

To the co-registrants of lanthanum oxide

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Subject: Compliance check La2O3
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Dear co-registrants,

On 22nd of April, ECHA has provided a draft decision to the registrants of lanthanum oxide (EC: 215-200-5, CAS: 1312-81-8). This draft decision contained requests for information on the following endpoints:

Annex VII

- Water solubility (OECD GD 29 – transformation/dissolution testing)
- Growth inhibition study aquatic plants (OECD TG 201)

Annex VIII

- Short-term toxicity on fish (OECD TG 203)
- Long-term toxicity testing on fish (if transformation/dissolution testing indicates the substance is poorly water soluble (i.e., < 1 mg/L)

Annex IX

- Long-term toxicity testing on fish (OECD TG 210)

Annex X

- Extended one-generation reproductive toxicity study by oral route in rats (OECD TG 443):
 - o 10 wk pre-mating exposure for P0
 - o Highest dose in P0 to be determined based on clear evidence of adverse effect on sexual function and fertility without severe suffering or deaths in P0, or to follow limit dose concept.
 - o Cohorts 1A and 1B (reproductive toxicity)
 - o Cohorts 2A and 2B (developmental neurotoxicity)

This draft decision has been discussed in the Rare Earth Consortium in order to prepare an answer on behalf of the registrants, which was provided to ECHA by the Lead Registrant Albemarle.

The draft decision was notified by ECHA to the competent authorities of the Member States. On 2nd of December, ECHA notified the members of the joint submission for lanthanum oxide of a proposal for amendment of the draft decision received from the Netherlands. The proposal for amendment was mainly to specify in the summary of the decision that investigations on learning and memory function are requested, including some changes in the section elaborating on this specific request. Originally, the choice between Morris water maze test and Radial arm maze test was given (for one time point), and Cincinnati water maze test was requested as well (for another time point). However, the Netherlands suggested only the Morris water maze test for the one time point and the Cincinnati water maze test for the other time point (see attached for the proposed change).

The proposed change was again discussed within the Consortium and a reply was submitted by the Lead Registrant Albemarle (on behalf of all registrants) before the deadline of 3rd of January 2023 imposed by ECHA.

The Consortium will now await the final decision before further discussing and deciding on the strategy for complying with ECHA's additional information request. This strategy might include inclusion of literature or other data that have become available recently, revision of the read across strategy and its justification, and/or testing, depending on the endpoint. Once decided, the members of the joint submission will be informed accordingly.

Impact on LoA (Letter of Access) costs

The costs of the LoA per tonnage band include a provision for future work on the dossier. Part of this provision has already been used. The balance will of course be used to finance the remaining work to perform on the dossier based on the final decision.

Depending on the total cost for complying with ECHA's request, the remaining provision may be insufficient. In such case, the cost of the LoA shall be adapted accordingly and an additional invoicing to the co-registrants can be deemed necessary.

Because the final decision is not known yet, it is not possible to provide any estimate of such financial impact on the LoAs for the time being.

In the meantime, if there are specific questions, please send an e-mail to the Consortium's mailbox, hosted by Arcadis (see below for the e-mail address).

With kind regards,

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

E-mail: rare-earth-consortium@arcadis.com

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