
# Risk Management Option Analysis Conclusion Document

**Substance Name: Disodium octaborate**

**EC Number: 234-541-0**

**CAS Number: 12008-41-2, 12280-03-4**

**Authority: Swedish Chemicals Agency**

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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

Disodium octaborate has a harmonised classification as Repr. 1B (H360FD) (Index no 005-020-00-3). Disodium octaborate is also covered by entry 30 of Annex XVII to REACH, unless the use is specifically derogated from this restriction. This means that it is restricted as such and in mixtures placed on the market for sale to the general public.

In addition, disodium octaborate is regulated in the Biocidal Product Regulation (Regulation (EU) 528/2012 and amendments).

## 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. The EC number 234-541-0 for disodium octaborate covers both anhydrous and hydrated forms of the substance.

| **Conclusions** | **Tick box** |
|---|---|
| Need for follow-up regulatory action at EU level: | X |
| *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 | |

## 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)

Disodium octaborate has a harmonised classification as toxic for reproduction (category 1B) and therefore fulfils the criteria for Article 57(c) in REACH. Disodium octaborate is registered in high tonnage and with wide dispersive uses within the scope of authorisation. As the available information does not, *prima facie*, demonstrate that there is a risk that is not adequately controlled and needs to be addressed at EU level, a restriction process is not considered further.

Similar borates, such as boric acid, diboron trioxide and disodium tetraborate anhydrous, are already included in the Candidate list and prioritised for inclusion in Annex XIV to REACH by ECHA. Disodium octaborate could be treated as a part of that chemical group of borates.

The authorisation process gives incentives for development of safer alternatives, whilst balancing the interest of socio-economic, human health or environmental benefits arising from a certain use. Until substitution is achieved, the authorisation process aims at ensuring the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are

progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.

The RMOA reaches the conclusion that the most appropriate risk management option for disodium octaborate is authorisation. There is a need to prepare an Annex XV dossier for SVHC identification with the intention of inclusion of disodium octaborate in the REACH Candidate list, and eventually in Annex XIV.

## 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 |
|---|---|---|
| Annex XV dossier for SVHC identification | February 2018 | Member State Sweden |