

Disodium octaborate

Substance information provided to support the first draft recommendation of substances for inclusion in Annex 14 of UK REACH

Periodically, HSE is required to recommend priority SVHCs from the UK Candidate List which should be subject to authorisation and to submit this recommendation to the Appropriate Authorities. This document provides background information on the prioritisation of disodium octaborate, as well as on the determination of its draft entry in the Authorisation List (Annex 14 of UK REACH).

Relevant information provided during the consultation on the inclusion of disodium octaborate on the Authorisation List will be taken into consideration when finalising the recommendation and will be reflected in the final background document.

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1. Identity of the substance

Identity of the substance in the UK Candidate List¹:

Name: Disodium octaborate

EC Number: 234-541-0

CAS Number: 12008-41-2

The EC number assigned to disodium octaborate covers both anhydrous and hydrated forms of disodium octaborate. However, the CAS number shown here only applies to the anhydrous form. The CAS number for disodium octaborate tetrahydrate is 12280-03-4. Both forms are included in the UK Candidate List entry and both forms are covered by the draft recommendation for inclusion in Annex 14. It is also the case that both forms are covered by the entry under index number 005-020-00-3 in the GB Mandatory Classification and Labelling (MCL) list²

2. Background information for prioritisation

The criteria that HSE should use to prioritise substances for inclusion in the Authorisation List are outlined in Article 58(3) of UK REACH. This states that priority shall normally be given to substances with:

- (a) PBT or vPvB properties³; or
- (b) wide dispersive use; or
- (c) high volumes.

An additional consideration under Article 58(3) is that the number of substances included in Annex 14 *“shall also take account of the Agency’s capacity to handle applications in the time provided for”*.

The criteria used by HSE are set out in more detail in the document titled “Approach to recommendation of priority substances for inclusion in Annex 14 (list of substances subject to authorisation) of UK REACH” [UK REACH: Authorisation list \(Annex 14\) \(hse.gov.uk\)](#)

Disodium octaborate was prioritised by ECHA and included in its [10th recommendation](#), which was submitted to the European Commission in April 2021. The information that ECHA used for its prioritisation exercise, which was finalised in March 2020 included information from UK based companies. For this reason, HSE has used the results from ECHA’s prioritisation exercise to inform its first draft recommendation. As HSE receives more registrations, it will reconsider the value of using EU information for this purpose.

2.1. Intrinsic properties

Disodium octaborate is identified as a Substance of Very High Concern (SVHC) according to Article 57(c) of UK REACH as it is classified in the GB MCL list as toxic for

¹ The UK Candidate List can be consulted here: <https://www.hse.gov.uk/reach/candidate-list.xlsx>

² The GB Mandatory Classification and Labelling list can be consulted here: <https://www.hse.gov.uk/chemical-classification/assets/docs/mcl-list.xlsx>

³ Persistent Bioaccumulative and Toxic (PBT) or very Persistent very Bioaccumulative (vPvB)

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reproduction, category 1B, H360FD (“May damage fertility. May damage the unborn child.”). It was included in the EU Candidate List for authorisation on 27 June 2018, following [ECHA’s decision ED/61/2018](#). It was included in the UK Candidate List on 31 December 2020 by virtue of Article 59(1A) of UK REACH.

2.2. Volume used in the scope of authorisation

According to ECHA’s [background document](#) developed in the context of its [10th recommendation](#) for inclusion of substances in Annex XIV of the EU REACH Regulation (ECHA, 2021), the amount of disodium octaborate manufactured and/or imported into the European Union (EU) on 5th June 2020 was in the range of 1,000 – 10,000 tonnes per year. Since ECHA did not have information on the tonnages per use, it applied a realistic worst-case assumption and assumed that all the registered tonnage is in the scope of authorisation.

More detailed information is provided in Annex 1.

2.3. Wide-dispersiveness of uses

Uses of disodium octaborate in the scope of authorisation and identified in EU registrations 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 with ECHA. These uses are in scope of the generic restriction (UK REACH Annex 17, entry 30) on the supply to the general public of substances classified as toxic to reproduction, category 1B as substances, as constituents of substances or in mixtures at concentrations of 0.3% or more. This same generic concentration limit applies to the requirement to seek authorisation to use mixtures containing substances listed on Annex 14. For this reason, consumer uses have not been taken into account for this prioritisation since uses that fall outside the scope of this restriction also fall outside the scope of a requirement to seek authorisation.

In addition to these uses, according to ECHA, disodium octaborate may be present in articles in volumes above 10 tonnes per year (e.g. cellulose insulation, construction materials, painted articles).

More detailed information is provided in Annex I.

2.4. Further considerations for priority setting

In recommending disodium octaborate for inclusion in Annex XIV of the EU REACH Regulation, ECHA considered the possibility that this substance might be used as a replacement for other borate compounds for some of their uses. These other compounds are boric acid (EC 233-139-2, 234-343-4), disodium tetraborate anhydrous (EC 215-540-4), diboron trioxide (EC 215-125-8) and tetraboron disodium heptaoxide, hydrate (EC 235-541-3). These were included in ECHA’s [6th recommendation](#), dated 1 July 2015. So far, the European Commission has declined to add these substances to Annex XIV of the EU REACH Regulation, and they do not appear in Annex 14 of UK REACH.

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HSE has no information to support or refute the assumption that disodium octaborate could be used as a replacement for these other borates.

2.5. Conclusion

Based on the information available to ECHA, disodium octaborate obtained a score of 25 out of a possible total score of 45 in the EU prioritisation exercise⁴.

A score of 1 out of 15 was assigned due to its hazard classification as toxic for reproduction, category 1B meeting the criteria of Article 57(c).

