EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000005430-84-02/F Helsinki, 5 November 2014

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

For Silicic acid, calcium salt, CAS No 1344-95-2 (EC No 215-710-8), 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 Silicic acid, calcium salt, CAS No 1344-95-2 (EC No 215-710-8), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band 1000 tonnes or more per year. This decision does not take into account any updates submitted after 24 July 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 11 November 2013.

On 17 December 2013 ECHA sent the draft decision to the Registrant and invited him to provided comments within 30 days of the receipt of the draft decision. The draft decision was based on the submission number [redacted].

On 30 January 2014 ECHA received comments from the Registrant on the draft decision.

On 14 February 2014 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA secretariat considered the Registrant's comments and update.

The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 24 July 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 to the draft decision within 30 days of the receipt of this 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. Name, molecular and structural formula or other identifier of the substance (Annex VI, 2.1 and 2.2), as specified under section III.A.1 below;
2. Composition of the substance (Annex VI, 2.3), as specified under section III.A.2 below:
3. The description of the analytical methods (Annex VI section 2.3.7.), as specified under section III.A.3 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

Based on the examination of the technical dossier, ECHA concludes that the information therein does not comply with the requirements of Article 10 of the REACH Regulation and 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.

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. Name, molecular and structural formula or other identifiers of the substance (Annex VI, 2.1 and 2.2)

ECHA notes that the Registrant has not provided sufficient information to identify the registered substance, as required by Annex VI, Sections 2.1 and 2.2 of the REACH Regulation. Based on the information included in Sections 1.1, 1.2 and 1.4 of the IUCLID dossier, it is not possible to unambiguously establish the identity of the substance registered.

Initially, the Registrant identified the registered substance as a well-defined mono-constituent substance. The Registrant shall note that in accordance with chapters 4.1 and 4.2 of the Guidance for identification and naming of substances under REACH (Version: 1.2, March 2012)) - referred to as "the Guidance" hereinafter, well-defined substances are these with fully defined qualitative and quantitative composition. Each constituent of a well-defined substance requires a complete chemical specification, including structural information. This implies that constituents of well-defined substances must be

unambiguously identifiable by their chemical name, structural information and other identifiers.

The registrant updated the dossier in response to the draft decision and revised the information provided on substance identity. The substance type was changed to UVCB and the registrant included a description of the manufacturing process. The name and numerical identifiers remained unchanged. ECHA notes that the naming of UVCB substances shall consist of two parts: the chemical name and the more detailed description of the manufacturing process, as indicated in chapter 4.3 of the aforementioned Guidance. As for well-defined substances, the information provided on a UVCB substance shall be sufficient to enable the registered substance to be unambiguously identified.

However, in Section 1.1 of the IUCLID dossier only generic EC (**215-710-8**) and CAS (**1344-95-2**) entries as well as a generic IUPAC name have been used to identify the registered substance. These entries refer to the generic chemical name "silicic acid, calcium salt", which does not relate to a specific substance but covers all possible calcium salts of silicic acid, including also all possible stoichiometries and their respective phases [redacted] of each salt. No molecular and structural information has been reported in Section 1.1, but instead the registrant included the comment "Please note that this UVCB substance comprises [redacted]." Based on the the name, numerical identifiers and the information on phases reported, it is not possible for ECHA to unambiguously establish the identity substance registered.

Based on information provided in the description field the substance may be regarded as a UVCB substance. However the process description is not sufficiently detailed to allow ECHA to unambiguously establish the identity of the substance registered. In addition, it is unclear whether the process description refers to one or more UVCB substances.

More specifically, the process description is not sufficiently detailed to allow ECHA to understand the impact of variations in the process on the composition of the registered substance. In particular, the content of quartz in the substance would require clarification as based on the description, the ratio of CaO:quartz reactants is varied from [redacted] ("*The two raw materials cement and/or calcium oxide are with mixed quartz powder in a mass ratio of* [redacted]*, respectively and water is added.*" In addition, the reported process duration and temperature vary from [redacted] hours and from [redacted] °C. The reported constituent concentration ranges in section 1.2 are also very variable and a significant proportion of the composition is now reported as [redacted] The origin of these variations is however unclear from the description currently present in the dossier.

