RISK MANAGEMENT OPTION ANALYSIS

CONCLUSION DOCUMENT

for

Hexamethylene diacrylate

EC No 235-921-9

CAS No 13048-33-4

Member State(s): Sweden

Dated: 15 April 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

Hexamethylene diacrylate (HDDA) is included in Annex VI of the CLP regulation with a harmonized classification as Skin. Sens 1, Skin irrit. 2, Eye irrit. 2

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	X
Harmonised classification and labelling	
Identification as SVHC (authorisation)	X
Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action	

3. FOLLOW-UP AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

3.1.1 Harmonised classification and labelling

HDDA has a harmonized classification as Skin sens 1. The data included in the RMOA indicate that HDDA is a potent sensitizer that may be classified as Skin sens 1A. Updating the classification to Category 1A would enforce labelling of products containing ≥0.01% HDDA. This would allow workers to avoid lower levels of HDDA than what is currently possible. However, data from the Swedish product register indicate that the large majority of the products contain ≥ 0.1 % HDDA and are already subject of labelling requirements according to CLP. Hence, the risk reducing effects from an updated classification are likely to be minor. At the moment, the Swedish Chemicals Agency has no intention to propose a harmonized classification as Skin sens. 1A for HDDA.

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

Data from experimental studies in animals and clinical studies in humans show that non cured HDDA is a potent skin sensitizer that can cause allergic contact dermatitis in humans. Contact allergy to HDDA is an irreversible condition that may cause symptoms of varying severity, from a mild rash to potentially life threatening skin reactions that require hospital care. It is not possible to determine a safe dose or to predict which individuals that are at risk of developing severe health effects.

Studies show that occupational allergic contact dermatitis has a negative impact on quality of life and is associated with high costs for the society. The reported volumes and

uses of HDDA indicate the occupational exposure in the EU is wide spread and increasing. Also, sensitization among exposed individuals is reported to occur with a high frequency. Thus, the collected data indicate that occupational exposure to HDDA is of societal concern in the EU.

The overall available information indicate that HDDA fulfil the criteria for SVHC roadmap 2020 and is of equivalent level of concern as CMR 1A/1B substances. It is therefore a need for a proposal to identify HDDA as a SVHC for inclusion on the Candidate list to Annex XIV (authorization).

An inclusion of HDDA on the Candidate list will promote substitution of HDDA to safer alternatives (substances and/or techniques). At a later stage, an eventual prioritization to Annex XIV will make producers and users of HDDA responsible to develop safer alternatives to HDDA. In those cases were substitution is not feasible, authorization will be granted if the applicant can ensure a safe use of HDDA. .

3.1.3 Restriction

We believe that restriction of HDDA under REACH is one possible option, and also that restriction of skin sensitizing acrylates as a group may be an alternative. However, we do not believe that restriction is the preferable way forward since it will be difficult to assess societal costs.

The severe health effects from HDDA (allergic contact dermatitis), the economic impact of such effects and the wide-spread occupational exposure indicate a societal concern. There is, however, a lack of information regarding the incidence of occupational allergic contact dermatitis from HDDA which makes difficult to estimate the total societal costs with accuracy. Detailed assessments of societal costs are from our experiences necessary to prove proportionality and get approval of the restriction proposal in ECHAs socioeconomic committee, SEAC.

In addition, assessment of proportionality require knowledge about substitution to safer alternatives (substances and/ot techniques). It is difficult for authorities to retrieve information about possible alternatives and to assess if substitution is possible. It can be assumed that such knowledge is much higher among producers and users of HDDA. Therefore, we are of the opinion that the issue of alternatives should be addressed under the authorisation process where the applicant is responsible to produce such information.

At the moment the Swedish Chemicals Agency has no intention to further investigate the possibilities for restriction.

4. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

Not applicable

5. 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 intention	Actor

Annex XV report – Proposal for identification as SVHC	April / 2015	Sweden