**Template #72: Carcinogenicity *(Version [9.2]-[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** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  |  |  |
|  | Endpoint | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- carcinogenicity: oral- carcinogenicity: inhalation- carcinogenicity: dermal- carcinogenicity, 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 by the value of the source field 'Route of administration', e.g. 'Carcinogenicity: oral' if the trigger field contains the value 'oral: feed'.As a fallback the generic phrase 'carcinogenicity' is selected, with default supplementary text = value of 'Route of administration'.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 boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Robust Study Summary' or in combination with 'Adequacy of study'. Explanation: The term 'Robust Study Summary' is actually used only to describe the technical content of a very detailed summary of an experimental study or of any other relevant information. It is a priori no synonym with the term 'Key study', although a key study should usually be submitted in the form of Robust Study Summary. However, a Robust Summary may also be useful for other adequate studies that are considered supportive of the key study or even for inadequate studies if they can be used for a weight-of-evidence analysis. Also for studies that are flawed, but indicate critical results, Robust Study Summaries highlighting the weaknesses of the studies need to be elaborated. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Used for classification | Check boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Used for classification'.Explanation: In some use cases it may be necessary to indicate those records that are used for the classification of that substance, e.g. according to UN GHS. If not relevant, disregard this field. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Used for SDS | Check boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'SDS information'. Explanation: 'SDS' stands for Safety Data Sheet. In some use cases it may be necessary to indicate those records that are used for the compilation of SDS information. If not relevant, disregard this field. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Study period: start date | DateDisplay: Basic |  | If applicable indicate the period during which the study was conducted, i.e. start and end date. Note: independent of the study period, the in-life period (i.e. the phase of a study following treatment in which the test system is alive/growing) may have to be specified for some toxicology endpoints. |  |
|  | End date | DateDisplay: Basic |  |  |  |
|  | Remark | Text (255 char.)Display: Basic |  |  |  |
|  | Reliability | List (picklist)Display: Basic | **Picklist values:**- 1 (reliable without restriction)- 2 (reliable with restrictions)- 3 (not reliable)- 4 (not assignable)- other: | Enter an appropriate reliability score, according to Klimisch et al. (1997):1 = reliable without restrictions: “studies or data [...] generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline [...] or in which all parameters described are closely related/comparable to a guideline method.”2 = reliable with restrictions: “studies or data [...] (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.”3 = not reliable: “studies or data [...] in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g. non-physiological pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment.”4 = not assignable: “studies or data [...] which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).”The 'other:' option may be selected if a different scoring system is used. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'.Note: The term reliability defines the inherent quality of a test report or publication relating to preferably standardised methodology and the way the method and results are described. More detailed criteria can be selected in field 'Justification'. |  |
|  | Rationale for reliability incl. deficiencies | List sup. (picklist with remarks - 32,000 char.)Display: Basic | **Picklist values:**- guideline study - [Reliability 1]- comparable to guideline study - [Reliability 1]- test procedure in accordance with national standard methods - [Reliability 1]- test procedure in accordance with generally accepted scientific standards and described in sufficient detail - [Reliability 1]- guideline study without detailed documentation - [Reliability 2]- guideline study with acceptable restrictions - [Reliability 2]- comparable to guideline study with acceptable restrictions - [Reliability 2]- test procedure in accordance with national standard methods with acceptable restrictions - [Reliability 2]- study well documented, meets generally accepted scientific principles, acceptable for assessment - [Reliability 2]- accepted calculation method - [Reliability 2]- data from handbook or collection of data - [Reliability 2]- significant methodological deficiencies - [Reliability 3]- unsuitable test system - [Reliability 3]- abstract - [Reliability 4]- secondary literature - [Reliability 4]- documentation insufficient for assessment - [Reliability 4]- results derived from a valid (Q)SAR model and falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 1 or 2]- results derived from a valid (Q)SAR model and falling into its applicability domain, with limited documentation / justification - [Reliability 2, 3 or 4]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 2 or 3]- results derived from a (Q)SAR model, with limited documentation / justification, but validity of model and reliability of prediction considered adequate based on a generally acknowledged source - [Reliability 2 or 3]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, and documentation / justification is limited - [Reliability 3 or 4]- results derived from a (Q)SAR model, with limited documentation / justification - [Reliability 4]- other: | Select an appropriate standard justification from the picklist, e.g. 'Comparable to guideline study with acceptable restrictions'. Additional explanations (e.g. deficiencies observed) can be entered in the related supplementary text field. Particularly if reliability scores 2 or 3 are assigned, indicate the concrete arguments for defending a study or relevant deficiencies.For QSAR results (i.e. 'Type of information' is '(Q)SAR') some pre-defined phrases are provided for indicating if the prediction results are considered reliable based on the scientifically validity of the (Q)SAR model used, its applicability to the query substance, and the adequacy of reporting. Please note: If (Q)SAR results are flagged as key study in field 'Adequacy of study', the relevance of the model used for the regulatory endpoint should be documented in the field where the (Q)SAR model is described, i.e. 'Justification for type of information', 'Attached justification' or 'Cross-reference'. | **Guidance for field condition:**Condition: Field active only if 'Type of information' is not 'experimental study planned' and not ‘experimental study planned (based on read-across)’.Condition 1: If 'Type of information' is not '(Q)SAR':- guideline study - [Reliability 1]- comparable to guideline study - [Reliability 1]- test procedure in accordance with national standard methods - [Reliability 1]- test procedure in accordance with generally accepted scientific standards and described in sufficient detail - [Reliability 1]- guideline study without detailed documentation - [Reliability 2]- guideline study with acceptable restrictions - [Reliability 2]- comparable to guideline study with acceptable restrictions - [Reliability 2]- test procedure in accordance with national standard methods with acceptable restrictions - [Reliability 2]- study well documented, meets generally accepted scientific principles, acceptable for assessment - [Reliability 2]- accepted calculation method - [Reliability 2]- data from handbook or collection of data - [Reliability 2]- significant methodological deficiencies - [Reliability 3]- unsuitable test system - [Reliability 3]- abstract - [Reliability 4]- secondary literature - [Reliability 4]- documentation insufficient for assessment - [Reliability 4]Condition 2: If 'Type of information' = '(Q)SAR':- results derived from a valid (Q)SAR model and falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 1 or 2]- results derived from a valid (Q)SAR model and falling into its applicability domain, with limited documentation / justification - [Reliability 2, 3 or 4]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 2 or 3]- results derived from a (Q)SAR model, with limited documentation / justification, but validity of model and reliability of prediction considered adequate based on a generally acknowledged source - [Reliability 2 or 3]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, and documentation / justification is limited - [Reliability 3 or 4]- results derived from a (Q)SAR model, with limited documentation / justification - [Reliability 4]- other: |
