**Template #58: Basic toxicokinetics *(Version [9.1]-[November 2021])***

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

| **Line no.** | **Field name** | **Field type**  **Display type** | **Picklist**  **Freetext template** | **Help text** | **Remarks**  **Guidance**  **Cross-reference** |
| --- | --- | --- | --- | --- | --- |
|  | **Administrative data** | **Header 1** |  |  |  |
|  |  | Confidentiality  Display: Basic |  |  |  |
|  | Endpoint | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - basic toxicokinetics in vitro / ex vivo - basic toxicokinetics in vivo - basic toxicokinetics, 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 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 source field 'Type of method' and 'Guideline' as a second indicator. As a fallback the generic phrase 'basic toxicokinetics' is selected. Note: The generic phrase is only used for migration, but otherwise deactivated in the picklist. For new entries a generic phrase is provided which consists of the OHT title followed by 'other', i.e. <OHT title>, other. |
|  | Type of information | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - experimental study - experimental study planned - experimental study planned (based on read-across) - (Q)SAR - calculation (if not (Q)SAR) - read-across based on grouping of substances (category approach) - read-across from supporting substance (structural analogue or surrogate) - mixture rules calculation - read-across from similar mixture/product - not specified - other: | Select the appropriate type of information, e.g. ' experimental study', ' experimental study planned' or, if alternatives to testing apply, '(Q)SAR', 'read-across ...'. In the case of calculated data, the value 'calculation (if not (Q)SAR)' should only be chosen if the study report does not clearly indicate whether it is based on '(Q)SAR'.  If the information is taken from a handbook or review article, select the relevant item, e.g. ‘experimental study’, if this is provided in the information source. Otherwise select ‘not specified’. Please note: In field ‘Reference type’ the option ‘review article or handbook’ should be selected. In general, the option 'not specified' should be selected if the submitter lacks the knowledge of the type of information. The option 'other:' can be used if another than a pre-defined item applies.  In the case of read-across, follow the instructions related to the relevant legislation, for instance as to whether the (robust) study summary should be entered in a separate data set defined for the read-across (source) substance and referenced in the target substance dataset.  If 'experimental study planned' or 'experimental study planned (based on read-across)' is indicated (in some legislations also defined as 'testing proposal' or 'undertaking of intended submission'), the submitter should include as much information as possible on the planned study in order to support the evaluation of the proposal. Typically, this would include at least the test guideline, information on the test material, the species and the route of administration in the corresponding distinct fields, as appropriate.  Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on whether specific fields should be completed and/or further details should be attached in field 'Attached background material'. |  |
|  | Adequacy of study | List (picklist)  Display: Basic | **Picklist values:** - key study - supporting study - weight of evidence - disregarded due to major methodological deficiencies - other information | Indicate the adequacy of a (robust) study summary in terms of usefulness for hazard/risk assessment purposes depending on the relevant legislation.  Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'.  Explanation:   - key study: In general, a key study is the study that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and representativity of data.   - supporting study: Any other adequate study that is considered supportive for the key study or key studies.   - weight of evidence: A record that contributes to a weight of evidence justification for the non-submission of a particular (adequate) study. The weight of evidence justification is normally endpoint-related, i.e. based on all available records included in the weight of evidence evaluation. A short reasoning for why a given record is used in this respect can be provided in field 'Detailed justification / remarks'.   - disregarded due to major methodological deficiencies: study that demonstrates a higher concern than the key study/ies, but is not used as key study because of flaws in the methodology or documentation. This phrase should be selected for justifying why a potentially critical result has not been used for the hazard assessment. The lines of argumentation should be provided in field 'Rationale for reliability incl. deficiencies', accompanied by the appropriate reliability score.  - other information: any other non-relevant information which does not need to be flagged specifically as 'disregarded due to major methodological deficiencies'.  Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. | **Guidance for field condition:** Condition: Field active only if 'Type of information' is not 'experimental study planned' and not ‘experimental study planned (based on read-across)’ and field 'Data waiving' is not populated (except for migrated data) |
