Helsinki, 09 October 2025

Addressee
Registrant of the Registered substance subject to this decision ("the Substance"), listed in Appendix E of this decision[1].

Registered substance subject to this decision ("the Substance")
Substance name: Tetradecamethylhexasiloxane
EC / List number: 203-499-5

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

DECISION ON SUBSTANCE EVALUATION

Under Article 46 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below:

Information required to clarify the potential risk related to PBT/ vPvB

1. Bioaccumulation in fish (test method: EU C.13/OECD TG 305) dietary exposure with the Substance, specified as follows:
   - The test must be conducted under flow-through conditions.
   - A ^{14}C radiolabelled test material must be used. The test substance must be ^{14}C radiolabelled with the radiolabel located in the most stable part of the molecule. A justification for the location of the radiolabel must be provided.
   - A reference substance must be used to demonstrate the adequacy of the food spiking technique.
   - In addition to measurements of total radioactivity, specific chemical analysis must be performed for the parent test substance concentrations in feed and fish samples at all sampling times.
   - Identification and quantification of major metabolites (>10% of the applied radioactivity) must be performed in fish samples.
   - Growth-corrected, lipid-normalised BCF and BMF values must be estimated from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO(2017)16).

Deadline

The above information must be submitted by **18 October 2027**.

[1] Appendix E is removed from the version of the adopted decision published on ECHA's web page.

How to comply with the information requested

To comply with this decision, you must:

- Submit the information in an updated registration dossier, by the deadlines indicated above. The information must comply with the IUCLID robust study summary format.
- Attach the full study report for the corresponding study in the corresponding endpoint of IUCLID.
- Update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

Justifications for the requests in this decision are provided within Appendix A. Procedural steps followed to reach the adopted decision and some technical guidance are detailed in Appendix C and D, respectively.

Appeal

This decision may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information**.**

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[2] under the authority of Mike Rasenberg, Director of Hazard Assessment

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

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Appendix A: Reasons to request information to clarify the potential risk(s)

Basis for substance evaluation

The objective of substance evaluation under REACH is to allow for the generation of further information on substances suspected of posing a risk to human health and/or the environment ('potential risk').

ECHA has concluded that further information on the Substance is necessary to enable the evaluating Member State Competent Authority (MSCA) to clarify a potential risk and whether regulatory risk management is required to ensure the safe use of the Substance.

The ECHA decision requesting further information is based on the following:

- There is a potential risk to human health and/or the environment, based on a combination of hazard and exposure information.
- Information is necessary to clarify the potential risk identified.
- There is a realistic possibility that the information requested would allow improved risk management measures to be taken.

1. Potential risk related to PBT/ vPvB

1.1. Potential hazard

The Substance, tetradecamethylhexasiloxane (L6), belongs to the group of linear siloxanes which are organo-silicone compounds that consist of – $(CH_3)_2SiO$ – structural units. All silicon atoms present are alternately connected to oxygen atoms and hydrocarbon (usually methyl) functional groups. Shorter chained linear siloxane L3 (EC no. 203-497-4) (ECHA, 2024) and L4 (EC no. 205-491-7) (ECHA, 2025) have been identified as substances of very high concern (SVHC) due to its vPvB properties. Shorter chained linear siloxanes L5 (EC no. 205-492-2) and L2 (EC no. 203-492-7) are evaluated for their potential PBT/vPvB properties in the Substance Evaluation process by the Norwegian Competent Authority (NO CA 2021c, 2025). In addition, cyclic siloxanes D4 (EC no. 209-136-7), D5 (EC no. 208-764-9) and D6 (EC no. 208-762-8) have been identified as SVHCs due to their PBT and/or vPvB properties (ECHA 2018a, b, c).

Information from these and other structurally related substances ("the source substances"), when applicable, has been used in the assessment of the Substance. The linear siloxanes (L2-L6) are silicon-oxygen (Si–O) compounds with a repeating backbone structure consisting of alternating silicon and oxygen atoms in a straight-chain arrangement differing only on the number of dimethyl-siloxane and trimethyl-siloxane units. The cyclic siloxanes (D4-D7) also consist of dimethyl-siloxane units in a cyclic (ring like) molecular structure. Therefore, due to the presence of the common structural unit the linear and cyclic substances show similar physicochemical properties.

Following assessment of all available relevant information on the Substance and the structurally related substances, the evaluating MSCA has identified the following potential hazards which must be clarified:

a) Potential P/vP properties

If a substance fulfils the criteria in Section 1.1.1 or 1.2.1 of Annex XIII to REACH, it is considered that it has persistent (P) or very persistent (vP) properties. For the purpose of

the P/vP assessment and to check whether the criteria are fulfilled, the information listed in Section 3.2.1 to Annex XIII, including results from simulation tests, must be considered. If no such data are available, it is necessary to consider the screening information of Section 3.1.1 to Annex XIII, such as screening tests and QSAR predictions.

Predictions with the Substance and experimental data from the structurally related substances were considered together.

Evidence based on experimental data on the Substance

No experimental data on the degradation of the Substance is available.

Evidence based on estimated data

In the registration dossier, you report hydrolysis half-lives of 12.1 h at pH 4, 5.8 h at pH 5, 6300 h at pH 7 and 36.5 h at pH 9 and 20-25°C determined for the Substance using a QSAR estimation method which has been developed for and applies specifically to linear and cyclic siloxanes. The model for hydrolysis at pH 7 is a multiple linear regression-based model on descriptors representing (i) ring strain, (ii) number of Si-O bond, and (iii) number of Si-H bond. The models for hydrolysis at pH 4, 5 and 9 are linear regression-based models where the descriptor is the half-life at pH 7. No further information is published on the model. Based on the information available in the registration dossier, the evaluating MSCA considers that the QSAR prediction for the Substance at pH 7 can be used as supporting information as the training set of the model includes similar substances. However, the number of substances included in the training set is relatively low which adds some uncertainty.

Based on the BIOWIN QSAR models, the Substance is potentially P/vP.

