ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002025-86-08/F Helsinki, 7 March 2013

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

For Sodium ethylenesulphonate, CAS 3039-83-6 (EC No 221-242-5), 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 Sodium ethylenesulphonate, CAS 3039-83-6 (EC No 221-242-5), submitted by [redacted] (Registrant), submission number [redacted], for the tonnage band of 1000 tonnes or more per year.

The compliance check was initiated on 29 March 2012.

On 16 August 2012 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 17 September 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 01 October 2012 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

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

II. Information required

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:

a. Name of the substance (Annex VI, 2.1.);
b. Composition of each substance (Annex VI, 2.3.);
c. Chromatogram (Annex VI, 2.3.6.);

d. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7).

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **7 June 2013.**

III. Statement of reasons

Based on the examination of the technical dossier and its attachments[1], 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 tonnes or more per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10 and with 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 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.

(a) Name of the substance (Annex VI, 2.1.)

ECHA notes that the Registrant identified the registered substance as a mono-constituent substance. In line with the Guidance for identification and naming of substances under REACH and CLP (Version: 1.1, November 2011), referred to thereinafter as the "Guidance for substance identification", mono-constituent substances are well-defined substances in which one constituent is present at a concentration ≥ 80% (w/w), referred to thereinafter as "main constituent". A mono-constituent substance is named as the name of the main constituent. ECHA observes that the Registrant did not provide appropriate information on the name of the substance, as required under Annex VI Section 2.1 of the REACH Regulation.

More specifically, ECHA notes that the name and CAS entry provided for the registered substance is "Sodium ethylenesulphonate". In principle, based on the above, the substance identified as "Sodium ethylenesulphonate" must refer to a mono-constituent substance in which Sodium ethylenesulphonate is present at a concentration ≥ 80% (w/w). ECHA, however, observes that the compositional information specified in the IUCLID dataset of the registered substance indicates that Sodium ethylenesulphonate is present in concentration less than 80% (w/w).

In addition the Registrant specified in the IUCLID dataset a constituent named as "[redacted]" present in concentration > 10%(w/w). Following the Guidance for substance identification a substance in which more than one constituent is present at a concentration ≥10% (w/w) and <80% (w/w) is regarded as a multi-constituent substance. Multi-constituent substances are named as the reaction mass of the main constituents.

[1] In particular report entitled "[redacted] 05 February 2010.

As a result, the compositional information provided refers to a multi-constituent substance for which Sodium ethylenesulphonate and [redacted] are the main constituents. In principle, the substance corresponding to the composition information should be a different substance than Sodium ethylenesulphonate.

The Registrant provided a justification for considering the registered substance as corresponding to the mono-constituent substance Sodium ethylenesulphonate. The justification given for deviating from the "80% rule" is based on an estimation of the hazardous profile of the constituents present in the substance using QSAR calculations/read-across approaches. The Guidance for substance identification describes the possibility to deviate from the "80% rule" on the basis of the physical-chemical properties and the hazard profile. According to the Guidance for substance identification such deviation could be justifiable "if the main constituent is <80%". This situation refers to the presence of one main constituent and excludes situations where more than one main constituent is present in the substance. The Registrant shall note that the composition of the registered substance is such that the approach proposed cannot be adopted, because two main constituents are present in the substance in concentration >10% (w/w) and <80% (w/w). This composition corresponds to a multi-constituent substance. A deviation from the "80%" rule is therefore not justifiable in this case.

ECHA points out that, in accordance with the criteria for substance sameness specified in paragraph 5 of the Guidance for substance identification, well-defined substances with different main constituents shall be regarded as different substances under REACH. ECHA therefore concludes that the provided CAS entry, chemical name and the composition specified in the dossier refer to different substances.

The Registrant shall note that manufacturing the substance in different qualities consisting of one main constituent in concentration ≥80% would lead to the production of a mono-constituent substance. Such mono-constituent substance is considered as different from the multi-constituent substance which is the subject of this registration. Any substance with a different composition than the multi-constituent substance covered by this registration has to be registered separately.

The Registrant is accordingly requested to provide a chemical name corresponding to the multi-constituent substance covered in this registration. The chemical name shall follow the generic format "Reaction mass of [names of the two main constituents]". 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, based on the available compositional information, 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 shall ensure that the molecular and structural information specified in IUCLID section 1.1 and the composition indicated in IUCLID section 1.2 are consistent with the chemical name and CAS number and CAS name assigned to the registered substance.

(b) Composition of each substance (Annex VI, 2.3.);

The substance composition corresponds to the chemical representation of what the substance consists of and it is a crucial parameter in its identification.

ECHA notes that the registration does not contain sufficient and appropriate 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.

More specifically, ECHA notes that the Registrant provided information on the lower concentration level of one of the main constituents (Sodium ethylenesulphonate) and only the typical concentration of the other constituents present in the substance. No information is provided on the upper concentration level of any constituent present in the substance. It follows that ECHA does not have any information on the variations in the composition of the registered substance.

In line with paragraph 4.2 of the Guidance for substance identification, the following applies to all well-defined substances, including the registered substance: for each constituent, including the main constituents and impurities, the typical, minimum and maximum concentration level shall be specified.
The Registrant is accordingly requested to complete or correct the above information on the composition of the registered substance provided in the registration dossier, for ECHA to have a precise chemical representation of what the substance consists of.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: The Registrant shall report the minimum, maximum and typical concentration of the main constituents and impurities in the appropriate fields in Section 1.2 of the IUCLID dossier.

Further technical details on how to report the composition of multi-constituent substances in IUCLID are available in paragraphs 2.1 and 2.2.1.2 of the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 1.0, June 2010

The Registrant shall ensure that the information provided on the composition of the substance is confirmed by the analytical data included in section 1.4 of the IUCLID dossier.

(c) Chromatogram (Annex VI, 2.3.6.)

ECHA notes that the registration dossier does not contain any chromatographic data which is required according to Annex VI, Section 2.3.6. of the REACH Regulation to support the indicated substance composition. The Registrant has also not included scientific justifications for not providing all of the required information.

The Registrant is therefore requested to submit a chromatogram for the registered substance. The report from the chromatographic analysis, including a peak list with the corresponding retention time and peak area shall be also included. If it is not technically possible or if it does not appear scientifically necessary to provide these chromatographic data, a scientifically based justification should be given.

As for the reporting of the information in the dossier, the results of the chromatographic analysis, or a scientific justification for not including these data should be attached in IUCLID section 1.4.

(d) The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7).

ECHA notes that the Registrant has not provided any detailed description of the analytical method used for the identification and quantification of the registered substance including its constituents as required by Annex VI, 2.3.7 of the REACH regulation.

More specifically ECHA notes that the registrant provided information on the result of quantitative analyses carried out on the registered substance. However, a description of the methods used, including details of the experimental protocol followed, standard used and calculations made has not been included in the IUCLID dossier.

In addition, ECHA notes that the registered substance consists of salts which have sodium ion as the cationic part. In order to confirm the identity of the registered substance, analytical information on the identification and quantification of all its constituents that are required to be reported is requested. The registration dossier, however, does not include analytical data enabling the identification and quantification of the sodium ion as required according to Annex VI, Section 2.3.7.

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, standard used, 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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

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Director of Regulatory Affairs