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
Date: 5 August 2021
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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
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 [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 1B.

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>
<thead>
<tr>
<th>Substance identity</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EC number:</strong></td>
<td>204-327-1</td>
</tr>
<tr>
<td><strong>EC name:</strong></td>
<td>6,6’-di-tert-butyl-2,2’-methylenedi-p-cresol</td>
</tr>
<tr>
<td><strong>CAS number:</strong></td>
<td>119-47-1</td>
</tr>
</tbody>
</table>
| **IUPAC name:**    | 2,2’-methylenebis(4-methyl-6-tert-butylylphenol)  
2,2’-methylenebis(6-tert-butyl-4-methylphenol)  
2,2’-methylenebis[6-tert-butyl-p-cresol]  
2-tert-butyl-6-[(3-tert-butyl-2-hydroxy-5-methylphenyl)methyl]-4-methylphenol  
6,6’-di-tert-butyl-2,2’-methylenedi-p-cresol |
| **Index number in Annex VI of the CLP Regulation** | 604-095-00-5 |
| **Molecular formula:** | C\textsubscript{23}H\textsubscript{32}O\textsubscript{2} |
| **Molecular weight range:** | 340.50 |
| **Synonyms:**      | DBMC  
2,2-methylen-bis-(4-methyl-6-tert butylphenol)  
bis(2-hydroxy-3-tert-butyl-5-methylphenyl)methane  
bis(6-hydroxy-3-methyl-5-tert-butylphenyl)methane p-cresol, 2,2’-methylenebis(6-tert-butyl-)  
2,2’-Methylene-bis(4-methyl-6-tertiary butyl phenol) |
ANNEX XV – IDENTIFICATION OF 6,6′-DI-TERT-BUTYL-2,2′-METHYLENEDI-P-CRESOL AS SVHC

Structural formula²:

![Structural formula image]

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.

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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>
<thead>
<tr>
<th>Index No</th>
<th>Chemical name</th>
<th>EC No</th>
<th>CAS No</th>
<th>Classification</th>
<th>Labelling</th>
<th>Spec. Conc. Limits, M-factors and ATEs</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>604-095-00-5</td>
<td>6,6’-di-tert-butyl-2,2’-methylene di-p-cresol; [DBMC]</td>
<td>204-327-1</td>
<td>119-47-1</td>
<td>Repr. 1B</td>
<td>H360F</td>
<td>GHS08 Dgr</td>
<td>H360F</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>From the ECHA dissemination site³</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Registrations</td>
<td>☑ Full registration(s) (Art. 10)</td>
</tr>
<tr>
<td></td>
<td>☐ Intermediate registration(s) (Art. 17 and/or 18)</td>
</tr>
</tbody>
</table>

7.2 CLP notification status

Table 4: CLP notifications

<table>
<thead>
<tr>
<th>Number of aggregated notifications</th>
<th>CLP Notifications⁴</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>29</td>
</tr>
<tr>
<td>Total number of notifiers</td>
<td>810</td>
</tr>
</tbody>
</table>

