EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114309001-73-01/F Helsinki, 19 October 2015

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

For ammonium carbamate, CAS No 1111-78-0 (EC No 214-185-2), 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 ammonium carbamate, CAS No 1111-78-0 (EC No 214-185-2), submitted by [redacted] (Registrant).

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 11 June 2015, 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 17 December 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. That draft decision was based on submission number [redacted].

On 30 January 2014 ECHA received comments from the Registrant on the draft decision.

On 6 August 2014 the Registrant updated his registration dossier with submission number [redacted].

ECHA received comments from the Registrant on the draft decision, concerning the information requirements of Annex I Sections 4, 5, 6, Annex VII Sections 7.2., 7.8., 8.3., 8.4.1., 8.4.2., Annex VIII Sections 8.4.2., 8.5.2., 9.2.1.1., Annex IX Sections 8.6.2. and 8.7.2. and Annex X Section 8.7.3.

The compliance check requirement to submit information of a two-generation reproductive toxicity study (EU B.35, OECD TG 416) or an extended one-generation reproductive toxicity study (EU B.56, OECD TG 443) has been removed from this draft decision due to legislative amendments to the REACH Regulation regarding Annex X, Section 8.7.3. In light of this, ECHA Secretariat did not consider further the Registrant's comments and update concerning the information requirement of Annex X, Section 8.7.3. However, ECHA Secretariat did

consider further the Registrant's comments and update concerning the information requirements of Annex I Sections 4, 5, 6, Annex VII Sections 7.2., 7.8., 8.3., 8.4.1., 8.4.2., Annex VIII Sections 8.4.2., 8.5.2., 9.2.1.1., Annex IX Sections 8.6.2. and 8.7.2. On the basis of all this information and change of scope, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 11 June 2015 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, a proposal for amendment to the draft decision was submitted.

On 17 July 2015 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment received and amended the draft decision.

On 27 July 2015 ECHA referred the draft decision to the Member State Committee.

By 17 August 2015 in accordance to Article 51(5), the Registrant provided comments on the proposal for amendment. The Member State Committee took the comments of the Registrant on the proposal for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 31 August 2015 in a written procedure launched on 20 August 2015.

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:

1. Environmental exposure assessment and risk characterisation (Annex I, Sections 5. and 6. of the REACH Regulation);
2. Revised exposure assessment and risk characterization for workers estimating the exposure for the use of the substance in accordance with the guidance for the model used (Annex I, Section 5.2.4 and 5.2.5.), as specified in section III.A.2 below.

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 **26 April 2016**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

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

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

1. Environmental exposure assessment and risk characterisation

Annex I, 5. of the REACH Regulation require the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider, in the exposure assessment, 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, 6. of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario and shall consider the human population (exposed as workers, consumer or indirectly via the environment and if relevant a combination thereof) 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.

In the CSR provided by the Registrant the exposure assessment for the environment is missing. The Registrant claims that no exposure assessment is necessary for the environment by stating that "In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) exposure estimation is not necessary. Consequently all identified uses of the substance are assessed as safe for the environment."

ECHA notes that the Registrant has classified the substance as Acute Tox. 4, Eye Damage 1 and thus, fulfilling the criteria set out in Article 14(4) of the REACH Regulation to require an exposure assessment and a risk characterisation in the chemical safety assessment.

With regard to the scope of the required exposure assessment, as stated above and in accordance with Annex I, 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. ECHA notes that effects were observed in the aquatic studies provided in the dossier (e.g. in the short-term toxicity study to fish an LC50 of 37 mg/L was obtained) and the Registrant states "acute harmful to fish/aquatic invertebrates/aquatic algae". I.e. the hazard assessment has to cover as well environmental hazards.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation of the REACH Regulation, the Registrant is requested to generate an exposure assessment and risk

characterisation for the environment. The chemical safety report shall be amended accordingly.

With regard to the comments provided by the Registrant challenging 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 chemical safety assessment 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 distinct 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 chemical safety assessment/report 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 chemical safety assessment 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 mortality of fish 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 Part B: Hazard assessment; Version: 2.1; December 2011).

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.

2. Revised exposure assessment and risk characterization for workers

Pursuant to Article 41(1)(c) of the REACH Regulation ECHA may verify that any required Chemical Safety Assessment and Chemical Safety Report comply with the requirements of Annex I and that the proposed risk management measures are adequate.

