and on properties requiring regulatory risk management action at EU level<sup>4</sup>. 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.

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<sup>3</sup> [Working with Groups - ECHA \(europa.eu\)](https://eucha.europa.eu)

<sup>4</sup> 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 website<sup>5</sup>.

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<sup>5</sup> <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
RAC	The Committee for Risk Assessment
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
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials

## 1 Overview of the group

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

The scope of this specific ARN is limited as the assessment of regulatory needs has been defined solely based on the presence of metals of which compounds are known or potential CMRs.

ECHA has grouped together slag substances which in general terms are residues from processing of primary and secondary metal sources. The group consists of 37 substances. All of them are UVCB type substances except three, viz. EC 293-671-6, which is reported to be mono-constituent substance, and List 701-306-3 and 931-787-1, which are reported to be multi-constituent substances. 26 substances have full registration, eight have intermediate registration and four are not registered. Two of the non-registered substances (EC 273-812-8 and EC 273-826-4) have harmonised classification.

The substances were sub-grouped based on the presence of metals (lead, manganese, chromium and vanadium) of which some compounds are known or potential CMRs. The slag substances may contain compounds of several metals and in such cases the assignment of a substance to a sub-group was done in the order of the presence of lead, manganese, chromium and vanadium. Each substance was allocated to only one of the subgroups. The substances which do not contain lead, manganese, chromium or vanadium were grouped in subgroup 'Other slag substances not containing compounds with known / potential to cause CMR hazard'.

Lead and chromium (VI) compounds have harmonised classification<sup>6,7</sup> and they have been identified as substances of very high concern (SVHCs) under REACH due to their CMR properties. A RAC evaluation in 2020 concluded occupational limit values for lead and its compounds<sup>8</sup>. Several chromium (VI) compounds are included in REACH Annex XIV (Authorisation list) and lead compounds are recommended to be included in Annex XIV. Entry 63 under REACH Annex XVII restricts lead in jewellery and in mouthable articles supplied to the general public.

ECHA has assessed separately the regulatory needs of simple manganese and vanadium compounds<sup>9,10</sup>. There are multiple studies with evidence of reproductive toxicity for manganese compounds. Many of the observed effects in animals are severe, e.g., offspring mortality, resorptions and impaired spermatogenesis.

For divanadium pentaoxide (EC 215-239-8) a process to establish a harmonised classification and labelling (CLH) is ongoing. RAC has concluded that the substance warrants harmonised classification as Carc. 1B (carcinogenic properties causing lung cancer), as well as Muta. 2, Repr. 2, Lact., STOT RE 1, Acute Tox. 3 and Acute Tox. 2.<sup>11</sup> As the lung cancer hazard relates to the release of tetra- and pentavalent

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<sup>6</sup> <https://echa.europa.eu/fi/information-on-chemicals/cl-inventory-database/-/discli/details/153460>

<sup>7</sup> <https://echa.europa.eu/fi/information-on-chemicals/cl-inventory-database/-/discli/details/14356>

<sup>8</sup> <https://echa.europa.eu/rac-opinions-on-scientific-evaluations-of-oels>

<sup>9</sup> <https://echa.europa.eu/documents/10162/99534c29-54e2-8fb3-f974-e6e84cbe6359>

<sup>10</sup> <https://echa.europa.eu/documents/10162/3e442cfa-cee2-7e3b-6109-1333792ec4c4>

<sup>11</sup> <https://www.echa.europa.eu/documents/10162/6c9565dd-6350-5498-4d9d-b239ddbc88c8>

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vanadium cationic species, these properties can (potentially) be read-across to all other substances in the group of vanadium compounds assessed by ECHA.

In addition, many substances contain significant amounts of silicon dioxide and/or different silicates. In some cases, the crystal structure of silicon dioxide (amorphous, quartz, cristobalite) is defined by the registrants but in many cases, this has not been done. Crystalline silica is known to cause silicosis, one type of pneumoconiosis.