8. Total tonnage of the substance

Table 5: Tonnage status

<table>
<thead>
<tr>
<th>Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18)⁵</th>
<th>1,000-10,000 tpa</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Use(s)</th>
<th>Contributing activities</th>
<th>Use likely to be in the scope of Authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacture</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formulation in rubber and non-rubber polymers (PC32)</td>
<td>ERC1, PROC1, PROC2, PROC3, PROC4, PROC8a, PROC8b, PROC9</td>
<td>Yes</td>
</tr>
<tr>
<td>Manufacturing of DBMC</td>
<td>ERC1, PROC1, PROC2, PROC3, PROC4, PROC8b, PROC9</td>
<td></td>
</tr>
<tr>
<td><strong>Formulation or repacking</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formulation in rubber and non-rubber polymers (PC32)</td>
<td>ERC3, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PC32</td>
<td>Yes</td>
</tr>
<tr>
<td>Formulation and industrial uses in PC15, 24 and 25</td>
<td>ERC2, PROC1, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9, PROC10, PROC13, PC17, PC24, PC25</td>
<td></td>
</tr>
<tr>
<td>Formulation of liquid lubricant mixtures</td>
<td>ERC2, PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PC17, PC24, PC25</td>
<td></td>
</tr>
<tr>
<td>Formulation (production of premixes for further formulation in various product categories)</td>
<td>ERC2, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PC1, PC13, PC17, PC24, PC25, PC32</td>
<td></td>
</tr>
<tr>
<td>Formulation of liquid rubber mixtures for tyre production</td>
<td>ERC2, PROC3, PROC5, PROC8a, PROC8b, PROC21, PC32</td>
<td></td>
</tr>
<tr>
<td>Formulation in PC13</td>
<td>ERC2, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PC13</td>
<td></td>
</tr>
<tr>
<td>Formulation in PC1</td>
<td>ERC3</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>Formulation of solid mixtures for rubber (non-tyre) and non-rubber plastic materials</td>
<td>PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9 PC1</td>
<td></td>
</tr>
<tr>
<td>Formulation of solid mixtures for tyre production</td>
<td>ERC3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PROC3, PROC5, PROC8b, PROC21 PC32</td>
<td></td>
</tr>
<tr>
<td>Formulation of liquid mixtures like adhesives, inks.</td>
<td>ERC2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9 PC1, PC18</td>
<td></td>
</tr>
<tr>
<td>Formulation into solid materials</td>
<td>ERC3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9 PC1, PC24</td>
<td></td>
</tr>
<tr>
<td>Formulation in PC1</td>
<td>ERC3</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9 PC1</td>
<td></td>
</tr>
<tr>
<td>Formulation and industrial uses in PC 17, 24 and 25</td>
<td>ERC2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PROC1, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9, PROC10, PROC13 PC17, PC24, PC25</td>
<td></td>
</tr>
<tr>
<td>Formulation of liquid rubber (non-tyre) and non-rubber plastic mixtures</td>
<td>ERC2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b PC32</td>
<td></td>
</tr>
<tr>
<td>Liquid formulation in Fuels</td>
<td>ERC2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b PC13</td>
<td></td>
</tr>
<tr>
<td>Formulation in PC13</td>
<td>ERC2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9 PC13</td>
<td></td>
</tr>
<tr>
<td>Uses at industrial sites</td>
<td>Uses by professional workers</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>-----------------------------</td>
<td>---</td>
</tr>
<tr>
<td><strong>Industrial use in adhesives and inks</strong></td>
<td><strong>Industrial use in rubbers</strong></td>
<td><strong>Yes</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Industrial use in lubricants and similar products</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Use as laboratory chemical (PC21)</strong></td>
<td><strong>Professional use in rubbers</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Industrial use in fuels</strong></td>
<td><strong>Professional use in rubbers</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Industrial use for tyre production</strong></td>
<td><strong>Professional use in rubbers</strong></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Use as laboratory chemical (PC21)</strong></td>
<td><strong>Professional use in rubbers</strong></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Industrial use for production of rubber (non-tyre) and non-rubber polymers</strong></td>
<td><strong>Professional use in rubbers</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**ANNEX XV – IDENTIFICATION OF 6,6’-DI-TERT-BUTYL-2,2’-METHYLENEDI-P-CRESOL AS SVHC**

- **ERC5**
  - PROC1, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9, PROC10, PROC13, PROC15
  - PC1
  - SU0

- **ERC4, ERC7**
  - PROC1, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9, PROC10, PROC13, PROC15
  - PC17, PC24, PC25

- **ERC0**
  - PROC15
  - SU0, SU3, SU22

- **ERC4**
  - PROC5, PROC8a, PROC8b, PROC9, PROC15
  - PC13

- **ERC5**
  - PROC14, PROC21
  - SU11, SU12

- **ERC0**
  - PROC15, PROC21
  - PC32

- **ERC4**
  - PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC10, PROC13, PROC15
  - PC17, PC24, PC25

- **ERC5**
  - PROC2, PROC3, PROC5, PROC8b, PROC9, PROC10, PROC13, PROC14, PROC15, PROC21
  - PC32
  - SU11, SU12

- **ERC8f**
  - PROC8a, PROC8b, PROC14, PROC15, PROC21
  - PC32
  - SU11, SU12

- **ERC8f**
  - PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC10, PROC13, PROC15
  - PC1

- **ERC8a, ERC8d**
  - PROC1, PROC2, PROC3, PROC4, PROC5, PROC8a, PROC8b, PROC9, PROC10, PROC13, PROC15
  - PC17, PC24, PC25
### Professional use in fuels
- ERC8a, ERC8b, ERC9a, ERC9b<br>- PROC1, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9, PROC10, PROC13<br>- PC13, PC17, PC24, PC25

### Professional use in PC17, PC24 and PC25
- ERC8a, ERC8d, ERC9a, ERC9b<br>- PROC1, PROC2, PROC3, PROC4, PROC5, PROC7, PROC8a, PROC8b, PROC9, PROC10, PROC13<br>- PC17, PC24, PC25

### Consumer use in fuels
- ERC8a, ERC8d, PC13
- ERC8a, ERC8d, ERC9a, ERC9b PC24
- ERC8f<br>- PC1
- ERC8a, ERC8d, ERC9a, ERC9b PC17, PC24, PC25

### Consumer use in PC17, PC24 and PC25
- AC10<br>- ERC10a, ERC11a<br>- AC 10, AC 13, ERC10a, ERC11a PROC 21

### Service life of tyres at industrial sites
- AC10<br>- ERC12c PROC21

### Service life of tyres at professional sites
- AC10<br>- ERC11a PROC21

### Service life of rubber (non-tyre) and non-rubber plastic articles at professional sites
- AC10, AC 13, ERC12c PROC 21

### Service life of rubber (non-tyre) and non-rubber plastic articles at industrial sites
- AC10, AC 13, ERC12c PROC 21

### Formulation in rubber and non-rubber polymers
- AC10, 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...
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

---

REFERENCES

References for Part I


References for Part II


