Risk Management Option Analysis Conclusion Document

Substance Name: **Alkanes, $C_{14-17,}$ chloro (Medium-chain chlorinated paraffins, MCCP)**

EC Number: **287-477-0**

CAS Number: **85535-85-9**

Authority: German CA

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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

A Risk Assessment Report (RAR) (EU, 2008) and the transitional Annex XV Report (UK, 2009) by the UK CA addressing human health and environmental endpoints revealed that a safe use for workers could not be demonstrated for the use of oil-based metal working fluids containing more than 10 % medium-chain chlorinated paraffins (MCCP). The registrants were therefore asked to implement a stepwise approach to reduce both dermal and inhalation exposure at the workplace and update theirs chemical safety reports (CSRs) accordingly.
Furthermore, MCCPs were subject to a targeted Substance Evaluation focussing on environmental endpoints by the UK CA which concluded that MCCPs have PBT and probably vPvB properties. A recently updated risk management options analysis (RMOA) by the same CA concluded that at various life cycle stages emissions into the environment are to be expected and that these releases are currently not minimised to the greatest extent technically and practically feasible. It advises to identify the MCCPs as a substance of very high concern (SVHC) followed by a restriction under REACH.
While the RMOA from the UK CA concentrates on the release of MCCP to the environment, human health risks are not addressed. In contrast, this present RMOA deals with human health related aspects of MCCP, only.
The toxicological data have been extensively reviewed in various evaluations: WHO (WHO, 1996), Canadian Environmental Protection Act (CEPA, 2008), EU Risk Assessment Report (EU, 2008), Scientific opinion on the risk assessment report on C14-17, chloro, human health part of the Scientific Committee on Health and Environmental Risks (SCHER, 2008), Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT, 2009), Federal Institute for Occupational Safety and Health (BAuA, 2011), Danish Ministry of the Environment (DEPA, 2013), United States Environmental Protection Agency (EPA) (DC, 2015). A scientific opinion by the European Food Safety Authority (EFSA) indicated no health concern regarding MCCP but limited the intake on consumption of fish meat only (EFSA Panel on Contaminants in the Food Chain et al., 2020).

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 for human health endpoints	**Tick box**
Need for follow-up regulatory action at EU level:	
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	

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

There are three different areas of concern that in its consequences warrant regulatory risk management. Firstly, there is uncertainty regarding toxicological data and human health endpoints. The effect of chain length and degree of chlorination on the toxicity of MCCP is not known. Moreover, the mode of action for the effect of MCCP on the thyroid and its hormones/regulation is still unclear, therefore a concern for endocrine disruption and neurodevelopmental toxicity cannot be ruled out. Furthermore, there is a lack of specific carcinogenicity test data for MCCP and a standard data gap for genotoxicity and toxicity to reproduction. These concerns should be clarified via Compliance Check (CCH) and/or Substance Evaluation (SEv), if needed. Depending on the new data, decisions on further risk management options or measures like e.g. restriction have to be taken. Further data may allow identification of MCCP as endocrine disruptors or classification for developmental toxicity.

Secondly, the author member state competent authority (aMSCA) has identified an uncontrolled risk for oil-based metal working fluids (MWF) with an MCCP content of more than 3 % MCCP. The problem regarding the MWFs has been pointed out already in the Annex XV transitional report by the UK CA and the registrants were asked to update their CSRs and include steps to reduce exposure to MCCP. However, until now the registrants neither provided new exposure data nor updated the risk management measures in the CSRs.

Thirdly, MCCP are found in significant amounts in certain consumer products, especially food contact materials or food supplements which are not registered under REACH. Although the source of MCCP in all of these products is not known, the aMSCA concludes that there is an uncontrolled risk for infants due to leakage of MCCP out of hand blenders into the prepared food. This is in contrast to previous evaluations, in which no significant exposure of consumers to MCCP was concluded.

3.1 Harmonised classification and labelling

MCCPs are included as a single entry in Annex VI with a harmonised classification as Aquatic acute 1 (H400) and Aquatic chronic 1 (H410) as well as Lact. (H362). A revision of this classification should be considered if new data become available concerning reproductive and developmental toxicity, and/or the genotoxic or carcinogenic potential of MCCP, e.g. via Compliance Check (CCH).

3.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

To the current state of knowledge the aMSCA does not consider SVHC identification followed by authorisation as an adequate RMO to address the concern human health because authorisation does not seem to be the most effective measure for consumer protection as it is not effective to control imported articles.

From the OSH perspective, SVHC identification and inclusion in Annex XIV are generally regarded as a very effective RMO if followed subsequently. However, the authorisation process should be pursued if substitution of a substance in all/most applications is required and needs to be promoted. In the case of MCCP in MWF, a risk was identified only for a well defined use while risks for other industrial and professional uses can be adequately controlled by appropriate RMMs. Therefore, authorisation is considered a disproportionate RMO by the aMSCA.

3.3 Restriction under REACH

A restriction of substances under REACH should be considered if an unacceptable risk to humans or the environment can be demonstrated that is not adequately controlled and needs to be addressed at EU level, according to Article 69(1) and 69(4). Restriction would apply to both imported articles and those manufactured in the European Union and in the case of MCCP would be a more effective regulatory option than authorisation.

According to current data, a preliminary risk characterisation ratio above 1 could be demonstrated for the use of hand blenders for food preparation for infants. It should be noted that the available data is mainly targeted on food applications (e.g. hand blenders, baking ovens) and more information on the occurrence of MCCP is needed. Additional data is necessary and should be requested within CCH and if appropriate eventually via SEv in order to refine hazard and risk assessment. A restriction proposal may be considered at a later stage as an appropriate measure to limit the risks for consumers.

In addition, the aMSCA reassessed the previous identified risk for the use of oil-based MWF in the scope of this RMOA. Based on the assessment of current REACH registration data and the information gained in the public consultation, the aMSCA concludes that the risks arising from the use of oil-based MWF containing MCCP in a concentrations of >3 % are not adequately controlled for workers (RCR>1).
The most effective strategy of regulating this specific use at the workplace would be a targeted restriction limiting the concentration of MCCP in oil-based MWF to concentrations of ≤3 %.
However, in a restriction proposal an unacceptable risk must be demonstrated. For the moment, standard data on toxicity to reproduction and mutagenicity are missing in the dossier. For a clearer description of the toxicological data, which is required for the risk assessment, generation of this data e.g. via CCH should first be awaited.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

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 follow-up	Actor
Targeted restriction for MCCP in oil-based MWF regulating this specific use at the workplace	After CCH/(SEv)	DE CA