Helsinki, 14 December 2016

Addressee: [redacted]

Decision number: CCH-D-2114350468-44-01/F
Substance name: Reaction mass of Quartz (SiO2) and aluminium and aluminium oxide and magnesium oxide
EC number: 910-038-8
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 01.08.2014

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

1. **Composition of each substance (Annex VI, Section 2.3.)**
2. **Description of the analytical methods (Annex VI, Section 2.3.7) for the registered substance:**;
3. **Name, molecular and structural formula or other identifier of the substance (Annex VI, 2.1. and 2.2.)**

You are required to submit the requested information in an updated registration dossier by **21 March 2017**. You shall also update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2. Advice and further observations are provided in Appendix 3.

The scope of this compliance check decision is limited to the standard information requirement(s) of Annex VI, Section 2 of the REACH Regulation.

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[1] by Kevin Pollard, Head of Unit, Evaluation E1

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

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. Composition of the substance (Annex VI, Section 2.3.)

"Composition of the substance" is an information requirement as laid down in Annex VI, Section 2.3. of the REACH Regulation. 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. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

In this respect, according to chapters 4.2 and 8.2 of the Guidance for identification and naming of substances under REACH and CLP (Version: 1.3, February 2014) – referred to as "the Guidance" thereinafter, you should note that, for well-defined substances, the following applies:

- Each main constituent (i.e. the constituent present at ≥80% for mono-constituent substance or each constituent present at ≥10% and <80% for multi-constituent substance) shall be identified and reported individually; and
- Each impurity present at ≥1% or relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually.
- For each constituent, the typical, minimum and maximum concentration levels shall be specified regardless of the substance type.
- The sum of typical concentrations for main constituents and impurities shall be 100%.

In the present dossier, you have reported one composition in section 1.2 and this composition identifies four main constituents and no impurities.

However, ECHA notes that up to [redacted]% of the substance is unaccounted for, i.e. the sum of the minimum concentration for the predominant main constituent [redacted] with the maximum concentration of the other main constituents ([redacted] %. Moreover, the XRF analysis provided in section 1.4 of the dossier shows different additional elements detected other than [redacted], which may indicate the presence of impurities that are not reported in the dossier. In addition, for each main constituent you have only specified the concentration range for the main constituents and no typical concentrations.

ECHA therefore concludes that the compositional information has not been provided to the required level of detail.

You should revise the composition providing missing constituents and impurities. Each impurity present at concentration ≥ 1 % or relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually. For each constituent the typical concentration and the minimum and maximum concentration levels shall be specified. The composition must be supported by appropriate quantitative and qualitative analyses. The sum of the typical concentrations should add up to ca. 100 %.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: the Registrant shall report individually any impurity required to be identified and specify at least one of the following identifiers: chemical name, CAS number, EC number, and/or molecular formula, as well as the minimum, maximum and typical concentration, in the appropriate fields in Section 1.2 of the IUCLID dossier. The concentration ranges provided must be representative for the substance as manufactured.

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

"Description of the analytical methods" is an information requirement as laid down in Annex VI, Section 2.3.7. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

You shall ensure that the composition is verifiable, i.e. supported by a description of the analytical methods for the identification and quantification of the constituents required to be reported, as required under Annex VI 2.3.7 of the REACH Regulation. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained. The analytical methods shall allow identification of the actual constituents that are present in the registered substance together with the information on their internal structure /phase (e.g. [redacted] etc.).

You have reported the following in the "analytical data and spectra field" in section 1.4: "*included Elemental Analysis: ICP-OES. Aluminia metal determination: Bromine methanol method. Chromatography, NMR UV, IR and X-ray spectroscopy are not suitable techniques for analysing the substance. The only suitable spectroscopic method is X-Ray-fluorescence.*" However, the only analytical data attached in the dossier is the qualitative XRF analysis and the indicated ICP-OES analysis and alumina metal determination by the bromide methanol method have not been provided.

ECHA notes that the qualitative XRF analysis provided is not sufficient for a proper identification of the substance, as it can only prove the presence of elements (e.g. [redacted]), but does not allow identification of the actual constituents (e.g. [redacted]) that are present in the substance. Moreover, the XRF analysis currently reported is a qualitative analysis only and does not allow the quantification of the constituents of the substance. Therefore the verification of the composition of the substance as reported in section 1.2 is not possible.

ECHA therefore concludes that you have not provided sufficient information on the descriptions of the methods used to determine the identity and composition of the registered substance as required by Annex VI, Section 2.3.7. of the REACH Regulation.

