ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 20 September 2016

Addressee: [redacted]

Decision number: TPE-D-2114343855-42-01/F
Substance name: hexamethylenediamine
EC number: 204-679-6
CAS number: 124-09-4
Registration number: [redacted]
Submission number: [redacted]
Submission date: 24.07.2015
Registered tonnage band: 1000+T

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA has taken the following decision.

Your testing proposal is accepted and you are requested to carry out:

1. **Long-term toxicity on terrestrial invertebrates (Annex X, Section 9.4.4.; test method: Earthworm reproduction test, OECD TG 222) using the registered substance.**

You are requested to perform as additional test:

2. **Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD TG 216) using the registered substance.**

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **27 June 2017**. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[1] by Claudio Carlon, Head of Unit, Evaluation E2

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

The decision of ECHA is based on the examination of the testing proposal submitted by you.

1. Long-term toxicity to terrestrial invertebrates (Annex IX, Section 9.4.1. and Annex X, Section 9.4.4.)

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

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX and X, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX and X, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), 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 "long-term toxicity to invertebrates" 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.

You have submitted a testing proposal for a long-term toxicity test to invertebrates (Earthworm Reproduction Test (*Eisenia fetida/Eisenia andrei*), OECD TG 222) with the following justification: "*While the submission substance is highly hydrophilic (log Pow <= 0.4) and does not show surface active properties, aliphatic amines readily dissociate at environmental pH and due to their positive charge are prone to bind on negatively charged solid matter. This holds especially true for oligofunctional amines, as results from the available adsorption-desorption study (OECD 106) show: HMD (two amine groups) showed strong binding. In spite of its adsorptive behavior, HMD proved to be readily biodegradable fulfilling the 10-day window requirement with total nitrification within 28 days. From these properties, rapid degradation in sewage treatment plants or the environment is expected which would lead to overall low environmental concentrations. In addition, due to adsorption on suspended matter or soil, bioavailable concentrations in the aquatic phase are expected to be very low. Due to the observed rapid mineralization, accumulation in soil or sediment is not to be expected. The PNEC for soil estimated by the equilibrium partitioning method (EPM) using experimentally determined adsorption data resulted in RCRs well below 1 for all uses and thus most probably there will be no concern for terrestrial organisms exposed predominantly via the soil pore water. However, internal exposure of terrestrial organisms incorporating solid matter might be a concern, as well as exposure to bound material by surface contact. To account for this, we propose to perform a chronic Earthworm Reproduction Test according to OECD 222. Earthworms incorporate soil particles and thus are exposed both via pore water and internally. By their thin cuticle they are also prone to be affected by exposure via surface contact. Therefore we consider this test most appropriate to cover routes of terrestrial exposure not accounted for by the EPM. This is in line with REACH Guidance on information requirements and chemical safety assessment, Chater R.7c, section R.7.11.5.3. Based on the decision table (Table R.7.11-2) available in this guidance, HMD is assigned a hazard category 3.*

Indeed, it is not very toxic to aquatic organisms (according to note 19 below the table, the EC/LC50 are effectively not below 1 mg/L). Furthermore, the substance is ionisable and presents an adsorption potential with Log Koc values between 2.8 and 4.6. Thus, according to the ECHA Guidance, a confirmatory long-term soil toxicity test has to be performed (e.g.with the most sensitive organism group as indicated from aquatic toxicity data). On this basis, invertebrates are the most sensitive species and a chronic test on earthworms

according to OECD 222 seems well appropriate." According to Section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive, whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance is ionisable at environmentally relevant pHs, i.e. has a high potential to adsorb to soil. Therefore ECHA agrees that a long-term testing is indicated and the proposed test is appropriate to fulfil the information requirement of Annex IX, Section 9.4.1., column 2.

Furthermore, 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* (version 2.0, November 2014), ECHA agrees with your conclusion and 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. The PNECscreen is calculated through EPM on the basis of aquatic toxicity data only. ECHA notes that the strategy pursued by you is based on this approach.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, you are requested to carry out the proposed study using the registered substance subject to the present decision: Earthworm reproduction test (OECD TG 222).

2. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

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 REACH Regulation.

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annex IX, Section 9.4. of the REACH Regulation. The Registrant must address the standard information requirements set out in Annex IX, Section 9.4., for different taxonomic groups: short-term toxicity testing on invertebrates (Annex IX, Section 9.4.1.), effects on soil micro-organisms (Annex IX, Section 9.4.2.), and short-term toxicity testing on plants (Annex IX, Section 9.4.3.).

You have sought to adapt the information requirement for "effects on soil micro-organisms". You provided the following justification for the adaptation: *"Waiving according to "column 2" in Annex IX and X of REGULATION (EC) No 1907/2006: a testing proposal for an Earthworm Reproduction Test according to OECD 222 is included in the dossier. According to guidance on data requirements and chemical safety assessment, part R.7C, chapter R.7.11.5.3, no further testing required in addition to screening assessment based on EPM.*

Further, STP microorganism toxicity was assessed, including the endpoint nitrification inhibition: toxicity turned out to be low (EC50 far above 100 mg/L)." ECHA notes that the proposed test that ECHA accepted under point (1) 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. Furthermore, ECHA observes that based on the information provided in the registration dossier the substance is toxic to aquatic microorganisms (3h EC50 of 291 mg/l for nitrification is estimated in the key study performed according to OECD TG 209, which is below the typical limit concentration of 1000 mg/l of this test). ECHA notes that according to Section R.7.11.5.3., Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), 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 to be derived. Therefore, your adaptation of the information requirement cannot be accepted. Consequently there is an information gap and it is necessary to provide information for this endpoint.

To address this endpoint, either a nitrogen transformation test (test method: EU C.21/OECD TG 216) or a carbon transformation test (test method: EU C.22/OECD TG 217) could be performed. According to Section R.7.11.3.1, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), ECHA considers the nitrogen transformation test (EU C.21/OECD TG 216) suitable for non-agrochemicals. For agrochemicals the carbon transformation test (EU: C.22/OECD TG 217) is also required.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, you are requested to carry out the following additional test using the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test, EU C.21/OECD TG 216.

Notes for your consideration

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, Section 9.4.3. and Annex X, Section 9.4.6. of the REACH Regulation.

Therefore, once results of the requested toxicity test on terrestrial invertebrates are available, the Registrant should 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 Annex 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 should update his technical dossier by clearly stating the reasons for adapting the information requirements of Annex IX, Section 9.4.3. and Annex X, Section 9.4.6. of the REACH Regulation.

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 Annex IX, Section 9.4.3. does not apply for the present endpoint.

Appendix 2: Procedural history

ECHA received your registration containing the testing proposal for examination pursuant to Article 40(1) on 24 July 2015.

This decision does not take into account any updates after **30 March 2016**, 30 calendar days after the end of the commenting period.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

In your comments you agreed to the draft decision. ECHA took your comment into account and did not amend the requests.

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your 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.

2. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

3. In relation to the information required by the present decision, the sample of the substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new test(s) 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 or imported by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new test(s) 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 test(s) to be assessed.