A chemical exposure assessment performed by a Registrant shall include an exposure assessment according to section 5 of Annex I of the REACH Regulation. Annex I, section 5.2.4 of the REACH Regulation, requires the Registrant to perform an estimation of the exposure levels for all human populations and each relevant route of exposure shall be addressed. Further, the estimation of exposure shall take account of implemented or recommended risk management, including the degree of containment. In addition, Annex I, section 5.2.5 of the REACH Regulation indicates that appropriate models can be used for the estimation of exposure levels.

ECHA notes that the Registrant has used ECETOC TRA version 2 to estimate exposure. For a variety of worker exposure scenarios the Registrant states that efficiency for gloves of 98% was used to estimate the exposure via dermal route. However, ECHA also notes that according to the guidance for the model used (ECETOC TR 107) the maximum pre-defined values for gloves are 95% for industrial users and 90% for professional users.

In addition, the Registrant has recognized in the CSR that "*another effectiveness value was used*" for respiratory protection to estimate exposure via inhalation route. In that regard, the Registrant has not included in the CSR any case specific justification (e.g. related to the substance or the specific recommended or implemented personal protection measures or based on relevant biomonitoring data) for deviating from the pre-defined efficacy factors in using ECETOC TRA.

ECHA also notes that, although the Registrant has not provided a transparent approach in the estimation of exposures, the Registrant seems to have assumed a linear relationship between concentration and estimated exposure for some scenarios in which the concentration of the registered substance in the mixture is [redacted]%. According to the guidance for the model mentioned above, 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 values would be higher and, consequently the RCRs would be also higher and above 1. Therefore, the risks arising from the use of the substance in a mixture might not be adequately controlled. As a general principle, exposure modifying factors applied within or to exposure models should

use the designed features within the model. Other unsupported or not validated external modifiers should not be applied.

As explained above, the information provided on the exposure estimates for the registered substance in the chemical safety report does not meet the requirements for preparing a chemical safety report as described in Annex I.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit in the chemical safety report the following information: revised exposure assessment and risk characterization for workers estimating the exposure for the use of the substance in accordance with the guidance for the model used: i) using the pre-defined values for efficacy of gloves and respiratory protection or a justification explaining why in this specific case using higher efficacy values are considered appropriate, and ii) without the application of modifying factors when the concentration of the substance in the mixture is higher than 25%.

Note for consideration by the Registrant regarding pre-natal developmental toxicity study (Annex X, 8.7.2.)

The draft decision initially sent to the Registrant contained a request for pre-natal developmental toxicity study in a first species (Annex IX, 8.7.2). On the basis of the new information provided in the dossier update, ECHA considers that the information requirement of pre-natal developmental toxicity study in a first species (Annex IX, 8.7.2.) is fulfilled by the read-across adaptation proposed by the Registrant.

However, ECHA does not consider that the Registrant has addressed the requirement of a pre-natal developmental toxicity study in a second species set out in Annex X, 8.7.2. The dossier contains currently four pre-natal developmental toxicity studies. Three studies in rats, mice and rabbits for sodium bicarbonate and one study in rats for ammonium chloride. There is no study in a second species addressing the pre-natal developmental toxicity for the ammonium ion (the most relevant hydrolysis product), neither has the Registrant provided a justification why this should be deemed not necessary.

The Registrant has included in the dossier update neither a testing proposal for a pre-natal developmental toxicity (PNDT) study in a second species nor a documented scientific justification why the second species PNDT could be omitted.

The requirement for a pre-natal developmental toxicity study in a second species should thus be addressed by the Registrant in the registration dossier. ECHA may evaluate this requirement in the follow up process to the present decision and/or perform a separate compliance check for this endpoint.

B. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also contained requests for a two-generation reproductive toxicity study (EU B.35, OECD TG 416) or an extended one-generation reproductive toxicity study (EU B.56, OECD TG 443) (Annex X, Section 8.7.3.), which have been removed from this draft decision due to legislative amendments to the REACH Regulation regarding Annex X, Section 8.7.3. Furthermore, the following information requests stemming from Annex I Sections 4, 5, 6, Annex VII Sections 7.2., 7.8., 8.3., 8.4.1., 8.4.2., Annex VIII Sections 8.4.2., 8.5.2., 9.2.1.1., Annex IX Sections 8.6.2. and 8.7.2, have been also removed from the draft decision because the updated registration

dossier addressed these requests. As these information requirements are no longer addressed in the present decision, ECHA Secretariat considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 6 months from the date of the adoption of the decision. The decision was therefore modified 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.

Authorised[1] by Guilhem de Seze, Head of Unit, Evaluation E1

[2] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.