Helsinki, 01 September 2015

Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXX-XX-XX/F)

DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For hexamethyldisiloxane, CAS No 107-46-0 (EC No 203-492-7)

Addressees: Registrant(s)[1] of hexamethyldisiloxane

This decision is addressed to all Registrants of the above substance with active registrations on the date on which the draft for the decision was first sent, with the exception of the cases listed in the following paragraph. A list of all the relevant registration numbers subject to this decision is provided as an annex to this decision.

Registrants meeting the following criteria are *not* addressees of this decision: i) Registrants who registered the above substance exclusively as an on-site isolated intermediate under strictly controlled conditions and ii) Registrants who have ceased manufacture/import of the above substance in accordance with Article 50(3) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by ECHA.

Based on an evaluation by the Health and Safety Executive as the Competent Authority of the United Kingdom (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision is based on the registration dossier(s) on 1 July 2014, i.e. the day until which the evaluating MSCA granted an extension for submitting dossier updates which it would take into consideration.

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

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of the United Kingdom has initiated substance evaluation for hexamethyldisiloxane, CAS No 107-46-0 (EC No 203-492-7) based on registration(s) submitted by the Registrant(s) and other relevant and available information and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

[1] The term Registrant(s) is used throughout the decision, irrespective of the number of registrants addressed by the decision.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to human health (suspected CMR – specifically carcinogenicity), exposure (consumer use) and aggregated tonnage (>1000 t/a), hexamethyldisiloxane was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2013. The updated CoRAP was published on the ECHA website on 20 March 2013. The Competent Authority of the United Kingdom was appointed to carry out the evaluation.

In the course of the evaluation, the evaluating MSCA noted additional concerns regarding human health exposure, environmental fate properties, environmental exposure, the PBT assessment and sediment toxicity.

The evaluating MSCA considered that further information was required to clarify the following concerns: human health exposure, environmental fate properties, environmental exposure, the PBT assessment and sediment toxicity. 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 14 March 2014.

On 29 April 2014 ECHA sent the draft decision to the Registrant(s) and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

Registrant commenting phase

By 5 June 2014 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay. By 1 July 2014 the Registrant(s) submitted an update of the registration dossier. The evaluating MSCA considered the comments received from the Registrant(s) and the dossier update.

On basis of this information Section II was amended. The Statement of Reasons (Section III) was changed accordingly. Initially parts of the decision were addressed to two of the member registrants in two separate draft decisions due to confidentiality reasons and when these were lifted the two separate draft decisions became redundant.

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH Regulation, on 15 January 2015 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, two Competent Authorities of the Member States and ECHA submitted proposals for amendment (PfAs) to the draft decision.

On 20 February 2015 ECHA notified the Registrant(s) of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA reviewed the proposals for amendment received and amended the draft decision accordingly.

By 23 March 2015, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments on the proposal(s) for amendment of the Registrant into account. The Member State Committee did not take into account the Registrant(s)' comments on the draft decision that were not related to the proposal(s) for amendment made and are therefore considered outside the scope of Article 51(5).

After discussion in the Member State Committee meeting on 20 to 23 April 2015, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 21 April 2015. ECHA took the decision pursuant to Article 52(2) and Article 51(6) of the REACH Regulation.

II. Information required

1. Information on prenatal developmental toxicity

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test method (in accordance with Article 13(3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:

Prenatal developmental toxicity study (test method EU B.31, OECD 414) in rats or rabbits by the inhalation route. The Registrants(s) shall select, with justification, the most appropriate animal species.

2. Additional information to support the environmental exposure assessment addressing the following issues:

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall also submit the following information regarding the registered substance subject to the present decision:

(a) Provide justification for the effect of an oil-water separator in the modelling of production and use as an intermediate at downstream industrial sites, as it is not included as an RMM for these scenarios. If there is insufficient justification, the effect of an oil-water separator shall be excluded from the environmental modelling of these scenarios.

(b) Update any exposure scenario where an oil-water separator is included as a RMM to include a technical specification of the separator. This shall make reference to BS EN 858-1 or similar international standard for separators, and specify the maximum discharge concentration of oil, in mg/l, the separator is designed to achieve. The Registrant(s) shall use this specification to update the level of removal assumed for the oil-water separator RMM in their environmental exposure modelling in section 9 of the Chemical Safety Report.

(c) Provide justification for the connection rate of households to WWTPs across the EU-28 used in the environmental exposure modelling. If there is insufficient justification, the connection rate of 82% reported in the Seventh Report on the Implementation of the Urban Waste Water Treatment Directive, 91/271/EEC[2] shall be used.

[2] European Commission, 2013. *Seventh Report on the Implementation of the Urban Waste Water Treatment Directive, 91/271/EEC.* (SWD(2013) 298 final).

(d) Provide justification for the dilution factors used for modelling the PECs at the production sites. If there is insufficient justification, standard default values from the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R16: Environmental Exposure Estimation shall be used.

(e) Provide justification for the values used to model releases for vessel cleaning for production and use as an intermediate at downstream industrial sites. If there is insufficient justification, standard default values from the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R16: Environmental Exposure Estimation shall be used.