Based on information reported in the REACH registration dossiers, many substances in the group have widespread professional uses in construction materials, road construction, fillers for earthwork, water treatment and fertilisers. For eight substances (EC/List 266-002-0, 266-004-1, 273-727-6, 294-409-3, 932-275-6, 701-258-3, 701-480-0, 920-632-9) consumer use is also reported for the same applications. For 13 substances (EC/List 266-970-4, 273-734-4, 273-735-4, 273-736-5, 273-800-2, 273-824-3, 273-828-5, 308-515-5, 701-306-3, 909-634-0, 919-559-5, 922-716-0, 931-787-7) only industrial use as intermediate (mainly in processes to manufacture metals and metal alloys) is reported. One substance (EC 282-220-9) is reported to be used as aggregate / in refractory product in industrial settings.

Slags are used in the production of cement. The restriction on hexavalent chromium compounds in cement was introduced in 2003 (later restriction entry 47 under REACH) since studies showed that cement preparations containing hexavalent chromium may cause allergic reactions in certain circumstances if there is direct and prolonged contact with the human skin<sup>12</sup>. According to the restriction, cement and cement-containing mixtures shall not be placed on the market, or used, if they contain, when hydrated, more than 2 mg/kg (0,0002%) soluble hexavalent chromium of the total dry weight of the cement<sup>13</sup>.

Slags are also used in the treatment of wastewater. Granular slag has been shown to remove, besides phosphate, metals (e.g. iron, manganese)<sup>14</sup> from waste water. To support the circular economy initiative, applications for the waste granular slag originating from the wastewater treatment process are looked for, including replacement of conventional aggregates in concrete.

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<sup>12</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003L0053>

<sup>13</sup> <https://echa.europa.eu/documents/10162/1f775bd4-b1b0-4847-937f-d6a37e2c0c98>

<sup>14</sup> Roychand et al. Resources, conservation and recycling, Vol. 15. January 2020. 104533. <https://www.sciencedirect.com/science/article/pii/S0921344919304392>

## 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 actions <sup>15</sup>	Relevant use(s) & exposure potential	Suggested regulatory actions
<p><b>Lead containing substances</b></p> <p>273-825-9 Slags, lead smelting</p> <p>297-907-9 Slags, lead-zinc smelting</p> <p><b>Manganese containing substances</b></p> <p>266-002-0 Slags, ferrous metal, blast furnace</p>	<p>Known or potential hazard for reproductive toxicity for carcinogenicity (EC 273-825-9)</p>	<p>Widespread professional uses in construction materials and fillers for earthwork. Potential for exposure for workers and consumers and release to environment.</p>	<p><b>Restriction</b></p> <p><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</p>

<sup>15</sup> The scope of this specific ARN is limited. The assessment of regulatory needs has been defined solely based on the presence of metals of which compounds are known or potential CMRs, so the hazards indicated here are not necessarily exhaustive.

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Subgroup name, EC/List no, substance name	Hazard driving regulatory actions <sup>15</sup>	Relevant use(s) & exposure potential	Suggested regulatory actions
266-004-1 Slags, steelmaking			level of placing on the market rather than at the level of uses.
273-728-1 Slags, ferromanganese-manufg.			
273-733-9 Slags, silicomanganese-manufg.			
294-409-3 Slags, steelmaking, converter			
701-265-1 Slags from smelting of oxidic stainless-steelmaking residues containing Chromium, Nickel, Molybdenum, Manganese and Iron.			
932-275-6 Calcium-Iron-Silicium-Magnesium-Manganese-Aluminium oxide equivalent			
932-476-9 Calcium-Iron-Silicium-Magnesium-Manganese-Aluminium oxide equivalent			

