Substance Name: Decamethylcyclopentasiloxane (D5)

EC Number: 208-764-9

CAS Number: 541-02-6

MEMBER STATE COMMITTEE

SUPPORT DOCUMENT

FOR IDENTIFICATION OF

DECAMETHYLCYCLOPENTASILOXANE (D5)

AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS PBT[1] AND vPvB[2] PROPERTIES

(ARTICLE 57D&E)

Adopted on 13 June 2018

[1] PBT means persistent, bioaccumulative and toxic. The substance is identified as PBT, if it contains equal to or more than 0.1 % (w/w) octamethylcyclotetrasiloxane (D4) (EC No: 209-136-7)
[2] vPvB means very persistent and very bioaccumulative

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IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Name: Decamethylcyclopentasiloxane (D5)

EC Number: 208-764-9

CAS number: 541-02-6

- D5 is identified as very persistent and very bioaccumulative (vPvB) substance according to Article 57 (e) of Regulation (EC) No 1907/2006 (REACH).

- D5 is identified as persistent, bioaccumulative and toxic (PBT) substance according to Article 57 (d) of Regulation (EC) No 1907/2006 (REACH) when it contains ≥ 0.1 % w/w octamethylcyclotetrasiloxane (D4) (EC No: 209-136-7).

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

The Member State Committee (MSC) provided an Opinion 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 (ECHA, 2015) 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. D5 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 vPvB substance (see RAC opinion on the restriction proposal: (ECHA, 2016; European Commission, 2018))[3].

<u>Persistence</u>

The Member State Committee (ECHA, 2015) 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, 2010), D5 has a degradation half-life in freshwater sediment of the order of 800-3,100 days at 24°C. MSC concludes that D5 meets the Annex XIII criteria for a very persistent (vP) substance in sediment according to Regulation (EC) No 1907/2006.*

[3] 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

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

Bioaccumulation

The Member State Committee (ECHA, 2015) 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 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.*
>
> [...]
>
> *D5 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 7,060 L/kg for Fathead Minnow Pimephales promelas (Drottar, 2005), based on total 14C measurements.*
> - *The steady state BCF for Common Carp Cyprinus carpio in the range 12,049 – 12,617 L/kg (based on parent compound analysis) or 10,550 – 11,048 L/kg when normalised to a 5 per cent lipid content (CERI, 2010b).*

After the MSC and RAC Opinion making processes new studies have been published. The relevant studies have been summarised in this document. 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
For D5 an assessment of ecotoxicity was carried out by RAC (ECHA, 2016). RAC noted that for human health hazard classification no full dataset was available. These have not been requested afterwards (a testing proposal evaluation is on-going). The toxicity of D5 has not been assessed for the purpose of the SVHC identification.

Relevant constituents, impurities and/or additives
D5 contains octamethylcyclotetrasiloxane (D4) as an impurity. D4 fulfils the PBT and vPvB criteria (see SVHC agreement of the Member State Committee on D4). Taking all information into account, including the concentration of D4 and the properties of the substance, D5 thereby fulfils the PBT criteria when it contains D4 in concentration of ≥0.1 % (w/w).

Conclusion
In its opinion on D4 and D5 (ECHA, 2015), 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.*

In conclusion, D5 is a vPvB substance when comparing all relevant and available information listed in REACH Annex XIII with the criteria set out in the same Annex, in a weight-of-evidence determination. Additionally, D5 is a PBT substance when it contains octamethylcyclotetrasiloxane (D4) (EC No. 209-136-7) which is typically present in concentrations above 0.1 per cent w/w. D4 fulfils the vPvB and PBT criteria of REACH as confirmed in the SVHC agreement of the Member State Committee on D4.

In conclusion, D5 meets the criteria for a vPvB substance according to Article 57(e) of REACH. It also meets the criteria for a PBT substance according to Article 57(d) of REACH when containing D4 above or equal to 0.1 % w/w.

Registration dossiers submitted for the substance: Yes

Introductory note

The Member State Committee (MSC) provided an opinion 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 (ECHA, 2015) during the process to restrict the use of these two substances. D5 was subsequently concluded by the Committee on Risk Assessment (RAC) - based on the opinion of the MSC- to fulfil the criteria of Annex XIII of REACH as a vPvB substance (see RAC opinion on the restriction proposal: (ECHA, 2016). The restriction of D4 and D5 entered into force in 31.1.2018 (European Commission, 2018).

Recently, RAC has published its opinion proposing harmonised classification and labelling for aquatic ecotoxicity of D4 (ECHA, 2018). The resulting revision of the existing classification for D4 is Aquatic Chronic 1 with hazard statement codes H410 with M-factor of 10. This revision of the environmental classification of D4 does not change the overall conclusions of the PBT/vPvB assessment and hence it does not bring any changes to the needs for risk reduction at the EU level.

This dossier largely cites and refers to the respective documents from the Member State Committee, RAC and UK which have already been discussed and agreed upon. The cited text passages have been marked in *italics*.

Justification

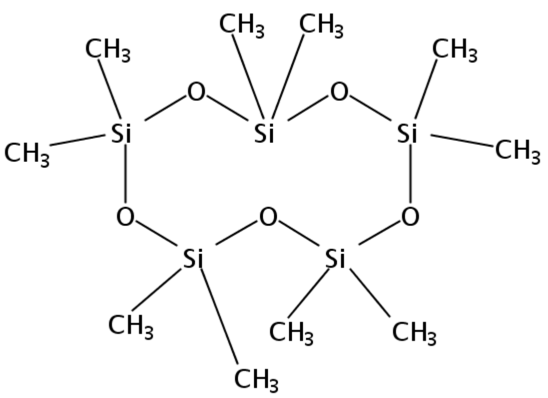
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	208-764-9
EC name:	Decamethylcyclopentasiloxane
CAS number (in the EC inventory):	541-02-6
CAS number: Deleted CAS numbers:	-
CAS name:	Cyclopentasiloxane, 2,2,4,4,6,6,8,8,10,10-decamethyl-
IUPAC name:	Decamethylcyclopentasiloxane
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	$C_{10}H_{30}O_5Si_5$
Molecular weight range:	370.77 g/mol
Synonyms:	D5, cyclopentasiloxane

