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Subject: Communication on testing and dossier update in view of compliance check
Our reference: Rare Earth Consortium
Project number: 30263212
Date: 20 March 2025

Dear co-registrants of lanthanum hydroxide,

As communicated in 2024, a final compliance check decision was received on 9th of November 2023 for lanthanum hydroxide (CAS: 14507-19-8, EC: 238-510-2).

This communication provides further news on the scheduled dossier update which is due 14th of August 2026.

- **Water solubility** (An VII, Section 7.7 – test method OECD GD 29)
 - ➔ The Consortium has **ordered transformation/dissolution testing from ECTX/BioXQ**. This testing consists of a 24-h screening test at 1 mg/L and 2 pH levels (pH 6 and 8). Depending on the results of this 24-h screening study, the need for and benefit to proceed to a full 28-d study will be decided upon. The T/D testing will be finalised in 2025.
 - ➔ **Related study cost: 5792 EUR for screening test / between 8195-11075 EUR for a full 28-d study** (depending on number of sampling occasions – to be determined).
- **Growth inhibition study aquatic plants** (An VII, Section 9.1.2 – test method OECD TG 201)
 - ➔ The Consortium has **ordered an algal growth inhibition study from Labcorp**. This study will be performed with La(NO₃)₃ and will be used in the different La compound dossiers under compliance check. In addition, an expert statement will be added on the interpretation of algal growth inhibition test results for rare earth compounds (written in 2018 based on all available data at that time and supported by equilibrium speciation modelling). Also, the Consortium is reviewing data from peer-reviewed literature and will consider adding the most relevant data to the dossier.
 - ➔ **Related study cost: approximately 26100 EUR.**
- **Long-term toxicity testing on aquatic invertebrates** (An VII, Section 9.1.1, column 2 (if T/D test confirms the substance is poorly soluble) or An IX, Section 9.1.5 – test method OECD TG 211)
 - ➔ The endpoint will be covered by a **reliable OECD 211 study performed with LaCl₃**. In addition, the Consortium is reviewing data from peer-reviewed literature and will consider adding the most relevant data to the dossier. No testing will be required.
- **Long-term toxicity testing on fish** (An VIII, Section 9.1.3, column 2 (if T/D test confirms the substance is poorly soluble) or An IX, Section 9.1.6 – test method OECD TG 210).
 - ➔ As no reliable data could be identified, the Consortium has **ordered a Fish Early Life Stage test from Labcorp**. This study will be performed with La(NO₃)₃ and will be used in the different La compound dossiers under compliance check that require the study. In addition, the Consortium is reviewing data from peer-reviewed literature and will consider adding the most relevant data to the dossier.
 - ➔ **Related study cost: approximately 88150 EUR.**

Other updates to the dossier might be needed to bring it in compliance with current best practices under REACH as well as the most recent IUCLID version. Also, relevant literature important for solidifying endpoint coverage might be added to the dossier for several endpoints.

In addition, if the T/D testing and additional long-term toxicity testing in fish results in classification for the aquatic environment, generic exposure scenarios will be developed, and a Chemical Safety Assessment will be added to the dossier.

Impact on LoA costs

The current costs of the LoA per tonnage band already include a provision for future work on the dossier. See: <http://www.rare-earth-consortium.eu/sites/default/files/substances/lanthanum-trihydroxide/may-2017-sief-communication-loas-available-for-lanthanum-trihydroxide-cas-14507-19-8-ec-238-510-2.pdf>

Part of this provision has already been used. The balance will of course be used to finance the abovementioned work on the dossier. Depending on the total cost for this update, the remaining provision maybe insufficient. In such case, the cost of the LoA per tonnage band shall be adapted accordingly and an additional invoicing to all the co-registrants can be deemed necessary.

Concerning the testing costs mentioned above:

- The testing costs for the T/D testing and the growth inhibition study in algae are considered relevant for all An VII or higher registrants.
- The testing costs for the FELS study are considered relevant for all An VIII or higher registrants (assuming confirmation of poor solubility in the T/D screening test).

Apart from the testing costs, all study monitoring costs and administrative costs for preparing the dossier update will be divided over the respective tonnage bands for which the endpoints under consideration are mandatory information requirements.

Costs related to inclusion of existing studies will be determined evaluating the 12-yr data protection rule by the time of re-submission.

With kind regards,

Arcadis Belgium nv/sa
on behalf of the members of the Rare Earth Consortium

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