~~Confidential~~

Helsinki, 05 May 2022

Addressees
Registrant of JS_93925-42-9 as listed in the last Appendix of this decision

Date of submission of the dossier subject to this decision
22/09/2020

Registered substance subject to this decision ("the Substance")
Substance name: Silicic acid (H4SiO4), tetraethyl ester, reaction products with bis(acetyloxy)dibutylstannane
EC number: 300-344-4

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 in B.2 below by the deadline of ***14 November 2022*** and all other information listed below, by the deadline of ***13 November 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. Long-term toxicity testing on aquatic invertebrates (triggered by Annex VII, Section 9.1.1., column 2; test method: EU C.20./OECD TG 211)– as further described in Appendix A

2. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: EU C.3./OECD TG 201)

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

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

1. Long-term toxicity testing on fish (triggered by Annex VIII, Section 9.1.3., column 2; test method: OECD TG 210) – as further described in Appendix B

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

3. Soil simulation testing (triggered by Annex VIII, Section 9.2.; test method: EU C.23./OECD TG 307) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided. – as further described in Appendix B

4. Sediment simulation testing (triggered by Annex VIII, Section 9.2.; test method: EU C.24./OECD TG 308) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and

solvents must be provided. – as further described in Appendix B

5. Identification of degradation products (triggered by Annex VIII, Section 9.2; test method: using an appropriate test method)– as further described in Appendix B

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 to REACH, for registration at 1-10 tpa;
- 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". In addition, you should follow the general recommendations provided under the Appendix entitled "General recommendations when conducting and reporting new tests for REACH purposes". For references used in this decision, please consult the Appendix entitled "List of references".

The studies relating to biodegradation are necessary for the PBT assessment. However, to determine the testing needed to reach the conclusion on the persistency of the Substance you should consider the sequence in which these tests are performed and other conditions described in Appendix entitled "Requirements to fulfil when conducting and reporting new tests for REACH purposes".

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. Long-term toxicity testing on aquatic invertebrates

Short-term toxicity testing on aquatic invertebrates is an information requirement under Annex VII to REACH (Section 9.1.1.). Long-term toxicity testing on aquatic invertebrates must be considered (Section 9.1.1., Column 2) if the substance is poorly water soluble.

You have provided a short-term toxicity testing on aquatic invertebrates study (OECD TG 202) but no information on long-term toxicity on aquatic invertebrates for the Substance.

We have assessed this information and identified the following issue:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7.8.5).

In your dossier you report that, based on CHESAR, the water solubility of the Substance is 1µ/L.

Therefore, the Substance is poorly water soluble and information on long-term toxicity on aquatic invertebrates must be provided.

In the comments to the draft decision, you submitted information regarding the water solubility of the Substance that is relevant to the current request. You put forward a series of considerations in support to your claim that the water solubility of the Substance is not below 1 mg/L.

ECHA has considered the information from your comments and agrees that the water solubility cannot be further clarified and can be considered as above the threshold value of 1 mg/L.

In the event of a dossier update providing corrected water solubility (i.e. ≥ 1mg/L) to which you refer in your comments, the trigger for requesting long-term toxicity testing on invertebrates would become inapplicable, as the Substance could not be regarded as poorly water soluble.

However, as the new information regarding water solubility is currently not available in your registration dossier, the request cannot be currently removed.

You should therefore submit the corrected water solubility information in place of conducting long-term toxicity study on aquatic invertebrates in an updated registration dossier by the deadline set out in the decision.

Finally, in line with your comments to the draft decision, ECHA notes that the reliability of the short-term toxicity studies are not addressed in this decision. In light of the data reported in your dossier at the time this decision was drafted and sent to you for commenting, short-term toxicity studies were not considered relevant to be addressed.

Study design

The Substance is difficult to test due to the low water solubility (1 µg/L), adsorptive properties (log kow 6.7) and potentially quickly hydrolysable. OECD TG 211 specifies that, for difficult

to test substances, you must consider the approach described in OECD GD 23 or other approaches, if more appropriate for your substance. In all cases, the approach selected must be justified and documented. Due to the properties of Substance, it may be difficult to achieve and maintain the desired exposure concentrations. Therefore, you must monitor the test concentration(s) of the Substance, or relevant transformation products where appropriate, throughout the exposure duration and report the results. If it is not possible to demonstrate the stability of exposure concentrations (i.e. measured concentration(s) not within 80-120% of the nominal concentration(s)), you must express the effect concentration based on measured values as described in OECD TG 211. In case a dose-response relationship cannot be established (no observed effects), you must demonstrate that the approach used to prepare test solutions was adequate to maximise the concentration of the Substance in the test solutions.

