

**Risk Management Option Analysis Conclusion Document**

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

**EC Number:** 204-327-1

**CAS Number:** 119-47-1

**Authority:** Denmark

**Date:** 14/6 2021

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# Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[[1]](#footnote-1).

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

### OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

The substance, 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol (DBMC) has been through a substance evaluation (SEV) and subsequently a proposal for a harmonised classification as Repr. 1B (H360F) has been adopted and included in the next ATP to CLP (17. ATP).

The RMOA points out that it may be appropriate to update the specific migration limit value for a group of substances, which includes DBMC (SML T (T= no. 13)) for DBMC in the EU legislation, Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

### CONCLUSION OF RMOA

The conclusion of the RMOA is based on the REACH and CLP data as well as other available relevant information, where appropriate.

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| **Conclusions** | **Tick box** |
| Need for follow-up regulatory action at EU level: |  x |
| *Harmonised classification and labelling* |  |
| *Identification as SVHC (authorisation)* | x |
| *Restriction under REACH* |  |
| *Other EU-wide regulatory measures* | x |
| Need for action other than EU regulatory action |  |
| No action needed at this time |  |

### Need for follow-up regulatory action at EU level

The need for further regulatory actions at EU level is based on the recent harmonised classification of DBMC as a reproductive toxicant in category 1B.

The Danish EPA has as a follow-up elaborated a RMOA for DBMC. The RMOA concludes that it would be appropriate as a next regulatory risk management (RRM) step to identify DBMC as a Substance of Very High Concern (SVHC) according to REACH Article 57c, and subsequently to include DBMC in Annex XIV of REACH.

With the harmonised classification of DBMC as a reproductive toxicant in category 1B, DBMC fulfils the criteria as a SVHC according to REACH Art. 57c.

DMBC has many uses, for instance, as an additive in e.g. polymers, and it is permitted in food contact materials. The substance may therefore also be permitted in drinking water installations.

Therefore, in order to further protect human health against DBMC it might be appropriate to update the specific migration limit value for DBMC in the EU legislation for food contact materials, which also relates to other regulations for uses of DBMC in drinking water installations.

### Harmonised classification and labelling

Not relevant as a harmonised classification as Repr. 1B (H360F) has recently been adopted, re. Index No. 604-095- 00-5.

### Identification as a substance of very high concern, SVHC (first step towards authorisation)

DBMC has recently been classified and labelled as a reproductive toxicant in category 1B according to the CLP regulation, and thus DBMC fulfils the criteria as a SVHC according to REACH Art. 57c.

As a next regulatory risk management step, it would be appropriate to identify DBMC as a SVHC to protect human health. This next step is relevant as DBMC is used in many processes with a wide range of uses, among others in the manufacture of rubber products and plastic, and it can be released from adhesives and sealants, lubricants and greases, fuels, hydraulic fluids etc.

Suppliers of articles, which contain substances on the Candidate List in a concentration above 0.1% w/w have to provide sufficient information to allow safe use of the article within 45 days of the receipt of the request. Furthermore, if articles contain a substance on the Candidate List, the EU and EEA producers or importers of those articles shall notify ECHA if the substance is present in those articles above a concentration of 0.1% w/w and in quantities totalling over one tonne per producer or importer per year. The notifications must be submitted no later than 6 months after the inclusion in the Candidate List.

EU and EEA suppliers of substances on the Candidate List (supplied either on their own or in mixtures) also shall provide their customers with a safety data sheet. The information and recommendations in the safety data sheet shall be used to minimise exposures and emissions to humans and to the environment.

The SVHC identification will result in obligations to communicate safe use information in the supply chain and obligations to respond to consumer requests on DBMC. These obligations not only refer to DBMC on its own or in mixtures but also to the presence of DBMC in articles.

### Restriction under REACH

Due to the wide dispersive use in different types of products, which also includes several types of consumer products, and the high tonnage, it may be a relevant next regulatory risk management step after uptake on the candidate list also to include DBMC in Annex XIV, as this RMM would regulate the uses of the substance and push towards substitution.

EU-wide risk has not been proven.

The Danish CA has no information on feasible alternatives to DBMC.

### Other Union-wide regulatory measures

*Food contact material*

DBMC has a specific migration limit (SML T) of 1.5 mg/kg food in Commission Regulation on materials and articles intended to come into contact with food (EU No 10/2011. The SML T refers to the sum of DBMC and 2,2′-methylene bis(4-ethyl-6-tert-butylphenol), CAS No. 88-24-4), and may reduce exposure via food. With the classification of DBMC as Rep 1B, it should be evaluated if the SML should be revised accordingly by EFSA in the Regulation (EC No. 10/2011). This revision could be a relevant tool for managing the risk of DBMC migrating from rubber and/or plastic in food contact materials.

Consequently, reduction of the SML for DBMC in plastics for food contact materials may also reduce exposure to DBMC from drinking water, as SMLs from the Regulation (EC No. 10/2011) are also used in drinking water regulations.

### Need for action other than EU regulatory action

Not relevant.

### No action needed at this time

Not relevant.

### TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

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| **Follow-up action** | **Date for follow-up**  | **Actor** |
| e.g. Annex XV dossier for restrictions | To be decided  | To be decided |
| SVHC for DBMC | August/2021 | Denmark |

1. For more information on the SVHC Roadmap: <http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation> [↑](#footnote-ref-1)