UK-CA'S REPORT ON THE IDENTIFICATION OF PBT AND vPvB SUBSTANCE RESULTS OF EVALUATION OF PBT/vPvB PROPERTIES OF D5

EXTRACT OF PBT INFORMATION FOR D5
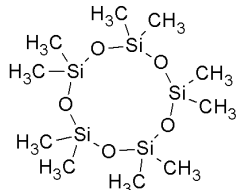
Introductory remarks

Information on the environmental fate and effects of D5 is extensive. As well as robust study summaries available in the REACH registration dossiers, the available data have been reviewed in great depth by regulators in Europe in a UK national assessment (EA, 2009) and a PBT Fact Sheet that was discussed and agreed by the ECHA PBT Expert Group in November 2012 (followed by submission of the document by the UK to ECHA as a formal dossier under the REACH transitional measures; EA, 2013; provided as Appendix 1), as well as Canada (Government of Canada, 2008; BoR, 2011). This report covers the available scientific literature published up to the end of 2013, using the PUBMED database and a search strategy that focussed on papers relevant to PBT assessment (particularly bioaccumulation). Further studies have been provided by the REACH registrants' representatives and some EU regulatory authorities.

Given the large amount of data available, and in the interests of conciseness, Sections B.1.3, B.4 and B.7 of this report only summarise the most important findings relevant to the PBT assessment. Key studies are formally referenced and (unless otherwise stated) original study reports have been reviewed by the dossier submitter (DS) and are considered to be relevant for inclusion in this assessment (i.e. reliable with or without restrictions). Full details and all other study references can be found in the other documents mentioned above (particularly Appendix 1, with new information in Appendix 2). Given the amount of detail presented in the appendices, robust study summaries have not been produced for the purposes of this report.

B. Information on hazard and risk

B.1 Identity of the substance and physical and chemical properties

B.1.1 Name and other identifiers of the substances

Name:	Decamethylcyclopentasiloxane
EC Number:	208-764-9
CAS Number:	541-02-6
IUPAC Name:	2,2,4,4,6,6,8,8,10,10-decamethyl-1,3,5,7,9,2,4,6,8,10-pentoxapentasilecane
Molecular Formula:	$C_{10}H_{30}O_5Si_5$
Structural Formula:	
Molecular Weight:	370.77 gmol^{-1}
Synonyms (and registered trade names):	2,2,4,4,6,6,8,8,10,10-decamethyl-1,3,5,7,9,2,4,6,8,10-pentaoxapentasilecane, 2,2,4,4,6,6,8,8,10,10-decamethyl-1,3,5,7,9,2,4,6,8,10-pentoxapentasilecane, 30535_FLUKA, 4-04-00-04128 (Beilstein Handbook Reference), 444278_ALDRICH, 541-02-6, BRN 1800166, C10H30O5Si5, CCRIS 1328, Cyclic dimethylsiloxane pentamer,

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Cyclopentasiloxane, decamethyl-, Decamethyl-
cyclopentasiloxane, Dimethylsiloxane pentamer, Dow Corning
245, Dow Corning 245 fluid, EINECS 208-764-9, HSDB 5683,
KF 995, LS-58254, NCGC00163981-01, NUC silicone VS
7158, Polydimethylsiloxane, SF 1202, Silicon SF 1202, Union
Carbide 7158 silicone fluid and VS 7158

The abbreviation D5 will be used for the substance throughout this report.

B.1.2 Composition of the substance

D5 is a monoconstituent substance. Decamethylcyclopentasiloxane is typically present in the substance at a concentration of $\geq$80% w/w.

Table 1.2.1 Constituents

Constituent	Typical concentration	Concentration range	Remarks
Decamethylcyclopentasiloxane EC no.: 208-764-9	$\geq$80%	80-100%	Main constituent

D5 may contain the analogue substance D4 (octamethylcyclotetrasiloxane, EC no. 209-136-7) as an impurity at concentrations of $\leq$1% w/w.

B.1.3 Physicochemical properties

Data in Table 1 were obtained from the public registration information on the ECHA website (http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances; date of access 9 September 2014).

Table 1   Summary of physicochemical properties

Property	Value	Comments
Physical state at 20 °C and 101.3 kPa	Liquid	-
Vapour pressure	33.2 Pa at 25 °C	Derived from a temperature-vapour pressure correlation using critically evaluated data (see EA (2009) for further discussion).
Water solubility	0.017 mg/L at 23 °C	Varaprath *et al*. (1996) (slow-stirring method)
n-Octanol/water partition coefficient (K_{OW})	8.02 ($\log_{10}$ value) at 25 °C	OECD Test Guideline 123 (slow-stirring method) Original report not reviewed by DS; considered 'reliable without restriction' by the registrants. EA (2009) discussed the preliminary findings from this study and found them to be consistent with other data.
Henry's Law constant	33 atm.m^3/mol at 24.6 °C [3.34×10^6 Pa.m^3/ mol]	Non-standard syringe method for simultaneous measurement of K_{OW},

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n-Octanol/air partition coefficient (K_{OA})	4.96 (log_{10} value) at 24 °C	K_{OA} and K_{AW}. Original report not reviewed by DS; considered 'reliable with restrictions' by the registrants as it was not conducted to GLP. EA (2009) discussed the preliminary findings from this study and found them to be consistent with other data.
Air/water partition coefficient (K_{AW})	3.13±0.13 (log_{10} value) at 24.6 °C	

Although log K_{OW} is an important surrogate property for environmental fate assessment, measured data for key end points (e.g. bioaccumulation) are available and therefore preferred.

