Risk Management Option Analysis Conclusion Document

Substance Name:

Metallic salts of alkyl phenol sulfides (“phenates”)

[1] Phenol, dodecyl-, sulfurized, calcium salts

[2] Phenol, dodecyl-, sulfurized, carbonates, calcium salts

[3] Phenol, dodecyl-, sulfurized, carbonates, calcium salts, overbased

EC Number:

[1] 272-486-4

[2] 272-233-8

[3] 272-234-3

CAS Number:

[1] 68855-45-8

[2] 68784-25-8

[3] 68784-26-9

Authority: Swedish Chemicals Agency

Date: 6 November 2018

All three substances are currently in the process of changing main identifiers leading to updated list numbers and names.

New list numbers and names for substances **[1]**-**[3]**:

[1] 701-249-4	Phenol, paraalkylation products with C10-15 branched olefins (C12 rich) derived from propene oligomerization, calcium salts, sulfurized, including distillates (petroleum), hydrotreated, solvent-refined, solvent-dewaxed, or catalyc dewaxed, light or heavy paraffinic C15-C50

[2] 701-208-0 Phenol, paraalkylation products with C10-15 branched olefins (C12 rich) derived from propene oligomerization, carbonates, calcium salts, sulfurized, including distillates (petroleum), hydrotreated, solvent-refined, solvent-dewaxed, or catalytic dewaxed, light or heavy paraffinic C15-C50

[3] 701-251-5 Phenol, paraalkylation products with C10-15 branched olefins (C12 rich) derived from propene oligomerization, carbonates, calcium salts, overbased, sulfurized including distillates (petroleum), hydrotreated, solvent-refined, solvent-dewaxed, or catalytic dewaxed, light or heavy paraffinic C15-C50

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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

Harmonised classification

The phenates all contain tetrapropenylphenol (TPP) as impurity (EC number 310-154-3) which has a harmonised classification for several hazard classes including reproductive toxicity (category 1B). TPP was included in the ninth adaptation to technical progress to the CLP regulation (Regulation (EC) No 1272/2008).

All phenates are classified as Repr. 1B in the Reach (Regulation (EC) No 1907/2006) registrations since they contain TPP in concentrations exceeding the general concentration limit of 0.3 weight%. The phenates are therefore covered by entry 30 in Annex XVII of the REACH Regulation. This means that it is restricted as such and in mixtures placed on the market for sale to the general public.

REACH registration

All three substances are currently in the process of changing main identifiers leading to updated list numbers and names.

Substance evaluation (SEv)

[1] Evaluation year was 2016. The SEv conclusion document was finalized November 2017.

[3] Evaluation year was 2013. The SEv conclusion document is to be finalized in the end of 2018.

TPP: Evaluation year 2018 for potential endocrine disrupting properties.

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. In the RMOA, only the concern for human health (Repr. 1B) has been assessed for phenates **[1]**-**[3]**.

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

3. NO ACTION NEEDED AT THIS TIME

TPP (EC number 310-154-3) was included in the ninth ATP to the CLP regulation (which applies from 1 March 2018). The substance fulfils the criteria for reproductive toxicity category 1B. According to the CLP regulation, the phenates shall be classified as reproductive toxicants due to the TPP impurity when exceeding 0.3 weight%. Harmonized classification of the phenates for Repr. 1B will not contribute further to safe use as it will not trigger additional risk management measures.

New data on exposure obtained during the SEv process for **[3]** do not indicate an unacceptable risk for the EU population at large. The CSR was updated during the SEv process taking into account the new exposure data. Due to the similar uses for all phenates, it is concluded that there is no indication of an EU-wide risk for workers or consumers for any of the phenates, provided that the registrations for **[1]** and **[2]** are updated in line with **[3]** and all risk management measures are implemented.

Due to the presence of reprotoxic TPP in concentrations exceeding the generic concentration limit, the phenates fulfil the SVHC roadmap 2020 criteria and may be considered for SVHC identification according to Reach Article 57(c). However, the described uses are limited to lubricant oil additives, there are no known uses in articles, and therefore no further information requirements due to Candidate listing is foreseen. Also, in the substance evaluation for **[3]**, the eMSCA concludes safe use for the substance. Thus, this category of substances does not appear to be a prioritized case for authorisation under Reach, which will likely be according to Article 60(2) (the adequate control route). SVHC identification may be an incentive for substitution, but no further added benefits are foreseen. It is recognized that industry continues to make efforts to lower the content of TPP in substances **[1]**-**[3]**. Industry claims that a further reduction of TPP content, however, requires time and investments in R&D.

Based on the reasoning above, the evaluating MSCA considers it more appropriate and time-effective to await the ongoing TPP substance evaluation process before re-assessing the needs for SVHC identification of the phenates. Both potential human health and environmental concern should be included in an updated assessment of potential risk management measures.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

The registrants updated the CSR of **[3]** during the SEv process, taking into account new exposure data. DNEL´s were derived for both the parent substance and TPP. Registrants should update the registrations of **[1]** and **[2]** with this new information without undue delay.