EUROPEAN CHEMICALS AGENCY

Helsinki, 26/07/2012

Decision number: TPE-D-0000002134-85-05/F

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

For 2,2'-dimethyl-4,4'-methylenebis(cyclohexylamine) CAS No. 6864-37-5 (EC No. 229-962-1), 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 testing proposal set out in the registration dossier for 2,2'-dimethyl-4,4'-methylenebis(cyclohexylamine), CAS No. 6864-37-5 (EC No. 229-962-1) submitted by [redacted] (Registrant), latest submission number [redacted] for [redacted].

In accordance with Articles 10(a)(ix) and 12(1)(e) of the REACH Regulation, the Registrant submitted the following testing proposal as part of the registration dossier to fulfil the information requirements set out in Annex X, 9.4:

Long-term toxicity to soil macroorganisms (OECD Guideline 222).

The examination of the testing proposals was initiated on 26 October 2010.

On 2 December 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 6 December 2011 ECHA received comments from the Registrant on ECHA's draft decision. 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 2 March 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 submitted proposals for amendment to the draft decision.

On 4 April 2012 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 has reviewed the proposals for amendment received and decided to amend the draft decision.

On 16 April 2012 ECHA referred the draft decision to the Member State Committee.

On 27 April 2012 the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 21 May 2012 in a written procedure launched on 10 May 2012.

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 is required to carry out the following proposed test using the test method indicated:

Earthworm Reproduction test (*Eisenia fetida/Eisenia andrei*), Long-term toxicity to terrestrial invertebrates, Annex X, 9.4.4. (test method: OECD 222).

Pursuant to Article 40(3)(c) of the REACH Regulation the Registrant is required to carry out the following additional test using the test method indicated:

Soil Microorganisms: Nitrogen Transformation test, Annex IX, 9.4.2. (test method: EU C.21/OECD 216).

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA **by 26 April 2013** 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 proposal of the Registrant for the registered substance:

1. Earthworm Reproduction test

According to Annex X, 9.4.4. of the REACH Regulation, long-term toxicity testing on invertebrates is required to fulfil the standard information requirements. As the data for the long-term toxicity on terrestrial invertebrates 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.

According to Annex X, 9.4., Column 2, the choice of the appropriate test(s) depends on the outcome of the chemical safety assessment. The Registrant reports in the chemical safety assessment that invertebrates were the most sensitive group as indicated from aquatic data. Furthermore, the Registrant reports that the substance falls into Soil Hazard Category 3. According to the ECHA Guidance on information requirements and chemical safety assessment, R.7C, R.7.11.6.3., p. 131, the approach for screening assessment of the substances in Soil Hazard Category 3 is to calculate the predicted environmental concentration multiplied by ten and divided by the predicted no-effect concentration from

the screening assessment (PEC×10/PNECscreen). A PNECscreen is derived from aquatic data using Equilibrium Partitioning Method (EPM). In addition to this a confirmatory long-term soil toxicity testing (e.g. one limit test with the most sensitive organisms group as indicated from aquatic toxicity data) should be conducted.

ECHA notes that the Registrant's justification for the proposed test follows the guidance on information requirements described above. ECHA also notes that the Registrant states in the chemical safety assessment that based on the outcome of this test and the screening level risk assessment, a decision will be rendered as to whether additional terrestrial toxicity testing is necessary for the test substance. This is also in line with the testing strategy of substances in Soil Hazard Category 3.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, a long term toxicity test on terrestrial invertebrates is required, where the Registrant proposes the Earthworm reproduction test in *Eisenia fetida* or *Eisenia andrei* (test method: OECD 222).

2. Soil Microorganisms: Nitrogen Transformation test

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 Regulation.

According to the above mentioned 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/OECD 216). In that regard the testing proposal for terrestrial invertebrates assessed above under 1. alone cannot be considered to be compliant with the information requirements for effects on terrestrial organisms. For the proposed testing to be compliant with the REACH Regulation it is in fact necessary to perform as well the nitrogen transformation test.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the test on soil microorganisms using the test method: Soil Microorganisms, Nitrogen Transformation Test (test method: EU C.21/OECD 216).

In his comments the Registrant expressed consent to the ECHA draft decision and agreed to perform the Earthworm Reproduction test and the Nitrogen Transformation Test as required in the decision. In his comments the Registrant also communicated that due to low laboratory capacities conducting the tests and consequently preparing the final reports and updating the dossier will only be possible by the end of December 2012. ECHA reminds the Registrant that the 9 months period to update the registration dossier with the information required by this decision is calculated from the date of this final decision. The schedule presented by the Registrant to submit the updated dossier to ECHA is therefore acceptable.

IV. <u>Adequate identification of the composition of the tested material</u>

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 your dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. The Registrant should 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.

More specifically, in relation to the proposed test, 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 study must be shared by the joint registrants concerned.

V. General requirements for the generation of information and Good Laboratory Practice

ECHA always 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). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

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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Jukka Malm
Director of Regulatory Affairs