

## Guidelines for Submission of Developmental and Reproductive Toxicity Data

Please ensure that the following information is included with your data submission where applicable. If possible, please submit data as a **tab delimited (txt) document, comma separated value (csv) document, or as a Microsoft Excel spreadsheet (xls orxlsx)**. Submissions in the form of study report documents from which data will need to be extracted will be accepted, but please contact NICEATM to discuss these submissions.

Structured data tables with the details listed below are preferred.

### Chemical information (regardless of assay data type):

- Chemical name
- CASRN or other identifier (where applicable)
- SMILES
- Formulation or active ingredient
- Physicochemical properties and source of data (if available)

### Assay information:

For both in vivo and in vitro studies, protocol details should be provided, including relevant information such as dosing regimen, time of effect observation, vehicle, positive control, etc. These materials can be in a separate document.

### In vivo data:

- Species, strain of the test organism
- Sex, age of test organism
- Protocol used (cite test guideline or supplemental reference where appropriate)
- Route of administration
- Doses tested
- Number of animals per dose group
- Test measurements and results (e.g., LEL and confidence interval or treatment-related effects observed, as appropriate)
- Concurrent measurements and results (e.g. maternal toxicity, toxicokinetics, as appropriate)
- Gestational or parturition date of maternal sacrifice

### In vitro data:

- Assay system (cite reference)

- Protocol used (cite test guideline or supplemental reference where appropriate)
- Cell type (if applicable)
- Species of cell type (if applicable)
- Assay endpoint(s)
- Concurrent measurements (e.g. cytotoxicity)
- Exposure duration
- Concentrations tested
- Number of replicates at each concentration
- Response values (e.g., IC50, EC50, maximal induction, etc.)

**In silico data:**

- Software or model used (cite reference)
- Model parameters (where applicable)
- Predicted values
- Model evaluation (i.e. external and/or cross validation results)