ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004368-68-05/F Helsinki, 22 August 2014

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

For hexamethylenediamine, CAS No 124-09-4 (EC No 204-679-6), 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 hexamethylenediamine, CAS No 124-09-4 (EC No 204-679-6), submitted by [redacted] (Registrant). ECHA notes that in the joint submission covering the current registration, the Chemical Safety Report (CSR) is not provided by the lead registrant on behalf of the member registrants. The scope of this compliance check is limited to the standard information requirements of Annex I and Section 2 of Annex VI, while the compliance check concerning the information requirements laid down in Annexes VII to X was done on the lead registrant dossier of this joint submission.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more tonnes 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 2 October 2013.

On 31 October 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.

By 2 December 2013 the Registrant did not provide any comments on the draft decision to ECHA.

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, proposal for amendment to the draft decision was submitted.

On 10 April 2014 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 the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment received and modified Section III of the draft decision.

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

By 12 May 2014 the Registrant did not provide any comments on the proposal for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 26 May 2014 in a written procedure launched on 15 May 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

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

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

1. Revised environmental exposure assessment and risk characterisation as specified in section III.A.1.a) to c) below (Annex I, sections 5 and 6.);
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)), including:
   - The type of material and its thickness, and
   - The typical or minimum breakthrough times of the glove material.

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 **31 August 2015**.

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 related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) 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.

1. *Revised environmental exposure assessment and risk characterisation*

According to Article 14(4) of the REACH Regulation, if the substance fulfils the criteria for any of the hazard classes of Annex I to Regulation (EC) No 1272/2008 listed in Article 14(4) of the REACH Regulation or is assessed to be a PBT or vPvB, the chemical safety assessment (CSA) shall include an exposure assessment and risk characterisation. The exposure assessment shall be carried out according to section 5 of Annex I and shall include exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards. Annex I, section 6 of the REACH Regulation requires the registrant to characterise the risk for each exposure scenario.

a) Justification of release factors

Pursuant to the Annex I, section 5.2.1 of the REACH Regulation the exposure estimation entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. Emission estimation shall be performed under the assumption that the risk management measures (RMMs) and operational conditions (OCs) described in the exposure scenario (ES) have been implemented. These RMMs and OCs should be included in the ESs provided in a CSR.

According to the Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012) the exposure scenario should contain information (about operational conditions and risk management measures) based on which the assumed release factors and daily use rates can be justified. Exposure scenarios making reference to the A and B tables of the Technical Guidance Document (TGD, 2003) without providing more specific information on the conditions of use are considered insufficient to meet the REACH requirements. Furthermore, the Guidance indicates that sector specific environmental release categories (spERCs) developed by industrial sector organisations can be used in place of the conservative default environmental release categories (ERCs) of ECHA guidance. As far as possible, spERCs have to be linked to the applied RMM and OC driving the release estimation.

In the present case, in the CSR the Registrant has provided 7 ESs: 1) manufacturing of the substance; 2bis) use as monomer at common sites; 3) use as intermediate; 4a) use in dry formulation (formulation); 4b) use in dry formulation (industrial end use); 5a) use in liquid formulation (formulation); 5b) use in liquid formulation (industrial end use).

ECHA notes that, in order to cover any exposures that may be related to the identified hazards, exposure estimation for most of the ESs (except ESs 4a, 4b and 5a) as stated by the Registrant in the CSR is based on "*A&B Table approach according TGD 2003*" or on sector specific environmental release category (spERC) release factors. In some ESs the Registrant stated that "*the relevance of calculated exposure estimation data are checked and validated helping internal measures of releases*", but did not provide any further documentation of this validation.

ECHA considers that clear and detailed justification (e.g. based on RMMs and/or OCs and/or substance properties) for using other than default ERC release factors in exposure estimation is not provided in the CSR (e.g. it is not clear whether not reduced release factors from A and B tables are used in exposure estimation or whether these factors are reduced by efficiencies of RMMs which are noted in the ESs etc.). Where internal measures of releases are available, the summary of results of these measurements is needed. This summary should be detailed enough for the reader to understand whether or not it covers

relevant scenarios for possible releases from the substance processing according to the relevant ES.