B.4 Environmental fate properties

B.4.1 Degradation

Air

D5 is volatile (with a vapour pressure of 33.2 Pa at 25 °C; see Section B.1.3) and its degradation half-life in the atmosphere is estimated to be around 10.4 days due to reaction with atmospheric hydroxyl radicals (assuming an average atmospheric hydroxyl radical concentration of 5×10^5 molecule/cm^3 and a measured rate constant of 1.55×10^{-12} cm^3/molecule/s – the half-life is probably shorter in urban and suburban areas). Reaction with other atmospheric photo-oxidants is likely to be negligible in comparison. The degradation products are expected to be silanols, which are removed from the atmosphere by wet deposition (either adsorbed onto particulates or dissolved).

Water

Despite its low water solubility (0.017 mg/L at 23 °C), D5 hydrolyses in water. A standard test modified to prevent volatile losses gives a hydrolysis half-life of 71 days at pH 7 and 9 days at pH 8 (both at 25 °C) (Dow Corning, 2005 & 2006a). Hydrolysis half-lives estimated from these data in EA (2009) are 315 days at pH 7 and 12 °C, and 64 days[1] at pH 8 and 9 °C (considered to represent typical freshwater and marine environments, respectively).

Standard tests suggest that D5 is not readily biodegradable (<1% mineralisation after 28 days) (original study reports have not been reviewed by the DS, but the available information is summarised in EA, 2009). Interpretation is complicated by the high volatility of the substance meaning that it is mostly found in the headspace of the test vessels. Additional studies suggest that D5 might be susceptible to biodegradation, particularly with adapted microorganisms in circumstances where the bioavailability of the substance is enhanced. However, mineralisation has not been confirmed, and the results cannot be used to predict the extent or time-frame for biodegradation in the environment.

Sediment

Based on OECD TG 308 sediment simulation studies, D5 has an estimated degradation half-life of 1,200-2,700 days in aerobic sediments and 800-3,100 days in anaerobic

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[1] According to comments submitted during public consultation (PC), a slightly different value has been estimated by Environment Canada (66 days at pH 8 and 9°C).

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sediments, at 24 °C (expected to be longer at lower temperatures) (Xu, 2010; full details are provided in Appendix 1).

D5 was also detected in sediment cores collected in 2006 from Lake Pepin, USA down to depths that correlated with the 1960s/70s (based on magnetic susceptibility measurements with reference cores that had previously been dated directly using ^{210}Pb measurements) (Powell, 2009 & 2010). As D5 was still detectable in these layers at least thirty years following deposition, and the levels found in subsequent layers appeared to track the increased use of D5 and the known implementation of improved waste water treatment in the area, the implication is that degradation of D5 in the sediment was slow (a half-life cannot be estimated from the data).

Soil

D5 degrades rapidly in dry soils (e.g. the soil half-life was measured as 0.08 days (1.9 hours) at a relative humidity of 32 per cent), but the rate of reaction reduces markedly with increasing soil moisture content (essentially no degradation is expected in soil at 100 per cent relative humidity) (Xu, 1999; Xu and Chandra, 1999). This is believed to involve an abiotic mechanism. It is probable that under some situations rapid degradation of D5 may occur, but in other situations the degradation will be much slower. The data do not allow a half-life to be derived that can be compared with the Annex XIII criteria (e.g. representative of conditions in a standard OECD TG 307 study).

The main degradation product is likely to be dimethylsilanediol. This is expected to undergo further degradation processes in the environment to ultimately form carbon dioxide and silicic acid and/or silica.

Other considerations

D5's high volatility and relatively long atmospheric half-life indicate that a significant portion of emissions will reside in the air. Monitoring data in locations truly remote from human activity are very sparse. However, studies indicate that D5 can undergo long-range transport to remote regions via the atmosphere. For example, Krogseth *et al.* (2013) detected mean D5 concentrations (± standard deviation) in Arctic air of 0.73±0.31 ng/m^3 in late summer and 2.94±0.46 ng/m^3 in early winter, at Svalbard[2]. The results were broadly in line with modelling predictions which suggest that concentrations in the Arctic are higher during winter, with variation in levels explained by the seasonality of hydroxyl radical concentrations.

(The potential for re-deposition to surface water and land will be considered in the planned restriction dossier.)

D5 is poorly soluble in water, volatile and also adsorbs strongly to soil and sediment (see Sections B.1.3 & B.4.2). These are important for assessing its overall environmental persistence, and various modelling approaches have been used to investigate this. The modelling is limited by a lack of sensitivity analysis, but in general terms, it predicts a relatively short persistence in the water column (due to volatilisation and to a lesser extent hydrolysis) but this depends on temperature and loss processes may be attenuated by adsorption to organic carbon. A significant proportion is expected to distribute to sediment where persistence may be much higher (depending on a number of site-specific factors including pH, water depth, temperature, sediment deposition rate,

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[2] The site's altitude means that most of the time it is above the local inversion layer, limiting the influence of local sources (such as from nearby Ny-Ålesund).

