~~Confidential~~

Helsinki, 23 March 2022

Addressees
Registrants of RECONSILE EC#240-464-3 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
23/07/2020

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Hexadecyltrimethoxysilane
EC number: 240-464-3
CAS number: 16415-12-6

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

DECISION ON TESTING PROPOSAL(S)

Based on Article 40 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***28 June 2023***.

The requested information must be generated using the Substance unless otherwise specified.

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

1. Long-term toxicity testing to sediment organisms (Annex X, Section 9.5.1.; test method: EU C.40/OECD TG 233 using spiked sediment or EU C.35/OECD TG 225 or EU C.27/OECD TG 218).

Reasons for the request(s) are explained in the following appendix entitled "Reasons to request information required under Annex X of REACH".

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 X to REACH, for registration at more than 1000 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 can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Approved[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 X of REACH

This decision is based on the examination of the testing proposal you submitted.

1. Long-term toxicity testing to sediment organisms

Long-term toxicity to sediment organisms is an information requirement under Annex X to REACH (Section 9.5.1.).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a Sediment-Water Chironomid Toxicity Test Using Spiked Sediment (test method: EU C.27/OECD TG 218).

Your registration dossier does not include any information on long-term toxicity on sediment organisms.

ECHA agrees that an appropriate study on long-term toxicity to sediment organisms is needed.

1.2. Test selection and study specifications

As also expressed in ECHA Guidance, Section R.7.8.9.1., when generating data on long-term toxicity on sediment organisms for the purposes of risk assessment, registrants must justify the appropriateness and sufficient sensitivity of the test protocol(s) to be used, based on, for example, substance properties/uses.

In the absence of a justification in your registration dossier, ECHA has held that the Sediment-Water Chironomid Toxicity Test Using Spiked Sediment (test method: EU C.27/OECD TG 218) is only appropriate to cover the information requirement for long-term toxicity to sediment organisms for substances which equilibration time (time to reach steady state in the body) is not anticipated to be very long (e.g. not highly lipophilic substance such as substance with log Kow < 5 and log Koc < 3; ECHA Guidance R.7.8.9.1. and R.7.8.14.2.) such as the Substance.

Under section 4.7 of your registration dossier you provide a Log Kow value for the Substance of 8.1 based on QSAR prediction (QSAR model: Adaption of KOWWIN v1.67 (EPI Suite) for the calculation of the n-octanol-water partition coefficient (Log Kow) of organosilicon compounds). Therefore, the equilibration time for the Substance is anticipated to be very long.

For such substance, the Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (test method: EU C.40/OECD TG 233), which is an extension of the proposed test, must be conducted (ECHA Guidance R.7.8.9.1. and R.7.8.14.2.). Alternatively, you may also consider conducting a Sediment-Water Lumbriculus Toxicity Test Using Spiked Sediment (test method: EU C.35/OECD TG 225).

Further, ECHA Guidance R.7.8.10.1 specifies that spiking the water phase does not accurately represent accumulation processes within the sediment lasting longer than the test period and is only regarded as applicable to simulate pesticide spray drift event and other type of exposure (e.g. chemical spill). For industrial chemicals with continuous and intermittent release, spiking the sediment must be conducted as this approach is intended to simulate accumulated levels of substance persisting in the sediment.

ECHA notes that the Substance is an industrial chemical with Industrial, Professional, and Consumer uses, as well as Article Service Life. This means that the substance has widespread uses which in turn result in continuous and intermittent releases to the environment.

Considering the environmental release pattern for the Substance, ECHA concludes that the study must be conducted by spiking the sediment phase.

In your comments to the draft decision:

A. you disagreed to the general exclusion of the adequacy of the OECD TG 218 to fulfil the information requirement, as it is applicable also for high log Pow substances. You pointed out that *"none of the ECHA guidance chapters cited in the draft decision (ECHA Guidance R.7.8.9.1. and R.7.8.14.2), actually cites that an OECD 218 cannot be used for high log Pow substances (i.e., substances with a log Pow >5)*".

