



Risk Management Option Analysis Conclusion Document

Substance Name: Cadmium hydroxide

EC Number: 244-168-5

CAS Number: 21041-95-2

Authority: Swedish Chemicals Agency

Date: 2017-05-12

DISCLAIMER

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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 2020¹.

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

The harmonised classification of cadmium hydroxide (Index No 048-013-00-0) includes Carc. Cat. 1B, Muta. Cat 1B and STOT RE 1 (effects on kidney and bone). Since cadmium hydroxide is a carcinogen and mutagen in category 1B it is covered by entry 28 in Annex XVII of REACH. This means that it is restricted as such and in mixtures placed on the market for sale to the general public.

Cadmium and its compounds, thus including cadmium hydroxide, are listed under entry number 23 in Annex XVII of REACH, which includes restrictions for many different uses.

Cadmium and cadmium compounds are also regulated in several other EU legislations, such as RoHS and the Toys directive.

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:	x
<i>Harmonised classification and labelling</i>	
<i>Identification as SVHC (authorisation)</i>	x
<i>Restriction under REACH</i>	
<i>Other EU-wide regulatory measures</i>	
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 Identification as a substance of very high concern, SVHC (first step towards authorisation)

Owing to the hazardous properties of the substance and the fact that cadmium hydroxide may to some extent be used as a substitute to other hazardous cadmium compounds already on the candidate list, there is a need for regulatory risk management for cadmium hydroxide. Identification as SVHC and subsequent inclusion in Annex XIV is considered the preferred risk management option, in line with previous regulation of six other cadmium compounds.

Cadmium hydroxide fulfils the SVHC Roadmap 2020 criteria.

Table: SVHC Roadmap 2020 criteria

	Yes	No
a) Art 57 criteria fulfilled?	x	
b) Registrations in accordance with Article 10?	x	
c) Registrations include uses within scope of authorisation?	x	
d) Known uses <u>not</u> already regulated by specific EU legislation that provides a pressure for substitution?	x	

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

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
Candidate list	August 2017	Sweden