ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114298528-31-01/F Helsinki, 24 April 2015

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

For magnesium sulphate, EC No 231-298-2 (CAS No 7487-88-9), 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 magnesium sulphate, EC No 231-298-2 (CAS No 7487-88-9), 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 tonnes per year. This decision does not take into account any updates submitted after 15 January 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 28 October 2013.

On 20 March 2014 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 22 April 2014 ECHA received comments from the Registrant on the draft decision. On 9 July 2014 the Registrant updated the dossier.

The ECHA Secretariat considered the Registrant's comments and update.

The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 15 January 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.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Composition of the substance (Annex VI, 2.3.), as further specified under section III.A.1;
2. Description of the analytical methods (Annex VI, 2.3.7.), as further specified under section III.A.2.

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 **31 July 2015.**

III. Statement of reasons

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

A. Information in the technical dossier related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Composition of the substance (Annex VI, 2.3.)

"Composition of the substance" is an information requirement as laid down in 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 cornerstone of all the REACH obligations. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the registration does not contain sufficient and appropriate information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, section 2.3. of the REACH Regulation. Initially the Registrant had reported two compositions in the dossier. The dossier has been updated by the Registrant following receipt of the draft decision. In the updated dossier, the Registrant replaced the initially reported compositional information with new information.

More specifically, the Registrant identified the substance as a well-defined mono-constituent substance with three compositions reported in the IUCLID section 1.2 of the updated dossier. The Registrant included in section 1.2 a theoretical composition for the anhydrous substance and two of the Registrant's compositions containing the hydrated forms. One of these latter two compositions reports magnesium sulphate heptahydrate as a main constituent with a typical concentration of [redacted]% and concentration range [redacted] % w/w and no impurity is reported. The identity of this hydrate is confirmed by the X-Ray diffraction spectrum attached in section 1.4 ("[redacted]"). The other composition reports magnesium sulphate hexahydrate and magnesium sulphate heptahydrate as the

main constituents, both with a typical concentration of [redacted]% and concentration ranges [redacted] % w/w also without any impurities reported. Also in this case the identity of main constituents can be confirmed by the X-Ray diffraction spectrum attached in section 1.4 of the updated dossier ("[redacted]").

However, ECHA observes that information on the substance composition for the Registrant's compositions has not been provided at the required level of detail: no specific information was provided on the impurity profile of the substance.

According to chapter 4.2.1 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014, referred to as the "Guidance" hereinafter), the Registrant is reminded that, for mono-constituent substances such as the registered substance, the following applies:

- All the impurities present at ≥ 1 % shall be identified and reported individually so the composition of the substance is accounted up to 100%, and
- All the impurities relevant for the classification and/or PBT assessment shall be identified and reported individually, irrespective of the concentration.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the correct composition of the registered substance as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: The Registrant shall report individually any impurity required to be identified and specify at least one of the following identifiers: chemical name, CAS number (if available), EC number (if available) and/or molecular formula, as well as the minimum, maximum and typical concentrations, in the appropriate fields in Section 1.2 of the IUCLID dossier. The Registrant shall also provide the concentration range of the main constituent and shall ensure that the information is consistent with the degree of purity.

Information on how to report a mono-constituent substance composition in IUCLID is specified 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: 2.0, July 2012), available on the ECHA website.

2. Description of the analytical methods (Annex VI, 2.3.7)

"Description of the analytical methods" is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA observes that the Registrant has not included in the updated dossier a sufficient description of the quantitative analysis that would provide an overview of the composition of the registered substance.

More specifically, the dossier submitted by the Registrant contains XRD analysis results including relevant diffractograms and a qualitative result table ([redacted] and [redacted]). However, the analytical report does not provide any information that would enable the magnesium content and sulfate content to be determined. For this type of substance, the magnesium content and sulfate content are required to be reported separately in the analytical report. In addition, no analytical method

is provided to take into account the potential presence of impurities of the substance. In the absence of this information, the composition of the registered substance cannot be verified.

ECHA therefore concludes that the Registrant did not provide sufficient information on the description of the analytical methods used for quantification of the composition of the registered substance.

Accordingly, in line with Annex VI, 2.3.7, the Registrant is requested to submit the description of the missing analytical methods that will enable the magnesium content and the sulphate content to be determined in order to confirm the identity of the registered substance. The information shall be sufficient for each method to be reproduced and shall therefore include details of the experimental protocol followed, the measurement results, any calculation made and the results obtained. In addition, the Registrant shall ensure that the composition reported in Section 1.2 is in line with the information provided in Section 1.4, which shall be sufficient to identify and quantify the substance.

As for the reporting of the method descriptions in the dossier, the information should be attached in Section 1.4 of the IUCLID Dossier.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: correct description of the methods used to identify and quantify the registered substance as specifically explained in the present decision. The Registrant shall ensure that the information is consistent throughout the dossier.

ECHA notes that the Registrant has included in his comments to the draft decision and in the updated dossier a statement aiming to justify why no quantitative analytical data is provided: "E*CHA requested in " DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006 for magnesium sulphate, CAS No 7487-88-9 (EC No 231-298-2), registration number:* [redacted] *determination of* Mg^{2+} *and* $SO4^{2-}$ *ions. We regret to inform you we can not submit such information. The substance is manufactured as a mixture as noted in Section 3.4. of this IUCLID file. We can only provide you summary information on ions for each mixture according to Fertilizers legislation. This information is not relevant for this substance."*

ECHA considers that this statement cannot justify the incomplete reporting of constituents (impurities) in the compositions submitted and the failure to provide supporting quantitative analytical data. If the substance is indeed manufactured as a mixture (blends of separate substances), then the substance can be characterised before that the mixture is prepared, as it seems to have been done for the qualitative analysis. Should the complex fertilizers be manufactured as synthetic fertilizers (multi- or UVCB substances), then the data can be generated on the manufactured substance. Therefore the Registrant should be able to provide sufficient quantitative data to confirm the substance compositions.

Note for consideration of the registrant

ECHA also invites the Registrant to reflect whether the fertilizers are available as mixtures (blends of different substances) or are (a) single substance(s). Should the fertilizer be a mixture, then registration for each of the components in the mixture is required. Should the fertilizer be manufactured as a substance, then registration of the substance as manufactured (e.g. as a mono-constituent, multi-constituent or UVCB substance) is required.

Further guidance on how to identify substances in registration dossier can be found in section 4 of the Guidance. In this respect, it is to be noted that multi-constituent substances can only be registered through registration of their individual constituents provided that the Registrant is able to demonstrate that he is able to benefit from the derogation as described in the Guidance, chapter 4.2.2.4 - Registration of individual constituents of a multi-constituent substance.

Should the Registrant consider that the substance shall rather be identified as a UVCB substance, the following shall apply:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature.
- For each constituent or group of constituents, the typical, minimum and maximum concentration levels shall be specified.

The Registrant is reminded that UVCB substances are substances which cannot be sufficiently identified by their chemical composition, because:

- The number of constituents is relatively large and/or
- The composition is, to a significant part, unknown and/or
- The variability of composition is relatively large or poorly predictable.

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/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]
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