EUROPEAN CHEMICALS AGENCY

Helsinki, 16 October 2017

Addressee: [redacted]

Decision number: CCH-D-2114375555-40-01/F
Substance name: cerium dioxide
EC number: 215-150-4
CAS number: 1306-38-3
Registration number: [redacted]
Submission number: [redacted]
Submission date: 28.02.2011

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.) of the registered substance;**
   - **Clarification of the origin of the [redacted] compounds reported as impurities of cerium oxid**
   - **Composition not fully accounted**
2. **Description of the analytical methods (Annex VI, Section 2.3.7);**

You are required to submit the requested information in an updated registration dossier by **23 January 2018**. 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, Jos Mossink, Head of Unit, Evaluation, Substance Identification & Data Sharing

[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.)

Annex VI, section 2.3. of the REACH Regulation requires that compositional information reported in a registration dossier is sufficient to enable the substance identity to be verified.

a) Clarification of the [redacted] compounds reported as impurities of cerium oxide

A mono-constituent substance is identified by the chemical name and other identifiers (including the molecular and structural formula) of the main constituent and the chemical identity of the impurities and/or additives, and their typical concentration(s) and concentration range(s).

Acording to Art 3(1) of the REACH Regulation, a substance "*means any element and its compounds in the natural state or obtained by any manufacturing process* [...] *and any impurity derived from the process used* [...]". According to Annex VI 2.3.1-3, impurities are reported under the composition in the registration dossier for the registered substance. Chapter 2.2 Table 2.2 of the Guidance on substance identification and naming of substance under REACH and CLP[2] (from here on referred to as the "Guidance") gives the following meaning for impurity:

> "*An unintended constituent present in a substance as manufactured. It may originate from the starting materials or be the result of secondary or incomplete reactions during the manufacture process. While it is present in the final substance it was not intentionally added*"

Hence, where compounds are intentionally added to a manufacturing process to manufacture a specific (doped) substance, these compounds are not impurities derived from the manufacturing process for the substance registered. They therefore cannot be reported as impurities in the composition record in section 1.2 of a registration dossier.

You have reported the IUPAC name, EC and CAS numerical identifiers for cerium dioxide as the substance identity for your registration. You have reported one main constituent in the composition records in section 1.2 of your dossier with the same identifiers. You have also reported the following rare earth metal compounds as impurities in one of these composition records:

[2] Guidance for identification and naming of substances under REACH and CLP, version 3.1 November 2015 available on the ECHA website at https://echa.europa.eu/guidance-documents/guidance-on-reach

[redacted]

Their reported concentration ranges are [redacted] % (w/w) (typical value [redacted] %), [redacted] % (w/w) (typical value [redacted] %) [redacted] % (w/w) (typical value [redacted]%) respectively in each impurity record. You have reported the following in the remarks fields of the impurity records

[...]*This impurity is present in some commercial products only* [...]

These [redacted] rare earth based compounds reported as impurities in the composition record in section 1.2 may not be impurities in the context of Art 3(1) and as defined in the Guidance. From the information reported in your dossier, it is not verifiable that these reported impurities were not intentionally added to manufacture a substance with properties that are dependent on the addition of these compounds. The rare-earth metal [redacted] compounds may have been added in order to manufacture [redacted] doped cerium oxide subtances.[3] As reported in the remarks field in the impurity records in section 1.2, these [redacted] based compounds are "*present in some commerical products only*". This may indicate that they are added intentionally to manufacture specific [redacted] doped cerium oxide substances.

In case the [redacted] compounds are intentionally added to a manufacturing process to manufacture [redacted] doped cerium dioxide substances, these compounds are not impurities derived from the manufacturing process for the cerium oxide substance registered. They therefore cannot be reported as impurities in the composition record in section 1.2 of your registration dossier for cerium oxide.

When the [redacted] compounds are intentionally added to a manufacturing process and the substance manufactured has as its main constituent [redacted] doped cerium dioxide (due to the [redacted] atoms entering the crystalline lattice), the substance identity is based on the identity of all these constituents.

Note that cerium dioxide, [redacted] doped cerium dioxide, [redacted] doped cerium dioxide have different substance identities as they differ in the structural and molecular formulae. Their qualitative and quantitative compositions differ in that the constituents have different identities and their molecular formulae include the dopant (e.g. CeO_2, [redacted] etc.).

