Annex 15 Report
Proposal for identification of a substance of very high concern (SVHC)

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

EC Number: 253-692-3

CAS Number: 37853-59-1

July 2026

Contents

1. Proposal

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

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1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] (BTBPE), has been identified as a substance of very high concern (SVHC) in accordance with the requirements set out in Annex 15 of EU REACH (ECHA, 2023). This is based on the substance fulfilling the very persistent and very bioaccumulative (vPvB) criteria under Annex 13 of EU REACH.

This technical report provides an independent scientific assessment by the Agency[1] on whether BTBPE should be identified as an SVHC under UK REACH. It considers only studies presented in the equivalent document produced by the European Chemicals Agency (ECHA), the EU Member State Committee (MSC) support document (ECHA, 2022b) unless stated otherwise. Relevant observations on studies made in the EU MSC support document have been summarised and Agency comments have been added where appropriate. A literature search was not performed because the existing information is considered to be sufficient for decision making.

It is proposed to identify BTBPE as vPvB according to Article 57(e) of UK REACH.

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

A weight-of-evidence determination according to the provisions of Annex 13 of UK REACH has been used to identify BTBPE as vPvB.

Persistence

BTBPE screens as potentially persistent (P) and very persistent (vP) based on quantitative structure-activity relationship (QSAR) predictions, and a non-standard biodegradability study (with significant limitations) that reported < 2% mineralisation over an extended time period which was well beyond the duration of a standard test design. The substance is not readily or inherently biodegradable based on this evidence.

There are several lines of evidence that indicate that BTBPE degrades slowly in the environment. The strongest indication comes from retrospective analysis of archived biosolid-amended soil samples from a long-running outdoor mesocosm study (de Jourdan *et al.*, 2013) that indicated no significant degradation of BTBPE over three years under

[1] The Health and Safety Executive (HSE) acting in its capacity as the Agency for UK REACH, and with support from the Environment Agency in accordance with Article 2B of UK REACH.

relevant environmental conditions and therefore a half-life in soil likely to be much longer than 180 days (the Annex 13 criterion for vP). Comparison of the variation of BTBPE concentrations over time with other brominated flame retardants (BFRs) in the same samples from this study indicated that BTBPE had a similar level of resistance to degradation as BFRs that are identified as persistent organic pollutants (POPs) under the Stockholm Convention (UNEP, 2023).

The other lines of evidence can be summarised as follows:

- There was no indication of degradation in the particulate matter used for a water/artificial 'sediment' mesocosm study over 56 days, although this study has significant limitations.
- Sediment core data show that BTBPE was still present many years after its movement into the sediment at multiple sites. This indicates that BTBPE degrades slowly under the environmental conditions prevalent in these sediments. However, this does not necessarily provide evidence of a lack of degradability under aerobic conditions.
- Several studies have reported the presence of BTBPE in remote regions far from known sources. This can only be used as supporting evidence as BTBPE distribution and transport in the environment has not been examined for this report.

There is some information to suggest that phototransformation can occur when the substance is adsorbed onto solid surfaces (half-life < 2 days), but this is unlikely to make a major contribution to degradation in aquatic and terrestrial environments. The Agency therefore concludes from the weight of evidence available that BTBPE fulfils the P and vP criteria of Annex 13 of UK REACH.

Bioaccumulation

BTBPE screens as potentially bioaccumulative (B) and very bioaccumulative (vB) as the range of predicted log K_{OW} values (7.65 to 9.39) exceeds the screening criteria for bioaccumulation (log K_{OW} > 4.5), though a reliable measured result would be preferred. Predicted bioconcentration factor (BCF) and bioaccumulation factor (BAF) values also indicate the potential for bioaccumulation (BCFs above 2,000 L/kg, with BAFs above 10,000 L/kg).

The key data come from a non-standard fish dietary bioaccumulation study (Tomy *et al.*, 2007), which indicate a low depuration rate constant (0.0128 ± 0.002 d^{-1}), which equates to a depuration half-life of 54 days. The information from this study can be used to estimate BCF values following internationally recognised methods (OECD, 2017), and 10 of the 13 models result in BCF values above 5,000 L/kg, the Annex 13 criterion for vB. The median BCF value is > 10,000 L/kg.

The other lines of evidence indicative of highly bioaccumulative properties can be summarised as follows:

- Fish depuration half-lives are available for several other SVHCs that have been identified as very bioaccumulative, e.g. medium-chain chlorinated paraffins (MCCPs) (≥ 55.7 days), two dechlorane isomers (30 to 70 days), o-terphenyl (8.1 days), and D5 (74 days). The species involved differ, but these data provide relevant benchmarks for comparison. The fish depuration half-life for BTBPE from the Tomy *et al.* (2007) study is similar to or longer than these values, and so may be considered to be a characteristic indicator of a high level of bioaccumulation.
- This is supported by a lack of any statistically significant depuration over 28 days in a second fish species used in a mesocosm study (de Jourdan *et al.*, 2014).
- There are reported biomagnification factor (BMF) and trophic magnification factor (TMF) values greater than one in some field studies, although the evidence is mixed and there is considerable uncertainty because of difficulties interpreting the results.
- BTBPE has been found in human breast milk and in the eggs of different bird species, indicating the maternal uptake of BTBPE and potential exposure at sensitive life stages.

The Agency concludes based on a weight of evidence approach that BTBPE fulfils the B and vB criteria of Annex 13 of UK REACH.

Conclusion

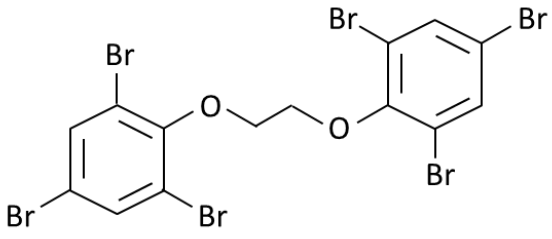
The Agency concludes based on the information available that BTBPE fulfils the vPvB criteria of Annex 13 of UK REACH and can therefore be identified as an SVHC in accordance with Article 57(e) of UK REACH.

2. Justification

2.1 Identity of the substance and physical and chemical properties

2.1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	253-692-3
EC name:	1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene]
SMILES[a]:	C1=C(C=C(C(=C1Br)OCCOC2=C(C=C(C=C2Br)Br)Br)Br)Br
CAS number:	37853-59-1
IUPAC[b] name:	1,1'-[ethane-1,2-diylbisoxy]bis[2,4,6-tribromobenzene] 1,2-Bis(2,4,6-tribromophenoxy)ethane 1,3,5-tribromo-2-[2-(2,4,6-tribromophenoxy)ethoxy]benzene
Index number in GB Mandatory Classification and Labelling (MCL) List[c]:	No mandatory classification
Molecular formula:	$C_{14}H_8Br_6O_2$
Molecular weight:	687.64 g/mol
Synonyms:	BTBPE
Structural formula:	

[a] SMILES: Simplified Molecular Input Line Entry System
[b] IUPAC: International Union of Pure and Applied Chemistry
[c] GB MCL list in accordance with the retained Regulation (EC) No 1272/2008 as amended for Great Britain

2.1.2 Composition of the substance

Substance type: mono-constituent

Table 2: Constituents other than impurities/additives

Constituents	Typical concentration
BTBPE	≥ 80%

2.1.3 Identity and composition of transformation products relevant for the SVHC assessment

No transformation products were considered in the EU MSC support document.

The Agency does not consider it necessary to consider transformation products due to the findings for the parent compound.

2.1.4 Identity and composition of structurally related substances (used in grouping or read-across approach)

No structurally related substances were considered in the EU MSC support document.

The Agency does not consider it necessary to consider structurally related products due to the findings for the parent substance.

2.1.5 Physicochemical properties

Physicochemical property information for BTBPE reported in the EU MSC support document are summarised in Table 3. As BTBPE is not registered under EU REACH, the data have been collated from publicly available sources. The Agency has not independently verified the reliability of this information unless otherwise stated.

The shake flask study to determine water solubility did not follow a standard guideline and there were some deviations from OECD Test Guideline (TG) 105. There was no confirmation that the toluene used to prepare the test substance solution was completely removed from the test system and the rate of stirring was not reported. The estimated water solubility of BTBPE is low and therefore the slow-stirring method is recommended to avoid emulsions or micro-droplet formation that can result in an overestimation of solubility. The EU MSC support document therefore concluded that the reported experimental water solubility of 200 µg/L is 'not fully reliable'. The Agency agrees with this conclusion.

