ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114309033-66-01/F Helsinki, 28 September 2015

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

For Aluminum oxide (Al2O3), solid soln. with cerium oxide (CeO2) and magnesium oxide, terbium-doped, EC No 310-017-8 (CAS No 102110-19-0), 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 for Aluminum oxide (Al2O3), solid soln. with cerium oxide (CeO2) and magnesium oxide, terbium-doped, EC No 310-017-8 (CAS No 102110-19-0), submitted by [redacted] (Registrant). The scope of this compliance check decision is limited to the standard information requirement of Annex VI, Section 2 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 10 to 100 tonnes per year.

This decision does not take into account any updates after the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

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

The compliance check was initiated on 30 June 2014.

On 27 May 2015 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 3 July 2015 the Registrant did not provide any comments on the draft decision to ECHA.

On 23 July 2015 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 for amendment of the draft decision within 30 days of the receipt of the notification.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Name, molecular and structural formula or other identifiers of the substance (Annex VI, 2.1 and 2.2);
2. Composition of each substance (Annex VI Section 2.3).

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **4 January 2016** an update of the registration dossier containing the information required by this decision.

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 requirements.

Information in the technical dossier related to the identity of the substance

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. Name, molecular and structural formula or other identifiers of the substance (Annex VI, 2.1 and 2.2)

ECHA notes that the Registrant has not provided sufficient information to identify the substance, as required by Annex VI, Sections 2.1 and 2.2 of the REACH Regulation. Based on the information included in Section 1.1 of the dossier, it is not possible to unambiguously establish the identity of the substance registered.

More specifically, the Registrant identified the registered substance as a well-defined mono-constituent substance. ECHA observes that a generic EC and IUPAC name "Aluminum oxide (Al2O3), solid soln. with cerium oxide (CeO2) and magnesium oxide, terbium-doped" has been provided for the identification of the registered substance. The CAS entry 102110-19-0 associated with the EC number 310-017-8 refers however to an unspecified substance, namely "[redacted]" of not defined stoichiometry and with a UVCB Subset Heading "[redacted]".

The XRDPD analysis shows a pattern that was assigned to a specific main constituent, terbium-doped aluminium cerium magnesium oxide of defined stoichiometry $Ce_{0,67}Tb_{0,33}MgAl_{11}O_{19}$ (which can be associated with the CAS registry entry 112568-99-7). However the Registrant concluded (in the attached report "[redacted]") that: "*$Ce_{0,67}Tb_{0,33}MgAl_{11}O_{19}$ may not be representative for all the investigated batches since the % of used terbium (the dopant) differs from batch to batch. However, this $Ce_{0,67}Tb_{0,33}MgAl_{11}O_{19}$ sample is the only reference that could be identified in the XRPD database.*"

Furthermore, a generic molecular formula ((Ce,Tb) $MgAl_{11}O_{19}$) and molecular weight range (767-774 g/mol) has been provided in section 1.1 of the dossier, indicating that the relative content of Ce and Tb may vary within certain limits. It is explained in the remarks field of section 1.1 and in the attached analytical report that the MW is calculated for specific stoichiometries of $Ce_{0,9}Tb_{0,1}MgAl_{11}O_{19}$ and $Ce_{0,5}Tb_{0,5}MgAl_{11}O_{19}$ that are expected as the minimum and maximum for the dopant(s) concentration. Additionally, in section 3.1 of the dossier the Registrant states: "*The substance is an inorganic substance that is the reaction product of high temperature calcination in which Ceriumoxide (CeO2), Aluminiumoxide (Al2O3), Magnesiumoxide (MgO) and Terbiumoxide (Tb4O7) in varying amounts are blended and subsequently fired in a production furnace to form a crystalline, chemical compound.*" This description indicates that the stoichiometry may vary due to the use of different materials in the process. In addition, significant variability in the composition of the registered substance is reported in section 1.2 of the registration dossier, as explained in details in section III, 2 below.

Therefore, based on the information provided in the dossier, the EC, CAS and IUPAC identifiers and the description of the substance and the manufacturing process are not consistent with the identification of the substance as being well-defined. These identifiers may cover in principle any mixed metal oxide that contains aluminium, cerium, magnesium and which is terbium-doped. Consequently ECHA concludes that the Registrant has not provided sufficient information on the identity of the substance.

