EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002188-72-03/F

Helsinki, 5 November 2012

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

For Reaction mass of Amides, rape-oil, N-(hydroxyethyl), ethoxylated and Glycerol, ethoxylated, (EC No. 932-164-2), 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 proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation for Amides, rape-oil, N-(hydroxyethyl), ethoxylated and Glycerol, ethoxylated, (EC No. 932-164-2), submitted [redacted] (Registrant):

- Fish, juvenile growth test (OECD 215), no indication of the substance to be tested; and
- Repeated dose 90-day oral toxicity in rodents (OECD 408), no indication of the species or substance to be tested given.

This decision is based on the registration dossier as submitted with submission number [redacted], for 1000 tonnes or more per year. This decision does not take into account any updates after 6 September 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.

The examination of the testing proposals was initiated on 22 March 2011.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 29 July 2011 until 12 September 2011. ECHA did not receive information from third parties.

On 11 January 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 17 January ECHA received comments from the Registrant concerning the relation between the testing requirements under the REACH Regulation and under the Cosmetics Regulation (EC) No 1223/2009 as the substance subject to this decision is used as raw material for cosmetics. ECHA responded to this issue in a separate communication to the Registrant, sent on 17 August 2012 and it is not further addressed in the present decision.

Therefore ECHA decided not to amend the draft decision.

On 6 September 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 did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) 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 proposed test using the indicated test method and the registered substance subject to the present decision:

1. Sub-chronic toxicity study (90-day) (Annex IX, 8.6.2., test method: EU B.26/OECD 408) in rats, oral route.

Pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant shall carry out the following additional tests using the indicated test methods and the registered substance subject to the present decision:

2. Long-term toxicity on invertebrates (*Daphnia sp.*) (Annex IX, 9.1.5., test method: EU C.20/OECD 211); and
3. Long-term toxicity on fish, with a standard species according to guideline (Annex IX, 9.1.6.1., test method: OECD 210)

while the originally proposed test for a Fish, juvenile growth test (OECD 215) proposed to be carried out is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

The Registrant shall determine the appropriate order of the studies taking into account the possible outcome and considering the possibilities for adaptations of the standard information requirements according to column 1 or 2 provisions of the relevant Annexes of the REACH Regulation. More specifically, prior to conducting the tests 2. and 3. above, the Registrant shall take into account the guidance related to integrated testing strategy, as specified in section III below, for aquatic toxicity testing to determine the sequence in which the tests are to be conducted.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **05 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.

1. Sub-chronic toxicity study (90-day)

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 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 testing by the oral route. In the light of the physical-chemical properties of the substance, assessment of toxicokinetics by the Registrant and the information provided on the uses and human exposure, ECHA considers that testing by the oral route is appropriate. According to the test method (EU B.26/OECD 408) the rat is the preferred rodent species and the test substance is usually administered orally. ECHA considers the default parameters appropriate and testing should be performed by the oral route with the rat to be used.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Repeated Dose 90-Day Oral Toxicity in Rodents study in rats, oral route (test method: EU method B.26/OECD 408) using the registered substance.

2. Long-term toxicity on invertebrates

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance with the testing proposal with Annexes IX, X or XI of the REACH Regulation.

A long-term toxicity testing on invertebrates is a standard information requirement as laid down in Annex IX, section 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. The Registrant has deviated from the standard information requirements with the following statement: *'In the acute toxicity tests on fish, Daphnia and algae, the most sensitive species was found to be the fish. Therefore, in accordance with Annex IX of REACH (9.1.6.) a long-term toxicity to fish study is proposed to further assess the substances effects on aquatic organisms'.* With this statement the Registrant omits the required information on this tonnage level for toxicity on invertebrates by referring to testing on fish only. No further justification is provided. Consequently there is an information gap and it is necessary to generate the data for this endpoint.

According to ECHA Guidance (Chapter R7b (version 1.1., August 2008), Figure R.7.8-4 p. 53) if based on acute 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, the long-term fish testing may no longer be necessary to be conducted.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following study: *Daphnia magna* Reproduction test (test method: EU method C.20/OECD 211) using the registered substance.

3. Long-term toxicity on fish

Pursuant to Article 40(3)(c) of the REACH Regulation, ECHA may require the Registrant to carry out one or more additional tests in case of non-compliance of the testing proposal with Annexes IX, X or XI of the REACH Regulation. Pursuant to Article 40(3)(d) of the REACH Regulation, ECHA may reject a proposed test.

Long-term toxicity testing on fish is a standard information requirement as laid down in Annex IX, section 9.1.6. 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 to cover this data requirement with performing a Fish, juvenile growth test according to OECD 215. On one hand, the REACH guidance Section R.7.b.7.8.4.1 (version 1.1., August 2008) specifies that OECD 215 is considered a sensitive indicator of toxicity, on the other hand it is considered to be of insufficient duration to examine all the sensitive points in the fish life-cycle. It provides a shorter and less expensive option to the FELS test for substances of logKow <5. The guidance further specifies that among the currently available standardised test methods, the FELS toxicity test (OECD 210) is considered as the most sensitive of the fish tests and ECHA cannot see reasons why this would not be applicable in the case at hand. The log Kow value in the dossier was reported to be in the range from 4.85 to 5.21. Therefore ECHA considers testing according to OECD 215 not justified and the Registrant is required to carry out the test according to OECD 210.

ECHA notes, that the short-term toxicity study has been conducted according to OECD 203, however the test organism *Leuciscus idus melanotus* has been used for testing, and that is not a standard organism for any of the test guidelines OECD 203, 210 or 215. As the Registrant has not indicated which species is to be tested for long-term toxicity, the standard organism according to OECD test guideline 210 is to be tested.

According to ECHA Guidance (Chapter R7b (version 1.1., August 2008), Figure R.7.8-4 p. 53) if based on acute 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, the long-term fish testing may no longer be necessary to be conducted. Therefore, prior to initiating the long-term fish study, the Registrant is to take account of this guidance related to the sequence of testing to determine whether testing on vertebrate animals is required. There were no indications in the dossier from the short-term toxicity studies on aquatic species that the fish would be substantially more sensitive than *Daphnia*.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following additional study: Fish early life stage (FELS) toxicity test (test method: OECD 210) using the registered substance and standard organism following the test guideline. Pursuant to Article 40 (3)(d) of the REACH Regulation, the proposed test for a fish, juvenile growth test (OECD 215) is rejected.

IV. 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.

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://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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