

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: 6,6'-di-*tert*-butyl-2,2'-methylenedi-*p*-cresol

EC Number: 204-327-1

CAS Number: 119-47-1

Submitted by: Denmark

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ABBREVIATIONS

AC: Article category
ATE: Acute toxicity estimate
DBMC: 6,6'-di-*tert*-butyl-2,2'-methylenedi-*p*-cresol
ERC: Environmental release category
PC: Product category
PROC: Process category
RAC: Risk Assessment Committee
RMOA: Regulatory Management Option Analysis
SU: Sector end use

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Substance name: 6,6'-di-*tert*-butyl-2,2'-methylenedi-*p*-cresol [DBMC]

EC number: 204-327-1

CAS number: 119-47-1

- The substance is proposed to be identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class toxic for reproduction category 1B¹.

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

6,6'-di-*tert*-butyl-2,2'-methylenedi-*p*-cresol is covered by index number 604-095-00-5 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1B (H360F May damage fertility).

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

- Toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance: Yes

¹ Classification in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008.

PART I

Justification

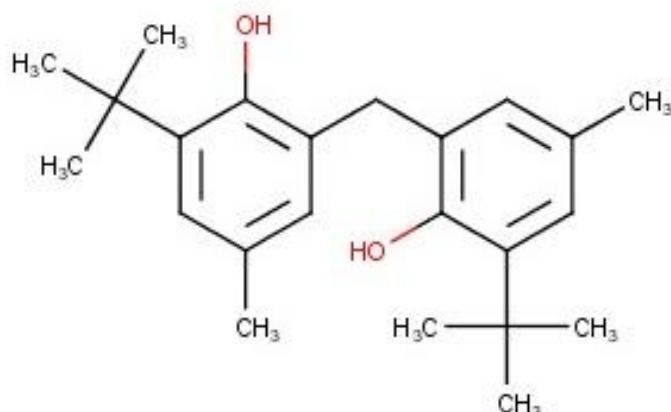
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	204-327-1
EC name:	6,6'-di- <i>tert</i> -butyl-2,2'-methylenedi- <i>p</i> -cresol
CAS number:	119-47-1
IUPAC name:	2,2'-methylenebis(4-methyl-6- <i>tert</i> -butylphenol) 2,2'-methylenebis(6- <i>tert</i> -butyl-4-methylphenol) 2,2'-methylenebis[6- <i>tert</i> -butyl- <i>p</i> -cresol] 2- <i>tert</i> -butyl-6-[(3- <i>tert</i> -butyl-2-hydroxy-5-methylphenyl)methyl]-4-methylphenol 6,6'-di- <i>tert</i> -butyl-2,2'-methylenedi- <i>p</i> -cresol
Index number in Annex VI of the CLP Regulation	604-095-00-5
Molecular formula:	C ₂₃ H ₃₂ O ₂
Molecular weight range:	340.50
Synonyms:	DBMC 2,2-methylen-bis-(4-methyl-6- <i>tert</i> .butylphenol) bis(2-hydroxy-3- <i>tert</i> -butyl-5-methylphenyl)methane bis(6-hydroxy-3-methyl-5- <i>tert</i> -butylphenyl)methane <i>p</i> -cresol, 2,2'-methylenebis(6- <i>tert</i> -butyl-) 2,2`-Methylene-bis(4-methyl-6- <i>tertiary</i> butyl phenol)

Structural formula²:



1.2 Composition of the substance

Name: 6,6'-di-*tert*-butyl-2,2'-methylenedi-*p*-cresol

Description: Solid white powder with a faint odour

Substance type: organic, mono-constituent substance

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 (c) 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 (c) of the REACH Regulation.

