EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002290-85-05/F Helsinki, 3 October 2012

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

For Alkyl Dimethyl Betaine, (List No. 931-700-2), registration number [redacted]

Addressee: [redacted]

Pursuant to Article 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for Alkyl Dimethyl Betaine (List No. 931-700-2), by [redacted] (Registrant).

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 the following testing proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) thereof for Alkyl Dimethyl Betaine (List No. 931-700-2), by [redacted] (Registrant).

- Annex IX, 9.1.5., column 2: Long-term toxicity testing on aquatic invertebrates (*Daphnia magna*) (OECD Guideline 211);
- Annex X, 9.4.4., Toxicity to soil macroorganisms except arthropods (*Eisenia fetida*) (OECD Guideline 222).

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 14 June 2012, 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.

On 16 November 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

On 30 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.

By 30 April 2012 the Registrant did not provide any comments on the draft decision to ECHA.

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 of the draft decision.

ECHA has reviewed the proposals for amendment received and has amended the draft decision accordingly.

On 18 July 2012 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(1) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

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

The Registrant did not provide any comments on the proposed amendments.

A unanimous agreement of the Member State Committee on the draft decision was reached on 3 September 2012 in a written procedure launched on 22 August 2012 and 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 REACH requirements. The decision does not prevent ECHA to initiate a compliance check on the present dossier at a later stage.

II. Testing required

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211); and
2. Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222).

ECHA notes that the Registrant refers to the registered substance in the technical dossier and in the Chemical Safety Report (CSR) using CAS number [redacted]. According to the CAS Registry, this CAS number refers to a substance that contains also C13 alkyl chains. Since the Registrant has registered a substance containing only C12 and C14 alkyl chains, the above mentioned tests shall be conducted using the registered substance subject to the present decision, assigned with List number 931-700-2.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **3 July 2013** an update of the registration dossier containing the information required by this decision.

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, the Registrant shall consider submitting a testing proposal for a long-term toxicity test on fish in order to fulfil the standard information requirement of Annex IX, 9.1.6.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance.

1. Long-term toxicity testing on invertebrates, Annex IX, 9.1.5.

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

Long-term toxicity testing on invertebrates is a standard information requirement as laid down in Annex IX, 9.1.5. of the REACH Regulation. The information on this endpoint is not available for the registered substance, but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant provided the following justification for conducting the proposed test: "A long-term toxicity-test with Daphnia magna (OECD 211) is proposed for alkyl dimethyl betaine (CAS [redacted]) to fulfil the standard information required according to Annex IX, column 2. and optain a long term results for alkyl dimethyl betaine for the risk assessment of the aquatic environment. Focussing on environmental effects assessment, long term data obtained for chronic ecotoxicity of cocamidopropyl betaine were used as read across. The ecotoxicology tests with this structural related substance, cocamidopropyl betaine, revealed lower values compared to the tests with alkyl dimethyl betaine. Using these values in the risk assessment represents a worst case situation and is sufficiently adequate for a conservative risk assessment. Therefore as a reasonable worst-case approach, the lowest long term NOEC of 0.135 mg/L from cocamidopropyl betaine for fish is used for PNEC derivation until further long term data for dimethyl betaines are available." ECHA can follow this approach and considers the justification to be plausible.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.1., August 2008), Chapter R7b, Figure R.7.8-4 page 53, if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. According to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and an applied assessment factor of 50 no risks are indicated, no long-term fish testing may need to be conducted.

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211) using the registered substance.

ECHA notes that according to OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance R7b, tables R. 7.8-2 - 3, if the registered substance is likely to be surface active, dispersions or emulsions can be formed in which bioavailability is difficult to ascertain and may lead to difficulties in interpreting the test results. The registered substance can form quaternary ammonium compounds which may increase the adsorption potential, leading to a loss of the registered substance from the test system. Therefore, valid Koc value and control of the pH range needs to be taken into consideration by the Registrant in the selection of the most appropriate test design in order for the test to be valid.

2. Long-term toxicity testing on invertebrates, Annex X, 9.4.4.

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

Long-term toxicity testing on invertebrates is a standard information requirement as laid down in Annex X, 9.4.4 of the REACH Regulation. The information on this endpoint is not available for the registered substance, but needs to be present in the technical dossier to meet the information requirements. Consequently, there is an information gap and it is necessary to generate the data for this endpoint.

The Registrant proposed an earthworm reproduction test (OECD 222) and justified the testing proposal for this endpoint by the following statement: "In order to fulfil the standard information required according to Annex X, Column I (9.4) a long-term toxicity test with soil macroorganisms (earthworms, OECD 222) is proposed for alkyl dimethyl betaine (Cas No. [redacted]) and following the integrated testing strategy ECHA guidance document R.7C. Depending on the result of that test eventually further studies would have to be conducted." ECHA can follow this approach and considers the justification to be plausible.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222) using the registered substance.

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 new studies meet real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for evaluation of the testing proposal. The Registrant must note, 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 tests, 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 of the same substance to agree to the tests proposed (as applicable to their tonnage level) 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). 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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