ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114293447-38-01/F Helsinki, 18 March 2015

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For trichlorosilane, CAS No 10025-78-2 (EC No 233-042-5), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration dossier for trichlorosilane, CAS No 10025-78-2 (EC No 233-042-5), submitted by [redacted] (Registrant).

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after 30 October 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

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

The compliance check was initiated on 3 October 2012.

On 20 February 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 20 March 2013 ECHA received comments from the Registrant on the draft decision. On 17 May 2013 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update. On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 30 October 2014 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI, section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

> The spectral data (Annex VI, 2.3.5.), High-pressure liquid chromatogram, gas chromatogram (Annex VI, 2.3.6.) and the description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.).

B. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1)(a) and (b), 41(3), 10(a)(vi), 12(1)(a), 13 and Annexes VII to IX of the REACH Regulation the Registrant shall submit the following information using the test methods as indicated and the registered substance subject to the present decision:

> Pre-natal developmental toxicity study in rats or rabbits, oral route (Annex IX, 8.7.2., EU B.31 or OECD 414).

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

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

C. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **25 March 2016** of the decision an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of 1000 or more tonnes per year in accordance with Article 6 and 11(2) of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and 13 and with Annexes VI to IX thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) and Annex VI, section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, section 2 lists information requirements that shall be sufficient to identify the registered substance.

ECHA notes that the Registrant has identified himself as [redacted] manufacturer. The technical dossier contains a file ("[redacted]") that indicates that the sample for which the analytical information is based on was manufactured in [redacted] (page 3 of this pdf file). Furthermore, the current dossier contains identical analytical information with another registration dossier with registration number [redacted] (Only Representative). It thus appears that the analytical data refers to the substance identification of this other dossier (where the only role in the supply chain flagged in IUCLID is Only Representative) and not the one for the current dossier (where the role in IULCID is flagged as Manufacturer).

During the 30-day commenting phase, the Registrant confirmed that the same substance is manufactured in both [redacted] and that the analytical data is representative of the substance produced in the two sites.

Analytical data differs for substances that are manufactured at different sites, even if the manufacture is based on the same specification. Every registration dossier must therefore contain information on the identity of the registered substance as manufactured by the Registrant concerned, cf., Section 2 of Annex VI to the REACH Regulation. That does not imply that the substances are not considered the same. Such information is however necessary to ascertain the sameness of the substances. This means that the Registrant cannot cover the Annex VI requirements indicated in this decision by using a sample manufactured in a different production site, despite the similarity of the processes. Therefore, the Registrant is required to provide analytical information specific to a sample of the substance he is manufacturing in his own production site [redacted].

Therefore, the Registrant is required to provide analytical data (Spectral data, High-pressure liquid chromatogram, gas chromatogram and description of the analytical methods) pertinent to the substance that he registers pursuant to Article 10(a)(ii),the third subparagraph of Article 11(1) as well as Annex VI, Sections 2.3.5., 2.3.6. and 2.3.7. of the REACH Regulation.

B. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Article 10(a)(vi) of the REACH Regulation, a registration for a substance produced in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

Pre-natal developmental toxicity (Annex IX, 8.7.2, EU B.31 or OECD 414)

The original dossier submission contained extensive use of read-across and grouping adaptations. For the reasons explained in the initial draft decision, ECHA considered the information provided by the Registrant not supporting the proposed read-across for the endpoints covered in the decision.

During the commenting phase and in the subsequent dossier update subject to the current decision (submission number [redacted]), the Registrant provided new information that documented the adaptation argument and allowed ECHA to conclude that the respective information requirements were met. This resulted in the removal of most requests from the draft decision.

Concerning pre-natal developmental toxicity, the updated dossier contains the experimental results from a study performed in 1980 using a read-across substance referred by the Registrant as "*soluble silicates*". The read-across is based on the assumption that external exposure to trichlorosilane results only in systemic exposure to soluble silicates comparable to the source substance.

