

To the co-registrants of neodymium oxide

Arcadis Belgium nv/sa
Gaston Crommenlaan 8 bus 101
9050 Ghent
Belgium
Tel 02 505 75 00
Fax 02 345 98 34
www.arcadis.com

Subject: Re-submission of Nd₂O₃ dossier in view of compliance check + adjustment of environmental classification + repeat of ASRI study

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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 and after careful consideration of alternative ways to cover the commented endpoints, the following studies were run:

An VII

- Section 7.7 - Water solubility: Transformation/dissolution 24-h screening study and 28-d full study with Nd₂O₃ (OECD guidance document 29). These tests were required for covering the water solubility endpoint as well as for determination of the environmental classification. **TOTAL COST = 17761.20 EUR.**
- Section 9.1.5 – Long-term toxicity to aquatic invertebrates with Nd(NO₃)₃ (OECD 211). Test performed with a water-soluble Nd salt according to the metal-specific guidance. **TOTAL COST = 22690.35 EUR.** It should be noted that the OECD 211 study is considered relevant for all co-registrants as it is triggered from An VII (Section 9.1.1, column 2) onwards due to poor water solubility (< 1 mg/L).

An VIII

- Section 9.1.4 – Activated sludge respiration inhibition testing with Nd(NO₃)₃ (OECD 209). Test performed with a water-soluble Nd salt according to metal-specific guidance. **TOTAL COST = 4498.20 EUR.**
- Section 9.1.6.1 - Long-term toxicity to fish – Fish, Early-Life Stage (FELS) test with Nd(NO₃)₃ (OECD 210). Test performed with a water-soluble Nd salt according to metal specific guidance. **TOTAL COST = 52544.25 EUR.** It should be noted that the OECD 210 study is considered relevant for all co-registrants in An VIII or higher, as it is triggered from An VIII (Section 9.1.3, column 2) onwards due to poor water solubility (< 1 mg/L).

An IX

- Section 8.6.2 – Sub-chronic toxicity study (90-d) via oral route with Nd₂O₃ (OECD 408) in combination with neurotoxicity testing (OECD 424). **TOTAL COST = 347780.90 EUR.**
- Section 8.7.2 – Pre-natal developmental toxicity study in a first species (rat) via oral route with Nd₂O₃ (OECD 414). **TOTAL COST = 167903.10 EUR.**

Due to the significant delay in the laboratory for higher-tier mammalian toxicity studies, the final report of the sub-chronic toxicity study was received very late. Therefore, a **dossier re-submission** had to be done, which took place on **16th of December 2024.**

This re-submission **included the studies mentioned above** and any **changes** that were required to take account of this data such as the derivation of **PNECs and DNELs and the toxicokinetics assessment.** **General updates** to the substance dataset were also performed to ensure the dataset is compliant with current REACH best practices as well as the latest version of IUCLID.

Previously, Nd₂O₃ was not classified for any physical, human health or environmental hazard. However, the results of the 28-d full transformation/dissolution study have shown that the substance – when strictly following the classification scheme given in the ECHA CLP guidance – needs to be **classified as Aquatic Chronic 1**. This classification was also

included in the dossier update. In addition, this classification meant that a **full CSR** was needed **including exposure scenarios** and this has also been added to the dossier.

We would like to inform you that **these changes will require members of the joint submission to update their dossiers**. For this reason, a **new generic CSR** is provided together with this communication.

Further, we would like to inform you that the **ASRI study (OECD 209) with Nd(NO₃)₃ performed at Labcorp was invalidated due to identified issues investigated during a GLP audit by the UK monitoring authority (MHRA)**. After considering the options offered by Labcorp, it has been agreed to **repeat the study at the cost of Labcorp** at a subcontracted laboratory (Agrochemex). **In addition, Labcorp agreed to pay an additional compensation of 3000 EUR** for the need to repeat study monitoring and update the dossier after finalisation of the study. It should be noted that repeating the study is not expected to result in a significantly different outcome of the study, but the current study's GLP status is invalidated and therefore repeating the study is required. **This is not expected to have (significant) cost implications for the registrants.**

Impact on LoA cost (Letter of Access)

The current costs of the LoA per tonnage band (as published in 2017) included a small provision of 10 kEUR (ten thousand EUR) 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](https://rare-earth-consortium.eu/may-2017-sief-communication-loas-available-for-neodymium-oxide-cas-1313-97-9-ec-215-214-1.pdf) (rare-earth-consortium.eu)

However, this provision is not sufficient to cover the testing mandated by ECHA's abovementioned compliance check decision for the neodymium oxide (EC 215-214-1, CAS 1313-97-9) dossier.

In a 27 August 2020 communication, an estimate of the additional testing costs (c.a. 700,000 EUR) was notified to the co-registrants of neodymium oxide. See: [august-2020-sief-communication-dossier-update-neodymium-oxide.pdf](https://rare-earth-consortium.eu/august-2020-sief-communication-dossier-update-neodymium-oxide.pdf)

Now that the dossier has been finalised, the balance will be calculated. It is noted that the total costs not only include the actual testing costs mentioned above, but also the consultancy and administrative costs for study monitoring, dossier update, and project management and meetings directly related to the dossier update. The cost of the LoA per tonnage band shall be adapted accordingly and an additional invoicing to the involved co-registrants will be necessary.

It is expected that the new LoA price for neodymium oxide will be calculated and published in 2025. This choice of timing is also aligned with the expiry of the 12 years data protection period under EU REACH for this substance.

Concerning the additional amounts that are expected to be invoiced to co-registrants who purchased an LoA, those companies will be informed individually and presented with a justification of the additional costs.

Please check our website for the latest information: <http://www.rare-earth-consortium.eu>. Should you have any comment or question about the dossier update or status of the LoA recalculation and expected future invoicing to co-registrants 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,

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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