EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114288481-43-01/F Helsinki, 10 december 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.

Subsequently, proposals for amendment to the draft decision were submitted.

On 18 July 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 28 July 2014 ECHA referred the draft decision to the Member State Committee.

By 18 August 2014 the Registrant did not provide any comments on the proposal(s) for amendment.

After discussion in the Member State Committee meeting on 16-18 September 2014, a unanimous agreement of the Member State Committee on the draft decision was reached on 16 September 2014.

ECHA took the decision pursuant to Article 51(6) 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. Description of the analytical methods (Annex VI, Section 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), as specified in section III.B below.

C. Information in the technical dossier derived from the application of Annex VI

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

1. Revised environmental release categories (ERC) used in the technical dossier (Annex VI, 3)

Note for consideration by the Registrant:

Failure to comply with the requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

D. 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 **17 June 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. Description of the analytical methods (Annex VI, Section 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.

ECHA notes that the Registrant provided analytical information with the aim of supporting the identification of the substance and compositional information included in section 1.2 of the IUCLID dossier, as required by Annex VI, Section 2.3.7.

More specifically, the Registrant provided in section 1.4 of the IUCLID dossier the attachments: "[redacted]", "[redacted]", "[redacted]", "[redacted]" and "[redacted]", which included spectral data required by Annex VI, Section 2.3.5, chromatographic data required by Annex VI, Section 2.3.6 and descriptions of analytical methods required by Annex VI, Section 2.3.7.

However, the analytical information in the attachments included in the registration dossier is not sufficient to allow the identity and composition of the registered substance to be verified, as the information is identical to the analytical information contained in a registration dossier submitted by a different legal entity. The analytical information is a fingerprint of a substance manufactured or imported by the Lead Registrant. Therefore, ECHA cannot establish whether the analytical information indeed relates to the substance covered by this registration or to the substance registered by the other legal entity.

Article 5 of the REACH Regulation requires legal entities to make sure that the substances they manufacture or place on the market are registered in accordance with Title II of the REACH Regulation. Based on Article 11(1) and 10(a)(ii) of the REACH Regulation, each Registrant is required to submit separately information on the identity of the substance he

registers. Annex VI of the REACH Regulation provides that "the information given shall be sufficient to enable each substance to be identified". Analytical information generated on a substance that is not manufactured or imported by the Registrant cannot be used as evidence that would allow ECHA to verify the identity and composition of the registered substance.

Therefore, ECHA concludes that the analytical information provided by the Registrant cannot, in absence of further justification, be considered appropriate to verify the identity and composition of the registered substance.

The spectral information shall be provided according to the requirements of Annex VI, Section 2.3.5. of the REACH Regulation. For chromatographic methods, the method description information shall include a legible print-out of the chromatogram as well as the report from the chromatographic analysis including the table of peak assignments that report the peak areas and corresponding amounts of each relevant constituent and impurity.

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 descriptions shall be given in such detail that the methods can be reproduced and shall therefore include detailed experimental protocols. The results of the analyses, generated on the substance as manufactured/imported by the Registrant, shall also be reported. The Registrant shall remove from the registration dossier any analytical information that has not been generated on the substance as manufactured/imported by the Registrant. If any of the analytical information currently present in the registration dossier is relevant for the registered substance, a valid justification as to why this is the case shall be provided. The Registrant shall ensure that the information is consistent throughout the dossier.

As for the reporting in the registration dossier, the information should be included in section 1.4 of the IUCLID 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 (CSR) 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 and risk characterisation 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 Risk Characterisation Ratios (RCR) 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 CSR shall be amended accordingly.

C. Information in the technical dossier derived from the application of Annex VI

Pursuant to Article 10(a)(iii) of the REACH Regulation, the technical dossier shall contain information on the manufacture and use(s) of the substance as specified in Annex VI, Section 3 of the REACH Regulation. This information shall represent all Registrant's identified uses. This information may include, if the registrant deems appropriate, the relevant use and exposure categories.

1. Revised environmental release categories (ERC) used in the technical dossier

According to Annex VI, section 3 of the REACH Regulation, the registration has to contain information on manufacture and use(s) of the substance(s) together with information on waste quantities and composition of waste resulting from manufacture of the substance, the use in articles and identified uses.

In Section 3.5 of the technical dossier the registrant describes different life cycle stages for the uses of the substance using various elements of REACH Guidance R.12 ("Use descriptor system"). The names of the identified uses and the related use descriptors suggest that the substance is applied in different purposes like "Use as a monomer in epoxid" or "Use as a processing aid (catalyst) in polymerisation reactions". The Registrant has chosen different environmental release categories (ERC) for the uses (in cases above: ERC 6 and ERC 3). In contrast, for the field describing the technical function of the substance, the Registrant always states that the substance is used as solvent in the different processes. As solvents commonly act as processing aids, the assignment of ERCs other than ERC4 for solvents is not within the specifications of Guidance document R.12. Also the Registrant has not provided a sound justification why the chosen ERCs will be suitable for uses of the substance as a solvent.

Another discrepancy is that the Registrant provided a life cycle step in Section "uses by professional workers" in Section 3.5 of the IUCLID dossier where he assigned an ERC4 for the Environmental releases. However, ERC4 refers to a use at industrial sites whereas "uses by professional workers" means wide dispersive uses by craftsman or professional workers at non-industrial sites. The assigned ERC4 is therefore not adequate and will lead to false results for the environmental exposure assessment.

Furthermore, as specified in Annex I, Section 5.2 of the REACH Regulation, the emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance. Where relevant, the Registrant has to consider the waste(s) from the different life-cycle stages, too. This request points on the fact that the Registrant has to quantify the proportion of waste(s) stemming from each life-cycle step together with suitable information on waste management measures to reduce or avoid exposure of humans or the environment to the substance during waste disposal and/or recycling. This information is not yet provided in the exposure scenarios of the CSR and therefore the provisions of Annex I are regarded to be not fulfilled.

As a result of those shortcomings, the Registrant is requested to review the description of his identified uses and to verify whether or not the technical function(s) of the substance match(es) the identified use(s). This should be taken into account when for the environmental exposure assessment and risk characterisation. The Registrant is also requested to provide information regarding amounts and handling of wastes from manufacture and the uses of the substance.

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://www.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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