EUROPEAN CHEMICALS AGENCY

Helsinki, 27 March 2017

Substance name: Octamethyltrisiloxane
EC number: 203-497-4
CAS number: 107-51-7
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 Octamethyltrisiloxane (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) 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 **3 January 2019**. 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

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[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.

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

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[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 octamethyltrisiloxane (hereinafter called 'L3') 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 (request 1)

The Concern(s) Identified

Octamethyltrisiloxane (L3) was placed on the Community Rolling Action Plan (CoRAP) due to concerns that it could be a vPvB/PBT substance. In the view of evaluating MSCA L3 is considered to screen as P/vP, and fulfil the B/vB and T criteria of Annex XIII of the REACH Regulation.

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 vPvB/PBT concern by requiring you to provide a measured environmental degradation half-life in sediment.

Why new information is needed

The available information for the PBT assessment is described below.

Bioaccumulation

L3 has a log Kow of 6.6 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 9,500 to 20,342 L/kg (depending on how the data are analysed). These values significantly exceed the Annex XIII criteria for both bioaccumulative (B) and very bioaccumulative (vB) in Annex XIII of REACH.

Supporting evidence is provided by a fish feeding study which determined lipid corrected steady state and kinetic BMF values of 0.38 and 0.86. When the kinetic value is corrected for growth, this indicates a BMF of around 0.74 to 0.83. Although this is below 1, ECHA does not consider that a BMF from a fish feeding study is equivalent to a field BMF. This is because, for instance, the only contaminant exposure is via food, and the fish exist in clean water, potentially allowing greater depuration to the media during uptake. This means that a dietary BMF close to, but below, 1 can still indicate equivalence to a BCF of above 2000 or 5000 L/kg.

In the Registration dossier you conclude that L3 is not B/vB, based on a weight of evidence approach. In the Chemical 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 there was a problem in maintaining the exposure of L3 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 fish bioconcentration Robust Study Summary (RSS) in the registration dossier states that steady state was reached at day 14 (lower concentration) and day 21 (higher concentration). The bioaccumulation study report explains that this is because the subsequent fish concentrations measured after those times were not statistically different. Therefore reaching steady state does not appear to be an issue for the L3 study. In any case, since a kinetic BCF (significantly exceeding 5000) is 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 fish depuration half-life 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, metabolism capacities, growth and

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[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

reproductive activity). Other complications were cited as 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 1 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). 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 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” evaluation but would not be the determining factor for a decision on bioaccumulation assessment. However, ECHA does note that the k2 calculated in the fish feeding study is 0.045 d^{-1} suggesting a BCF >5000 L/kg, when considering the OECD guidance, or when the Goss et al. (2013) calculations are amended to account for the feeding rate.

You also determine fugacity ratios for L3 based on the measured log Kow (6.6) and BCF values (steady state and kinetic for each concentration). These are in the region of 0.06 – 0.13, 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 your comments and associated registration update, you have included fugacity ratios calculated using a lower log Kow value (6.2). These increase the fugacity ratios by a factor of approximately 2.5. This lower log Kow is based on new experimental information assessing whether lipid partitioning can be assumed to be equal to octanol/water partitioning. This found 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 depending on the temperature. You conclude that Kow is a reasonable surrogate for Klw of methylsiloxanes in general.

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

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[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

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, also notes that the effect on fugacity ratio is significant as these increase by a factor of 2.5 in this case.

- There is an inverse relationship between fugacity ratio and log Kow, so it is not surprising that a high log Kow value (6.6) for L3 leads to a small fugacity ratio value. However this is contradicted by the measured fish BCF data, which indicate a very 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 up to 20,342 L/kg are the primary indication of a high level of accumulation in whole fish.

In support of the "B" assessment you have provided further environmental monitoring data from several locations. This is in addition to the data that the evaluating MSCA had previously reviewed. You note that in all environmental monitoring studies to date, L3 was either "not detected" or "less than the Method Detection Limit (MDL)" in both surface sediment and biota samples.

