Danish Ministry of the Environment
Environmental Protection Agency

RISK MANAGEMENT OPTION ANALYSIS

CONCLUSION DOCUMENT

for

Substance name

EC No 220-239-6

CAS No 2682-20-4

Member State(s): Danish EPA

Dated: 27 March 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.

1 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

Background

Methylisothiazolinone (MIT) is a preservative used in water based paints, glues, household products, in cosmetic products and toys (e.g. fingerpaint for children). A rapid increase in incidences of allergies from MIT has been observed by scientists in several countries, e.g. in France, Germany, Finland, Belgium, Great Britain, the Netherlands, Australia and Denmark over the past 5-10 years. The prevalence of allergy to MIT in dermatitis patients has reached 10% in the United Kingdom.

The Danish authorities believe that the continuous increase in incidences of allergy to MIT call for prioritising regulatory action in several sectors.

Classification and labelling

There is currently no harmonised classification for MIT under the CLP regulation. The Rapporteur Member State (RMS) under the biocides review programme has filed a proposal for the harmonised classification of the substance to ECHA in January 2015, including a proposal for a specific concentration limit. The proposal will be open for public consultation following compliance check by ECHA, and will be discussed at RAC possibly in the fall of 2015.

Cosmetic products

The cosmetic product regulation today includes a limit content of 100 ppm MIT in cosmetic products for leave on and rinse off purposes. Also, cosmetic products must carry a full ingredient list on the label.

In 2013, the Scientific Committee for Consumer Safety (SCCS) issued an opinion on the safety of MIT. The SCCS recommended that a limit of 15 ppm MIT is set for rinse-off cosmetic products while MIT should not be allowed in leave-on products. Implementation of the opinion in the Cosmetic Regulation is under discussion in the working group on cosmetics. Also, the Commission has commissioned the SCCS to revisit the opinion with respect to rinse-off products on the basis of new data.

Biocides regulation

The inclusion of MIT in product type (PT)13 (metal working fluids) on the positive list of biocidal active substances under the Biocides regulation (BPR) was adopted by the Biocide Product Committee in September 2014. This use does, however, not imply significant dermal exposure. There is only a low concern for skin sensitisation from MIT in this PT. Evaluation of the use of MIT in PT6 (in-can preservatives), PT11 (preservatives for liquid cooling and processing systems) and PT12 (slimicides) under the biocides review programme is pending. The RMS for MIT has indicated that their draft assessment report for use of the substance in PT 6 will be submitted after the classification of the substance has been discussed in RAC, even though the generic work plan for discussion of PT 6 substances is much later.

Toys

The Directive on Toys refers to a standard on finger paints where a limit for the content of MCIT:MIT 3:1 at 8 ppm and of MIT at 100 ppm was set recently. A proposal from EU Commission to limit the content for MCIT:MIT, MCIT and MIT in toys for children under three years of age and in toys intended to be put into the mouth at 1 ppm, 0.75 ppm and 0.25 ppm based on quantification limits, respectively, is currently being discussed in the EU working group on toys. It is expected that the proposal will be put

forward for vote in June 2015. However, no regulation of MIT in toys intended for children over the age of 3 is foreseen in the directive.

EU flower

The EU eco-labelling directive set out criteria for indoor paints at a maximum total content of isothiazolinones of 500 ppm. A limit for MIT of 200 ppm was adopted by the Member States for implementation in 2014. A Commission statement was issued that a reassessment of the use of MIT as a preservative and an evaluation of new scientific evidence and EU legislation will take place for the next revision of the criteria.

Industry initiatives

Cosmetic Europe recommended its members to phase out MIT in leave-on cosmetics in December 2013, in accordance with the recommendation from the SCCS. The European organisation for decorative paints CEPE recommended the declaration of MIT in paints from 15 ppm. Some producers of MIT have notified self-classification of products containing the substance of 1000 ppm and above (the generic limit is 1% or 10.000 ppm). This classification will lead to declaration of MIT from 100 ppm from June 2015 due to the rules of CLP.

RMOA

Denmark prepared a draft RMOA in March 2014. The present RMOA conclusion document reflects the final version of that RMOA. During its preparation, consideration was given to comments received from other MS and the Commission,to the recent development in different areas of regulation and to recent data on the continuing increase in incidences of allergy to MIT across Europe from MIT.

2. CONCLUSION OF RMOA

Conclusions	**Tick box**
Need for follow up regulatory action at EU level *[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]*	√
Harmonised classification and labelling	√
Identification as SVHC (authorisation)	
Restrictions	(√)
Other EU-wide measures, e.g. Biocidal product regulation, Cosmetics regulation, Toy Safety Directive, Ecolabelling.	√
No need for regulatory follow-up action	

3. FOLLOW-UP AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

3.1.1 Harmonised classification and labelling under CLP

A harmonised classification of MIT is required, as the substance is a biocide active substance. MIT is currently not listed in Annex VI of the CLP regulation.

The rapid increase and high incidences of sensitisation to MIT reported across Europe indicate that a harmonised classification for skin sensitisation in category 1A, including a low specific concentration level (SCL)

A harmonised classification of MIT for skin sensitisation (H317) including the setting of a low SCL would result in hazard communication with a danger pictogram on some of the mixtures containing MIT which are believed to have induced allergies in the scale experienced during the recent years.A large number of scientific articles over the past decadeshow that MIT is a potent sensitiser in humans. Numerous positive patch tests from dermatological clinics with MIT show that products as water based paints, glues, detergents or cosmetic products have induced sensitisation to MIT.

