~~Confidential~~

Helsinki, 05 November 2021

Addressees
Registrants of RECONSILE EC#236-818-1 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
17/05/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Bis(triethoxysilylpropyl)amine
EC number: 236-818-1
CAS number: 13497-18-2

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 testing proposal(s) listed below are rejected:

A. Testing proposal under Annex VIII to REACH

1. Pre-natal developmental toxicity study (EU B.31./OECD TG 414) using the analogue substance bis(trimethoxysilylpropyl)amine (EC No. 280-084-5).

Reasons for the rejection(s) are explained in Appendix A.

For references used in this decision, please consult the Appendix entitled "Guidance on REACH 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 to reject testing proposal under Annex VIII to REACH

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

1. 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 instead of a screening study (Section 8.7.1., column 2).

1.1. Information provided to fulfil the information requirement

You have submitted a testing proposal for a PNDT study according to OECD TG 414 with the analogue substance bis(trimethoxysilylpropyl)amine (EC No. 280-084-5).

You have not provided any justification why there is a need to perform this study. Furthermore, the data in your dossier do not indicate adverse effects on development. Therefore this study is not needed.

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.

ECHA considers that a PNDT study 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 adequacy of study/test material proposed was performed.

Appendix B: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 11 February 2020.

ECHA held a third-party consultation for the testing proposal(s) from 7 July 2020 until 21 August 2020. 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: Guidance on REACH and other supporting documents

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).

The OECD series on testing and assessment available online: https://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

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

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