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:**

  Reproductive toxicity (extended one-generation reproductive toxicity study) 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 reproductive toxicity 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 the reduction of corpora lutea number and consequent reduction of number of pups at the dose level of 3000/2000 ppm was considered to be adverse. No further indication of a test item related effect on reproduction was observed at any dose level; mating performance, fertility, duration of gestation as well as pre- and post-implantation loses in dose groups were similar to the control values.

  - available non-GLP studies: No non-GLP data are available for 2,4,6,8,10-pentamethylcyclopentasiloxane for the reproductive toxicity 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 Reproduction toxicity.