Structural formula:



1.2 Composition of the substance

Name: Decamethylcyclopentasiloxane

Description: -

Substance type: mono-constituent

Table 2: Constituents other than impurities/additives

Constituents	Typical concentration	Concentration range	Remarks
Decamethylcyclopentasiloxane (EC no: 208-764-9; D5)	> 97 %	97-100 %	-

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
Octamethylcyclotetrasiloxane (EC no: 209-136-7; D4)	< 1 %	0-1 %	-
Dodecamethylcyclohexasiloxane (EC no: 208-762-8; D6)	< 3 %	0-3 %	-
Other cyclic siloxanes	< 1 %	0-1 %	-

1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment

The assessment of degradation/transformation products and/or metabolites is not the focus of this document.

1.4 Identity and composition of structurally related substances (used in a grouping or read-across approach)

Table 4: Structurally related substance(s) identity

EC number:	209-136-7
EC name:	Octamethylcyclotetrasiloxane
SMILES:	C[Si]1(C)O[Si](C)(C)O[Si](C)(C)O[Si](C)(C)O1
CAS number (in the EC inventory):	556-67-2
CAS number:	556-67-2
CAS name:	Cyclotetrasiloxane, 2,2,4,4,6,6,8,8-octamethyl-
IUPAC name:	Octamethylcyclotetrasiloxane
Index number in Annex VI of the CLP Regulation	014-018-00-1
Molecular formula:	$C_8H_{24}O_4Si_4$
Molecular weight range:	296.62 g/mol
Synonyms:	D4, cyclotetrasiloxane

Substance type: mono-constituent

Structurally related substance(s) formula:

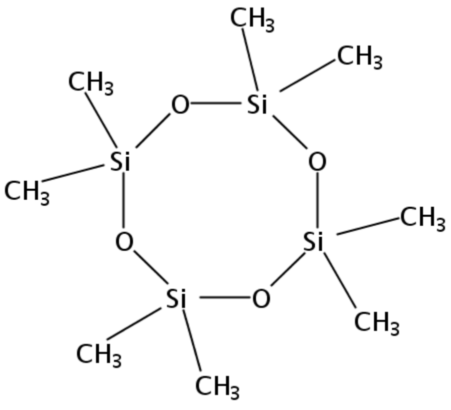
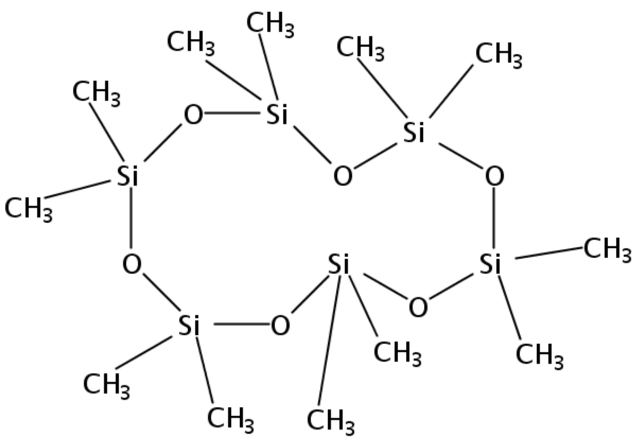


Table 5: Structurally related substance(s) identity

EC number:	208-762-8
EC name:	Dodecamethylcyclohexasiloxane
SMILES:	C[Si]1(C)O[Si](C)(C)O[Si](C)(C)O[Si](C)(C)O[Si](C)(C)O[Si](C)(C)O1
CAS number (in the EC inventory):	540-97-6
CAS number:	540-97-6
CAS name:	Cyclohexasiloxane, 2,2,4,4,6,6,8,8,10,10,12,12-dodecamethyl-
IUPAC name:	Dodecamethylcyclohexasiloxane
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	$C_{12}H_{36}O_6Si_6$
Molecular weight range:	444.92 g/mol
Synonyms:	D6, cyclohexasiloxane

Substance type: mono-constituent

Structurally related substance(s) formula:



1.5 Physicochemical properties

Table 6: Overview of physicochemical properties

Property	Description of key information	Value [Unit]	Reference/source of information
Physical state at 20°C and 101.3 kPa	-	*liquid*	*Visual observation*
Melting/freezing point	*Handbook data*	*-38 °C*	*The MERCK Index., Twelfth Edition. MERCK and CO. Inc, Whitehouse Station, New Jersey.*
Boiling point	*Handbook data*	*210 °C*	*The MERCK Index., Twelfth Edition. MERCK and CO. Inc, Whitehouse Station, New Jersey.*
Vapour pressure	*Handbook data*	*33.2 Pa at 25 °C*	*Physical Property Database, Design Institute for Physical Property Data (DIPPR) New York, N.Y., U.S.A.*
Density	*Handbook data*	*0.96 g/cm^3 at 20°C*	*The MERCK Index., Twelfth Edition. MERCK and CO. Inc, Whitehouse Station, New Jersey.*
Water solubility	*Measured*	*17.03 ppb at 23 °C and pH ca. 7*	*Environ. Toxicol. Chem. 15(8):1263-1265.*
Partition coefficient n-octanol/water (log value)	*Measured*	*8.023 at 25.3 °C*	*OECD Guideline 123 (Partition Coefficient (1-Octanol / Water), Slow-Stirring Method)*

2. Harmonised classification and labelling

No harmonised classification and labelling exists for D5.

3. Environmental fate properties

3.1 Degradation

3.1.1 Abiotic degradation

Relevant new studies on abiotic degradation were identified after the MSC opinion.

3.1.1.2 Hydrolysis

Data on hydrolysis is described in Annex 3 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.1, page 3 (ECHA, 2015).

A recent study (Xu et al., 2017) describes the fate of siloxanes in a landfill. Conditions at this site were not standardized and it is questionable whether they are suitable for concluding on degradation in the environment in general. However, the reported results do not seem to be in contradiction to earlier findings. As expected, volatilisation from water and hydrolysis were observed. Photo transformation was assumed to be of minor importance which is consistent within earlier assessments as well.

