

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

EC Number: 204-327-1

CAS Number: 119-47-1

**SUPPORT DOCUMENT FOR IDENTIFICATION OF
6,6'-DI-*TERT*-BUTYL-2,2'-METHYLENEDI-*P*-CRESOL
AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE
OF ITS TOXIC FOR REPRODUCTION (ARTICLE 57C)
PROPERTIES**

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ABBREVIATIONS

DBMC: 6,6'-di-*tert*-butyl-2,2'-methylenedi-*p*-cresol
RAC: Risk Assessment Committee

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 [DBMC]

EC number: 204-327-1

CAS number: 119-47-1

- The substance is 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

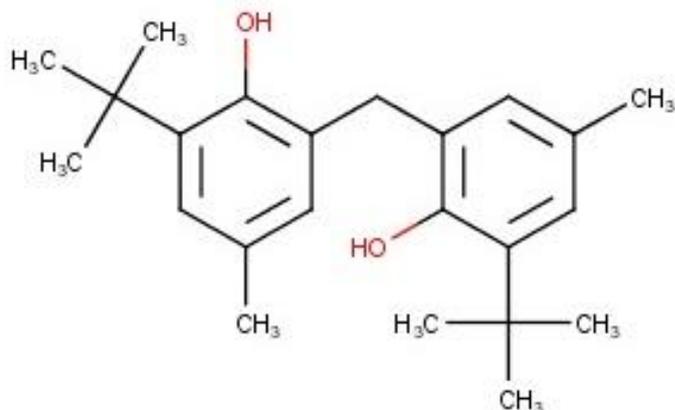
1. Identity of the substance and physical and chemical properties

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.

References

- 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)
- EU (2006): Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official Journal of the European Union, L396: 1-849.
- 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)