The Registrant shall note that in accordance with chapter 4.1 and 4.2 of the Guidance for identification and naming of substances under REACH (Version: 1.3, February 2014), referred to as "the Guidance" hereinafter, well-defined substances are those with fully defined qualitative and quantitative composition. Each constituent of a well-defined substance requires a complete chemical specification, including structural information. This implies that constituents of well-defined substances must have unique definitive molecular formulae. Contrary to well-defined substances, UVCB substances are those for which the constituents are either variable or partially unknown.

In line with Annex VI, Sections 2.1 and 2.2 the Registrant is requested to revise the name, molecular formula and other identifiers so that the registration unambiguously identifies the substance registered. The Registrant shall ensure that the information reported is consistent throughout the dossier.

Should the Registrant choose to describe the substance as a well-defined mono-constituent substance, the stoichiometry is required to be defined and cannot refer to undefined variables (e.g. x, y etc.) and ranges (e.g. $0 < x < 1$). In such a case, the molecular formula and name included in the IUPAC name field shall be revised to refer to specific values and ranges and a precise molecular weight shall be indicated. Regarding how to report the requested information in IUCLID the following applies:

- The revised chemical name that is representative of the stoichiometry shall be included in the IUPAC name field and the details of the grades (compositions of specific stoichiometry/dopant concentration(s) as relevant) covered by the registration shall be included in the Description field in Section 1.1 of the IUCLID, respectively. The composition of each grade shall be reported seperately in section 1.2. and sufficient analytical data for the grade(s) shall be included in section 1.4. Information referring to other substances shall be removed from section 1 of the dossier.
- The revised molecular and structural formula and other identifiers shall be included in their respective fields in Section 1.1 of the IUCLID dossier.

- The relevant appropriate CAS entry, if available, shall be included in the "CAS information" field. For the EINECS entry, see the technical instructions below.

If, however, the Registrant considers that the substance should rather be identified as a UVCB substance, he shall then follow the recommendations on naming provided in Section 4.3.1.2 of the Guidance. In that instance, the Registrant is also reminded that according to the Guidance, the naming of a UVCB substance consists of two parts: the chemical name and the more detailed description of the manufacturing process. Accordingly, the Registrant should report an appropriate chemical name of the substance that is representative of the registered substance and to provide details of the process used for the manufacturing of the registered substance. For UVCB substances, the main identifiers are typically related to the source of the substance and the specific manufacturing process used; e.g. "[process type] products of [reactant 1] and [reactant 2] and etc." The Registrant may also consider identifying the UVCB substance based on the products e.g. "mineral 1 and mineral 2 and mineral 3 etc." if this is more appropriate. In particular where the alpha - Al_2O_3 constituent is present in the substance in a significant amount, it shall be reflected in the IUPAC name of the registered substance.

The description of the manufacturing process shall include, as appropriate:

- The identity and ratio of starting materials /reactants, including also all auxiliary agents
- Calcination temperature and duration
- Any post-treatment carried out
- A description of any other relevant operating parameters or process

If the substance covered by the registration is manufactured according to different manufacturing processes, including the use of different sources, or ratios of starting materials, then the detailed description of the manufacturing process required hereinabove shall be reported separately for each manufacturing process. A manufacturing process may be considered different when the processing steps and/or processing parameters are different.

Regarding how to report the requested information in the IUCLID dossier, the following applies as appropriate:

- The relevant chemical name shall be included in the IUPAC name field in Section 1.1 of the IUCLID dossier.
- The relevant molecular and structural formula and other identifiers shall be included in their respective fields in Section 1.1 of the IUCLID dossier.
- Where the substance is identified as a UVCB, the description of the manufacturing process of the UVCB substance shall be included in the Description field in Section 1.1 of the IUCLID dossier.