Evidence based on experimental data from structurally related substances

In the registration dossier, you have used read across from degradation studies with other linear siloxanes (L3 and L4). The evaluating MSCA has used this information, together with information on other linear and cyclic siloxanes, in the persistency assessment of the Substance.

Information from OECD TG 111 tests with L3 and L4, included in your registration dossier, and with L2 (NO CA 2025) indicate that the hydrolysis rate of linear siloxanes decreases with increasing chain length and molecular size. A similar trend can be observed for the cyclic siloxanes D4 and D5. For the structurally similar substance L4, experimental hydrolysis half-life of 30 days at pH 7 and 25 °C was determined in an OECD TG 111. The evaluating MSCA converted this hydrolysis half-life to the environmentally relevant temperature of 12°C using the Arrhenius correction and it resulted in a half-life of 130 days. As the Substance has longer chain length than L4, the hydrolysis of the Substance is expected to be slower.

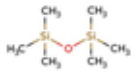
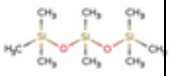
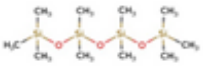
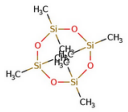
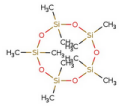
In ready biodegradation tests with the structurally related substances L2 (OECD TG 301C) (NO CA 2025) and L3 (OECD TG 310), 2% and 0% degradation, respectively, was observed after 28 days. In a review article by Rücker *et al.* (2023) the authors explored ready biodegradation and hydrolysis tests as well as various other types of experimental evidence on several organosiloxanes (including linear and cyclic siloxanes L2-L11 and D3-D6) that may be indicators of biodegradation in general and of the specific case of biodegradative Si–C bond cleavage. The findings by Rücker *et al.* (2023) support the conclusion that linear siloxanes have slow (ultimate) degradation in the environment as no convincing evidence on cleavage of Si-C bonds by non-adapted natural microorganisms has been found.

In OECD TG 308 studies available for L2 (NO CA 2025) and L3 (ECHA 2024) degradation

half-lives in sediment of approximately 192-360 days and 416 days, respectively, were determined. Information from these studies were used for reading across to L4 and L5 by the registrants of these substances. In the substance evaluation conclusion document of L5 (NO CA 2021c) it is indicated that, for the linear siloxanes, persistence (environmental half-life) is expected to increase with increasing chain length. This trend is expected for the linear siloxanes, including the Substance, because of a similar increase in hydrophobicity with increasing chain length (based on water solubility and organic carbon partitioning data). This trend is also supported by the results of the OECD TG 308 studies with L2 and L3. Further support for the expected trend in the linear siloxanes comes from the increasing hydrolysis half-lives of 17.4, 61 and 165 d at 10 °C for L2, L3 and L4, respectively. A similar trend of increasing sediment half-life is also observed for the cyclic siloxanes D4 (≈242 d at 24 °C) and D5 (≈1200 d at 24 °C) (ECHA 2018a and 2018b).

Considering all available information, it can be expected that the persistence of siloxanes with increasing chain length will be greater than or at least equal to the shorter chained siloxanes. As L2, L3, D4 and D5 have been demonstrated to have long half-lives in sediment fulfilling the criterion for vP, it can be assumed that the half-life in sediment of the Substance will similarly be well above 180 days.

Table 1. Overview of the experimental hydrolysis and degradation half-lives for the source substances

	L2	L3	L4	D4	D5
EC no.	203-492-7	203-497-4	205-491-7	209-136-7	208-764-9
Chemical structure					
Water solubility (mg/L)	9.3E-01	3.4E-02	6.7E-03	5.6E-02	1.7E-02
Log K_{ow}	5.2	6.6	8.21	6.49	8.03
Log K_{oc}	3.0	4.34	5.16	4.22	5.17
Hydrolysis $t_{1/2}$ (d) at 10-12°C (OECD TG 111)	14.3	61	165	16.7	315
DT_{50} sediment (d) (OECD TG 308, aerobic conditions)	192 days (first order kinetics) and 360 days (HS - FOCUS kinetics) at 12°C (whole system).	1180 – 2532 days at 12°C (whole system)	-	≈242 days at 24°C (whole system)	≈1,200 days at 24°C (whole system)

Conclusion on persistence

Based on the QSAR predictions, screening and simulation studies with the related siloxane substances and the observed trend of increasing persistence of linear siloxanes with increasing chain length, the evaluating MSCA considers that the available information is sufficient to conclude on the P/vP properties of the Substance.

b) Potential B/vB properties

If a substance fulfils the criteria in Section 1.1.2 or 1.2.2 of Annex XIII to REACH, it is considered to have bioaccumulative (B) or very bioaccumulative (vB) properties. For the purpose of the B/vB assessment and to check whether the criteria are fulfilled, the information listed in Section 3.2.2 of Annex XIII must be considered, including

bioconcentration factor (BCF) values.

Predictions with the Substance and information from the source substances, as well as monitoring data, were considered together.

Evidence based on experimental data on the Substance

No experimental data on the bioaccumulation of the Substance is available in the registration dossier.

Evidence based on estimated data

The Substance has high predicted log K_{ow} values above 10 (COSMOTherm 10.29 and KOWWIN 11.07). $Dmax_{aver}$ was estimated to be 16.9 or 17.6 Å using CATALOGIC BCF baseline model which is close to the value of 17.4 Å used as an indicator for limited uptake in the ECHA Guidance R.11. However, the Dmax value of the Substance varies significantly depending on the conformers of the molecule. The curved form of the Substance has a Dmax of 13.8-14.6 Å which is below the threshold of 17.4 Å and therefore not indicating limited uptake potential. Conversely, the log K_{ow} and the molecular size of the stretched form (20.1-19.6 Å) indicate potential limited uptake.

Log K_{oa} of 6.33 is predicted for the Substance by KOAWIN. As the log K_{ow} is above 2, and the predicted log K_{oa} is above 5, the Substance screens for potential bioaccumulation in air-breathing organisms.

Potential bioaccumulation in aquatic organisms

- *Evidence based on experimental data from structurally related substances*

A BCF study with L5 is included in the registration dossier. The Norwegian Competent Authority (NO CA) recalculated the results of the study during the Substance Evaluation of L5, and this resulted in BCF values well above 5000 L/kg (NO CA 2021c).