The registrant is also reminded that based on chapter 4.3 of the Guidance concerning the principles to be applied for the identification of UVCBs substances, any significant change in source or process would be likely to lead to a different substance. ECHA notes that a change is likely to be significant if it systematically leads to the manufacture of grades with significantly different compositions.

This is in particular relevant as in the updated dossier the registrant states that "*Depending on the hydrothermal process, CSH can be composed of either Tobermorite or Xonolite as dominating crystalline constituent*". The composition reported in the updated dossier in section 1.2 is consistent with this statement as the minimum concentration for each of these minerals is zero and the maximum is ca. [redacted] % (w/w) indicating that there are compositions where one mineral is absent. It is thus unclear whether grades of the same UVCB substance are manufactured in one manufacturing process or whether different manufacturing processes result in different substances. ECHA reminds the registrant that the deliberate

manufacture of one specific mineral (Tobermorite or Xonolite) would not readily be described as the manufacture of a UVCB substance.

In accordance with Annex VI, Section 2.1 of the REACH Regulation, the Registrant is requested to revise the chemical name included in the IUPAC name field and other identifiers of the substance, as appropriate, to make sure that they unambiguously identify the specific calcium silicate mineral(s) being manufactured/imported. The Registrant shall also describe the mineral phases covered by this registration. The Registrant shall note that the EC (**215-710-8**) and CAS (**1344-95-2**) entries used are overly generic and do not allow ECHA to unambiguously identify the registered substance.

As the substance is identified as a UVCB substance, a more detailed description of the manufacturing process shall be provided, allowing ECHA to understand the impact of variations in the process on the identity of the grades manufactured. The Registrant shall also consider whether the variations in the manufacturing process yield grades of the same substance or result in different substances. Where the registered substance is manufactured/imported as different grades of the same substance, information on the manufacturing parameters for each grade shall be provided.

The Registrant shall ensure that the information reported is consistent throughout the dossier.

Regarding how to report the requested information in IUCLID the following applies:

- The revised chemical name that is representative of the stoichiometries and mineral phases covered by the registration shall be included in the IUPAC name field and the details of the specific mineral(s) of the substance shall be included in the Description field in IUCLID Section 1.1, respectively. Each mineral (where relevant) is also required to be reported in the compositional and analytical Sections of the dossier (Sections 1.2 and 1.4 respectively), as described in details in Section 2 below.

- The revised description of the manufacturing process of the UVCB substance shall be included in the Description field in Section 1.1 of the IUCLID dossier. Where different grades are manufactured, details of the key process parameters for each grade shall be reported in the description field.

- The CAS number (**1344-95-2**) and CAS name currently present in the dossier shall be reported under the "Related CAS information" header in IUCLID Section 1.1. The relevant appropriate CAS entry, if available, shall be included in the "CAS information" field. For technical reasons the Registrant is requested at this stage, not to remove or revise the EC entry in the updated dossier. As this registration is linked to this EC entry in REACH-IT, the IT system will not accept the updated dossier as an update when the EC entry has changed. The Registrant is requested to include the following in the "Remarks field" of the reference substance: "This EC entry is not appropriate to identify the registered substance. This identifier cannot be modified in the present registration at this stage for technical reasons".

Further information on how to report the chemical name, other identifiers and the description of the manufacturing process is available in "Data Submission Manual Part 18 - How to report the substance identity in IUCLID 5 for registration under REACH" published on the ECHA website at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

2. 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 notes that the Registrant has not included sufficient information on the composition of the substance to enable the identity of the registered substance to be verified, as required under Annex VI, Section 2.3. of the REACH Regulation.

In the initial dossier the Registrant had reported one composition in Section 1.2 of the dossier. This composition identifieds its main constituent with the generic reference to "silicic acid, calcium salt" and reports water and quartz as impurities. From this limited information the specific stoichiometry and mineral phase of each constituent could not be established.

