# **Annex XV report**

# PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

**Substance Name:** 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (Tetrabromobisphenol-A;

TBBPA)

**EC Number:** 201-236-9

**CAS Number:** 79-94-7

Submitted by: Norwegian Environment Agency

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#### **ABBREVIATIONS**

ATP: Adaption to Technical Progress

CLP: Classification, labelling and packaging, Regulation (EC) No 1272/2008

EFSA: European Food Safety Authority ERC: Environmental release category OSH: Occupational Safety and Health

PC: Product category PROC: Process category

RAC: Risk Assessment Committee

RoHS: Restriction of Hazardous Substances in Electrical and Electronic Equipment

SU: Sector of use

SVHC: Substance of very high concern

TBBPA: 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol

TBBPS: Tetrabromobisphenol S

# PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

**Substance name:** 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol

**EC number:** 201-236-9

**CAS number:** 79-94-7

 The substance is proposed to be identified as a substance meeting the criteria of Article 57 (a) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class carcinogenicity category 1B.<sup>1</sup>

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

The Risk Assessment Committee (RAC) adopted its opinion on the proposal for harmonised classification and labelling (CLH) of 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol on 16 September 2021 and the substance is included in the draft 21st ATP to CLP. Once adopted, the resulting entry will be listed in Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 4 (the list of harmonised classification and labelling of hazardous substances) and classified in the hazard class carcinogenicity category 1B (hazard statement H350: "May cause cancer").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

Carcinogenicity category 1B in accordance with Article 57 (a) of REACH.

Registration dossiers submitted for the substance: Yes

<sup>&</sup>lt;sup>1</sup> Classification in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008.

# **PART I**

# **Justification**

# 1. Identity of the substance and physical and chemical properties

#### 1.1 Name and other identifiers of the substance

**Table 1: Substance identity** 

EC number:	201-236-9
EC name:	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol
CAS number (in the EC inventory):	79-94-7
CAS number:	79-94-7
IUPAC name:	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol
Index number in Annex VI of the CLP Regulation	604-074-00-0
Molecular formula:	C15H12Br4O2
Molecular weight range:	543.9 g/mol
Synonyms:	Tetrabromobisphenol A; 2,2-Bis(3,5-dibromo-4-hydroxyphenyl)propane; 2,2-bis(4-hydroxy-3,5-dibromophenyl)propane; 4,4'-isopropylidenebis(2,6-dibromophenol); 4,4'-(1-methylethylidene)bis(2,6-dibromophenol); 2,2',6,6'-tetrabromobisphenol A; 3,3',5,5'-tetrabromobisphenol A; 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; Tetrabromodiphenylpropane; TBBPA; TBBP-A

#### Structural formula:

#### 1.2 Composition of the substance

**Name:** 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol

**Description:** organic

Substance type: mono-constituent

Table 2: Constituents other than impurities/additives

Constituents	Typical concentration
2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A	≥80% w/w
EC no: 201-236-9	
CAS no: 79-94-7	

# 1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57(a) of the REACH Regulation.

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

Not relevant for the identification of the substance as SVHC in accordance with Article 57(a) of the REACH Regulation.

#### 1.5 Physicochemical properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (a) of the REACH Regulation.

## 2. Harmonised classification and labelling

The Risk Assessment Committee (RAC) adopted its opinion on the proposal for harmonised classification and labelling (CLH) of 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol on 16 September 2021 and the substance is included in the draft 21st ATP to CLP. Once adopted, the resulting entry will be listed in Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and classified in the hazard class carcinogenicity category 1B (hazard statement H350: "May cause cancer").

