

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Reaction mass of 2,6-di-tert-butylphenol and 2,4,6-tri-tert-butylphenol
Chemical Group:	phenol
List Number:	907-745-9
CAS Number:	NA
Submitted by:	Belgium
Published:	26/03/2014

Note

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

Contents

1	IDENTITY OF THE SUBSTANCE.....	3
1.1	Other identifiers of the substance	3
2	CLASSIFICATION AND LABELLING.....	4
2.1	Harmonised Classification in Annex VI of the CLP	4
2.2	Self classification	4
2.3	Proposal for Harmonised Classification in Annex VI of the CLP	4
3	INFORMATION ON AGGREGATED TONNAGE AND USES	5
4	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE	5
4.1	Legal basis for the proposal	5
4.2	Selection criteria met (why the substance qualifies for being in CoRAP)	5
4.3	Initial grounds for concern to be clarified under Substance Evaluation	6
4.4	Other completed/ongoing regulatory processes that may affect suitability for substance evaluation	6
4.5	Preliminary indication of information that may need to be requested to clarify the concern	7
4.6	Potential follow-up and link to risk management	7

1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	Reaction mass of 2,6-di-tert-butylphenol and 2,4,6-tri-tert-butylphenol
IUPAC name:	Reaction mass of 2,6-di-tert-butylphenol and 2,4,6-tri-tert-butylphenol
Index number in Annex VI of the CLP Regulation	NA
Molecular formula:	See table 2a, 2b below
Molecular weight or molecular weight range:	See table 2a, 2b below
Synonyms/Trade names:	

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:

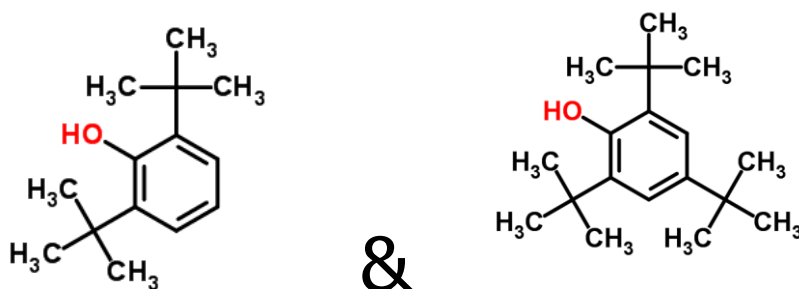


Table 2a: Identity constituent 1

EC name:	2,6-di-tert-butylphenol
EC number:	204-884-0
IUPAC name:	2,6-di-tert-butylphenol
Index number in Annex VI of the CLP Regulation	NA
Molecular formula:	C ₁₄ H ₂₂ O
Molecular weight or molecular weight range:	206.32 g/mol

Table 2b: Identity constituent 2

EC name:	2,4,6-tri-tert-butylphenol
EC number:	211-989-5
IUPAC name:	2,4,6-tri-tert-butylphenol
Index number in Annex VI of the CLP Regulation	NA
Molecular formula:	C ₁₈ H ₃₀ O
Molecular weight or molecular weight range:	262.43 g/mol

1.2 Similar substances/grouping possibilities

For some tests in the dossier the analogue CAS 128-37-0, butylated hydroxytoluene was tested (carcinogenicity, toxicity to reproduction, genetic toxicity, repeated dose toxicity)

For some test in the dossier the analogue EC 204-327-1, 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol was tested (developmental toxicity)

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

NA

2.2 Self classification

- In the registration
Eye Dam. 1; H318: Causes serious eye damage
Aquatic Acute 1; H400: Very toxic to aquatic life
Aquatic Chronic 1; H410: Very 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:
The substance is not registered in the C&L Inventory.

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

NA

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA 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	
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<u>Professional uses:</u> Fuel additives			

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

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

4.2 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

4.3 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 type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" 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 checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p>The substance consists of two constituents of which one constituent (2,4,6-tri-tert-butylphenol) is potentially a PBT/vPvB candidate. Specific experimental values for this constituent are lacking and QSAR-predictions indicate a vPvB and/or PBT character.</p>		

4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input checked="" type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
<p>A TPE has been performed on 2,6-di-tert-butylphenol (one of the constituents). Results are expected by 29-07-2014 for:</p> <ol style="list-style-type: none"> 1. Sub-chronic toxicity study (90-day) in rats, oral route 2. Long-term toxicity testing on aquatic invertebrates 	

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

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

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

Further information and tests should focus on the fate and the behavior of 2,4,6-tri-tert-butylphenol.

At the moment no specific experimental data for this constituent are available and there is also no full registration dossier for this PBT-suspected constituent.

4.6 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
---	--------------------------------------	---	--

Depending on the outcome of the evaluation an identification as SVHC may be initiated if warranted.