(f) Justify the reasons for the values chosen for releases to air for production and use as an intermediate at downstream industrial sites. In particular provide specific evidence for the values used for the factors for vapour balancing for road tankers. Also provide specific evidence for why vapour balancing is relevant for containers smaller than road tankers, which are used to transport hexamethyldisiloxane. If there is insufficient justification, standard default values from the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R16: Environmental Exposure Estimation shall be used.

(g) Provide justification for the values chosen for releases to wastewater for production and ”use as an intermediate at downstream industrial sites”. If there is insufficient justification, standard default values from the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R16: Environmental Exposure Estimation shall be used.

(h) Provide justification for the releases to wastewater for “use in semiconductor and electronics manufacture” to be used in the environmental exposure modelling. If there is insufficient justification, standard default values from the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R16: Environmental Exposure Estimation shall be used.

(i) Provide justification for the use of the Release Factors (RFs) by specifying RMMs/operational conditions for “formulation of personal care products and automotive care products” used in the environmental exposure modelling. If there is insufficient justification, standard default values from the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R16: Environmental Exposure Estimation shall be used.

(j) Provide more information on the professional personal care use of hexamethyldisiloxane by justifying the values assumed in the modelling. If necessary the Registrant(s) shall provide separate exposure scenarios for professional use and household use of personal care products. Specifically this shall include regional and local tonnages, and estimation of the volume a typical salon uses and proportion discharged to wastewater. The Registrant(s) shall also provide tonnage data for hexamethyldisiloxane where 90% emission to wastewater is assumed and where 10% is assumed. Any assumptions shall be fully justified with clear evidence for these. If data are lacking, standard default values from the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R16: Environmental Exposure Estimation shall be used.

(k) Provide environmental exposure assessments for the following scenarios; scenario 7 (Use of automotive care products (Professional worker)), 11 (Formulation of medical adhesives and pharmaceuticals), 12 (Use in non-metal surfaces), and 13 (Use in Organic Rankine Cycle (ORC) as a working fluid).

3. Information on the PBT assessment;

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall also submit the following information using the indicated test methods (in accordance with Article 13(3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:

(a) **Hydrolysis as a function of pH (test method: Hydrolysis as a function of pH, EU C.7./OECD 111).** This shall be modified so that the study is conducted in the presence of dissolved organic carbon (DOC), using the method developed by Kozerski et al (2007)[3] for a related substance). The Registrant(s) shall update their environmental exposure assessment and PBT assessment with the results.

(b) **Sediment simulation testing (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.**

(c) **Bioaccumulation in aquatic species (test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305, aqueous exposure or dietary exposure).** The test does not need to be conducted if the results of requirement 3(b) lead to the conclusion that the substance is not persistent (P).

(d) **Long-term toxicity testing on fish (test method: fish, early-life stage (FELS) toxicity test, OECD 210).** Due to the physicochemical properties of the substance, prior to conducting the test the Registrant(s) shall refer to REACH guidance R7B, table R7.8-3 *Summary of difficult testing issues* to ensure the validity of the study. In particular they shall consider the recommendations for testing volatile substances. The test does not need to be conducted for PBT assessment purposes if the results of requirements 3(b) and 3(c) lead to the conclusion that the substance meets the Annex XIII PBT/vPvB criteria or alternatively that the substance does not meet either the P or B criteria.

A tiered approach is proposed to address the PBT concerns. The studies detailed in 3(c) and 3(d) should only be carried out if necessary, as outlined in section III below.

4. Information on sediment toxicity:

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall also submit the following information using the indicated test method[s] (in accordance with Article 13(3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:

(a) **Long-term toxicity to sediment organisms (test method: Sediment-water Lumbriculus toxicity test using spiked sediment, OECD 225),** modified as follows: sufficient food shall be supplied at the start of the test to last for the whole test period.

[3] Kozerski G E, Powell D E, and Shawl H R, 2007. Preliminary Assessment of the Loss and Degradation of Octamethylcyclotetrasiloxane (D4) in Natural Lake Sediments under Laboratory Conditions. Dow Corning Formal Technical Report, 2007-I0000-58163. Midland, MI: Dow Corning Corporation.

(b) **Long-term toxicity to sediment organisms (test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218**), modified as follows: sufficient food shall be supplied at the start of the test to last for the whole test period.

(c) **Long-term toxicity to sediment organisms (test method: 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***), modified as follows: sufficient food shall be supplied at the start of the test to last for the whole test period.

For the requested sediment toxicity tests above (II.4(a) – (c)), a tiered approach may be used by the Registrant(s) whereby the study using *Lumbriculus* (OECD 225) is initially conducted. Further sediment testing would then be required unless the Chemical Safety Report indicates that this is not necessary.

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **08 September 2018** an update of the registration(s) containing the information required by this decision[4], including robust study summaries and, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

1. Pre-natal developmental toxicity

During the evaluation it was noted that there were no pre-natal developmental studies available for hexamethyldisiloxane. The Registrant(s) considered that sufficient information on developmental toxicity was provided by the two-generation reproductive toxicity study (OECD 416), which incorporates an investigation into DNT endpoints according to an EPA guideline.