A score of 12 out of 15 was assigned due to the volume that is in the scope of authorisation which has been estimated as 1,000 - 10,000 tonnes per year.

A score of 12 out of 15 was assigned due to the wide dispersiveness of uses and taking account of the presence of this substance in articles in volumes >10 tonnes per year.

This score of 25, strengthened by grouping considerations (previously ECHA has recommended other boron compounds for inclusion in Annex 14, so far none have been added to Annex 14 of EU REACH by the European Commission), gave disodium octaborate priority among the substances on the EU Candidate List and resulted in ECHA recommending it for inclusion in the EU Authorisation List.

In deciding which substances to include in its first recommendation HSE took account of this prioritisation score. HSE also considered information that was submitted to ECHA during the public consultation on its 10th draft recommendation and published in ECHA's Response to Comments (RCOM) document⁵. More detail on the information that HSE took into account is provided in the initial assessment summary document⁶. HSE is recommending that disodium octaborate is added to the UK Authorisation List – however, this draft recommendation will be revised in line with GB specific information received in the commenting period.

3. Background information for the proposed Annex XIV entry

3.1. Latest application and sunset dates

HSE proposes the following transitional arrangements as referred to in Article 58(1)(c):

Latest application date (LAD): Date of inclusion in Annex 14 plus 18, 21 or 24

⁴ To help it identify priority substances, [ECHA has developed a scoring system which it uses to rank SVHCs against these criteria](#). A SVHC can score a maximum of 45 points, 15 for each criterion, based on its inherent properties, use profile and the tonnage that is put to uses within the scope of authorisation. This scoring system is set out in sections 5.1 – 5.5 of its guidance note "Prioritisation of substances of very high concern (SVHCs) for inclusion in the authorisation list (Annex XIV)" 2014 (amended 2020) https://echa.europa.eu/documents/10162/17232/recom_gen_approach_svhc_prior_2020_en.pdf/fbbd748b-22dc-38c2-9b4c-58c6bc80c930

⁵ The comments submitted to ECHA in response to the inclusion of disodium octaborate in ECHA's draft 10th recommendation can be viewed here: <https://echa.europa.eu/documents/10162/5a3d61a3-4eab-e0d2-d92f-71124857a963>

⁶The initial assessment summaries are available here: <https://www.hse.gov.uk/reach/authorisation-list.htm>

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Sunset date: months
18 months after LAD

HSE will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the consultation. It has been estimated that a period of 18 months is required to prepare good quality applications for authorisation. When setting the LADs, HSE also considers its capacity to process authorisation applications. If a high workload is anticipated, a later LAD may be allocated.

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

3.2. Review period for certain uses

Review periods will be considered during the decision on whether to grant authorisation for specific applications submitted by manufacturers, importers or downstream users. All authorisation decisions will include specific review periods based on information provided in the application.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

HSE proposes not to recommend exemptions for uses of disodium octaborate based on Article 58(1)(e) in combination with Article 58(2) of UK REACH.

According to Article 58(2) of UK REACH, it is possible to exempt from the authorisation requirement uses or categories of uses *'provided that, on the basis of the existing specific 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'*.

In deciding whether to recommend an exemption, HSE considers if:

- There is existing legislation addressing the specific use (or categories of use) that is proposed to be exempted;
- The existing 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 14; generally, the legislation in question should specifically refer to the substance to be included in Annex 14 either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;
- The existing 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) has to allow more stringent requirements than the specific minimum requirements set out in the legislation in question to be imposed. 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).

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Requests for exemption from authorisation under Article 58(2) for a particular use will be assessed by HSE on a case-by-case basis.

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

HSE proposes not to recommend including in Annex 14 any exemption from authorisation for the use of disodium octaborate for PPORD.

At the EU level, no exemptions for PPORD have been recommended for any substance. If an operator wishes to use a substance included in Annex 14 for a PPORD activity, it is possible for the operator to obtain authorisation for that use of the substance in accordance with Articles 60 to 64 of UK REACH.

ECHA noted in its background document that no PPORD notifications had been submitted to it for disodium octaborate by 5 June 2020. By 28 July 2021 no PPORD notifications had been received by HSE.

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4. References

ECHA (2021). Background document for disodium octaborate. Document developed in the context of ECHA's 10th recommendation for the inclusion of substances in Annex XIV.

<https://echa.europa.eu/documents/10162/ca647770-6617-9d16-daa7-64fd6757527c>

Annex I: Further information on uses

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

According to ECHA (2021), disodium octaborate is registered for use 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 to ECHA, that most of disodium octaborate volume supplied (to the 28 EU member states at that time) (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 characterised⁷ 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.

⁷ The categories listed here (life cycle stage, sector of use (SU), product categories (PC) and article categories (AC)) were developed by ECHA in Chapter R12 of its Guidance on Information Requirements and Chemical Safety Assessment. Further details of the use descriptor system are available here: https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf/ea8fa5a6-6ba1-47f4-9e47-c7216e180197

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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).

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).

Declarations

Within this document we have provided links to the following ECHA documents and information found on ECHA's website:

The following documents:

- [ED/61/2018](#): Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV (Decision of the European Chemicals Agency) dated 20 June 2018
- [Recommendation of the European Chemicals Agency of 14 April 2021](#) for the inclusion of substances in Annex XIV to REACH (List of Substances subject to Authorisation).
- [Recommendation of the European Chemicals Agency of 1 July 2015](#) for the inclusion of substances in Annex XIV to REACH (List of Substances subject to Authorisation)
- [Comments on ECHA's Draft 10th Recommendation for Disodium octaborate](#) (EC number: 234-541-0) and references to responses dated 14 April 2021
- [ECHA \(2021\)](#). Background document for disodium octaborate dated 14 April 2021

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Further information

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