|  | Robust study summary | Check box  Display: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Robust Study Summary' or in combination with 'Adequacy of study'.   Explanation: The term 'Robust Study Summary' is actually used only to describe the technical content of a very detailed summary of an experimental study or of any other relevant information. It is a priori no synonym with the term 'Key study', although a key study should usually be submitted in the form of Robust Study Summary. However, a Robust Summary may also be useful for other adequate studies that are considered supportive of the key study or even for inadequate studies if they can be used for a weight-of-evidence analysis. Also for studies that are flawed, but indicate critical results, Robust Study Summaries highlighting the weaknesses of the studies need to be elaborated.   Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Used for classification | Check box  Display: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Used for classification'.  Explanation: In some use cases it may be necessary to indicate those records that are used for the classification of that substance, e.g. according to UN GHS. If not relevant, disregard this field.   Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Used for SDS | Check box  Display: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'SDS information'.   Explanation: 'SDS' stands for Safety Data Sheet. In some use cases it may be necessary to indicate those records that are used for the compilation of SDS information. If not relevant, disregard this field.   Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Study period | Text (255 char.)  Display: Basic |  | If applicable indicate the period during which the study was conducted, i.e. start and end date, using an unambiguous date format, e.g. 'From 12 MAY 1999 to 15 AUG 2000' or 'From May 12, 1999 to Aug. 15, 2000'.   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. |  |
|  | Reliability | List (picklist)  Display: Basic | **Picklist values:** - 1 (reliable without restriction) - 2 (reliable with restrictions) - 3 (not reliable) - 4 (not assignable) - other: | Enter an appropriate reliability score, according to Klimisch et al. (1997):  1 = reliable without restrictions: “studies or data [...] generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline [...] or in which all parameters described are closely related/comparable to a guideline method.”  2 = reliable with restrictions: “studies or data [...] (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.”  3 = not reliable: “studies or data [...] in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g. non-physiological pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment.”  4 = not assignable: “studies or data [...] which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).”  The 'other:' option may be selected if a different scoring system is used. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.  Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'.  Note: The term reliability defines the inherent quality of a test report or publication relating to preferably standardised methodology and the way the method and results are described. More detailed criteria can be selected in field 'Justification'. |  |
|  | Rationale for reliability incl. deficiencies | List sup. (picklist with remarks - 32,000 char.)  Display: Basic | **Picklist values:** - guideline study - [Reliability 1] - comparable to guideline study - [Reliability 1] - test procedure in accordance with national standard methods - [Reliability 1] - test procedure in accordance with generally accepted scientific standards and described in sufficient detail - [Reliability 1] - guideline study without detailed documentation - [Reliability 2] - guideline study with acceptable restrictions - [Reliability 2] - comparable to guideline study with acceptable restrictions - [Reliability 2] - test procedure in accordance with national standard methods with acceptable restrictions - [Reliability 2] - study well documented, meets generally accepted scientific principles, acceptable for assessment - [Reliability 2] - accepted calculation method - [Reliability 2] - data from handbook or collection of data - [Reliability 2] - significant methodological deficiencies - [Reliability 3] - unsuitable test system - [Reliability 3] - abstract - [Reliability 4] - secondary literature - [Reliability 4] - documentation insufficient for assessment - [Reliability 4] - results derived from a valid (Q)SAR model and falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 1 or 2] - results derived from a valid (Q)SAR model and falling into its applicability domain, with limited documentation / justification - [Reliability 2, 3 or 4] - results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 2 or 3] - results derived from a (Q)SAR model, with limited documentation / justification, but validity of model and reliability of prediction considered adequate based on a generally acknowledged source - [Reliability 2 or 3] - results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, and documentation / justification is limited - [Reliability 3 or 4] - results derived from a (Q)SAR model, with limited documentation / justification - [Reliability 4] - other: | Select an appropriate standard justification from the picklist, e.g. 'Comparable to guideline study with acceptable restrictions'. Additional explanations (e.g. deficiencies observed) can be entered in the related supplementary text field. Particularly if reliability scores 2 or 3 are assigned, indicate the concrete arguments for defending a study or relevant deficiencies.  For QSAR results (i.e. 'Type of information' is '(Q)SAR') some pre-defined phrases are provided for indicating if the prediction results are considered reliable based on the scientifically validity of the (Q)SAR model used, its applicability to the query substance, and the adequacy of reporting. Please note: If (Q)SAR results are flagged as key study in field 'Adequacy of study', the relevance of the model used for the regulatory endpoint should be documented in the field where the (Q)SAR model is described, i.e. 'Justification for type of information', 'Attached justification' or 'Cross-reference'. | **Guidance for field condition:** Condition: Field active only if 'Type of information' is not 'experimental study planned' and not ‘experimental study planned (based on read-across)’. Condition 1: If 'Type of information' is not '(Q)SAR': - guideline study - [Reliability 1] - comparable to guideline study - [Reliability 1] - test procedure in accordance with national standard methods - [Reliability 1] - test procedure in accordance with generally accepted scientific standards and described in sufficient detail - [Reliability 1] - guideline study without detailed documentation - [Reliability 2] - guideline study with acceptable restrictions - [Reliability 2] - comparable to guideline study with acceptable restrictions - [Reliability 2] - test procedure in accordance with national standard methods with acceptable restrictions - [Reliability 2] - study well documented, meets generally accepted scientific principles, acceptable for assessment - [Reliability 2] - accepted calculation method - [Reliability 2] - data from handbook or collection of data - [Reliability 2] - significant methodological deficiencies - [Reliability 3] - unsuitable test system - [Reliability 3] - abstract - [Reliability 4] - secondary literature - [Reliability 4] - documentation insufficient for assessment - [Reliability 4] Condition 2: If 'Type of information' = '(Q)SAR': - results derived from a valid (Q)SAR model and falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 1 or 2] - results derived from a valid (Q)SAR model and falling into its applicability domain, with limited documentation / justification - [Reliability 2, 3 or 4] - results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 2 or 3] - results derived from a (Q)SAR model, with limited documentation / justification, but validity of model and reliability of prediction considered adequate based on a generally acknowledged source - [Reliability 2 or 3] - results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, and documentation / justification is limited - [Reliability 3 or 4] - results derived from a (Q)SAR model, with limited documentation / justification - [Reliability 4] - other: |
|  | Data waiving | List (picklist)  Display: Basic | **Picklist values:** - study technically not feasible - study scientifically not necessary / other information available - exposure considerations - study waived due to provisions of other regulation - other justification | If appropriate, indicate here that the study has been waived, i.e. not performed. Select the basis from the picklist (e.g. 'study technically not feasible' or 'other justification'). Include a more detailed justification in the field 'Justification for data waiving' and, as needed, in field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference'. Please note: the option 'study scientifically not necessary / other information available' covers cases where it can be justified that performance of a specific study prescribed by the relevant legislation is scientifically not necessary because reliable information is provided in other part(s) of the submission document.  The option 'study waived due to provisions of other regulation' can be used for indicating that another, overlapping regulation allows or requires the waiving of a specific information requirement. This should then be detailed in the justification fields.  If waiving is based on several lines of argumentation (e.g. ‘exposure considerations’ and ‘study scientifically not necessary / other information available’), create separate records for each.  Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use data waivers. | **Guidance for field condition:** Condition: Deactivate this field if any of the following fields is populated: 'Type of information', 'Adequacy of study', 'Reliability', 'Rationale for reliability'. |
|  | Justification for data waiving | List multi. (multi-select list with remarks - 32,000 char.)  Display: Basic | **Picklist values:** - other: | In addition to the more generic justification selected in the preceding field 'Data waiving', it is highly recommended to provide a detailed justification. To this end you can either select one or multiple specific standard phrase(s) if it/they give an appropriate rationale of the description given in the preceding field 'Data waiving' or 'other:' and enter free text. Additional specific explanations should be provided if the pre-defined phrase(s) do no sufficiently describe the justification.  More details can be provided using the following fields:  - Text field adjacent to this field 'Justification for data waiving' (available after selecting any picklist item in this field);  - Field 'Justification for type of information';  - Field 'Attached justification';  - Cross-reference (for referencing / linking to a justification or information referred to in the justification which is stored in another record, e.g. a record describing physico-chemical properties information used to support a data waiver)  Please note: The pre-defined phrases are not necessarily exhaustive and may not always apply. Consult the guidance documents and waiving options in the relevant regulatory frameworks. If no suitable phrase is available from the picklist, enter a free text justification using the 'other:' option. | **Guidance for field condition:** Condition: Deactivate this field if any of the following fields is populated: 'Type of information', 'Adequacy of study', 'Reliability', 'Rationale for reliability'. |
|  | Justification for type of information | Text template  Display: Basic | **Freetext template:  Option 1 Type 'Waiving of standard information'** JUSTIFICATION FOR DATA WAIVING [Specific explanation in addition to field 'Justification for data waiving'] **Option 2 Type 'Experimental study planned / Testing proposal on vertebrate animals'** TESTING PROPOSAL ON VERTEBRATE ANIMALS [Please provide information for all of the points below. The information should be specific to the endpoint for which testing is proposed. Note that for testing proposals addressing testing on vertebrate animals under the REACH Regulation this document will be published on the ECHA website along with the third party consultation on the testing proposal(s).]  NON-CONFIDENTIAL NAME OF SUBSTANCE: - Name of the substance on which testing is proposed to be carried out - Name of the substance for which the testing proposal will be used [if different from tested substance]  CONSIDERATIONS THAT THE GENERAL ADAPTATION POSSIBILITIES OF ANNEX XI OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION [please address all points below]: - Available GLP studies - Available non-GLP studies - Historical human/control data - (Q)SAR - In vitro methods - Weight of evidence - Grouping and read-across - Substance-tailored exposure driven testing [if applicable] - Approaches in addition to above [if applicable] - Other reasons [if applicable]  CONSIDERATIONS THAT THE SPECIFIC ADAPTATION POSSIBILITIES OF ANNEXES VI TO X (AND COLUMN 2 THEREOF) OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION: - [free text]  FURTHER INFORMATION ON TESTING PROPOSAL IN ADDITION TO INFORMATION PROVIDED IN THE MATERIALS AND METHODS SECTION: - Details on study design / methodology proposed [if relevant] **Option 3 Type 