Kemikalieinspektionen
Swedish Chemicals Agency

Risk Management Option Analysis Conclusion Document

Substances: Skin sensitizing substances in textile articles on the EU market

Authority: Swedish Chemicals Agency

Date: November 23rd 2016

Version 2.1
October 2015

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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

At present there is no one body of legislation for regulating the content of chemical substances in textile articles in the EU. There are, however, a number of legislative acts which either regulate parts of the life-cycle in the case of articles in general or contain a ban or restrictions relating to certain substances that may be present in textiles. An overview of the current legislations on chemical substances in textiles is presented in the table below.

Table 1. Overview of current EU legislations on chemical substances in textiles

Legal act	**Regulation**
REACH Regulation (EU) 1907/2006	A number of substances are restricted for use in textiles (REACH Annex XVII) [2]
Biocides Regulation (EU) 528/2012	The use of biocides in textile articles requires authorisation.
POP Regulation (EC) 850/2004	Some restricted substances may be used in textile production.
EU Ecolabel (EU) 2014/350	Contain criteria that companies must comply with to label their textile articles with EU Ecolabel, a voluntary environmental label

In addition to current EU legislations presented in table 1, the European Commission (EC) are planning to present a proposal on restriction of hazardous substances (CMR 1A and 1B) in textile articles and clothing for consumer use under Article 68(2) of Regulation EC No 1907/2006 (REACH).

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	X
Identification as SVHC (authorisation)	
Restriction under REACH	X
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

[2] Summarized in Table 1 in RIVM report 2014-0155 (RIVM, 2015)

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

3.1 Restriction under REACH

KemI has identified restriction under REACH Article 69 in the form of an EU wide ban of placing textile articles that contain skin sensitizing on the market to be the most appropriate RMO. A total ban has the potential to efficiently reduce the risks for allergic textile dermatitis. Such measures can lead to a significant increase in quality of life among already allergic individuals and can prevent new cases to occur. We also consider restriction under REACH Article 69 in the form of labelling requirements of textile articles as that contain skin sensitizing substances as a possible alternative way forward.

The costs for the textile sector and authorities are difficult to estimate at this stage. However, taking both options (total ban and labelling requirements) into consideration we find it likely that the cost-benefit for a total ban will outweigh the cost-benefit for labelling requirements. However, in order to carry out an in depth analysis on the proportionality of a total ban additional information about the prevalence of textile dermatitis in the EU as well as the possibilities for substitution to safer alternatives is needed. KemI will continue to gather relevant information on the prevalence of contact allergies to disperse dyes and other textile relevant substances in EU member states. We hope that the collected information on prevalence and cost estimations will give us a sufficient ground to assess if a restriction proposal is needed. The final RMOA will be updated when new information has become available and we have reached a conclusion.

Regarding scope, KemI believes that the restriction should cover a list of substances with a harmonised classification as Skin Sens. 1/1A/1B that may be present in finished textile articles should be included in the restriction. It is important that the list will be possible to update with additional substances if new relevant information about hazardous properties and use in textiles becomes available. In addition, the scope in the EU Commission's proposal on a restriction of CMR substances in textiles under REACH Article 68.2 need to be considered when preparing a restriction dossier in order to create a harmonised legislation for textile articles. Grouping possibilities of substances based on chemical properties and structural similarities will also be explored as a part of the preparation of a restriction dossier.

3.2 Harmonised classification and labelling

KemI consider that a harmonised classification of substances as Skin Sensitizing 1/1A/1B is an appropriate criteria for inclusion in a possible restriction. This will facilitate the process of assessing which substances that should be included in a restriction. In order for a restriction that only covers harmonised classified substances to be effective it is essential that more textile relevant skin sensitizers become harmonised classified.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

If KemI find that there is sufficient documentation justifying a risk management measure, we will decides to prepare a proposal for restriction.

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
Preparatory work, information gathering. If KemI find that there is sufficient documentation justifying a risk management measure, we will decide to prepare a proposal for restriction.	2017 - 2018	Member State Sweden
Annex XV and XVI dossier for restriction	Jan / 2019	Member State Sweden