Assessment of regulatory needs

Authority: European Chemicals Agency

Date: 7 December 2021

Group Name: Simple Manganese Compounds

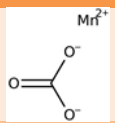
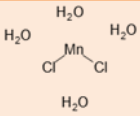
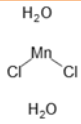
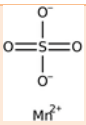
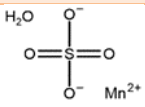
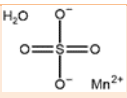
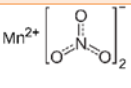
Chemical structure: -

Revision history

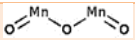
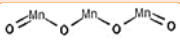
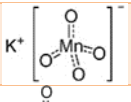
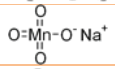
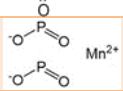
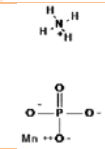
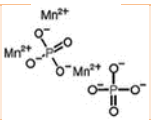
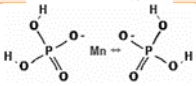
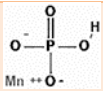
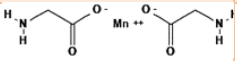
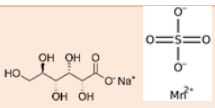
Version	*Date*	*Description*
1.0	7 December 2021	

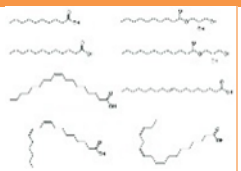
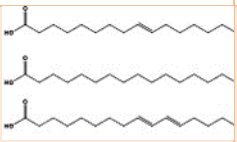
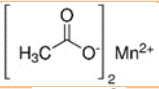
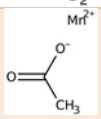
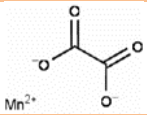
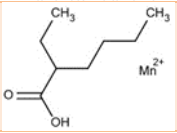
Note: *The grey-shaded sections are mostly intended for RMOA*

Substances within this group:

Sub-group	EC/List number	CAS number	Substance name	Chemical structures	Registration status (full, OSII or TII, NONS) highest tonnage band among all the registrations (t/y)[1]
I	209-942-9	598-62-9	manganese carbonate		Full, >1000
	231-869-6	7773-01-5	manganese dichloride		Full, 100-1000
	603-826-5	13446-34-9	dichloromanganese tetrahydrate		Not registered; covered by reg. 231-869-6*
	682-147-6	20603-88-7	manganese chloride, dihydrate		Not registered; covered by reg. 231-869-6*
	232-089-9	7785-87-7	manganese sulphate		Full, >1000
	600-072-9	10034-96-5	manganese sulfate monohydrate		Not registered; covered by reg. 232-089-9*
	600-150-2	10101-68-5	manganese sulfate tetrahydrate		Not registered; covered by reg. 232-089-9*
	233-828-8	10377-66-9	manganese dinitrate		Full, >1000
	242-599-3	18820-29-6	manganese sulphide	MnS2	Full, 100-1000

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

Sub-group	EC/List number	CAS number	Substance name	Chemical structures	Registration status (full, OSII or TII, NONS) highest tonnage band among all the registrations (t/y)[1]
	215-202-6	1313-13-9	manganese dioxide		Full >1000
	215-264-4	1317-34-6	dimanganese trioxide		Full, 10-100
	215-266-5	1317-35-7	trimanganese tetraoxide		Full, >1000
	215-695-8	1344-43-0	manganese oxide	MnO	Full, >1000
	231-105-1	7439-96-5	manganese	Mn	Full, >1000
II	231-760-3	7722-64-7	potassium permanganate		Full, >1000
	233-251-1	10101-50-5	sodium permanganate		Not (publicly) available
III	233-143-4	10043-84-2	manganese bis(phosphinate)		Not (publicly) available
	233-257-4	10101-66-3	ammonium manganese(3+) diphosphate		Full, 100-1000
	237-997-9	14154-09-7	trimanganese bis(orthophosphate)		Not (publicly) available
	242-520-2	18718-07-5	manganese bis(dihydrogen phosphate)		Full, 100-1000
	257-147-0	51349-94-1	manganese hydrogen phosphate		Not (publicly) available
IV	945-591-4	Not (publicly) available	manganese glycinate, reaction product of manganese sulphate with glycine		Not (publicly) available
	946-400-7	Not (publicly) available	Reaction products of sodium glucoheptonate with manganese sulfate and sodium hydroxide		Not (publicly) available

