ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000003263-81-04/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 Pentaethylenehexaamine CAS 4067-16-7 (EC No 223-775-9), 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 Pentaethylenehexaamine CAS 4067-16-7 (EC No 223-775-9) submitted by [redacted] (Registrant), latest submission number [redacted] for 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.

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 Annex IX and X:

- Annex IX, 7.16 Dissociation constant, OECD Guideline 112 (Dissociation constants in water). The test substance was not specified.
- Annex IX, 7.17 Viscosity, OECD Guideline 114 (Viscosity of liquids). The test substance was not specified.
- Annex X, 9.4.4, Long-term toxicity testing on invertebrates, unless already provided as part of Annex IX requirements. OECD Guideline 222 (Earthworm reproduction test (Eisenia fetida/Eisenia andrei)). The test substance was not specified.

The examination of the testing proposals was initiated on 28 September 2010.
In addition to the above testing proposals, the registration dossier originally contained testing proposals also for a combined repeated dose toxicity study with the reproduction / developmental toxicity screening test (OECD 422) to cover the standard information requirements for a prenatal developmental toxicity study and a two-generation reproductive toxicity study.

ECHA opened a third party consultation for the testing proposals including testing on vertebrate animals that was held from 28 February 2011 until 14 April 2011. ECHA received comments from third parties concerning the two testing proposals involving vertebrate animals. However, as these testing proposals were subsequently removed from the dossier, the comments are not relevant for this decision.

ECHA
EUROPEAN CHEMICALS AGENCY

On 25 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 22 December 2011 ECHA received comments from the Registrant. In its comments the Registrant agreed to carry out the requested physico-chemical and terrestrial tests on the registered substance. Moreover, the Registrant updated its dossier on 30 January 2012 and removed the testing proposals for a combined repeated dose toxicity study with the reproduction / developmental toxicity screening test (OECD 422) to cover the standard information requirements for a prenatal developmental toxicity and the two-generation reproductive toxicity study.
ECHA considered the Registrant's comments received. On basis of the comments and the updated dossier, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

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 proposed test(s) using the indicated test methods and the registered substance Pentaethylenehexaamine CAS 4067-16-7 (EC No 223-775-9):

1. Annex IX, 7.16 Dissociation constant, OECD Guideline 112
2. Annex IX, 7.17 Viscosity, OECD Guideline 114

3. Annex X, 9.4.4, Long-term toxicity testing on invertebrates, OECD Guideline 222 (Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*))

Once results of the requested toxicity test on terrestrial invertebrates (point 3 above) are available, 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, as specified under section III.3-4.a) below. 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 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:

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

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

Pursuant to Article 40(3)(a) ECHA may accept the proposed test.

1. **Dissociation constant**

According to Annex IX, 7.16 of the REACH Regulation, Dissociation constant is required to fulfil the standard information requirements. As the proposed test are not available for the registered substance but needs to be present in the technical dossier to meet the information requirement, it is necessary to generate the data and to perform the test. The Registrant has proposed that the test is carried out according to OECD Guideline 112. The Registrant will use Pentaethylenehexaamine CAS 4067-16-7 as the test substance. ECHA considers these parameters as appropriate.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Dissociation constant (test method: OECD 112) using the registered substance Pentaethylenehexaamine CAS 4067-16-7 (EC No 223-775-9).

2. Viscosity

According to Annex IX, 7.17 of the REACH Regulation, Viscosity is required to fulfil the standard information requirements. As the proposed test are not available for the registered substance but needs to be present in the technical dossier to meet the information requirement, it is necessary to generate the data and to perform the test.

ECHA
EUROPEAN CHEMICALS AGENCY

The Registrant has proposed that the test is carried out according to OECD Guideline 114. The Registrant will use for Pentaethylenehexaamine CAS 4067-16-7 (EC No 223-775-9) as the test substance. ECHA considers these parameters as appropriate.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Viscosity (test method: OECD 114) using the registered substance Pentaethylenehexaamine CAS 4067-16-7 (EC No 223-775-9).

3 – 4. Effects on terrestrial organisms

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.).

In the present case, 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.

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

The Registrant proposed a long-term toxicity test on terrestrial invertebrates (OECD 222), without any justification. ECHA states that 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 (May 2008), 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.
Once results of the above requested test are available, 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.

More particularly, 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 respectively governing short- and long-term toxicity testing on plants.

The Registrant shall therefore 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 (November 2012).

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.

b) Soil micro-organisms (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 micro-organisms 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.

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 9.4does not apply for the present endpoint.

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 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 examination of the testing proposal. The Registrant must note, 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.

ECHA
EUROPEAN CHEMICALS AGENCY

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 grade(s) 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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