EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114288480-45-01/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 [redacted]. 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 6 November 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.

On 28 January 2014 ECHA received comments from the Registrant on the 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 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 did not amend 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 proposals 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 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 a revised environmental exposure assessment and risk characterisation (Annex I, sections 5 and 6.) as specified below:

1. revised PNEC values used for the risk characterisation in soil and sediment;
2. revised environmental release factors used for the exposure assessment;
3. combined exposure and risk assessments for the environment;
4. dilution flow rate that take account of spatial and temporal variations in the exposure pattern;
5. revised receiving water flow rate.

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.

B. 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.

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 (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

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 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.

The Registrant has provided environmental exposure assessment and risk characterisation which contain several deficiencies as indicated below.

1. Revised PNEC values used for the risk characterisation in soil and sediment

Pursuant to Annex I, Section 0.5. the chemical safety assessment shall be based on the information on the substance contained in the technical dossier and on other available and relevant information.

Annex I, Section 3.3.1. of the REACH Regulation requires to establish a Predicted No Effect Concentrations (PNEC) for each environmental sphere based on the available information and to use an appropriate assessment factor to the effect values. ECHA *Guidance on information requirements and chemical safety assessment Chapter R.10* (May 2008) provides further details for deriving PNECs.

ECHA notes that, for calculating the risk characterisation ratios (RCRs) presented in section 10 of his chemical safety report (CSR), the Registrant has used PNEC values for sediment and soil that are not consistent with the PNEC values derived in section 7 of the CSR. ECHA understands that the PNECs for soil and sediment presented in section 7 of the CSR have been calculated using the equilibrium partitioning method (EPM). However, the Registrant has not provided explanation for the contradictory PNEC values presented in section 10 of the CSR, and in particular on how these values have been derived. PNECs presented in section 10 of the CSR and used for calculating RCRs are deemed to be incorrect.

In his comments submitted on 28 January 2014, the Registrant agreed to revise the PNEC values used for the risk characterisation in soil and sediment and indicated that he would recalculate all risk characterisation ratios for soil and sediment and amend his CSR accordingly. ECHA acknowledges the Registrant's commitment. As the dossier has not been updated yet, the draft decision has not been modified with regard to this issue.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to revise the PNEC values used for the risk characterisation in soil and sediment and to subsequently recalculate all risk characterisation ratios for soil and sediment. The CSRshall be amended accordingly.

2. Revised environmental release factors used for the exposure assessment

Pursuant to 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. Pursuant to Annex I, section 5.1.1. of the REACH Regulation, exposure scenarios (ES) shall include, where relevant, a description of operational conditions (OCs) and of risk management measures (RMMs). As indicated in Annex I, section 5.2.2. of the REACH Regulation, emission estimation shall be performed under the assumption that the risk management measures and operational conditions described in the exposure scenario have been implemented. These RMMs and OCs should be included in the exposure scenarios 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), operational conditions "*consist of a set of actions, tools, parameters such as amount of substance, process temperature and pH, duration and frequency of release, type of use (e.g. indoor or outdoor), containment of process (open or closed), continuous or batch process (leading to an intermittent release), capacity of surroundings, etc. having, as a side effect, an impact on the release and the exposure*". Risk management measures "*consist of technologies and procedures aimed at either reducing the releases and/or preventing a release pathway. Examples of risk management measures intended to reduce release are filters, scrubbers, biological or physico-chemical wastewater treatment plants etc.*" Both OCs and RMMs have an impact on the type and amount of release and the resulting exposure.

The release factors associated with Environmental Release Categories (ERCs) cited in ECHA's guidance R.16 can be used for a first tier assessment of the emissions. However, better information may be available that could then be used instead. In particular, release factors can be refined by taking into account RMMs and OCs. In this case, it is important to explicitly link such RMMs and OCs to the release factors and communicate them properly to the downstream users in the exposure scenarios. Sector specific environmental release categories (spERCs) developed by industrial sector organisations can be used in place of the conservative default ERCs of ECHA's guidance R.16. However, spERCs have to be linked to the applied RMMs and OCs driving the release estimation and that shall be described in the exposure scenarios. ECHA's guidance R.16 also indicates that A and B tables of the Technical Guidance Document (TGD, 2003) can be considered for refining release factors, as long as specific information on RMMs and on OCs are provided in the exposure scenarios, otherwise they are considered insufficient to meet the REACH requirements.

