Risk Management Option Analysis Conclusion Document

Substance Name: Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC)

EC Number: 250-863-4; 257-187-9; 915-617-9

CAS Number: 31906-04-4; 51414-25-6

Authority: Swedish Chemicals Agency

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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

HICC has a harmonised classification as Skin Sens. 1A, with a generic concentration limit of 0.1%. Labelling of products is effective at concentrations of and above 0.01%. No restrictions apply to the use of HICC in products that are regulated under REACH.

The International Fragrance Association, IFRA, has issued recommendations on maximal limits (IFRA standards) of HICC in many consumer product categories, including such regulated under REACH. In 2009, they decreased the maximum limit of HICC in many consumer product categories from 1.5% (2003) to 0.02-0.2%, depending on the type of product.

In August 2017, HICC was included in Annexes II and III ("List of substances prohibited in cosmetic products") to Regulation (EC) No 1223/2009 (Commission Regulation (EU) 2017/1410, published in the OJ L202, p. 1[2]). The transitional period is two years for placing products containing HICC on the market and four years for their withdrawal.

2. BACKGROUND

The voluntary restrictions on the maximum levels of HICC to be used in consumer products made by industry in 2009 was in 2012 deemed to be insufficient by the Scientific Committee on Consumer Safety, SCCS. SCCS therefore recommended that HICC should not be used in consumer products. As a consequence, the European Commission made a proposal to amend Annex II and III to the Cosmetics Regulation ("List of substances prohibited in cosmetic products") to include HICC.

The Swedish Chemicals Agency finalised an RMOA for HICC in 2015. We identified two possible risk management options: 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 in the RMOA as proposed by ECHA[3], indicated that HICC may be identified as a SVHC according to REACH Article 57(f).

2. Restriction under REACH
   An unacceptable risk was indicated for HICC based on that HICC is a high potency skin sensitizer, have a wide-spread use at low concentrations in many commonly used consumer products and that the published number of cases of skin allergy caused by HICC is exceptionally high (>1500). Moreover, that previous actions made to control the outburst of skin allergy caused by HICC had not been effective.

Conclusion of the 2015 RMOA
The risk reducing potential of identifying HICC as an SVHC to be added to the candidate list was deemed quite low since most products on the market contain HICC at concentrations below 0.1% (Swedish Product Registry). Therefore, the Swedish Chemicals Agency did not consider identification as SVHC as the best RMO.

A union wide restriction of HICC was considered a possible option since it would complement the anticipated ban of HICC in cosmetics products and lead to a complete abolishment of the exposure among workers and consumers. On the other hand, a restriction was considered both time- and resource consuming. Further, it might be difficult

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R1410&from=EN
[3] Identification of substances as SVHCs due to equivalent level of concern to CMRs (Article 57(f)) – sensitisers as an example (ECHA, 2012)

to prove proportionality and risk on an EU level since the use of HICC in products that are regulated under REACH is small compared to the use in cosmetics.

In the 2015 conclusion document the Swedish Chemicals Agency proposed to await and observe what impact the ban of HICC in cosmetic products would have on the incidence of contact allergy to HICC, and to revisit the RMOA conclusion in a couple of years.

3. UPDATED CONCLUSION OF RMOA

Cosmetics industry was generally positive to a ban of HICC in cosmetic products[4] and reports in 2015 was that several cosmetics companies had started to, or had already, substituted HICC in their products. The Swedish Chemicals Agency therefore hoped that the ban of HICC in cosmetics would lead to a voluntary phasing out by industry of HICC also in products regulated under REACH. According to the Swedish Products Registry the average levels of HICC in products have decreased slightly between years 2014 and 2016, however the number of products containing HICC, as well as the number of companies using HICC, have increased. Thus, industry seems not yet to have started to phase out HICC in REACH products.

Since HICC is used in both cosmetics and in products regulated under REACH, it is difficult to predict how big an impact the ban in cosmetics will have on the incidence of contact allergy to HICC. If sensitisation occurs mostly by exposure to HICC via cosmetic products, the incidence of skin allergy to HICC would decrease significantly after the transitional period and skin allergy to HICC would disappear in due time. If sensitisation also occurs from exposure to HICC via products regulated under REACH, the problem will prevail. Since the transitional period for HICC is two years for placing cosmetic products containing HICC on the market and four years for their withdrawal, the effect of the ban on the incidence of skin allergy to HICC may be observable in 3-4 years' time, at the earliest. It should however be noted that patch test data suitable for confidently calculating incidences of contact allergy are rare and may not be available for analysis. The Swedish Chemicals Agency make the assessment that it will not be possible to conclude whether exposure to HICC via REACH products contributes significantly to sensitisation or not within a reasonable amount of time. It would therefore not be ethical to further await what effect the ban in cosmetics will have on the incidence of HICC-induced skin allergy.

It is clear that if industry does not voluntarily phase out HICC then workers and consumers will continue to be exposed to the fragrance. Contact allergy is a lifelong condition, meaning that all those who have been sensitised to HICC have the ability to develop allergic contact dermatitis (elicitation) if exposed to the fragrance. It has been argued that labelling would help already sensitised individuals to avoid elicitation. However, avoidance as a risk management strategy would only be successful if consumers are aware of the cause of their contact allergy and at the same time, that the levels of HICC in products are above the labelling limit (0.01% for skin sensitizers classified in category 1A). According to the Swedish Products Registry, the levels of HICC in many products regulated under REACH are currently below 0.01% and are therefore exempted from labeling. In addition, the elicitation threshold for HICC has been reported to be as low as 0.7 µg/cm2[5]. This threshold may correspond to levels in products that are below the labelling limit, depending on the exposure scenario. Overall, it seems difficult for already sensitised individuals to avoid exposure and manifestations of allergy to HICC.

[4] www.ifraorg.org/en-us/library/document/23431#.U_MIXe5vncs

[5] Fisher et al. (2011). Can exposure limitations for well-known contact allergens be simplified? An analysis of dose–response patch test data. *Contact Dermatitis*, 64, 337–342

4. RESTRICTION UNDER REACH

In the light of the above, the Swedish Chemicals Agency conclude that it is likely that products covered by REACH contributes to the overall problem of skin allergy to HICC. If industry does not clearly declare the intention to phase out the use of HICC in products regulated under REACH within the same period as for cosmetics, the Swedish Chemicals Agency considers a union wide restriction to be the most appropriate RMO. At present, we are not able to proceed with such a task due to time- and resource constraints. We are therefore inviting other Member States to take action.