ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000003447-71-03/F Helsinki, 16 August 2013

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 dossier for potassium formate, CAS No 590-29-4 (EC No 209-677-9), 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 per year. This decision does not take into account any updates submitted after 20 June 2013, 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 13 December 2012.

On 2 May 2013 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 3 June 2013 the Registrant did not provide any comments on the draft decision to ECHA.

On 20 June 2013 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

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 spectral data (Annex VI, 2.3.5.);
b. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.).

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 **18 November 2013**.

III. Statement of reasons

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 tonnes or more per year in accordance with Article 6 and 11(2) of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and 13 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.

Missing information related to substance identity

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) Spectral data (Annex VI, 2.3.5.)

ECHA observes that the registration does not contain any NMR or mass spectra which are required according to Annex VI Section 2.3.5. of the REACH Regulation to support the identity of the registered substance. ECHA points out that the identity of the substance cannot be confirmed based exclusively on the infrared data. Mass spectrocopic analysis is a powerful tool for structure characterisation of the type of substance as the registered one, as are also NMR spectroscopic analyses such as a 1H-NMR or a 13C-NMR due to characteristic chemical shifts and spin-spin coupling which also reflect the relative abundance of individual atoms.

The Registrant is therefore requested to submit a mass spectrum including the corresponding interpretation of the fragmentation scheme. Alternatively, an NMR spectrum such as 1H-NMR, together with the integration curve, and 13C-NMR can be provided.

As for the reporting of the spectral data in the registration dossier, the information should be included in IUCLID section 1.4.

The Registrant shall ensure that the description of the analytical method used for the recording of the mass or NMR spectra is specified in the dossier, in line with the requirements under Annex VI section 2.3.7.

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

ECHA observes that the Registrant did not provide sufficient descriptions of the analytical methods used for the quantification of the constituent required to be reported in the composition of the registered substance, as requested according to Annex VI section 2.3.7.

More specifically ECHA notes that the Registrant provided the descriptions for quantification methods to determine formate content by titration with HCl and potassium content by flame emission spectrometry (FES). However, the Registrant reported both of the results expressed as potassium formate content, whereas the potassium and formate contents were not provided separately. For this type of substance, the cation and the anion contents are required to be reported separately in the analytical report (further details on the reporting of the identification and quantification of the cation and anion can be found under point 1.4 in the document "Questions and Answers on Substance Identification" available on the ECHA webpage).

In addition, the Registrant has not specified the solvent content present in the sample used for the analytical measurements. The analytical results for the sample Potassium Formate solution, [redacted] indicate the content of the main constituent (potassium formate content = [redacted]%) outside the concentration range indicated in section 1.2 [redacted]%). Without information on the solvent content of the sample it is not possible to verify the composition reported in section 1.2.

Accordingly, the Registrant is requested to submit more detailed information on the analytical methods used for the quantification of the registered substance. The results of titration and FES analyses (including contents of potassium and formate) shall be reported separately. Furthermore, the Registrant is requested to provide a description of the method used for the quantification of the solvent content of the sample used for the analyses, and the results thereof. The descriptions shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocols followed, the measurement results, any calculations made and the final results obtained.

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

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