Furthermore, ECHA observes that in ES 3 the estimated substance removal from wastewater via sewage treatment is [redacted]%. ECHA notes that this information is not consistent with other information contained in the dossier (e.g. "*wastewater emission controls are not applicable as there is no direct release to wastewater*") and thus, the information provided by the Registrant is considered as inconsistent. ECHA also notes that it is not clear whether waste water treatment is necessary to work within the scope of ES 3.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide in the relevant ESs (that is, all the other ESs than ESs 4a, 4b and 5a), where non-default ERC release factors are used for exposure estimation, a clear and detailed justification (e.g. based on RMMs and/or OCs and/or substance properties) for any non-default ERC release factors used in the exposure estimation and to specify if waste water treatment is needed for exposure estimation for ES 3. The chemical safety report shall be amended accordingly.

b) Receiving water flow rate

Pursuant to the Annex I, section 5.2.1 of the REACH Regulation the exposure estimation entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. Emission estimation shall be performed under the assumption that the risk management measures (RMMs) and operational conditions (OCs) described in the exposure scenario (ES) have been implemented. ES shall include, where relevant, a descripton of the duration and frequency of emissions of the substance to the different environmental compartments and sewage treatment systems and the dilution in the receiving environmental compartment (Annex I, section 5.1.1).

ECHA states that in line with Annex I, section 5.1.1., one of the OCs, which should be included in the ESs provided in the CSR, is in this case the dilution in the receiving environmental compartment, which depends on the receiving surface water (e.g. river) flow rate.

According to the Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012) the default receiving surface water flow rate is 18000 m3/d (corresponding to a dilution factor of 10). The flow rate or the dilution factor can be changed according to the site specific data. ECHA notes that according to this Guidance in case of site-specific assessments the dilution factor that is applied for calculation of the local concentration in surface water should not be greater than 1000.

In the present case, ECHA notes that the exposure estimation for exposure scenario ES2bis is based on non-default local receiving water flow rate of [redacted] m3/d. Reference for the value of receiving water flow rate used is not provided nor is there any summary (detailed enough to understand whether or not it covers the relevant scenario for possible substance fate in the environment) of any values measured provided by the Registrant.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide in the ES2bis a clear and detailed justification for the non-default receiving surface water flow rate used in the exposure estimation. The chemical safety report shall be amended accordingly.

c) Local predicted environmental concentrations in sea water and in marine sediment

According to Section 5.0 of Annex I of the REACH Regulation the objective of the exposure assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. Pursuant to Annex I, section 5.2.4 of the REACH Regulation an estimation of the exposure levels shall be performed for all environmental spheres for which exposure to the substance is known or reasonably foreseeable.

In the present case, ECHA notes that for a number of ESs (e.g. 2bis) local PECs in sea water and marine sediment are claimed as "n.a." ("not applicable") without any further justification or qualitative exposure estimates. For example, in the absence of the data on the location of 'common sites', they may also be placed close to a sea, i.e. the substance may be released to marine environment and exposure of sea water and marine sediments would become relevant. ECHA points out that it has to be explained why these local PECs are not relevant.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide a justification why the local PECs in sea water and marine sediment are not relevant or he has to, in the alternative, qualitatively or quantitatively estimate relevant PECs. The chemical safety report shall be amended accordingly.

2. Documentation that risks to workers are adequately controlled

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 II, section 0.1.2 of the REACH Regulation the information provided in the Safety Data Sheet shall be consistent with that in the CSR. The requirements of Safety Data Sheets are specified in Annex II (amended by Commission Regulation (EU) No 453/2010).

According to section 8.2.2.2(b) of Annex II to the REACH Regulation, the type of gloves to be worn when handling the substance or mixture 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, including:

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

The Registrant in the CSR indicated the following for hand protection: "*For processes where the possibility for exposure arises, wear appropriate protective gloves resistant to chemical substances (in accordance with standard EN 374-1). Gloves should be selected according to the application and the duration of use at the work station. Observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. Gloves should be discarded and replaced if there is any indication of degradation or chemical breakthrough.*"

In section 11 of the technical registration dossier in the part for Exposure controls/personal protection, the following is stated: "*Risk management measures are described in the CSR attached.*"

ECHA notes that the substance is classified as causing severe skin burns. To ensure the safe use of a substance it is essential to have detailed guidance on risk management measures, e.g. personal protective equipment. Although the gloves are reported in the CSR as required personal protective equipment to prevent dermal exposure to the substance, the material type of gloves to be worn, its thickness and typical or minimum breakthrough time when handling the substance is not specified.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested 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 in the CSR.

IV. 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/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Leena Ylä-Mononen
Director of Evaluation