For multi-constituents/UVCBs, the analytical method must be adequate to monitor qualitative and quantitative changes in exposure to the dissolved fraction of the test material during the test (e.g. by comparing mass spectral full-scan GC or HPLC chromatogram peak areas or by using targeted measures of key constituents or groups of constituents).

If you decide to use the Water Accommodated Fraction (WAF) approach, in addition to the above, you must:

- use loading rates that are sufficiently low to be in the solubility range of most constituents (or that are consistent with the PEC value). This condition is mandatory to provide relevant information for the hazard and risk assessment (ECHA Guidance, Appendix R.7.8.1-1, Table R.7.8-3);
- provide a full description of the method used to prepare the WAF (including, among others, loading rates, details on the mixing procedure, method to separate any remaining non-dissolved test material including a justification for the separation technique);
- prepare WAFs separately for each dose level (i.e. loading rate) and in a consistent manner.

2. Growth inhibition study aquatic plants

Growth inhibition study aquatic plants is an information requirement under Annex VII to REACH (Section 9.1.2.).

You have provided the following information:

i. OECD TG 201 key study ([redacted] 2011) with the Substance
ii. Supporting study following no test guideline ([redacted] 1985) with "*tin compounds*"

We have assessed this information and identified the following issues:

A. Study (i) with the Substance

To fulfil the information requirement, a study must comply with OECD TG 201 and the requirements of OECD GD 23 (ENV/JM/MONO(2000)6/REV1) if the substance is difficult to test (Article 13(3) of REACH). Therefore, the following specifications must be met:

Characterisation of exposure

- a reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of determination (*i.e.* detection and quantification) and working range must be available. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;

- the test media prepared specifically for analysis of exposure concentrations during the test is treated identically to those used for testing (*i.e.* inoculated with algae and incubated under identical conditions);

Additional requirements applicable to difficult to test substances
Test solutions preparation methods

- test materials are tested at concentrations below their saturation concentrations in the test medium;
- if the test material is tested at the saturation concentration, evidence must be provided that all reasonable efforts have been taken to achieve a saturation concentration, which include:
  1) an analytical method validation report demonstrating that the analytical method is appropriate, and
  2) information on the saturation concentrations of the test material in water and in the test solution, and
  3) the results of a preliminary experiment demonstrating that the test solution preparation method is adequate to maximize the concentration of the test material in solution;

Analytical verification of exposure

- for UVCBs, it must be demonstrated that concentrations were consistently maintained within 80-120% of the initial or mean measured values over the exposure duration. Preferably, the demonstration should be based on a comparison of the mass spectral full-scan GC or HPLC chromatogram peak area. A justification shall be provided if other method is used, demonstrating its applicability.

Your registration dossier provides an OECD TG 201 key study (i) showing the following:

Characterisation of exposure

- you have used the total organic carbon (TOC) method for analytical monitoring of exposure concentrations however you have not reported the method specifications;
- the test media prepared specifically for analysis of exposure concentrations was not inoculated with algae;

Additional requirements applicable to difficult to test substances
Test solutions preparation methods

- Nominal loading rates at which test was conducted ranged from 1 mg/L to 320 mg/L. You have reported a water solubility of 1µ/L.
- the test material was tested above reported water solubility and no evidence was provided demonstrating that:
  1) the analytical method used is appropriate; and
  2) saturation concentration of the test material in the test solution was determined; and
  3) the test solution preparation method used is adequate to maximize the concentration of the test material in solution

Analytical verification of exposure

- no evidence that concentrations were consistently maintained within 80-120% of the initial or mean measured values over the exposure duration was provided

Based on the above, there are critical methodological deficiencies resulting in the rejection of the key study (i) results. More specifically, regarding:

- Characterization of exposure: you have used the total organic carbon (TOC) method for analytical monitoring of exposure concentrations with samples from

test media that were not inoculated with algae. The performed analysis of exposure concentrations was not carried out at the same conditions of the test therefore it is not considered representative. Furthermore, TOC is considered as a nonspecific method with low sensitivity (i.e. above reported water solubility of the Substance) and you have not justified why specific analysis, such as by GC or HPLC as recommended in OECD GD 23, are not suitable for the Substance.

