

## Justification for the selection of a candidate CoRAP substance

<b>Substance Name (Public Name):</b>	p-Cresol
<b>Chemical Group:</b>	Organic
<b>EC Number:</b>	203-398-6
<b>CAS Number:</b>	106-44-5
<b>Submitted by:</b>	UK CA
<b>Published:</b>	20/03/2013

### 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 Name and other identifiers of the substance

Table 1: Substance identity

<b>Public Name:</b>	p-Cresol
<b>EC number:</b>	203-398-6
<b>EC name:</b>	p-Cresol
<b>CAS number (in the EC inventory):</b>	106-44-5
<b>CAS number:</b>	106-44-5
<b>CAS name:</b>	Phenol, 4-methyl-
<b>IUPAC name:</b>	4-methylphenol
<b>Index number in Annex VI of the CLP Regulation</b>	604-004-00-8
<b>Molecular formula:</b>	C <sub>7</sub> H <sub>8</sub> O
<b>Molecular weight or molecular weight range:</b>	108
<b>Synonyms:</b>	1-Hydroxy-4-methylbenzene, 4-Cresol, 4-Hydroxytoluene, p-Hydroxytoluene, p-Methylhydroxybenzene, p-Methylphenol, p-Oxytoluene, p-Cresol (8CI), p-cresol, p-Cresylic acid, p-Tolyl alcohol

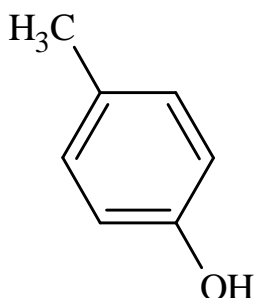
**Type of substance**

Mono-constituent

Multi-constituent

UVCB

**Structural formula:**



## **2 CLASSIFICATION AND LABELLING**

### **2.1 Harmonised Classification in Annex VI of the CLP**

Index number: 604-004-00-8

Acute Tox. 3\* ; H311; Toxic in contact with skin.

Acute Tox. 3\* ; H301; Toxic if swallowed.

Skin Corr. 1B ; H314; Causes severe skin burns and eye damage.

(\*Classification also applicable for m-cresol, o-cresol & mix-cresol).

### **2.2 Proposal for Harmonised Classification in Annex VI of the CLP**

Not applicable.

### **2.3 Self classification**

Self-classification given on the dissemination site is consistent with harmonised classification and additionally includes;

Aquatic Chronic 3; H412; Harmful to aquatic life with long lasting effects.

Additional classifications in the inventory;

Skin Corr. 1C; H314; causes severe skin burns and eye damage.

Eye Dam. 1; H318; Causes severe eye damage.

STOT SE 1; H370; causes damage to organs.

### 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 checked="" type="checkbox"/> Aggregated tonnage
<input checked="" type="checkbox"/> Suspected endocrine disruptor	<input type="checkbox"/> Other (provide further details below)	

The results of several screening tools for endocrine disruption suggest p-cresol may be an endocrine disruptor. Due to its use in consumer products further investigation is needed.

In addition, an increased incidence of tumours was reported in carcinogenicity studies conducted with a mixture of 60:40 m/p cresol. Therefore, a review of the carcinogenic potential of p-Cresol is also required.

#### 3.3 Information on aggregated tonnage and uses

<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 – 1000,000 tpa	<input type="checkbox"/> > 1000,000 tpa		
<input type="checkbox"/> Confidential			
Tonnage band given on the dissemination site is 10,000 – 100,000 tpa.			
<input checked="" type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<p>Industrial use:</p> <ul style="list-style-type: none"> <li>use in polymer production</li> <li>use in the processing of solid and liquid polymers</li> <li>use as an isolated intermediate for chemical synthesis</li> <li>use as a solvent for electric wire enameling</li> </ul> <p>Article service life Solvent in the pharmaceutical industry</p> <p>Consumer use: article service life</p>			

### 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 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 checked="" type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
<p>p-cresol been reviewed (as part of a category) under the OECD SIDS program (<a href="http://webnet.oecd.org/hpv/ui/SIDS_Details.aspx?id=5b4d4ad9-0990-41c0-aa92-10f8ecb7acb6">http://webnet.oecd.org/hpv/ui/SIDS_Details.aspx?id=5b4d4ad9-0990-41c0-aa92-10f8ecb7acb6</a> )</p>	

### 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 type="checkbox"/> Information on uses
<input type="checkbox"/> Other (provide further details below)	
<p>The following may be needed;</p> <p>Further information to clarify the endocrine disruption potential and/or carcinogenicity.</p> <p>Clarification on the exposure assessments</p>	

### 3.6 Potential follow-up and link to risk management

<input type="checkbox"/> Restriction	<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>This will depend on the outcome of the evaluation.</p>			