Helsinki, 27 March 2017

Substance name: Dodecamethylpentasiloxane
EC number: 205-492-2
CAS number: 141-63-9
Date of Latest submission(s) considered[1]: 18 August 2016
Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)
Addressees: Registrant(s)[2] of dodecamethylpenta-siloxane (Registrant(s))

DECISION ON SUBSTANCE EVALUATION

1. Requested information

Based on Article 46(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), you are requested to submit the following information using the registered substance subject to this decision:

1) Sediment simulation testing; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24. / OECD 308, including the identification of transformation products, at a temperature of 12 °C;

2) OECD 218 Sediment-Water Chironomid Toxicity Test Using Spiked Sediment.

3) ASTM E1706-95b (1999) standard test methods for measuring the toxicity of sediment-associated contaminants with freshwater invertebrates: 28-day survival and growth test or 42-day survival, growth and reproduction test using the amphipod *Hyallela azteca*.

Tests 1, 2 and 3 should be carried out as a tiered testing strategy.
Test 2 is required unless the outcome of test 1 is the substance is not P;
Test 3 is required unless the outcome of test 2 indicates the substance is T.

For the toxicity testing (requests 2 and 3), you shall measure the test substance concentration in the sediment, porewater and overlying water. All food shall be added to the sediment prior to the commencement of the test.

[1] This decision is based on the registration dossier(s) on the day until which the evaluating MSCA granted an extension for submitting dossier updates which it would take into consideration.

[2] The terms Registrant(s), dossier(s) or registration(s) are used throughout the decision, irrespective of the number of registrants addressed by the decision.

4) Exposure assessment and risk characterisation for environment:

Provide further information and justification on the input parameters used for the exposure assessment for ES3: Professional & consumer use of personal care products or alternatively, provide separate scenarios for professional consumer use and household consumer use of personal care products, including clear justification of the environmental emission factors chosen for each;

You shall provide an update of the registration dossier(s) containing the requested information, including robust study summaries and, where relevant, an update of the Chemical Safety Report by **5 July 2020**. However, if the sediment toxicity testing (requirements 2 and 3 above) is **not** required at all, the deadline for updating the registration dossier(s) shall be **3 January 2019**. If only test 2 is required, the deadline for updating shall be **4 October 2019**.

The timeline has been set to allow for sequential testing as appropriate. The deadline takes into account the time that you, the Registrant(s), may need to agree on who is to perform any required tests.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Further information, observations and technical guidance as appropriate are provided in Appendix 3. Appendix 4 contains a list of registration numbers for the addressees of this decision. This Appendix is confidential and not included in the public version of this decision.

2. Who performs the testing

Based on Article 53 of the REACH Regulation, you are requested to inform ECHA who will carry out the study/ies on behalf of all Registrant(s) within 90 days. Instructions on how to do this are provided in Appendix 3.

3. Appeal

You can appeal this decision to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals

Authorised[3] by Leena Ylä-Mononen, Director of Evaluation

[3] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

Based on the evaluation of all relevant information submitted on dodecamethylpentasiloxane (hereinafter called 'L5') and other relevant available information, ECHA concludes that further information is required in order to enable the evaluating Member State Competent Authority (MSCA) to complete the evaluation of whether the substance constitutes a risk to the environment.

The evaluating MSCA will subsequently review the information submitted by you and evaluate if further information should be requested in order to clarify the concern for

- PBT and vPvB
- Risks to the benthic compartment

PBT and vPvB concerns (requests 1-3)

The Concern(s) Identified

L5 was placed on the Community Rolling Action Plan (CoRAP) due to concerns that it could be a PBT substance. In the view of the evaluating MSCA the substance is considered to screen as P/vP, and fulfil the B criteria of Annex XIII of the REACH Regulation. There is uncertainty for the "T" assessment resulting from the available sediment toxicity data.

As the chemical is supplied in volumes exceeding 100 tonnes/year, and applications include those with a wide dispersive use, it is important to clarify the PBT concern by requiring you to provide a measured environmental half-life in sediment.

Why new information is needed

The available information for the PBT assessment is described below.

Bioaccumulation

L5 has a log Kow of 9.41 and therefore screens as B and vB. In a fish bioconcentration test using Fathead Minnow provided in the registration dossier, lipid normalised (5%) values for the two concentrations tested were between 3098 and 3831 L/kg for the lower concentration, and between 2675 and 3458 L/kg for the higher concentration. Growth correction of the data is not required as growth was not significant in the test. The fish BCF therefore exceeds 2000 L/kg but is below 5000 L/kg.

In the Registration dossier you conclude that L5 is not B/vB, based on a weight of evidence determination using expert judgement. In the Chemicals Safety Report (CSR) you cite the ECHA PBT guidance (R11) suggesting that valid BCF values may not be possible for low solubility chemicals from aqueous fish bioconcentration studies due to the difficulty in maintaining test substance concentration.

In response ECHA notes that there is no indication of any problem in maintaining the exposure of L5 in this particular study. R11 also states that the aqueous test *may still be applied to strongly hydrophobic substances (having log Kow >6.0) if a stable and fully dissolved concentration of the test substance can be maintained in the water*.