Sub-group	EC/List number	CAS number	Substance name	Chemical structures	Registration status (full, OSII or TII, NONS) highest tonnage band among all the registrations (t/y)[1]
V	232-445-3	8030-70-4	Fatty acids, tall-oil, manganese salts		Not (publicly) available
	947-666-7	Not (publicly) available	Fatty acids, C16-18 (even numbered), manganese(II) salts		Not (publicly) available
VI	211-334-3	638-38-0	manganese di(acetate)		Full, 100-1000
	612-176-1	6156-78-1	manganese(2+);diacetate;tetrahydrate		Not registered; covered by reg. 211-334-3*
	211-367-3	640-67-5	manganese oxalate		Cease manufacture
	240-085-3	15956-58-8	2-ethylhexanoic acid, manganese salt		Full, 100-1000

***** These substances are hydrates of other substances in the group and can be therefore covered under REACH under the registration of the anhydrous form of the substance.

This table does not contain group members that are only notified under the CLP Regulation. Should further regulatory risk management action on one or more substances in the group be considered, ECHA will make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

Contents

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The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessments of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

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

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

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

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

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

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

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

Glossary

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	Persistent, mobile in water and toxic
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the manganese with different ionic charge (mainly 2+, but also 3+, 4+ and 7+), the cation and the anions being organic and inorganic ions.

The group includes 29 manganese compounds. The substances were grouped to six sub-groups:

I. Simple inorganic salts, oxides and manganese metal
II. Permanganates
III. Phosphates
IV. Organometallic complexes
V. Fatty acid salts
VI. Simple organic salts

The sub-grouping was done based on chemical properties of the substances affecting their potential hazardous properties. Also, the use of read across among the substances and the clarity of substance identity was considered in the sub-grouping.

Based on information reported in the REACH registration dossiers, manganese compounds are used in mining and metallurgical operations for iron, steel, ferrous and nonferrous alloys. Manufacturing of dry-cell batteries, additives, pigments, dyes and inks are also reported. Some manganese compounds are used as feed additives and fertilisers. Other uses include use as laboratory chemicals, water treatment products, intermediates, ceramic, glass and clay production, washing and disinfecting products, cosmetics and pharmaceutical products. They are used as alloying element, additive to steel, plating agent, surface active agent, catalyst, chelating agent, filler, flux agent, welding agent, semi-conductor, oxidising agent, anti-scaling agents, corrosion inhibitor, bleaching agent, process regulator, dye, pigment, foodstuff additive.

In general, it can be said that the vast majority of the uses are widespread with potential for exposure to humans (professional and industrial workers as well as consumers) and release to the environment. Moreover, there are many substances with article service life indicated.

Manganese sulphate and manganese dioxide have a harmonised classification and labelling as STOT RE 2 and acute tox 4, respectively and potassium permanganate ($KMnO_4$) has a harmonised classification for Repr. 2. The opinion of the Risk Assessment Committee (RAC) concluded Repr. 1B classification for 2-Ethylhexanoic acid and its salts (2-ethylhexanoic acid, manganese salt falls under this group classification proposal)[3]. A Regulatory Management Options Analysis (RMOA) on EC 232-089-9 (manganese (II) sulphate ($MnSO_4$) (anhydrous, monohydrate and others)) concluded no further risk management measures are needed for the time being based on the present knowledge due to the uncertainty about exposure levels and associated risks (especially for farmers) from the main use in fertiliser or feed applications.

