Risk Management Option Analysis Conclusion Document

Substance Name:

[1] Zinc bis[bis(dodecylphenyl)] bis(dithiophosphate)

[2] Zinc bis[bis(tetrapropylenephenyl)] bis(hydrogen dithiophosphate)

(Abbreviated as aryl-based ZDDPs in this document.)

EC Number:

[1] 259-048-8

[2] 234-277-6

CAS Number:

[1] 54261-67-5

[2] 11059-65-7

Authority: Swedish Chemicals Agency

Date: 11 November 2019

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA or the Member States may initiate at a later stage. Risk Management Option Analyses and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

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 aryl-based ZDDPs contain a constituent/impurity which has a harmonised classification for several hazard classes including reproductive toxicity (category 1B).

The aryl-based ZDDPs are classified as Repr. 1B in the REACH registrations when they contain the constituent in concentrations exceeding the general concentration limit of 0.3 weight%. The substances are covered by entry 30 in Annex XVII of the REACH Regulation which means that they are restricted as such and in mixtures placed on the market for sale to the general public when the concentration of the constituent exceeds 0.3 weight%.

Substance evaluation (SEv)

Constituent of concern: Evaluation year 2018 for potential endocrine disrupting properties.

RMOA

Constituent of concern: Separate RMOA for constituent of concern will be initiated in 2019 by another MSCA.

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, the concerns for human health (Repr. 1B, potential endocrine (ED) properties) and environment (potential ED properties) have been assessed.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	(x)
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

The aryl-based ZDDPs contain a constituent of concern in >0.3 weight% that fulfils the criteria for reproductive toxicity (category 1B). According to the CLP regulation, the aryl-based ZDDPs shall be classified as Repr. 1B when the constituent concentration exceeds 0.3 weight%. In addition, there is an ongoing assessment of potential human health and environmental ED properties of the constituent.

The aryl-based ZDDPs are used as lubricant additives. They are registered in high tonnages and there are reported industrial, professional and consumer uses. The aryl-

based ZDDPs are therefore a source for human exposure and environmental emissions of the constituent of concern. Environmental emissions of the constituent of concern originating from the use of lubricants have been predicted, and the substance has also been detected in screening studies in the environment.

On the basis of a previous human health assessment of an similar class of lubricant additives, and the available information assessed in this RMOA, it is concluded that there is presently no indication of an EU-wide risk for workers or consumers for the aryl-based ZDDPs. For environment, a previous risk assessment for the constituent of concern concludes that there are potential risks from end-uses in lubricant additives. However, the risk assessment is conservative using exposure modelling data and needs to be refined with more detailed data on emissions and environmental concentrations.

Overall, although a clear risk can not be demonstrated based on available data, there is an overall concern when considering both human health and the environment that needs to be reassessed when the potential endocrine disrupting properties of the constituent of concern have been evaluated.

3.1 (POTENTIAL) IDENTIFICATION AS A SUBSTANCE OF VERY HIGH CONCERN , SVHC (FIRST STEP TOWARDS AUTHORISATION)

Due to the presence of the reprotoxic constituent in concentrations exceeding the generic concentration limit, the aryl-based ZDDPs fulfil the SVHC roadmap 2020 criteria and may be considered for SVHC identification according to REACH Article 57(c). There are wide disperse uses within the scope of authorisation. In addition, a potential (future) ED identification for human health and the environment for the constituent of concern would have the effect that the aryl-based ZDDPs may also fulfil the REACH Article 57(f) criteria for SVHC. There is therefore an overall concern when considering both human health and the environment and SVHC identification would lead to incentives for substitution.

The authorisation process provides a pressure for substitution to safer alternatives. The identification of the aryl-based ZDDPs as SVHC with eventual inclusion in Annex XIV is therefore considered an appropriate measure to stimulate further substitution, or alternatively, to lower the concentration of the constituent of concern below the thresholds listed in REACH Article 56(6). It is recognized that industry continues to make efforts to lower the content of the constituent of concern in relevant lubricants but that a further reduction of the concentration of the constituent requires time and investments in R&D.

Before an SVHC identification process is initiated for the aryl-based ZDDPs, the evaluating MSCA considers it appropriate to await the ED assessment of the constituent of concern. The aryl-based ZDDPs may then be considered for SVHC identification once the overall concern has been clarified.

It is recognized that further clarifications on substance identity may be needed and should be finalized before any regulatory risk management measures are considered.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Reassessment of overall concern for potential SVHC identification once the ED properties for human health and the environment for the constituent of concern have been clarified.