EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000002672-75-06/F Helsinki, 8 October 2013

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

For Amines, polyethylenepoly-, triethylenetetramine fraction, CAS No. 90640-67-8 (EC No. 292-588-2), 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) thereof for Amines, polyethylenepoly-, triethylenetetramine fraction, CAS No. 90640-67-8 (EC No. 292-588-2), by [redacted] (Registrant).

- Dissociation constants in water (OECD 112)
- Viscosity of liquids (OECD 114)
- Earthworm reproduction test (Eisenia fetida/Eisenia andrei) (OECD 222)
- Two-generation reproduction toxicity study via dermal route (OECD 416) to be carried out with trientine (CAS No 112-24-3).

The present decision relates only to the examination of the testing proposals:

- Dissociation constants in water (OECD 112)
- Viscosity of liquids (OECD 114)
- Earthworm reproduction test (Eisenia fetida/Eisenia andrei) (OECD 222)

The testing proposal for fulfilling the information requirement for a reproductive toxicity study (Annex X, 8.7.3.) is addressed in a separate decision although all these were initially addressed together in the same draft decision.

The present decision is based on the registration dossier as submitted jointly 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 20 June 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 registration 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 proposals from 5 April 2011 until 20 May 2011. ECHA did receive information from a third party (see section III below).

On 18 July 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 5 September 2012 ECHA received comments from the Registrant partly agreeing to ECHA's draft decision.

ECHA considered the Registrant's comments received. On the basis of the comments, Section II and III were amended.

On 20 June 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 submitted proposals for amendment to the draft decision.

On 26 July 2013 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 not to amend the draft decision.

On 5 August 2013 ECHA referred the draft decision to the Member State Committee.

By 26 August 2013 the Registrant did not provide comments on the proposed amendments.

A unanimous agreement of the Member State Committee on the draft decision relating to dissociation constant, viscosity in liquids and long-term toxicity on terrestrial invertebrates was reached on 9 September 2013 in a written procedure launched on 29 August 2013. ECHA took the decision pursuant to Article 51(6) 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. Dissociation constants in water (Annex IX, 7.16.; test method: OECD 112);
2. Viscosity of liquids (Annex IX, 7.17.; test method: OECD 114);
3. Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4.; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222)

the following additional test pursuant to Article 40(3)(c) of the REACH Regulation:

4. Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms; nitrogen transformation test, EU C.21/OECD 216).

The Registrant shall determine the need to perform a plant toxicity test based on the outcome of the OECD 222 test and the considerations set out in Table R.7.11.-2 of the Guidance on Information Requirements and Chemical Safety Assessment Chapter R7.C., and if relevant, submit a testing proposal to ECHA accordingly.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **8 July 2014** an update of the registration dossier containing the information required by this decision.

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 and scientific information submitted by a third party.

1. Dissociation constant

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

Dissociation constant data is a standard information requirement as laid down in Annex IX, section 7.16. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be presented in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to generate data for this endpoint.

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, the Registrant is required to carry out the proposed study: Dissociation constants in water (Annex IX, 7.16.; test method: OECD 112) using the registered substance; Amines, polyethylenepoly-, triethylenetetramine fraction.

2. Viscosity

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

Viscosity data is a standard information requirement as laid down in Annex IX, section 7.17. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be presented in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to generate data for this endpoint.

Therefore, pursuant to Article 40(3)(a)of the REACH Regulation, the Registrant is required to carry out the proposed study: Viscosity of liquids (Annex IX, 7.17.; test method: OECD 114) using the registered substance; Amines, polyethylenepoly-, triethylenetetramine fraction.

3. Effects on terrestrial organisms (Tests 3 and 4 in section II)

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

In order to fulfil the standard information requirements set out in Annexes IX and X, section 9.4., the Registrant should provide the following studies: (i) long-term toxicity testing on invertebrates (section 9.4.4.), (ii) effects on soil micro-organisms (section 9.4.2.) and (iii) long-term toxicity testing on plants (section 9.4.6.).

The Registrant considered that long-term toxicity testing on terrestrial organisms is necessary and proposed an earthworm reproduction test according to OECD 222 in order to fulfil all three standard information requirements in section 9.4 of Annexes IX and X of the REACH Regulation. However, the proposed test only addresses invertebrates (i.e. the information requirement in Annex X, section 9.4.4.) and does not address the other two trophic levels requested for this tonnage band (i.e. the information requirements in Annex IX, sections 9.4.2. and Annex X, section 9.4.6.). Moreover, the registration dossier contains no justification for waiving of the studies in sections 9.4.2 and 9.4.6.

The test proposed by the Registrant is not sufficient, on its own accord, to fulfil all the information requirements outlined in Annexes IX and X, 9.4., since it does not fulfil the information requirements laid down in Annexes IX and X, sections 9.4.2. and 9.4.6.

