

Dear SIEF members,

The Lead Registrant for the substance NEODYMIUM OXIDE (CAS 1313-97-9; EC 215-214-1), NPM Silmet OÜ, has received a notification of a draft decision on a compliance check. The Lead Registrant and the SIEF members are invited to send any comments to ECHA within a period of 30 days.

The draft decision was shared with the SIEF members, who are requested to share comments before the **15th of December 2017** at the latest. The LR will reply to ECHA and share the comments that were made.

For your information the following endpoints need to be re-assessment and further information is to be provided:

1. 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;

2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route with the registered substance ;

3. 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) with the registered substance;

4. 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) with the registered substance; More information is detailed in the draft decision: the studies used to cover the endpoints are mentioned as well as the reason why ECHA considers the approach insufficient.

5. 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) with the registered substance

Since this draft decision will trigger **additional testing** and therefore **impact the final cost of the LoAs**, please take the time to share your comments on this matter. Should the foreseen provisions for future costs per tonnage bands already included in the price of the LoAs become insufficient, the LR has the right to invoice additional amounts to SIEF members having already purchased a LoA in the past. The additional amount will be determined at a later stage, taking into account the additional cost per tonnage bands.

Looking forward to hearing from you,

With kind regards,

ARCADIS on behalf of the members of the Rare Earth Consortium

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