Risk Management Option Analysis Conclusion Document

Substance Name: **Barium chromate**
EC Number: **233-660-5**
CAS Number: **10294-40-3**

Authority: **Dutch National Institute for Public Health and the Environment**
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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 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

The subject of this RMOA is the substance Barium chromate. This substance has been registered in May 2018, and is suspected Carc 1B (also in self-classification). Barium chromate has currently no harmonised classification, and may serve as an alternative for the other chromate compounds currently on Annex XIV. Entry 024-017-00-9 specifies the following: Chromium (VI) compounds, with the exception of barium chromate and of compounds specified elsewhere in this Annex. This RMOA explores the possible appropriate RMO's, among which CLH in order to include barium chromate in the current group of classified chromate compounds. Other processes are currently not ongoing with respect to barium chromate.

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)	X
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

Chromium (VI) compounds, with the exception of barium chromate, have been classified as Carc Cat 1B (H350i), Entry 024-017-00-8. Classification for barium chromate has not yet been harmonized. As indicated above, the exclusion of barium chromate may be due to the poor solubility and the limited data on carcinogenicity that are available. This, however, does not exclude the possibility that poorly soluble hexavalent chromium compounds including barium chromate are equally carcinogenic as, or even more carcinogenic than, soluble hexavalent chromium compounds (Health Council, 2016). According to the ECHA website, about 46 out of ~300 notifiers self-classified the substance as Carc Cat 1B. Harmonizing this classification may therefore be expected to significantly improve the communication on its hazard properties throughout the supply chain.

The variation in the experimental designs of the animal studies and the lack of reliable data regarding poorly soluble hexavalent chromium compounds do not allow a clear conclusion on the nature of these interferences. There are no new critical animal

experiments on poorly soluble hexavalent chromium compounds that have been published after 1998. Based on the evaluation of US EPA, there is sufficient evidence in humans as well as in experimental animals for the carcinogenicity of hexavalent chromium compounds by the inhalation route of exposure. Read-across of information between hexavalent chromium compounds is feasible. So far, the IARC has categorised Chromium (VI) compounds as carcinogenic to humans (Group 1). The Health Council of the Netherlands and the ACGIH categorised both water soluble and water insoluble chromates as “confirmed human carcinogen” (Health Council, 2016; ACGIH, 2016). Hence, the data available might be sufficient for these organisations to identify Barium Chromate as Carc group 1 but may well be insufficient to classify the substance as Carc.1B under CLP.

Overall, this information suggests that it may be possible to harmonise the classification of barium chromate to Carc Cat 1B under CLP. A harmonised classification as Carc Cat 1B will harmonize the current differences in classification between the different notifiers and will allow for further addressing its concerns through SVHC identification based on article 57a. A harmonised classification as Carc Cat 1B will also trigger further regulatory measures under the Occupation Safety and Health Directive at EU countries.

3.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

Once Barium Chromate is classified as Carc Cat. 1B, identifying Barium Chromate as SVHC may address the concern for this substance and prevent for regrettable substitution that may be triggered by substitution of the Chromates that are already on Annex XIV.

Based on the available information, barium chromate may meet the Art 57 (a) criteria after harmonised classification to Carc Cat 1B will be adopted in the Annex VI of CLP. SVHC identification followed by Authorisation under REACH will then become a possible risk management measure. Such action would be in line with the regulatory measures concluded and implemented for other Chromium (VI) compounds, which are already listed in Annex XIV. This action for Barium Chromate would force industry to actively look for substitutes and phase out the use of barium chromate wherever possible. It moreover would prevent for regrettable substitution of those Chromium (VI) compounds that are already listed in Annex XIV and for which authorisation for use has to be obtained. Provided that the substance will obtain a harmonised classification as Carc Cat 1B, SVHC identification could be considered.

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 intention	Actor
Prepare CLP Annex VI dossier	2020	The Netherlands
Prepare SVHC dossier		