² Source: European Chemicals Agency: <https://echa.europa.eu/da/registration-dossier/-/registered-dossier/13380> (accessed 06/2021)

1.5 Physicochemical properties

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

2. Harmonised classification and labelling

6,6'-di-*tert*-butyl-2,2'-methylenedi-*p*-cresol is covered by Index number 604-095-00-5 in part 3 of Annex VI to the CLP Regulation as follows:

Table 2: Classification according to Annex VI, Table 3 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	Chemical name	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors and ATEs	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
604-095-00-5	6,6'-di- <i>tert</i> -butyl-2,2'-methylene di- <i>p</i> -cresol; [DBMC]	204-327-1	119-47-1	Repr. 1B	H360F	GHS08 Dgr	H360F			

3. Environmental fate properties

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

4. Human health hazard assessment

Please see Chapter 2 (Harmonised classification and labelling). The RAC opinion on the proposed harmonised classification and labelling as Repr. 1B (H360F) was adopted on 13 June 2019 by consensus. The substance was added to Table 3, Annex VI of CLP via Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 (EU, 2021).

5. Environmental hazard assessment

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

6. Conclusions on the SVHC Properties

6.1 CMR assessment

6,6'-di-*tert*-butyl-2,2'-methylenedi-*p*-cresol is covered by index number 604-095-00-5 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1B (H360F May damage fertility).

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

- toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

6.2 PBT and vPvB assessment

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

Part II

7. Registration and C&L notification status

7.1 Registration status

Table 3 Registration status

From the ECHA dissemination site ³	
Registrations	<input checked="" type="checkbox"/> Full registration(s) (Art. 10) <input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)

7.2 CLP notification status

Table 4: CLP notifications

	CLP Notifications ⁴
Number of aggregated notifications	29
Total number of notifiers	810

8. Total tonnage of the substance

Table 5: Tonnage status

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18) ⁵	1,000-10,000 tpa
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³ Source: European Chemicals Agency, <https://echa.europa.eu/da/registration-dossier/-/registered-dossier/13380> (accessed 06/2021)

⁴ Source: C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed 06/2021)

⁵ Source: European Chemicals Agency, <https://echa.europa.eu/da/registration-dossier/-/registered-dossier/13380> (accessed 06/2021)

9. Information on uses of the substance

The registered substance is used by consumers and professionals in adhesives and sealants, lubricants and greases, fuels, hydraulic fluids, polymers, metal working fluids and as a laboratory chemical. This substance is used for the manufacture of rubber (e.g. tyres, shoes, toys) and plastic products (e.g. food packaging and storage, toys, mobile phones). The registered uses and the contributing activities for DBMC are reported in the table below.

Table 6: Uses

	Use(s)	Contributing activities	Use <u>likely</u> to be in the scope of Authorisation
Manufacture	Formulation in rubber and non-rubber polymers (PC32) Manufacturing	ERC1 PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC9	Yes
	Manufacturing of DBMC	ERC1 PROC1, PROC2, PROC3, PROC4, PROC8b, PROC9	
Formulation or repacking	Formulation in rubber and non-rubber polymers (PC32)	ERC3 PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9 PC32	Yes
	Formulation and industrial uses in PC15, 24 and 25	ERC2 PROC1, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9, PROC10, PROC13 PC17, PC24, PC25	
	Formulation of liquid lubricant mixtures	ERC2 PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9 PC17, PC24, PC25	
	Formulation (production of premixes for further formulation in various product categories)	ERC2 PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9 PC1, PC13, PC17, PC24, PC25, PC32	
	Formulation of liquid rubber mixtures for tyre production	ERC2 PROC3, PROC5, PROC8a, PROC8b, PROC21 PC32	
	Formulation in PC13	ERC2 PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9 PC13	

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	Formulation in PC1	ERC3 PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9 PC1	
	Formulation of solid mixtures for rubber (non-tyre) and non-rubber plastic materials	ERC3 PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC21 PC32	
	Formulation of solid mixtures for tyre production	ERC3 PROC3, PROC5, PROC8b, PROC21 PC32	
	Formulation of liquid mixtures like adhesives, inks.	ERC2 PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9 PC1, PC18	
	Formulation into solid materials	ERC3 PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC14, PROC21 PC1, PC24	
	Formulation in PC1	ERC3 PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9 PC1	
	Formulation and industrial uses in in PC 17, 24 and 25	ERC2 PROC1, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9, PROC10, PROC13 PC17, PC24, PC25	
	Formulation of liquid rubber (non-tyre) and non-rubber plastic mixtures	ERC2 PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b PC32	
	Liquid formulation in Fuels	ERC2 PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b PC13	
	Formulation in PC13	ERC2 PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9 PC13	

