EUROPEAN CHEMICALS AGENCY

Decision Number: TPE-D-0000002403-84-05/F Helsinki, 13 November 2012

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For disodium dihydrogen ethylenediaminetetraacetate, CAS 139-33-3 (EC No 205-358-3), 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 40(1) of the REACH Regulation, ECHA has examined a testing proposal set out in the registration dossier for disodium dihydrogen ethylenediaminetetraacetate, CAS 139-33-3 (EC No 205-358-3), submitted by [redacted] (Registrant), submission number [redacted], for 1000 tonnes or more per year.

In accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation, the Registrant submitted the following testing proposal as part of the registration dossier to fulfil the information requirement set out in Annex IX:

- 90-day inhalation toxicity study in rats, (OECD 413),

The examination of the testing proposal was initiated on 1 October 2010.

ECHA opened a third party consultation for the testing proposal including testing on vertebrate animals that was held from 16 June 2011 until 01 August 2011. ECHA did receive information from third parties (see section III below).

On 28 March 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.

On 24 April 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

ECHA considered the Registrant's comments received and did not amend the draft decision.

On 14 June 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 submitted proposals for amendment to the draft decision.

On 18 July 2012 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide

comments on those proposals for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received and decided to amend the draft decision accordingly.

On 30 July 2012 ECHA referred the draft decision to the Member State Committee.

On 16 August 2012, the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

After discussion in the Member State Committee meeting on 19-21 September 2012, a unanimous agreement of the Member State Committee on the draft decision as referred to MSC was reached on 19 September 2012. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the requirements of the REACH Regulation. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Testing required

Pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant shall carry out the following test using the indicated test method and the registered substance:

- Sub-chronic toxicity study (90-day) in rats, inhalation route (Annex IX, 8.6.2., test method: EU B.29/OECD 413).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **13 May 2014** an update of the registration dossier containing the information required by this decision.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrants.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal submitted by the Registrant for the registered substance and scientific information submitted by third parties.

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A sub-chronic toxicity study (90-day) is a standard information requirement as laid down in Annex IX, section 8.6.2. of the REACH Regulation.

The Registrant has included a reliable 13-week study on the registered substance by the oral route. However, the Registrant has also identified that 5-day exposure to the registered substance, via the inhalation route causes adverse effects with high potency (LOAEC < 30 mg/m3). There is severe toxicity in this 5-day study, and the length of this study (5 days) is too short for evaluating the chronic toxicological effects. Thus, in accordance with the column 2 requirements of Annex IX 8.6.2, there is both "toxicity of particular concern (e.g.

serious/severe effects)" and "indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation."

As no other repeated dose inhalation study is available and inhalation exposure has been identified, a further study has been proposed by the Registrant in accordance with column 2 of Annex IX 8.6.2.: the Registrant has proposed a sub-chronic toxicity study (90-day) in rats, by the inhalation route (test method: EU B.29/OECD 413) to provide this information.

b) Consideration of third party information

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

The third party submitted the following comments for consideration:

1. Animal welfare considerations

Considering that 6 out of 20 animals died at the highest dose group in the range finding study, in case the study is performed, the dose should be reduced below 300 mg/m3 air to avoid mortality after longer exposure duration.

2. Previous exposure and risk assessment for EDTA and its salts

The EU-RAR report concludes that for Na_4EDTA there is no need for further information or testing. The cosmetic ingredients review expert panel found these ingredients safe as used in cosmetic formulations. It should be evaluated if tests waiving can be justified based on exposure and if there is a need to establish an OEL value.

3. Read-across

In case the 90-day study will have to be conducted for Na2H2 EDTA, data should be used from edetic acid and all salts of EDTA in a read across approach.

ECHA concludes as follows:

1. Animal welfare considerations

It is the registrant's responsibility to set the dose level appropriately. Third parties are invited, as specified by Article 40(2) of the REACH Regulation to submit "scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal". As the comment about animal welfare considerations cannot be regarded as information or studies, ECHA concludes that this is not a sufficient basis to fulfil the data/information requirement.

2. "Previous exposure and risk assessment"

The third party has proposed a strategy of test waiving and questioned the need to establish an OEL. However, third parties are invited, as specified by Article 40(2) of the REACH Regulation to submit "scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal". As the proposal for a strategy as such cannot be regarded as information or studies, ECHA concludes that this is not a sufficient basis to fulfil the data/information requirement. With respect to previous risk assessments, ECHA notes that the Registrant has provided novel information which has not been addressed in the references cited and this testing proposal addresses the information need. In summary, these arguments do not provide a basis for rejecting the testing proposal.

3. "Read-across"

The third party has proposed a strategy of test waiving for other substances. However, third parties are invited, as specified by Article 40(2) of the REACH Regulation to submit "scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal". As the proposal for a strategy for substances other than the registered substance cannot be regarded as information or studies that address the relevant substance, ECHA concludes that this is not a sufficient basis to fulfil the data/information requirement. There is no basis for rejecting the testing proposal.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Sub-chronic toxicity study (90-day) in rats, inhalation route (test method: EU B.29/OECD 413) on the substance subject to the present decision.

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the generation of information is tailored to real information needs in order to prevent unnecessary testing. The information submitted in the registration dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. It is noted, however, that this information, or the information submitted by other registrants of the same 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 proposed test, 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 the joint registrants of the same substance to agree with the test proposed in the testing proposal (as applicable to their tonnage level) and to document the necessary information on its composition. The substance identity information of the registered substance and of the sample tested must enable ECHA to confirm the relevance of the testing for the substance actually registered by each joint registrant. Finally, the study must be shared by the joint registrants concerned.

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

ECHA always 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). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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 appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the 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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Geert Dancet
Executive Director