EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004724-72-03/F Helsinki, 17 December 2014

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

For Silicic acid, aluminum sodium salt, CAS No 1344-00-9 (EC No 215-684-8), 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, aluminum sodium salt, CAS No 1344-00-9 (EC No 215-684-8), 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 of 1000 tonnes or more tonnes 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 4 November 2013.

On 17 December 2013 ECHA sent the draft decision to the Registrant and invited him in accordance with Article 50(1) of the REACH Regulation to provide comments on 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. On basis of this information, only the deadline in Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

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 **26 May 2015**.

B. Note for consideration by the Registrant

Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

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 in Section 1.1. of the dossier as an inorganic UVCB substance and has used only generic EC (**215-684-8**) and CAS (**1344-00-9**) entries and the generic chemical name included in the IUPAC name field "Silicic acid, aluminum sodium salt" to describe the substance. These generic EC and CAS entries as well as the IUPAC name cover all possible sodium aluminum salts of silicic acid, including also all possible stoichiometries and their respecitve phases (i.e. all amorphous and crystalline phases) of each salt. The reported molecular formula ("nSiO2*mAl2O3*zNa2O") also is not specific, as the ratio of the elements (values of n, m and z) are not defined. While the structural information (structural formula, SMILES notation, InChi code) and the molecular weight refer to a 1:1:1 Si, Al, Na salt, this salt cannot exist due to the overall change imbalance of such a salt. The identifers used in section 1.1 of the IUCLID dossier to describe the registered substance thus do not allow ECHA to unambiguously identify the registered substance.

Information provided in Section 3.1 of the dossier concerning the description of the manufacturing process describes the substance as "[redacted]." This description refers solely to the amorphous phase of a "sodium aluminosilicate". However, from the "name and other identifiers" included in Section 1.1 of the dossier it is not clear whether this description refers to the registered substance.

Regarding point (ii), no description of the manufacturing process 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 (215-684-8) and CAS (1344-00-9) entries currently reported in the dossier are not sufficient for the identification of substances of defined stoichiometries and/or phases and shall thus be revised.

ECHA acknowledges the comments of the registrant that there is no need to identify the substance with more precise EC and CAS entries. However, ECHA notes that the Registrant indicated that the registered substance is narrower in scope than that currently identified by the name and numerical identifiers in the dossier; specifically synthetic amorphous sodium aluminium silicate. Therefore the name and numerical identifiers shall be revised to allow ECHA to unambiguously identify the registered substance.

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 (if any) .
- 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 ECHA notes that the information provided in Section 3.1 of the IUCLID dossier indicates that in the manufacturing process different source materials may be used; "[redacted]." This description indicates that sources of aluminium other than aluminium sulfate can also be used ("metal salts"). It also indicates that the ratio of Si to Na may be controlled via the reactant, sodium silicate that is used in a form of an aqueous solutions (e.g. water glass), resulting in a variation of the ratio of Si to Na from 2 to 4. The reaction scheme provided in the dossier [redacted]" does not define the ratio (stoichiometry) of the other reactants. Section 3.1 also indicates, that, in addition to the use of different starting materials, certain other process parameters (e.g. temperature, reaction time, mixing rate, pH) may be controlled by the Registrant, "[redacted]."

The Registrant shall thus 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 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.

[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

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 substances would 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.

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 '*Synthetic Amorphous NAS represents a nano structured substance. This means external particle size (aggregate and agglomerate) exceeds 100 nm, while size of theoretical primary particle is below 100 nm. NAS does not contain free primary particles'.* 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 the registered 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 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 it intends to cover chemically surface treated grades of high specific surface area in the dossier, information on these grades in terms of their manufacturing process, their respective composition, phase(s) and form(s) (including information about particle sizes) will also need to be provided. This is particularly relevant as in the description of the manufacturing process included in section 3.1, the Registrant mentions surfac treatment; "[redacted]." The Registrant shall note that chemically surface treated

[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.

grades of high specific surface area can only be covered by the registration if they have been reported in the dossier. 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 registrants intends to cover nanoforms with this registration as specified by the EU recommendation for nanomaterials[5], the respective particle sizes covered by this registration should also be reported in Section 4.5 of IUCLID (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 entry 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 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 approprriate 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 primary particles of the substance and to allow ECHA to identify each grade covered by the registration.

