

Risk Management Option Analysis Conclusion Document

Substance Name: Phenol, heptyl derivatives

EC Number: 276-743-1

CAS Number: 72624-02-3

Authority: Austria, in cooperation with Germany

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020¹.

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

¹ For more information on the SVHC Roadmap: <http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation>

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

A written procedure was carried out in the Endocrine Disruptor Expert Group in April/May 2016 regarding the endocrine disrupting properties of phenol, heptyl, derivs. for the environment. In summary, the provided comments largely support the identification of phenol, heptyl, derivs. as an endocrine disruptor for the environment.

Phenol, heptyl derivs. is part of the US EPA HPV Challenge program. Evaluation has started in 2003. Since then several data gaps have been closed by additional tests by industry and finalised health and environmental effect data have been made available.² Additionally in a second approach alkyl phenols (as a whole group, including Phenol, heptyl derivs.) have been evaluated by another industry "sponsor".

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	Tick box
Need for follow-up regulatory action at EU level:	
<i>Harmonised classification and labelling</i>	
<i>Identification as SVHC (authorisation)</i>	x
<i>Restriction under REACH</i>	
<i>Other EU-wide regulatory measures</i>	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

Phenol, heptyl derivs. are usually used in lubricant additives as polymer. According to the registrant(s) information, phenol, heptyl derivs. is imported in the EU in polymerised form and formulated to commercial mixtures.

On the basis of current knowledge it can be expected that these mixtures are used industrially, and by professionals and consumers in lubricants and greases in vehicles or machinery, which will result in wide dispersive indoor use and outdoor use in closed and open systems.

The residual content of unreacted monomer (phenol, heptyl derivs.) in the polymer material which is imported, is suggested by the registrant(s) to be very low.

Several compounds within the group of alkylphenols are known to act as endocrine disruptors in the environment. 4-nonylphenol, branched and linear and 4-tert-octylphenol are already on the candidate list because of their endocrine disrupting properties in the environment.

Based on in vivo and in vitro findings and read across within the group of alkylphenols it

² https://java.epa.gov/oppt_chemical_search/ (search term 72624-02-3)

is concluded that phenol, heptyl derivs. fulfils the WHO/IPCS definition for endocrine disruptors for the environment and it is anticipated that the criteria of Art 57 (f) are fulfilled.

A written procedure was carried out in the Endocrine Disruptor Expert Group in April/May 2016 regarding the endocrine disrupting properties of Phenol, heptyl derivs. for the environment. In summary, the provided comments largely support the identification of phenol, heptyl derivs. as an endocrine disruptor for the environment.

The consideration of further risk management measures is appropriate due to the fact that phenol, heptyl derivs. may enter the environment as residual monomer and cause adverse endocrine disrupting effects. Thus reduction of relevant emission sources as a mid-term goal and substitution on long-term are considered appropriate.

Currently no factual information exists that phenol, heptyl derivs. might be used as substitute for other alkylphenols already identified (or in the process of identification) as SVHCs. However, based on its similar structure and physico-chemical properties, phenol, heptyl derivs. has the potential of being used as substitutes.

Apart from its use in polymer production phenol, heptyl derivs. may also be used as an intermediate in the manufacture of other chemicals. It needs to be clarified, how high the content of residual phenol, heptyl derivs. is in those compounds and final products. The identification of phenol, heptyl derivs. as SVHC due to its endocrine disrupting properties is therefore considered as an important first step for the subsequent investigation of compounds which contain phenol, heptyl derivs. and thus lead to an exposure to the environment by phenol, heptyl derivs.

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

Based on an in depth assessment of the available *in vivo* and *in vitro* findings and read across within the group of alkylphenols it is the opinion of the eMSCA that phenol, heptyl derivs. fulfils the WHO/IPCS definition for endocrine disruptors for the environment and thus should be considered as an Endocrine Disruptor (ED) and identified as SVHC according to the criteria of article 57 (f).

For Endocrine Disruptors no specific classification category under CLP-Regulation exists. Therefore, the Candidate List is presently the only means for the formal identification of an endocrine disrupting substance within the EU chemical policy, as it allows to reach a consensus on European level on substances which exhibit serious effects on the environment.

Furthermore the identification of phenol, heptyl derivs. as an endocrine disruptor by inclusion into the Candidate List would be an important step for further risk management measures considering other substances containing residual concentrations of free phenol, heptyl derivs. (such as certain reaction products including polymers which may contain unreacted concentrations of the monomer.) which may exhibit adverse effects.

The SVHC roadmap encourages the grouping of substances with similar properties, structure and/or uses in order to avoid substitution of one substance of the group by another one. Several compounds within the group of alkylphenols are known to act as endocrine disruptors in the environment. 4-nonylphenol, branched and linear and 4-tert-octylphenol are already on the candidate list because of their endocrine disrupting properties in the environment. Phenol, heptyl derivs. clearly falls into this group of substances.

Based on the fact that a broad band of lubricants additives exists, it can be assumed that

alternatives are available or will be available in near future for specific purposes. In order to follow a consistent approach within the group of alkylphenols and to reduce emission to the environment of endocrine disrupting substances it is proposed to elaborate an Annex XV SVHC Dossier for phenol, heptyl derivs. The identification of phenol, heptyl derivs. as SVHC would in this way form the basis for the elaboration of further risk management measures for other compounds containing phenol, heptyl derivs.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. 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.

Follow-up action	Date for follow-up	Actor
Annex XV dossier for SVHC identification	08/2016	MS CA Austria