**Template #70: Genetic toxicity in vitro *(Version [11.2]-[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** |  |  |  |
|  |  | Confidentiality  Display: Basic |  |  |  |
|  | Endpoint | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - in vitro DNA damage and/or repair study - in vitro chromosome aberration study in mammalian cells - in vitro / micronucleus study - in vitro gene mutation study in bacteria - in vitro gene mutation study in mammalian cells - in vitro transformation study in mammalian cells - genetic toxicity in vitro, 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. | **Guidance for data migration:** The relevant target phrase is selected as triggered primarily by the value(s) of source field 'Guideline'. If not sufficient, fields s 'Type of genotoxicity', 'Type of study' and 'Species / strain' are used as secondary trigger fields. For instance, the if the Guideline contains the string 'sister Chromatid' or 'repair' or 'recombination' then the phrase 'in vitro DNA damage and/or repair study' is selected. As a fallback the generic phrase 'genetic toxicity in vitro' is selected. Note: The generic phrase is only used for migration, but otherwise deactivated in the picklist. For new entries a generic phrase is provided which consists of the OHT title followed by 'other', i.e. <OHT title>, other. |
|  | 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 box  Display: 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 box  Display: 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 box  Display: 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 | Date  Display: 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 | Date  Display: 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:** - an in vitro chromosome aberration study in mammalian cells or in vitro micronucleus study does not need to be conducted because adequate data from an in vivo test are available - [study scientifically not necessary / other information available] - an in vitro chromosome aberration study in mammalian cells or in vitro micronucleus study does not need to be conducted because the substance is known to be carcinogenic category 1A or 1B and germ cell mutagenic category 1A, 1B or 2, and appropriate risk management measures are implemented - [study scientifically not necessary / other information available] - an in vitro chromosome aberration study in mammalian cells or in vitro micronucleus study does not need to be conducted because the substance is known to be germ cell mutagenic category 1A or 1B, and appropriate risk management measures are implemented - [study scientifically not necessary / other information available] - an in vitro gene mutation study in bacteria study does not need to be conducted because the substance is known be germ cell mutagenic category 1A or 1B, and appropriate risk management measures are implemented - [study scientifically not necessary / other information available] - an in vitro gene mutation study in bacteria study does not need to be conducted because the substance is known to be germ cell mutagenic category 1A, 1B or 2 and carcinogenic category 1A or 1B, and appropriate risk management measures are implemented - [study scientifically not necessary / other information available] - an in vitro gene mutation study in bacteria study does not need to be conducted for nanoforms where it is not appropriate - [study scientifically not necessary / other information available] - an in vitro mutagenicity study does not need to be conducted because this test is not applicable for the substance - [study scientifically not necessary / other information available] - an in vitro gene mutation study in mammalian cells does not need to be conducted because a positive result was found in in vitro chromosome aberration study in mammalian cells - [study scientifically not necessary / other information available] - an in vitro gene mutation study in mammalian cells does not need to be conducted because a positive result was found in in vitro gene mutation study in bacteria - [study scientifically not necessary / other information available] - an in vitro gene mutation study in mammalian cells does not need to be conducted because a positive result was found in in vitro micronucleus study - [study scientifically not necessary / other information available] - an in vitro gene mutation study in mammalian cells does not need to be conducted because adequate data from a reliable in vivo mammalian gene mutation test are available - [study scientifically not necessary / other information available] - an in vitro gene mutation study in mammalian cells does not need to be conducted because the substance is known to be germ cell mutagenic category 1A or 1B, and appropriate risk management measures are implemented - [study scientifically not necessary / other information available] - an in vitro gene mutation study in mammalian cells does not need to be conducted because the substance is known to be germ cell mutagenic category 1A, 1B or 2 and carcinogenic category 1A or 1B, and appropriate risk management measures are implemented - [study scientifically not necessary / other information available] - 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 template  Display: 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. SOFTWARE  2. MODEL (incl. version number)  3. SMILES OR OTHER IDENTIFIERS USED AS INPUT FOR THE MODEL  4. 