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Uses at industrial sites	Industrial use in adhesives and inks	ERC5 PROC1, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9, PROC10, PROC13, PROC15 PC1 SU0	Yes
	Industrial use in lubricants and similar products	ERC4, ERC7 PROC1, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9, PROC10, PROC13, PROC15 PC17, PC24, PC25	
	Use as laboratory chemical (PC21)	ERC0 PROC15 PC21 SU0, SU3, SU22	
	Industrial use in fuels	ERC4 PROC5, PROC8a, PROC8b, PROC9, PROC15 PC13	
	Industrial use for tyre production	ERC5 PROC14, PROC21 SU11, SU12	
	Use as laboratory chemical (PC21)	ERC0 PROC15, PROC21	
	Industrial use for production of rubber (non-tyre) and non-rubber polymers	ERC5 PROC2, PROC3, PROC5, PROC8b, PROC9, PROC10, PROC13, PROC14, PROC15, PROC21 PC32 SU11, SU12	
Uses by professional workers	Professional use in rubber and non-rubber polymers	ERC8f PROC8a, PROC8b, PROC14, PROC15, PROC21 PC32 SU11, SU12	Yes
	Professional use in adhesives and inks	ERC8f PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC10, PROC13, PROC15 PC1	
	Professional use in lubricants and similar products	ERC8a, ERC8d PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC10, PROC13, PROC15 PC17, PC24, PC25	

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	Professional use in fuels	ERC8d PROC5, PROC8a, PROC8b, PROC9, PROC15 PC13	
	Professional use in PC17, PC24 and PC25	ERC8a, ERC8d, ERC9a, ERC9b PROC1, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9, PROC10, PROC13 PC17, PC24, PC25	
Consumer uses	Consumer use in fuels	ERC8a, ERC8d, PC13	Yes
	Consumer use in lubricants and similar products containing the substance	ERC8a, ERC8d, ERC9a, ERC9b PC24	
	Consumer use in adhesives containing the substance	ERC8f PC1	
	Consumer use in PC17, PC24 and PC25	ERC8a, ERC8d, ERC9a, ERC9b PC17, PC24, PC25	
Article service life	Service life of tyres at industrial sites	AC10 ERC12c PROC21,	Yes
	Service life of tyres at professional sites	AC10 ERC11a PROC 21	
	Service life of rubber (non-tyre) and non-rubber plastic articles at professional sites	AC 10, AC 13 ERC10a, ERC11a PROC 21	
	Service life of rubber (non-tyre) and non-rubber plastic articles at industrial sites	AC 10, AC 13 ERC12c PROC 21	
	Formulation in rubber and non-rubber polymers	AC 10, AC 13 ERC3	
	Service life of rubber (non-tyre) and non-rubber plastic articles for consumers	AC10g, AC13, AC13d ERC10a, ERC11a	
	Service life of tyres for the general population	AC10, AC10g ERC10a	

ERC 0: Other: not relevant, since only a small amount is used; ERC2: Formulation into mixture; ERC3: Formulation into solid matrix; ERC4: Use of non-reactive processing aid at industrial site (no inclusion into or onto article); ERC5: Use at industrial site leading to inclusion into/onto article; ERC7: Use of functional fluid at industrial site; ERC8a: Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor); ERC8d: Widespread use of non-reactive processing aid (no inclusion into or onto article, outdoor); ERC8f: Widespread use leading to inclusion into/onto article (outdoor); ERC9a: Widespread use of functional fluid (indoor); ERC9b: Widespread use of functional fluid (outdoor); ERC10a: Widespread use of articles with low

