EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004298-67-05/F Helsinki, 7 October 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For ethylenediamine, CAS No 107-15-3 (EC No 203-468-6), 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 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for ethylenediamine, CAS No 107-15-3 (EC No 203-468-6), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 6 March 2014, 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 compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 22 July 2013.

On 5 November 2013 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 4 December 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 6 March 2014 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 for amendment of the draft decision within 30 days of the receipt of the notification.
Subsequently, proposals for amendment to the draft decision were submitted.

On 10 April 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 22 April 2014 ECHA referred the draft decision to the Member State Committee.

By 12 May 2014, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment and on the draft decision. The Member State Committee took the comments of the Registrant on the proposals for amendment into account. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).

After discussion in the Member State Committee meeting on 10-13 June 2014, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 12 June 2014.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annex VIII of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

- *In vitro* cytogenicity study in mammalian cells (Annex VIII, 8.4.2., test method: EU B.10./OECD 473) or *in vitro* micronucleus study (Annex VIII, 8.4.2., test method: OECD 487);

B. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1)(c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report (CSR):

1. Revision of Part A of the CSR (Annex I, Section 0.13.); or
   Revision of the exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) which corresponds to the risk management measures as summarised in Part A of the CSR.
   For further specifications of the requirement see Section III.B. below.
2. Documentation for the recommended personal protective equipment, i.e. gloves to be worn need to be specified clearly when handling the substance or mixture (Article 14(6), Annex I, 5.1.1., in conjunction with Annex II, 0.1.2. and 8.2.2.2.(b)(i)), including:
   - The type of material and its thickness, and

- The typical or minimum breakthrough times of the glove material.

3. Revised exposure assessment and risk characterisation for workers via dermal route or a justification why the efficiency values used for gloves are considered appropriate (Art. 41.1(c) of the REACH Regulation and Annex I, Section 5.2.4 and 5.2.5.) , as specified in section III.3.B.3. below.

C. Deadline for submitting the required information

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **14 October 2015**.

D Note for consideration by the Registrant

The Registrant 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 to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

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

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 10(a)(vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII, VIII, IX, and X of the REACH Regulation.

In vitro cytogenicity study in mammalian cells or *in vitro* micronucleus study (Annex VIII, 8.4.2.)

An "in vitro cytogenicity study in mammalian cells" or an "*in vitro* micronucleus study" is a standard information requirement as laid down in Annex VIII, Section 8.4.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier the Registrant has provided a Sister Chromatid Exchange test (SCE) in Chinese hamster ovary (CHO) cells study (pre-GLP, no guideline followed) for the endpoint of *in vitro* cytogenicity. However, this study does not fulfil the information requirements for this endpoint, as it does not provide information equivalent to data generated by the corresponding test methods referred to in Article 13(3) of the REACH

Regulation (Annex XI, Section 1.1.2.). Furthermore, there are no relevant *in vivo* cytogenicity studies available in the dossier.

ECHA notes that the technical dossier includes a negative *in vivo* Dominant Lethal Test (DLT). Nevertheless, the data from the DLT was performed neither with the registered substance nor according to the relevant test guideline (OECD 478). The OECD 478 study does not provide data equivalent to the corresponding test methods referred to in Article 13(3) of the REACH Regulation (Annex XI, Section 1.1.2.). ECHA furthermore notes that the Registrant did not provide a justification for reading across data from the other substance to the registered substance. The submission of the study therefore cannot cover data requirement for the endpoint of *in vitro* cytogenicity (Annex VIII 8.4.2.) of the registered substance.

The registration dossier does not contain any justified adaptation in accordance with column 2 of Annex VIII, Section 8.4.2. or with the general rules of Annex XI for this standard information requirement.

Consequently there is an information gap and it is necessary to provide information for this endpoint.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* cytogenicity study in mammalian cells (test method: EU B.10./OECD 473) or *in vitro* mammalian cell micronucleus study (test method: OECD 487).

It is noted that on 4 December 2013 ECHA received comments from the Registrant agreeing to carry out an in vitro cytogenicity study in mammalian cells (OECD 473).

B. Information related to the chemical safety assessment and chemical safety report

1. Revision of Part A of the Chemical Safety Report or revision of the exposure assessment and risk characterisation (Annex I, Sections 5. and 6.)

