~~Confidential~~

Helsinki, 03 November 2022

Addressees
Registrants of RECONSILE EC# 214-685-0 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
04/03/2022

Registered substance subject to this decision ("the Substance")
Substance name: Trimethoxy(methyl)silane
EC number: 214-685-0

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 ***23 May 2024***.

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

Information required from all the Registrants subject to Annex IX of REACH

1. Long-term toxicity on terrestrial invertebrates also requested below (triggered by Annex IX, Section 9.4.1., column 2) with analogue substance Methylsilanetriol, EC number 219-489-9

Information required from all the Registrants subject to Annex X of REACH

2. Long-term toxicity testing on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: EU C.33/OECD TG 222) with analogue substance Methylsilanetriol, EC number 219-489-9

The reasons for the decision(s) are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

In the requests above, the same study has been requested under different Annexes. This is because some information requirements may be triggered at lower tonnage band(s). In such cases, only the reasons why the information requirement is triggered are provided for the lower tonnage band(s). For the highest tonnage band, the reasons why the standard information requirement is not met and the specification of the study design are provided. Only one study is to be conducted; all registrants concerned must make every effort to reach an agreement as to who is to carry out the study on behalf of the others under Article 53 of REACH.

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 requirements for testing and reporting new tests under REACH, see Appendix 4.

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

Appendix 1: Reasons for the decision
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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 1: Reasons for the decision

Contents

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Reasons for the decision(s) related to the information under Annex IX of REACH

1. Long-term toxicity testing on terrestrial invertebrates

1 Short-term toxicity to invertebrates is an information requirement under Annex IX to REACH (Section 9.4.1). Long-term toxicity testing must be considered (Annex IX, Section 9.4., column 2) if the substance has a high potential to adsorb to soil or is very persistent.

1.1. Information provided to fulfil the information requirement

2 Based on the information in your registration dossier the Substance is considered as not readily bioavailable: on the basis that no significant biodegradation is expected for the main hydrolysis product of the Substance (methylsilanetriol, EC No. 219-489-9) you conclude that it is P/vP.

3 Therefore, the Substance is considered potentially highly persistent in soil. On this basis information on long-term toxicity on terrestrial invertebrates must be provided.

4 You have submitted a testing proposal for an Earthworm Reproduction Test (EU C.33/OECD TG 222).

5 For the assessment of the testing proposal and for the test selection and study specifications, see request 2.

Reasons for the decision(s) related to the information under Annex X of REACH

2. Long-term toxicity testing on terrestrial invertebrates

6 Long-term toxicity to invertebrates is an information requirement under Annex X to REACH (Section 9.4.4.).

2.1. Information provided to fulfil the information requirement

7 You have submitted a testing proposal for an Earthworm Reproduction Test (EU C.33/OECD TG 222) with the following justification: "The Substance belongs to the Hazard category 3 as described in the ITS for Effects on terrestrial organisms. The testing proposal is submitted to generate the necessary confirmatory information to the screening assessment conducted based on the equilibrium partitioning method (EPM)".

8 You intend to test the main hydrolysis product of the Substance: methylsilanetriol (EC No. 219-489-9, CAS No. 2445-53-6).

9 As specified by you in your justification for the testing proposal, the Substance falls under the soil hazard category 3 and in this context a confirmatory long-term toxicity test on terrestrial organisms is required (ECHA Guidance R.7.11.5.3., Table R.7.11-3).

10 Your registration dossier does not include any information on long-term toxicity to terrestrial invertebrates.

11 ECHA agrees that an appropriate study on long-term toxicity terrestrial on invertebrates is needed as specified in your testing proposal.

2.2. Grouping of substances and read-across approach

12 ECHA understands that you intend to fulfil the information required for Long-term toxicity on terrestrial invertebrates, by way of adaptation under Annex XI, Section 1.5 ('Read-across and grouping of substances').

13 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.

14 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].

2.2.1. Information provided to support the read-across approach

15 You have provided justification for the read-across in IUCLID Section 6.3. and Section 7.2. of your CSR.

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[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

16 You intend to read-across between the main hydrolysis product of the Substance, methylsilanetriol, EC No. 219-489-9 (CAS RN 2445-53-6) as source substance and the Substance as target substance.

17 You have provided the following reasoning for the prediction of the terrestrial toxicity to be based on testing the main hydrolysis product of the Substance:

(i) In IUCLID Section 6.3., you claim that "*Due to the rapid hydrolysis of the substance, the chemical safety assessment is based on the silanol hydrolysis product methylsilanetriol.*"

(ii) In IUCLID Section 5.1.2., you provide an OECD TG 111 study (2004) with the Substance. This study includes the identifiers of two hydrolysis products of the Substance (methanol, EC number 200-659-6; methylsilanetriol, EC number 219-489-9). Further, it includes the hydrolysis half-life of the Substance (DT_{50}: 2.2 hours at pH 7, 25°C).

18 ECHA understands that you predict the properties of the Substance using a read-across hypothesis which is based on the rapid formation of a transformation product that corresponds to the selected source substance. The properties of your Substance are predicted to be quantitatively equal to those of the selected source substance.

2.2.2. Assessment of the information provided

19 ECHA agrees that the information you provided indicates that the Substance hydrolyses fast to form the selected source substance. Based on the available hydrolysis data, the Substance is expected to be unstable over the duration of terrestrial toxicity tests. With a half-life of 2.2 hours at pH 7, the loss of the parent substance is expected to be fast. It can be assumed that any (transient) intermediate hydrolysis products are unlikely to have an impact as, by the time the Substance reaches the soil, hydrolysis would have already taken place. In this context, ECHA Guidance R.7.11.4.3 specifies that the terrestrial hazard assessment needs to consider the properties (including toxic effects) of degradation products that may be formed in soil. ECHA also notes that methanol would also be formed during the hydrolysis, but this substance is partitioning to the atmosphere and is not expected to remain in the soil compartment.

2.2.3. Conclusion on the read-across approach

20 Considering the above, ECHA concludes that the read-across is plausible and that testing the main known hydrolysis product is acceptable.

2.3. Test selection and study specifications

21 The proposed EU C.33/OECD TG 222 is appropriate to cover the information requirement for long-term toxicity on terrestrial invertebrates (Guidance on IRs and CSA, Section Guidance on IRs and CSA, SectionR.7.11.3.1).

2.4. Outcome

22 Your testing proposal is accepted under Article 40(3)(a) and you are requested to conduct the test with methylsilanetriol, EC number 219-489-9, as specified above.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

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

Guidance on data-sharing; ECHA (2017).

All Guidance on REACH is available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF), ECHA (2017)
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs), ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

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

Appendix 2: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 19 November 2021.

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 did not receive any comments within the commenting period.

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 3: Addressees of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

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

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1. Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.

(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries[4].

(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2. 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.

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

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers[5].

2. General recommendations for conducting and reporting new tests

References to Guidance on REACH and other supporting documents can be found in Appendix 1.

[5] https://echa.europa.eu/manuals