

Justification for the selection of a substance for CoRAP inclusion

– UPDATE –

Substance Name (Public Name):	2,2',6,6'-tetrabromo-4,4'- isopropylidenediphenol
Chemical Group:	
EC Number:	201-236-9
CAS Number:	79-94-7
Submitted by:	Danish Environmental Protection Agency
Date:	20/03/2015

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

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1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Substance identity

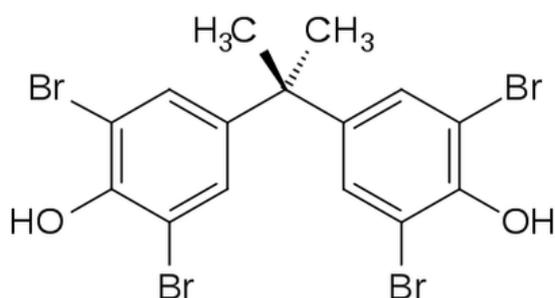
EC name:	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol
IUPAC name:	4,4'-propane-2,2-diylbis(2,6-dibromophenol)
Index number in Annex VI of the CLP Regulation	604-074-00-0
Molecular formula:	C ₁₅ H ₁₂ Br ₄ O ₂
Molecular weight or molecular weight range:	543.87
Synonyms/Trade names:	<p>Tetrabromobisphenol A; Phenol, 4,4'-isopropylidenebis[2,6-dibromo-(6CI,7CI,8CI); 2,2',6,6'-Tetrabromobisphenol A; 2,2-Bis(3,5-dibromo-4-hydroxyphenyl)propane; 2,2-Bis(4-hydroxy-3,5-dibromophenyl)propane; 3,3',5,5'-Tetrabromobisphenol A; 3,5,3',5'-Tetrabromobisphenol A; 4,4'-(1-Methylethylidene)bis[2,6-dibromophenol]; 4,4'-Isopropylidenebis[2,6-dibromophenol]; TBBA; TBBP-A; BA-59P; F-2016; F-2400; F-2400E; FR-1524 Fire Guard FG2000 Firemaster BP 4A Saytex RB-100 Tetrebrom Bromdian; Tetrabromodian; Tetrabromodiphenylolpropane</p>

Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:**1.2 Similar substances/grouping possibilities**

A number of TBBPA derivatives with different substituents on the aromatic rings are described in EFSA's report from 2011.

2 CLASSIFICATION AND LABELLING**2.1 Harmonised Classification in Annex VI of the CLP****Table 2: Harmonised classification**

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
604-074-00-0	Tetrabromo-bisphenol-A; Tetrabromo-4,4'-isopropylidene diphenol	201-236-9	79-94-7	Aquatic Acute 1	H400		
				Aquatic Chronic 1	H410		

2.2 Self classification

- In the registration
No further classification is proposed.

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

No further classification is proposed.

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa	
<input checked="" type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa	
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa	
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential	
<input checked="" type="checkbox"/> Industrial use <input checked="" type="checkbox"/> Professional use <input checked="" type="checkbox"/> Consumer use <input type="checkbox"/> Closed System			
<p>About 90% of the consumption of the substance in the EU is as reactive flame retardants for printed circuit boards, 5% was used as reactive flame retardants for other applications while about 5% was used as additive flame retardants. When used as a reactive flame retardant the substance becomes covalently bound in the polymer but might be present in trace concentrations as unreacted monomer.</p> <p>The main use of TBBPA as an additive in articles is for electrical & electronic equipment exterior casings. According to the registration dossier, the substance is used primarily as a non-reactive additive flame retardant in acrylonitrile butadiene styrene (ABS), which is a common thermoplastic used to make light and rigid moulded articles such as electrical & electronic equipment exterior casings. Furthermore, consumers may be exposed via larger plastic articles, toys or small plastic articles. TBBPA and its derivatives have also been found in e.g. textiles, building materials, paints and fillers.</p>			

4 OTHER COMPLETED/ONGOING REGULATORY PROCESSES THAT MAY AFFECT SUITABILITY FOR SUBSTANCE EVALUATION

<input checked="" type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input type="checkbox"/> Testing proposal	<input checked="" type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)

