NON-CONFIDENTIAL NAME OF SUBSTANCE:
- Name of the substance on which testing is proposed to be carried out:
Butyl(dialkyloxy(dubutoxyphosphoryloxy)titanium(trialkyloxy) titanium phosphate

CONSIDERATIONS THAT THE GENERAL ADAPTATION POSSIBILITIES OF ANNEX XI OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION:
- Available GLP studies:
  - Acute toxicity: oral
  - Acute toxicity: demal
  - Skin irritation: in vivo
  - Eye irritation: in vivo
  - Skin sensitisation: in vivo (non-LLNA)
  - Short-term repeated dose toxicity: oral
  - In vitro gene mutation study in bacteria
  - In vitro cytogenicity / chromosome aberration study in mammalian cells
  - In vitro gene mutation study in mammalian cells
  - Screening for reproductive / developmental toxicity

- Available non-GLP studies: No further studies available

- Historical human data: No further data available

- (Q)SAR: There are no adequately validated (Q)SAR models to address the endpoint.

- In vitro methods: There are no validated and regulatory accepted in vitro methods to address this endpoint.

- Weight of evidence: There is an insufficient weight of evidence from several independent sources to address the endpoint.

- Grouping and read-across: There is an unacceptable level of uncertainty regarding identification and selection of structurally and/or mechanistically related source substances.

- Substance-tailored exposure driven testing: The registered substance is only handled in industrial or commercial installations using closed systems and/or handled only as preparations at low concentrations, a sub-chronic study should be considered.

CONSIDERATIONS THAT THE SPECIFIC ADAPTATION POSSIBILITIES OF ANNEXES VI TO X (AND COLUMN 2 THEREOF) OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION:
Annex IX Column 2 specific rules for adaptation for this endpoint are not applicable for the registered substance:
  - the available short-term toxicity study results do not show severe toxicity effects according to the criteria for classifying the substance as R48;
  - a reliable chronic toxicity study is not available;
  - while the substance is subjected to solvolysis, and, in the presence of water polymeric complexes are formed, there is insufficient data on the cleavage products; and
  - the substance is reactive with water forming polymeric complexes.

Annex XI general rules for adaptations of the standard testing regime are not applicable for the registered substance; specifically:
  - Use of existing data:
    Existing data does not address the endpoint;

  - Weight of evidence:

There is an insufficient weight of evidence from several independent sources to address the endpoint;

- Qualitative or quantitative structure-activity relationship ((Q)SAR):
  There are no adequately validated (Q)SAR models to address the endpoint;

- In vitro methods:
  There are no validated and regulatory accepted in vitro methods to address this endpoint;

- Grouping of substances and read-across approach:
  There is an unacceptable level of uncertainty regarding identification and selection of structurally and/or mechanistically related source substances;

- Testing is not technically possible:
  It is technically possible to assess the registered substance for this endpoint; and

- Substance-tailored exposure-driven testing:
  The registered substance is only handled in industrial or commercial installations using closed systems and/or handled only as preparations at low concentrations, a sub-chronic study should be considered.

FURTHER INFORMATION ON TESTING PROPOSAL IN ADDITION TO INFORMATION PROVIDED IN THE MATERIALS AND METHODS SECTION:
As there were difficulties associated with the administration of the registered substance during both the 28-day and the reproduction/developmental toxicity screening studies, the administration methods employed should be scrutinized to ensure the most accurate and humane method is employed during the proposed 90-day oral repeated dose study.