ECHA considers the data provide useful supporting information for risk assessment and risk management, when considered with use pattern and supply volume. With respect to the "B" weight of evidence ECHA does not consider that the data provide strong evidence when compared to the available fish BCF values for judging whether the Annex XIII are met.

In your comments, you note that a recent Canadian regulatory assessment concluded that L3 was not likely or has low potential to biomagnify through food webs. This conclusion is indicated by you to be based on BMF, fugacity ratio and environmental monitoring data. In reply, ECHA highlights that the Canadian regulations are not same as REACH. This Substance Evaluation is focussed on whether L3 fulfils the REACH Annex XIII criteria. As stated above, the substance has an aquatic BCF value well in excess of the vB threshold in REACH Annex XIII. ECHA also notes that the Canadian assessment includes a number of points consistent with the REACH assessment, for example *There is consistency between lines of evidence, to infer that MDM* [L3] *will be highly bioaccumulated from both water and the diet.*

Therefore, ECHA concludes that the substance definitely meets the B and vB criteria of Annex III and no further information is required for "B" assessment.

Toxicity
No statistically significant effects were observed in the aquatic ecotoxicity tests, but toxicity was observed in two of the four sediment toxicity tests in the registration dossier. The effects in a long-term *Lumbriculus* toxicity study performed using artificial sediment suggest that the Annex XIII T aquatic criteria would be met when the sediment NOEC (1.1 mg/kg dw) is converted to a dissolved water concentration (0.00132 mg/L) using the equilibrium partitioning calculation described in the REACH PBT guidance (R11).

You have argued that the *Lumbriculus* study using artificial sediment is an outlier in the sediment toxicity dataset based on two statistical tests using Dixon's Q and Grubbs' z tests. ECHA considers that a comparison of the sediment toxicity data using an outlier analysis is inappropriate in this instance. Such an approach is not included in the REACH sediment endpoint guidance (7B) nor in the PNEC derivation guidance (R10). Instead, where four or more tests using the same species and same conditions are available, a geometric mean can be used. Alternatively where five or more tests for different species are available a Species Sensitivity Distribution (SSD) can be constructed, with an HC5 (hazardous concentration for 5% of the species) derived. As the available data do not fulfil either of these options, ECHA sees no reason to disregard the more sensitive *Lumbriculus* test result from the dataset, and use this for the PBT assessment.

In your comments, you agree that the benthic compartment is of concern, and that toxicity is observed in the *Lumbriculus* study using artificial sediment. However, for several reasons they consider that the L3 *Lumbriculus* study conducted in natural sediment (NOEC = 38 mg/kg dw, LOEC ≥38 mg/kg dw) carries greater weight than the study conducted in artificial sediment (NOEC = 1.1 mg/kg dw, LOEC = 1.6 mg/kg dw).

Firstly, you acknowledge that artificial sediment has the advantage of being well characterised but claim that it may be less physically stable and separate into layers and does not contain significant amounts of microbial flora. You also state that for substances that tend to adsorb strongly to organic matter the difference between a natural sediment, i.e. more fully equilibrated, and an artificial sediment is likely to have an impact on the outcome of the assessment by affecting the bioavailability of the substance. You speculate that differences between natural and artificial sediment will affect bioavailability for substances that strongly adsorb to organic matter.

In response ECHA agrees that one of the advantages of artificial sediment is that it is well characterised. There are two significant further benefits. The first is that the use of artificial sediment provides a baseline for which to compare benthic toxicity amongst different substances. Artificial sediment also provides a standard sediment which is expected to represent the range of different natural sediments that exist in the environment. It is unclear how representative the Glen Charlie pond sediment selected by you is for natural sediments in general. Artificial sediment is also "recommended" in the *Chironomus* test guideline, and "preferably used" in the *Lumbriculus* test guideline.

