
# SUBSTANCE EVALUATION CONCLUSION

## as required by REACH Article 48

## and

## EVALUATION REPORT

**for**

# Substance name: Phenol

**EC No: 203-632-7**

**CAS No: 108-95-2**

**Evaluating Member State(s):** Denmark

Dated: 15 October 2021

# Evaluating Member State Competent Authority

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## Year of evaluation in CoRAP: 2015

Member State concluded the evaluation without any further need to ask more information from the registrants under Article 46(1) decision.

**Further information on registered substances here:**

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

This document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

# Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

# Contents

# Part A. Conclusion

## 1. CONCERN(S) SUBJECT TO EVALUATION

The Substance, Phenol (EC number 203-632-7, CAS RN 108-95-6) was originally selected for substance evaluation in order to clarify concerns about:

- Suspected Mutagenic (evaluated in Part B, section 7.9.5)
- Other hazard based concerns: Repeated dose toxicity (evaluated in Part B, section 7.9.4)
- Consumer use (evaluated in Part B, section 7.12.1(.1))
- Exposure of workers (evaluated in part B, section 7.12.1(.2))
- High (aggregated) tonnage (concern for human exposure: Part B, section 7.12.1)
- High RCR (evaluated in part B, section 7.12.1)

During the evaluation no additional concerns were identified.

## 2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

A compliance check (CCH) decision was issued on 27 October 2020: A transgenic rodent somatic and germ cell gene mutation assay (Annex X, Section 8.4., column 2; test method: OECD TG 488 from 2020) was requested (https://echa.europa.eu/documents/10162/5559883e-53f1-7c7a-72e5-b4c13d40b689).

## 3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the substance has led the evaluating Member State to the following conclusions, as summarized in the table below.

**Table 1**

| CONCLUSION OF SUBSTANCE EVALUATION | |
|---|---|
| **Conclusions** | **Tick box** |
| Need for follow-up regulatory action at EU level | X |
| Harmonised Classification and Labelling | |
| Identification as SVHC (authorisation) | |
| Restriction (depending on the outcome of the RMOA) | X |
| Other EU-wide measures | |
| No need for regulatory follow-up action at EU level | |

## 4. FOLLOW-UP AT EU LEVEL

### 4.1. Need for follow-up regulatory action at EU level

#### 4.1.1. Harmonised Classification and Labelling

n.a.

#### 4.1.2. Identification as a substance of very high concern, SVHC (first step towards authorisation)

n.a.

### 4.1.3. Restriction

For many occupational exposure scenarios the RCR values are close to one. Although none of these exposure scenarios constitutes a calculated risk by itself, workers are also exposed to phenol from other sources in their everyday life as general consumers. Consequently, the available information in the registration dossier and the publicly available literature on worker exposure and contributing sources of exposure to the general population does not demonstrate safe use of phenol.

To ensure safe use of the substance, regulatory risk management is needed. The eMCSA plans to prepare a Risk Management Option Analysis (RMOA) suggesting the conduction of a restriction proposal according to REACH article 69(4) that aims at restricting the contribution of occupational exposure to the maximum tolerated dose taking into account other exposure sources.

The current harmonised classification of phenol (Muta. 2, STOT RE 2*, Acute Tox. 3*, Skin Corr. 1B) was assigned based on translation from classification under Directive 67/548/EEC to the CLP regulation 1272/2008.
The available data on mutagenicity is sufficient for a Muta. 2 classification, which is the existing classification of phenol. However, as germ cell mutagenicity has not yet been clarified, the need for a Muta 1 classification cannot be excluded.
The eMSCA is of the opinion that the available data on repeated dose toxicity confirm the current STOT RE 2 classification.
An evaluation and classification shall be done in accordance with Articles 9-13 of the CLP regulation whenever data for the substance are available according to Annex VII of CLP (1272/2008). In order to include all relevant endpoints in a new classification proposal under CLP, this process will be initiated when the concerns for gene mutations and germ cell mutagenicity have been clarified taking all data generated up until that time-point into account in a wait of evidence analysis.

If a classification as Muta. 1b is confirmed as a possible result of CCH, the restriction proposal would take this classification into account, too.

### 4.1.4. Other EU-wide regulatory risk management measures

n.a.

## 5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

Not applicable.

## 6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Indication of a tentative plan is not a formal commitment by the evaluating Member State. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

**Table 2**

| FOLLOW-UP | | |
|---|---|---|
| **Follow-up action** | **Date for intention** | **Actor** |
| RMOA: Restriction proposal to reduce the allowed contribution from occupational exposure. | January 2023 (tentative) | DK |

# Part B. Substance evaluation

## 7. EVALUATION REPORT

### 7.1. Overview of the substance evaluation performed

The Substance, Phenol (EC number 203-632-7, CAS RN 108-95-6) was originally selected for substance evaluation in order to clarify concerns about:

- Suspected Mutagenic (evaluated in Part B, section 7.9.5)
- Other hazard based concerns: Repeated dose toxicity (evaluated in Part B, section 7.9.4)
- Consumer use (evaluated in Part B, section 7.12.1(.1))
- Exposure of workers (evaluated in part B, section 7.12.1(.2))
- High (aggregated) tonnage (concern for human exposure: Part B, section 7.12.1)
- High RCR (evaluated in part B, section 7.12.1)

During the evaluation no additional concerns were identified.

**Table 3**

| EVALUATED ENDPOINTS | |
|---|---|
| **Endpoint evaluated** | **Outcome / conclusion** |
| Mutagenicity | Concern unresolved.<br>Inn a compliance check decision, ECHA requested a TGR (TG OECD 488) (deadline: 2 August 2022).<br>Classification proposal will be considered. |
| Other hazard based concern (repeated dose toxicity and DNEL setting) | Concern refuted<br>No further action needed under SEV. |
| Human exposure (consumer use, exposure of workers, high (aggregated) tonnage, high RCR) | Concern confirmed<br>Regulatory action planned (RMOA proposing a restriction). No further action under SEV. |

### 7.2. Procedure

Phenol was included in the Community rolling action plan (CoRAP) in 2014. The substance evaluation (SEV) was initiated in March 2015 and the Competent Authority of Denmark (hereafter called the evaluating MSCA (eMSCA)) was appointed to carry out the evaluation.

Pursuant to Article 45(4) of REACH, the eMSCA carried out the evaluation and considered that further information was required. Therefore, a draft decision (DD) was prepared pursuant to Article 46(1) of REACH to request further information on the endpoints of mutagenicity and human exposure. The DD was submitted to ECHA on 15 March 2016.

In June 2016, the eMCSA received comments to the DD from the registrant. In the meantime the Substance was handed to ECHA for a compliance check due to the identification of a presumed data gap on standard information requirements for the endpoint of mutagenicity. Hence, the preparation of a revised DD was terminated.

