RISK MANAGEMENT OPTION ANALYSIS

CONCLUSION DOCUMENT

for

Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC)

EC No 250-863-4; 257-187-9; 915-617-9

CAS No 31906-04-4; 51414-25-6

Member State(s): Sweden

Dated: 21 may 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

According to the RAC opinion published online 21 March 2014, a harmonised classification of HICC as Skin Sens. Category 1A, with a general concentration limit of 0.1%, has been agreed upon. HICC is not yet included in Annex VI of CLP.

The Scientific Committee on Consumer Safety, SCCS (2011, 2012) has recommended that HICC should not be used in consumer products. In February 2014, the European Commission proposed to include HICC in Annex II to the Cosmetics Regulation ("List of substances prohibited in cosmetic products"). The proposed transitional period for HICC is two years for placing products containing HICC on the market and five years for their withdrawal. The proposal is currently under public consultation. The consultation period has been extended and a decision is expected in the end of 2015.

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.

Two possible risk management options were identified for HICC; 1) identifying HICC as a SVHC to be added to the Candidate List, and 2) banning the manufacturing, use and release on the market of HICC.

1. **Identification as a substance of very high concern (SVHC)**
   A preliminary ELoC assessment, carried out as proposed by ECHA[2], indicate that HICC may be identified as a SVHC according to REACH Article 57(f). However, the risk reducing potential of adding HICC to the candidate list is likely to be quite low. Therefore, the Swedish Chemicals Agency does not consider identification as SVHC as the best RMO and do not wish to prepare an Annex XV dossier at the moment.

   The International Fragrance Association (IFRA) recommend the maximum concentration limit of HICC in finished consumer products to 0.02 to 0.2%, depending on the type of product. Approximately 90-95% of the total volume of HICC is used by companies that are members of IFRA and are abiding by IFRAs code of practice. It is thus likely that a large part of the products on the market contain low levels of HICC, below 0.1%. Therefore, only a very limited number of products would be subjected to information requirements and authorization under REACH if HICC should be added to the candidate list and Annex XIV.

2. **Restriction**
   It may be possible to restrict manufacturing, release on the market and use of a substance if there is evidence of an unacceptable risk. For HICC the unacceptable risk lies in the following:

   - HICC is a high potency skin sensitizer, harmonized classified as Skin Sens 1A.
   - There is a widespread use of HICC at low concentrations in many commonly used consumer products.
   - The number of cases of skin allergy caused by HICC is exceptionally high. HICC is the substance for which most cases of skin allergy has been reported in Europe in the last decade, with over 1500 new cases published in the scientific literature.

[2] Identification of substances as SVHCs due to equivalent level of concern to CMRs (Article 57(f)) – sensitisers as an example (ECHA, 2012)

- So far the actions made to control the outburst of skin allergy caused by HICC have not been reflected in the available evidence. The incidence of skin allergy caused by HICC has remained at a constant and high level.
- Given the widespread use of HICC and its potency, a complete ban of the manufacturing, placing on the market and use of HICC would be the most appropriate restriction. A ban within REACH would, together with a prohibition of the use in cosmetics, would abolish the risk of exposure to HICC and of developing skin allergy as a consequence thereof, for both consumers and workers.
- Earlier this year, IFRA has, in a public statement, broadly welcomed the proposal to prohibit the use of HICC in cosmetic products, made by the European Parliament and the Council on cosmetic products. The statement suggests that industry have already found or is in the process of finding substitutes for HICC for use in cosmetics. It has been reported that some cosmetics companies has already stopped using HICC and that others has implemented disengagement plans to find alternatives.

The Swedish Chemicals Agency consider a union wide restriction of HICC as a possible RMO. Such regulatory action would complement the prohibition of HICC in cosmetic products and lead to a complete abolishment of the exposure among workers and consumers. However, restriction is a time- and resource consuming process and it may take a long time before a proposal comes into force. In addition, we foresee that it may be difficult to get through a restriction proposal for HICC after the use in cosmetic products have been prohibited. The remaining uses only represent a small part of the total use and we believe it will be difficult to prove proportionality and risk on an EU level for such small use.

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

3. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

3.1 Need for other actions than EU regulatory action

In the light of the above, The Swedish Chemicals Agency believe that there is no reason for regulatory action at the EU level at this point. Instead, we prefer to await the effects from the recommendation from SCCS and proposed ban of HICC in cosmetic products, which will hopefully lead to a voluntary phasing out of HICC from consumer products. However, there is a need to monitor the incidence of contact allergy to HICC the coming years. If contact allergy to HICC remain to be a problem we believe that restriction under REACH should be considered.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

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