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concentration of particulate and dissolved organic carbon, rate of sediment burial and re-suspension, etc.). The modelled effective half-life of D5 in sediment is around 87 days (Lake Pepin, USA), and ~2,060 days (Lake Ontario, Canada/USA).

B.4.2 Environmental distribution

Adsorption potential

A reliable experimental study over a range of conditions for three different soils gave a mean log K_{oc} (organic carbon-water partition coefficient) of 5.17 from the adsorption isotherm experiments (Durham, 2007). This is equivalent to a K_{oc} of 1.5×10^5 L/kg. A higher log K_{oc} value (mean: 6.16, range: 5.8-6.33) has been measured with filtered river water samples. No effect of ageing has been found on adsorption in tests with soils and sediments.

It is therefore likely that D5 will adsorb strongly to organic matter in sediment and soil. The very low water solubility and high volatility also indicate that leaching from soil is not expected to be a significant process in the environment.

B 4.3 Bioaccumulation

Several studies have been performed that allow the derivation of a fish bioconcentration factor (BCF), three of which are considered reliable and relevant in the context of this report:

- A steady-state BCF of 7,060 L/kg based on total ^{14}C measurements was measured for Fathead Minnow *Pimephales promelas* (Drottar, 2005; full details of this study are provided in EA, 2009). Chemical analysis indicated that a large proportion of the body burden (83 per cent) was parent compound and so the BCF based on parent compound alone would be around 5,860 L/kg.

  BCFs in the range 2,000-5,000 L/kg and above were also measured as part of a fish early life stage test with this species (Parrott *et al*., 2010); the fish were growing rapidly and normalisation to a "standard" lipid content of 5 per cent would increase the reported BCFs by a factor of around 1.3-1.7 times.

- The steady state BCF for Common Carp *Cyprinus carpio* was reported to be 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 (the kinetic lipid-normalised BCF is higher still) (CERI, 2010; full details are provided in Appendix 2[3]). The depuration half-life was estimated to be between 19 and 22 days.

Two reliable fish dietary bioaccumulation studies are available that permit the derivation of a biomagnification factor (BMF):

- A dietary BMF of 0.63 (steady state lipid normalised value), 1.39 (growth-corrected kinetic value; not lipid-normalised) or 3.9 (lipid-normalised and growth-corrected kinetic value) was measured in Rainbow Trout *Oncorhynchus mykiss* (Dow Corning, 2006b; full details of this study are provided in EA, 2009). The results are based on total ^{14}C measurements, although a similar value would be expected for the parent compound.

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[3] This Japanese-government funded study is not included in the CSRs.

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The mean measured concentration of D5 in fish (<u>minus</u> liver and digestive tract) was 111 mg/kg wet weight (ww) after 35 days of uptake. Fish growth was significant, and the growth-corrected depuration rate constant was 0.00939 day^{-1}. The growth-corrected depuration half-life can be estimated as 74 days from this study, and whole-body autoradiography showed that a significant amount of radioactivity remained in the liver 42 days after exposure ceased.

- A dietary BMF of 0.96-1.21 (growth-corrected and lipid-normalised) has been measured in *C. carpio* (CERI, 2011; full details are provided in Appendix 1).

  The mean measured concentration of D5 in fish was 21.4 mg/kg ww after 13 days of uptake. Fish growth was significant, and the growth-corrected depuration rate constant was ~0.023 day^{-1}. Consequently, the growth-corrected depuration half-life was ~30 days. (Steady-state does not appear to have been reached during the 13-day uptake phase.)

A method for estimating BCF values from the growth-corrected depuration rate constant derived from dietary studies is given in the REACH Guidance Document and further methods are given in EA (2011) and Brooke *et al*. (2012). Most of these methods are based on the weight of the fish, and the validity of such estimates is unknown. Since reliable measured BCF data are already available, an extrapolation from BMF data has not been carried out for the purposes of this report. Although there is currently no guidance for the interpretation of dietary studies against the B/vB criteria, the DS notes the following:

- EA (2012) reports the results of an analysis of depuration rate constants (k_2) and found that a value ≤ 0.065 day^{-1} (or a lipid-normalised k_2 ≤0.085 day^{-1}) was consistent with a BCF of ≥5,000 L/kg (normalised to a 5% lipid content)[4]. Thus the low rate of depuration seen in the feeding studies with *O. mykiss* and *C. carpio* is consistent with the BCF for D5 being >5,000 L/kg[5].

- Inoue *et al.* (2012) investigated the correlation of dietary BMF with BCF in *C. carpio* for eight aromatic compounds with log K_{OW} values in the range 4.3-9.0. This indicated that a BMF (growth-corrected and lipid-normalised) above 0.31 corresponds to a BCF (lipid normalised) over 5,000 L/kg. D5's BMF of 0.96-1.21 in *C. carpio* therefore appears to correlate with a BCF >5,000 L/kg when compared with other highly bioaccumulative substances, although the general applicability of this correlation is unknown.