The CCH was initiated in February 2020, and the Member State Committee reached a unanimous agreement on the draft decision on a CCH during its MSC-71 meeting. In the decision, a transgenic rodent somatic and germ cell gene mutation assay (Annex X, Section 8.4., column 2; test method: OECD TG 488 from 2020) was requested to be performed in transgenic mice or rats, oral route, on the following tissues: liver and glandular stomach; germ cells and duodenum must be harvested and stored for up to 5 years. Duodenum must be analysed if the results of the glandular stomach and of the liver are negative or inconclusive. The deadline for submission of the requested information is 2 August 2022.

Following the decision on CCH, the eMCSA resumed the Substance evaluation (SEV) and by informal communication, the registrant agreed to update the exposure section in the CSR in accordance with their response to comments (that were received by the eMCSA in June 2016 in response to the original DD). An updated version of the CSR was uploaded in IUCLID on 9 June 2021.

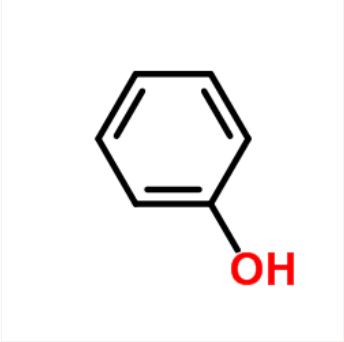
## 7.3. Identity of the substance

**Table 4**

| SUBSTANCE IDENTITY | |
|---|---|
| **Public name:** | Phenol |
| **EC number:** | 203-632-7 |
| **CAS number:** | 108-95-2 |
| **Index number in Annex VI of the CLP Regulation:** | 604-001-00-2 |
| **Molecular formula:** | C6H6O |
| **Molecular weight range:** | 94.1112 |
| **Synonyms:** | Carbolic Acid;<br>Monohydroxybenzene;<br>Phenylalcohol |

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

**Structural formula:**




## 7.4. Physico-chemical properties

**Table 5**

| OVERVIEW OF PHYSICOCHEMICAL PROPERTIES | |
|---|---|
| **Property** | **Value** |
| Physical state at 20°C and 101.3 kPa | Solid at 20°C and 101.3 kPa<br>Reliable information available from peer-review source |
| Vapour pressure | 0.2 hPa at 20°C |
| Water solubility | 84 g/L at 20°C |

| | |
|---|---|
| Partition coefficient n-octanol/water (Log Kow) | 1.47 at 30°C |
| Flammability | non flammable |
| Explosive properties | non explosive |
| Oxidising properties | non oxidising |
| Granulometry | Data waived |
| Stability in organic solvents and identity of relevant degradation products | Data waived |
| Dissociation constant | pKa at 20°C: 9.9 |

## 7.5. Manufacture and uses

### 7.5.1. Quantities

**Table 6**

| AGGREGATED TONNAGE (PER YEAR) | | | | |
|---|---|---|---|---|
| ☐ 1 – 10 t | ☐ 10 – 100 t | ☐ 100 – 1000 t | ☐ 1000- 10,000 t | ☐ 10,000-50,000 t |
| ☐ 50,000 – 100,000 t | ☐ 100,000 – 500,000 t | ☐ 500,000 – 1000,000 t | ☒ > 1000,000 t | ☐ Confidential |

### 7.5.2. Overview of uses

**Table 7**

| USES | Use(s) |
|---|---|
| **Uses as intermediate** | E.g. in manufacturing of bisphenol A, caprolactam, agrochemicals etc.<br><br><u>Environment release categories (ERCs)</u><br>ERC6a: Use of substance as intermediate/Agrochemical uses<br><br><u>Process categories (PROCs)</u><br>PROC 1: Production of substances in closed process, storage (indoor)<br>PROC 3: Production in closed batch processes with occasional controlled exposure (Indoor)<br>PROC 4: Production processes, where opportunity for exposure arises (indoor)<br>PROC 5: Open mixing process (indoor)<br>PROC 6: Calendering<br>PROC 7: Industrial spraying (indoor)<br>PROC 8a/b: Transfer at non-dedicated and dedicated facilities<br>PROC 9: Transfer into small containers (indoor)<br>PROC 10: Roller application and brushing (indoor)<br>PROC 13: Dipping and pouring (indoor)<br>PROC 14: Tabletting, compression, extrusion, pelletisation, granulation (indoor)<br>PROC 15: Laboratory activities (indoor) |

| | |
|---|---|
| | PROC 28: Cleaning / maintenance not covered otherwise (indoor),<br><br>Product categories (PCs)<br>PC 0: Other: light stabilizers, Chelating agent<br>PC 12: Fertilisers<br>PC 21: Laboratory chemicals<br>PC29: Pharmaceuticals<br>PC 30: Photo-chemicals<br>PC 35: Washing and cleaning products<br>PC 39: Cosmetics, personal care products |
| **Formulation** | Distribution of the substance as well as recycling and recovery, and formulation of phenol containing products such as reaction mixtures, coatings, adhesives, production of textiles and cleaning agents.<br><br>Environment release categories (ERCs)<br>ERC2: formulation and repackaging<br><br>Process categories (PROCs)<br>PROC 1: Production of substance in closed process, storage (indoor)<br>PROC 3: production in closed batch processes with occasional controlled exposure (indoor)<br>PROC 5: Open mixing process (Indoor)<br>PROC 6: Calendaring<br>PROC 7: Industrial spraying (indoor)<br>PROC 8a/b: Transfer at non-dedicated and dedicated facilities<br>PROC 9: Transfer into small containers (indoor)<br>PROC 10: Roller application and brushing (indoor)<br>PROC 13: Dipping and pouring (indoor)<br>PROC 14: Tabletting, compression, extrusion, plletisation, granulation (indoor)<br><br>Product categories (PCs)<br>PC 1: Adhesives, sealants<br>PC 3: Air care products<br>PC 4: Anti-freeze and de-icing products<br>PC 8: Biocidal products (e.g.disinfectants, pest control)<br>PC 9a: Coating and paints, thinners, paint removers<br>PC 9b: Fillers, putties, plasters, modelling clay<br>PC 12: Fertilisers<br>PC 15: Non-metal-surface treatment products<br>PC 21: Laboratory chemicals<br>PC 23: Leather treatment products<br>PC 24: Lubricants, greases, release products<br>PC 27: Plant protection products<br>PC 29: Pharmaceuticals<br>PC 30: Photo-chemicals<br>PC 31: Polishes and wax blends<br>PC 32: Polymer preparations and compounds<br>PC 35: Washing and cleaning products<br>PC 38: Welding and soldering products, flux products<br><br>Technical function of the substance: Cleaning agent, diluent, solvent, fuel additive, intermediate/precursor, monomer, resin (prepolymer) |
| **Uses at industrial sites** | **Phenolic resin and polymer manufacturing preparation and processing**<br><br>Phenol used as monomer in polymer manufacturing and processing. Additive handling (e.g., pigments, stabilisers, fillers, plasticisers etc.), moulding, curing, material re-works, phenolic resin processing for downstream use. |