Table 3: Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008) from the RAC opinion (RAC, 2021)

Index	Chemical	EC No	CAS	Classif	Classification		Labelling		Spec.	Notes
No	name		No	Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram , Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)	Conc. Limits, M- factors and ATEs <sup>2</sup>	
604- 074- 00-0	2,2',6,6'- tetrabromo- 4,4'- isopropylidene diphenol; tetrabromobisp henol-A	201- 236-9	79- 94-7	Carc. 1B Aquatic Acute 1 Aquatic Chronic 1	H400	GHS08 GHS09 Dgr	H350 H410			

## 3. Environmental fate properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (a) of the REACH Regulation.

#### 4. Human health hazard assessment

Please see section 2 (Harmonised classification and labelling).

#### 5. Environmental hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (a) of the REACH Regulation.

<sup>&</sup>lt;sup>2</sup> Acute Toxicity Estimate

## 6. Conclusions on the SVHC Properties

#### 6.1 CMR assessment

The Risk Assessment Committee (RAC) adopted its opinion on the proposal for harmonised classification and labelling (CLH) of 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol on 16 September 2021 and the substance is included in the draft 21<sup>st</sup> ATP to CLP. Once adopted, the resulting entry will be listed in Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and classified in the hazard class carcinogenicity category 1B (hazard statement H350: "May cause cancer").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification in the hazard class:

carcinogenicity category 1B in accordance with Article 57 (a) of REACH.

#### 6.2 PBT and vPvB assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (a) of the REACH Regulation.

#### **6.3 Assessment under Article 57(f)**

Not relevant for the identification of the substance as SVHC in accordance with Article 57(a) of the REACH Regulation.

#### Part II

## 7. Registration and C&L notification status

#### 7.1 Registration status

#### **Table 4 Registration status**

From the ECHA dissemination site <sup>3</sup>			
Registrations	⊠ Full registration(s)     (Art. 10)		
Registrations	$\Box$ Intermediate registration(s)		
	(Art. 17 and/or 18)		

#### 7.2 CLP notification status

#### Table 5: CLP notifications

	CLP Notifications <sup>4</sup>
Number of aggregated notifications	12
Total number of notifiers	714

## 8. Total tonnage of the substance

#### **Table 6: Tonnage status**

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art  $18)^3$   $\geq 10~000$  to < 100~000 t/pa

#### 9. Information on uses of the substance

Tetrabromobisphenol-A (TBBPA) is a brominated flame retardant commonly used in epoxy coated circuit boards (Cannon et al., 2019), printed circuit boards, paper, and textiles (Dunnick et al., 2017). TBBPA has the largest worldwide production of any brominated flame retardant (Knudsen et al., 2014), with a global production volume over 100 000 tons per year in 2004

<sup>&</sup>lt;sup>3</sup> <u>https://echa.europa.eu/registration-dossier/-/registered-dossier/14760/1/2</u> (accessed 04.04.2022)

<sup>4</sup> C&L Inventory database, <a href="https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/72824">https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/72824</a> (accessed 04.04.2022)

(IARC, 2018). The International Bromine Council (BSEF) has also stated that TBBPA is the most widely used brominated flame retardant in the world<sup>5</sup>.

In a recent report developed under RoHS (RoHS Annex II Dossier for TBBPA Restriction proposal for substances in electrical and electronic equipment under RoHS), the use of TBBPA in electrical and electronic equipment (EEE) placed on the market, is reported as following: "The primary use of TBBP-A is as a precursor in the production of brominated epoxy resins that function as reactively flame-retarded substrate in printed wiring boards (PWB). It is also used as an additive flame retardant in thermoplastic EEE components, for example housings that consist of ABS plastic. The most recent available data (2014) on proportions for the different types of application indicate that ~90 % of TBBP-A are used for the production of FR4 PWB in form of a reactive flame retardant, while only 10 % are used as an additive flame retardant. However, according to Fraunhofer ITEM IPA, Wibbertmann & Hahn (2018), the available literature data on uses varies widely (~70-90 % reactive use)" (European Commission, 2021). More details on the global market are available in the same report (European Commission, 2021)

According to information available in ECHAs dissemination site and presented in the table below, TBBPA is used by consumers, in articles, by professional workers (widespread uses), in formulation or re-packing and at industrial sites. It is mainly used as intermediate and in polymers, and in flame retardant polymer articles.

