Decision number: TPE-D-2114313126-63-01/F Helsinki, 11 January 2016

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

For Fatty acids, C16-18, reaction products with diethanolamine, EC No 293-014-3 (CAS No 91032-08-5), 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 the following testing proposal submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for Fatty acids, C16-18, reaction products with diethanolamine, EC No 293-014-3 (CAS No 91032-08-5), submitted by [redacted] (Registrant).

- Developmental toxicity / teratogenicity study (OECD 414).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year.

This decision does not take into account any updates after 05 August 2015, i.e. 30 calendar days after the end of the commenting period.

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 from initiating a compliance check on the registration at a later stage.

ECHA received the registration dossier containing the above-mentioned testing proposal for further examination pursuant to Article 40(1) on 3 December 2013.

ECHA held a third party consultation for the testing proposal from 16 March 2015 until 30 April 2015. ECHA received information from third parties (see section III below).

On 28 May 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 25 June 2015 ECHA received comments from the Registrant on the draft decision. In his comments, the Registrant requested an extension of the deadline to submit a dossier update from 5 August 2015, i.e. 30 calendar days after the end of the commenting period, to 4 September 2015.

The ECHA Secretariat considered the Registrant's comments and agreed to the extension of the deadline. On 21 July 2015 ECHA communicated the Registrant via REACH-IT that the new deadline was 7 September 2015. However, ECHA did not receive any dossier update from the Registrant by the new deadline. Therefore, no amendments were made to the draft decision.

On 29 October 2015 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.

II. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following proposed test pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision:

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, oral route.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **18 January 2017** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

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. Tests required pursuant to Article 40(3)

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

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 pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. 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 provide information for this endpoint.

The Registrant has submitted a testing proposal for a pre-natal developmental toxicity study according to EU B.31/OECD 414 to be performed with the registered substance subject to the present decision with the following justification: *"No data are available regarding the pre-natal developmental toxicity of the test item. A study according to OECD 414 is proposed to fill the data gap."*

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

The Registrant did not specify the species to be used for testing. He did not specify the route for testing. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

b) Consideration of the information received during third party consultation

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.

Third party information 1:
Third parties have indicated that the tonnage level of the registered substance does not require conducting a pre-natal developmental toxicity study.

ECHA notes that the substance subject to the present decision is registered for the tonnage band of 100 to 1000 tonnes per year. For this tonnage band a pre-natal developmental toxicity study is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation.

Third party information 2:
Third parties have indicated that based on the physicochemical properties, the substance is predicted to be poorly bioavailable and that the substance displays a low toxicity profile.

ECHA notes that it is the Registrant's responsibility to consider and justify in the registration dossier any adaptation of the information requirements in accordance with Annex IX, Section 8.7., column 2, third indent. This adaptation specifies that a pre-natal developmental toxicity study does not need to be conducted if "the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure." ECHA notes that all three criteria need to be met.

ECHA observes that the third parties comment reflects only on the criterion concerning absorption and the lack of evidence of toxicity. However, no toxicokinetic data has been provided to support the argumentation that no systemic absorption occurs via relevant routes of exposure. Furthermore, an adaptation would also need to demonstrate that the other conditions of the adaptation possibility are fulfilled.

Therefore, the criteria listed in Column 2 of Annex IX, Section 8.7., third indent are not met and the information requirements for the pre-natal developmental toxicity study cannot be adapted on this basis.

Third party information 3:
Third parties have indicated that the registered substance would fit in subcategory II (fatty alkanolamides, Group B - dihydroxy compounds) of the Fatty Nitrogen Derived Amides Category for which human health hazards have been assessed on a screening level in the US High Production Volume Challenge Program. Thus, the third parties have suggested that a read-across approach could be used to fulfil the information requirements. Thus, an OECD 414 study with amides, coco, N,N-bis (hydroxyethyl) at oral doses of 100, 300 and 1000 mg/kg bw/d did not show major treatment-related effects. Furthermore, the third parties also note that a testing proposal of a prenatal developmental toxicity study has been included in the registration dossier of fatty acids, tall-oil, reaction products with triethanolamine.

ECHA acknowledges that the third party has proposed a read-across approach for the Registrant to consider.

ECHA notes that it is the Registrant's responsibility to consider and justify any adaptation of the information requirements in accordance with the relevant conditions as established in Annex XI, Section 1.5. Therefore, the Registrant may assess whether he can justify a read-across as suggested by the third parties. If the information requirement can met by way of adaptation, he may include the adaptation argument with all necessary documentation according to Annex XI, Section 1.5 in an updated. However, the Registrant is reminded that this decision does not take into account any updates of the registration submitted later than 05 August 2015, i.e. 30 calendar days after the end of the commenting period. Later updates of the registration will however be examined in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

ECHA notes that the information provided by the third party is insufficient for demonstrating that the conditions of Annex XI, Section 1.5. of the REACH Regulation are met. For example, the third party has mentioned a category of substances within the US High Production Volumen Challenge Program but he has not provided a hypothesis and definition of that category according to the conditions of Annex XI, Section 1.5. of the REACH Regulation and neither he has justified as to why the registered substance belongs to that category. In addition, there is no information about how the endpoint has been adequately addressed in the category. An OECD 414 study performed with the substance amides, coco, N,N-bis(hydroxyethyl) is mentioned but details of the study are missing.

Therefore, the information provided by the third party in itself would not be sufficient to adapt the standard information requirement.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the proposed study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in rats or rabbits, oral route (test method: EU B.31/OECD 414).

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new study 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 examination of the testing proposal. The Registrant must note, however, that this information has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In addition, it is important to ensure that the particular sample of substance tested in the new study 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. If the registration of the substance covers different grades, the sample used for the new study must be suitable to assess these.

Finally, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

V. 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://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] 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.