- Test solution preparation: you have neither specified presence of micelles or undissolved material nor determined the saturation limit of the Substance in test solution. Also, you have provided no justification on the adequacy of the analytical method and on test solution preparation method. The test material was tested at concentrations above the water solubility, but you have provided no evidence that all reasonable efforts have been taken to achieve a saturation concentration.
- Analytical verification of exposure: due to limitations described above, you have not demonstrated that the TOC measurements relate do dissolved material only. You have not demonstrated that the exposure concentrations were achieved and maintained within 80-120 % of the nominal loading concentration throughout the test, hence you have not justified the reporting of effect values based on nominal loading rates. On this basis, it is not possible to conclude to what extent the algae were exposed to the test material and whether the observed effects were due to intrinsic properties of the Substance.

Therefore, the requirements of OECD TG 201 are not met.

B. Study (ii) with "*tin compounds*"

Your registration dossier provides a supporting study (ii) following no test guideline, reporting algal inhibition based on three different methods (including cell adaptation) with organotin compounds.

You report the test material to be [redacted] and you also refer to [redacted] compounds. Therefore, it is clear that the studies were not performed with the Substance.

While you have not identified this information as a read-across approach, the test material used is different than the Substance and therefore ECHA understands that with study (ii) you seek to adapt the information requirements using a read-across adaptation under Annex XI, Section 1.5 of REACH.

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.

A. Predictions for ecotoxicological properties

ECHA notes the following deficiencies with regards to the prediction of ecotoxicological properties:

i) Absence of read-across documentation

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 source study(ies).[2]

You have provided studies conducted with other substances than your Substance in order to comply with the REACH information requirement. You have not provided documentation as to why this information is relevant for your Substance.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substance(s).

ii) *Adequacy and reliability of source studies*

Under Annex XI, Section 1.5., the results to be read across must have an adequate and reliable coverage of the key parameters specified in the corresponding test method referred to in Article 13(3), in this case the OECD TG 201 . Therefore, the following specifications must be met:

- Key parameter to be measured: the concentrations of the test material leading to a 50 % and 0% (or 10%) inhibition of growth at the end of the test are estimated. Growth must be expressed as the logarithmic increase in biomass (average specific growth rate) during the exposure period;

Technical specifications impacting the sensitivity/reliability of the test

- culture conditions allow full expression of the system response to toxic effects (optimal sensitivity), by provision of unrestricted exponential growth under nutrient sufficient conditions and continuous light;
- If species other than the recommended by OECD TG 201 are used, it should be confirmed that exponential growth of the selected test algae can be maintained throughout the test period under test conditions;

Reporting of the methodology and results

- the results of algal biomass determined in each flask at least daily during the test period are reported in a tabular form;

Validity criteria

- exponential growth in the control cultures is observed over the entire duration of the test;
- at least 16-fold increase in biomass is observed in the control cultures by the end of the test;
- the mean coefficient of variation for section-by-section specific growth rates (days 0-1, 1-2 and 2-3, for 72-hour tests) in the control cultures is ≤ 35%;
- the coefficient of variation of average specific growth rates during the whole test period in replicate control cultures is ≤ 7% in tests with [*Pseudokirchneriella subcapitata* / *Desmodesmus subspicatus*]. For other less frequently tested species, the value is ≤ 10%;

Characterisation of exposure

- a reliable analytical method for the quantification of the test material in the test solutions with reported specificity, recovery efficiency, precision, limits of

[2] ECHA guidance Chapter R.6, Section R.6.2.6.1

determination (*i.e.* detection and quantification) and working range must be available. Alternatively, a justification why the analytical monitoring of exposure concentrations is not technically feasible must be provided;

Your registration dossier provides study (ii), which is composed of 3 experiments: 1) a test of algal population growth to different concentrations of toxicant; 2) a test to estimate lethal concentrations of organotins; and 3) a test to learn if organisms could adapt to TPTO and TBTO (i.e. [redacted] compounds). The test design specifications of the experiments show the following deficiencies:

Key parameter to be measured

- for experiment (2), EC50 and LC50 were calculated by extrapolation, based on the percentage of dead cells in each concentration of the test material. For experiment (3), you have not reported effect values;

Technical specifications impacting the sensitivity/reliability of the test

- the lighting cycle was 14 h light: 10 h darkness in all experiments;
- you have used algae species not listed under recommended test species and you have not provided information regarding their growth under test conditions;

Reporting of the methodology and results

- tabulated data on the algal biomass determined daily for each treatment group and control are not reported;

Validity criteria

- you have provided no supporting data nor indication that validity criteria were fulfilled, instead you claim 'limited details of methodology';

Characterisation of exposure

- you have performed analysis of test concentration based on elemental tin only, without providing performance parameter nor correlation between measured concentrations and substance concentration.

