ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004572-75-03/F Helsinki, 4 August 2014

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

For potassium formate, CAS No 590-29-4 (EC No 209-677-9), 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 potassium formate, CAS No 590-29-4 (EC No 209-677-9), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VI, 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 tonnes per year. This decision does not take into account any updates submitted after 6 March 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 29 October 2013.

On 3 December 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 45 days of the receipt of the draft decision.

By 17 January 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 6 March 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

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)
2. Spectral data (infra-red and either nuclear magnetic resonance or mass spectrum) (Annex VI, 2.3.5)

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 **11 November 2014.**

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.

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.

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

"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 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 (as explained under points (i) and (ii) thereinafter).

(i)The compositional information indicates a high concentration [redacted] (w/w)) of [redacted]. ECHA considers that the [redacted] which is included in the composition acts as a solvent. The Registrant should note that in accordance to Article 3(1) of the REACH Regulation, solvents are not regarded as a part of a substance as a substance is defined as "substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition".
Therefore the quantity of [redacted] which can be removed without affecting the stability of the substance and changing its composition should not be included in the composition of the substance.

(ii) Furthermore, the Registrant has only specified the typical concentration range as [redacted] (w/w). However the Registrant did not report the concentration range for the main constituent by providing the upper and lower concentration limit.

In line with the observation under point (i), the Registrant is accordingly requested to indicate in IUCLID section 1.2 only that amount of [redacted] which cannot be removed without affecting the stability or the composition of the substance. For any quantity of [redacted] which cannot be removed, the Registrant should include a scientific justification in the Remarks field of the reference substance dataset of "[redacted]" in IUCLID section 1.2. Additionally the Registrant shall provide the analytical data for the determination of the composition of the substance, including the amount of [redacted] in IUCLID section 1.4.
In line with the observation under point (ii), the Registrant is accordingly requested to specify in IUCLID section 1.2 the upper and lower limit of the concentration range of the main constituent and any impurities present in the substance.

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 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 the revised composition in IUCLID section 1.2. The Registrant shall ensure that the degree of purity corresponds to the concentration range of the main constituent. Furthermore [redacted] 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.

1. Spectral data (infra-red and either nuclear magnetic resonance or mass spectrum) (Annex VI, 2.3.5)

"Spectral data" (ultra-violet, infra-red and either nuclear magnetic resonance or mass spectrum) is an information requirement as laid down in Annex VI, Section 2.3. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement (as explained under points (i) and (ii) thereinafter).

(i) ECHA notes that the registration does not contain either a nuclear magnetic resonance (NMR) spectrum or Mass spectrum (MS) which is required to support the identity of the registered substance. ECHA points out that the identity of the substance cannot be confirmed based exclusively on the infra-red spectrum which the Registrant included in section 1.4 of the IUCLID dossier.

ECHA regards this required information scientifically necessary for the identification of the registered substance as NMR spectroscopic analyses, such as a 1H-NMR or a 13C-NMR, are powerful tools for structure characterisation and elucidation due to characteristic chemical shifts and spin-spin coupling which also reflect the relative abundance of individual atoms. Alternatively, mass spectroscopic analysis, which is an appropriate analytical method to characterise the substance and determine its elemental composition, can be provided.

(ii) Furthermore ECHA observes that the provided infra-red spectrum in IUCLID section 1.4 shows a broad absorption band between 3000 cm-1 and 3700 cm-1. ECHA considers that this band refers to the high concentration of [redacted] present in the substance as solvent.

The Registrant should note that any analytical data should be generated on the actual substance for which the registration refers to after removing the amount of [redacted] which is not necessary for stabilising the substance.

In line with the observation under point (i), the Registrant is accordingly requested to provide the missing NMR spectrum, such as a 1H-NMR or a 13C-NMR or, alternatively, a mass spectrum including the corresponding interpretation of the fragmentation scheme.

In line with the observation under point (ii), the Registrant is accordingly requested to provide analytical data relating to infra-red spectrum generated on the actual substance for which the registration refers to after removing the amount of [redacted] which is not necessary for the stabilising of the substance.

Regarding how to report the spectral data of the registered substance in IUCLID, the following applies: the Registrant shall report the revised composition in IUCLID section 1.4.

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 spectral data 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://www.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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