AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof

AS SUBSTANCES OF VERY HIGH CONCERN

under Articles 57 and 59 of Regulation (EC) 1907/2006

Adopted on 28 November 2022

This agreement concerns

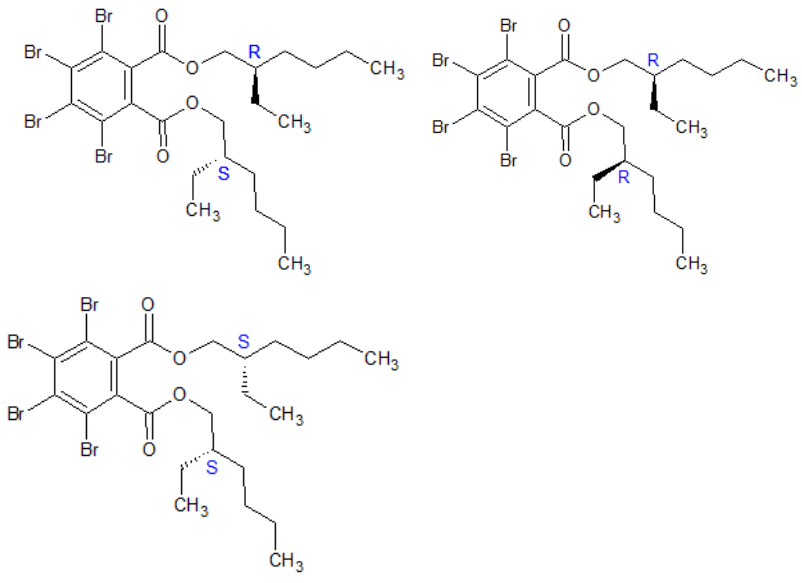
Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof

EC number: -

CAS number: -

Molecular formula: $C_{24}H_{34}Br_4O_4$

Structural formula:



The Member State Committee agreed that:

1. **Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof (TBPH) are substances under Article 57 (e) of Regulation (EC) 1907/2006 (REACH), which are very persistent and very bioaccumulative (vPvB) in accordance with the criteria and provisions set out in Annex XIII of REACH.**

2. **TBPH must be added to the Candidate list of substances of very high concern**.

Annex 1: Scientific evidence for identification of a substance of very high concern

The information below is based on Support Document (Member State Committee, 28 November 2022)

Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof (TBPH) are identified as very persistent and very bioaccumulative (vPvB) according to Article 57 (e) of Regulation (EC) No 1907/2006 (REACH).

Bis(2-ethylhexyl) tetrabromophthalate is a diastereoisomer consisting of three stereoisomers. There is experimental information available for the whole substance, but not for the single constituents. The diastereoisomers have the same molecular formula and sequence of bonded elements and differ only in the 3D representation of the structure. That is why based on their chemical structure and in line with the PBT guidance, the three isomers are expected to behave similarly in the environment and the whole substance approach can be reasonably assumed. As the isomers are structurally similar, and in the absence of other evidence, the properties of the isomers are expected to be reasonably similar to the properties determined for the whole substance.

A weight-of-evidence determination according to the provisions of Annex XIII of REACH is used to identify the substance and its isomers as vPvB. All available relevant information (such as the results of standard tests, monitoring and modelling, and (Q)SAR results) was considered together in a weight-of-evidence approach.

Persistence:

The information available on hydrolysis is difficult to interpret considering contradicting results. However, due to its low water solubility and high organic carbon normalised adsorption coefficient (Koc), TBPH is expected to sorb to particles and to mainly distribute to sediment in the aquatic environment. Hydrolysis is expected to be hindered by adsorption potential of TBPH onto sediment and particulate matter. Therefore, hydrolysis is not considered to be a relevant degradation mechanism for TBPH.

AOPWIN v1.92 predicts that TBPH has an atmospheric half-life of 5.8 hours in the gas-phase and it is degraded by sunlight when dissolved in different organic solvents. However, TBPH has a very low vapour pressure, and it is predicted to distribute mainly to the particulate phase of the atmosphere. The sorbed fraction is likely to be resistant to atmospheric oxidation. This is confirmed by air monitoring data (including from remote areas), thus indicating the long-range transport potential of TBPH via air. Photodegradation in the atmosphere is therefore not considered to be a relevant removal process for TBPH.

BIOWIN predictions (low reliability) indicate that TBPH screens as potentially persistent (P) or very persistent (vP) and this is supported by screening studies where very little degradation was observed for TBPH. Furthermore, results from an inherent degradation test (reliable with restrictions) performed according to OECD guideline 302C (7% degradation in 28 days) indicate that TBPH is persistent. It is worth noting that REACH guidance R.11 states "*Lack of degradation (<20% degradation) in an inherent biodegradability test equivalent to the OECD TG 302 series may provide sufficient information to confirm that the P-criteria are fulfilled without the need for further simulation testing for the purpose of PBT/vPvB assessment. Additionally, in specific cases it may be possible to conclude that the vP-criteria are fulfilled with this result if there is additional specific information supporting.*"

No simulation study is available for TBPH. However, in accordance with REACH Annex XIII Section 3.2.1. (d), a DT_{50} >200 days from a non-guideline outdoor mesocosm study (reliable with restrictions) is considered in the assessment of P or vP properties of TBPH as part of a weight-of-evidence approach. The study used an artificial sediment with a high organic carbon (OC) content and potentially with different microbial communities (e.g., density and diversity of microorganisms) compared to a natural sediment. Many conditions (high temperature compared to EU standard conditions, pre-exposure of micro-organisms to test conditions and exposure to sunlight leading to abiotic degradation (photolysis)) under which the study was conducted favoured dissipation/ degradation. Despite those favourable conditions, there was no dissipation/biodegradation of TBPH in the sediment of this test system. Overall, the study is considered to be relevant for the PBT assessment. The study can be used to show that TBPH is very persistent in the sediment of this test system. Furthermore, the presence of TBPH in all environmental compartments including air, surface water sediment, and in remote areas such as the Tibetan Plateau and the Arctic, gives further support to conclude that the substance is very recalcitrant to degradation.
Overall, based on the available information and considering a weight-of-evidence approach, it is concluded that TBPH is very persistent. Annex XIII, point 3.2.1.(d) of the REACH Regulation requires that any relevant information for the assessment of the persistence of the substances be considered. Therefore, it is concluded that TBPH fulfils the P and vP criterion of REACH Annex XIII.