Furthermore, during the 12-month substance evaluation period of this Substance, you provided informally to the evaluating MSCA a BCF study with the cyclic siloxane D7 (EC no. 203-496-9), which is not registered under REACH. D7 has a similar high log K_{ow} value above 10 and a similar molecular size to the Substance in the curved form. The depuration rate of D7 was slow (0.044-0.063 day^{-1}) but since the uptake rate was also slow, a BCF value of approximately 200 L/kg (based on total radioactivity) was determined in the study. However, as D7 is highly hydrophobic, the freely dissolved concentration of the test substance, and consequently the bioavailability, was likely lower than that measured based on total radioactivity. Therefore, the uptake rates determined in the study may underestimate the real uptake of D7 as part of the test substance may not have been bioavailable due to adsorption to particles. In addition, there is no information available on the possible metabolites of the test substance. Therefore, the evaluating MSCA considers that the BCF value determined for D7 has uncertainties and cannot be used to conclude on the bioaccumulation of the Substance.

Based on BCF values determined for other linear siloxanes (L2, L3, L4 and L5) (ECHA 2024, NO CA 2025, NO CA 2021a,b,c), fish bioaccumulation appears to peak at L3. L3 has a higher log K_{ow} value than L2, which explains why the BCF value is higher. Above L3, BCF values of the linear siloxanes appear to decrease with increasing log K_{ow}. This is likely to be due to decreasing bioavailability of the larger linear siloxanes. Despite the decreasing trend beyond L3, the BCF value for L4 is still sufficiently large for the substance to meet the vB criteria. Based on the results of an OECD TG 305 study with L5, recalculated by the NO MSCA in the Substance evaluation (NO CA 2021c), L5 was considered to likely meet

the criteria for vB.

A similar trend is observed for the cyclic siloxanes (D4, D5, D6 and D7) in the available laboratory and field studies. D4, D5 and D6 have usually quite similar high bioaccumulation (ECHA 2015, ECHA 2018c) and a decreasing trend in bioaccumulation is observed from D6 to D7 (*e.g.*, Guo *et al.* 2021; Cui *et al.* 2019).

Based on the available information on laboratory bioaccumulation studies in fish performed with linear (L2-L5) and cyclic (D4-D7) siloxanes, the depuration rates of the siloxanes appear to decrease with increasing chain length. Therefore, the Substance is likely to show slow depuration in fish, similar to or lower than that of L5. However, due to the higher log K_{ow} and molecular size, the Substance may have more limited uptake than L5.

In your comments to the draft decision, you consider that the available information on structurally similar substances indicate that the Substance is highly unlikely to bioaccumulate in aquatic organisms. You refer to the aquatic bioconcentration in fish study with the structurally related substance D7 and you note that the observed low uptake was expected on the basis of its high log Kow >10 and large molecular size, the depuration rate was also low and the lipid normalised BCF D7 (lipid-normalised to 5%) were in the range of 53 L/kg to 284 L/kg, indicating very low bioaccumulation potential.

As indicated above, the aquatic bioconcentration in fish study with the structurally related substance D7 has uncertainties and cannot be used to conclude on the bioaccumulation of the Substance. Furthermore, while the evaluating MSCA agrees that a log Kow > 10 may be an indication of potential low uptake, further evidence for hindrance of uptake are needed for supporting low bioaccumulation potential (see section R.11.4.1.2.1 of Chapter R.11 of the Guidance on IR&CSA). More specifically significant uptake of a substance in vertebrates after prolonged exposure is a contra-indication to using the above indicator. As noted below, the Substance and other longer structurally related linear siloxanes have been detected in aquatic organisms and in humans at significant concentrations in the available field and monitoring studies. Therefore, your comments on the draft decision do not provide conclusive evidence to rule out that the Substance may be bioaccumulative.

- *Evidence based on monitoring data on the Substance and structurally related substances*

The evaluating MSCA searched for further information on the uptake of the Substance by organisms in the scientific literature. The Substance has been detected in fish and aquatic invertebrates in several field studies (*e.g.*, Chen *et al.* 2022, 2024; Guo *et al.* 2021; Wang *et al.* 2021). It is noted that the detection frequencies and concentrations in biota for the Substance are low in several studies, but they are low also in the sampled environmental matrices (sediment and surface water) (*e.g.*, Chen *et al*. 2022, 2024; Wang *et al.* 2021). This could be due to the lower use and subsequent lower exposure to the Substance, as other longer chained linear siloxanes (*e.g.*, L9-L13) are detected more frequently both in the environmental matrices and in biota (*e.g.*, Xue *et al.* 2019; Zhi *et al.* 2019; Chen *et al.* 2022; Jia *et al.* 2015).

In some studies, the concentrations of these other longer linear siloxanes in biota are similar (*e.g.*, Chen *et al.* 2022) or even higher (*e.g.*, Chen *et al.* 2024; Xue *et al.* 2019) than those of the cyclic siloxanes D4-D6 identified as vB (ECHA 2018a, b, c).

Field BMF and TMF values above 1, although not fully reliable, have been determined for longer chain linear siloxanes (L7-L10) in some studies (Xue *et al.* 2019; Kim *et al.* 2020). Due to the high hydrophobicity and high adsorption potential of the longer chained linear siloxanes, the aquatic exposure may be less relevant while accumulation via dietary exposure could occur.

Potential bioaccumulation in air-breathing organisms:

- *Evidence based on experimental data from structurally related substances*

Toxicokinetic studies on the structurally related substances L5 and L2 are included in the registration dossier of the Substance.

In a non-guideline toxicokinetic study that investigated the oral absorption, distribution and elimination of L5 in two male rats following a single gavage dose, the absorption was found to be approximately 25% of the administered dose. Elimination was rapid (65 and 97% by 24 and 48 hours, respectively), so by 96 hours after dosing there were only trace amounts of the test substance in tissues and organs (0.09% of administered dose across all tissues and organs). Approximately 74% of the administered dose was found in faeces, 23% in expired air and 2.2% in urine.