3.1.1.3.1 Phototransformation in air

Data on phototransformation in air is described in Annex 3 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.1, page 3 (ECHA, 2015).

After the UK-CA finalised its assessment of D4 and D5, a publication of Safron and co-workers (Safron et al., 2015) on the reaction of cyclic volatile methyl siloxanes with OH radicals became available. The authors applied the relative rate technique to study the kinetics of the reaction in a temperature range between 313 and 353 K. The Arrhenius equation was used to extrapolate from these results to a temperature of 298 K, yielding reaction rate constants of $1.9 \cdot 10^{-12}$ cm^3 $molecules^{-1}$ s^{-1} for D4, $2.6 \cdot 10^{-12}$ cm^3 $molecules^{-1}$ s^{-1} for D5 and $2.8 \cdot 10^{-12}$ cm^3 $molecules^{-1}$ s^{-1} for D6, respectively. These rate constants are within a magnitude but greater than the values observed in two studies at 297 K which were described previously (ECHA, 2015; Environment Agency, 2013a; Environment Agency, 2013b). Consequently, the corresponding atmospheric half-lives would be smaller.[4] While the study by Safron et al. (Safron et al., 2015) appears to be well-conducted, the extrapolation from higher temperatures to 298 K is expected to introduce some uncertainty. Therefore, the room-temperature data are preferred.

A recent study (Kim and Xu, 2017) examined hydroxyl radical reaction rate constants for linear and cyclic volatile methyl siloxanes at room temperature, applying a relative rate method and using n-hexane as a reference compound. The study appears to be well-conducted and the observed reaction rate constants were 0.95×10^{-12} cm^3 $molecules^{-1}$ s^{-1} for D4, 1.46×10^{-12} cm^3 $molecules^{-1}$ s^{-1} for D5 and 2.44×10^{-12} cm^3 $molecules^{-1}$ s^{-1} for D6, respectively. These results are in good agreement with the earlier measurements of Atkinson for D4 (1.01×10^{-12} cm^3 $molecules^{-1}$ s^{-1}) and D5 (1.55×10^{-12} cm^3 $molecules^{-1}$ s^{-1}) (Atkinson, 1991), which are described in the relevant sections of Annexes 2 and 3 of the MSC opinion (ECHA, 2015).

3.1.2 Biodegradation

No new relevant studies on biodegradation were identified after the MSC opinion.

3.1.2.1.2 Screening tests

Screening tests are described in Annex 3 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.1, page 3 (ECHA, 2015).

3.1.2.1.3 Simulation tests (water and sediments)

Simulation tests are described in Annex 3 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.1, pages 3-4 (ECHA, 2015) and in Annex 3a to MSC opinion on the persistency and bioaccumulation of D4 and D5, page 1 (ECHA, 2015). Detailed descriptions of the simulation tests are available in the PBT evaluation factsheets for D4 and D5 (Environment Agency 2013a, 2013b).

The sediment simulation tests (Xu, 2010) used for the evaluation of D5 in the MSC opinion (ECHA, 2015) and in Environment Agency (2013b) are used also in the SVHC identification for D5 and D6. The support document for D6 (ECHA, 2018) includes a detailed description of this

[4] About 8.4 d for D4, 6.2 d for D5 and 5.7 d for D6, assuming an average atmospheric hydroxyl radical concentration of 5×10^5 molecule cm^{-3}.

test and it is noted that the discussion regarding the deviations from test guideline in this test (Xu, 2010) has been updated compared to the previous report on D5 (Environment Agency, 2013b). However, the conclusion that this test can be used for P/vP assessment is not changed.

3.1.2.2 Biodegradation in soil

Data on biodegradation in soil is described in Annex 3 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.1, page 4 (ECHA, 2015).

3.1.3 Modelling data

Modelling data is described in Annex 2 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.1, pages 4-5 (ECHA, 2015).

Several new studies were published, or submitted for publication, after the adoption of the MSC opinion. These studies are discussed below.

A recently submitted manuscript questions the persistence of D4, D5 and other cyclic volatile methyl siloxanes based on multi-media modelling (Kim et al., 2018). In case of a cessation of emissions, modelling studies generally show a relatively fast initial reduction in concentrations, which is caused by the degradation of airborne siloxanes. However, these models also show that concentrations in sediment persist with half-lives exceeding the REACH Annex XIII trigger for persistence in sediments, a finding that is consistent with an earlier study of Xu and Wania (Xu and Wania, 2013). Consequently, these modelling results support the conclusion that D4 and D5 should be considered as persistent under REACH, rather than refute this conclusion.

In their PBT/vPvB and LRT analysis of cyclic volatile methyl siloxanes, Bridges and Solomon conclude that D4, D5 and D6 should not be regarded as persistent (Bridges and Solomon, 2016). However, while using largely the same data as the Member State Committee in its opinion (ECHA, 2015), their assessment methodology differs from the methodology applied under REACH. For D4, Bridges and Solomon (Bridges and Solomon, 2016) do not cite the Xu (Xu, 2009) study on persistence in aerobic sediment previously cited by the UK and MSC that reports a degradation half-life of 242 days at 24°C and which was used to support a conclusion that D4 meets the vP criterion. Finally, the authors give a high weight to modelling studies on the overall persistence of cyclic volatile methyl siloxanes. According to these, the major (airborne) part of the siloxanes would be degraded within 3 months of the end of release. However, removal from sediment is predicted to take longer with half-lives of 1 year or more. As provided in Annex XIII of REACH and explained in ECHA Guidance on PBT/vPvB assessment (ECHA, 2017a), a substance should be considered persistent or very persistent if any of the compartment specific criteria are exceeded. REACH does not consider overall persistence as criterion for PBT/vPvB identification. The rapid removal of airborne cyclic volatile methyl siloxanes or consequent apparent low overall persistence cannot refute the PBT/vPvB concerns for sediment and the paper hence acknowledges that the substances are very persistent in sediment and hence supports the MSC opinion.