|  | Data waiving | List (picklist)Display: Basic | **Picklist values:**- study technically not feasible- study scientifically not necessary / other information available- exposure considerations- study waived due to provisions of other regulation- other justification | If appropriate, indicate here that the study has been waived, i.e. not performed. Select the basis from the picklist (e.g. 'study technically not feasible' or 'other justification'). Include a more detailed justification in the field 'Justification for data waiving' and, as needed, in field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference'. Please note: the option 'study scientifically not necessary / other information available' covers cases where it can be justified that performance of a specific study prescribed by the relevant legislation is scientifically not necessary because reliable information is provided in other part(s) of the submission document.The option 'study waived due to provisions of other regulation' can be used for indicating that another, overlapping regulation allows or requires the waiving of a specific information requirement. This should then be detailed in the justification fields.If waiving is based on several lines of argumentation (e.g. ‘exposure considerations’ and ‘study scientifically not necessary / other information available’), create separate records for each.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use data waivers. | **Guidance for field condition:**Condition: Deactivate this field if any of the following fields is populated: 'Type of information', 'Adequacy of study', 'Reliability', 'Rationale for reliability'. |
|  | Justification for data waiving | List multi. (multi-select list with remarks - 32,000 char.)Display: Basic | **Picklist values:**- a carcinogenicity study does not need to be conducted because the substance is classified as germ cell mutagen category 1A or 1B and the default presumption is that a genotoxic mechanism for carcinogenicity is likely - [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 templateDisplay: Basic | **Freetext template:Option 1 Type 'Waiving of standard information'**JUSTIFICATION FOR DATA WAIVING[Specific explanation in addition to field 'Justification for data waiving']**Option 2 Type 'Experimental study planned / Testing proposal on vertebrate animals'**TESTING PROPOSAL ON VERTEBRATE ANIMALS[Please provide information for all of the points below. The information should be specific to the endpoint for which testing is proposed. Note that for testing proposals addressing testing on vertebrate animals under the REACH Regulation this document will be published on the ECHA website along with the third party consultation on the testing proposal(s).]NON-CONFIDENTIAL NAME OF SUBSTANCE:- Name of the substance on which testing is proposed to be carried out- Name of the substance for which the testing proposal will be used [if different from tested substance]CONSIDERATIONS THAT THE GENERAL ADAPTATION POSSIBILITIES OF ANNEX XI OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION [please address all points below]:- Available GLP studies- Available non-GLP studies- Historical human/control data- (Q)SAR- In vitro methods- Weight of evidence- Grouping and read-across- Substance-tailored exposure driven testing [if applicable]- Approaches in addition to above [if applicable]- Other reasons [if applicable]CONSIDERATIONS THAT THE SPECIFIC ADAPTATION POSSIBILITIES OF ANNEXES VI TO X (AND COLUMN 2 THEREOF) OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION:- [free text]FURTHER INFORMATION ON TESTING PROPOSAL IN ADDITION TO INFORMATION PROVIDED IN THE MATERIALS AND METHODS SECTION:- Details on study design / methodology proposed [if relevant]**Option 3 Type 'QSAR prediction'**1. SOFTWARE2. MODEL (incl. version number)3. SMILES OR OTHER IDENTIFIERS USED AS INPUT FOR THE MODEL4. SCIENTIFIC VALIDITY OF THE (Q)SAR MODEL[[Explain how the model fulfils the OECD principles for (Q)SAR model validation. Consider attaching the QMRF and/or QPRF or providing a link]- Defined endpoint:- Unambiguous algorithm:- Defined domain of applicability:- Appropriate measures of goodness-of-fit and robustness and predictivity:- Mechanistic interpretation:5. APPLICABILITY DOMAIN[Explain how the substance falls within the applicability domain of the model]- Descriptor domain:- Structural domain:- Mechanistic domain:- Similarity with analogues in the training set:- Other considerations (as appropriate):6. ADEQUACY OF THE RESULT[Explain how the prediction fits the purpose of classification and labelling and/or risk assessment]**Option 4 Type 'Read-across (analogue)'**REPORTING FORMAT FOR THE ANALOGUE APPROACH[Please provide information for all of the points below. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]1. HYPOTHESIS FOR THE ANALOGUE APPROACH[Describe why the read-across can be performed (e.g. common functional group(s), common precursor(s)/breakdown product(s) or common mechanism(s) of action]2. SOURCE AND TARGET CHEMICAL(S) (INCLUDING INFORMATION ON PURITY AND IMPURITIES)[Provide here, if relevant, additional information to that included in the Test material section of the source and target records]3. ANALOGUE APPROACH JUSTIFICATION[Summarise here based on available experimental data how these results verify that the read-across is justified]4. DATA MATRIX**Option 5 Type 'Read-across (category)'**REPORTING FORMAT FOR THE CATEGORY APPROACH[Please provide information for all of the points below addressing endpoint-specific elements that were not already covered by the overall category approach justification made available at the category level. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]1. HYPOTHESIS FOR THE CATEGORY APPROACH (ENDPOINT LEVEL)[Describe why the read-across can be performed]2. CATEGORY APPROACH JUSTIFICATION (ENDPOINT LEVEL[Summarise here based on available experimental data how these results verify that the read-across is justified]**Option 6 Type 'Weight of Evidence justification'**JUSTIFICATION FOR WEIGHT OF EVIDENCE- Relevance (including coverage) and reliability of each source of information compared with the study normally required for the information requirement.- Weighing of the sources of information (including overall coverage) to reach an overall conclusion for the information requirement.- Assessment of the uncertainty in the conclusion compared with the study normally required for the information requirement. | This field can be used for entering free text. As appropriate, one of the freetext templates can be selected (e.g. Justification for read-across (analogue)) to use pre-defined headers and bulleted elements. Delete/add elements as appropriate.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on what should be taken into account when providing justifications or whether specific reporting formats should be used.Explanations:Option 1: Type 'Waiving of standard information':This field should be used for entering any further lines of argumentation, if necessary, in addition to those provided in the field 'Justification for data waiving'.Option 2: Type 'Experimental study planned / Testing proposal':Further details can be entered here on the study design / methodology proposed in addition to details given in the distinct fields on test guideline, test material, species, route of administration and other relevant fields.Option 3: Type 'QSAR prediction':For describing a (Q)SAR model it is recommended to provide the QMRF as attachment instead of using the free text template.The QSAR Model Reporting Format (QMRF) is a harmonised template for summarising and reporting key information on QSAR models, including the results of any validation studies. The information is structured according to the OECD validation principles and can be compiled using the QMRF editor application.The JRC QSAR Model Database is intended to help to identify valid (Q)SARs (e.g. for the purpose of REACH). It provides information on the validity of QSAR models and can be browsed for published QMRFs.Based on this freetext template details on the QSAR model used can be given, in addition to the information provided in field 'Principles of method if other than guideline'.Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature.Option 4: Type 'Read-across (analogue)' and Option 5: Type 'Read-across (category)'This freetext template can be used and modified as appropriate for providing a justification for read-across, particularly if it is endpoint-specific.Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature. |  |