Log K_{OW} was measured using a shake flask study which had some deviations from the current OECD TG 107 (not stated in the support document). It was noted that the shake flask method is not recommended for substances where log K_{OW} values are suspected to be greater than 4 because of potential transfer of octanol microdroplets into the aqueous phase leading to an overestimation of the concentration of the test substance in the water. The experimental value is also well below the value predicted from looking at the values

for other brominated aromatic substances (Stieger *et al.*, 2014). The experimental log K_{OW} value of 3.14 was therefore considered unreliable and the Agency agrees with this conclusion.

The Agency has checked and agrees with the predicted log K_{OW} value of 9.14 using KOWWIN v1.69 of EPISuite v4.11. The model includes the relevant fragments CH_2, aromatic carbon, and bromine and oxygen attached to an aromatic ring and therefore the Agency concludes that BTBPE is within the applicability domain.

Table 3: Overview of physicochemical properties of BTBPE reported in the EU MSC support document

Property	Value
Physical state at 20°C and 101.3 kPa	Solid, white powder
Melting/freezing point (°C)	224 – 227 (measured)
Boiling point (°C)	> 502 (estimated)
Vapour pressure (Pa at 25°C)	2.26×10^{-11} (measured) 3.88×10^{-11} (estimated using MPBPVP v1.43 of EPISuite v4.11)
Water solubility (µg/L at 25°C)	200 (measured, but not fully reliable) 2.8×10^{-4} to 19 (estimated)
n-Octanol–water partition coefficient (log K_{OW})	3.14 (measured, but not reliable) 8.16 (COSMOtherm 19.0.1) 9.14 (KOWWIN in EPISuite v4.11) Other estimations: 7.65 to 9.39

2.2 Mandatory classification and labelling

BTBPE is not listed on the GB mandatory classification and labelling (MCL) list nor on Annex 6 of Regulation (EC) No 1272/2008.

2.3 Environmental fate properties

2.3.1 Degradation

2.3.1.1 Abiotic degradation

The information on abiotic degradation presented in the EU MSC support document is summarised in Table 4.

Table 4: Summary of abiotic degradation data reported in the EU MSC support document

Abiotic degradation process	Information presented	Results
Hydrolysis	No experimental data Outside the applicability domain of estimation models	BTBPE does not contain functional groups susceptible to hydrolysis
Oxidation	Yu *et al.* (2017) Chemical calculations and kinetic modelling approach	Atmospheric half-life: 11.8 days (vapour phase). The half-life was recalculated in the support document as 10.7 days using an OH radical concentration of 7.5 x 10^5 molecules/cm^3.
Phototransformation	Zhang *et al.* (2016) Investigation of the degradation of BTBPE in hexane or methanol under ultraviolet (UV) light.	Estimated direct photolysis half-life in surface water at 40°N latitude (Southern Europe) ranged from 1.5 days in summer to 17.1 days in winter. Thirteen degradation products were identified including 2,4,6-tribromophenol and 2,4-dibromophenol.
	Cao *et al.* (2022) Investigation of degradation of BTBPE in THF/water solutions under UV irradiation.	Photodegradation rate constant for BTBPE (0.012 min^{-1}) was longer than for BDE-155 (0.0447 min^{-1})
	Yu (1979) in GLCC (2002) Investigation of the degradation of BTBPE on a silica gel under UV light.	Half-life ~0.4 days (in first day, then decreased to 1.7 days)

BTBPE does not have functional groups susceptible to hydrolysis. The atmospheric half-life was estimated to be 11.8 days but the vapour pressure of BTBPE is very low and therefore degradation in air is not likely to be relevant to its environmental fate. As BTBPE is predicted to be particle bound in air, the atmospheric residence time of any BTBPE that is present in air is likely to be governed by the fate of those particles.

The EU MSC support document presents a study of the photodegradation of BTBPE in either methanol or hexane (Zhang *et al.*, 2016). Degradation occurred via ether cleavage and by debromination, with 13 transformation products identified including bromophenols. Cao *et al.* (2022) studied photodegradation in a mixture of tetrahydrofuran and water (6:4) at pH 7.5 to 7.6 that showed similar degradation products. However, as has been pointed out in the EU MSC support document for bis(pentabromophenyl)ether (ECHA, 2012), although studies involving organic solvents show that organobromine substances can lose bromine atoms, it is doubtful whether the results can be extrapolated directly to the

environment. The organic solvent itself could act as a hydrogen donor to any radical species formed from the initial cleavage of the carbon-bromine bond, and so the products formed and rate of reaction seen in such studies may be different to those involving water. Also, where the water solubility is low, as is the case for BTBPE, the substance is likely to be associated mainly with particulate phases. The Agency concludes that these studies are not likely to be relevant to the environmental fate of BTBPE.

Photolysis reactions on solid surfaces are likely to be more relevant to the environmental fate of BTBPE (e.g. when adsorbed onto artificial surfaces such as windows). Yu *et al.* (2017) is one such study and reports short half-lives (< 2 days) for BTBPE and the identification of one transformation product as 2-(2',4',6'-tribromophenoxy)ethanol (0.5 to 6% of applied radioactivity). Nevertheless, the proportion of emitted substance that would be subject to such reactions is still likely to be low, and shading and quenching reactions will also lower its importance in more natural media (such as sewage sludge).

2.3.1.2 Biodegradation

2.3.1.2.1 Biodegradation in the aqueous environment

2.3.1.2.1.1 Estimated data

Estimated biodegradation data from the BIOWIN models of EPISuite™ produced the following results:

BIOWIN 2: 0.000 (does not biodegrade fast)
BIOWIN 3: 0.7473 (recalcitrant)
BIOWIN 6: 0.0130 (does not biodegrade fast)

It is stated that the aromatic bromide and aromatic ether fragments are recognised by the models; the BIOWIN 6 model also recognises aromatic H and linear CH_2. The BIOWIN 6 model validation and training sets include similar substances (e.g. decabromodiphenyl ether, dibromobiphenyl, and several brominated phenols). The datasets for BIOWIN 2 and 3 include brominated phenols and benzenes. The EU MSC support document concluded that the predictions are reliable, and the Agency agrees with this conclusion.

2.3.1.2.1.2 Screening tests

One non-standard biodegradability screening test for BTBPE is presented in the EU MSC support document (summarised in Table 5).

Table 5: Summary of screening test results for BTBPE reported in the EU MSC support document

Reference	Study type	Results
Calandra (1976)	Non-guideline study	Observed CO_2 evolution was

in GLCC (2002)	Pre-adapted inoculum 1, 100 and 10,000 mg/L BTBPE (assuming weight/volume concentrations) Duration: 183 or 211 days Limited information was available so reliability could not be fully assessed	between 0.53 and 1.41% at the end of the study. Positive control (glucose) showed 71% CO_2 evolution after 28 days.

- Calandra (1976) in GLCC (2002)

The inoculum for this study was derived from fresh settled sludge and garden soil and was pre-adapted before the definitive test, and so was more similar to inherent biodegradation tests than a ready biodegradability screening study. The ^{14}C-labelled test substance was weighed directly into the test medium containing the inoculant (when 0.01% and 1.0%) or added in ethyl acetate (1 ppm). $^{14}CO_2$ production was monitored at least weekly and reached a maximum of 1.41% (1 mg/L system after 183 days). Although the method was non-standard and there was limited information available meaning that the reliability could not be fully assessed, the EU MSC support document concluded that as low levels of degradation were observed and conditions were more similar to an inherent test than a ready biodegradability test, this suggests that BTBPE may at least be persistent.

The Agency notes that there was no information on the viability of the microbial population after 28 days and the concentration of test substance was several orders of magnitude above the water solubility value at the higher two concentrations used. The Agency concludes that despite some significant limitations, the study provides some evidence that BTBPE is not readily or inherently biodegradable

2.3.1.2.1.3 Biodegradation studies (simulation tests)

One non-standard aquatic simulation study is included in the EU MSC support document (Table 6), which considered it to be reliable with restrictions (Klimisch score 2).

Table 6: Summary of aquatic simulation data reported in the EU MSC support document

Reference	Study type	Results
de Jourdan *et al.* (2013)	Outdoor mesocosm study with sediment trays containing 1:1:1 mix of topsoil, manure and compost. BTBPE applied at 500 ng/g solids. Reliable with restrictions (Klimisch score 2)	No significant decrease of BTBPE concentration in the water compartment over 42 days or the artificial 'sediment' compartment over 56 days. The dissipation DT_{50} was 187 days at 19.6°C in the artificial 'sediment'

		(converted to 383 days at 12°C) but was considered unreliable due to poor data fitting and the regression was not statistically significant.

