EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004721-78-03/F Helsinki, 17 September 2014

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

For Silicic acid, magnesium salt, CAS No 1343-88-0 (EC No 215-681-1), 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 Silicic acid, magnesium salt, CAS No 1343-88-0 (EC No 215-681-1), 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 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 19 November 2013.

On 19 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.

On 31 January 2014 ECHA received comments from the Registrant on the draft decision.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

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. Name, molecular and structural formula or other identifier of the substance (Annex VI, 2.1 and 2.2): Information which is suitable and necessary to allow ECHA to establish and verify the name and the identity of the registered substance, as specified under section III.A.1 below;
2. Composition of the substance (Annex VI, 2.3): Information which is suitable and necessary to allow ECHA to establish and verify the composition and the identity of the registered substance, 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 **2 January 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 substance, as required by Annex VI, Section 2.1 and 2.2 of the REACH Regulation. Based on the information included in Section 1.1 of the dossier, it is not possible to unambiguously establish the identity of the substance registered.

More specifically, ECHA notes that the Registrant identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). The naming of UVCB substances such as the registered substance shall consist of two parts: (i) the chemical name and (ii) a more detailed description of the manufacturing process, as indicated in chapter 4.3 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.2, March 2012) - referred to as "the Guidance" thereinafter.

ECHA notes that the Registrant has not provided sufficient information on the above points (i) and (ii) to enable the identity of the substance to be verified.

More specifically regarding point (i), the Registrant identified the registered substance as an inorganic UVCB substance and has used generic EC (215-681-1) and CAS (1343-88-0) entries and the generic IUPAC name "Silicic acid, magnesium salt" to describe the substance. These generic EC and CAS entries as well as the IUPAC name cover all possible magnesium salts of silicic acid, including also all possible stoichiometries and their respecitive phases (i.e. all amorphous and crystalline phases) of each salt. The molecular formula is more specific, as a range of values for the stoichiometry is reported; "MgO.xSiO2, the molar ratio (x) typically ranges from 1.5-4.0". However, these identifiers are not consistent with the specific structural information formula that refer to a 1:1 Si:Mg salt. The Registrant has additionally includes 2 synonyms in Section 1.1, magnesium silicate and magnesium trisilicate, that refer to the 1:1 and 1:3 salts respectively. Moreover, the following text was included on page 7 of the CSR "*Silicic acid, magnesium salt is a UVCB substance which has been allocated to CAS number 1343-88-0. It is a synthetic amorphous magnesium silicate which includes the subset dimagnesium trisilicon octaoxide (also known as magnesium trisilicate) which has been allocated to CAS number 14987-04-3.*" From the name and other identifiers it is not clear whether the registration refers to magnesium silicate or magnesium trisilicate or another magnesium salt of silicic acid. The identifiers used to describe the registered substance thus do not allow ECHA to unambiguously identify the registered substance.

Regarding point (ii), no description of the manufacturing process for the UVCB substance registered was included in Section 1.1 of the dossier. As described in chapter 4.3 of the Guidance, this information is an essential element for the identification of UVCB substances.

Accordingly, in line with Annex VI, Sections 2.1 and 2.2, the Registrant is requested to revise the name and other identifiers such that the registration unambiguously allows identification of the registered substance. This includes the provision of a detailed description of the manufacturing process, including the chemical identity of the source and information on the most relevant steps of the manufacturing process. The Registrant shall ensure that the information reported is consistent throghout the dossier

Concerning the name, the Registrant is required to provide information that allows for an accurate and complete identification of the substance. The name of a UVCB substance shall adequately reflect the source materials and the process. It shall be consistent with the molecular and structural formula and other identifiers reported in the dossier. The Registrant shall note that the EC (215-681-1) and CAS (1343-88-0) entries and the IUPAC name currently reported in the dossier are not sufficient for the identification of substances of defined stoichiometries and/or phase and shall thus be revised.

Concerning the description of the manufacturing process, this description shall be sufficiently detailed to allow ECHA to understand which starting materials are used, and how any other steps and process parameters may affect the substance composition and therefore its identity.

This description of the manufacturing process shall include, as appropriate:

- The stoichiometries of each composition (grade) manufactured/imported
- The identity and ratio of starting materials /reactants, including also all auxiliary agents for each grade manufactured/imported
- Information on post-treatment carried out

- A description of any other relevant operating parameters or process descriptor, which are necessary to obtain the registered substance and which may affect the substance composition

If the substance covered by the registration is manufactured according to different manufacturing processes, including the use of different sources, the detailed description of the manufacturing process required above shall be reported separately for each manufacturing process. A manufacturing process may be considered different when the sources, the processing steps and/or processing parameters are different. The Registrant shall note that substances manufactured according to different manufacturing processes may indicate multiple substances and consequently the requirement for multiple registrations.

