~~Confidential~~

Helsinki, 10 March 2022

Addressees
Registrant(s) of RECONSILE EC#278-947-6 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
17/05/2018

Registered substance subject to this decision ("the Substance")
Substance name: Trichloro(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silane
EC number: 278-947-6

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

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below, by the deadline of ***17 March 2023***.

Requested information must be generated using the Substance unless otherwise specified.

A. Information required from all the Registrants subject to Annex VII of REACH

1. Water solubility (Annex VII, Section 7.7.; test method: EU A.6./OECD TG 105/OECD GD 29)

2. Partition coefficient n-octanol/water (Annex VII, Section 7.8.; using an appropriate test method)

3. Ready biodegradability (Annex VII, Section 9.2.1.1.; test method: OECD TG 301A/B/C/D/E/F or OECD TG 310)

B. Information required from all the Registrants subject to Annex VIII of REACH

1. Hydrolysis as a function of pH (Annex VIII, Section 9.2.2.1.; test method: EU C.7./OECD TG 111)

Reasons for the request(s) are explained in the following appendices:

- Appendices entitled "Reasons to request information required under Annexes VII to VIII of REACH", respectively.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you, and in accordance with Articles 10(a) and 12(1) of REACH:

- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You must also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general testing and reporting requirements provided under the Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

Appeal

This decision, when adopted under Article 51 of REACH, 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[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

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

Appendix A: Reasons to request information required under Annex VII of REACH

1. Water solubility

Water solubility is a standard information requirement in Annex VII to REACH.

You have adapted this information requirement based on the Substance being hydrolytically unstable. In addition, you have provided a QSAR prediction for the proposed silanol hydrolysis product.

We have assessed this information and identified the following issue(s):

1. According to Annex VII, Section 7.7, Column 2, the study does not need to be conducted if the Substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours).

You have provided a hydrolysis study, which is rejected as explained under request B.1 of this decision. Therefore you cannot adapt the information requirement for water solubility based on information from the provided hydrolysis study, as it cannot serve as evidence of the Substance being hydrolytically ustable.

In the comments to the draft decision you reiterate your adaptation of the information requirement according to Annex VII, Section 7.7, Column 2. You indicate the following: "*the registrants agree to conduct the hydrolysis study. If the substance is demonstrated to have a half-life of <12 h at pH 4, 7 and 9, the water solubility endpoint can be waived in accordance with Column 2 of REACH Annex VII. Should this not be the case, a water solubility study according to OECD TG 105 will be attempted*". As indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

2. Assessment of your (Q)SAR adaptation

Annex XI, Section 1.3. specifies that the following conditions must be fulfilled whenever a (Q)SAR approach is used:

1. the prediction needs to be derived from a scientifically valid model,
2. the substance must fall within the applicability domain of the model,
3. results need to be adequate for the purpose of risk assessment or classification and labelling, and
4. adequate and reliable documentation of the method must be provided.

With regard to these conditions, we have identified the following issue(s):

You have provided a QSAR prediction for the proposed silanol hydrolysis product *[2-(perfluorohexyl)ethyl]silanetriol:* "HYDROLYSIS PRODUCT Water solubility 4.8.467 Peter Fisk Associates 2017".

The QPRF included the following statements: "*The descriptor values for the substance, except for nOH (defined range = 0-2; substance descriptor = 3), fall within the descriptor ranges defined in Section 5.1 of the QMRF."* And that "*An uncertainty of ±1.2 log units for the value of log (water solubility / mol/l) has been calculated using the regression statistics. The uncertainty may be greater for this substance..".* Furthermore, "*the precise values of the water solubility for these substances cannot be predicted with confidence but a qualitative statement (highly soluble, moderately soluble, low solubility) can be made."*

Therefore, the provided information indicates that structure used as input for the prediction falls outside applicability domain as defined by the model developer and a safe hazard conclusion is not possible due to uncertainty of the results. The conditions of Annex X Section 1.3 are not met.

