**Template #75-2: Endocrine disrupter screening - in vitro *(Version [1.0]-[July 2023])***

The following table gives a detailed description of the type of information prompted for by the data entry fields.

| **Line no.** | **Field name** | **Field type****Display type** | **Picklist****Freetext template** | **Help text** | **Remarks** **Guidance** **Cross-reference** |
| --- | --- | --- | --- | --- | --- |
|  | **Administrative data** | **Header 1** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  |  |  |
|  | Endpoint | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- endocrine disrupter screening - in vitro- endocrine disrupter screening - in chemico- other: | From the picklist select the relevant endpoint addressed by this study summary. In some cases there is only one endpoint title, which may be entered automatically depending on the software application.If multiple study types are covered by the same data entry form, the specific study type should be selected. If none matches, select the more generic endpoint description '<Generic endpoint>, other' (e.g. Skin irritation / corrosion, other) and give an explanation in the adjacent text field. The generic endpoint title reflects the title of the corresponding OECD Harmonised Template (OHT).Please note: For (Q)SAR studies, if an 'in silico' option does not exist, the generic endpoint title should be selected, normally with no need to fill in the adjacent text field, as '(Q)SAR' needs to be indicated in field 'Type of information' and the model should be described in field 'Justification of non-standard information' or 'Attached justification'. A specific endpoint title may be used, if addressed by the (Q)SAR information, i.e. the model behind has been validated by experimental data addressing this endpoint.Note: For the purpose of OHTs, an 'endpoint' is defined in the rather broad sense as an observable or measurable inherent property of a chemical substance which may be specified by the relevant regulatory framework as 'information requirement' (e.g. Boiling point, Sub-chronic toxicity: oral, Fish early-life stage toxicity). In a narrower sense, the term '(eco)toxicity endpoint' refers to an outcome or effect observed in a study. |  |
|  | Type of information | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- experimental study- experimental study planned- experimental study planned (based on read-across)- (Q)SAR- calculation (if not (Q)SAR)- read-across based on grouping of substances (category approach)- read-across from supporting substance (structural analogue or surrogate)- read-across from similar mixture/product- mixture rules calculation- weight of evidence justification/conclusion- not specified- other: | Select the appropriate type of information, e.g. ' experimental study', ' experimental study planned' or, if alternatives to testing apply, '(Q)SAR', 'read-across ...'. In the case of calculated data, the value 'calculation (if not (Q)SAR)' should only be chosen if the study report does not clearly indicate whether it is based on '(Q)SAR'.If the information is taken from a handbook or review article, select the relevant item, e.g. ‘experimental study’, if this is provided in the information source. Otherwise select ‘not specified’. Please note: In field ‘Reference type’ the option ‘review article or handbook’ should be selected. In general, the option 'not specified' should be selected if the submitter lacks the knowledge of the type of information. The option 'other:' can be used if another than a pre-defined item applies.In the case of read-across, follow the instructions related to the relevant legislation, for instance as to whether the (robust) study summary should be entered in a separate data set defined for the read-across (source) substance and referenced in the target substance dataset.If 'experimental study planned' or 'experimental study planned (based on read-across)' is indicated (in some legislations also defined as 'testing proposal' or 'undertaking of intended submission'), the submitter should include as much information as possible on the planned study in order to support the evaluation of the proposal. Typically, this would include at least the test guideline, information on the test material, the species and the route of administration in the corresponding distinct fields, as appropriate.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on whether specific fields should be completed and/or further details should be attached in field 'Attached background material'. |  |
|  | Adequacy of study | List (picklist)Display: Basic | **Picklist values:**- key study- supporting study- weight of evidence- disregarded due to major methodological deficiencies- other information | Indicate the adequacy of a (robust) study summary in terms of usefulness for hazard/risk assessment purposes depending on the relevant legislation.Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'.Explanation: - key study: In general, a key study is the study that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and representativity of data. - supporting study: Any other adequate study that is considered supportive for the key study or key studies. - weight of evidence: A record that contributes to a weight of evidence justification for the non-submission of a particular (adequate) study. The weight of evidence justification is normally endpoint-related, i.e. based on all available records included in the weight of evidence evaluation. A short reasoning for why a given record is used in this respect can be provided in field 'Detailed justification / remarks'. - disregarded due to major methodological deficiencies: study that demonstrates a higher concern than the key study/ies, but is not used as key study because of flaws in the methodology or documentation. This phrase should be selected for justifying why a potentially critical result has not been used for the hazard assessment. The lines of argumentation should be provided in field 'Rationale for reliability incl. deficiencies', accompanied by the appropriate reliability score.- other information: any other non-relevant information which does not need to be flagged specifically as 'disregarded due to major methodological deficiencies'.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. | **Guidance for field condition:**Condition: Field active only if 'Type of information' is not 'experimental study planned' and not ‘experimental study planned (based on read-across)’ and field 'Data waiving' is not populated (except for migrated data) |
|  | Robust study summary | Check boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Robust Study Summary' or in combination with 'Adequacy of study'. Explanation: The term 'Robust Study Summary' is actually used only to describe the technical content of a very detailed summary of an experimental study or of any other relevant information. It is a priori no synonym with the term 'Key study', although a key study should usually be submitted in the form of Robust Study Summary. However, a Robust Summary may also be useful for other adequate studies that are considered supportive of the key study or even for inadequate studies if they can be used for a weight-of-evidence analysis. Also for studies that are flawed, but indicate critical results, Robust Study Summaries highlighting the weaknesses of the studies need to be elaborated. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Used for classification | Check boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Used for classification'.Explanation: In some use cases it may be necessary to indicate those records that are used for the classification of that substance, e.g. according to UN GHS. If not relevant, disregard this field. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Used for SDS | Check boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'SDS information'. Explanation: 'SDS' stands for Safety Data Sheet. In some use cases it may be necessary to indicate those records that are used for the compilation of SDS information. If not relevant, disregard this field. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Study period: start date | DateDisplay: Basic |  | If applicable indicate the period during which the study was conducted, i.e. start and end date. Note: independent of the study period, the in-life period (i.e. the phase of a study following treatment in which the test system is alive/growing) may have to be specified for some toxicology endpoints. |  |
|  | End date | DateDisplay: Basic |  |  |  |
|  | Remark | Text (255 char.)Display: Basic |  |  |  |
|  | Reliability | List (picklist)Display: Basic | **Picklist values:**- 1 (reliable without restriction)- 2 (reliable with restrictions)- 3 (not reliable)- 4 (not assignable)- other: | Enter an appropriate reliability score, according to Klimisch et al. (1997):1 = reliable without restrictions: “studies or data [...] generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline [...] or in which all parameters described are closely related/comparable to a guideline method.”2 = reliable with restrictions: “studies or data [...] (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.”3 = not reliable: “studies or data [...] in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g. non-physiological pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment.”4 = not assignable: “studies or data [...] which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).”The 'other:' option may be selected if a different scoring system is used. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'.Note: The term reliability defines the inherent quality of a test report or publication relating to preferably standardised methodology and the way the method and results are described. More detailed criteria can be selected in field 'Justification'. |  |