Table 7: Uses

	Use(s)	Registered use (If not, specify the source of the information)	Use <u>likely</u> to be in the scope of Authorisation
Uses as intermediate		Yes	No
Formulation or repacking	Use as a reactive intermediate in manufacture of polymer resin ERC: 3, 5, 6c PROC: 0, 1, 2, 3, 4, 5, 8a, 8b, 9, 15 PC: 0, 19, 32  Use as an additive in the manufacture of polymer resin ERC: 3, 4, 5 PROC: 0, 4, 5, 8a, 8b, 9, 12, 14 PC: 32	Yes	No Yes
Uses at industrial sites	Use as a reactive intermediate in manufacture of polymer resin ERC: 0, 3, 5, 6c, PROC: 0, 1, 2, 3, 4, 5, 8a, 8b, 9, 15 PC: 0, 19, 32 SU: 0, 8, 10, 12	Yes	No

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<sup>&</sup>lt;sup>5</sup> Digital brochure from BSEF on 27 Jul 2020 "TBBPA in Electrical & Electronic Equipment": <a href="https://www.bsef.com/publications/tbbpa-in-electrical-electronic-equipment/">https://www.bsef.com/publications/tbbpa-in-electronic-equipment/</a>

Use as an additive un the manufacture of polymer resin		Yes
PROC: 0, 4, 5, 8a, 8b, 9, 12, 14 PC: 32 SU:0, 10, 12		
Manufacture of polymer articles from polymer resins containing additive flame retardant ERC: 5, 6d		Yes
21, 24 PC: 0, 32 SU: 12, 16, 17		No
ERC: 4 PROC: 0 PC: 32 SU: 12		Voc
Use in the manufacture of polymer resin ERC: 5 PROC: 4, 5, 8a, 8b, 9, 12 PC: 32 SU: 12		Yes
Professional and consumer use of flame retardant polymer articles ERC: 10a, 11a PROC: 21 SU: 19	Yes	Yes
Professional and consumer use of flame retardant polymer articles ERC: 10a, 11a PC: 32	Yes	Yes
Waste stage - Disposal to landfill ERC: 9b PC: 32		No
Professional use of flame retardant polymer articles AC: 2, 13 ERC: 10a, 11a PROC: 0	Yes	No
Consumer use of flame retardant polymer articles AC: 2, 13 ERC: 10a, 11a		No
Professional and consumer use of flame retardant polymer articles  AC: 2, 13  ERC: 10a, 11a  PROC: 21		No
	polymer resin ERC: 3, 4, 5 PROC: 0, 4, 5, 8a, 8b, 9, 12, 14 PC: 32 SU:0, 10, 12  Manufacture of polymer articles from polymer resins containing additive flame retardant ERC: 5, 6d PROC: 0, 4, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 15, 21, 24 PC: 0, 32 SU: 12, 16, 17  Waste stage ERC: 4 PROC: 0 PC: 32 SU: 12  Use in the manufacture of polymer resin ERC: 5 PROC: 4, 5, 8a, 8b, 9, 12 PC: 32 SU: 12  Professional and consumer use of flame retardant polymer articles ERC: 10a, 11a PROC: 21 SU: 19  Professional and consumer use of flame retardant polymer articles ERC: 10a, 11a PC: 32  Waste stage - Disposal to landfill ERC: 9b PC: 32  Professional use of flame retardant polymer articles AC: 2, 13 ERC: 10a, 11a PROC: 0  Consumer use of flame retardant polymer articles AC: 2, 13 ERC: 10a, 11a  Professional and consumer use of flame retardant polymer articles AC: 2, 13 ERC: 10a, 11a	polymer resin ERC: 3, 4, 5 PROC: 0, 4, 5, 8a, 8b, 9, 12, 14 PC: 32 SU:0, 10, 12  Manufacture of polymer articles from polymer resins containing additive flame retardant ERC: 5, 6d PROC: 0, 4, 5, 6, 7, 8a, 8b, 9, 10, 13, 14, 15, 21, 24 PC: 0, 32 SU: 12, 16, 17  Waste stage ERC: 4 PROC: 0 PC: 32 SU: 12  Use in the manufacture of polymer resin ERC: 5 PROC: 4, 5, 8a, 8b, 9, 12 PC: 32 SU: 12  Professional and consumer use of flame retardant polymer articles ERC: 10a, 11a PROC: 21 SU: 19  Professional and consumer use of flame retardant polymer articles ERC: 10a, 11a PC: 32  Waste stage – Disposal to landfill ERC: 9b PC: 32  Professional use of flame retardant polymer articles AC: 2, 13 ERC: 10a, 11a PROC: 0  Consumer use of flame retardant polymer articles AC: 2, 13 ERC: 10a, 11a Professional and consumer use of flame retardant polymer articles AC: 2, 13 ERC: 10a, 11a