For four substances (Mn chloride, Mn dioxide, trimanganese tetraoxide, potassium permanganate) additional data (pre-natal developmental toxicity (PNDT) in 1st

[3] https://echa.europa.eu/documents/10162/bf135420-8873-7c68-44f9-20154f6eb4f5

species, or sub-chronic toxicity) generation via compliance check is needed. For potassium permanganate, there is a CCH in decision making, where PNDT in 2nd species and an extended one-generation reproductive toxicity study (EOGRTS) have been requested.

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

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

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

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

Based on currently available information, there is a need for (further) EU regulatory risk management – combination of restriction (for reproductive toxicity, repeated dose toxicity and neurotoxicity hazards) **and authorisation** (for reproductive toxicity and possibly neurotoxicity) due to the potential for release and exposure of all substances in the group.

There are multiple studies with evidence of reproductive toxicity (adverse effects on sexual function and fertility). Many of the observed effects in animals are severe, e.g. offspring mortality, resorptions and impaired spermatogenesis. One substance (KMnO4) has a harmonised classification and labelling for Repr. 2; H361d. There are a number of experimental and epidemiological studies, where neurotoxicity has been observed, and there is some preliminary evidence for developmental neurotoxicity. Although the latest performed studies in isolation might not indicate a hazard for reproductive toxicity, a weight of evidence analysis on all available information needs to be performed under CLH to conclude on reproductive toxicity and neurotoxicity of manganese.

The need for regulatory risk management action is strongest for the substances in sub-groups I and II, but it is expected to apply to other substances from sub-groups III to VI, following data generation steps to clarify the hazard.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as Repro 1B (and STOT RE for neurotoxicity[4]). Regarding the environment, there is concern that the self-classification in many of the registration dossiers may not be adequately reflecting the ecotoxicological data. The environmental classification may be assessed together with classifications for human health in CLH proposal(s).

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

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

- harmonised classification as CMR cat. 1 will trigger regulatory action under the Cosmetic products regulation (EC) No 1223/2009, since CMR cat. 1 are restricted by this regulation and
- harmonised classification as CMR cat 1 would render the substances unacceptable co-formulants in plant protection products.

Professional use is typically widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with typically frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by Occupational Health and Safety (OSH) legislation. Consumers may be co-exposed to the substances used by professionals. Therefore, a **restriction** of the substance as such or in mixtures (concentration limit in mixtures) used by professionals is suggested after CLH. Moreover, restricting substances in articles used by professionals or consumers (reported for substances in sub-groups 1, 3, 4 and 6) is proposed as potential for exposure from articles cannot be excluded. 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 which aims to extend to professional users under REACH the level of protection granted to consumers.

For the remaining industrial uses where potential for exposure cannot be excluded it is suggested to use **authorisation** to control risks. For the majority of the uses, given the properties of manganese and its unique chemistry there seem to be a low potential for alternatives and thus substitution. At the current state-of-art, for the most technically specific applications of manganese compounds (e.g. in the metallurgic industry, in the electronics industry) there may not be a foreseeable potential for substitution. For uses that can't be substituted quickly, it will effectively ensure risk management at industrial (and perhaps certain professional (e.g. hospital) sites (yet to be determined)). For other uses, authorisation can be expected to drive substitution.

An EU-wide exposure limit for workers under Occupational Health and Safety (OSH) legislation or REACH as an alternative risk management option to authorisation for

[4] If prenatal neurotoxicity exists, this can be captured under developmental reproductive toxicity. Only adult neurotoxicity is covered by the STOT RE endpoint.

industrial uses was also considered, especially for high tonnage substances (widely) used by workers. Introducing EU-wide exposure limits for workers under OSH or REACH for all or some of the other substances within the group could be an option under REACH restriction if a restriction proposal is submitted in any case; moreover, authorisation also better promotes substitution than an OEL/DNEL would. Therefore, for the time being, even though a clear decision between the two regulatory options for uses at industrial sites is not possible, authorisation is suggested as the next regulatory risk management option. This proposal will be revisited once the hazard will be clarified after data generation, preferably when developing further the restriction on e.g. restriction on mixtures used by professionals and articles which should also support clarifying what are those industrial uses in need for EU RRM action.

Note that several substances show concern for repeated dose toxicity and that this is to be considered in any future restriction.

