Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Phenol
Chemical Group:	-
EC Number:	203-632-7
CAS Number:	108-95-2
Submitted by:	Denmark
Date:	17/03/2015

Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

Contents

1 IDENTITY OF THE SUBSTANCE

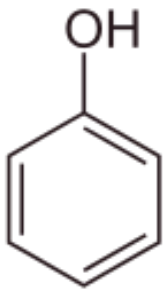
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	phenol
IUPAC name:	phenol
Index number in Annex VI of the CLP Regulation	604-001-00-2
Molecular formula:	C6H5OH
Molecular weight or molecular weight range:	94.11
Synonyms/Trade names:	Carbolic acid, hydroxybenzene, benzenol, phenylic acid, phenic acid, monohydroxybenzene phenylalcohol

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Table 2: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
604-001-00-2	phenol	203-632-7	108-95-2	Acute Tox. 3 Acute Tox. 3 Skin Corr.1B Acute Tox. 3 Muta. 2 STOT RE 2	H301 H311 H314 H331 H341 H373	*Skin Corr. 1B; H314: C ≥ 3%* *Skin Irrit. 2; H315: 1% ≤ C < 3%* *Eye Irrit. 2; H319: 1% ≤ C < 3%*	-

2.2 Self classification

- In the registration

  No deviations from harmonized classification in the registration

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

  Eye Dam. 1: H318;

  Acute Tox. 1:H330;

  Aquatic Acute 1: H400;

  Aquatic Chronic 2; H411;

  Aquatic Chronic 3; H412;

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

No current proposal for harmonised classification.

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

A joint registration in the 1,000,000 – 10,000,000 tpa band is listed as active, while another registration is listed as inactive.

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

Industrial use, professional use, and use in closed systems are described in the registration dossier.

Consumer use is not included in the registration dossier. However, the EU RAR included use of phenol in consumer products (e.g. use of floor wax), concluding that there may be a risk to the health of consumers from phenol exposure. Also, the Danish Environmental Protection Agency has performed surveys of exposure through consumer products which in some cases show relatively high levels of exposure that may lead to unacceptable cumulative exposure. Therefore, more information on consumer exposure appears to be a relevant than that currently included in the registration dossier for phenol.

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)	

Existing Substances Regulation: An EU RAR report from 2006 under Reg 793/93/EEC is available. The report amongst other concludes that there is a need for limiting the risks to human health of the workers, of the consumers and to humans via the environment.

BPR: Phenol has been phased out as a biocide active substance as it was not supported in any product type in the notification phase (2004-2008). Thus the substance may no longer be used as a biocidal active substance.

Other: Phenol was prohibited in cosmetic products in 2005.

5 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1 Legal basis for the proposal

☒ Article 44(2) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

5.2 Selection criteria met (why the substance qualifies for being in CoRAP)

☒ 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

5.3 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)
Suspected Mutagen: Phenol is a classified mutagen cat.2 on Annex VI to CLP. The substance was recently reviewed by the EFSA panel. Based on the available information, the panel concluded that phenol does not have biologically relevant genotoxicity *in vivo* for the oral route of exposure. Concern for in vivo genotoxicity still remains for other routes of exposure (dermal, inhalation), especially at the initial site of contact. The registration dossier includes 48 references on *in vitro* and 28 references on *in vivo* genotoxicity. However, germ cell genotoxicity has not been adequately investigated in the studies available in the dossier (1 study investigates strand breaks in testicular DNA).		

[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

Other hazards: Human health hazard based concerns include repeated dose toxicity for the consumer and DNELs (oral, dermal and inhalation) and for the worker (inhalation) have been proposed in the joint report.

The proposed DNELs should be evaluated, including consideration to EU RAR (2006) values used for risk characterisation and the lowered TDI (1.5 mg/kg bw/day proposed by EFSA (Scientific Opinion on the toxicological evaluation of phenol, EFSA journal 2013; 11(4):3189) compared to the previous TDI from 1984.

Exposure of consumers: Exposure of consumers is not described in the registration dossier. The registrant indicates that consumers should not be exposed to phenol. However, the EU RAR concluded that consumer exposure to phenol through application of floor waxes leads to concern with respect to systemic repeated dose toxicity by inhalation. Also the Danish EPA has information from surveys of consumer products that exposure of the consumer to phenol occurs from consumer products such as e.g. computers, playing consoles, TV sets, chargers and transformers, pressing irons and tents. Due to the phasing-out of phenol as a biocidal active substance, concern from exposure to phenol via disinfectants is considered not to be relevant any longer. Also, phenol is prohibited in cosmetic products since 2005.

Exposure of workers: The risk assessment report from 2006 concluded that there was a need for limiting the risks at the workplace; risk reduction measures which are already being applied shall be taken into account. Concerns relate to production and further processing, formulation of phenolic resins and use of phenolic resins with or without spraying technique. The end-points of concern are corrosivity to skin and eyes and systemic toxicity following repeated inhalation, and in some cases, also through dermal exposure.

The REACH registration data include scenarios for industrial and worker exposure. Some of scenario result in RCR closed to or equal to 1, based on the DNELs proposed.

High RCR: Some scenarios included in the registration report result in high RCRs. For consumer exposure no scenario is included in the joint registration. However, the EU RAR from 2006, as well as national Danish surveys conclude that exposure of consumers may lead to risk for human health, especially in relation to combined exposure.

5.4 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)

It should be evaluated if the current harmonized mutagen cat.2 classification is sufficient or if a more stringent classification should be proposed. Further testing on genotoxicity may be required if the available information is judged to be insufficient to conclude on possible germ cell mutagenic potential, in view of classification and risk characterisation.

The TDI-value was reduced in 2013. The hazard assessment proposed in the registration dossier, especially for repeated dose toxicity, should be scrutinised in order to secure harmonisation of evaluation basis in different regulatory contexts.

No information on consumer uses or exposure to phenol or phenol in mixtures is included in the lead registration dossier. However, Danish surveys show that phenol may be contained in a number of products accessible to the consumer (mineral wool, solvents, glues, wood panels). The EU risk assessment report from 2006 identifies consumer exposure and combined exposure to give rise to human health risk. Exposure scenarios of the professional user should be evaluated for their accuracy and completeness, as some result in high RCR, and because the EU RAR indicated risk to the worker through exposure to phenol. It may be necessary to require that the registrant includes exposure scenarios for consumer uses as well as exposure assessment and risk characterization for these uses.

5.5 Potential follow-up and link to risk management

☒ Harmonised C&L	☒ Restriction	☐ Authorisation	☐ Other (provide further details)

It should be evaluated if the current harmonized mutagen cat.2 classification is sufficient or if a more stringent classification should be proposed.

The EU RAR concluded that there was concern for human health of workers and for consumers. However, in the registration dossier some worker exposure scenarios show high RCR. As the TDI recently has been reduced, evaluation of the proposed DNELs and consequent risk characterization on the basis of SeV may lead to the conclusion that there is still an unacceptable risk to the worker.

No information on exposure of the consumer is available in the lead registration dossier, as consumer use is not recommended by the registrant. However, it appears from data in the EU RAR, as well as data from surveys performed by the Danish Protection Agency that phenol is present in consumer products, leading to exposure of the consumer at higher levels than the new TDI.

Should the substance evaluation show that the concerns concluded in the EU RAR (2006) are still relevant, risk mitigation measures reducing exposure of different user groups should be implemented. Eventually, a restriction of the use phenol by workers and/or consumers may therefore be relevant.