

Decision number: CCH-D-0000004540-82-03/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). ECHA notes that in the joint submission covering the current registration, the Chemical Safety Report (CSR) is not provided by the lead registrant on behalf of the member registrants. The scope of this compliance check is limited to the standard information requirements of Annex I and Section 2 of Annex VI, while the compliance check concerning the information requirements laid down in Annexes I and VII to X was done on the lead registrant dossier of this joint submission.

This decision is based on the registration as submitted with submission number [REDACTED], for the tonnage band 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 07 November 2013.

On 28 November 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 13 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

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.

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 (CSR) 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 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: "PPE (personal protective equipment) required is based on a qualitative assessment. The substance is

classified as corrosive (H314), wearing gloves and goggles to protect eyes and skin will be mandatory, to reduce exposition as low as reasonably achievable." and "Dermal Protection: Yes (chemically resistant gloves conforming to EN374)."

However, the Registrant did not specify further protective work wear, conforming to a European standard, that may be required to protect against unspecified contact and spillage in the CSR.

In section 11 of the technical registration dossier in the part for Exposure controls/personal protection, the following is stated: "Skin:Wear Protective gloves to prevent skin exposure" and "Clothing:Wear appropriate protective clothing to minimize contact with skin".

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, 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/web/guest/regulations/appeals>. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



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