Pursuant to Articles 10(b) and and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

ECHA notes that the Registrant has submitted an exposure assessment and a risk characterisation as part of his registration dossier, as it is required pursuant to Article 14(4)(a)(b) and (c) and Section 0.6.2. of Annex I of the REACH Regulation. ECHA also notes that the Registrant has provided information in Part A of the Chemical Safety Report (CSR). ECHA however notes that the CSR is inconsistent and therefore incompliant:

A CSR shall include in its format Part A:

- a summary of the risk management measures that are described in the relevant exposure scenarios;

- a declaration that the risk management measures (RMM) outlined in the relevant exposure scenarios for the manufacturer's or importer's own use(s) are implemented by the manufacturer or importer; and
- a declaration that the risk management measures for the identified uses are communicated to distributors and downstream users in the safety data sheet(s).

Part A of the CSR provided by the Registrant states the RMM that are implemented by the Registrant and that he communicates to the downstream users.

These RMM stated in Part A of the CSR should correspond to the RMM outlined in the relevant exposure scenarios for the identified uses in Part B Section 9 of the CSR. However, the description of the RMMs outlined in Part A of the CSR does not correspond to the RMM outlined in the relevant exposure scenarios for the identified uses (Part B Section 9 of the CSR, Exposure scenarios 1 to 7) which are required for controlling the environmental release and exposure of the chemical substance. Indeed, the Registrant states in a number of exposure scenarios that "*the risk assessment is based on using additional abatement techniques, to reach the maximum possible release resulting in a RCR<1 for the local environment. Alternatively increased dilution through river flow rates or STP capacity can result in a RCR<1.*" Therefore, the Registrant has identified the need for additional RMM in order to ensure that the risks to the environment posed by the substance are controlled. These additional RMM, stated in the description of the exposure scenarios by the Registrant, that are needed to ensure a RCR < 1 are that the waste water should be treated in a sewage treatment plant or equivalent (ES 2, ES 3 and ES 4); that no application of sludge to soil is assumed (ES 2, ES 3 and ES 4); that waste water is treated by ion-exchange, that there is an incineration of waste streams (ES 1); that vent-gases are assumed to be led via scrubbers and scrubber, and that water should be led to waste (ES 1, ES 2 and ES 4).

ECHA therefore finds that the RMMs that the Registrant declares to be implemented and communicated do not correspond to the ones for which he has demonstrated that they lead to an adequately controlled risk.

Therefore, the Registrant is requested to update his CSR rendering it consistent. He can achieve this in two ways, i.e. either by amending Part A of the CSR to bring it in line with the RMMs that he has outlined in his exposure scenario (Annex I, Section 0.13.), or by rendering the exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) consistent with Part A of the Chemical Safety Report and demonstrating that by such RMMs the risk is adequately controlled.

It is noted that on 4 December 2013 ECHA received comments from the Registrant agreeing to revise part A of the CSR to include all RMM outlined in the relevant exposure scenarios.

Taking into consideration that according to the current exposure scenarios, the risk characterisation ratio (RCR) for the aquatic environment including sediment systems for ES 1, ES 2 and ES 3 is 0.99, 0.99 and 0.97, respectively, ECHA notes that it is unlikely that the Registrant could demonstrate that the risks are adequately controlled based on the RMMs that he has outlined in Part A of the CSR. Without the additional abatement RMM, the risk characterisation for the substance would be expected to be > 1, thus indicating that the predicted environmental concentrations (PECs) would be above the predicted no effect concentrations (PNECs) for the aquatic and sediment compartments.

Further information is available in Data Submission Manual 19 -How to submit a CSR as part of a joint submission, available at:
http://echa.europa.eu/doc/reachit/dsm_19_how_joint_csr_en.pdf.

2. Documentation for the recommended personal protective equipment, i.e. gloves to be worn need to be specified clearly when handling the substance or mixture (Article 14(6), Annex I, 5.1.1., in conjunction with Annex II, 0.1.2. and 8.2.2.2.(b)(i)), including:
   - The type of material and its thickness, and
   - The typical or minimum breakthrough times of the glove material.

Article 14(6) as well as Annex I, 0.1., 5.1.1., 5.2.4. and 6.2. of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in a CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented.