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<p><b>Lead containing substances</b></p> <p>266-970-4 Slags, copper refining</p> <p>273-800-2 Slags, lead reverbatory smelting</p> <p>273-812-8 Leach residues, lead slag</p> <p>273-824-3 Residues, zinc smelting</p> <p>273-826-4 Slags, precious metal recovery lead refining</p> <p>273-828-5 Slags, tellurium</p> <p>308-515-5 Slags, precious metal refining</p> <p><b>Manganese containing substances</b></p> <p>273-734-4 Slags, steelmaking, vanadium</p> <p>293-671-6 Slags, ilmenite electrothermal smelting</p>	<p>Known or potential hazard for reproductive toxicity for carcinogenicity (EC 266-970-4, 273-824-3, 273-828-5, 308-515-5)</p>	<p>Industrial intermediate uses. Low potential for exposure.</p>	<p><b>Currently no need for EU RRM</b></p> <p><u>Justification:</u> For intermediate uses in industrial settings 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>
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Subgroup name, EC/List no, substance name	Hazard driving regulatory actions <sup>15</sup>	Relevant use(s) & exposure potential	Suggested regulatory actions
922-716-0 Products of roasting of "slags, steelmaking, vanadium"			
<p><b>Chromium containing substances</b></p> <p>273-727-6 Slags, ferrochromium-manufg.</p> <p>273-729-7 Slags, ferronickel-manufg.</p> <p>273-736-5 Slags, tin-smelting</p> <p>919-559-5 Leach of products of roasting of "slags, steelmaking, vanadium"</p>	<p>Known or potential hazard for carcinogenicity for mutagenicity of Cr (VI) for reproductive toxicity (List 919-559-5)</p>	<p>Widespread professional and consumer uses in construction materials, fillers for earthwork, and sandblasting. Potential for exposure for workers and consumers and release to environment.</p> <p>Industrial intermediate uses. Low potential for exposure.</p>	<p>CCH for EC 273-727-6 EC 273-729-7</p> <p><b>(Potential) last action (after data generation): Currently no need for EU RRM</b></p> <p><u>Justification:</u> Substances are not expected to contain hexavalent chromium. The current restriction for hexavalent chromium is well placed to cover the risks related to the exposure for / release of possible hexavalent chromium from the substances used in cement production.</p>
<p><b>Vanadium containing substances</b></p> <p>282-220-9 Slags, ferrovandium-manufg., aluminothermic</p> <p>701-306-3 Reaction mass of sodium pyrovanadate and sodium</p>	<p>Known or potential hazard for carcinogenicity for mutagenicity for reproductive toxicity</p>	<p>Industrial uses as aggregate and as raw material for refractory products as well as intermediate. Potential for exposure for industrial workers.</p>	<p><b>Currently no need for EU RRM</b></p> <p><u>Justification:</u> According to the reported uses, potential for exposure and release to environment is low. 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>

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Subgroup name, EC/List no, substance name	Hazard driving regulatory actions <sup>15</sup>	Relevant use(s) & exposure potential	Suggested regulatory actions
<p>orthovanadate and diiron trioxide and sodium sulfate and sodiumironsulfide</p> <p>909-634-0 Reaction mass of calcium oxide and silicon dioxide and vanadium dioxide and aluminium oxide</p> <p>931-787-7 Reaction mass of aluminium oxide and vanadium dioxide</p>			
<p><b>Other slag substances</b></p> <p>266-968-3 Slags, copper smelting</p> <p>273-732-3 Slags, phosphorus-manufg.</p> <p>282-217-2 Slags, ferromolybdenum-manufg., silicothermic</p> <p>310-060-2 Slags, elec. furnace smelting, iron silicate</p>	<p>Not assessed. For further information see Annex 1.</p>	<p>Widespread professional and consumer use in construction materials, fillers for earthwork, fertilisers, water treatment and abrasive agents. Industrial uses in construction materials and fillers for earthwork and as intermediate.</p> <p>Potential for exposure for workers and consumers and release to environment.</p>	<p><b>Currently no need for EU RRM</b></p> <p><u>Justification:</u> Overall, no or unlikely hazard that would lead to concern for the reported uses.</p>

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Subgroup name, EC/List no, substance name	Hazard driving regulatory actions <sup>15</sup>	Relevant use(s) & exposure potential	Suggested regulatory actions
701-258-3 Slag, pig iron ladle refining, non-granulated, water-cooled			
701-480-0 Iron silicate, copper smelting and refining			
909-586-0 Reaction mass of aluminium and aluminium oxide and calcium oxide and magnesium oxide			
920-632-9 Slags, nickel smelting			
940-591-0 Slags, granulated, resulting from plasma-enhanced gasification of non-hazardous municipal waste			
940-884-3 Slags, sponge iron production by coal reduction in retort			
953-903-5 aluminium, magnesium and silicon oxides and hydroxides from refinement of aluminium salt slag residues			

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### 3 Justification for the need for regulatory risk management action at EU level

**Suggested regulatory risk management action** for two lead containing substances (EC 273-825-9 and 297-907-9) and for eight manganese containing substances (EC/List 266-002-0, 266-004-1, 273-728-1, 273-733-9, 294-409-3, 701-265-1, 932-275-6 and 932-476-9)

Based on currently available information, there is a potential hazard for reproductive toxicity hazards.

