EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002721-80-04/F Helsinki, 3 June 2013

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

For Amides, C16-C18 (even), N,N'-ethylenebis, (EC No 931-299-4), 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) thereof for Amides, C16-C18 (even) , N,N'-ethylenebis, (EC No 931-299-4), by [redacted] (Registrant).

- OECD Guideline 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment), using N,N'-ethylenedi(stearamide) CAS No 110-30-5;
- OECD Guideline 222 (Earthworm Reproduction Test (Eisenia fetida/Eisenia andrei));
- OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents) including macroscopic and histopathologic changes of reproductive organs.

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 8 March 2013, 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.

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 present dossier at a later stage.

On 6 October 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.

ECHA held a third party consultation for the testing proposal from 15 August 2011 until 29 September 2011. ECHA did not receive information from third parties.

On 20 September 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 18 of October 2012 ECHA received comments from the Registrant.

ECHA considered the Registrant's comments received. The comments are reflected in the Statement of Reasons (Section III) whereas no amendments to the Testing Required (Section II) were made.

On 8 March 2013 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.

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. Sub-chronic toxicity study (90-day) in rats, oral route (Annex IX, 8.6.2.; test method: EU B.26/OECD 408). It is at the Registrant's discretion to perform the intended additional examinations during the testing program;
2. Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222).

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

3. Long-term toxicity to sediment organisms (Annex X, 9.5.1.; test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218)

while the originally proposed test for a Sediment-water Chironomid toxicity using spiked sediment, OECD 218 proposed to be carried out using the analogue substance ,N'-ethylenedi(stearamide) CAS No 110-30-5 is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **3 December 2014** an update of the registration dossier containing the information required by this decision.

Once results of the proposed test on long-term toxicity to terrestrial 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 terrestrial organisms, the Registrant shall consider submitting further testing proposals for tests on terrestrial organisms.

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 proposals submitted by the Registrant for the registered substance.

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

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 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 did not clearly specify the testing material. ECHA concludes that the test material should be the registered substance, as documented in section 1.1 and 1.2 of the IUCLID dossier.

The Registrant proposed testing by the oral route. In the light of the physico-chemical properties of the substance and the information provided on the uses and human exposure, ECHA considers that testing by the oral route is appropriate.

The Registrant proposed to extend the sub-chronic toxicity study (90 day) by including additional examinations/parameters macroscopic and histopathologic changes of reproductive organs. ECHA notes, that it is at the Registrant's discretion to perform the intended additional examinations during the testing program and use the results to ensure the safe use of the substance. However, the Registrant is reminded that the proposed extension of this study does not fulfil the standard information requirements in the registration dossier for reproductive toxicity set out in Annex X, 8.7.3. unless Annex X, 8.7. column 2 adaptation is applied.

In his comments submitted to ECHA on 18 October 2012 the Registrant referred to a hypothetical adaptation to the standard information requirement that was however not further elaborated or documented. More explicitly, the Registrant claimed that there would be structural similarity of the registered substance subject to the present decision to an analogue substance for which a repeated dose toxicity study (90-day) would be available that could potentially be used to predict properties of Amides, C16-C18 (even), N,N'-ethylenebis. This claim as such cannot be considered a robust hypothesis for read-across in accordance with Annex XI, 1.5. of the REACH Regulation. No further documentation has been provided to support this claim and hence no prediction can be made as regards the intrinsic properties of the registered substance subject to the present decision.

b) 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, oral route (test method: EU B.26/OECD 408) using the registered substance.

2. Long-term toxicity on terrestrial invertebrates

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.

Long-term toxicity to terrestrial invertebrates is a standard information requirement as laid down in Annex X, section 9.4.4. of the REACH Regulation. Column 2 of section 9.4.4. of Annex X further indicates that this information requirement must be fulfilled unless the chemical safety assessment leads to the conclusion that the test is not needed. 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). The Registrant provided the following justification for conducting the proposed test:

"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 N-(2-Octadecanoylaminoethyl)octadecanamide 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."

Data from the registration dossier indicates that the substance has a high potential to absorb to soil (logKoc 8.6-8.9), is insoluble in organic solvents and does not readily biodegrade.

The Registrant did not clearly specify the testing material. ECHA concludes that the test material should be the registered substance, as documented in section 1.1 and 1.2 of the IUCLID dossier.

In his comments submitted to ECHA on 18 October 2012 the Registrant confirmed that he intends to perform this study with the registered substance subject to the present decision.

b) Outcome

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.

3. Long-term toxicity to sediment organisms

a) Examination of the testing proposal

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

According to column 1 of Section 9.5.1. of Annex X of the REACH Regulation, long-term toxicity to sediment organisms is a standard information requirement. 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 a sediment-water Chironomid toxicity test using spiked sediment (OECD 218) and the analogue substance N'-ethylenedi(stearamide) CAS No 110-30-5 as test substance. The Registrant provided no justification why the proposed test should be performed with that substance. Consequently ECHA can not conclude on the validity of the proposed test with another than the registered substance and that such testing would be tailored to real information needs. No argument or justification has been provided that would indicate that the physicochemical or toxicological properties of the registered substance and the substance suggested for testing are likely to be similar as required by Annex XI, 1.5. of the REACH Regulation. Consequently, the testing proposal does not meet the requirements of adaptation as set out by Annex XI, 1.5. of the REACH Regulation and has to be considered non-compliant with this provision.

The information currently available in the dossier is not considered as sufficient to conclude on the long-term toxicity potential of the registered substance in sediment organisms and thus it is necessary to generate additional data for this endpoint with the registered substance.

In his comments submitted to ECHA on 18 October 2012 the Registrant confirmed that he intends to perform this study with the registered substance subject to the present decision.

b) Outcome

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the additional study: Long-term toxicity to sediment organisms (Annex X, 9.5.1.; test method: Sediment-water Chironomid toxicity using spiked sediment, OECD 218) using Amides, C16-C18 (even), N,N'-ethylenebis. Pursuant to Article 40(3)(d) of the REACH Regulation, the originally proposed test for long-term toxicity to sediment organisms with test method OECD 218 and using the analogue substance N'-ethylenedi(stearamide) CAS No 110-30-5 is rejected.

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 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).

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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