~~Confidential~~

Helsinki, 08 November 2021

Addressees
Registrants of RECONSILE EC#224-588-5 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
29/03/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: 3-trimethoxysilylpropane-1-thiol
EC number: 224-588-5
CAS number: 4420-74-0

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(3)(d) of Regulation (EC) No 1907/2006 (REACH), the following testing proposals using an analogue substance 3-(triethoxysilyl)propanethiol (CAS 14814-09-6) are rejected:

A. Testing proposals under Annex VIII to REACH

1. Sub-chronic toxicity study (90-day), oral route (EU B.26./OECD TG 408);

2. Pre-natal developmental toxicity study (EU B.31./OECD TG 414).

Reasons for the rejections are explained in Appendix A.

For references used in this decision, please consult the Appendix entitled "List of references - ECHA Guidance and other supporting documents".

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 Christel Schilliger-Musset, 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 for the decision

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

A. Testing proposals under Annex VIII to REACH

1. Sub-chronic toxicity study

A sub-chronic toxicity study (90 days) shall be proposed if the frequency and duration of human exposure indicates that a longer term study is appropriate under Annex VIII to REACH (Section 8.6.1., column 2).

1.1. Information provided

You have submitted a testing proposal for a sub-chronic toxicity study (90 day) according to OECD TG 408 with an analogue substance 3-(triethoxysilyl)propanethiol (CAS 14814-09-6).

Your dossier contains a non-TG/GLP short-term (19 days) dermal repeated dose toxicity study ([redacted], 1975; you scored the study with the reliability score of 4 (not assignable)) and a read-across justification document in IUCLID section 13.

ECHA requested your considerations for alternative methods to fulfil the information requirement for repeated dose toxicity. You provided your considerations and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

However, you have not provided any justifications for a 90-day sub-chronic toxicity study; your dossier contains no reliable information on repeated dose toxicity for the Substance or any other members of the analogue group.

ECHA considers that, in the absence of justifications, a sub-chronic toxicity study (90 day) is not necessary at this tonnage band.

1.2. Outcome

Under Article 40(3)(d) of REACH, the proposed test is rejected.

In the testing proposal examination, ECHA has only assessed the need for the test. This assessment resulted in the rejection of the testing proposal. Therefore, no assessment of the proposed read-across approach was performed as the information requirement is not triggered at this tonnage level.

2. Pre-natal developmental toxicity study

A pre-natal developmental toxicity (PNDT) study may be proposed in case of serious concerns about the potential for adverse effects on development under Annex VIII to REACH (Section 8.7.1., column 2).

2.1. Information provided

You have submitted a testing proposal for a PNDT study according to OECD TG 414 with an analogue substance 3-(triethoxysilyl)propanethiol (CAS 14814-09-6).

Your dossier contains a read-across justification document in IUCLID section 13.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Developmental toxicity. You provided your considerations and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

However, you have not provided any indication of serious concerns about the potential for adverse effects on development; your dossier contains no information on developmental toxicity, and the read-across justification document does not address developmental toxicity.

ECHA considers that, in the absence of indications of serious concerns about the potential for adverse effects on development, a PNDT study is not necessary at this tonnage band.

2.2. Outcome

Under Article 40(3)(d) of REACH, the proposed test is rejected.

In the testing proposal examination, ECHA has only assessed the need for the test. This assessment resulted in the rejection of the testing proposal. Therefore, no assessment of the proposed read-across approach was performed as the information requirement is not triggered at this tonnage level.

Appendix B: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 19 August 2020.

ECHA held a third party consultation for the testing proposal(s) from 23 November 2020 until 7 January 2021. ECHA did not receive information from third parties.

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 C: List of references - ECHA Guidance[2] 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)[3]

RAAF - considerations on multi-constituent substances and UVCBs (RAAF UVCB, March 2017)[4]

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.

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

OECD Guidance documents[5]
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.

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

Appendix D: Addressees of this decision

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]

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.