This mesocosm study investigated the persistence of several BFRs including BTBPE. Each mesocosm had a diameter of 3.9 m and a water depth of 1 m (total water volume of 12,000 L). Water was sourced from an irrigation pond, fed by an on-site well. Sediment trays (52.1 x 25.4 x 5.7 cm) containing organics-rich soil (1:1:1 mixture of topsoil:manure:compost) were added to each mesocosm such that > 50% (approximately 12 m^2) of the bottom surface of the mesocosm was covered. The sediment used in the mesocosms had high organic content, with 11.6% dry total carbon, 1.6% dry inorganic carbon, and 10.0% dry organic carbon. Mesocosms were established in May 2008, before application of BTBPE by subsurface injection in dimethyl sulfoxide (DMSO, 125 mL) and toluene (5 mL) to three mesocosms in July 2008 to achieve a concentration of 500 ng/g 'sediment' in the upper 5 cm (not stated if dry or wet weight). Two of the three mesocosms were treated a second time at the same concentration in July 2009. A control mesocosm was included where only solvent was added, equivalent to that used for the treated mesocosms. Water column (approximately 4 L) and sediment samples were taken on days 1, 4, 7, 14, 28, 42, and 70 after the second treatment. Three sediment samples were taken as 3 cm cores from two separate smaller sediment trays on opposite sides of the mesocosm. The separate trays minimised disturbance of the sediment in the mesocosms. The paper does not describe any steps to prevent aerial deposition and does not report the control results.

Several areas of uncertainty were noted in the EU MSC support document:

- The use of topsoil/manure/compost instead of natural sediment, in particular the high organic carbon (OC) content (10%) compared to the range stated in OECD TG 308 (2.5 to 7.5% for the high OC sediment and 0.5 to 2.5% for the low OC sediment). The support document states that 10% is within the range of natural sediments in Europe.
- There is a lack of information on oxygen concentration and pH in the original report. The support document states that additional information from the authors of the study was that the oxygen concentration in the water column of the mesocosms remained quite stable and at acceptable levels during the whole 2009 study period. The pH was reported for approximately 5 weeks around the first application of test substance in 2008 and was 8.6 ± 0.5 for both the control and treated mesocosms.
- No microbial characterisation was conducted. However, both the irrigation water and artificial sediment would have been expected to contain microorganisms and the mesocosms were set up over a year prior to the second application of BTBPE, giving time for a microbial community to establish. It is also highlighted that as two

applications of BTBPE were made, the microbial community should be considered pre-exposed to BTBPE.

A high organic matter content could lead to higher adsorption than in a typical water-sediment system, reducing bioavailability. The microbial communities present were likely to be different from those in natural sediments because of the use of a topsoil / manure / compost mixture and it is unclear how viable this population would be in an aqueous environment or how its diversity would change over time. The first application of BTBPE occurred only a few weeks after the establishment of the microcosms and there was no characterisation of the microbial community during the study. Overall, the Agency concludes that the impact of use of the topsoil / manure / compost mixture on degradation is difficult to predict and therefore adds uncertainty to the study results.

The oxygen demand of the topsoil/manure/compost mixture could potentially be high. Although it is stated that the oxygen level in the water column was acceptable for the duration of the study, the Agency notes that it is not clear whether aerobic or anaerobic conditions were prevalent in the sediment phase.

Other major differences from studies conducted to OECD TG 308 include the likely large variability in temperature over the course of the test (temperature was not reported in the original study but a geomean of 19.6°C after the second treatment is stated in the EU MSC support document), exposure to natural sunlight that introduces the possibility of photodegradation, and the pre-exposure of the microbial community before the second treatment. The support document states that the high test temperature compared to EU standard conditions, sunlight, and pre-exposure favour dissipation or degradation. The Agency agrees that these study conditions are potentially favourable for dissipation or degradation.

The Agency notes that the fitting of the data is likely to be unreliable because no notable degradation occurred (the rate constant is not likely to be statistically different from zero). The Agency agrees that there is no evidence of any degradation or dissipation of BTBPE in the particulate matter used for this study over 56 days. Given the uncertainties associated with the study, the Agency does not consider it to be conclusive, but it provides some evidence to indicate persistence.

2.3.1.2.1.4 Sediment core data

The EU MSC support document contains data for sediment cores from three published studies, and a brief summary of each is presented in Table 7; no comment is made on the reliability of these studies in the EU MSC support document.

Table 7: Sediment core data for BTBPE reported in the EU MSC support document

Reference	Study type	Results
Hoh *et al.* (2005)	Analysis of a sediment core from Lake Michigan, USA.	BTBPE found in sediment at increasing concentration from 1973 to 1985, after which concentrations were relatively constant until 1992. BTBPE was not detected in sediment layers representing 1993-2004 (for reasons reported as 'unclear').
Qiu *et al.* (2007)	Analysis of a sediment core from Lake Ontario, USA.	BTBPE found in sediment at increasing concentration from 1980 to 2000 (surface layer).
Lee *et al.* (2022)	Analysis of sediment cores from a highly industrialised saltwater lake (Lake Shihwa, Korea).	BTBPE found in sediment cores with highest concentrations from 1975-1990, after which concentrations decreased.

The EU MSC support document concludes that as BTBPE has been detected in 20 to 40 year-old sediment layers these studies indicate that it is degraded very slowly in anaerobic sediment, which can be used as part of a weight of evidence.

The Agency notes that anaerobic conditions are likely to be prevalent in sub-surface sediment layers and that the dating of different parts of a sediment core may rely on some assumptions (e.g. around deposition rates of suspended matter, lack of disturbance and bioturbation, etc.). REACH guidance (ECHA, 2024) recommends not to judge whether a substance has an environmental half-life exceeding the P/vP thresholds using only anaerobic simulation data. This is because generally it is expected that an anaerobic half-life would be greater than an aerobic half-life where the main route of degradation is aerobic. Therefore, the Agency agrees that sediment core data indicate that BTBPE can persist over long periods in sediments, but this is of limited relevance for the purposes of a persistence assessment. The Agency has therefore not performed its own reliability assessment of each study.

The Agency also notes other studies are available, such as Yang *et al.* (2012), that similarly show presence of BTBPE in sediment layers over a number of years.

2.3.1.2.1.5 Biodegradation in soil

One non-standard soil simulation study is included in the EU MSC support document (Table 8), which was considered to be reliable with restrictions (Klimisch score 2).

Table 8: Summary of soil biodegradation data reported in the EU MSC support document

Reference	Study type	Results
Venkatesan and Halden (2014)	Outdoor mesocosm study involving biosolid-amended soil, with retrospective analysis of archived samples Reliable with restrictions (Klimisch score 2)	Concentrations of BTBPE remained constant over 3 years

- Venkatesan and Halden (2014)

Mesocosms (plastic containers: 25 cm deep, 30 cm wide and 30 to 80 cm long) were filled with biosolids from an activated sludge treatment plant mixed with agricultural soil at a volumetric ratio of 1:2 and exposed to ambient weather conditions. Salad crops were grown in the first year and then the mesocosms were left fallow. Soil cores (top 20 cm) were taken 57, 115, 520, 859, and 995 days after mixing, with three control and three test mesocosm analysed at each sampling point and three cores taken per mesocosm and pooled before storage. The Agency notes that three cores is a small number given the likely heterogeneity of the biosolid:soil mixture.

The study was originally conducted to investigate the persistence of pharmaceuticals and personal care products in biosolid-amended soils, but additional samples for each timepoint were archived and stored at -20°C. Venkatesan and Halden (2014) analysed the archived soils for a number of BFRs, including BTBPE. Samples were Soxhlet extracted using dichloromethane and then prepared for final analysis using gas chromatography with mass spectrometry detection approximately following EPA method 1614. A spiked recovery of 76.2% was reported but no specific details of replicate analysis were provided.

The EU MSC support document reproduced plots from the original report that indicated variable concentrations of BTBPE but no notable decline with time. No concentration data are available for day 0 and specific data are not provided to indicate variability at all sampling points (the plot includes minimum and maximum concentrations at each sampling time but it is only available for 2 out of 5 of the timepoints). BTBPE was not detected in any of the control samples that were not amended with biosolids. As the biosolids were from a treatment plant it was assumed to have been pre-exposed to BTBPE.

The EU MSC support document notes some shortcomings with this study including:

- The ratio of biosolid:soil was high compared to typical application rates.
- The number and volume of samples were limited and replicate samples were not always available.
- Extended storage of samples could have allowed chemical degradation to occur.

Although there were only five samplings in three years and there was high variability in replicate concentrations in two samplings, the EU MSC support document concluded that BTBPE persisted in the soil over three years.