Further studies are available that provide additional insight into the bioaccumulative behaviour of this substance:

- A laboratory accumulation study (Krueger *et al.*, 2008a) with the sediment worm *Lumbriculus variegatus* gave bioaccumulation factors (BAF) in the range 0.5 – 5 depending on dose . Taking the sediment organic carbon content and mean lipid content of the worms into account allows biota-sediment accumulation factors (BSAF) of 0.96 – 8.65 to be derived (see EA, 2013)[6]. The study has limitations

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[4] Goss *et al*. (2013) propose that a substance is not expected to bioaccumulate if the rate constant for elimination is higher than 0.01 d^{-1}. This is based on a first principles approach without considering actual data. In contrast, EA (2012) is based on an analysis of laboratory feeding studies.

[5] D5 was not included in the BCF data set that formed the basis for the analysis.

[6] The REACH registrations cite slightly different values (0.46 to 4.3) that were derived in the original test report

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because the exposure concentration declined during the uptake phase, the concentration in the worms was also lower after 28 days than mid-way through uptake, and the worms reproduced during the study.

The kinetic bioaccumulation factor (i.e. the ratio of the uptake and depuration rate constants) was calculated to be 4.5 for the low dose group and 2.0 for the high dose group.

If it is assumed that exposure was mainly via pore water, the equivalent BCF is in the range 1,000-24,000 L/kg, although there is considerable uncertainty in these estimates as the pore water might not have been in equilibrium with the sediment.

- A laboratory study with the amphipod *Hyalella azteca* gave mean BSAFs of 0.053 and 0.82 in two sediments (Norwood *et al.*, 2010). Although high BCFs can also be derived in this study (>1,000 L/kg) these are considered to be unreliable due to the variability in the measured water concentrations.

- BSAF values above one have been determined in some samples of Flathead Mullet *Mugil cephalus* from rivers in Japan (SIAJ, 2011) and midge larvae and mayfly nymphs from Lake Pepin, USA (Powell *et al.*, 2009a).

- BSAF values were investigated in the ragworm *Hediste diversicolor* and Flounder (*Pleuronectes flesus*) in a UK estuary (both species are benthic feeders) (Kierkegaard *et al*., 2011). D5 concentrations ranged from 60 to 260 µg/kg dw (2,600-8,700 µg/kg organic carbon) in sediment, 51 to 760 µg/kg ww in ragworm and 12 to 300 µg/kg ww in Flounder fillet. Lipid levels were not measurable in many of the samples and so a "benchmarking" ratio approach was used, based on the ratio of the multi-media bioaccumulation factor (mmBAFs) for D5 to that of PCB-180 (a known bioaccumulative substance). This approximates to the ratio of the BSAF for D5 to that for PCB-180 in the same sample. The ratio was above 1, indicating that D5 was bioaccumulating to a greater extent than PCB-180 in these organisms.

- The bioaccumulation potential for D5 in mammals appears to be much lower than may be expected based on the fish BCF or log K_{OW} alone, particularly in relation to inhalation exposure (as discussed in EA, 2009 and Appendix 1). This relates to the more rapid elimination kinetics (via respired air given the high K_{AW} value) and more rapid metabolism in rodents compared with fish. The toxicokinetics of D5 in mammals exposed via oral routes appear to be less clear than for inhalation and, although it is likely that rapid metabolism and/or excretion does occur, it is possible that some of the D5 is available for storage in the lipid compartments of the animal.

- Several field studies are available[7]. The interpretation of such studies is evolving and it is clear that they can be complicated by a range of factors such as

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from the mean measured exposure concentration over the 28-day uptake period and the measured concentration in the organisms measured on day 28. The validity of this approach (particularly at the higher concentration group) can be questioned for the following reasons:
  - The concentration of D5 in the sediment appeared to decrease during the test.
  - The concentration of D5 in the organisms in the 1,000 mg/kg dry weight (nominal) treatment group was slightly higher on day 14 of the uptake than found on day 28 of the uptake.
To try to investigate these uncertainties further, the DS performed a re-analysis using the data obtained at each time point separately (see EA, 2013). This is the basis for the values cited in this report.

[7] The DS is also aware of a further relevant study which has been published since the close of the PC in December 2014 (Jia *et al*., 2015). This has not been evaluated, but the abstract indicates that a statistically

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migratory behaviour of the species sampled, difficulties in establishing trophic position and feeding relationships, concentration gradients in water and/or sediment, and measurement limitations (e.g. in terms of temporal and spatial coverage, sample numbers (especially for larger species), specific tissue versus whole body, contamination during sampling, processing and analysis, etc.). The DS therefore considers that the findings should be treated with caution:

o Lake Pepin, USA (Powell *et al.*, 2009a): the trophic magnification factor (TMF) of D5 is less than one (0.1-0.2) in this predominantly benthic food chain. The levels of D5 were highest in benthic invertebrates (for BSAFs, see above). The results suggest that uptake from food rather than bioconcentration is the dominant uptake route in this food chain.

o Oslofjord, Norway (Powell *et al.*, 2009c and 2010b): the overall TMF for D5 is below one (0.3-0.4) in this benthi-pelagic food web.

o Lake Erie, Canada (McGoldrick *et al.*, 2014; this study is summarised in Appendix 2): TMFs were below 1 in this predominantly benthic food chain, although a TMF above 1 was suggested from one of the food web configurations (with a 65% probability that the TMF is above 1 when both zooplankton and the top predator (Walleye) were excluded). PCB-180 was also found to have a TMF below 1 for some food web configurations.

o Tokyo Bay, Japan (Powell, 2012): the overall TMF for D5 is below one in this marine pelagic food web (0.5), although one individual BSAF was above one for Japanese Scaled Sardine and BMFs were equal to one for the Red Barracuda – Dotted Gizzard Shad (juvenile) and Red Barracuda – White Croaker feeding relationships.