As indicated in Section 1 above lead and manganese compounds are known to have reproductive toxicity hazards. One lead containing substance (EC 273-825-9) has self-classification as Carc. 1B and Repr. 1A whereas the other one (EC 297-907-9) does not have classifications although it should have for Repr. 1A, Acute Tox. 4, STOT RE 2, Aquatic Acute 1 and Aquatic Chronic 1 based on the harmonised classification with index number 082-001-00-6<sup>6</sup>. Two of the manganese containing substances (EC 273-728-1 and 273-733-9) have self-classification as Repr. 2 whereas other six manganese containing substances (EC/ List 266-002-0, 266-004-1, 294-409-3, 701-265-1, 932-275-6 and 932-476-9) do not have classifications.

Based on the reported uses, there is potential for exposure of the substances for professional workers and general population during construction works e.g., concrete (cement) preparation and cutting, sandblasting and road construction. In particular, exposure indoors is relevant but outdoor exposure could also be significant at local sites. Co-exposure to general population e.g., in densely populated areas like cities is possible. Also, exposure for workers (and general population) is possible when used as fertiliser and in landfill.

The professional uses mentioned above 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.

Therefore, a **restriction of the substance as such or as a concentration limit of CMR compound in the substance used by professionals** is suggested. 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<sup>16</sup> (CSS) which aims to extend to professional users under REACH the level of protection granted to consumers.

Furthermore, the Restrictions Roadmap under the CSS summarises substances where restrictions are discussed as a potential regulatory management option or

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<sup>16</sup> European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

revising an existing restriction could be necessary. Some of the (groups of) substances listed in the roadmap are relevant for slags, e.g. lead in consumer articles, other substances in infill material, substances in fertilisers, and simple manganese compounds<sup>17</sup>.

The fertiliser regulation (EU 2019/1009) provides a harmonised approach for assessing hazardous substances in fertilisers under the CE marking within the context of the EU single market. Similarly, common assessment methods for the release of dangerous substances from construction products are developed under the construction product regulation (CPR, EU 2011/305) for CE marking<sup>18</sup>.

The fertilisers regulation includes limit values for lead and manganese in specific fertilisers, however, as compliance with harmonised rules remain optional it does not alone seem to be sufficient to address the reproductive toxicity concern of slag substances in fertilisers used by professional workers. Similarly, the CPR is not expected to include limit values for the exposure of professional workers to CMR substances in (road) construction products. Moreover, the current assessment method considers release parameters (emission) rather than content. Therefore, the proposed restriction is considered justified to minimise exposure of professional workers for the substances from fertilisers and construction products.

Slags have been reported to be used in landfills. The landfill directive (1999/31/EC) sets out operational requirements for landfill sites with the objective to protect both human health and the environment. However, it appears as the current legal framework does not necessarily protect professional workers and inhabitants in the immediate surrounding during the use of slag substances in landfill works and therefore an EU wide restriction seems warranted here as well.

The local effects for people near application sites (e.g., skin, eye and respiratory tract irritation) and for environment (e.g., leaching of high alkaline compounds to ground or surface waters) are out of scope of this assessment. The competent authority of The Netherlands is in process of drafting an RMOA for five steel making slags (EC/List 266-002-0, 266-004-1, 294-409-3, 932-275-6, and 932-476-9) and to investigate the need for risk mitigation measures for leaching of (heavy) metals and the local effects.

**Currently no need to suggest (further) regulatory risk management actions** for the lead containing (EC 266-970-4, 273-800-2, 273-812-8, 273-824-3, 273-826-4, 273-828-5, 308-515-5) and manganese containing (EC/List 273-734-4, 293-671-6, 922-716-0) substances which have only intermediate uses, and for any of the chromium containing (EC/List 273-727-6, 273-729-7, 273-736-5, 919-559-5), vanadium containing (EC/List 282-220-9, 701-306-1, 909-634-0, 931-787-7) or other metals containing (EC/List 273-732-3, 282-217-2, 310-060-2, 701-258-3, 701-480-0, 909-586-0, 920-632-9, 940-591-0, 940-884-3, 953-903-5) substances.

