

Decision number: CCH-D-2114293851-41-01/F

Helsinki, 26 February 2015

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 4 September 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 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.

By 28 April 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 4 September 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.

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. Information related to molecular and structural formula of each substance (Annex VI, Section 2.2 of the REACH Regulation), as specified in Section III.A. below.
2. 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.2 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 **3 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. Information related to the name, molecular and structural formula of the substance

ECHA notes that the Registrant has not provided sufficient information to identify the substance, as required by Annex VI, Section 2.1 and 2.2 of the REACH Regulation. Based on the information included in Section 1.1 of the dossier, it is not possible to unambiguously establish the identity of the substance registered.

More specifically, although the Registrant identified the registered substance as a well-defined mono-constituent substance, the information provided does not fulfil the requirements for the unambiguous identification of mono-constituent substances.

The Registrant shall note that in accordance with chapter 4.1 and 4.2 of the Guidance for identification and naming of substances under REACH (Version: 1.2, March 2012), referred to as "the Guidance" thereafter, well-defined substances are these with fully defined qualitative and quantitative composition. Each constituent of a well-defined substance requires a complete chemical specification, including structural information. This implies that constituents of well-defined substances must have a unique definitive molecular formula. According to Section 4.1 of the Guidance, any variations of composition of well-defined substances are specified by the upper and lower limit of the concentration range(s) of the main constituent(s). Consequently, there cannot be variations in the structural formula or in the molecular weight.

ECHA notes, however, that the registration dossier contains such variations of the structural formula and the molecular weight. In the molecular formula field the following formula was provided:

"Al₃/2H₂O₄S; General formula Al₂(OH)_x(SO₄)_(3-x/2), with x=0 and x=3 and x ranging from 0 to 3." Such a formula is not specific, because it contains a variable, x, which ranges from 0 to 3.

In addition, the molecular weight was described as a range (215.06-342.14) in section 1.1 of the registration dossier. Also this does not fulfil the requirement to provide a specific molecular weight for a well-defined mono-constituent substance, where variations are described by the upper and lower limit of the concentration range(s) of the main constituent(s) only.

Therefore the registrant is requested to specify the information in Section 1.1 to unambiguously define the structural formula and the molecular weight of the registered substance by referring to specific information, and not to ranges. The stoichiometry reported in the molecular formula field is required to be referred specifically to the registered substance, Aluminium sulfate and cannot be reported as undefined variables (e.g. x, etc.) and ranges (e.g. 0 >x <1).

Furthermore, where the registration dossier also refers to substances other than the registered substance, such information must be removed. As described above, the registered substance is described as aluminium sulphate, a well-defined mono-constituent substance. However, some information provided in IUCLID section 1.1, including molecular formula, description, molecular weight and synonyms, may refer to what is potentially another substance with a different name, different formula and/or different molecular weight.

In the molecular formula field the following formula was provided:

"Al₃/2H₂O₄S; General formula Al₂(OH)_x(SO₄)_(3-x/2), with x=0 and x=3 and x ranging from 0 to 3."

When x is larger than 0 and up to 3, the formula does not refer to aluminium sulphate, but e.g. to aluminium hydroxy sulfate Al₂(OH)_x(SO₄)_(3-x/2), e.g., when x is ranging from >0 to <3

In addition, the molecular weight is given as a range (215.06-342.14) in IUCLID section 1.1. Where the molecular weight differs from the molecular weight of the registered substance, namely aluminium sulphate, it may describe a different substance. Moreover, in the "Synonyms" field of section 1.1 the Registrant has indicated two names (Sulfuric acid, aluminium salt, basic and Polyaluminium sulphate). In the description field the Registrant states that "Substance in category of soluble aluminium salts: Aluminium (hydroxy) sulphate".

Aluminium sulfate (Al₂(SO₄)₃; EC number 233-135-0; CAS number 10043-01-3; CAS name Sulfuric acid, aluminum salt (3:2)) is regarded under REACH as a different substance than any substance with a different sulfate/aluminium molar ratio. Therefore any specific basic analogue of a metal-containing salt is considered as a different substance than that metal-containing salt itself.

Consequently, the Registrant is requested to submit clarify the inconsistency between the measured Al and sulfate contents and the composition reported in section 1.2.

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.

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: a sufficient description of the methods used to identify and quantify the registered substance, as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier

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.



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