Bioaccumulation:

With an experimental log octanol-water partition coefficient (K_{ow}) of 10.2 TBPH screens as potentially (very) bioaccumulative according to REACH Guidance Chapter R.11 and it is not expected to be rapidly absorbed. This is confirmed by toxicokinetic studies showing that a major part of a given dose is excreted unchanged. However, a small fraction of the substance is absorbed and accumulates in tissues of the exposed organisms. This is confirmed by monitoring data which indicate an uptake of TBPH by biota.
In the available fish dietary bioaccumulation studies only a small part of the total given doses of TBPH were found in the fish at the end of the uptake period. This is probably because TBPH is poorly absorbed in the gut of the fish and not because of metabolism and excretion. No difference was detected with respect to the concentration of TBPH incubated with active or heat killed common carp (*Cyprinus carpio*) liver microsomes. Furthermore, TBPH had among studied Novel brominated flame retardants (NBFRs) the single lowest *in vitro* biotransformation rate in liver microsomes from the Blacktip grouper (*Epinephelus fasciatus*) and the lowest together, with hexabromobenzene, in liver microsomes from the Indian Ocean oriental sweetlips (*Plectorhynchus orientalis*). This also indicates that TBPH is very poorly metabolised by fish.
Biomagnification factors (BMF) were measured in two of the fish dietary bioaccumulation studies (reliable with restrictions). The BMFs were of similar magnitude in both studies (0.02 for Atlantic killifish, (*Fundulus heteroclitus*) and 0.038 for rainbow trout (*Oncorhynchus mykiss*). It is important to note that the TBPH concentration in the food was very high in both studies which may have resulted in reduced bioavailability and as a consequence underestimated the BMF values. Fish Bioconcentration factors (BCF) were derived from data generated in the dietary study with rainbow trout using the 15 models within the OECD TG 305 BCF estimation tool and all BCFs predicted except one (method 3) were above 5000. It is worth noting that these calculated BCFs have some uncertainties considering: a possible overestimation of the uptake rate constant (k1) estimated by the models thus leading to an overestimation of the BCFs; a high log Kow for TBPH (10.2) which is higher than the applicability domain of the 15 models; the model where a BCF < 2000 (method 3) was developed from data on Carp (*Cyprinus carpio*) while the applicability for other species is unknown. However, the studies indicate that TBPH is poorly metabolised with slow depuration rates (K_2 of 0.031 and 0.044) and very long half-lives in fish (15.6 and 22 days) which could become of a bioaccumulation concern once the substance has entered the food chain. Indeed, the comparison of the non-corrected

depuration rate constants (K_2) from the dietary bioaccumulation studies (0.031 and 0.044) with the criteria proposed by Brooke and Crookes, 2012 (K2 of 0.085 equals - BCF 5000 and a K2 of 0.178 equals BCF 2000) indicates that TBPH is very bioaccumulative, i.e., has a BCF>5000. A benchmark approach comparing laboratory depuration rate constants and BMF values for TBPH and substances identified as SVHC based on their vPvB properties provides further indications that TBPH has vB properties.
Other information in accordance with REACH Annex XIII points 3.2.2 (b) and (c) such as field and biomonitoring data support the above conclusion as they point towards bioaccumulation of TBPH in biota. A trophic magnification factor (TMF) of 2.42 for TBPH has been measured in a limnic food chain study from China, indicating trophic magnification. A TMF of 1.62 in a marine food chain study from China points in the same direction (although not statistically significant). Tentative BMFs (fish/crabs, fish/fish), although uncertain, indicate that TBPH is biomagnified in fish. In addition, a positive correlation between trophic level and TBPH concentration has been found in resident predatory birds of Korea. Finally, the ubiquitous presence of TBPH in biota (mussel, fish, birds, mammals (including in human plasma)) also in Arctic species such as ringed seal and polar bear (an endangered species) and the transfer of TBPH from human mothers to their babies via breast milk gives further indication that TBPH is very bioaccumulative.

Based on the weight-of-evidence of the data available and considering assessment information in accordance with REACH Annex XIII points 3.2.2 (a), (b) and (c), it is concluded that TBPH fulfils the vB criterion of REACH Annex XIII (BCF > 5000).

In conclusion:

Based on the information available, it is concluded that Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof meet the criteria for a very persistent and very bioaccumulative substance in accordance with Annex XIII of the REACH Regulation, and thereby they fulfil the criteria set out in REACH Article 57 (e).

Annex 2: Procedure

1. On 26 August 2022, Sweden presented a proposal under Article 59(3) and Annex XV of the REACH Regulation on identification of Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof (TBPH) as substances which satisfy the criteria of Article 57 (e) of REACH.
2. On 2 September 2022, the Annex XV dossier was circulated to Member States and the Annex XV report was made available to interested parties on the ECHA website as required by Articles 59(3) and 59(4).
3. TBPH received comments from both Member States and interested parties on the proposal.
4. On 16 November 2022, the dossier was referred to the Member State Committee (MSC) and agreed in the written procedure of the MSC with closing date of 28 November 2022.