

14. 10. 2014

Note for the attention of Watze de Wolf, Chairman of the Member State Committee

Ref: Request to the Member State Committee (MSC) for an opinion on the persistence and bioaccumulation of the substances D4 and D5 against the criteria in Annex XIII of REACH

This note is to request the MSC pursuant to Article 77(3)(c) of the REACH Regulation, to draw up an opinion on the persistence and bioaccumulation of the substances D4 and D5 against the criteria in Annex XIII of REACH.

1. Background

Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5) have not been identified through the Article 59 process, set out in REACH, as being Substances of Very High Concern. However, there are concerns that they may meet the criteria in Annex XIII of REACH as substances with PBT or vPvB properties.

The substances are identified as follows:

Substance Name: Octamethylcyclotetrasiloxane

IUPAC Name: 2,2,4,4,6,6,8,8-octamethyl-1,3,5,7,2,4,6,8-tetraoxatetrasiloxane

EC Number: 209-136-7

CAS Number: 556-67-2

Molecular Formula: $C_8H_{24}O_4Si_4$

Substance Name: Decamethylcyclopentasiloxane

IUPAC Name: 2,2,4,4,6,6,8,8,10,10-decamethyl-1,3,5,7,9,2,4,6,8,10-pentoxapentasiloxane

EC Number: 208-764-9

CAS Number: 541-02-6

Molecular Formula: $C_{10}H_{30}O_5Si_5$

The UK Competent Authority (UK-CA) has indicated through an entry on the Registry of Intentions that they will submit in January 2015 a proposal to restrict these substances from being placed on the market or used in concentrations equal to or greater than 0.1% by weight of each in personal care products which are washed off in normal use conditions (<http://echa.europa.eu/registry-of-current-restriction-proposal-intentions/-/substance/6318/search/+term>). Following submission and a positive conformity check, the hazards and risks of the proposal would be evaluated by ECHA's Risk Assessment Committee (RAC) and an opinion given on these aspects (amongst others).

The restriction proposal for D4 and D5 will be based on the persistence and bioaccumulation properties hazard assessment by the UK-CA:

- D4 meets the definition of a PBT and a vPvB substance and
 - D5 meets the definition of a vPvB substance
- in accordance with Annex XIII of the REACH Regulation.

EU-wide opinion forming on the PBT or vPvB hazard assessment is generally performed through the identification of a substance as a Substance of Very High Concern where the involvement of the MSC may be triggered. To avoid that RAC has to prepare an opinion on whether the P and B criteria in Annex XIII are met and introduce a potential risk of divergent opinions between ECHA committees, the MSC will be tasked with giving an opinion on the persistence and bioaccumulative properties of the substances D4 and D5, which can then be used in the further deliberation of RAC. On 1 October 2014, the UK-CA submitted to ECHA their PBT report for D4 and D5 which will be used in the hazard assessment of the Annex XV report¹.

2. Terms of Reference

Pursuant to Article 77(3)(c) of the REACH Regulation, the Member State Committee shall draw up an opinion on whether the relevant properties of D4 and D5 meet the criteria for being persistent or very persistent or bioaccumulative or very bioaccumulative in Annex XIII of REACH. The opinion will be based on the information prepared by the UK-CA and submitted to ECHA on the 1st of October 2014 and the comments and responses received to the planned Public Consultation (see below).

3. Approach taken for the MSC opinion development

A 45-day public consultation on the hazard assessment as proposed by the UK-CA will be organised by the ECHA Secretariat starting mid October and the UK-CA (as dossier submitter of the restrictions proposal) has agreed to prepare responses to comments received. MSC Secretariat is to design & implement the process for MSC opinion forming through an appropriate adaptation of the RAC and SEAC frameworks for dealing with requests for opinions according to Article 77(3) of the REACH Regulation². MSC is expected to submit its opinion to the RAC Chairman and its Rapporteur for RAC's deliberations on the Restrictions proposal to be submitted on D4 and D5.

4. Timescale for the MSC opinion

The opinion of the MSC should preferably be adopted by the time of its 41st plenary meeting on 20-24 April 2015. If the adoption of the opinion is not feasible by the indicated target date, I wish to be informed.

5. Remuneration

The task for MSC following from this request is not considered to fulfil any of the requirements of a transfer of funds to the competent authorities of the Member States pursuant to Article 14(1) of Regulation (EC) 340/2008 and therefore no remuneration will be paid by the Agency.



Geert Dancet
Executive Director

Cc: Jukka Malm, Jack de Bruijn

¹ Email with attachments from the UK REACH Competent Authority to the Director of Regulatory Risk Management, ECHA

² Documents RAC/10/2021/12 and SEAC/06/2010/07