   A second study indicated that the TMF for D5 was ≤1, although the BSAF was above one for some species at the bottom of the food chain (Powell *et al.*, 2014; this study is summarised in Appendix 2).

o Lake Opeongo, Canada (Powell *et al.*, 2009b and 2010a): mean BMFs were estimated to be 5.2 (95 per cent confidence interval 3.0 to 8.6) for the Lake Trout-Perch relationship and 2.3 (95 per cent confidence interval 1.5 to 3.5) for the Lake Trout-Cisco relationship, with bootstrap analysis indicating that there was a high probability that the BMF values were above 1. Biomagnification may therefore be occurring in this pelagic food web, although the analytical background concentrations were relatively high and variable, and it is also possible that contamination might have occurred during sampling, which causes significant uncertainties in this finding.

o Lake Mjøsa and Lake Randsfjorden, Norway (Borgå *et al.*, 2013a & 2013b; summarised in Appendix 2): the TMF determined in both lakes was similar and the overall combined TMF was 2.91 with a 95% confidence interval of 2.11-4.02. These results confirm the findings of a previous study in one of the lakes (Borgå *et al.*, 2012). In addition, the

significant positive correlation was not found between lipid normalized D5 concentrations and trophic level in marine organisms (r^2 = 0.44, *p* < 0.0001). The estimated TMF was 1.77 (95% confidence interval: 1.41 - 2.24, 99.8% probability of observing a TMF > 1). This re-emphasises the problems in assessing the actual level of trophic magnification.

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levels of D5 in the pelagic food chain correlated with reference substances that are known to biomagnify (PCB-153 and p,p'-DDE).

o Lake Champlain, USA (Powell, 2014a&b; summarised in Appendix 2 although a full study report is not yet available): The TMF was above 1 (in the range 1.6 – 2.1 depending on the calculation method, with the probability that the TMF exceeded 1.0 in the region of 99%) for this freshwater benthipelagic food web, but in the range 0.2 – 10 when exposure "correction" was applied. The report's conclusion was that a reliable TMF could not be obtained for D5.

o Lake Ontario, Canada/USA: An uncompleted study on a freshwater benthipelagic food web derived a TMF of 1.3-1.7 depending on the calculation method (CES personal communication, 25 April 2014; a full study report is not yet available - see Appendix 2). Benchmarking against PCB-180 gives a TMF of 0.5, or 0.4 when 'concentration gradient-correction' is applied, although the relevance of these corrections is questionable.

It is apparent that different conclusions can be drawn from some studies depending on the food chain configuration that is assumed. It therefore appears that trophic magnification may occur in some food webs whereas trophic dilution occurs in others. This variability might be the result of a deviation from thermodynamic equilibrium between sediment and water for those systems that receive the substance adhered to suspended particles from a sewage treatment plant (rather than from atmospheric deposition or direct emission). Other explanations may include variable exposure and food web dynamics.

- Regardless of whether D5 undergoes trophic magnification or not, the field studies show that it can be found throughout aquatic food webs at many locations, from zooplankton to American Mink *Mustela vison*, Grey Seal *Halichoerus grypus* and Pilot Whale *Globicephala* sp. (in addition to the references cited above, also TemaNord, 2005; Evenset *et al.*, 2009; Woodburn and Durham, 2009; Woodburn *et al.*, 2011; Kierkegaard *et al.*, 2010 & 2013[8]).

Biota levels are generally highest in samples collected from close to sources of emission. Concentrations have been reported up to 1-3 mg/kg wet weight (ww) in tissues of some fish species, for example Roach *Rutilus rutilus*, Ide (or Orfe) *Leuciscus idus* and European Eel *Aguilla aguilla* in the River Rhine, Germany (EVONIK Industries, 2007; summarised in EA, 2009 – a full report is not available[9]) and Atlantic Herring *Clupea harengus* and European Plaice *Pleuronectes platessa* in Oslofjord, Norway (Powell *et al.*, 2009c & 2010b). Whole body concentrations achieved during laboratory bioconcentration studies were up to around 20 mg/kg ww or more for Fathead Minnow *P. promelas* (Drottar, 2005) and 17 mg/kg ww for Common Carp *C. carpio* (CERI, 2010).

Comparisons of wet weight biota concentration data between substances are complicated by differences in the scale and route of exposure, lipid content of

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[8] This study is cited in EA (2013) [Appendix 1] as Kierkegaard *et al*. (2012) as it was in press at the time.

[9] Full details of this study have not been made available to the DS by the company involved. It is important because it suggests high tissue concentrations in fish close to point sources. In contrast, the majority of biota monitoring studies have been carried in out in large lakes or marine environments where concentrations are expected to be lower. This may introduce bias to the available monitoring information.