In the CSR, you state that steady state may be difficult to achieve for highly lipophilic and adsorbing substances. However, the robust study summary (RSS) in the registration dossier states that steady state was reached at day 21 for both test concentrations (where a plateau was reached). Therefore reaching steady state does not appear to be an issue for the L5 study. In any case, since a kinetic BCF can be derived, achievement of steady state is not essential to reach a conclusion.

In your PBT assessment,you consider that the depuration rate constant (k2) from the fish bioconcentration test carries the most weight for the bioaccumulation assessment. You argue that this is a more reliable metric as it is *independent of the exposure concentration and route of exposure*. ECHA does not understand why these issues would be a concern in this instance, and highlights that the REACH Annex XIII criteria specify a BCF value exceeding 2000 or 5000 L/kg. Therefore while a depuration half-life might be useful when a valid BCF value is not available, where the half-life information comes from the same test, ECHA considers that the BCF value should be preferred for comparison with the Annex XIII criteria. ECHA would agree that interpreting a fish dietary study with respect to the Annex XIII criteria is more challenging, and notes the draft OECD guidance for this test does tentatively suggest the use of the k2 value for use in PBT assessment (described in more detail below).

In the CSR, you argue that the half-life in the fish in the test is <70 days, which according to Goss et al. (2013)[4] is indicative of a chemical that is not bioaccumulative. ECHA disagrees with this assertion, principally as the value derived by Goss et al. (2013) is not animal specific. Different taxa have markedly different rates of metabolic capacity, and so it is not appropriate to derive a single half-life applicable across all species. In the Member State Committee (MSC) opinion (ECHA, 2015)[5] for the P and B assessment of octamethylcyclotetrasiloxane (D4, EC 209-136-7) and decamethylcyclopentasiloxane (D5, EC 208-764-9), the value cited by Goss et al. (2013) was considered not to take account of a number of sources of variation in elimination half-lives (e.g. due to differences in organism size, lipid contents, metabolic capacities, growth and reproductive activity). When the assumptions used to derive the 70-d value were analysed it was shown that the biomagnification factor (BMF) could exceed one when the elimination half-life was as short as 7.7 days when the conditions more closely mirrored the fish dietary bioaccumulation test guideline (for example, uptake is greater due to a higher feeding rate than assumed by Goss et al. (2013), and food lipid content is greater than the standard lipid content of the fish).

[4] Goss, K. U., et al. (2013). "Elimination half-life as a metric for the bioaccumulation potential of chemicals in aquatic and terrestrial food chains." Environmental Toxicology and Chemistry **32**(7): 1663-1671.
[5] ECHA, 2015. Member State Committee (MSC) Opinion on persistency and bioaccumulation of Octamethylcyclotetrasiloxane (D4) EC Number: 209-136-7 CAS Number: 556-67-2 And Decamethylcyclopentasiloxane (D5) EC Number: 208-764-9 CAS Number: 541-02-6 according to a MSC mandate Adopted on 22 April 2015

The MSC opinion also highlights that the kinetic processes of bioconcentration are dependent on the fish size; as the uptake rate constant can vary with size, the corresponding depuration rate constant will also vary, leading to a range of BCF values depending on the age of the fish. A comparison of the depuration rate constant in fish bioconcentration tests to the measured fish BCF value is described in a report published by the Environment Agency[6], and cited in the draft OECD guidance for the OECD 305 Fish Bioaccumulation test method. The analysis indicates that a (lipid normalised) k2 value below 0.085 d^{-1} (i.e. a half-life of 8.2 days) is consistent with a BCF exceeding 5000 L/kg. This is considerably shorter than the 70 days proposed by Goss et al. (2013). ECHA appreciates that there is some uncertainty in the analysis, for instance it does not account for different fish species, and is based on data for around 150 chemicals. Therefore, this line of argument would be used as part of a "weight of evidence" analysis but would not be the determining factor for a decision on bioaccumulation assessment.

You also determine fugacity ratios for L5 based on the measured log Kow (9.4) and BCF values (steady state and kinetic for each concentration). These are in the region of 5E-05 to 6E-05, and you state that they indicate that the chemical in the organism is at a lower fugacity (or chemical activity) than in the water. You state that the value of the ratios suggests that either uptake may be less than expected or alternatively elimination is faster than might be expected based on lipophilicity.

The original calculations were made assuming that n-octanol and lipid are equivalent. In their comments and associated registration update, you have included fugacity ratios calculated using a lower log Kow value (9.0). These increase the fugacity ratios by a factor of approximately 1.8. This lower log Kow is based on new experimental information assessing whether lipid/water partitioning can be assumed to be equal to octanol/water partitioning. This found that partitioning of cyclic volatile methyl siloxanes between storage lipids and air or water was similar but not identical to octanol. The storage lipid values were between 0.2 and 0.4 log units below the octanol values depending on the temperature. You conclude that the Kow is a reasonable surrogate for Klw of methylsiloxanes in general.

You conclude that the concentration in the organism tends to be at a lower concentration than in the water. You note, however, that a true steady state may not have been reached in the BCF study.

ECHA has not reviewed the cited report, but has the following observations:

- The study appears to have been performed on cyclic rather than linear siloxanes, so the general applicability of the results is unknown.