The EU MSC support document benchmarked the results for BTBPE to those of other BFRs. It states that the degradation for a range of BFRs presented in the study corresponded well with other available sources of information. For example, there was degradation of lower brominated substances such as di- and tribromodiphenyl ethers (BDEs) but no clear degradation of more brominated substances (e.g. penta- up to decaBDEs), which is consistent with reports that degradation is strongly dependent on the degree of bromination. The EU MSC support document also compared the degradation of individual BFRs in the study with estimated half-lives calculated according to Rorije *et al.* (2011) using BIOWIN3 values. It concluded that the experimental results for a range of different BFRs were consistent with the estimated half-lives, and that the estimated half-life for BTBPE was 9 years.

The Agency notes that there were several significant differences from a study conducted to OECD TG 307. The mesocosms were exposed to light and ambient weather conditions, there was no attempt to collect leachates, the number of replicates was very limited, and crops were grown on the soil in the first year. Although a suitable organic matter content range for test soils is not specified in the guideline, in this study it is likely to have been much higher compared to typical soils or even biosolid amended soils. It is possible that the high organic matter content could have reduced bioavailability of BTBPE. The spiked recovery (76.2%) falls within the 70 to 110% range stated in the guideline but there were no details of the repeatability of the analytical method for BTBPE, and there was no detail of soil sampling or storage before analysis. Some of these differences complicate the interpretation of the study but it is made simpler by the fact that there was no evidence of degradation.

The Agency notes that a mixture of biosolid and soil will inevitably be a heterogenous mixture and the limited number of soil cores taken and lack of replication in the analysis is a weakness in the study reflected in the variability of concentrations of test substances reported over time. The Agency concludes that the reliability of the study is not assignable (Klimisch score 4) but agrees that despite the uncertainties, the lack of degradation observed in the study over three years, and the benchmarking with other BFRs provides evidence that BTBPE has a very long half-life in soil (> 1 year).

2.3.1.3 Detection in remote regions

The EU MSC support document includes the results of several studies that determined the presence of BTBPE in remote regions. The ECHA Guidance Chapter R.11 (ECHA, 2017) states that the presence of a substance in remote areas (long distances from populated areas and known point sources) may be used as part of a weight of evidence approach for persistence assessment but that the evidence should be scrutinised carefully with respect

to the distribution and transport of the substance. These studies, summarised in Table 9, show the presence of BTBPE in remote areas far from known sources.

The studies examined a variety of matrices including different biota. Sample collection and handling methods were often not described in full. They were also multi-residue studies involving a number of analytes in addition to BTBPE. The analytical methods are described in enough detail to understand the procedure but not always to be able to repeat it. There was generally not enough detail to ascertain whether there were any adjustments to data, if there were any outliers or rejected data, or if replicate or duplicate analysis was carried out.

The Agency notes that the reliability of monitoring data can often be overlooked in regulatory assessments. Most of the studies were relevant and included the data required under the Criteria for Reporting and Evaluating Exposure Datasets (CREED) reliability assessment framework (Merrington *et al.*, 2024) but were missing some of the recommended data. Overall, the Agency concludes that in general the studies are 'usable with restrictions' at the CREED silver assessment level.

The Agency has not examined the distribution and transport of BTBPE in the environment in any detail for this report and therefore the presence of BTBPE in remote regions can only be considered as supporting evidence.

Table 9: Monitoring data for BTBPE in remote regions reported in the EU MSC support document

Reference	Location and sample type	Concentration (+ detection frequency (DF) where stated)
Snow and ice (concentrations expressed as ng/L)		
Hermanson *et al.* (2010)	Svalbard, Norway Ice core (covering approximately 1953 to 2005; n = 3)	0.0149 to 0.095
Meyer *et al.* (2012)	Devon Ice Cap, Nunavut, Canada Snow pit (n = 3; total of 26 different depth samples)	< 0.005 to 0.120 (DF = 20% of horizons representing 1992 to 2006; no clear trend)
Biota (concentrations expressed as ng/g wet weight (ww) unless otherwise stated)		
NCP (2013)	Canadian Arctic Ringed seal	Tissue not stated BTBPE: > 0.02 (DF = 20%)
NCP (2013) AMAP (2017)	Canadian Arctic Canis lupus (Wolf)	0.008 to 0.2

McKinney *et al.* (2011)	Canadian Arctic, Alaska, Hudson bay, European Arctic Polar bear, adipose tissue	Concentrations not reported Canadian Arctic: DF = 25% Other regions: DF = 0%
Strid *et al.* (2013)	Iceland Greenland shark, liver (n=15)	< 0.016 to 8.1 ng/g fat (DF = 67%; LOD = 0.016 ng/g fat)
Vorkamp *et al.* (2015)	Ittoqqortoormiit, East Greenland Black guillemot, eggs (n=4), Polar bear, adipose tissue (n=5)	Black guillemot eggs: 0.013 to 0.017 (DF = 100%; LOD = 0.012) Polar bear adipose tissue: < 0.065 to 0.27 (DF = 80%) (DF = 20%)
Verreault *et al.* (2007)	Bear Island, Norway Glaucous gull, egg yolk (n = 31) and plasma (male n = 19 and female n =30)	Egg yolk: < 0.27 to 0.96 (DF = 29%; LOQ = 0.27) Plasma (male): (DF = 5%; LOQ = 0.20) Plasma (female): DF = 0% (LOQ = 0.20)
Sagerup *et al.* (2010)	Svalbard and Bjørnøya, Norway Brünnich's guillemot, eggs (n = 10)	0.0005 to 1.125 DF = 40%
Schlabach *et al.* (2011)	Faroe Islands Black guillemot, eggs (n = 2)	0.019 and 0.024

Note: Specific details about sample numbers is provided where available but are sometimes missing from the original reports.

2.3.1.4 Summary and discussion of degradation

Environmental half-lives from a standardised soil or water-sediment simulation test (OECD TG 307 or 308) would usually be used to assess the persistence of hydrophobic substances such as BTBPE under UK REACH. However, in the absence of any REACH registrations for the substance, conclusions are based on academic studies supplemented by predictions where relevant. Academic studies are not typically designed (or intended) to address regulatory requirements, so must be interpreted with caution when regulatory studies are not available.

There is some information to suggest that phototransformation can occur when the substance is adsorbed onto solid surfaces (half-life < 2 days), but this is unlikely to make a major contribution to degradation in aquatic and terrestrial environments. In contrast, there are several lines of evidence that indicate that BTBPE degrades slowly in the environment, although none of these is ideal. The strongest evidence comes from retrospective analysis of archived biosolid-amended soil samples from a long-running outdoor mesocosm study (Venkatesan and Halden, 2014). This indicated no significant degradation of BTBPE over three years under relevant environmental conditions. Comparison of the variation of BTBPE concentrations over time with other BFRs in the same samples indicated that BTBPE had a similar level of resistance to degradation as BFRs that are identified as persistent organic pollutants (POPs) under the Stockholm Convention (UNEP, 2023). It

can therefore be concluded that BTBPE has a very long half-life in soil under the conditions of this study (>1 year). There is some uncertainty because of the high level of biosolids used which might have affected the bioavailability of the substance, although the actual influence on degradation rates is unknown.

The other lines of evidence can be summarised as follows:

- Estimated biodegradation data from the BIOWIN models of EPISuite™ suggest that the substance does not biodegrade fast. The predictions are within the applicability domain of the models.
- A non-standard biodegradability study with significant limitations reported < 2% mineralisation over an extended time period, well beyond the duration of a standard test design. The substance is not readily or inherently biodegradable based on this evidence.
- There was no evidence of degradation in the particulate matter used for a water/artificial 'sediment' mesocosm study over 56 days (de Jourdan *et al.*, 2013), although this study has significant limitations.
- Sediment core data show that BTBPE was still present many years after its movement into the sediment at multiple sites. This indicates that BTBPE degrades slowly under the environmental conditions prevalent in these sediments. However, this does not necessarily provide evidence of a lack of degradability under aerobic conditions.
- Several studies that have reported the presence of BTBPE in remote regions far from known sources. This can only be used as supporting evidence as BTBPE distribution and transport in the environment has not been examined for this report.

2.3.2 Bioaccumulation

2.3.2.1 Bioaccumulation in aquatic organisms (pelagic & sediment organisms)

2.3.2.1.1 Screening data

The measured log K_{OW} value of 3.14 is considered to be unreliable (see Section 2.1.5). The predicted log K_{OW} values range from 7.65 to 9.39 and exceed the screening criteria for bioaccumulation (log K_{OW} > 4.5).