The first step toward authorisation is SVHC identification of the classified manganese substances under article 57(c) (Repr.) and potentially also including the additional hazard of STOT RE to cover neurotoxicity under article 57(f) of REACH.

For all substances in the group there is inconclusive evidence on human health ED hazard due to very limited relevant findings. The evidence is not considered sufficient to raise a concern or to suggest follow-up with further testing (and it is expected that the suggested classification for reproductive hazards will lead to efficient RMMs). However, in several studies reproductive effects are indicated, and an ED mode of action cannot be excluded. The mode of action can be considered in the context of preparation of the CLP report. There is currently no information available to assess the endocrine disrupting properties of manganese for the environment.

The PBT assessment is applicable to organometallic substances. There is no information to assess the bioaccumulation potential of manganese glycinate, reaction product of manganese sulphate with glycine (EC 945-591-4), however a Log Pow of 3 is given in the dossier (a poorly reported study) and the screening criteria for B/vB is hence not met. Due to limited information, compliance check is needed for EC 945-591-4 to clarify its potential for PBT/vPvB. After the data generation, the conclusion on PBT/vPvB hazard should be taken into account in any restriction proposal for this substance.

In light of the above proposal for harmonised classification for toxic to reproduction, it is proposed that the CLH proposal(s) to be put forward also cover aquatic toxicity, where appropriate. For environment and in particular for aquatic toxicity, it is expected that after compliance check, registrants would adequately self-classify the substances and then implement the relevant RMMs which would be sufficient to ensure safe use in accordance with environmental legislation[5]. However, in case aquatic toxicity is confirmed with harmonised classification and labelling, this would strengthen the RMM measures.

[5] Any regulatory actions may consider the high risk characterisation ratios (RCRs) in certain ENV compartments for MnCl2, MnSO4, Mn(NO3)2, MnO2, Mn.

3 Conclusions and actions

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

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Sub-group I: Simple inorganic salts, oxides and manganese metal 209-942-9, $MnCO_3$ 231-869-6, $MnCl_2$ (603-826-5 and 682-147-6)* 232-089-9, $MnSO_4$ (600-072-9 and 600-150-2)* 233-828-8, $Mn(NO_3)_2$ 242-599-3, MnS 215-202-6, MnO_2 215-264-4, Mn_2O_3 215-266-5, Mn_3O_4 215-695-8, MnO	Known or potential hazard for reproductive toxicity and STOT RE (neurotoxicity)	Known or potential hazard for aquatic toxicity	Uses: pigments, coatings, inks, Fertilisers, metal surface treatment, welding, electronic equipment, glass/clay/ceramics, adhesives, sealants, water treatment.	**Need for EU RRM: Restriction in combination with authorisation** Justification: The harmonised classification as toxic to reproduction would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry. Professional use is typically widespread (at many sites and many users) with relatively low levels of operational controls and risk	**First step:** CLH **Next steps (if hazard confirmed):** Restriction, SVHC identification and authorisation

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
231-105-1, Mn				management measures but with typically 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 level of placing on the market rather than at the level of uses. Specific restriction for use in articles as potential exposure from articles cannot be excluded. For industrial uses, authorisation is suggested as the most appropriate option in particular in view of the high number of substances with low tonnages.	

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Sub-group II: Permanganates 231-760-3, $KMnO_4$ 233-251-1, $NaMnO_4$	Known or potential hazard for reproductive toxicity and for STOT RE (EC 231-760-3)	Known or potential hazard for aquatic toxicity	Uses: widespread use as oxidising agent.	**Need for EU RRM: Restriction in combination with authorisation** <u>Justification:</u> The harmonised classification as toxic to reproduction would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry. Professional use is typically widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with typically frequent	**First step:** CLH **Next steps (if hazard confirmed):** SVHC identification, restriction and authorisation