[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

[5] 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. 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 as its main constituent the same reference substance as in section 1.1 "sodium aluminium silicate" with sodium sulfate and diiron trioxide reported as impurities. From this limited information, due to the inconsistencies in the identifiers of the reference substance, as reported in Section III.A.1, the compositions of the specific stoichiometric ratio(s) and its corresponding phase(s) and form(s) where relevant cannot be verfied.

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 stoichiometry, phase and form, as relevant. 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. 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 stoichiometry, 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 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 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}SiNMR spectra, IR spectra and XRD patterns for one grade of the substance registered. This information is sufficient to determine that the substance includes silica functional groups (NMR and IR spectra) and that the phase of the test sample is amorphous (XRD pattern). It is not however sufficient for the determination of the chemical composition of any of the specific stoichiometric ratios registered by this legal entity, their respective phase(s) and form(s) as relevant.

In addition ECHA notes that the analytical information included in the registration dossier is identical to the analytical information contained in a registration dossier submitted by a different legal entity. The analytical information is a fingerprint of a substance manufactured or imported by a specific registrant. Therefore, ECHA cannot establish whether the analytical information indeed relates to the substance covered by this registration or to the substance registered by the other legal entity.

Article 5 of the REACH Regulation requires legal entities to make sure that the substances they manufacture or place on the market are registered in accordance with Title II of the REACH Regulation. Based on Article 11(1) and 10(a)(ii) of the REACH Regulation, each Registrant is required to submit separately information on the identity of the substance he registers. Annex VI of the REACH Regulation provides that "the information given shall be sufficient to enable each substance to be identified". Analytical information generated on a substance that is not manufactured or imported by the Registrant cannot be used as evidence that would allow ECHA to verify the identity and composition of the registered substance.

Therefore, ECHA concludes that the analytical information provided by the Registrant cannot, in absence of further justification, be considered appropriate to verify the composition of the registered substance.

In line with Annex VI, 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 generated on the substance as manufactured/imported by his specific legal entity and shall cover all compositions registered by his legal entity. This information shall be sufficient to enable the substance identified in Section 1.1 of the dossier and all respective grades reported in Section 1.2 to be verified. The Registrant may use any method or combination of methods to do this (e.g. elemental analyis, XRF, BET method, XPS, TGA etc). The Registrant shall note that a description of each method used shall be included in such detail that the method may be reproduced.

The Registrant shall remove from the registration dossier any analytical information that has not been generated on the substance as manufactured/imported by the Registrant. If any of the analytical information currently present in the registration dossier is relevant for the registered substance, a valid justification as to why this is the case shall be provided.

B. Deadline for submitting the required information

In the draft decision communicated to the Registrant, the time indicated to provide the requested information was 3 months from the date of adoption of the decision. In his comments on the draft decision of 17 December 2014, the Registrant requested an extension of the timeline to 9 months. He sought to justify this request by indicating in his comments that it will take at least 9 months to prepare a data package that he considers will address the information requested. In addition, he provided a quote from two test labs (Technische Universität Dresden and Aqura analytical solutions) where it is indicated that the results and report of the analysis of 7 silicic acid aluminium sodium salt samples from different manufacturers can be delivered 4-5 months after arrival in the lab.

ECHA however notes that data from 3 of the methods included in the quote (XRD, NMR and IR) are already included in the dossier. In addition, ECHA reminds the Registrant that only data relevant for his legal entity is required and data from other manufacturers is not required. In addition, ECHA notes that it can be expected thatthe Registrant already has sufficient data at hand to enable the substance identity and composition to be verified for each grade as this information would normally be included in technical specifications provided to customers (e.g. Certificates of Analysis, technical specifications, quality control data, etc.). An internet search showed that information on the technical specification are in fact made available to resellers of the Registrant's products and are published on the reseller's website. Therfore it is not anticipated that new extensive analysis would be needed to sufficiently identify the registered substance including all forms, stoichiometries etc. However as the Registrant has indicated that he would like to obtain new data from external laboratories related to identity of the substance he manufactures/imports, an extension of 2 months is granted. Therefore, ECHA has partially granted the request and set the deadline to 5 months.

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]
Leena Ylä-Mononen
Director of Evaluation