However, OECD test guideline 414 (prenatal developmental toxicity test) is designed to provide general information concerning the effects of prenatal exposure on the pregnant test animal and on the developing organism; this may include assessment of maternal effects as well as death, structural abnormalities, or altered growth in the foetus. Functional deficits, although an important part of development, are not part of this guideline. They may be tested for in a separate study, or as an adjunct to 414 using the guideline for developmental neurotoxicity. Therefore, the inclusion of the EPA guideline on neurotoxicity in a two-generation study does not provide equivalent information to OECD guideline 414. As a pre-natal developmental toxicity study is a standard information requirement according to REACH Annex IX, 8.7.2. an information gap was identified. Absence of the data that the legislator codified as minimum requirements for a substance at a certain annual tonnage level is of concern because the intrinsic properties of the substance need to be understood in order to ensure safe use.

Some information on the developmental toxicity potential of HMDS can be obtained from the available studies that is however not suitable to conclude on developmental toxicity. In a standard two-generation study (OECD TG 416), rats were exposed to HMDS via inhalation at concentrations of up to 5,000 ppm . No gross external abnormalities were

[4] The deadline set by the decision already takes into account the time that registrants may require to agree on who is to perform any required tests and the time that ECHA would require to designate a registrant to carry out the test(s) in the absence of the aforementioned agreement by the registrants (Article 53(1) of the REACH Regulation).

reported. Early post-natal survival was very slightly decreased at the top concentration, (two dams with 100% litter loss by PND 1) in the F1 generation and none in the F2 generation. Two dams receiving 100 ppm experienced total litter loss between days 4 and 21 post-partum. No further adverse effects on pups were observed. There was no toxicologically significant general toxicity.

In the one-generation study, which was consistent with the standard OECD TG (TG 415), rats were exposed to HMDS via inhalation at concentrations of up to 5000 ppm. In this study, pup survival was decreased at the top concentration (88.6% at 5000 ppm compared to 92.3-99.3% historical control incidence), with the majority of pup deaths confined to 3 litters. Necropsy of these pups did not indicate the deaths were treatment-related. Again, there was no toxicologically significant general toxicity.

These changes did not achieve statistical significance when compared to concurrent controls, and were within the available historical control incidence therefore it was first concluded that the changes were likely to be chance findings rather than a treatment-related adverse effect. However, a PfA was received from one Member State expressing concern that, whilst not statistically significant, the increased postnatal pup mortality in the period just after birth observed in both the one- and two-generation studies suggested that the substance may cause prenatal developmental toxicity manifested after birth as the observed increased rate of postnatal mortality. The Registrant(s) in their comments on the PfA upheld their argument that the available studies did not reveal any teratogenic/developmental effects, the post-natal mortality was limited and not statistically significant and a pre-natal developmental toxicity study would not provide any useful information regarding potential adverse developmental effect.

However, as the significance of the findings in the available studies are open to question requesting the missing pre-natal developmental study is required to clarify the uncertainties regarding developmental toxicity of HMDS.

The administration route shall be inhalation because this route of exposure is the most relevant human exposure route due to the physical chemicals properties and use of the registred substance.

Therefore, pursuant to Article 46(1) of the REACH Regulation the Registrant(s) are requested to carry out the following study on the registered substance subject to this decision: Pre-natal developmental toxicity study (test method EU B.31, OECD 414) in rats or rabbits by the inhalation route. The Registrant(s) shall select, with justification, the most appropriate animal species.

2. Additional information on the environmental exposure assessment:

This information is requested in relation to the additional concerns over environmental exposures that were identified during the evaluation.

The environmental exposure assessment provided in Section 9 of the chemical safety report (CSR) lacks justification for the choice of several parameters and values. These affect the environmental concentrations predicted by the Registrant(s) from their environmental modelling. This is significant because if the predicted effect concentrations (PECs) are underestimated, the risk characterisation ratios (RCRs) would also be under-estimated and so the risk management measures (RMMs) might not be sufficient.
An oil-water separator is not specified as a RMM for production or use as an intermediate at downstream industrial sites emission scenarios, so it is not appropriate to include the effect

of the separator in reducing the concentrations of hexamethyldisiloxane in the modelling to calculate the environmental emissions. If the RMMs are updated to include a separator, the Registrant(s) need to specify the type of separator as these vary considerably in the levels of removal achieved. The level of removal often depends on where the effluent is being discharged – for example surface or wastewater (it is not clear where the wastewater in the production or use as an intermediate at downstream industrial sites emission scenarios is discharged). Secondly the efficiency of separators is generally specified based on the oil concentration achieved in their effluent, for example <5 mg/l or <100 mg/l of oil. This is not the same as the assumption made by the Registrant(s) that a proportional removal of the substance occurs regardless of the oil volume emitted. The Registrant(s) claim that 1 kg of substance (in 10,000 m^3 of wastewater) would be reduced by 90% by an oil-water separator, so a concentration of 0.1 mg/l would be reduced to 0.01 mg/l. By comparison, a Class One oil-water separator (used for direct discharge to surface water) is specified to discharge 5 mg/l of oil or less. In this situation, it appears likely that the substance would remain largely dissolved and be unaffected by the separator, causing PECs to be higher than currently estimated.

