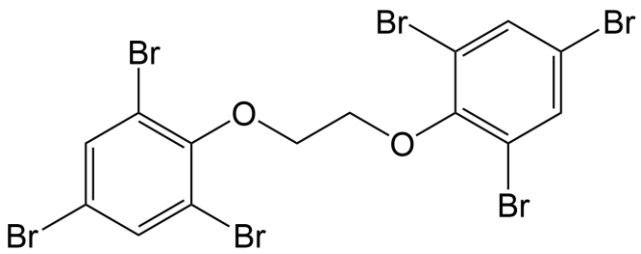
AGREEMENT OF THE MEMBER STATE COMMITTEE
ON THE IDENTIFICATION OF

1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene]

AS A SUBSTANCE OF VERY HIGH CONCERN
under Articles 57 and 59 of Regulation (EC) 1907/2006
Adopted on 28 November 2022

This agreement concerns
1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene]
EC number: 253-692-3
CAS number: 37853-59-1
Molecular formula: $C_{14}H_8Br_6O_2$
Structural formula:



The Member State Committee agreed that:

1. **1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] (BTBPE) is a substance under Article 57 (e) of Regulation (EC) 1907/2006 (REACH), which is very persistent and very bioaccumulative (vPvB) in accordance with the criteria and provisions set out in Annex XIII of REACH.**

2. **BTBPE 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)

1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] (BTBPE) is identified as very persistent and very bioaccumulative (vPvB) according to Article 57 (e) of Regulation (EC) No 1907/2006 (REACH).

A weight-of-evidence determination according to the provisions of Annex XIII of REACH has been used to identify the substance as vPvB. All available relevant information (such as the results of standard and non-standard tests, monitoring and modelling, and quantitative structure–activity relationship ((Q)SAR) results) was considered together in a weight-of-evidence approach.

Persistence:

BTBPE had negligible degradation in a non-standard biodegradation screening study that used pre-adapted inoculum, inoculum:test substance concentration ratio similar to an inherent test and extended duration. According to ECHA Guidance Chapter R.11, 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. The conditions of the test with BTBPE were not completely equivalent to OECD TG 302 tests and limited information on the test is available, and hence, its reliability cannot be fully assessed. Nevertheless, the very low degradation observed in the test vessels with conditions similar to an inherent test and pre-adapted microorganisms suggests that BTBPE may be at least persistent (P). Biowin QSAR predictions are consistent with the experimental data for BTPBE showing that the substance screens for potentially persistent (P) or very persistent (vP).

BTBPE was found to be persistent in soil treated with biosolids in a mesocosms study (reliable with restrictions). The study was run over three years and the BTBPE concentrations were found to be stable over the whole study period. Other higher brominated flame retardants, such as polybrominated diphenyl ether (PBDE) congeners from penta- to deca-BDE, as well as hexabromobenzene (HBB) and pentabromoethylbenzene (PBEB) also remained stable in the study, while some of the less brominated tested substances like di- and tri-BDEs showed decreasing concentrations over time. These observations are in line with other available data on the biodegradation of these substances and the soil mesocosms experiment appears to represent realistic environmental conditions. The study therefore shows clearly that the half-life of BTBPE in soil is higher than the 120 days set in Annex XIII of REACH as criterion for a persistent substance and also higher than the criterion of 180 days for a very persistent substance.

Negligible degradation of BTBPE was also observed in sediment phase in a water-sediment mesocosms study (reliable with restrictions). A sediment DT50 of 187 days for BTBPE (>380 days when converted to 12°C) is reported in the study. This study is not a guideline study and the results have to be treated with care as inhomogeneous distribution in the mesocosms and several processes e.g., sediment-to-water diffusion and resuspension may have influenced the results. The test 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 BTBPE 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 BTBPE is very persistent in the sediment of this test system. The result from this study goes well in line with the other available evidence and adds to the weight-of-evidence indicating that BTBPE fulfils the vP criterion of REACH Annex XIII.

