

Decision number: CCH-D-2114297337-37-01/F

Helsinki, 23 March 2015

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

For iron trichloride, CAS No 7705-08-0 (EC No 231-729-4), 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 iron trichloride, CAS No 7705-08-0 (EC No 231-729-4), submitted by [REDACTED] (Registrant).

This decision is based on the registration 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 submitted after 15 January 2015, 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 registration at a later stage.

The compliance check was initiated on 7 November 2013.

On 17 December 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 45 days of the receipt of the draft decision. That draft decision was based on submission number [REDACTED].

On 8 January 2014 ECHA received comments from the Registrant on the draft decision.

On 12 June 2014 and 20 October 2014 the Registrant updated his registration dossier with submissions [REDACTED] and [REDACTED] respectively.

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

On 15 January 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.

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

II. Information required

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

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Nature and order of magnitude of any additives (Annex VI, 2.3.4.) as specified under section III.1 below; and
2. Spectral data (Annex VI, 2.3.5), as specified under section III.2 below.

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit the information required by this decision in the form of an updated registration to ECHA by **30 September 2015**.

III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein does not comply with the requirements of Article 10 of the REACH Regulation and Annex VI 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.

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 requirements.

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

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Nature and order of magnitude of any additives (Annex VI, 2.3.4.)

ECHA observes that the Registrant has reported two compositions for the substance: "Iron trichloride" and "Iron trichloride (technical grade)". For both compositions the Registrant reported in the Additives section [REDACTED]. Following the draft decision, the Registrant updated the registration dossier on 20 October 2014 (update submission no. [REDACTED]). In the updated dossier the [REDACTED] is specified as a stabiliser for both compositions. However, the Registrant did not include any further information on the stabilising function of [REDACTED] in the substance, although in the draft decision he was requested to provide, in addition to a specific statement, also information about the stabilising function of [REDACTED] in the substance. Therefore, it remains unclear how [REDACTED] stabilises the manufactured substance, and the validity of the presence of [REDACTED] as an additive in section 1.2 of the IUCLID dossier cannot be confirmed.

ECHA notes that in accordance with section 2.2 of the Guidance for identification and naming of substances under REACH and CLP¹ (Version: 1.2, March 2012), referred to as "the Guidance" thereafter, an additive is a "substance that has been intentionally added to stabilise the substance". The role of an additive is therefore limited to preserving the stability of the manufactured substance. Intentionally added substances or solvents with other functions are not considered as additives under REACH and therefore should not be included in the composition.

Therefore, in accordance with the above and pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide specific statement and information about the stabilising function of [REDACTED] in the substance. If [REDACTED] is not a stabiliser, it shall be removed from the "Additives" field and the composition reported in section 1.2 of the IUCLID dossier shall be revised accordingly. If the [REDACTED] is an impurity resulting from the manufacturing process, it shall be reported under the "Impurities" field.

As for the reporting of the data in the registration dossier, the information should be included in section 1.2.

2. Spectral data (Annex VI, 2.3.5)

ECHA notes that the Registrant has not provided sufficient spectral data to determine the identity and composition of the substance registered, as required by Annex VI, 2.3.5. of the REACH Regulation.

More specifically, the registered substance iron trichloride is an inorganic substance. For these the Guidance recommends in section 4.2.1.3 the use of X-ray diffraction (XRD) for the identification of the substance.

In his comments to the draft decision, the Registrant indicated that the registration dossier includes an X-ray diffractogram measured on the substance, and that this diffractogram would be included on p. 39 of the attachment "[REDACTED]". [REDACTED] included in section 1.4 of the IUCLID dossier. ECHA notes that there is a method description for an XRD measurement on p. 19 of this attachment. This method description was included in the original dossier, and is also present in the updated registration dossier. However, there is no corresponding X-ray diffractogram in the dossier measured on the registered substance. ECHA notes that the graph included on p. 39 of the attachment is not an X-ray diffractogram but the graph is an X-ray fluorescence (XRF) spectrogram which is only showing that the sample contains the elements Fe and Cl. Furthermore, there are two X-ray diffractograms in the same attachment on ps. 30 and 32. However, they have both been measured on aluminium sulphate, which is a different substance from iron trichloride. Therefore, the Registrant has not included in the dossier any X-ray diffractogram recorded on the registered substance. Without this information the identity of the substance cannot be verified.

Therefore, in accordance with the above and pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide the X-ray diffractogram, which shall be measured on the dry substance. This is necessary to verify the identity of the inorganic substance.

¹ available on the ECHA website at: http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf.

The Registrant shall ensure that the description of the analytical methods used for the recording of the X-ray diffractogram is specified in the dossier, in line with the requirements under Annex VI section 2.3.7. This information shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

As for the reporting of the data in the registration dossier, the information should be attached in IUCLID section 1.4.

IV. 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.



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