The Registrant(s) currently assume a 90% connection rate of households to waste water treatment plants (WWTPs) across the EU for use in the regional background concentration calculation for private use emissions. However, the ECHA guidance (Information Requirements and Chemical Safety Assessment, Chapter R16: Environmental Exposure Estimation) specifies a default value of 80%. More recently the *Seventh Report on the Implementation of the Urban Waste Water Treatment Directive, 91/271/EEC*, published by the European Commission, reported that 82% of the waste water in the EU was put through secondary treatment in the year 2009/2010. The Registrant(s) justify the use of the higher value using EUROSTAT statistics for connection rates. However, these data are only for the EU-15 area, and therefore may not reflect the connection rate in the other 13 Member States. Unless the Registrant(s) have data showing 90% is appropriate for all 28 Member States, the modelling shall be revised using the 82% connection rate.

The information requested below is required to investigate whether the current PEC values are accurate. There is a concern that the PECs may be underestimated by the Registrant(s), and therefore risks might not be correctly characterised, or addressed using appropriate risk management measures.

The Registrant(s) use the maximum REACH default dilution factors for receiving waters for both fresh and marine waters, based on confidential site-specific data at production sites . It is unclear what these data represent, and the Registrant(s) need to justify why the maximum values are applicable. This shall include confirmation about whether the river data were derived from low flow (10^{th} percentile) conditions. Where site specific data indicate dilution factors below the generic dilution factor used in the assessment, the registrant shall ensure the assessment is clear and why the approach used is protective. If there is insufficient justification or the river data do not represent low flow conditions, standard default values from the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R16: Environmental Exposure Estimation, shall be used.

Cleaning of vessels for the production and use as an intermediate at downstream industrial sites emission scenarios is considered by the Registrant(s) to be negligible on the basis that it is only carried out once or twice a year. However it is unclear whether this infrequent cleaning process is a source of significant release (for example the vessels may be purged to air or via liquid rinsing). If the Registrant(s) cannot provide sufficient justification, standard default values from the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R16: Environmental Exposure Estimation, shall be

used. If the modelling and scenarios are accurate, the exposure scenario shall be updated to state that the substance shall not be released to wastewater and appropriate RMMs need to be specified, for example 'incineration of any vessel washings'.

Section 9.1.2.4.1 of the CSR describes vapour balancing as standard practise for road tankers, and uses a factor of 0.05 to reduce the releases to air for hexamethyldisiloxane. The Registrant(s) need to justify why the upper figure described in the Emission Scenario Document is appropriate for road tankers transporting hexamethyldisiloxane. The Registrant(s) also needs to justify why the vapour balancing factor is relevant when filling or emptying any container used for hexamethyldisiloxane. This is because although 20 m^3 tanks are listed as containers used to transport hexamethyldisiloxane, drums and intermediate bulk container (IBC) are also listed. In particular the emission scenario uses a loading of 2 t/d which appears appropriate for IBCs, rather than tankers. If the Registrant(s) cannot provide sufficient justification, standard default values from the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R16: Environmental Exposure Estimation, shall be used.

The Registrant(s) provide an estimate of the loss to wastewater due to minor spillages. However it is unclear how the values proposed (1 kg/d spillage, 10% to drain) were derived and there should be more evidence to support the assumptions made. If the Registrant(s) cannot provide sufficient justification, standard default values from the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R16: Environmental Exposure Estimation shall be used. Alternatively it may be necessary to consider monitoring to confirm the estimations.

The Registrant(s) need to provide justification for the values assumed for releases to air and water for use as an intermediate at downstream industrial sites. The scenario references *information in the public domain* and *information from producers* but it is not clear how either have been used in estimating the values. If, as the Registrant(s) state, there is an *absence of more detailed knowledge* (or justification) then standard default values shall be used. It may be necessary to consider monitoring to confirm the estimations.

Cleaning of vessels in use as an intermediate at downstream industrial sites is read-across from the production emission scenario, where cleaning emissions were considered negligible because of dedicated equipment. It is unclear whether this assumption is reasonable for use as an intermediate at downstream industrial sites, which includes batch processing. This type of processing suggests cleaning may be more frequent, and hence exposure more significant. Therefore the Registrant(s) need to provide more information on this aspect, and may need to model emissions from vessel cleaning for intermediate use. Alternatively, the RMMs shall be updated to state that no aqueous discharge is permitted.

There is no environmental exposure assessment conducted for use of hexamethyldisiloxane as a laboratory reagent, which the Registrant(s) justifies based on the small volume of chemical used (<10 g per day) and because there is no intentional discharge to wastewater. The Registrant(s) shall update the RMM to specify no disposal to wastewater.

For exposure scenario (ES) 5 (formulation of personal care products and automotive care products) the Registrant(s) used non-ERC (exposure release categories) default RFs and made reference to the Technical Guidance Document (2003) "A Table". In ECHA's view, the use of these RFs is not justified (Risk Management Measures, RMMs, with efficiencies and/or operational conditions leading to such releases are not clearly described). Therefore the Registrant(s) are required to justify the use of the A Table RFs by RMMs/operational conditions. Otherwise they shall use ERC default RFs for the exposure assessment of this

use.

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

Use of hexamethyldisiloxane in semiconductor and electronics manufacture is indicated by the Registrant(s) to be a very small scale use with no intentional release to wastewater, so an environmental exposure assessment has not been conducted. There needs to be information about the volume of the substance used in the scenario (e.g. kg/day) to justify the claim of 'very small scale'. The scenario also needs to be clear why environmental exposure does not occur, as Section 2.2.5 of the CSR indicates that wastewater from the air abatement system is sent to the on-site treatment plant. As hexamethyldisiloxane is used as a solvent, this would appear to be a significant exposure route. Alternatively if there is no release of the substance to wastewater, the RMMs shall be updated to clearly state this.