In the updated dossier, the registrant revised the reported composition to include the substance constituents. Two specific crystal phases of calcium silicate type minerals were reported with concentration ranges from [redacted] and [redacted] % (w/w) respectively, quartz was reported with a range of [redacted] % w/w while [redacted] % of the substance composition was reported as a single constituent "[redacted]".

ECHA notes that the description of the constituent "[redacted]", which may constitute up to [redacted] % of the registered substance is not sufficiently detailed to allow ECHA to establish the identity of this constituent.

According to chapter 4.3 of the Guidance, the Registrant shall note that, for UVCB substances the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually;
- All known constituents and the constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature. The identification of these unknown constituents must allow ECHA to establish the composition of the substance as manufactured.
- For each constituent or group of constituents, the typical, minimum and maximum concentration levels shall be specified.

In accordance with Annex VI, Section 2.3. of the REACH Regulation, the Registrant is required to further specify the identity of the constituent reported as "[redacted]" in Section 1.2 with its respective typical, minimum and maximum concentrations. The chemical name and other identifiers for this constituent shall specify the stoichiometry and mineral phase where appropriate. This information shall be sufficient to enable the specific constituents of the substance registered by this legal entity to be identified and shall be consistent with the information included in Section 1.1 on the "name and other identifiers" for the substance, and also with the analytical information included in Section 1.4.

In the updated dossier, the description of the manufacturing process included in section 1.1 indicates variability in the process parameters. As explained under section III.A.1 above it is not clear whether the variability in the composition reported in the updated dossier ([redacted] and [redacted], [redacted] % w/w, [redacted]) is due to the intrinsic variability in composition or rather reflects the intentional variation of process parameters to manufacture specific grades/substances. It is thus unclear whether grades of the same

UVCB substance are manufactured in one manufacturing process or whether different manufacturing processes result in different substances.

Consequently, where the Registrant covers different grades of the same substance in a registration, the Registrant shall report separately the compositional information of each grade. This means that if the substance covered by the registration has two (or more) different compositions, then these must be presented separately. Corresponding analytical data to enable the identity and composition of each grade listed in 1.2 to be verified shall be included in Section 1.4. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A 8 of the "Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH". The grades reported are required to demonstrably refer to one UVCB substance.

ECHA highlights that failure to report separately the compositional information of each grade of a substance may result in one or more grades not being covered by this registration.

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

ECHA notes that the Registrant has not provided sufficient information on the methods used to determine the identity and composition of the substance registered by his legal entity as required by Annex VI, Section 2.3.7. of the REACH Regulation.

In its initial dossier the Registrant had not included information in Section 1.4 of the dossier that would enable the stoichiometry or phase purity of the substance constituents to be verified. The results of elemental analysis were reported as hypothetical oxides and there was no separate quantification of the silicate content of the mineral or quartz content of the substance. Quartz was reported as an impurity in Section 1.2 with a typical concentration of [redacted] % w/w. The X-Ray diffraction (XRD) data included indicated the presence of three specific minerals, tobermorite, xonotlite and quartz. However, no description of the quantitative analysis which would confirm the content of these minerals in the substance was included. The information submitted was therefore not sufficient for the determination of the chemical composition of the substance registered.

In the updated dossier, the Registrant provided additional quantitative analytical data on the phase purity (XRD data and Rietveld analysis). These data are sufficient to quantify the substance constituents in terms of their stoichiometry and phase purity. However in the updated dossier, the description of the manufacturing process indicates that process parameters such as the reactant ratios, the reaction duration and temperature vary significantly. It thus cannot be established whether the data submitted refers to a specific grade or is intended to be representative of all grades manufactured.

Consequently, in line with Annex VI, 2.3.7, the registrant is requested to clarify the relevance of the submitted analytical data for all compositions of the substance registered. The information provided shall be sufficient to enable the substance identified in Section 1.1 of the dossier and all respective minerals reported in Section 1.2 to be verified.

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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