ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004742-74-03/F Helsinki, 3 October 2014

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

For sodium xylenesulphonate, CAS No 1300-72-7 (EC No 215-090-9), 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 sodium xylenesulphonate, CAS No 1300-72-7 (EC No 215-090-9), submitted by [redacted] (Registrant).

ECHA notes that in the joint submission covering the current registration, the Chemical Safety Report (CSR) is provided by the lead registrant on behalf of the member registrants. The scope of this compliance check is limited to the standard information requirements of Section 2 of Annex VI, while the compliance check concerning the information requirements laid down in Annexes VII to X was done on the lead registrant dossier of this joint submission.

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 12 June 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 10 July 2013.

On 10 February 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.

By 12 March 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 12 June 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), 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, 2.1.); and
2. Composition of the substance (Annex VI, 2.3.).

B. Deadline for submitting the required information

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 **10 April 2015**.

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.

A. 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 the substance (Annex VI, 2.1)

ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). Information required to be provided on the naming of UVCB substances such as the registered substance shall consist of two parts: (1) the chemical name and (2) a detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.2, March 2012) - referred to as "the Guidance" hereinafter. ECHA observes that the Registrant did not provide sufficient information on the naming of the registered substance, as required under Annex VI Section 2.1 of the REACH Regulation (as explained under points (i) and (ii) hereinafter).

(i) The chemical name provided for the registered substance in section 1.1 of the IUCLID dossier is "sodium dimethylbenzenesulfonate". Such name corresponds to a substance predominantly consisting of isomers of dimethylbenzenesulphonate.

However, ECHA notes that the composition included in section 1.2 of the IUCLID dossier indicates the presence of a considerable amount of sulphonated aromatic hydrocarbons other than dimethylbenzenesulphonate isomers. In particular, the reported concentration for the constituent sodium 4-ethylbenzenesulfonate typically exceeds two of the three possible groups of dimethylbenzenesulphonate isomers and contributes up to [redacted]% of the composition. The relative contribution of this constituent over the dimethylbenzenesulphonates is therefore not considered insignificant.

In line with the above, ECHA considers that the chemical name provided does not reflect the overall identity of the predominant constituents that are present in the composition of the registered substance.

For the same reason, the assigned EC 215-090-9 and CAS 1300-72-7 entries with EC name "sodium xylenesulphonate" and CAS name "Benzenesulfonic acid, dimethyl-, sodium salt (1:1)" are not considered appropriate identifiers of the registered substance.

(ii) ECHA observes that the Registrant has provided in section 3.1 of the IUCLID dossier a generic description of the manufacturing process which is not sufficiently detailed for the identification of the registered UVCB substance.

In particular, in such description, different sources are mentioned ("*Hydrotropes are produced by sulfonation of an aromatic hydrocarbon solvent (i.e., toluene, xylene or cumene)*"). The chemical name "*aromatic hydrocarbon solvent*" covers any hydrocarbon solvent showing aromaticity. A multitude of substances may be generally described as "*aromatic hydrocarbon solvent*". This is also highlighted by the examples included in the above description provided by the Registrant. The Registrant shall note in fact that toluene, xylene or cumene are considered as three different substances. These three substances show indeed the same aromatic parent structure, however the alkyl groups attached to the parent chain differ in type and number.

The Registrant shall note that, in accordance with chapter 4.3. of the Guidance, any significant change of the source or process used for the manufacturing of UVCBs would be likely to lead to different substances which shall be registered separately. ECHA therefore concludes that the description given for the sources used for manufacturing does not specifically refer to the registered substance.

Furthermore, the Registrant did not specify the ratio and identity of all the starting materials, including the sulfonation agent used for the production of the substance.

In addition, the relevant process parameters (e.g. temperature, pressure), including also the parameters determining the level of sulfonation in the constituents of the manufactured substance, have not been included in the manufacturing process description.

ECHA therefore concludes that the manufacturing process has not been provided to a sufficient level of detail for the identification of the registered substance.