'QSAR prediction'** 1. SOFTWARE  2. MODEL (incl. version number)  3. SMILES OR OTHER IDENTIFIERS USED AS INPUT FOR THE MODEL  4. SCIENTIFIC VALIDITY OF THE (Q)SAR MODEL [[Explain how the model fulfils the OECD principles for (Q)SAR model validation. Consider attaching the QMRF and/or QPRF or providing a link] - Defined endpoint: - Unambiguous algorithm: - Defined domain of applicability: - Appropriate measures of goodness-of-fit and robustness and predictivity: - Mechanistic interpretation:  5. APPLICABILITY DOMAIN [Explain how the substance falls within the applicability domain of the model] - Descriptor domain: - Structural domain: - Mechanistic domain: - Similarity with analogues in the training set: - Other considerations (as appropriate):  6. ADEQUACY OF THE RESULT [Explain how the prediction fits the purpose of classification and labelling and/or risk assessment] **Option 4 Type 'Read-across (analogue)'** REPORTING FORMAT FOR THE ANALOGUE APPROACH [Please provide information for all of the points below. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]  1. HYPOTHESIS FOR THE ANALOGUE APPROACH [Describe why the read-across can be performed (e.g. common functional group(s), common precursor(s)/breakdown product(s) or common mechanism(s) of action]  2. SOURCE AND TARGET CHEMICAL(S) (INCLUDING INFORMATION ON PURITY AND IMPURITIES) [Provide here, if relevant, additional information to that included in the Test material section of the source and target records]  3. ANALOGUE APPROACH JUSTIFICATION [Summarise here based on available experimental data how these results verify that the read-across is justified]  4. DATA MATRIX **Option 5 Type 'Read-across (category)'** REPORTING FORMAT FOR THE CATEGORY APPROACH [Please provide information for all of the points below addressing endpoint-specific elements that were not already covered by the overall category approach justification made available at the category level. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]  1. HYPOTHESIS FOR THE CATEGORY APPROACH (ENDPOINT LEVEL) [Describe why the read-across can be performed]  2. CATEGORY APPROACH JUSTIFICATION (ENDPOINT LEVEL [Summarise here based on available experimental data how these results verify that the read-across is justified] | 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':  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 - 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:** - assessment report - data waiving: supporting information - exposure-related information - read-across source - read-across: supporting information - (Q)SAR model reporting (QMRF) - reference to other assay used for intermediate effect derivation - reference to same study - reference to other study - other: | Select the appropriate reason of the cross-reference, i.e.  - 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)  - 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 (OMRF) (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 (http://www.oecd.org/ehs/templates/Generic%20elements%20for%20all%20OHTs%20(added%20online%20Feb%202017).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** |  |  |  |
|  | Objective of study | List multi. (multi-select list)  Display: Basic | **Picklist values:** - absorption - bioaccessibility (or bioavailability) - distribution - enzyme clearance - enzyme inhibition / induction - excretion - hepatic clearance  - mass balance - metabolism - not specified - tissue distribution - toxicokinetics - other: | Indicate the purpose of the study. The field is repeatable. Select the respective toxicokinetic aspect(s) investigated.  Multiple selection is possible. If not listed, select 'other' and specify. |  |
|  | **Test guideline** | **Block of fields (repeatable) Start** |  | Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'.  Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline). |  |
|  | Qualifier | List (picklist)  Display: Basic | **Picklist values:** - according to guideline - equivalent or similar to guideline - no guideline followed - no guideline available - no guideline required | Select appropriate qualifier, i.e.  - 'according to guideline' (if a given test guideline was followed);  - 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline);  - 'no guideline followed' (if none of above qualifiers apply. If so, fill in field 'Principles of method if other than guideline');  - 'no guideline available' (if so, fill in field 'Principles of method if other than guideline').  - 'no guideline required' (if so, fill in field 'Principles of method if other than guideline'). |  |
|  | Guideline | List (picklist)  Display: Basic | **Picklist values:** - EPA OPP 85-1 (Metabolism and Pharmacokinetics) - EPA OPPTS 870.7485 (Metabolism and Pharmacokinetics) - EPA OPPTS 870.8223 (Pharmacokinetic Test) - EPA OPPTS 870.8320 (Oral/dermal pharmacokinetics) - EPA OPPTS 870.8340 (Oral and Inhalation Pharmacokinetic Test) - EPA OPPTS 870.8360 (Pharmacokinetics of Isopropanol) - EPA OPPTS 870.8380 (Inhalation and Dermal Pharmacokinetics of Commercial Hexane) - EPA OPPTS 870.8500 (Toxicokinetic Test) - EPA OTS 795.2230 (Pharmacokinetic Test) - EPA OTS 795.2280 (Oral/Dermal Pharmacokinetics) - EPA OTS 795.2300 (Pharmacokinetic Test) - EPA OTS 795.2310 (Pharmacokinetics of Isopropanol) - EPA OTS 795.2320 (Inhalation and Dermal Pharmacokinetics of Commercial Hexane) - EPA OTS 795.2350 (Toxicokinetic Test) - EPA OTS 798.7485 (Metabolism and Pharmacokinetics) - EU Method B.36 (Toxicokinetics) - OECD Guideline 319A (Determination of in vitro intrinsic clearance using cryopreserved rainbow trout hepatocytes (RP-HEP) - OECD Guideline 319B (Determination of in vitro intrinsic clearance using rainbow trout liver S9 sub-cellular fraction (RP-S9)  - OECD Guideline 417 (Toxicokinetics) - other: | Select the applicable test guideline, e.g. 'OECD Guideline xxx'. If the test guideline used is not listed, choose 'other:' and specify the test guideline in the related text field. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.  If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'. The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields.  Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'. | **Guidance for field condition:** Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Version / remarks | Text (2,000 char.)  Display: Basic |  | In this text field, you can enter any remarks as applicable, particularly:  - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline);  - To indicate if the study was performed prior to the adoption of the test guideline specified;  - To indicate if the methodology used was based on an extension of the test guideline specified;  - To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section. | **Guidance for field condition:** Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Deviations | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - yes - no - not applicable - not specified | In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS. | **Guidance for field condition:** Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | **Test guideline** | **Block of fields (repeatable) End** |  |  |  |