Also, it appears from comparison of human data and standard animal tests conducted with MIT that sensitised humans are more sensitive to MIT than animals.

As 100 ppm is the maximal concentration allowed in cosmetic products,, and as 80% of paints contain less than 100 ppm (Personal communication from the Danish Paints and Adhesives association, 2012), it indicate that the concentration in the vast majority of applications of MIT is ≤100 ppm. This interpretation of the common concentration of MIT in products is confirmed by findings in a recent Danish survey of consumer products (to be published www.mst.dk).

Skin contact with products containing around 100 ppm or lower is thus to be responsible for the dramatic increase in number of cases of sensitisation. The Scientific Committee for Consumer Safety (SCCS) in their recent opinion on MIT stated: "The wealth of clinical data demonstrates that 100 ppm MI (MIT) sensitises.".

It therefore appears relevant to attribute an SCL for the classification of MIT as skin sensitiser (H317) below this level of 100 ppm.

The SCCS proposes that the level of MIT permitted in rinse-off cosmetics should be based on the maximum permitted level of MIT in combination with MCIT in MCIT: MIT 3:1 which is 3.8 ppm, is taken as a starting point for regulating MIT. As MIT is considered less potent than MCIT, the committee concludes their opinion stating that a concentration of 15 ppm is considered safe for the consumer with respect of induction of contact allergy for rinse-off cosmetic products .

The Danish EPA urges that the evaluation by the SCCS be considered for in the harmonised classification of MIT.

3.1.2 Restriction under REACH

As described in section 1, there is a risk of sensitisation from the use of a large number of different types of mixtures containing MIT. A restriction on Annex XVII under REACH of the content of MIT in different mixtures and articles could be considered.

As the toys safety directive does not allow for limiting the use of chemical substances, e.g. MIT, in toys for children above three years of age, a restriction under REACH could be considered for the use of MIT in toys for this group of children.

A REACH restriction may also be relevant to address the concern that airborne exposure to MIT from large painted surface causes sensitisation reactions in subjects entering newly painted rooms, as this exposure situation would fall outside the scope of the BPR. However, more data are needed to map the mechanism behind this effect and the relation between the content of MIT in the mixture and the exposure levels in the air. As of now the data merely indicate a cause-effect relation based on a number of cases of professionals and consumers being sensitised to MIT when entering newly painted rooms.

3.1.3 Other Union-wide regulatory risk management measures

3.1.3.1 Biocides Product Regulation

Regulation of MIT under the BPR is under way. However, the general workplan for the review of biocidal active substances would mean an unacceptable delay in the regulation of this potent sensitiser. The rapidly developing incidence of sensitisation from MIT stresses the necessity of pushing forward the review process of MIT in product types where exposure cannot be excluded.

A thorough risk assessment should be conducted and provisions restricting the content of MIT in biocidal products should be considered in relation to the possible inclusion of MIT on the positive list under the BPR for use as an in-can preservative and in other product types when relevant.

3.1.3.2 Cosmetic Products Regulation

Cosmetics are major sources of exposure to MIT. Implementation of the opinion of the SCCS would lead to a ban of MIT in leave-on products, and reduced exposure to MIT through regulation of MIT in rinse-off products to less than 15 ppm. Such a step would hopefully lead to a decrease the number of in allergy cases from MIT caused by cosmetic products.

3.1.3.3 Toys Directive and standards

The planned regulation of MIT in toys for children under the age of 3 should be supported. Possibilities to reduce the content of MIT in other toys should be seeked.

3.1.3.4 EU Flower

The criteria for the ecolabelling with the EU Flower to-day include a limit for MIT of 200 ppm in indoor paint. In view of the recent information, this level may be insufficient to protect the consumer from sensitisation to MIT. The consumer may thus be exposed to sensitising levels of MIT, even when choosing EU Flower labelled paint. It is therefore important that the criteria for MIT content should revisited on the basis of the latest scientific information as soon as possible.

3.1.3.5 Voluntary measures

Voluntary initiatives from Industry to reduce or substitute the use of MIT and to inform the user of MIT content in products are also welcomed.

Cosmetics Europe has recommended their members not to use MIT in leave-on cosmetic products, and CEPE (The European Organisation on decorative paints) has encouraged their members voluntarily to declare MIT on the label of paints.

In conclusion, the Danish EPA believes that urgent efforts should be done in parallel in several legislative contexts, notably under Classification and Labelling (CLP), the Biocides Product Regulation (BPR), the Cosmetic Product Regulation (CPR) in view of reducing exposure to MIT. Regulation under REACH may also prove relevant, but it is considered that such an initiative should await the outcome of other initiatives.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Follow-up action	Date for intention	Actor
CLP: Adoption of harmonised classification with low SCL	Late 2015?	RMS (Slovenia) has filed proposal in January 2015. Public consultation, RAC opinion and Commission proposal for Annex VI amendment pending
CPR: Restriction of use of MIT in cosmetic leave-on and rinse off products	Summer/Fall 2015?	Commission to propose amendment to Annex I to the CPR
BPR: Restriction of use of MIT as in-can preservative and preserved end-use products	Early 2016	Commission, based on advice from Biocidal Product Committee
• Limit for MIT under Toy directive • Further initiatives to reduce MIT in toys	June 2015 ?	Vote on Commission proposal Commision? Standard organisation? Other?
Lowering EU Flower limit on MIT in criteria	2016?	Commission
Possible Annex XV dossier for restrictions	Later than 2016	MS (DK, ECHA, others?) However, the relevance of this RMO will depend on other risk mitigation measures and further scientific documentation.