

**Risk Management Option Analysis Conclusion Document**

**Group Name:** **Borate minerals**

**CAS Numbers: 1319-33-1 [1], 92908-33-3 [2], 1318-33-8 [3], 854267-07-5 [4], 92908-12-8 [5], 12045-88-4 [6]**

**EC Numbers: 296-662-5 [2], 296-640-5 [5]**

**Authority: Swedish Chemicals Agency**

**Date: 3 December 2021**

**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]](#footnote-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.

### OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

There are no ongoing processes for these substances except for this RMOA.

### 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 |  |

### Need for follow-up regulatory action at EU level

### Harmonised classification and labelling

None of the borate minerals in this RMOA are registered under REACH since naturally occurring minerals are exempted from registration in accordance with Annex V of REACH. Based on the available information, the SE CA expect the toxicokinetics and reproductive toxicological effects of the borate minerals to be similar to boric acid and refined inorganic borates on a boron equivalents basis. Hence, the SE CA proposes harmonized classification of the borate minerals for reproductive toxicity, based on read-across of data from boric acid and refined inorganic borates.

If the proposal for harmonized classification for reproductive effects in category 1B is adopted, the borate minerals would be covered by entry 30 of REACH Annex XVII, which means that the substances would be restricted for supply to consumers on their own, as constituents or in a mixture in concentrations above or equal to the classification limit.

Depending on the outcome of the CLH proposal, the need for further regulatory risk management such as SVHC identification could be considered.

### 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** |
| CLP Annex VI dossier | 2022 | Member State |

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> [↑](#footnote-ref-1)