Risk Management Option Analysis Conclusion Document

Substance Name: manganese dichloride [1]; manganese sulphate [2]; manganese carbonate [3]; manganese dinitrate [4]; manganese sulphide [5]; manganese dioxide [6]; dimanganese trioxide [7]; trimanganese tetraoxide [8]; manganese oxide [9]; manganese [10]

EC Number: 231-869-6 [1]; 232-089-9 [2]; 209-942-9 [3]; 233-828-8 [4]; 242-599-3 [5]; 215-202-6 [6]; 215-264-4 [7]; 215-266-5 [8]; 215-695-8 [9]; 231-105-1 [10]

CAS Number: 7773-01-5 [1]; 7785-87-7 [2]; 598-62-9 [3]; 10377-66-9 [4]; 18820-29-6 [5]; 1313-13-9 [6]; 1317-34-6 [7]; 1317-35-7 [8]; 1344-43-0 [9]; 7439-96-5 [10]

Authority: Swedish Chemicals Agency

Date: 2024-03-04

Version 2.1
October 2015

DISCLAIMER

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 or the Member States may initiate at a later stage. Risk Management Option Analyses 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 Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance, and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

For information on other completed or ongoing EU processes or legislations, please refer to the ARN document on simple manganese compounds (ECHA, 2020).

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	X
Identification as SVHC (authorisation)	
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

3.1 Harmonised classification and labelling

In 2020, ECHA published an assessment of regulatory needs (ARN) for simple manganese compounds, including 29 substances allocated to six sub-groups. The conclusion of the ARN was that there is a need for further EU regulatory risk management (combination of authorisation and restriction) for primarily substances in sub-groups I and II, but also expected for sub-groups III to VI following data generation steps to clarify the hazard. As a first step, the ARN proposed CLH (STOT RE neurotoxicity, Repr. 1B) for substances in sub-group I, i.e, simple inorganic salts, oxides and manganese metal. Concern for environmental hazards was proposed to be assessed together with classifications for human health in CLH proposal(s).

The SE CA has prepared a modified RMOA focussing on further assessing and discussing the reproductive toxicity and neurotoxicity data for the 10 manganese compounds in sub-group I of the ECHA ARN document on simple manganese compounds (ECHA, 2020), in relation to the criteria for harmonised classification and labelling. Regulatory risk management measures of the substances were discussed briefly. The SE CA preliminary conclusion after further analysis of the data available in the publicly disseminated REACH registrations is that CLH proposal(s) for STOT RE 1 (CNS), H370, and Repr. 2, H361fd, could be considered justified for the manganese compounds in sub-group I.

According to Article 36(1)(d) of the CLP Regulation, a substance fulfilling the criteria for classification as toxic to reproduction (Repr. 1A, 1B or 2) shall normally be subject to harmonised classification. Harmonised classification for reproductive toxicity and neurotoxicity would have the benefit of making all notifiers having to comply and label substances and mixtures accordingly. Hence, CLH proposal(s) could be considered for risk management of the manganese compounds in sub-group I.

If the manganese compounds in sub-group I are confirmed as STOT RE 1 and Repr. 2, it is foreseen that SVHC identification (and subsequently authorisation) will only be possible based on STOT RE 1 (fulfilling the criteria of Article 57(f) of the REACH Regulation) and not reproductive toxicity. Restriction according to Article 68(1) could be considered in case an EU-wide risk is identified. Presently, manganese compounds are in the Restrictions Roadmap[2].

[2] https://ec.europa.eu/docsroom/documents/49734

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

The SE CA has identified further actions but does not wish to continue working on the substances at this time.

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for follow-up	Actor
CLP Annex VI dossier		Interested Member State is welcome to proceed