In relation to stability, ECHA highlights that the test guideline provides procedures to ensure that separation into layers does not occur. For instance paragraph 24 in test guideline 225 states that: *Mixing of dry constituents is also acceptable if it is demonstrated that after addition of overlying water a separation of sediment constituents (e.g. floating of peat particles) does not occur* […]. The ECHA guidance (REACH Endpoint Guidance 7B) indicates separation can cause clay particles to settle on the surface preventing the penetration of certain species into the sediment layer. However the RSS does not indicate that this occurred in the L3 *Lumbriculus* study. The use of artificial sediment avoids the introduction of other flora and fauna, such as microbial flora, as this provides an additional variable in the test. ECHA acknowledges that the REACH Endpoint Guidance 7B indicates that artificial sediment can be conditioned to transform the organic matter into a more environmentally realistic form. It is not clear whether any conditioning was performed for the L3 *Lumbriculus* study. Without evidence it is not possible to understand whether separation occurred or had a significant effect on the outcome of the test. In any case it would be expected that the sediment composition (particularly the amount of organic carbon (OC)) would have more effect on adsorption. It is noted that the artificial sediment used had an OC content of 1.9% (within the range specified in the TG). No OC content is specified in the test guideline where natural sediment is used, although ECHA notes that the OC content of the natural sediment used by you in the *Lumbriculus* test was 3.1%. Again many other chemicals are tested with artificial sediment, and this provides a baseline of standard organic carbon to compare L3 toxicity with other chemicals. Overall, ECHA acknowledges that the issue cited by you may occur in theory, but there is no evidence (e.g. from the observations or measurements detailed in the RSS, and following the test guideline including paragraph 24) that the effect did occur or adversely affect the outcome of the test.

You also argue that the data available for the siloxanes analogue group indicate that artificial sediments tend to result in higher pH in the studies. You claim that this may also have a further compounding effect on the toxicity observed. You explain that the higher pH may cause separation of inorganic and organic matter due to physicochemical interaction and a stability concern. Overall You anticipate that the test substance would be in the predominantly organic phase resulting in higher exposure.

Similar to some of your previous points, whilst in theory these effects may occur, there is no evidence from the test using L3 that they did occur, or if they did the extent to which they occurred and the resulting significance on the test result.

According to the RSS for the L3 *Lumbriculus* test the pH of the overlying water was between 8.2 and 8.4, which is within the validity criteria of the OECD 225 test guideline (pH 6 – 9). The pH of the overlying water in the natural sediment test was 7.2 - 8.1. ECHA further notes that in a test on *Hyallela azteca* using D5 and two natural sediments (from Lakes Erie and Restoule), the measured pH of overlying water was reported in the RSS as: Lake Erie study: Day 1: 8.18, Day 28: 8.37; Lake Restoule: Day 1: 8.37, Day 28: 8.38. This suggests that higher pH can also occur in natural sediments.

ECHA concludes that there is no reason to disregard effects seen in the artificial sediment at a pH within the test guideline criteria. If there are differences in toxicity at different pH within the environmentally relevant pH range, it is reasonable to consider these. This is consistent with the approach for metal aquatic toxicity assessment, where the pH a study was performed at is an important consideration in PNEC and hazard classification determination.

In a dossier update referenced in your comments, you indicate that significant concentration losses occurred in the artificial sediment test. ECHA agrees that initial measured concentrations were significantly below nominal values. However the decline over the test itself was much less. Results are based on mean measured concentrations, but as the bulk of the losses occurred before the test commenced the results will not be significantly skewed by the concentration drop.

Overall ECHA agrees that there are differences in toxicity between the tests for L3 performed using natural and artificial sediment. However, it is unclear how representative the chosen natural sediment (Glen Charlie Pond) is for natural sediment in general. It is also unclear whether any of the possible confounding issues for artificial sediment cited by you occurred in the test in question or had a significant effect on the result.

