EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114289315-43-01/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 2-diethylaminoethanol, CAS No 100-37-8 (EC No 202-845-2), 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 2-diethylaminoethanol, CAS No 100-37-8 (EC No 202-845-2), submitted by [redacted] (Registrant).

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 16 July 2013.

On 18 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 17 December 2013 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

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 proposal(s) 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.

The present decision relates solely to a compliance check requesting information in form of *in vitro* gene mutation study in bacteria (Annex X, 8.4.1.), pre-natal developmental toxicity study (Annex X, 8.7.2.), environmental exposure assessment and risk characterisation (Annex I, sections 5 and 6), revised exposure assessment and risk characterisation for dermal route (Annex I, sections 5 and 6), a revised exposure assessment and risk characterisation for inhalation route (Annex I, sections 5 and 6) and documentation for the recommended personal protective equipment (Annex I, 5.1.1. in conjunction with Annex II, 0.1.2. and 8.2.2.2(b)). The other compliance check requirement of two-generation reproductive toxicity study is addressed in a separate decision although all information requirements were initially addressed together in the same draft decision.

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

By 18 August 2014 the Registrant provided 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 relating to the request for *in vitro* gene mutation study in bacteria, pre-natal developmental toxicity study, environmental exposure assessment and risk characterisation for dermal and inhalation route, and documentation for the recommended personal protective equipment as modified at the meeting was reached on 17 September 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)(vi) and/or (vii), 12(1)(e), 13 and Annexes VII and X of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. *In vitro* gene mutation study in bacteria (Annex VII, 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. /OECD 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102, as specified in section III.A.3 below;

2. Pre-natal developmental toxicity study (Annex X, 8.7.2.; test method: EU B.31./OECD 414) in rabbits, oral route.

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 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. 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:

1. Environmental exposure assessment and risk characterisation (Annex I, sections 5 and 6), as specified in Section III point B.1 below;
2. A revised exposure assessment and risk characterisation for dermal route (Annex I, sections 5 and 6), as specified in Section III point B.2 below;
3. A revised exposure assessment and risk characterisation for inhalation route (Annex I, sections 5 and 6), as specified in Section III point B.3 below;
4. Documentation for the recommended personal protective equipment (Annex I, 5.1.1. in conjunction with Annex II, 0.1.2. and 8.2.2.2(b)), as specified under Section III point B.4 below.

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 December 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 derived from the application of Annexes VII to XI

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

1. *In vitro* gene mutation study in bacteria with an additional, fifth strain of bacteria (Annex VII, 8.4.1.)

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. 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.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA.

Other tests may be used if the conditions of Annex XI are met. More specifically, Section 1.1.2 of Annex XI provides that existing data on human health properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3) may be used if the following conditions are met:

(1) Adequacy for the purpose of classification and labelling and/or risk assessment;
(2) Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);

(3) Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) adequate and reliable documentation of the study is provided.

According to paragraph 13 of the current OECD 471 test guideline (updated 1997) at least five strains of bacteria should be used. These should include four strains of S. typhimurium (TA1535; TA1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four S. typhimurium strains have GC base pairs at the primary reversion site and it is known that they may not detect certain oxidising mutagens, cross-linking agents and hydrazines. Such substances may be detected by E.coli WP2 strains or S. typhimurium TA102 which have an AT base pair at the primary reversion site.

In the present case, the Registrant has provided two studies from the years 1987 and 1989 according to OECD 471 with an assigned reliability score of 2 and 1 respectively. The tests used four different strains of S. typhimurium TA [1535, TA 1537, TA 98 and TA 100].

ECHA concludes that a test using E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102 has not been submitted by the Registrant and that the test using one of these is required to conclude on *in vitro* gene mutation in bacteria. This means that the study does not meet the current guidelines, nor can it be considered as providing equivalent data according to the criteria in Annex XI.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant indicated his agreement to perform the test requested.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to complete the following information derived with the registered substance subject to the present decision: Bacterial reverse mutation test (test method: EU B.13/14. / OECD 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102.

