

AGREEMENT OF THE MEMBER STATE COMMITTEE
ON THE IDENTIFICATION OF
OCTAMETHYLCYCLOTETRASILOXANE (D4)
AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of
Regulation (EC) 1907/2006¹

Adopted on 13 June 2018

This agreement concerns

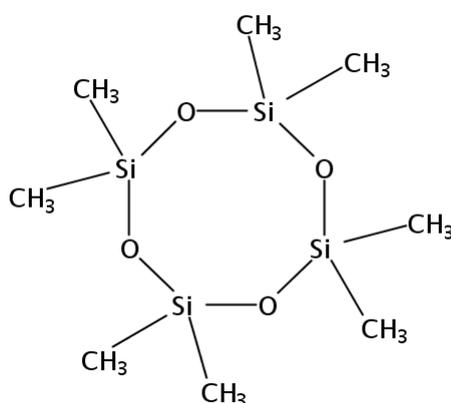
Substance name: Octamethylcyclotetrasiloxane (D4)

EC number: 209-136-7

CAS number: 556-67-2

Molecular formula: C₈H₂₄O₄Si₄

Structural formula:



¹Regulation (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

Germany presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (01 March 2018, submission number SPS-014015-18) on identification of *Octamethylcyclotetrasiloxane (D4)* 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):

Octamethylcyclotetrasiloxane (D4) 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, 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,

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

Persistence, bioaccumulation and toxicity (PBT)

In 2015 the Member State Committee (MSC) provided an opinion² on the persistent and bioaccumulative properties of D4 and D5 at the request of the Executive Director of ECHA under Article 77(3)(c) of REACH during the process to restrict the use of these two substances. A weight-of-evidence determination according to the provisions of Annex XIII of REACH was used to form the opinion. All available relevant information (such as the results of standard tests, monitoring and modelling, information from the application of the category and analogue approach (grouping, read-across) and (Q)SAR results) was considered together in a weight-of-evidence approach by the MSC. D4 was subsequently concluded by the Risk Assessment Committee (RAC) - based on the opinion of the MSC - to fulfil the criteria of Annex XIII of REACH as a PBT and vPvB substance (see RAC opinion³ on the restriction proposal and the corresponding Commission decision⁴ on it).

Persistence

The Member State Committee in its opinion² concluded that:

With regard to the assessment of persistence, MSC concludes that the experimental observations in simulation and monitoring studies lead to the conclusion that both D4 and D5 meet the vP criterion as specified in REACH Annex XIII.

MSC has evaluated non-degradation processes and concluded that these do not have a large impact on the sediment removal half-life, and thus cannot be used to refute the relevance of the sediment compartment in the assessment of persistence.

Based on OECD TG 308 sediment simulation studies (Xu, 2009a; Xu, 2009b), D4 has an estimated degradation half-life of 365 days in anaerobic sediment and 242 days in aerobic sediment at 24°C, MSC concludes that D4 meets the Annex XIII criteria for a very persistent (vP) substance in sediment according to Regulation (EC) No 1907/2006.

After the MSC and RAC opinion making processes, new studies have been published. The relevant studies have been summarised in the Support document to this agreement. This new information supports the earlier conclusion.

Bioaccumulation

The Member State Committee in its opinion² concluded that:

With regard to the assessment of bioaccumulation, MSC concludes that D4 and D5 are very bioaccumulative based on high fish BCF values, supported by multiple lines of evidence on biomagnification in dietary studies, and elimination half-lives. In addition, the available field data provides evidence that bioaccumulation and trophic magnification

² ECHA (2015): Member State Committee's Opinion on Persistency and bioaccumulation of Octamethylcyclotetrasiloxane (D4) (EC No: 209-136-7, CAS No: 556-67-2) and Decamethylcyclopentasiloxane (D5) (EC No. 208-764-9, CAS No. 541-02-6). <https://echa.europa.eu/about-us/who-we-are/member-state-committee/opinions-of-the-msc-adopted-under-specific-echa-s-executive-director-requests>

³ ECHA (2016): Committee for Risk Assessment (RAC) Opinion on an Annex XV dossier proposing restrictions on OCTAMETHYLCYCLOTETRASILOXANE, DECAMETHYLCYCLOPENTASILOXANE. <https://echa.europa.eu/documents/10162/18ea3a03-0da4-4a8d-a522-5b467c3a9307>

⁴ The restriction on D4 and D5 entered into force in 31.1.2018 (European Commission, 2018): http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2018.006.01.0045.01.ENG

have been shown to 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.