In the absence of specific evidence, as a reasonable worst case it must be assumed that the toxic effects seen are a result of inherent toxicity. This is also consistent with the ECHA guidance (REACH Endpoint Guidance 7B) which concludes "*On the whole, due to the level of characterisation and reproducibility possible, artificial sediment is generally considered superior to natural substrate (OECD 2004a and b*[7] *) unless effects at a specific local site are being considered".*

The concern of ECHA is that rather than the artificial sediment causing greater toxicity, your choice of natural sediment may cause an under-estimate of toxicity for the purpose of consistent risk assessment.

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[7] These refer to OECD test guidelines 218 and 219 respectively

In conclusion ECHA sees no reason to discount the *Lumbriculus* result using artificial sediment. As this is the most sensitive endpoint, this will be used for the "T" assessment below, and sediment PNEC derivation.

In further comments, you note that there are no "T" criteria for sediment or soil organisms in REACH Annex XIII or the guidance. You note the existence of an equilibrium partitioning approach where pelagic testing is not possible. However you say 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 criterion for sediment toxicity. ECHA also agrees that in principle direct studies on pelagic organisms would be preferred to assess the 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 L3 in pelagic tests. 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 of these characteristics. In fact there would be a concern if the reverse 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, p145 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 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. Using the equilibrium partitioning calculation for L3, the back-calculated sediment NOEC for the T threshold of 0.01 mg/L is 22 mg/kg dw, and the actual *Lumbriculus* NOEC is 2.9 mg/kg dw (normalised to 5% OC). Or alternatively, the pore water NOEC is calculated as 0.00132 mg/L. Therefore the *Lumbriculus* result for L3 is significantly lower than the equilibrium partitioning “T” threshold for L3.

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

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

Overall ECHA sees no reason in this case to disregard the L3 sediment toxicity data for the T assessment using the equilibrium partitioning approach. ECHA concludes that the data tentatively indicate that the T threshold is met based on the sediment toxicity data. As L3 already meets the vB threshold, if it determined to be vP, a definitive conclusion on T would not be required. If L3 is determined to be P but not vP, any further information requirements for T will be considered in a follow up decision.

Based on current information ECHA considers that L3 may meet the criteria for classification as STOT RE 2 (target organ: liver). This is based on adverse liver weight increases of >50% in males at dose levels below the guidance value for classification, according to the Guidance on the Application of the CLP criteria, accompanied by liver enlargement, changes in histopathology and altered clinical chemistry consistent with liver toxicity. In particular the observation of possible protoporphyrin accumulation is considered relevant to the human risk assessment as it is indicative of a potential to cause porphyria in humans. Furthermore, an increase in liver weight of the magnitude reported has the potential to impact on other organs systems, although no further information is available on this aspect.

You have indicated that you plan to carry out investigative work to clarify the mode of action for the adverse liver weight increases. You consider if the pigment accumulation can be shown not to be protoporphyrin, but rather inorganic particles, such as silica, and that this is responsible for the bile duct blockage, a case can be made to show this is not of relevance to classification. As outlined above, there is not a requirement from ECHA for this work with respect to the "T" assessment but an assessment of the new information will be made when it is available.

Overall, ECHA tentatively concludes that the substance meets the T criteria on the basis of sediment organism toxicity, and no further information is required for "T" at the moment. There is also a concern that the substance may meet the T criteria on the basis of mammalian toxicity, but no further data are currently requested for this.

Persistence

L3 is not readily biodegradable (0% in 28 days) and therefore screens as P and vP. As the substance is assessed by ECHA to meet the B and T criteria, it is important to assess whether the P criteria is met.