2. Pre-natal developmental toxicity study (Annex X, 8.7.2.)

Pre-natal developmental toxicity studies (test method EU B.31/OECD 414) on two species are part of the standard information requirements for a substance registered for [redacted] (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

There is information available on this endpoint only for a pre-natal developmental toxicity study in a first species (rat) for the registered substance in the technical dossier. However, there is no information available for a pre-natal developmental toxicity study in a second species. Consequently there is an information gap for Annex X, Section 8.7.2. and it is necessary to provide information for this endpoint.

ECHA observes that the Registrant has neither provided any study record of a pre-natal developmental toxicity study in a second species in the dossier that would meet the information requirement of Annex X, Section 8.7.2. nor adapted this information requirement.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The test in the first species was carried out by testing a rodent species and ECHA therefore considers that the test in a second species should be carried out in a non-rodent species. According to the test method EU B.31/OECD 414, the rabbit is the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rabbit as a second species to be used.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant proposes to use a read-across approach to cover the requirements for pre-natal developmental toxicity study in a second species. The Registrant has also provided a read-across justification in his comments referring to new information for five substances having ethanolamine as a common chemical feature.

Based on the information provided, ECHA understands that the hypothesis is based on i) ethanolamine common structure, ii) common mode-of-action (effects on choline-metabolism).

ECHA notes, however, that any final assessment can only be based on a thorough assessment of both, the studies and the proposed mode of action. ECHA notes firstly that the Registrant has not updated the registration dossier providing the relevant robust study summaries and thus allowing assessing their validity and reliability. Secondly the Registrant has not provided a robust scientific presentation on the current knowledge of the mode of action.

Therefore, ECHA considers that the read-across approach cannot be accepted because it does not fulfil the requirements defined in Annex XI, 1.5. since adequate and reliable documentation has not been provided.

With regard to the read-across strategy for pre-natal developmental toxicity study, ECHA notes that the Registrant has provided reference to data from two source substances: ethanolamine (MEA) and diethanolamine (DEA). Although the Registrant's argument is that all ethanolamines show similar effects due to the same mode-of-action, the data to which the Registrant is referring to shows that the two substances clearly differ as regards the effects: no developmental toxicity was observed for MEA, while DEA did give rise to effects on the offspring. However, as stated above without the relevant robust study summaries and a clear and extensive presentation on the current knowledge of the mode of action, ECHA cannot conclude in the read-across approach.

In addition, even if the substances share a common mode-of-action there is no proof that other mode-of-action is possible or even if the different ethanolamines behave differently within that mode-of-action or which one could constitute the worst case scenario.

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: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rabbits by the oral route.

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

According to Article 14(3), the CSA shall include human health, physicochemical and environmental hazard assessments. If the substance fulfils the criteria for any of the hazard classes or categories referred to in Article 14(4) of the REACH Regulation, the CSA shall also include exposure assessment including the generation of exposure scenarios (or the identification of relevant use and exposure categories if appropriate) and exposure estimation, as well as risk characterisation. The additional steps of the CSA shall be carried out in accordance with Section 5 (for the exposure assessment) and 6 (for Risk characterisation) of Annex I of the REACH Regulation.

1. Environmental exposure assessment and risk characterisation (Annex I, sections 5 and 6)

Annex I, section 5 of the REACH Regulation requires the Registrant to generate 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 5.0).

Annex I, section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario and shall consider the human population and the environmental spheres for which exposure to the substance is known or reasonable foreseeable, under the assumption that the risk management measures described under exposure scenario in the Section 5 have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

ECHA's Guidance on information requirements and chemical safety assessment, Part B: Hazard Assessment, section B.8.4. (pages 47 to 48) states that "if no adverse effects have been observed in studies at the highest recommended concentration/doses tested, this would normally indicate that no hazard has been identified and no DNEL or PNEC can be derived and hence exposure assessment for that route of exposure, type of effect or protection target would not be needed".

In the CSR provided by the Registrant the exposure scenarios or exposure estimations for the environment are missing. The Registrant claims that no exposure assessment is necessary for environment since no hazard was identified in the environmental hazard assessment.