In a toxicokinetic study equivalent or similar with OECD TG 417, rats were exposed to 5000 ppm of radiolabelled L2 via inhalation for 6 hours. At the end of the exposure period, approximately 3% of the total radioactivity was retained in the rats. Parent L2 was measured in blood and tissues (*i.e.*, brain, fat, kidney, liver, lung and ovaries). The highest concentrations were found in fat and ovaries. The majority of the radioactivity (75%) was eliminated within 24 hours post-exposure. The terminal half-lives of elimination of radioactivity from blood, brain, fat, kidney, liver, lung and ovaries were 67, 31, 33, 44, 56, 53 and 22 hours, respectively. Approximately 37% of the recovered radioactivity was excreted in urine, 50 % in expired volatiles and about 1 % in faeces. Collected tissues and the carcass accounted for less than 0.1% and 2% of the recovered radioactivity, respectively. Urinary excretion consisted of polar metabolites while 71 % of the expired radioactivity was attributed to parent L2 with the remainder as metabolites.

Based on the Henry's Law Constants (HLC), the Substance (HLC of 7.1×10^7 Pa m^3/mole) has higher volatility than L5 (HLC of 2.0×10^7 Pa m^3/mole) and L2 (HLC of 3.7×10^5 Pa m^3/mole) and hence similar fast elimination via exhalation could occur. On the other hand, based on log K_{ow} values, the Substance (log K_{ow} of 10-11) is more lipophilic than L5 (log K_{ow} of 9.4) and especially L2 (log K_{ow} of 5), and therefore, it could have higher accumulation in fat tissues. Hence, the available information does not allow concluding on the bioaccumulation potential of the Substance in air-breathing organisms.

- *Evidence based on monitoring data on the Substance and structurally related substances*

In a study (Xu *et al.* 2015) on the occurrence of siloxanes (D4-D6 and L5-L16) in humans in China, the Substance was present in the plasma of industrial workers at the highest concentrations among the studied siloxanes. Other longer chained siloxanes (L7-L16) have also been measured in human plasma in China (Xu *et al.* 2015; Guo *et al.* 2019, 2020). Furthermore, in Xu *et al.* (2015), other longer chained linear siloxanes (L8-L10) were observed in the fat tissues of the general public with concentrations increasing with age from 16 to 66 years. This may indicate potential accumulation of higher chained linear siloxanes, including the Substance, in human fat tissue.

Conclusion on bioaccumulation

Based on available information on other structurally related siloxanes, slow depuration in fish can be expected for the Substance. The Substance has been detected in biota, including in humans, in several field and monitoring studies, although the detection frequency and concentrations are often low. However, other longer chained linear siloxanes (ranging from L7-L16) are frequently detected in organisms in the available field

studies, sometimes at similar or even higher concentrations than cyclic siloxanes D4-D6 known to be vB. This indicates that the Substance and longer chained linear siloxanes are taken up by organisms. The low occurrence of the Substance in field studies may be due to lower exposure (likely due to lower usage and emissions than that of other siloxanes).

In conclusion, and as noted above for both the linear and cyclic siloxanes there is a trend of increasing BCF with increasing chain length followed by a decrease of the BCF. However, there is uncertainty at which chain length the BCF is below the vB and B thresholds. Even though the uptake of the Substance is expected to be slow, as the depuration rate is also expected to be slow, accumulation of the Substance in the long run is likely to occur.

Therefore, the available information is not sufficient to draw a conclusion on the potential B/vB properties of the Substance. Further information on bioaccumulation is needed.

c) Potential T properties

If a substance fulfils the criteria in Section 1,1.3 of Annex XIII to REACH, it is considered that it fulfils the toxicity (T) criterion. For the purpose of the T assessment and to check whether the criteria are fulfilled, the information listed in Section 3.2.3 of Annex XIII, such as results of long-term toxicity tests, must be considered.

Evidence based on experimental data on the Substance

There is no experimental aquatic toxicity data for the Substance.

Evidence based on experimental data from structurally related substances

- Evidence on potential aquatic toxicity

Read across from aquatic toxicity tests with L4 and L5 is used in the registration dossier. The evaluating MSCA has taken into account also available aquatic tests with L2 and L3. Based on the available information, only L2 showed adverse effects in daphnia and algae with NOEC/EC10 of 85-90 µg/L. For the other linear siloxanes, no adverse effects were observed in fish (L3, L4), daphnia (L3, L4, L5) and algae tests (L3, L4) at concentrations close to their water solubility. Therefore, it appears that the toxicity in aquatic organisms is higher for shorter linear siloxanes and decreases with increasing chain length. Consequently, the Substance is not expected to show adverse effects in standard pelagic aquatic toxicity tests with fish, daphnia and algae at the water solubility limit.

- Evidence for toxicity on human health

In the registration dossier, there is no repeated dose toxicity, reproductive toxicity or carcinogenicity data on the Substance. However, information on structurally similar substances has been included in the registration dossier for these endpoints. The evaluating MSCA considers that it is currently not possible to exclude that the Substance may meet the T criteria for human health. The need for requesting further information on repeated dose toxicity, reproductive toxicity and/or carcinogenicity will be assessed at a later stage.

Conclusion on toxicity

The available and current information is not sufficient to draw a conclusion on the potential T properties of the Substance. No further information on toxicity is requested in this decision but depending on the outcome of the information requested in this decision, further information may be necessary and may be requested in a follow-up decision.

1.2. Potential exposure

According to the information you submitted in the registration dossier, the aggregated tonnage of the Substance manufactured or imported in the EU is in the range of 1 - 10 tonnes per year.

Furthermore, you reported that among other uses, the Substance is used by industrial workers, professionals, and consumers in heat transfer fluids, laboratory chemicals, automotive care products, cosmetics and personal care products.

Therefore, significant exposure to the environment cannot be excluded.

1.3. Identification of the potential risk to be clarified

Based on all information available in the registration dossier, there is sufficient evidence to justify that the Substance may cause adverse effects to the environment.