Very recently a multimedia modelling study on linear and cyclic volatile methylsiloxanes (Panagopoulos and MacLeod, 2018) was published. The authors report that modeled residence times of all chemicals (including D4, D5, D6) in the sediment compartment exceed the REACH criterion for degradation half-life in freshwater sediment. In a specific regional modelling for Aventfjorden, Svalbard, different residence times in sediment were obtained when applying different modelling parameters. It should be noted that although the authors point out that the substances cannot be considered non-persistent based on the modelling results, residence time is not a relevant parameter for comparing to the P/vP criteria of REACH as it is dependent on many other factors than just degradation. It is also noted that degradation half-lives are needed as model input parameters for calculating residence times.

Krogseth *et al.*, (2017b) calculated, based on a fugacity model, half-lives for D4, D5 and D6 in sediment of 20, 2600 and 75000 years, respectively. The study also cites half lives in sediment for D4, D5 and D6 based on measured data (at pH 7.9) of 1, 8.5 and 8.5 years, respectively (Xu and Wania, 2013 as cited by Krogseth et al., 2017b). These data are consistent with other studies.

3.1.4 Summary and discussion of degradation

In its opinion on the persistency and bioaccumulation of D4 and D5 (ECHA, 2015), the Member State Committee states the following:

> *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, 2010), D5 has a degradation half-life in freshwater sediment of the order of 800-3,100 days at 24°C. MSC concludes that D5 meets the Annex XIII criteria for a very persistent (vP) substance in sediment according to Regulation (EC) No 1907/2006.*

Among the new studies published after the MSC and RAC opinion making processes, three studies, summarised above, were identified to be relevant for the degradation assessment. These studies were evaluated and taken into account for the overall weight-of-evidence determination. These studies support the conclusion that the substance is very persistent in sediment.

3.2 Environmental distribution

3.2.1 Adsorption/desorption

Data on adsorption/ desorption is described in Annex 3 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.2, page 5 (ECHA, 2015).

3.2.2 Volatilisation

Data on volatilisation is described in Annex 2 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.1, page 3 (ECHA, 2015).

3.2.3 Distribution modelling

Data on distribution modelling is described in Annex 2 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.1, pages 4-5 (ECHA, 2015).

3.2.4 Field data

Field data is described in Annex 2 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.1, pages 4-5 (ECHA, 2015).

Two new relevant studies were found after the MSC opinion:

Ahrens and co-workers examined temporal variations of siloxanes in the atmosphere (Ahrens et al., 2014). Samples of D4, D5, D6 and other volatile methylsiloxanes were generated with passive and active sampling techniques. These data show concentration gradients from north (less populated areas) to south (urban areas). Data showing seasonal trends and for the influence of snowfall events were also raised. The seasonal trends can be explained with the increasing OH radical concentration during seasons with high solar radiation.

In a recent monitoring study, environmental contaminants in air and precipitation in Norway have been examined (Bohlin-Nizzetto P. and Aas W., 2016). The concentrations of D4, D5 and D6 in air were in general agreement with previous years. However, compared to earlier measurements, data indicate an increase of D5 concentrations in summer and winter and of D6 concentrations in summer. The concentrations of cVMS are at the same levels as PAHs and three orders of magnitude greater than the concentrations of legacy POPs (i.e. PFAS). This suggests continuous emissions.

3.2.5 Summary and discussion of environmental distribution

In its opinion on persistency and bioaccumulation of D4 and D5 (ECHA, 2015), the Member State Committee states that:

> *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.*

New studies were published after the MSC and RAC opinions. These studies were evaluated and taken into account for the overall weight-of-evidence determination. These studies are not considered to contest the overall conclusion on persistence as provided in MSC and RAC opinions.

3.3 Data indicating potential for long-range transport

Long-range transport properties are briefly described in Annex 3 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.1, page 4 (ECHA, 2015).

A more detailed discussion is given in the UK proposal for a restriction on the use of D4 and D5 in wash-off personal care products (Health & Safety Executive, 2015). Furthermore, long-range transport was discussed in the RAC Opinion (ECHA, 2016). Several new relevant studies are available (Bohlin-Nizzetto P. and Aas W., 2016; Mackay et al., 2015; Safron et al., 2015; Sanchis et al., 2015a; Sanchis et al., 2015b; Warner et al., 2015). The potential for long-range transport is not assessed in this dossier.

3.4 Bioaccumulation

3.4.1 Bioaccumulation in aquatic organisms (pelagic & sediment organisms)

Bioaccumulation studies are described in Annex 3 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.3, pages 5-7 (ECHA, 2015) and in Annex 3a to the MSC opinion on the persistency and bioaccumulation of D4 and D5, pages 1-3 and 19 – 21 (ECHA, 2015).

A "new" publication has become available after the MSC opinion. In a recent publication, Domoradzki et al examined the metabolism of D4 and D5 in rainbow trout (Domoradzki et al., 2017). ^{14}C-marked D4 and D5 were administered orally as a single dose. However, this study was submitted to the Member State Committee previously and is described and discussed in its opinion on D4 and D5 (ECHA, 2015), pages 16 to 17.

Furthermore, the registration dossier for D4 cites a study of Domoradzki and co-workers on Whole Body Autoradiography (WBA) that was conducted in conjunction with dietary bioaccumulation studies with radiolabelled D4 and D5 to assess distribution and metabolism in rainbow trout (ECHA, 2017b). The registrant concludes that the study indicates metabolism and elimination of D4 and D5 via the digestive tract over time. Only qualitative information is given, but the registrant considers that this study supports the findings of the feeding study mentioned above (Domoradzki et al., 2017). This study was already discussed by the Member State Committee (ECHA, 2015), which concluded the following:

> *[...] the observed half-lives in fish for D4 and D5 are consistent with the potential to bioconcentrate to high levels in aqueous bioconcentration studies and the potential to biomagnify in a dietary bioaccumulation study. The observed half-lives for D4 and D5 thus support the concern for bioaccumulation (B and vB) that arises from the aqueous and dietary laboratory bioaccumulation studies.*

3.4.2 Bioaccumulation in terrestrial organisms (soil dwelling organisms, vertebrates)

Bioaccumulation studies in terrestrial organisms are described in Annex 3 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.3, pages 7 (ECHA, 2015).