In the current registration dossiers, you consider that the hydrolysis half-life of 13.7 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 the freshwater environment, and at pH 7 the hydrolysis half-life equates to 52 days at 12 °C, which exceeds the Annex XIII criteria for persistence (P). Therefore the available hydrolysis data cannot be used to show the chemical is not 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 L3 may be 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 L3 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 long degradation half-lives in sediment, meeting the REACH Annex XIII criteria for vP. L3 has a similar log Kow and log Koc value to D4, which is also not readily biodegradable. This provides some indication that L3 might also be expected to be vP in sediment. However, D4 and D5 are cyclic molecules, and L3 is a linear molecule so there is uncertainty in being able to directly read-across the results of either D4 or D5 to L3. You acknowledge that L3 screens as P/vP in sediment due to the lack of biodegradation (0% in 28 days) in the ready biodegradation test.

You assess L3 as not being persistent in soil as the degradation half-lives in a non-standard soil degradation test are all below 120 days (the Annex XIII criterion). This study 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 120 days to 24 days at 22.5 °C (56 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 L3 in the system is dependent on the humidity, with the degradation half-life increasing with humidity. Degradation half-lives in drier conditions are relatively short (a few days) whereas degradation half-lives 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 220 days at 12 °C.

This non-standard test is difficult to compare to 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 307 TG. 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 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, of L3 would not be judged from a soil degradation study. Finally the use pattern of L3 does not indicate that 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 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 L3 in soil. Therefore, despite being useful supporting information, the environmental degradation half-life of L3 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 L3 screens as P and vP, but there is insufficient evidence to show conclusively that the substance is not P/vP in any compartment.

In conclusion as ECHA considers that the chemical meets the vB and tentatively meets the T criteria in Annex XIII, for the PBT assessment it is important to investigate whether or not the substance fulfils the P and/or vP criteria.

Considerations on the test method and testing strategy

Persistence

Three simulation test methods are available to assess persistence (OECD TG 307, OECD TG 308 and OECD TG 309), but in the view of ECHA the characteristics of the chemical, in particular volatility, mean that the only option that is likely to be feasible is the sediment simulation study (OECD TG 308). The benthic compartment is also where persistence is suspected for L3 based on the knowledge gained from the cyclic siloxanes.

L3 has a vapour pressure of 530 Pa and as volatile substances are not recommended for evaluation in the OECD TG 307 this option is not considered further.

An OECD TG 309 could be considered, however the test guideline indicates that the test is applicable to non-volatile or slightly volatile substances. Therefore, OECD TG 309 is unlikely to be a suitable choice of test method in the present case . One other option could be an OECD TG 309 containing DOC. It is known from D4 and D5 that the hydrolysis of siloxanes is significantly impeded by the presence of DOC. However again the volatility of L3 suggests to ECHA that such a test would not be feasible.

A further reason for testing degradation in sediment is that the cyclic siloxanes D4 and D5 are very persistent in sediment (ECHA, 2015). As described above, despite the structural differences, the environmental fate characteristics provide suspicion that a long-degradation half-life in sediment is possible for L3. Sediment is also likely to be a significant environmental sink for L3, for example you assess the sediment compartment in their 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, CAS no. 107-46-0, EC no. 203-492-7) under the 2013 CoRAP. L2 is the (next) lower homologue in the linear siloxane category.

In your comments you note that as sediment simulation testing is currently underway with L2, you propose to await the results for 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 L3 might be P or vP. Therefore it is necessary that any data submitted to fulfil this 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 emphasises that it would not be acceptable for the L3 "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 study on L3, 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 chose 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 L3 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.

Alternative approaches and Proportionality of the request

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.

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:

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

2) Exposure information (request 2)

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 L3 in this scenario. These data are important for two purposes:

1. Assessing whether current risk management measures for the professional and 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 L3 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 L3. In particular an estimate of the split between wash-off and leaveon 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.
In your comments,you agreed to update the dossier in this respect.

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.

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 and potential sediment risks, Octamethyltrisiloxane, CAS No 107-51-7 (EC No 203-497-4) 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 proposal(s) for amendment to the draft decision. These were minor editorial changes to the Reasons (Appendix 1) which were 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 and are reflected in the Reasons (Appendix 1). 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.