Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	4-tert-butylpyrocatechol
EC Number:	202-653-9
CAS Number:	98-29-3
Authority:	PL MSCA
Date:	22/03/2016

Note

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

Table of Contents

1 IDENTITY OF THE SUBSTANCE

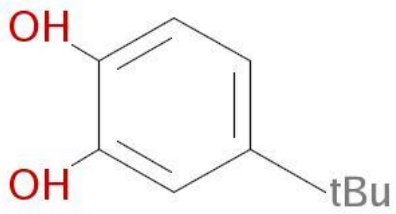
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	4-tert-butylpyrocatechol
IUPAC name (public):	4-tert-butylbenzene-1,2-diol
Index number in Annex VI of the CLP Regulation:	The substance is not listed in Annex VI (table 3.1) of Regulation (EC) n°1272/2008 (CLP)
Molecular formula:	$C_{10}H_{14}O_2$
Molecular weight or molecular weight range:	166.217
Synonyms:	-

Type of substance × Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

EC name (public):	4-tert-butylphenol
EC number:	202-679-0
CAS number:	98-54-4
IUPAC name (public):	4-tert-butylphenol
Index number in Annex VI of the CLP Regulation:	n.a.
Molecular formula:	$C_{10}H_{14}O$
Molecular weight or molecular weight range:	150.2176
Synonyms:	-

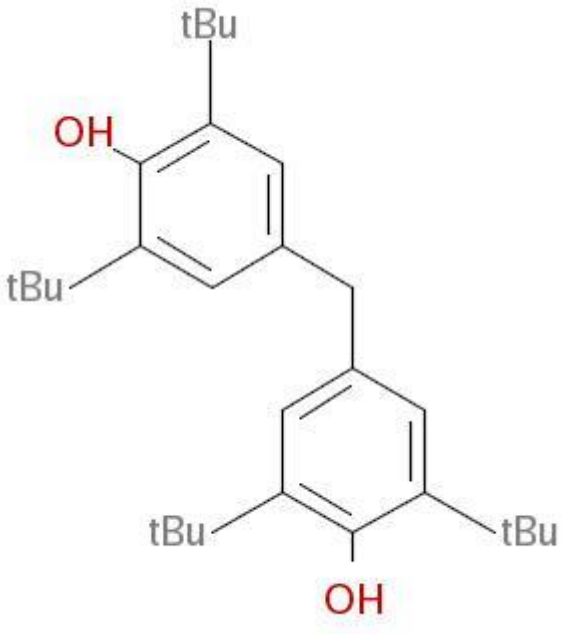
Type of substance × Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:

EC name (public):	2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol
EC number:	204-279-1
CAS number:	118-82-1
IUPAC name (public):	4,4'-methylenebis(2,6-di-tert-butylphenol)
Index number in Annex VI of the CLP Regulation:	n.a.
Molecular formula:	$C_{29}H_{44}O_2$
Molecular weight or molecular weight range:	424,67
Synonyms:	-

Type of substance × Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



Type of substance × Mono-constituent ☐ Multi-constituent ☐ UVCB

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

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

ECHA decision on testing proposal(S) set out in a registration pursuant to article 40(3) of Regulation (EC) NO 1907/2006 – Decision number: TPE-D-0000002592-75-05/F, Helsinki, 10 January 2013.

Tests required pursuant to Article 40(3)(a) of the REACH Regulation:

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).
2. Pre-natal developmental toxicity study in rats or rabbits, oral route (Annex IX, 8.7.2.; test method EU B.31/OECD 414). Testing proposal for Two generation Reproduction Toxicity was sent to Commission

Additional test required pursuant to Article 40(3)(c) of the REACH Regulation:

3. Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.; test method Fish, early-life stage toxicity test /OECD 210).

Registrant was required to submit by *10 October 2014* an update of the registration dossier containing the information requested by this decision.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

The substance is not classified under Annex VI of the CLP.

3.1.2 Self classification

- In the registration:

Self-classification according to criteria of Regulation (EC) n°1272/2008 (CLP):

- Acute Tox. 4 H302: Harmful if swallowed.
- Acute Tox. 4 H312: Harmful in contact with skin.
- Skin Corr. 1B H314: Causes severe skin burns and eye damage.
- Eye Damage 1 H318: Causes serious eye damage.
- Skin Sens. 1 H317: May cause an allergic skin reaction.
- Aquatic Acute 1 H400: Very toxic to aquatic life.
- Aquatic Chronic 2 H411: Toxic to aquatic life with long lasting effects.

