14 April 2021

Background document for disodium octaborate

Document developed in the context of ECHA's tenth recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during the consultation, or relating to content of registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the consultation on the inclusion of disodium octaborate in the Authorisation List or in the registration dossiers[1] as well as the MSC opinion[2] were taken into consideration when finalising the recommendation and are reflected in the present background document.

Contents

[1] As of the last day of the consultation, i.e. 5 June 2020
[2] Opinion of the Member State Committee on the draft tenth recommendation of the priority substances to be included in Annex XIV, adopted on 10 February 2021

1. Identity of the substance

Identity of the substance as provided in the Candidate List[3]:

Name: disodium octaborate
EC Number: 234-541-0
CAS Number: 12008-41-2

As stated in the Annex XV SVHC report (2018), it should be noted that EINECS[4] numbers include both anhydrous and hydrated forms of a substance. There are frequently different CAS numbers for anhydrous and hydrated forms. The CAS number associated to the EINECS number is often for the anhydrous form only, and therefore the CAS number shown does not always describe the entry as accurately as the EINECS number. In this case, for example, EC entry 234-541-0 covers also the substance disodium octaborate tetrahydrate (CAS 12280-03-4).

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation[5]. Results of the prioritisation of all substances included in the Candidate List by July 2019 and not yet recommended or included in Annex XIV of the REACH Regulation are available at https://echa.europa.eu/documents/10162/13640/prior_results_cl_subst_march_2020_en.pdf.

The prioritisation results of the substances included in the draft 10th recommendation have been updated as necessary after the consultation. The updated results are available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft10threc_substances_april2021_en.pdf.

As stated above, registration information as available on the last day of consultation (5 June 2020) was considered. Therefore, the impact of the UK withdrawal from the EU (for which the transition period ended 31 December 2020) was not taken into account.

2.1. Intrinsic properties

Disodium octaborate was identified as a Substance of Very High Concern (SVHC) according to Article 57 (c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360FD ("May damage fertility. May damage the unborn child.") and was therefore included in the Candidate List for authorisation on 27 June 2018, following ECHA's decision ED/61/2018.

[3] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[4] EINECS stands for European Inventory of Existing Commercial Chemical Substances. EINECS in combination with two other lists (i.e. European List of New Chemical Substances (ELINCS) and "No longer polymers" (NLP-list)) is called the EC inventory. Each substance in the EC inventory has an EC number allocated by the European Commission. Please consult ECHA's website for more information.
[5] Document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf

2.2. Volume used in the scope of authorisation

The amount of disodium octaborate manufactured and/or imported into the EU is according to registration data (ECHA, 2020) in the range of 1,000 – 10,000 t/y.

Some uses appear not to be in the scope of authorisation, such as the use as active substance in biocidal products. However, as tonnage per use information is not provided in registrations, realistic worst-case assumptions are applied and all tonnage is considered in the scope of authorisation.

Therefore, the volume in the scope of authorisation is estimated to be in the range of 1,000 – 10,000 t/y.

More detailed information is provided in Annex I.

2.3. Wide-dispersiveness of uses

Registered uses of disodium octaborate in the scope of authorisation include various uses at industrial sites (e.g. formulation of mixtures, use in paints, coatings, cement, cellulose insulation, construction materials and adhesives) and by professional workers (e.g. use in paints, coatings, cellulose insulation, construction materials and as micronutrient in fertilisers).

Consumer uses of micronutrient fertilisers and construction materials are also registered. However, as there is a generic restriction on CMR substances (Annex XVII, entry 30) to be used as substances or in mixtures sold to the general public above the concentration limit, consumer uses of the substance should not take place and are not considered for the prioritisation.

Furthermore, the substance is used in articles in volumes above 10 t/y (e.g. cellulose insulation, construction materials or painted articles).

More detailed information is provided in Annex I.

2.4. Further considerations for priority setting

Based on structural similarities it is assumed that disodium octaborate can potentially replace other borate compounds already recommended for inclusion in Annex XIV[6] in some of their uses.

[6] Borates recommended in the 6th Annex XIV recommendation are boric acid (EC 233-139-2, 234-343-4), disodium tetraborate, anhydrous (EC 215-540-4), diboron trioxide (EC 215-125-8), tetraboron disodium heptaoxide, hydrate (EC 235-541-3).

2.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Disodium octaborate is classified as toxic for reproduction 1B meeting the criteria of Article 57 (c) Score: 1	The amount of disodium octaborate used in the scope of authorisation is in the range of 1,000 - 10,000 t/y Score: 12	Disodium octaborate is used at industrial sites and by professional workers. Initial score: 10 Furthermore, the substance is used in articles in volumes >10 t/y. Refined score: 12	25	Grouping with other borates recommended in the 6th Annex XIV recommendation

Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, disodium octaborate receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, disodium octaborate **is recommended for inclusion in Annex XIV**.

3. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[7] and as further specified in the practical implementation document[8]. The draft Annex XIV entries for all the substances that underwent consultation are available at https://echa.europa.eu/documents/10162/13640/10th_recom_draft_axiv_entries_en.pdf.

The final draft Annex XIV entries that ECHA recommends are available at https://echa.europa.eu/documents/10162/13640/10th_axiv_recommendation_april2021_en.pdf.