|  | Rationale for reliability incl. deficiencies | List sup. (picklist with remarks - 32,000 char.)Display: Basic | **Picklist values:**- guideline study - [Reliability 1]- comparable to guideline study - [Reliability 1]- test procedure in accordance with national standard methods - [Reliability 1]- test procedure in accordance with generally accepted scientific standards and described in sufficient detail - [Reliability 1]- guideline study without detailed documentation - [Reliability 2]- guideline study with acceptable restrictions - [Reliability 2]- comparable to guideline study with acceptable restrictions - [Reliability 2]- test procedure in accordance with national standard methods with acceptable restrictions - [Reliability 2]- study well documented, meets generally accepted scientific principles, acceptable for assessment - [Reliability 2]- accepted calculation method - [Reliability 2]- data from handbook or collection of data - [Reliability 2]- significant methodological deficiencies - [Reliability 3]- unsuitable test system - [Reliability 3]- abstract - [Reliability 4]- secondary literature - [Reliability 4]- documentation insufficient for assessment - [Reliability 4]- results derived from a valid (Q)SAR model and falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 1 or 2]- results derived from a valid (Q)SAR model and falling into its applicability domain, with limited documentation / justification - [Reliability 2, 3 or 4]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 2 or 3]- results derived from a (Q)SAR model, with limited documentation / justification, but validity of model and reliability of prediction considered adequate based on a generally acknowledged source - [Reliability 2 or 3]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, and documentation / justification is limited - [Reliability 3 or 4]- results derived from a (Q)SAR model, with limited documentation / justification - [Reliability 4]- other: | Select an appropriate standard justification from the picklist, e.g. 'Comparable to guideline study with acceptable restrictions'. Additional explanations (e.g. deficiencies observed) can be entered in the related supplementary text field. Particularly if reliability scores 2 or 3 are assigned, indicate the concrete arguments for defending a study or relevant deficiencies.For QSAR results (i.e. 'Type of information' is '(Q)SAR') some pre-defined phrases are provided for indicating if the prediction results are considered reliable based on the scientifically validity of the (Q)SAR model used, its applicability to the query substance, and the adequacy of reporting. Please note: If (Q)SAR results are flagged as key study in field 'Adequacy of study', the relevance of the model used for the regulatory endpoint should be documented in the field where the (Q)SAR model is described, i.e. 'Justification for type of information', 'Attached justification' or 'Cross-reference'. | **Guidance for field condition:**Condition: Field active only if 'Type of information' is not 'experimental study planned' and not ‘experimental study planned (based on read-across)’.Condition 1: If 'Type of information' is not '(Q)SAR':- guideline study - [Reliability 1]- comparable to guideline study - [Reliability 1]- test procedure in accordance with national standard methods - [Reliability 1]- test procedure in accordance with generally accepted scientific standards and described in sufficient detail - [Reliability 1]- guideline study without detailed documentation - [Reliability 2]- guideline study with acceptable restrictions - [Reliability 2]- comparable to guideline study with acceptable restrictions - [Reliability 2]- test procedure in accordance with national standard methods with acceptable restrictions - [Reliability 2]- study well documented, meets generally accepted scientific principles, acceptable for assessment - [Reliability 2]- accepted calculation method - [Reliability 2]- data from handbook or collection of data - [Reliability 2]- significant methodological deficiencies - [Reliability 3]- unsuitable test system - [Reliability 3]- abstract - [Reliability 4]- secondary literature - [Reliability 4]- documentation insufficient for assessment - [Reliability 4]Condition 2: If 'Type of information' = '(Q)SAR':- results derived from a valid (Q)SAR model and falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 1 or 2]- results derived from a valid (Q)SAR model and falling into its applicability domain, with limited documentation / justification - [Reliability 2, 3 or 4]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 2 or 3]- results derived from a (Q)SAR model, with limited documentation / justification, but validity of model and reliability of prediction considered adequate based on a generally acknowledged source - [Reliability 2 or 3]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, and documentation / justification is limited - [Reliability 3 or 4]- results derived from a (Q)SAR model, with limited documentation / justification - [Reliability 4]- other: |
|  | Data waiving | List (picklist)Display: Basic | **Picklist values:**- study technically not feasible- study scientifically not necessary / other information available- exposure considerations- study waived due to provisions of other regulation- other justification | If appropriate, indicate here that the study has been waived, i.e. not performed. Select the basis from the picklist (e.g. 'study technically not feasible' or 'other justification'). Include a more detailed justification in the field 'Justification for data waiving' and, as needed, in field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference'. Please note: the option 'study scientifically not necessary / other information available' covers cases where it can be justified that performance of a specific study prescribed by the relevant legislation is scientifically not necessary because reliable information is provided in other part(s) of the submission document.The option 'study waived due to provisions of other regulation' can be used for indicating that another, overlapping regulation allows or requires the waiving of a specific information requirement. This should then be detailed in the justification fields.If waiving is based on several lines of argumentation (e.g. ‘exposure considerations’ and ‘study scientifically not necessary / other information available’), create separate records for each.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use data waivers. | **Guidance for field condition:**Condition: Deactivate this field if any of the following fields is populated: 'Type of information', 'Adequacy of study', 'Reliability', 'Rationale for reliability'. |
|  | Justification for data waiving | List multi. (multi-select list with remarks - 32,000 char.)Display: Basic | **Picklist values:**- other: | In addition to the more generic justification selected in the preceding field 'Data waiving', it is highly recommended to provide a detailed justification. To this end you can either select one or multiple specific standard phrase(s) if it/they give an appropriate rationale of the description given in the preceding field 'Data waiving' or 'other:' and enter free text. Additional specific explanations should be provided if the pre-defined phrase(s) do no sufficiently describe the justification.More details can be provided using the following fields:- Text field adjacent to this field 'Justification for data waiving' (available after selecting any picklist item in this field);- Field 'Justification for type of information';- Field 'Attached justification';- Cross-reference (for referencing / linking to a justification or information referred to in the justification which is stored in another record, e.g. a record describing physico-chemical properties information used to support a data waiver)Please note: The pre-defined phrases are not necessarily exhaustive and may not always apply. Consult the guidance documents and waiving options in the relevant regulatory frameworks. If no suitable phrase is available from the picklist, enter a free text justification using the 'other:' option. | **Guidance for field condition:**Condition: Deactivate this field if any of the following fields is populated: 'Type of information', 'Adequacy of study', 'Reliability', 'Rationale for reliability'. |
|  | Justification for type of information | Text templateDisplay: Basic | **Freetext template:Option 1 Type 'Waiving of standard information'**JUSTIFICATION FOR DATA WAIVING[Specific explanation in addition to field 'Justification for data waiving']**Option 2 Type 'Experimental study planned / Testing proposal on vertebrate animals'**TESTING PROPOSAL ON VERTEBRATE ANIMALS[Please provide information for all of the points below. The information should be specific to the endpoint for which testing is proposed. Note that for testing proposals addressing testing on vertebrate animals under the REACH Regulation this document will be published on the ECHA website along with the third party consultation on the testing proposal(s).]NON-CONFIDENTIAL NAME OF SUBSTANCE:- Name of the substance on which testing is proposed to be carried out- Name of the substance for which the testing proposal will be used [if different from tested substance]CONSIDERATIONS THAT THE GENERAL ADAPTATION POSSIBILITIES OF ANNEX XI OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION [please address all points below]:- Available GLP studies- Available non-GLP studies- Historical human/control data- (Q)SAR- In vitro methods- Weight of evidence- Grouping and read-across- Substance-tailored exposure driven testing [if applicable]- Approaches in addition to above [if applicable]- Other reasons [if applicable]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:- [free text]FURTHER INFORMATION ON TESTING PROPOSAL IN ADDITION TO INFORMATION PROVIDED IN THE MATERIALS AND METHODS SECTION:- Details on study design / methodology proposed [if relevant]**Option 3 Type 'QSAR prediction'**1. SOFTWARE2. MODEL (incl. version number)3. SMILES OR OTHER IDENTIFIERS USED AS INPUT FOR THE MODEL4. SCIENTIFIC VALIDITY OF THE (Q)SAR MODEL[[Explain how the model fulfils the OECD principles for (Q)SAR model validation. Consider attaching the QMRF and/or QPRF or providing a link]- Defined endpoint:- Unambiguous algorithm:- Defined domain of applicability:- Appropriate measures of goodness-of-fit and robustness and predictivity:- Mechanistic interpretation:5. APPLICABILITY DOMAIN[Explain how the substance falls within the applicability domain of the model]- Descriptor domain:- Structural domain:- Mechanistic domain:- Similarity with analogues in the training set:- Other considerations (as appropriate):6. ADEQUACY OF THE RESULT[Explain how the prediction fits the purpose of classification and labelling and/or risk assessment]**Option 4 Type 'Read-across (analogue)'**REPORTING FORMAT FOR THE ANALOGUE APPROACH[Please provide information for all of the points below. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]1. HYPOTHESIS FOR THE ANALOGUE APPROACH[Describe why the read-across can be performed (e.g. common functional group(s), common precursor(s)/breakdown product(s) or common mechanism(s) of action]2. SOURCE AND TARGET CHEMICAL(S) (INCLUDING INFORMATION ON PURITY AND IMPURITIES)[Provide here, if relevant, additional information to that included in the Test material section of the source and target records]3. ANALOGUE APPROACH JUSTIFICATION[Summarise here based on available experimental data how these results verify that the read-across is justified]4. DATA MATRIX**Option 5 Type 'Read-across (category)'**REPORTING FORMAT FOR THE CATEGORY APPROACH[Please provide information for all of the points below addressing endpoint-specific elements that were not already covered by the overall category approach justification made available at the category level. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]1. HYPOTHESIS FOR THE CATEGORY APPROACH (ENDPOINT LEVEL)[Describe why the read-across can be performed]2. CATEGORY APPROACH JUSTIFICATION (ENDPOINT LEVEL[Summarise here based on available experimental data how these results verify that the read-across is justified]**Option 6 Type 'Weight of Evidence justification'**JUSTIFICATION FOR WEIGHT OF EVIDENCE- Relevance (including coverage) and reliability of each source of information compared with the study normally required for the information requirement.- Weighing of the sources of information (including overall coverage) to reach an overall conclusion for the information requirement.- Assessment of the uncertainty in the conclusion compared with the study normally required for the information requirement. | This field can be used for entering free text. As appropriate, one of the freetext templates can be selected (e.g. Justification for read-across (analogue)) to use pre-defined headers and bulleted elements. Delete/add elements as appropriate.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on what should be taken into account when providing justifications or whether specific reporting formats should be used.Explanations:Option 1: Type 'Waiving of standard information':This field should be used for entering any further lines of argumentation, if necessary, in addition to those provided in the field 'Justification for data waiving'.Option 2: Type 'Experimental study planned / Testing proposal':Further details can be entered here on the study design / methodology proposed in addition to details given in the distinct fields on test guideline, test material, species, route of administration and other relevant fields.Option 3: Type 'QSAR prediction':For describing a (Q)SAR model it is recommended to provide the QMRF as attachment instead of using the free text template.The QSAR Model Reporting Format (QMRF) is a harmonised template for summarising and reporting key information on QSAR models, including the results of any validation studies. The information is structured according to the OECD validation principles and can be compiled using the QMRF editor application.The JRC QSAR Model Database is intended to help to identify valid (Q)SARs (e.g. for the purpose of REACH). It provides information on the validity of QSAR models and can be browsed for published QMRFs.Based on this freetext template details on the QSAR model used can be given, in addition to the information provided in field 'Principles of method if other than guideline'.Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature.Option 4: Type 'Read-across (analogue)' and Option 5: Type 'Read-across (category)'This freetext template can be used and modified as appropriate for providing a justification for read-across, particularly if it is endpoint-specific.Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature. |  |
|  | **Attached justification** | **Block of fields (repeatable) Start** |  | The Attached justification feature can be used in case the justification is best provided in form of attached document(s).Copy this block of fields for attaching more than one file.Refer to the relevant legislation-specific guidance document as to the recommended use of the Attached justification feature. |  |
|  | Attached justification | Attachment (single)Display: Basic |  | Upload file by clicking the upload icon. |  |
|  | Reason / purpose | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- data waiving: supporting information- exposure-related information- read-across: supporting information- (Q)SAR model reporting (QMRF)- (Q)SAR prediction reporting (QPRF)- (Q)SAR model and prediction reporting (QMRF/QPRF)- (Q)SAR: supporting information- weight of evidence: supporting information- justification, other: | Indicate the reason for / purpose of the attached document. Select the relevant item from the picklist or, if none applies, select 'justification, other:' and specify. |  |
|  | **Attached justification** | **Block of fields (repeatable) End** |  |  |  |
|  | **Cross-reference** | **Block of fields (repeatable) Start** |  | The cross-reference feature can be used to refer to related information that is provided in another record of the dataset. This can be done either by entering just free text in the 'Remarks' field or by creating a link to the relevant record. The field 'Reason / purpose' allows for selecting a standard reason from the picklist and optionally to add free text explanation in the related supplementary text field.Refer to the relevant legislation-specific guidance document as to the recommended use of cross-references. |  |
|  | Reason / purpose for cross-reference | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- adverse outcome pathway (AOP)- assessment report- data waiving: supporting information- defined approach- exposure-related information- method used in study- read-across source- (Q)SAR model reporting (QMRF)- read-across: supporting information- reference to other assay used for intermediate effect derivation- reference to other study- reference to same study- weight of evidence source- other: | Select the appropriate reason of the cross-reference, i.e.- adverse outcome pathway (AOP) (in case the information is related to a key event that is part of an AOP). Consult the AOP wiki at: https://aopwiki.org) and provide the reference in the remarks field- assessment report (for referring to a record that contains an assessment report as attachment)- data waiving: supporting information (for referring to a record containing relevant endpoint information that is used to justify a data waiver)- defined approach for combining with results from another methods (in vitro, in chimico, in silico) - exposure-related information (for referring to a record containing exposure-related information that is used for instance to justify a data waiver)- read-across source (for linking to another study summary used for read-across. This can be useful in cases where results are derived from one or several read-across sources and recorded in a separate (target) study summary.)- read-across supporting information (for linking to another record which contains read-across justification that applies also for the current study summary)- (Q)SAR model reporting (QMRF) (for referring to a record containing the relevant model description. Note: The (Q)SAR prediction should be reported specifically for each endpoint in the field 'Justification for type of information'.)- reference to other assay used for intermediate effect derivation (for optional indication in a study summarising 'intermediate effects' if reference is made to the outcome of another assay)- reference to same study (e.g. if different species were tested and the results recorded in different records), - reference to other study (e.g. if another study is considered relevant in the interpretation of the test results), - other: (to be specified). |  |
|  | Related information | Link to endpoint (single)Display: Basic |  | As appropriate, select the record containing the related information, thus creating a link. | **Cross-reference:**AllSummariesAndRecords |
|  | Remarks | Text (32,768 char.)Display: Basic |  | This field can be used for including any remarks. |  |
|  | **Cross-reference** | **Block of fields (repeatable) End** |  |  |  |
|  | **Data source** | **Header 1** |  |  |  |
|  | Reference | Link to lit. reference (multiple)Display: Basic |  | Indicate the bibliographic reference of the study report or publication the study summary is based on. Provide general information such as Title, Author, Year, Bibliographic source, Testing Facility, Report Number, Study number, Report date etc., as requested in the core template for literature search (https://www.oecd.org/ehs/templates/Generic%20elements%20for%20all%20OHTs.zip). Always enter the primary reference in the first block of fields or sort it to the first position, if there are more than one reference to be cited. Copy this block of fields for specifying any other references related to this record (e.g. report of a preliminary study or other documentation). If results of a study report have been published, indicate the full citation of that publication(s) in addition to the reference of the original study. |  |
|  | Data access | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- data submitter is data owner- data submitter has Letter of Access- data no longer protected- data published- data submitter has permission to refer- not applicable- other: | Select appropriate indication for data access. Enter 'Not applicable' if the summary consists of information that is commonly accessible such as guidance on safe use.Select 'data submitter has permission to refer' if the information requirement can be covered based on a permission to refer to old data as issued by the relevant regulatory agency. In addition, provide, in the adjacent free-text field, the statement according to instructions you received from the relevant regulatory authority together with the permission to refer. |  |