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

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<sup>17</sup> <https://ec.europa.eu/docsroom/documents/49734/attachments/1/translations/en/renditions/native>

<sup>18</sup> [https://single-market-economy.ec.europa.eu/tools-databases/cp-ds-legislation-substances-construction-products\\_en](https://single-market-economy.ec.europa.eu/tools-databases/cp-ds-legislation-substances-construction-products_en)

## ASSESSMENT OF REGULATORY NEEDS

The reproductive toxicity hazard has been identified for the lead and manganese containing substances. All the lead containing substances with only intermediate uses have (self-)classification as Repr. 1A and many also as Carc 1A/B. One manganese containing substance (List 922-716-0) with only intermediate uses have self-classification for Carc., Muta. and Repr. 1B. Other two manganese containing substances (EC 273-734-4 and EC 293-671-6) do not have classifications.

The exposure potential of these lead and manganese containing substances used as intermediates in industrial settings are expected to be low. Furthermore, the substances EC 273-812-8 and EC 273-826-4 are not registered. Therefore, no EU regulatory risk management action is currently proposed for any of the lead or manganese containing substances with only intermediate uses. 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. Furthermore, when defining the final scope of the potential restriction described above, it should be assessed in detail whether the substances proposed for the restriction could be substituted by the substances for which no action is current proposed to avoid any regrettable substitution.

Carcinogenicity and mutagenicity hazard(s) has been identified for the chromium (VI) containing substances. Only one of the chromium containing substances (List 919-559-5) is self-classified as Muta 1B and Repr. 1B whereas three others (EC 273-727-6, 273-729-7 and 273-736-5) do not have classifications. Based on reported uses, the substances EC 273-727-6 and EC 272-729-7 are used by professional workers during construction work, e.g., in concrete (cement) preparation, sand blasting and road construction whereas substances EC 272-736-5 and List 919-559-5 are used only as intermediates. A restriction for hexavalent chromium in cement production is in place as clarified in Section 1 above.

Based on compositional information reported in the registration dossiers of the chromium containing substances, it is not possible to conclude if the substances contain constituents with hexavalent chromium. No EU regulatory risk management action is currently proposed. Compliance check (CCH) is proposed to confirm the absence/presence of constituents with hexavalent chromium. The registrants of chromium containing substances are invited to update their dossiers and report the compositional information in a manner which allows confirming the absence/presence of constituents with hexavalent chromium.

Potential carcinogenicity, mutagenicity and reproductive toxicity hazard(s) have been identified for the vanadium containing substances in the ECHA's assessment of the regulatory needs of simple vanadium compounds (see Section 1 above). None of the vanadium containing substances have (self-)classification for CMR properties.

One vanadium containing substance (EC 282-220-9) has industrial uses as aggregate and as raw material for refractory products and three others (List 701-306-1, 909-634-0, 931-787-7) only as intermediates. The exposure potential resulting from these uses is expected to be low. Therefore, no EU regulatory risk management action is currently proposed for any of the vanadium containing substances. 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.

Based on the absence of metals of which compounds are known or potential CMRs, no CMR hazards have been identified for the substances containing only other

metals than lead, manganese, chromium or vanadium. Therefore, no EU regulatory risk management action is currently proposed for those substances.

**Currently no need to suggest (further) regulatory risk management actions for** silicon dioxide and silicates containing substances.

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

Many substances in the group (belonging to all the sub-groups defined above) contain significant amounts of silicon dioxide and/or different silicates. In many cases, the crystallinity of the silicon dioxide or silicates is not defined by the registrants.

Crystalline silica is known to cause silicosis, one type of pneumoconiosis. In January 2018, the European Commission issued a revision of the Carcinogens and Mutagens at Work Directive (2017/2398/EC<sup>19</sup>). The directive implements a binding limit value of 0.1 mg/m<sup>3</sup> on “works involving exposure to respirable crystalline silica dust generated by a work process”. This legal limit will apply to workplaces where silica-containing materials such as concrete, bricks, or rocks are mined, quarried, cut, crushed, manufactured or ground. Member States were expected to develop national legislation implementing this legal limit at the latest by January 2020.

Therefore, no EU RRM is proposed for substances containing respirable crystalline silica, even if exposure is potential during sandblasting, construction work etc., as a binding limit already exists since Directive (EU) 2017/2398.