<input type="checkbox"/> Annex XIV (Authorisation)	<input checked="" type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
<p>TBBPA is on the List of Chemicals for Priority Action of the Oslo/Paris convention (for the Protection of the Marine Environment of the North-East Atlantic (OSPAR)). OSPAR classification is based on other and more restrictive criteria than the criteria found in EC regulations. A risk assessment under ESR was finalized in 2008.</p>	

5 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1 Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

5.2 Selection criteria met (why the substance qualifies for being in CoRAP)

- Fulfils criteria as CMR/ Suspected CMR
- Fulfils criteria as Sensitiser/ Suspected sensitiser
- Fulfils criteria as potential endocrine disrupter
- Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
- Fulfils criteria high (aggregated) tonnage (*tpa* > 1000)
- Fulfils exposure criteria
- Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R	<input checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input checked="" type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p><i>Human hazard</i></p> <p><i>In vitro</i> studies have demonstrated that TBBPA has a high potency in competing with T4 for binding to transthyretin (TTR) in animals, however no firm conclusions regarding the affinity of TBBP-A for TTR <i>in vivo</i> can be drawn from the limited data available. The main target for TBBPA human toxicity is thyroid hormone homeostasis, and most of the studies indicated a decrease in serum T4. In addition, weak estrogenic potency has been found, but TBBPA did not induce CYP1, CYP2B1 or CYP3A mRNA, protein and respective monooxygenase activities. The BMDL10 of 16 mg/kg bw for changes in circulating thyroid hormone levels could, in principle, be used as the basis to derive a human health based guidance value.</p> <p>Furthermore, Environment Canada/Health Canada reported that there is some recent evidence to suggest that TBBPA may be capable of disrupting normal functioning of the thyroid system in amphibians and fish, and enhancing immune system activity in marine bivalves. This may further support the findings already described.</p> <p>In addition, TBBPA can undergo debromination resulting in formation of Bisphenol A. The risk associated with Bisphenol A has been evaluated by EFSA in 2014. France recently submitted a dossier to ECHA for classifying Bisphenol A as toxic to reproduction cat. 1B.</p> <p>Furthermore, studies demonstrate the presence of TBBPA in breast milk and suggest that milk represents a substantial route of excretion for TBBPA in humans.</p> <p>The potential for endocrine disrupting effects and toxic effects on reproduction and development seems relevant in the justification for the selection of TBBPA for CoRAP inclusion.</p> <p><i>Environmental hazards</i></p> <p>The ecotoxicity data for TBBPA have been reviewed in detail in ECB (2008).</p> <p>Based on the available data there is not sufficient evidence to conclude that TBBPA meets the bioaccumulation criteria for B or vB. This conclusion is furthermore supported by the 2011 EFSA risk assessment of TBBPA where the Scientific Panel on Contaminants in the Food Chain and based on mammalian data concluded that "No significant retention or bioaccumulation was observed in tissues, including adipose tissue. Most of the TBBPA and/or corresponding metabolites are eliminated in the faeces, mainly through biliary excretion."</p>		

¹ CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)

Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)

Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

Based on currently available information TBBPA does not meet the REACH PBT criteria as concluded in the risk assessment report from 2008. However it is possible that it fulfils Article 57(f) as quasi PBT on the basis of its environmental toxicity and persistency.

As already described in the human health part some recent evidence suggests that TBBPA may be capable of disrupting normal functioning of the thyroid system in amphibians and fish, and enhancing immune system activity in marine bivalves.

The concerns regarding possible endocrine disrupting properties seem relevant in the justification for the selection of TBBPA for CoRAP inclusion.

Exposure

Consumers may be exposed via larger plastic articles, toys and small plastic articles.

The main use of TBBPA as an additive in articles is for electrical & electronic equipment exterior casings. However, TBBPA and derivatives were in 1997 also found in e.g. textiles, building materials, paints and fillers.

5.4 Preliminary indication of information that may need to be requested to clarify the concern

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input checked="" type="checkbox"/> Information on uses
<input checked="" type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

Depending on the outcome of the substance evaluation, it might be necessary to request further information on human toxicity, use and exposure, PBT properties and ED potential.

5.5 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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Depending on the outcome of the substance evaluation and a subsequent RMO analysis, it might be necessary to put forward a proposal for harmonized classification, restriction or inclusion on the candidate list.