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				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 level of placing on the market rather than at the level of uses. For industrial uses, authorisation is suggested as the most appropriate option in particular in view of the high number of substances with low tonnages.	
Sub-group III: Phosphates 233-143-4, MnO_4P_2 233-257-4, $NH_4MnP_2O_7$	Known or potential hazard for reproductive toxicity and for STOT RE	Known or potential hazard for aquatic toxicity (ECs 233-143-4, 233-257-4 and 237-997-9)	Uses: Food nutrient, additive, fertilisers, metal coatings, surface treatment, pigments.	**Need for EU RRM: Restriction in combination with authorisation** <u>Justification:</u> The harmonised classification as toxic	**First step:** CCH **Next steps (if hazard confirmed):** CLH, restriction, SVHC identification and authorisation

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
237-997-9, $Mn_3(PO_4)_2$ 242-520-2, $H_4MnO_8P_2$ 257-147-0, $HMnO_4P$				to reproduction would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry. Professional use is typically widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with typically 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 level of placing on the	

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				market rather than at the level of uses. Specific restriction for use in articles as potential exposure from articles cannot be excluded. For industrial uses, authorisation is suggested as the most appropriate option in particular in view of the high number of substances with low tonnages.	
Sub-group IV: Organo-metallic complexes 945-591-4 946-400-7	Known or potential hazard for reproductive toxicity and STOT RE	Known or potential hazard for aquatic toxicity (EC 945-591-4) Inconclusive hazard for PBT/vPvB (EC 945-591-4)	Uses: Fertilisers, inks, cosmetics.	**Need for EU RRM: Restriction in combination with authorisation** <u>Justification:</u> The harmonised classification as toxic to reproduction would trigger the restriction entry 30 and by that ensure that the substances are not	**First step:** CCH **Next steps (if hazard confirmed):** CLH, restriction, SVHC identification and authorisation

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				included in consumer mixtures above the limits specified in that entry. Professional use is typically widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with typically 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 level of placing on the market rather than at the level of uses. Specific restriction for use in articles as potential exposure	

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				from articles cannot be excluded. For industrial uses, authorisation is suggested as the most appropriate option in particular in view of the high number of substances with low tonnages.	
Sub-group V: Fatty acid salts 232-445-3 947-666-7	Known or potential hazard for reproductive toxicity and STOT RE	Known or potential hazard for aquatic toxicity (EC 947-666-7)	Uses: Pigments, coatings, inks, lubricants (polymer production) and surface treatment.	**Need for EU RRM: Restriction in combination with authorisation** <u>Justification:</u> The harmonised classification as toxic to reproduction would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry.	**First step:** CCH **Next steps (if hazard confirmed):** CLH, restriction, SVHC identification and authorisation

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				Professional use is typically widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with typically 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 level of placing on the market rather than at the level of uses. Specific restriction for use in articles as potential exposure from articles cannot be excluded. For industrial uses, authorisation is	

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				suggested as the most appropriate option in particular in view of the high number of substances with low tonnages.	
Sub-group VI: Simple organic salts 211-334-3, manganese di(acetate) (612-176-1)* 211-367-3, manganese oxalate** 240-085-3, 2-ethyl hexanoic acid, manganese salt	Known or potential hazard for reproductive toxicity and STOT RE	Known or potential hazard for aquatic toxicity (ECs 211-367-3 and 240-085-3)	Uses: 211-367-3 – Washing, cleaning, disinfectants. 240-085-3 – Pigments, coatings, inks	**Need for EU RRM: Restriction in combination with authorisation** <u>Justification:</u> The harmonised classification as toxic to reproduction would trigger the restriction entry 30 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry. Professional use is typically widespread (at many sites and many users) with relatively low levels	**First step:** CCH **Next steps (if hazard confirmed):** CLH, restriction, SVHC identification and authorisation

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				of operational controls and risk management measures but with typically 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 level of placing on the market rather than at the level of uses. Specific restriction for use in articles as potential exposure from articles cannot be excluded. For industrial uses, authorisation is suggested as the most appropriate option in particular in view of the high number of	

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				substances with low tonnages.	

* These substances are hydrates of other substances in the group and can be therefore covered under REACH under the registration of the anhydrous form of the substance.