- ECHA acknowledges that on face value the differences between Kow and Klw are small, but notes that the effect on fugacity ratio is significant (e.g. almost doubling in this case).

[6] Depuration rate constant: growth correction and use as an indicator of bioaccumulation potential". Brooke, DN & Crookes MJ. 2012. Environment Agency, Bristol, UK. ISBN: 978-1-84911-283-3.

- There is an inverse relationship between fugacity ratio and log Kow, so it is not surprising that a high log Kow value (9.4) for L5 leads to a small fugacity ratio value. However this is contradicted by the measured fish BCF data, which indicate a high level of accumulation.

- Substances with a high BCF are likely to have fugacity ratios below 1 because the theoretical maximum fugacity ratio for biota/water for water exposure alone is 1. For example, in the case of another siloxane (D5), the fish BCF values exceeded 5000 L/kg and BMF and trophic magnification factor (TMF) values exceeded 1, yet the fugacity ratio was below 1. This suggests that fugacity ratios are not a reliable surrogate for the fish BCF value for REACH "B" assessment.

- There is no regulatory acceptance of fugacity ratios for REACH purposes and there is no accepted standard method for deriving the ratios (for example the assumptions required for some of the parameters).

Overall, while ECHA recognises that fugacity ratios may provide an additional theoretical perspective on the interpretation of bioaccumulation data, their use should receive a low weighting in any assessment of bioaccumulation in which reliable measured BCF data are available. In this case the (lipid normalised) BCF values of 2675 – 3831 L/kg are the primary indication of a high level of accumulation in whole fish.

Therefore, ECHA concludes that the substance definitely meets the B but not the vB criteria of Annex XIII, and no further information is required for "B" assessment.

Persistence

You have read-across ready biodegradation data from Octamethyltrisiloxane L3, EC 203-497-4) in the registration dossier of L5. Therefore, you conclude that L5 is not readily biodegradable (0% in 28 days) and screens as P and vP. As the substance is assessed by ECHA to meet the B criterion, it is important to assess whether the P and T criteria are met.

In the current registration dossiers, you consider that the hydrolysis half-life, which is read-across from Decamethyltetrasiloxane (L4, EC number: 205-491-7), of 30 days at pH 7 and 25 °C demonstrates that the substance is not persistent in the aquatic environment. However, a temperature of 12 °C is relevant for freshwater environments, and at pH 7 the half-life of L4 equates to 130 days at 12 °C, which exceeds the REACH Annex XIII criteria for very persistent (vP). Therefore the available hydrolysis data cannot be used to show the chemical is not (v)P. ECHA also notes that hydrolysis rates for the cyclic siloxanes D4 and D5 were significantly impeded by dissolved organic carbon (DOC) (ECHA, 2015). Therefore ECHA is concerned that the hydrolytic half-lives for L4 and therefore L5 may be even longer in the environment, where DOC is present, than suggested by the results in pure water.

No information is available on the potential for hydrolysis of L5 in sediments. It would be expected that adsorption onto sediment will reduce the potential for hydrolysis in sediments compared with water (as is the case for some cyclic siloxanes, e.g. D4 and D5, as summarised in ECHA, 2015).

ECHA notes that the cyclic siloxanes D4 and D5 both have a long degradation half-life in sediment, meeting the REACH Annex XIII criteria for vP. L5 has a similar log Kow and log Koc value to D5, which is also not readily biodegradable. This provides some indication that L5 might also be expected to be vP in sediment. However, D4 and D5 are cyclic molecules, and L5 is a linear molecule so there is uncertainty in being able to directly read-across the results of either D4 or D5 to L5. You acknowledge that L5 screens as P/vP in sediment due to the lack of biodegradation (0% in 28 days) in the ready biodegradation test.

You assess L5 as not being persistent in soil as the degradation half-life in a non-standard soil degradation test for L4 (read-across to L5) is below 120 days (the Annex XIII criterion). Testing was performed at a number of relative humidities (RH) (i.e. 32% to 100%) and a temperature of 22.5 °C using open and closed systems.You have adjusted the result at 100% RH, the longest degradation half-life, to account for volatilisation in the headspace, which reduces the degradation half-life from 107 to 56 days at 22.5 °C (this is 125 days at 12 °C).

ECHA acknowledges that degradation in soil has been observed in the study. The results indicate that the degradation half-life of L4 in the system is dependent on the humidity, with the degradation half-life increasing with humidity. Half-lives in drier conditions are relatively short (a few days) whereas degradation half-life in high humidity conditions are much longer. If the head space is not accounted for, the degradation half-life at 100% RH would be above 230 days at 12 °C

The non-standard test is difficult to compare with the conditions of the OECD 307 test guideline (TG) study recommended in the REACH guidance for persistence determination. Significant issues include not being able to compare the moisture content between the test and the requirements of OECD TG 307. For example, the 100% RH soil does not represent a soil as wet as the standard soil in the OECD TG 307. In addition, a standard OECD TG 307 study uses four soils sampled from the field, whose structure is preserved (apart from sieving). In contrast the soil for the non-standard study was air-dried. It also used much smaller containers and amounts of soil. Taken together it is not known how comparable the results are.