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release (outdoor); ERC11a: Widespread use of articles with low release (indoor); ERC12c: Use of articles at industrial sites with low release;

PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions; PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions; PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions; PROC 4: Chemical production where opportunity for exposure arises; PROC 5: Mixing or blending in batch processes; PROC 7: Industrial spraying PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities; PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities; PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing); PROC 10: Roller application or brushing; PROC 13: Treatment of articles by dipping and pouring; PROC 14: Tableting, compression, extrusion, pelletisation, granulation; PROC 15: Use as laboratory reagent; PROC 21: Low energy manipulation of substances bound in materials and/or articles; PROC 21: Low energy manipulation of substances bound in materials and/or articles

AC: AC10: Rubber articles; AC10g: Other rubber articles; AC 13: Plastic articles; AC13d: Plastic articles: Articles intended for food contact

PC: PC 1: Adhesives, sealants PC 13: Fuels; PC15: Non-metal-surface treatment products; PC 17: Hydraulic fluids Fuels; PC 18: Ink and toners; PC 24: Lubricants, greases, release products; PC 25: Metal working fluids; PC 32: Polymer preparations and compounds

SU 0: Other: Uses of substances as such or in preparations at industrial sites; SU 11: Manufacture of rubber products; SU 12: Manufacture of plastics products, including compounding and conversion, SU3, SU22 Industrial/Professional uses: Public domain

10. Information on structure of the supply chain

There are three active registrants for DBMC. Information on the structure of the supply chain has not been assessed.

11. Additional information

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

There are no similar substances on the Candidate List.

11.2 Alternatives

The availability of alternatives has not been assessed.

11.3 Existing EU legislation

In addition to the classification of DBMC in the CLP Regulation (EU, 2021; EU, 2008), DBMC is regulated in the EU legislation: Commission Regulation on materials and articles intended to come into contact with food (EU No 10/2011), which sets out safety requirements for plastic materials and restriction conditions for some substances on the positive list. DBMC is on the positive list with a SML(T) (total specific migration limit) of 1.5 mg/kg food. SML(T) is the maximum permitted sum of particular substances that can migrate from a food packaging material or food container into food or food simulants

expressed as total of moiety of the substances indicated. It is a safety limit derived from toxicological studies. The SML(T) for DBMC refers to the sum of DBMC and 2,2'-methylene bis(4-ethyl-6-tert-butylphenol), CAS No. 88-24-4), and may lead to a reduced exposure via food.

11.4 Previous assessments by other authorities/ongoing regulatory activities

A Regulatory Management Option Analysis (RMOA) on the substance was prepared by Denmark in June 2021 concluding that identification of DBMC as a SVHC would be appropriate as the substance fulfils the criteria of REACH Article 57 (c)⁶.

⁶ Source: European Chemicals Agency, <https://echa.europa.eu/documents/10162/38e8164d-0337-856d-dd47-145d19a7a67c> (accessed 06/2021)

REFERENCES

References for Part I

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- EU (2008): Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packing of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L353: 1-1355.
- EU (2021): Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 (EU, 2021), <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0849&from=EN>
- RAC (2018): CLH REPORT FOR 6,6'-DI-TERT-BUTYL-2,2'-METHYLENEDI-P-CRESOL (DBMC), <https://echa.europa.eu/documents/10162/d96611de-d60f-4aec-8335-250e7338d9c3> (accessed 06/2021)

References for Part II

- ECHA (2021): 6,6'-di-*tert*-butyl-2,2'-methylenedi-*p*-cresol. Information on registered substances, published on ECHA's website <https://echa.europa.eu/da/registration-dossier/-/registered-dossier/13380> (accessed 06/2021)
- ECHA (2021): C&L Inventory, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed 06/2021)
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EU 2011: Plastic Food Contact Materials (FCMs) per Regulation 10/2011/EU (Union List), Directive 282/2008/EC on Recycled Plastic FCMs, 28 March 2008, amended by Regulation 2015/1906/EU, 23 October 2015

EU (2021): Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 (EU, 2021). <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0849&from=EN>