## 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: Geraniol
EC Number (omit if confidential): 203-377-1
CAS Number (omit if confidential): 106-24-1

Date of considerations: 6 September 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** (instruction: please address all points below):

  - available GLP studies
    Available GLP studies are part of the registration dossiers. None of them fulfil the requirements of an extended one-generation study.

  - available non-GLP studies
    There are no reliable non-GLP studies available to assess the reproductive toxicity of Geraniol.

  - historical human data
    Databases on human studies (epidemiological evidence or case histories) were searched and no contributing information on reproductive effects of Geraniol were found.

  - (Q)SAR
    There are no reliable QSAR models addressing the endpoint of reproductive toxicity to the extent that is assessed in the extended one-generation study.

  - *in vitro* methods
    With regards to in vitro studies for reproductive toxicity, the regulatory acceptance of these studies and approaches to replace the animal testing for reproductive toxicity has not been achieved as they do not provide equivalent information and thus cannot be used alone for classification and labelling and/or risk assessment.

  - weight of evidence
    Considering the lack of *in vitro* methods, QSAR models and multigeneration studies on the substance itself and potential analogues, a weight-of-evidence

assessment is not possible.

- grouping and read-across
  Potential candidates for read-across are structurally similar compounds such as Reaction mass of 2,6-Octadien-1-ol, 3,7-dimethyl-, (E) and 2,6-Octadien-1-ol, 3,7-dimethyl-, (Z)- (EC 80-54-6) as well as Nerol (CAS 106-25-2). The available data on these substances are not sufficient to cover data requirement on reproductive toxicity according to Annex X.

- substance-tailored exposure driven testing:
  An exposure based waiving for Geraniol is not appropriate.

- 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** (instruction: free text):
  Based on the existing data and hazard and use profile of the substance, adaptation options as defined in Annexes VI to X were not applicable for his substance and this endpoint.