Following a proposal for amendment, the requirements below were added to this decision. These were previously in a separate draft decision addressed to one registrant, however as the scenarios are now included in the lead registration, the requirements are now included in the present decision.

An environmental exposure scenario for "Use of automotive care products (Professional worker)**"** has not been provided by the Registrant(s) due to the low tonnage used. However, low overall tonnage for an application does not necessarily prevent high local exposure if there are significant releases from specific sites. This may well be possible for a "down the drain" use. With the present CSR entry it is also unclear how any risks would be managed if the supply volume for this use increased. The Registrant(s) are required to address these points by providing an environmental exposure assessment.

In the CSR the Registrant(s) state that "Use in non-metal surface treatment" is a minor use in comparison to a number of others, and that as there are no risks for those, there would be no risks for this lower volume use. On this basis there is no environmental exposure scenario provided. ECHA does not think this is sufficient as the volume is not quantified, and the Registrant(s) indicate, but do not quantify, an emission to wastewater. The Registrant(s) are required to address these points by providing an environmental exposure assessment.

In the CSR the Registrant(s) state that "Formulation of medical adhesives and pharmaceuticals" is a minor use in comparison to a number of others, and that as there are no risks for those, there would be no risks for this lower volume use. On this basis there is no environmental exposure scenario provided. ECHA does not think this is sufficient as the volume is not quantified, and the Registrant(s) indicate, but do not quantify, an emission to wastewater. The Registrant(s) are required to address these points by providing an environmental exposure assessment.

In the CSR the Registrant(s) state that "Use in in Organic Rankine Cycle (ORC) as a working

fluid" is a minor use in comparison to a number of others, and that as there are no risks for those, there would be no risks for this lower volume use. On this basis there is no environmental exposure scenario provided. ECHA does not think this is sufficient. The size of a system is unclear, but if the entire system is drained this may be a significant volume of the registered substance requiring disposal. This could result in significant environmental exposure. The CSR states that this would be "probably incinerated", but as this is not a definite RMM, it does not necessarily prevent environment assessment.
Pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the information requested in Section II (Request 2: Information on environmental exposure).

3. Information on the PBT assessment:

This information is requested in relation to the additional concerns over the PBT assessment that were identified during the evaluation.

The Registrant(s)' PBT assessment concludes that although the substance may be persistent/very persistent (P/vP) in the sediment compartment (but is not P/vP in the soil or surface water compartments), it is not bioaccumulative/very bioaccumulative (B/vB) based on a weight of evidence approach, and not toxic (T). During the evaluation, it was considered that a conclusive decision cannot be made on the basis of the available data, and that hexamethyldisiloxane is a potential PBT or vPvB substance. Further details are provided below. The Registrant(s)' PBT assessment also references the conclusion of the Oslo-Paris Commission for the Protection of the Marine Environment of the North-East Atlantic (OSPAR) that the substance is not PBT. However, the OSPAR assessment does not include the key bioaccumulation test in the registration dossier, so is no longer relevant.

The substance has a rapid hydrolysis half-life in pure water (1.5 h at pH 5, 116 h at pH 7 and 12.4 h at pH 9, and 25 ºC), and the Registrant(s) have used these values in their chemical safety assessment (CSA). It is known that the rate of hydrolysis for related substances (cyclic siloxanes) is significantly impeded by the presence of organic carbon (EA[5], 2013a and b), yet there is no examination of this issue for hexamethyldisiloxane by the Registrant(s).

During the evaluation, this was identified as an important omission for the assessment of the environmental fate of the substance, both for the PBT evaluation and environmental exposure assessment. Currently the registrants conclude that hexamethyldisiloxane is not P in the aquatic compartment. However, in the opinion of ECHA the hydrolysis rate in pure water may not reflect its actual environmental persistence (P). Hydrolysis half-life also affects the modelling of the predicted environmental concentrations (PECs).

During the evaluation, it was concluded that the hydrolysis half-life value in pure water may not be appropriate for the CSA in this instance. The Registrant(s) are required to conduct a hydrolysis study in the presence of DOC, using the method developed by Kozerski et al (2007) to provide more accurate information to enable assessment of the concern.

The Registrant(s) have commented that the standard REACH Annex VII requirement for a hydrolysis study is already met. ECHA agrees that a valid test according to OECD 111 is summarised in the registration dossier. However substance evaluation allows ECHA to ask for data beyond the standard REACH endpoints to investigate a concern.

In their dossier(s) the Registrant(s) claim that the Annex XIII persistence criteria for water

[5] PBT Factsheets for Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5)

are not met due to rapid hydrolysis. ECHA does not think the weight of evidence from other siloxanes, where dissolved organic carbon (DOC) is known to have significant impact on hydrolysis rates, can be ignored. Therefore the concern that HMDS might be persistent in freshwater needs to investigated.

This test would also help address comments from the Registrant(s) regarding the feasibility of the sediment simulation and toxicity tests. ECHA thinks this is a further, significant, reason to conduct the study.

