Risk Management Option Analysis Conclusion Document

Substance Name: Dodecamethylcyclohexasiloxane (D6)

EC Number: 208-762-8

CAS Number: 540-97-6

Authority: United Kingdom

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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

D6 meets the criteria of Article 57(e) of Regulation (EC) 1907/2006 (REACH) as it is concluded to fulfil the vPvB criteria of REACH Annex XIII.

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 (authorisation)	√
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 (first step towards authorisation)

Any further risk management work on D6 will have implications for other related siloxane substances that are undergoing substance evaluation (because they may be the main substitutes for D4 and D5 if D6 is no longer allowed to be used). The evaluating Member State had originally intended to wait for the completion of the evaluation work for the linear siloxanes, the reaction of the cosmetics industry to the restriction of cyclic siloxanes in wash-off products (which might have triggered a general move away from this type of substance) and receipt of additional monitoring information before deciding on the best course of action for the whole siloxane group. However, the initiation of parallel risk management activity by Germany and the Commission on D4 and D5 means that action on D6 needs to be taken now.

3.1 Restriction under REACH

ECHA is currently working on a further restriction proposal "*concerning the use of D4 and D5 in leave-on cosmetic products and for other consumer or professional products"* at the request of the European Commission (European Commission 2016). D6 is used in some applications that are being addressed by ECHA, particularly leave-on cosmetics. As it has the same vPvB properties as D5 and could be an alternative to D4 and D5 in some products, the Commission has requested that ECHA include D6 in the restriction proposal. This is more efficient than initiating a separate project (in terms of both working with the affected industry sectors and the public consultation process).

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Follow-up action	Date for follow-up	Actor
Annex XV dossier for restrictions	January 2019	ECHA