| | |
|---|---|
| | Environment release categories (ERCs)<br>ERC4: Phenolic Resin processing (DU uses of Phenolic Resins)<br>ERC6c: Polymer manufacturing and processing<br><br>Process categories (PROCs)<br>PROC 1: Production in closed process without likelihood of exposure (indoor)<br>PROC 2: Production in closed continuous process with occasional controlled exposure (indoor)<br>PROC 3: Production in closed batch processes with occasional controlled exposure (indoor)<br>PROC 4: Production processes, where opportunity for exposure arises (indoor)<br>PROC 5: Open mixing process<br>PROC 6: Calendering<br>PROC 8a/b: Transfer at non-dedicated and dedicated facilities<br>PROC 9: Transfer into small containers (indoor)<br>PROC 10: Roller application, brushing<br>PROC 13: Dipping and pouring<br>PROC 14: Tabletting, compression, extrusion, pelletisation, granulation<br>PROC 15: Laboratory activities (indoor)<br>PROC 28: Cleaning / maintenance not covered otherwise, (indoor and outdoor)<br><br>**Rubber production and processing**<br><br>Handling of processed polymers into rubber products<br><br>Environment release categories (ERCs)<br>ERC6d: Rubber production and processing<br><br>Process categories (PROCs)<br>PROC 1: Production in closed process (indoor)<br>PROC 2: Production in closed continuous process with occasional controlled exposure (indoor)<br>PROC 3: Production in closed batch processes with occasional controlled exposure (indoor)<br>PROC 4: Production processes, where opportunity for exposure arises (indoor)<br>PROC 5: Open mixing process<br>PROC 6: Calendering<br>PROC 7: Spray process<br>PROC 8a/b: Transfer at non-dedicated and dedicated facilities<br>PROC 9: Transfer into small containers (indoor)<br>PROC 10: Roller application, brushing<br>PROC 13: Dipping and pouring<br>PROC 14: Tabletting, compression, extrusion, pelletisation, granulation<br>PROC 28: Cleaning / maintenance not covered otherwise, (indoor and outdoor)<br><br>**Use as binder or release agent**<br><br>Environment release categories (ERCs)<br>ERC5: Use as binder or release agent<br><br>Process categories (PROCs)<br>PROC 1: Use in closed process (indoor)<br>PROC 2: Use in closed continuous process with occasional controlled exposure (indoor<br>PROC 3: Use in closed batch processes with occasional controlled exposure (indoor)<br>PROC 4: Chemical production where opportunity for exposure arises (indoor)<br>PROC 5: Open mixing process |

| | |
|---|---|
| | PROC 6: Calendering<br>PROC 7: Spray process<br>PROC 8a/b: Transfer at non-dedicated and dedicated facilities<br>PROC 9: Transfer into small containers (indoor and outdoor)<br>PROC 10: Roller application, brushing<br>PROC 13: Dipping and pouring<br>PROC 28: Cleaning / maintenance not covered otherwise<br><br>**Uses in coatings**<br><br>Cross linker function in paints, inks, adhesives, thinners paint removers etc.)<br><br><u>Environment release categories (ERCs)</u><br>ERC4: Uses in coatings<br><br><u>Process categories (PROCs)</u><br>PROC 5: Open mixing process<br>PROC 8a: Transfer at non-dedicated facility<br>PROC 10: Roller application / brushing (indoor)<br>PROC 13: Dipping and pouring (indoor and outdoor)<br><br>**Use in laboratories**<br><br><u>Environment release categories (ERCs)</u><br>ERC4: Use in laboratories<br><br><u>Process categories (PROCs)</u><br>PROC 10: Roller application / brushing<br>PROC 15: Laboratory activities (indoor)<br>PROC 19: Manual activities involving hand contact<br>PROC 28: Cleaning / maintenance not covered otherwise (indoor and outdoor),<br><br><u>Product categories (PCs)</u><br>PC 0: Other uses (Light stabilizer, use in ceramic industry, construction materials, sanitary materials<br>PC 1: Adhesives, sealants<br>PC 3: Air care products<br>PC 4: Anti-freeze and de-icing products<br>PC 8: Biocidal products (e.g.disinfectants, pest control)<br>PC 9a: Coating and paints, thinners, paint removers<br>PC 9b: Fillers, putties, plasters, modelling clay<br>PC 9c: Finger paints<br>PC 12: Fertilisers<br>PC 15: Non-metal-surface treatment products<br>PC 21: Laboratory chemicals<br>PC 24: Lubricants, greases, release products<br>PC 27: Plant protection products<br>PC 29: Pharmaceuticals<br>PC 30: Photo-chemicals<br>PC 31: Polishes and wax blends<br>PC 32: Polymer preparations and compounds<br>PC 35: Washing and cleaning products<br>PC 38: Welding and soldering products, flux products<br>PC 39: cosmetics and personal care products<br>PC 40: extraction agent<br><br>**Production of leader treatment products**<br><br><u>Environment release categories (ERCs)</u><br>ERC6a: Downstream users formulation<br><br><u>Process categories (PROCs)</u><br>PROC1, PROC2, PROC3, PROC5, PROC 8a/b |

| | |
|---|---|
| **Uses by professional workers** | **Phenolic resin and polymer manufacturing preparation and processing**<br><br>Manufacturing and processing of formulated polymers. Downstream uses of phenol resins<br><br>Environment release categories (ERCs)<br>ERC8a: Phenolic resins processing<br>ERC8c: Polymer manufacturing and processing<br><br>Process categories (PROCs)<br>PROC 1: Production in closed process without likelihood of exposure (indoor)<br>PROC 2: Production in closed continuous process with occasional controlled exposure (indoor)<br>PROC 3: Phenolic Resin processing<br>PROC 4: Phenolic Resin processing<br>PROC 8a/b: Transfer at non-dedicated and dedicated facilities<br>PROC 9: Transfer into small containers (indoor)<br>PROC 11: non-industrial spraying<br>PROC 14: Tabletting, compression, extrusion, pelletisation, granulation<br>PROC 15: Phenolic resin processing<br><br>**Use in laboratories**<br><br>Environment release categories (ERCs)<br>ERC8a: Use in laboratories<br><br>Process categories (PROCs)<br>PROC 10: Roller application, brushing<br>PROC 15: laboratory activities<br><br>**Uses in coatings**<br><br>Cross linker function in paints, inks, adhesives, thinners paint removers etc.)<br><br>Environment release categories (ERCs)<br>ERC8b: Uses in coatings<br><br>Process categories (PROCs)<br>PROC 5: Open mixing process<br>PROC 8a: Transfer at non-dedicated facility<br>PROC 10: Roller application / brushing (indoor)<br>PROC 13: Dipping and pouring (indoor and outdoor)<br><br>**Use as binders and release agents**<br><br>Environment release categories (ERCs)<br>ERC8b: Use as binders and release agents<br><br>Process categories (PROCs)<br>PROC 1: use in closed process<br>PROC 2: Use in closed continuous process with occasional controlled exposure (indoor)<br><br>**Agrochemical uses**<br><br>Use of fertilizers/chelating agents<br><br>Environment release categories (ERCs)<br>ERC8b: Agrochemical uses<br><br>Process categories (PROCs)<br>PROC 4: Production processes, where opportunity for exposure arises (indoor) |