Furthermore, the available monitoring data from sediment core studies indicate that BTBPE has been found in 20-40 year old sediment layers in Lake Ontario and Lake Michigan in the USA and a saltwater lake in Korea. These findings, suggest that the degradation in the environment may be slow and provide indirect evidence that BTBPE can persist in sediments for more than two-four decades. Based on the weight of the evidence available and considering the substance is very persistent in the soil compartment, BTPBE is likely to meet the P/vP criteria of REACH Annex XIII in the sediment compartment (degradation half-life in sediment > 180 days).

Monitoring data for BTBPE support the above conclusions, as the substance has been detected in remote areas, e.g., in air and snow pits in the Norwegian and Canadian Arctic, respectively. These findings further strengthen the conclusion that BTBPE is very persistent in the environment.

Based on a weight-of-evidence approach and considering assessment information in accordance with REACH Annex XIII Section 3.2.1.(d), it is concluded that BTBPE meets both the 'persistence' (P) (degradation half-life in soil > 120 days) and 'very persistent' (vP) criteria of REACH Annex XIII (degradation half-life in soil > 180 days) in accordance with Annex XIII, points 1.1.1 and 1.2.1, of the REACH Regulation.

Bioaccumulation:

Based on the predicted log octanol-water partition coefficient (Kow) values in the range of 7.88-9.39, which are considered more reliable than the available measured log Kow value of 3.14, BTBPE screens B/vB (log Kow >4.5).

In a non-standard laboratory dietary bioaccumulation in fish study (reliable with restrictions), a low depuration rate constant of 0.0128 day^{-1} (indicative of a bioconcentration factor (BCF) > 5000) and a long depuration half-life of 54 days for muscle tissue of rainbow trout were determined, indicating very slow depuration of BTBPE in fish. These values are similar or higher than the whole body depuration rates and half-lives in fish determined for substances concluded to be SVHCs due to vPvB properties, e.g. Dechlorane Plus, some of the vPvB congeners of medium chain chlorinated paraffins (MCCP) and vPvB constituent of terphenyl hydrogenated. Furthermore, in this study BTBPE does not seem to be metabolised by fish. Fish BCFs were derived from data generated in the above dietary study with rainbow trout using the 14 models within the OECD TG 305 BCF estimation tool in methods 1 and 2. Based on the 14 models, 11 BCFs predicted were above 5000 thus indicating a high bioaccumulation potential for BTBPE.

A supporting mesocosms study with fathead minnows (low reliability) confirms the findings of the dietary study as no significant decrease of the concentration of BTBPE in the fish was observed after 28 days depuration period.

Field data used as supporting information in the B assessment point towards the bioaccumulation potential of BTBPE and thus confirm the conclusions from experimental data. Several field studies on bioaccumulation indicate that BTBPE has trophic magnification factor (TMF) and biomagnification factor (BMF) values above 1 in some of the studied food webs and predator/prey relationships, respectively, which are clear indications that BTBPE is able to biomagnify. According to REACH Guidance Chapter R.11,

food chain transfer and secondary poisoning are basic concerns in relation to PBT and vPvB substances, and therefore an indication of a biomagnification potential (BMF and/or TMF > 1) can on its own be considered as a basis to conclude that a substance meets the B or vB criteria.

BTBPE has been detected in human serum, hair and mother milk samples which indicates that BTBPE is absorbed to some extent in humans. In addition, monitoring data demonstrate widespread contamination of wildlife by BTPBE at all trophic levels (including predatory species (e.g., polar bears which are listed on the IUCN red list of threatened species)). BTBPE has also been detected in biota samples from remote regions, including the Arctic. These data provide supporting evidence that BTPBE is taken up by organisms in the environment.

Based on a weight-of-evidence approach and considering assessment information in accordance with REACH Annex XIII points 3.2.2 (a), (b) and (c), it is concluded that BTBPE meets the 'bioaccumulation' criterion (B) and the 'very bioaccumulative' criterion (vB) in accordance with Annex XIII, points 1.1.2 and 1.2.2, of the REACH Regulation.

In conclusion:

In conclusion, BTBPE is identified as a vPvB substance according to Article 57(e) of REACH by comparing all relevant and available information listed in Annex XIII of REACH with the criteria set out in the same Annex, in a weight-of-evidence determination.

Annex 2: Procedure

1. On 26 August 2022, Spain presented a proposal under Article 59(3) and Annex XV of the REACH Regulation on identification of 1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] as a substance 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. 1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] 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.