In the present case, the Registrant has provided 6 exposure scenarios in the CSR:

- ES1: "Production of chemical at production site [redacted]"
- ES2: "Maintenance of the production site"
- ES3: "Use as catalyst at the [redacted]"
- ES4: "Formulation of preparations"
- ES5: "Use as intermediate (extern customer)"
- ES6: "Use in laboratory"

For ES1 ("Production of chemical at production site [redacted]"), the Registrant has assumed that no releases occur to the environment (release factors are 0% for air, water and soil). By comparison, default release factors recommended for ERC1 (Manufacture of chemicals) in ECHA's Guidance chapter R.16 are: 5%, 6% and 0.01%, respectively for air, water and soil. In the exposure scenario, the Registrant indicated that a spERC has been applied, but he did not provide any reference to a spERC factsheet or detailed information on the conditions of use or on risk management measures. The following statement is provided in the scenario: "[redacted], *no emissions to the different env. compartments* ([redacted])". [redacted] supposedly refers to a proprietary name for a closed process, but without any further information this statement does not constitute an adequate justification for assuming the absence of releases to the environment. In particular no specific risk management measures are mentioned for air and water.

For ES3 ("Use as catalyst at the [redacted]), the Registrant claims that no releases to the soil, water and air compartments occur when the substance is used as a catalyst, and thus for this scenario as well, release factors are set to 0% for air, water and soil. By comparison, default release factors recommended for ERC4 (Industrial use of processing aids) in ECHA's Guidance chapter R.16 are: 100%, 100% and 5%, respectively for air, water and soil. ECHA notes that, by definition, a catalyst is not consumed, and is indeed generally recovered, but some losses could still occur. However, the efficiency of the recovery and the corresponding risk management measures are not indicated in the scenario. Therefore, ECHA concludes that the Registrant's claim of no releases to the environment is unjustified, as the fact that the substance is used as a catalyst does not constitute an adequate justification for assuming an absence of release to the environment.

For ES4 ("Formulation of preparations"), the Registrant has assumed the following factors: 0.5%, 0.7%, 0.01% for air, water and soil respectively. By comparison, default release factors recommended for ERC2 (Formulation of mixtures) in ECHA's Guidance chapter R.16 are: 2.5%, 2% and 0.01%, respectively for air, water and soil. The Registrant claims that the release factors he has applied are based on A and B tables of the Technical Guidance Document (TGD, 2003). No further justification is provided for using these release factors, in particular, the exposure scenario does not specify any risk management measures. As indicated in section R.16.3.5.2 of the ECHA's guidance, specific information on risk management measures and operational conditions must be provided when using A and B tables of the TGD, otherwise they are considered insufficient to meet the REACH requirements. Furthermore, ECHA notes that the release factors reported in this scenario are actually not in line with the recommendations of the A and B tables of the TGD. The Registrant has applied Table A3.3 (Industrial use of chemicals used in synthesis) and the annual site tonnage for this use is reported to be [redacted]. However, Table A3.3 for an annual site tonnage [redacted] t/year and for a wet process, indicates a release factor for water of 2% (i.e. same as the one recommended by ECHA guidance R.16 for ERC2) and not 0.7% as reported in the exposure scenario. Therefore, ECHA concludes that the release factors applied by the Registrant for this exposure scenario cannot be considered sufficient to meet the REACH requirements.