** Cease manufacture

Annex 1: Harmonised classifications and self-classifications reported by registrants

Data extracted on 19 February 2020.

Sub-group	EC /List No	Substance name	Harmonised classification	Classification in registrations
I	209-942-9	manganese carbonate	-	STOT SE 1, H370 STOT RE 1, H372 Aquatic Chronic 2, H411
	231-869-6	manganese dichloride	-	Aquatic Chronic 1, H410 Acute Tox. 4, H302 Eye Damage 1, H318 STOT Rep. Exp. 2, H373
	232-089-9	manganese sulphate	STOT RE 2 Aquatic Chronic 2 H373 H411	Aquatic Chronic 1, H410 Eye Damage 1, H318 STOT Rep. Exp. 2, H373
	233-828-8	manganese dinitrate	-	Oxid. Solid 2, H272 Oxid. Solid 3, H272 Aquatic Chronic 3, H412 Acute Tox. 4, H302 Eye Damage 1, H318 Skin Corr. 1C, H314 STOT Rep. Exp. 2, H373

Sub-group	EC /List No	Substance name	Harmonised classification	Classification in registrations
	242-599-3	manganese sulphide	-	Eye Irrit. 2, H319 Skin Sens. 1, H317 Skin Irrit. 2, H315
	215-202-6	manganese dioxide	Acute Tox. 4 Acute Tox. 4 H332 H302	Acute Tox. 4, H302 Acute Tox. 4, H312 Acute Tox. 4, H332 STOT Rep. Exp. 1, H372 STOT Rep. Exp. 2, H373
	215-264-4	dimanganese trioxide	-	-
	215-266-5	trimanganese tetraoxide		Repr. 2, H361
	215-695-8	manganese oxide	-	-
	231-105-1	manganese	-	-
	600-072-9	manganese sulfate monohydrate	-	-
	600-150-2	manganese sulfate tetrahydrate	-	-
	603-826-5	dichloromanganese tetrahydrate	-	-
	682-147-6	manganese chloride, dihydrate	-	-
II	231-760-3	potassium permanganate	Ox. Sol. 2 Repr. 2 Acute Tox. 4	Oxid. Solid 2, H272 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Sub-group	EC /List No	Substance name	Harmonised classification	Classification in registrations
			Aquatic Acute 1 H272 H361d H302 H400 H410	Acute Tox. 4, H302 Eye Damage 1, H318 Skin Corr. 1C, H314 STOT Rep. Exp. 2, H373
	233-251-1	sodium permanganate	-	Aquatic Chronic 1 Oxid. Solid 2, H272 Aquatic Acute 1, H400 Acute Tox. 4, H302 Skin Corr. 1B, H314
III	233-143-4	manganese bis(phosphinate)	-	-
	233-257-4	ammonium manganese (3+) diphosphate	-	-
	237-997-9	trimanganese bis(orthophosphate)	-	STOT Rep. Exp. 2, H373
	242-520-2	manganese bis (dihydrogen phosphate)	- -	Aquatic Chronic 3, H411 Eye Irrit. 2, H319 STOT Rep. Exp. 2, H373
	257-147-0	manganese hydrogen phosphate	-	Aquatic Chronic 3, H412 Eye Irrit. 2, H319 STOT Rep. Exp. 2, H373 STOT Rep. Exp. 2, H373

Sub-group	EC /List No	Substance name	Harmonised classification	Classification in registrations
IV	945-591-4	manganese glycinate, reaction product of manganese sulphate with glycine	-	-
	946-400-7	reaction products of sodium glucoheptonate with manganese sulfate and sodium hydroxide	-	-
V	232-445-3	fatty acids, tall-oil, manganese salts	-	STOT Rep. Exp. 2, H373
	947-666-7	fatty acids, C16-18 (even numbered), manganese (II) salts	-	-
VI	211-334-3	manganese di(acetate)	-	-
	211-367-3	manganese oxalate*	-	Acute Tox. 4, H302 Acute Tox. 4, H312
	240-085-3	2-ethylhexanoic acid, manganese salt	-	Aquatic Chronic 2, H411 Eye Irrit. 2, H319 Repr. 2, H361 STOT Rep. Exp. 2, H373
	612-176-1	manganese(2+);diacetate;tetrahydrate	-	-

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

Data extracted in February 2020, except EC 947-666-7 in May 2020.

