Risk Management Option Analysis Conclusion Document

Substance Name: 2-ethylhexyl acrylate
EC Number: 203-080-7
CAS Number: 103-11-7

Authority: Swedish Chemicals Agency
Date: 12 July 2017

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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

2-EHA has a harmonized classification in Annex VI of the CLP legislation (EC) No 1272/2008.

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
607-107-00-7	2-ethylhexyl acrylate	203-080-7	103-11-7	Skin Irrit. 2 Skin sens. 1 STOT SE 3	H315 H317 H335		Note D

In 2005, 2-EHA was evaluated under the Existing Substance Regulation 793/93/EEC[2].

In September 2016 ECHA published a compliance check decision for 2-EHA[3]. In the decision ECHA requests the following additional studies from the registrant:

- Pre-natal developmental toxicity study (OECD TG 414)
- Extended one-generation reproductive toxicity study (OECD TG 443)
- Long-term toxicity testing on fish (OECD TG 210)
- Bioaccumulation in aquatic species (OECD TG 305)

The information should be submitted in an updated registration dossier by 4 October 2019.

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:	No
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
No action needed at this time	Yes

3. NO ACTION NEEDED AT THIS TIME

Harmonised Classification and Labelling: 2-EHA have a harmonised classification as Skin Sens. 1. The overall available evidence indicate that 2-EHA may fulfil the CLP classification criteria as Skin Sens.1B, but there are also animal studies suggesting that 2-EHA has a strong skin sensitising potency. According to the CLP guidance, classification into sub-categories is only allowed if data are sufficient and that care should be taken when classifying substances into category 1B when category 1A cannot be excluded. In such cases classification into category 1 should be considered[4]. Thus, because of the conflicting results from animal studies we find it most appropriate that 2-

[2] https://echa.europa.eu/documents/10162/9f1d81f1-cede-4f8d-8e49-4db7b1693e0d
[3] https://echa.europa.eu/documents/10162/fa5b50d0-7bc3-786c-d16e-bf236514c003
[4] Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 (3.4.2.2.)

EHA keep the current classification as Skin Sens. 1.

Identification as SVHC for inclusion on the Candidate list: Identification of SVHC under Reach article 57(f) must include an assessment of whether the substance is of equivalent level of concern (ELoC) to CMR substances category 1A/1B. ECHA's general approach paper[5] for identification of SVHC under article 57(f) can be used as support in the ELoC assessment. The table below gives an overview of the ELoC assessment for 2-EHA including the ELoC factors described in ECHA's general approach.

Table. Overview and conclusions of the ELoC assessment for 2-EHA

ELoC factor	**Available evidence to justify ELoC to CMR-substances**
Possible serious health effects?	No such reports available: Overall, the available data from animals and humans indicate that 2-EHA has a moderate skin sensitising potency. In addition, available case reports of contact allergy to 2-EHA describe patients who suffer from allergic reactions of moderate severity.
Irreversibility of health effects?	Yes: 2-EHA can cause irreversible contact allergy.
Delay of health effects?	Yes: Contact allergy is per se a delayed health effect. One case report describe a patient that were exposed to 2-EHA for months before developing symptoms and seeking medical care.
Is it possible to derive a 'safe concentration'?	Uncertain: The registrant have suggested a DNEL for 2-EHA based on data from a LLNA. The use of assessment factors in the derivation of the DNEL may be questioned and it might very well be that the overall uncertainty is too high for a safe level to be derived. Additional uncertainty is brought on by other available animal data suggesting that 2-EHA has a stronger potency than what is indicated by the LLNA.
Impaired quality of life?	Likely: 2-EHA can cause occupational allergic contact dermatitis which is generally associated with a negative impact on quality of life. We have found no studies of a direct link between contact allergy to 2-EHA and a decreased quality of life, However, based on available data it can be assumed that people who suffer from occupational contact allergy to 2-EHA to some degree experience a negative impact on quality of life.
Societal concern?	Unlikely: The overall scientific literature suggests that contact allergy to 2-EHA is relatively uncommon in comparison to allergy to other acrylates with similar uses. Therefore, 2-EHA seems not to contribute to any large extent to the total societal concern from occupational contact allergy to (meth)acrylates.

In conclusion, the Swedish Chemicals Agency does not consider that the available evidence demonstrates that 2-EHA is of equivalent level of concern to CMR substances category 1A/1B. In our view, 2-EHA does not fulfil the SVHC Roadmap to 2020 criteria.

Restriction under REACH: There is evidence that 2-EHA has the potential to cause allergic skin reactions in humans. However, there is no reliable data describing how

[5] "Identification of substances as SVHCs due to equivalent level of concern to CMRs (Article 57(f)) – sensitisers as an example": http://echa.europa.eu/documents/10162/13657/svhc_art_57f_sensitisers_en.pdf

common contact dermatitis to 2-EHA is in the EU. It is therefore not possible to accurately estimate the societal costs from contact allergy to 2-EHA. Thus, there is no *prima facie* evidence that the current uses 2-EHA pose an unacceptable risk which has to be addressed by a ban on an EU-wide basis.

EU workplace health and safety legislation: The EU directives for occupational health and safety mention substitution of substances with other hazardous properties than CMR to safer alternatives only in general terms [6]. We believe that REACH is more efficient to achieve substitution of hazardous substances at the work-place because it enables EU wide regulations of specific hazardous compounds.

The Directives for Indicative Occupational Exposure Limit values include IOELs for four skin sensitising acrylates (n-butyl acrylate, methyl methacrylate, methylacrylate and ethylacrylate). However, these air levels have not been set in order to protect against skin exposure. Setting an IOEL for 2-EHA would therefore most likely not be an efficient means to minimize allergic skin reactions to 2-EHA at the work place.

Overall conclusion: Based on the information contained in this RMOA the Swedish MSCA considers that there is currently no need for regulatory measures for 2-EHA under REACH or CLP, nor do we find it justified to suggest specific regulatory action under the EU workplace health and safety legislation.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

The compliance check of 2-EHA resulted in requirements for new studies on developmental and reproductive toxicity, studies in fish and studies of bioaccumulation in aquatic species (see section 2). When the new data is available, in October 2019 at the latest, the need for risk management of 2-EHA should be re-evaluated.

Follow-up action	Date for intention	Actor
Re-evaluation of available data after the REACH registration dossier have been updated.	End of 2019	Swedish MSCA

[6] The Chemical Agents Directive (98/24/EC) and the Carcinogens and Mutagens Directive (2004/37/EC).