| | |
|---|---|
| | PROC 5: Open mixing process<br>PROC 8a/b: Transfer at dedicated and non-dedicated facilities |
| **Consumer Uses** | In surveys of chemical substances in consumer products, the Danish EPA has found that phenol was emitted from various "Do it yourself" products sold in consumer shops such as paints, adhesives, fillers, a wax/polish product and a membrane product (Danish EPA, 2020). This is supported by information in the Nordic product registers (SPIN database: http://spin2000.net/) indicating that one or several uses probably leads to consumer exposure.<br><br>Previously phenol was also found in other consumer products such as sex toys, fetish clothing (Danish EPA, 2006a), waders (Danish EPA, 2004), creams for treatments of sports pains and injuries (Danish EPA, 2006b) and various electronics (Danish EPA, 2006c). |
| **Article service life** | E.g. paper phenolic circuit board and phenol resin impregnated paper.<br><br>Environment release categories (ERCs)<br>ERC10a; ERC11a: Paper phenolic circuit board and phenol resin impregnated paper |

## 7.6. Classification and Labelling

### 7.6.1. Harmonised Classification (Annex VI of CLP)

**Table 8**

| HARMONISED CLASSIFICATION ACCORDING TO ANNEX VI OF CLP REGULATION (REGULATION (EC) 1272/2008) | | | | | | | |
|---|---|---|---|---|---|---|---|
| **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: Monohydroxy benzene; Phenylalcohol; carbolic acid | 203-632-7 | 108-95-2 | Acute Tox. 3*<br>Acute Tox. 3*<br>Acure Tox. 3*<br>Skin Corr. 1B<br>Muta. 2<br>STOT RE 2* | H301;<br>H311;<br>H331;<br>H314;<br>H341;<br>H373; | Skin Corr. 1B; H314: ≥3%<br>Skin Irrit. 2; H315:1%≤ C ≤3%<br>Eye Irrit. 2 H319; 1% ≤ C ≤ 3% | |

### 7.6.2. Self-classification

- In the registration(s):

The registrant(s) attributes the following classifications:

Acute Tox. 3; H301 (toxic if swallowed)
Acute Tox. 3; H311 (toxic in contact with skin)
Acute Tox 3; 331 (toxic if inhaled)
Skin Corr. 1B; H314 (Causes severe skin burns and eye damage)
Muta. 2; H341 (suspected of causing genetic defects)
STOT Rep. Exp. 2 Affected organs: kidney, liver, skin, nervous system; H373 (May cause damage to organs)

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

Acute Tox. 1; H330 (Fatal if inhaled)
Acute Tox. 4; H302 (Harmful if swallowed)
Acute Tox. 4; H312 (Harmful in contact with skin)
Eye Dam. 1; H318 (Causes serious eye damage)
Skin Irrit. 2; H315 (Causes skin irritation)
Skin Sens. 1; H317 (May cause an allergic skin reaction)
STOT SE 1; H370 (causes damage to organs)
STOT SE 2; H371 (May cause damage to organs)
STOT SE 3; H335 (May cause respiratory irritation Eye Irrit. 2; H319 (Causes serious eye irritation)
STOT RE 1; H372 (Causes damage to organs through prolonged or repeated exposure)
Muta. 1B; H340 (May cause genetic defects)
Repr. 1B; H360 (May damage fertility or the unborn child)
Cars. 2; H351 (Suspected of causing cancer)
Aquatic Acute 1; H400 (Very toxic to aquatic life)
Aquatic Chronic 1; H410 (Very toxic to aquatic life with long lasting effects Aquatic Chronic 2; H411 (Toxic to aquatic life with long lasting effects

## 7.7. Environmental fate properties

Not evaluated by the eMSCA

## 7.8. Environmental hazard assessment

Not evaluated by the eMSCA

## 7.9. Human Health hazard assessment

### 7.9.1. Toxicokinetics

Not evaluated by the eMSCA

### 7.9.2. Acute toxicity and Corrosion / Irritation

Not evaluated by the eMSCA

### 7.9.3. Sensitisation

Not evaluated by the eMSCA

### 7.9.4. Repeated dose toxicity

#### 7.9.4.1. Oral route

Other hazard based concern was previously raised by the eMCSA for repeated dose toxicity by the oral route for consumers, as the tolerable daily intake (TDI) for phenol was lowered by EFSA from 1.5 mg/kg bw/day to 0.5 mg/kg bw/day in a report published in 2013 (EFSA 2013). In that report, EFSA comprehensively reviewed the available toxicological studies, mainly those using an oral route of exposure. In the newest version of the substance dossier, the EFSA TDI of 0.5 mg/kg bw/day was adopted by the phenol registrants and applied for extrapolation of DNEL values for long-term inhalation, dermal and oral exposure of the general population.

There are a number of repeated dose toxicity studies available where phenol has been dosed through the drinking water. Effects in these studies on body weights and body weight gain is potentially linked to the characteristic odour of phenol, leading to a decreased water consumption.

Two of the available studies are carcinogenicity studies in rats and mice, which include a restricted number of endpoints as their main objective were to assess a possible carcinogenic potential of phenol (NCI 1980). In both species the effects were reduced water intake and reduction of body weight gains, with LOEL of 280 mg/kg bw/day (2500 ppm) in mice. In rats, a LOEL of 200 mg/kg bw/day (2500 ppm) for water consumption and 450 mg/kg bw/day (5000 ppm) for reduced body weights were reported.

