5 March 2020

Draft 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 on the Authorisation List or in the registration dossiers (as of the last day of the consultation, i.e. 5 June 2020) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

Contents

1. Identity of the substance

Identity of the substance as provided in the Candidate List[1]:

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[2] 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[3]. 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.

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.

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, 2019) 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.

[1] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[2] 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.
[3] Document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_svhc_prior_2020_en.pdf

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, 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[4] in some of their uses.

[4] 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	Further considerations
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + 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, it is proposed to prioritise disodium octaborate for inclusion in Annex XIV.

3. Background information for the proposed Annex XIV entry

3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements:

Latest application date (LAD): Date of inclusion in Annex XIV plus **18, 21 or 24 months**

Sunset date: 18 months after LAD

ECHA will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the consultation. ECHA will apply the Annex XIV entries approach[5] and the criteria described in the implementation document[6]. According to these documents, substances for which the available information indicates a relatively high number of uses and/or complex supply chain(s) are allocated to the “later” LAD slots.

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

[5] General approach can be accessed at https://echa.europa.eu/documents/10162/13640/recom_gen_approach_draft_axiv_entries_2020_en.pdf

[6] 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

The time needed to prepare an authorisation application of sufficient quality has been estimated to require 18 months in standard cases. When setting the LADs ECHA has also to take into account the anticipated workload of ECHA's Committees and Secretariat to process authorisation applications. This is done by allocating the substances proposed to be included in the final recommendation in slots, normally 3, and setting the application dates with 3 months intervals in between these slots (standard LAD slots: 18, 21 and 24 months).

For substances to be included in the 10th recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for disodium octaborate.

In general, ECHA does not propose any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. Setting review periods in Annex XIV for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. Such information is generally not available to ECHA at the recommendation step. It is to be stressed that, in the next step of the authorisation process, i.e. during the decision on whether authorisation is granted based on specific applications by manufacturers, importers or downstream users of the substance, all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

ECHA proposes not to 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.

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses '*provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*'.

ECHA considers the following elements in deciding whether to recommend an exemption of a use of a substance:

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;

- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;

- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in

the EU legislation in question. Legislation setting only a general framework of requirements or the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

Where interested parties are considering making a request for exemption from authorisation under Art. 58(2) for a particular use, it is strongly recommended that they take into account ECHA's previous responses to Art. 58(2) exemption requests[7]. It is noted that any Art. 58(2) request is assessed case-by-case.

Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation[8], there is no need to propose an additional specific exemption.

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

ECHA proposes not to recommend to include in Annex XIV any exemption from authorisation for the use of disodium octaborate for PPORD.

So far, ECHA has not considered it appropriate to recommend specific exemptions for PPORD for any substance. ECHA notes that an operator may use a substance included in Annex XIV for a PPORD activity if that operator has obtained authorisation for that use of the substance in accordance with Articles 60 to 64 of the REACH Regulation.

No PPORD notifications have been submitted for disodium octaborate[9].

[7] See analysis of most relevant pieces of legislation e.g. in sections C.2.8 – C.2.12 in https://echa.europa.eu/documents/10162/13640/8th_recom_respdoc_methylpyrrolidone_en.pdf, or in section C.2 in https://echa.europa.eu/documents/10162/13640/9th_recom_respdoc_lead_stabilisers_en.pdf including references given therein

[8] Generic exemptions from the authorisation requirement: https://echa.europa.eu/documents/10162/13640/generic_exempt_auth_2020_en.pdf

[9] As of 15 September 2019

4. References

Annex XV SVHC report (2018): Proposal for identification of a substance as a CMR Cat 1A or 1B, PBT, vPvB or a substance of an equivalent level of concern. Disodium octaborate. Submitted by Sweden, February 2018.

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

ECHA (2019): Disodium octaborate. ECHA's dissemination website on registered substances. Accessed on 15 September 2019.

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

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, 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 are made based on currently available information and will be used, together with any relevant information from consultation, to allocate the substance to a specific LAD slot in the final recommendation.

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 is assumed to be above 100 based on the use profile.

The supply chain can be characterised[10] 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, C, 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: PC 1, PC9a, PC12, 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

[10] 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

the construction sector (relevant sector of use categories e.g. SU13, SU15, SU16, SU18, SU19).

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: AC1, AC2, AC4, AC7, AC8).