

Helsinki, 16 June 2020

Addressee

Registrant of [REDACTED] EC# 214-685-0 listed in the last Appendix of this decision

Date of submission for the dossier subject of this decision

21/06/2011

Registered substance subject to this decision, hereafter 'the Substance'

Substance name: Trimethoxy(methyl)silane

EC number: 214-685-0

CAS number: 1185-55-3

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

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of **21 September 2021**.

1. Requirements applicable to all the Registrants subject to Annex VII of REACH

1. Skin sensitisation (Annex VII, Section 8.3.) with the Substance

i. in vitro/in chemico skin sensitisation information on molecular interactions with skin proteins (OECD TG 442C), inflammatory response in keratinocytes (OECD TG 442D) and activation of dendritic cells (OECD TG 442E)(Annex VII, Section 8.3.1.); and

ii. Only if the in vitro/in chemico test methods specified under point i) are not applicable for the Substance or the results obtained are not adequate for classification and risk assessment, in vivo skin sensitisation (Annex VII, Section 8.3.2.; test method: EU B.42./OECD TG 429);

Conditions to comply with the requests

You are bound by the requests for information corresponding to the REACH Annexes applicable to your own registered tonnage of the Substance at the time of evaluation. Therefore you have to comply with the requirements of Annexes VII, VIII and IX of REACH, as you have registered a substance at 100-1000 tpa;

The Appendices state the reasons for the requests for information to fulfil the requirements set out in the respective Annexes of REACH.

The Appendix entitled Observations and technical guidance addresses the generic approach for the selection and reporting of the test material used to perform the required studies and provides generic recommendations and references to ECHA guidance and other reference documents.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information.

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>.

Approved¹ 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 requests to comply with Annex VII of REACH

Under Articles 10(a) and 12(1) of REACH, a technical dossier registered at 1 to 10 tonnes or more per year must contain, as a minimum, the information specified in Annex VII to REACH.

1. Skin sensitisation (Annex VII, Section 8.3.)

Skin sensitisation is a standard information requirement in Annex VII, Section 8.3. to the REACH Regulation. Column 1 of Section 8.3. requires the registrants to submit information allowing a conclusion whether the substance is a skin sensitiser and whether it can be presumed to have the potential to produce significant sensitisation in humans (Cat. 1A), and risk assessment, where required.

You have adapted this information requirement by using a Grouping of substances and read-across approach under Annex XI, Section 1.5.

You provided the following studies:

- A key study (██████████, 1992) with the analogue Methyltriethoxysilane; triethoxy(methyl)silane / 2031-67-6 / 217-983-9 according to OECD 406 in guinea pig.
- Two supporting studies, (██████████, 2000) with the analogue trimethoxy(vinyl)silane / 2768-02-7 / 220-449-8 and (██████████, 1998) with analogue tetramethylsilane / 75-76-3 / 200-899-1, both according to OECD 406 in guinea pig.

In addition, you have provided one supporting study (██████████, 2009) with the Substance according to OECD TG 406 in guinea pig Kilimish score 3.

We have assessed this information and identified the following issue(s):

1. Read across adaptation

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.

Additional information on what is necessary when justifying a read-across approach can be found in the ECHA Guidance R.6 and related documents.

You predict the properties of the Substance from the structurally similar substances i.e. the source substances: Methyltriethoxysilane/ triethoxy(methyl)silane, EC No. 217-983-9 (CAS No. 2031-67-6); trimethoxy(vinyl)silane, EC No. 220-449-8 (CAS No. 2768-02-7); and tetramethylsilane EC No. 200-899-1 (CAS No. 75-76-3).

You have not provided a read-across justification document but provided the following reasoning for the prediction of toxicological properties:

In the "Endpoint conclusion" of IUCLID Section 7.4. you stated that *"In order to be able to base the classification decision on unequivocal information, weight of evidence was acquired from three other substances which are also methyl functional alkoxysilanes. All these substances show no sensitizing properties. In addition the hydrolysis product of the substance*

methyltrisilanol is a main metabolite of cyclic and linear methyl siloxanes and all these substances are not sensitizers."

ECHA understands that your hypothesis is based on structural similarity, similar behaviour in one property (sensitization) and on the formation of common (bio)transformation products (hydrolysis).

