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.

Public substance name: O,O,O-triphenyl phosphorothioate
EC Number (omit if confidential): 209-909-9
CAS Number (omit if confidential): 597-82-0

Date of considerations: 10 November 2016

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

  Sub-chronic toxicity (90-day): oral 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
    There are no GLP studies available covering sub-chronic repeated dose toxicity information requirements.

  - available non-GLP studies
    There are no non-GLP studies available covering sub-chronic repeated dose toxicity information requirements.

  - historical human data
    No historical human data that could be used to address subchronic toxicity are available.

  - (Q)SAR
    At present there is no valid (Q)SAR model available to address repeated dose toxicity (ECHA Guidance in Information Requirements and Chemical Safety Assessment Chaper R 7a: Endpoint specific guidance).

  - *in vitro* methods
    At present there are no valid in vitro methods available to address repeated dose toxicity (ECHA Guidance in Information Requirements and Chemical Safety Assessment Chaper R 7a: Endpoint specific guidance).

  - weight of evidence
    No data to be used in a weight of evidence approach addressing subchronic toxicity are available.

  - grouping and read-across
    A structurally related compound has been identified. However, the data

available for the read-across substance are not sufficient to address subchronic toxicity.

- substance-tailored exposure driven testing
  not applicable

- [approaches in addition to above
  not applicable

- other reasons [if applicable]
  not applicable

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

According to Column 2 Annex IX of REACH Regulation a sub-chronic repeated dose toxicity study does not need to be conducted if:

- a reliable short-term toxicity study (28-days) is available showing severe toxicity effects
- a reliable chronic toxicity study is available
- the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day "limit test", particularly if such a pattern is coupled with limited human exposure

All points outlined above do not apply for the substance. Thus, in order to fulfill information requirements stated in column 1 Annex IX of REACH Regulation for substances manufactured or imported in quantities of 100 tpa or more, a sub-chronic toxicity study (90-days) is proposed.