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: 2,4,6,8,10-pentamethylcyclopentasiloxane
EC Number (omit if confidential): 228-204-7
CAS Number (omit if confidential): 6166-86-5

Date of considerations: 10 January 2018

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

  Sub-chronic toxicity (90-day): oral with the substance 2,4,6,8-tetramethylcyclotetrasiloxane

- **Considerations that the general adaptation possibilities of Annex XI of the REACH Regulation were not adequate to generate the necessary information**:

  - available GLP studies: No data are available for the registration substance, 2,4,6,8,10-pentamethylcyclopentasiloxane, for the repeated dose endpoint via any exposure route. However, an OECD TG 422 study (Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test) via the inhalation route is available for the structurally analogous substance 2,4,6,8-tetramethylcyclotetrasiloxane. The study showed that the urinary tract and thyroid gland were the target organs. The major treatment related findings were bladder stones at 3000/2000 and 1000 ppm, histopathological findings in the urinary tract at 3000/2000 and 1000 ppm, reversible reduction of food consumption and bodyweights gain and reversible pathology change observed in the thyroid gland in males at the dose level of 100 ppm.

  - available non-GLP studies: No data are available for 2,4,6,8,10-pentamethylcyclopentasiloxane for the repeated dose endpoint via any exposure route.

  - historical human data: No data available

  - (Q)SAR: No data available

  - *in vitro* methods: There are no validated alternative in vitro test methods.

  - weight of evidence: Insufficient data available

  - grouping and read-across: The proposed study forms part of a planned grouping approach. It is intended that the proposed study be used as read-across within

an analogue group or category approach for other siloxanes that are registered in accordance with the REACH Regulation. The proposed test material is a structural analogue of the registration substance.

- substance-tailored exposure driven testing: not applicable
- approaches in addition to above: not applicable
- other reasons: not applicable

- **Considerations that the specific adaptation possibilities of Annexes VI to X (and column 2 thereof) were not applicable**: There are no applicable Column 2 adaptations of Annexes VI to X for Repeated dose toxicity.