

RISK MANAGEMENT OPTIONS ANALYSIS

CONCLUSION DOCUMENT

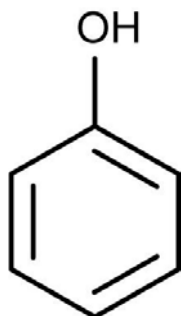
for

Phenol

EC number: 203-632-7

CAS number: 108-95-2

Chemical structure:



Member State: Denmark

Dated: August 2014, Final version

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

1. OVERVIEW OF OTHER REGULATORY PROCESSES / EU LEGISLATION

The Danish EPA is currently conducting a survey of each substances listed on the Danish List of Undesirable Substances (LOUS). Access to the surveys carried out so far can be found at the following link:

http://www.mst.dk/English/Chemicals/assessment_of_chemicals/LOUS_2012_2015/.

Phenol was included on LOUS due to high tonnage use in Denmark and because the substance of its harmonised classification as acutely toxic, dangerous by prolonged exposure and mutagenic in category 2.

The survey carried out for phenol provides an overview of the use and the environmental and human health aspects of the substance. The results of this publicly available survey have been used as the main background information for this RMO. Information from the more than 40 confidential CSR's filed in relation to registration dossiers have not been included at this point.

The current status of phenol pertaining to relevant community legislation is summarised in Table 1 below.

Table 1. Relevant legislation pertaining to the manufacture and use of phenol

Legal instrument	EU/national	Status of phenol
REACH regulation	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	Registered in 1,000,000-10,000,000 T per year range There is one joint registration representing 44 registrants and one independent registrant.
CLP regulation	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures	Harmonised classification ¹ : Acute tox 3: H301/311/311 Skin Corr. 1B; H314 Muta.2; H341 STOT RE 2; H373 Self classification (CLP Inventory): 93 notifiers out of 2,870 notifiers add Aquatic Chronic 2; H411
Directive on Chemicals Agents at Work	Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. Commission Directive 2009/161/EU establishing a third list of indicative occupational exposure limit values.	Indicative Occupational Exposure Limit (IOEL) for phenol: - 8 mg/m ³ (2 ppm) as 8 hour time-weighted average (TWA). - 16 mg/m ³ (4 ppm) as short-term exposure limit (STEL) i.e. a 15-minute period.

¹ H301; Toxic if swallowed; H311; Toxic in contact with skin; H331; Toxic if inhaled;
H314; Causes severe skin burns and eye damage;
H341; Suspected of causing genetic defects;
H373; May cause damage to organs through prolonged or repeated exposure.
H411: Toxic to aquatic life with long lasting effects

Legal instrument	EU/national	Status of phenol
		A "skin notation" is assigned to the occupational exposure limit value of phenol, indicating the risk of significant uptake through the skin.
Biocide Regulation	Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.	Phenol has not been supported in the notification phase of the review programme. Therefore phenol is not allowed in any biocidal products within the EU.
Cosmetics Regulation	Regulation (EC) No 1223/2009 on cosmetic products.	Phenol is included in list of substances prohibited in cosmetic products (substance no. 1175, Annex 2). The substance was also included on the list of prohibited cosmetic ingredients in the cosmetics directive in 2005 (substance no. 1175, Annex II, 2005/80/EC).
VOC directive	Directive 2004/42/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC.	The "VOC" directive that aim to avoid/ reduce ozone formation potential of the VOCs in connection with photo-chemical reactions in the ambient air defines 12 subcategories for coating products applied to buildings and 5 subcategories for vehicle refinishing products for which limits are set with regard to the content of volatile organic compounds, VOC. The maximum VOC content has been set in the range of 30 - 840 g/l depending of the product.
Waste Framework Directive	Directive 2008/98/EC on waste.	According to the Directive a concentration of phenol in waste at a concentration that triggers classification of a mixture according to the CLP Regulation (in this case 1%) will render the waste hazardous.
Food contact material regulation	Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.	Phenol is authorised as monomer or other starting substance or macromolecule obtained from microbial fermentation in production of FCM made of plastic.
Food flavouring regulation	Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC with later amendments.	Phenol is listed in the register of flavouring substances used in or on foodstuffs.
Smoke flavourings in food	Commission Implementing Regulation (EU) No .../.. of xxx establishing the Union list of authorized smoke flavourings primary product for use as such in or on foods and/or for the production of derived smoke flavourings.	A limit value for phenol is listed in the specifications of the smoke flavourings.

Legal instrument	EU/national	Status of phenol
	The Regulation is adopted but not published yet.	
Water framework Directive	Directive 2000/60/EC on establishing a framework for Community action in the field of water policy.	Phenol is not included in the amended list of priority substances, but as a consequence of phenols classification with Mut. 2 it is covered by the ANNEX VIII indicative list of the main pollutants.
Water pollutant	Council Decision 2006/61/EC on the conclusion, on behalf of the European Community, of the UN-ECE Protocol on Pollutant Release and Transfer Registers.	Phenol is listed in Annex II as pollutant, with a threshold for release to water and land of 20 kg/year, and threshold for off-site transfers of pollutants.

2. CONCLUSION OF RMOA

Conclusions	Tick box
Need for follow up regulatory action at EU level <i>[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]</i>	
Substance evaluation	X
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action	

Based on concern that phenol may constitute a concern for human health through combined exposure, as well as through individual exposure scenarios, the substance qualifies for substance evaluation. The Danish EPA has proposed phenol for inclusion in the list of substances for prioritisation by ECHA for substance evaluation, with special focus on risk for the workers, risk for the consumers through specific exposure scenarios, and risk from combined exposure.