[3] It is known that rare earth metal doped cerium dioxides are manufactured for their specific properties that differ from those of non-doped cerium oxides (e.g. Physical, chemical and electrochemical properties of pure and doped ceria; Mogensen et al., Solid State Ionics 129 (2000) 63–94). For example, gadolinium doped cerium dioxide is commercially known as GDC or GCO is marketed as a component of solid oxide fuel cells according to information available in supplier websites such as the Sigma-Aldrich catalog (http://www.sigmaaldrich.com/catalog/product/aldrich/572357?lang=fi&region=FI). Lanthanum doped cerium oxide (abbreviated as LDC in some scientific literature) is also used as an anode material in fuel cell applications (e.g. http://rd.springer.com/article/10.1007/s10853-016-9736-7)

Each dopant intentionally added to a manufacturing process yields a substance with specific properties (i.e. [redacted] doped cerium dioxide does not have the same substance identity as [redacted] doped cerium dioxide). Hence cerium dioxide and doped cerium dioxide cannot be considered the same [4], i.e. [redacted] doped and/or [redacted] doped cerium dioxide substances cannot be registered under the identifiers for cerium dioxide.

You are therefore requested to revise the substance identity information reported in section 1.2 of your dossier and clearly report what you are covering with this registration. In case [redacted] compounds are reported as impurities, you are requested to clarify the origin of these impurities in section 1.2 and revise as appropriate the composition based on the considerations described above. In this case your registration will not cover [redacted] doped cerium oxide.

Should [redacted] compounds intentionally be added, these compounds cannot be reported as impurities in the cerium oxide composition and will need to be removed. [redacted] doped and/or [redacted] doped cerium dioxides in principle would be registered separately.

If your manufacturing process results in cerium oxide and doped cerium oxides the information submitted in accordance with Annex VI(2) shall be sufficient to enable the substance identity to be verified. You will need to revise as appropriate the name and other numerical identifiers, the compositional information and the description of the analytical methods, so that these cover both cerium oxide and the [redacted] doped cerium oxides.

The technical reporting of the identity information in the technical registration dossier will depend on the revisions made:

- Where the registration is for cerium dioxide, only impurities that are derived from the cerium dioxide manufacturing process should be reported in the impurity section (i.e. where e.g. [redacted] is present as an impurity). It needs to be clearly stated in the remarks field in the impurity record that the rare each compound is an impurity resulting from the manufacture of cerium oxide. Any [redacted] compounds that are not impurities derived from the cerium oxide manufacturing process are to be removed from the composition records in section 1.2.

[4] Note that according to EINECS reporting rules, chemicals which were doped with metals were reportable in cases where the dopant enters the crystalline lattice and therefore had their own substance identity.* This principle was also implemented under the 6th and 7th amendments of Directive 67/548/EEC as documented in the non-confidential draft of the Manual of Decisions (section 2.10.1 Luminescent Materials and section 2.7 phosphate catalyst doped metal ions).** The placing on the market of doped chemical not listed in EINECS was subject to notification under the 6th and 7th amendments of Directive 67/548/EEC even if the precursors were themselves already listed in EINECS. The rationale is based on the definition of a substance as the outcome of a manufacturing process. As indicated in the Guidance, the EINECS rules should be regarded as the common base for identifying and naming substances.
* Compilation of EINECS: description and definitions used for UVCB substances: plant products (post reacted) naturally occurring substances, micro-organisms, petroleum products, soaps and detergents, and metallic compounds; Toxicological and Environmental Chemistry, 1999, Vol. 69, pages 403-416
** Manual Of Decisions For Implementation Of The Sixth And Seventh Amendments To Directive 67/548/EEC On Dangerous Substances (directives 79/831/EEC and 92/32/EEC) 2002 EUR 20519EN

- Where the registration is supposed to cover cerium dioxide and specific doped cerium dioxide, you will need to revise the substance identity information to refer to the substances registered explicitly. Technical instructions on how to fill fields in IUCLID 6 in the identity sections are given below
    - The name and other identifiers reported in section 1 will refer to the substances registered (e.g. cerium oxide and [redacted] doped cerium oxide)
    - The current CAS number can be reported in the "other identifiers" field.
    - The current EC number cannot be removed from the EC number field due to technical reasons relating to the submission of your updated dossier in REACH-IT. You will need to report the following in the remarks field "*The EC number xxx reported is not an appropriate numerical identifier for this registration. This identifier could not be modified or deleted in the (ad date) registration update for technical reasons*". In this case, you will be contacted at a later stage to formalise the change of numerical identifiers to one appropriate for your substance identity.
    - Composition records for each cerium dioxide and specific doped cerium dioxide are to be reported in section 1.2 of your dossier.
    - Analytical data that is sufficient to verify the identity and compositional information is to be attached to section 1.4 of your dossier.