3.4.3 Field data

Field data on bioaccumulation is described in Annex 3 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.3, pages 7 – 10 (ECHA, 2015) and in Annex 3a to the MSC opinion on the persistency and bioaccumulation of D4 and D5, pages 3 - 19 (ECHA, 2015).

Two review articles were published after the MSC Opinion was agreed, which are largely based on the same data, but draw a different conclusion due to differences in the underlying bioaccumulation assessment approach:

- In 2015, Gobas et al review the available data on bioaccumulation of D5 (Gobas et al., 2015a). This review contains an analysis of field studies with observed TMF values smaller, nearly equal to or larger than 1. The authors indicate that uncertainty in the measurements and knowledge gaps may cause these differences in observed TMFs.

  Based on a comparison of BCF, BMF and TMF values with modelling results the authors conclude that D5 undergoes biotransformation because otherwise the observed concentrations in biota would be greater. While it can be recognised that there may be biotransformation of D5, it is noted that the uncertainty of the modelling results should be taken into account, in particular with respect to uncertainties in field measurements in general.

  The authors conclude that D5 is not bioaccumulative. Their analysis is mainly based on the Canadian assessment process (Gobas et al., 2015a) and hence, the underlying criteria for bioaccumulation differ from the criteria of REACH. Particularly, the indication of biotransformation is given a significant weight and is decisive for the conclusion. Such approach is not coherent with bioaccumulation assessments carried out under the REACH-Regulation. Hence, the author's conclusion is in contradiction to the Member State Committee Opinion (ECHA, 2015), although both are largely based on the same data.

- On request of industry, Bridges and Solomon (Bridges and Solomon, 2016) conducted a quantitative weight-of-evidence analysis of the PBT/vPvB properties and the long-range transport potential of cyclic volatile methyl siloxanes. In the bioaccumulation part of their PBT/vPvB and LRT analysis of cyclic volatile methyl siloxanes, Bridges and Solomon conclude that D4, D5 and D6 are not bioaccumulative (Bridges and Solomon, 2016). While the high BCF values are considered reliable, the authors consider these values to be of little relevance. With respect to the fish dietary bioaccumulation studies, the difference in steady-state and kinetic BCF values is highlighted. The authors gave the greatest weight to field studies on trophic biomagnification. Hence, their conclusion that D4 and D5 are not bioaccumulative is based on biomagnification solely, and neglects bioconcentration completely. All of the discussed field studies have already been assessed by the Environment Agency and were considered in the Opinion of the Member State Committee in 2015. Furthermore, it should be noted that even if a conclusion was drawn on biomagnification solely, the authors omit that accumulation via the diet was shown in certain food webs.

However, the dossier submitter considers in agreement with the opinion of the Member State Committee (ECHA, 2015) the following:

> *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.*

A new assessment using fugacity approach became available after the MSC Opinion:

A study by Gobas and co-workers (Gobas et al., 2015b) uses available data to analyse the environmental fate and toxicity of D5 using fugacity and activity ratios. For this analysis, data on ecotoxicity and bioaccumulation were used as well as monitoring data from biota, environmental compartments and WWTPs. The authors emphasise that the underlying data were collected from various sources and at different times, and that they should hence not be over-interpreted.

With regard to data relevant for bioaccumulation, all fugacity ratios were found to be significantly lower than 1. This actually means that the D5 content in biota is lower than it would be expected based on partitioning solely and that D5 is probably metabolised. This does not contradict the high BCF values measured for D5, which are above the trigger value for vB. Whereas metabolism may prevent D5 from accumulating via the food chain in these cases, D5 still bioaccumulates significantly in fish due to its high lipophilicity. As noted in the relevant ECHA guidance documents (ECHA, 2017a), *high bioaccumulation in a part of the food chain may have unpredictable effects throughout other parts of the food chain as well*. The REACH guidance (ECHA, 2017a) also reflects that *there is a lack of agreement on how to interpret fugacity ratios and the method has not yet been validated sufficiently*. The Member State Committee (ECHA, 2015) states the following:

> *In summary, the fugacity approach has not been accepted for regulatory decision-making worldwide and not validated for D4 and D5. In his response to the comments made during the public consultation, the DS also remarks that such an approach should also be validated with confirmed PBT and vPvB substances before any conclusions can be drawn from such an assessment. Therefore, MSC supports the conclusion of the DS that this approach is not suitable to conclude that D4 and D5 are not bioaccumulative.*

New information on several field studies on trophic magnification became available after the MSC opinion or – in the case of Jia et al. (Jia et al., 2015) – after the public consultation on the hazard assessment, but before the MSC Opinion. Due to the many underlying uncertainties of field studies, the Dossier Submitter considers that the results should be regarded with caution.

- Jia et al. studied the biomagnification of methyl siloxanes in a marine food web at Dalian Bay, China (Jia et al., 2015). Though relevant, this study is only briefly mentioned and not evaluated in the documents of the MSC Opinion, as it was published after the public consultation. It was hence mentioned in a footnote, but not completely included in the assessment. It is described for D5 in Annex 3 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.3, page 7 (ECHA, 2015), footnote.
  Care was taken to avoid cross-contamination of the samples and BDE-99 (2,2′,4,4′,5-pentabromodiphenyl ether) was analysed as a reference compound for benchmarking. A TMF of 1.77 was derived for D5, which was found to be significantly greater than 1 (95% confidence interval: 1.41−2.24, 99.8% probability of the observing TMF > 1). For D4 and D6, TMF values of 1.16 (0.94−1.44, 94.7%) and 1.01 (0.84−1.22, 66.9%) were determined, which were not significantly greater than 1. The TMF for BDE-99 was 3.27 (2.49−4.30, 99.7%). Gobas et al. (Gobas et al., 2015a) reviewed this study with respect to D5 and recalculated a TMF of 1.39 (0.99−1.94) based on individual data instead of mean concentrations. This recalculated TMF is still greater than 1, but marginally exceeds

the criterion for statistical significance ($p=0.054$, significant if $p < 0.05$). Furthermore, Gobas et al. criticise the use of BDE-99 as a reference compound because in some cases, TMFs < 1 have been observed for this compound as well. On one hand, PCB-153 or PCB-180 would indeed be a better reference compound for determining biomagnification solely. On the other hand, TMFs > 1 have been observed for BDE-99 as well and as it is a POP substance, a comparison with BDE-99 is considered adequate when discussing bioaccumulation in general.