Main types of applications structured by product or article types/SUBSTANCE GROUP	I. Simple Inorganic Salts, Oxides	II. Permanganates	III. Phosphates	IV. Simple Organic Salts	V. Organometallic complexes	VI. Fatty acid salts
Food Flavouring / Nutrient / Feed Additive	F, I, A		F, I			
Oxidising agent		F, I, P				
Cosmetics	F, I		F			F
Pigments/coatings/inks	F, I, P, C, A		F, I, P, C, A	F, I, P, C, A		F, I, P, C, A
Fertilisers	F, I, P, C, A		F, I, P, C		F, P, C	
Plating agent/metal surface treatment/corrosion inhibitor/insulators	F, I, P, A		F, I, P, A			
Steel and Metal Working / Alloying Metal / Additive in Metallurgy	F, I, P, C, A					

Main types of applications structured by product or article types/SUBSTANCE GROUP	I. Simple Inorganic Salts, Oxides	II. Permanganates	III. Phosphates	IV. Simple Organic Salts	V. Organometallic complexes	VI. Fatty acid salts
Use in Welding	F, I, P, C, A					
Production of Batteries, Electrolytes, Dielectrics, Conductors, Electronic Equipment	F, I, A					
Lubricants and Surface Treatment Products	F, I, P, C, A					F, I, P
Washing, Cleaning and Disinfecting Products	F, I, P			F, I, P, C, A		
Laboratory Reagent	F, I, P	I, P		P		
Production of Glass, Ceramic, Clay	F, I, A					
Adhesives and Sealants	I, P, A					
Use as Intermediate	F, I					
Anti-scaling agent	F, I					
Use as a Catalyst	F, I					
Polymer Production / Industrial Formulation / Additive in Plastic Production	I	I		F, I		I, P, C, A

Main types of applications structured by product or article types/SUBSTANCE GROUP	I. Simple Inorganic Salts, Oxides	II. Permanganates	III. Phosphates	IV. Simple Organic Salts	V. Organometallic complexes	VI. Fatty acid salts
Pharmaceutical Products	F					
Water Treatment	F, I, P	F, I, P				

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

Overview of main uses for sub-group I: Simple inorganic salts, oxides and manganese metal (10 registered substances) – oxidation states (OS) 0 – 4.

Main types of applications structured by product or article types	209-942-9 manganese carbonate OS 2	231-869-6 manganese dichloride OS 2	232-089-9 manganese sulphate OS 2	233-828-8 manganese dinitrate OS 2	242-599-3 manganese sulphide OS 2	215-202-6 manganese dioxide OS 4	215-264-4 dimanganese trioxide OS 3	215-266-5 trimanganese tetraoxide OS 2 and 3	215-695-8 manganese oxide OS 2	231-105-1 manganese OS 0
Food Flavouring / Nutrient / Feed Additive	F		I					F, A		
Cosmetics			F, I							
Pigments/coatings/ inks	F, I, P	F, P, A	F, I, P, C, A			F, I, P, C, A		I, A	F, I, P, A	
Fertilisers	F, I, P, C	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A				I, P	F, P, A	

Main types of applications structured by product or article types	209-942-9 manganese carbonate OS 2	231-869-6 manganese dichloride OS 2	232-089-9 manganese sulphate OS 2	233-828-8 manganese dinitrate OS 2	242-599-3 manganese sulphide OS 2	215-202-6 manganese dioxide OS 4	215-264-4 dimanganese trioxide OS 3	215-266-5 trimanganese tetraoxide OS 2 and 3	215-695-8 manganese oxide OS 2	231-105-1 manganese OS 0
Plating agent/metal surface treatment/corrosion inhibitor/insulators	I, P		F, I	F, I, P, A					P, A	
Steel and Metal Working / Alloying Metal / Additive in Metallurgy			F, I		F, I, A					F, I, P, C, A
Use in Welding	I							F, A	F, I	F, I, P, C, A
Production of Batteries, Electrolytes, Dielectrics, Conductors, Electronic Equipment				I, A		F, I, A	A	F, I, A	A	
Lubricants and Surface Treatment Products		I, P	F, I, P, C, A					F, A	I	
Washing, Cleaning and Disinfecting Products		F, I, P	F, I							
Laboratory Reagent		I, P	F, I, P							

