

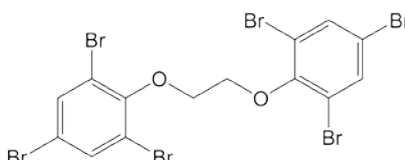
Regulatory Management Option Analysis (RMOA)

Authority: Spain

Date: 30/03/2022

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

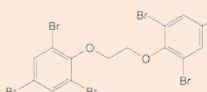
General structure:



Revision history

<i>Version</i>	<i>Date</i>	<i>Description</i>
1	30/03/2022	First RMOA document submitted.

Substances within this group:

EC/List number	CAS number	Substance name [and Substance name acronyms (*)]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)
253-692-3	37853-59-1	1,1'-[ethane-1,2-diylbis(oxy)]bis[2,4,6-tribromobenzene]		Not registered

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Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is voluntary, i.e., it is not part of the processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website¹.

¹ <https://echa.europa.eu/understanding-assessment-regulatory-needs>

Glossary

CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
PMT	Persistent, mobile in water and toxic
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the substance/group of substances

BTBPE is an additive brominated flame retardant used in thermoplastics and synthetic resins.

The substance is not registered under REACH. In the C&L inventory, there are 30 notifications for the substance, and hence, there could be use of the substance at low tonnages (< 1 t/y) in the EU. Furthermore, the substance may be present in articles imported into the EU.

BTBPE belongs to the group of “novel” brominated flame retardants, that have been developed as replacements to “legacy” brominated flame retardants, e.g. polybrominated diphenyl ethers (PBDEs), hexabromocyclododecane (HBDCD) and tetrabromobisphenol A (TBBA). BTBPE has been produced since 1970’s and it is used as a replacement especially to Octa-BDE (Renner 2004).

2 Justification for the need for regulatory risk management action at EU level

BTBPE appears to fulfil REACH Annex XIII criteria based on its vPvB properties, and therefore, it seems to fulfil the REACH Art. 57e criteria.

Although there are currently no registered uses of the substance in the EU, it can be used as a replacement to octa-BDE, which has been banned in the EU and is listed in the Annex A of the Stockholm POP Convention. Furthermore, as BTBPE is used in plastic products like computers, televisions, and mobile cell phones, it can be present in articles imported into the EU.

The substance is used as an additive flame retardant, and hence, exposure of the environment to the substance may occur during use and waste stage of articles containing the substance.

BTBPE has been found in various environmental compartments, biota, human serum and indoor dust in Europe (e.g. German Environmental Specimen Bank, 2022; Haglund et al, 2016; Karlsson et al 2007; Lee et al, 2016).

An inclusion of the substance in the REACH Candidate List based on its vPvB properties is considered an appropriate next risk management step, as it would clearly establish that the substance fulfils the Annex XIII criteria.

Inclusion in the Candidate List will also generate further information on the presence of the substance in articles through Substance in articles and SCIP notifications.

After inclusion of the substance in the Candidate List it could be further assessed whether a restriction would be the best further risk management measure.

As there are currently no uses registered under REACH, the substance would not receive high prioritisation score for inclusion into the Authorisation List according to ECHA’s current prioritisation approach. However, it could be prioritised in order to avoid regrettable substitution if it is considered that it may have similar uses with other substances in the Authorisation List. After inclusion in the Authorisation List, a restriction on the use in articles could be proposed according

to Art. 69(2) of REACH. However, this management option is considered not to be the most efficient as the substance is not registered under REACH.

Therefore, as the substance can be present in imported articles, restriction banning the use in articles, or certain types of articles according to article 68(1), could be the most efficient risk management measure. The information that will be obtained on the presence of the substance in articles as a consequence of the SVHC identification could help assessing whether an EU-wide risk exists and a restriction should be proposed.

As BTBPE seems to have long-range transport potential and there are also some indications on potential endocrine disrupting effects, the substance may also be a potential candidate for the inclusion in the Stockholm Convention on POPs. However, this should be further assessed after the inclusion of the substance in the Candidate List.