|  | **Attached justification** | **Block of fields (repeatable) Start** |  | The Attached justification feature can be used in case the justification is best provided in form of attached document(s).Copy this block of fields for attaching more than one file.Refer to the relevant legislation-specific guidance document as to the recommended use of the Attached justification feature. |  |
|  | Attached justification | Attachment (single)Display: Basic |  | Upload file by clicking the upload icon. |  |
|  | Reason / purpose | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- data waiving: supporting information- exposure-related information- read-across: supporting information- (Q)SAR model reporting (QMRF)- (Q)SAR prediction reporting (QPRF)- (Q)SAR model and prediction reporting (QMRF/QPRF)- (Q)SAR: supporting information- weight of evidence: supporting information- justification, other: | Indicate the reason for / purpose of the attached document. Select the relevant item from the picklist or, if none applies, select 'justification, other:' and specify. |  |
|  | **Attached justification** | **Block of fields (repeatable) End** |  |  |  |
|  | **Cross-reference** | **Block of fields (repeatable) Start** |  | The cross-reference feature can be used to refer to related information that is provided in another record of the dataset. This can be done either by entering just free text in the 'Remarks' field or by creating a link to the relevant record. The field 'Reason / purpose' allows for selecting a standard reason from the picklist and optionally to add free text explanation in the related supplementary text field.Refer to the relevant legislation-specific guidance document as to the recommended use of cross-references. |  |
|  | Reason / purpose for cross-reference | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- adverse outcome pathway (AOP)- assessment report- data waiving: supporting information- defined approach- exposure-related information- method used in study- read-across source- (Q)SAR model reporting (QMRF)- read-across: supporting information- reference to other assay used for intermediate effect derivation- reference to other study- reference to same study- weight of evidence source- other: | Select the appropriate reason of the cross-reference, i.e.- adverse outcome pathway (AOP) (in case the information is related to a key event that is part of an AOP). Consult the AOP wiki at: https://aopwiki.org) and provide the reference in the remarks field- assessment report (for referring to a record that contains an assessment report as attachment)- data waiving: supporting information (for referring to a record containing relevant endpoint information that is used to justify a data waiver)- defined approach for combining with results from another methods (in vitro, in chimico, in silico) - exposure-related information (for referring to a record containing exposure-related information that is used for instance to justify a data waiver)- read-across source (for linking to another study summary used for read-across. This can be useful in cases where results are derived from one or several read-across sources and recorded in a separate (target) study summary.)- read-across supporting information (for linking to another record which contains read-across justification that applies also for the current study summary)- (Q)SAR model reporting (QMRF) (for referring to a record containing the relevant model description. Note: The (Q)SAR prediction should be reported specifically for each endpoint in the field 'Justification for type of information'.)- reference to other assay used for intermediate effect derivation (for optional indication in a study summarising 'intermediate effects' if reference is made to the outcome of another assay)- reference to same study (e.g. if different species were tested and the results recorded in different records), - reference to other study (e.g. if another study is considered relevant in the interpretation of the test results), - other: (to be specified). |  |
|  | Related information | Link to endpoint (single)Display: Basic |  | As appropriate, select the record containing the related information, thus creating a link. | **Cross-reference:**AllSummariesAndRecords |
|  | Remarks | Text (32,768 char.)Display: Basic |  | This field can be used for including any remarks. |  |
|  | **Cross-reference** | **Block of fields (repeatable) End** |  |  |  |
|  | **Data source** | **Header 1** |  |  |  |
|  | Reference | Link to lit. reference (multiple)Display: Basic |  | Indicate the bibliographic reference of the study report or publication the study summary is based on. Provide general information such as Title, Author, Year, Bibliographic source, Testing Facility, Report Number, Study number, Report date etc., as requested in the core template for literature search (https://www.oecd.org/ehs/templates/Generic%20elements%20for%20all%20OHTs.zip). Always enter the primary reference in the first block of fields or sort it to the first position, if there are more than one reference to be cited. Copy this block of fields for specifying any other references related to this record (e.g. report of a preliminary study or other documentation). If results of a study report have been published, indicate the full citation of that publication(s) in addition to the reference of the original study. |  |
|  | Data access | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- data submitter is data owner- data submitter has Letter of Access- data no longer protected- data published- data submitter has permission to refer- not applicable- other: | Select appropriate indication for data access. Enter 'Not applicable' if the summary consists of information that is commonly accessible such as guidance on safe use.Select 'data submitter has permission to refer' if the information requirement can be covered based on a permission to refer to old data as issued by the relevant regulatory agency. In addition, provide, in the adjacent free-text field, the statement according to instructions you received from the relevant regulatory authority together with the permission to refer. |  |
|  | Data protection claimed | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- yes, but willing to share- yes, but not willing to share | Indicate as appropriate. Note: 'yes' should be selected only if 'Data submitter is data owner' or 'Data submitter has Letter of Access'. Options 'yes, but willing to share' or 'yes, but not willing to share' may be relevant for specific regulatory programmes where the submitter is requested to indicate whether he is willing to share studies conducted (e.g. with vertebrates).In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. 'for justification see attached document X') |  |
|  | **Materials and methods** | **Header 1** |  |  |  |
|  | **Test guideline** | **Block of fields (repeatable) Start** |  | Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'.Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline). |  |
|  | Qualifier | List (picklist)Display: Basic | **Picklist values:**- according to guideline- equivalent or similar to guideline- no guideline followed- no guideline available- no guideline required | Select appropriate qualifier, i.e.- 'according to guideline' (if a given test guideline was followed);- 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline);- 'no guideline followed' (if none of above qualifiers apply. If so, fill in field 'Principles of method if other than guideline');- 'no guideline available' (if so, fill in field 'Principles of method if other than guideline').- 'no guideline required' (if so, fill in field 'Principles of method if other than guideline'). |  |
|  | Guideline | List (picklist)Display: Basic | **Picklist values:**- OECD Guideline 451 (Carcinogenicity Studies)- OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies)- EU Method B.32 (Carcinogenicity Test)- EU Method B.33 (Combined Chronic Toxicity / Carcinogenicity Test)- EPA OPP 83-2 (Carcinogenicity)- EPA OPP 83-5 (Combined Chronic Toxicity / Carcinogenicity)- EPA OPPTS 870.4200 (Carcinogenicity)- EPA OPPTS 870.4300 (Combined Chronic Toxicity / Carcinogenicity)- EPA OTS 798.3300 (Carcinogenicity)- EPA OTS 798.3320 (Combined Chronic Toxicity / Carcinogenicity)- other: | Select the applicable test guideline, e.g. 'OECD Guideline xxx'. If the test guideline used is not listed, choose 'other:' and specify the test guideline in the related text field. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'. The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields.Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Version / remarks | Text (2,000 char.)Display: Basic |  | In this text field, you can enter any remarks as applicable, particularly:- To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline);- To indicate if the study was performed prior to the adoption of the test guideline specified;- To indicate if the methodology used was based on an extension of the test guideline specified;- To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Deviations | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- no- not applicable- not specified | In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | **Test guideline** | **Block of fields (repeatable) End** |  |  |  |
