

Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	Phenol, dodecyl-, sulfurized, calcium salts
Chemical Group:	
EC Number:	272-486-4
CAS Number:	68855-45-8
Submitted by:	France
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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

Public Name:	Phenol, dodecyl-, sulfurized, calcium salts
EC number:	272-486-4
EC name:	Phenol, dodecyl-, sulfurized, calcium salts
CAS number (in the EC inventory):	68855-45-8
CAS number:	68855-45-8
CAS name:	Phenol, dodecyl-, sulfurized, calcium salts
IUPAC name:	Phenol, dodecyl-, sulfurized, calcium salts
Index number in Annex VI of the CLP Regulation	Not relevant
Molecular formula:	A molecular formula for this substance does not exist because it is an UVCB. The molecular formula for a theoretical representative structure is $C_{36}H_{58}Ca_2O_4S_x$ where $x = 1-3$.
Molecular weight or molecular weight range:	From 450 to 1750 g/mol according to the registration dossier
Synonyms:	

Type of substance: Mono-constituent Multi-constituent UVCB

Structural formula

Not available in the registration data

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

None

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None

2.3 Self classification

The registration data includes the following self classification:

According to CLP criteria:

- Repr. 1B H360: May damage fertility or the unborn child
- Aquatic Chronic 4 H413: May cause long lasting harmful effects to aquatic life

According to DSD criteria:

- Repr. Cat. 2; R60 May impair fertility
- R53 May cause long-term adverse effects in the aquatic environment

In addition are the following classification(s) included in the Classification and Labelling Inventory:

Eye Irrit. 2, H319: Causes serious eye irritation

Aquatic Chronic 4, H413: May cause long lasting harmful effects to aquatic life

Repr. 2, H361: Suspected of damaging fertility or the unborn child

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

The substance is a potential CMR considering the current self classification identified and the proposal for harmonized classification of its impurity Phenol, dodecyl-, branched [Tetrapropenylphenol (TPP)] which is present in the substance in a concentration range that might trigger classification of the substance.

The substance is a potential PBT:

- P (vP) is met through screening criteria,
- T is met due to the impurity
- the non-B status proposed in the registration data is however questioned due to data lacking and poor quality of the data and rationale.

Therefore further information on B is needed. The overall PBT assessment appears to be insufficient (for instance information is lacking and the assessment doesn't address each component individually).

Besides the high aggregated tonnage, uses appear to be wide dispersive (according to the PROCs described) and several consumer uses are identified by the registration data (probably as a mixture) that may raise a concern if the substance is to be classified as reprotoxicant (Repr. 1B or 2) because of the pending harmonized classification of one of its impurity.

3.3 Information on aggregated tonnage and uses

<input type="checkbox"/> 1 - 10 t	<input type="checkbox"/> 10 - 100 t	<input type="checkbox"/> 100 - 1000 t	<input checked="" type="checkbox"/> 1000 - 10,000 t	
<input type="checkbox"/> 10,000 - 100,000 t	<input type="checkbox"/> 100,000 - 1000,000 t	<input type="checkbox"/> > 1000,000 t	<input type="checkbox"/> Confidential	
Aggregated Tonnage:				
<input checked="" type="checkbox"/> Industrial Use	<input checked="" type="checkbox"/> Professional Use	<input checked="" type="checkbox"/> Consumer Use	<input type="checkbox"/> Closed System	

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

<input type="checkbox"/> Compliance Check	<input checked="" type="checkbox"/> Annex VI (CLP)
<input type="checkbox"/> Testing Proposal(s)	<input type="checkbox"/> Annex XIV (Authorisation)
<input type="checkbox"/> Substance Identification Issues	<input type="checkbox"/> Annex XVII (Restriction)
<input type="checkbox"/> ESR Programme	<input type="checkbox"/> Other (provide further details below)
C&L proposal of the impurity (TPP) as Repr. 2 may affect the CMR status of the substance.	

3.5 Information to be requested to clarify the suspected risk

<input type="checkbox"/> Information on toxicological properties	<input checked="" type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on uses
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Other (provide further details below)
<input checked="" type="checkbox"/> Information on physico-chemical properties	

Physico-chemical data to be requested (linked with the environmental fate and behaviour): water solubility, Kow, Koc, etc. of the substance itself and not from QSAR calculations or read-across, clarification of the substance identity, etc.

Information on fate and behaviour to be requested:

- data on the B criterion on the substance itself and not from QSAR calculations or read-across (read across to be deeply assessed too)
- P and B definitive assessment if the B criteria is suspected through the screening approach

If the P and B criteria are met, the registration data would need to be updated (definitive assessment of the P criterion, emission characterisation)

Information on worker/consumer exposure and on the consumer uses is expected given the pending Repr. 2 harmonized classification and the current Repr.1B self-classification of the impurity.

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 below)

To be determined following the outcome of the substance evaluation process.