~~Confidential~~

Helsinki, 05 November 2021

Addressees
Registrants of RECONSILE EC#240-465-9 listed in the last Appendix of this decision

Date of submission of the dossier subject of a decision
28/02/2018

Registered substance subject to this decision, hereafter 'the Substance'
Substance name: Triethoxyhexadecylsilane
EC number: 240-465-9
CAS number: 16415-13-7

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 proposals listed below 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) using the analogue substance hexadecyltrialkoxysilane (EC No. 240-464-3);
2. Pre-natal developmental toxicity study (EU B.31./OECD TG 414) using the analogue substance hexadecyltrialkoxysilane (EC No. 240-464-3).

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

For references used in this decision, please consult the Appendix C 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 request information required under Annex VIII of REACH

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

1. **Sub-chronic toxicity study (90-days)**

You have submitted a testing proposal for a sub-chronic toxicity (90-day) study according to OECD TG 408 with the analogue substance hexadecyltrialkoxysilane (EC No. 240-464-3). with the following justification:

"No data in order to evaluate repeated dose toxicity of the registered substance are available. A testing proposal for a 90-day study according to OECD TG 408 is submitted for the structural analogue substance hexadecyl(trimethoxy)silane <…>. As soon these data is available they will be included in the dossier. In the meantime a qualitative risk assessment will be performed."

A sub-chronic toxicity study (90 days) is an information requirement under Annex VIII to REACH (Section 8.6.1., Column 2) if: the duration of human exposure indicates a longer term study appropriate, such as in case of uses leading to significant long-term exposure of consumers and professionals; and one of the following conditions are met:

(1) other available data indicate that the substance may have a dangerous property that cannot be detected in a short-term toxicity study; or

(2) appropriately designed toxicokinetic studies reveal that the substance (or its metabolites) accumulates in certain tissues or organs which would possibly remain undetected in a short-term toxicity study but which are liable to result in adverse effects after prolonged exposure.

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 notes that the use of the Substance (EC 240-465-9) reported in the dossier (coupling agent (filler activator) during processing (into articles) of tyres) does not lead to significant long-term exposure of consumers and professionals. Furthermore, there is no data on the Substance which indicates that potential adverse effects cannot be detected in a short-term toxicity study. Moreover, there are no toxcokinetic studies on the Substance. On this basis, the criteria for conducting a Sub-chronic toxicity study are not met.

ECHA concludes that at this stage there is no information gap at Annex VIII for a sub-chronic toxicity (90 days).

Therefore, 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 the proposed test material nor of the adequacy of the proposed test in relation to the information requirements at this tonnage band were performed.

2. **Pre-natal developmental toxicity study**

You have submitted a testing proposal for a pre-natal developmental toxicity (PNDT) study according to OECD TG 414 with the analogue Substance with the following justification:

"*No data in order to evaluate developmental toxicity are available. A testing proposal for a developmental toxicity study according to OECD TG 414 is submitted for the structural analogue substance hexadecyl(trimethoxy)silane <…>. As soon these data is available they will be included in the dossier*."

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).

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 notes that you have not provided any justification as to why a PNDT study is needed at this tonnage band. Furthermore, the data in your dossier does not indicate adverse effects on development. Therefore, there is no need for a PNDT study.

ECHA concludes that at this stage there is no information gap at Annex VIII for a PNDT study.

Therefore, 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 the proposed test material nor of the adequacy of the proposed test in relation to the information requirements at this tonnage band were performed.

Appendix B: Procedure

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 2 March 2020.

ECHA held a third party consultation for the testing proposals 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: 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 and the corresponding information requirements applicable to them

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