



Danish Ministry of the Environment
Environmental Protection Agency

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol

EC Number: 204-327-1

CAS Number: 119-47-1

Authority: Denmark

Date: 22/03/2016

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

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1 IDENTITY OF THE SUBSTANCE

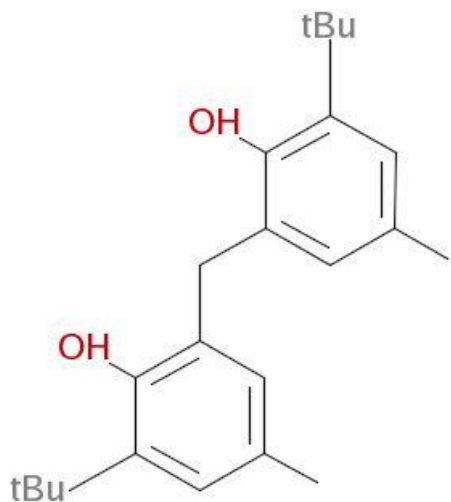
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol
IUPAC name (public):	2,2'-methylenebis(6-tert-butyl-4-methylphenol)
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	C ₂₃ H ₃₂ O ₂
Molecular weight or molecular weight range:	340
Synonyms:	-

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



Other relevant information about substance composition

None.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check, Final decision
		<input checked="" type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
	Restriction	<input type="checkbox"/> Annex XVII
Harmonised C&L	<input type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	
Other processes / EU legislation	<input type="checkbox"/> Other (provide further details below)	

A testing proposal for a 2-generation reproductive toxicity study (OECD 416) was submitted by the registrant(s). However, a final decision has not been issued by ECHA and has been put on hold together with the other testing proposals for OECD 416.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Not available.

3.1.2 Self classification

In the registration: Repr. 2 (H361)

The following hazard classes are among the aggregated self classifications in the C&L Inventory:

Repr. 2 (H361)
Aquatic Chronic 4 (H413)
Eye Irrit. 2 (H319)
Skin Sens. 1 (H317)
Aquatic Chronic 3 (H412)
Aquatic Chronic 2 (H411)
Aquatic Acute 1 (H400)

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 - 10 tpa	<input type="checkbox"/> 10 - 100 tpa	<input type="checkbox"/> 100 - 1000 tpa
<input checked="" type="checkbox"/> 1000 - 10,000 tpa	<input type="checkbox"/> 10,000 - 100,000 tpa	<input type="checkbox"/> 100,000 - 1,000,000 tpa
<input type="checkbox"/> 1,000,000 - 10,000,000 tpa	<input type="checkbox"/> 10,000,000 - 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential
Joint submission.		

4.2 Overview of uses

The substance is used in the polymers industry as antioxidant and/or stabilizer, and in the rubber industry as additive. In consumer products the substance is used in lubricants, greases, release products and metal working fluids.

Table: Uses

<input checked="" type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

- Article 44(2) (refined prioritisation criteria for substance evaluation)
 Article 45(5) (Member State priority)

5.2. Selection criteria met (why the substance qualifies for being in CoRAP)

- Fulfils criteria as CMR/ Suspected CMR
 Fulfils criteria as Sensitiser/ Suspected sensitiser
 Fulfils criteria as potential endocrine disrupter
 Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB
 Fulfils criteria high (aggregated) tonnage (*tpa* > 1000)
 Fulfils exposure criteria
 Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R	<input checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

¹ CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)

Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)

Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

Human hazard

In the reported repeated dose toxicity studies, effects on sperm in the cauda epididymis and histopathological changes in the testis, such as degeneration of step 19 spermatids and vacuolation of Sertoli cells, were observed in the 42.3 mg/kg and higher dose groups. In a reproductive/developmental toxicity screening study, the effects on reproductive parameters, such as decrease in number of corpora lutea, implantation scars and pups born, were observed in the 200 mg/kg/day and higher dose groups but not 50 mg/kg/day. As for the developmental toxicity, low body weight gain of offspring and increased number of stillbirths were observed at 800 but not 200 mg/kg/day. No teratogenic effects were observed in a study with rats up to 375 mg/kg/day.

Due to effects on male reproductive organs, antiandrogenic and estrogenic effects are suspected. Due to the structure of the substance, effects on thyroid are suspected as well.

The potential for endocrine disrupting effects and toxic effects on reproduction and development seem relevant in the justification for the selection of 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol for CoRAP inclusion.

5.4 Preliminary indication of information that may need to be requested to clarify the concern

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input checked="" type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)

Further studies may be requested to clarify the concern for reproductive toxicity and endocrine disruption.

5.5 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
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If the substance is concluded to meet the criteria for classification as REPR cat. 1B a proposal for harmonised classification will be submitted. Depending on the outcome nomination for the Candidate List as SVHC may also be considered based on CMR and/or endocrine disrupting properties.