ECHA notes the following shortcomings with regards to the predictions of toxicological properties.

A. Absence of read-across documentation

Annex XI, Section 1.5 requires that whenever read-across is used, adequate and reliable documentation of the applied method must be provided. Such documentation must provide a justification for the read-across including a hypothesis, explanation of the rationale for the prediction of properties and robust study summary(ies) of the source study(ies).

You have provided studies conducted with other substances than your Substance in order to comply with the REACH information requirements. You have not provided documentation as to why this information is relevant for your Substance.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substance(s).

B. Absence of supporting information

Annex XI, Section 1.5 of the REACH Regulation states that "*physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for reference substance(s)*". For this purpose "*it is important to provide supporting information to strengthen the rationale for the read-across*"². The set of supporting information should allow to verify the crucial aspects of the read-across hypothesis and establish that the properties of the Substance can be predicted from the data on the source substance(s).

As indicated above, your read-across hypothesis is based on the (bio)transformation of the Substance and of the source substance(s) to a common compound(s). In this context, information characterising the rate and extent of the hydrolysis of the Substance and of the source substance(s) is necessary to confirm the formation of the proposed common hydrolysis product and to assess the impact of the exposure to the parent compounds.

You have not provided any experimental data or other adequate and reliable information, neither about the hydrolysis of your Substance nor about the hydrolysis of the source substance.

In the absence of this information, you have not provided supporting evidence establishing that the proposed common hydrolysis product is formed as assumed in your read-across hypothesis. Therefore, you have not provided sufficient supporting information to strengthen the rationale for the read-across.

In the absence of such documentation, ECHA cannot verify that the properties of your Substance can be predicted from the data on the source substances. Therefore, your

² Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of Chemicals, Section R.6.2.2.1.f

adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. and your grouping and read-across approach is rejected.

2. Reliability of [REDACTED] study

To fulfil an information requirement or be appropriate for an adaptation, a study must be reliable, i.e. assigned with a Klimisch score of 1 or 2 (ECHA Guidance R.4).

You have provided a supporting study ([REDACTED], 2009) with the Substance according to OECD 406 in guinea pig. You have assigned the study a score of 3 in the Klimisch reliability scale (not reliable).

The Substance was a weak sensitiser in the Buehler Test. You claim that the result was ambiguous based on the following.

In the first challenge, the same positive skin reactions in the test group and the control group were observed. During re-challenge, positive reactions were observed in the high dose group. Due to the strong reaction in the control group in the first challenge the result of the second challenge is questionable and an irritation reaction cannot be excluded even if no reaction in the control group in the re-challenge was seen. Therefore interpretation of the results is difficult and a final assessment concerning the sensitizing properties of the substance is not possible.

ECHA agrees on the assigned reliability for the study and on the reasoning you provided.

Conclusion

Taking into account the abovementioned issues (read-across and low reliability study), the information requirement is not fulfilled.

Appendix E: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of REACH.

The compliance check was initiated on 10 May 2019.

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

ECHA did not receive any comments within the 30-day notification 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 F: Observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

3. Test guidelines, GLP requirements and reporting

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

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

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: 'How to report robust study summaries'³.

4. Test material

Selection of the test material(s)

The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

While selecting the test material you must take into account 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.

Technical reporting of the test material

The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

Technical instructions are available in the manual "How to prepare registration and PPOD dossiers"⁴.

³ <https://echa.europa.eu/practical-guides>

⁴ <https://echa.europa.eu/manuals>

5. List of references of the ECHA Guidance and other guidance/ reference documents⁵

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 in this decision.

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 in this decision.

ECHA Read-across assessment framework (RAAF, 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.

OECD Guidance documents⁷

Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals – No 23, referred to as OECD GD23.

Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment – No 43, referred to as OECD GD43.

⁵ <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

⁶ <https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across>

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

Appendix G: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them

Registrant Name	Registration number	(Highest) Data requirements to be fulfilled
[REDACTED]	[REDACTED]	[REDACTED]

Note: where applicable, the name of a third party representative (TPR) may be displayed in the list of recipients whereas the decision is sent to the actual registrant.