Where the current EC identifier is not sufficient to identify the registered substance, because it would be necessary either to take account of further constituents of the substance or reflect the range of stoichiometry of elements, the Registrant shall indicate in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC entry 310-017-8 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". The Registrant shall also specify, in the same "Remarks" field, any available and appropriate EC/list number for the substance. In addition, the Registrant

should note that ECHA has established processes, subject to certain conditions, enabling registrants to adapt the EC/list identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

Further information on how to report the chemical name, the molecular and structural formula, other identifiers and the description of the manufacturing process is available in the "Data Submission Manual Part 18 - How to report the substance identity in IUCLID 5 for registration under REACH" published on the ECHA website at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

Where the substance is identified as mono-constituent, the current EINECS and associated CAS entry are not appropriate and require revision. However for technical reasons it is not possible to revise the entry as the updated dossier would be considered as a new submission with associated fees in the IT system. The Registrant shall then indicate in the "Remarks" field of the reference substance in IUCLID section 1.1, the following: "The EC entry 310-017-8 currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified or deleted at this stage in the present registration update for technical reasons". The Registrant shall also specify, in the same "Remarks" field, any available and appropriate EC/list number for the substance. In addition, please note that ECHA has established processes, subject to certain conditions, enabling registrants to adapt the EC/list identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

2. Composition of each 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 cornerstone of all the REACH obligations. ECHA notes that the Registrant has not included sufficient information on the composition of the registered the substance.

ECHA notes that the Registrant has reported one main constituent "Aluminum oxide (Al2O3), solid soln. with cerium oxide (CeO2) and magnesium oxide, terbium-doped" present at [redacted]% (typically [redacted]%) and the following impurities aluminium oxide (Al_2O_3 alpha) [redacted]% (typically [redacted]%), Spinel ($Mg(AlO_2)_2$) [redacted]% (typically [redacted]%) and other unknown impurities [redacted]% (typically [redacted]%) in section 1.2.

The Registrant asserts both in the remarks field for this constituent and in the analytical report attached in section 1.4 that Al_2O_3 is an unreacted starting material and shall be reported as an impurity: *"As in accordance with the ECHA guidance (the) reaction product(s) contribute(s) to the composition of the substance and determine(s) the naming of the substance (and not unreacted raw materials), aluminiumoxide (Al2O3) is reported as an impurity and not as a constituent of a reaction mass, although the concentration of the reaction product CAT may be well below 80% (w/w) and the concentration of unreacted aluminiumoxide (Al2O3) may be up to 40% (w/w)."*).

As a preliminary consideration, ECHA observes that the reported concentration ranges are overly broad, and the origin of these variations is not given. Therefore it cannot be verified whether the registration potentially covers more than one substance.

Based on the limited information provided in the dossier, different products are obtained and marketed, depending on the content of the differing oxides therein. For example, the analytical report attached in section 1.4 shows that different commercial products containing different amounts of the Tb-doped cerium magnesium oxide, Al_2O_3 and spinel are

manufactured. It is therefore ambiguous whether Al_2O_3 is only an unintended impurity or rather a constituent that contributes towards and is essential for the desired technical properties of the substance. As Al_2O_3 may be absent or present at concentration up to [redacted]%, in some compositions it makes up a significant part of the substance. Therefore the absence or presence of Al_2O_3 would normally be a factor determining the identity of the registered substance, and as a consequence needs to be reflected in its name, as indicated hereinabove (section III, 1).

In accordance with Article 41(3) and 41(4) of the REACH Regulation, the Registrant is accordingly required to revise the compositional information reported in section 1.2 based on the revised identity information in section 1.1, in order to ensure that the dossier refers to one substance. The concentration range values must be representative for the registered substance, as manufactured, and it should be clarified how the minimum and maximum values for each group of constituents have been arrived at and/or more details on the manufacturing process which could justify broad concentration ranges should be provided.

If the Registrant covers different grades of the same substance in a registration, the Registrant shall report separately the compositional information of each grade. This means that if the substance covered by the registration has two (or more) different compositions, then these must be presented separately. Corresponding analytical data, to enable the identity and composition of each grade listed in 1.2 to be verified, shall be included in Section 1.4. Information on how to report several compositions in IUCLID is specified in paragraph 2.3, Q&A 8 of the "Data Submission Manual – Part 18: How to report the substance identity in IUCLID 5 for registration under REACH".

ECHA highlights that failure to report separately the compositional information of each grade of a substance may result in one or more grades not being covered by this registration.

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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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