D4 meets the Annex XIII criteria for a very bioaccumulative (vB) substance according to Regulation (EC) No 1907/2006 based on the following studies:

- A steady-state BCF of 12,400 L/kg for Fathead Minnow *Pimephales promelas* (Fackler et al., 1995) based on total 14C measurements.
- A steady state BCF for Common Carp *Cyprinus carpio* in the range of 3,000 – 4,000 L/kg (based on parent compound analysis) (CERI, 2007 and 2010a). The kinetic BCF in one of the studies was in the range 4,100 - 5,500 L/kg.

After the MSC and RAC opinion making processes new studies have been published. The relevant studies have been summarised in the Support document to this agreement. The new information does not deviate from the diverse data available earlier on bioaccumulation. The new data do not provide any reason to change the conclusion that the substance is vB reached by MSC and RAC.

Toxicity

In its opinion³ on the UK proposal⁵ for a restriction on the use of D4 and D5 in wash-off personal care products, the Committee for Risk Assessment states that

*D4 has a long-term NOEC of around 4 – 6 µg/L for rainbow trout (*Oncorhynchus mykiss*), although RAC notes that there is some uncertainty in this value, and a long-term NOEC of 7.9 µg/L for *Daphnia magna* survival. [...] Significant toxicity to invertebrates is also apparent in sediment organism studies.*

The Committee for Risk Assessment in its opinion concludes that

D4 meets the REACH Annex XIII criteria for toxicity based on both aquatic and mammalian endpoints.

New studies were published after the MSC opinion² and RAC opinion³ were adopted. These studies were evaluated and taken into account for the overall weight-of-evidence determination. However, these studies are not considered to contest the conclusions on toxicity to fish and daphnids that were previously evaluated by the MSC and RAC. Hence, they do not change the overall conclusion on toxicity.

Recently, RAC has published its opinion⁶ proposing harmonised classification and labelling for aquatic ecotoxicity. The resulting revision of the existing classification is Aquatic Chronic 1 with hazard statement codes H410 with M-factor of 10. Hereby the fulfilment of the T criterion of Annex XIII section 1.1.3 a) of REACH is reconfirmed.

⁵UK proposal for a restriction on the use of D4 and D5 in wash-off personal care products (2015). https://echa.europa.eu/previous-consultations-on-restriction-proposals/-/substance-rev/9444/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=209-136-7&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true

⁶ ECHA (2018): Committee for Risk Assessment (RAC) Opinion on an Annex XV dossier proposing harmonised classification of OCTAMETHYLCYCLOTETRASILOXANE. <https://echa.europa.eu/documents/10162/2af6a9de-216c-dc41-859d-95aa8c9c14a7>

D4 is covered by index number 014-018-00-1 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class reproductive toxicity category 2 (hazard statement H361f “Suspected of damaging fertility”). Therefore, the criterion for toxicity of Annex XIII section 1.1.3 b) of REACH is fulfilled.

Conclusion

In its opinion² on D4 and D5, the Member State Committee states that:

Based on the information presented by the DS and careful consideration of the comments received in the public consultation, MSC supports the opinion of the DS that D4 and D5 both meet the vPvB criteria in Annex XIII of REACH.

The Committee for Risk Assessment in its restriction opinion³ concludes that:

D4 meets the REACH Annex XIII criteria for toxicity based on both aquatic and mammalian endpoints.

Furthermore, RAC has provided an opinion⁶ proposing harmonised classification of D4 as Aquatic Chronic 1. This provides a very recent endorsement of the relevance of the currently available ecotoxicity data.

Overall conclusion

In conclusion, D4 meets the criteria for a PBT and vPvB substance according to Article 57(d) and (e) of REACH by comparing all relevant and available information according to Annex XIII of REACH with the criteria set out in the same Annex, in a weight-of-evidence determination.

Reference:

Support Document on *D4* (Member State Committee, 13 June 2018)