ECHA also notes that the OECD TG 307 is not recommended for volatile substances. Your suggestion to account for the chemical in the headspace confirms the difficulty. Therefore, making a comparison is artificial as the persistence, with respect to the REACH Annex XIII criteria, would not be judged from a soil degradation study. Finally the use pattern of L5 does not indicate direct emission to soil is likely. Rather the substance would be expected to be applied to soil in sewage sludge, and so the environmental fate is likely to be different compared to direct application (for example volatilisation may be reduced due to higher adsorption to organic carbon in the sludge).

Consequently, ECHA cannot use the non-standard data described above to reach a robust conclusion about the persistence of L5 in soil. Therefore, despite being useful supporting information, the environmental degradation half-life of L4, and therefore L5, in soil remains unknown, and ECHA considers that the study does not provide a sufficient weight of evidence to indicate whether the soil degradation half-life is above or below the P/vP threshold of REACH Annex XIII. This is consistent with the MSC opinion (ECHA, 2015) for D4 and D5 which concluded that the available data do not allow a reliable soil degradation half-life to be derived.

Overall, ECHA concludes that the available evidence suggests that L5 screens as P and vP, but there is insufficient evidence to show conclusively that the substance is not P/vP in any compartment.

Therefore, degradation simulation testing (request 1) is required to conclude on P.

Toxicity

No statistically significant effects were observed in the aquatic ecotoxicity tests that are read-across by you from L4. You have also read-across sediment toxicity data from L4 (*Hyallela*) and D6 (dodecamethylcyclohexasiloxane, EC No. 208-762-8, CAS No. 540-97-6) (*Chironomus*). There are two studies for D6 performed with chironomids, one using artificial sediment (NOEC <22 mg/kg dw) and one using natural sediment (NOEC >620 mg/kg dw).

You had originally read-across sediment toxicity for *Lumbriculus* from D6 as well (NOEC >420 mg/kg d.w.). However, in a recent registration update you include a *Lumbriculus* test performed using L5 (carried out for non-REACH purposes). This was conducted using natural sediment from the same source as the *Hyallela* study read-across from L4, albeit with a marginally different particle size distribution. No effects were observed in the study up to a maximum (mean-measured) concentration of 19 mg/kg dw. Normalised to 5% organic carbon, this is 38 mg/kg dw.

ECHA has reviewed the D6 registration data for sediment toxicity which are cited in the Siloxanes Analogue report included in the L5 registration. In the D6 registration, the Registrant(s) has disregarded the chironomid test using artificial sediment stating that the "*peat based carbon source and high pH values interfered with the test system to exhibit toxicity that is mediated by the interaction of the substance with components of artificial sediment with peat based carbon source at high pH*". ECHA notes that OECD TG 218 specifies the use of peat as the organic carbon source for artificial sediment. The RSS indicates that the final sediment pH was 7.1, which is within the range allowed by OECD TG 218 (6.5 -7.5). The pH of the overlying water was stated to range between 8.2 to 8.5, which is again within the permitted pH range (6-9) of the test guideline. The emergence of the control animals was 84% (meeting the validity criteria of OECD TG 218: ≥70%) and mean emergence time was 17.7 d (meeting the validity criteria of OECD TG 218: occurring between 12 and 23 days).

Therefore the control results suggest that the test itself was valid, and not impacted by pH or carbon source. The other validity criteria (physico-chemical conditions) were also within the required range.

Therefore, ECHA concludes that there is nothing to suggest that the toxicity observed in the test is anything other than intrinsic toxicity of D6 to chironomids within the standard conditions of the OECD test guideline. Therefore the NOEC value of <22 mg/kg dw should be considered in the PNEC derivation and PBT assessment, and is actually the most sensitive of the sediment toxicity data available from L4 and D6.

The REACH PBT guidance (R11) provides a method to convert the sediment NOEC to a dissolved water concentration using the equilibrium partitioning calculation to allow comparison with the REACH Annex XIII T aquatic criteria. This tentatively indicates that although the effects in that test would fulfil the T criteria, the value (<0.0002 mg/L) is potentially greater than the water solubility of L5 (0.00007 mg/L at 23 °C), i.e. toxicity may only occur above the water solubility limit of L5. However, this comparison uses a NOEC calculated using the physico-chemical properties of the analogue and the water solubility of L5, which introduces uncertainty to any conclusion. There is further uncertainty as the value is unbounded ("less-than"), so it is unclear where the true value lies.

No effects were observed in the *Hyallela* test performed with L4 (and read-across to L5), using natural sediment. However there are no data on the sensitivity of *Hyallela* in toxicity tests using artificial sediment for comparison with other taxa, which introduces some uncertainty given the results for D6.

Overall, ECHA considers that it is not possible to reach a conclusion on "T" due to the high level of uncertainty in the interpretation of the available sediment data. To reduce the uncertainty, ECHA concludes that further sediment toxicity testing needs to be performed for L5.

In your comments, you note that there are no "T" criteria for sediment or soil organisms in REACH Annex XIII or the guidance. You note the applicability of the equilibrium partitioning approach where pelagic testing is not possible. However you state that as pelagic data are available, and indicate no effects, these should be given more weight in the assessment.