On this basis, your adaptation is rejected and the information requirement is not fulfilled.

2. Partition coefficient n-octanol/water

Partition coefficient n-octanol/water is a standard information requirement in Annex VII to REACH.

You have adapted this information requirement based on the statements of "*the study does not need to be conducted because the substance decomposes*" and "*In contact with water, the substance undergoes very rapid hydrolysis*".

We have assessed this information and identified the following issue(s):

Annex VII, Section 7.8, Column 2 states that the test does not need to be conducted if the study cannot be performed since the substance decomposes. In such a case a calculated value for partition coefficient as well as details of the calculation must be provided. Results derived from a (Q)SAR constitute a calculated value, if the requirements under Annex XI, Section 1.3 are fulfilled:

1. the prediction needs to be derived from a scientifically valid model,
2. the substance must fall within the applicability domain of the model,
3. results need to be adequate for the purpose of risk assessment or classification and labelling, and
4. adequate and reliable documentation of the method must be provided.

In case of rapid hydrolysis the registrant needs to provide evidence in the form of a hydrolysis endpoint study record (study summary) and should consider testing for the hydrolysis products instead, as information on the properties of (environmentally and toxicologically) relevant degradation products are needed for conducting the risk assessment of the substance to be registered (ECHA Guidance R.7a).

You have provided information on hydrolysis in your dossier. As explained under request B.1 below, the information provided in your dossier for hydrolysis is rejected, and cannot therefore be used to adapt the information requirement for partition coefficient. Therefore, there is no evidence provided that the test on partition coefficient cannot be performed due to the Substance decomposing.

In addition, instead of providing a calculated value for partition coefficient for the Substance as well as details of the calculation, you have provided a QSAR prediction (a calculation) for the proposed silanol hydrolysis product *[2-(perfluorohexyl)ethyl]silanetriol:* KEY HYDROLYSIS PRODUCT Partition coefficient 4.7.7024 Peter Fisk Associates 2017.

In the (Q)SAR prediction reporting format (QPRF) attached to the endpoint regarding the applicability domain you identify that "*The current compound contains 13 fluorine atoms; this is higher than the maximum number in the training set, which may increase the uncertainty in the prediction".*

Therefore, the provided information indicates that the structure used as input for the prediction falls outside applicability domain as defined by the model developer and a safe hazard conclusion is not possible due to uncertainty of the results.

In the comments to the draft decision you reiterate your adaptation of the information requirement according to Annex VII, Section 7.8, Column 2. You indicate the following: "*the registrants agree to conduct the hydrolysis study. If the substance is demonstrated to decompose rapidly in contact with water, the partition coefficient endpoint can be waived in accordance with Column 2 of REACH Annex VII. A partition coefficient study using an HPLC method will be attempted if the results of the hydrolysis study suggest that this may be technically feasible*".

As indicated in your comments, this strategy relies essentially on data which is yet to be generated, therefore no conclusion on the compliance can currently be made. You remain responsible for complying with this decision by the set deadline.

Furthermore, in the comments to the draft decision you have also provided the following information on the partition coefficient of the proposed silanol hydrolysis product:

1. You have sought to adapt this information requirement according to Annex VII, Section 7.8, Column 2. You justified your approach based on the fact that the study does not need to be conducted because the silanol hydrolysis product of the Substance has a high surface activity. In this context you refer to a read-across approach (i.e. Annex XI, Section 1.5 of REACH) on the surface activity enpoint in which you consider an existing surface activity study on the analogue substance (i.e. trimethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl) silane (CAS 85857-16-5, EC 288-657-1) that is already included in the registration dossier. You have provided the following reasoning: "*A partition coefficient study with the silanol hydrolysis product is also not required in accordance with Column 2 of REACH Annex VII; the study is considered to be not technically feasible because the substance has a high surface activity (surface tension <22 mN/m at 20°C). The conclusion on surface activity is based on an OECD 115 study with the analogue substance trimethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silane (CAS 85857-16-5, EC 288-657-1). The analogue substance produces the same silanol hydrolysis product as the target substance with a half-life of 0.4 h at pH 4, 8.8 h at pH 7, 0.1 h at pH 9 and 20-25°C. The surface tension study was conducted with a solution aged for 43 h (approximately 5 half-lives); therefore, the result represents the surface tension of the common hydrolysis product*".

