Dear SIEF members,

The Lead Registrant for the substance Dierbium Trioxide EC No 235-045-7 (CAS No 12061-16-4) , Treibacher Industrie AG, 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.

Please find attached the draft decision and share with us your comments before the **15th of September 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. Description of the analytical methods (Annex VI, Section 2.3.7.) on the registered substance;Water solubility (Annex VII, Section 7.7.; test method: OECD series on Testing and Assessment Number 29 - Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous media) with the registered substance;

2. Sub-chronic toxicity study (90-day), inhalation route (Annex IX, Section 8.6.2.; test method: OECD TG 413) in rats using nose-only exposure and including bronchoalveolar lavage (BAL) analysis with the registered substance;

3. 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;

4. 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;

5. 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;

6. Adsorption/desorption screening (Annex VIII, Section 9.3.1.; test method: Adsorption/desorption using an appropriate test method, with the registered substance;

7. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, aqueous exposure 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.

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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Visit the site here: http://www.rare-earth-consortium.eu