

To the co-registrants of Dierbium Trioxide

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Dear co-registrants,

The Lead Registrant for the substance Dierbium Trioxide EC No 235-045-7 (CAS No 12061-16-4), Treibacher Industrie AG, 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 Compliance Check issued by ECHA on January 21st, 2019](#) 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 Lead Registrant communicated to ECHA its intention to **downgrade the tonnage band of the Joint Submission, from Annex IX (100-1000 tpy) to Annex VIII (10-100 tpy)**. As only members of the consortium are affected by this decision, no SIEF communication was circulated.

The following tests are currently conducted in order to meet with 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, it was decided that there is a need for a more reliable acute Ecotoxicity Reference Value and therefore an acute toxicity to fish study (see below) was ordered. When the results of this study are available, it will be decided whether further T/D testing is necessary in view of the determination of environmental classification;
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: Fish, Acute Toxicity Test, OECD TG 203) with Erbium trinitrate pentahydrate (EC No 233-436-7; CAS No 10031-51-3). This test is performed with a water-soluble erbium compound 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 aquatic invertebrates (Annex IX*, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with Erbium trinitrate pentahydrate. This test is performed with a water-soluble erbium compound 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) with Erbium trinitrate pentahydrate. This test is performed with a water-soluble erbium compound because aquatic toxicity data for inorganic metal compounds should be generated with water soluble salts according to the metal-specific guidance.

* 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 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 and update of the registration dossier imply an increase of costs considered in the LoA calculation and of the costs of the LoA itself (in consideration of the tonnage band).

The **additional testing costs** are estimated at approximately **110.000 €** (ca 41 k€ for Annex VII, ca 69 k€ for Annex VIII). 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.

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 Dierbium Trioxide EC No 235-045-7 (CAS No 12061-16-4), 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

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