2.3.2.1.2 Predicted data

The EU MSC support document does not present predicted bioaccumulation data so the Agency has considered two software packages. For both packages, a calculated log K_{OW} of 8.16 was used as an input value. The Agency notes that there are a range of estimated log K_{OW} values available (see Table 3) and that this adds uncertainty to the results of the modelling.

BCF values were predicted with the BCFBAF v3.02 model of EPISuite™ v4.11 For the regression-based mode, the BCF is 3,590 L/kg ww (wet weight) (log BCF = 3.56). For the Arnot-Gobas model, a BCF of 2,541 L/kg ww (log BCF = 3.405) and an estimated BAF of 9.617 x 10^6 L/kg ww is calculated for the upper trophic level, including biotransformation rate estimates.

The bioaccumulation estimation tool (BET) v1.03 within EAS-E-Suite v0.982 (ARC, 2026; accessed 16 April 2026) was also used to assess bioaccumulation potential. BTBPE is in the chemical information database of the tool and the default chemical inputs were chosen except for log K_{OW} where the predicted value of 8.16 was added and selected. The aqueous exposure bioaccumulation prediction (laboratory) was above 10,000 for freely dissolved substance but below 2,000 for total substance in the aqueous phase (25,900 and 615 L/kg ww, respectively). Field aquatic bioaccumulation predictions also indicate bioaccumulation potential with all BAF values much greater than 10,000 L/kg whether based on freely dissolved (range 5.37 x 10^4 to 1.23 x 10^5) or total substance (range 1.34 x 10^7 to 3.05 x 10^7) in the aqueous phase. There were also indications of bioaccumulation from field bioaccumulation predictions. The BET report is presented in Appendix A.

2.3.2.2 Aquatic bioaccumulation data

Three aquatic bioaccumulation studies are presented in the EU MSC support document, as summarised in Table 10, with further details provided below the table.

Table 10: Summary of aquatic bioaccumulation data reported in the EU MSC support document

Reference	Study type	Results / comments
CITI (1976) in GLCC (2002)	Aqueous exposure over 8 weeks using *Cyprinus carpio* (Common carp) Not reliable (Klimisch score 3)	Exposure concentration 0.03 ppm: BCF: 11.9 – 43.6 L/kg Exposure concentration 0.3 ppm: BCF: 5.2 - 56.6 L/kg
Tomy *et al.* (2007)	Flow-through dietary exposure for 49 days (uptake phase) followed by a 154-day depuration phase using *Oncorhynchus mykiss* (Rainbow trout) Reliable with restrictions (Klimisch score 2)	BCF values calculated from the depuration rate constant (k_2 = 0.0128 d^{-1}) using the OECD BCF estimation tool: Method 1: Median $BCF_{kinetic}$: 13,218 L/kg Method 2: $BCF_{kinetic}$: 50,873 L/kg
de Jourdan *et al.* (2014)	Outdoor mesocosm exposure for 42 days (uptake	Rapid uptake and no change in concentration from day 7-42.

	phase) followed by a 28-day depuration phase using *Pimephales promelas* *(*Fathead minnow) Reliability not stated	No depuration observed over 28-day depuration phase.

- CITI (1976) in GLCC (2002)

This is the only study that reports a BCF arising from aqueous exposure, and the EU MSC support document concludes that it is not reliable. This is based on the exposure concentrations being above the water solubility of BTBPE, the small number of fish exposed (two sacrificed at each of four sampling times), the high variability of concentrations in the fish with no clear increasing trend with time indicating steady state was not reached, and the high variability in whole body BCF values reported (5.2 to 56.5 L/kg).

The Agency agrees that it is likely that both nominal concentrations in CITI (1976) were above the solubility limit of BTBPE in the test medium and quite possibly by a large margin, resulting in underestimation of BCF values. It is possible to determine approximate BCF values by assuming that the concentration in water was at the solubility limit but the estimated solubility of BTBPE varies by several orders of magnitude, leading to a very wide possible range of BCF values. The Agency therefore agrees that the data from this study cannot be considered reliable for the bioaccumulation assessment.

- Tomy *et al.* (2007)

This was a flow-through dietary study where the test species was *Oncorhynchus mykiss* (Rainbow trout) with an initial mean weight of 202 g. The fish were exposed to BTBPE through spiking of commercial fish food, where the measured arithmetic mean concentration was 46.2 ± 2.0 ng/g; the lipid content of the food was 13.6 ± 0.5%. The daily feeding rate was equal to 1.0% of the mean weight of the fish, adjusted after each sampling time for growth measured from the mean weight of sacrificed fish.

There were 51 fish held in 800 L aquaria used for each treatment in both the exposure and control groups. The study reports test water temperature as 12°C, pH as 7.9 to 9.1, dissolved oxygen was maintained at saturation throughout the study, and a 12 h light:12 h dark photoperiod was used. Four fish were sampled from the exposed and the control tanks on days 0, 7, 14, 28, and 49 of the uptake phase, and on days 7, 14, 28, 56, 116, and 154 of the depuration phase. Blood, liver, bile, kidney, gastrointestinal tract, and carcass were dissected from the fish and stored at -90°C before analysis. Only muscle tissue was used for the bioaccumulation calculations. BTBPE was extracted from homogenised muscle tissue using accelerated solvent extraction and after gel permeation chromatography clean-up, the samples were analysed by gas chromatography with mass

spectrometric detection (GC-MS). Lipid content in the muscle was also determined, and all results were corrected for lipid content.

The study was not conducted to a specific guideline. The EU MSC support document compared the study to OECD TG 305 and concluded that it was reliable with restrictions despite a lack of detail in places and some deviations. The main uncertainties are summarised as follows:

- It is stated that the concentrations of BTBPE in the food did not decline during the study (day 0 to the end of the depuration phase at day 203) but this could not be assessed as insufficient data was presented.
- There was no information presented on the homogeneity of BTBPE in the treated food.
- Test water temperature was reported as 12°C, just below the recommended range of 13 to 17°C. The temperature should vary less than ± 2°C but no information on temperature variability was presented
- There was no information on concentrations or frequency of detection of BTBPE in the control fish, although it is stated that when detected, BTBPE concentrations were subtracted from those of exposed fish.
- Concentrations were measured in muscle tissues and not the whole body and it is possible that the whole fish depuration rate could differ from that for muscle.

The Agency notes the following in relation to the validity criteria of OECD TG 305:

- The report states that the dissolved oxygen was always maintained at a level of saturation but no measurements or further details are provided.
- The study reports no mortality in either the treated or the control samples but does not state whether there were any other adverse effects or disease.
- The study states that the lipid-based concentrations of BTBPE in treated food were determined to be 46.2 ± 2.0 ng/g (n = 4). It does not state when sampling of the food occurred nor does it demonstrate the homogeneity of BTBPE in the spiked food. Concentration in the untreated food was 0.2 ± 2.0 ng/g (n = 4).

The Agency also notes the following difficulties in assessing the study because of the lack of information available:

- The loading rate was determined to be 12.9 g of fish (wet weight) per litre of water, approximately 10 times the recommended maximum in the guideline to maintain adequate dissolved oxygen concentration and to minimise organism stress.
- The range of mass and length of the individual fish used in the study are not reported although it is stated that the initial mean weight was 202 ± 7 g. It is therefore not possible to check the reported rate constant for growth.

- BTBPE in the fish is reported in nanomoles and not as a concentration. There is no information presented on the amount of muscle extracted and therefore concentration of BTBPE in the fish muscle cannot be determined.
- The uptake and depuration data are only presented in a plot and therefore it is not possible to check the accuracy of the depuration rate constant.

A number of the deviations described above introduce uncertainty into the study and the Agency concludes that the reliability of the study is not assignable (Klimisch score 4).

A linear uptake was observed with no steady state reached after the 49-day uptake phase. Depuration could be fitted with first order kinetics (rate constant = 0.0128 ± 0.002 day^{-1}). The study reported BMF values for each of the days during uptake, ranging from 1.12 to 5.16 based on assimilation efficiency, mean feeding rate, and the depuration rate constant. However, the EU MSC support document states that there are inconsistencies in the data, and that it is not clear how the BMF was calculated (the results are not consistent with the equations and parameter values presented in the published paper). The Agency has reviewed the original report and agrees that the calculation of the BMF is unclear, and so should not be used.

