

7 February 2024

## **Draft background document for bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof**

### **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.*

Only for the purpose of easier reading, **bis(2-ethylhexyl) tetrabromophthalate** is used throughout this document when referring to 'bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof'.

**Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the consultation on the inclusion of bis(2-ethylhexyl) tetrabromophthalate 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: Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof  
EC Number: -  
CAS Number: -

## 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

Bis(2-ethylhexyl) tetrabromophthalate was identified as a Substance of Very High Concern (SVHC) according to Article 57(e) as it meets the criteria of a vPvB substance and was therefore 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 bis(2-ethylhexyl) tetrabromophthalate manufactured and/or imported into the EU is according to registration data (ECHA, 2023) in the range of 100 - 1,000 t/y.

Some uses appear not to be in the scope of authorisation, such as laboratory uses to the extent the conditions for the generic exemption for uses in scientific research and development are met. The volume corresponding to these uses is unknown.

Therefore, in conclusion, the volume 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 bis(2-ethylhexyl) tetrabromophthalate in the scope of authorisation include uses at industrial sites (e.g. use in the production of rubber articles, use of plastics, masterbatch or compound in extrusion applications; use as adhesives) and uses by professional workers (e.g. application of reactive adhesives and sealants, one component foam) (ECHA, 2023).

Furthermore, according to registration data, the substance is used in e.g. rubber and plastic articles, from which releases 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

The Restrictions Roadmap under the Chemical Strategy for Sustainability<sup>2</sup> published by the Commission includes an entry for substances used as flame retardant within Pool 1 i.e. Planned restrictions not yet on the RoI for restriction. In January 2024 the Commission has mandated ECHA to draft an investigation report on flame retardants, with a particular focus on aromatic brominated flame-retardants<sup>3</sup>, that includes bis(2-ethylhexyl) tetrabromophthalate in its scope. This report will support the Commission in deciding whether to request ECHA to prepare a restriction dossier.

The mandate issued is not considered as a justification for postponing the recommendation of bis(2-ethylhexyl) tetrabromophthalate. At this stage there is insufficient certainty on whether a restriction will be proposed, and on its scope and timing.

A call for evidence for this investigation report is open until 5 April, and ECHA invites interested parties to provide information on bis(2-ethylhexyl) tetrabromophthalate via this call for evidence as well<sup>4</sup>.

## 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)		
Bis(2-ethylhexyl) tetrabromophthalate is identified as vPvB meeting the criteria of Article 57 (e)  Score: 13	The amount of bis(2-ethylhexyl) tetrabromophthalate used in the scope of authorisation is in the range of 100 - 1,000 t/y.  Score: 9	Bis(2-ethylhexyl) tetrabromophthalate is used at industrial sites and by professional workers  Initial score: 10  Furthermore, the substance is used in articles  Refined score: 12	34	No considerations justifying not recommending the substance at this stage

### Conclusion

On the basis of the prioritisation criteria, bis(2-ethylhexyl) tetrabromophthalate receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, it is proposed to prioritise bis(2-ethylhexyl) tetrabromophthalate for inclusion in Annex XIV.

<sup>2</sup> <https://ec.europa.eu/docsroom/documents/49734>

<sup>3</sup> See <https://echa.europa.eu/current-activities-on-restrictions>

<sup>4</sup> [Current calls for comments and evidence - ECHA \(europa.eu\)](https://echa.europa.eu/current-calls-for-comments-and-evidence)

## 3. Background information for the proposed Annex XIV entry

### 3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements (ECHA, 2024b):

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 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 bis(2-ethylhexyl) tetrabromophthalate.

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 bis(2-ethylhexyl) tetrabromophthalate 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 to include in Annex XIV any exemption from authorisation for the use of bis(2-ethylhexyl) tetrabromophthalate 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 bis(2-ethylhexyl) tetrabromophthalate<sup>5</sup>.

