AGREEMENT OF THE MEMBER STATE COMMITTEE

ON THE IDENTIFICATION OF

DODECAMETHYLCYCLOHEXASILOXANE (D6)

AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of
Regulation (EC) 1907/2006[1]

Adopted on 13 June 2018

This agreement concerns

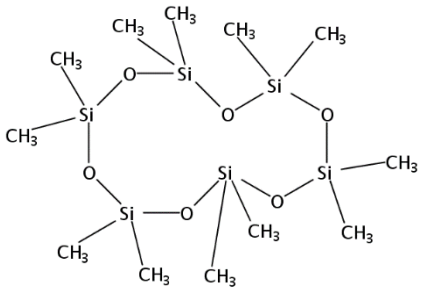
Substance name: Dodecamethylcyclohexasiloxane (D6)

EC number: 208-762-8

CAS number: 540-97-6

Molecular formula: $C_{12}H_{36}O_6Si_6$

Structural formula:



[1]Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

ECHA presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (02 March 2018, submission number SPS-013929-17) on identification of *Dodecamethylcyclohexasiloxane (D6)* as a substance of very high concern due to its persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) properties.

The Annex XV dossier was circulated to Member States on 8 March 2018 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 22 May 2018 and was discussed in the meeting on 12-14 June 2018 of the Member State Committee.

Agreement of the Member State Committee in accordance with Article 59(8):

Dodecamethylcyclohexasiloxane (D6) is identified as a substance of very high concern because

- it meets the criteria of Article 57 (d) of Regulation (EC) 1907/2006 (REACH) as a substance which is persistent, bioaccumulative and toxic when it contains ≥ 0.1 % w/w octamethylcyclotetrasiloxane (D4) (EC No. 209-136-7), and
- it meets the criteria of Article 57 (e) of Regulation (EC) 1907/2006 (REACH) as a substance which is very persistent and very bioaccumulative (vPvB) due to its intrinsic properties, but also
- it meets the criteria of Article 57 (e) of Regulation (EC) 1907/2006 (REACH) as a substance which is very persistent and very bioaccumulative (vPvB) when it contains ≥ 0.1 % w/w decamethylcyclopentasiloxane (D5) (EC No. 208-764-9) or ≥ 0.1% w/w octamethylcyclotetrasiloxane (D4) (EC No. 209-136-7)

in accordance with the criteria and provisions set out in Annex XIII of Regulation (EC) 1907/2006 (REACH).

UNDERLYING ARGUMENTATION
FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN

A weight-of-evidence determination according to the provisions of Annex XIII of REACH is used to identify the substance as vPvB based on its intrinsic properties. All available relevant information (such as the results of standard tests, monitoring and modelling, information from the application of the analogue approach (grouping, read-across), benchmarking approach and (Q)SAR results) was considered together in a weight-of-evidence approach.

Persistence

D6 is considered to be not readily biodegradable and so meets the screening persistent (P) and very persistent (vP) criteria. Read-across from D4 and D5 to D6 has been considered appropriate for the assessment of persistence. Based on the comparison of physico-chemical properties of D4, D5 and D6, D6 can be expected to be more persistent than D4 and D5. Data for the analogue substances D4 and D5 provide that the vP criterion is met in sediment (see the MSC SVHC agreements for D4 and D5).

Bioaccumulation

The available data from laboratory bioaccumulation tests show that D6 meets the vB criterion based on a kinetic BCF of 4 419-12 632 l/kg in common carp (*Cyprinus carpio*) among which the more reliable method of fitting the data provides BCFs > 5 000. In addition, the available field data provides evidence that biomagnification and trophic magnification occur in certain food webs in the environment. The available information on biomagnification and trophic magnification factors (BMF/TMF) in the field indicating that biodilution occurs in some food chains or in parts of some food chains, does not invalidate the other lines of evidence. Correlation of levels of D6 in some pelagic food webs with levels of known biomagnifying substances (TMFs >1) e.g. PCB-153 and p,p,-DDE (as part of a benchmarking approach), also tends to demonstrate that D6 can biomagnify. A comparison of the TMF data for D6 with that for D4 and D5 suggests that D6 has a generally similar biomagnification potential to both D4 and D5 in the environment based on the TMF. A similar picture is seen when comparing the D6 BCF values in *Cyprinus carpio* with those for D4 and D5 where the D6 values are similar or higher. However, the BCF for D6 is lower than those for D4 and D5 when comparing the data for *Pimephales promelas*. Taking together all lines of evidence on bioaccumulation potential, it can be concluded that D6 meets the vB criterion.

Toxicity

Several data are available on human health toxicity and ecotoxicity of D6, but these were not assessed for this report.

Relevant constituents, impurities and/or additives

D6 contains D4 and/or D5 as impurities. D4 fulfils the PBT and vPvB criteria and D5 meets the vPvB criteria (see the MSC SVHC agreements for D4 and D5)). Taking all information into account, including the concentration of D4/D5 and the properties of these substances, D6 thereby fulfils the PBT criteria with D4 in concentration of ≥0.1 % (w/w) and the vPvB criteria with either one or both D4 and D5 in concentration of ≥0.1 % (w/w).

Conclusion

D6 meets the criteria for a vPvB substance according to Article 57 (e) of REACH based on its intrinsic properties. Additionally, D6 meets the criteria for a vPvB substance when it contains octamethylcyclotetrasiloxane (D4) (EC No. 209-136-7) and/or decamethylcyclopentasiloxane (D5) (EC No. 208-764-9) in concentrations ≥ 0.1 % w/w. Furthermore, D6 meets the criteria for a PBT substance when it contains D4 in concentrations above or equal to 0.1 % w/w.

Overall conclusion

In conclusion, dodecamethylcyclohexasiloxane (D6) is identified as a PBT/vPvB substance according to Article 57(d) and (e) of REACH by comparing all relevant and available information listed in Annex XIII of REACH with the criteria set out in the same Annex, in a weight-of-evidence determination.

Reference:

Support Document to MSC SVHC agreement on D6 (Member State Committee, 13 June 2018)

SVHC agreement on octamethylcyclotetrasiloxane (D4) (EC No: 209-136-7) (Member State Committee, 13 June 2018)

SVHC agreement on decamethylcyclopentasiloxane (D5) (EC No: 208-764-9) (Member State Committee, 13 June 2018)