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** |  |  |  |
|  | **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:** - EPA OPP 84-2 - [genetic toxicity in vitro, other] - EPA OPPTS 870.5100 - Bacterial Reverse Mutation Test (August 1998) - [in vitro gene mutation study in bacteria] - EPA OPPTS 870.5140 - Gene Mutation in Aspergillus nidulans - [genetic toxicity in vitro, other] - EPA OPPTS 870.5250 - Gene Mutation in Neurospora crassa - [genetic toxicity in vitro, other] - EPA OPPTS 870.5265 (The Salmonella typhimurium Bacterial Reverse Mutation Test) - [in vitro gene mutation study in bacteria] - EPA OPPTS 870.5300 - In vitro Mammalian Cell Gene Mutation Test - [in vitro gene mutation study in mammalian cells] - EPA OPPTS 870.5375 - In vitro Mammalian Chromosome Aberration Test - [in vitro cytogenicity / chromosome aberration study in mammalian cells] - EPA OPPTS 870.5500 - Bacterial DNA Damage or Repair Tests - [in vitro DNA damage and/or repair study] - EPA OPPTS 870.5550 - Unscheduled DNA Synthesis in Mammalian Cells in Culture - [in vitro DNA damage and/or repair study] - EPA OPPTS 870.5575 - Mitotic Gene Conversion in Saccharomyces cerevisiae - [in vitro DNA damage and/or repair study] - EPA OPPTS 870.5900 - In vitro Sister Chromatid Exchange Assay - [in vitro DNA damage and/or repair study] - EPA OPPTS 870.8800 (Morphologic transformation of cells in culture) - [in vitro transformation study in mammalian cells] - EPA OTS 795.2850 (Morphologic Transformation of Cells in Culture) - [in vitro transformation study in mammalian cells] - EPA OTS 798.5100 (Escherichia coli WP2 and WP2 UVRA Reverse Mutation Test) - [in vitro gene mutation study in bacteria] - EPA OTS 798.5140 (Gene Mutation in Aspergillus nidulans) - [genetic toxicity in vitro, other] - EPA OTS 798.5250 (Gene Mutation in Neurospora crassa) - [genetic toxicity in vitro, other] - EPA OTS 798.5265 (The Salmonella typhimurium Bacterial Reverse Mutation Test) - [in vitro gene mutation study in bacteria] - EPA OTS 798.5300 (Detection of Gene Mutations in Somatic Cells in Culture) - [in vitro gene mutation study in mammalian cells] - EPA OTS 798.5375 (In Vitro Mammalian Chromosome Aberration) - [in vitro cytogenicity / chromosome aberration study in mammalian cells] - EPA OTS 798.5500 (Bacterial DNA Damage or Repair Tests) - [in vitro DNA damage and/or repair study] - EPA OTS 798.5550 (DNA Damage and Repair, Unscheduled DNA Synthesis in Mammalian Cells In Vitro) - [in vitro DNA damage and/or repair study] - EPA OTS 798.5575 (Saccharomyces cerevisiae Mitotic Recombination Assay) - [in vitro DNA damage and/or repair study] - EPA OTS 798.5900 (In Vitro Sister Chromatid Exchange Assay in Mammalian Cells) - [in vitro DNA damage and/or repair study] - EU Method B.10 (Mutagenicity - In Vitro Mammalian Chromosome Aberration Test) - [in vitro cytogenicity / chromosome aberration study in mammalian cells] - EU Method B.13/14 (Mutagenicity - Reverse Mutation Test Using Bacteria) - [in vitro gene mutation study in bacteria] - EU Method B.15 (Gene Mutation - Saccharomyces cerevisae) - [genetic toxicity in vitro, other] - EU Method B.16 (Mitotic Recombination - Saccharomyces cerevisiae) - [in vitro DNA damage and/or repair study] - EU Method B.17 (Mutagenicity - In Vitro Mammalian Cell Gene Mutation Test) - [in vitro gene mutation study in mammalian cells] - EU Method B.18 (DNA Damage and Repair - Unscheduled DNA Synthesis - Mammalian Cells In Vitro) - [in vitro DNA damage and/or repair study] - EU Method B.19 (Sister Chromatid Exchange Assay In Vitro) - [in vitro DNA damage and/or repair study] - EU Method B.21 (In Vitro Mammalian Cell Transformation Test) - [in vitro transformation study in mammalian cells] - JAPAN: Guidelines for Screening Mutagenicity Testing Of Chemicals - [genetic toxicity in vitro, other] - OECD Guideline 471 (Bacterial Reverse Mutation Assay) - [in vitro gene mutation study in bacteria] - OECD Guideline 472 (Genetic Toxicology: Escherichia coli, Reverse Mutation Assay) - [in vitro gene mutation study in bacteria (before 21 July 1997)] - OECD Guideline 473 (In Vitro Mammalian Chromosomal Aberration Test) - [in vitro cytogenicity / chromosomal aberration study in mammalian cells (from 26 September 2014)] - OECD Guideline 473 (In Vitro Mammalian Chromosome Aberration Test) - [in vitro cytogenicity / chromosome aberration study in mammalian cells (before 26 September 2014)] - OECD Guideline 476 (In Vitro Mammalian Cell Gene Mutation Test using the Hprt and xprt genes) - [in vitro gene mutation study in mammalian cells (from 28 July 2015)] - OECD Guideline 476 (In Vitro Mammalian Cell Gene Mutation Test) - [in vitro gene mutation study in mammalian cells (before 28 July 2015)] - OECD Guideline 479 (Genetic Toxicology: In Vitro Sister Chromatid Exchange Assay in Mammalian Cells) - [in vitro DNA damage and/or repair study (before 2 April 2014)] - OECD Guideline 480 (Genetic Toxicology: Saccharomyces cerevisiae, Gene Mutation Assay) - [genetic toxicity in vitro, other (before 2 April 2014)] - OECD Guideline 481 (Genetic Toxicology: Saccharomyces cerevisiae, Mitotic Recombination Assay) - [in vitro DNA damage and/or repair study (before 2 April 2014)] - OECD Guideline 482 (Genetic Toxicology: DNA Damage and Repair, Unscheduled DNA Synthesis in Mammalian Cells In Vitro) - [in vitro DNA damage and/or repair study (before 2 April 2014)] - OECD Guideline 487 (In vitro Mammalian Cell Micronucleus Test) - [in vitro cytogenicity / micronucleus study] - OECD Guideline 490 (In Vitro Mammalian Cell Gene Mutation Tests Using the Thymidine Kinase Gene) - [in vitro gene mutation study in mammalian cells] - 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 template  Display: 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. |  |
|  | Type of assay | List (picklist)  Display: Basic | **Picklist values:** - Bacillus subtilis recombination assay - [in vitro DNA damage and/or repair study] - bacterial forward mutation assay - [in vitro gene mutation study in bacteria] - bacterial reverse mutation assay - [in vitro gene mutation study in bacteria] - comet assay - [in vitro DNA damage and/or repair study] - gene mutation assay in fungi - [genetic toxicity in vitro, other] - in vitro mammalian cell micronucleus test - [in vitro cytogenicity / micronucleus study] - in vitro mammalian chromosome aberration test - [in vitro cytogenicity / chromosome aberration study in mammalian cells] - in vitro mammalian cell gene mutation test using the Hprt and xprt genes - [in vitro gene mutation study in mammalian cells] - in vitro mammalian cell gene mutation tests using the thymidine kinase gene - [in vitro gene mutation study in mammalian cells] - in vitro mammalian cell transformation assay - [in vitro transformation study in mammalian cells] - mitotic recombination assay with Saccharomyces cerevisiae - [in vitro DNA damage and/or repair study] - sister chromatid exchange assay in mammalian cells - [in vitro DNA damage and/or repair study] - SOS/umu assay - [in vitro DNA damage and/or repair study] - yeast cytogenetic assay - [genetic toxicity in vitro, other] - other: | As appropriate supplement the information provided in field 'Endpoint' and indicate the type of assay used. |  |
|  | **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 template  Display: 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 available  RADIOLABELLING INFORMATION  - 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 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 medium  TREATMENT 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 SPECIFICS  Provide any other relevant information needed for characterising the tested material. |  |
|  | Specific details on test material used for the study (confidential) | Text template  Display: 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 available  RADIOLABELLING INFORMATION  - 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 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 medium  TREATMENT 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 SPECIFICS  Provide any other relevant information needed for characterising the tested material. |  |
|  | **Method** | **Header 2** |  |  |  |
|  | Target gene | Text (2,000 char.)  Display: Basic |  | Indicate the target gene (HPRT, XPRT, TK, ATPase, other: specify) only if necessary to characterise the test system. |  |
|  | **Species / strain** | **Block of fields (repeatable) Start** |  | Indicate the species and tester strain(s) used in the type of study indicated in the respective field above. Copy this field block for each tester strain. |  |