Pursuant to Annex VI, section 5 and Annex II, section 0.1.2. of the REACH Regulation the information provided in the registration dossier shall be consistent with that in the Safety Data Sheet (SDS). The requirements of Safety Data Sheets are specified in Annex II of the REACH Regulation. According to Annex I, 0.3., 0.5. and 5.1.1. applied Risk Management Measures (RMM) have to be indicated in the CSR. Annex II, section 8.2.2.2. (b)(i), requires the Registrant to describe the relevant RMM in detail (e.g. the type of gloves to be worn shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of dermal exposure) in order to minimise the exposure for workers handling the registered substance. In particular, the following requirements for hand protection in order to avoid dermal exposure need to be provided consistently in the SDS and CSR:

— the type of material and its thickness,
— the typical or minimum breakthrough times of the glove material.

In the CSR, the use of personal protective equipment is advised e.g. in chapter 9.1.1.. However, detailed characteristics are lacking e.g. type of material, thickness, design etc. Some more detailed advice is provided in the technical dossier IUCLID section 11, guidance on safe use, where for hand protection the glove material is identified as butyl-rubber. However, the breakthrough time or thickness of the glove material is not identified. Not all materials are well suited to protect against exposure to all substances, mixtures or materials. This has to be specified further to match the specific substances. A concern is raised if workers are not properly informed to use the right type of e.g. gloves to protect themselves against exposure to chemicals. The use of unsuited material may even result in higher level of exposure, than not using any protection at all, as the inside of contaminated gloves, may be covered with migrated substance – and the skin inside a glove is often humid – corresponding to exposure under occlusion.

Information on the specification of personal protective equipment shall be provided for all scenarios where the use of personal protective equipment is advised. In particular, the type of material of the gloves for all exposure scenarios where the use of gloves is advised.

On 12 May 2014 ECHA received comments from the Registrant on the proposal(s) for amendment agreeing to update the CSR with the requested information in section A and

to update the CSR with specific information on type of Personal Protective Equipment to be used.

The Registrant is accordingly required to provide documentation for the recommended material type, its thickness and the typical or minimum breakthrough time for the glove type recommended, with regard to the amount and duration of dermal exposure.

Notes for consideration by the Registrant:
Regarding how to report the gloves specifications, the information should be included both in section 11 of the technical IUCLID dossier (Guidance on Safe Use) which is the disseminated part of the dossier and in the CSR where the appropriate measures to adequately control the risk are to be reported.

It is the responsibility of the Registrant to ensure consistency of the information within the CSR, and between the CSR, IUCLID section 11 and the safety data sheet.

3. Revised exposure assessment and risk characterisation for workers via dermal route or a justification why the efficiency values used for gloves are considered appropriate (Art. 41.1(c) of the REACH Regulation and Annex I, Section 5.2.4 and 5.2.5.), as specified in section III.

Pursuant to Article 41.1(c) of the REACH Regulation ECHA may verify that any required Chemical Safety Assessment and Chemical Safety Report comply with the requirements of Annex I and that the proposed risk management measures are adequate.

A chemical exposure assessment performed by a Registrant shall include an exposure assessment according to section 5 of Annex I of the REACH Regulation. Annex I, section 5.2.4 of the REACH Regulation, requires the Registrant to perform an estimation of the exposure levels for all human populations and each relevant route of exposure shall be addressed. Further, the estimation of exposure shall take account of implemented or recommended risk management, including the degree of containment. In addition, Annex I, section 5.2.5 of the REACH Regulation indicates that appropriate models can be used for the estimation of exposure levels.

ECHA notes that the Registrant has used ECETOC TRA to estimate exposure for a variety of worker exposure scenarios using efficiency for gloves of 98% to estimate the exposure via dermal route. However, ECHA notes that according to the guidance for the model used (ECETOC TR 114) the maximum pre-defined values are 95% for industrial users and 90% for professional users. The registrant has not included in the CSR any case specific justification (e.g. related to the substance or the specific recommended or implemented personal protection measures or based on relevant biomonitoring data) for deviating from the recommended efficiency factor in using ECETOC TRA.

As explained above, the information provided on the dermal exposure estimates for the registered substance in the chemical safety report does not meet the requirements for preparing a chemical safety report as described in Annex I. Consequently, it is necessary to revise the dermal exposure estimates or to provide a justification explaining why in this specific case using higher efficiency values for gloves (98%) is considered appropriate.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit in the CSR the following information: revised exposure assessment

and risk characterisation for workers via dermal route using the pre-defined values for gloves efficiency stated above or a justification explaining why in this specific case using higher efficiency values for gloves (98%) is considered appropriate.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by other joint registrants for identifying the 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 information required by the present decision, the sample of substance used for the new study 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 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 substance tested in the new study 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 study 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 study 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 an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on 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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