

To the co-registrants of dierbium trioxide

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Subject: Status update transformation/dissolution testing
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Dear co-registrants,

As previously communicated on August 27, 2020 via [REC website](#), a compliance check decision was received for dierbium trioxide (EC 235-045-7, CAS 12061-16-4, final decision dd 21 January 2019;). As a result of this decision – among others – a Transformation/Dissolution study (T/D, OECD 29) had to be performed, to cover the endpoint ‘water solubility’ as well as to determine the environmental classification of the substance.

This test had to be performed to understand the solubility of the substance under environmentally relevant conditions and to enable comparison of the obtained dissolved erbium concentrations with Ecotoxicity Reference Values (ERVs) derived based on testing with ‘water soluble’ erbium salts. This is in line with the ECHA Guidance on the Application of the CLP Criteria (Version 5.0, July 2017) and the approach detailed for metals and inorganic metal compounds.

The results obtained during the 24-h screening T/D test showed that the dissolved erbium concentration at the pH maximising dissolution exceeded the acute ERV for erbium by a factor of roughly ten. Following the CLP guidance, the metal compound should therefore be considered as readily soluble. Hence, no further T/D testing was done after the screening assay and appropriate classification was duly applied: Aquatic Acute Cat. 1 and Aquatic Chronic Cat. 1. with an M-factor of 1. The table below lists the hazard statement codes and precautionary statements associated with this classification.

<u>Hazard statement codes</u>	
H410	Very toxic to aquatic life with long lasting effects
<u>Precautionary statements</u>	
P273	Avoid release to the environment
P391	Collect spillage
P501	Dispose of contents/container to ...

Given that previously dierbium trioxide was not classified for aquatic toxicity, the applied classification is a considerable change. This is in part due to the design of the T/D study undertaken for dierbium trioxide which followed the OECD protocol, applying a loading rate of 100 mg/L during the 24-h screening test. However, 100 mg/L is not an active cut-off level for acute aquatic classification under CLP. Whereas the classification derived from the 24-h T/D screening test has currently already been applied, options to obtain T/D data which better match CLP classification

criteria for acute aquatic toxicity, are currently being explored. Any options that arise which may alleviate the classification for the aquatic environment, will be further communicated.

Impact on LoA cost (Letter of Access)

As the T/D study is also a required study under the water solubility endpoint under REACH, which is an Annex VII endpoint, an impact on future LoA costs is anticipated.

As it concerns an Annex VII endpoint, the cost is considered relevant for all registrants in all tonnage bands.

The current costs of the LoA per tonnage band already include a provision for future work on the dossier. See: <http://www.rare-earth-consortium.eu/sites/default/files/substances/dierbium-trioxide/sief-communication-loas-available-for-dierbium-trioxide-cas-12061-16-4-ec-235-045-7.pdf>

Part of this provision has already been used. The balance will of course be used to finance the abovementioned work on the dossier. Depending on the total cost for this update, the remaining provision may be insufficient. In such case, the cost of the LoA per tonnage band shall be adapted accordingly and an additional invoicing to all the co-registrants can be deemed necessary.

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 test or the dossier update for the substance DIERBIUM TRIOXIDE (CAS 12061-16-4; EC 235-045-7), you can reach us at rare-earth-consortium@arcadis.com.

With kind regards,

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on behalf of the members of the Rare Earth Consortium

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