Additionally ECHA notes that the evidence from the soil degradation studies on siloxanes suggests several mechanisms affect the degradation, for example clay mineral content. This could mean the removal may not be as simple as the Registrant(s) suggest.

Since the substance is not readily biodegradable, it screens as P/vP. The Registrant(s) originally stated in their CSR that the substance "*is probably P/vP in sediment*", although this has been amended in an IUCLID update to "may be P/vP", without any further information. There is therefore no unequivocal information for assessing persistence in sediment. Since hexamethyldisiloxane is released to wastewater and is highly adsorbing, it is appropriate to investigate fate in sediment.

The Registrant(s) commented that the sediment simulation study may be technically difficult to perform. Whilst this is acknowledged it is noted that a sediment simulation study was performed on a substance with a similar Henry's Law constant (octamethylcyclotetrasiloxane, EINECS number 209-136-7).

The Registrant(s) have also proposed that the substance "may be persistent in sediment". However this is not acceptable as clarity for the P/vP status in sediment for HMDS is important. This is because the chemical meets the screening criteria for other PBT endpoints which require vertebrate testing. As vertebrate testing should be avoided if other options exist, the simulation study should be conducted first.

The Registrant(s) also propose to perform the sediment toxicity testing using *Lumbriculus* prior to the simulation testing. ECHA appreciates that some pre-test work may be necessary. There is one deadline for all tests and data requirements in this decision. Therefore ECHA thinks this provides the Registrant(s) with sufficient scope to investigate the feasibility of the simulation study. The requirement to conduct a test in accordance with Kozerski et al. (2007), specified as Hydrolysis as a function of pH (test method: Hydrolysis as a function of pH, EU C.7./OECD 111 (Section II, request3a)) in this decision, will help provide information on the feasibility of the sediment simulation study.

Hexamethyldisiloxane has an estimated log Kow value of approximately 5. A fish bioconcentration study is available in the registration dossier (Mansunobu, 1995), however some parameters were not reported in the original robust study summary (e.g. lipid normalisation or the influence of growth, whether steady state was reached, so there was uncertainty about the exact bioconcencentration factor (BCF) value. The Registrant(s) have tried to address some of the deficiencies by providing further information and additional analysis.

There remains no measured information for fish growth during the study. Instead the Registrant(s) have estimated a growth rate constant based on other bioaccumulation data for carp from the same laboratory that performed the test for HMDS. The Registrant(s) have also conducted modelling to estimate a kinetic BCF as there was no depuration period in the study. Following growth correction and lipid normalisation, the Registrant(s) calculate the

kinetic BCF values to be 1,652 and 1,971 for the lower and higher test concentrations, or 1,260 and 1,940 based on a steady state approach. A further approach using probabilistic modelling produced median kinetic BCF values of 1,420 and 1,469, and 95th percentile values of 1,509 and 1,566 for the low exposure concentration using two different estimated growth constants.

ECHA does now agree that steady state appears to have been reached in the study (by day 42 for the lower concentration, and day 13 for the higher concentration). Using the averaged fish concentrations between day 42-70 and 14-56 ECHA estimates the lipid normalised BCF values to be 1,374 and 1,957 l/kg for the lower and higher exposure concentrations respectively. However these values exclude growth correction.

ECHA has a number of concerns for the growth correction estimation proposed by the Registrant(s). These include that it is unknown whether the fish in the test using HMDS were the same size as those in the studies being compared. It also requires assumptions when extrapolating tests using different feeding rates.

ECHA considers that there is large uncertainty in the modelling approaches used by the Registrant(s) to derive the k1 and k2 for the kinetic BCF. This is because there are few data points prior to steady state for the fitting to the uptake/depuration kinetics assumed by the Registrant(s). This is particularly for the higher concentration where the first data point is steady state – i.e. the fit is effectively being applied between only two points. Ideally there should be a number of data points available prior to steady state. Further uncertainty is introduced as k1 and k2 are fitted together, so both parameters become uncertain, rather than one.

An alternative approach for kinetic BCF estimation performed by ECHA (based on a k1 derived from fish weight) suggests the BCF values might be between 1,340 – 2,870 l/kg-ww, but again with significant uncertainty in the estimation.

When ECHA uses the mean k1 and k2 values assumed by the Registrant(s) for the probabilistic modelling, the mean kinetic BCF values are approximately 2,090 and 2,220 l/kg-ww, which does not agree with the modelling output for the 95th percentile produced by the Registrant(s) (which are below these values). ECHA is also concerned that the growth constants used in this modelling represent a narrower range than suggested by the Registrant(s)'- original data mining. In addition, the standard deviation is very small and may not reflect the true variability in this parameter (noting the points above with respect to the extrapolation for different fish sizes and feeding rates). A further disadvantage of this approach is that it is not possible to model the higher concentration, where concern is greater with respect to the B threshold.

Therefore regardless of whether a kinetic modelling approach or a steady approach is used it remains uncertain whether the fish BCF for the higher concentration in the test exceeds 2,000.

A further concern for the test is that two fish were taken at each sample point compared to the four fish that are now required in the test guideline. This also increases the uncertainty in concluding B/vB for the study.

