

## Justification for the selection of a candidate CoRAP substance

<b>Substance Name (Public Name):</b>	Mono- and/or di- and/or tri(1-phenylethyl)- m-cresol and p-cresol
<b>EC Number:</b>	700-427-9
<b>CAS Number:</b>	Not available
<b>Submitted by:</b>	Federal Public Service Health, Food Chain Safety and Environment, Risk Management Service, Belgium
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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

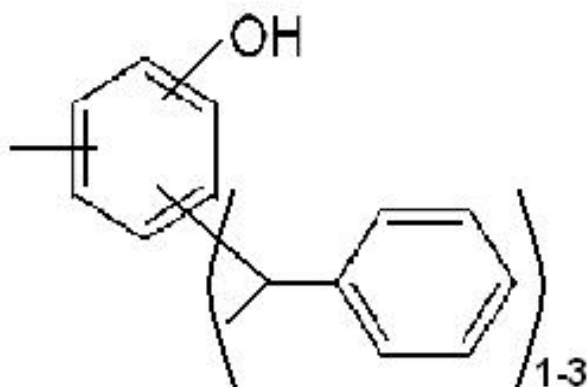
## 1.1 Name and other identifiers of the substance

Table 1: Substance identity

<b>Public Name:</b>	Mono- and/or di- and/or tri(1-phenylethyl)-m-cresol and p-cresol
<b>EC number:</b>	700-427-9
<b>EC name:</b>	Mono- and/or di- and/or tri(1-phenylethyl)-m-cresol and p-cresol
<b>CAS number (in the EC inventory):</b>	NA
<b>CAS number:</b>	NA
<b>CAS name:</b>	NA
<b>IUPAC name:</b>	Mono- and/or di- and/or tri(1-phenylethyl)-m-cresol and p-cresol
<b>Index number in Annex VI of the CLP Regulation</b>	NA
<b>Molecular formula:</b>	$C_nH_{n+1}O$ with $n = 15$ or $23$ or $31$
<b>Molecular weight or molecular weight range:</b>	212.29 (mono), 316.44 (di), 420.59 (tri) g/mol
<b>Synonyms:</b>	Atlen SK

**Type of substance**     Mono-constituent     Multi-constituent     UVCB

**Structural formula:**



## 2 CLASSIFICATION AND LABELLING

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

No harmonised classification.

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

None proposed.

### 2.3 Self classification

Self classification by the registrant:

According to CLP: Skin sens. 1; H317: May cause an allergic skin reaction.

According to DSD: X<sub>i</sub>; R43; May cause sensitization by skin contact.

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

#### Persistence

The test method used to study ready biodegradability is not appropriate for UVCB substances. The substance is not readily biodegradable after direct addition and ultrasonification (7% degradation in 28 days). However, when the substance was dissolved in acetone (to increase bioavailability), it was found to be readily biodegradable.

It is claimed that this was done due to the very low water solubility, although the water solubility is around 10 mg/l.

Therefore the conclusion on the substance being readily biodegradable seems unjustified.

#### Bioaccumulation

Information on bioaccumulation is lacking and in combination with the uncertainties on persistency, this constitutes an information gap that should be investigated further.

### 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	
<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			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<p>The substance is used to manufacture synthetic rubbers which in turn find an application in the production of articles, used by both professionals as by consumers.</p> <p>Manufacture of substance:</p> <p>PROC 1 : Use in closed process, no likelihood of exposure          PROC 2 : Use in closed, continuous process with occasional controlled exposure          PROC 8a : Transfer of substance or preparation from/to vessels/large containers at non-dedicated facilities.          PROC 8b : Transfer of substance or preparation from/to vessels/large containers at dedicated facilities.          PROC 15 : Use as a laboratory reagent</p> <p>Formulation of substance :</p> <p>PROC 1 : Use in closed process, no likelihood of exposure          PROC 3 : Use in closed batch process          PROC 4 : Use in batch and other process where opportunity of exposure arises          PROC 8a : Transfer of substance or preparation from/to vessels/large containers at non-dedicated facilities.          PROC 8b : Transfer of substance or preparation from/to vessels/large containers at dedicated facilities.          PROC 14 : Production of preparations or articles by tableting, compression, extrusion, pelletisation          PROC 21 : Low energy manipulation of substances bound in materials and/or articles</p> <p>Processing of synthetic rubber :</p> <p>PROC 1 : Use in closed process, no likelihood of exposure          PROC 5 : Mixing or blending in batch processes for formulation of preparations and articles          PROC 6 : Calendering operations          PROC 8a : Transfer of substance or preparation from/to vessels/large containers at non-dedicated facilities.          PROC 8b : Transfer of substance or preparation from/to vessels/large containers at dedicated facilities.          PROC 9 : Transfer of substance or preparation into small containers          PROC 14 : Production of preparations or articles by tableting, compression, extrusion, pelletisation          PROC 21 : Low energy manipulation of substances bound in materials and/or articles</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 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)	
<p>A testing proposal is presented for the following end points;</p> <ul style="list-style-type: none"> <li>• Dissociation constant</li> <li>• Viscosity</li> <li>• Two generation reproductive toxicity study in rats: oral route.</li> <li>• Prenatal developmental toxicity study: oral route.</li> <li>• Repeated dose toxicity: oral</li> </ul>	

### 3.5 Information to be requested to clarify the suspected risk

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behavior	<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 available test data on biodegradation seem doubtful and relevant information on bioaccumulation is not present. These two types of information are necessary to come to an adequate conclusion on the PBT character. Also exposure information is lacking and could be necessary to assess the risk for the environment.</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>It is still too early to give a reliable indication of the appropriate follow-up actions.</p>			