

Dear SIEF members,

The Lead Registrant for the substance Praseodymium (III IV) oxide (CAS 12037-29-5; EC 234-857-9), NPM Silmet AS, has received **a final decision on a testing proposal from ECHA.**

Based on Article 40 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA has taken the following decision.

The Lead Registrant is requested to perform:

1. Transgenic rodent somatic and germ cell gene mutation assays (Annex IX, Section 8.4., column 2; test method: EU B.58./OECD TG 488); in transgenic mice or rats, via the oral route, on the following tissues: liver and glandular stomach using the registered substance, or

In vivo mammalian alkaline comet assay (Annex IX, Section 8.4., column 2; test method: OECD TG 489) in rats, oral route, on the following tissues: liver, glandular stomach and duodenum using the registered substance

while the originally proposed test for an unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo (OECD TG 486) is rejected.

The Lead Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

The Lead Registrant is required to submit the requested information in an updated registration dossier by **7 August 2018**, and update the chemical safety report, where relevant.

Since this final decision will trigger **additional testing**, this will have an **impact on the final cost of the LoAs** for Annex VIII and Annex IX co-registrants. The Lead Registrant has initiated a transgenic rodent assay (OECD 488) at BioSafety Research Center. Final results are expected by Q3 2018.

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.

With kind regards,

Arcadis on behalf of the members of the Rare Earth Consortium