In an oral two-generation reproduction toxicity study by Ryan et al. (2001), the duration corresponded to that of a 90-day study. A NOAEL of 71 mg/kg bw/day and LOAEL of 300 mg/kg bw/day (5000 ppm) was set based on reduced water consumption, decreased food consumption, decreased body weight/body weight gain and increased organ to body weight ratios. In a gavage developmental toxicity study by York et al. (1997) reduced maternal body weight gain in rats exposed to phenol by gavage from GD6 to GD16 was observed and a NOAEL of 120 mg/kg bw/day was set. These two studies were considered to be the most robust toxicity studies by the EFSA panel that performed a dose-response analysis of these data using the benchmark dose (BMD) approach. The lower 95 % confidence bound (one-sided) of the BMD, denoted BMDL, was then taken as the reference point.
The Panel noted that the lowest point of departure was provided by York et al. (1997) for reduced maternal body weight gain. Therefore, the Panel used the BMDL10 of 52 mg/kg bw/day from this study to derive a TDI for phenol. The Panel considered it appropriate to apply a standard uncertainty factor (UF) of 100 to account for inter- and intra-species variability and derived a TDI of 0.5 mg/kg bw/day. Further adjustment factors to account for the short duration of the treatment in the York study were not considered necessary, as data from other studies of longer duration such as the Ryan study and the 90-day and chronic oral toxicity studies from NTP in 1980 support the effect levels seen in the York study (EFSA, 2013).

In the EU risk assessment report (RAR) (ECB, 2006) concerns were raised on the effects of phenol on immunotoxicity and on haematological parameters, amongst other a reduction in the erythrocyte count based on a study in mice dosed for 28 days (Hsieh et al. 1992). The study showed a dose-related decrease in red blood cell counts, as well as immune suppression in functional immune assays. No structural effects were found on the spleen and thymus weights, and in an evaluation by the EFSA panel in 2013 (EFSA 2013) it was concluded that the study suffered from significant deficiencies leading to the decision not to consider the study for the derivation of a TDI for oral exposure to phenol. The eMSCA agrees that evidence of immunotoxic and haematological effects of phenol is too week to lead to DNEL setting.

There are at least three reports published on accidental repeated oral exposure of humans via contamination of drinking water after phenol spillage (Baker et al., 1978 (Southern Wisconsin); Jarvis et al., 1985 (North Wales); Kim et al., 1994 (Nakdong river in Korea)). In these reports, gastrointestinal illness (diarrhoea, nausea and vomiting), dark urine and mouth sores were described in response to drinking the contaminated water. There are however limitations in these studies. Among others, it is difficult to estimate for how long time the concentration of phenol was actually increased in the drinking water and it may be only the first approx. 24 hours after contamination. In addition, a significant amount of chlorophenols is formed when phenol react with chloride in the water which is expected to contribute significantly to the observed effects in humans.

**Table 9: oral route study summaries**

| Method | Results | Remarks | Reference |
|---|---|---|---|
| Long term exposure (daily exposure 103 weeks) of rats (males and females) (Fischer 344) through drinking water ad libitum | NOAEL: 450 mg/kg bw/day (5000 ppm); The highest dose tested because observed reduced body weight is related to reduced water | 2 (reliable with restrictions)<br>limited number of parameters tested | NCI (1980) |

| Method | Results | Remarks | Reference |
|---|---|---|---|
| Method equivalent or similar to OECD TG 451 (carcinogenicity study) rat male/female<br>0, 2500, 5000 ppm (nominal in water; analytical concentration of the high dose: 5237+-509 ppm).<br>The ingested doses were approximately 0, ca. 200 and ca. 450 mg/kg bw/day<br>Vehicle: tap water | consumption (flavour aversion to phenol);<br>LOEL: 200 mg/kg bw/day 2500 ppm (male/female) (reduced water consumption)<br>LOEL: 450 mg/kg bw/day (5000 ppm) in males/females: reduced body weight | (carcinogenicity study)<br>Test material phenol | |
| 2 generation study Sprague-Dawley rat (oral: drinking water ad libitum)<br>Nominal concentrations I water of 0, 200, 1000, and 5000 ppm corresponding to 0, 15, 71, and 300 mg/kg bw/day (actually ingested)<br>Vehicle: tap water<br>Exposure of P generation: 10 weeks prior to mating, during the 2-week mating period until sacrifice; totally 13 weeks. | NOAEL: 71 mg/kg bw/day (1000 ppm (male)<br>LOAEL: 300 mg/kg bw/day (5000 ppm) (male): reduced water consumption, decreased food consumption, decreased body weight/body weight gain, increased organ to body weight ratios | Only P generation included in this table<br>2 (reliable with restrictions)<br>Test material phenol | Ryan BM, Selby R, Gingell R, Waechter JM, Butala JH, Dimond SS, Dun (2001) |
| rat (Sprague-Dawley) male/female<br>oral subchronic (13 weeks) through drinking water<br>0, 200, 1000, 5000 ppm (nominal in water), corresponding to 25, 107, 360 mg/kg bw/day for females (actual ingested) and 18, 83, 308 mg/kg bw/day for males (actual ingested)<br>Vehicle: water<br>equivalent or similar to OECDTG 424 | NOAEL: 5000 ppm (male/female) (360 or 308 mg/kg bw/day in females or males, respectively)<br>NOEL: 200 ppm (male/female)<br>LOEL:reduced water consumption at 1000 ppm (107 mg/kg bw/day in females and 83 mg/kg bw/day in males) | 2 (reliable with restrictions)<br>Test material: phenol | Unpublished report (1998) |
| Developmental study:<br>Rats were exposed by gavage to 0, 60, 120 or 360 mg/kg bw/day on GD 6-16<br>Equivalent to OECD TG 414 | Maternal toxicity NOAEL: 120 mg/kg bw/day based on reduced BWG at the highest dose (360 mg/kg bw/day). A $BMDL_{10}$: 52 mg/kg bw/day was calculated by EFSA for their opinion development. | 2 (reliable with restrictions)<br>Study not included in the registration | York RG, 1997, referred from EU RAR/ EFSA opinion, 2013 |

| Method | Results | Remarks | Reference |
|---|---|---|---|
| Oral chronic of male and female B6C3F1 mice (103 weeks daily ad libitum in drinking water)<br><br>0, 2500, 5000 ppm (nominal in water; analytical concentration of the high dose: 5237+-509 ppm), corresponding to actual ingested doses of 0, ca. 280 and 370 mg/kg bw/day.<br><br>Vehicle: tap water<br><br>equivalent or similar to OECD TG 451 (carcinogenicity study) | NOAEL: 370 mg/kg bw/day (5000 ppm) (male/female) reduced body weight related to reduced water consumption; limited number of parameters tested (carcinogenicity study)<br><br>LOEL: 280 mg/kg bw/day (2500 ppm) (male/female) (reduced water consumption and body weight gain) | 2 (reliable with restrictions)<br><br>Test material: phenol | NCI (1980) |
| Oral exposure of humans for via contamination of drinking water by 100% phenol of in Southern Wisconsin.<br><br>Intake of 0.14-3.42 mg/kg bw/day | Human illness characterized by diarrhea, mouth sores, dark urine, burning of the mouth in seventeen individuals. | Small dataset. Human illness was reported by seventeen individuals | Baker et al., 1978 |
| Oral exposure of humans via contamination of drinking water by phenol. 250 households that received water from the River Dee in north Wales diluted in reservoir A (high exposure area), and 94 control households that received water from the River Dee after dilution in reservoir B (low exposure area). Elevation of phenol was observed in drinking water for 24 hours. | Gastrointestinal illness (defined as nausea, vomiting, diarrhoea, or abdominal pain) | Difficult to determine to what extent effects are caused by the formation of chlorophenols in the water supply | Jarvis et al., 1985 |
| Oral exposure of humans via contamination of drinking water by 100% phenol in Nakdong river in Korea. | Significant increase in gastrointestinal symptoms defined as nausea, vomiting, diarrhea or abdominal pain. | Difficult to differentiate between effects of phenol and chlorophenols | Kim et al., 1994 |

