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Decision number: TPE-D-0000004010-95-03/F Helsinki, 10 December 2013

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

For TETRAETHYLENEPENTAMINE, LINEAR, CYCLIC AND BRANCHED, CAS 90640-66-7 (EC No 292-587-7), 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 testing proposals set out in the registration dossier for ***Tetraethylenepentamine, linear, cyclic and branched,* CAS 90640-66-7 (EC No 292-587-7)** submitted by [redacted] (Registrant), latest submission number [redacted], for above 1000 tonnes 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.

In accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation, the Registrant submitted the following testing proposals as part of the registration dossier to fulfil the information requirements set out in Annexes IX and X:

- Annex IX, 7.16: Dissociation constants in water, according to OECD 112, test substance not specified
- Annex X, 9.4.4: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), according to OECD 222 with read-across substance polyethylenepolyamine, CAS 268-626-9 (HEPA)

The examination of the testing proposals was initiated on 06 October 2010.

On 8 November 2011 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 9 December 2011 ECHA received comments from the Registrant. On 6 February 2012 the Registrant updated his registration dossier.

ECHA considered the Registrant's comments received and did not amend the draft decision.

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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, one Competent Authority of a Member State submitted a proposal for amendment to the draft decision.

On 26 July 2013 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on this proposal for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposal for amendment received and decided to amend the draft decision accordingly.

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 amendment.

A unanimous agreement of the Member State Committee on the draft decision 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.

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 test using the indicated test method and the registered substance subject to the present decision:

1. Dissociation constant (Annex IX, 7.16, OECD TG 112)

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

2. Long-term toxicity testing on invertebrates (Annex X, 9.4.4, OECD TG 222);

While the originally proposed test on read-across substance HEPA is rejected according to Article 40(3)(d) of the REACH Regulation for the purpose of fulfilling the information requirement in this dossier.

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

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

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Once results of the requested toxicity test on terrestrial invertebrates are available, in accordance with Annex I of the Reach Regulation, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. He shall furthermore consider whether there is a need to investigate further the effects on terrestrial organisms in order to fulfil the information requirements of section 9.4 of Annexes IX and X and if necessary, submit testing proposals for additional terrestrial toxicity tests. If the Registrant concludes that no further investigation of effects on terrestrial organisms is required, he shall update his technical dossier by clearly stating the reasons for adapting any information requirement of Annex IX, section 9.4. and Annex X, section 9.4. of the REACH Regulation.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **10 December 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 of the Registrant for the registered substance.

The proposed tests (dissociation constant and long-term toxicity testing on invertebrates) referred to in Section II above are part of the information requirements as laid down in Annex IX and X of the REACH Regulation. As the information on these endpoints is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements, it is necessary to generate data performing the studies as indicated in Section II above using the registered substance as the test material.

Specific considerations for the requests relating to effects on terrestrial organisms (see Section II, 2. and 3.)

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 cases of non-compliance of the testing proposal with Annexes IX, X or XI.

The Registrant must address the standard information requirements set out in Annexes IX and X, section 9.4., for different taxonomic groups: effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.).

The information on the endpoint 'effects on terrestrial organisms' is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements.

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a) Terrestrial Invertebrates (Annex IX, 9.4.1. and Annex X, 9.4.4.)

ECHA observes that in the testing proposal on long-term toxicity testing on invertebrates the Registrant has suggested using the read-across substance *"HEPA (polyethylenepolyamine, CAS 268-626-9)"* as test material based on structural similarities. In relation to this, the Registrant has stated that *'HEPA is the worst case estimation because this part of the multi consituent proves to be the most toxic to aquatic organisms'*. However, the Registrant has failed to provide any adequate and reliable documentation in the dossier to support this assertion. Furthermore, the Registrant has failed to establish why the results from this study would be adequate for the classification and labelling and the risk assessment of the substance registered. Based on the above, the Registrant has failed to meet the requirements of Annex XI, Section 1.5. governing grouping of substances and read-across approach. ECHA considers therefore that the testing with the read-across substance HEPA would be insufficient to meet the information requirement concerning long-term terrestrial toxicity testing on invertebrates (Annex X, 9.4.4) for the registered substance.

The Registrant proposed a long-term toxicity test on terrestrial invertebrates (OECD 222), without any justification. This test is suitable to address the information requirement of Annex X, section 9.4.4. and at the same time that of Annex IX, section 9.4.1.

Based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to section R.7.11.6., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (November 2012), ECHA considers that the substance would fall into soil hazard category 3. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity to invertebrates (Annex X, 9.4.4.); test method: Earthworm reproduction test (Eisenia fetida/Eisenia andrei) (OECD 222), using the registered substance, while the originally proposed test on the read-across substance HEPA is rejected in accordance with Article 40(3)(d) of the REACH Regulation.

Notes for consideration by the Registrant:

As the Guidance advocates performing an initial screening assessment based upon the EPM, together with a confirmatory long-term soil toxicity test (the long-term toxicity to terrestrial invertebrates test, specified above), which the Registrant is requested to carry out by the present decision, ECHA considers that at this stage it is not possible to determine whether a test will be required to fulfil the standard information requirements of Annex IX, 9.4.3. and Annex X, 9.4.6. of the REACH Regulation.

The Registrant shall determine the need to perform further terrestrial toxicity tests on plants based on the outcome of the requested toxicity test on terrestrial invertebrates and the considerations set out in Table R.7.11.-2, section R7.C. of the ECHA Guidance on information requirements and chemical safety assessment (May 2008).

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b) Soil microorganisms (Annex IX, section 9.4.2.)

The hazard to soil microbial communities is a standard information requirement under Annex IX, section 9.4.2. of the REACH Regulation. ECHA notes that the registration dossier does not contain data for this endpoint and that the proposed test that ECHA accepted under subsection (a) above is not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test (test method: EU C.21 or OECD 216).

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following additional study: Effects on soil micro-organisms (Annex IX, 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216), using the registered substance.

Notes for consideration by the Registrant:

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of column 2 of Annex IX, Section 9.4. does not apply for the present endpoint.

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 generation of information is tailored to real information needs in order to prevent unnecessary testing. The information submitted in the registration dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. It is noted, 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 the joint registrants of the same substance to agree with the tests proposed in the testing proposal (as applicable to their tonnage level) and to document the necessary information on its composition. The substance identity information of the registered substance and of the sample tested must enable ECHA to confirm the relevance of the testing for the substance actually registered by each joint registrant. Finally, the studies must be shared by the joint registrants concerned.

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 reads:

> *"Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable."*

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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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