ECHA has assessed the provided information on study (ii) and has identified the following major deficiencies:

- Key parameter to be measured: Effect concentrations of experiment 2 are extrapolated based on cell mortality rather than based on biomass, as per OECD TG 201 recommendation. While you have considered mortality caused by the Substance you have not consider the growth inhibition as a clear correlation to control cultures over exposure time is not reported. Regarding experiment 3, no effect values were reported as the experiment seems to have been performed only to assess the behaviour of cultures pre-adapted to toxicants, therefore, ECHA understands that you have disregarded the experiment results.
- Technical specifications impacting the sensitivity/reliability of the test: As continuous light cycle was not used, growth suffered restrictions that may have impacted the sensitivity of all experiments. Furthermore, you have performed all experiments with non-standard species. As no information regarding growth conditions was provided and in experiment 3 the test substance was added after 48h growth, it is not clear what was the biomass at the time of exposure nor if it could have impacted the sensitivity of the test (e.g. nutrient limitation or relative test concentration).
- Reporting of the methodology and results and validity criteria: A robust study summary allowing independent assessment of study validity was not provided for

all experiments. In the absence of biomass data, in particular for the control cultures, it is not possible to assess the validity of any of the reported experiments.
- Characterisation of exposure: The analytical data used for derivation of effect values is claimed to be a measurement of elemental tin and it is not clear if data extrapolation, considering relative content of tin in the substance structure, was performed therefore, it is not clear how does the reported effect value relates to the toxicological properties of the test substance.

Therefore, the study (ii) does not provide an adequate and reliable coverage of the key parameters specified in OECD TG 201 and it is not considered adequate to predict the properties of the Substance.

B. Conclusions on the read-across approach

As explained above, you have not established that relevant properties of the Substance can be predicted from data on the analogue substance. Therefore, your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

On this basis, the information requirement is not fulfilled.

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

Study design

OECD TG 201 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix [A.1].

3. Ready biodegradability

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

You have provided the following justification to omit the study: "*the study does not need to be conducted because the substance is inorganic metal organic substance*".
ECHA understands that you have adapted this information requirement under Annex VII, Section 9.2.1.1, column 2.

We have assessed this information and identified the following issue:

Under Section 9.2.1.1., Column 2, Annex VII to REACH, the study may be omitted if the substance is inorganic (i.e. does not contain carbon). Ready biodegradability study is a screening test for persistency assessment where the test substance is provided as the sole source of carbon for energy and growth. As inorganic substances may not normally degrade biotically, biodegradability studies are therefore not required for inorganic substances (ECHA Guidance R.7b Section R.7.9).

You have identified the Substance as 'inorganic metal organic substance' in your adaptation. Furthermore, in section 1.1 of IUCILD you have identified the Substance as 'organometallic'. Therefore, ECHA understands you agree that the Substance comprises an organic component.

In addition you have argued in your dossier that the Substance will not be readily biodegraded.

The Substance being an organometal comprises an organic component (i.e. contains carbon atoms) and not only inorganic metals. Annex VII, Section 9.2.1.1, column 2 adaptation is strictly applicable to inorganic substances (e.g. metals and metal salts).

Therefore, as your Substance cannot be identified as inorganic the condition of this adaptation is not met and your adaptation is rejected.

As regards your claim that the Substance will not be readily biodegraded ECHA remarks that you have not provided any data to support your claim.

On this basis, the information requirement is not fulfilled.

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

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

1. Long-term toxicity testing on fish

Short-term toxicity testing on fish is an information requirement under Annex VIII to REACH (Section 9.1.3.). Long-term toxicity testing on fish must be considered (Section 9.1.3., Column 2) if the substance is poorly water soluble.

You have provided two short-term toxicity testing on fish studies (OECD TG 203) on source substances but no information on long-term toxicity on fish for the Substance.

