EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004609-66-03/F Helsinki, 30 June 2014

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

For sodium methanolate, CAS No 124-41-4 (EC No 204-699-5), 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 methanolate, CAS No 124-41-4 (EC No 204-699-5), 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 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 7 November 2013.

On 17 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 31 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

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. Composition of the substance (Annex VI, 2.3.)
2. Spectral data (Annex VI, 2.3.5.)
3. The description of the analytical methods or the appropriate bibliographical references for the identification of the substance (Annex VI, 2.3.7.)

B. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

> Documentation for the recommended personal protective equipment, i.e. skin protection (Article 14(6), Annex I, section 5.1.1., in conjunction with Annex II, 0.1.2. and 8.2.2.2. (b) of the REACH Regulation), as specified under section III. 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 **7 January 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. The composition of the substance (Annex VI, 2.3.)

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. 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.

The registered substance corresponds, according to the EC name assigned by the Registrant in section 1.1 of the IUCLID dossier, to sodium methanolate and it is registered as a mono-constituent substance. However, in section 1.2 of the IUCLID dossier the Registrant reported [redacted] as being the content of sodium methanolate in the substance. Moreover, ECHA notes that in the report *"Material Safety data Sheet"* submitted in section 1.4 and in the Chemical Safety report submitted in section 13 of the IUCLID dossier, the substance is reported as being a solution of [redacted] sodium methanolate in methanol.

ECHA notes that the Registrant specified the physical state of the registered substance as white powdered solid in the Chemical Safety Report attached in section 13 of the IUCLID dossier. At the same time no specific stabilizing agent is reported by the Registrant that would be necessary for the chemical integrity of the substance in solid form. On the basis of such information ECHA concludes that the substance is also produced in a solid form for which the presence of a stabilizing agent is not needed. As a consequence, the substance is

also produced without methanol as a stabiliser. Therefore, ECHA considers that the methanol which is included in the composition of the substance acts in reality as a solvent.

The Registrant shall note that in accordance with Article 3(1) of the REACH Regulation a substance is defined as "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". Consequently, solvents which may be separated without affecting the stability of a substance or changing its composition are not regarded as a part of a substance.

Therefore the composition of the registered substance shall be reported excluding the quantity of methanol which can be removed without affecting its stability or changing its composition.

The Registrant is accordingly requested to revise the information in IUCLID section 1.2. The composition of the substance shall be reported without any amount of methanol which can be removed without affecting its stability or changing its composition. For any quantity of methanol which cannot be removed, the Registrant shall include a scientific justification in IUCLID section 1.2 and provide the correspondent analytical data for the identification and quantification of methanol in IUCLID section 1.4. Moreover any analytical data reported in IUCLID section 1.4, shall be generated on the actual substance after removing the quantity of methanol which can be removed without affecting the stability of the substance and changing its composition.

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.

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.

2. The spectral data (Annex VI, 2.3.5. of the REACH Regulation)

ECHA notes that the registration does not contain any Infra-red (IR) spectrum nor nuclear magnetic resonance (NMR) spectrum or Mass spectrum (MS) which are required according to Annex VI, Section 2.3.5. of the REACH Regulation to support the identity of the registered substance.

ECHA regards this required information scientifically necessary for the identification of the registered substance as:

- IR spectrum displays characteristic vibration bands for the covalent bonds of organic compounds such as the registered substance; and

- NMR spectroscopic analyses such as a ^{1}H-NMR or a ^{13}C-NMR are powerful tools for structure characterisation and elucidation of the substance due to characteristic chemical shifts and spin-spin coupling which also reflect the relative abundance of individual atoms. Alternatively to NMR, a mass spectrum which is an appropriate analytical method to characterise the substance and determine its elemental composition, can be provided.

Accordingly, the Registrant is reuqested to provide the missing IR and NMR (such as a ^{1}H-NMR or ^{13}C-NMR) spectral data or, as an alternative to the NMR spectrum, mass spectra from a mass spectroscopic analysis of the registered substance including the corresponding interpretation of the fragmentation scheme) is considered necessary for the identification of the registered substance.

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

3. The description of the analytical methods (Annex VI, 2.3.7.)

ECHA observes that the Registrant did not provide any description of the analytical methods used for the identification and quantification of the constituents required to be reported in the composition of the registered substance, as requested according to Annex VI section 2.3.7.

The registered substance corresponds, according to the information submitted by the Registrant in section 1.1 of the IUCLID dossier, to sodium methanolate. Nevertheless, the description of the analytical method used for the identification and quantification of sodium ion and methanolate on the registered substance is missing from the dossier.

The Registrant is accordingly requested to provide a description of the analytical methods and results thereof used for the identification and quantification of sodium ion and methanolate and any impurity present in the composition of the registered substance required to be reported in the registration dossier. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

As for the reporting of the above data in the registration dossier, the information shall be attached in IUCLID section 1.4.

B. Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

Article 14(6) as well as Annex I, 0.1., 5.1.1., 5.2.4. and 6.2. of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in a chemical safety assessment. The exposure shall be estimated and risks shall be characterised under the assumption that relevant risk management measures have been implemented. This shall be documented in the chemical saftey report (CSR).

Pursuant to Annex II, section 0.1.2. of the REACH Regulation the information provided in the Safety Data Sheet shall be consistent with that in the CSR. The requirements of Safety Data Sheets are specified in Annex II (amended by Commission Regulation (EU) No 453/2010).

According to section 8.2.2.2(b)(i) of Annex II to the REACH Regulation, the type of gloves to be worn when handling the substance or mixture shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of dermal exposure, including:

- The type of material and its thickness,
- The typical or minimum breakthrough times of the glove material.

According to section 8.2.2.2(b)(ii) of Annex II to the REACH Regulation, if necessary to protect a part of the body, the type and quality of protection equipment necessary other than the hands shall be specified, such as gauntlets, boots, bodysuit based on the hazards associated with the substance or mixture and the potential for contact.

The Registrant indicated in the CSR the following for hand protection: "Wear suitable gloves (tested to EN374)". Regarding protection equipment other than gloves the registrant has specified the need of use of coveralls and rubber boots.

In section 11 of the technical registration dossier in the part for Exposure controls/personal protection no additional information has been given.

ECHA notes that the substance is classified as causing severe skin burns. To ensure the safe use of a substance, it is essential to have detailed guidance on risk management measures as set out by the provisions quoted above, e.g. personal protective equipment. Although the gloves are reported in the CSR as required personal protective equipment to prevent dermal exposure to the substance, the material type of gloves to be worn, the thickness and typical or minimum breakthrough time when handling the substance is not specified. With regard to the dermal exposure to other parts of the body than the hands, although some information is given, the type and quality of protection equipment are not specified.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide documentation for the recommended material type, its thickness and the typical or minimum breakthrough time for the glove type recommended within the CSR. With regard to the dermal exposure to other than the hands, the type and quality of protection equipment shall be specified, such as gauntlets, boots, or bodysuit based on the hazards associated with the substance or mixture and the potential for contact. In addition, the CSR should be updated as well to indicate the minimum specification for protective clothing to the standard EN 13034:2005, Chemical protective clothing offering limited protection against liquid chemicals (type 6 and type PB [6] equipment).

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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