

**Risk Management Option Analysis Conclusion Document**

**Substance Name:** **Alkanes, C14-17, chloro**

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

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

**Authority: United Kingdom**

**Date: November 2019**

**DISCLAIMER**

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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]](#footnote-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.

### OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Medium-chain chlorinated paraffins (MCCPs) was included in the first Community Rolling Action Plan under the REACH Regulation. The UK CA has now completed its Substance Evaluation, and concludes that MCCPs has PBT (and probably vPvB) properties. REACH calls for minimisation of emissions of, and exposures to, PBT/vPvB substances as far as technically and practically possible (recital 70). The purpose of the Risk Management Options Analysis (RMOA) is, therefore, to review the available evidence to determine what additional regulatory actions, if any, are required to minimise releases of MCCPs to the environment and the form that these measures could take. Previous work under the Existing Substances Regulation (and transitional activities) did not identify a need for further action to address human health risks, so the RMOA does not consider measures to protect human health.

Sweden has submitted a proposal to add MCCPs to the Restriction of the Use of Certain Hazardous Substances (RoHS) in Electrical and Electronic Equipment (EEE) Directive (2011/65/EU).

### 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.

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| **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 |  |

### Need for follow-up regulatory action at EU level

The UK CA has concluded that MCCPs has PBT/vPvB properties. This is not, by itself, sufficient to trigger minimisation of emissions and exposure. The registrants’ Chemical Safety Reports (CSRs) assess environmental risk on the basis of PEC/PNEC ratios. The CSRs indicate that there will be environmental releases from various life cycle stages for all registered uses. There is therefore an unacceptable risk, since releases do not appear to be minimised to the greatest extent technically and practically feasible. EU-wide follow up actions are necessary to address that requirement.

### Harmonised classification and labelling

The UK CA does not intend to propose amendment to the harmonised classification of MCCPs at the present time. Multiplication factors for mixtures could be added for aquatic hazards in due course once the outcome of additional risk management is known.

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

The UK CA has concluded that MCCPs meets the Annex XIII criteria for PBT and probably vPvB. To provide support for the restriction process, the UK CA considers it appropriate to prepare and submit an SVHC dossier. This would enable public consultation on the proposal to formally identify MCCPs as a SVHC and place it on the Candidate List. The registrants do not consider that MCCPs meets the Annex XIII criteria, so SVHC identification would create legal certainty and oblige the registrants to review their risk management measures and provide advice on safe use to downstream users. Article importers would be obliged to notify ECHA of MCCPs imports (in articles) exceeding 1 tonne per year, where the concentration in the article exceeds 0.1% (w/w).

### Restriction under REACH

MCCPs is described by a single CAS number, but contains thousands of constituents. It is supplied at high tonnage with a wide dispersive use pattern within the EU. Releases to the environment are estimated at approximately 300 tonnes per year, and arise from product formulation, use and service life. Existing operational controls and risk management measures identified in the lead registrant’s CSR do not prevent service life releases from products manufactured in the EU or imported from outside the region. SVHC identification would imply eventual authorisation or restriction. Restriction is preferred as a more effective regulatory instrument for the following reasons:

* Imported goods containing MCCPs - such as textiles - could be brought within the scope of a restriction, but would lie outside the scope of authorisation. Restriction would therefore create a level playing field for all European stakeholders.
* PBT/vPvB properties may not be associated with some types of MCCP product (specifically, those with a chlorine content of ≤45 % by weight). A restriction could address the risks whilst derogating uses of lower chlorine content products.
* A restriction could be defined to exclude uses with minimal releases to the environment; this is not possible with authorisation.

Available information suggests that alternatives may be available for some uses, though this might be associated with increased cost. A restriction proposal would give industry the opportunity to submit detailed socio-economic information on alternatives (at the Public Consultation stage or earlier). Notification of the intention to propose a restriction could be made at the same time as SVHC dossier submission.

### Other Union-wide regulatory measures

The UK CA does not intend to initiate any other EU-wide regulatory measures for MCCPs.

### Need for action other than EU regulatory action

The UK CA recognises that EU/EEA level voluntary initiatives led by industry may provide opportunities for the early reduction of emissions, in advance of statutory obligations.

The UK CA is considering the potential for developing a nomination for MCCPs under the Stockholm Convention on Persistent Organic Pollutants (POPs). This could be pursued co-operatively with EU member states or non-EU countries. The REACH restriction could be processed in parallel with a POPs nomination.

### No action needed at this time

No additional EU-wide regulatory risk management measures are foreseen*.*

### 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.

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| **Follow-up action** | **Date for follow-up** | **Actor** |
| Annex XV dossier for SVHC identification | Q1 2020 | To be confirmed |
| Annex XV dossier for restriction | Q1 2021 | To be confirmed |

Note: The timing of the UK’s exit from the EU is likely to affect which actors would be involved in the formal submission of any dossier. This requires further discussion.

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> [↑](#footnote-ref-1)