

Final decision: CCH-D-0000002628-68-03/F

Helsinki, 20.11.2012

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**For zirconium dioxide, CAS No 1314-23-4 (EC No 215-227-2), 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 zirconium dioxide, CAS No 1314-23-4 (EC No 215-227-2) 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 **16 August 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 scope of this compliance check is limited to the standard information requirements of Annex VI, Section 2.3. of the REACH Regulation. This compliance check decision does not prevent ECHA from initiating further compliance checks on the present dossier at a later stage.

The compliance check was initiated on 10 April 2012.

On 28 June 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.

By 30 July 2012 the Registrant did not provide any comments on the draft decision to ECHA.

On 16 August 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.

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:

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

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 **20 February 2013**.

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 Article 6 and 11(2) of the REACH Regulation, does not comply with the requirements of Articles 10 and 13 and with 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.

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.

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 corner stone of all the REACH obligations.

ECHA notes that the registration does not contain appropriate 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.

The Registrant is reminded that, in line with paragraph 4.3 of the Guidance for identification and naming of substances under REACH and CLP, the following applies to mono-constituent substances such as the registered substance:

- The main constituent shall be identified and reported individually; and
- All the impurities present at ≥ 1 % shall be identified and reported individually; and
- All the impurities relevant for the classification and/or PBT assessment shall be identified and reported individually.

For each constituent, including the main constituents and any impurity, the typical, minimum and maximum concentration level shall be specified. The Registrant shall ensure complying with these requirements when revising the compositional information of the registered substance.

The Registrant shall ensure that the composition reported in the dossier is verifiable and therefore supported by a description of the analytical methods used for the identification and quantification of the main constituent and impurities required to be reported in the composition. The description shall be sufficient for the methods to be reported and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained.

More specifically, the Registrant identified the registered substance as the mono-constituent

substance zirconium dioxide (EC number 215-227-2; CAS number 1314-23-4). However, ECHA observes that the composition reported in the dossier covers, besides the pure zirconium dioxide, also zirconium dioxide present together with other oxide constituents reported as impurities. Several of these other oxide constituents, in particular [REDACTED], are well established dopants for zirconium dioxide. ECHA points out that such chemicals cannot be considered as impurities in the context of Article 3(1) of REACH: they are not unintended constituents derived from the manufacturing process but contribute to the composition of doped zirconium dioxide following deliberate addition at some stage in the chemical processing for the manufacturing of doped substances.

Dopants are relevant for the identification of the substance and would require to be included in the name for the substance registered. Therefore, dopants cannot be included as impurities in the composition reported in section 1.2 of your dossier. ECHA also underlines that the placing on the market of doped substances which are not themselves listed in EINECS were subject to notification under the 6th and 7th amendment of Directive 67/548/EEC even if the precursors were themselves listed in EINECS.

ECHA therefore concludes that the reported composition is not limited to the mono-constituent substance zirconium dioxide but covers also other substances corresponding to doped zirconium dioxide substances. ECHA points out that REACH applies to substances as defined in Article 3(1) and a registration dossier shall refer to one substance only (Article 10). Accordingly, the name and composition reported in a registration dossier are required to refer to a single substance.

The Registrant is accordingly requested to revise the composition information included in the dossier so that it is specific for the substance zirconium dioxide which is the subject of this registration. For this purpose, the Registrant shall delete the compositional information relating to doped zirconium dioxide substances. The Registrant shall note that separate registration obligations apply under REACH for the manufacturing or import of any specific doped zirconium dioxide.

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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Jukka Malm
Director of Regulatory Affairs