We have assessed this information and identified the following issue:

Poorly water soluble substances require longer time to reach steady-state conditions. As a result, the short-term tests does not give a true measure of toxicity for this type of substances and the long-term test is required. A substance is regarded as poorly water soluble if, for instance, it has a water solubility below 1 mg/L or below the detection limit of the analytical method of the test material (ECHA Guidance R.7.8.5).

As already explained under Section A.1, the Substance is poorly water soluble and information on long-term toxicity on fish must be provided.

In the comments to the draft decision, you submitted information regarding the water solubility of the Substance that is relevant to the current request. These comments are already addressed in Section A.1 above.

In the event of a dossier update providing corrected water solubility (i.e. ≥ 1mg/L) to which you refer in your comments, the trigger for requesting long-term toxicity testing on fish would become inapplicable, as the Substance could not be regarded as poorly water soluble.

However, as the new information regarding water solubility is currently not available in your registration dossier, the request cannot be currently removed.

You should therefore submit the corrected water solubility information in place of conducting long-term toxicity study on fish, in an updated registration dossier by the deadline set out in the decision.

Finally, in line with your comments to the draft decision, ECHA notes that the reliability of the short-term toxicity studies are not addressed in this decision. In light of the data reported in your dossier at the time this decision was drafted and sent to you for commenting, short-term toxicity studies were not considered relevant to be addressed.

ECHA appreciates your willingness to follow up on the acute toxicity of the Substance and we may follow up on the aquatic toxicity information requirements in a future decision.

Study design

To fulfil the information requirement for the Substance, the Fish, Early-life Stage Toxicity Test (test method OECD TG 210) is the most appropriate (ECHA Guidance R.7.8.2.).

OECD TG 210 specifies that for difficult to test substances OECD GD 23 must be followed. As already explained above, the Substance is difficult to test. Therefore, you must fulfil the requirements described in 'Study design' under Appendix [A.1].

2. Hydrolysis as a function of pH

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

You have provided a key study [redacted] 2011), OECD TG 111 with the Substance, in your dossier.

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

To fulfil the information requirement, a study must comply with OECD TG 111 (Article 13(3) of REACH). Therefore the following requirements must be met:

- a main hydrolysis testing (tier 2) must be conducted at three temperatures in the range of 10-70°C (preferably with at least one temperature below 25°C utilised) and at pH values of 4, 7 and 9.
- identification of hydrolysis products (tier 3) using appropriate analytical method must be performed for major hydrolysis products (present at least ≥ 10 % of the applied dose)

Your have provided a study report indicating the following:

- main hydrolysis testing was conducted at pHs 4, 7 and 9, but only at a single temperature of 20°C;
- you have not provided analytical identification of all hydrolysis products (tier 3 test), as you have based your analysis on the formation of ethanol (claimed to be one of the hydrolysis products).

The reported study does not meet the requirements of the test guideline. In particular, although you follow the formation of ethanol (i.e. one of the claimed hydrolysis products), you do neither identify nor quantify other hydrolysis products.

On this basis, the information requirement is not fulfilled.

In the comments to the draft decision, you agree to perform the requested study and you elaborate on the foreseen analytical difficulties.

ECHA acknowledges the difficulties on performing analytical monitoring and addresses it in Appendix E of this decision.

Study design

Based on the Substance molecular structure(s), it is foreseen that it will hydrolyse into tin-containing compounds, ethanol and silicic acid derivatives. In view of study feasibility, and prioritizing the foreseen transformation products of higher concern, ECHA recommends you to focus on the identification and quantification of tin-containing transformation products.

3. Soil simulation testing

and

4. Sediment simulation testing

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

This information requirement is triggered in case the chemical safety assessment (CSA) indicates the need for further degradation investigation (Annex I, Section 4; Annex XIII,

Section 2.1), such as if the substance is a potential PBT/vPvB substance (ECHA Guidance R.11.4.). This is the case if the Substance itself or any of its constituent or impurity present in concentration ≥ 0.1% (w/w) or relevant transformation/degradation product meets the following criteria:

- it is potentially persistent or very persistent (P/vP) as:
  - there is currently no indication of the biodegradability potential of the Substance, and
- it is potentially bioaccumulative or very bioaccumulative (B/vB) as:
  - it has a high potential to partition to lipid storage (*e.g.* log K_{ow} > 4.5).

Your registration dossier provides the following:

- The Substance is claimed not readily biodegradable however, no experimental data is available to demonstrate it as you have attempted to adapt the ready biodegradability information requirement (please see Appendix A.3 of this decision);
- The Substance is claimed to have high potential to partition to lipid storage (Log K_{ow} of 6.7 based on QSAR).