|  | Data protection claimed | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- yes, but willing to share- yes, but not willing to share | Indicate as appropriate. Note: 'yes' should be selected only if 'Data submitter is data owner' or 'Data submitter has Letter of Access'. Options 'yes, but willing to share' or 'yes, but not willing to share' may be relevant for specific regulatory programmes where the submitter is requested to indicate whether he is willing to share studies conducted (e.g. with vertebrates).In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. 'for justification see attached document X') |  |
|  | **Materials and methods** | **Header 1** |  |  |  |
|  | Type of study | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- ARTA 22Rv1/MMTV GR-KO- ARTA AR-CALUX®- ARTA AR-EcoScreen™- ERTA ERα CALUX®- ERTA STTA- ERTA VM7Luc- hrER binding CERI assay- hrER binding FW assay- H295R Steroidogenesis Assay- (Q)SAR- other: | Indicate which kind of test was performed. |  |
|  | **Test guideline** | **Block of fields (repeatable) Start** |  | Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'.Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline). |  |
|  | Qualifier | List (picklist)Display: Basic | **Picklist values:**- according to guideline- equivalent or similar to guideline- no guideline followed- no guideline available- no guideline required | Select appropriate qualifier, i.e.- 'according to guideline' (if a given test guideline was followed);- 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline);- 'no guideline followed' (if none of above qualifiers apply. If so, fill in field 'Principles of method if other than guideline');- 'no guideline available' (if so, fill in field 'Principles of method if other than guideline').- 'no guideline required' (if so, fill in field 'Principles of method if other than guideline'). |  |
|  | Guideline | List (picklist)Display: Basic | **Picklist values:**- OECD Guideline 455 (Performance-Based Test Guideline for Stably Transfected Transactivation In Vitro Assays to Detect Estrogen Receptor Agonists and Antagonists) - [ERTA STTA, ERTA VM7Luc, ERTA ERα CALUX]- OECD Guideline 456 (H295R Steroidogenesis Assay) - [H295R Steroidogenesis Assay]- OECD Guideline 458 (Stably Transfected Human Androgen Receptor Transcriptional Activation Assay for Detection of Androgenic Agonist and Antagonist Activity of Chemicals) - [ARTA STTA, ARTA AR-CALUX, ARTA 22Rv1/MMTV GR-KO]- OECD Guideline 493 (Performance-Based Test Guideline for Human Recombinant Estrogen Receptor (hrER) In Vitro Assays to Detect Chemicals with ER Binding Affinity) - [hrER binding FW assay, hrER binding CERI assay]- EPA OPPTS 890.1550 (Steroidogenesis (Human Cell Line - H295R)) - [H295R Steroidogenesis Assay]- other: | Select the applicable test guideline, e.g. 'OECD Guideline xxx'. If the test guideline used is not listed, choose 'other:' and specify the test guideline in the related text field. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'. The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields.Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Version / remarks | Text (2,000 char.)Display: Basic |  | In this text field, you can enter any remarks as applicable, particularly:- To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline);- To indicate if the study was performed prior to the adoption of the test guideline specified;- To indicate if the methodology used was based on an extension of the test guideline specified;- To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Deviations | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- no- not applicable- not specified | In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | **Test guideline** | **Block of fields (repeatable) End** |  |  |  |
|  | Principles of method if other than guideline | Text templateDisplay: Basic | **Freetext template:Option 1 Method of non-guideline study**- Principle of test:- Short description of test conditions:- Parameters analysed / observed:**Option 2 (Q)SAR**- Software tool(s) used including version:- Model(s) used:- Model description: see field 'Justification for non-standard information', 'Attached justification' and/or 'Cross-reference'- Justification of QSAR prediction: see field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' | If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate use either of the pre-defined freetext template options for 'Method of non-guideline study' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate.For a non-guideline experimental study a high-level freetext template can be used for summarising the principle of test, test conditions and parameters analysed / observed. If the freetext template for (Q)SAR is selected, indicate the QSAR model(s) or platform including version and the software tool(s) used. Detailed justification of the model and prediction should be provided in field(s) 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' as appropriate.Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate. |  |
|  | GLP compliance | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes (incl. QA statement)- yes- no- not specified | Indicate whether the study was conducted following Good Laboratory Practice or not. In case 'yes’ is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed. |  |
|  | Other quality systems, standards or guidance followed | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- OECD Guidance Document no. 286 on Good In Vitro Method Practices (GIVIMP)- ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories.- not specified- other: | Indicate whether the study was conducted following a laboratory-specific quality system or standard such as the OECD guidance on Good In Vitro Method Practice (OECD GIVIMP). Other quality systems, not listed, may be added under 'other'.When selecting OECD GIVIMP, the submitter ensures that the following elements (if applicable) are documented and/or reported:The purpose of the study.Test and control items: The chemical name, CAS-number lot/batch number of the test and control items. The purity, stability homogeneity, solubility and solvent/vehicle of the test and control item was stated or is traceable according to information given regarding manufacturer and lot/batch number. In case of mixtures, the composition of different constituents. In case of nanomaterials, clear identification of the tested nanomaterial (e.g. particle size, shape, particle size distribution, surface area, coating).Test System: The in vitro test system (e.g. tissue or organ fragment / organ explant/ dissociated cells / primary cells culture/ continuous or finite cell line/ stem cells/ complex culture system/ re-differentiated cells/ sub-cellular fractions like cytosol and microsomes/ proteins) was described, justified and characterised to confirm/authenticate the identity. The source or supplier of the test system. Metabolic competence of the test system was described. The number of passages of the test system used,. The test system mass, volume, or dimensions. The type of media used. The use of serum or animal free chemically-defined alternatives. The use of growth factors was described. The use of antibiotics. The incubation temperature, humidity and CO2. All measures taken to avoid or screen for contamination by mycoplasma, bacteria, fungi and virus were described.Apparatus, materials and reagents: The apparatus was described. The limit of detection or limit of quantitation of the apparatus. The materials and reagents. The culture dimensions (mm2 or ml). The use of animal-derived materials or reagents (e.g. Trypsin, antibodies, collagen, Matrigel etc.). The use of fully animal-free materials and reagents.Test item treatment: The test item concentrations/dose levels. Biological fluid characterisation was described (quantification of proteins and cells/tissue present). Binding to biological fluid and culture material. Test system number, density, dimension, quantity used during treatment. The duration of treatment. The number of replicates per concentration/dose. The number of times the experiment was repeated (independent biological runs).Data collection and analysis: The experimental design and layout (e.g. plate layout) and relevant acceptance criteria. The time points for data collection. The effect of the test item on cytotoxicity was measured. Other observations that may impact the results (e.g. autofluorescence, absorbance by the test system). Details on calculation of results. All results were clearly presented, including negative and failed runs. The statistical methods and software used. A clear description on how to interpret read outs, evaluation/data interpretation criteria and criteria for decision-making was given.Funding and competing interests: The funding sources for the study. Any competing interests were disclosed or it was explicitly stated that the authors did not have any competing interests. Information on the overall availability of the IPR protected components, including whether they are commercially available or require a Material Transfer Agreement or other licensing agreements. (See OECD Guiding principles on good practices for the availability/distribution of protected elements in OECD test guidelines). |  |
|  | **Test material** | **Header 2** |  |  |  |
|  | Test material information | Link to entity (single)Display: Basic |  | Select the appropriate Test Material Information (TMI) record. If not available in the repository, create a new one. You may also copy (clone) an existing TMI record, edit it and store it as new TMI.To change the link to an existing TMI, click the Delete button, then the Link button and proceed as described above.Depending on the purpose of the reporting or data submission, the information that must be provided may change. As a minimum, the chemical name, identifier and/or CAS number and molecular weight must be provided. | **Cross-reference:**TEST\_MATERIAL\_INFORMATION |