ECHA agrees that the REACH Annex XIII criteria do not include a criteria for sediment toxicity. ECHA also agrees that in principle studies on pelagic organisms would be preferred to assess the long-term NOEC or EC10. However, the REACH PBT guidance states (R11, p. 60): "*In such cases [where log Kow >6], it may be both impractical and uninformative to test pelagic species via the water phase. Tests with sediment dwelling species may provide more useful information on the toxicity of the substance in the [benthic] compartment in which it will be mainly found".*

ECHA recognises that it was feasible to test L5 (or read-across substances) in pelagic tests, and since L5 is of lower water solubility, it is reasonable to conclude that it will not be more toxic to pelagic organisms. However, the guidance does not indicate that toxicity in the benthic compartment should be disregarded; rather, it provides useful information for the "T" assessment.

You argue that the absence of toxicity in the available pelagic studies means that the validity of the equilibrium partitioning approach has not been shown. ECHA disagrees that toxic effects should be used as a measure of validity of the approach. The guidance on the calculation does not require this (REACH guidance R10 10.5.2.1). ECHA considers that as equilibrium partitioning is a physico-chemical calculation, its validity is dependent on the suitability and relevance of these characteristics. In fact there would be a concern if the reverse logic were applied, i.e. the lack of pelagic effects were used to argue that there would be no effect in benthic organisms. For instance REACH endpoint guidance 7b, p. 145 states: "*Furthermore, it has to be considered that for substances that do not exhibit a toxic effect when tested in water only test systems because equilibrium was not reached during exposure phase may nevertheless exert significant toxic effects in sediment tests. Therefore, for these substances a read-across from pelagic data to sediment data is not possible. In such cases, it should be considered to perform toxicity test on sediment organisms (whole sediment tests) at lower tonnage levels (in accordance with annex VI to REACH).*"

You comment that sediment toxicity studies include exposure by direct contact and dietary consumption as well as pore water. ECHA agrees and notes that in the use of the equilibrium partitioning calculation for risk assessment, an extra factor of ten is applied to the screening RCRs for substances with log Kow >5 to account for potential exposure via these additional exposure routes (i.e. to porewater exposure). ECHA has considered how this might apply for judging "T". When the back-calculated sediment porewater NOEC is more or less equal to the T threshold of 0.01 mg/L, as a rough approximation it could be argued that if direct contact and dietary consumption were then subtracted, it is more likely that toxicity from porewater exposure alone would not result in "T" (i.e. the NOEC for porewater exposure only would be > 0.01 mg/L). However where the sediment NOEC is significantly below the equivalent "T" threshold, there is sufficient uncertainty in the different exposure pathways that porewater toxicity equivalent to a NOEC of 0.01 mg/L cannot be excluded. "Significantly below" is defined as when the equilibrium partitioning NOEC is around an extra factor of ten below the aquatic T threshold, which would be 0.001 mg/L. Hence this approach assumes the extra factor of ten applied to the RCR is applied direct to the PNEC to account for the exposure.

While there are no effects in fish, *Daphnia* and algae, effects in other taxa cannot be automatically excluded, nor can toxicity occuring via porewater.

A further argument to include the sediment toxicity data is that a broader range of taxa provides a more comprehensive assessment – i.e. there is greater confidence in the evaluation as a wider range of species is represented with different feeding habits and living conditions.

Overall ECHA sees no reason in this case why the requested L5 sediment toxicity data should not be used in the T assessment using the equilibrium partitioning approach.

Considerations on the test method and testing strategy

Persistence (request 1)

Three simulation test methods are available to assess persistence (OECD TG 307, OECD TG 308 and OECD TG 309). L5 is relatively volatile (vapour pressure = 7.8 Pa at 25°C), and volatile substances are not recommended for evaluation with OECD TG 307. In any case direct emissions to soil appear unlikely to be significant based on the use pattern in the registration dossiers (indirect exposure via sewage sludge is a possibility). L5 is also very insoluble (water solubility in pure water is 0.00007 mg/L, or 70 ng/L). This means an OECD TG 309 study is very unlikely to be feasible, and the chemical is outside the range of solubilities recommended in the test guideline. On this basis, ECHA considers that only the sediment degradation simulation test is feasible, and this is also the main compartment of concern. The cyclic siloxanes D4 and D5 are both very persistent in sediment (ECHA, 2015). As described above, despite the structural differences, the environmental fate characteristics provide suspicion that a long-half-life in sediment is possible for L5. Sediment is also likely to be a significant environmental sink for L5, for example you assess the sediment compartment in your CSR due to the "high sediment adsorption potential of the substance and the potential for persistence in the sediment"

Finally the choice of a sediment simulation study is consistent with the test agreed by the Member State Committee to assess persistence of Hexamethyldisiloxane (L2, EC#203-492-7) under the 2013 CoRAP. L2 is the lowest homologue in the linear siloxane category.

In your comments you note that as a sediment stability study (prior to sediment simulation testing) is currently underway with L2, you propose to await the results of this study before attempting further sediment simulation studies with linear siloxanes. A read-across approach may then be applied, supported by further testing if required.

