

To the co-registrants of Neodymium Oxide

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Dear co-registrants,

The Lead Registrant for the substance Neodymium Oxide EC No 215-214-1 (CAS No 1313-97-9), NPM Silmet OÜ, received in 2017 a notification of a draft decision on a compliance check. The Lead Registrant and the SIEF members shared their comments to ECHA.

The **final decision on a Compliance Check issued by ECHA on November 26th, 2018** concluded on the necessity to conduct a series of additional tests in order to meet the requirements for the tonnage band 100-1000 tpy.

The following tests are currently conducted in order to meet the requests from ECHA:

- Transformation/Dissolution Screening Study (Annex VII, Section 7.7 Water Solubility, test method: 24 hours Transformation/Dissolution Screening Study, OECD TG 29) with the registered substance. This test is performed to understand the solubility of the substance in environmentally relevant conditions. The results of the Transformation/Dissolution test are also to be used for the determination of environmental classification. Based on the results of the screening test, no further T/D testing is considered required.
- Long-term toxicity testing on aquatic invertebrates (Annex IX\*, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211). This test is performed with Nd trinitrate, a water-soluble neodymium salt, because aquatic toxicity data for inorganic metal compounds should be generated with water soluble salts according to the metal-specific guidance.
- Long-term toxicity testing on fish (Annex IX\*, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210). This test is performed with Nd trinitrate, a water-soluble neodymium salt, because aquatic toxicity data for inorganic metal compounds should be generated with water soluble salts according to the metal-specific guidance.
- Activated sludge respiration inhibition testing (Annex VIII, Section 9.1.4.; test method: Activated sludge, respiration inhibition test (carbon and ammonium oxidation), OECD TG 209). This test is performed with Nd trinitrate, a water-soluble neodymium salt, because aquatic toxicity data for inorganic metal compounds should be generated with water soluble salts according to the metal-specific guidance.
- Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.43./OECD TG 424) in rats, and in accordance with paragraph 16 of OECD TG 424, the study protocol shall be combined with method EU B.26 or OECD TG 408, with the registered substance
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat), oral route with the registered substance.

\* Although these tests are related to the Annex IX (100-1000 tpy) data requirements, they are relevant for lower tonnage bands as well as they are needed for the derivation of a reliable long-term Ecotoxicity Reference Value and the determination of the environmental classification of the substance.

- The OECD 211 test is relevant for all co-registrants (rationale: As stated in REACH Annex VII: The long-term aquatic toxicity study on Daphnia (Annex IX, section 9.1.5) shall be considered if the substance is poorly water soluble.).
- The OECD 210 is required for Annex VIII co-registrants only. (rationale: As stated in REACH Annex VIII: The long-term aquatic toxicity study on fish (Annex IX, section 9.1.6) shall be considered if the substance is poorly water soluble.)

As mentioned in the previous SIEF communication related to the notification of this draft decision, additional testing is associated to increased costs considered in the LoA calculation.

The **additional testing costs** are estimated at approximately **700.000 €** (ca 44 k€ for Annex VII, ca 62 k€ for Annex VIII and ca. 593k€ for Annex IX). Note that these costs do not include the costs linked to the study monitoring, dossier and CSR update and project management; these costs will also be integrated in the LoA calculation at a later stage, likely triggering an increase of the cost of the LoA for the different tonnage bands.

The LoA costs will be re-assessed during 2020 at the occasion of the yearly exercise. If the impact of these additional costs is significant on the LoA-costs, additional amounts could be invoiced to the co-registrants who purchased a LoA. Those companies will be informed individually.

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 tests or the dossier update for the substance Neodymium Oxide EC No 215-214-1 (CAS No 1313-97-9), you can reach us at [rare-earth-consortium@arcadis.com](mailto:rare-earth-consortium@arcadis.com).

With kind regards,  
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