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individual organisms, and sampling/analytical methodology. Nevertheless, the highest levels of D5 found in fish are similar to measured freshwater fish concentrations of up to 9.4 mg/kg ww for hexabromocyclododecane (HBCDD, CAS no. 25637-99-4) (EC, 2008a; ECHA, 2008a) and up to 1.4 mg/kg ww for pentabromodiphenyl ether (pentaBDE, CAS no. 32534-81-9) (Appendix 1 of ECHA, 2012a). Molar concentration is inversely proportional to the molecular weight (MW). The MW of D5 (370.8 g/mole) is around 58-88 per cent of the MW for these two substances (MWs in the range 565-642 g/mole), so there will be more D5 molecules present in the fish than both HBCDD and pentaBDE when the concentrations are the same.

- Appendix 2 of this report extends this idea further by comparing D5 concentrations in laboratory fish bioconcentration tests with other substances that have already been agreed to meet the vB criterion by the Member State Committee. Whole body concentrations achieved during laboratory bioconcentration studies were up to around 29 mg/kg ww for Fathead Minnow *P. promelas* (Drottar, 1995) and 13 mg/kg ww for Common Carp *C. carpio* (CERI, 2010). Higher concentrations have been observed in feeding studies, i.e. 110 mg/kg ww (not including liver) after 35 days of uptake in *P. promelas* (Dow Corning, 2006b) and 21.4 mg/kg ww after 13 days of uptake in *C. carpio* (CERI, 2011).

  The analysis shows that D5 can achieve whole fish concentrations similar to a range of substances that are widely accepted as being very bioaccumulative (e.g. UV-328 and UV-320, long chain perfluorocarboxylic acids, musk xylene, hexaBDE and HBCDD).

- D5 is also present in biota in remote regions, including fish (e.g. Atlantic Cod *Gadus morhua* and Polar Cod *Boreogadus saida*) and birds (e.g. Black-legged Kittiwake *Rissa tridactyla* and Glaucous Gull *Larus hyperboreus*) in the European Arctic (Campbell, 2010). The levels are generally low (often close to the limit of detection, and frequently not detectable) but higher levels (up to 60 µg/kg lipid in Kittiwake liver and 128 µg/kg lipid in samples of Polar Cod) have also been reported. Although some of the high levels might be linked to local sources (i.e. WWTP discharge points), D5 is still detectable in some of the samples from more remote locations.

B.7 Environmental hazard assessment

B 7.1 Aquatic compartment (including sediments)

The solubility of D5 in pure water is 0.017 mg/L (17 µg/L) at 23 °C (see Section B.1.3).

D5 is not toxic to fish at concentrations up to its water solubility limit in acute studies. The NOECs from two standard guideline fish early life stage (FELS) studies with Fathead Minnow *Pimephales promelas* were ≥14 µg/L (Lee, 2009) and ≥8.66 µg/L (Parrott *et al.*, 2010), respectively (the highest concentration tested in each case). It is therefore concluded that D5 is not toxic to fish early life stages.

D5 is not toxic to *Daphnia magna* in both short-term studies and a 21-day reproduction study at concentrations up to 15 µg/L (effectively the water solubility limit). (Original study reports have not been reviewed by the DS, but the available details are summarised in EA, 2009.)

D5 is not toxic to the alga *Pseudokirchneriella subcapitata* at concentrations up to

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12 µg/L (effectively the water solubility limit). (The original study report has not been reviewed by the DS, but the available details are summarised in EA, 2009.)

Long-term sediment toxicity studies are available for four species (*Hyalella azteca, Chironomus riparius*, *Caenorhabditis elegans* and *Lumbriculus variegatus*), although the test for one of the species (*Ca. elegans*) is of questionable validity. The lowest NOECs from these studies are 70 mg/kg dry weight for *Ch. riparius* (Krueger *et al*., 2008b) and 62 mg/kg dry weight for *H. azteca* (Norwood *et al.*, 2010). If the results are normalised to a standard organic carbon content of 5 per cent, the lowest $NOEC_{standard}$ is 109 mg/kg dry weight for *Ch. riparius*. For comparison with pelagic organisms (assuming that the effects occur due to exposure via pore water), the equivalent pore water concentration is estimated to be around 0.014 mg/L using the methods outlined in the REACH Guidance. This value is close to the solubility limit for D5 in pure water.

B 7.2 Terrestrial compartment

D5 has been shown to cause effects in long-term toxicity tests on two plant species (barley *Hordeum vulgare* and durum wheat *Triticum durum*), springtails *Folsomia candida* and earthworms *Eisenia andrei*. The affected plants are monocots; no significant effects were noted with two dicot species (red clover *Trifolium pretense* and radish *Raphanus sativus*) (Soil Toxicology Laboratory, 2010; Velicogna *et al.*, 2012).

The lowest reported IC_{50} was 209 mg/kg dry weight for barley (individual dry mass of barley roots after 14 days; other effects were noted at higher concentrations on shoot and root length). The organic carbon content of the soil used in the test was not given and so it is not possible to normalise the reported effect concentrations to a standard organic carbon content of 2 per cent, nor is it possible to estimate the equivalent pore water concentration at these exposure levels.

The results are based on the initial concentration of D5 in soil. Significant loss through volatilisation would be expected in the test system used and so the actual exposure concentrations (and hence effect concentrations) may be significantly lower than those based on the initial concentration.