Overall ECHA considers that it is not possible to reach a reliable conclusion on B/vB based on the available data because growth correction cannot be reliably estimated, a kinetic BCF value cannot be derived as depuration was not measured and the number of fish sampled was half what is now required in fish bioconcentration testing.

The Registrant(s) state that although the available BCF for hexamethyldisiloxane meets the criteria for B, the trophic magnification factors (TMFs) derived from bioaccumulation field studies with D4 and D5, supported by a calculated fugacity ratio of 0.36 for hexamethyldisiloxane, provide a weight of evidence that suggests that linear siloxanes will probably not bioaccumulate in the environment, i.e. B/vB would not apply. Since no BMF or TMF data are available for hexamethyldisiloxane, it is premature to read-across from the cyclic siloxanes, and in any case, lack of biomagnification cannot be used with confidence in the PBT context (as indicated in the REACH Guidance, Chapter R.11). It is also noted that the - PBT Expert Group has agreed that the cyclic siloxanes D4 and D5 both meet the vB criterion due to their fish BCF values exceeding 5,000 l/kg, and that the TMF data are equivocal for D5. In addition, the appropriateness of the fugacity modelling is unclear, particularly given the concerns about the reliability of the BCF value, and issues relating to the solubility of the substance in lipids. Its relevance is also questionable as the calculated fugacity ratio is contradicted by the measured BCF data, which shows that bioaccumulation in fish does occur. So, depending on the needs of the PBT assessment, it may become necessary to clarify whether the BCF does in fact exceed 2,000 l/kg, and this would require a new test.

Regarding the T criterion, the evaluation concluded that there is uncertainty relating to the derivation of results from both the long-term Daphnia and algal tests, but notes that the no-effect concentrations (NOECs) for both studies are close to 0.01 mg/l. However the Registrant(s) have provided additional information to clarify these uncertainties and derived new NOECs which indicate that the T criteria are not met for algae or Daphnia. Acute fish toxicity has been observed, but there is no long-term fish test. The Registrant(s) have provided a read-across argument and a QSAR prediction to fulfil the long-term fish toxicity endpoint. However, the data were not considered to be adequate during the evaluation. Firstly the Registrant(s) propose that results from a long-term fish test using octamethyltrisiloxane (L3, CAS no. 107-51-7) can be read-across to hexamethyldisiloxane. During the evaluation, the read-across was not considered to be robust because L3 has a lower water solubility and higher Kow value than hexamethyldisiloxane, and has no effects up to its water solubility limit in any aquatic test, whereas hexamethyldisiloxane exhibits toxicity in all available key aquatic tests. The Registrant(s) have also provided a QSAR Model Reporting Format (QMRF) to externally validate the use of the ECOSAR neutral organics chronic fish toxicity Quantitative structure–activity relationship (QSAR) for organo-siloxanes. During the evaluation, this validation was not considered to be valid for a number of reasons:

- Five out of the eight data points in the external validation data set are taken from fish bioaccumulation studies, which are not a robust measure of chronic fish toxicity.
- Only three of the validation substances fall within the validity domain of the QSAR (log Kow <8).
- For the three substances with Fish, early-life stage (FELS) results, only two fall within the validity domain of the model.
- Although the QSAR predicts that none of the validation substances will express chronic fish toxicity above the water solubility limit, toxicity was observed for one of the two validation substances using a FELS test.

The Registrant(s) have also attempted to derive a NOEC from the QSAR result (which is a "Chronic Value", ChV), but have not provided a robust justification, and there appears to be significant error in making such an extrapolation. Overall, the evaluation concluded that the chronic toxicity of fish has not been established reliably. As there is no clear pattern in taxa sensitivity in acute tests, it cannot be ruled out that the long-term fish NOEC will be lower than 0.01 mg/l. This means the REACH Annex XIII T criterion is potentially met, and a

reliable long-term fish toxicity test is required to determine whether the substance meets the T criterion under the conditions of the test.

Overall, the evaluation concluded that there is insufficient information to conclude the PBT assessment, and that the substance screens as PBT and vPvB. Therefore further information is required to evaluate this concern. In the interests of animal welfare and in line with current guidance (ECHA Guidance on information requirements and chemical safety assessment, Chapter R.11: PBT Assessment), a tiered approach is proposed investigating persistence first:

i) As a first step, a reliable sediment biodegradation half-life is required to determine whether the registered substance meets the Annex XIII P/vP criteria under the conditions of the test, and also to identify any transformation products. The test needs to be performed at a temperature of 12 °C to represent the average environmental temperature for the EU. Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study on the registered substance: Aerobic and anaerobic transformation in aquatic sediment systems (test method EU C.24/OECD TG 308).

   As a second step in the data collection process, if the results of the sediment simulation test demonstrates that the substance is P or vP, a reliable fish bioaccumulation test is required to determine whether the registered substance meets the Annex XIII B/vB criterion under the conditions of the test. This shall preferably be performed using aqueous exposure. Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study on the registered substance: Bioaccumulation in aquatic species (test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305, [aqueous exposure/dietary exposure]). It is emphasised that a new bioaccumulation test would not be required if hexamethyldisiloxane is concluded to not meet the P criteria.

ii) As the third step in the data collection process, if the results of the sediment simulation and the bioaccumulation test demonstrate that the substance is P and B, but not vPvB, a reliable long-term fish toxicity test is required to determine whether the registered substance meets the REACH Annex XIII T criterion under the conditions of the test. Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study on the registered substance: Long-term toxicity testing on fish (test method: Fish, early-life stage (FELS) toxicity test, OECD 210). It is emphasised that the FELS test would not be required if hexamethyldisiloxane is concluded to be vPvB, not P but B and P, not B. However, it should be noted that, if after fulfilling the requirements as set out in request 3, the environmental risk assessment results in RCRs > 1 then the Registrant(s) would need to conduct this test as a standard REACH information requirement.