- In your comments to the draft decision, you included clarification relating to the impurities that originate from the manufacture of cerium dioxide and your commitment to revising the reporting in your updated dossier.

b) Reporting of 100 % of the substance

Following the principles outlined in section 4.2 of the Guidance for the compositional information reported for well-defined substance needs to account for all constituents, i.e. "cover the composition up to 100%". It also outlines that

- Each main constituent (i.e. the constituent that contributes to ≥ 80% for a mono-constituent substance identity or each constituent that contributes at ≥ 10% and < 80% for multi-constituent substance identity) is required to be identified and reported individually; and

- Each impurity present at ≥ 1% or relevant for the classification and/or PBT assessment of the registered substance is required to be identified and reported individually.

- The typical, minimum and maximum concentration values for each reported constituent are required to be reported.

You reported two different composition records in section 1.2 of your IUCLID dossier, "*bulk cerium oxide*" and "*nano cerium oxide*". The "*nano cerium oxide*" composition record reports a main constituent concentration range of [redacted] %(w/w). No impurities were reported.

Therefore [redacted]% (w/w) of the compositional information covered by the substance identity is unaccounted for. Consequently, the compositional information provided is not sufficient as the impurity profile is not reported.

You are accordingly requested to revise the compositional information reported in section 1.2 of the dossier such that the compositional profile in the "*nano cerium oxide*" composition block is fully accounted for.

Further technical details on how to report details on the constituents of a substance in IUCLID are available in the section 9.4.2 of ECHA manual "How to prepare registration and PPORD dossiers" (https://echa.europa.eu/manuals).

In your comments to the draft decision, ECHA notes your statement that [...] *In our registration dossier, we have indicated a nanoform composition. It concerns the colloidal Cerium dioxide (6 to 7 t/y from 2013 to 2016). We had reported a variable purity in the dossier (from 80 to 100%) because we had considered the substance definition of a mono-constituent substance that was mentioned in the Guidance document (as decribed in § 1 of this document). But in reality, this nano Cerium dioxide is* [redacted]*% pure.*[...]. ECHA notes that based on this clarification, you do not have impurities to report in the composition record. Updating your dossier with the revised reporting of the compositional information as outlined in your comments would address the request made.

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

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.

According to Annex VI, section 2.3.7 of the REACH Regulation, a registration dossier shall report a description of the analytical methods or the appropriate bibliographic references for the identification of the substance and where appropriate for the identification of impurities and additives. The reporting shall be given in sufficient detail that the methods may be reproduced.

You have included XRF data reporting the elemental content expressed as hypothetical oxides in files attached to section 1.4 of your dossier ("[redacted]" and "[redacted]") for both composition records ("*bulk cerium oxide*" and "*nano cerium oxide*") reported in section 1.2. In these reports, the content of [redacted] and [redacted] is expressed as hypothetical [redacted] respectively. In both cases, it is reported as "< [redacted] %). No quantitative data for the impurities [redacted], [redacted] and [redacted] reported in the "*bulk cerium oxide*" composition record was included in section 1.4.

The XRF data is not sufficient for the verification of the impurities currently reported in the "*bulk cerium oxide*" composition record. The hypothetical oxide content reported does not refer to chemical constituents but rather the content of an element (e.g [redacted]) in a given test sample expressed as hypothetical oxides (e.g. [redacted] expressed as [redacted]). XRF data alone is not sufficient to verify the identity or quantification of the impurities reported in 1.2 ([redacted]). In addition the sample selected for testing does not seem to have detectable [redacted] content based on the values reported (< [redacted] % which may refer to the detection limit for the method used). Where the three reported impurities are impurities from the manufacture of Cerium oxide, quantitative and qualitative information is required to be reported to enable the compositional information reported in section 1.2 to be verified. Note that solely impurities from the manufacture of Cerium oxide are to be reported in the composition of cerium oxide.

You are accordingly requested to provide sufficient quantitative analytical data that will enable the impurities reported in section 1.2 of your dossier to be verified. You may report the use of any method or combination of methods provided the data reported is sufficient to enable the identity and composition to be verified.

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 data provided on the quantification of the substance shall be consistent with the composition and identity reported for the substance.

Technical instructions on how to report the requested information:

- the quantitative analytical method description shall be attached in IUCLID Section 1.4.

In your comments to the draft decision, you clarified that the current analytical data submitted refers to what is registered by you and that the compositional information reported in section 1.2 will be revised. This request would be addressed with the revision to the compositional reporting as outlined in your comments.

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 14 October 2015.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

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

ECHA took into account your comments and did not amend the requests.

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.

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2019.

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

3. 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.