

Note for the attention of Dr Tim Bowmer, Chairman of the Committee for Risk Assessment

Ref: Request to the Committee for Risk Assessment to set a DNEL for 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)

The Committee for Risk Assessment (RAC) is requested to review the draft background report prepared by ECHA and based on it to recommend a Derived No Effect Level (DNEL) for DOTE.

1. Background

Since 2012, RAC recommends DNELs and dose response relationships for Annex XIV substances prior to receiving applications for authorisation (AfAs). The DNELs and dose response (DR) relationships serve as non-legally binding 'reference values'. They provide applicants with a clear signal as to how RAC is likely to evaluate these key elements of the risk assessment of an application. Reference values in the form of DNELs for threshold substances and/or dose response relationships for non-threshold (mainly) carcinogens are published in advance of applications for authorisation, so providing greater consistency and better use of the legally defined periods (e.g. the latest application date).

DOTE has been listed in the Annex XIV to REACH by the Commission Regulation (EU) 2022/586 of 8 April 2022 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance). The substance has been listed due to its intrinsic property referred to in Article 57c - Toxic for reproduction (category 1B). The Regulation sets the Latest application date on the 1st November 2023 and the Sunset date on the 1st May 2025.

2. Terms of Reference

In accordance with Article 77 (3) (c) of the REACH Regulation, RAC is requested to evaluate the background report and to provide an advice on the DNEL in a draft **RAC note** and to agree the final version. The note should focus on the following elements of the background report:

- Review of published studies of recognised national and international organisations and authorities;
- Review of the scientific literature;
- Overview of SVHC, including the reasoning for its inclusion in Annex XIV of the REACH Regulation;
- Risk assessment of the intrinsic property referred to in Article 57 of the REACH Regulation;
- Derivation of DNEL.

Helsinki, 19.05.2022

3. Timescale for the RAC note

Considering the Latest application date (1st November 2023) and the time when the ECHA will deliver to RAC the background report, RAC should adopt its note and recommend DNELs for DOTE by the 31st December 2022.

The RAC note on DOTE will be published on the ECHA website.

4. Remuneration

The task for RAC following from this request is not considered to fulfil any of the requirements of a transfer of funds to the competent authorities of the Member States pursuant to Article 14(1) of Regulation (EC) 340/2008 and therefore no remuneration of the rapporteurs will be paid by the Agency.

*[signed]*¹

Shay O'Malley
Acting Executive Director.

Cc: Peter van der Zandt, Matti Vainio, Thierry Nicot, Piotr Sosnowski, Ulrike Reuter

¹ As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.