ECHA acknowledges the suggestion. This Decision is about obtaining information to address the concern that L5 might be P or vP. Therefore it is necessary that any data submitted to fulfil this request is available in a timely manner within the deadline set. Should you wish to fulfil this request by read-across this would be acceptable provided it is in compliance with the ECHA read-across framework. ECHA highlights that it would not be acceptable for the L5 "P" results to be delayed by the submission of data for L2 (which are not due to be submitted until 2018).

In your registration dossier update,you include the following proposal for the sediment simulation study on L5, if required:
The registrants propose to use a modified version of the test guideline used to account for the combination of high air/water partitioning coefficient and low water solubility of the substance.

The modifications proposed may include: a) use of a custom-made incubation vessel which satisfies the OECD 308 requirements, but minimises the headspace volume; b) selection of a spiking solvent and method to ensure distribution of the test material mainly in the sediment phase; c) use of a method to minimise volatility during the test procedure.

The registrants recommend that the stability of test substance concentrations in the sediment under realistic test conditions be explored as part of method development for the linear siloxanes. Subsequent testing is subject to satisfactory results from the stability studies.

ECHA acknowledges your proposal. There is no objection to minimising headspace. With respect to spiking solvent, if you wish you can choose to directly spike the sediment (rather than the overlying water). In the view of ECHA this would be preferable to using a spiking solvent, which the test guideline only permits "if unavoidable" (paragraph 35). ECHA acknowledges the volatility of the substance, but it is not clear what is proposed to "minimise volatility during the test", if headspace is already reduced. "Realistic test conditions" are not specified by you. It is acknowledged that method development may be required, and previous experience from other siloxanes or developments for L5 may be helpful. You and your respective Contract Research Organisations are likely to be best placed to assess the most appropriate way to perform the test.

Overall the test performed should meet the validity criteria of the OECD test guideline, and provide results suitable for comparison with the Annex XIII criteria of REACH.

<u>Toxicity (requests 2 and 3)</u>

If, following sediment simulation testing, the substance is found to be P (or vP) further testing is required to clarify the PBT status of the substance. In the draft decision sent to the you both a Lumbriculus test (OECD 225) and a Chironomid test (OECD 218) using artificial sediment were requested.

Organisms appear to be more sensitive in tests performed using artificial sediment compared to a single selected natural sediment. However, due to the differences in feeding method (for example mixing all of the food into sediment at the start compared to adding food during the study), and pH ranges not necessarily in line with the recommendations in the test guidelines, this is difficult to be sure of.

ECHA strongly prefers studies to be performed with artificial sediment as this provides a test comparable with other standard sediment toxicity tests (as well as the study indicating highest toxicity for D6). If you choose a natural sediment test, pentachlorophenol (CAS no. 87-86-5) shall also be run as a reference substance in the test to demonstrate the comparability of the test results (the reason is given below).

For any new sediment toxicity study, you shall determine the concentrations to be used based on the outcome of a range-finding test. ECHA has performed a back-calculation from the water solubility of L5 (0.00007 mg/L) assuming that this represents an aqueous sediment toxicity NOEC, to determine what the equivalent sediment NOEC (mg/kg dw) value is. The NOEC would need to be <14 mg/kg dw (normalised to 5% OC) to provide a NOEC below the water solubility of L5 – i.e. to indicate T. This means any new sediment toxicity test for L5 needs to be performed at concentrations up to at least 14 mg/kg dw to cover the possibility of "T". If this is not feasible, for example the solubility in the whole system is exceeded, you shall provide justification for this.

ECHA notes that in the RSS for the *Hyallela* test read-across from L4, the Registrant(s) states that the NOEC in the test of ≥68 mg/kg dw exceeds the organic carbon solubility of the test substance, which they calculate to be 36 mg/kg. While ECHA appreciates the lack of effects in that study, ECHA does not agree that sediment toxicity is as straightforward as you suggest, i.e. that only the amount of organic carbon (OC) is relevant for assessing the intrinsic toxicity of a substance in sediment. The test is designed as a bioassay, and therefore reflects what is occurring in the whole system, composed of sediment, overlying water and pore water. There is a progressive aging and dynamic equilibrium between the three phases, which can be skewed one way or the other depending on the characteristics of the chemical, water, sediment and overall test system. This is aside from the influences of uptake in the animals and their actual behaviour and biology. Therefore while a chemical may exceed the theoretical OC solubility, this does not mean the concentrations spiked into the system above such a value could not exist in the environment.

The analytical measurements required by the study guideline are not designed to establish the bioavailability of the test substance, particularly in each of the phases. This means it is then difficult to correct the effects for only one of the phases.

The OC solubility is also likely to vary depending on the particle size and structure of the organic carbon. It is unclear how this is accounted for in the calculation. Finally the OC solubility is based on a measured Koc, but the Koc for individual sediments may not be the same, and in this instance (i.e. L4 *Hyallela* tests) the Koc is derived from measurements in three soils rather than sediment.

Therefore ECHA does not agree with the use of organic carbon solubility to differentiate effects in sediment toxicity tests, and hence its broader use. You shall therefore not use the organic carbon solubility in sediment alone to establish the maximum test concentration.

For the toxicity testing, you shall measure the test substance concentration in the sediment, pore water and overlying water. All food shall be added to the sediment prior to the commencement of the test.