The study was not performed according to GLP standards, nor according to an international test guideline. It is not possible to verify adequate and reliable coverage of the key parameters of the study performed that are addressed in the corresponding test method referred to in Article 13(3) of the REACH Regulation as a requirement read-across application pursuant to Annex XI, 1.5. of the REACH Regulation. For example, the study is lacking sufficient number of appropriately examined dams and foetuses, it inadequately examined foetuses, it is having inadequate justification for the choice of dose and if the choice of doses meets the guideline requirements.

According to Annex XI, 1.1.2., non-GLP or non-guideline studies may be acceptable if they have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3). In the current case, the test fails the requirement of Annex XI, 1.1.2 for the reasons given above.

Furthermore, ECHA notes that the read-across hypothesis has remaining areas of uncertainty, for example a definitive demonstration of which exact silanetriol-derived species become systemically available and, therefore, Annex XI, 1.5 conditions are not met and properties of the registered substance subject to the present decision cannot be predicted for the endpoint of pre-natal developmental toxicity based on data available for "soluble silicates". On these grounds, adaptation of the standard information requirement cannot be accepted.

Consequently there is an information gap and it is necessary to generate the data for this endpoint. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used. The Registrant is accordingly requested to submit the information on pre-natal developmental toxicity, in rats or rabbits, oral route, using test method B.31 according to Commission Regulation (EC) No 440/2008 or OECD Guideline 414.

Specifically for this endpoint, ECHA notes that the following considerations should be taken into account when selecting the test material in order for the dossier to contain the most relevant physicochemical, toxicological and ecotoxicological information (Article 12(1)).

- The registered substance is classified as corrosive, and according to the fourth paragraph of Annex IX of the REACH Regulation *in vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. The use of the breakdown product helps in avoiding testing of an agent at a concentration or dose level that causes corrosivity (i.e. the parent compound);

- A higher systemic dose of the breakdown product may be achieved when dosing is not limited by the corrosive effect, and this will avoid the risk of underestimating the long term effects due to lower doses;

- Dosing with the breakdown compound appears more reliable, as uncontrolled reaction of the parent compound with vehicle, or variation caused by differences in pH of vehicle as a result of dilution may interfere with dosing of the parent compound.

Concerning the pre-natal developmental toxicity effects of hydrochloric acid, ECHA notes that there is an OECD SIDS report for hydrochloric acid concluding that "*No reliable studies have been reported regarding toxicity to reproduction and development in animals after oral, dermal or inhalation exposure to hydrogen chloride/hydrochloric acid. Because protons and chloride ions are normal constituents in the body fluid of animal species, low concentrations of hydrogen chloride gas/mist or solution do not seem to cause adverse effects to animals. In fact, the cells of gastric glands secrete hydrochloric acid into the cavity of the stomach and orally administered sulfuric acid, which results in pH change as well, did not cause developmental toxicity to laboratory animals. These facts indicate that hydrogen chloride/hydrochloric acid is not expected to have developmental toxicity*". If in accordance with the considerations above the test is performed on silanetriol, the data thus generated in combination with the available information on the pre-natal developmental toxicity effects of hydrochloric acid, should allow concluding on the pre-natal developmental toxicity of the registered substance.

The Registrant is accordingly required to submit the information on pre-natal developmental toxicity, in the rat or the rabbit, oral route, using test method B.31 according to Commission Regulation (EC) No 440/2008 or OECD 414, using the registered substance or the non-corrosive hydrolysis product (silanetriol).

Finally, the Registrant is reminded that a pre-natal developmental toxicity study on a second species is part of the standard information requirements as laid down in Annex X, Section 8.7.2. for substances registered for 1000 tonnes or more per year (see sentence 2 of introductory paragraph 2 of Annex X).

The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, Section 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if weight of evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed. If the Registrant considers that testing is necessary to fulfil this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the conclusion that no study on a second species is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, Section 8.7.2.

C. Deadline for submitting the required information

In the draft decision communicated to the Registrant, the time indicated to provide the requested information was 30 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested studies on other environmental and human health endpoints. As these studies are not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 12 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

In relation to the information required by the present decision, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the study to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
Leena Ylä-Mononen
Director of Evaluation