ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004599-59-03/F Helsinki, 25 September 2014

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

For Dimethylamine, CAS No 124-40-3 (EC No 204-697-4), 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 Dimethylamine, CAS No 124-40-3 (EC No 204-697-4), 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 per year. This decision does not take into account any updates submitted after 12 June 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 31 October 2013.

On 16 December 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 45 days of the receipt of the draft decision.

By 30 January 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 12 June 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.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Spectral data (infra-red, nuclear magnetic resonance or mass spectrum) (Annex VI, 2.3.5.);
2. Description of the analytical methods (Annex VI, 2.3.7.).

B. 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:

1. Environmental exposure assessment and risk characterisation (Annex I, Sections 5. and 6.);
2. Revised exposure assessment and risk characterisation for workers and for all uses (except intermediate uses which are under strictly controlled conditions) (Annex I, 5.2.4. and 6.3. of the REACH Regulation).

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 **1 April 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 in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Spectral data (infra-red, nuclear magnetic resonance or mass spectrum) (Annex VI, 2.3.5.);

"Spectral data" is an information requirement as laid down in Annex VI, Section 2.3.5. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has provided an infra-red (IR) spectrum as the only spectral data with the registered substance. In addition, ECHA notes that the IR spectrum provided does not contain any data between 500 and 3700 cm^{-1}, and as such cannot confirm the substance identity.

ECHA notes that the registration dossier does not contain any nuclear magnetic resonance (NMR) or mass spectrum (MS) for the identification of the main constituent of the registered

substance which is required according to Annex VI, Section 2.3.5. of the REACH Regulation to support the identity of the registered substance.

NMR spectroscopic analyses such as a ^{1}H-NMR or a ^{13}C-NMR are powerful tools for structure characterisation and elucidation due to characteristic chemical shifts and spin-spin coupling which also reflect the relative abundance of individual atoms. As all reported constituents contain characteristic hydrogen and carbon atoms, NMR is an appropriate analytical method to characterise the substance.

Alternatively, a mass spectrum including the corresponding interpretation of the fragmentation scheme is also an appropriate analytical method to characterise the substance.

As for the reporting of the spectral data in the registration dossier, the information should be included in IUCLID section 1.4. The Registrant shall ensure that the description of the analytical methods used for the recording of the spectra is specified in the dossier in such detail to allow the methods to be reproduced, in line with the requirements under Annex VI section 2.3.7.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: a full infra-red spectrum and nuclear magnetic resonance. Alternatively to the NMR data, a mass spectrum including the corresponding interpretation of the fragmentation scheme can be provided as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

2. Description of the analytical methods (Annex VI, 2.3.7.)

"Description of the analytical methods" is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has provided a gas chromatogram that apparently has been used to quantify the composition of the registered substance.

ECHA notes that the Registrant has provided a peak list including retention times, area % and peak allocation. However, the Registrant has not provided a detailed description of the conditions for recording the chromatogram and the identification of the different constituents present in the composition of the registered substance as requested in Annex VI, Section 2.3.7. of the REACH Regulation.

Further, ECHA notes that the level of detail has to be such that the method can be reproduced. For the description of the method for a gas chromatographic analysis should include the following information:

- Details of sample/standard preparation;
- Column specification (such as diameter, packing, length);
- Temperature, also temperature range if used;
- Injection temperature;
- Identity of carrier gas and pressure of carrier gas;
- Detector type.

As for the reporting of the description of the analytical methods in the registration dossier, the information should be included in IUCLID section 1.4.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct description of the methods used to identify and quantify the registered substance as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

B. 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. Environmental exposure assessment and risk characterisation

According to Article 14(1) and (4) and Annex I, Section 0.6., the Registrant is required to perform a chemical safety assessment (CSA) for the registered substance. The CSA shall cover 1) Human health hazard assessment, 2) Human health hazard assessment of physicochemical properties, 3) Environmental hazard assessment and 4) PBT and vPvB assessment. If as a result from these steps, the substance meets the criteria for any hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008 (CLP Regulation), or is assessed to be a PBT or vPvB, the CSA shall also include the additional steps: Exposure assessment, including generation of exposure scenario(s) and exposure estimation, and Risk characterisation. The additional steps of the CSA shall be carried out in accordance with Sections 5 (for Exposure assessment) and 6 (for Risk characterisation) of Annex I of the REACH Regulation.

Further, according to Annex I, section 5.0., the objective of the exposure assessment is to make quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. The assessment shall consider all stages of the life-cycle of the substance and shall cover any exposures that may relate to the hazards identified in Sections 1 to 4 of chapter 0.6 of Annex I.