You are therefore requested to provide description and results of an appropriate analysis (e.g. an XRD or any other suitable alternative data that can provide the same level of information) that would enable identification of the specific constituents as listed in section 1.2: [redacted]. The analysis should also be able to provide further information about the internal structure (phase) of the constituents (e.g. [redacted] etc.), as it is normally required for these types of substances (Guidance sections 4.2.3 and 7.5).

You should also provide an appropriate quantitative analysis that would prove the composition of the substance as reported in section 1.2. You may use any method or combination of methods to do this (e.g. elemental analysis, gravimetry, quantitative XRD etc.).

A description of the analytical methods shall also be included. The analytical data should allow verification of the identity and composition of the registered substance and must be consistent with the information reported in sections 1.1 and 1.2. You shall note that a description of each method used shall be included in such detail that the method can be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained. For X-ray based methods you shall provide details of sample/standard preparation, voltage, current, X-ray source and define the refinement method for quantitative XRD.

The analytical data, including the description of the analytical methods and the actual results of analysis shall be reported in IUCLID section 1.4.

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

A. IUPAC name

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2. 1. of the REACH Regulation. The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore fundamental for substance identification. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

According to the Guidance, a multi-constituent substance is a substance with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification parameters of REACH Annex VI section 2. Multi-constituent substances are those where more than one well-defined constituent is present in a concentration ≥10% (w/w) and < 80% (w/w). Only main constituents that are present at typically ≥10% (w/w) contribute to the name of the substance.

ECHA notes that you have identified the registered substance as a well-defined (multi-constituent) substance with the IUPAC name " Reaction mass of aluminium and aluminium oxide and magnesium oxide and quartz (SiO2)" in section 1.1 of the IUCLID dossier.

However, the current name assigned to the substance is not in line with the naming rules described in the Guidance, as based on the composition listed in section 1.2 of the dossier, some constituents that are included in the substance name are present at concentration lower than 10% (e.g. [redacted]).

ECHA therefore concludes that the chemical name currently used is inconsistent with the rest of the information given in the dossier, and as a result is not representative for the registered substance.
Consequently, the IUPAC name of the substance shall be modified following the rules for naming of multi-constituent substances defined in the Guidance:the name will have to be revised based on each constituent present at concentration ≥10%, therefore excluding from the name of the substance constituents as [redacted] that are present at concentration <10%.

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

the revised name shall be reported in the IUPAC name field in section 1.1 of IUCLID.

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B. Separate additional issue: UVCB versus WDS

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2. 1. of the REACH Regulation. The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore fundamental for substance identification. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

According to the Guidance well-defined substances (WDS) are those with a defined qualitative and quantitative composition which can be sufficiently identified based on the identification parameters of REACH Annex VI section 2. Substances which cannot be sufficiently identified by composition and the above parameters are "UVCB substances": Substances of Unknown or Variable composition, Complex reaction products or Biological materials.

ECHA would like to point out that you have reported relatively large variability in the composition of the substance: the predominant main constituent [redacted] is present at [redacted]%. Furthermore, in the current dossier up to [redacted] of the substance composition is unaccounted for, as indicated in section 1 hereinabove. Additionally, in several sections of the Chemical Safety Report (CSR) attached in section 13, the substance is referred to as "[redacted]", which indicates that the substance is the by-product of a metallurgic process and as such may have a variable and complex composition. This observation is also supported by the XRF analysis provided in section 1.4, where additional elements other than [redacted] are detected.

If the substance is manufactured such that the composition is highly variable and, as a consequence, the substance cannot be identified based on individual well-defined constituents, the substance shall be rather identified as a UVCB substance. Examples of UVCB substances of this kind are outlined in section 4.3.2.1 of the Guidance. Should the substance be identified as a UVCB substance, further information is required to appropriately identify the registered substance in accordance with section 4.3 of the Guidance.

More specifically, the naming of a UVCB substance consists of two parts: the chemical name and the more detailed description of the manufacturing process. If your substance is a UVCB substance, you will need to specify a chemical name of the substance that is representative of the registered UVCB substance and to provide details of the process used for the manufacturing of the registered substance. The description of the manufacturing process 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. It shall include, as appropriate,the ratio of reactants and any relevant operating parameters (e.g. temperature and pressure).

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

The revised chemical name shall be reported in the IUPAC name field in section 1.1 of IUCLID. The description of the manufacturing process of the UVCB substance shall be included in the "Description of composition" field in Section 1.2 of IUCLID.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 20 August 2015.

ECHA notified you of the draft decision and invited you to provide comments.

ECHA did not receive any comments by the end of the commenting period.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

2. 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 your Member State.

3. Further technical details on how to report the composition of well-defined substances in IUCLID are available in the Manual "How to prepare registration and PPORD dossiers" on the ECHA website.