ECHA notes that the Registrant has classified the substance as Flam. Liquid 3, Acute Tox. 4 (Oral), Acute Tox. 3 (dermal), Acute Tox. 3 (inhalation), Skin Corr. 1B and Eye Damage 1 and thus, fulfilling the criteria set out in Article 14(4) of the REACH Regulation to provide a CSA.

Additionally, ECHA notes that effects were observed in certain environmental toxicity studies provided by the Registrant. In particular, in the short-term toxicity studies to aquatic invertebrates an EC50 of 83.6 mg/L and an EC50 of 165 mg/L were obtained for the non-neutralised and neutralised substance respectively. Similarly, in the toxicity studies to aquatic algae an EC50 of 44 mg/L and a LOEC of 10 mg/L were obtained. These results do not support the Registrant's claim that no hazard was identified for the registered substance in the environmental hazard assessment since the effects are observed at a concentration lower than the highest recommended concentration (i.e. 100 mg/L for acute aquatic toxicity test).

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant challenges the request for exposure assessment for not being consistent in the understanding of the term 'hazard' in the provisions of the REACH and CLP Regulation, and to neglect general principles of EU law, ECHA points out the following:

Generally, two of the main purposes of both the REACH and CLP Regulation are to ensure a high level of protection of human health and the environment (Article 1(1) of the REACH and CLP Regulation respectively). The additional steps in a CSA of exposure assessment and risk characterisation serve this objective as they allow estimating and characterising any risk to mankind or the environment. The formal arguments of the Registrant that this shall be done only for CLP-classified hazards ignore this overall context.

Both the REACH and CLP Regulation distinguish between the terms 'hazard', 'hazardous' and 'hazard classes'. The legislator would have used the term 'hazard classes' only if that was his intention for Annex I, Section 5 to the REACH Regulation. This becomes clear from the disctinct references used in Article 3 of the CLP Regulation, Article 14(4) and Annex I, Sections 0.6.3. and 5. to the REACH Regulation. Under REACH, a hazard is identified by the results generated from the tests used to fulfil the information requirements set out in Annexes VII to XI. Pursuant to Article 13(3) of the REACH Regulation tests define endpoints/effects to be observed and reported for identification of (no)effect levels/concentrations as well as a limit dose and therefore, if a hazard is identified it is when an adverse effect is observed below that limit dose.

The REACH and CLP Regulations can be interpreted in a coherent and consistent way without reducing unnecessarily their respective scopes. The CSA/CSR is regulated by law in order to assess and document that any risks arising from a substance are adequately controlled during manufacture and use. The burden of safe use lies with operators. ECHA therefore considers the additional steps of exposure assessment and risk characterisation for any identified hazard irrespective of classification as a measure in line with the precautionary principle that is underpinning the REACH Regulation (Article 1(3)) and which the Registrant seems to ignore.

Pursuant to Annex I, Section 3.0.2. of the REACH Regulation five environmental spheres shall be assessed for hazards. Annex I, Sections 5 and 6 require an exposure assessment and risk characterisation for the "environmental spheres for which exposure to the substance is known or reasonably foreseeable". Following the Registrant's argumentation, the environmental exposure assessment and risk characterisation would only be possible for the aquatic environmental sphere since the results for a number of standard data requirements for the other environmental spheres (e.g. information on soil/sediment toxicity,) do not lead to the classification of substances as hazardous, as no hazard classes or classification criteria exist. It cannot be correct that a large part of standard data requirements set out in the REACH Annexes would become irrelevant. Instead, the legislator has a clear intention to use the standard information required in Annexes VII to X of the REACH Regulation for the hazard assessment without prejudice of classification needs.

For reasons of proportionality, the requirement of a CSA is limited to those substances meeting the criteria for classification of any hazard class/category set out in Article 14(4) of the REACH Regulation/Annex I CLP Regulation. In that regard the request by ECHA to understand exposure and risk of the substance subject to the present decision is not exceeding of what is appropriate and necessary to attain the objectives of the legislation. The identified hazard in this case has been demonstrated by aquatic toxicity to invertebrates and toxicity to aquatic algae as outlined in above. At the same time, as ECHA is not requiring exposure assessment and risk characterisation on all environmental endpoints, it does not exceed what is necessary to address the concern.