- Recently, a study was published on the bioaccumulation of cyclic volatile methylsiloxanes in a pelagic food web of Tokyo Bay (Powell et al., 2017). Data were evaluated with the bootstrap method and compared to the re-evaluated results of other field studies.

  These results had been submitted to the UK Competent Authorities before the MSC Opinion. They are described for D5 in Annex 3 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.3, page 8 (ECHA, 2015) and in Annex 3a to the MSC opinion on the persistency and bioaccumulation of D4 and D5, pages 9 – 13 and 18 - 19 (ECHA, 2015).

- Very recently, Powell and co-workers submitted a paper regarding the bioaccumulation of cyclic volatile methylsiloxanes in the aquatic marine foodwebs of Oslofjord (Powell et al., 2018). These results had also been previously submitted to the UK Competent Authorities and are already discussed for D5 in Annex 3 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.3, pages 8 and 9 (ECHA, 2015) and in Annex 3a to the MSC opinion on the persistency and bioaccumulation of D4 and D5, pages 18 - 19 (ECHA, 2015).

- Woodburn et al. submitted a manuscript about the trophic dilution of cyclic volatile methylsiloxanes in Lake Pepin (Woodburn K., 2017). Samples for siloxanes were taken in September 2007 and May 2008. These results had been previously submitted to the UK Competent Authorities and are discussed as (Powell D.E., 2009) for D5 in Annex 3 to the MSC opinion on the persistency and bioaccumulation of D4 and D5, section B.4.3, pages 7 and 8 (ECHA, 2015) and in Annex 3a to the MSC opinion on the persistency and bioaccumulation of D4 and D5, pages 18 – 19 (ECHA, 2015).

  The new manuscript additionally includes data for the reference chemical PCB-180, samples of which were taken in May and July 2010. The calculated TMFs for D4, D5 and D6 (range 0.2 to 0.4) correspond to the findings that were already discussed in the documents mentioned above. Additionally, the TMF for the reference chemical PCB-180 was determined to be 2.2 ± 0.5. As samples for PCB-180 were taken later, the Dossier Submitter considers that they should not be used for benchmarking the siloxane TMFs.

- Siloxanes were measured by Ruus et al in a NIVA monitoring project at Inner Oslofjord (Ruus et al., 2016). The area is an urban fjord neighboured by settlements, among them Oslo. Samples were analysed for several legacy and emerging contaminants, among them D4, D5 and D6.

  A TMF of 0.44 was calculated for D4. As D4 was not detected in blue mussel, this species was omitted from the regression. No TMF values were given for the other siloxanes. While some legacy POPs like PCB-180 yield a TMF larger than 1, a TMF of 0.53 was determined for SCCPs, which are considered as very bioaccumulative under REACH and which are also included in the Stockholm Convention. Furthermore, several relationships between biological variables and contaminant concentrations are analysed and discussed.

  In a follow-up study conducted in 2016, the concentrations of siloxanes (D4, D5 and D6) displayed no significant relationship with trophic position (Ruus et al., 2017).

- Krogseth and co-workers conducted a research project on the fate of cyclic volatile methyl siloxanes in Lake Storvannet at Hammerfest, Norway (Krogseth, 2014; Krogseth et al., 2017a; Krogseth et al., 2017b), including both fate modelling and measurements. The results did not indicate trophic magnification in Lake Storvannet. Based on the measured concentrations in fish muscle and sediment, BSAF values for fish were determined

(Krogseth et al., 2017a): BSAF values for D4 were less than or equal to 6.2 for char and 1.5 ± 1.1 in sticklebacks. BSAF values for D5 were 1.0 ± 0.7 for char, 0.2 ± 0.1 for trout and 0.8 ± 0.7 for sticklebacks. For D6, the BSAF values were less than or equal to 1.0 for char and 0.2 ± 0.1 for sticklebacks.

- Sanchis et al. found unexpected high concentrations of the cyclic volatile methyl siloxanes D3, D4, D5 and D6 in Antarctic soils, vegetation, phytoplankton and krill (Sanchis et al., 2015b). Measured concentrations in krill were significantly greater than in phytoplankton, indicating biomagnification via the diet. The authors found an increase in BMF with increasing hydrophobicity and derived the following expression:

  $$\log BMF_{cVMS} = 0.51 \log K_{OW} - 1.12.$$

  The reliability of this study was questioned by two comments (Mackay et al., 2015; Warner et al., 2015) and responded to by the authors (Sanchis et al., 2015a).

  While this study was not yet available at the time of the MSC opinion on D4 and D5, it was subsequently mentioned in the RAC opinion. It should however be noted that RAC considered this study with a focus on long range transport rather than bioaccumulation.

- The Norwegian Institute for Water Research (NIVA) and the Norwegian Institute for Air Research (NILU) prepared a monitoring study on pollutants in Norwegian lakes that became available recently (Fjeld et al., 2016). Both NIVA and NILU have extensive experience in the analytics of cyclic volatile methyl siloxanes. The original report is in Norwegian and could therefore not be scrutinised. However, the summary and an extended abstract are available in English. Furthermore, the Norwegian Competent Authority gave a brief summary to the Dossier Submitter.