3 Conclusions and actions

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
EC 253-692-3	Inconclusive hazard for ED	Known or potential hazard for PBT/vPvB	The substance has no registered uses in the EU but it is likely to be present in articles imported into the EU. The articles are used by consumers. As the substance is used as an additive flame retardant especially in plastics, exposure of the environment during article service-life and waste stage can occur. The substance has been found in various environmental compartments, biota, human serum and indoor dust in Europe.	Need for EU RRM: Restriction Justification: The substance seems to fulfil the criteria of Art. 57e of REACH. It can be used as a replacement for other substances banned in the EU and it can be present in articles imported into the EU.	First step: SVHC identification Next steps (if hazard confirmed): Restriction

Annex 1: Harmonised classifications and self-classifications reported by registrants

Data consulted on 21 March 2022.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
253- 692-3	37853 -59-1	1,1'- [ethane- 1,2- diylbisoxy]b is[2,4,6- tribromobe nzene]	-	Not registered	Not classified [29 out of 30] Skin Irrit. 2 H315 [1 out of 30] Eye Irrit. 2 H319 [1 out of 30] STOT Single Exp. 3 H335, affected organs: Lungs, inhalation [1 out of 30]

Annex 2: Overview of uses based on information available in registration dossiers

Data consulted on 3 March 2022.

The substance is not registered under REACH. In the C&L inventory, there are 30 notifications for the substance, and hence, there could be use of the substance at low tonnages (< 1 t/y) in the EU.

Based on publicly available information, BTBPE is used as an additive flame retardant (e.g. PubChem), i.e. it is incorporated to polymeric matrices through physical mixing and does not chemically bind to them. It is marketed for use in acrylonitrile-butadiene-polystyrene (ABS), high-impact polystyrene (HIPS), thermoplastics, thermoset resins, polycarbonate, and coatings (WHO, 1997) and textiles (Lassen, 2006). BTBPE is especially efficient for applications in which thermal stability at high processing temperatures is important (Lassen, 2006). The applications known are in electric and electronic equipment, such as computers, televisions, and mobile cell phones (Thuresson 2004), and construction materials (sealant around window frames) available to consumers or in the domestic environment (EBRC, 2011). Furthermore, BTBPE may be available to consumers in preparations that need flame retardancy like adhesives used for construction (EBRC, 2011).

BTBPE belongs to the group of “novel” brominated flame retardants, that have been developed as replacements to “legacy” brominated flame retardants, e.g. polybrominated diphenyl ethers (PBDEs), hexabromocyclododecane (HBCD) and tetrabromobisphenol A (TBBA). BTBPE has been produced since 1970's and it is used as a replacement especially to Octa-BDE (Renner 2004) in ABS and it can also replace deca-BDE in some applications (Lassen et al., 2006).

Trade names of BTBPE include Firemaster 680, Firemaster FF 680 (FI 680, FA 680, FM 680) and MC-680.

BTBPE was included in the 2007 OECD List of high production volume chemicals meaning that it was produced or imported at levels greater than 1,000 tonnes per year in at least one member country/region (OECD, 2009). The substance is also included in the High production volume list in the United States (USEPA, 2022). The Great Lakes Chemical Corporation was the only US producer of BTBPE and production volumes in the USA were 4500–22,500 tons/year between 1986 and 1994 (Covaci et al., 2011), but decreased to 450–4500 tons/year in 1998 (CECBP, 2008, Covaci et al., 2011). The production stayed on this level until at least 2005 (CECBP, 2008). Current production amounts are missing. However, BTBPE is offered online by several suppliers, mostly Chinese (Chembid, 2022, Chemical Book 2022).

According to Ahi *et al.* (2008 from Lassen et al 2014), BTBPE was produced and used in China, but information on its production and consumption is not available.

The public information on EU-27 average net imports and exports of BTBPE for 2006-2007 is indicated as 82 t/y and 9.6 t/y, respectively (Lassen et al., 2014). No other information has been found.

Based on the information published in the SPIN Database², use of BTBPE at low quantities may have occurred in Sweden in year 2018. In the KemiStat³, which contains data on the chemical products and substances registered in the Swedish Product and Pesticide Registers in years 1993-2016, use of BTBPE is reported only for years 1997-1999 in the range of 2.2 to 6.6 tonnes per year. For years 2009-2016, according to KemiStat one product containing the substance was registered but the tonnage data is claimed confidential.

² <http://www.spin2000.net/spinmyphp/>

³ <https://apps.kemi.se/kemistat/start.aspx?sprak=e>

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data consulted on 3 March 2022.

Switzerland has performed a PBT evaluation for the substance under REACH and the evaluation has been discussed in ECHA's PBT Expert Group. The PBT EG provides informal scientific advice on questions related to the identification of PBT and vPvB properties of chemicals. This advice is non-binding and does not anticipate or interfere with decision-making under the REACH Regulation, which exclusively remains the responsibility of the competent bodies designated in the REACH Regulation. The substance was discussed at the 22nd and 24th PBT-EG meetings and the experts considered that the vPvB criteria are fulfilled.

There are no other completed or ongoing regulatory risk management activities for the substance.

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