|  | Species / strain / cell type | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 - [bacteria] - S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and TA 102 - [bacteria] - S. typhimurium TA 1535, TA 1537, TA 98, TA 100 and E. coli WP2 - [bacteria] - S. typhimurium TA 1535 - [bacteria] - S. typhimurium TA 1537 - [bacteria] - S. typhimurium TA 1535 pSK1002 - [bacteria] - S. typhimurium TA 97 - [bacteria] - S. typhimurium TA 97a - [bacteria] - S. typhimurium TA 98 - [bacteria] - S. typhimurium TA 100 - [bacteria] - S. typhimurium TA 1538 - [bacteria] - S. typhimurium TA 102 - [bacteria] - S. typhimurium, other: - [bacteria] - E. coli WP2 - [bacteria] - E. coli WP2 uvr A - [bacteria] - E. coli WP2 uvr A pKM 101 - [bacteria] - E. coli, other: - [bacteria] - bacteria, other: - [bacteria] - Saccharomyces cerevisiae - [yeast] - yeast, other: - [yeast] - Chinese hamster Ovary (CHO) - [mammalian cell line] - Chinese hamster lung (CHL/IU) - [mammalian cell line] - Chinese hamster lung fibroblasts (V79) - [mammalian cell line] - mouse lymphoma L5178Y cells - [mammalian cell line] - human lymphoblastoid cells (TK6) - [mammalian cell line] - mammalian cell line, other: - [mammalian cell line] - lymphocytes: - [primary culture] - hepatocytes: - [primary culture] - primary culture, other: - [primary culture] - other: - not specified | Select as appropriate. If not available from picklist, select 'other' and specify. |  |
|  | Details on mammalian cell type (if applicable) | Text template  Display: Detailed | **Freetext template:** CELLS USED - Type and source of cells: - Suitability of cells: - Normal cell cycle time (negative control):  For cell lines: - Absence of Mycoplasma contamination: - Number of passages if applicable: - Methods for maintenance in cell culture: - Cell cycle length, doubling time or proliferation index : - Modal number of chromosomes: - Periodically checked for karyotype stability: [yes/no] - Periodically ‘cleansed’ of spontaneous mutants: [yes/no]  For lymphocytes: - Sex, age and number of blood donors: - Whether whole blood or separated lymphocytes were used: - Whether blood from different donors were pooled or not: - Mitogen used for lymphocytes:  MEDIA USED - Type and composition of media, CO2 concentration, humidity level, temperature, if applicable: | For robust study summaries, describe relevant details on cell cultures if applicable. 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. |  |
|  | Additional strain / cell type characteristics | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - DNA polymerase A deficient - acetyltransferase proficient - acetyltransferase deficient - nitroreductase deficient - p53 proficiency for cell lines - not applicable - other: - not specified | For robust study summaries, indicate additional strain characteristics (e.g. 'DNA-Polymerase-A-deficient') only if necessary to characterise the test system. Otherwise, leave this subfield empty. |  |
|  | **Species / strain** | **Block of fields (repeatable) End** |  |  |  |
|  | Cytokinesis block (if used) | Text (2,000 char.)  Display: Basic |  | If a cytokinesis blocking substance (e.g. cytoB) was used, indicate its identity and its concentration and duration of cell exposure. |  |
|  | Metabolic activation | List (picklist)  Display: Basic | **Picklist values:** - with - with and without - without - not applicable - not specified | Indicate whether metabolic activation was applied or not. Select 'not applicable' for mammalian cell lines when no exogenous metabolic system is required. |  |
|  | Metabolic activation system | Text template  Display: Basic | **Freetext template:** Type and composition of metabolic activation system: - source of S9 - method of preparation of S9 mix - concentration or volume of S9 mix and S9 in the final culture medium - quality controls of S9 (e.g., enzymatic activity, sterility, metabolic capability) | For robust study summaries, specify metabolic activation system, if any. Indicate the type and composition of and acceptability criteria for the metabolic activation system used. Alternatively or in addition refer to appropriate table(s), which can be uploaded in the rich text field “Any other information on materials and methods incl. tables”. Use predefined table or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (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. |  |
|  | Test concentrations | Text (2,000 char.)  Display: Basic |  | Indicate the test concentrations without and with metabolic activation, and for the different treatment harvest schedules.  For robust study summaries or as requested by the regulatory programme, include the maximum dose level used, for instance if maximum recommended concentration for the test, limited by solubility (in solvent and/or culture medium, and presence of precipitates) or cytotoxicity indicating the parameter measured and the targeted level of cytotoxicity, and a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) if any. Use table numbers in the sequence in which you refer to them in the Remarks text (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. |  |
