

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name): 4-tert-butylphenol

Chemical Group:

EC Number: 202-679-0

CAS Number: 98-54-4

Submitted by: Germany

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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 1: Substance identity

EC name:	4-tert-butylphenol
IUPAC name:	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 g/mol
Synonyms/Trade names:	1-tert-Butyl-4-hydroxybenzene 4-(2-Methyl-2-propanyl)phenol p-tert-butylphenol 4-(1,1-Dimethyl)ethylphenol Butylphen Terbutol Phenol, p-tert-butyl- (8CI) NSC 3697 PTBP

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

None

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

There is no harmonized classification of 4-tert-butylphenol according to Annex VI of Regulation (EC) No 1272/2008.

2.2 Self classification

- In the registration:

Classification		Labelling		Specific Concentration limits, M-Factors
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	
Skin Irrit. 2	H315	H315		
Eye Dam 1	H318	H318		
Repr 2	H361	H361		
STOT SE 3	H335	H335		
Aquatic Chronic 2	H411	H411		

Signal Words:

Danger

Pictograms:

GHS05

GHS07

GHS08

GHS09

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

Classification		Labelling		Specific Concentration limits, M-Factors
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	
Skin Corr 1B	H314	H314		
Skin Corr. 1C	H314	H314		
Skin Sens. 1	H317	H317		
Eye Irrit. 2	H319	H319		
Resp. Sens. 1	H334	H334		
Acute Tox. 4	H302	H302		
		H336		

STOT RE 1	H372	H370	
Aquatic Chronic 1	H410	H410	
Aquatic Chronic 3	H412	H412	
Not Classified			

Signal Words:

Warning

Pictograms:

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

A CLH dossier has been prepared for p-tertbutylphenol.

In June 2012 the following RAC opinion was adopted and published:

Classification		Labelling		Specific Concentration limits, M-Factors
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	
Skin Irrit. 2	H315	H315		
Eye Dam 1	H318	H318		
Repr 2	H361f	H361f		

Signal Words:

Danger

Pictograms:

GHS05

GHS08

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 type="checkbox"/> 1000 – 10,000 tpa	<input checked="" 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 checked="" type="checkbox"/> Confidential
In addition to the tonnage band for the joint submission, there is a registration for Intermediate use only for which the tonnage is confidential.		

<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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PC 1: Adhesives, sealants
 PC 9a: Coatings and paints, thinners, paint removes
 PC 32: Polymer preparations and compounds

The major use of 4-tert-butylphenol is as a monomer in chemical synthesis, e.g. for the production of polycarbonate, phenolic resins, epoxy resins.

- PtBP is used in the synthesis of polycarbonate polymers
- The application of phenolic resins are as intermediates in contact and pressure sensitive adhesives, coatings, printing inks and electrical varnishes.

Epoxy resins are used as hardening agents in paints and varnishes and in industrial corrosion protective coatings.

- The application of phenolic resins are as intermediates in contact and pressure sensitive adhesives, coatings, printing inks and electrical varnishes. A further use is for tack improvement in rubber compounding (tyre manufacture) and phenolic resins are ethoxylated for the production of oilfield chemicals (specialised surfactants).

Due to its water solubility releases of ptBP are expected primarily to the aquatic compartment. To a limited extend release to air and to soil can be expected.

Regarding consumers the main exposure from final products is expected to be from adhesives and possibly canned food. Consumers may also be exposed to ptBP in drinking water from drinking water reservoirs coated with epoxy-based paints or from pipelines. Consumers may moreover be exposed to ptBP from polycarbonate used for food contact material. [Ref. RA, Norway, 2009]

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

- 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 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 checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p>4-tert-butylphenol gives some evidence for being an endocrine disruptor for the environment.</p> <p>There are some in vitro tests which evaluate the impact of 4-tert-butylphenol on vitellogenin (VTG) induction in rainbow trout cells or the binding to estrogen receptors from rainbow trout or humans. The potency derived was comparable or even a little bit higher than for 4-tert-octylphenol. The tests show 4-tert-butylphenol to have endocrine properties.</p> <p>In vivo: An extended ELS (early life stage test) study with P.promelas is available that does not give clear evidence if 4-tert-butylphenol is an endocrine disrupter or not. There are some alterations (e.g. histology and secondary sexual characteristics) that give advice for 4-tert-butylphenol to have endocrine properties.</p> <p>Also two adverse effects were affected. But there is no clear evidence that the effects were endocrine mediated.</p> <p>No clear conclusion about endocrine disrupting properties of 4-t-butylphenol is possible. Therefore a substance evaluation of 4-tert-butylphenol is proposed.</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 type="checkbox"/> Testing proposal	<input checked="" type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input checked="" 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)	
CLP: RAC opinion adopted 12-6-2012: see 2.3	
ESR: The Risk Assessment report was finalised in 2008.	

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 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)

Information on ED potential needed to clarify the concern may lead to the request of relevant fish toxicity studies including fish sexual development test or fish full life cycle.

4.6 Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details)
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If concern is substantiated a SVHC-identification according to art. 57 f will be proposed.