ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000005087-73-03/F Helsinki, 5 August 2014

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

For potassium methanolate, CAS No 865-33-8 (EC No 212-736-1), 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 methanolate, CAS No 865-33-8 (EC No 212-736-1), 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.

Subsequently, proposals for amendment to the draft decision were submitted.

On 10 April 2014 ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 22 April 2014 ECHA referred the draft decision to the Member State Committee.

By 12 May 2014 the Registrant did not provide any comments on the proposals for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 26 May 2014 in a written procedure launched on 15 May 2014. ECHA took the decision pursuant to Article 51(6) 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:

Composition of the substance (Annex VI, 2.3.)

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 and respiratory protection (Article 14(6), Annex I, section 5.1.1., in conjunction with Annex II, 0.1.2. and 8.2.2.2. (b) and 8.2.2.2. (c) 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 **12 February 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.

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 chemical name assigned by the Registrant in section 1.1 of the IUCLID dossier, to potassium methanolate and it is registered as a mono-constituent substance. However, the compositional information in section 1.2 of the IUCLID dossier reports ca. [redacted] as content of potassium methanolate and ca. [redacted] of methanol reported as being an additive.

In accordance with section 2.2 of ECHA "Guidance for the identification and naming of substances under REACH and CLP" ((Version: 1.2, March 2012; referred to as "the Guidance" thereinafter), an additive is a "substance that has been intentionally added to stabilise the substance". The role of an additive is therefore limited to preserving the chemical integrity of the manufactured substance. Intentionally added substances or solvents with other functions are not considered as additives under REACH.

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 other 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 as an additive 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, if any, the Registrant shall include a scientific justification in IUCLID section 1.2.

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.

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 safety 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).

Hand protection
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 need to wear coveralls when using the substance, though he did not specify the type and quality.

In section 11 of the technical registration dossier in the part for Exposure controls/personal protection, the following is stated: "Skin and body protection: Protective clothing".

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. 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.

Respiratory protection
According to section 8.2.2.2.(c) of Annex II to the REACH Regulation, for gases, vapours, mist or dust, the type of protective equipment to be used shall be specified based on the hazard and potential for exposure, including air-purifying respirators, specifying the proper purifying element (cartridge or canister), the adequate particulate filters and the adequate masks.

The Registrant indicates that the substance may be used as a solid. ECHA considers that exposure of workers by the inhalation route to the substance as a powder may be possible, for example during the transfer operations (PROC 8a and PROC 9) mentioned for manufacture, formulation and industrial uses.

The Registrant indicated within the CSR the need to use a Type A filter for organic vapours and then different information is provided in the IUCLID section 11 Guidance on safe use the requirement for "Breathing apparatus with filter. (filter P3)". The Registrant shall ensure consistency within the dossier on selection of appropriate respiratory protective equipment and be clear on when either a vapour respirator and/or a particulate respirator is

most appropriate. Annex II, 0.1.2. requires consistency between the CSR and the information contained within the safety data sheet.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide documentation, with regard to the dermal exposure to other than the hands, of the type and quality of protection equipment, 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 shall 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). The CSR shall also be amended to ensure the advice on use of respiratory protective equipment is consistent and addresses the potential for exposure to the substance by the inhalation route. If exposure by the inhalation route to the solid substance is not anticipated this shall be clearly stated and justified.

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.

Director of Evaluation