|  | Principles of method if other than guideline | Text template  Display: Basic | **Freetext template:  Option 1 Method of non-guideline study** - Principle of test: - Short description of test conditions: - Parameters analysed / observed: **Option 2 (Q)SAR** - Software tool(s) used including version: - Model(s) used: - Model description: see field 'Justification for non-standard information', 'Attached justification' and/or 'Cross-reference' - Justification of QSAR prediction: see field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' | If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate use either of the pre-defined freetext template options for 'Method of non-guideline study' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate.  For a non-guideline experimental study a high-level freetext template can be used for summarising the principle of test, test conditions and parameters analysed / observed.   If the freetext template for (Q)SAR is selected, indicate the QSAR model(s) or platform including version and the software tool(s) used. Detailed justification of the model and prediction should be provided in field(s) 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' as appropriate.  Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate. |  |
|  | GLP compliance | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - yes (incl. QA statement) - yes - no - not specified | Indicate whether the study was conducted following Good Laboratory Practice or not. In case 'yes’ is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed. |  |
|  | **Test material** | **Header 2** |  |  |  |
|  | Test material information | Link to entity (single)  Display: Basic |  | Select the appropriate Test Material Information (TMI) record. If not available in the repository, create a new one. You may also copy (clone) an existing TMI record, edit it and store it as new TMI.  To change the link to an existing TMI, click the Delete button, then the Link button and proceed as described above.  Depending on the purpose of the reporting or data submission, the information that must be provided may change. As a minimum, the chemical name, identifier and/or CAS number and molecular weight must be provided. | **Cross-reference:** TEST\_MATERIAL\_INFORMATION |
|  | Additional test material information | Link to entity (multiple)  Display: Basic |  | Select additional Test material information record if relevant. For example, in longer terms studies more than one batch of test material can be needed or there may be differences between the labelled and unlabelled test materials. | **Cross-reference:** TEST\_MATERIAL\_INFORMATION |
|  | Specific details on test material used for the study | Text template  Display: Basic | **Freetext template:** SOURCE OF TEST MATERIAL - Source (i.e. manufacturer or supplier) and lot/batch number of test material: - Purity, including information on contaminants, isomers, etc.:  RADIOLABELLING INFORMATION (if applicable) - Radiochemical purity: - Specific activity: - Locations of the label: - Expiration date of radiochemical substance:  STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL - Storage condition of test material: - Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage: - Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis: - Solubility and stability of the test material in the solvent/vehicle and the exposure medium: - Reactivity of the test material with the incubation material used (e.g. plastic ware):  TREATMENT OF TEST MATERIAL PRIOR TO TESTING - Treatment of test material prior to testing (e.g. warming, grinding): - Preliminary purification step (if any): - Final concentration of a dissolved solid, stock liquid or gel: - Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):  FORM AS APPLIED IN THE TEST (if different from that of starting material) - Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:  INFORMATION ON NANOMATERIALS - Chemical Composition: - Density: - Particle size & distribution: - Specific surface area: - Isoelectric point: - Dissolution (rate):  TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable) - Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:  OTHER SPECIFICS - Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.  Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.  If applicable, relevant available information on the following items should be given:  SOURCE OF TEST MATERIAL  - Source and lot/batch No. of test material  - Expiration date of the lot/batch  - Purity test date: provide if available  RADIOLABELLING INFORMATION  - Radiochemical purity  - Specific activity  - Locations of the label  - Expiration date of radiochemical substance  STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL  - Storage condition of test material  - Stability under test conditions  - Solubility and stability of the test substance in the solvent/vehicle  - Reactivity of the test substance with the solvent/vehicle or the cell culture medium  TREATMENT OF TEST MATERIAL PRIOR TO TESTING  - Treatment of test material prior to testing (e.g. warming, grinding)  - Preliminary purification step  - Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used  - Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)  FORM AS APPLIED IN THE TEST (if different from that of starting material)  Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.  FORMULATED PRODUCT (for biocides/pesticides)  Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.  OTHER SPECIFICS  Provide any other relevant information needed for characterising the tested material. |  |
