EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000002963-68-04/F Helsinki, 18 September 2013

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

For Zirconium praseodymium yellow zircon, CAS No 68187-15-5 (EC No 269-075-7), 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 praseodymium yellow zircon, CAS No 68187-15-5 (EC No 269-075-7, submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirement of Annex VIII, Section 8.4.2. of the REACH Regulation.

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of more than 1000 tonnes per year. This decision does not take into account any updates after 20 June 2013, 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 dossier at a later stage.

The compliance check was initiated on 21 September 2012.

On 14 December 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 20 December 2012 the Registrant requested extension of the deadline for providing comments. ECHA granted extension by seven calendar days so that the new deadline for submitting comments was 21 January 2013.

On 18 January 2013 ECHA received comments from the Registrant.

The ECHA Secretariat considered the Registrant's comments.

The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 20 June 2013 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)(b), 41(3), 10(a)(vi), 12(1)(e), 13 and Annex VIII of the REACH Regulation the Registrant shall submit the following information using one of the indicated test methods and the registered substance subject to the present decision:

> *In vitro* cytogenicity study in mammalian cells (Annex VIII, 8.4.2., test method: EU B.10/ OECD 473) or *in vitro* micronucleus study (Annex VIII, 8.4.2.; test method: OECD 487).

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 **18 September 2014**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirement. The scope of the present decision is the *in vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study (Annex VIII, 8.4.2. of the REACH Regulation). In accordance with Articles 10(a)(vi) and 12(1)(e) of the REACH Regulation, any registration for a substance manufactured or imported by a registrant at the tonnage level of 1000 tonnes or more per year shall contain this information.

The technical dossier contained an adaptation to the standard information requirement that forms the scope of the present decision. The Registrant has justified the adaptation with the argument that genetic toxicity testing *in vitro* (clastogenicity and gene mutation) is "scientifically unjustified" and "scientifically not relevant" according to Annex XI, Section 1 of the REACH Regulation because the registered substance might "be considered as chemically inert due to the characteristics of the synthetic process [...], rendering the substance to be of a unique, stable crystalline structure in which all atoms are tightly bound and not prone to dissolution in environmental and physiological media" and that the registered substance might be therefore "considered as biologically inert". However, the Registrant does not provide a specific legal basis for adaptation of the information requirement. Moreover, ECHA notes e.g. that under the influence of gastric fluid, the average total concentration of released praseodymium was 0.35 mg/L after 2 hours. The release of elements in gastric fluid indicates that the argument that the registered substance is not prone to dissolution in physiological media and is therefore biologically inert, is not adequately supported. The adaptation therefore fails to meet any requirement of Annex XI.

In the comments, the Registrant states that any decision regarding additional testing for the inorganic pigment zirconium praseodymium yellow zircon should be postponed until new scientific information becomes available through the Rare Earth Consortium for basic praseodymium compounds. According to the Registrant, genetic toxicity studies are currently ongoing. ECHA understands that the results of these tests are proposed to be used

in a read-across approach to possibly predict the properties of the registered substance once the studies have been concluded. On 21 May 2013, ECHA was informed by the Registrant's consultant that the results of the tests will not be available in time and, therefore, the dossier will not be updated before ECHA notifies its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation; the Registrant acknowledged that the decision therefore cannot take into account any updates received after the notification date. Hence, the read-across approach currently lacks reliable documentation and justification and cannot be considered in this draft decision.

No valid adaptation was provided, and no test information for this endpoint is included in the registration dossier. Consequently there is an information gap and it is necessary to generate the data for this endpoint. Therefore, the Registrant is requested to submit the information for this endpoint using one of the abovementioned test methods on the registered substance.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by the Registrant and by other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In relation to the information required by the present decision, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new study is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade registered to enable the relevance of the study to be assessed.

V. General requirements for the generation of information

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VI. 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