Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

Risk Management Option Analysis Conclusion Document

Substance Name:	**p-(1,1-dimethylpropyl)phenol**
EC Number:	**201-280-9**
CAS Number:	**80-46-6**
Authority:	**Germany**
Date:	**2016-06-15**
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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 2020[1].

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

For p-(1,1-dimethylproply)phenol (ptPP) a substance evaluation is ongoing. Although the initial concern was endocrine disruption for the environment, the ongoing substance evaluation does not influence these RMO considerations. No additional data requirements were deemed necessary during substance evaluation to clarify the concern of endocrine disruption with regard to the environment.

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:	
Harmonised classification and labelling	
Identification as SVHC	✓
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

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

3.1 Harmonised classification and labelling

Endocrine disruption is not an endpoint for which harmonised classification and labelling according to CLP can be applied.

3.2 Identification as a substance of very high concern, SVHC

Based on an in depth assessment during substance evaluation, it is the opinion of the eMSCA that ptPP meets the Art 57f criteria due to its endocrine disrupting properties for the environment which are considered to be of very high concern.

- Several in vitro and in vivo studies are available which clearly show that ptPP acts as an estrogen agonist both in vitro and in vivo. In vivo data for several fish species show that this alteration of the function of the endocrine system results in adverse effects in intact organisms. They provide a clear link between the mode of action and the adverse effects observed. Data for other fish species substantiate the estrogen mode of action and adverse effects observed fit to this mode of action.
- Effects observed are considered severe (e.g. change in reproduction). Available studies indicate that they are long-lasting and may occur even after short term exposure. One fish study indicates that effect persist even after exposure has ceased and may increase in subsequent generations.

Due to the endocrine disrupting properties for the environment, substitution of the substance and subsequent reduction of its emission to water is considered as appropriate.

Available exposure information indicates that ptPP enters the environment at concentrations close to those causing endocrine mediated effects. No systematic monitoring is available but ptPP was found in the environment in some monitoring studies.

Based on the available hazard information ptPP is a substance of very high concern. It results in relevant emission to the environment. Thus, even though the information available by the submitted registrations indicate that the substance is used as an intermediate only, it must be considered as a relevant SVHC according to the SVHC Roadmap 2020 which gives an EU-wide commitment for having all relevant currently known substances of very high concern included in the Candidate List by 2020 to promote substitution and to avoid uses as potential substitute for other SVHCs.

ptPP is a possible substitute for 4-nonylphenol and 4-tert-octylphenol with regard to their uses in phenolic and epoxy resins. Both substances have been identified as SVHC due to their endocrine disrupting properties for the environment.

SVHC identification is essential in order to verify the very high concern for ptPP and thus enable further risk management measures. It would trigger further information requests and would be a strong signal for substitution.

Further considerations are needed to analyse most appropriate further risk management measures which may include SVHC identification of substances which contain ptPP as an impurity or residue or restrictions.

3.3 Restriction under REACH

Depending on the information on relevant sources for ptPP triggered by SVHC identification, future restriction of the corresponding uses to limit these emissions may be considered necessary.

3.4 Other Union-wide regulatory measures

Not applicable.

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

Not applicable.

5. NO ACTION NEEDED AT THIS TIME

Not applicable.

6. 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 (Art 57f with regard to the environment	08/2016	Germany