This is, in particular, relevant as the information in Section 1.1 and in the CSR contains references to "magnesium silicate" and "magnesium trisilicate". ECHA notes that "magnesium silicate" and "magnesium trisilicate" are considered as different substances with their own EC entries (magnesium silicate 237-413-2 and trisilicate 239-076-7). The Registrant shall consider whether a change of the materials and/or the process parameters yields grades of the same substance or results in different substances. Where the registered substance is manufactured/imported as different grades (i.e. compositions of specific phases and forms) of the same substance, information on the manufacturing parameters shall be reported separately for each grade. For each grade the respective composition of defined stoichiometric ratio, phase(s) (amorphous, crystalline) and form(s) (fibers, powders, nanopowders, surface treated forms, etc. as relevant) shall also be reported.

In this respect ECHA notes that amorphous silicas are known to have grades (compositions of specific form e.g. powders, ultra-fine powders, etc.) that meet the EU recommendation for nanomaterials[1] in terms of primary particle size and/or specific surface area.

To ensure a high level of protection of human health and the environment, the REACH Regulation imposes the determination of hazards and risk irrespective of the form of the substances concerned. This includes more specifically nanoforms of substances, which may trigger specific hazardous properties and risks, as already highlighted by various institutions, including the European Parliament.[2]

In fact, the current scientific knowledge establishes that the risks of nanoforms of substanceswould require separate assessment. Indeed, the specific risks of nanoforms are not founded on mere hypotheses that have not been scientifically confirmed. These risks have actually been fully demonstrated by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).[3] The fact that there is still some degree of scientific uncertainty as to the existence or extent of such risks does not, by itself, discharge registrants from characterising nanoforms in order to carry out their duties under the REACH Regulation. Based on the above, the Registrant is compelled to scientifically assess the potentially adverse effects of nanoforms.

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[1] Commission Recommendation on the Definition of Nanomaterials of 20 October 2011, 2011/696/EU, *http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF*

[2] "*Whereas nanomaterials [...] potentially present significant new risks due to their minute size, such as increased reactivity and mobility, possibly leading to increased toxicity in combination with unrestricted access to the human body, and possibly involving quite different mechanisms of interference with the physiology of human and environmental species*". Recital D of European Parliament Resolution of 24 April 2009 on Regulatory aspects of nanomaterials.

[3] "*There is sufficient evidence that there can be a change in some properties of the material at the nanoscale which is, for instance, due to the increase in surface-to-volume ratio. These nanospecific properties raise concerns over their potential to cause harm to humans and the environment. The chemical reactivity of nanoparticles often relates to the surface area. Consequently, the chemical reactivity per mass dose increases for smaller particles of the same type. This effect may or may not be associated with an increase in biological activity or toxicity*". SCENIHR, Opinion of 8 December 2010 on *Scientific Basis for the Definition of the Term «nanomaterial »*, page 31.

Furthermore, it is self evident that in order to determine the hazardous properties and the appropriate risk management measures for substances in different forms, it is necessary to characterise the substance in terms of its physical form, in particular regarding nanoforms, before determining the corresponding hazards and assessing the exposure of humans and the environment and the associated risk management measures. The characterisation of nanoforms of the substance is a pre-requisite to the determination of all the hazardous properties and appropriate risk management measures concerning the registered substance. Therefore, it is essential that suitable information on nanoforms is submitted, especially in order to identify precisely whether the registered substance includes nanoform.

In his comments to the draft decision, the Registrant notes that '*the substance subject to the present decision meets the EU Recommendation Definition for a nanomaterial given in 2011/696/EU yet has an external particle size exceeding 100nm*'. ECHA notes that the EU Recommendation explicitly includes aggregates and agglomerates within the scope of "nanomaterial" when the smallest constituent particle is less than 100 nm and/or the volume specific surface area is > 60 m2/cm3. Where amorphous magnesium silicate grades meet these criteria, they are nanomaterials according to the EU recommendation. Consequently, where the Registrant intends to cover grades that meet the definition in the EU recommendation for nanomaterials in this registration dossier, information on these grades in terms of their of their manufacturing process, their respective composition, phase(s) and form(s) (including information about particle sizes) will need to be included in section 1 of the dossier.

Similarly, the Registrant shall note that where he intends to cover chemically surface treated grades of high specific surface area in the dossier, information on these grades in terms of of their manufacturing process, their respective composition, phase(s) and form(s) (including information about particle sizes) will also need to be provided. In this respect, the Registrant shall note that the FAQ available on the ECHA website concerning the exemption from registration obligations for chemically surface treated substances[4] is not applicable to high surface area particulates, as the question tackled by this FAQ only relates to "macroscopic particles" of low specific surface area.