|  | Principles of method if other than guideline | Text templateDisplay: Basic | **Freetext template:Option 1 Method of non-guideline study**- Principle of test:- Short description of test conditions:- Parameters analysed / observed:**Option 2 (Q)SAR**- Software tool(s) used including version:- Model(s) used:- Model description: see field 'Justification for non-standard information', 'Attached justification' and/or 'Cross-reference'- Justification of QSAR prediction: see field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' | If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate use either of the pre-defined freetext template options for 'Method of non-guideline study' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate.For a non-guideline experimental study a high-level freetext template can be used for summarising the principle of test, test conditions and parameters analysed / observed. If the freetext template for (Q)SAR is selected, indicate the QSAR model(s) or platform including version and the software tool(s) used. Detailed justification of the model and prediction should be provided in field(s) 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' as appropriate.Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate. |  |
|  | GLP compliance | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes (incl. QA statement)- yes- no- not specified | Indicate whether the study was conducted following Good Laboratory Practice or not. In case 'yes’ is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed. |  |
|  | **Test material** | **Header 2** |  |  |  |
|  | Test material information | Link to entity (single)Display: Basic |  | Select the appropriate Test Material Information (TMI) record. If not available in the repository, create a new one. You may also copy (clone) an existing TMI record, edit it and store it as new TMI.To change the link to an existing TMI, click the Delete button, then the Link button and proceed as described above.Depending on the purpose of the reporting or data submission, the information that must be provided may change. As a minimum, the chemical name, identifier and/or CAS number and molecular weight must be provided. | **Cross-reference:**TEST\_MATERIAL\_INFORMATION |
|  | Additional test material information | Link to entity (multiple)Display: Basic |  | Select additional Test material information record if relevant. For example, in longer terms studies more than one batch of test material can be needed or there may be differences between the labelled and unlabelled test materials. | **Cross-reference:**TEST\_MATERIAL\_INFORMATION |
|  | Specific details on test material used for the study | Text templateDisplay: Basic | **Freetext template:**SOURCE OF TEST MATERIAL- Source (i.e. manufacturer or supplier) and lot/batch number of test material:- Purity, including information on contaminants, isomers, etc.:RADIOLABELLING INFORMATION (if applicable)- Radiochemical purity:- Specific activity:- Locations of the label:- Expiration date of radiochemical substance:STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material:- Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage:- Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis:- Solubility and stability of the test material in the solvent/vehicle and the exposure medium:- Reactivity of the test material with the incubation material used (e.g. plastic ware):TREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding):- Preliminary purification step (if any):- Final concentration of a dissolved solid, stock liquid or gel:- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):FORM AS APPLIED IN THE TEST (if different from that of starting material)- Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:INFORMATION ON NANOMATERIALS- Chemical Composition:- Density:- Particle size & distribution:- Specific surface area:- Isoelectric point:- Dissolution (rate):TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable)- Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:OTHER SPECIFICS- Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.If applicable, relevant available information on the following items should be given:SOURCE OF TEST MATERIAL- Source and lot/batch No. of test material- Expiration date of the lot/batch- Purity test date: provide if availableRADIOLABELLING INFORMATION- Radiochemical purity- Specific activity- Locations of the label- Expiration date of radiochemical substanceSTABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material- Stability under test conditions- Solubility and stability of the test substance in the solvent/vehicle- Reactivity of the test substance with the solvent/vehicle or the cell culture mediumTREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding)- Preliminary purification step- Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)FORM AS APPLIED IN THE TEST (if different from that of starting material)Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.FORMULATED PRODUCT (for biocides/pesticides)Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.OTHER SPECIFICSProvide any other relevant information needed for characterising the tested material. |  |
|  | Specific details on test material used for the study (confidential) | Text templateDisplay: Basic (Confidential) | **Freetext template:**SOURCE OF TEST MATERIAL- Source (i.e. manufacturer or supplier) and lot/batch number of test material:- Purity, including information on contaminants, isomers, etc.:RADIOLABELLING INFORMATION (if applicable)- Radiochemical purity:- Specific activity:- Locations of the label:- Expiration date of radiochemical substance:STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material:- Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage:- Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis:- Solubility and stability of the test material in the solvent/vehicle and the exposure medium:- Reactivity of the test material with the incubation material used (e.g. plastic ware):TREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding):- Preliminary purification step (if any):- Final concentration of a dissolved solid, stock liquid or gel:- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):FORM AS APPLIED IN THE TEST (if different from that of starting material)- Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:INFORMATION ON NANOMATERIALS- Chemical Composition:- Density:- Particle size & distribution:- Specific surface area:- Isoelectric point:- Dissolution (rate):TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable)- Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:OTHER SPECIFICS- Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.If applicable, relevant available information on the following items should be given:SOURCE OF TEST MATERIAL- Source and lot/batch No. of test material- Expiration date of the lot/batch- Purity test date: provide if availableRADIOLABELLING INFORMATION- Radiochemical purity- Specific activity- Locations of the label- Expiration date of radiochemical substanceSTABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material- Stability under test conditions- Solubility and stability of the test substance in the solvent/vehicle- Reactivity of the test substance with the solvent/vehicle or the cell culture mediumTREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding)- Preliminary purification step- Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)FORM AS APPLIED IN THE TEST (if different from that of starting material)Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.FORMULATED PRODUCT (for biocides/pesticides)Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.OTHER SPECIFICSProvide any other relevant information needed for characterising the tested material. |  |
|  | **Test animals** | **Header 2** |  |  |  |
|  | Species | List (picklist)Display: Basic | **Picklist values:**- rat- mouse- cat- cattle- dog- gerbil- guinea pig- hamster- hamster, Armenian- hamster, Chinese- hamster, Syrian- hen- miniature swine- monkey- pig- primate- rabbit- sheep- other: | Select species as appropriate. If not available from picklist, select 'other' and specify. |  |