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<sup>5</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 12th 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 bis(2-ethylhexyl) tetrabromophthalate. ECHA's dissemination website on registered substances. Accessed on 20 July 2023. <https://echa.europa.eu/search-for-chemicals>

Annex XV SVHC report (2022): Annex XV report. Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. Substance name: bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof, EC Number: -, CAS Number: -. 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 main applications

Based on registration information (ECHA, 2023) the main applications of the substance appear to be in plastics, rubber, foams as well as in adhesives and sealants. The substance is reported to be used as such or in mixtures by industrial and professional workers, but not by consumers. The substance ends-up in articles (plastic and rubber) used by workers and consumers.

The Annex XV SVHC report (2022) provides additional details on the uses of the substance compared to registrations, that can be summarised as follow:

- Information from US EPA (2015) mentioned in the Annex XV SVHC report (2022) indicates that the substance is used as a flame retardant and as a plasticizer for flexible polyvinylchloride and for use in wire and cable insulation, film and sheeting, carpet backing, coated fabrics, wall coverings and adhesives. It confirms that the substance can be used as additive flame retardant in polyurethane foam (PUF).
- Information from the SPIN database confirms some (possibly limited) uses of the substance in Denmark, Sweden, Finland and Norway over the last past 10 years. The technical uses of the preparations reported in the SPIN database include fillers, flame retardants and extinguishing agents. According to the SPIN database the industrial use of the substance includes the following categories: Wholesale and retail trade and repair of motor vehicles and motorcycles, Construction of buildings, Civil engineering and Specialised construction activities.
- Information from the Swedish Product register indicates that the substance is mainly used in sealants and sealing products, probably as a flame retardant.

Bis(2-ethylhexyl) tetrabromophthalate belongs to the chemical family of aromatic brominated compounds, a family of chemicals widely known for their use for flame-retardancy, together with other halogenated compounds. Those compounds have been the subject of a number of investigations by Authorities, among which the Regulatory strategy for Flame retardants published by ECHA in 2023<sup>6</sup>. According to this report, halogen-containing flame retardants are used additively and reactively for the fire protection equipment of practically all plastics due to their excellent effect. Flame retardants with aromatically bounded bromine represent a significant share of the flame-retardants market in the EU.

In January 2024, the Commission has mandated ECHA to prepare an investigation report on flame retardants, with a particular focus on aromatic brominated flame-retardants<sup>7</sup>, that includes Bis(2-ethylhexyl) tetrabromophthalate in its scope. This report will support the Commission in deciding whether to request ECHA to prepare a restriction dossier. The level of details on uses and tonnage per use available in the registration dossiers of Bis(2-ethylhexyl) tetrabromophthalate leaves uncertainty on the share of the market tonnage going to different uses (flame retardant, other uses).

A call for evidence for this investigation report is open until 5 April, and ECHA invites interested parties to provide information on Bis(2-ethylhexyl) tetrabromophthalate via this call for evidence as well<sup>8</sup>.

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<sup>6</sup> [Report Flame retardants \(europa.eu\)](https://echa.europa.eu/report-flame-retardants)

<sup>7</sup> See <https://echa.europa.eu/current-activities-on-restrictions>

<sup>8</sup> [Current calls for comments and evidence - ECHA \(europa.eu\)](https://echa.europa.eu/current-calls-for-comments-and-evidence)

## 2. Structure and complexity of supply chains

The following assumptions on the structure and complexity of supply chains associated to uses of bis(2-ethylhexyl) tetrabromophthalate in the scope of authorisation are made. These 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.

Bis(2-ethylhexyl) tetrabromophthalate 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 substances is currently used.

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

Bis(2-ethylhexyl) tetrabromophthalate seems to be used in the following product categories: Adhesives and sealants; Polymer preparations and compounds (relevant product categories: PC1, PC32).

A number of sectors is relying on the substance in some of their uses including manufacturers of plastic products, manufacturers of rubber products, manufacturers of computer, electronic and optical products, electrical equipment and the building and construction work sector (relevant sector of use categories: SU11, SU12, SU16, SU19).

Uses of bis(2-ethylhexyl) tetrabromophthalate in the scope of authorisation seem to be relevant for the production of a number of article types such as plastic, rubber, electrical/electronic articles (relevant article categories: AC2, AC10, AC13).

Some of (the) use descriptors categories listed above were not explicitly selected by registrants in their registrations but could be derived from other information on uses available in the dossiers.