RISK MANAGEMENT OPTION ANALYSIS

CONCLUSION DOCUMENT

for

SODIUM HYDROXIDE AND POTASSIUM HYDROXIDE IN DRAIN CLEANING PRODUCTS FOR CONSUMER USE

EC No: 215-185-5, 215-181-3

CAS No: 1310-73-2, 1310-58-3

Member State: Sweden

Dated: 6 March 2015

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

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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 other 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

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Sodium hydroxide has a harmonized classification as Skin Corr. 1A and potassium hydroxide has a harmonized classification as Skin Corr. 1A and Acute Tox.4 under the CLP Regulation (Regulation (EC) No 1272/2008). Due to the classification as corrosive it is required that consumer products which contain sodium hydroxide or potassium hydroxide for more than 2% and may be accessible to children should be provided with a child-resistant fastening and a tactile warning of danger according to Article 35(2) in the CLP Regulation.

Except for the harmonized classification, there is no EU regulation with focus on the use of sodium hydroxide or potassium hydroxide in consumer products such as drain cleaning products.

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.

Information gathered from several European Poisons Information Centre indicates that there are a few thousand incidents in the EU each year related to drain cleaners mainly based on sodium hydroxide. More than 90% of these are due to accidents – mostly among non-professional users. Between a tenth and half of the reported cases occur among children who are exposed to the corrosive substances via opened packages or via grains that remain in the drains. Ingestion/mouth contact is the main exposure route among children. Accidents in the home thus occur despite of product labelling and child-resistant fastenings. Regarding adults, poisonings often occur by mistaking products or during the cleaning of the drain when corrosive liquid splashes in eyes or on skin. This is mainly the case when a plumber opens the drain without knowing that corrosive products have been used by the consumer who has failed to open the drain.

Sodium hydroxide and potassium hydroxide have a harmonized classification as Skin Corr. 1A under the CLP Regulation (Regulation (EC) No 1272/2008). The corrosive property of the substances is a relevant hazard end point for the exposure of drain cleaners.

Sodium hydroxide and potassium hydroxide do not fulfil any of the REACH Article 57 criteria and can thus not be included in the Candidate List. A restriction covering the use as drain cleaner intended for consumer use or conditions for such use appears to be a better option.

However, due to the uncertainties related to risk reduction capacity and proportionality of an EU-wide ban, this RMOA proposes that voluntary actions by AISE[2] and its member organisations is the most preferable RMO, at least in the short term. If more information e.g. relating to the health economic consequences of accidental exposure – emerge, this

[2] International Association for Soaps, Detergents and Maintenance Products

conclusion might change.

Conclusions	Tick box
Need for follow up regulatory action at EU level	(√)
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restrictions	(√)
Other EU-wide measures	
No need for regulatory follow-up action at EU level at this time	√
Need for actions other than EU regulatory actions	√
No actions needed	

3. CURRENTLY NO REGULATORY FOLLOW-UP FORESEEN AT EU LEVEL

3.1 Need for other actions than EU regulatory actions

Due to the uncertainties related to risk reduction capacity and proportionality of a ban, this RMOA proposes that voluntary actions by AISE and its member organisations is the most preferable RMO, at least in the short term. Depending of the outcome of the voluntary actions, regulatory action such as a restriction at EU level might need to be taken up for discussion in a couple of years.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Depending of the outcome of the voluntary actions, regulatory action such as a restriction at EU level might need to be taken up for discussion in a couple of years.

Follow-up action	Date for action	Actor
Evaluate the outcome of voluntary action, and consider need for regulatory action (e.g. REACH Restriction)	2017	Sweden