Decision number: CCH-D-2114321245-61-01/F Helsinki, 08 March 2016

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

For (1-hydroxyethylidene)bisphosphonic acid, sodium salt, EC No 249-559-4 (CAS No 29329-71-3), 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 (1-hydroxyethylidene)bisphosphonic acid, sodium salt, EC No 249-559-4 (CAS No 29329-71-3), submitted by [redacted] (Registrant).
The scope of this compliance check decision 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 after the date when the draft decision was notified to the Registrant under Article 50(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 20 April 2015.

On 14 September 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 21 October 2015 ECHA received comments from the Registrant agreeing to ECHA's 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 21 January 2016 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.

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. Composition of the substance (Annex VI, Section 2.3.);
2. Description of the analytical methods (Annex VI, Section 2.3.7.).

B. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **15 June 2016** an update of the registration dossier containing the information required by this decision.

II. 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. Composition of the substance (Annex VI, Section 2.3)

"Composition of the substance" is an information requirement as laid down in Annex VI, Section 2.3. of the REACH Regulation. 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 cornerstone of all the REACH obligations. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the Registrant reported five different compositions in section 1.2 of the IUCLID dossier, namely:

[redacted]

The process description provided states that "[redacted]".

From the provided information is in not clear whether the Registrant indeed manufactures a single distinct substance with variation in the level of neutralisation of the phosphonic acid groups or whether the level of neutralisation is controlled yielding up to four distinict substances. For each of the compositions listed, the concentration range of the main constituent is indicated to be [redacted]% w/w which would suggest that up to four distinct substances are covered by this Registration. The analytical data provided only refers to the fully neutralised composition with four [redacted] cations while there is no analytical data for the other compositions listed.

ECHA therefore concludes that the registration contains inconsistent information preventing the establishment of the composition of the registered substance and therefore its identity, as required under Annex VI, Section 2.3 of the REACH Regulation.

The Registrant shall ensure that all reported compositions in the dossier refer to one and the same substance as further defined in the Guidance for identification and naming of substances under REACH (Version: 1.2, March 2012) - referred to as "the Guidance" thereinafter. All inconsistent compositional information shall be removed from the dossier.

Additionally, the Registrant shall ensure that the name and identifiers used to describe the registered substance are chosen in accordance with the rules described in the Guidance. In case the current identifiers are not appropriate to describe the registered substance, the Registrant shall not remove or modify at this stage this EC entry 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 indicate, in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC entry 249-559-4 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". The Registrant should also specify, in the same "Remarks" field, any available and appropriate EC number for the substance. Any available CAS entry for the registered substance should be reported under the "CAS information" header of the reference substance in IUCLID section 1.1.

The Registrant should note that ECHA has established processes, subject to certain conditions, enabling registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned. Should the Registrant consider that the EC identifier provided in his dossier should be adapted to cover a different substance or if it actually covers several other substances, he is thus encouraged to contact ECHA for a possible adaptation of the registration.

The Registrant shall ensure that the correct identifiers are used throughout the registration whenever reference to the specific substance which is subject of this registration is made.

ECHA highlights that the Registrant shall also ensure that the compositional information is verifiable and therefore supported by qualitative and quantitative analytical data, as required under Annex VI section 2.3.7. 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.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant indicated his agreement to address this issue and to provide a better description of the process and the composition of the substance having regard ot the analytical characterisation of the substance.

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

"Description of the analytical methods" is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has provided details of anion chromatography which was used for quantification of the main constituent(s). However it is unclear how exactly the quantification has been done as the calculations used to determine the substance purity are absent from the registration dossier.

ECHA concludes that the description of the analytical method is not detailed enough to allow verification of the reported results.

The Registrant is therefore requested to provide a description of the analytical methods used for the identification and quantification of the constituents and groups of 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.

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

The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical results obtained.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant indicated his agreement to address this issue and to provide new analytical characterisation in an update of the registration dosser.

III. 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.

Authorised[1][1] by Claudio Carlon, Head of Unit, Evaluation E2

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.