

Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	2,4-di-tert-butylphenol
Chemical Group:	
EC Number:	202-532-0
CAS Number:	96-76-4
Submitted by:	BE CA
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NOTE

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

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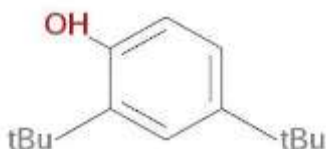
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1 IDENTITY OF THE SUBSTANCE**1.1 Name and other identifiers of the substance****Table 1: Substance identity**

Public Name:	2,4-di-tert-butylphenol
EC number:	202-532-0
EC name:	2,4-di-tert-butylphenol
CAS number (in the EC inventory):	96-76-4
CAS number:	96-76-4
CAS name:	
IUPAC name:	2,4-bis(1,1-dimethylethyl)phenol
Index number in Annex VI of the CLP Regulation	Not applicable.
Molecular formula:	C ₁₄ H ₂₂ O
Molecular weight or molecular weight range:	206.3239
Synonyms:	Phenol, 2,4-bis(1,1-dimethylethyl)- (9CI) Phenol, 2,4-di-tert-butyl- (8CI) 2,4-Bis(1,1-dimethylethyl)phenol 2,4-Bis(tert-butyl)phenol 2,4-Di-tert-butylhydroxybenzene

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not applicable

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable

2.3 Self classification

The registration data includes the following self classification:

According to CLP criteria:

- Skin corrosion/irritation, Skin irrit.2, H315 - Causes skin irritation
- Serious eye damage/eye irritation, Eye Damage 1, H318 - Causes serious eye damage
- Hazardous to the aquatic environment (long term), Aquatic Chronic 1, H410 - Very toxic to aquatic life with long lasting effects
- Hazardous to the aquatic environment (short-term), Aquatic Acute 1, H400 - Very toxic to aquatic life

According to DSD criteria:

- Xi; R38 Irritant: Irritating to skin.
- Xi; R41 Irritant: Risk of serious damage to eyes.
- N; R50/53 Dangerous for the environment: Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.

In addition are the following classification(s) included in the Classification and labeling inventory:

- Acute Toxicity oral, Acute Tox. 4, H302 - Harmful if swallowed.
- Serious eye damage/eye irritation, Eye Irrit.2, H319 - Causes serious eye irritation.
- Specific target organ toxicity-single, STOT SE 3, H335 - May cause respiratory irritation.
- Specific target organ toxicity-single, STOT SE 2, H371 - May cause damage to organs.
- Specific target organ toxicity-repeated, STOT RE 2, H373 - May cause damage to organs through prolonged or repeated exposure.

3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

3.1 Legal basis for the proposal

- Article 44(1) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

3.2 Grounds for concern

<input checked="" type="checkbox"/> (Suspected) CMR	<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> (Suspected) Sensitiser	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> High RCR
<input type="checkbox"/> (Suspected) PBT	<input type="checkbox"/> Exposure of sensitive populations	<input type="checkbox"/> Aggregated tonnage
<input checked="" type="checkbox"/> Suspected endocrine disruptor	<input type="checkbox"/> Other (provide further details below)	

There are data gaps in the registration data regarding reproductive toxicity => more clarification would be needed.

QSAR toolbox profiler ERBA flagged the substance to have strong potential for estrogen receptor binding => more clarification would be needed.

There are some signs of possible corrosivity => further clarification would be needed.

3.3 Information on aggregated tonnage and uses

<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input checked="" type="checkbox"/> 100 – 1000 tpa *2
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	
<input type="checkbox"/> 100,000 – 1000,000 tpa	<input type="checkbox"/> > 1000,000 tpa	
<input type="checkbox"/> Confidential		

There are three registrations/joint submissions for the substance, two of them indicates tonnage band between 100-1000 tpa and the other one indicates intermediate use of the substance for which the tonnage band is not disseminated.

JUSTIFICATION DOCUMENT FOR THE SELECTION OF A CORAP SUBSTANCE

<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
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Industrial uses
 Manufacture and formulation of fuel additives and fuel blends
 Use of fuel additives and additised fuels
 Chemical intermediate
 Formulation of lubricant additives, lubricants and greases
 Lubricant and lubricant additive
 Formulation of fuel additives and fuel blends
 Fuels and fuel additives
 The PROCs are: 1,2,3,4,5,7,8a,8b,9,10,13,15,16 and 17

Professional uses
 Use of fuel additives and additised fuels
 Lubricant and lubricant additive
 Fuels and fuel additives
 Plastic additive
 Rubber additive
 Intermediate for the production of another chemical
 The PROCs are: 1,2,3,4,5,7,8a,8b,9,10,11,12,13,14,16,17,20 and 21

Consumer uses
 Use of fuel additive and additised fuels
 Lubricant and lubricant additive
 Fuels and additives
 The PCs are: 13 and 24

3.4 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
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	

A testing proposal examination is ongoing for the following end-points.

- Long-term tox. aquatic invert.
- Repeated tox. oral

Information on other completed/ongoing regulatory processes was not found.

3.5 Information to be requested to clarify the suspected risk

<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 checked="" type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input checked="" type="checkbox"/> Information on uses
<input checked="" type="checkbox"/> Other (provide further details below)	
<p>When going through the registration data more in detail other items might come up that need clarification. The above only reflects the most probable information to be requested to clarify the suspected risk, other options are however still open.</p>	

3.6 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details)
<p>A first step could be to propose harmonized classification and labeling for 2,4-di-tert-butylphenol. Depending on the outcome of the evaluation however other/further RMMs (any of the above) could be initiated if warranted.</p>			