

**Risk Management Option Analysis Conclusion Document**

**Substance Name:** Bis(2-ethylhexyl) tetrabromophthalate

**EC Number:** 247-426-5

**CAS Number:** 26040-51-7, 122857-50-5

**Authority: Swedish Chemicals Agency**

**Date: 2020-12-16**

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# Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[[1]](#footnote-1).

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

### OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

**Completed or ongoing processes**

A testing proposal evaluation was performed in 2015 and resulted in a request for a pre-natal developmental toxicity study (test method: OECD 414) in rats or rabbits via the oral route.

A compliance check (CCH) was performed and a decision was sent to the Registrant(s) in 2016 with requests for a sub-chronic toxicity study (90-day), an in vitro gene mutation study in bacteria, a screening study for reproductive/developmental toxicity (OECD 421 or 422) and a dietary bioaccumulation study. In response to the requests in the CCH decision the Registrant(s) provided the requested information including a waiver for the screening study for reproductive/developmental toxicity which was accepted by ECHA. Also, the registration was updated with assessments of the potential endocrine disrupting properties of bis(2-ethylhexyl) tetrabromophthalate for the environment and human health.

Bis(2-ethylhexyl) tetrabromophthalate was included in the Community Rolling Action Plan (CoRAP) for evaluation in 2019. The initial concerns were suspected PBT/vPvB, potential endocrine disruptor, wide dispersive use, and exposure of the environment. The evaluation started in April 2019 using the Lead registrant’s dossier from March 2019. An extensive literature search was performed in the autumn 2019 mainly focused on finding monitoring data.

A draft conclusion on the persistence and bioaccumulation properties was circulated to the PBT EG for comments in a written procedure in December 2019. Another written consultation with the PBT EG was performed in May 2020. The eMSCA concluded in July 2020 that TBPH meets the REACH Annex XIII vPvB criteria based on a weight of evidence approach including all available information (i.e. laboratory studies, monitoring data, (Q)SAR-predictions). There are indications for ED properties of the substance, based on the in vitro data, but these indications cannot be confirmed in vivo, based on the available information. However, as the eMSCA concluded that the substance meets the vPvB-criteria, no further information requests regarding ED concern were considered.

There are no ongoing processes for this substance except for this RMOA.

### CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

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| **Conclusions** | **Tick box** |
| Need for follow-up regulatory action at EU level: |  |
| *Harmonised classification and labelling* |  |
| *Identification as SVHC (authorisation)* | X |
| *Restriction under REACH* |  |
| *Other EU-wide regulatory measures* |  |
| Need for action other than EU regulatory action |  |
| No action needed at this time |  |

### Need for follow-up regulatory action at EU level

### Identification as a substance of very high concern, SVHC (first step towards authorisation)

Bis(2-ethylhexyl) tetrabromophthalate has in a substance evaluation, performed by the Swedish Chemicals Agency, been considered to fulfil the criteria for Article 57e (vPvB) of the REACH Regulation. It is also considered to meet the SVHC Roadmap relevancy criteria.

The Swedish Chemicals Agency therefore proposes to identify bis(2-ethylhexyl) tetrabromophthalate as an SVHC for inclusion in the Candidate List, in order to obtain a transparent communication regarding the vPvB properties of the substance.

### TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

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| **Follow-up action** | **Date for follow-up** | **Actor** |
| Submission of REACH Annex XV dossier for SVHC | August/2021 | Sweden |

1. For more information on the SVHC Roadmap: <http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation> [↑](#footnote-ref-1)