ECHA respects the principle of equal treatment as it requires for any substance meeting the criteria for classification in any of the hazard classes/categories an exposure assessment and risk characterisation.

Finally, the Registrant cannot claim that ECHA's action would jeopardise legal certainty as ECHA has issued guidance on when exposure assessment and risk characterisation are expected (Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose[concentration]-response for human health; Version: 2.1; November 2012).

In conclusion, the arguments by the Registrant cannot lead to omit the required data that is needed in order to comply with the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to generate an exposure assessment and risk characterisation for the environment. The CSR shall be amended accordingly.

2. A revised exposure assessment and risk characterisation for dermal route (Annex I, sections 5 and 6)

Annex I, section 5 of the REACH Regulation requires the Registrant to generate 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. Each relevant route of human exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed (Section 5.2.4).

Further, Annex I, section 6.5. of the REACH Regulation states that "for those human effects and those environmental spheres for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out".

The registered substance is corrosive (Skin Corr. 1B and Eye Damage 1) and this is considered by the Registrant to be enough evidence not to provide a quantitative exposure estimate for systemic dose arising from dermal challenge. Thus, the Registrant provided a qualitative assessment instead.

However, ECHA notes that the Registrant describes scenarios for which the substance is used in a diluted form (e.g. use as metal working fluids, use as additive in concrete and cement, use as additive in coatings). In these cases, the substance might be below the limits of corrosivity and thus, there is an opportunity for significant exposure by dermal route and, in this case, a quantitative assessment would be more appropriate. In fact, the Registrant provides in the CSR a DNEL dermal, derived from oral, which can be used in the assessment.

Additionally, the OECD SIDS report for the registered substance provided by the Registrant shows that a significant skin penetration rate was estimated for human skin on the basis of the physico-chemical properties of the registered substance (3.44 mg/cm^2).

Further, it is also noted that in the qualitative assessment, the Registrant claims that the use of risk management measures (RMM), such as chemical resistant gloves, protective clothing and suitable eye protection, are required if any contact with skin and/or eye is foreseen. However, the use of gloves as a risk management measure in some metal working activities may not always be recommended or practicable.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide an adequate quantitative assessment and generate exposure estimations and risk characterisation for those exposure scenarios via dermal route where a diluted form of the substance is used. The CSR shall be amended accordingly.

3. A revised exposure assessment and risk characterisation for inhalation route (Annex I, sections 5 and 6)

Annex I, Section 5 of the REACH Regulation requires the Registrant to generate 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.

Further, Annex I, Section 5.2. of the REACH Regulation requires the Registrant to provide exposure estimation for each scenario.

Annex I section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario and shall consider the human population and the environmental spheres for which exposure to the substance is known or reasonably foreseeable. Further, Annex I, Section 6.4. states that "*for any exposure scenario, the risk to humans and the environment can be considered to be adequately controlled, throughout the lifecycle of the substance that results from the manufacture or identify uses, if the exposure levels estimated [...] do not exceed the appropriate DNEL or the PNEC*".

The Registrant has used a quantitative approach to carry out the exposure assessment and risk characterization for inhalation route. The model used by the Registrant to estimate the exposure levels is ECETOC TRA v2.0.

ECHA notes that the following deficiencies have been observed in the exposure assessment and risk characterisation of the registered substance for the inhalation route:

