EUROPEAN CHEMICALS AGENCY

~~HIGHLY RESTRICTED~~

Decision number: CCH-D-0000004686-64-03/F Helsinki, 29 August 2014

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

For sodium formate, CAS No 141-53-7 (EC No 205-488-0), 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 sodium formate, CAS No 141-53-7 (EC No 205-488-0), 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 12 June 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 28 November 2013.

On 13 December 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.
By 27 January 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 12 June 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. Spectral data (ultra-violet, and either a nuclear magnetic resonance or a mass spectrum; or appropriate alternative method(s) for inorganic substances, as specified in Section III.A.1 below; Annex VI, 2.3.5.)
2. High pressure liquid chromatogram or gas chromatogram; or an appropriate alternative chromatographic method for ionic substances, as specified in Section III.A.2 below (Annex VI, Section 2.3.6.)
3. Description of the analytical methods, as specified in Section III.A.3 below(Annex VI, Section 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 **8 December 2014** of the decision.

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) Spectral data (ultra-violet, and either a nuclear magnetic resonance or a mass spectrum)

ECHA notes that the registration dossier does not contain sufficient spectral data as required according to Annex VI, Section 2.3.5. of the REACH Regulation to support the indicated substance identity. The Registrant has provided an Infra-red (IR) spectrum but has not provided an Ultraviolet-Visible (UV) spectrum. Furthermore, the Registrant has not provided one of either a Nuclear magnetic resonance (NMR) spectrum or a Mass spectrum (MS). Instead the Registrant has provided the following justifications for omitting UV and NMR information respectively *"UV: will not select between different formates"* and *"NMR: gives no further information than FTIR"*.

These justifications are not acceptable. ECHA points out that spectral data (infra-red, ultra-violet, and either a nuclear magnetic resonance or a mass spectrum) is a standard requirement of Annex VI, Section 2.3.5. ECHA regards the required spectral data as scientifically necessary for the identification of the registered substance. For inorganic substances, the use of X-Ray Diffraction (XRD), X-Ray Fluorescence (XRF) or Atomic Absorption Spectroscopy (AAS) may be more suitable as qualitative alternatives to UV and NMR or MS. It is the responsibility of the Registrant to present appropriate spectral and analytical data.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the missing spectral data for the registered substance (ultra-violet, and either a nuclear magnetic resonance or a mass spectrum). Alternative methods may be appropriate for this inorganic substance, as explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

2) High pressure liquid chromatogram or gas chromatogram

ECHA notes that the registration dossier does not contain any chromatographic data as required according to Annex VI, Section 2.3.6. of the REACH Regulation to support the indicated substance identity. Instead the Registrant has provided the following justification for omitting chromatographic data "*NA, detected as formic acid*".

ECHA considers this justification unacceptable as chromatographic techniques such as ion exchange chromatography can provide qualitative and quantitative information on anionic and ionisable constituents in the substance. ECHA points out that a high pressure liquid chromatogram or gas chromatogram is a standard requirement of Annex VI, Section 2.3.6.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit chromatographic data for the registered substance. ECHA considers ion exchange chromatography or similar techniques for chromatographic separation of ions as appropriate. The Registrant shall ensure that the information is consistent throughout the dossier.

3) Description of the analytical methods

ECHA notes that the registration dossier does not contain a sufficient description of the analytical methods as required according to Annex VI, Section 2.3.7. of the REACH Regulation to support the indicated substance identity.

More specifically, ECHA notes that the described analytical method for the quantification of formate in the substance is not specific for the quantification of this ion as it consists of a generic acid–base titration and consequently (weak) bases other than formate may also be titrated.

Furthermore, the description of the analytical method used to quantify sodium is not sufficient for the method to be reproduced. The Registrant refers to "*ISO standard 9964-3:1993 - Water quality - Determination of sodium and potassium -- Part 3: Determination of sodium and potassium by flame emission spectrometry*". However, the description provided is not sufficient as there is no information on the sample preparation, on the actual results (in terms of sodium content) obtained and on how the errors in the measurement was taken into account.

Finally, as regards the quantification of impurities, ECHA notes that the protocol followed and the results obtained (in particular the gas chromatogram and details of the calculations) have not been provided.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit an appropriate description of the analytical methods, and the results thereof, for the identification and quantification of the formate ion and sodium counter-ion in the substance, as well as the protocol and the results for the quantification of impurities, as specifically explained above. The description shall be given in such detail that the method

can be reproduced. 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.

[redacted]
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