EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114313749-43-01/F Helsinki, 08 January 2016

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

For aluminium sulphate, CAS No 10043-01-3 (EC No 233-135-0), 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 aluminium sulphate, CAS No 10043-01-3 (EC No 233-135-0), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VII, Section 2 of the REACH Regulation.

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 after the deadline for updating (19 March 2015) communicated to the Registrant by ECHA on 11 February 2015.

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 25 October 2013.

On 27 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].

By 28 April 2014 the Registrant did not provide any comments on the draft decision to ECHA. On 29 August 2014 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's update. On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

The Registrant updated his registration also after 19 March 2015, the deadline given for updating, and therefore too late in the decision making process for being considered. If still relevant, the dossier update will be considered by ECHA in line with its follow up process after the deadline established in the present decision has passed.

On 29 October 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

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. Spectral data and description of the analytical methods (Annex VI Section 2.3.5 and 2.3.7 of the REACH Regulation), as specified in section III.A.1 below;

2. Composition of the substance (Annex VI, Section 2.3.).

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 **15 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.

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. Spectral data and description of the analytical methods

"Spectral data" is an information requirement as laid down in Annex VI, Section 2.3.5. of the REACH Regulation. "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 did not provide sufficient information on the analytical methods for the identification and quantification of the registered inorganic substance, as requested according to Annex VI section 2.3.7.

More specifically, ECHA notes that the Registrant provided results of the quantitative analysis of aluminium (Al) and sulfate (SO_4) content by inductive coupled plasma spectrometry (ICP), titration and gravimetry. However, as these methods are quantitative only, they do not allow unambigous identification of the registered substance. For solid inorganic substances such as the registered substance, an X-ray diffraction (XRD) analysis is a suitable analytical method and therefore it is required in order to unambiguously identify the substance phase(s). ECHA notes that the registration did not include any method description or results for an XRD analysis. Thus, the identity of the substance cannot be sufficiently verified.

In the updated dossier, neither XRD nor any other alternative method that would allow identification of the registered substance has been provided. Instead in section 1.4 of the updated dossier, it is stated that the substance is "*Only manufacture as aqueous solutions : no solids sample*". This justification is not acceptable as the registered substance is known to be stable in the solid form, hence solid sample is easily obtainable from the solution. This is also confirmed by the Registrant in Remarks field of the reference substance in section 1.1: "The substance is possibly dried into solid form containing crystal water."

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit a description of the XRD analytical method and the results from this analysis measured on the substance subject to the present decision.

The method description shall include details of the experimental protocol followed, the calculations used and the results and the XRD diffractogram obtained. The information shall be sufficient for the method to be reproduced.

As for the reporting of the data in the registration dossier, the information should be attached in section 1.4 of the IUCLID dossier. The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical results obtained.

The Registrant is reminded that this decision does not take into account any updates submitted after 19 March 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

2. Composition of the substance

Section 2.3 of the REACH Regulation requires that each registration dossier contains appropriate information on the composition of the registered substance to establish its identity.

In that respect, according to chapter 4.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, for well-defined mono-constituent substances, the following applies:

- The main constituent shall be identified and reported individually, with its typical concentration and concentration range;
- Each impurity present at ≥1% or relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually, independently from their concentration;
- Unknown constituents shall be identified by a generic description of their chemical nature;
- The compositional information should be completed up to 100%.

ECHA notes that Section 1.2 of the dossier initially reported fully accounted composition of the registered substance. As a result, the draft decision notified to the Appellant in accordance with Article 50 of the REACH Regulation did not identify incompliance in that respect. However, while highlighting the incompliance relating to Spectral data and description of the analytical methods mentioned in point 1 above, the draft decision also pointed out the resulting discrepancy with the composition reported in a comprehensive manner.

More specificallyECHA observed in the draft decision that "*the Registrant has reported in IUCLID Section 1.4 the results of titration and gravimetric analysis in [redacted]. However, the data provided in Table 1 of this document indicates aluminium and sulfate contents ([redacted] % and [redacted] % (w/w) respectively) that were signifcantly lower than expected for aluminum sulfate ([redacted] and [redacted] % (w/w) respectively) based on the purity of ca. [redacted] % (w/w) for the composition reported initially in section 1.2. Information included in the "[redacted]" also attached to section 1.4 indicates that aluminium sulfate only accounts for [redacted] % of the composition of the test sample and a back-calculation was used to estimate the composition of the "[redacted]" of [redacted] % (w/w). However the water content is not quantified so that based on the information included in section 1.4, it was not possible to verify the substance composition reported in section 1.2.*"

ECHA notes that, instead of correcting the incompliance relating to Spectral data and description of the analytical methods mentioned in point 1 above, the Registrant decided to align the composition reported in section 1.2 with the results of quantive analysis.

As a result, the update resulted in making incompliant the reported composition, which was intially fully accounted. More specifically, the main constituent is reported in the updated dossier with concentration [redacted]% w/w and remark "*Substance is manufactured only in aqueous solution.*" As a result, ca [redacted]% of the composition is unaccounted for. While ECHA understands that the substance is manufactured in aqueous solution, the registrant has not reported the re-calculated composition of the substance, so 100 % of the substance composition is not accounted for.

The Registrant is accordingly requested to revise the composition of the registered substance in section 1.2 of the IUCLID dossier, so it accounts to 100%. The Registrant shall ensure that the composition reported in the dossier is consistent with the analytical results obtained. If the composition is derived from the aqueous solution using a back-calculation, it needs to be supported by relevant calculations and the appropriate analytical data, including quantification of water.

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, 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.

Further technical details on how to report the composition of well-defined substances in IUCLID are available in the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 2.0, July 2012) on the ECHA website.

The Registrant is reminded that this decision does not take into account any updates submitted after 19 March 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

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

Authorised[1] by Leena Ylä-Mononen, Director of Evaluation

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