|  | Additional test material information | Link to entity (multiple)Display: Basic |  | Select additional Test material information record if relevant. For example, in longer terms studies more than one batch of test material can be needed or there may be differences between the labelled and unlabelled test materials. | **Cross-reference:**TEST\_MATERIAL\_INFORMATION |
|  | Specific details on test material used for the study | Text templateDisplay: Basic | **Freetext template:**SOURCE OF TEST MATERIAL- Source (i.e. manufacturer or supplier) and lot/batch number of test material:- Purity, including information on contaminants, isomers, etc.:RADIOLABELLING INFORMATION (if applicable)- Radiochemical purity:- Specific activity:- Locations of the label:- Expiration date of radiochemical substance:STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material:- Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage:- Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis:- Solubility and stability of the test material in the solvent/vehicle and the exposure medium:- Reactivity of the test material with the incubation material used (e.g. plastic ware):TREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding):- Preliminary purification step (if any):- Final concentration of a dissolved solid, stock liquid or gel:- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):FORM AS APPLIED IN THE TEST (if different from that of starting material)- Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:INFORMATION ON NANOMATERIALS- Chemical Composition:- Density:- Particle size & distribution:- Specific surface area:- Isoelectric point:- Dissolution (rate):TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable)- Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:OTHER SPECIFICS- Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.If applicable, relevant available information on the following items should be given:SOURCE OF TEST MATERIAL- Source and lot/batch No. of test material- Expiration date of the lot/batch- Purity test date: provide if availableRADIOLABELLING INFORMATION- Radiochemical purity- Specific activity- Locations of the label- Expiration date of radiochemical substanceSTABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material- Stability under test conditions- Solubility and stability of the test substance in the solvent/vehicle- Reactivity of the test substance with the solvent/vehicle or the cell culture mediumTREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding)- Preliminary purification step- Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)FORM AS APPLIED IN THE TEST (if different from that of starting material)Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.FORMULATED PRODUCT (for biocides/pesticides)Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.OTHER SPECIFICSProvide any other relevant information needed for characterising the tested material. |  |
|  | Specific details on test material used for the study (confidential) | Text templateDisplay: Basic (Confidential) | **Freetext template:**SOURCE OF TEST MATERIAL- Source (i.e. manufacturer or supplier) and lot/batch number of test material:- Purity, including information on contaminants, isomers, etc.:RADIOLABELLING INFORMATION (if applicable)- Radiochemical purity:- Specific activity:- Locations of the label:- Expiration date of radiochemical substance:STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material:- Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage:- Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis:- Solubility and stability of the test material in the solvent/vehicle and the exposure medium:- Reactivity of the test material with the incubation material used (e.g. plastic ware):TREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding):- Preliminary purification step (if any):- Final concentration of a dissolved solid, stock liquid or gel:- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):FORM AS APPLIED IN THE TEST (if different from that of starting material)- Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:INFORMATION ON NANOMATERIALS- Chemical Composition:- Density:- Particle size & distribution:- Specific surface area:- Isoelectric point:- Dissolution (rate):TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable)- Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:OTHER SPECIFICS- Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.If applicable, relevant available information on the following items should be given:SOURCE OF TEST MATERIAL- Source and lot/batch No. of test material- Expiration date of the lot/batch- Purity test date: provide if availableRADIOLABELLING INFORMATION- Radiochemical purity- Specific activity- Locations of the label- Expiration date of radiochemical substanceSTABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material- Stability under test conditions- Solubility and stability of the test substance in the solvent/vehicle- Reactivity of the test substance with the solvent/vehicle or the cell culture mediumTREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding)- Preliminary purification step- Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)FORM AS APPLIED IN THE TEST (if different from that of starting material)Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.FORMULATED PRODUCT (for biocides/pesticides)Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.OTHER SPECIFICSProvide any other relevant information needed for characterising the tested material. |  |
|  | **Test system** | **Header 2** |  |  |  |
|  | Type of test system | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- cell line- physical / chemical based- human recombinant Estrogen Receptor (hrER)- other: | A test system is any biological, chemical or physical system or a combination thereof used in a study (OECD (2018), Guidance Document on Good In Vitro Method Practices (GIVIMP), OECD Series on Testing and Assessment, No. 286, OECD Publishing, Paris).Examples of physical chemical based test systems: serum protein, peptide, enzyme.Select complex biological test system for example in case of: 3D model, induced pluripotent stem cells, organ on a chip, co-cultures, etc.Select 'other:' in case you don't find a suitable option, for example when your test system is a test kit or a lower in vivo organism. |  |
|  | Test system identity | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- AR-CALUX ® cell line- AR-Ecoscreen TM cell line- ERα-CALUX ® cell line- hERα-HeLa-9903- human recombinant ERα- human NCI-H295R adeno-carcinoma cell line- VM7Luc4E2- 22Rv1/MMTV\_GR-KO- other: | The test systems listed are those from existing test guidelines. Select the test system used or select other and provide the test system identity. Furthermore, provide information on:- Source / supplier- Catalogue / batch number- Species and strain (as relevant) of the origin of the test system.In case a co-culture of cell lines is used, or S9 mix or microsomes are used in combination with a cell line, the user is asked select 'other' and to provide the identity of all components under 'remarks'. In the later fields for 'details on the test system' and 'metabolic competence' the test system can be further described. |  |
|  | Genetic modification of the test system | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- genetically modified by supplier- not applicable- not genetically modified- other: | When applicable, provide the following information on the genetic modification:- Gene inserted- Gene species (e.g. human, rat, mouse)- Additional information on modification |  |
|  | Details on test system and experimental conditions | Text templateDisplay: Basic | **Freetext template:Option 1 ERTA STTA, ERTA ERα CALUX® and ERTA VM7Luc**CELLS- Source and type of cells:- ER endogenously expressed? If not, which receptor(s) were Transfected:- Reporter construct(s) used (including source species):- Transfection method:- Selection method for maintenance of stable transfection:- Transfection method relevant for stable lines:- Number of cell passages (from thawing):- Passage number of cells at thawing:- Methods for maintenance of cell cultures:TEST CONDITIONS- Cell counting method used for seeding prior to testing and measures taken to ensure homogeneous cell number distribution:- Solubility limitations:- Description of the methods of assessing viability applied:- Composition of media, CO2 concentration:- Concentrations of test chemical:- Volume of vehicle and test chemical added:- Incubation temperature and humidity:- Duration of treatment:- Cell density at the start of - and during treatment:- Positive and negative reference standards:- Reporter reagents (product name, supplier and lot):- Criteria for considering test runs as positive, negative or equivocal:ACCEPTABILITY CHECK- Fold inductions for each assay plate and whether they meet the minimum required by the test method based on historical controls:- Actual values for acceptability criteria, e.g. log10EC50, log10PC50, logIC50 and Hillslope values, for concurrent positive controls and reference standards:**Option 2 H295R Steroidogenesis Assay**CELLS- Source and type of cells:- Number of cell passages (cell passage identifier) of cells used in test:- Description of procedures for maintenance of cell cultures:PRE-TEST REQUIREMENTS- Description and results of chemical hormone-assay interference test:- Description and results of hormone extraction efficiency measurements:- Standard and calibration curves for all analytical assays to be conducted:- Detection limits for the selected analytical assays:TEST CONDITIONS- Cell counting method used for seeding prior to testing and measures taken to ensure homogeneous cell number distribution:- Composition of media:- Concentration of test chemical:- Cell density (estimated or measured cell concentrations at 24 hours and 48 hours):- Solubility of test chemical (limit of solubility):- Incubation time and conditions:**Option 3 ARTA 22Rv1/MMTV GR-KO, ARTA AR-CALUX® and ARTA AR-EcoScreen™**CELLS- Source and type of cells:- Storage and maintenance conditions- Passage number and level of confluence of cells used for testingTEST CONDITIONS- Cell counting method used for seeding prior to testing and measures taken to ensure homogeneous cell number distribution:- Luminometer used (e.g. model), including instrument settings:- Luciferase substrate used (product name, supplier, lot):- Type of plates and their supplier and code:- Application procedure and exposure time as specified in the protocol:- List of the acceptability criteria to be met:- Description of any modification of the test procedure:- Reference to the cytotoxicity procedure:**Option 4 hrER binding CERI assay and hrER binding FW assay**RECEPTORS- Source of receptors (supplier, catalog No., lot, species of receptor, active receptor concentration provided from supplier, certification from supplier):- Characterization of receptors (including saturation binding results) (Kd, Bmax):- Storage of receptors:- Radiolabeled ligand (supplier, catalog No., lot, specific activity):TEST CONDITIONS- Solubility limitations under assay conditions:- Composition of binding buffer:- Concentration of receptor:- Concentration of tracer (i.e. radiolabeled ligand):- Concentrations of test chemical:- Percent vehicle in final assay:- Incubation temperature and time:- Method of bound/free separation:- Positive and negative controls/reference substances:- Criteria for considering tests as positive, negative, or equivocal:ACCEPTABILITY CHECK- Actual IC50 and Hillslope values for concurrent positive controls/reference substances: | Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof. |  |
