Risk Management Option Analysis Conclusion Document

Substance Name: Ethylene glycol
EC Number: 203-473-3
CAS Number: 107-21-1

Authority: NL-CA
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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

The subject of this RMOA is the increasing application of ethylene glycol in the production of car tires, which can subsequently be granulated to rubber infill in artificial grass playing fields. The possible concern has been evaluated in this RMOA.

Ethylene glycol is classified as Acute Tox. 4 under CLP (H302) and is harmful if swallowed.

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)	
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

Based on the assessment of possible toxicity and exposures of humans to ethylene glycol used in sealants for (car) tires, it is concluded unlikely such use will result in significant adverse effects on human health or the environment. Sealants may become more and more popular for use in tires but it is not expected to reach significant levels that potentially causes unwanted effects, considering the amount of ethylene glycol ending up in rubber crumb is likely negligible. Based on the current classification under CLP, the substance does not meet the SVHC criteria. The toxicity data available in the registration dossier do not suggest a need for further classification under CLP and there is currently no identified risk to motivate restriction. Substitution of ethylene glycol by propylene glycol may be considered by voluntary action from a precautionary perspective as effects caused by propylene glycol are observed at higher doses of exposure and hence propylene glycol can be considered less toxic.

The evidence suggests reproductive toxicity is not a concern and no problems in workers have been reported with the current use and safety measures. Additionally there is no environmental concern since environmental (aquatic) toxicity is very low and the substance is readily biodegradable. Although the data in the registration dossier does not support classification as acute tox. 4, it is important to keep this classification since abuse, drinking or accidental exposure can lead to adverse effects. Classification does facilitate informing both workers and consumers about potential risks by unintended use. Restriction or other risk management options are considered not cost-effective to prevent the current type of abuse.