|  | High dose level used | List (picklist)  Display: Basic | **Picklist values:** - yes - no | Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided. |  |
|  | Justification for deviation from the high dose level | Text template  Display: Basic | **Freetext template:** Justification for deviation from the high dose level | Provide a justification for deviating from the high dose level. |  |
|  | Vehicle / solvent | Text template  Display: Detailed | **Freetext template:** - Vehicle(s)/solvent(s) used: [none; no data; acetone; arachis oil; beeswax; carbowaxe; castor oil; cetosteryl alcohol; cetyl alcohol; CMC (carboxymethyl cellulose); coconut oil; corn oil; cotton seed oil; DMSO; ethanol; glycerol ester; glycolester; hydrogenated vegetable oil; lecithin; macrogel ester; maize oil; olive oil; paraffin oil; peanut oil; petrolatum; physiol. saline; poloxamer; polyethylene glycol; propylene glycol; silicone oil; sorbitan derivative; soya oil; theobroma oil; vegetable oil; aqueous solvents (water or saline or culture medium)]  - Justification for choice of solvent/vehicle:  - Justification for percentage of solvent in the final culture medium: | Indicate whether and which vehicle(s)/solvent(s) was/were used or state 'none' or 'no data' as applicable. Indicate if different vehicle/ solvent were used for tests with and without metabolic activation.  Provide the percentage or volume of vehicle/solvent in the medium (e.g. 'DMSO (1% or 0.1 ml per 10 ml medium') and a justification for the choice of solvent/vehicle.  Also indicate whether vehicle (or negative) controls (i.e. consisting of culture medium or medium with solvent or vehicle alone) were tested for their compatibility with the test chemical, test system and their lack of genetic toxicity at the concentrations used.  Use freetext template and delete/add elements as appropriate. Note that the list of substances provided is not exhaustive. |  |
|  | **Controls** | **Block of fields (repeatable) Start** |  | Indicate whether vehicle, true negative and/or positive controls were tested. Repeat this block of fields as necessary, particularly if controls or different substances were used for tests with and without metabolic activation or cytokinesis block. If necessary, indicate so in the supplementary remarks field or in subfield 'Remarks'. |  |
|  | Untreated negative controls | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - yes - no - other: - not specified | Indicate whether untreated negative controls (i.e. consisting of culture medium without solvent / vehicle or test substance, and otherwise treated in the same way as the treatment groups) were tested for their compatibility with the test chemical, test system and their lack of genetic toxicity at the concentrations used . Any explanations can be given in the supplementary remarks field. |  |
|  | Negative solvent / vehicle controls | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - yes - no - other: - not specified | Indicate whether solvent / vehicle controls (i.e. consisting of solvent or vehicle alone, without test substance, and otherwise treated in the same way as the treatment groups) were tested. Any explanations can be given in the supplementary remarks field. In particular, indicate the concentration (and/or volume) of vehicle added. |  |
|  | True negative controls | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - yes - no - other: - not specified | Indicate whether true negative control(s) (i.e. substances with known lack of genotoxicity) was/were tested and specify the substance(s) and concentration (and/or volume) in the supplementary remarks field. |  |
|  | Positive controls | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - yes - no - other: - not specified | Indicate whether positive controls (i.e. substances with known genotoxicity) were tested. If so, indicate what substance(s) was/were used as positive control(s) in field “Positive control substance”. |  |
