Kemikalieinspektionen
Swedish Chemicals Agency

Risk Management Option Analysis Conclusion Document

Substance Name: 3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate
EC Number: 223-861-6
CAS Number: 4098-71-9

Authority: Swedish Chemicals Agency
Date: 20 December 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

3-isocyanatomethyl-3,5,5-trimethylcyclohexyl isocyanate or Isophorone diisocyanate (IPDI) has a harmonised classification as Resp. Sens. 1 according to CLP.

The Swedish Chemicals Agency submitted a draft RMOA for IPDI in June 2013. The RMOA identified that further risk management options should be considered to protect industrial workers from occupational exposure to IPDI as the inhalation exposure estimates were at considerable levels and close to occupational exposure limits (OELs). Moreover, new cases of occupational asthma related to diisocyanates exposure are reported. The most appropriate RMO was suggested to be identification of IPDI as an SVHC under Article 57(f) based on equivalent level of concern to that of CMRs and thus inclusion into the Candidate List and eventually into REACH Annex XIV.

Later, an RMOA for diisocyanates as a group was submitted by the German MSCA in October 2014, concluding that the most appropriate RMO was restriction.

In February 2016, the German MSCA submitted a proposal for restriction of diisocyanates, including IPDI in the scope. The proposed restriction limits the use of diisocyanates in industrial and professional applications to those cases where a combination of technical and organisational measures, as well as a minimum standardised training package, have been implemented. ECHA's Committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) have now agreed with the proposal to restrict the use of diisocyanates in the workplace.

In Sweden, the use of diisocyanates has been regulated in a similar manner to what is proposed for more than 20 years. The regulation requires training and medical examinations for workers exposed to diisocyanates. The employer is responsible for these measures but the training is usually carried out by expert consultants. The requirements are well known both by employers and employees in Sweden and have reduced but not eliminated the number of workers developing asthma.

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:	
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 action needed at this time	✓

2. NO ACTION NEEDED AT THIS TIME

The proposed restriction for diisocyanates is considered by RAC and SEAC as an appropriate measure to diminish the risk of developing occupational asthma from exposures to diisocyanates. An advantage with the proposed restriction is that all diisocyanates (aromatic, aliphatic, prepolymers with free diisocyanate) are covered in one regulatory measure and further that minimum levels of common handling standards are defined in EU. Since IPDI is included in the proposed restriction of diisocyanates as a group, no further action is considered necessary now. In case follow-up evaluations of the suggested restriction show that workers are still not sufficiently protected this conclusion should be revised.

3. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Follow-up action	Date for follow-up	Actor