Decision number: CCH-D-0000003026-83-03/F Helsinki, 15 August 2013

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

For trisodium hydrogendicarbonate, CAS No 533-96-0 (EC No 208-580-9), 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 dossier for trisodium hydrogendicarbonate, CAS No 533-96-0 (EC No 208-580-9), submitted by [redacted] (Registrant).

The scope of this compliance check is limited to the standard information requirement of Annex VII, Section 8.4, and Annex VIII, Section 8.4 of the REACH Regulation.

This decision is based on the registration dossier 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 after 20 June 2013, 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 dossier at a later stage.

The compliance check was initiated on 28 September 2012.

On 14 December 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 14 January 2013 the Registrant did not provide any comments on the draft decision to ECHA.

On 20 June 2013 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.

II. Information required

Pursuant to Articles 41(1)(b), 41(3), 10(a)(vi), 12(1)(e), 13 and Annexes VII and VIII of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.; test method: EU B.13/14/OECD 471);
2. *In vitro* cytogenicity study in mammalian cells (Annex VIII, 8.4.2., test method: EU B.10/OECD 473) or *in vitro* micronucleus study (Annex VIII, 8.4.2.; test method: OECD 487);
3. *In vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3.; test method: EU B.17/OECD 476), provided that there is a negative result in the studies requested under a. and b.

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 **15 August 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. The scope of the present decision are the *in vitro* gene mutation study in bacteria (Annex VII, 8.4.1. of the REACH Regulation), the *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study (Annex VIII, 8.4.2 of the REACH Regulation) and the *in vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3. of the REACH Regulation). In accordance with Articles 10(a)(vi) and 12(1)(e) of the REACH Regulation, any registration for a substance manufactured or imported by a registrant at the tonnage level of 1000 tonnes or more per year shall contain this information.

1. Mutagenicity, *in vitro* gene mutation study in bacteria

The technical dossier contains an adaptation to the standard information requirement concerning *in vitro* gene mutation study in bacteria (Annex VII, 8.4.1.). The Registrant has justified the adaptation with the argument that

"In accordance with section 1 of REACH Annex XI , testing does not appear scientifically necessary. The substance is naturally present in cells and the structure does not indicate a genotoxic potential. Moreover, the substance already present in the tissue culture media of the in vitro test systems for genetic toxicity testing, and needed for normal function of the cells in culture. Testing sodium sesquicarbonate in vitro will affect the cellular homeostasis due to osmolarity and/or pH of the culture medium which might give rise to aspecific effects. In addition, mutagenicity tests performed on sodium bicarbonate gave negative results (OECD, 2002; SIDS Dossier)."

In accordance with the REACH Regulation any adaptation and the reasons for it shall be clearly stated by the Registrant. The Registrant has failed to specify which adaptation he has found to be applicable for the endpoint in question and based on the reasoning provided by the Registrant, ECHA cannot identify the conditions of which adaptation the Registrant sought to fulfil. He has not demonstrated why conditions of any adaptation are fulfilled.

Furthermore, ECHA notes that weblinks to information sources (which may or may not contain elements on which an adaptation could be justified) are not sufficient to demonstrate that the conditions of an adaptation are fulfilled. Even if the Registrant had clearly stated the adaptation he seeks to apply, he would have had to include adequate and reliable documentation. However, ECHA notes that that there is no test data on the genotoxicity presented in the technical dossier or the chemical safety report to substantiate the presented argument. Having regard to the reference to test results brought forward by the Registrant, ECHA highlights that a (robust) study summary is required to be included in IUCLID as part of adequate and reliable documentation in order to allow an (independent) assessment of the study.

ECHA concludes that the adaptation argument does not fulfil the requirements of the REACH Regulation.

No valid adaptation was provided, and no test information for this endpoint is included in the registration dossier. Consequently there is an information gap and it is necessary to generate the data for this endpoint. Therefore, the Registrant is requested to submit the information for this endpoint using the abovementioned test method on the registered substance.

2. Mutagenicity, *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study

The technical dossier contained an adaptation to the standard information requirement concerning *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study (Annex VIII, 8.4.2.). The Registrant has justified the adaptation with the same argument as for the endpoint covered by subsection 1 of Section III of the present decision.

For the same reasons as explained above, ECHA concludes that the adaptation argument does not fulfil the requirements of the REACH Regulation.

No valid adaptation was provided, and no test information for this endpoint is included in the registration dossier. Consequently there is an information gap and it is necessary to generate the data for this endpoint. Therefore, the Registrant is requested to submit the information for this endpoint using one of the abovementioned test methods on the registered substance.

3. Mutagenicity, in vitro gene mutation study in mammalian cells.

According to Annex VIII, section 8.4.3. of the REACH Regulation, the *in vitro* gene mutation study in mammalian cells is required if there is a negative result in the *in vitro* studies specified under Annex VII, section 8.4.1. and Annex VIII, section 8.4.2.

The technical dossier contained an adaptation to the standard information requirement concerning *in vitro* gene mutation study in mammalian cells (Annex VIII, 8.4.3.). The Registrant has justified the adaptation with the same argument as for the endpoints covered by subsections 1 and 2 of Section III of the present decision.

For the same reasons as explained above, ECHA concludes that the adaptation argument does not fulfil the requirements of the REACH Regulation.

No valid adaptation was provided, and no test information for this endpoint is included in the registration dossier. Consequently there is an information gap and it is necessary to generate the data for this endpoint. Therefore, the Registrant is requested to submit the information for this endpoint using the abovementioned test method on the registered substance provided there is a negative result in both studies requested under II.a. and II.b.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and by other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the information required by the present decision, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the studies to be assessed.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA reminds registrants of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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.

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Jukka Malm
Director of Regulatory Affairs