|  | Strain | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- AKR - [mouse]- Abyssinian - [guinea pig]- Angora - [rabbit]- B6C3F1 - [mouse]- Balb/c - [mouse]- Beagle - [dog]- Belgian Hare - [rabbit]- Brown Norway - [rat]- C3H - [mouse]- C57BL - [mouse]- CAF1 - [mouse]- CB6F1 - [mouse]- CBA - [mouse]- CD-1 - [mouse]- CF-1 - [mouse]- Californian - [rabbit]- Chinchilla - [rabbit]- Crj: CD(SD) - [rat]- DBA - [mouse]- DBF1 - [mouse]- Dunkin-Hartley - [guinea pig]- Dutch - [rabbit]- FVB - [mouse]- Fischer 344 - [rat]- Fischer 344/DuCrj - [rat]- Flemish Giant - [rabbit]- Hartley - [guinea pig]- Himalayan - [rabbit]- ICL-ICR - [mouse]- ICR - [mouse]- Lewis - [rat]- Long-Evans - [rat]- Macaca fascicularis - [monkey]- Marmoset - [monkey]- Mulatta arctoides - [monkey]- NMRI - [mouse]- New Zealand Black - [rabbit]- New Zealand Red - [rabbit]- New Zealand White - [rabbit]- Nude - [mouse]- Nude Balb/cAnN - [mouse]- Nude CD-1 - [mouse]- Osborne-Mendel - [rat]- Peruvian - [guinea pig]- Pirbright-Hartley - [guinea pig]- Polish - [rabbit]- Rainbow trout - [fish]- SIV 50 - [mouse]- SKH/HR1 - [mouse]- San Juan - [rabbit]- Sencar - [mouse]- Sherman - [rat]- Shorthair - [guinea pig]- Sprague-Dawley - [rat]- Strain A - [mouse]- Swiss - [mouse]- Swiss Webster - [mouse]- Tif:MAGf - [mouse]- Vienna White - [rabbit]- Wistar - [rat]- Wistar Kyoto (WKY) - [rat]- Zucker - [rat]- not specified- other: | Select strain as appropriate. If not available from picklist, select 'other' and specify. |  |
|  | Details on species / strain selection | Text (2,000 char.)Display: Detailed |  | For robust study summaries or as requested by the regulatory programme, provide details explaining the choice of species and strain. |  |
|  | Sex | List (picklist)Display: Basic | **Picklist values:**- female- male- male/female- not specified | Select as appropriate. If females were used, indicate in field “Details on test animals and environmental conditions” whether nulliparous and non-pregnant. |  |
|  | Details on test animals or test system and environmental conditions | Text templateDisplay: Detailed | **Freetext template:**TEST ANIMALS- Source:- Females (if applicable) nulliparous and non-pregnant: [yes/no]- Age at study initiation:- Weight at study initiation:- Fasting period before study:- Housing:- Diet (e.g. ad libitum):- Water (e.g. ad libitum):- Acclimation period:DETAILS OF FOOD AND WATER QUALITY: ENVIRONMENTAL CONDITIONS- Temperature (°C):- Humidity (%):- Air changes (per hr):- Photoperiod (hrs dark / hrs light):IN-LIFE DATES: From: To: | 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.Explanations:- Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum.- Water: Describe type (e.g. drinking water) and whether it was provided ad libitum.- Food quality and water quality: provide analytical information on the nutrient and dietary contaminant levels. Similarly provide analytical information on the drinking water used in the study.- IN-LIFE DATES: If required, specify the in-life dates (i.e. the phase of a study following treatment in which the test system is alive/growing). |  |
|  | **Administration / exposure** | **Header 2** |  |  |  |
|  | Route of administration | List (picklist)Display: Basic | **Picklist values:**- oral: gavage- oral: capsule- oral: feed- oral: drinking water- oral: unspecified- inhalation: aerosol- inhalation: dust- inhalation: gas- inhalation: mist- inhalation: vapour- inhalation: mixture of gas, vapour and aerosol- inhalation: mixture of vapour and aerosol / mist- inhalation: mixture of gas and vapour- inhalation- dermal- implantation- infusion- intramuscular- intraperitoneal- intratracheal- intravenous- subcutaneous- other:- not specified | Select route of administration as appropriate, usually 'oral: gavage'. If another route was used, provide a justification and reasoning in field 'Details on exposure'. In the case of an inhalation study, also specify if 'nose only' or other. |  |
|  | Type of inhalation exposure (if applicable) | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- nose only- head only- snout only- nose/head only- whole body- other:- not specified | If route of administration is 'inhalation', indicate type of inhalation exposure, e.g. 'nose only'. Any remarks can be entered in the supplementary remarks subfield. |  |
|  | Vehicle | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- unchanged (no vehicle)- acetone- air- arachis oil- beeswax- carbowaxe- castor oil- cetosteryl alcohol- cetyl alcohol- clean air- 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- oxygen- paraffin oil- peanut oil- petrolatum- physiological saline- poloxamer- polyethylene glycol- propylene glycol- silicone oil- sorbitan derivative- soya oil- theobroma oil- vegetable oil- water- other:- not specified | Select the vehicle used. If not available from picklist, select 'other'.Note that some of the vehicles provided in this list are used for specific routes of administration only. |  |
|  | Mass median aerodynamic diameter (MMAD) | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- nm- µm- mm- other: | For inhalation studies, specify the mass median aerodynamic diameter (MMAD) of the distribution of particle sizes. Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. |  |
|  | Geometric standard deviation (GSD) | Numeric (decimal)Display: Basic |  | Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. |  |
|  | Remarks on MMAD | Text (2,000 char.)Display: Basic |  | Enter any remarks related to the mass median aerodynamic diameter. |  |
|  | Details on exposure | Text templateDisplay: Detailed | **Freetext template:Option 1 Route = oral** PREPARATION OF DOSING SOLUTIONS:  DIET PREPARATION - Rate of preparation of diet (frequency): - Mixing appropriate amounts with (Type of food):  - Storage temperature of food:  VEHICLE - Justification for use and choice of vehicle (if other than water):  - Concentration in vehicle:  - Amount of vehicle (if gavage):  - Lot/batch no. (if required):  - Purity:**Option 2 Route = inhalation** GENERATION OF TEST ATMOSPHERE / CHAMBER DESCRIPTION - Exposure apparatus: - Method of holding animals in test chamber: - Source and rate of air: - Method of conditioning air: - System of generating particulates/aerosols: - Temperature, humidity, pressure in air chamber:  - Air flow rate:  - Air change rate:  - Method of particle size determination:  - Treatment of exhaust air:  TEST ATMOSPHERE - Brief description of analytical method used:  - Samples taken from breathing zone: yes/no  VEHICLE (if applicable) - Justification for use and choice of vehicle:  - Composition of vehicle: - Type and concentration of dispersant aid (if powder):  - Concentration of test material in vehicle: - Lot/batch no. of vehicle (if required):  - Purity of vehicle:**Option 3 Route = dermal** TEST SITE - Area of exposure:  - % coverage:  - Type of wrap if used:  - Time intervals for shavings or clipplings:   REMOVAL OF TEST SUBSTANCE - Washing (if done):  - Time after start of exposure:  TEST MATERIAL - Amount(s) applied (volume or weight with unit): - Concentration (if solution): - Constant volume or concentration used: yes/no - For solids, paste formed: yes/no  VEHICLE - Justification for use and choice of vehicle (if other than water):  - Amount(s) applied (volume or weight with unit): - Concentration (if solution): - Lot/batch no. (if required):  - Purity:   USE OF RESTRAINERS FOR PREVENTING INGESTION: yes/no | Select freetext template for the respective type of study 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 HPVC, Pesticides NAFTA or EU REACH) thereof. |  |
|  | Analytical verification of doses or concentrations | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- no- not specified | Indicate whether the doses or concentrations were analytically verified. |  |
|  | Details on analytical verification of doses or concentrations | Text (32,768 char.)Display: Detailed |  | For robust study summaries or as requested by the regulatory programme, include a short description on the method of analysis in the supplementary remarks field. If any problems occurred in any of these procedures, then they should be reported in more detail. If this could have affected the veracity or conclusions of the study, discuss this in field 'Rationale for reliability incl. deficiencies'.Further route-dependent information to be included:- For oral studies: State whether the analytical data indicated that the difference between nominal and actual dosage (if diet is route of administration) or concentrations (for drinking water study) was acceptable.If diet is the route of administration, briefly record when and at what dose levels the dosage analyses were made and include the results (range of values) of (i) Homogeneity analysis, (ii) Stability analysis and (iii) Concentration analysis.It may be appropriate to include a cross-reference to another study in which stability analysis was performed and reported. If so, a justification should also be included briefly explaining the rationale of referring to another study.- For inhalation studies: State whether the analytical data indicated that the difference between nominal and actual concentrations was acceptable.- For dermal studies: State whether the analytical data indicated that the difference between nominal and actual concentrations of the test substance in the vehicle was acceptable. |  |