The information you provided on manufacture and uses demonstrates a potential for exposure of the environment.

Based on this hazard and exposure information the Substance poses a potential risk to the environment.

As explained in Section 1.1 above, the available information is not sufficient to conclude on the potential hazard and in particular on B/vB/T. Consequently, further data is needed to clarify the potential risk related to PBT/ vPvB.

1.4. Further risk management measures

If the potential risk is confirmed, the evaluating MSCA will analyse the options to manage the risk(s) and will assess the need for further regulatory risk management measures in the form of:

- **Harmonised classification of the Substance as PBT or vPvB, as defined in the CLP Regulation:** This would result in stricter risk management measures than those currently in place, such as improved measures at manufacturing sites, better waste management and revised instructions on safe use, if appropriate. Furthermore, the potential classification would also have consequences for the classification of mixtures containing the Substance, due to this classification's generic concentration limits for products.
- **Identification as a substance of very high concern (SVHC) under Article 57(d or e) of REACH:** The SVHC identification would trigger additional information duties of producers and importers to ECHA according to Article 7(2) of REACH and information duties in the supply chain and for consumers according to Article 33 of REACH.
- **Authorisation or a restriction of the Substance to further limit the use(s) of the Substance:** This would result in stricter risk management measures than those currently in place, such as improved measures at manufacturing sites, better waste management and revised instructions on safe use, if appropriate.

1.5. How to clarify the potential risk

The information resulting from Request 1 will provide information on bioaccumulation in aquatic organisms and will constitute the first tier in a testing strategy to conclude on potential PBT/vPvB properties of the Substance.

The evaluating MSCA will review the information you submitted as an outcome of the first tier of the testing strategy and evaluate whether a second tier of the testing strategy may be triggered and further information on bioaccumulation in air-breathing organisms and/or on toxicity may be requested in a follow-up decision.

1.5.1. Request 1: Bioaccumulation in fish

1.5.1.1. Aim of the study

As detailed in Section 1.1. above, information on bioaccumulation is required to conclude on the potential hazard for bioaccumulation. Therefore, a study is required that investigates the bioaccumulation in aquatic organisms.

The requested study will generate information on bioconcentration in aquatic organisms that can relate to the criteria in Annex XIII, section 1.1 of REACH for Bioaccumulative (B) and 1.2 for very Bioaccumulative (vB).The information on bioaccumulation in aquatic species is a standard information requirement under Section 9.3.2 in Annex IX of REACH and can be requested under Section 9.3, column 2 of Annex VIII of REACH if additional information on bioaccumulation as set out in Annex XIII, point 3.2.2, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex. However, as the Substance is registered at the Annex VII level, this information can only be requested under the substance evaluation process. Furthermore, considering the properties of the Substance, specifications beyond the test guideline requirements are considered necessary. Therefore, the substance evaluation is considered to be the most appropriate process.

The requested study will also allow to determine estimated BCF values that can be compared with the Annex XIII criteria for B/vB, as well as BMF and other parameters relevant for assessing the bioaccumulation of the Substance, such as the depuration rate.

In your comments to the draft decision, you agree to conduct the request for a dietary bioaccumulation study in fish with the Substance.

However, you highlight the uncertainties arising from the comparison of an estimated BCF value generated from a BMF study with the regulatory criteria for aquatic bioaccumulation. You note that the methods for derivation of uptake rate constants (Annex 8, OECD TG 305, 2012) will likely result in a very wide range of BCF values and that the database used to develop the uptake estimation methods (training data set) is not representative of siloxane functionalities. Finally, you refer to a publication by Gobas et al (2025) in which the authors highlight the lack of strong correlation between the BCFww and the BMF_L.

The evaluating MSCA notes that the estimation of uptake rate constant may be uncertain for the Substance due to its high log Kow value above 10. However, as the estimated uptake rate constants are mainly determined by the ventilation flow, the lack of siloxane functional groups in the substances used to build the models might affect in lesser degree the uncertainty of the predictions.

As indicated in Section R.11.4.1.2.3 of Chapter R.11 of the Guidance on IR&CSA, there have been several observations indicating that a lipid normalised dietary BMF_L is unsuitable as an endpoint for bioaccumulation from a regulatory perspective. This is because normalising a BMF from a dietary study to both, the lipid content of the fish and the lipid content of the diet, makes the resulting BMF_L dependent on feeding conditions. Therefore, if using a correlation of dietary BMF and BCF results to interpolate other BMF results, it must be ensured that the BMF values were obtained under similar conditions (i.e. fish species, fish weight/size, diet lipid content, feeding rate, fish lipid content and

temperature). Otherwise, the estimated BCFs have high uncertainty.

The preferred endpoint from the OECD TG 305 dietary exposure test is the BCF value estimated from experimentally derived elimination rate constant, which can be directly compared to the REACH Annex XIII criteria, unless it can be demonstrated that the uptake rate constant (k1) cannot be reliably estimated with the available methods. As describe in the Guidance document on aspects of OECD TG 305 (OECD, 2017) due to the uncertainty in the three methods described therein, it is recommended to produce predictions according to all methods before assessing the relevance of each method result. The estimated BCF values and their uncertainties will be considered in a Weight-of-Evidence approach for the assessment of bioaccumulation, together with other information on bioaccumulation.

1.5.1.2. Specification of the requested study

Test conditions

The test must be carried under flow-through conditions to limit potential exposure of test substance via water as a result of any desorption from spiked food or faeces, to maintain adequate dissolved oxygen concentrations and help to ensure clean water and remove influences of e.g., excretion products (OECD TG 305).

Radiolabelling of the test material

The test must be performed using as test material the Substance with ^{14}C-radiolabelling. The radiolabelling must be in the most stable part of the molecule. A justification for the location of the radiolabel must be provided.

Exposure to the test material

The nominal concentrations and measured concentrations of the test substance in the food must be provided. A homogeneous distribution of the test material and stability of the test material concentration in the fish feed must be demonstrated.