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<sup>19</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017L2398>

## Annex 1: Overview of classifications

Data extracted on 20 February 2023

### Lead containing substances

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
266-970-4	67711-94-8	Slags, copper refining		Carc. 1A H350 Repr. 1A H360 Acute Tox. 4 H302 Skin Sens. 1 H317 STOT Rep. Exp. 2 H373, affected organs: central nervous system, blood and kidneys STOT Rep. Exp. 1 H372, affected organs: central nervous system, blood and kidneys Aquatic Acute 1 H400 Aquatic Chronic 2 H411
273-800-2	69029-58-9	Slags, lead reverbatory smelting	Repr. 1A H360Df Acute Tox. 4 H302 STOT Rep. Exp. 2 H373 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	Carc. 1B H350 Muta. 1B H340 Repr. 1A H360 Acute Tox. 4 H302 Acute Tox. 4 H332 Skin Irrit. 2 H315 Eye Damage 1 H318 Effect on or via lactation H362 STOT Rep. Exp. 1 H372, affected organs: central nervous system, blood and kidneys Aquatic Acute 1 H400 Aquatic Chronic 1 H410
273-812-8	69029-71-6	Leach residues, lead slag	Repr. 1A H360Df Acute Tox. 4 H302 STOT Rep. Exp. 2 H373	

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
			Aquatic Acute 1 H400 Aquatic Chronic 1 H410	
<b>273-824-3</b>	69029-83-0	Residues, zinc smelting		Carc. 1A H350 Repr. 1A H360 Aquatic Chronic 1 H410 STOT Rep. Exp. 2 H373, affected organs: lungs Aquatic Acute 1 H400 Skin Sens. 1 H317 Skin Irrit. 2 H315 Acute Tox. 4 H302 Aquatic Chronic 2 H411 STOT Single Exp. 3 H335, affected organs: lungs Skin Corr. 1B H314 STOT Rep. Exp. 2 H373, affected organs: Central nervous system and reproductive system
<b>273-825-9</b>	69029-84-1	Slags, lead smelting	Repr. 1A H360Df Acute Tox. 4 H302 STOT Rep. Exp. 2 H373 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	Carc. 1B H350 Repr. 1A H360 Effect on or via lactation H362 STOT Rep. Exp. 1 H372, affected organs: central nervous system, blood and kidneys Aquatic Acute 1 H400 Aquatic Chronic 2 H411
<b>273-826-4</b>	69029-85-2	Slags, precious metal recovery lead refining	Repr. 1A H360Df Acute Tox. 4 H302 STOT Rep. Exp. 2 H373 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	
<b>273-828-5</b>	69029-86-3	Slags, tellurium	Repr. 1A H360Df Acute Tox. 4 H302 STOT Rep. Exp. 2 H373	Carc. 1A H350 Repr. 1A H360 Acute Tox. 3 H301 Skin Sens. 1 H317

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
			Aquatic Acute 1 H400 Aquatic Chronic 1 H410	Acute Tox. 4 H332 Aquatic Chronic 2 H411 Skin Corr. 1A H314 STOT Rep. Exp. 2 H373, affected organs: unspecific
<b>297-907-9</b>	93763-87-2	Slags, lead-zinc smelting	Repr. 1A H360Df Acute Tox. 4 H302 STOT Rep. Exp. 2 H373 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	
<b>308-515-5</b>	98072-60-7	Slags, precious metal refining		Carc. 1A H350 Repr. 1A H360 Acute Tox. 3 H301 Acute Tox. 4 H332 Skin Corr. 1B H314 Skin Irrit. 2 H315 Eye Damage 1 H318 Skin Sens. 1 H317 STOT Rep. Exp. 1 H372, affected organs: Central nervous system, systems for reproduction and respiratory tract STOT Rep. Exp. 1 H372, affected organs: The central nervous system, systems for reproduction and respiratory tract STOT Single Exp. 3 H335, affected organs: The central nervous system, systems for reproduction and respiratory tract Aquatic Acute 1 H400 Aquatic Chronic 1 H410

ASSESSMENT OF REGULATORY NEEDS

**Manganese containing substances**

None of the substances have harmonised classification.