Furthermore, the information in your dossier is currently incomplete and therefore:

- it is not possible to conclude on the toxicity of the Substance (see Appendices A.1, A.2 and B.1 of this decision).

The information above indicates that the Substance is a potential PBT/vPvB substance. The Substance is claimed to have low water solubility (1 µg/L) and high partition coefficient (log Kow of 6.7), indicating high potential to adsorb to soil and sediment.

Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation. Based on the adsorptive properties of the Substance, soil and sediment represent relevant environmental compartments.

In the comments to the draft decision, you submitted information regarding the predicted partition coefficient n-octanol/water (Kow) of the Substance that is relevant to the current requests.

You claim that the log Kow value in the dossier is incorrect since it was predicted based on a wrong representative structure and corresponding SMILES. According to your comments, the SMILES used for the log Kow prediction reported in the dossier corresponds to a chemical structure comprising triethylsilyl moieties that are not present in the Substance since such moieties "*cannot be formed from UVCB educt tetraethoxysilane*".

Therefore, in your comments you have provided the corrected structure, a representative SMILES and a new log Kow value (i.e. log Kow=1.56) predicted using a QSAR model based on fragment algorithm (EpiSuite KOWWIN version 1.69).

First, ECHA agrees that the SMILES used in your dossier as input for the QSAR prediction of log Kow is not representative of the Substance. Therefore, the predicted log Kow value of 6.7 provided in the dossier is not reliable.

Second, ECHA agrees that the new SMILES provided in the comments is representative of the Substance and is therefore an acceptable input parameter for QSAR predictions. Regarding the new QSAR prediction for log Kow of 1.56 provided in your comments, although not currently documented, ECHA considers that it can be used to conclude that log Kow of the Substance is below 4.5.

In the event of a dossier update providing new information regarding partition coefficient n-octanol/water to which you refer in your comments, the trigger for requesting soil and sediment simulation studies would become inapplicable.

However, as the new information regarding partition coefficient n-octanol/water is currently not available in your registration dossier, the requests cannot be currently removed.

You should therefore submit the corrected log Kow information in place of conducting the simulation studies (i.e. in soil and sediment compartments), in an updated registration dossier by the deadline set out in the decision.

ECHA may further pursue clarification of persistency and bioaccumulation in a future decision, based on potential PBT/vPvB concern of the degradation/transformation products.

Study design

Simulation degradation studies must include two types of investigations (ECHA Guidance R.7.9.4.1.):

1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and
2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

In accordance with the specifications of OECD TG 307, you must perform the test using at least four soils representing a range of relevant soils (*i.e.* varying in their organic content, pH, clay content and microbial biomass).

In accordance with the specifications of OECD TG 308, you must perform the test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture. If the Substance may also reach marine waters, at least one of the water-sediment systems should be of marine origin.

The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (ECHA Guidance R.16, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 307 and OECD TG 308.

In accordance with the specifications of OECD TG 307 and OECD TG 308, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (ECHA Guidance R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (ECHA Guidance R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 307 and OECD TG 308; ECHA Guidance R.11.4.1.).

5. Identification of degradation products

Further degradation testing must be considered if the chemical safety assessment (CSA) according to Annex I indicates the need to investigate further the degradation of the substance (Annex VIII, Section 9.2., Column 2).

As already explained under Appendix B, Sections 3 and 4, the Substance is a potential PBT/vPvB substance. Therefore, the chemical safety assessment (CSA) indicates the need for further degradation investigation.

You have not provided information on the identity of transformation/degradation products for the Substance.

On this basis, the information requirement is not fulfilled.

In your comments to the draft decision, you submitted information regarding the predicted log Kow of the Substance that is relevant to the current request. The comments are addressed in Sections B.3-4 above.

In the event of a dossier update providing new information regarding partition coefficient n-octanol/water to which you refer in your comments, the trigger for requesting identification of degradation products would become inapplicable.

However, as the new information regarding partition coefficient n-octanol/water is currently not available in your registration dossier, the request cannot be currently removed.

You should therefore submit the corrected log Kow information in place of conducting the identification of degradation products, in an updated registration dossier by the deadline set out in the decision.

