

Decision number: CCH-D-0000002552-79-03/F

Helsinki, 4 July 2012

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**For Product of Semi-Dry Absorption method of Flue Gas Desulphurization, 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 dossier for Product of Semi-Dry Absorption method of Flue Gas Desulphurization submitted by [REDACTED] (Registrant), latest submission number [REDACTED], for the tonnage band of 1000 tonnes or more per year.

The compliance check was initiated on 24 January 2012.

On 10 February 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 9 March 2012 ECHA received comments from the Registrant where it was committed that by the end of March 2012 the Registrant would submit an update of the dossier with additional information addressing requests in the draft decision.

On 29 March 2012 the Registrant updated his registration dossier.

ECHA considered the Registrant's comments received and information on substance identity provided in the update of the registration dossier, and did amend the draft decision.

On 25 May 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.

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

II. Information required

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, 2.1.): a description of the manufacturing process of the UVCB substance to identify the name of the registered substance as specified under point III.(a) below;
- b) Composition of the substance (Annex VI, 2.3.): information to establish and verify the composition and the name of the registered substance, as specified under section III.(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 **4 September 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 or more per year in accordance with Articles 6 and 11(2) of the REACH Regulation, does not comply with the requirements of Articles 10, 12 and 13 and with Annexes VI, and IX to XI 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.

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 substance (Annex VI, 2.1.)

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) UVCB substances cannot be sufficiently identified by their chemical composition. The main identifier for UVCB substances is the description of the manufacturing process, including final or most relevant steps of the processing. ECHA observes that the Registrant did not provide sufficient and appropriate information on the naming of the registered substance, as required under Annex VI Section 2.1 of the REACH Regulation.

More specifically, in the update of the registration dossier (submission number [REDACTED]) the Registrant has provided detailed description of the technological processes used for desulfurization of exhaust gases from the coal-fired power plants. Based on this information, the description covers not only the desulfurization manufacturing process carried out with preliminary dust (ash) extraction step but also the desulfurization with partial or no dust extraction. As a result, substances referred to as "pure SDA" or the "mixture SDA Product and ash" in the registration dossier can be obtained. ECHA notes that significant differences

in the composition of the "pure SDA" and the "mixture SDA Product and ash" can exist depending on whether the preliminary dust extraction step is applied or not. The raw materials that feed the desulfurization manufacturing step (the combustion exhaust gases) are different – they can be composed of gases mainly (e.g. CO₂, SO₂, SO₃, HCl, HF etc.) or they can contain these gases and a particulate matter (ashes drifting together with flue gases). Such significant differences in the reactants will be reflected in the composition of the final product, as it is demonstrated in the attachment provided in section 13 of the updated dossier [REDACTED]

[REDACTED]). The combustion exhaust gases are reacted with adsorbent composed of Ca(OH)₂ and water. As a result, the final product may consist of mainly inorganic salts being reaction products of Ca(OH)₂ with gases (e.g. CO₂, SO₂, SO₃, HCl, HF etc.), or these salts with reaction products of ashes with Ca(OH)₂.

The preliminary dust (ash) extraction in the manufacturing process having a significant effect on the composition of the substance, ECHA considers that the application or non application of such step in the process is to be considered as a significant difference in the manufacturing process. In line with chapter 4.3 of the above-mentioned Guidance, any significant changes in the source or technological process is expected to lead to different substances. Accordingly, ECHA regards the substances referred to as "pure SDA" and the "mixture SDA Product and ash" as different substances under REACH, which require separate registrations.

ECHA notes that the Registrant referred to the substance manufactured without preliminary dust extraction as a "mixture". In addition, the Registrant reported in the dossier a composition for a "pure SDA product" determined by subtracting the constituents originating from the ash from the isolated "SDA product". ECHA points out that the product isolated from the desulfurization-based manufacturing process shall be regarded as a substance as such. Where the isolated substance includes in its composition constituents originating from the ash, these constituents shall be regarded under REACH as part of the composition of the manufactured substance and cannot be considered part of any other substance in a mixture with the "pure SDA product".

ECHA also notes that, in line with the identity of the test material used for documenting the properties of "SDA product", the substance which is the subject of this registration is manufactured with preliminary dust extraction.

Accordingly, the Registrant is requested to remove from the dossier any information which does not refer to the registered substance i.e. SDA product, obtained by the desulfurization process with preliminary dust separation step.

The Registrant shall also ensure that the chemical name and the description of the manufacturing process take into account the dust extraction steps. The chemical name and the description of the manufacturing process shall be representative for the registered substance.

Regarding how to report the chemical name and description of the UVCB substance, the information shall be included in the IUPAC name field and the Description field in IUCLID section 1.1, respectively.

b) Composition of the substance (Annex VI Section 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 corner stone of all the REACH obligations.

ECHA notes that the registration dossier contains three different compositions: the first one refers to the Substance Identification profile, the second one refers to the composition of "pure SDA Product based on recalculation from Silicate analysis for mixture of Ash and SDA product", the third one (which is used twice) refers to the "mixture of ash and SDA product". As indicated in Section III(a) of the present decision, the registered substance ("SDA Product") can be obtained only in the desulfurization process with preliminary dust separation step. Therefore only the first indication as to the composition refers to the registered substance. However, this composition is not specific for the Registrant, but contains only constituents and their corresponding concentration ranges as they were agreed within the SIEF.

Therefore, the Registrant shall remove composition(s) which do not refer to the registered substance, i.e. obtained only in the desulfurization process with preliminary dust separation step. In addition, the Registrant shall revise the first listed composition and provide information which is specific for the manufactured substance. This information shall be supported by relevant analytical data. The Registrant is requested to submit the missing description of the analytical method(s) used for the identification and quantification of the registered substance (SDA product, obtained by the desulfurization process with preliminary dust separation step) including its constituents, and the corresponding results thereof. 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. As for the reporting of the data in the registration dossier, the information should be attached in IUCLID section 1.4.

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 on the ECHA website at: http://echa.europa.eu/documents/10162/17248/substance_id_report_iuclid_en.pdf

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. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.



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