Risk Management Option Analysis Conclusion Document

Substance Name: Glutaraldehyde

EC Number: 203-856-5

CAS Number: 111-30-8

Authority: Swedish Chemicals Agency

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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

This substance is regulated under the Biocidal Products Regulation, the Cosmetics Regulation and there are national OELs. Under REACH, there are no ongoing processes for this substance except for this RMOA. The substance has harmonised classifications as Acute Tox. 2 (H330), Acute Tox. 3 (H301), Aquatic Acute 1, Aquatic Chronic 2, **Resp. Sens. 1**, Skin Corr. 1B, **Skin Sens. 1A**, STOT SE 3.

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 (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

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

Glutaraldehyde is a respiratory sensitizer and a potent skin sensitizer. An important use of the substance is as biocide, a use covered by the Biocidal Products Regulation. Other uses include, among others, use for leather tanning and x-ray film processing.

Based on our evaluation of the substance we consider that glutaraldehyde may meet the criteria of Article 57f, being of equivalent level of concern to CMR substances. We believe that inclusion in the Candidate List may be an important step to further raise the awareness of this substance. Inclusion in Annex XIV is the consequence of candidate listing, which we hence consider as the most appropriate risk management measure for this substance.

Based on the respiratory sensitizing properties of the substance, it is a candidate for substitution under the Biocidal Products Regulation. We consider that identification of glutaraldehyde as an SVHC and inclusion in Annex XIV would regulate uses of the substance under REACH in the same way as biocidal uses under BPR (i.e. phase-out/substitution, based on its property as a respiratory sensitizer), and thus leading to coherence between EU regulations.

Although the respiratory sensitising property of the substance would be the main reason

for identification as SVHC, the proposed measure will also indirectly lead to prevention of skin sensitisation and contact allergy.

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	February/2021	Sweden