The Registrant has waived the exposure assessment and risk characterisation for the environment on the basis that no hazard has been identified in the chemical safety assessment.

ECHA notes that the registered substance has a harmonised classification (i.e. according to the CLP Regulation) as: Flam. Liq. 1; Acute Tox. 4; Skin Corr. 1B and Acute Tox. 4 (for the aqueous form) and as: Press.Gas; Flam. Gas 1; Skin Irrit. 2; Eye Dam. 1; Acute Tox. 4; STOT SE 3 (for the gaseous form). Therefore, accordingly to Article 14(4) and Annex I, Section 0.6, as the substance meets the criteria for classification the CSA shall include two additional steps, meaning that Exposure assessment and Risk characterisation are required.

With regard to the scope of the required exposure assessment, as stated above and in accordance with Annex I, section 5.0., it has to cover all hazards that have been identified according to Sections 1 to 4 of Annex I of the REACH Regulation.

It is clear from the information submitted jointly and present in the lead registrant's dossier that hazard for the environment has been identified for the registered substance. For fish, 50 day NOEC is 0.6 mg/L. For algae, 96 hour EC50 is 9 mg/L. For *Daphnia*, 24 hour EC50 is 48 mg/L. Therefore, the Registrant is required to carry out the exposure assessment and

subsequent risk characterisation also for the environment in order to address hazard identified for the environment. As further outlined in ECHA *Guidance on information requirements and chemical assessment, chapter B.8 Scope of Exposure Assessment* (version 2.1, December 2011), such identified hazards (among others) necessitating exposure assessment are the *"hazards for which there are classification criteria and there is information on these properties of the substance showing that it does have these properties, but the severity of the effects is lower than the criteria for classification and so the substance is not classified"*. Moreover, the above mentioned guidance specifies further (in Section 8.4.2.2) that *"if there are ecotoxicity data showing effects in aquatic organisms, but the substance is not classified as dangerous for the aquatic environment, an aquatic PNEC can nevertheless be derived thus indicating a hazard to the aquatic environment. /.../ Hence, quantitative exposure assessment, i.e. derivation of PECs, is mandatory for the water, sediment and soil environmental compartments."*

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to perform an environmental exposure assessment covering all life-cycle stages of the registered substance originating from manufacture and identified uses, and subsequently perform risk characterisation for each exposure scenario to demonstrate the safe use of the substance, and update the dossier accordingly.

2. Revised exposure assessment for workers and for all uses (except intermediate use which is under strictly controlled conditions)

Article 14(6) as well as Annex I, 0.1, 5.2.4 and 6.2-6.4 of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in the 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. Annex I 5.2.5 states that appropriate models can be used for the estimation of exposure levels.

The ECHA Guidance on information requirements and chemical safety assessment Chapter R.14: Occupational Exposure Estimation (ECHA, version: 2.0, May 2010) advises that estimation of exposure can be made from either (a) actual exposure measurements or (b) exposure estimation by analogous situations or exposure models.

In the present case, ECHA notes that according to the information provided in the technical registration dossier and in the CSR, the registered substance is a vapour at normal temperature and pressure. The Registrant has used the ECETOC TRA model for estimating occupational exposure, however this model should not be used for gases, as stated in ECETOC's own guidance on domain of reliable applicability: "*The TRA tool does not predict exposure to gases*". ECHA considers that both inhalation and dermal exposure estimates may be unreliable. There are currently no modelling techniques available for determining occupational inhalation exposure to gases. Therefore, in this case, the requirement to provide an assessment of exposure is most likely to be met through presentation of workplace measurements which could demonstrate actual exposure in accordance with the RMM and strictly controlled conditions mentioned within the CSR for the substance, as described in the above Guidance. Dermal exposure is most likely to be over-estimated in this case and, other than provision of advice on appropriate risk management measures, need not be developed further.

Accordingly, ECHA concludes that the Registrant has submitted RCRs for this substance that are unreliable because the modelling used for the exposure assessments is outside the

domain of the applicability of the model used. The model used is not appropriate and therefore resulting estimates are not appropriate for comparison with the DNEL.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide a revised CSR with appropriate exposure estimations for workers and for identified uses (except intermediate use which is under strictly controlled conditions). A revised risk characterisation is required to demonstrate that the long-term inhalation DNEL is unlikely to be exceeded at downstream user sites and to demonstrate safe use. The chemical safety report shall be amended accordingly.

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.

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