Manufacture of polymer articles from polymer resins containing additive flame retardants AC: 2, 13	Yes
ERC: 5, 6d, 12a PROC: 0, 14, 21, 24	

## 10. Information on structure of the supply chain

No information available.

#### 11. Additional information

# 11.1 Substances with similar hazard and use profiles on the Candidate List

There are several bisphenols and brominated flame retardants in the Candidate List, however there are no other brominated bisphenols in the Candidate List, so no relevant information is available.

#### 11.2 Alternatives

Alternatives are described in the section on alternatives in the RoHS Annex II dossier for TBBPA (European Commission, 2021): "the discussion on alternatives addresses the two application areas - reactive applications in printed wiring boards (PWBs) and additive applications in plastic housings. In relation to epoxy resins (reactive use of TBBP-A in PWBs), it is understood that industry is actively investigating substitution strategies for brominated flame retardants. The stakeholder contributions to support this study mention that halogen-free PWB laminate materials were available. However, no concrete alternatives are proposed as they would not have all necessary safety approvals and greater percentages of the substitutes would be required within the products. In addition, ASD<sup>6</sup> states that "the substitutes are unlikely to perform sufficiently well when subjected to heat and vibration in high-stress environments" and TMC<sup>7</sup> points out that "they do not exist for all applications, especially in high-frequency circuitry."

Nonetheless, the most successful and already applied alternatives to TBBP-A in PWBs are phosphorus compounds like DOPO (9,10-Dihydro-9-oxa-10-phosphaphenanthrene-10-oxide), polyphosphates or metal phosphinates, from time to time in combination with inorganic synergists like ATH® or silica, bound to epoxy resins. Concerning DOPO, moderate human health concern is assumed but this compound and its derivates are expected to be highly environmental persistent. Commonly used substitutes for TBBP-A in housings for EEE (additive use) also include halogen free organic phosphorus compounds. The human health hazards of the organophosphate esters are estimated to be lower than those of TBBP-A though some substitution candidates still meet the PBT criteria regarding the environmental risks. In this area elimination is also possible

<sup>&</sup>lt;sup>6</sup> AeroSpace and Defence Industries Association of Europe (ASD)

<sup>&</sup>lt;sup>7</sup> Test and Measurement Coalition

<sup>8</sup> Aluminium trihydroxide (ATH)

through the substitution of polymers such as ABS<sup>9</sup> and HIPS<sup>10</sup> with polymers such as PC<sup>11</sup> and PPE<sup>12</sup>."