B 7.3 Atmospheric compartment
No relevant information is available.

B 7.5 Non compartment specific effects relevant for the food chain (secondary poisoning)

D5 did not cause treatment-related effects in an OECD TG 206 reproduction test using Japanese quail (*Coturnix coturnix japonica*) at concentrations up to 1,000 mg/kg feed. (Appendix 1 contains a summary of a preliminary range-finding test; Appendix 2 contains a summary of the information included in the REACH registrations (updated in October 2014), but the DS has not evaluated the original test report.)

D5 is not classified for human health hazards on the basis of carcinogenicity, mutagenicity, reproductive toxicity or specific target organ toxicity. Nevertheless, it does have some effects in mammals (as described in EA, 2009):

- Liver enlargement was observed in rats following both oral and inhalation dosing, thought to result from a phenobarbital-type enzyme induction response

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(a mechanism that is not relevant to humans). A consistent NOAEL could not be identified following oral exposure, but a LOAEL of 25 mg/kg/day was determined in a 14-day study on the basis of a 13 per cent increase in liver weight. The inhalation NOAEL of 28 ppm equates to an extrapolated oral NOAEL of 19 mg/kg/day. No functional or histopathological changes appear to accompany the liver weight change.

- An increased incidence of uterine endometrial adenomas and adenocarcinomas is observed in rats following inhalation exposure (NOAEL of 40 ppm). Although these tumours occur by a mechanism that is not relevant to humans, they might be relevant to other mammal and bird species. The carcinogenic effect occurs late in life, so appears not to be an effect that influences the sustainability of a population at a general level.

- The REACH registrations use a 2-generation reproductive toxicity study using inhalation dosing as the key study for assessing risks from secondary poisoning (a similar study using oral exposure has not been performed). The NOAEC for parental toxicity, reproductive toxicity, and neonatal toxicity is considered to be at least 160 ppm (actual 2,496 mg/m^3). The related substance D4 has been shown to cause effects on reproduction in mammals via inhalation (and is classified for such effects). This is believed to be due to interference with luteinising hormone pathways. Although no adverse effects were seen in reproductive toxicity tests carried out with D5 via inhalation exposure, the maximum concentrations achievable were below those at which D4 caused effects. Therefore, it cannot currently be ruled out that D5 could cause similar effects on reproduction if higher systemic doses were achieved (e.g. following oral dosing). However, it should be noted that administration of D5 by the oral route results in a different kinetic profile than administration by inhalation, with more D5 being bound and not available for interaction with tissues by the oral route.

B.8 PBT and vPvB assessment

B 8.1 Assessment of PBT/vPvB Properties – Comparison with the Criteria of Annex XIII

Persistence

A substance is considered to be persistent (P) if it has a degradation half-life >60 days in marine water or >40 days in fresh or estuarine water, or >180 days in marine sediment or >120 days in freshwater or estuarine sediment or soil. A substance is considered to be very persistent (vP) if it has a half-life >60 days in marine, fresh or estuarine water, or >180 days in marine, freshwater or estuarine sediment, or soil.

D5 has a hydrolysis half-life of 365 days at pH 7 and 12 °C (freshwater), and 64 days at pH 8 and 9 °C (marine water), and is not readily biodegradable.

It has a degradation half-life in freshwater sediment of the order of 800-3,100 days at 24 °C, expected to be longer at lower temperatures. Persistence in sediment is supported by sediment core data from Lake Pepin, USA.

The available data do not allow a reliable soil degradation half-life to be derived.

It is therefore concluded that D5 meets the Annex XIII criteria for a very persistent (vP) substance in water and sediment (a decision cannot be made for soil).

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Note: The registrants conclude that the substance meets the P and vP criteria for sediment. They also conclude that D5 does not meet the P or vP criteria in water based on a hydrolysis half-life of 73.4 days at pH 7 and 25°C. The DS notes that this is wrong, since this half-life meets both the P and vP criteria (updated submission of 14 October 2014).

Bioaccumulation

A substance is considered to be bioaccumulative (B) if it has a bioconcentration factor (BCF) >2,000 L/kg or very bioaccumulative (vB) if it has a BCF >5,000 L/kg. REACH Annex XIII also allows a weight of evidence approach.

The measured fish BCF for D5 is 5,860 L/kg in Fathead Minnow (*P. promelas*) and >10,000 L/kg in Common Carp (*C. carpio*). These clearly meet the Annex XIII criteria for vB.

In addition, BMFs above one have been reported from dietary bioaccumulation studies with Rainbow Trout (*O. mykiss*) and *C. carpio*. The low observed depuration rate constants are consistent with the BCF for D5 being >5,000 L/kg in both species. The depuration half-life in fish is long at around 74 days in *O. mykiss*, with a significant amount of D5 still present in the liver 42 days after exposure had ceased. Both studies lead to significant whole body concentrations (e.g. ca. 110 mg/kg ww without liver in one study).

Other types of bioaccumulation study provide additional indications of bioaccumulative behaviour. For example, BSAF values above one have been measured for benthic invertebrates. Field studies provide a mixed picture of the bioaccumulation behaviour of D5, which could be linked to different sources of the substance that in turn might lead in some cases to deviation from thermodynamic equilibria. It appears that trophic magnification is possible for some pelagic food webs, and BMFs are above one for some fish feeding relationships.