B. You further explained that the Substance is not classified for any hazard class. In addition, you state that "*In none of the aquatic toxicity studies were effects observed.*" You further explain that recently conducted studies according to OECD TG 408 and OECD TG 414 did not show any adverse effects.

ECHA has assessed your comments on the draft decisions and notes the following:

A. ECHA acknowledges that it is technically feasible to conduct an OECD TG 218 on highly lipophilic substances (i.e., log Kow > 5 and/or log Koc > 3). In addition, ECHA agrees that the guidance sections referenced in the draft decision do not explicitly exclude the use of OECD TG 218 for highly adsorptive substances in general. Rather, the guidance explains considerations that should be taken into account in the substance-specific test selection process. On this basis ECHA no longer excludes the Sediment-Water Chironomid Toxicity Test Using Spiked Sediment (test method: EU C.27/OECD TG 218) from the possible test selection. However, if you decide to conduct a study according to the OECD TG 218, you need to provide a justification as to why this test method is the most appropriate and sensitive test protocol based on, for example, substance properties/uses (ECHA Guidance R.7.8.9.1).

   As explained in ECHA Guidance R.7.8.10.1 and R.7.8.14.2, for strongly adsorbing substances, equilibration between sediment and water can take up to several weeks. Thus, tests with sediment ingesting organisms (e.g., OECD TG 225) and with longer exposure duration (e.g., OECD TG 233) are preferred, as these are expected to model chronic exposure from all relevant routes more closely.

B. ECHA Guidance R.7.8.10.1. and R.7.8.10.3 specifies that substances that do not exhibit toxic effects when tested in water-only test systems (i.e., pelagic tests) may nevertheless exert significant toxic effects in sediment tests. This consideration is especially relevant for substances that are poorly water soluble, have a high adsorption potential, or exhibit a binding behaviour that is not driven by lipophilicity. For these substances, the lack of effects seen in aquatic testing may be because equilibrium was not reached during the exposure phase.

   Therefore, the lack of effects seen in aquatic toxicity studies referred to in your comments on the draft decision under point iv. above, cannot be used to exclude to observe toxic effects in long-term toxicity studies on sediment organisms nor be seen as a justification that the OECD TG 218 is the most appropriate method.

   Moreover, lack of effects seen in studies conducted according to OECD TG 408 and

OECD TG 414 do not provide specific information addressing the data gap identified above.

In conclusion, ECHA has taken your comments to the draft decision into account and has modified the draft decision to include the option to conduct an OECD TG 218. However, you must provide a justification as to why the method selected among the three options given in this decision (i.e., OECD TG 218, OECD TG 233, or OECD TG 225) is the most appropriate for risk assessment purposes.

1.3. Outcome

Your testing proposal is accepted under Article 40(3)(a) and (b) of REACH, and you are requested to conduct the test with the Substance, as specified above.

As explained under Section 1.2. above, ECHA expects you to provide a justification for the test method selection.

Appendix B: 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[2].

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:
   - the variation in compositions reported by all members of the joint submission,
   - 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 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[3].

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

Appendix C: Procedure

The information requirement for an Extended one-generation reproductive toxicity study (EOGRTS; Annexes IX or X, Section 8.7.3.) is not addressed in this decision. This will be addressed in a separate decision once the information from the Sub-chronic toxicity study (90-day) requested in a previous ECHA decision (communication number: TPE-D-2114425319-49-01/F) is provided; due to the fact that the results from the 90-day study is needed for the design of the EOGRTS.

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 27 March 2020.

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

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

ECHA took into account your comments and amended the request.

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 D: List of references - ECHA Guidance[4] 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)[5]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[6]

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.

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

OECD Guidance documents[7]
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.

[7] http://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

Appendix E: Addressees of this decision and the corresponding information requirements applicable to them

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]
[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.