

Final decision: CCH-D-0000002626-72-03/F/RECT

Helsinki, 29 October 2012

**DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006****For Flue dust, portland cement, CAS No 68475-76-3 (EC No 270-659-9),  
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).

On 28 September 2012 the registrant lodged an Appeal with the Board of Appeal of the European Chemicals Agency (A-007-2012) against the European Chemicals Agency's (ECHA) decision of 31 July 2012 requesting the registrant to submit certain information in order to bring the registration into compliance. On 29 October ECHA decided to rectify parts of its initial decision. This Decision thus replaces the Agency's decision of 31 July 2012.

**I. Procedure**

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration dossier for Flue dust, portland cement, CAS No 68475-76-3 (EC No 270-659-9) submitted by [REDACTED] (Registrant).

This decision is based on the registration dossier 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 after 14 June 2012, 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.

The compliance check was initiated on 23 March 2012.

On 04 April 2012 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 04 May 2012 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

On 31 May 2012 the Registrant updated his registration dossier.

ECHA considered the Registrant's comments received and did amend the draft decision.

On 14 June 2012 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States did not propose amendments to the draft decision and ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

Following an Appeal lodged by the registrant on 28 September 2012, ECHA decided on 29 October 2012 to rectify parts of its initial decision.

This compliance check decision does not prevent ECHA to initiate further compliance checks on the present dossier at a later stage.

## II. Information required

- 1) Pursuant to Articles 41(1)(a), 41(3) and 10(a)(ii) as well as Annex VI , section 2 of the REACH Regulation the Registrant shall submit for the registered substance:
  - a. Name or other identifier of the substance (Annex VI, Section 2.1): Information which is suitable and necessary to allow ECHA to establish and verify the name and identity of the registered substance, as specified under section III:1(a) below; and;
  - b. 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 name of the registered substance, as specified under section III:1(b) below

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by 01 November 2012.

## III. Statement of reasons

Based on the examination of the technical dossier, ECHA concludes that the information therein, submitted by the Registrant for registration of the above mentioned substance for the purpose of registration within the applicable tonnage band of 1000 tonnes per year in accordance with Article 6 of the REACH Regulation, does not comply with the requirements of Article 10 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.

### 1) Missing information related to substance identity

Pursuant to Article 10(a)(ii) and Annex VI, section 2 of the REACH Regulation, the technical dossier of the registration shall include information on the identity of the substance. Annex VI, section 2 lists information requirements that shall be sufficient to identify the registered substance.

#### (a) Name or other identifier of the registered substance (Annex VI, 2.1.)

The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore essential parts of substance identification and the corner stone of all the REACH obligations.

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 shall consist of two parts: the chemical name and the more detailed description of the manufacturing process.

According to the ECHA "Guidance for the identification and naming of substances under REACH and CLP" (Version: 1.1, November 2011), the Registrant should note that for UVCB substances presenting a large number of constituents, the following applies:

- Chemical composition alone is not sufficient for substance identification, but the substance should be identified by its name, its origin or source and most relevant steps taken during processing.

The process should be described precisely enough to enable the substance to be identified unambiguously and should include information on the identity of the starting materials, the relevant process steps involved and associated process parameters (including the identity of any substance/solvent involved in an extraction process, the cut-off range of any fractioning step, the operating parameters used (temperature, pressure), and the identity and ratio of any reactant used.

Based on the information provided in the Registrant's comments and in the updated dossier ECHA concludes that significant changes existing in the manufacturing process of the flue dusts from Portland cement production are likely to lead to different substances under REACH.

More specifically, the Registrant has provided a description of the manufacturing process of the Portland cement clinker and "flue dust from production of cement clinker" (the registered substance). Information on the composition of the raw meal for the Portland cement production and on the fuels used has been provided. Based on this information variations in the concentration of some constituents exist, depending on the raw materials used and the reaction progress. It is fully understandable and acceptable that inherent variations in the composition of the source used for the manufacturing of a UVCB substance exist. It was also indicated in the Registrant's comments and updated dossier, that different extraction points (and therefore extraction temperatures and calcination degrees) would significantly influence the substance composition. However, no further details on the extraction/collection steps together with relevant process circumstances were provided. It was also not demonstrated how the compositions from different collection points may vary. The highest variations are observed for Calcite (■), Lime (■) and Belite (■). Based on the Registrant's comments, variations in the concentration of these three constituents (calcite, lime and belite) depend on the degree of calcination of the raw meal (and therefore, on the extraction point /reaction progress). The manufacturing process leading to the compositions where a constituent (e.g. Calcite) is not present in the substance therefore appears to be considerably different than the process resulting in a composition where this constituent is predominant. As the reaction progress (and therefore calcination degree /point of extraction) is a crucial and controlled parameter of the manufacturing process of the flue dust, and considerable variations in the composition of different dust fractions are expected, this parameter is regarded as crucial in determining the outcome of the manufacturing process. Therefore dust fractions collected at significantly different extraction points/temperatures are likely to be regarded as different substances under REACH and registered separately.

In line with the above, the Registrant is requested to provide detailed information on the manufacturing process of specific fraction(s) of the flue dust. The reaction progress (extraction point/ degree of calcination) shall be considered as important parameter determining the substance identity. The collection circumstances (temperature at individual extraction point, reaction progress) of the process shall be clearly specified for each dust fraction. Accordingly, the chemical/IUPAC name of the substance shall be revised.

Regarding how to report the name and other identifiers of the registered substance in IUCLID, the following applies:

- The Registrant should report the chemical (generic) name of the registered substance in the IUPAC name filed of IUCLID section 1.1 and give detailed description of the starting material and of the manufacturing process in writing in the description field.

(b) Composition of the registered 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.

ECHA notes that the registration does not contain sufficient information for establishing the composition of the registered substance and therefore its identity, as required under Annex VI, Section 2.3. of the REACH Regulation.

More specifically, the Registrant has provided information on the composition(s) of the registered substance and on the variation in the concentrations of the main constituents. For some compositions exceptionally wide concentration ranges have been provided. While inherent variations due to the composition of the raw materials are perfectly acceptable, compositions referring to different fractions of the flue dust may be regarded as different substances as explained under section III:1(a). Furthermore, for some constituents the minimum concentration values were not provided. ECHA therefore concludes that the reported composition covers fractions/grades which differ significantly by their composition and appear thus not to be manufactured under the same process conditions.

In line with the above, the Registrant is requested to provide compositional information which refers solely to the specific fraction(s)/grade(s) being one substance.

Following section 4.3 of the above mentioned Guidance for identification and naming of substances under REACH, the Registrant should note that for UVCB substances such as the registered substance, the following applies:

- All constituents present in the substance with a concentration of  $\geq 10\%$  shall be identified and reported individually; and
- All constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Any other known constituent shall also be specified; and
- Unknown constituents shall be identified as far as possible, by a generic description of their chemical nature; and

- Constituents present in a specific crystalline form shall be reported as such (i.e. as respective minerals). Amorphous constituents should be reported as hypothetical oxides unless more specific information is provided.

For each constituent and group of constituents, the typical lower and upper concentration level shall be indicated. The concentration values shall be representative for the manufactured substance.

Regarding how to report the composition of the registered substance in IUCLID, the following applies: The Registrant should report the composition of the registered substance in IUCLID section 1.2. For each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

Further technical details on how to report the composition of UVCB substances in IUCLID are available in paragraphs 2.1 and 2.2.2 of the Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH (version: 1.0, June 2010) on the ECHA website.

#### 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://echa.europa.eu/appeals/app\\_procedure\\_en.asp](http://echa.europa.eu/appeals/app_procedure_en.asp). The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



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