### 7.9.4.2. Inhalation route

No new information relating to the toxicity by repeated exposure by inhalation of phenol have been made available in the registration of phenol when compared to the recommendation report from the evaluation of the Scientific Expert Group on Occupation Exposure Limit (OEL) in 2003 (SCOEL, 2003) and the EU risk assessment report (RAR) from 2006 (ECB, 2006). The NOAEC chosen for risk characterisation of workers is similar to the one used in EU-RAR and OEL setting, namely 20 mg/m$^3$, which is based on a study

from 1961 in male rhesus monkeys (Sandage C., 1961). The eMSCA agrees with the registrants' evaluation of the end-point and with the DNEL setting at 8 mg/m$^3$ which is also used for extrapolation of the DNEL value for dermal exposure of workers.

**Table 10: Inhalation route study summaries**

| Method | Results | Remarks | Reference |
|---|---|---|---|
| Species: Rat, rabbit and Guinea pigs<br>Duration: sub chronic study (inhalation: vapour) (whole body)<br>Exposure concentrations: 100-200 mg/m$^3$ (analytical conc.) | NOAEC: ca. 100 mg/m$^3$ in air: no clinical signs, no effects at necropsy or at histopathology one dose | 4 (not assignable) limited validity<br>Test material phenol.<br>No information on purity | Deichmann WB, Kitzmiller KV, Witherup S (1944) |
| Species: rat (Fischer 344) male/female<br>Exposure subacute (2 weeks) inhalation of vapour (nose only) 6 hours per day, 5 days per week<br>Nominal concentrations: 0.0, 0.50, 5.0, and 25 ppm<br>Target concentrations: 0, 1.9, 19, 96 mg/m$^3$)<br>Analytical conc.: 0.00, 0.52 ± 0.078, 4.9 ± 0.57 and 25 ± 2.2 ppm<br>Vehicle: demineralized & distilled water; air in inhalation chamber<br>Exposure: equivalent or similar to OECD TG 412 (Repeated Dose Inhalation Toxicity: 28/14-Day) | NOAEC: 25 ppm (male/female) (overall effects (higher concentrations not tested)) | 2 (reliable with restrictions)<br>Test material: phenol<br>No information on purity | Hoffman GM, Dunn BJ, Morris CR, Butala JH, Dimond SS, Gingell R, Waechter (2001) |
| Species: Monkey (Macaca mulatta), rats, mice<br>Sex: male<br>Duration: subchronic (90 d) whole body inhalation(8 h/d, 5 d per week)<br>Concentration: 5 ppm (19.6 mg/m3) (nominal conc.)<br>4.7 ppm(18.5 mg/m3) (analytical conc.)<br>Vehicle: air | NOAEC: 5 ppm (19.6 mg/m$^3$ based on liver pathology | 2 (reliable with restrictions)<br>Test material phenol<br>No information on purity<br>Used for OEL setting | Sandage C (1961) |
| 20 workers<br>Occupational exposure to 21 mg/m$^3$ in average (5.4 ppm)<br>Over 13.2 years<br>Blood samples collected at end of shift at the end of the week. | LOAEL: 21 mg/m$^3$: Elevated liver enzyme levels and increased clotting time. | Shortcomings in reporting.<br>Study used in EU RAR for risk characterisation | Shamy et al., 1994, reported from EU RAR, 2006. |

#### 7.9.4.3. Dermal route

Only one study on repeated dose toxicity of phenol by the oral route was identified. This study is described in table 11.

**Table 11: Dermal route study summaries**

| Method | Results | Remarks | Reference |
|---|---|---|---|
| Rabbits (albino, common species). Repeated dermal application of phenol in aqueous solution on 18 days at concentrations: 1.18%, 2.37%, 3.56%, 4.75%, 5.93% and 7.12%<br><br>Four animals pr. Exposure group. | NOAEL for systemic toxic effects: 130 mg/kg bw/day (1.18%)<br><br>LOAEL for systemic toxic effects: 260 mg/kg bw/day<br><br>NOAEL for local effects on the skin: 260 mg/kg bw/day | 4 (not assignable) limited validity/ reporting and few animals tested. | Deichmann et al., 1950 |

#### 7.9.4.4. Conclusion of repeated dose toxicity

Concern was raised by the eMCSA for repeated dose toxicity by the oral route for consumers, as the TDI for phenol was lowered by EFSA from 1.5 mg/kg bw/day to 0.5 mg/kg bw/day in a report published in 2013 (EFSA 2013), but not included in the DNEL calculation in the registration dossier. In the newest version of the registration dossier however, the EFSA TDI of 0.5 mg/kg bw/day was adopted and applied for extrapolation of DNEL values for long-term inhalation, dermal and oral exposure of the general population.

The applied DNEL values for workers follow the suggestion by the Scientific Expert Group on Occupation Exposure Limit (OEL) in 2003 (SCOEL, 2003) and the EU risk assessment report (RAR) from 2006 (ECB, 2006).

In conclusion, the eMSCA has no residual concern for the extrapolation of DNEL values applied in the substance dossier of phenol.

It is the eMSCA's opinion that the available data on repeated dose toxicity is sufficient to fulfil the current STOT RE 2 classification. However, the category of the STOT RE classification will be further evaluated following the clarification of the mutagenicity concerns enabling taking all data generated up until that time-point into account in a weight of evidence analysis.

### 7.9.5. Mutagenicity

Phenol is mutagenic *in vitro* and *in vivo* and has a harmonised classification for mutagenicity as Muta 2, H341; Suspected of causing genetic defects. The available *in vitro and in vivo* genotoxicity data is however unable to address the remaining concerns about mutagenicity in somatic cells and the potential of phenol and/or its reactive metabolites to induce heritable chromosomal aberrations and/or gene mutations in germ cells.