|  | Metabolic competence of the test system | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- limited metabolic activity, specify- metabolic activity, specify- unknown metabolic activity- other information on metabolic competence, describe:- not applicable | Select the option that fits best and describe the knowledge about the metabolic competence (i.e. Phase I and/or II biotransformation capacity) of the test system under remarks.For example, when the test system used is cryopreserved human pooled liver tissue homogenate 9000 g fraction (S9) procured from a commercial supplier, select “metabolic activity, specify” and specify:contains phase I and II metabolic enzymes present in the microsomal (e.g. cytochrome P450s, Flavin-containing monooxygenase, uridine 5’-diphospho-glucuronosyltransferases, carboxylesterases) and cytosolic (e.g. sulfotransferases, glutathione S-transferases, methyltransferases, N-acetyl transferases, xanthine oxidase, aldehyde oxidase) fractions. |  |
|  | **Detection method** | **Header 2** |  |  |  |
|  | Detection method used | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- analytical method (e.g. LC/MS)- chromatography- complex detection methods (e.g. imaging)- fluorescence- luminescence- radioactivity- UV/VIS absorption- other: | Indicate the readout used. Select a detection method type from the picklist and provide the type of instrument (e.g. HPLC, Spectrophotometer, Flow cytometer) or chose 'other: and specify the type or equipment used / analysis performed. |  |
|  | Details on detection method | Text templateDisplay: Basic | **Freetext template:Option 1 Semi or non-quantitative detection methods**SEMI OR NON-QUANTITATIVE DETECTION METHODSInstrument type and model:**Option 2 Quantitative analytical methods**QUANTITATIVE ANALYTICAL METHODSInstrument type and model:COMPOUND (ANALYTE): ...- Method ID:- Extraction solvent/technique:- Cleanup strategies:- Derivatisation (if any):- Instrument/detector (if further details):- Standardisation method:- Stability of standard solution:- Retention times:- Detection limit (Limit of Quantification)- Other: INTERFERING SUBSTANCE(S): STABILITY OF PARENT AND TRANSFORMATION PRODUCTS AT VARIOUS STAGES OF ANALYSIS:PROBLEMS / PRECAUTIONS:- Special problems encountered:- Precautions to be taken during:- analysis of samples:- handling of samples:- storage of samples: TOTAL TIME FOR COMPLETION: | Quantitative analytical methods:'Briefly describe further details on the principles of the method used to detect the analytes (to be specified, e.g. ''parent compound'', ''parent and transformation products'' or ''transformation product: .....'') in matrices. Use free text template and delete/add elements as appropriate. For example, add specific parameters in the case of inorganic chemicals. As an option you may include an excerpt from the study report.Note: If a residue analytical method is recorded, the details for the so-called data collection or data-gathering method should be specified here. As to the terms ''data collection method'' and ''enforcement method'' see help text for field ''Instrument / detector''.Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof. |  |
|  | **Test design** | **Header 2** |  |  |  |
|  | **Test material preparation** | **Header 3** |  |  |  |
|  | Concentration selection of the test material | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- human exposure levels- interference with the detection method (e.g. auto fluorescence)- interference with the test system (e.g. cytotoxicity or pH)- maximum allowed concentration according to the test guideline- prior information of response (e.g. dose-range finding experiment)- solubility in exposure medium- solubility in solvent- unknown- other: | For data interpretation it is important to know on what basis the highest concentration tested was selected.Prior information of response and interference with the test system can e.g. be obtained through literature or with experimental data in a dose-range finding experiment.Example for TG455 (transactivation assay with hERα-HeLa-9903 cell line):In a preliminary test the appropriate concentration range of the test chemical was determined for identifying any solubility and cytotoxicity problems, i.e. the test chemical was tested up to the maximum concentration of 1 μL/mL, 1 mg/mL, or 1 mM, whichever is the lowest. Based on the observed extent of cytotoxicity or lack of solubility, a first definite run was performed to test the chemical at log-serial dilutions starting at the maximum acceptable concentration (e.g. 1 mM, 100μM, 10μM, etc.) and the presence of cloudiness, precipitate or cytotoxicity was noted. Concentrations in a second run (and if necessary in a third run) were adjusted as appropriate to better characterise the concentration-response curve and to avoid concentrations which are found to be insoluble or to induce excessive cytotoxicity.Any free text explanation can be given in the adjacent text field to justify the dose level selected. |  |
|  | Vehicle / solvent | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- acetone- acetonitrile- DMSO- ethanol- isopropanol- mix DMSO:acetonitrile- saline- treatment/exposure medium- water- X-VIVOTM 15- 1:1 mix, acetone:acetonitrile- 1:1 mix, water:acetonitrile- not required- not specified- other: | If a vehicle or solvent was used, select the relevant item or use 'other:' and specify. You can give further relevant information in the supplementary remarks field, e.g. lot/batch no., purity, concentration, etc.In case a solvent is used that is different from those recommended in the in vitro method Standard Operating Procedure or test guideline, a justification for the choice must be provided. |  |
|  | Dilution steps / dose intervals | Text templateDisplay: Basic | **Freetext template:**DILUTION STEPS PERFORMEDProvide the following information (where available):- Dilution steps from ‘stock solution’ in the vehicle/solvent including the final % of vehicle/solvent in the exposure medium- Dose intervals in case of dose range- Number of concentrations prepared | Indicate if the test material was further diluted before exposure of the test system. In case of dose range, provide the amount of concentrations and dilution factor.Example for TG455 (transactivation assay with hERα-HeLa-9903 cell line):For the dose-range finding experiment, the test chemical was dissolved in DMSO (or other suitable solvent), and serially diluted with the same solvent at a common ratio of 1:10 to prepare solutions for dilution with media. |  |
|  | **Control and reference items** | **Header 3** |  |  |  |
|  | Controls / reference items used | List (picklist)Display: Basic | **Picklist values:**- yes- no- not specified- not required | Indicate whether controls / reference substances were used. If 'yes' is selected, the details can be entered in the repeatable block 'Controls / reference substances'. |  |
|  | **Controls / reference items** | **Block of fields (repeatable) Start** |  | Indicate whether solvent/vehicle controls, negative controls, true negative controls (i.e. negative reference substances) and/or positive controls (i.e. positive reference substances) were tested concurrently. Repeat this block of fields as necessary.In case of a robust study summary or as requested by the regulatory programme, also provide information in the supplementary remarks field, e.g. to the identity, supplier, lot and purity of the control substance(s) and the concentration / amount applied. | **Guidance for field condition:**Condition: Block of fields active only if 'Controls / reference substances used' is 'yes' |
|  | Type of controls used | List (picklist)Display: Basic | **Picklist values:**- negative/untreated controls- positive control item- reference item- solvent / vehicle controls- true negative control item- other: | Select the type of control used to demonstrate the proper performance of the test system and therefore the validity of the experiments. More than one control/reference item can be provided.See (GIVIMP, OECD guidance document 286 in the series on testing and assessment).Solvent / vehicle controls consist of solvent or vehicle alone, without test item (test material), and otherwise treated in the same way as the treatment groups.Negative / untreated controls consist of culture medium without solvent / vehicle or test item, and otherwise treated in the same way as the treatment groups.True negative controls include items (e.g. chemicals) with known lack of activity.Positive controls include items with known activity. Reference items are substances with known activity, used as basis for comparison with the test item (test material). |  |