2. Regarding the QSAR prediction on the partitioning coefficient for the proposed silanol hydrolysis product addressed above, in your comments on the draft decision you have provided new information on the model prediction. You indicate the following: "*The external validation dataset for KOWWIN contains eight substances with 7 to 23 aliphatic fluorines. The errors (difference between predicted and measured values) for these substances are in the range -0.4 to 0.7 with a root-mean-square error of 0.3. The correlation coefficient and standard error of a regression of estimated log KOW against measured log KOW for these eight analogues are 0.98 and 0.31, respectively, compared to 0.98 and 0.22 for the training set. This indicates that the QSAR is performing reasonably well for substances with more than six aliphatic fluorines. Therefore, given the technical unfeasibility of conducting tests, it is considered appropriate to use the KOWWIN QSAR to predict the log KOW of the parent and/or the silanol hydrolysis product*". You also indicate the registration dossier will be updated by including QPRF document.

We have assessed this information provided in the comments to the draft decision and identified the following issues:

1. Regarding the Column 2 adaptation, Annex VII Section 7.8. for the proposed silanol hydrolysis product

Annex VII, Section 7.8, Column 2 states that the test does not need to be conducted if the study cannot be performed since the substance is surface active. In such a case a calculated value for partition coefficient as well as details of the calculation must be provided.

You consider that the study does not need to be conducted because the silanol hydrolysis product of the Substance has a high surface activity based on read-across.

As explained under Section B.1. there is currently no reliable information on hydrolysis properties of the Substance, therefore you have not provided any evidence that could show a rapid hydrolys and/or the hydrolysis products identified during the study (i.e. Silanol hydrolysis product).

Furthermore, there is currently no reliable information on the surface activity properties of the proposed silanol hydrolysis product due to the following:

Annex XI, Section 1.5 requires that whenever read-across is used adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the study(ies) on the source substance(s) (Guidance on IRs and CSA, Section R.6.2.6.1.).

You have provided a robust study summary for the surface activity study conducted with another substance(s) than the Substance in order to comply with the REACH information requirement. However, you have not provided documentation as to why this information is relevant for the Substance.

In the absence of such documentation, the surface activity properties of the Substance cannot be reliably predicted from the data on the source substance(s).

As a consequence, there is no evidence provided that the test on partition coefficient cannot be performed due to hydrolysis product being surface active.

2. Regarding the QSAR prediction on the proposed silanol hydrolysis product

ECHA considers the maximum number of instances of fragments in the training set as the applicability domain boundaries for EPISuite models. Nonetheless, ECHA acknowledges your analysis of the performance of the model on substances with a high number of aliphatic fluorines from the external validation dataset of KOWWIN. This analysis shows that the EPISuite prediction for the proposed silanol hydrolysis product is plausible despite being outside of the applicability domain. However, as this additional information is currently not available in your dossier, the incompliance identified in this decision remains. Therefore, you need to submit this information in an updated registration dossier.

Regarding your comments on a possible update of the registration dossier, please note that this decision does not consider updates of the registration dossiers after the date on which you were notified of the draft decision according to Article 50(1) of REACH (see section 5.4. of ECHA's Practical Guide "How to act in Dossier Evaluation). You remain responsible for complying with this decision by the set deadline.

On this basis, your adaptation is rejected and the information requirement is not fulfilled.