Based on the available aquatic toxicity information and information on stability and biodegradation of the substance ECHA considers that according to section R.7.11.6 of ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R7.C ("Guidance R7.C") the substance can be considered as a Hazard Category 3. In the context of an integrated testing strategy for soil toxicity, this would allow the Registrant to perform an initial screening assessment in order to identify the need to perform further studies. The screening assessment as described in Table R.7.11.-2, Guidance R7.C includes a comparison of the PEC with the PNECscreen (based on equilibrium partitioning method - EPM; with the application of an appropriate correction factor), together with a confirmatory long-term soil toxicity test. Based on the result of the initial screening assessment, further long-term testing may be needed.

The Registrant has proposed to undertake a long-term toxicity test to earthworms (OECD 222). According to Table R.7.11.-2, Guidance R7.C, such a long term test could be considered as the confirmatory long-term soil toxicity test.

According to the guidance the PNECscreen is calculated through EPM on the basis of aquatic toxicity data only. Intrinsic properties of soil microbial communities however are not addressed through the EPM extrapolation method. Thus, ECHA considers that the hazard to soil microbial communities needs to be evaluated as a standard information requirement under Annex IX. 9.4.2. Therefore, ECHA concludes that the application of an integrated testing strategy could only be applied to the need to perform either a long term toxicity test for soil invertebrates or plants, or to perform both of them, and that the effects on soil micro-organisms need to be ascertained by performing a relevant test (EU Method C.21 or OECD 216).

In his comments to the draft decision submitted on 5 September 2012 the Registrant disagreed on ECHA's draft decision to perform the toxicity to micro-organisms test (EU C.21 or OECD 216). According to the Registrant acute toxicity to aquatic micro-organisms was

assessed in a respiration inhibition test (EC10= 42.5mg/L). Furthermore, the Registrant noted that acute toxicity to aquatic species was assessed at three trophic levels with algal and invertebrate having a similar sensitivity (Algae EC50= 20 mg/L, Daphnia EC50 31.1 mg/L). According to the Registrant in view of the greater sensitivity of aquatic species and considering that the PNEC for soil is extrapolated from the PNEC freshwater derived from a conservative endpoint, there is no need to perform the toxicity to soil micro-organisms test.

However, ECHA considers that following the reasoning provided further above the effects on soil micro-organisms need to be ascertained by performing a relevant test (EU Method C.21 or OECD 216). ECHA notes that the Registrant did not provide any supporting evidence of his statement that toxicity to aquatic micro-organisms can be extrapolated to the toxicity of soil micro-organisms at the same ratio as PNEC freshwater (based on the most sensitive aquatic toxicity endpoint) is extrapolated to PNEC for soil. Furthermore, ECHA notes that inhibition of respiration was observed in the toxicity to activated sludge study at the higher concentrations tested. It is clearly indicated in the Guidance R7.C section R.7.11.5.3, page 125, that where inhibition of sewage sludge microbial activity has been observed in Annex VIII testing, a test on soil microbial activity will additionally be necessary for a valid PNEC soil to be derived.

Furthermore, ECHA considers that it is not possible to determine *a priori* whether the results obtained from the toxicity screening assessment will be sufficient to fulfil the information requirement in section 9.4. of Annexes IX and X of the REACH Regulation.

Pursuant to Article 40(3)(c) ECHA may take a decision permitting the registrant to carry out the proposed test in accordance to Article 40(3)(a) but requiring the registrant to carry out one or more additional tests in cases of non-compliance of the testing proposal with Annexes IX, X, and XI of the REACH Regulation.

Therefore, pursuant to Article 40(3)(a) ECHA has accepted the Registrant's testing proposal and the Registrant is requested to perform

- long-term toxicity to invertebrates (Annex X, 9.4.4, OECD 222) using the registered substance; Amines, polyethylenepoly-, triethylenetetramine fraction.

In light of the guidance mentioned above, the Registrant is also required pursuant to Article 40(3)(c) to carry out the following test to fulfil the information requirements in section 9.4.2 of Annexes IX of the REACH Regulation using the registered substance; Amines, polyethylenepoly-, triethylenetetramine fraction:

- Toxicity to micro-organisms (Annex IX, 9.4.2., EU Method C.21 or OECD 216)

Furthermore, ECHA notes that the option to perform a long-term toxicity test on terrestrial plants as an alternative confirmatory long-term toxicity test on terrestrial organisms was removed from the draft decision as the Registrant in his comments confirmed his initiative to start with an OECD 222 test as a confirmatory long-term toxicity test. The Registrant shall determine the need to perform the plant toxicity test based on the outcome of the OECD 222 test and the considerations set out in Table R.7.11.-2 of Guidance R7.C., and if relevant submit a testing proposal to ECHA accordingly.

4. Deadline for submitting the information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 30 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested one other study. As the study is not addressed in the present draft decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 9 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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.

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 are 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 grade 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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