  In this study, cyclic volatile methyl siloxanes were analysed in fish from the lakes Mjøsa, Randsfjorden and Femunden and in the planktonic crustacean Mysis from Mjøsa (Fjeld et al., 2016). Generally, greatest concentrations in fish were observed in Mjøsa, followed by Randsfjorden. The main sources for cyclic volatile methyl siloxanes in these lakes are expected to be local discharges via wastewater treatment plants. Samples from Femunden (remote lake) were below the quantification limits. The authors compiled data from different surveys from 2010 to 2016 and calculated a common trophic magnification factor (TMF) in Mjosa and Randsfjorden of 2.34 for D5 (95% confidence interval: 2.03-2.70) and 1.92 for D6 (95% confidence interval: 1.62-2.30).

In summary, the new information on trophic magnification does not deviate from the diverse data available earlier.

Several new studies examined cyclic volatile methyl siloxanes in the environment. While the analytics of siloxanes are challenging and some environmental findings are influenced by point sources, the frequent detection of cyclic methyl siloxanes indicates that there is generally a background contamination of these substances:

- Wang et al. measured cyclic volatile methyl siloxanes in the blood of turtles, cormorants and seals from Canada (Wang et al., 2017). Sampling sites were chosen to include both places supposed to be contaminated and places expected to show background contamination only. D3, D4, D5 and D6 were detected in all samples. The observed concentrations varied with sampling site and species.
- In a monitoring study on predatory freshwater fish from Canadian lakes, all samples contained D4, D5 and D6 above quantification limits, with D5 being most abundant (McGoldrick et al., 2014).
- Sanchis and co-workers (Sanchis et al., 2016) examined the presence of volatile methyl siloxanes in market seafood and freshwater fish from different sites at the Xuque River in Spain. Cyclic volatile methyl siloxanes were detected in almost all freshwater samples at a concentration between pg/g and ng/g. Market samples showed a significant greater concentration, which is consistent with the expected contamination during storage and handling.

- Huber and co-workers examined the eggs of seabird species from remote Norwegian colonies for a broad range of legacy and emerging contaminants (Huber et al., 2015). Concentrations of cyclic volatile methyl siloxanes were below the limits of detection in the majority of eggs. The greatest concentrations of D5 and D6 were detected in eggs from common eider from Sklinna with 3.4 ng/g and 0.8 ng/g, respectively. D4 was not detected in any of the bird eggs.
- Lu and co-workers (Lu et al., 2017) investigated the spatial distribution of nine cyclic and linear VMSs (also D4, D5, and D6) in eggs of European starlings (*Sturnus vulgaris*) and three gull species collected across Canada. Presence of D4, D5, and D6 was reported for both the starling and gull species. For starlings breeding near landfill sites, the overall volatile methyl siloxane content was significantly greater (median: 178 ng g^{-1} wet weight (ww)) compared with those from urban industrial (20 ng g^{-1} ww) and rural sites (1.3 ng g^{-1} ww). The median volatile methyl siloxane concentrations in gull eggs were up to 254 ng g^{-1} ww.
- Lucia et al. studied the occurrence of several emerging contaminants in Arctic biota (Lucia et al., 2016). Samples were collected in Svalbard, Norway at the west coast of Spitsbergen. The highest siloxane concentrations were found for D5 in glaucous gull eggs, ranging from 3.06 to 40.1 ng/g. The respective concentrations for D4 are lower and range from below the level of quantification up to 5.77 ng/g. D6 concentrations in these samples are generally below the level of quantification. In Arctic char and the eggs of black-legged kittiwakes, detected concentrations of D4, D5 and D6 were below the limit of quantification. The inconsistency in concentrations of cVMS between glaucous gulls and the other species sampled could be a result of the large range of the glaucous gull. Further the study indicated “interferences” for 2/3 of D4 detects and 3/5 D5 detects.
- Industry submitted two confidential draft interim reports (Powell D., 2015a; Powell D., 2015b) with first results of a long-term monitoring project in Inner Oslofjord for D4 and D5. Further details on these reports are summarised in the confidential annex.

3.4.4 Summary and discussion of bioaccumulation

In its opinion on D4 and D5 (ECHA, 2015), the Member State Committee states 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 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.*
>
> *D5 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 7,060 L/kg for Fathead Minnow Pimephales promelas (Drottar, 2005), based on total 14C measurements.*
> - *The steady state BCF for Common Carp Cyprinus carpio in the range 12,049 – 12,617 L/kg (based on parent compound analysis) or 10,550 – 11,048 L/kg when normalised to a 5 per cent lipid content (CERI, 2010b).*

New studies were published after the MSC and RAC opinions. These studies, summarised above, were evaluated and taken into account for the overall weight-of-evidence determination. However, these studies are not considered to contest the evidence of the studies on bioconcentration in fish and hence, they do not change the overall conclusion on bioaccumulation.

4. Human health hazard assessment

Not assessed for D5.

5. Environmental hazard assessment

Environmental hazards have not been assessed.

6. Conclusions on the SVHC Properties

6.1 CMR assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (e) of REACH.

6.2 PBT and vPvB assessment

6.2.1 Assessment of PBT/vPvB properties

The Member State Committee (MSC) provided an Opinion 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 (ECHA, 2015) 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. D5 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 vPvB substance (see RAC opinion on the restriction proposal: (ECHA, 2016; European Commission, 2018))[5].

6.2.1.1 Persistence

In its opinion on D4 and D5 (ECHA, 2015), the Member State Committee 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.*
>
> [...]

[5] 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

Based on OECD TG 308 sediment simulation studies (Xu, 2010), D5 has a degradation half-life in freshwater sediment of the order of 800-3,100 days at 24°C. MSC concludes that D5 meets the Annex XIII criteria for a very persistent (vP) substance in sediment according to Regulation (EC) No 1907/2006.

New studies were published after the MSC and RAC opinions. These studies were evaluated and taken into account for the overall weight-of-evidence determination. This new information supports the earlier conclusion.

6.2.1.2 Bioaccumulation

In its opinion on D4 and D5 (ECHA, 2015), the Member State Committee 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 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.

[...]

