Risk Management Option Analysis Conclusion Document

Substance Name:	**Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP)**
EC Number:	**-**
CAS Number:	**-**
Authority:	**Austria**
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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 reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) no regulatory measures have been set so far.

An RMO Analysis for the reaction products has been elaborated and discussed among Member States, ECHA and Commission. The concern is based on an impurity[2] that has been identified already as an SVHC by the Member State Committee and included in the Candidate List.

2. CONCLUSION OF RMOA

This conclusion is based on 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 (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

Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) are used in the formulation of lubricant additives, lubricants and greases. These are used industrially and by professionals in lubricants and greases in vehicles or machinery or by application of lubricant to work pieces or equipment. No more detailed information on the types of industry branches using the reaction products is available. Wide dispersive indoor uses and outdoor uses in closed and open systems by industrials, professionals and consumers have been reported via registration. Main consumer use seems to be in gear oils available in public supply. Numerous gear oils containing the reaction products in concentrations up to 2,5% have been identified via web search.

Reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) contain an impurity which has already been identified as a substance of very high concern due to its endocrine disrupting properties in the environment. The impurity is present in concentrations above 0.1%[3] in the

[2] The type and percentage of impurity are considered confidential information by the registrant.

[3] Ref. to REACH, Article 56 (6)a.

reaction products, therefore the reaction products should be considered for further risk management as well.

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

Within the framework of the RMO-Analysis it was investigated if the content of the SVHC impurity could be reduced to a level below 0,1%. According to the registrant it would at present not be technically or economically feasible to reduce this impurity further.

Considering the key concern of the impurity as endocrine disruptor for the environment, it should be noted that in general it is difficult to derive a threshold level for an endocrine disrupting compound. Therefore, the releases to the environment should be as low as possible. Further risk management of the reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) containing the SVHC impurity is therefore considered necessary. Furthermore, reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) meet the Roadmap 2020 criteria for potential SVHC identification due to the SVHC impurity.

The identification of reaction products of 1,3,4-thiadiazolidine-2,5-dithione, formaldehyde and 4-heptylphenol, branched and linear (RP-HP) as SVHC is therefore proposed as a first risk management step.

Following SVHC identification of the reaction products, authorisation is proposed as further risk management measure in order to reduce further release of the impurity to the environment. It is considered as most appropriate option as it encourages/forces industry to intensify their efforts towards substitution, which may otherwise not happen without such legal pressure. Already the candidate listing may be a driver towards substitution. For certain uses, for which alternatives are already available candidate listing might be sufficient to trigger substitution. This ideal situation would be most resource efficient for both industry and authorities. For other specific uses, subsequent listing in Annex XIV would be a strong incentive for industry towards using alternatives. Listing in Annex XIV also shifts the burden of proof on substitution to the applicants of authorizations, who have the major competence for the alternatives assessment for their specific processes/techniques.
The reaction products including impurity are contained in mixtures, but not in articles, thus authorization will apply also to imported products, e.g. gear oils.

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 / 2017	Austria