Main types of applications structured by product or article types	209-942-9 manganese carbonate OS 2	231-869-6 manganese dichloride OS 2	232-089-9 manganese sulphate OS 2	233-828-8 manganese dinitrate OS 2	242-599-3 manganese sulphide OS 2	215-202-6 manganese dioxide OS 4	215-264-4 dimanganese trioxide OS 3	215-266-5 trimanganese tetraoxide OS 2 and 3	215-695-8 manganese oxide OS 2	231-105-1 manganese OS 0
Production of Glass, Ceramic, Clay						F, I		I, A		
Adhesives and Sealants						I, P, A				
Use as Intermediate	I	☐				F, I		F, I		
Anti-scaling agent				F, I						
Use as a Catalyst						F, I	F, I	F, I	I	
Pharmaceutical Products			I							F

Overview of main uses for sub-group II: Permanganates (2 registered substances) – oxidation state 7.

Main types of applications structured by product or article types	231-760-3 potassium permanganate OS 7	233-251-1 sodium permanganate OS 7
Oxidising agent	F, I, P	F, I, P
Laboratory Reagent	I, P	

Polymer Production / Industrial Formulation / Additive in Plastic Production	I	
Water Treatment	F, I, P	

Overview of main uses for sub-group III: Phosphates (5 registered substances) – oxidation state 2/3.

Main types of applications structured by product or article types	233-143-4 manganese bis(phosphinate) OS 2	233-257-4 ammonium manganese (3+) diphosphate OS 3	237-997-9 trimanganese bis(orthophosphate) OS 2	242-520-2 manganese bis(dihydrogen phosphate) OS 2	257-147-0 manganese hydrogen phosphate OS 2
Food Flavouring / Nutrient / Feed Additive	F, I				
Cosmetics		F			
Pigments/coatings/inks		F, I, P, C, A			
Fertilisers			F, I, P, C		
Plating agent/metal surface treatment/corrosion inhibitor/insulators			F, I, A	F, I, P	F, I

Overview of main uses for sub-group IV: Organometallic complexes (2 registered substances) – oxidation state 2.

Main types of applications structured by product or article types	945-591-4 Manganese glycinate, reaction product of manganese sulphate with glycine OS 2?	946-400-7 Reaction products of sodium glucoheptonate with manganese sulfate and sodium hydroxide OS 2
Fertilisers	P, C	F, P, C

Overview of main uses for sub-group V: Fatty acid salts (2 registered substances) – oxidation state 2.

Main types of applications structured by product or article types	232-445-3 Fatty acids, tall-oil, manganese salts OS 2?	947-666-7 Fatty acids, C16-18 (even numbered), manganese (II) salts OS 2
Cosmetics	F	
Pigments/coatings/inks	F, I, P, C, A	
Lubricants and Surface Treatment Products	F, I, P	
Polymer Production / Industrial Formulation / Additive in Plastic Production		I, P, C, A

Overview of main uses for sub-group VI: Simple organic salts (3 registered substances) – oxidation state 2.

Main types of applications structured by product or article types	211-334-3 manganese di(acetate) OS 2	211-367-3 manganese oxalate OS 2	240-085-3 2-ethylhexanoic acid, manganese

			salt OS 2
Pigments/coatings/inks			F, I, P, C, A
Washing, Cleaning and Disinfecting Products		F, I, P, C, A	
Laboratory Reagent	P		
Polymer Production / Industrial Formulation / Additive in Plastic Production	F, I		

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

Data extracted on 26 February 2020.

EC/List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
215-202-6					Yes	
231-760-3					Yes	PPP (not approved)
232-089-9	Yes				Yes	
240-085-3					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.