For ES5 ("Use as intermediate (extern customer)"), the Registrant has also applied release factors derived from the A and B tables of the TGD (2003): 0.5%, 0.7%, 0.01% for air, water and soil respectively. By comparison, default release factors recommended for ERC6A (Industrial use of intermediates) by ECHA's Guidance chapter R.16 are: 5%, 2% and 0.1%, respectively for air, water and soil. No further justification is provided for using these release factors in this scenario either. In particular, the Registrant has not indicated risk management measures that would need to be applied for achieving these release factors.

Therefore, ECHA concludes that the release factors applied by the Registrant for this exposure scenario are not properly justified and cannot be considered sufficient to meet the REACH requirements.

In his comments submitted on 28 January 2014, the Registrant agreed to revise the description of the exposure scenarios (including OCs and RMMs) and to communicate the conditions of use to the downstream users. ECHA acknowledges the Registrant's commitment. As the dossier has not been updated yet, the draft decision has not been modified with regard to this issue.
Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to revise release factors for exposure scenarios ES1, ES3, ES4, and ES5 in order to ensure that either the default ERC release factors are used or that any non-default ERC release factors are adequately justified (e.g. based on risk management measures). The CSR shall be amended accordingly.

3. Combined exposure and risk assessments for the environment

Pursuant to Annex I, section 6.2. of the REACH Regulation the risk characterisation shall consider the overall environmental risk caused by the substance by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

Chapter R.16: Environmental Exposure Estimation of the Guidance on information requirements and the chemical safety assessment (ECHA, version: 2.1, October 2012) further specifies that combined risk needs to be considered when several uses occur at the same site. For assessing the combined risk, the local releases to water of all uses taking place at the same site should be summed up. The assessment of combined risk should be reported in the "combined risk" section of the CSR.

ECHA notes that a combined risk assessment for the environment has not been provided by the Registrant. In the CSR, releases from uses described in ES1 ("Production of chemical at production site [redacted]"), ES2 ("Maintenance of the production site") and ES3 ("Use as catalyst at the [redacted]") are assessed as independent point source releases, as if these uses were occurring at different sites. However, based on the information provided in the CSR, production (ES1), maintenance of the production site (ES2), and use of the substance as catalyst (ES3) do take place at the same site. Therefore, the resulting combined risk for this site needs to be assessed and reported in the CSR.

In his comments submitted on 28 January 2014, the Registrant explained that no combined exposure was necessary since he claimed that no release of the substance is expected from production (ES1) or from use as catalyst (ES3). ECHA acknowledges the Registrant's comment and indeed agrees that if absence of release can be demonstrated for ES1 and ES3 then a combined risk assessment will not be needed (i.e. combined exposure would then be actually equivalent to exposure due to maintenance of the production site (ES2) only). However, the Registrant shall demonstrate in the dossier itself that releases for ES1 and ES3 are negligible and shall explain in the dossier itself that combined exposure between ES1, ES2 and ES3 is not needed if releases for ES1 and ES3 are proven to be negligible. Since absence of release for ES1 and ES3 has not been properly justified yet in the dossier itself, the draft decision has not been modified with regard to this issue.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to provide a combined risk assessment for the environment in the CSR.

4. Dilution flow rate that take account of spatial and temporal variations in the exposure pattern

Pursuant to Annex I, section 5.2.4. of the REACH Regulation, exposure estimation shall take account of spatial and temporal variations in the exposure pattern.

In particular, the dilution of the substance into the receiving surface water may vary due to the different seasonal conditions. Chapter R.16.6.6.2 of the ECHA's Guidance on information requirements and the chemical safety assessment (ECHA, version: 2.1, October 2012) recommends that the low-flow rate or 10th percentile of the flow rate be used, or, alternatively, when only average flow rate is available, that the flow rate be estimated as one third of this average.

For estimating the exposure to the aquatic compartment for exposure scenarios ES1 ("Production of chemical at production site [redacted]"), ES2 ("Maintenance of the production site") and ES3 ("Use as catalyst at the [redacted]"), the Registrant has based his calculation of the local freshwater dilution factor on the average flow rate of [redacted] river. However, a dilution factor based on the average flow rate does not reflect seasonal variations of the flow rate, and in particular does not cover exposure patterns when the dilution capacity of the river is lower.