In your comments you agree to carry out the requested OECD TG 218 chironomid test for L5 unless the sediment simulation testing (including read-across) indicates that this is not necessary (i.e. the substance is not P/vP). You propose to use natural sediment. You state that an appropriate reference substance with a non-polar narcotic mode-of-action will be included to demonstrate the comparability of the study results to studies conducted in artificial sediment. You updated dossier(s) notes that reference toxicants under consideration include pyrethroid substances.

You comment that dose concentrations for the study will be determined based on a range-finding test, and modelling of the dynamic equilibrium in the sediment system will be performed in order to determine conditions at which undissolved substance may be present. You will also attempt analysis of the sediment, pore water and overlying water. Your updated dossier indicates that dose concentrations for the study will be determined based on a range-finding test, with concentrations twice the limit of organic-carbon solubility considered.

ECHA acknowledges that you agree to carry out the test, and ECHA agrees with the suggested approach for determining suitable test concentrations, in particular noting that a range-finding study will be performed.

For the reference substance, ECHA proposes pentachlorophenol (PCP) as it is offered in both OECD TG 218 and 225. While other reference substances, such as specific metal salts, are also suggested in the test guideline these were considered less appropriate to address the concern in this case. ECHA agrees with you that in principle a non-polar narcotic mode-of-action is required for the reference substance. ECHA therefore considers that pyrethroid substances as contemplated by you would be inappropriate in this case as these are recognised insecticides and therefore unlikely to be non-polar narcotics. Pyrethroid substances exhibit very significant aquatic ecotoxicity (for example, the harmonised environmental classification for permethrin (EC no. 258-067-9) is H400, H410, with an assessment factor of 1000). ECHA is concerned that if the pyrethroid is similarly highly toxic to benthic organisms, this could mask any effects that different sources of sediment have on the observed toxicity. In contrast the validation work for the OECD 225 test guideline determined a range of NOECs for different endpoints in the range of 2.1 – 20 mg/kg dw for PCP. Pyrethroid substances are also not suggested in either OECD TG 218 or 225. In conclusion, ECHA does not consider that pyrethroid substances are likely to be appropriate reference substances in this case, and a different chemical is needed. PCP remains the preference of ECHA, but if a further non-polar narcotic substance with well characterised sediment toxicity is preferred by you and is well justified (bearing in mind the points above for pyrethroid substances), this can be used.

You comment that the requested feeding regime (adding all of the food at the start of the test) is not appropriate for the *Hyallela* test, and not in line with the test guideline. ECHA notes that the request was made to address the concern that adding food during the test could reduce the uptake of the substance via contaminated food. This concern is highlighted in paragraph 3 of OECD TG 218, and food addition at the start is suggested as a way to address the issue. In OECD TG 225 for *Lumbriculus*, food is always added at the start. ECHA appreciates that *Lumbriculus* has different feeding preferences and lifecycle to *Hyallela* and acknowledges that the request does not follow the standard test guideline for *Hyallela*. However, a valid test using *Hyallela azteca* where all food was added at the start was performed under the Existing Substances Regulation for tetrabromobisphenol-A (EC no. 201-236-9). Therefore ECHA considers that provision of all the food at the start of the test is a reasonable approach for L5.

The draft decision sent to you for commenting contained a request for a *Lumbriculus* test, but as noted above, data for this endpoint have recently become available for L5 and were included in the dossier update. In your comments, you indicate that you will consider the need to repeat this study using the approaches requested in this decision for chironomids and *Hyallela* (regarding reference substances, dosing and analysis). In reply, ECHA notes that the new *Lumbriculus* test for L5 was performed at concentrations exceeding the required 14 mg/kg stated above for "T" assessment. As no effects were observed, this would indicate that the "T" criteria via equilibrium partitioning is not met in the test. However, this interpretation depends on the applicability of the results determined from a natural sediment, for example the need for a reference substance. As the chironomid and, if required, *Hyallela* tests will provide an indication of the relevance of sediment type, at this point ECHA has deleted the requirement for the *Lumbriculus* test, and will assess these data before deciding if a repeat *Lumbriculus* test is required. Such a request would then be specified in a further decision.

<u>Alternative approaches and proportionality of the request</u>

ECHA considers that the requested testing is necessary to confirm the PBT status of the substance.

You may adapt the testing requested above according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification and an adequate and reliable documentation. More specifically, there might be an option of adaption using read-across, however, you did not provide the information needed to apply this.

The sediment toxicity testing (requests 1, 2 and 3) is required as part of a tiered approach, and would not be needed if the substance is shown not to be P. However if the substance is (v)P and B, then the concern would remain that it is potentially PBT and therefore "T" testing is justified.

Conclusion

Therefore, based on the substance evaluation and pursuant to Article 46(1) of the REACH Regulation, ECHA concludes that you are required to carry out the following study using the registered substance subject to this decision:

1) Sediment simulation testing; test method: Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24. / OECD 308 at a temperature of 12 °.

If the result of this study shows the substance is P (or vP) then the following additional tests are required to be carried out using the tiered strategy outlined above;

2) OECD 218 Sediment-Water Chironomid Toxicity Test Using Spiked Sediment.