|  | Duration of treatment / exposure | Text (2,000 char.)Display: Basic |  | Indicate duration in days, weeks or months, e.g. '104 weeks' or '18 months'. |  |
|  | Frequency of treatment | Text (2,000 char.)Display: Basic |  | Indicate the frequency of the administration of doses to the test animals (e.g., 'daily, 7 days each week'). Use of non-standard dosing regime (e.g. a five-day per week regime) should be justified. |  |
|  | Post exposure period | Text (2,000 char.)Display: Basic |  | Indicate observation period (in days, weeks, months) after last exposure to the test material. Specify, if there are differences for treatment and recovery groups or other individual groups. |  |
|  | **Doses / concentrations** | **Block of fields (repeatable) Start** |  | Indicate the dose or concentration levels applied and the basis of quantity used. Copy this block of fields for each numeric value and to record values on a different basis, i.e. mg/kg bw/day (nominal), mg/kg bw/day (actual dose received), mg/kg diet ,mg/L drinking water, mg/kg bw (total dose), ppm if applicable. Conversion of the dose / conc. values to the relevant unit used for the effect levels may be required. |  |
|  | Dose / conc. | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- mg/kg bw/day (nominal)- mg/kg bw/day (actual dose received)- mg/kg bw/day- mg/kg bw (total dose)- mg/kg diet- mg/L drinking water- mg/L air- mg/L air (nominal)- mg/L air (analytical)- mg/m³ air- mg/m³ air (nominal)- mg/m³ air (analytical)- ppm- ppm (nominal)- ppm (analytical)- microbial active substances- cells/kg bw/day (actual dose received)- cells/kg bw/day (nominal)- cells/kg bw/day- cells/kg bw (total dose)- cells/kg diet- cells/L drinking water- cells/L air- cells/m³ air- CFU/kg bw/day (actual dose received)- CFU/kg bw/day (nominal)- CFU/kg bw/day- CFU/kg bw (total dose)- CFU/kg diet- CFU/L drinking water- CFU/L air- CFU/m³ air- ITU/kg bw/day (actual dose received)- ITU/kg bw/day (nominal)- ITU/kg bw/day- ITU/kg bw (total dose)- ITU/kg diet- ITU/L drinking water- ITU/L air- ITU/m³ air- IU/kg bw/day (actual dose received)- IU/kg bw/day (nominal)- IU//kg bw/day- IU/kg bw (total dose)- IU/kg diet- IU/L drinking water- IU/L air- IU/m³ air- OB/kg bw/day (actual dose received)- OB/kg bw/day (nominal)- OB/kg bw/day- OB/kg bw (total dose)- OB/kg diet- OB/L drinking water- OB/L air- OB/m³ air- spores/kg bw/day (actual dose received)- spores/kg bw/day (nominal)- spores/kg bw/day- spores/kg bw (total dose)- spores/kg diet- spores/L drinking water- spores/L air- spores/m³ air- nanoforms- particles/kg bw/day (nominal)- particles/kg bw/day (actual dose received)- particles/kg bw/day- particles/kg bw (total dose)- particles/kg diet- particles/L drinking water- particles/L air- particles/L air (nominal)- particles/L air (analytical)- particles/m³ air- particles/m³ air (nominal)- particles/m³ air (analytical)- surface area/kg bw/day (nominal)- surface area/kg bw/day (actual dose received)- surface area/kg bw/day- surface area/kg bw (total dose)- surface area/kg diet- surface area/L drinking water- surface area/L air- surface area/L air (nominal)- surface area/L air (analytical)- surface area/m³ air- surface area/m³ air (nominal)- surface area/m³ air (analytical)- other: | Enter numeric value.The following units should only be used in the case of microbial active substances:- cells- CFU (colony-forming unit)- ITU (International Toxic Unit)- IU (International Unit)- OB (occlusion bodies)- spores |  |
|  | Remarks | Text (2,000 char.)Display: Basic |  | Enter any remarks related to dose / concentration values. |  |
|  | **Doses / concentrations** | **Block of fields (repeatable) End** |  |  |  |
|  | No. of animals per sex per dose | Text (2,000 char.)Display: Basic |  | Enter value or specify according to dose if different number of animals per dose, e.g. '10 in each dose group of main study; 10 f and 5 m in interim sacrifice group'. Also specify number of animals in recovery group if applicable.For robust study summaries or as requested by the regulatory programme, also include a detailed table on the animal assignment in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) 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. |  |
|  | Control animals | List multi. (multi-select list with remarks)Display: Basic | **Picklist values:**- yes- yes, concurrent no treatment- yes, concurrent vehicle- yes, plain diet- yes, sham-exposed- yes, historical- no- other:- not specified | Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify. |  |
|  | Details on study design | Text templateDisplay: Detailed | **Freetext template:**- Toxicokinetic data- Dose selection rationale:- Rationale for animal assignment (if not random):- Rationale for selecting satellite groups:- Post-exposure recovery period in satellite groups:- Section schedule rationale (if not random): | Include any details on the study design including toxicokinetic data if available, a brief description of the rationale for dose selection (e.g. consideration of known or suspected nonlinearities or inflection points in the dose response, toxicokinetics, precursor lesions, markers of effect, or indicators of the operation of key underlying biological process, key (or suspected) aspects of mode of action, consideration of anticipated human exposure level), animal assignment and selection of satellite groups including the duration of the post-exposure recovery period. As appropriate state study type(s) and briefly describe the results from range-finding or other studies used as basis for dose selection. More comprehensive details may be attached.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. |  |
|  | Positive control | Text (2,000 char.)Display: Detailed |  | Indicate if a positive control was used and if necessary indicate purity, Lot/batch No. |  |
|  | 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 templateDisplay: Basic | **Freetext template:**Justification for deviation from the high dose level | Provide a justification for deviating from the high dose level. |  |
|  | **Examinations** | **Header 2** |  |  |  |
|  | Observations and examinations performed and frequency | Text templateDisplay: Detailed | **Freetext template:**CAGE SIDE OBSERVATIONS: Yes / No / No data - Time schedule:  - Cage side observations checked in table [No.?] were included.   DETAILED CLINICAL OBSERVATIONS: Yes / No / No data - Time schedule:   DERMAL IRRITATION (if dermal study): Yes / No / No data - Time schedule for examinations:  BODY WEIGHT: Yes / No / No data - Time schedule for examinations:  FOOD CONSUMPTION AND COMPOUND INTAKE (if feeding study):  - Food consumption for each animal determined and mean daily diet consumption calculated as g food/kg body weight/day: Yes / No / No data  - Compound intake calculated as time-weighted averages from the consumption and body weight gain data: Yes / No / No data  FOOD EFFICIENCY: - Body weight gain in kg/food consumption in kg per unit time X 100 calculated as time-weighted averages from the consumption and body weight gain data: Yes / No / No data  WATER CONSUMPTION AND COMPOUND INTAKE (if drinking water study): Yes / No / No data - Time schedule for examinations:  OPHTHALMOSCOPIC EXAMINATION: Yes / No / No data - Time schedule for examinations: - Dose groups that were examined:  HAEMATOLOGY: Yes / No / No data - Time schedule for collection of blood: - Anaesthetic used for blood collection: Yes (identity) / No / No data - Animals fasted: Yes / No / No data - How many animals: - Parameters checked in table [No.?] were examined.  CLINICAL CHEMISTRY: Yes / No / No data - Time schedule for collection of blood: - Animals fasted: Yes / No / No data - How many animals: - Parameters checked in table [No.?] were examined.  URINALYSIS: Yes / No / No data - Time schedule for collection of urine: - Metabolism cages used for collection of urine: Yes / No / No data - Animals fasted: Yes / No / No data - Parameters checked in table [No.?] were examined.  NEUROBEHAVIOURAL EXAMINATION: Yes / No / No data - Time schedule for examinations: - Dose groups that were examined: - Battery of functions tested: sensory activity / grip strength / motor activity / other:   OTHER: | Indicate if and which examinations were performed and the time schedule for those examinations. Also indicate the dose groups that were examined if not all. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) 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').If other observations (e.g. neurotoxicity, immunotoxicity) are reported in another study summary, include a note in the block 'Cross-reference' and refer to that summary.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. |  |