|  | Description of reference and control items used | List sup. (picklist with remarks - 2,000 char.)Display: Basic | **Picklist values:**- 17α-estradiol - [CAS 57-91-0]- 17α-methyltestosterone - [CAS 58-18-4]- 17β-estradiol (E2) - [CAS 50-28-2]- 4-hydroxytamoxifen - [CAS 68047-06-3]- 5α-Dihydrotestosterone - [CAS 521-18-6]- aminoglutethimide - [CAS 125-84-8]- atrazine - [CAS 1912-24-9]- bicalutamide - [CAS 90357-06-5]- bisphenol A - [CAS 80-05-7]- chorionic gonadotropin (HCG) - [CAS 9002-61-3]- combination of raloxifene hydrochloride [CAS 84449-90-1] and 17β-estradiol (E2) - [CAS 50-28-2] - [CAS 84449-90-1 and CAS 50-28-2]- corticosterone - [CAS 50-22-6]- cycloheximide - [CAS 66-81-9]- DMSO - [CAS 67-68-5]- Di(2-ethylhexyl)phthalate - [CAS 117-81-7]- Di-n-butyl-phtalate (DBP) - [CAS 84-742-2]- ethanol - [CAS 64-17-5]- flutamide - [CAS 13311-84-7]- forskolin - [CAS 66575-29-9]- hydroxyflutamide - [CAS 52806-53-8]- levonorgestrel - [CAS 797-63-7]- linuron - [CAS 330-55-2]- medium- mestanolone - [CAS 521-11-9]- methoxychlor - [CAS 72-43-5]- norethindrone - [CAS 68-22-4]- norethynodrel - [CAS 68-23-5]- octyltriethoxysilane - [CAS 2943-75-1]- prochloraz - [CAS 67747-09-5]- resveratrol - [CAS 501-36-0]- tamoxifen - [CAS 10540-29-1]- water - [CAS 7732-18-5]- other: | Select the reference or control item used or provide the name and identifier (e.g. CAS number), and in the remarks field the purity and concentration (range) used.If 'other:' is selected, provide the name and identity (CAS number) in the additional text field.For each selection (including the 'other:'), provide purity (%) and concentration (range or single concentration) in the field 'Remarks'. |  |
|  | Remarks | Text (32,768 char.)Display: Basic |  | Additional information, such as solvents used. |  |
|  | **Controls / reference items** | **Block of fields (repeatable) End** |  |  |  |
|  | **Experimental conditions** | **Header 3** |  |  |  |
|  | Additional analysis: e.g. cytotoxicity assay or other | List multi. (multi-select list with remarks - 2,000 char.)Display: Basic | **Picklist values:**- ATP assay- BrdU or EdU incorporation into DNA- cell counting- cell death / apoptosis markers- LDH-release- mitochondrial depolarisation assay- neutral red uptake- observation of cell shape- other cytotoxicity assay, specify- other type of analysis, specify- penetration of dyes in non-viable cells (e.g. trypan blue, propidium iodide)- resazurin reduction assay (alamar blue or similar)- retention of dyes in viable cells (e.g. fluorescein diacetate or calcein-AM)- staining of proteins or DNA in the overall cell mass- tetrazolium dye reduction assays (MTT or similar)- no other analysis performed | This picklist was established on basis of GIVIMP annex I (OECD, 2018).Select the viability assay used to measure cytotoxicity: Select 'other cytotoxicity assay' in case another type of cytotoxicity assay was used. Select 'other type of analysis' in case another or another type of analysis was performed that is important for the interpretation of results (e.g. pH, autofluorescence, etc.).In the remarks field any additional information can be provided. |  |
|  | **Data analysis** | **Header 3** |  |  |  |
|  | Acceptance criteria for the test material results | Text templateDisplay: Basic | **Freetext template:**Provide a description or list of the study acceptance criteria: | Acceptance criteria: Criteria for when results can be accepted, i.e. a set of well-defined parameters describing aspects of the method such as range for positive and negative controls (GIVIMP, OECD, 2018).For cell-based methods, the acceptance criteria should include the level of cytotoxicity or other type of interference that is accepted / not accepted.Any free text explanation can be given to specify which criteria exist for acceptance of results, e.g. related to reference and control substances or vehicle/solvent control, cytotoxicity or other interference, capturing of full dose-response, minimum/maximum response to be observed or outliers. |  |
|  | Data calculation and statistics | Text templateDisplay: Basic | **Freetext template:**- Calculations performed- Statistical methods used- Where relevant, provide the method used to exclude outliers. | Provide the method used to calculate the results from raw data to the parameters calculated, such as normalisation, use of calibration curve, subtraction of control values, calculation of averages, Standard deviations etc.List the statistical methods used to derive the parameters to be reported. Include a statement on the appropriateness of the statistical analysis used. Parameters, their explanation and values should be provided in the "Test results" section.Examples for TG455 (transactivation assay with hERα-HeLa-9903 cell line):For the calculation of EC50 and maximum induction level, Graphpad Prism statistical software was used.The calculations of PC10, PC50 and PCMax in ER agonist assay and IC30 and IC50 in ER antagonist assay were made by using the spreadsheet available with the Test Guideline on the OECD public website.Specify if outlier analysis is performed and what (statistical) method was used to exclude values. |  |
|  | Evaluation / data interpretation criteria | Text templateDisplay: Basic | **Freetext template:**- Evaluation / data interpretation criteria:- Results will be expressed as: | Describe the evaluation criteria used in the study to judge if the test material is positive, negative or equivocal.Example for TG455 (transactivation assay with hERα-HeLa-9903 cell line)Decision criteria for ER agonist assayPositive: RPCMax is equal to or exceeds 10% of the response of the positive control in at least two of two or two of three runs.Negative: RPCMax fails to achieve at least 10% of the response of the positive control in two of two or two of three runs.Decision criteria for ER antagonist assayPositive: IC30 is calculated in at least two of two or two of three runs.Negative: IC30 fails to calculate in two of two or two of three runs. |  |
|  | **Any other information on materials and methods incl. tables** | **Header 2** |  |  |  |
|  |  | Text (rich-text area)Display: Basic |  | In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry. |  |
|  | **Results and discussion** | **Header 1** |  |  |  |
|  | **Test results** | **Header 2** |  |  |  |
|  | **Test results** | **Block of fields (repeatable) Start** |  | Report the parameters obtained and effective concentration(s) for the type of effect specified in the 'Test results' fields. Copy this field block for entering more than one experiment if necessary, e.g. for a test guideline or if different concentration ranges were tested.One experiment may include more than one replicate for each tested concentration. An independent experiment is usually carried out with independently prepared controls, test system, reagents used for analysis and on a different time.Set this flag if a key observation should be identified for the conclusion section. |  |
|  | Key result | Check boxDisplay: Basic |  | Set this flag if a key observation should be identified for the conclusion section. |  |
|  | Concentration selection of the test material | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- human exposure levels- interference with the detection method (e.g. auto fluorescence)- interference with the test system (e.g. cytotoxicity or pH)- maximum allowed concentration according to the test guideline- prior information of response (e.g. dose-range finding experiment)- solubility in exposure medium- solubility in solvent- unknown- other: | For data interpretation it is important to know on what basis the highest concentration tested was selected.Prior information of response and interference with the test system can e.g. be obtained through literature or with experimental data in a dose-range finding experiment.Example for TG455 (transactivation assay with hERα-HeLa-9903 cell line):For the dose-range finding experiment, the test chemical was dissolved in DMSO (or other suitable solvent), and serially diluted with the same solvent at a common ratio of 1:10 to prepare solutions for dilution with media. In a following preliminary test the appropriate concentration range of the test chemical was determined for identifying any solubility and cytotoxicity problems. Therefore, the test chemical was tested up to the maximum concentration of 1 μL/mL, 1 mg/mL, or 1 mM, whichever is the lowest. This was followed by a first definite run testing the chemical at log-serial dilutions starting at the maximum acceptable concentration (e.g. 1 mM, 100μM, 10μM, etc.). Concentrations in a second run (and if necessary in a third run) were adjusted as appropriate to better characterise the concentration-response curve and to avoid concentrations which are found to be insoluble or to induce excessive cytotoxicity.Any free text explanation can be given in the adjacent text field to justify the dose level selected. |  |
|  | Concentration range tested | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- %- g/L- g/kg- mg/mL- mg/L- mg/kg- mmol/L- mol/L- ng/L- nmol/L- pg/L- pmol/L- ppb- ppm- µg/L- µg/kg- µmol/L- other:- s-1M-1 | Indicate the lowest and highest concentration tested.Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. |  |
|  | Number of replicates and outliers | Text templateDisplay: Basic | **Freetext template:**- Number of replicates:- Information on outlier removal:- Impact of outlier removal on the results: | Specify the number of replicates per concentration and if any values were excluded after outlier analysis. |  |
|  | **Parameter and result** | **Block of fields (repeatable) Start** |  |  |  |
