

7 February 2024

## Draft background document for barium diboron tetraoxide

### Document developed in the context of ECHA's twelfth 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 barium diboron tetraoxide in the Authorisation List or in the registration dossiers (as of the last day of the consultation, i.e. 7 May 2024) 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 as provided in the Candidate List<sup>1</sup>:

Name: barium diboron tetraoxide  
EC Number: 237-222-4  
CAS Number: 13701-59-2

## 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 (ECHA, 2020a). Results of the prioritisation of all substances included in the Candidate List by July 2023 and not yet recommended or included in Annex XIV of the REACH Regulation is available in ECHA (2024a).*

### 2.1. Intrinsic properties

Barium diboron tetraoxide 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 (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.") Barium diboron tetraoxide was included in the Candidate List for authorisation on 17 January 2023, following ECHA's decision D(2022)9120-DC.

### 2.2. Volume used in the scope of authorisation

The amount of barium diboron tetraoxide manufactured and/or imported into the EU is according to registration data (ECHA, 2023) in the range of 100 - <1,000 t/y. All tonnage appears to be in the scope of authorisation. Therefore, in conclusion, the volume used in the EU in the scope of authorisation is estimated to be in the range of 100 - <1,000 t/y.

### 2.3. Wide-dispersiveness of uses

Registered uses of barium diboron tetraoxide in the scope of authorisation include uses at industrial sites (e.g. use in coatings and paints, thinners, paint removes) and uses by professional workers (e.g. in paints and coatings) (ECHA, 2023). Registration dossiers also include consumer uses. However, supply to the general public is restricted pursuant to REACH Annex XVII entry 30. Therefore, consumer uses above the specified concentration limits should not take place and were not considered for the priority assessment.

According to registrations and substance in article notifications the substance is used in coated and painted articles. Release of the substance from these articles cannot be excluded.

More detailed information on uses is provided in Annex I.

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<sup>1</sup> For further information please refer to the Candidate List and the respective support document at <https://www.echa.europa.eu/candidate-list-table>.

## 2.4. Further considerations for priority setting

Based on structural similarities barium diboron tetraoxide might be used as a substitute for other borates that were already recommended in the 6<sup>th</sup>, 10<sup>th</sup> and 11<sup>th</sup> Annex XIV recommendations<sup>2</sup>. There are indications on the potential for using substances in the same type of applications (e.g. in coatings and paints).

## 2.5. Conclusion

Verbal descriptions and scores			Total score (= IP + V + WDU)	Further considerations for priority setting
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)		
Barium diboron tetraoxide is classified as toxic for reproduction 1B meeting the criteria of Article 57(c)  Score: 1	The amount of barium diboron tetraoxide used in the scope of authorisation is in the range of 100 - 1,000 t/y.  Score: 9	Barium diboron tetraoxide is used at industrial sites and by professional workers  Initial score: 10  Furthermore, the substance is used in articles  Refined score: 12	22	Grouping with other borates

### Conclusion

On the basis of the prioritisation criteria further strengthened by grouping considerations, barium diboron tetraoxide receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise barium diboron tetraoxide for inclusion in Annex XIV.

<sup>2</sup> Borates recommended in the 6<sup>th</sup> 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). Disodium octaborate (EC 234-541-0) was recommended in the 10<sup>th</sup> recommendation and orthoboric acid, sodium salt (List No. 799-969-7) in the 11<sup>th</sup> recommendation.

## 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 (ECHA, 2020b) and the criteria described in the implementation document (ECHA, 2020c). 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.

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 12<sup>th</sup> recommendation, ECHA currently sees 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 barium diboron tetraoxide.

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 barium diboron tetraoxide 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 general responses to Art. 58(2) exemption requests (ECHA, 2020d). 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 (ECHA, 2024c), 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 including in Annex XIV any exemption from authorisation for the use of barium diboron tetraoxide 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 barium diboron tetraoxide<sup>3</sup>.

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<sup>3</sup> As of 20 July 2023.