Selection of test method

Guidance for determining appropriate test methods for the partition coefficient n-octanol/water is available in the ECHA Guidance on information requirements and chemical safety assessment R.7a, chapter R.7.1.8 (version 6.0, July 2017).

3. Ready biodegradability

Ready biodegradability is an information requirement in Annex VII to REACH (Section 9.2.1.1.).

You have adapted this information requirement by using a Grouping of substances and read-across approach and provided the following information:

(i) '*Ready Biodegradability Test of Dynasylan F8261 (Study No. [redacted])*', according to OECD TG 301C, conducted with the substance [2-(Perfluorohexyl)ethyl]triethoxysilane, EC No. 257-473-3);

(ii) '*Determination of the biodegradability of Dynsylan F8261 using the modified Sturm test (EC guideline 92/69 EEC C.4-C)*', according to EU Method C.4-C, conducted with the substance [2-(Perfluorohexyl)ethyl]triethoxysilane, EC No. 257-473-3).

We have assessed this information and identified the following issue(s):

Grouping of substances and read-across approach

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[2,3].

Scope of the grouping

In your registration dossier you have formed a large group (category) of Reconsile siloxane and silane substances. You have provided several read-across justification documents in IUCLID Section 13 as well as endpoint specific justifications within the respective endpoint sections of IUCLID and the CSR.

You have indicated that the Substance belongs to the group of III-17 Highly fluorinated chains, "*a chemical group with some known effects from non-Si chemistry and (eco)toxicology*."
For this information requirement, you define the structural basis for the grouping in the document "*Biodegradation: Main analogue group*" as: "*organosilicon substance that are themselves, or that hydrolyse to, organosilicon compounds without reactive functional groups in the side chain*". You list all substances belonging to analogue groups I-1 to III-23 in this grouping for biodegradation but in the endpoint summary you refer to data only within the sub-class III-17 of highly fluorinated chains. ECHA understands that the sub-class III-17, as described in the Appendix on Reason common to several requests, is the applicability domain of the grouping and will assess your predictions on this basis.

[2] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)
[3] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

Prediction for biodegradation

For this endpoint, you use data on a source substance which belongs to the above mentioned grouping: [2-(perfluorohexyl)ethyl]triethoxysilane (EC No. 257-473-3; CAS No 51851-37-7).

You provide the following reasoning for the prediction of this information requirement: "*In contact with water, [2-(perfluorohexyl)ethyl]trichlorosilane (CAS No: 78560-45-9) hydrolyses very rapidly to form [2-(perfluorohexyl)ethyl]silanetriol and hydrochloric acid. The hydrolysis products of [2-(perfluorohexyl)ethyl]triethoxysilane are [2-(perfluorohexyl)ethyl]silanetriol and ethanol.*

Ethanol is readily biodegradable (OECD 2004b).

Hydrochloric acid is inorganic and biodegradation is therefore not relevant.".

ECHA understands that you predict the properties of the Substance using a read-across hypothesis which is based on the formation of common hydrolysis products. The properties of your Substance are predicted to be quantitatively equal to those of the source substance.

We have assessed this information and identified the following issues with regards to the prediction of biodegradation:

Supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*" (Guidance on IRs and CSA, Section R.6.2.2.1.f.). The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on other category members.

Supporting information must include information on the formation of the common compound.

As indicated above, your read-across hypothesis is based on hydrolysis of the category members to a common compound(s). In this context, information characterising the rate and extent of the hydrolysis of the category members is necessary to confirm the formation of the proposed common hydrolysis product and to assess the impact of the parent compounds on the prediction.

You have provided hydrolysis data for the source substance. However, you have not provided any experimental information about the hydrolysis of the Substance to support your claims regarding formation of a common compound. To characterise the hydrolysis rate of the Substance, you have provided information on other source substances in the Reconsile siloxane and silane substances category. As described below in request B.1, this read-across is rejected.