|  | Specific details on test material used for the study (confidential) | Text template  Display: Basic (Confidential) | **Freetext template:** SOURCE OF TEST MATERIAL - Source (i.e. manufacturer or supplier) and lot/batch number of test material: - Purity, including information on contaminants, isomers, etc.:  RADIOLABELLING INFORMATION (if applicable) - Radiochemical purity: - Specific activity: - Locations of the label: - Expiration date of radiochemical substance:  STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL - Storage condition of test material: - Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage: - Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis: - Solubility and stability of the test material in the solvent/vehicle and the exposure medium: - Reactivity of the test material with the incubation material used (e.g. plastic ware):  TREATMENT OF TEST MATERIAL PRIOR TO TESTING - Treatment of test material prior to testing (e.g. warming, grinding): - Preliminary purification step (if any): - Final concentration of a dissolved solid, stock liquid or gel: - Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):  FORM AS APPLIED IN THE TEST (if different from that of starting material) - Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:  INFORMATION ON NANOMATERIALS - Chemical Composition: - Density: - Particle size & distribution: - Specific surface area: - Isoelectric point: - Dissolution (rate):  TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable) - Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:  OTHER SPECIFICS - Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.  Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.  If applicable, relevant available information on the following items should be given:  SOURCE OF TEST MATERIAL  - Source and lot/batch No. of test material  - Expiration date of the lot/batch  - Purity test date: provide if available  RADIOLABELLING INFORMATION  - Radiochemical purity  - Specific activity  - Locations of the label  - Expiration date of radiochemical substance  STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL  - Storage condition of test material  - Stability under test conditions  - Solubility and stability of the test substance in the solvent/vehicle  - Reactivity of the test substance with the solvent/vehicle or the cell culture medium  TREATMENT OF TEST MATERIAL PRIOR TO TESTING  - Treatment of test material prior to testing (e.g. warming, grinding)  - Preliminary purification step  - Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used  - Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)  FORM AS APPLIED IN THE TEST (if different from that of starting material)  Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.  FORMULATED PRODUCT (for biocides/pesticides)  Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.  OTHER SPECIFICS  Provide any other relevant information needed for characterising the tested material. |  |
|  | Radiolabelling | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - yes - no - other: - not specified | Indicate if labelled or non-labelled test material was used. Details on labelled material to be described in field 'Details on test material'. In the supplementary remarks field, any further explanations can be provided, e.g. for indicating that both labelled and unlabelled substances were used. |  |
|  | **Test animals** | **Header 2** |  |  |  |
|  | Species | List (picklist)  Display: Basic | **Picklist values:** - cat - cattle - dog - fish - gerbil - guinea pig - hamster - hamster, Armenian - hamster, Chinese - hamster, Syrian - hen - miniature swine - monkey - mouse - pig - primate - rabbit - rat - 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 different sexes were used in multiple test runs recorded in the same record, select 'male/female' and differentiate in field 'Doses / concentrations'. |  |
|  | Details on test animals or test system and environmental conditions | Text template  Display: Detailed | **Freetext template:** TEST ANIMALS - Source: - Age at study initiation: - Weight at study initiation: - Housing: - Diet (e.g. ad libitum): - Water (e.g. ad libitum): - Acclimation period: - Health status:    ENVIRONMENTAL CONDITIONS  - Temperature (°C): - Humidity (%): - Air changes (per hr): - Photoperiod (hrs dark / hrs light): - Fasting period   IN-LIFE DATES: From: To:  IN VITRO TEST SYSTEM  • If purchased - Commercial source: - Strain: - Animal weight: - Relevant organ weight: - Relevant indices:  • If prepared in house - Fill in Reporting Template in Annex 2 of TG 319A or TG 319B: - Other test system relevant information: | 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).  IN VITRO TEST SYSTEM: Information to be reported for clearance tests conducted along TG 319A or TG 319B |  |
|  | **Administration / exposure** | **Header 2** |  |  |  |
|  | Route of administration | List (picklist)  Display: Basic | **Picklist values:** - application in vitro - dermal - implantation - infusion - inhalation - inhalation: aerosol - inhalation: dust - inhalation: gas - inhalation: mist - inhalation: mixture of gas and vapour - inhalation: mixture of gas, vapour and aerosol - inhalation: mixture of vapour and aerosol / mist - inhalation: vapour - intramuscular - intraperitoneal - intratracheal - intravenous - not specified - oral: capsule - oral: drinking water - oral: feed - oral: gavage - oral: unspecified - subcutaneous - other: | Select as appropriate. If not available from picklist, select 'other' and specify. |  |
|  | Vehicle | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - unchanged (no vehicle) - acetone - arachis oil - beeswax - carbowaxe - castor oil - cetosteryl alcohol - cetyl alcohol - CMC (carboxymethyl cellulose) - coconut oil - corn oil - cotton seed oil - DMSO - ethanol - glycerol ester - glycolester - hydrogenated vegetable oil - lecithin - macrogel ester - maize oil - methylcellulose - olive oil - 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 'unchanged (no vehicle)' if none was used or select vehicle used if any. If not available from picklist, select 'other' and specify. Further information can be given in the supplementary remarks field.  Note that some of the vehicles provided in this list are used for specific routes of administration only. |  |
