EUROPEAN CHEMICALS AGENCY

Final decision: CCH-D-0000002665-70-03/F Helsinki, 29 January 2013

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

For ammonium nitrate, CAS No 6484-52-2 (EC No 229-347-8), 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 dossier for ammonium nitrate, CAS No 6484-52-2 (EC No 229-347-8) submitted by [redacted] (Registrant). The scope of the present decision is limited to the obligation to submit missing information related to substance identity, pursuant to Article 10(a)(ii) and Annex VI, section 2, and to submit a CSR pursuant to Article 14 and Annex I of the REACH Regulation.

This decision is based on the registration dossier 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 after 2 November 2012, 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 to initiate further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 2 May 2012.

On 31 July 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 30 August 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 2 November 2012 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

1) Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI , section 2 of the REACH Regulation the Registrant shall submit for the registered substance:

   a. The composition of the substance (Annex VI, 2.3). Any information which is suitable and necessary to allow ECHA to establish and verify the composition and name of the registered substance, as specified under section III (a) below;

   b. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.) as specified under section III (b) below;

(2) Pursuant to Articles 41(1)(a) (c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit the following information:

   a chemical safety report ("CSR") for the registered substance.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the required CSR in the form of an updated IUCLID dossier to ECHA by **29 May 2013**.

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 requirement.

1) Missing information related to substance identity

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of 1000 or more tonnes per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Articles 10 and with Annex VI thereof. Consequently, the Registrant is requested to submit the information mentioned above that is needed to bring the registration into compliance with the relevant information requirements.

Pursuant to Article 10(a)(ii) and Annex VI, section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, section 2 lists information requirements that shall be sufficient to identify the registered substance.

(a) Composition of the substance (Annex VI section 2.3 of the REACH Regulation)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the corner stone of all the REACH obligations.

ECHA observes that the Registrant did not provide appropriate information on the composition of the substance, as required under Annex VI Section 2.3 of the REACH Regulation.

More specifically, the Registrant identified the registered substance as the well-defined mono-constituent substance ammonium nitrate. The reported concentration range for the main constituent present in the substance, however, varies from [redacted]% (w/w) to [redacted]% (w/w). In line with the Guidance for identification and naming of substances under REACH and CLP (Version: 1.1, November 2011) – referred to as "the Guidance" thereinafter, mono-constituent substances are well-defined substances in which one constituent is present at a concentration ≥ 80% (w/w). ECHA concludes that the reported composition does not refer to the mono-constituent substance ammonium nitrate which is the subject of this registration.

Moreover, the lower concentration level of the main constituent, [redacted]% (w/w), cumulated with the upper concentration level of water (the only impurity specified in the IUCLID dossier), [redacted]% (w/w), indicates that up to [redacted]% (w/w) of the composition has not been accounted for. However, the Registrant did not report the presence of any other impurity in the composition. ECHA can therefore not verify that all individual impurities required to be identified have been reported in the composition of the registered substance.
In line with paragraph 4.3 of the Guidance, the following constituents shall be identified and reported individually in the composition of a mono-constituent substance:

- The main constituent;
- All the impurities present at ≥ 1 %; and
- All the impurities relevant for the classification and/or PBT assessment.

For each constituent, including the main constituent and any impurity, the typical, minimum and maximum concentration level shall be specified.

In addition, the compositional information indicates a high concentration of water. In accordance to Article 3(1) of the REACH Regulation a substance shall not include a solvent which may be separated without affecting the stability of the substance or changing its composition. The quantity of such solvent, including water reported by Registrant in the composition, shall be excluded from the composition of the registered substance.

The Registrant is accordingly requested to complete and correct the above information on the composition of the registered substance provided in the registration dossier, for ECHA to have a precise chemical representation of what the substance consists of.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: The Registrant shall report the revised composition in IUCLID Section 1.2. In addition, the Registrant shall report individually any impurity required to be identified and specify at least one of the following identifiers: chemical name, CAS number, EC number and/or molecular formula, as well as the minimum, maximum and typical concentration, in the appropriate fields in Section 1.2 of the IUCLID dossier. The Registrant shall ensure that the degree of purity corresponds to the concentration range of the main constituent. Furthermore water shall be removed as far as possible from the composition of the substance.

Further technical details on how to report the composition of mono-constituent substances in IUCLID are available in paragraph 2.2.1.1 of Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 1.0, June 2010) on the ECHA website.

(b) Description of the analytical methods (Annex VI section 2.3.7 of the REACH Regulation)

ECHA notes that the Registrant included, in IUCLID section 1.4, an X-ray diffractogram and IR spectrum which enable the substance to be qualitatively identified. However, the Registrant did not provide any description of the analytical methods used for the

quantification of the constituents required to be reported in the composition, as requested according to Annex VI section 2.3.7.

The Registrant is accordingly requested to provide a description of the analytical methods used for the quantification of the main constituent and any impurity required to be reported in the composition of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained. Given the ionic nature of the substance, ECHA points out that the analytical methods to be described for the quantification of the main constituent shall consist in both the quantification of the ammonium cation and the quantification of the nitrate anion.

As for the reporting of the analytical data in the registration dossier, this information shall be attached in IUCLID section 1.4.

2) Missing Chemical Safety Report

Pursuant to Article 10(b) of the REACH Regulation the registration shall include a CSR when required under Article 14, in the format specified in Annex I to the REACH Regulation. The CSR shall document the chemical safety assessment that has been carried out following the requirements set out in paragraphs 3 to 7 of Article 14 of the REACH Regulation for the registered substance subject to the present decision.

The registration dossier for the registered substances subject to the present decision neither contains a CSR nor does it provide for a valid justification why a chemical safety assessment was omitted and not documented pursuant to Article 14(2) of the REACH Regulation. The Registrant is therefore requested to submit the CSR for the registered substance subject to the present decision.

When documenting the outcome of the chemical safety assessment, the Registrant may use the recent version of the Chemical Safety Assessment and Reporting tool (Chesar, version 1.2), designed to help registrants to carry out their chemical safety assessments and preparing their CSR, available at http://chesar.echa.europa.eu/.

Regarding how to write a CSR or submit a CSR further information is provided in the "Guidance on information requirements and chemical safety assessment", Part F. Chemical Safety Report, version 2, July 2008.

IV. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Jukka Malm
Director of Regulatory Affairs