Furthermore, the ready biodegradation studies are performed with presence of activated sludge or other source of inoculum (up to 30 mg suspended solids/L). You have not explained or provided supporting documentation why the presence of the inoculum in the test media would not influence the claimed hydrolysis rates, as compared to hydrolysis investigated in a OECD TG 111 study (as provided for the source substance EC No. 257-473-3).

In the absence of this information, you have not provided supporting evidence establishing that the proposed common hydrolysis product is formed, and what is the rate of formation of the common hydrolysis product in the relevant media for the endpoint. Therefore, you have not provided sufficient supporting information to strengthen the rationale for the read-across.

On this basis, you have not established that relevant properties of the Substance can be predicted from data on the source substance. Therefore, your read-across approach under Annex XI, Section 1.5. is rejected and the information requirement is not fulfilled.

In the comments to the draft decision, you agree to perform the requested study.

You also indicate the following: "*the registrants believe that the approach of reading across not readily biodegradable and concluding that the silanol hydrolysis product may be vP is conservative and justified by the available data. The available evidence for organosilicon compounds indicates that very little or no biodegradation is observed for the silane part of the molecule in standard studies (some degradation may be observed for certain organic side-chains). The persistence of highly fluorinated compounds is well known. Therefore, it is considered highly unlikely that either the silane (trichlorosilane for the parent or trisilanol for the hydrolysis product) or organic (tridecafluorooctyl) parts of the molecule will biodegrade under the conditions of OECD 301 or OECD 310".*

You refer to "expectations" but you do not provide specific information addressing the issues identified above. Therefore, your comments do not change the assessment outcome.

On this basis, the information requirement is not fulfilled.

Appendix B: Reasons to request information required under Annex VIII of REACH

1. Hydrolysis as a function of pH

Hydrolysis as a function of pH is an information requirement in Annex VIII to REACH (Section 9.2.2.1.).

You have adapted this information requirement by using a Grouping of substances and read-across approach and provided the following endpoint study records:

i. Key study "*R-A Hydrolysis* [redacted] *2001*", according to OECD TG 111, performed with the substance trichloro(methyl)silane EC 200-902-6, CAS 75-79-6
ii. Supporting study "*R-A Hydrolysis* [redacted] *2001*") which is "conducted according to a test protocol that is comparable to the appropriate OECD test guideline method", performed with the substance dichloro(methyl)(3,3,3-trifluoropropyl)silane EC 211-623-4, CAS 675-62-7
iii. Supporting study "R-A Hydrolysis [redacted] 2015", a non guideline study performed with the substance Trichloro(2,4,4-trimethylpentyl)silane EC 242-262-0, CAS 18379-25-4
iv. Supporting study "R-A Hydrolysis.[redacted] 2001", which is "conducted according to a test protocol that is comparable to the appropriate OECD test guideline method", performed with substance Dichloro(diphenyl)silane EC 201-251-0, CAS 80-10-4
v. Supporting study "R-A Hydrolysis [redacted] 2001", according to "a test protocol that is comparable to the appropriate OECD test guideline method", performed with substance dichloro(dimethyl)silane / EC 200-901-0, CAS 75-78-5.

In addition, you have provided ESRs for the following four studies which you do not intend to use as studies to fulfil the hydrolysis information requirement, but that provide "*The hydrolysis half-life of substances used for read-across in other areas*" (p. 40 CSR).

- Supporting study, "R-A Hydrolysis [redacted] 2014-copy(1)" a QSAR prediction on analogue substance [2-(Perfluorohexyl)ethyl]trimethoxysilane; trimethoxy(3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl)silane EC 288-657-1, CAS 85857-16-5 (a source substance for surface activity)
- Supporting study "R-A Vapour stability in air Hydrolysis [redacted] 2009" a non standard study on analogue substance dichloro(dimethyl)silane EC 200-901-0, CAS 75-78-5 (hydrolysis in air indicated by you as relevant for inhalation exposure assessment)
- Supporting study "R-A Nose-only vapour inhalation Hydrolysis [redacted] 2013" on analogue substance dichloro(dimethyl)silane EC 200-901-0, CAS 75-78-5 (stability study under conditions typical of nose-only vapour inhalation exposures)
- Supporting study "R-A Hydrolysis [redacted] 2016" an OECD 111 study on analogue substance [2-(Perfluorohexyl)ethyl]triethoxysilane EC 257-473-3, CAS 51851-37-7 (a source substance for aquatic toxicity and ready biodegradation)