|  | Details on exposure | Text template  Display: Detailed (Confidential) | **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: **Option 2 Route = inhalation**  TYPE OF INHALATION EXPOSURE: nose only / head only / nose/head only / whole body / other: / no data    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 **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    USE OF RESTRAINERS FOR PREVENTING INGESTION: yes/no **Option 4 In vitro application** IN VITRO APPLICATION  - Concentration of test material and reference chemical: - Method of preparation of stock solution(s) of test material and reference chemical: - Cell culture medium characteristics (temperature, pH): - Incubation temperature: - Cell density in suspension for incubation (nominal and measured): - Test set-up (multiple via or simple via approach): - Number of replicates (if more than one is used per run): - Number of independent runs: - Time points: - Description of any preliminary experiments: | 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. |  |
|  | Duration and frequency of treatment / exposure | Text (2,000 char.)  Display: Basic |  | Indicate duration and frequency of application, e.g. 'single application' or 'multiple application: 14 days, 2 doses per day, 5 days per week'. |  |
|  | **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 diet - mg/L drinking water - mg/kg bw (total dose) - 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) - other: - CFU/kg bw/day (actual dose received) - CFU/kg bw/day (nominal) - CFU/kg bw/day - CFU/kg diet - CFU/L drinking water - CFU/kg bw (total dose) - CFU/L air - CFU/m³ air - IU/kg bw/day (actual dose received) - IU/kg bw/day (nominal) - IU//kg bw/day - IU/kg diet - IU/L drinking water - IU/kg bw (total dose) - IU/L air - IU/m³ air - OB/kg bw/day (actual dose received) - OB/kg bw/day (nominal) - OB/kg bw/day - OB/kg diet - OB/L drinking water - OB/kg bw (total dose) - OB/L air - OB/m³ air - spores/kg bw/day (actual dose received) - spores/kg bw/day (nominal) - spores/kg bw/day - spores/kg diet - spores/L drinking water - spores/kg bw (total dose) - spores/L air - spores/m³ air | Enter numeric value. |  |
|  | Remarks | Text (2,000 char.)  Display: Basic |  | Enter any remarks related to dose / concentration values / pilot study / main study. |  |
|  | **Doses / concentrations** | **Block of fields (repeatable) End** |  |  |  |
|  | No. of animals per sex per dose / concentration | Text (2,000 char.)  Display: Basic |  | Enter value or specify according to dose if different number of animals per dose / concentration, e.g. '4 in each dose / concentration group with single application; 2 f and 4 m in multiple application group'.  In case of a robust study summary, include animal numbers per sex in table on animal assignment. |  |
|  | Control animals | List multi. (multi-select list with remarks)  Display: Basic | **Picklist values:** - yes - yes, concurrent no treatment - yes, concurrent vehicle - yes, historical - yes, plain diet - yes, sham-exposed - no - not relevant - not specified - other: | Indicate whether and what type of concurrent control groups were used. Multiple selection is possible. If not listed, select 'other' and specify. |  |
|  | Positive control reference chemical | Text (2,000 char.)  Display: Detailed |  | Indicate if a positive control was used and if appropriate indicate purity, Lot/batch No. |  |
|  | Details on study design | Text template  Display: Detailed | **Freetext template:** - Dose selection rationale:   - Rationale for animal assignment (if not random): | Include further details on the study design including a brief description on dose selection and animal assignment rationale if appropriate. 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 HPVC, Pesticides NAFTA or EU REACH) thereof. |  |
|  | Details on dosing and sampling | Text template  Display: Detailed | **Freetext template:** TOXICOKINETIC / PHARMACOKINETIC STUDY (Absorption, distribution, excretion) - Tissues and body fluids sampled (delete / add / specify): urine, faeces, expired air, blood, plasma, serum or other tissues, cage washes, bile - Time and frequency of sampling: - Other:  METABOLITE CHARACTERISATION STUDIES - Tissues and body fluids sampled (delete / add / specify): urine, faeces, tissues, cage washes, bile: - Time and frequency of sampling: - From how many animals: (samples pooled or not) - Method type(s) for identification (e.g. GC-FID, GC-MS, HPLC-DAD, HPLC-MS-MS, HPLC-UV, Liquid scintillation counting, NMR, TLC): - Limits of detection and quantification: - Other (validation of method):  TREATMENT FOR CLEAVAGE OF CONJUGATES (if applicable):  ANALYTICAL METHOD - Complete description including: limit of detection and quantification, variability and recovery efficiency, matrix used for standard preparations, internal standard | Include details on dosing and sampling. Use freetext template and delete/add elements as appropriate. As an option you may include an excerpt from the study report. |  |
|  | Statistics | Text (2,000 char.)  Display: Detailed |  | List parameters that were analysed by which statistical methods, computer programme used. |  |
|  | **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** |  |  |  |
|  | Preliminary studies | Text (32,768 char.)  Display: Basic |  | Briefly describe the results of preliminary / pilot study or studies if any. |  |
|  | **Main ADME results** | **Block of fields (repeatable) Start** |  | Briefly describe the most relevant results with regard to absorption, distribution, metabolism, excretion and any other aspects related to toxicokinetics. Further details can be given in the below fields 'Details on absorption', 'Details on distribution in tissues', 'Details on excretion' and/or 'Any other information on results incl. tables'.  If required, copy block of fields to include several parameters.  Absorption: Include degree of absorption in %. In case of a robust study summary, include a function relating excretion of radioactivity (in urine, feces, etc.) to sampling time.  Distribution: For each treatment group / study design or combined groups, describe levels of radioactivity measured at given time points in tissues/organs.  Excretion: For each treatment group / study design or combined groups, describe levels of radioactivity measured at given time points in tissues and excreta including total recovery.  Material balance: Indicate mass balance of study.  Metabolism including clearance: describe any decrease of the test chemical concentration from the incubation vial measured to determine the clearance in vitro. |  |
