Decision number: CCH-D-2114311795-48-01/F Helsinki, 30 March 2016

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

For Titanium tetrachloride, EC No 231-441-9 (CAS No 7550-45-0), 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 for Titanium tetrachloride, EC No 231-441-9 (CAS No 7550-45-0), submitted by [redacted] (Registrant). The scope of this compliance check decision is limited to the standard information requirements of Annexes IX/X, Section 8.7.2. of the REACH Regulation. ECHA stresses that it has not checked the information provided by the Registrant and other joint registrants for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 or more tonnes per year. This decision does not take into account any updates after the deadline for updating (13 March 2015) communicated to the Registrant by ECHA on 4 February 2015.
This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 15 May 2014.

On 14 November 2014 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 18 December 2014 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 23 July 2015 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.

Subsequently, proposals for amendment to the draft decision were submitted.

On 28 August 2015 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 7 September 2015 ECHA referred the draft decision to the Member State Committee.

By 28 September 2015, in accordance to Article 51(5), the Registrant provided comments on the proposal for amendment. The Member State Committee took the comments on the proposal for amendment of the Registrant into account.

After discussion in the Member State Committee meeting on 27-29 October 2015, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 27 October 2015.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes

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

1. Pre-natal developmental toxicity study (Annex IX, 8.7.2.; test method: EU B.31./OECD 414) in rats or rabbits, oral route.

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. In this regard ECHA invites the Registrant to take into account the considerations set out in section III of this decision.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

B. Deadline for submitting the required information

Pursuant to Article 41(4) and 22(2) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **6 April 2017**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirement.

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.):

A "pre-natal developmental toxicity" for a first species is a standard information requirement as laid down in Annex IX, section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the substance subject to the present decision to meet this information requirement.

The Registrant has proposed to adapt the information requirement of prenatal developmental toxicity (Annex IX, Section 8.7.2. of the REACH Regulation).
The Registrant has sought to justify this adaptation with a reference to rapid hydrolysis of the substance.

However, ECHA notes that Column 2 of Section 8.7. of Annex IX of the REACH Regulation does not include the possibility of adapting the information requirement, based on rapid hydrolysis, for the pre-natal developmental toxicity study.

ECHA notes that the Registrant has not provided study records of the studies made on the two hydrolysis products titanium dioxide (TiO2) and aqueous hydrogen chloride (HCl), and therefore, these studies cannot be used to meet the respective information requirement. Furthermore, the Registrant has proposed to adapt the information requirement of Annex IX, Section 8.7.2. The Registrant has made a reference to corrosivity and poor systemic absorption of the registered substance.

According to introductory paragraph 4 of Annex IX of the REACH Regulation "*in vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided". Thus, introductory paragraph 4 of Annex XI is not a legal basis for waiving the standard information requirement for corrosive substances. It merely advises registrants to avoid testing corrosive substances at corrosive concentrations. Accordingly, pursuant to this provision the registrant should endeavour to test the substance at non-corrosive concentration(s).

Concerning poor systemic absorption ECHA would like to point out that neither column 2 of Annex IX, 8.7. nor the general rules for adaptation of Annex XI include such possibility to adapt this standard information requirement.

In the case it was the intention of the Registrant to apply the adaptation rule as set out in the third indent of Column 2 of Annex IX, 8.7., ECHA would like to clarify that in addition to the condition of "no systemic absorption" it is also necessary to document that the substance is of "low toxicological activity" and that there is "no or no significant human exposure".

Since the Registrant has not provided sufficient information to show that conditions of an adaptation in Column 2 of Annex IX, 8.7. are met, the adaptation of the information requirement suggested by the Registrant cannot be accepted. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In his comment, the Registrant has provided information on the rapid hydrolysis of the registered substance, and proposed an adaptation claiming that it is not technically possible to test the registered substance. ECHA points out that rapid hydrolysis, as such, does not make testing impossible, but it rather implies that the test animals would be exposed to the hydrolysis products of the test substance. The Registrant claims that the registered substance hydrolyses to HCl and to TiO2. The Registrant has partly addressed these hydrolysis products. In his comment, the Registrant has explained and provided a justification, why generation of data on the hydrolysis product HCl would not be necessary in this case.

Concerning the hydrolysis product TiO2, the Registrant mentions in his comment an ongoing testing programme, which includes the pre-natal developmental toxicity study(ies) (OECD TG 414) on that substance. ECHA understands that the Registrant has considered the possibility to make use of these toxicity data on TiO2 in support of his registration but the Registrant has not explained further how these data might be used for that purpose.