In the dietary test, it is important to make sure that the uptake of the applied doses is as complete as possible. For example, potential crystallisation of the test material in the spiked food can reduce its bioavailability and must be avoided. Therefore, when selecting the test concentration and spiking method you must ensure that a homogenous distribution of the test material in the food is obtained. Paragraph 119 of OECD TG 305 provides some advice about possible solutions for spiking the test substance to the food. It is also recommended to follow the instructions on spiking included in section 4.2. of the OECD Guidance Document No. 264 on Aspects of OECD TG 305 on Fish Bioaccumulation (OECD, 2017). Due to the very low predicted solubility (1-2 ng/L) and high log K_{ow} (10-11) of the Substance, which could lead to reduced bioavailability and homogeneity in the spiked food, use of a reference substance is required to assess whether the food spiking technique is adequate to ensure maximum homogeneity and bioavailability of test substances as indicated in the paragraph 114 of the OECD TG 305. You must also provide a scientific justification of the used spiking procedure.

In your comments to the draft decision, you indicate that hexachlorobenzene, which is mentioned in the OECD TG 305 as a possible reference substance, is listed as a Persistent Organic Pollutant and its use is highly restricted. ECHA agrees that in conjunction with the contract research organisation, you must identify a suitable hydrophobic reference substance with a reliable dataset on uptake and biomagnification.

Furthermore, due to the potential volatility of the Substance (predicted Henry's Law

Constants $7.1x10^7$ $Pa.m^3$/mole at 25°C), it is recommended that the stability of the spiked Substance in the food after preparation is assessed before the definitive test, to ensure that the validity criterion of the OECD TG 305 regarding the concentration of the test substance in fish food before and at the end of the uptake phase being within a range of ± 20% (based on at least three samples at both time points) is fulfilled. This is necessary to ensure that a correct test substance concentration is used in the calculation of the assimilation efficiency and BMF value. If the concentration in the spiked food cannot be adequately maintained within the limit of the validity criterion, you may need to prepare the spiked food more than once during the uptake phase of the definitive test.

Chemical analysis of the parent Substance and metabolites

In addition to measurements of total radioactive residues, separation procedures (*e.g.*, TLC or HPLC) must be employed prior to radio-detection to enable quantitative analysis of the parent test substance in feed and fish at all sampling times. If total radioactive residues are measured alone (*e.g.*, by combustion or tissue solubilisation), the BMF, depuration rate and estimated BCF values are based on the total of the parent substance, any retained metabolites in fish and also assimilated carbon. Measuring the parent substance in feed is necessary to ensure that a correct parent substance concentration is used in the calculation of assimilation efficiency and BMF. Therefore, results determined based on total radioactive residues may not be directly comparable to a BCF or BMF derived by specific chemical analysis of the parent substance only.

The major metabolites in fish must be characterised, as a minimum at the end of the uptake phase (cf. paragraph 6, 65 and 147 of the OECD TG 305). According to the OECD TG 305, major metabolites are those representing ≥ 10% of total residues in fish tissues, those representing ≥ 5% at two consecutive sampling points, those showing increasing levels throughout the uptake phase, and those of known toxicological concern.

If metabolites representing ≥ 10% of total radiolabelled residues in the fish tissue are identified and quantified, then it is also recommended to identify and quantify metabolites in the spiked feed.

Estimated BMF and BCF values

In addition to growth-corrected lipid-normalised kinetic BMF value, you must also estimate the corresponding BCF values from the dietary test data according to Annex 8 of the OECD 305 TG and OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO(2017)16).

Feeding rate and food lipid content

The evaluating MSCA reminds that according to OECD TG 305 (paragraphs 126 and 140) the feeding rate should be selected such that fast growth and high increase of lipid content of fish are avoided. High feeding rate and/or high lipid content of food could lead to fast growth and large increase in fish lipid content, which make the interpretation of the results and derivation of study parameters more difficult. Therefore, the fish are fed at a fixed ration dependent on species, for *e.g.*, approximately 1-2 % of wet body weight per day in the case of rainbow trout (OECD TG 305 paragraph 140). The OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation (ENV/JM/MONO(2017)16) recommends using a feeding rate at or near the upper limit of the range given in the OECD TG 305 (*i.e.*, 2 % of the body weight per day).

The lipid content of the food should be in the limits indicated in the OECD TG 305. The paragraph 117 of the guideline states that test diets with total lipid content between 15

and 20% (w/w) have commonly been used in the development of the method. However, in the Annex 7 of the guideline an example of a suitable food composition, as commercially supplied, is given and a raw fat content of ≤ 15 % is indicated. According to the OECD TG 305, the lipid content of food should, however, not be very much lower than this upper limit to ensure that fish health is appropriately maintained.

Request for the full study report

You must submit the full study report which includes:

- a complete rationale of test design and interpretation of the results
- the analytical method used for the quantification of the test material in feed and tissue samples must be described. The recovery efficiency, precision, limits of determination (*i.e.* detection and quantification) and working range must be reported. If relevant, the method used for the identification and quantification of metabolites is described.
- access to all information available in the full study report, such as implemented method, raw data collected, interpretations and calculations, consideration of uncertainties, argumentation, etc.

This will enable the evaluating MSCA to fully and independently assess all the information provided, including the statistical analysis, and to efficiently clarify the potential hazard for the PBT/ vPvB of the Substance.

1.5.1.3. Alternative approaches and how the request is appropriate to meet its objective

The request is:

- Appropriate, because it will provide information which will clarify bioaccumulation in fish of the Substance. This will enable the evaluating MSCA to conclude on bioaccumulation in aquatic organisms.
- The least onerous measure because there is no equally suitable alternative method available to obtain the information that would clarify the potential hazard.

  According to section R.11.4.1.2.2 of Chapter R.11 of the Guidance on IR&CSA, in most cases where experimental information on bioaccumulation in aquatic species is needed, the freshwater amphipod *Hyalella azteca* bioconcentration test (HYBIT) (OECD TG 321) should be considered whenever possible, to avoid vertebrate testing, or alternatively an aqueous exposure bioconcentration fish test according to OECD TG 305-I can be performed. These studies give results that can be directly compared with the B/vB criteria in Annex XIII. However, for substances for which it is not possible to maintain and measure fully dissolved aqueous concentrations reliably, as is the case for the Substance, a Dietary Exposure Bioaccumulation Fish Test according to OECD TG 305-III should be considered.

