EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004532-79-03/F Helsinki, 11 August 2014

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

For xylene, CAS No 1330-20-7 (EC No 215-535-7), 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 xylene, CAS No 1330-20-7 (EC No 215-535-7), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

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 6 March 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 registration at a later stage.

The compliance check was initiated on 24 September 2013.

On 18 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.

On 3 February 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 6 March 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

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

Pursuant to Articles 41(1)(a), 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. Name or other identifier of the substance (Annex VI, Section 2.1.), as specified in Section III.1. below;
2. Description of the analytical methods (Annex VI, Section 2.3.7.), as specified in Section III.2. below.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **18 November 2014**.

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 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. Name or other identifier of each substance (Annex VI, Section 2.1.)

According to Annex VI, Section 2.1 of the REACH Regulation, name or other identifier of each substance shall be provided. This includes the name in the IUPAC nomenclature or other international chemical name(s) (Annex VI, Section 2.1.1); as well as CAS name and CAS number (if available) (Annex VI, Section 2.1.4).

In accordance with the Guidance for identification and naming of substances under REACH and CLP (Version: 1.2, March 2012)[1] - referred to as "the Guidance" thereinafter, a substance is defined as a Unknown or Variable composition, Complex reaction products or Biological materials (UVCB) when the number of constituents is relatively large and/or the composition is to a significant part unknown and/or the variability of composition is relatively large or poorly predictable. The Guidance also defines multi-constituent substances as well-defined substances in which more than one constituent is present at a concentration >10% (w/w) and <80% (w/w) (referred to thereinafter as "main constituent"). A multi-constituent substance is named as the reaction mass of the main constituents.

ECHA notes that the Registrant has identified the registered substance as a UVCB. However, the composition information, the analytical data included in the registration dossier and the sum of the typical concentration values specified for the identified constituents clearly

[1] http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf

indicate that the registered substance has a well-known composition. As a consequence, in accordance with the Guidance, the registered substance should rather be regarded as a multi-constituent substance.

Moreover, ECHA notes that the name provided (xylene) and the numerical identifiers used for defining the registered substance (EC number 215-535-7 and CAS number 1330-20-7) refer to a substance containing all the possible isomers of xylene (ortho-, meta- and para-xylene). However, the IUPAC name and identifiers used to identify the substance do not reflect the substance composition. The composition of the substance provided in section 1.2 of the IUCLID dossier shows that ethylbenzene is present at a typical concentration >10% (w/w). As a consequence, ECHA considers that the IUPAC name provided by the Registrant is not representative of the composition of the registered substance, because the presence of the main constituent ethylbenzene is not reflected in the name of the substance.

Therefore, ECHA concludes that the provided chemical name and EC/CAS entries do not reflect the substance composition as reported in Section 1.2 and substantiated by the provided analytical data.

The Registrant is accordingly requested to provide a chemical name corresponding to the specific multi-constituent substance covered in this registration. The chemical name shall follow the generic format "Reaction mass of [names of the main constituents]". All main constituents present in the registered substance shall be reflected in the name of the registered substance. The Registrant shall also specify any available and appropriate CAS number and CAS name reflecting the identity of the main constituents of the substance. The Registrant shall delete from the registration any information referring to different substances than the multi-constituent substance which is the subject of this registration.

As for the reporting of the information in IUCLID, the chemical name shall be indicated in the "IUPAC name" field in IUCLID section 1.1. The CAS number and CAS name shall be reported under the "CAS information" header in IUCLID section 1.1.

The Registrant is requested not to remove or modify at this stage the EC entry currently assigned to this registration for technical reasons, the registration being linked to that EC entry in REACH-IT. The Registrant is requested to include the following in the "Remarks field" of the reference substance: "The EC entry currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified in the present registration at this stage for technical reasons".

Furthermore, the Registrant shall ensure that the molecular and structural information specified in IUCLID section 1.1 (smiles notation, InChI code and structural formula) are consistent with the chemical name and CAS number and CAS name assigned to the registered substance.

Finally, ECHA points out that, in accordance with the criteria for substance sameness specified in paragraph 5 of the Guidance for identification and naming of substances under REACH and CLP, multi-constituents substances with different main constituents shall be regarded as different substances and subject to different registrations under the REACH Regulation.

2. Description of the analytical methods (Annex VI, Section 2.3.7.)

ECHA observes that the Registrant did not provide sufficient detailed description of the analytical method used for the identification and quantification of the different constituents

present in the composition of the registered substance, which is requested according to Annex VI section 2.3.7.

More specifically ECHA notes that the Registrant provided a chromatographic report including a table (Table 1, page 4 of the report) that gives information on concentration values of a number of constituents or groups of constituents present in the registered substance.

Such table however does not reflect the presence of all the peaks shown in the chromatogram included in the report. More specifically, a number of peaks which relative retention time values correspond to about 0.5 – 1.6 min are shown in the chromatogram. These peaks have not been identified; in addition no peak table listing all the peaks shown on the chromatogram with the corresponding retention time values and peak area has been attached to the chromatogram. It is not clear if these peaks correspond to constituents/groups of constituents included in the composition of the registered substance or if their presence is linked to the analytical methodology used to determine the composition of the substance. As a consequence it is not clear how the result of the chromatographic analysis translate into the concentrations of the constituents/groups of constituents present in the registered substance.

ECHA therefore concludes that the chromatographic report provided for the registered substance does not contain sufficient information for determining the composition of the registered substance.

The Registrant is accordingly requested to provide a description of the analytical methods used for the identification and quantification of the constituents required to be reported in the composition of the registered substance. The description 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. A clarification on the presence of the peaks shown in the chromatogram and not reported in the composition table included in the analytical report shall be provided. If such peaks correspond to constituents that are part of the composition of the registered substance, these constituents shall be identified, quantified and reported in the composition section of the IUCLID dossier. The Registrant is also requested to provide a peak table listing all the peaks shown on the chromatogram with the corresponding retention time values and peak area.

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

During the commenting phase the Registrant proposed to "submit before the end of 2014 a spontaneous update addressing the issues raised within the draft decision, specifically on substance identification". The Registrant substantiates the proposal stating that "this time is required as careful discussion with all the registrants will be required as it may have unintended consequences to the supply chain which will need to be resolved."

ECHA acknowledges the Registrant's commitment to update the substance identity information as required by the present decision. However, ECHA considers that the deadline provided (3 months from the date of the decision) is sufficient to consider consequences in the supply chain as well as to update the substance identity information according to the requests formulated in the present decision. In fact, ECHA considers the information requested as administrative, hence the need for a longer deadline is not justified.

Therefore, the requests and deadline set in the decision are maintained and the Section II of the decision is not amended based on the comments provided by the Registrant.

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://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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