

**Risk Management Option Analysis Conclusion Document**

**Substance Name: Barium diboron tetraoxide**

**EC Number: 237-222-4**

**CAS Number: 13701-59-2**

**Authority: Swedish Chemicals Agency**

**Date: 7 March 2022**

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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]](#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

Barium diboron tetraoxide currently has a harmonised classification as Acute Tox 4, H302 (oral) and H332 (inhalation) based on the group entry “barium salts, with the exception of barium sulphate, salts of 1-azo-2-hydroxynaphthalenyl aryl sulphonic acid, and of salts specified elsewhere in Annex VI of EC No 1272/2008”. As of the 18th ATP to Annex VI of CLP (adopted by the Commission but not yet published in the EU Official Journal) barium diboron tetraoxide will be separated from the group entry since it is included in a separate entry as toxic to reproduction category 1B (H360FD), acute inhalation toxicity category 4 (H332) and acute oral toxicity category 3 (H301).

### 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* |  |
| *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 |  |

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

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

**SVHC Roadmap 2020 criteria**

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

Barium diboron tetraoxide has a harmonised classification as toxic to reproduction (Category 1B) and therefore meets the criteria for identification as SVHC for inclusion in the Candidate List according to Article 57 (c) of REACH.

Barium diboron tetraoxide is registered at medium tonnages and uses are within the scope of authorisation.

Barium diboron tetraoxide only has limited uses/functions (in formulation of paints and coatings). However, these uses/functions overlap with some of the uses/functions of borates currently included in the Candidate List. This indicates that barium diboron tetraoxide could be a potential substitute for these borates.

The Swedish Chemicals Agency concludes that inclusion of barium diboron tetraoxide in the Candidate list of substances of very high concern is the most appropriate risk management option. This is to prevent regrettable substitution of borates already on the Candidate list and as an incentive for substitution of barium diboron tetraoxide itself. If there are uses in which barium diboron tetraoxide cannot be substituted, the authorisation system will apply to assure proper control of the risks to professional and industrial workers.

### 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** |
| Annex XV dossier for SVHC identification | August 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)