BCF values in the EU MSC support document were estimated using the guidance document on aspects of OECD TG 305 on fish bioaccumulation (OECD, 2017) and the associated OECD BCF estimation tool. The key inputs were growth rate (k_g) which was 0.0051 day^{-1}, log K_{OW} of 8.16, and depuration rate constant (k_2) of 0.0128 day^{-1}. The OECD tool produces a number of estimated BCF values from two different methods. For method 1, 10 out of the 13 models estimated BCFs above 5,000 L/kg, two models gave BCFs above 2,000 but below 5,000 L/kg, and one model resulted in a BCF below 2,000 L/kg; the median value was 13,218 L/kg. Method 2 gave a BCF of 50,873 L/kg. The Agency has checked the results using same inputs and agrees with these values. The Agency notes that there is some uncertainty associated with the log K_{OW} value as there are a range of predicted values available. The Agency repeated the modelling with the lowest and highest predicted log K_{OW} values (7.65 and 9.39 respectively). Although the actual BCF values of the individual models dependant on log K_{OW} were different, the pattern of BCF values with respect to the 2,000 and 5,000 L/kg criteria were unchanged.

Additional evidence for bioaccumulation potential was provided in the EU MSC support document by comparing the half-life for depuration for BTBPE from this study (54 days) with other SVHCs identified as vPvB. These included seven medium-chain chlorinated paraffins (MCCPs; half-life: 55.7 to 337.9 days), two dechlorane isomers (30 to 70 days), o-terphenyl (8.1 days), octamethylcyclotetrasiloxane (D4; 105 days) and decamethylcyclopentasiloxane (D5; 74 days). The half-life for BTBPE was comparable to many of these substances, adding weight to the conclusion that BTBPE is very bioaccumulative. The Agency agrees that this comparison is appropriate.

- de Jourdan *et al.* (2014)

The aquatic mesocosm study by de Jourdan *et al.* (2013) reported in Section 2.3.1.2.1.3 was extended and *Pimephales promelas* (Fathead minnow) introduced to some mesocosms. The nominal water concentration of 0.3 mg/L likely exceeded the water solubility of BTBPE but was chosen to result in 500 ng BTBPE/g sediment in the upper 5 cm of sediment. Twenty-four fish (approximately 5 cm in length) were introduced into three treated and three solvent control mesocosms. The exposure period was 42 days followed by transfer to a control mesocosm for the depuration phase of 28 days. The water column was analysed for the test substance in filtered particulates at 14 timepoints up to 70 days but results were not reported. Three fish per mesocosm were sampled on day 7, 14, 28, and 42 of the exposure phase and day 7 and 28 of the depuration phase.

Uptake was very fast and measured growth-adjusted concentrations in fish were not statistically different from the first measurement at day 7 until the end of the uptake phase on day 42. This was unexpected for a substance with a high log K_{OW} and it was speculated that the solvent DMSO may have enhanced biological availability. The Agency notes that the possible influence of adsorption to the skin was not mentioned by the study authors. No statistically significant decrease in BTBPE concentrations in fish were observed during depuration, suggesting a very long half-life (>28 days). 2,6-Dibromophenol (2,6-DBP) was detected in the fish and followed a similar concentration trend to BTBPE. The EU MSC support document notes that tribromophenol (TBP) was detected in the particulates and that it was possible that 2,6-DBP formed from metabolism of BTBPE or from TBP in the fish, although there was no TBP reported in the fish.

The study did not show any significant trends in fish concentrations from the first observation in the uptake phase to the end of depuration. There was also no measurement of concentrations in water, and no reports of mortality or adverse effects on the fish. The Agency considers that this study adds supporting evidence of the slow depuration of BTBPE.

2.3.2.3 Field data

The EU MSC support document presents the results from several studies that investigated the potential for bioaccumulation in the environment. There were seven studies that reported trophic magnification factors (TMFs), two of which were considered as unreliable because of uncertainties or missing information. The results of the other five studies are briefly summarised in Table 11. TMF values ranged from 0.4 to 2.83.

Table 11: Summary of TMF values reported in the EU MSC support document and concentration ranges of sampled species

Reference	Study location	Reported TMF	Concentration range (ng/g lw)[1]
Zheng *et al.* (2018)	Lake Taihu, South China	2.83	< 0.043 to 0.776 ng/g ww
Liu *et al.* (2021)	Bohai Sea, China	2.3	2.6 to 15
Hou *et al.* (2022)	Xisha Islands, South China Sea	1.9	< 0.060 to 0.403
Wu *et al.* (2010)	Electronic waste recycling site in South China	0.4	1.71 to 518
Kurt-Karakus *et al.* (2019)	Lake Ontario, Canada	0.53	< MDL[2] to 35.2

[1] Concentration presented as ng/g lipid weight (lw) unless stated otherwise.
[2] Method detection limit (MDL) stated as 0.0008 ng/g (plankton) and 0.118 ng/g (forage fish) – not lipid weight.

In addition there were a number of other field studies presented in the EU MSC support document, summarised as follows:

- Six studies reported biomagnification factors (BMFs) with values ranging from 0.001 (trout / goby in Lake Ontario) to 48.9 (tilapia / shrimp, suburb of Guangzhou).
- One study reported a bioaccumulation factor (BAF), where values ranged from 86 (Crucian carp) to 25,900 (prawn).
- One study reported a biota-sediment accumulation factor (BASF), where values ranged from 0.08 (filter feeding bivalve) to 0.5 (also a filter feeding bivalve).

The field data provide a mixed picture where evidence for bioaccumulation was seen in some food webs and not in others. The EU MSC support document highlights that some species will likely have a greater ability to biotransform BTBPE than others and points out a number of issues with the individual studies, for example comparison of different tissues (such as whole body and muscle), collection of species at different sites and at different times, and inconsistency in the information reported.

The Agency recognises that many academic studies are difficult to interpret either due to limited information, use of specific tissue types rather than whole bodies, sampling in different years / locations, uncertainties in the determination of trophic level, analytical issues, and small sample sizes. One or more of these issues were present in most of the studies reported in the EU MSC support document, including the studies reporting TMF values. This information can therefore only be considered as providing supporting information in the bioaccumulation assessment.

BTPBE has been found in eggs of various bird species. For example, concentrations of BTBPE up to 0.17 µg/kg lipid weight (lw) and mean 0.11 µg/kg lw were determined in Northern fulmar eggs from the Faroe Islands (Karlsson *et al.*, 2006). Maximum concentrations of BTBPE in egg pools of Herring gulls collected in 2004 from six sites in the Great Lakes were 0.7 and 1.8 µg/kg ww in two studies (Gauthier *et al.*, 2007; Gauthier *et al.*, 2009). The presence in eggs shows maternal uptake and exposure of embryos at sensitive stages of development.

2.3.2.4 Presence in humans

BTBPE has been detected in breast milk in China in 28% of 11 samples with a concentration range from not detected (value not reported) up to 0.085 ng/g lipid weight (Chen *et al.*, 2019). This indicates the potential for uptake of BTBPE into humans and the possibility of exposure prior to weaning.

2.3.2.5 Summary and discussion of bioaccumulation

Typically, the assessment of bioaccumulation potential under UK REACH is based on standard fish bioaccumulation data (obtained using OECD TG 305), with preference given to dietary exposure for hydrophobic substances such as BTBPE. However, no standard studies are available, so conclusions are based on academic studies supplemented by predictions where relevant. Academic studies are not usually designed (or intended) to address regulatory requirements, so must be interpreted with caution when regulatory studies are not available.

The key data come from a non-standard fish dietary bioaccumulation study (Tomy *et al.*, 2007). The low depuration rate constant (0.0128 ± 0.002 day^{-1}) equates to a depuration half-life of 54 days. The information from this study can be used to estimate BCF values following internationally recognised methods (OECD, 2017), and 10 of the 13 models result in BCF values above 5,000 L/kg: the median BCF value is >10,000 L/kg.

The other lines of evidence indicative of highly bioaccumulative properties can be summarised as follows:

- BTBPE has a range of predicted log K_{OW} values, all above 4.5. This suggests a high potential for bioaccumulation, though a reliable measured result would be preferred. BCFs above 2,000 L/kg are predicted using models such as BCFBAF v3.02 and EAS-E-Suite, with much higher BAFs (> 10,000 L/kg).
- Fish depuration half-lives are available for several other SVHCs that have been identified as very bioaccumulative, e.g. MCCPs (≥55.7 days), two dechlorane isomers (30 to 70 days), o-terphenyl (8.1 days), and D5 (74 days). The species involved differ, but these data provide relevant benchmarks for comparison. The fish depuration half-life for BTBPE from the Tomy *et al.* (2007) study (54 days) is similar to or longer than these values, and so may be considered to be a characteristic indicator of a high level of bioaccumulation.