EC/ List No	CAS No	Substance name	Classification in registrations
266-002-0	65996-69-2	Slags, ferrous metal, blast furnace	
266-004-1	65996-71-6	Slags, steelmaking	
273-728-1	69012-28-8	Slags, ferromanganese-manufg.	Repr. 2 H361
273-733-9	69012-33-5	Slags, silicomanganese-manufg.	Repr. 2 H361
273-734-4	69012-34-6	Slags, steelmaking, vanadium	
293-671-6	91081-64-0	Slags, ilmenite electrothermal smelting	
294-409-3	91722-09-7	Slags, steelmaking, converter	
701-265-1		Slags from smelting of oxidic stainless-steelmaking residues containing Chromium, Nickel, Molybdenum, Manganese and Iron.	
922-716-0		Products of roasting of "slags, steelmaking, vanadium"	Carc. 1B H350 Muta. 1B H340 Repr. 1B H360 Acute Tox. 4 H332 Aquatic Chronic 3 H412 Skin Sens. 1 H317 Eye Irrit. 2 H319 STOT Rep. Exp. 2 H373 Acute Tox. 4 H302 Resp. Sens. 1 H334
932-275-6	91722-10-0	Calcium-Iron-Silicium-Magnesium-Manganese-Aluminium oxide equivalent	
932-476-9	91722-10-0	Calcium-Silicium-Magnesium-Aluminium-Iron-Manganese oxide equivalent	

## ASSESSMENT OF REGULATORY NEEDS

### Chromium containing substances

None of the substances have harmonised classification.

EC/ List No	CAS No	Substance name	Classification in registrations
273-727-6	69012-27-7	Slags, ferrochromium-manufg.	
273-729-7	69012-29-9	Slags, ferronickel-manufg.	
273-736-5	69012-35-7	Slags, tin-smelting	
919-559-5		Leach of products of roasting of "slags, steelmaking, vanadium"	Muta. 1B H340 Repr. 1B H360 Aquatic Chronic 3 H412 Skin Corr. 1B H314 Acute Tox. 4 H302 Eye Irrit. 2 H319 Skin Sens. 1B H317 STOT Rep. Exp. 2 H373 Resp. Sens. 1 H334

### Vanadium containing substances

None of the substances have harmonised classification.

EC/ List No	CAS No	Substance name	Classification in registrations
282-220-9	84144-98-9	Slags, ferrovandium-manufg., aluminothermic	
701-306-1		Reaction mass of sodium pyrovanadate and sodium orthovanadate and diiron trioxide and sodium sulfate and sodium iron sulfide	
909-634-0		Reaction mass of calcium oxide and silicon dioxide and vanadium dioxide and aluminium oxide	Eye Damage 1 H318 Skin Irrit. 2 H315 STOT Single Exp. 3 H335, affected organs: lungs
931-787-7		Reaction mass of aluminium oxide and vanadium dioxide	

### Other slag substances not containing compounds known / potential to cause CMR hazard

None of the substances have harmonised classification.

EC/ List No	CAS No	Substance name	Classification in registrations
266-968-3	67711-92-6	Slags, copper smelting	

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Classification in registrations
<b>273-732-3</b>	69012-32-4	Slags, phosphorus-manufg.	
<b>282-217-2</b>	84144-95-6	Slags, ferromolybdenum-manufg., silicothermic	
<b>310-060-2</b>	102110-59-8	Slags, elec. furnace smelting, iron silicate	
<b>701-258-3</b>		Slag, pig iron ladle refining, non-granulated, water-cooled	
<b>701-480-0</b>		Iron silicate, copper smelting and refining	
<b>909-586-0</b>		Reaction mass of aluminium and aluminium oxide and calcium oxide and magnesium oxide	
<b>920-632-9</b>		Slags, nickel smelting	
<b>940-591-0</b>		Slags, granulated, resulting from plasma-enhanced gasification of non-hazardous municipal waste	Eye Damage 1 H318
<b>940-884-3</b>		Slags, sponge iron production by coal reduction in retort	
<b>953-903-5</b>		aluminium, magnesium and silicon oxides and hydroxides from refinement of aluminium salt slag residues	

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

Data extracted on 20 February 2023.