  According to OECD TGs 321 and 305, the aqueous exposure test is most applicable to organic chemicals with log K_{ow} values between 1.5 and 6.0 but may still be used with highly hydrophobic chemicals (having log K_{ow} >6.0), if a stable and fully dissolved concentration of the test chemical in water can be demonstrated. According to OECD TG 305, for strongly hydrophobic substances (log K_{ow} > 5 and a water solubility below ~ 0.01-0.1 mg/L), testing via aqueous exposure may become increasingly difficult. The Substance has a predicted log K_{ow} above 10 (various QSAR models) and a

predicted water solubility of 1-2 ng/L (WSKOW and WATERNT). In the aqueous exposure bioconcentration studies in fish with the structurally related substances L5 and D7, there is uncertainty in the freely dissolved exposure concentrations and bioavailability of the test substances, and hence, the determined uptake rate constants (k_1) and BCF values have high uncertainty. As the water solubility of the Substance is well below the water solubility of L5 and D7, the evaluating MSCA considers that an aqueous exposure test is not feasible for the Substance. Therefore, a dietary exposure OECD TG 305 III is requested.

A benchmarking approach to conclude on the bioaccumulation of the Substance based on the estimated depuration rate and information on the structurally relevant substances is not possible. The Substance has higher log K_{ow} and molecular size (which are close to the indicative threshold for potential limited uptake) than the structurally relevant substances already concluded to be B/vB (L3, D4, D5 and D6) or that have BCF values higher than 5000 L/kg (L4 and L5). Hence, although the depuration rate of the Substance can be expected to be lower than that of the structurally related substances, the uptake rate may also be lower, and therefore, it is not possible to reliably conclude on the BCF value of the Substance based on benchmarking.

Appendix B: References

1. General references

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment

Citation	Reference
ECHA (2011)	Chapter R.4 Evaluation of available information.
ECHA (2008)	Chapter R.6 QSARs, read-across and grouping.
ECHA (2019)	Appendix to Chapter R.6 for nanoforms.
ECHA (2017a)	Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7.
ECHA (2022)	Appendix to Chapter R.7a for nanomaterials.
ECHA (2023a)	Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9.
ECHA (2017b)	Appendix to Chapter R.7b for nanomaterials.
ECHA (2023b)	Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13.
ECHA (2021)	Appendix to Chapter R.7c for nanomaterials.
ECHA (2008a)	Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds.
ECHA (2023c)	Chapter R.11 PBT/vPvB assessment.
ECHA (2016)	Chapter R.16 Environmental exposure assessment.

OECD Guidance documents

Citation	Reference
OECD GD 23	Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29	Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150	Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151	Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

2. Relevant references not included in the registration dossier

Citation	Reference
Chen *et al.* (2022)	Chen W, Kang YJ, Lee HK, Lee M, Moon HB. 2022. Nationwide monitoring of cyclic

	and linear siloxanes in sediment and bivalves from Korean coastal waters: Occurrence, geographical distribution, and bioaccumulation potential. Mar Pollut Bull. 185:114201.
Chen *et al.* (2024)	Chen W, Lee S, Moon HB. 2024. Cyclic and linear siloxane contamination in sediment and invertebrates around a thermal power plant in Korea: Source impact, distribution, seasonal variation, and potential for bioaccumulation. Chemosphere 349:140779.
Cui *et al.* (2019)	Cui, S; Fua, Q; Anb, L; Yua, T; Zhanga, F; Gaoa, F; Liua, D and Jia, H. 2019. Trophic transfer of cyclic methyl siloxanes in the marine food web in the Bohai Sea, China. Ecotoxicology and Environmental Safety, 178: 86-93. https://doi.org/10.1016/j.ecoenv.2019.04.034
ECHA (2015)	ECHA 2015. Persistency and bioaccumulation of Octamethylcyclotetrasiloxane (D4) (EC No: 209- 136-7, CAS No: 556-67-2) and Decamethylcyclopentasiloxane (D5) (EC No. 208-764-9, CAS No. 541-02-6). Available at: https://echa.europa.eu/documents/10162/17233/art77-3c_msc_opinion_on_d4_and_d5_20150422_en.pdf/57c2de97-0420-4cc2-bd32-021006bab026
ECHA (2018a)	ECHA (2018a). Support document for identification of Octamethylcyclotetrasiloxane (D4) as a Substance of Very High Concern because of its PBT and vPvB properties (Article 57D&E). Adopted on 13 June 2018. Available at: https://www.echa.europa.eu/documents/10162/115f70a9-a387-1525-d49f-b715e84996e4
ECHA (2018b)	ECHA (2018b). Support document for identification of Decamethylcyclopentasiloxane (D5) as a Substance of Very High Concern because of its PBT and vPvB properties (Article 57D&E). Adopted on 13 June 2018. Available at: https://www.echa.europa.eu/documents/10162/ddd97c9a-fe79-6f50-ff1a-c1d4bf305aab
ECHA (2018c)	ECHA (2018c). Support document for identification of Dodeamethylcyclohexasiloxane (D6) as a Substance of Very High Concern because of its PBT and vPvB properties (Article 57D&E). Adopted on 13 June 2018. Available at: https://www.echa.europa.eu/documents/10162/a9682f4b-fc3e-cd99-3db9-b0f9f383c3c5
ECHA (2024)	ECHA (2024). Support document for identification of octamethyltrisiloxane as a Substance of Very High Concern because of its vPvB (Article 57e) properties. Adopted on 10 December 2024. Available at: https://echa.europa.eu/documents/10162/528cc7c8-c20c-8445-761c-f75c1dcdbdc1
ECHA (2025)	ECHA (2025). Support document for identification of decamethyltetrasiloxane as Substance of Very Hight Concern because of its cvPvB (Article 57e) properties. Adopted on 10 June 2025. Availble at: https://echa.europa.eu/documents/10162/e9f427a1-e41c-d61a-726a-89666f3de869.
Gobas *et al.* (2025)	Gobas FAPC, Berg NM, Redman AD, Parkerton T, Camenzuli L. 2025. Assessing bioaccumulation with biomagnification factors from dietary bioaccumulation tests. Integrated Environmental Assessment and Management, 2025, 1–11.
Guo *et al.* (2019)	Guo J, Zhou Y, Cui J, Zhang B, Zhang J. 2019. Assessment of volatile methylsiloxanes in environmental matrices and human plasma. Sci Total Environ. 668:1175-1182.
Guo *et al.* (2020)	Guo J, Zhou Y, Sun M, Cui J, Zhang B, Zhang J. 2020. Methylsiloxanes in plasma from potentially exposed populations and an assessment of the associated inhalation exposure risk. Environ Int. 143:105931.
Guo *et al.* (2021)	Guo W, Dai Y, Chu X, Cui S, Sun Y, Li YF, Jia H. 2021. Assessment bioaccumulation factor (BAF) of methyl siloxanes in crucian carp (Carassius auratus) around a siloxane production factory. Ecotoxicol Environ Saf. Apr 15: 213.
Jia *et al.* (2015)	Jia H, Zhang Z, Wang C, Hong WJ, Sun Y, Li YF. 2015. Trophic transfer of methyl siloxanes in the marine food web from coastal area of Northern China.