In his comments submitted on 28 January 2014, the Registrant explained that the river flow rate and effluent discharge rate of the Sewage Treatment Plant (STP) were adapted according to the local conditions at the [redacted] and were considering seasonal variation in the exposure pattern. He indicated that the river flow rate used for the assessment actually corresponded to the low-flow rate of the river [redacted]. It was calculated as the flow rate representing the water level of the river [redacted]) which dropped below the average water level during 10% of the year (i.e. 10th-percentile) averaged over the past 73 years. ECHA acknowledges this clarification, which is deemed acceptable. However this shall be included in the dossier itself. As the dossier has not been updated yet, the draft decision has not been modified with regard to this issue.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to amend his exposure assessment for the aquatic compartment for exposure scenarios ES1, ES2 and ES3 in order to take account of seasonal variations in the river flow rate. The CSR shall be amended accordingly.

5. Revised receiving water flow rate

Pursuant to Annex I, section 5.1.1. of the REACH Regulation, exposure scenarios shall include, where relevant, a description 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.

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 should be 18000 m^3/day and the default municipal STP discharge rate should be 2000 m^3/day, resulting in a default local dilution factor of 10. The Guidance also specifies that these default values can however be changed according to site specific data (Table R.16.20, p 104 of Guidance R.16).

ECHA notes that for exposure scenarios ES4 ("Formulation of preparations") and ES5 ("Use as intermediate (extern customer)"), the Registrant has assumed a river flow rate of 400,000 m^3/day and a municipal STP discharge rate of 10,000 m^3/day, resulting in a local freshwater dilution factor of 41. The Registrant claims that these values are recommended by the Technical Guidance Document (TGD, 2003), Part IV. ECHA would like to emphasise that the Technical Guidance Document was in support of the former pieces of legislation on new notified substances (Commission Directive 93/67/EEC), on existing substances (Commission Regulation (EC) No 1488/94) and on biocides (Directive 98/8/EC). For the REACH Regulation the Registrant shall rather follow the recommendation of the current specific ECHA's Guidance, i.e., in the absence of site specific data, a default a river flow rate of 18,000 m^3/day and a municipal STP discharge rate of 2000 m^3/day (resulting in a default local dilution factor of 10).

Values mentioned in TGD (2003) Part IV are statistically aggregated data and thus cannot be regarded as site specific data. In TGD (2003) Part IV, the value of 10,000 m^3/day was for effluent discharge rate of industrial STPs (but not for municipal STPs as assumed in the CSR) and was derived from data of high production volume (HPV) intermediates produced and processed in [redacted] (74 sites). The river flow rate of 400,000 m^3/day was derived as the median of the 10^{th} percentiles of river flows for 480 production sites in [redacted]. These sites were located on relatively large rivers. The Registrant has not demonstrated that the value of 400,000 m^3/day he has assumed for the river flow rate, and the value of 10,000 m^3/day he has assumed for the municipal STP discharge rate are relevant for his assessment:

- these values were derived from data of HPV intermediates, so it is not proved that they are relevant for this substance, for example for exposure scenario ES4 which is for "formulation of preparations";
- the value of 10,000 m^3/day was derived for industrial STPs, whereas the Registrant uses this value as effluent discharge rate for municipal STPs.

In his comments submitted on 28 January 2014, the Registrant agreed to use the default values for river flow rate and effluent discharge rate in the risk characterisation for ES4 and ES5. ECHA acknowledges the Registrant's commitment. As the dossier was not updated, the draft decision was not modified with regard to this issue.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to revise his assessment for exposure scenarios ES4 and ES5 by using default values recommended in ECHA's Guidance R.16. for the river flow rate and the municipal STP discharge rate or by using adequate site specific data, if available. Site specific data shall fulfil the quality requirements specified in chapter R.16.4.2. of ECHA's Guidance R.16. The CSR 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://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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