## 4. References

*Note: Documents supporting the draft Annex XIV recommendations are available under [Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#) (filter by the substance name or EC number). Further information relevant for the consultation can be accessed at [Consultation on draft recommendation for inclusion in the Authorisation List - ECHA \(europa.eu\)](#). In absence of specific links in the references listed below, the above links are relevant.*

ECHA (2024a): Prioritisation assessment results of the Candidate List substances assessed - Substances included in the Candidate List by July 2023 and not yet recommended for inclusion in Annex XIV. ECHA's 12<sup>th</sup> draft recommendation. 7 February 2024.

ECHA (2024b): Draft 12<sup>th</sup> Recommendation of Priority Substances to be included in Annex XIV of the REACH Regulation (List of Substances Subject to Authorisation). 7 February 2024.

ECHA (2024c): Generic exemptions from the authorisation requirement. 7 February 2024.

ECHA (2020a): Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV). Prioritisation approach.

ECHA (2020b): Preparation of draft Annex XIV entries for substances recommended to be included in Annex XIV. General approach.

ECHA (2020c): Setting Latest Application Dates. Practical implementation document for the Annex XIV entries approach.

ECHA (2020d): ECHA's general responses on issues commonly raised in consultations on draft recommendations.

ECHA (2023): Substance barium diboron tetraoxide (EC 237-222-4). ECHA's dissemination website on registered substances. Accessed on 20 July 2023. <https://echa.europa.eu/search-for-chemicals>

KemI (2022): RMOA Conclusion document on barium diboron tetraoxide (EC 237-222-4) [Assessment of regulatory needs list - ECHA \(europa.eu\)](#)

Annex XV SVHC report (2022): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Substance name: Barium diboron tetraoxide, EC Number: 237-222-4, CAS Number: 13701-59-2. Submitted by Sweden, August 2022. [Registry of SVHC intentions until outcome - ECHA \(europa.eu\)](#).

ECHA (2015): ECHA's guidance on use description: [https://echa.europa.eu/documents/10162/13632/information\\_requirements\\_r12\\_en.pdf](https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf)

## Annex I: Further information on uses

### 1. Further details on the type of applications

According to registration information barium diboron tetraoxide is used in paints and coatings (e.g. coatings of PVC truck foil and coating of electrical wire) at industrial sites and by professional workers. Consumer uses in paints are reported in the registration dossiers, however, supply to the general public is restricted pursuant to REACH Annex XVII entry 30. Therefore, consumer uses above the specified concentration limits should not take place.

According to registrations and substance in article notifications the substance is used in coated and painted articles. Release of the substance from these articles cannot be excluded.

### 2. Structure and complexity of supply chains

The following assumptions on the structure and complexity of supply chains associated to uses in the scope of authorisation are made. They are 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.

Barium diboron tetraoxide 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 where the substance is currently used.

The supply chain can be characterised (according to ECHA, 2015) by the following actors: formulators, users at industrial sites, professional workers and consumers, articles producers, articles assemblers (multi-layer assembling chain) (relevant life cycle stages: F, IS, PW, C, SLs).

Barium diboron tetraoxide seems to be used in the following product categories: Coatings, paints, thinners, paint removes and polymer preparations and compounds (relevant product categories: PC 9a, PC 32).

The main sector relying on the substance in some of their uses include manufacturers of articles and paints (relevant sector of use categories: SU 0: manufacture of articles, paints).

Uses of the substance in the scope of authorisation seem to be relevant for the production of a number of article types.

Information on uses has been retrieved from registration dossiers, information from substance in article notifications and/or the Annex XV SVHC report (2022) and/or the RMOA conclusion document on barium diboron tetraoxide (KemI, 2022).

### 3. Grouping considerations

Registered uses for barium diboron tetraoxide are limited to applications such as use in paints and coatings. However, these uses overlap with some of the uses of borates currently included in the Candidate List according to their respective REACH registrations (e.g. disodium octaborate EC 234-541-0 and disodium tetraborate, anhydrous EC 215-540-4). Based on the identified overlaps of uses and the chemical similarities, barium diboron tetraoxide may be used as an alternative to these borates. Hence, there is a potential risk for regrettable substitution (Annex XV SVHC report, 2022).

The Annex XV SVHC report (2022) further refers to possible alternatives for barium diboron tetraoxide in the formulation of paints and coatings, which have been identified based on overlapping uses and functions in the SPIN database and in their respective REACH registrations: calcium phosphate, calcium molybdate, aluminium hydroxide and magnesium hydroxide.