Hazard statements:

- H302+H312: Harmful if swallowed or in contact with skin.
- H314: Causes severe skin burns and eye damage.
- H317: May cause an allergic skin reaction.
- H400: Very toxic to aquatic life.
- H411: Toxic to aquatic life with long lasting effects.

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
  - Acute Tox. 3 H311: Toxic in contact with skin.
  - Acute Tox. 4 H332: Harmful if inhalated.
  - Carc. 2 H351: Suspected of causing cancer.
  - Repr. 2 H361: Suspected of damaging fertility or the unborn child.
  - Eye Irrit. 2 H319: Causes serious eye irritation.
  - Skin Irrit. 2 H315: Causes skin irritation.
  - STOT SE 3 H335: May cause respiratory irritation.
  - Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects.

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Classification due to skin/eye irritation/damage can be proposed.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
× Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
×1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential
Joint Submission		

4.2 Overview of uses

Table: Uses

Part 1:

× Manufacture	× Formulation	× Industrial use	☐ Professional use	☐ Consumer use	☐ Article service life	☐ Closed system

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

X 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)

X Fulfils criteria as CMR/ Suspected CMR

X Fulfils criteria as Sensitiser/ Suspected sensitiser

X Fulfils criteria as potential endocrine disrupter

X Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB

X Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)

X Fulfils exposure criteria

☐ Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☐ C ☐ M ☐ R	Suspected CMR[1] ☐ C X M ☐ R	X Potential endocrine disruptor
X Sensitiser	☐ Suspected Sensitiser[1]	
☐ PBT/vPvB	X Suspected PBT/vPvB[1]	☐ Other (please specify below)
Exposure/risk based concerns		
☐ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
X Exposure of environment	X Exposure of workers	☐ Cumulative exposure
☐ High RCR	☐ High (aggregated) tonnage	☐ 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

Suspected PBT:

4-tert-butylpyrocatechol is not readily biodegradable thus P criterion is fulfilled. The other PBT criteria need to be verified in the course of substance evaluation.

Suspected ED:

4-tert-butylpyrocatechol is included in the endocrine disruption exchange database (TEDX). Moreower it is similar to 4-tert-butylphenol for which there are some evidence for being an environmental endocrine disruptor.

Suspected CMR:

The substance is suspected mutagen. There is in vitro genotoxicity study for which a test result is positive. In in vitro mammalian chromosome aberration test clastogenic effects was observed together with a high level of cytotoxicity (CSR). Moreover, significant dose-dependent increases in mutant frequencies were observed in L5178Y mouse lymphoma cells incubated with 0.08 to 5.0 µg/mL p-tert-butylcatechol in the absence of S9 activation enzymes (NTP, 2002).

Additional concern:

There are self-classifications notified by the companies (http://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/cl-inventory/view-notification-summary/113995). The following endpoints should be checked in the course of substance evaluation: acute oral and dermal toxicity, skin and eye irritation/corrosion and toxicity to aquatic environment.

There is a risk for workers due to dermal and inhalation exposure to 4-tert-butylpyrocatechol. Therefore an analysis of exposure/risk should be performed in the course evaluation.

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

X Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☐ Information on exposure
X Information on ecotoxicological properties	☐ Information on uses
X Information ED potential	☐ Other (provide further details below)
At the moment it is difficult to indicate what additional information will be needed.	

5.5 Potential follow-up and link to risk management

X Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
According to Local lymph node assay stimulation index was exceeded to a maximum SI of 63.26 at the concentration of 5%. In an in vivo assay (Guinea Pig Maximization Test) following an induction phase (at 3.4% intradermal + 16.7% topical), challenge I using a 7.5% test concentration resulted in 83% (20/24) of animals showing positive skin reactions, and challenge II using a 10% test concentration resulted in 75% (18/24) of animals showing positive skin reactions. Taking into consideration the potential skin sensitization a classification as a skin sensitizer may be required. Other actions will depend on the results of the substance evaluation.			