A proposal for amendment was suggested to require the PBT testing simultaneously. However ECHA does not consider that this is appropriate as this could potentially require unnecessary vertebrate testing. For instance a bioaccumulation test would not be required for "B" if the substance were found to not be "P". The proposal for simultaneous testing is also contrary to the REACH R11 PBT guidance which clearly states that PBT testing is performed in the order P, B then T, for both the animal welfare reasons, and proportionality. The deadline for submitting the required information has been extended to 36 months from an original proposal of 15 months, although a PfA was received suggesting 42 months.

ECHA considers 36 months is a reasonable period of time for the Registrant(s) to deliver this test programme when it is clear to them what may or may not be required, and can be planned for accordingly. ECHA also considers that it is possible and proportionate to require the results to be submitted more quickly than 42 months, and this longer period of time is therefore judged to be excessive, particularly when balanced with the need to address the concerns for the chemical.

4. Information on sediment toxicity

This information is requested in relation to the additional concerns over sediment toxicity that were identified during the evaluation.

To fulfil the endpoint for sediment toxicity, the Registrant(s) have provided a table of the available sediment data for five organosilicon substances (L3, D4, D5, D6 and Vi4-D4). The Registrant(s) argue in Section 7.1.2.2. of the CSR that grouping the results by species, molecular weight, log Kow, log Koc and organic carbon (OC) solubility does not indicate any patterns, and so no single factor explains the variation in toxicity. Due to this a "group approach" has been used by deriving one geometric mean of the OC-normalised NOECs for all of the substances. This gives a result of 83 mg/kg, and the Registrant(s) apply an assessment factor of 50 to this value to derive a sediment PNEC for hexamethyldisiloxane.

During the evaluation, it was considered that this grouping approach was not relevant. The Registrant(s) have effectively combined data from different substances, species, end points, sediment types and time periods to derive a single value without any scientific justification. This approach also ignores differences in test conditions and result derivation (i.e. whether reported as nominal, initial measured or mean measured concentration). Finally, the choice of assessment factor is not adequately justified. The expected high adsorption potential of the substance and suspected persistence in sediment, both acknowledged by the Registrant(s) in their CSR, mean that the benthic compartment is likely to be an important sink for hexamethyldisiloxane. Overall, the evaluation concluded that inadequate information is available for the sediment toxicity endpoint and so long-term toxicity testing to sediment-dwelling organisms is required.

The Registrant(s) do not disagree with a need to investigate effects in sediment, although they do note potential technical problems due to the possibility of volatility and hydrolysis. However, it is noted that the registration dossier for the analogous substance L3, decamethyltetrasiloxane (CAS no. 141-62-8), does have a sediment toxicity test using *Hyallela azteca* available. While L2 is more volatile than L3, it is also more soluble, and the Henry's Law Constant for L2 is actually lower than for L3. The hydrolysis rates for L2 and L3 in pure water appear similar. Again the presence of DOC would be expected to impede degradation - although some test material losses did occur in the L3 sediment toxicity study, a valid test appears to have been performed. Again a study performed in accordance with Kozerski et al. (2007) for L2 will provide useful information on this issue. Overall as a sediment toxicity test was possible for L3, at this stage ECHA considers that there are no clear reasons why sediment testing using L2 is not feasible. Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following studies on the registered substance:

- Long-term toxicity to sediment organisms (test method: Sediment-water Lumbriculus toxicity test using spiked sediment, OECD 225);
- Long-term toxicity to sediment organisms (test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218);

- Long-term toxicity to sediment organisms (test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218, modified to use the amphipod *Hyallela azteca*).

The following modification is necessary for these tests: sufficient food shall be supplied at the start of the test to last for the whole test period. This is important, because the addition of fresh food during the test may result in the organisms eating uncontaminated food (and so reduce exposure to the test substance). It follows the approach adopted under the Existing Substances Regulation (EC No. 793/93) for other hydrophobic substances in sediment (e.g. tetrabromobisphenol-A).

A tiered approach may be used. Initially a study using *Lumbriculus* shall be conducted. Further sediment testing would then be required unless the CSR indicates that this is not necessary.

The Registrant(s) are reminded of the obligation to review the environmental classification and the PNECs once the above data have been generated.

IV. Adequate identification of the composition of the tested material

In relation to the required experimental studies, 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 tests 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. Finally, the tests must be shared by the Registrant(s).

V. Avoidance of unnecessary testing by data- and cost-sharing

In relation to the experimental studies the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). Registrant(s) 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 Registrant(s) to perform the studies on behalf of all of them.

VI. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be

filed only when the appeal fee has been paid.

Authorised[6] by Leena Ylä-Mononen, Director of Evaluation

Annex: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

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