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

- The revised chemical name shall be included in the IUPAC name field.
- The revised structural and molecular information shall be reported in the appropriate IUCLID fields in Section 1.1.
- Details of the grades (composition(s) of specific stoichiometry, its phase and form where relevant) of the UVCB substance shall be included in the Description field in IUCLID Section 1.1, respectively together with the description of the manufacturing process used. The composition of each grade shall be reported seperately in section 1.2. and sufficient analytical data for the grade shall be included in section 1.4. If the registrant intends to cover nanoforms with this registration, the respective particle sizes covered by this registration should also be reported in Section 4.5 of the joint IUCLID dossier (i.e. in the form of particle size distribution).
- The relevant appropriate CAS entry shall be included in the "CAS information" field, if available.The current CAS number (1343-88-0) and corresponding CAS name shall be reported under the "Related CAS information" header in IUCLID Section 1.1. 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

[4] Q&A pair [38] "Do I have to register chemically surface treated substances?" available ate http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/topic/reach

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, the molecular and structural formula, 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.

ECHA highlights that failure to report sufficient information on each grade of a substance in the dossier, including nanoforms, whether surface treated or not, may result in these grades not being covered by this registration.

In the absence of suitable information, ECHA cannot be in a position to determine whether the registration covers any specific nanoforms of the substance. Only the Registrant of the substance knows the relevant forms under which the substance is manufactured or imported. Only the Registrant is therefore able to determine the particle size distribution of constituent particles and to report sufficient information on the respective grades manufactured. The information should be sufficient to ensure that ECHA is in a position to determine the particle size distribution of constituent particles of the substance and to allow ECHA to identify each grade covered by the registration.

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.

Specifically, the Registrant has reported one composition in Section 1.2 of the dossier and this composition identifies its main constituent with the same reference substance as in section 1.1 "Silicic acid, Magnesium salt" with no listed impurities. From this limited information and due to the inconsistencies in the identifiers of the reference substance, as reported in Section III.A.1, the composition(s)of the substance manufactured/imported by this legal entity) cannot be established.

In accordance with section 4.2 the Guidance, the composition shall normally be described up to 100%, and each constituent requires a complete chemical specification, including structural information. For UVCB substances section 4.3 of the Guidance recognizes that they either cannot be fully specified with the IUPAC name of the constituents, as not all the constituents can be identified, or they may be specified with a lack of specificity due to variability of the exact composition. However, also for UVCB substances the chemical composition and the identity of the constituents should still be reported as far as known.

The Registrant is required to further specify the identity of each specific constituent reported in Section 1.2. The name and other identifiers for each constituent shall specify the stiochiometry phase and form, as relevant. This information shall be sufficient to enable the

specific constituents of th,e 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. Further technical details on how to report details on the constituents of a substance in IUCLID are available in the "Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH".

Where the Registrant covers different grades (compositions of specific phase and form as relevant) 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 grades, 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. For each grade, the name and other identifiers for each constituent shall specify the phase and form that the composition refers to. This information shall be sufficient to enable the specific grades of the substance registered by this legal entity to be verified and shall be consistent with the information included in Section 1.1 on the "name and other identifiers" for the substance. All grades reported are required to refer to the same substance identified in Section 1.1 of the dossier. Instructions on how to do this are available in the IUCLID user manual "Nanomaterials in IUCLID 5" available on the IUCLID website at http://iuclid.eu/index.php?fuseaction=home.documentation and also in the "Data Submission Manual Part 18 - How to report the substance identity in IUCLID 5 for registration under REACH" available on the ECHA website at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

As noted in reported in Section III.A.1, 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.

Specifically the Registrant has included ^{29}Si NMR spectra, IR spectra and XRD patterns for four grades of the substance registered ("[redacted]", "[redacted]", "[redacted]" and "[redacted]") in Section 1.4 of the dossier. This information is sufficient to determine that the substance includes silica functional groups (NMR and IR spectra) and that the phase of the four grades is amorphous (XRD patterns). The analytical information included in Section 1.4 of the dossier indicates that the dossier is specific for the amorphous phase though the information provided is not sufficient to determine if this data refers to magnesium silicate, magnesium trisilicate or a magesium salt of silicic acid with a different stocihiometry. The information submitted is therefore not sufficient for the determination of the chemical composition of the specific stoichiometric ratios registered by this legal entity, their respective phase(s) and form(s) as relevant.

In line with Annex VI, Section 2.3.7, the Registrant shall include information on the methods used to quantify all substance constituents in terms of their stoichiometries, phase and form where relevant. This information shall be sufficient to enable the substance identified in Section 1.1 of the dossier and all constituents reported in Section 1.2 to be verified. Where grades of the substance are registered, sufficient data that will enable the identity and composition of each grade to be verfied shall be included. The Registrant may

use any method or combination of methods to do this (e.g. elemental analysis, gravimetry, quantitative XRD, BET, etc.). The Registrant shall note that a description of each method used shall be included in such detail that the method may be reproduced.

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.

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