This information has not been assessed under this endpoint as based on the information provided in your dossier and the CSR you do not intend to use these studies to fulfil this information requirement.

We have assessed the information provided (i-v) and identified the following issue(s):

Grouping of substances and read-across approach

Annex XI, Section 1.5. specifies two conditions which must be fulfilled whenever a read-across approach is used. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6. and related documents[4,5].

Scope of the grouping

In your registration dossier you have formed a large group (category) of Reconsile siloxane and silane substances. You have provided several read-across justification documents in IUCLID Section 13 as well as endpoint specific justifications within the respective endpoint sections of IUCLID and the CSR.

You have indicated that the Substance belongs to the group of III-17 Highly fluorinated chains, "*a chemical group with some known effects from non-Si chemistry and (eco)toxicology*."

However, for this information requirement you define the structural basis for the grouping as chlorosilanes which includes also substances outside the group of III-17. In the document 'Reconsile Category/Analogue/QSAR strategy', you specify the chlorosilanes as: "*Substances with the general formula Cl(4-x)SiRx where R can be hydrogen (-H) or an organic group*". ECHA understands that this is the applicability domain of the grouping and will assess your predictions on this basis.

Prediction for hydrolysis

In the endpoint summary you provide hydrolysis data for five source substances as described above (i-v).

You provide the following reasoning for the prediction of this information requirement: "*In establishing the proposed read-across, the effects of the side-chains on the reaction rate were considered in the light of the available data and likely reaction mechanisms*" and conclude that "*Given the very rapid hydrolysis rates in water (≤17 seconds at 1.5°C and pH 4, 7 and 9) observed for all tested chlorosilanes, and the lack of significant variation in the half-lives for the different substances, it is considered appropriate to read-across this result to [2-(perfluorohexyl)ethyl]trichlorosilane".*

ECHA understands that you predict the properties of the Substance using a read-across hypothesis where the properties of your Substance are predicted to be quantitatively equal to those of the source substances.

We have assessed this information and identified the following issues with regards to the prediction of hydrolysis:

[4] Read-Across Assessment Framework (RAAF). 2017 (March) ECHA, Helsinki. 60 pp. Available online: Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across)

[5] Read-across assessment framework (RAAF) - considerations on multi-constituent substances and UVCBs. 2017 (March) ECHA, Helsinki. 40 pp. Available online: https://doi.org/10.2823/794394

Supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*" (Guidance on IRs and CSA, Section R.6.2.2.1.f.). The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on other category members.

As indicated above, your read-across hypothesis assumes that the rapid hydrolysis of chlorosilanes is not influenced by the side-chain of the category members. You have provided information on hydrolysis rates for several chlorosilane substances. The set of substances includes many chlorosilanes which differ largely in structure by the side-chains. The provided information indicates fast hydrolysis of the category members.

To assess the potential influence of the perfluorination on hydrolysis rates, you have provided hydrolysis data for one fluorinated chlorosilane: Dichloromethyl(3,3,3-trifluoropropyl) silane (CAS 675-62-7). This source substance includes only one perfluorinated carbon (molecular weight 211.09) while the Substance has much higher perfluorinated carbon chain length (C6, molecular weight 481.54). You have not provided information on substances that would have longer (fluorinated) carbon chain than that of the Substance.

Regarding the identity of the hydrolysis products, you state that "*The hydrolysis products are [2-(perfluorohexyl)ethyl]silanetriol and hydrochloric acid*". You have not provided any justification or evidence for this claim.