|  | Positive control substance | List multi. (multi-select list with remarks)  Display: Basic | **Picklist values:** - 2-acetylaminofluorene - triethylenemelamine - 3-methylcholanthrene - 4-nitroquinoline-N-oxide - 7,12-dimethylbenzanthracene - 9,10-dimethylbenzanthracene - 9-aminoacridine - 2-nitrofluorene - sodium azide - monomeric acrylamide - N-dimethylnitrosamine - N-ethyl-N-nitro-N-nitrosoguanidine - benzo(a)pyrene - congo red - colchicine - cumene hydroperoxide - cyclohexylamine - cyclophosphamide - cytosine arabinoside - ethylmethanesulphonate - ethylnitrosurea - furylfuramide - methylmethanesulfonate - mitomycin C - streptonigrin - vinblastine - other: - not specified | If applicable, indicate which substance(s) was/were used as positive control(s). Multiple items can be selected. If different substances were used for tests with and without metabolic activation or for different tester strains or for the different treatment harvest schedules, include a remark in subfield 'Remarks'.  If other than the reference substance(s) specified in the test guidelines was/were used, include a brief justification.  Final concentration, conditions and durations of treatment and recovery periods.  Note that the list of substances provided is not exhaustive. |  |
|  | Remarks | Text (255 char.)  Display: Basic |  | Enter any remarks related to the recorded controls as appropriate. |  |
|  | **Controls** | **Block of fields (repeatable) End** |  |  |  |
|  | Details on test system and experimental conditions | Text template  Display: Detailed | **Freetext template:** NUMBER OF REPLICATIONS: - Number of cultures per concentration (single, duplicate, triplicate) - Number of independent experiments  METHOD OF TREATMENT/ EXPOSURE: - Cell density at seeding (if applicable): - Test substance added in medium; in agar (plate incorporation); preincubation; in suspension; as impregnation on paper disk  TREATMENT AND HARVEST SCHEDULE: - Preincubation period, if applicable: - Exposure duration/duration of treatment: - Harvest time after the end of treatment (sampling/recovery times):  FOR CHROMOSOME ABERRATION AND MICRONUCLEUS: - Spindle inhibitor (cytogenetic assays): indicate the identity of mitotic spindle inhibitor used (e.g., colchicine), its concentration and, duration and period of cell exposure. - If cytokinesis blocked method was used for micronucleus assay: indicate the identity of cytokinesis blocking substance (e.g. cytoB), its concentration, and duration and period of cell exposure. - Methods of slide preparation and staining technique used including the stain used (for cytogenetic assays): - Number of cells spread and analysed per concentration (number of replicate cultures and total number of cells scored): - Criteria for scoring micronucleated cells (selection of analysable cells and micronucleus identification): - Methods, such as kinetochore antibody binding, to characterize whether micronuclei contain whole or fragmented chromosomes (if applicable): - Criteria for scoring chromosome aberrations (selection of analysable cells and aberration identification): - Determination of polyploidy: - Determination of endoreplication:  FOR GENE MUTATION: - Expression time (cells in growth medium between treatment and selection): - Selection time (if incubation with a selective agent): - Fixation time (start of exposure up to fixation or harvest of cells): - Method used: agar or microwell plates for the mouse lymphoma assay. - If a selective agent is used (e.g., 6-thioguanine or trifluorothymidine), indicate its identity, its concentration and, duration and period of cell exposure. - Number of cells seeded and method to enumerate numbers of viable and mutants cells: - Criteria for small (slow growing) and large (fast growing) colonies:  METHODS FOR MEASUREMENT OF CYTOTOXICITY - Method, e.g.: background growth inhibition; mitotic index (MI); relative population doubling (RPD); relative increase in cell count (RICC); replication index; cytokinesis-block proliferation index; cloning efficiency; relative total growth (RTG); relative survival (RS); other: - Any supplementary information relevant to cytotoxicity:  METHODS FOR MEASUREMENTS OF GENOTOXICIY  - OTHER: | 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. |  |
|  | Rationale for test conditions | Text (2,000 char.)  Display: Detailed |  | Provide the rationale for selection of concentrations and number of cultures, including cytotoxicity data and solubility limitations, if available. |  |
|  | Evaluation criteria | Text (2,000 char.)  Display: Detailed |  | Describe the evaluation criteria used in the study to judge if a substance is positive, negative or equivocal. |  |
|  | Statistics | Text (2,000 char.)  Display: Detailed |  | List parameters that were analysed and the statistical methods used; include a statement on the appropriateness of the statistical analyses used. If inappropriate, provide alternative/rationale. |  |