- This is supported by a lack of any statistically significant depuration over 28 days in a second fish species used in a mesocosm study (de Jourdan *et al.*, 2014).
- There are reported BMF and TMF values greater than one in some field studies, although the evidence is mixed and there is considerable uncertainty because of difficulties interpreting the results of many of these studies.
- BTBPE has been found in human breast milk and in the eggs of different bird species, indicating the maternal uptake of BTBPE and potential exposure at sensitive life stages.

2.4 Conclusions on the SVHC properties

2.4.1 PBT and vPvB assessment

2.4.1.1 Persistence

The combination of BIOWIN 2, BIOWIN 3, and BIOWIN 6 results indicate that BTBPE screens as potentially P/vP (values for BIOWIN 2 or BIOWIN 6 < 0.5 and BIOWIN 3 < 2.25). BTBPE also screens as potentially P/vP based on a non-standard biodegradability study with significant limitations that reported < 2% mineralisation over an extended time period (well beyond the duration of a standard test design). The substance is not readily or inherently biodegradable based on this evidence.

There are several lines of evidence that indicate that BTBPE degrades slowly in the environment. The strongest evidence comes from retrospective analysis of archived biosolid-amended soil samples from a long-running outdoor mesocosm study (Venkatesan and Halden, 2014). This indicated no significant degradation of BTBPE over three years under relevant environmental conditions and therefore a half-life in soil likely to be much longer than 180 days (one of the vP criteria of Annex 13 of UK REACH). Comparison of the variation of BTBPE concentrations over time with other BFRs in the same samples from this study indicated that BTBPE had a similar level of resistance to degradation as BFRs that are identified as persistent organic pollutants (POPs) under the Stockholm Convention (UNEP, 2023).

The other lines of evidence can be summarised as follows:

- There was no evidence of degradation in the particulate matter used for a water/artificial ‘sediment’ mesocosm study over 56 days (de Jourdan *et al.*, 2013), although this study has significant limitations.
- Sediment core data show that BTBPE was still present many years after its movement into the sediment at multiple sites. This indicates that BTBPE degrades slowly under the environmental conditions prevalent in these sediments. However, this does not necessarily provide evidence of a lack of degradability under aerobic conditions.

- Several studies that have reported the presence of BTBPE in remote regions far from known sources. This can only be used as supporting evidence as BTBPE distribution and transport in the environment has not been examined for this report.

There is some information to suggest that phototransformation can occur when the substance is adsorbed onto solid surfaces (half-life < 2 days), but this is unlikely to make a major contribution to degradation in aquatic and terrestrial environments. The Agency therefore concludes from the weight of evidence available that BTBPE fulfils the P and vP criteria of Annex 13 of UK REACH.

2.4.1.2 Bioaccumulation

BTBPE screens as potentially bioaccumulative as the range of predicted log K_{OW} values (7.65 to 9.39) exceeds the screening criteria for bioaccumulation (log K_{OW} > 4.5). Predicted BCF and BAF values also indicate the potential for bioaccumulation (BCFs above 2,000 L/kg, with BAFs above 10,000 L/kg).

The key data come from a non-standard fish dietary bioaccumulation study (Tomy *et al.*, 2007), which indicate a low depuration rate constant (0.0128 ± 0.002 day^{-1}), which equates to a depuration half-life of 54 days. The information from this study can be used to estimate BCF values following internationally recognised methods (OECD, 2017), and 10 of the 13 models result in BCF values above 5,000 L/kg: the median BCF value is >10,000 L/kg.

The other lines of evidence indicative of highly bioaccumulative properties can be summarised as follows:

- Fish depuration half-lives are available for several other SVHCs that have been identified as very bioaccumulative, e.g. MCCPs (≥ 55.7 days), two dechlorane isomers (30 to 70 days), o-terphenyl (8.1 days), and D5 (74 days). The species involved differ, but these data provide relevant benchmarks for comparison. The fish depuration half-life for BTBPE from the Tomy *et al.* (2007) study (54 days) is similar to or longer than these values, and so may be considered to be a characteristic indicator of a high level of bioaccumulation.
- This is supported by a lack of any statistically significant depuration over 28 days in a second fish species used in a mesocosm study (de Jourdan *et al.*, 2014).
- There are reported BMF and TMF values greater than one in some field studies, although the evidence is mixed and there is considerable uncertainty because of difficulties interpreting the results of many of these studies.
- BTBPE has been found in human breast milk and in the eggs of different bird species, indicating the maternal uptake of BTBPE and potential exposure at sensitive life stages.

Based on a weight of evidence approach, the Agency concludes that BTBPE fulfils the B and vB criteria of Annex 13 of UK REACH.

2.4.1.3 Overall conclusions on the PBT and vPvB properties

Based on the information available, the Agency concludes that BTBPE fulfils the vPvB criteria of Annex 13 of UK REACH and can therefore be identified as an SVHC in accordance with Article 57(e) of UK REACH.

3. Information on use, exposure and alternatives

3.1 UK and EU REACH registration status and tonnage

The substance is not registered under UK or EU REACH.

In addition, no Downstream User Import Notifications (DUINs[2]) have been submitted under UK REACH.

3.2 General description of uses and exposure

BTBPE is used as an additive flame retardant, being incorporated into polymeric matrices through physical mixing. It is utilised in acrylonitrile-butadiene-polystyrene (ABS), high-impact polystyrene (HIPS), thermoplastics, thermoset resins, polycarbonate, coatings and textiles. Reported applications include in electronic equipment and construction materials which may be available to consumers (ECHA, 2022a).

Available information suggests that the substance is used/has been used as a replacement for other brominated flame retardants, such as Octa-BDE (ECHA, 2022a).

3.3 Alternatives

No information available.

[2] GB based companies who imported substances from EU-based suppliers before UK REACH became law on 1 January 2021 had no EU REACH registration obligations as they were classed as Downstream Users (DUs). As they are now importers from outside of GB, they may have registration obligations under UK REACH. However, a transitional measure allows former DUs to suspend the registration until one of three deadlines (depending on tonnage and hazard). Where the identity of these imported substances was known, they could be included in a Downstream User Import Notification (DUIN) submitted to the Agency.

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Appendix A

The following is the summary report from BET v1.03 within EAS-E-Suite v0.982 for the bioaccumulation assessment of BTBPE:

Chemical Summary

Chemical assessed
CAS: 037853-59-1
Name: 1,2-Bis(2,4,6-tribromophenoxy)ethane
Molar Mass (g/mol): 687.64
SMILES: Brc1cc(Br)cc(c1OCCOc1c(Br)cc(cc1Br)Br)Br
IOC Type: N

Partitioning at 25°C
Log K_{OW}: 8.16
Log K_{OA}: 14.952

Bioaccumulation Thresholds
BCF: Non B: < 2,000; B: > 2,000; vB: > 5,000

Screening Criteria
Screening criteria based on assumptions that octanol is a reasonable surrogate for biopartitioning to storage lipids are commonly used in bioaccumulation assessments to evaluate the potential of chemicals to bioaccumulate. For example, under European REACH legislation:

- A log K_{OW} > 4.5 indicates the possibility of a substance to accumulate in aquatic organisms.
- The combination of a log K_{OA} > 5 with a log K_{OW} > 2 indicates the possibility of a substance to accumulate in air-breathing organisms.

For Ionizable Organic Chemicals (IOCs) that are appreciably dissociated at system pH and for many surface active substances, log K_{OW} is not a valid screening criterion for assessing bioaccumulation potential. The sliders to the left allow one to consider various BCF, BAF and BMF thresholds that change colors in the BET output below highlighting when bioaccumulation values exceed the selected criteria.

Laboratory predictions

This section reports BET model predictions for representative laboratory organisms.

Aqueous Exposure Bioaccumulation Predictions

Organism	k1 (L-water/kg-ww/d)	kT (1/d)	BCF (L-total/kg-ww)	BCF (L-free/kg-ww)

Generic Lab Fish	2.97e+02	1.2e-02	1.52e+03	2.48e+04

- k1 (L-water/kg-ww/d): chemical uptake rate constant from water.
- kT (1/d): total (terminal) chemical elimination rate constant.
- BCF (L-total/kg-ww): bioconcentration factor referenced to the total chemical concentration in the water (freely dissolved (bioavailable) chemical + chemical sorbed to suspended matter).
- BCF (L-free/kg-ww): bioconcentration factor referenced to the freely dissolved (bioavailable) chemical concentration in the water.