Study design

Regarding the selection of appropriate and suitable test method(s), the method(s) will have to be substance-specific. Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported, when analytically possible. In addition, degradation half-life, log K_{ow} and potential toxicity of the transformation/degradation may need to be investigated. You may obtain this information from the degradation studies requested in Appendix B, Sections 3 to 4 or by some other measure. If any other method is used for the identification of the transformation/degradation products, you must provide a scientifically valid justification for the chosen method.

To determine the degradation rate of the Substance, the requested studies according to OECD TG 308 and 307 (Appendices B.3 and B.4) must be conducted at 12°C and at a test material application rate reflecting realistic assumptions. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline) and at higher application rate (*e.g.* 10 times).

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[3].

B. Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

1. Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

a) the variation in compositions reported by all members of the joint submission,
b) the boundary composition(s) of the Substance,
c) 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

a) 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.
b) The reported composition must include the careful identification and description of the characteristics of the Tests Materials in accordance with OECD GLP (ENV/MC/CHEM(98)16) and EU Test Methods Regulation (EU) 440/2008 (Note, Annex), namely all the constituents must be identified as far as possible as well as their concentration. Also any constituents that have harmonised classification and labelling according to the CLP Regulation must be identified and quantified using the appropriate analytical methods,

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

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

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

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

A. Strategy for the PBT/vPvB assessment

Under Annex XIII, the information must be based on data obtained under conditions relevant for the PBT/vPvB assessment. You must assess the PBT properties of each relevant constituent of the Substance present in concentrations at or above 0.1% (w/w) and of all relevant transformation/degradation products. Alternatively, you would have to justify why you consider these not relevant for the PBT/vPvB assessment.

You are advised to consult ECHA Guidance R.7b (Section R.7.9.), R.7c (Section R.7.10) and R.11 on PBT assessment to determine the sequence of the tests needed to reach the conclusion on PBT/vPvB. The guidance provides advice on 1) integrated testing strategies (ITS) for the P, B and T assessments and 2) the interpretation of results in concluding whether the Substance fulfils the PBT/vPvB criteria of Annex XIII.

When determining the sequence of simulation degradation testing you are advised to consider the intrinsic properties of the Substance, its identified uses and release patterns as these could significantly influence the environmental fate of the Substance. You must revise your PBT assessment when the new information is available.

B. Environmental testing for substances containing multiple constituents

Your Substance contains multiple constituents and, as indicated in ECHA Guidance R.11 (Section R.11.4.2.2), you are advised to consider the following approaches for persistency, bioaccumulation and aquatic toxicity testing:

- the "known constituents approach" (by assessing specific constituents), or
- the "fraction/block approach, (performed on the basis of fractions/blocks of constituents), or
- the "whole substance approach", or
- various combinations of the approaches described above

Selection of the appropriate approach must take into account the possibility to characterise the Substance (i.e. knowledge of its constituents and/or fractions and any differences in their properties) and the possibility to isolate or synthesize its relevant constituents and/or fractions.

Appendix E: Procedure

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 16 November 2020.

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

ECHA took into account your comments and amended the requests and the deadline.

You have provided comments during the decision-making phase which were found to indirectly address the information requested in the draft decision, by removing triggers for higher tonnage information requirements.

Dependent on the dossier update correcting information regarding water solubility (WS) and n-octanol/water partitioning coefficient (Kow), as provided in your comments, the requests for Long-term toxicity testing on aquatic invertebrates, Long-term toxicity testing on fish, Sediment simulation, Soil simulation and Identification of degradation products would became inapplicable.

Consequently, it is considered that the initially provided 30 months deadline is excessive for the remaining requests.

Reasoning for final deadline

Based on the remaining studies requested in this decision in case of update of WS and Kow (i.e. growth inhibition study on aquatic plants, ready biodegradability and hydrolysis as a function of the pH), the standard deadline to submit the information would be reduced to 6 months.

ECHA has however further considered the foreseen difficulties of testing the Substance, to which you refer in your comments, which may require development of specific analytical methods to detect and quantify the hydrolysis products. On this basis, an additional 12 months extension of the standard deadline is considered appropriate.

Overall, ECHA has set the deadline to submit the information requested in this decision to 18 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 F: List of references - ECHA Guidance[5] 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)[6]

RAAF - considerations on multiconstituent substances and UVCBs (RAAF UVCB, March 2017)[7]

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[8]

[5] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[6] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across
[7] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/3f79684d-07a5-e439-16c3-d2c8da96a316
[8] 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 G: 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.