|  | **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** | **Block of fields (repeatable) Start** |  | Include the main test results in this block of fields for each tester strain and metabolic activation system used. Multiply this block of fields as often as required. (Note: If only one strain was tested, subfield 'Species/strain' may be left empty.)  In case of a robust study summary or as requested by the regulatory programme, also provide the relevant raw data including statistical analysis and p-values if any, in field 'Additional information on results' and/or refer to detailed tables on the genotoxicity and cytotoxicity results, which can be uploaded in the rich text field 'Any other information on results incl. tables'. Use table numbers in the sequence in which you refer to them (e.g. '... see Table 1'). |  |
|  | Key result | Check box  Display: Basic |  | Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Species / strain | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - S. typhimurium TA 1535 - [bacteria] - S. typhimurium TA 1537 - [bacteria] - S. typhimurium TA 1535 pSK1002 - [bacteria] - S. typhimurium TA 97 - [bacteria] - S. typhimurium TA 97a - [bacteria] - S. typhimurium TA 98 - [bacteria] - S. typhimurium TA 100 - [bacteria] - S. typhimurium TA 1538 - [bacteria] - S. typhimurium TA 102 - [bacteria] - S. typhimurium, other: - [bacteria] - E. coli WP2 - [bacteria] - E. coli WP2 uvr A - [bacteria] - E. coli WP2 uvr A pKM 101 - [bacteria] - E. coli, other: - [bacteria] - bacteria, other: - [bacteria] - Saccharomyces cerevisiae - [yeast] - yeast, other: - [yeast] - Chinese hamster Ovary (CHO) - [mammalian cell line] - Chinese hamster lung (CHL/IU) - [mammalian cell line] - Chinese hamster lung fibroblasts (V79) - [mammalian cell line] - mouse lymphoma L5178Y cells - [mammalian cell line] - human lymphoblastoid cells (TK6) - [mammalian cell line] - mammalian cell line, other: - [mammalian cell line] - lymphocytes: - [primary culture] - hepatocytes: - [primary culture] - primary culture, other: - [primary culture] - other: - not specified | Indicate the species/strain or cell type tested. Multiply this block of fields for each tester strain. |  |
|  | Metabolic activation | List (picklist)  Display: Basic | **Picklist values:** - with - with and without - without - not applicable - not specified | Indicate whether metabolic activation was applied or not. |  |
|  | Genotoxicity | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - positive - ambiguous - negative - not determined - not specified - other: | Indicate result of the test conducted with the tester strain(s), or cell types and the metabolic activation system specified. If positive or equivocal, include concentration(s) in the supplementary remarks field or representative table. Upload predefined or other appropriate table(s) if any in the rich text field 'Any other information on results incl. tables' and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (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. |  |
|  | Cytotoxicity / choice of top concentrations | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - cytotoxicity - no cytotoxicity - no cytotoxicity, but tested up to precipitating concentrations - no cytotoxicity nor precipitates, but tested up to recommended limit concentrations - not determined - not specified - other: | Indicate whether cytotoxicity was observed. If yes, specify the respective test concentration(s) in the supplementary remarks field and provide details on the cytotoxicity measurement. 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. |  |
|  | Vehicle controls validity | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - valid - not valid - not applicable - not examined - not specified - other: | Indicate whether test with vehicle control(s) (i.e. vehicle without test substance,) is valid. |  |
|  | Untreated negative controls validity | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - valid - not valid - not applicable - not examined - not specified - other: | Indicate whether test with untreated controls, if applicable (i.e. no vehicle and no test substance) is valid. |  |
|  | True negative controls validity | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - valid - not valid - not applicable - not examined - not specified - other: | Indicate whether test with true negative control(s) (i.e. substances with known lack of genotoxicity) is valid. |  |
|  | Positive controls validity | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - valid - not valid - not applicable - not examined - not specified - other: | Indicate whether test with positive control(s), i.e. substance(s) with known genotoxicity, is valid. |  |
|  | **Test results** | **Block of fields (repeatable) End** |  |  |  |