|  | Parameter | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- % viable cells- |CV| of log EC50- |CV| of log IC50- 95% CI- DPM- EC10- EC20- EC50- IC10- IC20- IC30- IC50- LEC- LOEC- log EC10- log EC20- log EC50- log IC10- log IC20- log IC30- log IC50- log PC10- log PC50- log PC80- NOEC- OD- PC10- PC50- PC80- PCMax- PCMin- relative binding affinity (RBA)- relative fluorescence units (RFU)- RPCMax- RPCMin- SD- SEM- TCxMax (maximum induction)- TCxMin (minimum induction)- other: | This picklist displays either the parameters specific to the selected method, or general parameters in case another method is used.Provide the relevant parameters, representative of the effect measured, that are calculated for your method. Existing test guidelines and OHTs for in vitro methods (e.g. OHT 66-1) may provide additional suggestions for other type of parameters.For guideline methods, all relevant parameters are listed.In case of a non-guideline method, the listed parameters are from existing OECD test guidelines, where the use of the parameters is explained.Provide in the remarks field, other information that provides explanation of the parameter.Explanation of some parameters:No-observed effect concentration (NOEC) is defined as the test concentration below the lowest concentration that did result in a significant effect in the specific experiment.Lowest-observed effect concentration (LOEC) is the lowest concentration out of the tested concentrations at which a statistically significant difference from the control group is observed.IC50 is the half maximal effective concentration of an inhibitory test chemical.PC50 is the concentration of a test chemical at which the measured activity in an agonist assay is 50% of the maximum activity induced by the positive control.PC values can be used when incomplete or ambiguous dose response curves are obtained and EC values cannot be calculated. |  |
|  | Result for the parameter | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- %- g/L- g/kg- mg/mL- mg/L- mg/kg- mmol/L- mol/L- ng/L- nmol/L- pg/L- pmol/L- ppb- ppm- µg/L- µg/kg- µmol/L- other:- s-1M-1 | Provide the result for the selected parameter and select the appropriate unit. |  |
|  | **Parameter and result** | **Block of fields (repeatable) End** |  |  |  |
|  | **Other observations** | **Block of fields (repeatable) Start** |  |  |  |
|  | Observation | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- absorbance by the test material- auto fluorescence- cytotoxicity- pH change- precipitation- no other observations- other: | Indicate other observations that are important for results interpretation such as information on cytotoxic concentrations, precipitation observed at specific concentrations, other parameters measured. Specify the observation and respective test concentration(s). Alternatively or in addition, use the field 'Any other information on results incl. tables'. If you refer to table(s), use appropriate table numbers (e.g. ‘… see Table 1’).Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof. |  |
|  | Concentration | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- %- g/L- g/kg- mg/mL- mg/L- mg/kg- mmol/L- mol/L- ng/L- nmol/L- pg/L- pmol/L- ppb- ppm- µg/L- µg/kg- µmol/L- other:- s-1M-1 | Provide the result for other observations and select the appropriate unit. |  |
|  | **Other observations** | **Block of fields (repeatable) End** |  |  |  |
|  | Results for the test material | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- binder- data inconclusive- equivocal- negative- non-binder- positive- supposedly negative- technically compromised- not interpretable- not specified- other: | The options in the picklist are derived from existing in vitro OECD test guidelines.Indicate the result of the test conducted.In the remarks field additional information can be added. For example when selecting binder additional information could be 'competitive', 'non competitive', 'specific' or 'non-specific'.Example for TG455 (transactivation assay with hERα-HeLa-9903 cell line), ER agonist assay:- Positive if: RPCMax is equal to or exceeds 10% of the response of the positive control in at least two of two or two of three runs.Negative if: RPCMax fails to achieve at least 10% of the response of the positive control in two of two or two of three runs. |  |
|  | Acceptance of results | List multi. (multi-select list with remarks)Display: Basic | **Picklist values:**- minimum response by the test system obtained- negative control item- no acceptance criteria were used- positive control item- reference item- solvent / vehicle controls- test material- variability within replicate measurements- other: | Select the element for which acceptance criteria exist and indicate in the remarks field if the results are valid or invalid.In case results are invalid, please describe in the next field 'Remarks on results' why the result is invalid (e.g. precipitation observed, toxicity of the test material, co-elution with the peptide, etc.), and what is the impact of invalid data on the results. |  |
|  | Remarks on results | Text (32,768 char.)Display: Basic |  | This field can be used for:- explaining expert judgement, in case it was applied;- providing a justification;- giving a qualitative description of results in addition to or if no numeric value(s) were derived;- providing information in case a result may be over-estimated or under-estimated;- giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field;- explaining the impact on the results in case one or more acceptance criteria were not met;- any additional information. |  |
|  | **Attached material** | **Block of fields (repeatable) Start** |  |  |  |
|  | Type of attachment | List multi. (multi-select list with remarks)Display: Basic | **Picklist values:**- chromatogram- cytotoxicity results (where relevant)- data analysis file (calculation of parameters)- graph- picture- plate layout (where applicable)- raw data- table- other: | Choose the type of document from the picklist or select 'other:'.For test guidelines that provide a reporting template (data analysis file), that file must be completed and can be uploaded here or in the overall results section. Upload file(s) containing data or results by clicking the ‘Select files’ button. As appropriate, enter any additional information, e.g. language. The file name and the filename extension is displayed after uploading the document. |  |
|  | Attachment | Attachment (single)Display: Basic |  | Attach the document indicated in the field "Type of attachment". |  |
|  | **Attached material** | **Block of fields (repeatable) End** |  |  |  |
|  | **Test results** | **Block of fields (repeatable) End** |  |  |  |
|  | **Overall remarks, attachments** | **Header 1** |  |  |  |
|  | Overall remarks | Text (rich-text area)Display: Basic |  | In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry. |  |
|  | **Attachments** | **Block of fields (repeatable) Start** |  | Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula).Copy this block of fields for attaching more than one file. |  |
|  | Type | List (picklist)Display: Basic | **Picklist values:**- full study report- illustration (picture/graph)- other: | Specify the type of attachment inserted, for example the 'full study report'. |  |
|  | Attached (confidential) document | Attachment (single)Display: Basic (Confidential) |  | An electronic copy of the full study report or other documents can be attached as Word, pdf or other file types. |  |
|  | Attached (sanitised) documents for publication | Attachment (single)Display: Basic |  | An electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. This attachment should be sanitised if needed. |  |
|  | Remarks | Text (255 char.)Display: Basic |  | As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory. |  |
|  | **Attachments** | **Block of fields (repeatable) End** |  |  |  |
|  | **Applicant's summary and conclusion** | **Header 1** |  |  |  |
|  | **Interpretation of results / observations** | **Header 2** |  |  |  |
|  | Overall results and conclusion | Text templateDisplay: Basic | **Freetext template:**Describe the overall result as:a) based on observations O1, O2, …Onb) the test materialc) triggers/does not triggerd) a certain mechanism (process/object/action)e) on a certain biological level | Provide the overall result for the test material, on basis of one or more experiments and all observations reported in this template.Convey a clear statement on the mechanistic information obtained.Add the effect concentration in the next fields.Example for TG455 (transactivation assay with hERα-HeLa-9903 cell line), ER agonist assay:The RPCMax exceeded 10% of the response of the positive control in at least two of two or two of three runs. Therefore, the test substance can be judged as estrogen receptor agonist. |  |
|  | Type of result | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- quantitative- qualitative | Indicate if the results are qualitative when the result is yes/no or positive/negative or quantitative when dose-response information is obtained and an effect level (concentration) can be determined. |  |
|  | Effect concentration | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- EC10- EC20- EC50- IC10- IC20- IC30- IC50- LEC- LOEC- log EC10- log EC20- log EC50- log IC10- log IC20- log IC30- log IC50- log PC10- log PC50- log PC80- NOEC- PC10- PC50- PC80- PCMax- PCMin- RPCMax- RPCMin- TCxMax (maximum induction)- TCxMin (minimum induction)- not determined- other: | Where available, provide the effect concentration taking into account results from more than one experiment.Explanation of some parameters:No-observed effect concentration (NOEC) is defined as the test concentration below the lowest concentration that did result in a significant effect in the specific experiment.Lowest-observed effect concentration (LOEC) is the lowest concentration out of the tested concentrations at which a statistically significant difference from the control group is observed.IC50 is the half maximal effective concentration of an inhibitory test chemical.PC50 is the concentration of a test chemical at which the measured activity in an agonist assay is 50% of the maximum activity induced by the positive control. |  |
|  | Concentration | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- %- g/L- g/kg- mg/mL- mg/L- mg/kg- mmol/L- mol/L- ng/L- nmol/L- pg/L- pmol/L- ppb- ppm- µg/L- µg/kg- µmol/L- other:- s-1M-1 | Provide the effect concentration and select the appropriate unit. |  |
|  | Remarks | Text (32,768 char.)Display: Basic |  | Include any remarks as appropriate. |  |
|  | **Executive summary** | **Header 2** |  |  |  |
|  |  | Text (rich-text area)Display: Basic |  | If required by the respective national/regional programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, upload the respective free text template if available from the drop-down list or copy it from the corresponding document.You may also provide information on other existing data or studies that confirm the results obtained.Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof. |  |