

**CONSIDERATIONS OF ALTERNATIVE METHODS ON TESTING PROPOSALS IN YOUR REGISTRATION**

Please complete this form and provide information for each of the points below.

If you have more than one testing proposal, please copy and paste the three bullet points within the same document and complete the details as appropriate for each testing proposal.

This document will be published on ECHA website along with the third party consultation on the testing proposal(s).

Public substance name: tert-dodecanethiol  
EC Number (omit if confidential): 246-619-1  
CAS Number (omit if confidential): 25103-58-6

Date of considerations: 29 November 2021.

- **Hazard endpoint for which vertebrate testing was proposed:**

Fish early-life stage toxicity study with tert-dodecanethiol (EC Number 246-619-1, CAS Number 25103-58-6) according to the OECD Test Guideline 210.

- **Considerations that the general adaptation possibilities of Annex XI of the REACH Regulation were not adequate to generate the necessary information** (instruction: please address all points below):

- available GLP studies

None

- available non-GLP studies

None

- historical human data

Not relevant

- (Q)SAR

To our knowledge, there is no appropriate QSAR for estimating chronic toxicity with same endpoints as the OECD TG 210.

- *in vitro* methods

To our knowledge, there is no validated *in vitro* test method for estimating chronic toxicity with same endpoints as the OECD TG 210.

- weight of evidence

There are not enough available data for a weight of evidence approach.

- grouping and read-across

There are no identified groups of substances or similar substances for a read across approach.

- substance-tailored exposure driven testing [if applicable]

- [approaches in addition to above [if applicable]]

- other reasons [if applicable]

- **Considerations that the specific adaptation possibilities of Annexes VI to X (and column 2 thereof) were not applicable** (instruction: free text):

No datum for long-term toxicity to fish is available for the registered substance. In accordance with the Decision of the Board of Appeal in case A-011-2018, the REACh Annex IX, Section 9.1., Column 2 does not allow omitting the need to submit information on long-term toxicity to fish under Column 1. Therefore, fish long-term toxicity testing is a standard information requirement under annex IX of REACh regulation EC 1907/2006. Therefore, an OECD 210 study is proposed and cannot be waived.