	Environ Sci Technol. 49(5):2833-40.
Kim *et al.* (2020)	Kim J, Woodburn K, Coady K, Xu S, Durham J, Seston R. 2020. Comment on "Bioaccumulation of Methyl Siloxanes in Common Carp (Cyprinus carpio) and in an Estuarine Food Web in Northeastern China". Arch Environ Contam Toxicol. 78(2):163-173.
NO CA (2021a)	Substance Evaluation Conclusion and Evaluation Report for Octamethyltrisiloxane (L3). Norway Environmental Agency, Trondheim, December 2021.
NO CA (2021b)	Substance Evaluation Conclusion and Evaluation Report for Decamethyltetrasiloxane (L4). Norway Environmental Agency, Trondheim, December 2021.
NO CA (2021c)	Substance Evaluation Conclusion and Evaluation Report for Dodecamethylpentasiloxane (L5). Norway Environmental Agency, Trondheim, December 2021.
NO CA (2025)	Substance Evaluation Conclusion and Evaluation Report for Hexamethyldisiloxane (L2). Norway Environmental Agency, Trondheim, January 2025.
Rücker *et al.* (2023)	Rücker C, Grabitz E, Kümmerer K. 2023. Are Si-C bonds cleaved by microorganisms? A critical review on biodegradation of methylsiloxanes. Chemosphere.321:137858.
Wang *et al.* (2021)	Wang W, Cho HS, Kim K, Park K, Oh JE. 2021. Tissue-specific distribution and bioaccumulation of cyclic and linear siloxanes in South Korean crucian carp (carassius carassius). Environ Pollut. 288:117789.
Xu *et al.* (2015)	Xu L, Shi Y, Liu N, Cai Y. Methyl siloxanes in environmental matrices and human plasma/fat from both general industries and residential areas in China. Sci Total Environ. 505:454-63.
Xue *et al.* (2019)	Xue X, Jia H, Xue J. Bioaccumulation of Methyl Siloxanes in Common Carp (Cyprinus carpio) and in an Estuarine Food Web in Northeastern China. 2019 Arch Environ Contam Toxicol. 76(3):496-507.
Zhi *et al.* (2019)	Zhi, L; Xu, L; He, X; Zhang, C and Cai, Y. 2019. Distribution of methylsiloxanes in benthic 2 mollusks from the Chinese Bohai Sea. Journal of Environmental Science, 76: 199-207. https://doi.org/10.1016/j.jes.2018.04.026

Appendix C: Procedure

This decision does not imply that the information you submitted in your registration dossier(s) is in compliance with the REACH requirements. ECHA may still initiate a compliance check on your dossiers.

12-month evaluation

Due to initial grounds of concern for PBT/vPvB, the Member State Committee agreed to include the Substance in the Community rolling action plan (CoRAP) to be evaluated in 2024. Spain is the competent authority ('the evaluating MSCA') appointed to perform the evaluation.

In accordance with Article 45(4) of REACH, the evaluating MSCA performed its evaluation based on the information in the registration dossier(s) you submitted on the Substance and on other relevant and available information submitted.

The evaluating MSCA completed its evaluation considering that further information is necessary to clarify the following concerns: PBT/vPvB.

Therefore, it submitted a draft decision (Article 46(1) of REACH) to ECHA.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations (CROs).

Decision-making

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

ECHA received your comments and forwarded them to the evaluating MSCA.

In your comments on the draft decision, you highlight the difficulties in obtaining radiolabelled test materials and note that these may impact your ability to meet the deadline indicated in the draft decision. However, you have not specified the required extension of the deadline nor provided documentary evidence to support your claim. The evaluating MSCA took your comments into account and the request and deadline were not amended.

Appendix D: Requirements when conducting and reporting new tests for REACH purposes

1. Test methods, GLP requirements and reporting

1. Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.
2. Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.
3. Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[3].

2. Test material

2.1. Selection of the test material(s)

The test material(s) used to generate the new data must be selected taking into account the following:

- The boundary composition(s) of the Substance.
- The impact of each constituent/impurity on the test results for the endpoint to be assessed. For example, if a constituent/impurity of the Substance is known to have an impact on (eco)toxicity, the selected test material(s) must contain that constituent/impurity.

2.2. Information on the test material(s) needed in the updated dossier

You must report the composition of the test material(s) selected for each study, under the 'Test material information' section, for each respective endpoint study record in IUCLID. The reported composition must include all constituents of each test material and their concentration values and other parameters relevant for the property to be tested.

This information is needed to assess whether the test material(s) is relevant for the Substance.

Technical instructions on how to report the above is available in the manual "How to prepare registration and PPORD dossiers[4].

[3] https://echa.europa.eu/practical-guides
[4] https://echa.europa.eu/manuals