3) ASTM E1706-95b (1999) standard test methods for measuring the toxicity of sediment-associated contaminants with freshwater invertebrates: 28-d survival and growth test or 42-day survival, growth & reproduction test using the amphipod *Hyallela azteca*.

For the toxicity testing you shall measure the test substance concentration in the sediment, porewater and overlying water. All food shall be added to the sediment prior to the commencement of the test.

Exposure information – Request 4

ECHA has reviewed the exposure scenario for "Professional & consumer use of personal care products" (ES3) in your CSR. There are a number of assumptions that require clarification to be able to make a robust assessment of the environmental emissions of L4 in this scenario. These data are important for two purposes:

1. Assessing whether current risk management measures for the professional & consumer use are adequate;

2. Providing data to inform choices for risk management if this is required as a result of the chemical being determined to be PBT or vPvB.

Firstly, you have used the approach from the UK Risk Assessment of D5 in 2009 to determine the releases to air and water for the environmental modelling. This is an assumption that the use results in 90% of the chemical being released to air and 10% to water. There is no supporting justification for why the uses of L5 are the same as D5. In addition, "consumer use" releases of D5 have been assessed more recently for the REACH Restriction dossier. This suggests that releases are different depending on whether the personal care product is for "wash-off" or "leave-on" use. The balance of wash-off and leave-on is not provided in the registration information, but is needed for an accurate assessment of the consumer/professional use personal care emission scenario. Therefore you shall update the exposure assessment using up to date data appropriate for the uses of L5. In particular an estimate of the split between wash-off and leave-on products, together with a justified release factor for each to air and water shall be provided.

Secondly, it is unclear whether the exposure scenario "use of personal care products" adequately addresses environmental emissions from both professional salons and from household uses. Currently the scenario assumes environmental releases from both uses are the same. However, ECHA considers that the emissions may not be the same, for example due to the number of emission days and volumes used at salons compared to individual households.

Therefore, you are required to update the exposure scenario to justify why the modelling parameters used are applicable to both professional use and household use. If this is not possible,you shall provide separate scenarios for professional consumer use and household consumer use, including clear justification of the environmental emission factors chosen for each.

In your comments,you agreed to update the dossier(s) in this respect.

References

ECHA, 2015. Member State Committee (MSC) Opinion on persistency and bioaccumulation of Octamethylcyclotetrasiloxane (D4) EC Number: 209-136-7 CAS Number: 556-67-2 And Decamethylcyclopentasiloxane (D5) EC Number: 208-764-9 CAS Number: 541-02-6 according to a MSC mandate Adopted on 22 April 2015

Goss, K. U., et al. (2013). "Elimination half-life as a metric for the bioaccumulation potential of chemicals in aquatic and terrestrial food chains." Environmental Toxicology and Chemistry **32**(7): 1663-1671.

EA, 2012. Depuration rate constant: growth correction and use as an indicator of bioaccumulation potential". Brooke, DN & Crookes MJ. 2012. Environment Agency, Bristol, UK. ISBN: 978-1-84911-283-3

Appendix 2: Procedural history

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to PBT, vPvB properties (clarification of P and T) and sediment risks, dodecamethylpentasiloxane, CAS No 141-63-9 (EC No 205-492-2) was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2015. The updated CoRAP was published on the ECHA website on 17 March 2015. The Competent Authority of the United Kingdom (hereafter called the evaluating MSCA) was appointed to carry out the evaluation.

Pursuant to Article 45(4) of the REACH Regulation the evaluating MSCA carried out the evaluation of the above substance based on the information in your registration(s) and other relevant and available information.

In the course of the evaluation, the evaluating MSCA identified no additional concerns.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 17 March 2016.

The decision making followed the procedure of Articles 50 and 52 of the REACH Regulation.

ECHA notified you of the draft decision and invited you to provide comments.

Registrant(s)' commenting phase

ECHA received comments from you and forwarded them to the evaluating MSCA without delay.

The evaluating MSCA took into account the comments from you, which were sent within the commenting period, and they are reflected in the Reasons (Appendix 1).

Proposals for amendment by other MSCAs and ECHA and referral to Member State Committee

The evaluating MSCA notified the draft decision to the Competent Authorities of the other Member States and ECHA for proposal(s) for amendment.

Subsequently, the evaluating MSCA received a proposal for amendment to the draft decision. This was not accepted.

ECHA referred the draft decision, together with your comments, to the Member State Committee.

ECHA invited you to comment on the proposed amendment(s). Any comments on the proposal(s) for amendment were taken into account by the Member State Committee. The Member State Committee did not take into account any comments on the draft decision as they were not related to the proposal(s) for amendment made and are therefore considered outside the scope of Article 52(2) and Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-52 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided by you in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on your dossier(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

3. In relation to the required experimental study/ies, the sample of the substance to be used shall have a composition that is within the specifications of the substance composition that are given by all Registrant(s). It is the responsibility of all the Registrant(s) to agree on the tested material to be subjected to the test(s) subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation.

4. In relation to the experimental stud(y/ies) the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). You are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who is to carry out the study on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at:
https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

   Further advice can be found at
http://echa.europa.eu/regulations/reach/registration/data-sharing. If ECHA is not informed of such agreement within 90 days, it will designate one of the Registrants to perform the stud(y/ies) on behalf of all of them.