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: 2,6-dimethyloct-7-en-2-ol
EC Number (omit if confidential): 242-362-4
CAS Number (omit if confidential): 18479-58-8

Date of considerations: 10 July 2017

- Hazard endpoint for which vertebrate testing was proposed:

  Reproductive toxicity (extended one-generation reproductive toxicity study) with the registered substance;

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

  - available GLP studies

    There are no avilailable studies to meet the Reach Iinformation requirement, GLP or non GLP.
    The data that was presented was not considered sufficient by ECHA. An OECD 416 study had been proposed. This was changed on request from ECHA to the currently proposed study

  - available non-GLP studies
    None

  - historical human data
    None

  - (Q)SAR
    Not suitable for this endpoint

  - in vitro methods
    None available to meet the information requirment

  - weight of evidence
    There are no data on which to build a weight of evidence approach

  - grouping and read-across
    There are no data in suitable analogues.

  - substance-tailored exposure driven testing
    Not applicable for this substance

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

The adaptaion for this endpoint

The substance is not known to be a genotoxic carcinogen or germ cell mutagen.
It is not classified for reproductive or developmental toxicity.
There are no data from toxicokinetic studies showing that no systemic absorption occurs via relevant routes of exposure.