In line with the observation under point (i), the Registrant is accordingly requested to revise the chemical name assigned to the registered substance. The Registrant shall ensure that the chemical name is representative of the specific substance which is the subject of this registration. Based on the information currently contained in the dossier and taking into account the complexity of the composition due to the presence of different regioisomers of the sulfonated ortho-, meta- and para- xylenes, ECHA invites the Registrant to consider if a chemical name such as "[redacted]" would be appropriate for the identification of the registered substance.

The Registrant shall also delete the CAS information currently assigned to the substance and provide instead any available CAS information specifically corresponding to the substance. As for the EC entry currently assigned, the Registrant shall not delete or modify at this stage the EC entry with EC number 215-090-9 currently assigned to this registration for technical reasons, the registration being linked to that EC entry in REACH-IT. To ensure unambiguous identification of the registered substance, the Registrant shall however specify in the dossier that the EC entry currently assigned does not specifically correspond to the registered substance and shall refer to any available and appropriate EC number specifically corresponding to the substance.

As for the reporting of the information in IUCLID, the IUPAC name and any available CAS entry for the registered substance should be reported in the "IUPAC name" field and under the "CAS information" header of the reference substance in IUCLID section 1.1, respectively. The CAS entry with CAS number 1300-72-7 may be reported under the "Related CAS information" header in IUCLID section 1.1 The Registrant should specify, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC entry 215-090-9 currently assigned does not specifically correspond to the registered substance. This identifier can technically not be modified or deleted at this stage in the present registration update". The Registrant should also specify, in the same IUCLID field, any available and appropriate EC number for the substance.

In line with the observations under point (ii), the Registrant is requested to provide the missing information on the manufacturing process description. This information shall include:

- The identity and ratio of the reactants, The Registrant shall ensure that the specific starting material generically referred to as aromatic hydrocarbon solvent in the registration dossier is designated using a chemical name that accurately reflects its identity. Further information for the identification and naming of substances, including the starting materials, is available in the Guidance.
- The relevant process steps and parameters such as temperature and pressure, including also the parameters determining the level of sulfonation in the constituents of the manufactured substance.

If the substance covered by the registration is manufactured according to different manufacturing processes, including the use of different sources, then the detailed description of the manufacturing process required hereinabove shall be reported separately for each manufacturing process. A manufacturing process may be considered different when the processing steps and/or processing parameters are different.

As for the reporting of the information in IUCLID, the description should be specified in the "Description" field in IUCLID section 1.1.

2. Composition of the substance (Annex VI, 2.3)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the corner stone of all the REACH obligations.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, section 2.3. of the REACH Regulation.

The Registrant indicated in section 1.2 of the IUCLID dossier broad concentration ranges for the following xylene derivatives:

- m-xylene, sulfonic acid derivs., sodium salts ([redacted]%)
- sodium 2,5-dimethylbenzenesulfonate ([redacted] %)
- o-xylene, sulfonic acid derivs., sodium salts ([redacted]%)

Such broad concentration ranges are not justified by the manufacturing process description due to its lack of detail, as already pointed out in section A.1.(ii) above. Such broad concentration ranges would also indicate that the reported composition varies so much that [redacted] can be either one of the predominant constituents or totally absent. ECHA therefore considers that, without further clarification on the concentration values reported in the dossier, the reported composition is not representative of the specific substance subject to this registration.

The Registrant shall therefore clarify the reason for such broad concentration ranges or reduce the scale of the reported ranges. In any case, the Registrant shall note that the concentration range values must be representative for the substance as manufactured. In addition, the Registrant shall clarify how the minimum and maximum values for each group of constituents were obtained (i.e. information on the batch selection, sampling procedure, the measured values, calculations used, etc.).

Finally, ECHA wishes to stress that, where the registration covers different grades of the same substance in a dossier, the Registrant shall report separately the compositional information of each grade. This means that if the substance has two (or more) different compositions, then these must be presented separately. For each grade, the Registrant shall indicate, in the "Brief description" field of the corresponding composition, which of the manufacturing process descriptions required to be specified in the Description field of IULCID section 1.1 refers to that grade. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A8 of the "Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH" (version: 2.0, July 2012), available on the ECHA website.

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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