[7] General approach can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_2020_en.pdf
[8] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_impl_doc_2020_en.pdf

3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements disodium octaborate:

Latest application date (LAD):	Date of inclusion in Annex XIV plus **24 months**
Sunset date:	18 months after LAD

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV).

Allocation of (groups of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the "later" LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain. Groups of substances are considered together.

ECHA made the final LAD allocation using all available relevant information including that received in the consultation.

A summary of the information available is provided in Annex I.

3.2. Review period for certain uses

In its draft recommendation ECHA had seen no ground to include in Annex XIV any review period for disodium octaborate.

During the consultation ECHA did not receive comments requesting upfront review periods for specific uses.

ECHA therefore **does not recommend to include in Annex XIV any review periods** for uses of disodium octaborate.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

In its draft recommendation ECHA had not proposed any exemptions for uses of disodium octaborate on the basis of Article 58(1)(e) in combination with Article 58(2) of the REACH Regulation.

During the consultation ECHA did not receive any requests for exemptions for the substance.

ECHA therefore **does not recommend exemptions** for uses of disodium octaborate on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

3.3.2 Exemption of product and process oriented research and development (PPORD)

In its draft recommendation ECHA had not proposed to include in Annex XIV any exemption from authorisation for the use of disodium octaborate for PPORD.

During the consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

No PPORD notifications had been submitted by the end of the consultation.

ECHA therefore **does not recommend exempting any use of disodium octaborate for PPORD** from authorisation.

4. References

Annex XV SVHC report (2018): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Disodium octaborate. Submitted by Sweden, February 2018.

https://echa.europa.eu/documents/10162/d52fda04-9460-5bac-1bb7-aad4ec9c4960

ComRef (2021): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 05/03/2020 – 05/06/2020 on ECHA's proposal to include disodium octaborate in its 10th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/10th_recom_comref_disodium_octaborate_en.rtf

ECHA (2020): Disodium octaborate. ECHA's dissemination website on registered substances. Accessed on 5 June 2020.

https://echa.europa.eu/search-for-chemicals

RCOM (2018): "Responses to comments" document. Document compiled by Sweden from the commenting period 08/03/2018 – 23/04/2018 on the proposal to identify disodium octaborate as a Substance of Very High Concern.

https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e18260bc78

RCOM (2021): "Responses to comments" document. Document compiling the responses to comments from commenting period 05/03/2020 – 05/06/2020 on ECHA's proposal to include disodium octaborate in its 10th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/10th_recom_respdoc_disodium_octaborate_en.pdf

Annex I: Further information on uses

1. Further details on the type of applications, functions and market trend per use

According to registration information disodium octaborate is used in a broad range of applications such as paints and coatings, cement, cellulose insulation, construction materials, adhesives, micronutrient fertilisers, production of frits and slag stabilisation treatment. Article service life is registered for use in frits, cellulose insulation, construction materials, painted and coated articles and marine ropes. Similar to boric acid, disodium octaborate can exhibit a multitude of functions.

Disodium octaborate tetrahydrate (EC 234-541-0, CAS 12280-03-4) is approved as a biocidal active substance (approval valid until August 2021). There are also biocidal products approved that contain disodium octaborate tetrahydrate for use as wood preservatives (PT 08). It is noted that disodium octaborate tetrahydrate is a candidate for substitution as active substance. The use as active substance in biocidal products does not fall within the scope of authorisation. However, it is not possible to take account of this for the assessment of the volume in the scope of authorisation as no tonnage information relating to this use is provided in registration dossiers.

During the identification as SVHC (RCOM, 2018), the European Borates Association commented, that most of disodium octaborate volume (around 95%) is used in fertilisers as micronutrient. Due to lacking tonnage per use information the given percentage cannot be confirmed by registration information. In any case, the use as micronutrient in fertilisers falls within the scope of authorisation.

2. Structure and complexity of supply chains

The following assumptions were made to allocate the substance to a specific LAD slot.

Disodium octaborate is manufactured and/or imported by a limited number of registrants. No precise and up-to-date information is available on the number of industrial sites, but it is assumed to be above 100 based on the use profile.

The supply chain can be characterised[9] by the following actors: formulators, users at industrial sites (including article producers), professional workers and users of articles (including article assemblers (multi-layer assembling chain) (relevant life cycle stages: F, IS, PW, SL (multi-layer)).

Disodium octaborate seems to be used in a number of product categories, e.g. adhesives, sealants, coatings, fertilisers, inks and toners, leather treatment, lubricants (relevant product categories e.g. PC 1, PC9a, PC12, PC17, PC18, PC23, PC24).

A number of sectors is relying on the substance in some of their uses including e.g. manufacturers of paper, cement, fabricated metal products, electronic products, furniture and the construction sector (relevant sector of use categories e.g. SU13, SU15, SU16, SU18, SU19).

[9] Categories listed here after (life cycle stage, SU, PC and AC) make reference to the use descriptor system described in ECHA's guidance on use description: https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

Uses of disodium octaborate in the scope of authorisation seem to be relevant for the production of a number of article types such as e.g., stone, plaster, cement, glass and ceramic articles, vehicles, machinery, electronic articles, metal articles, paper articles (relevant article categories, e.g. AC1, AC2, AC4, AC7, AC8).