There is unequivocal evidence that D5 can be found in a wide range of organisms (particularly fish and aquatic invertebrates but also birds and mammals) throughout aquatic food chains, including top predators such as American Mink *Mustela vison*, Grey Seal *Halichoerus grypus* and Pilot Whale *Globicephala* sp. Concentrations have been reported up to 1-3 mg/kg ww for some wild fish species at locations with significant local sources. This is similar to contamination levels of other substances (HBCDD and pentaBDE) that are considered to meet the vB criteria (and maximum concentrations achieved in fish bioconcentration tests are similar to a range of substances that are considered to meet the vB criterion). Although accumulation in air-breathing mammals is expected to be lower than in other aquatic organisms, the top predator in some food chains may not be air breathing (e.g. sharks, which have not been sampled).

D5 is also found in fish, birds and marine mammals sampled from remote regions with low background levels in abiotic media (e.g. Svalbard in the European Arctic). Levels are generally very low (often close to the analytical detection limit, and frequently not detectable). Nevertheless, higher levels (e.g. up to 60 µg/kg lipid in Kittiwake liver and 128 µg/kg lipid in samples of Polar Cod) have also been reported. It is possible that these elevated concentrations reflect local sources (i.e. WWTP discharge points), although it is not clear if this can explain all such findings.

Overall, D5 meets the Annex XIII criteria for vB based on the fish BCF, and supported by the other available data, particularly trophic magnification and the detection of D5 in wildlife at high concentrations.

Note: The registrants (updated submission of 14 October 2014) accept that the substance meets the B and vB criteria based on laboratory fish bioconcentration data. However, they consider that the weight of evidence from laboratory and field biomagnification data (supported

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by fugacity modelling, which is not considered in this report since actual measured data are preferred) indicates that D5 is unlikely to biomagnify in the food chain and therefore should not be considered as B/vB. Nevertheless, this contradicts the view of the ECHA PBT Expert Group as well as the ECHA Guidance for PBT assessment (Chapter R11), which states that "an indication of biomagnification potential can on its own right be considered to conclude that a substance meets the B or vB criteria but ***absence of such a biomagnification potential cannot be used to conclude that these criteria are not fulfilled***" (emphasis added). The DS considers that a lack of biomagnification potential, although clearly important for a complete overview of the ways that a substance may accumulate in organisms, is not sufficient to outweigh the fact that it meets the B or vB criteria based on BCF alone (since accumulation in any part of the food chain might be a significant concern). In any case, there *is* evidence of biomagnification in some food chains for D5 (as recognised by the registrants).

Toxicity

A substance fulfils the toxicity criterion (T) when:

- *the long term no observed effect concentration (NOEC) for marine or freshwater organisms is less than 0.01 mg/L; or*

- *the substance is classified as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B) or toxic for reproduction (category 1A, 1B or 2); or*

- *there is other evidence of chronic toxicity, as defined by the classifications STOT (repeated exposure), category 1 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume) or category 2 (oral, dermal, inhalation of gases/vapours, inhalation of dust/mist/fume, according to Regulation (EC) No 1272/2008.*

The available aquatic toxicity data for fish, invertebrates and algae show that D5 does not cause toxic effects in either short- or long-term studies at concentrations up to (or close to) its water solubility limit. Therefore it can be concluded that D5 does not meet the Annex XIII T criteria based on the available data on its toxicity to pelagic organisms.

D5 is toxic to sediment and soil organisms. The calculated pore water concentration in the sediment tests corresponding to the lowest NOEC is around 0.014 mg/L (close to the water solubility limit of the substance), so the sediment data are consistent with the substance not meeting the Annex XIII criteria. It is not possible to carry out the calculation for the available soil toxicity data.

D5 is not classified for human health hazards relevant to the Annex XIII T criteria. No adverse effects have been observed in an avian reproduction test. Other toxic effects (e.g. liver enlargement, increased incidence of uterine endometrial adenomas and adenocarcinomas) may be relevant for wildlife, but are not considered sufficiently adverse to trigger the criteria. There may be a data gap for reproductive effects in mammals following oral exposure.

Overall, D5 is not considered to meet the T criteria on the basis of the available evidence.

Note: The registrants conclude that D5 does not meet the T criteria. The DS notes that they do not consider sediment or soil toxicity in their assessment (updated submission of 14 October 2014).

Conclusion

D5 meets the REACH Annex XIII criteria for a vPvB substance.

Note: In the summary of PBT properties in the CSRs (updated submission of 14 October 2014), the registrants accept that D5 meets the current REACH Annex XIII criteria for vPvB properties

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on the basis of available laboratory data. However, they consider that REACH guidance on the use of weight-of-evidence for PBT/vPvB assessment is limited; this is an area of science still changing, and areas of development and uncertainty are still being discussed amongst technical leaders in the field. The registrants' assessment of the weight-of-evidence is that D5 meets neither the vPvB nor PBT criteria. **The DS disagrees with this conclusion.**

D5 is also a PBT/vPvB containing substance, as D4 may be present as an impurity above 0.1 per cent w/w.

None of the REACH registrants identifies D5 as a PBT/vPvB-containing substance, because they take a similar view about the bioaccumulative properties of the impurity D4 as they do for D5.

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