EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004623-76-03/F Helsinki, 27 June 2014

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

**For sodium hydrogensulfite, CAS No 7631-90-5 (EC No 231-548-0), 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 sodium hydrogensulfite, CAS No 7631-90-5 (EC No 231-548-0), 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 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 6 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.

By 31 January 2014 the Registrant did not provide any comments on the draft decision to ECHA.

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 39 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:

Description of the analytical methods (Annex VI, 2.3.7.), as further specified under section III.A.

**B. Information related to chemical safety assessment and chemical safety report**

Pursuant to Articles 41(1), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

Revised exposure assessment and risk characterisation for the environment.

**C. Deadline for submission of the information**

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 **5 January 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.

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

ECHA observes that the Registrant has not included a sufficient description of the qualitative and quantitative analyses required by Annex VI, Section 2.3.7. of the REACH Regulation that would provide an overview of the identity and composition of the registered substance.

More specifically, ECHA notes the following insufficiencies:

- The Registrant provided descriptions of methods used for the identification and quantification of the substance (titration, attachment "[redacted]"; Inductively coupled plasma, attachment "[redacted]"; ion chromatography, attachment "[redacted]"). However, the results from these measurements were not included in the dossier, and therefore the information presented in the attachments do not enable to establish the composition of the registered substance. Furthermore, ECHA notes that for this type of substance the information included in section 1.4 of the technical dossier is required to include separately the identification and quantification of the cationic and anionic species, in this case sodium and hydrogensulphite, respectively, with the corresponding results.

- The Registrant reported in section 1.2 two impurities: disodium sulfate and disodium sulfite. However, the Registrant has not included in section 1.4 descriptions of the methods, or the results thereof, for the identification and quantification of these impurities.
- The sample used for the analyses was a [redacted] aqueous solution of sodium hydrogensulfite, whereas the composition included in section 1.2 has been reported for dry substance. The Registrant has not included in the dossier quantification results that would allow to confirm the composition of the dry substance. ECHA notes that the Registrant provided the value of [redacted] %(m/m) for the quantification of sodium hydrogensulphite in an aqueous solution, based on a "mathematic method" without further specifying what this method is (attachment "[redacted]"). This solution was indicated to be the marketed endproduct as indicated in section 1.2 in the "Remarks" field of the main constituent. However, this is not sufficient to confirm the composition of the substance; the quantification of water in the aqueous solution used for the analyses is also needed for this confirmation.

In the absence of the above-mentioned information, the identity and composition of the substance cannot be verified.

ECHA therefore concludes that the Registrant did not provide sufficient information on the description of the analytical methods used for identification and quantification of the registered substance, including the main constituent and the impurities.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide descriptions of the analytical methods and the corresponding results for the identification and quantification of the substance, including the main constituent and the impurities. The descriptions 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.

For chromatographic methods, the information shall include a legible print-out of the chromatogram as well as the report from the chromatographic analysis including the table of peak assignments that report the peak areas and corresponding amounts of each relevant constituent. For wet-chemistry based methods the Registrant shall provide the experimental values in form of the volume of the titrant used, the weight of the sample, and any other information that is necessary to reproduce the calculations.

The method descriptions and results for the identification and quantification of the cation(s) and anion(s) shall be provided separately and it shall be clear how they correspond to the composition reported in section 1.2. The Registrant shall ensure that the analyses carried out and the results obtained allow to verify the composition of the dry substance reported in section 1.2 (both for main constituent and for impurities). If quantification is carried out on aqueous solution, the information shall include also the quantification of water in the solution in IUCLID section 1.4.

In addition, the Registrant shall ensure that the composition reported in section 1.2 is in line with the information provided in section 1.4, which shall be sufficient to identify and quantify the substance.

As for the reporting of the method descriptions in the dossier, the information should be attached in section 1.4 of the IUCLID Dossier.

## B. Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report (CSR) which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

Revised exposure assessment and risk characterisation

Article 14(6) as well as Annex I, Sections 0.1., 5.2.4. and 6.2. to 6.4. of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in the CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented. Furthermore, pursuant to Annex VI, Section 5. of the REACH Regulation the information provided in the registration dossier must be consistent with that in the Safety Data Sheet. The requirements of Safety Data Sheets are specified in Annex II of the REACH Regulation.

The CSR for the registered substance does not include an environmental exposure assessment nor a risk characterisation for the environment. Instead, the CSR section 10 mentions that risk characterisation for all environmental compartments and all exposure scenarios would not be relevant. However, the dossier does include an attachment named "Exposure scenario addendum" where exposure scenarios, environmental releases, operational conditions, risk management measures and predicted environmental concentrations (PECs) are reported.

According to Annex I, Section 6. of the REACH Regulation, the risk characterisation shall be carried out for each exposure scenario for the environmental spheres for which exposure to the substance is known or reasonably foresseable. The risk characterisation consists of a comparison of the PECs in each environmental sphere with the predicted no-effect cocnentrations (PNECs).

Based on the PECs reported in the attachment and the PNECs reported in the technical dossier, the derived risk characterisation ratios (RCRs) for the fresh and marine water compartments are considerably higher (above 1 in all cases) than the ones reported by the Registrant for all exposure scenarios. For exposure scenario 1, for example, the reported PEC for freshwater is 2.52 mg/L, the reported PNEC is 1.09 mg/L and, thus, the correct RCR should be 2.3 instead of the reported 0.9. The same is the case for all other exposure scenarios for both fresh and marine water.

The Registrant needs to justify the discrepancy between the actual and reported RCR values and potentially revise the PEC and RCR calculations. According to Annex I, Section 5.1.1. of the REACH Regulation, *"if the initial assumptions lead to a risk characterisation indicating that risks to human health and the environment are not adequately controlled, then it is necessary to carry out an iterative process with amendment of one or a number of factors in hazard or exposure assessment with the aim to demonstrate adequate control"*.

The Registrant shall as well revisit all available information in the addendum document and ensure consistency with the information provided in the technical dossier and the CSR. In all cases, according to REACH Article 14, *"any registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 31"*.

In summary, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested either to refine his chemical safety assessment or to demonstrate that the risks identified for the aquatic compartment (freshwater and marine) and for all exposure scenarios are controlled. The chemical safety report sheet shall be amended accordingly.

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.

[redacted]
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