D5 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 7,060 L/kg for Fathead Minnow Pimephales promelas (Drottar, 2005), based on total 14C measurements.*
- *The steady state BCF for Common Carp Cyprinus carpio in the range 12,049 – 12,617 L/kg (based on parent compound analysis) or 10,550 – 11,048 L/kg when normalised to a 5 per cent lipid content (CERI, 2010b).*

After the MSC and RAC Opinion making processes new studies have been published. The relevant studies have been summarised in this document. 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.

6.2.1.3 Toxicity

For D5 an assessment of ecotoxicity was carried out by RAC (ECHA, 2016). RAC noted that for human health hazard classification no full dataset was available. These have not been requested afterwards (a testing proposal evaluation is on-going). The toxicity of D5 has not been assessed for the purpose of the SVHC identification.

6.2.1.4 Assessment based on relevant constituents, impurities and/or additives

According to the introductory section of Annex XIII to REACH,

[...] The identification shall also take account of the PBT/vPvB properties of relevant constituents of a substance and relevant transformation and/or degradation products. [...]

As recommended in ECHA's Guidance on PBT/vPvB assessment[1], if a constituent, impurity or

[1] https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

additive of a substance fulfils the PBT/vPvB properties (based on the assessment of the registrant or of ECHA), a ≥0.1 % (w/w) threshold applies for concluding the substance as fulfilling the same PBT or vPvB criteria. For substances containing PBT/vPvB constituents, impurities or additives in individual amounts <0.1 % (w/w) of the substance, the same conclusion need not normally be drawn. This limit of 0.1% (w/w) is set based on a well-established practice recognised in European Union legislation to use this limit as a generic limit[2]. Individual concentrations < 0.1% (w/w) normally need not be considered. This is also in line with the threshold used for considering PBT and vPvB substances in mixtures (Article 14(2)(f) of REACH).

D5 contains D4 as impurity. D4 has been assessed by MSC (ECHA 2015) and RAC (ECHA 2016) as PBT and vPvB (see also the SVHC agreement of the Member State Committee on D4). The properties of the impurity, its concentration and taking into account all information available on the substance, render the substance D5 also to fulfil PBT properties as release of substance D5 would unavoidably cause release and exposure of D4 (when present in D5), which is a PBT substance.

Consequently, as provided above, D5 fulfils PBT criteria with D4 in concentration of ≥0.1 % (w/w).

6.2.2 Summary and overall conclusions on the PBT and vPvB properties

MSC provided an opinion 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 (ECHA, 2015) 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. D5 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 vPvB substance (see RAC opinion on the restriction proposal: (ECHA, 2016; European Commission, 2018))[6].

Persistence

The Member State Committee (ECHA, 2015) 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.*

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[2] The limit of 0.1% (w/w) is indicated in the European Union legislation, where there is no specific reason (e.g., based on toxicity) to establish a concentration limit specific to the case. Examples of this generic concentration limit are, i.a., another category of substances of very high concern according to Article 57 of REACH, where the default concentration of Carcinogenic/Mutagenic (category 1A/1B) ingredients in a mixture requiring a Carcinogen/Mutagen (1A/1B) classification of the mixture under Regulation (EC) No 1272/2008 is 0.1% (w/w). Furthermore, Articles 14(2)(f), 31(3)(b) and 56(6)(a) of REACH apply a similar principle and the same concentration limit for PBT/vPvB substances in mixtures regarding some obligations under REACH. Additionally, the Judgments of the General Court (Seventh Chamber, extended composition) of 7 March 2013 in cases T-93/10, T-94/10, T-95/10 and T-96/10 (see in particular paragraphs 117 to 121) confirmed the validity of this approach for PBT/vPvB constituents of a substance.

[6] The restriction on D4 and D5 entered into force in 31.1.2018 (European Commission, 2018) http://eur-lex.europa.eu/legal-content/DE/TXT/?qid=1517401506365&uri=CELEX:32018R0035

[...]

Based on OECD TG 308 sediment simulation studies (Xu, 2010), D5 has a degradation half-life in freshwater sediment of the order of 800-3,100 days at 24°C. MSC concludes that D5 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 this document. This new information supports the earlier conclusion.

Bioaccumulation

The Member State Committee (ECHA, 2015) 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 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.

[...]

D5 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 7,060 L/kg for Fathead Minnow Pimephales promelas (Drottar, 2005), based on total 14C measurements.*
- *The steady state BCF for Common Carp Cyprinus carpio in the range 12,049 – 12,617 L/kg (based on parent compound analysis) or 10,550 – 11,048 L/kg when normalised to a 5 per cent lipid content (CERI, 2010b).*

After the MSC and RAC opinion making processes new studies have been published. The relevant studies have been summarised in this document. 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

For D5 an assessment of ecotoxicity was carried out by RAC (ECHA, 2016). RAC noted that for human health hazard classification no full dataset was available. These have not been requested afterwards (a testing proposal evaluation is on-going). The toxicity of D5 has not been assessed for the purpose of the SVHC identification.

Relevant constituents, impurities and/or additives

D5 contains octamethylcyclotetrasiloxane (D4) as impurity. D4 fulfils the PBT and vPvB criteria (see SVHC agreement of the Member State Committee on D4). Taking all information into account, including the concentration of D4 and the properties of the substance, D5 thereby fulfils the PBT criteria with D4 in concentration of ≥0.1 % (w/w).

Conclusion

In its opinion on D4 and D5 (ECHA, 2015), 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.*

In conclusion, D5 is a vPvB substance when comparing all relevant and available information listed in REACH Annex XIII with the criteria set out in the same Annex, in a weight-of-evidence determination. Additionally, D5 is a PBT substance when it contains octamethylcyclotetrasiloxane (D4) (EC No. 209-136-7) which may be present in concentrations typically above 0.1 per cent w/w. D4 fulfils the vPvB and PBT criteria of REACH as confirmed in the MSC SVHC agreement on D4.

In conclusion, D5 meets the criteria for a vPvB substance according to Article 57(e) of REACH. It also meets the criteria for a PBT substance according to Article 57(d) of REACH when containing D4 as an impurity above or equal to 0.1 % w/w.

6.3 Equivalent level of concern assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (e) of REACH.

References

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