Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	p-(1,1-dimethylpropyl)phenol
Chemical Group:	
EC Number:	201-280-9
CAS Number:	80-46-6
Submitted by:	Germany
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

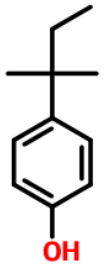
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	p-(1,1-dimethylpropyl)phenol
IUPAC name:	4-(1,1-Dimethylpropyl)phenol
Index number in Annex VI of the CLP Regulation	n.a.
Molecular formula:	$C_{11}H_{16}O$
Molecular weight or molecular weight range:	164.24 g/mol
Synonyms/Trade names:	4-(1,1-Dimethylpropyl)phenol p-tert-Amylphenol p-tert-Pentylphenol Phenol, p-(1,1-dimethylpropyl)- (5CI); Phenol, p-tert-pentyl- (6CI,8CI); 4-t-Amylphenol; 4-t-Pentylphenol; 4-tert-Amylphenol; 4-tert-Pentylphenol; Amilfenol; BirexSE; NSC 403672; NSC 4965; p-(α,α-Dimethylpropyl)phenol;

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 p-(1,1-dimethylpropyl)phenol 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 Sens. 1	H317	H317		
Skin Corr. 1B	H314	H314		
Eye Dam. 1	H318			
Aquatic Chronic 1	H410	H410		
STOT SE 3	H335			

Signal Words: Danger **Pictograms**: GHS05, GHS07, 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 Sens. 1B	H317	H317		
Skin Corr. 1A	H314	H314		
Skin Corr. 1C	H314	H314		
Acute Tox. 4	H332	H332		
Acute Tox. 4	H302	H302		
Acute Tox. 4	H312	H312		
Skin Irr 2	H315			
Aquatic Acute 1	H400			
Aqua Chronic 2	H411	H411		
Not Classified				

Other Signal Words: Warning Other Pictograms: GHS08

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA 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

☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Closed System

The substance p-(1,1-dimethylpropyl)phenol is used in the production of phenolic resins and lacquers. It is also used in the production of ethoxylated resins, some of which are used in oilfield applications.
Other use categories are cleaning/washing agents, surface active agents, paints. Also use in consumer products are given: adhesive, sealants, coatings and paints, thinners and paint removes.
A wide dispersive use can be assumed.

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

p-(1,1-dimethylpropyl)phenol gives evidence for being an endocrine disruptors for the environment:

A result from a in vitro study gives evidence for p-(1,1-dimethylpropyl)phenol to be an endocrine substance due to induction of vitellogenin in carp hepatocytes. The potency is approx. in the same range like 4-nonylphenol.

There are also in vivo studies for fishes available that show effects due to the definition of the WHO/IPCS:

“An endocrine disrupter is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations” (IPCS/WHO; cited in (European Commission, 1999)).

Effects appeared in several species of fish that showed p-(1,1-dimethylpropyl)phenol to have endocrine properties (indicative effects). So for example vitellogenin in fishes is elevated. Also adverse effects for fish population were determined.

However no clear conclusion about endocrine disrupting properties of p-(1,1-dimethylpropyl)phenol is possible yet. Therefore a substance evaluation of p-(1,1-dimethylpropyl)phenol is proposed.

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

☐ Compliance check, Final decision	☐ Dangerous substances Directive 67/548/EEC
☐ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	

[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

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☐ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☒ Information ED potential	☐ 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

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☒ Other (provide further details)
If concern is substantiated a SVHC-identification according to art. 57 f will be proposed.			