Dietary Exposure Bioaccumulation Predictions

Organism	kD (kg/kg/d)	kW (kg/kg/d)	kT (1/d)	BMFL (kg-lw/kg-lw; Diet)	BMFA* (gut temperature) (activity/activity; Diet)	BMFA* (gut temperature) (activity/activity; Ingesta)	BMFL Growth Cor.(kg-lw/kg-lw; Diet)	BMFA* Growth Cor. (gut temperature) (activity/activity; Diet)
Generic Lab Fish	4.84e-03	0.00e+00	1.20e-02	1.21e+00	1.42e+00	1.42e+00	1.49e+00	1.74e+00
Generic Lab Rat	5.40e-02	1.14e-01	8.47e-02	3.55e-01	3.42e-01	3.42e-01	3.61e-01	3.49e-01

- kD (kg-diet/kg-ww/d): chemical uptake rate constant from diet.
- kW (L-water/kg-ww/d): chemical uptake rate constant from water.
- kT (1/d): total (terminal) chemical elimination rate constant.
- BMFL (kg-lw/kg-lw; Diet): biomagnification factor calculated on the chemical concentrations in the total lipids (adipose and membrane lipid) of the consumer and its diet.
- BMFA (activity/activity; Diet): biomagnification factor calculated on a chemical activity (or fugacity for neutral chemicals) basis.
- BMFA (activity/activity; Ingesta): biomagnification factor calculated on a chemical activity (or fugacity for neutral chemicals) basis and normalizes exposure from the total quantity of ingested chemical (diet and drinking water).

*These values are temperature dependent. Temperature correction in EAS-E Suite relies on the enthalpies of phase change. Assumed default enthalpies of phase change are provided in the chemical information tab. However, the use of chemical specific values would be recommended.

Field predictions

This section reports predicted B-metrics for field organisms and food webs

Field Aquatic Bioaccumulation Predictions

Organism	BAF (L-total/kg-ww)	BAF (L-free/kg-ww)
Zooplankton	1.26e+05	1.17e+07
Benthic_invertebrate	1.88e+05	1.75e+07
Aquatic_invertebrate	2.51e+05	2.33e+07
Planktivorous_fish	3.32e+05	3.08e+07
Benthivorous_fish	4.23e+05	3.93e+07
Omnivorous_fish	5.26e+05	4.89e+07

- BAF (L-total/kg-ww): bioaccumulation factor calculated as the ratio of the chemical concentration in the organism (COrg) and the total chemical concentration in the water (CWtotal) at steady-state as COrg/CWtotal.
- BAF (L-free/kg-ww): bioaccumulation factor calculated as the ratio of the chemical concentration in the organism (COrg) and the freely dissolved (bioavailable) chemical concentration in the water (CWfree) at steady-state as COrg/CWfree.

Field Biomagnification Predictions

Worm-Shrew-Owl

Organism	BMFL (kg-lw/kg-lw; Diet)	BMFA (activity/activity; Diet)	BMFA (activity/activity; Ingesta)
Soil Invertebrate	NA	NA	NA
Common Shrew	1.95e+00	1.49e+00	1.49e+00
Robin	3.11e+00	2.52e+00	2.52e+00
Barn Owl, Tawny Owl	3.68e+00	3.30e+00	3.30e+00

Caribou-Wolf

Organism	BMFL (kg-lw/kg-lw; Diet)	BMFA (activity/activity; Diet)	BMFA (activity/activity; Ingesta)
Caribou, deer	7.86e-02	6.33e-02	6.33e-02
Wolf	2.69e+00	2.64e+00	2.64e+00

Aquatic

Organism	BMFL (kg-lw/kg-lw; Diet)	BMFA (activity/activity; Diet)	BMFA (activity/activity; Ingesta)
Phytoplankton	NA	NA	NA
Zooplankton	8.59e-01	2.04e+00	2.04e+00
Filter feeder (mussel)	1.38e+00	2.02e+00	2.02e+00
Freshwater Drum	1.02e+00	1.04e+00	1.04e+00
Alewife (< 4 yr)	8.93e-01	9.12e-01	9.12e-01
Yellow Perch	9.94e-01	9.48e-01	9.48e-01
Trout	1.06e+00	9.95e-01	9.95e-01
EaGull	4.79e+00	4.57e+00	4.57e+00
Otter	1.81e+00	1.72e+00	1.72e+00
Seal	6.84e-01	6.22e-01	6.22e-01
Polar Bear	7.59e+00	7.70e+00	7.70e+00

Agricultural and far-field human

Organism	BMFL (kg-lw/kg-lw; Diet)	BMFA (activity/activity; Diet)	BMFA (activity/activity; Ingesta)
Trout	1.06e+00	9.95e-01	9.95e-01
Beef	3.07e-02	2.39e-02	2.39e-02
Dairy	2.97e-02	2.31e-02	2.31e-02
Chicken, Turkey	1.39e-01	1.12e-01	1.12e-01
Hen	5.22e-02	4.21e-02	4.21e-02
Pork	1.92e-01	1.49e-01	1.49e-01
Human	3.65e-01	3.44e-01	3.44e-01

Chemical input

Symbol	Parameter	Unit	Value	Warning	Input.Type
Name	Chemical name		1,2-Bis(2,4,6-tribromo phenoxy)ethane		User Input
CAS	Chemical abstract service registration number		037853-59-1		User Input
SMILES	SMILES notation		Brc1cc(Br)cc(c1OCCOc1c(Br)cc(cc1Br)Br)Br		User Input
M	Molar mass	g/mol	687.64		User Input
Log KOW,N	log10 octanol-water partition ratio, neutral	L/L	8.16		User Input
Log KOA,N	log10 octanol-air partition ratio, neutral	L/L	14.952	Warning! Extreme values	User Input
Log KSlW,N	log10 storage lipid-water partition ratio, neutral	L/L	8.17		User Input
Log KMlW,N	log10 membrane lipid-water partition ratio, neutral	L/L	7.64		User Input
Log KPrW,N	log10 protein-water partition ratio, neutral	L/L	5.86		User Input
Log KSaW,N	log10 serum albumin-water partition ratio, neutral	L/L	6.4		User Input
BP	Boiling point	Celsius	552.025	Warning! Extreme values	User Input
MP	Melting point	Celsius	224.54		User Input
VP	Vapor pressure	Pa	4.57e-12		User Input
WatSol	Water solubility	mg/L	0.199		User Input

BioHL - fish	Biotransformation half-life fish (@ 0.01kg)	Hours	2004.05		User Input
BioHL - mammal	Biotransformation half-life mammal (@ 70kg)	Hours	823.67		User Input
EnvHL - outdoor air	Degradation half-life outdoor air	Hours	25.92		User Input
EnvHL - surface water	Degradation half-life surface water	Hours	14191.29		User Input
EnvHL - sediment	Degradation half-life sediment/solid	Hours	127721.61		User Input
EnvHL - indoor air	Degradation half-life indoor air	Hours	51.84		User Input
EnvHL - soil	Degradation half-life soil	Hours	28382.58		User Input
Scaling Factor KPrW	Scaling Log KPrW, A	Unitless	1		User Input
Scaling Factor KPrW	Scaling Log KPrW, B	Unitless	1		User Input
IRT	Intake rate threshold	mg/kg-ww/d	0.0028		User Input
IEC	Internal effect concentration□	mmol/kg-ww	5e-07		User Input
iTTC	Internal Threshold of Toxicological Concern	nmol/L-Blood	0.1		User Input

Glossary

Agency, the	HSE
B	Bioaccumulative
BAF	Bioaccumulation factor
BASF	Biota-sediment accumulation factor
BCF	Bioconcentration factor
BMF	Biomagnification factor
BFR	Brominated flame retardant
BTBPE	1,1'-[ethane-1,3,diylbisoxy]bis[2,4,6-tribromobenzene
CAS	Chemical Abstracts Service
CREED	Criteria for reporting and evaluating exposure datasets
DU	Downstream User
DUIN	Downstream User Import Notification
DT_{50}	Time taken for 50% decline in mass or concentration. If the decline is described by first order kinetics then this is also called the half-life
ECHA	European Chemicals Agency
EC	European Community
EU	European Union
GB	Great Britain
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	n-Octanol–water partition coefficient
MCCPs	Medium-chain chlorinated paraffins
MCL	Mandatory classification and labelling
MSC	Member State Committee
OC	Organic carbon
OECD	Organisation for Economic Cooperation and Development
P	Persistent
POP	Persistent organic pollutant
QSAR	Quantitative structure activity relationship
REACH	Registration, evaluation, authorisation and restriction of chemicals
SMILES	Simplified Molecular Input Line Entry System
SVHC	Substance of very high concern
TG	Test guideline

TMF	Trophic magnification factor
UK	United Kingdom
vB	Very bioaccumulative
vP	Very persistent
vPvB	Very persistent and very bioaccumulative

Further information

This publication is available on the HSE website here.

Published by the Health and Safety Executive 07/26.