While the rapid hydrolysis rates for the substances support your hypothesis claiming that the side-chain does not influence hydrolysis rates, the structural variability of the substances is too large to substantiate that the large perfluorinated side chain in the Substance would not affect the hydrolysis rates.

Therefore, you have not provided evidence that higher perfluorinated carbon chain would not influence hydrolysis rates. Furthermore, you have not documented why the hydrolysis products are [2-(perfluorohexyl)ethyl]silanetriol and hydrochloric acid.

In the absence of such information, you have not established that the category members are likely to have similar properties. Therefore you have not provided sufficient supporting information to strengthen the rationale for the read-across.

On this basis, you have not established that relevant properties of the Substance can be predicted from data on the source substance. Therefore, your read-across approach under Annex XI, Section 1.5. is rejected and the information requirement is not fulfilled.

In the comments to the draft decision, you agree to perform the requested study.

You also indicate that *"due to the predicted very rapid hydrolysis, it is not expected that a full guideline study can be conducted".* However, as the information is currently not available in your registration dossier, you have not provided any evidence that could show a rapid hydrolysis.

On this basis the information requirement is not fulfilled.

Appendix C: Requirements to fulfil when conducting and reporting new tests for REACH purposes

A. 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[6].

B. Test material

1. Selection of the Test material(s)

   The Test Material 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 must contain that constituent/ impurity.

2. Information on the Test Material needed in the updated dossier
   - You must report the composition of the Test Material 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 is relevant for the Substance.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[7].

[6] https://echa.europa.eu/practical-guides
[7] https://echa.europa.eu/manuals

Appendix D: Procedure

You submitted a testing proposal for a soil simulation study (Annex IX, 9.2.1.3., with an analogue substance), however this testing proposal is on hold pending the receipt of the data requested in this decision. This is because the results of the studies requested are required to assess the need for the soil simulation testing (triggered by Annex VIII, Section 9.2).

This decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 01/02/2021.

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

ECHA took into account your comments and did not amend the request(s).

Deadline to submit the requested information in this decision

In the draft decision communicated to you, the time indicated to provide the requested information was 6 months from the date of adoption of the decision.

In your comments on the draft decision, you requested ECHA to extend the standard granted time to a total of 12 months. Your request was based on the proposal of a step-wise approach, where you intend to conduct the requested hydrolysis as a function of pH test (Appendix B, section B.1) before conducting the other requested physico-chemical studies (i.e. Appendix A, A.1. water solubility and A.2. partition coefficient).

You justified your request stating that a total of 12 months are needed to conduct first the hydrolysis study, and then based on the results of the hydrolysis study develop the best approach to conduct the water solubility and the partition coefficient studies.

ECHA agrees that physico-chemicals studies can be performed subsequent to the hydrolysis test, in order to determine whether they are technically feasible with the Substance and/or whether it is more relevant to test the hydrolysis products. ECHA took this information into account and granted 6 months extension to the original deadline.

On this basis, ECHA has extended the deadline to 12 months.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix E: List of references - ECHA Guidance[8] and other supporting documents

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 where relevant.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 where relevant.

Read-across assessment framework (RAAF, March 2017)[9]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[10]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

Data sharing
Guidance on data-sharing (version 3.1, January 2017), referred to as ECHA Guidance on data sharing in this decision.

OECD Guidance documents[11]

[8] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[9] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[10] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[11] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Guidance Document on aqueous–phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD 23.

Guidance document on transformation/dissolution of metals and metal compounds in aqueous media – No 29, referred to as OECD GD 29.

Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption – No 150, referred to as OECD GD 150.

Guidance Document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test – No 151, referred to as OECD GD 151.

Appendix F: Addressees of this decision and their corresponding information requirements

You must provide the information requested in this decision for all REACH Annexes applicable to you.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.