Tetrabromobisphenol S (TBBPS) was introduced into the market as a substitute to tetrabromobisphenol A (TBBPA) (Barańska et al., 2022). TBBPS is not registered under REACH<sup>13</sup>

#### 11.3 Existing EU legislation

From 1 March 2021, the use of halogenated flame retardants is not allowed in the enclosure and stand of electronic displays (halogenated flame retardant means a flame retardant that contains any halogen). The legal basis for the ban can be found in the Commission Regulation (EU) 2019/2021 of 1 October 2019 laying down ecodesign requirements for electronic displays pursuant to the Ecodesign Directive (2009/125/EC of the European Parliament and of the Council). The ban was questioned by The International Bromine Council (BSEF) which filed a legal challenge against the European Commission (Case T-113/20<sup>14</sup>). The European Court of Justice has rejected this challenge. At the same time, under the Sustainable Products Initiative, the Commission has proposed to widen the scope of the Ecodesign directive beyond energy related products and make it applicable to the broadest possible range of products (see the proposed Ecodesign for Sustainable Products Regulation, ESPR<sup>15</sup>).

The Directive 2011/65/EU (RoHS 2) lays down rules on the restriction of the use of hazardous substances in electrical and electronic equipment in the EU.

DG Environment requested a study to support the review of the list of restricted substances under RoHS 2 (pack 15; reported in European Commission, 2021). TBBPA was assessed as part of the study with a view of its possible future restriction.

The adoption by the European Commission of a delegated act for adding tetrabromobisphenol A in the list of restricted substances under RoHS is planned for the fourth quarter of 2022. (European Commission, 2022). According to EU Issue Tracker the work on the assessment is now temporarily on hold (in newsletter, 3 June 2022<sup>16</sup>).

The adoption of a harmonised classification under CLP in the hazard class carcinogenicity category 1B will trigger risk management measures under other pieces of EU legislations, e.g. the Occupational Safety and Health (OSH) Framework Directive and the Waste Framework Directive.

For references to REACH and CLP, see EU (2006; 2007; 2008 and 2009).

# 11.4 Previous assessments by other authorities/ongoing regulatory activities

ECHA: The Assessment of Regulatory needs on Tetrabromobisphenol A (TBBPA) and its derivatives that was published in December 2021 (ECHA, 2021)

<sup>&</sup>lt;sup>9</sup> Acrylonitrile Butadiene Styrene

<sup>&</sup>lt;sup>10</sup> High impact polystyrene

<sup>&</sup>lt;sup>11</sup> Polycarbonate

<sup>&</sup>lt;sup>12</sup> Polyphenylenether

<sup>&</sup>lt;sup>13</sup> Infocard accessed 9 August 2022 https://echa.europa.eu/en/substance-information/-/substanceinfo/100.049.575

<sup>&</sup>lt;sup>14</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62020TN0113

<sup>15</sup> https://environment.ec.europa.eu/publications/proposal-ecodesign-sustainable-products-regulation\_en

<sup>&</sup>lt;sup>16</sup> Newsletter from EU Issue Tracker: RoHS II Directive (Pack 15): Work Temporarily on Hold

RoHS: TBBPA has been assessed in a study to support the review of the list of restricted substances under RoHS 2 (pack 15) (reported in European Commission, 2021).

EFSA: Scientific Opinion on Tetrabromobisphenol A (TBBPA) and its derivatives in food (EFSA, 2011)

The ongoing substance evaluation for TBBPA to clarify ED and PBT/vPvB properties. Link to ECHA: <u>Substance evaluation - CoRAP - ECHA (europa.eu)</u>

Existing substances: EU RAR TBBPA (2008)

#### REFERENCES

#### References for Part I

Committee for Risk Assessment (RAC). Opinion proposing harmonised classification and labelling at EU level of 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; tetrabromobisphenol-A. 16 September 2021. Available at <a href="https://echa.europa.eu/documents/10162/ec6d02f7-6724-02c9-91e5-ea7beade2b31">https://echa.europa.eu/documents/10162/ec6d02f7-6724-02c9-91e5-ea7beade2b31</a>

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