

To the co-registrants of neodymium oxide

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Subject: Status update transformation/dissolution testing
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Dear co-registrants,

As previously communicated, a compliance check decision was received for neodymium oxide (EC 215-214-1, CAS 1313-97-9, final decision dd 26 November 2018). As a result of this decision – among others – a Transformation/Dissolution study (T/D, OECD 29) needed to be performed, to cover the endpoint ‘water solubility’ as well as to determine the environmental classification of the substance.

This test needed to be performed to understand the solubility of the substance under environmentally relevant conditions and to enable comparison of the obtained dissolved neodymium concentrations with Ecotoxicity Reference Values (ERVs) derived based on testing with ‘water soluble’ neodymium salts. This is in line with the ECHA Guidance on the Application of the CLP Criteria (Version 5.0, July 2017) and the approach detailed for metals and inorganic metal compounds.

The results obtained during the 24-h screening T/D test showed that the dissolved neodymium concentration at the pH maximising dissolution was above the acute ERV for neodymium. Following the CLP guidance, the metal compound should be considered as readily soluble in such case. Therefore, no further T/D testing was done after the screening assay and appropriate classification was duly applied: Aquatic Chronic Cat. 1 (under CLP and GHS) and Aquatic Acute Cat. 2 (only under GHS). It should be noted that the aquatic acute classification might even be challenged because of the ERV being very close to the 1 mg/L cut-off, and therefore, even Aquatic Acute Cat. 1 may be imposed.

Discussions with the Rare Earth Consortium members have shown this classification is problematic for a number of reasons, but in particular due to the alteration it will imply in packaging requirements and the possibility of having to change packaging for shipments.

The T/D study undertaken for Nd₂O₃ followed the OECD protocol. However, it has been noted by Eurometaux that the strategy for T/D testing applied by the metal industry deviates from this protocol as well as the CLP guidance. For instance, the loading rate during the 24-h screening test should be 1 mg/L instead of 100 mg/L. The reason for this is that the 100 mg/L loading rate is not an active cut-off level for acute aquatic classification under CLP. ECHA is aware of this difference and unofficially accepts a T/D study using the approach followed by metal industry as well as the standard OECD guideline study.

With this knowledge, the impact of this difference in study design has been considered, and a decision has been made to perform an additional 28-d T/D study at the 1 mg/L loading rate with sampling occasions at 24 h, 7 d and 28 d (at pH 6, the maximising pH). The results of this study might lower or even completely remove the current acute and/or chronic classification for neodymium oxide.

This additional T/D study has recently been contracted with BIOXQ bv laboratories in Belgium who are a specialist facility experienced in the conduct of such studies. The cost of the study is estimated to be ca. 9,500 EUR (study design, monitoring, analysis of results, update of the registration dossier, etc. not included) and it is expected that the study will be completed and reported in Q3 2023.

Impact on LoA cost (Letter of Access)

As the T/D study is also a required study under the water solubility endpoint under REACH, which is an Annex VII endpoint, an impact on future LoA costs is anticipated.

As it concerns an Annex VII endpoint, the cost is considered relevant for all registrants in all tonnage bands.

The current costs of the LoA per tonnage band already include a provision for future work on the dossier. See: [may-2017-sief-communication-loas-available-for-neodymium-oxide-cas-1313-97-9-ec-215-214-1.pdf \(rare-earth-consortium.eu\)](#)

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 may be 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.

Please check our website for the latest information: <http://www.rare-earth-consortium.eu>. Should you have any comment or question on the status of the ongoing test or the dossier update for the substance neodymium oxide (EC 215-214-1, CAS 1313-97-9), you can reach us at rare-earth-consortium@arcadis.com.

With kind regards,

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on behalf of the members of the Rare Earth Consortium

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