|  | Sacrifice and pathology | Text templateDisplay: Detailed | **Freetext template:**GROSS PATHOLOGY: Yes (see table) / No / Not specifiedHISTOPATHOLOGY: Yes (see table) / No / Not specified | Indicate if and which examinations were performed. Also indicate the dose groups that were examined if not all. Note if not all collected tissues were examined. As appropriate include detailed table(s) in the rich text field 'Any other information on results incl. tables'. Upload predefined or other appropriate table(s) 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').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. |  |
|  | Other examinations | Text (32,768 char.)Display: Detailed |  | Describe any other examinations. |  |
|  | Statistics | Text (2,000 char.)Display: Detailed |  | List parameters that were analysed and the statistical methods used; include a statement that the Reviewer considers the analyses used to be appropriate. 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** |  |  |  |
|  | **Results of examinations** | **Header 2** |  |  |  |
|  | Clinical signs | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Dermal irritation (if dermal study) | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Mortality | List (picklist)Display: Detailed | **Picklist values:**- mortality observed, treatment-related- mortality observed, non-treatment-related- no mortality observed- not examined- not specified | Indicate whether mortality was observed and whether it was treatment-related or not. |  |
|  | Description (incidence) | Text (32,768 char.)Display: Detailed |  | Describe the incidence of mortality by sex and dose group.An explanation should be provided when there was a need to humanely sacrifice animals in pain or showing signs of severe and enduring distress. |  |
|  | Body weight and weight changes | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Food consumption and compound intake (if feeding study) | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Food efficiency | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Water consumption and compound intake (if drinking water study) | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Ophthalmological findings | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Haematological findings | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Clinical biochemistry findings | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Endocrine findings | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by dose group. At a minimum provide a qualitative description where dose effect related observations were seen.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Urinalysis findings | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Behaviour (functional findings) | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Where relevant describe functional investigations in relation to motor activity, sensory function, grip strength or bizarre behaviour (e.g. walking backwards).Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Immunological findings | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Organ weight findings including organ / body weight ratios | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Gross pathological findings | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Neuropathological findings | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Histopathological findings: non-neoplastic | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Histopathological findings: neoplastic | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Other effects | List (picklist)Display: Detailed | **Picklist values:**- effects observed, treatment-related- effects observed, non-treatment-related- no effects observed- not examined- not specified | Indicate whether any effects were observed and whether they were treatment-related or not. Select 'not examined' or 'not specified' as applicable. |  |
|  | Description (incidence and severity) | Text (32,768 char.)Display: Detailed |  | Describe the incidence and severity of effects by sex and dose group. At a minimum provide a qualitative description where dose effect related observations were seen, whether the effects observed are adverse or non-adverse and if the data allows, whether the effects are reversible or irreversible.Particularly with comprehensive data, include a table in the rich text field 'Any other information on results incl. tables'. Narrative accompanying such tabular data should mainly address the toxicological significance of the results and not repeat the details presented in the table(s).NOTE: Depending on the regulatory programme some form of a table(s) (predefined table) may be mandatory. |  |
|  | Details on results | Text (32,768 char.)Display: Detailed |  | Provide any other relevant details if not entered in the specific "Description" fields for the examined parameters. |  |
|  | Relevance of carcinogenic effects / potential | Text (32,768 char.)Display: Basic |  | Discuss carcinogenic effects / potential, i.e. state if there was (not) a treatment related increase in tumour incidence as compared to controls and specify tumour type if applicable. Indicate if dosing was not considered adequate. Discuss weight of evidence with respect to relevance of tumours observed for human health. This should be in line with information entered under 'Target system / organ toxicity'.Discuss conclusions given in supporting documentation. |  |
|  | **Effect levels** | **Header 2** |  |  |  |
|  |  | **Block of fields (repeatable) Start** |  |  |  |
|  | Key result | Check boxDisplay: 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. |  |
|  | Dose descriptor | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- T25- NOAEC- NOAEL- NOEC- NOEL- LOAEC- LOAEL- LOEC- LOEL- BMD05- BMDL05- BMDL10- BMD:- BMC05- BMCL05- BMCL10- BMC:- dose level:- conc. level:- other: | Select the relevant dose descriptor, i.e. the exposure level that corresponds to a quantified level of effects, e.g. NOAEL or LOAEL. If a benchmark dose / concentration was calculated, select appropriate BMD indicator (e.g. 'BMD05' or 'BMD:' and specify in the related text field). If the critical effects at a specific dose or concentration level are reported only, select 'dose. level:' or 'conc. level:' and specify.Where no value could be achieved based on the method and boundaries used, the upper or lower dose level for the relevant dose descriptor can be reported as appropriate with relevant qualifier, e.g. NOAEL >200 mg/kg bw/day or NOAEL <200 mg/kg bw/day. An additional explanation may be given in field 'Remarks on result', e.g. 'not determinable due to absence of adverse toxic effects'. |  |
|  | Effect level | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- mg/kg bw/day (nominal)- mg/kg bw/day (actual dose received)- mg/kg bw/day- mg/kg bw (total dose)- mg/kg diet- mg/L drinking water- mg/L air- mg/L air (nominal)- mg/L air (analytical)- mg/m³ air- mg/m³ air (nominal)- mg/m³ air (analytical)- ppm- ppm (nominal)- ppm (analytical)- microbial active substances- cells/kg bw/day (actual dose received)- cells/kg bw/day (nominal)- cells/kg bw/day- cells/kg bw (total dose)- cells/kg diet- cells/L drinking water- cells/L air- cells/m³ air- CFU/kg bw/day (actual dose received)- CFU/kg bw/day (nominal)- CFU/kg bw/day- CFU/kg bw (total dose)- CFU/kg diet- CFU/L drinking water- CFU/L air- CFU/m³ air- ITU/kg bw/day (actual dose received)- ITU/kg bw/day (nominal)- ITU/kg bw/day- ITU/kg bw (total dose)- ITU/kg diet- ITU/L drinking water- ITU/L air- ITU/m³ air- IU/kg bw/day (actual dose received)- IU/kg bw/day (nominal)- IU//kg bw/day- IU/kg bw (total dose)- IU/kg diet- IU/L drinking water- IU/L air- IU/m³ air- OB/kg bw/day (actual dose received)- OB/kg bw/day (nominal)- OB/kg bw/day- OB/kg bw (total dose)- OB/kg diet- OB/L drinking water- OB/L air- OB/m³ air- spores/kg bw/day (actual dose received)- spores/kg bw/day (nominal)- spores/kg bw/day- spores/kg bw (total dose)- spores/kg diet- spores/L drinking water- spores/L air- spores/m³ air- nanoforms- particles/kg bw/day (nominal)- particles/kg bw/day (actual dose received)- particles/kg bw/day- particles/kg bw (total dose)- particles/kg diet- particles/L drinking water- particles/L air- particles/L air (nominal)- particles/L air (analytical)- particles/m³ air- particles/m³ air (nominal)- particles/m³ air (analytical)- surface area/kg bw/day (nominal)- surface area/kg bw/day (actual dose received)- surface area/kg bw/day- surface area/kg bw (total dose)- surface area/kg diet- surface area/L drinking water- surface area/L air- surface area/L air (nominal)- surface area/L air (analytical)- surface area/m³ air- surface area/m³ air (nominal)- surface area/m³ air (analytical)- other: | Enter a single numeric value in the first numeric field if you select no qualifier or '>', '>=' or 'ca.'. Use the second numeric field if the qualifier is '<' or '<='. For a range use both numeric fields together with the appropriate qualifier(s) if applicable. |  |