|  | Additional information on results | Text template  Display: Detailed | **Freetext template:** TEST-SPECIFIC CONFOUNDING FACTORS - Data on pH: - Data on osmolality: - Possibility of evaporation from medium: - Water solubility: - Precipitation and time of the determination: - Definition of acceptable cells for analysis: - Other confounding effects:  RANGE-FINDING/SCREENING STUDIES (if applicable):  STUDY RESULTS - Concurrent vehicle negative and positive control data  For all test methods and criteria for data analysis and interpretation: - Concentration-response relationship where possible - Statistical analysis; p-value if any - Any other criteria: e.g. GEF for MLA  Ames test: - Signs of toxicity - Individual plate counts - Mean number of revertant colonies per plate and standard deviation  Chromosome aberration test (CA) in mammalian cells: - Results from cytotoxicity measurements:  o For lymphocytres in primary cultures: mitotic index (MI)   o For cell lines: relative population doubling (RPD), relative Increase in cell count (RICC), number of cells treated and cells harvested for each culture, information on cell cycle length, doubling time or proliferation index.  - Genotoxicity results (for both cell lines and lymphocytes)  o Definition for chromosome aberrations, including gaps   o Number of cells scored for each culture and concentration, number of cells with chromosomal aberrations and type given separately for each treated and control culture, including and excludling gaps   o Changes in ploidy (polyploidy cells and cells with endoreduplicated chromosomes) if seen   Micronucleus test in mammalian cells: - Results from cytotoxicity measurements:  o In the case of the cytokinesis-block method: CBPI or RI; distribution of mono-, bi- and multi-nucleated cells   o When cytokinesis block is not used: RICC, RPD or PD, as well as the number of cells treated and of cells harvested for each culture   o Other observations when applicable (complete, e.g. confluency, apoptosis, necrosis, metaphase counting, frequency of binucleated cells)   - Genotoxicity results  o Number of cells with micronuclei separately for each treated and control culture and defining whether from binucleated or mononucleated cells, where appropriate   Gene mutation tests in mammalian cells: - Results from cytotoxicity measurements:  o Relative total growth (RTG) or relative survival (RS) and cloning efficiency   - Genotoxicity results:  o Number of cells treated and sub-cultures for each cultures   o Number of cells plated in selective and non-selective medium   o Number of colonies in non-selective medium and number of resistant colonies in selective medium, and related mutant frequency   o When using the thymidine kinase gene on L5178Y cells: colony sizing for the negative and positive controls and if the test chemical is positive, and related mutant frequency. For the MLA, the GEF evaluation.   HISTORICAL CONTROL DATA (with ranges, means and standard deviation, and 95% control limits for the distribution as well as the number of data) - Positive historical control data: - Negative (solvent/vehicle) historical control data: | Enter any additional information that could be relevant for evaluating this study summary. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. |  |
|  | Remarks on result | List sup. (picklist with remarks - 2,000 char.)  Display: Basic | **Picklist values:** - mutagenic potential (based on QSAR/QSPR prediction) - no mutagenic potential (based on QSAR/QSPR prediction) - ambiguous mutagenic potential (based on QSAR/QSPR prediction) - not determinable - not determinable because of methodological limitations - not measured/tested - other: | This field can be used for:  - giving a qualitative description of results in addition to or if no numeric value(s) were derived;  - 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; or  - entering any additional information by selecting 'other:'. |  |
|  | **Any other information on results incl. tables** | **Header 2** |  |  |  |
|  |  | Text (rich-text area)  Display: Basic |  | In this field, you can enter any other remarks on results. 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.  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. |  |
|  | **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** |  |  |  |
|  | Conclusions | Text (32,768 char.)  Display: Basic |  | Enter any conclusions if applicable in addition to the information given in fields 'Key results' and 'Interpretation of results' (if any). | **Guidance for data migration:** Target field for the removed field  'Interpretation of results'. Multiple source values are separated by line break. |
|  | Executive summary | Text (rich-text area)  Display: Basic |  | If relevant for the respective regulatory programme, briefly summarise the relevant aspects of the study including the conclusions reached. If a specific format is prescribed, copy it from the corresponding document or upload it if provided as htm or html document.  Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof. |  |