Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

Risk Management Option Analysis Conclusion Document

Substance Name: **Octamethylcyclotetrasiloxane (D4)**
EC Number: **209-136-7**
CAS Number: **556-67-2**

Substance Name: **Decamethylcyclopentasiloxane (D5)**
EC Number: **208-764-9**
CAS Number: **541-02-6**

Authority: **German CA**
Date: **2017-12-15**

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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

REACH restriction processes

A restriction dossier on D4 and D5 in wash-off personal care products was submitted by the UK in 2015 (UK Health & Safety Executive 2015). Prior to this, in November 2012 the ECHA PBT Expert Group agreed that D4 and D5 meet the PBT/vPvB and vPvB criteria of REACH Annex XIII, respectively. Further, the MSC adopted its opinion on D4 and D5 that both substances meet the criteria for vP and vB in April 2015.

The restriction proposal on D4 and D5 in wash-off personal care products was agreed upon at the REACH Committee Meeting on May 10th 2017.

In April 2017, ECHA submitted its intention to restrict the use of D4 and D5 in leave-on personal care products and other consumer/professional products not yet covered in the UK restriction proposal.

Harmonized C&L

The German CA submitted a CLH dossier for D4 proposing a revision of the harmonised classification for the environment. This would result in the following Annex VI entry in the CLP Regulation:

Repr. 2, H361f***

Aquatic Chronic 1, H410

Aquatic Chronic 1, M-factor=10

(UNEP) Stockholm convention (POPs Protocol)

In April 2016, the European Commission has proposed to nominate D4 for regulation under the Stockholm Convention. Discussions on this Commission proposal are still ongoing.

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:	
Harmonised classification and labelling	
Identification as SVHC	x
Restriction under REACH	
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

3.1 Identification as a substance of very high concern, SVHC (Candidate listing without subsequent inclusion in Annex XIV)

According to the REACH Regulation (Recital (70)), emissions of PBT/vPvB substances should be minimized. Furthermore, the SVHC Roadmap to 2020[2] aims to have all relevant substances of very high concern included in the Candidate List by 2020. D4 and D5 can be considered relevant substances of very high concern.

The PBT Expert Group agreed that D4 meets the REACH Annex XIII criteria for identification as a PBT and vPvB substance and D5 meets the REACH Annex XIII criteria for identification as a vPvB substance in November 2012.

The need for a minimization of emissions is also substantiated by the potential for long-range transport and the wide dispersive use of D4 and D5.

D4 and D5 are used in personal care products in wide dispersive uses with emissions to the environment via sewage treatment plants. Furthermore, D4 and D5 are present as an impurity in silicone polymers above 0.1% during manufacture and formulation. Given their persistency and volatility, exposure of the environment to these PBT/vPvB substances can be assumed.

While Candidate Listing is often seen solely as a first step to authorisation, it has direct effects even when the substance is not included in Annex XIV. Candidate Listing will lead to a formal recognition of the PBT and vPvB properties. It would require the registrants to acknowledge the PBT/vPvB status of D4 and D5 and to minimize emissions of these substances to the environment by the help of substance tailored operational conditions and risk management measures. The present hazard assessment can also be seen as a supporting first step for potential future risk management options.

Furthermore, Candidate Listing triggers the obligation for suppliers of articles to pass on information on the respective substances in the supply chain and upon request provide information to consumers.

[2] https://echa.europa.eu/svhc-roadmap-to-2020-implementation

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**
Annex XV dossier for the identification of Octamethylcyclotetrasiloxane (D4) as SVHC	February 2018	DE-CA
Annex XV dossier for the identification of Decamethylcyclopentasiloxane (D5) as SVHC	February 2018	DE-CA