|  | Based on | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- test mat.- test mat. (total fraction)- test mat. (dissolved fraction)- act. ingr.- act. ingr. (total fraction)- act. ingr. (dissolved fraction)- element- element (total fraction)- element (dissolved fraction)- other:- not specified | Indicate whether the concentration is based on the test material (test mat.), active ingredient (act. ingr.) or element. As appropriate the measured / addressed fraction can be specified for either of these entities by selecting the relevant item, e.g. 'element (dissolved fraction)' or 'test mat. (total fraction)'. Further information can be given in the supplementary remarks field, e.g. for specifying the type of fraction if it is not clear per se from the test material specification.Select 'not specified' if the effect concentration type is not known. |  |
|  | Sex | List (picklist)Display: Basic | **Picklist values:**- female- male- male/female- not specified | Select from drop-down list. |  |
|  | Basis for effect level | List multi. (multi-select list with remarks - 32,000 char.)Display: Basic | **Picklist values:**- behaviour (functional findings)- body weight and weight gain- clinical biochemistry- clinical signs- dermal irritation- food consumption and compound intake- food efficiency- gross pathology- haematology- histopathology: neoplastic- histopathology: non-neoplastic- immunology- mortality- neuropathology- ophthalmological examination- organ weights and organ / body weight ratios- serum/plasma biochemistry- serum/plasma hormone analyses- sperm measures- urinalysis- water consumption and compound intake- other endocrine activity endpoints- other: | Indicate the parameter(s) used to establish the given effect level. Multi-selection of different pre-defined values is possible. If none is available, you can select 'other:'. Any explanations can always be entered in the related supplementary text field. |  |
|  | Remarks on result | List sup. (picklist with remarks - 2,000 char.)Display: Basic | **Picklist values:**- not determinable due to absence of adverse toxic effects- 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 on the effect level by selecting 'other:' |  |
|  |  | **Block of fields (repeatable) End** |  |  |  |
|  | **Target system / organ toxicity** | **Header 2** |  |  |  |
|  |  | **Block of fields (repeatable) Start** |  | Record the target system(s) where toxicity was observed that is considered of biological relevance and the specific target organ(s).Copy this block of fields for referring to different target systems, lowest effective dose(s) / concentration(s) and/or treatment relationship, dose response relationship and relevance for humans. |  |
|  | Key result | Check boxDisplay: 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. |  |
|  | Critical effects observed | List (picklist)Display: Basic | **Picklist values:**- yes- no- not specified | Flag to indicate if critical effects were observed in the study within specific organs or systems. |  |
|  | Lowest effective dose / conc. | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- mg/kg bw/day (nominal)- mg/kg bw/day (actual dose received)- mg/kg bw (total dose)- mg/kg diet- mg/L drinking water- ppm- microbial active substances- cells/kg bw/day (nominal)- cells/kg bw/day (actual dose received)- cells/kg bw (total dose)- cells/kg diet- cells/L drinking water- CFU/kg bw/day (nominal)- CFU/kg bw/day (actual dose received)- CFU/kg bw (total dose)- CFU/kg diet- CFU/L drinking water- ITU/kg bw/day (nominal)- ITU/kg bw/day (actual dose received)- ITU/kg bw (total dose)- ITU/kg diet- ITU/L drinking water- IU/kg bw/day (nominal)- IU/kg bw/day (actual dose received)- IU/kg bw (total dose)- IU/kg diet- IU/L drinking water- OB/kg bw/day (nominal)- OB/kg bw/day (actual dose received)- OB/kg bw (total dose)- OB/kg diet- OB/L drinking water- spores/kg bw/day (nominal)- spores/kg bw/day (actual dose received)- spores/kg bw (total dose)- spores/kg diet- spores/L drinking water- nanoforms- particles/kg bw/day (nominal)- particles/kg bw/day (actual dose received)- particles/kg bw (total dose)- particles/kg diet- particles/L drinking water- surface area/kg bw/day (nominal)- surface area/kg bw/day (actual dose received)- surface area/kg bw (total dose)- surface area/kg diet- surface area/L drinking water- other: | Enter a numeric value and select the unit in the next field for indicating the lowest dose / concentration with significant and/or severe toxic effects on the target organ(s) affected.The following units should only be used in the case of microbial active substances:- cells- CFU (colony-forming unit)- ITU (International Toxic Unit)- IU (International Unit)- OB (occlusion bodies)- spores |  |
|  | System | List (picklist)Display: Basic | **Picklist values:**- autonomic nervous system- cardiovascular- central nervous system- ear- endocrine system- eye- female reproductive system- gastrointestinal tract- haematopoietic- hepatobiliary- immune system- integumentary- male reproductive system- musculoskeletal system- nervous system- peripheral nervous system- respiratory system: lower respiratory tract- respiratory system: upper respiratory tract- somatic nervous system- urinary- other: | Select any specific system where toxicity was observed that is considered of biological relevance. |  |
|  | Organ | List multi. (multi-select list)Display: Basic | **Picklist values:**- abdominal cavity- adrenal glands- alveolar duct- alveoli- ampulla- aorta- appendix- artery- bile duct- bladder- blood- blood vessel- bone- bone marrow- brain- bronchi- bronchioles- bulbourethral gland- caput- carotid artery- cartilage- cauda epididymis- cervix- choroid- ciliary body- clitoral gland- coagulating gland- cochlea- colon- cornea- corpus- corpus penis- Cowper’s glands- diaphragm- dorsolateral prostate gland- duodenum- erythrocyte development- fallopian tubes- forebrain- gall bladder- gametes- germ cells- glans penis- gonad- hard palate- heart- hindbrain- ileum- intestine- iris- islet of Langerhans- jejunum- kidney- lacrimal gland- larynx- lens- leucocyte development- Levatorani plus bulbocavernous muscle complex- Leydig cells- liver- lungs- lymph node- lymphoreticular tissue- mammary gland- mesenteric lymph node- midbrain- mucosa-associated lymphoid tissue- myofibres- myofilaments- nasal cavity- neurons- non-sensory epithelia- not specified- oesophagus- oral cavity- ovary- oviduct- pancreas- parathyroid gland- parotid gland- penile urethra- peritoneum- pharynx- pineal gland- pituitary gland- placenta- platelet formation- pleura- preputial gland- rectum- retina- salivary glands- sclera- seminal vesicle- seminiferous tubules- Sertoli cells- skin- skin associated lymphoid tissue- spinal cord- spleen- sternum- stomach- sublingual gland- submandibular gland- tendon- testes- thoracic cavity- thymus- thyroid gland- tongue- tooth- trachea- ureter- urethra- uterus- vagina- vas deferens- vascular system- vein- ventral prostate gland- vestibular system- vitreous humour- zymbal gland- other: | Select from the multiple drop-down list the target organ(s) where toxicity was observed. This field provides context-related picklist values depending on the selection made in the preceding field 'System'. |  |
|  | Treatment related | List (picklist)Display: Basic | **Picklist values:**- yes- no- not specified | Flag to indicate if the effects in systems and/or organs are treatment related. | **Guidance for field condition:**Condition: Field active only if 'Critical effects observed' is 'yes' |
|  | Dose response relationship | List (picklist)Display: Basic | **Picklist values:**- yes- no- not specified | Flag to indicate if the effects observed and reported in systems and/or organs are in a dose-response manner. | **Guidance for field condition:**Condition: Field active only if 'Critical effects observed' is 'yes' |
|  | Relevant for humans | List (picklist)Display: Basic | **Picklist values:**- yes- no- not specified- presumably yes | Flag to indicate if the effects observed and reported in systems and/or organs on the basis of animal experiments are also relevant for humans. Choose “no” from the picklist if the effects in target system/organ are species specific and not relevant for humans. | **Guidance for field condition:**Condition: Field active only if 'Critical effects observed' is 'yes' |
|  |  | **Block of fields (repeatable) End** |  |  |  |
|  | **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). |  |
|  | 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. |  |