#### 7.9.5.1. Description of the available data on mutagenicity

*Chromosomal aberrations and genotoxicity in vitro*

Phenol has yielded positive results *in vitro* in several chromosomal aberration tests, including the micronucleus test in different mammalian cell lines with and without metabolic activation (Ivett at al., 1989; Miller et al., 1995; Glatt et al., 1989; Yager et al., 1990). Furthermore, Phenol has yielded positive results in sister chromosome exchange tests as well as yielded positive results in the induction of DNA strand breaks in mouse lymphoma cells with metabolic activation. Phenol also induced DNA strand breaks in human

lymphocytes, murine spermatogonial cells and chick liver hepatocellular cells (LMH) in non-guideline *in vitro* comet assays (Li et al., 2005; Nowak et al., 2017).

*Gene mutations in vitro*

Phenol has yielded negative results in the Ames test in several reliable, well-conducted studies for all five strains (TA1535, TA97, TA98, TA100, TA102) with and without metabolic activation (Gilbert et al., 1980; Haworth et al., 1983; Glatt et al., 1989; Hu et al., 2020). In one study however, using a special modified medium (ZML medium) instead of common Vogel-Bonner medium, a weakly positive result for TA 98 was observed with a maximum effect of about 2.5-fold increase in mutant frequency (Gocke et al., 1981).

In mammalian cells, phenol has yielded positive results for gene mutations (at the hprt locus and Na+/K+ locus and in the mouse lymphoma assays) with and without metabolic activation (Paschin and Bahitova, 1982; Wangenheim and Bolcsfoldi, 1988; McGregor et al., 1988; Tsutsui et al., 1997; Hu et al., 2020).

*Chromosomal aberrations in vivo*

A negative result has been reported in a rodent bone marrow aberration test using 110-510 mg/kg bw by i.p. and p.o. exposure (Thompson and Gibson, 1984). However, only 3 animals per group were used and only 30 metaphases analysed per animal making the study unreliable (eMSCA Klimisch 3).

Contradictory results have been observed in several mouse bone marrow micronucleus (MN) tests similar to the OECD 474 performed by either oral or i.p. exposure, but positive results have been found in some tests using doses of 40-300 mg/kg bw (references are listed in ECHA decision on a compliance check for phenol (ECHA 2020)). All tests used polychromatic bone marrow erythrocytes and used a low number of animals (typically 3-5 per group). It was noted in some studies, which used high doses close to LD50 (265, 300 mg/kg bw) that prolonged hypothermia occurred concurrently with the occurrence of micronuclei. The lowering of core body temperature in response to toxicants is an adaptive mechanism that can be seen in rodents which is hypothesised to be linked to a body temperature sensitive impairment of microtubule assembly during mitosis. In light of this, it has been suggested by the registrant that the mutagenic effect of the substance is due to an indirect threshold mode of action that may not be physiologically relevant to humans. Taking this into account, it has been attempted to artificially maintain core body temperature of the animals while performing micronucleus assays, but this approach did not succeed in the reviewed studies (Spencer et al. 2007, SOT Annual Meeting 2003). The study by Spencer et al. (2007), however, showed that the disruption of the spindle apparatus only explained some of the MN generated in mice in response to phenol exposure and it is noted that some studies using lower doses of phenol (40, 80, 160, 180 mg/kg bw) also produced MN. The core body temperature of the test animals was not reported in these studies, but in the study by Spencer et al. (2007) a significant reduction in temperature when using 100 mg/kg bw was not observed.

Even though, the MN studies deviated from the OECD test guideline 474 a weight of evidence approach of all available studies makes it possible to reach the overall conclusion that phenol causes MN induction in exposed mice.

*Gene mutations in vivo*

As described in the decision on the compliance check (ECHA 2020), the phenol dossier contains several *in vivo* studies investigating gene mutations:

- Sex-linked recessive lethal assays in Drosophila melanogaster, including the study from Woodruff et al (1985),
- DNA strand break test in testes of rats from, Skare and Schrotel (1984),
- DNA damage tests in rats, including the study from Reddy et al. (1990),
- DNA damage test in mice from Kolachana ef a/. (1993),
- *In vitro-in vivo* replicative DNA synthesis test in rats from Takasawa et al. (1994),
- *In vitro-in vivo* replicative DNA synthesis test in mice from Miyagawa et al. (1995),

- Induction of LacZ-mutations in tissues of treated Muta-TM mice, inhalation and dermal routes, Reliability. 3, GLP compliant, no test guideline followed, ECB (1999; final report in 2006).

The eMSCA did however not consider any of these studies adequate or reliable enough to follow up on the gene mutation concern according to the adaptation rule in REACH Annex XI, Section 1.1.2. The data gap was discussed with ECHA, and phenol was handed over for a compliance check. As a consequence, the information requirement for a second *in vivo* somatic cell genotoxicity study, OECD TG 488 in liver, glandular stomach and duodenum, was requested. The deadline for submission of the requested information in the compliance check is 2 August 2022 (ECHA 2020).

*Germ cell genotoxicity in vivo:*

The potential of phenol and/or its reactive metabolites to induce heritable mutations has not been adequately investigated. Only one study was identified which investigated germ cell genotoxicity *in vivo*: A non-guideline study by Skare and Schrotel (1984) using the alkaline elution technique to measure DNA single strand breaks in testicular cells from rats exposed to 7.9-79 mg/kg phenol (single) and 4-39.5 mg/kg (5-day) exposures and by i.p. injection. Positive controls produced strand breaks. The result of phenol was negative. However, the dose used was low and it is unclear if this technique, which investigates single strand breaks is suitable for germ cell testing due to the highly variable results for sperm cells resulting from other more recent single strand break tests such as the OECD 489 (Comet assay).

In the decision on CCH (ECHA 2020), it was noted that a subsequent germ cell genotoxicity study (TGR/OECD TG 488, or CA on spermatogonia/OECD TG 483, depending on the concern raised by the substance) may still be required under Annex X of REACH, in case 1) an *in vivo* genotoxicity test on somatic cell is positive, and 2) no clear conclusion can be made on germ cell mutagenicity. According to the OECD 488 the tissues (or tissue homogenates) can be stored under specific conditions and used for DNA isolation for up to 5 years. Hence, in order to limit additional animal testing the registrant was requested to collect male germ cells (from the seminiferous tubules) at the same time as the other tissues (liver, glandular stomach and duodenum).

#### 7.9.5.2. Conclusion of Mutagenicity

The available *in vitro* and *in vivo* genotoxicity data raise a concern for both chromosomal aberrations and gene mutation effects of phenol, and the next evaluation step of the substance in this regard is the assessment of the TGR (TG 488) requested in the decision on a compliance check. The deadline for the submission of the results of the test is 13 August 2022.