- In the estimation of exposures, the Registrant has assumed a linear relationship between concentration and estimated exposure when the concentration of the registered substance in the mixture is [redacted]%. According to the guidance for the model used by the Registrant (ECETOC TRA v.2 Technical Report No. 107) if the concentration of the substance in a mixture is > 25 %, the mixture should be treated like the pure substance and only concentrations < 25 % lead to modifying factors <1. As a consequence the estimated exposure value long-term for inhalation would be higher (e.g. the exposure estimate for PROC 5 in exposure scenario 6 (outdoor) would be 34.18 mg/m³ instead of the reported value of 11.964 mg/m³). Thus, the RCRs would be also higher and above 1 (e.g. PROC 5 in exposure scenario 6 (outdoor) of 4.66 (DNEL reported in table 25: 7.34 mg/m³)). Therefore, the risks arising from the use of the substance in a mixture might not be adequately controlled.
- The Registrant has derived DNELs for the inhalation route but the risk characterisation ratios were calculated using the OEL determined by the German MAK for the registered substance (i.e. 5 ppm (24 mg/m3)) as the Registrant has explained in section 9 of the CSR. However, as stated in ECHA's Guidance, Chapter R.8., Appendix 8-13, "*a Registrant cannot use a national OEL in place of a DNEL without an evaluation of the scientific background for setting the national OEL. [...] In this evaluation, the approach used for setting the national OEL should be compared to the approach for deriving DNELs as described in the in the main body of this chapter, and any differences in approach should be taken into account*". ECHA notes that the Registrant has not provided such evaluation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation of the REACH Regulation, the Registrant is requested to revise the exposure assessment and risk characterisation for the inhalation route addressing the issues identified above and to submit in the chemical safety report the following information:

- Exposure estimations for the use of the substance in a mixture in accordance with the guidance for the model used, without the application of modifying factors when the concentration of the substance in the mixture is higher than 25%..
- Risk characterisation ratios for inhalation route using the DNELs derived according to ECHA's Guidance or an evaluation of the scientific background for setting the national OEL showing that the approach used for setting the national OEL is comparable to the approach for deriving DNEL.

4. Documentation for the recommended personal protective equipment (Annex I, 5.1.1. in conjunction with Annex II, 0.1.2. and 8.2.2.2(b))

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 SDS are specified in Annex II of the REACH Regulation (amended by Commission Regulation (EU) No 453/2010).

According to Annex I, 0.3., 0.5. and 5.1.1. the applied Risk Management Measures (RMM) have to be indicated in the CSR. Annex II, section 8.2.2.2. (b), requires the Registrant to describe the relevant RMM in detail 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 order to avoid exposure via inhalation route, the following requirements for respiratory protection need to be provided consistently in the SDS and CSR:

- Type of filters used for the mask

In the CSR, the Registrant indicated the following for hand protection: "*Diethylethanolamine is classified as corrosive (R34). Working with this substance requires a stringent use of appropriate chemical resistant gloves, protective clothing and suitable eye protection if any skin/eye contact is foreseen*". No information was provided for the respiratory protection used.

No information was provided in section 11 of the technical registration dossier for hand protection or respiratory protection.

ECHA notes that the substance is classified as Skin Corr. 1B and Eye Damage 1.

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 and respiratory protection are reported in the CSR as required personal protective equipment to prevent dermal and inhalation exposure to the substance, the material type of gloves to be worn is specified, its thickness and typical or minimum breakthrough time, and the type of filter used in filtering devices for respiratory protection are not specified.

It is recognised that many exposure scenarios for the registered substance will result in exposure to a mixture of chemicals and the appropriate advice on the specific glove requirements for these undefined situations will be within the safety data sheets relating to product formulations. The selection of glove will be determined by the most relevant components of those mixtures and this information is not required within the CSR or section 11 of IUCLID.

Therefore, pursuant to Article 41(1)(c) 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. The Registrant is also requested to provide documentation for the recommended type filter in filtering devices for the respiratory protection.

Notes for consideration by the Registrant:

Following the proposal for amendment received from a Competent Authority on the exposure assessment, with particular reference to the duration for the use of Personal Protective Equipment (PPE), ECHA invites the Registrant to consider the duration of the tasks in the exposure scenarios and the recommended wearing time for the PPE when specifying the recommended PPE in the CSR.

Regarding how to report the gloves and respiratory protective equipment 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 among the CSR, IUCLID section 11 and the SDS.

C. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 30 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also addressed another study (two-generation reproductive toxicity study, Annex X, Section 8.7.3). As this study is not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 12 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

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 studies 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 studies 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 studies 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 studies to be assessed.

V. 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/web/guest/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