ECHA recognises that it may be possible that the properties of the hydrolysis product TiO2 can be covered by the results of the testing programme to which the Registrant referred. However, ECHA notes that the Registrant has at present made no assessment of how these data may be used to address the pre-natal developmental toxicity potential of TiCl4.

ECHA notes that a number of pre-natal developmental toxicity studies (OECD 414) on different forms of TiO2 are reported in registrations on the ECHA dissemination website. In this regard, ECHA also notes that TiO2 has different physical forms, which may affect its solubility and bioavailability and, therefore, may have a bearing on its toxicological properties.

ECHA considers that the reported ongoing testing programme, which contains several pre-natal developmental toxicity tests on different grades of TiO2, which have already now been conducted, may provide relevant information in addressing the information requirement for a pre-natal developmental toxicity study for TiCl4. To this end, however, in order to be able to predict the properties of the registered substance in accordance with Annex XI, 1.5. of the REACH Regulation, the Registrant must be able to document and justify in his registration that the TiO2 released from hydrolysis of TiCl4 is similar to that TiO2, for which pre-natal developmental toxicity studies are available, and that these pre-natal developmental toxicity studies are adequate for use in the prediction of the properties of the registered substance, and that a record(s) of the study(ies) is(are) made available.

In a proposal for amendment, a Member State suggested that the Registrant is reminded that, taking account of the reactivity of the substance, it may be possible to construct an exposure-based waiving argument in accordance with Section 3 of Annex XI. In his comment to the proposal for amendment, the Registrant refers to this proposal. Consequently, ECHA has examined Use categories and Product categories reported by the Registrant and found that, while some processes are probably run under strictly controlled conditions, there are others which according to the registration are not. Furthermore, there are uses of the substance for which the strictly controlled conditions as specified in article 14 (4) of REACH have not been documented in the registration dossier.

Therefore the Registrant cannot be advised to rely on Annex XI, Section 3.

Another Member State suggested in its proposal for amendment that the Registrant is requested in section II of the draft decision to submit a pre-natal developmental toxicity study on the substance **or** a relevant hydrolysis product and to provide justification for the choice of the form used. However, ECHA considers that a sufficient justification of the read-across from TiO2 to the registered substance is currently missing.

On this basis and with respect to the 'Note for consideration of the Registrant' above in Section II.A., and because of the rapid hydrolysis of the substance and corrosivity of the other hydrolysis product, ECHA is of the opinion that the Registrant should consider, whether any of these studies made on TiO2 can be used to adapt the information requirement for the substance subject to this decision. In this case, read-across may be a possible approach to reducing the number of new vertebrate animal tests conducted, and also reducing costs. For a read-across to be acceptable there needs to be a clear and robust justification for the proposed approach which as far as possible follows the ECHA read-across guidance http://echa.europa.eu/documents/10162/17250/pg_report_readacross_en.pdf).

The Registrant shall ensure that the information and studies raised in his comment, if used to support an adaptation of the information requirement, are reported transparently in the registration dossier.

At present, no documented justification according to Annex XI, which explains how data from TiO2 can be used to support the adaptation and no study record(s) on pre-natal developmental toxicity of TiO2, is included in the dossier submission.

Therefore, the adaptations of the information requirement suggested by the Registrant cannot at this stage be accepted.

According to the test method EU B.31/OECD 414, as referred to in in Annex IX, Section 8.7.2. of the REACH Regulation, 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.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity (test method: EU B.31./OECD 414) in rat or rabbit, oral route.

Notes for consideration by the Registrant

In addition, 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.

2. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 12 months from the date of adoption of the decision. In a Member State proposal for amendment, a deadline of 18 months was proposed. However, in his comments on this Member State proposal for amendment the Registrant indicated that the studies on the analogue substance, based on which he intended to update his adaptation argument according to Annex XI, Section 1.5, were already available in an updated registration dossier on the analogue substance. The Registrant thus concluded that no extra time was necessary. ECHA cannot conclude on the validity of the adaptation the Registrant intends to propose when updating his dossier. However, in ECHA's view a reasonable time period for providing the required information is 12 months from the date of the adoption of the decision. The decision was therefore not modified in this regard.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. The Registrant is reminded of his responsibility and that of joint Registrants to ensure that the joint registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In relation to the information required by the present decision, the sample of substance used for the new studies 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 studies 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 studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies 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.

Authorised[1] by **Claudio Carlon**, Head of Unit, Evaluation **E2**

[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.