RISK MANAGEMENT OPTIONS ANALYSIS

CONCLUSION DOCUMENT

for

Octamethylcyclotetrasiloxane

EC No 209-136-7

CAS No 556-67-2

Member State(s): United Kingdom

Dated: 30 June 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. OVERVIEW OF OTHER REGULATORY PROCESSES / EU LEGISLATION

Harmonised classification and labelling

The harmonised classification for D4 under the CLP Regulation is Repro. 2 (H361f) and Aquatic Chronic 4 (H413). The implementation of the 2nd ATP to the CLP Regulation will produce a more stringent environmental classification as the lowest reliable aquatic NOEC is around 4.4 µg/l (equivalent to Aquatic Chronic 1). Some companies who have made notifications under the CLP Regulation also propose additional classifications (Flam. Liq. 3, Acute Tox. 4).

Echa's PBT Expert Group

In November 2012 the PBT Expert Group agreed that D4 meets the Annex XIII criteria for identification as PBT and vPvB. Information from the scientific literature published since November 2012 supports the conclusions reached by the PBT Expert Group.

Echa's Member State Committee

In April 2015 the Member State Committee gave its opinion that D4 meets the criteria for vP and vB.
http://echa.europa.eu/en/about-us/who-we-are/member-state-committee/opinions-of-the-msc-adopted-under-specific-echa-s-executive-director-requests

European assessments

EA, 2009. Environmental Risk Assessment Report: Octamethylcyclotetrasiloxane. ISBN: 978-1-84911-031-0. Environment Agency April 2009. Available from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/290565/scho0309bpqz-e-e.pdf

EA, 2013. D4 PBT Evaluation Factsheet. Final version of April 2013. Available at http://echa.europa.eu/documents/10162/13628/octamethyl_pbtsheet_en.pdf

Echa, 2015. D4/D5 Annex XV restriction dossier. Available from http://echa.europa.eu/registry-of-submitted-restriction-proposal-intentions/-/substance-rev/8620/term

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)	
Restrictions	√
Other EU-wide measures	
No need for regulatory follow-up action	

3. FOLLOW-UP OF REGULATORY RISK MANAGEMENT ACTION AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

3.1.1 Harmonised classification and labelling

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

3.1.3 Restriction

D4 is a high tonnage substance. It is present in a very wide variety of consumer products and therefore has significant potential for environmental release. The greatest concerns for this substance relate to their presence the aquatic environment and the RMOA has identified a need to minimise emissions. In terms of achieving the highest level of emission reduction for least cost, and given the nature of the risk (i.e. that aquatic concentrations can be reduced by controls on emissions to waste water rather than emissions to air), we propose to prioritise risk management based on the magnitude of aquatic emissions. The RMOA has identified that use in personal care products creates the greatest emissions to the aquatic environment.
The UK considers a targeted restriction for the manufacture and use of personal care products will be the most appropriate route to reduce releases to the aquatic environment.

Of the measures available under the REACH Regulation, restriction is preferred to authorisation because:

- It provides a more flexible approach to achieve the aims of emission reduction as it can be targeted to those applications that pose the greatest risk (i.e. waste water discharges from relatively minor uses of the substance).
- It is likely to achieve a significant reduction in environmental concentrations more quickly.
- It can cover all relevant parts of the life cycle, including the presence of D4 as an impurity in polymeric products (where relevant) and higher molecular weight homologues like D6.
- It will avoid the creation of an unnecessary burden on companies whose products do not lead to significant waste water discharges.
- It will prevent the substitution of D5 with D4.

Alternative products already exist , and the fact that the manufacturers of personal care products are already substituting this substance indicates that they have (or are developing) effective substitutes.

Other uses of silicone polymers containing D4 as an impurity that may lead to releases to the aquatic environment have also been considered. Use of silicone polymers for antifoaming was considered to create the greatest potential risk, particularly use in the paper and pulp and oil and gas sectors. Analysis of the use patterns in these sectors, the Risk Management Measures (RMMs) already in place and the physical conditions of the processes have led to the conclusion that releases are likely to be minimal and do not warrant further consideration at this time. It has been proposed in the restriction text that the Commission could review the emissions from other sources after a period of 10 years of entry into force of the restriction. This would give relevant industry sectors time to consider the importance of other relevant sources, and could include a review of monitoring data to see if the proposed restriction has effectively removed inputs to wastewater treatment plants.

3.1.4 Other Union-wide regulatory risk management measures

The Commission could consider whether D4 should be identified as a Water Framework Directive Priority (Hazardous) Substance as part of the next round of negotiations.

4. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Follow-up action	Date for intention	Actor
Annex XV dossier for restriction	April 2015	UK