Currently, there is a potential risk of human health effects due to the mutagenic properties of phenol as the available *in vitro* and *in vivo* genotoxicity data is unable to address the remaining concerns about the potential of phenol and/or its reactive metabolites to induce heritable chromosomal aberrations and/or gene mutations in somatic cells and germ cells. Hence, it is not yet known whether the current classification as Muta Cat 2 is sufficient or if a harmonised classification as Muta Cat 1B is more appropriate.

No studies investigating genotoxicity of phenol by dermal or inhalation exposure has been identified. Therefore, mutagenicity by other exposure routes than the oral route cannot be excluded.

### 7.9.6. Carcinogenicity

Not evaluated by the eMSCA.

### 7.9.7. Toxicity to reproduction (effects on fertility and developmental toxicity)

Not evaluated by the eMSCA

### 7.9.8. Hazard assessment of physico-chemical properties

Not evaluated eMSCA

### 7.9.9. Selection of the critical DNEL(s) / DMEL(s) and / or qualitative / semi-quantitative descriptors for critical health effects

See section 7.9.4

### 7.9.10. Conclusions of the human health hazard assessment and related classification and labelling

With respect to the endpoint of mutagenicity, a data-gap on standard information requirements for the endpoint of mutagenicity was identified in a compliance check and a TGR study has been requested (deadline of submission: 2 August 2022). Currently no further action on this endpoint is planned under SEV. Depending on the outcome of the test requested under compliance check and the following clarification of germ cell mutagenicity, it may be relevant to revisit the classification for mutagenicity of phenol.

The eMCSA has no residual concerns on the registrants' DNEL settings related to the endpoint of repeated dose toxicity based on the latest dossier update dated May 2021. Regarding the classification for repeated dose toxicity, the eMSCA is of the opinion that the current STOT RE 2 classification is warranted.

## 7.10. Assessment of endocrine disrupting (ED) properties

Not evaluated by the eMSCA

## 7.11. PBT and VPVB assessment

Not evaluated by the eMSCA

## 7.12. Exposure assessment

### 7.12.1. Human health

Phenol is registered in high aggregated tonnage (> 1000,000 t) and can be used as an intermediate for the manufacture of e.g. bisphenol A, caprolactam and other substances, which can ultimately be used for the production of articles. Phenol is also used directly in some products such as paper phenolic circuit board and phenol resin impregnated paper and there are many products (chemical mixtures and articles) with a potential for releasing phenol. In addition to exposure of workers, some of these products results in exposure of consumers and the general population on a regular basis and others on occasional basis. Exposure of the entire general population including adults, children and other vulnerable population is expected.

#### 7.12.1.1. Consumer

There is no description of consumer applications of mixtures/preparations in the registrant CSR. However, a recent Danish survey of chemicals in consumer products found that phenol was emitted in significant levels from various "Do it yourself" chemical mixtures intended for consumers including products such as paints, adhesives, fillers, a wax/polish product and a membrane product (Danish EPA, 2020). This finding is supported by information in the Nordic product registers (SPIN database: http://spin2000.net/) indicating that one or several uses in chemical mixtures probably lead to consumer exposure.

Phenol was previously also found to be emitted from other consumer products such as sex toys, fetish clothing (Danish EPA, 2006a), waders (Danish EPA, 2004), creams for treatments of sports pains and injuries (Danish EPA, 2006b), flooring materials (Yu and Kim, 2009; Reiser et al., 2002; Hodgson, 1999) and in various electronics such as computers, playing consoles, TV sets, chargers and transformers (Danish EPA, 2006c, Wensing et al., 2002). In addition consumer exposure to phenol is expected to occur via food, food contact materials, medicines as well as through the air/smoke e.g. from automobile exhaust, human and animal metabolism, different combustion processes and cigarette smoke (ECB 2006 and Danish EPA 2014). Phenol has continuously been measured in indoor air (Edwards et.al., 2001; Järnström H, 2007; Chin Jo-Yu et.al. (2014)).

In the dossier CSR, consumer exposure to paper phenolic circuit board and phenol resin impregnated paper is accounted for. The calculated RCR value for the combined exposure to these products is just below 0.2, which, by itself, does not demonstrate a risk to consumers. This RCR value was calculated for adults only. It is however also expected that children and other vulnerable population groups are exposed to phenol to some extent from many sources on a regular basis for some products and for others on occasional basis. Hence, it can also be discussed whether “infrequent use” corresponding to events occurring between once a month and once every 6 months, as applied in the calculations performed by the registrants, is adequate, or if exposure should rather be considered to be “occasional” corresponding to events occurring between once a week to once a month according to the guideline for consumer exposure related to the applied exposure model (ECETOC 2014).

#### 7.12.1.2. Worker

The REACH registration data include occupational exposure scenarios for industrial and worker exposure. Workers exposure occur from various processes such as mixing, calendaring, spraying, transfer and pouring, roller application and brushing, tabletting, compression, extrusion, palletisation, granulation, laboratory activities in addition to cleaning and maintenance processes.

Phenol is toxic, and the use of personal protective equipment (PPE) by workers is essential to avoid excessive exposure and hence substance induced adverse effects. In some of the exposure scenarios presented in the CSR, a 95% protection level from gloves is expected. It is, however, not clear how this high level of protection is ensured by the registrant. According to ECETOC TRA v3 guideline (ECETOC 2012), the highest value for professional settings is 90% with basic employee training and 95% is only considered to be realistic for industrial settings when special employee training is in place. There is a concern that downstream users will fail to ensure the use of suitable personal protective equipment if they are not adequately informed. The use of unsuited material may for instance even result in higher level of exposure than not using any protection at all, as the inside of contaminated gloves, may be covered with migrated substance – and the skin inside a glove is often humid – corresponding to exposure under occlusion. Hence, the eMCSA expects that information on how to achieve this high level of 95% protection by using PPE is thoroughly passed on through the supply chain to downstream users by the registrant.

Although a significant number of calculations in the dossier result in relatively high RCR values above 0.85, none of the calculated RCR values covering the various occupational exposure scenarios exceeds one by itself. It is however vital to consider that workers are also exposed from phenol in their everyday life as general consumers.

#### 7.12.1.3. Conclusion on human health exposure

Overall, the available information in the registration dossier and the publicly available literature on worker exposure and contributing sources of exposure to the general population does not demonstrate safe use. In conclusion, the available data indicate that there is a potential risk for workers from the exposure of phenol.

To ensure safe use of the substance, regulatory risk management is needed. The eMCSA plans to prepare a Risk Management Option Analysis (RMOA) suggesting the conduction of

a restriction proposal according to REACH article 69(4) that aims at restricting the contribution of occupational exposure to the maximum tolerated dose taking into account other exposure sources.

### 7.12.2. Environment

Not Evaluated by the eMSCA.

### 7.12.3. Combined exposure assessment

Not evaluated by the eMSCA

## 7.13. Risk characterisation

Not evaluated by the eMSCA.

## 7.14. References

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