### Lead containing substances

Main types of applications structured by product or article types	266-970-4	273-800-2	273-824-3	273-825-9	273-828-5	297-907-9	308-515-5
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents			I			F, I	
PC 9b: Fillers, putties, plasters, modelling clay				F, P, A		F, I	
PC 7: Base metals and alloys			I				
PC 21: Laboratory chemicals			I				
PC 19: Intermediate	I	I	I	I	I	I	I
Construction applications						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

Manganese containing substances

Main types of applications structured by product or article types	266-002-0	266-004-1	273-728-1	273-733-9	273-734-4	293-671-6	294-409-3	701-265-1	922-716-0	932-275-6	932-476-9
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents	P, C	P, C					P, C			P, C	
PC 37: Water treatment chemicals	P, C	P, C					P, C			P, C, A	
PC 2: Adsorbents	P, C	P, C					P, C			P, C	
PC 12: Fertilisers	P, C	P, C	P				P, C				
PC 8: Biocidal products (e.g. disinfectants, pest control)	F, I, P, A	F, I, P, A					F, I, P, A			F, I, P, A	
PC 15: Non-metal-surface treatment products	F, I, P, C	P					F, I, P			P	
PC 1: Adhesives, sealants	F, I, P, C		I	I							
PC 9b: Fillers, putties, plasters, modelling clay	F, I, P, C, A	F, I, P, C, A	F, I	F, I, P			F, I, P, C, A	I, P		F, I, P, C, A	F, I, P, A
PC 9a: Coatings and paints, thinners, paint removes	P					I					
PC 14: Metal surface treatment products	P	P					P			P	
PC 38: Welding and soldering products, flux products						F					

## ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	266-002-0	266-004-1	273-728-1	273-733-9	273-734-4	293-671-6	294-409-3	701-265-1	922-716-0	932-275-6	932-476-9
<b>PC 7: Base metals and alloys</b>		I	F, I	F, I		F	I	I			
<b>PC 19: Intermediate</b>	I, <b>P</b>		I	I	I						

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

### Chromium containing substances

Main types of applications structured by product or article types	273-727-6	273-729-7	273-736-5	919-559-5
<b>PC 4: Anti-freeze and de-icing products</b>	<b>P, C</b>			
<b>PC 15: Non-metal-surface treatment products</b>	<b>P, C</b>			
<b>PC 9b: Fillers, putties, plasters, modelling clay</b>	F, I, <b>P, C, A</b>	I, <b>P</b>		
<b>PC 14: Metal surface treatment products</b>		I		
<b>PC 7: Base metals and alloys</b>			I	
<b>PC 19: Intermediate</b>			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.

ASSESSMENT OF REGULATORY NEEDS

**Vanadium containing substances**

Main types of applications structured by product or article types	282-220-9	701-306-3	909-634-0	931-787-7
<b>PC 7: Base metals and alloys</b>	I			I
<b>PC 19: Intermediate</b>		I		
<b>Aggregate</b>	I			
<b>Component in refractory products</b>	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

Other slag substances not containing compounds known / potential to cause CMR hazard

Main types of applications structured by product or article types	282-217-2	310-060-2	701-258-3	701-480-0	909-586-0	920-632-9	940-884-3	953-903-5
PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents			P, C					
PC 37: Water treatment chemicals			P, C					
PC 2: Adsorbents			P, C					
PC 12: Fertilisers			P, C				P	
PC 35: Washing and cleaning products							I, P	
PC 8: Biocidal products (e.g. disinfectants, pest control)			I, P, A					
PC 15: Non-metal-surface treatment products				F, I, P		F, I, P		
PC 1: Adhesives, sealants				C				
PC 13: Fuels							I	
PC 32: Polymer preparations and compounds							I	I
PC 9b: Fillers, putties, plasters, modelling clay	I, P		F, I, P, A	I, P, C, A		F, I, P, C, A		

ASSESSMENT OF REGULATORY NEEDS

Main types of applications structured by product or article types	282-217-2	310-060-2	701-258-3	701-480-0	909-586-0	920-632-9	940-884-3	953-903-5
PC 9a: Coatings and paints, thinners, paint removes				C		P		
PC 14: Metal surface treatment products		I		F, I, P, C		F, I, P		
PC 38: Welding and soldering products, flux products								F
PC 7: Base metals and alloys		I, A	I					F
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.

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

Data extracted on 7 March 2023.

EC/List number	RMOA	Authorisation		Restriction*		CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)		
266-002-0	YES						
266-004-1	YES						
273-800-2	YES			YES			
273-812-8	YES			YES			
273-825-9	YES			YES			
273-826-4	YES			YES			
273-828-5	YES			YES			
294-409-3	YES						
297-907-9	YES			YES			
932-275-6	YES						
932-476-9	YES						

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

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