|  | Type | List (picklist)  Display: Basic | **Picklist values:** - absorption - clearance - distribution - excretion - metabolism - other: | Select either 'absorption', 'distribution', 'metabolism', 'excretion' or 'other:' from drop-down list. |  |
|  | Results | Text (255 char.)  Display: Basic |  | Briefly describe the most relevant results. |  |
|  | **Main ADME results** | **Block of fields (repeatable) End** |  |  |  |
|  | **Toxicokinetic / pharmacokinetic studies** | **Header 2** |  |  |  |
|  | Details on absorption | Text (32,768 char.)  Display: Basic |  | In case of a robust study summary, describe further details on absorption. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').  Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof. |  |
|  | Details on distribution in tissues | Text (32,768 char.)  Display: Basic |  | In case of a robust study summary, describe further details on distribution. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').  Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof. |  |
|  | **Transfer into organs** | **Block of fields (repeatable) Start** |  | Indicate the transfer of the radiolabelled test substance into organs. Copy this block of fields for each transfer type and/or different test runs if applicable. |  |
|  | Key result | Check box  Display: Basic |  | Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.  Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Test no. | List (picklist)  Display: Basic | **Picklist values:** - #1 - #2 - #3 - #4 - #5 - #6 - #7 - #8 - #9 - #10 | Select a consecutive test number from drop-down list if more than one test runs are reported. |  |
|  | Transfer type | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - blood/brain barrier - blood/placenta barrier - secretion via gastric mucosa - other: | Select type of transfer (e.g. 'blood/brain transfer') from picklist. |  |
|  | Observation | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - distinct transfer - slight transfer - no transfer detectable - not determined - other: | Select the qualitative description (e.g. 'distinct transfer') that characterises the observed transfer of radiolabelled test substance into the brain or spinal cord or into the placenta and on the secretion of radioactivity via the gastric mucosa, respectively. As appropriate, include quantitative data and/or any explanations in the supplementary remarks field. |  |
|  | **Transfer into organs** | **Block of fields (repeatable) End** |  |  |  |
|  | Details on excretion | Text (32,768 char.)  Display: Basic |  | In case of a robust study summary, describe further details on excretion. As appropriate include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').  Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof. |  |
|  | **Toxicokinetic parameters** | **Block of fields (repeatable) Start** |  | Select toxicokinetic parameter from picklist and enter the corresponding value(s) with unit in the related text field.  Examples: (i) Half-life 1st: 23.4 hrs (male, single administration study); (ii) C(time): 88 μg/l at 40 hrs  Copy this block of fields for each parameter. If multiple test runs are recorded, enter test numbers in subfield 'Test No.'. |  |
|  | Key result | Check box  Display: Basic |  | Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.  Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Test no. | List (picklist)  Display: Basic | **Picklist values:** - #1 - #2 - #3 - #4 - #5 - #6 - #7 - #8 - #9 - #10 | Select a consecutive test number from drop-down list if more than one test runs are reported. |  |
|  | Toxicokinetic parameters | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - half-life 1st: - half-life 2nd: - half-life 3rd: - AUC: - Cmax: - C(time): - Tmax: - other: | Select parameter from drop-down list.  Explanations:  - AUC: Area under the plasma (blood) level vs. time curve from zero up to a certain measured time point (specify the time);  Cmax: Maximum (peak) concentration;  C(time): Maximum concentration at a specified time after administration of a given dose;  Tmax: Time to reach peak or maximum concentration following administration |  |
|  | **Toxicokinetic parameters** | **Block of fields (repeatable) End** |  |  |  |
|  | **Metabolite characterisation studies** | **Header 2** |  |  |  |
|  | Metabolites identified | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - no - not measured - yes - not specified | Indicate whether metabolites were identified. |  |
|  | Details on metabolites | Text (32,768 char.)  Display: Basic |  | List the metabolites identified, include percent of radioactive dose given, where they were identified, when, if applicable, how they were identified, if applicable, how much parent was present in the excreta.  In case of a robust study summary, also include a detailed table in the rich text field 'Any other information on results incl. tables'. Upload predefined table(s) if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').  When available, include summary of metabolic pathways and attach figures in field 'Attached background material'. Mention which are major vs. minor pathways. Attach the submitter's postulated pathway as a figure.  Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD HPVC, Pesticides NAFTA or EU REACH) thereof. |  |
|  | **Enzymatic activity** | **Header 2** |  |  |  |
|  | Enzymatic activity measured | Text (32,768 char.)  Display: Basic |  | Indicate the results of any enzymatic activity measured (induction, inhibition or biotransformation of test material). Identify enzyme(s) involved, rate of activity, time points measured, data from individual vials, time point for each independent run, calculated clearance and summary statistics, and method used to follow the activity. Specify whether measurements were done in vivo or in vitro, in main study or supplemental approach. |  |
|  | **Bioaccessibility (or Bioavailability)** | **Header 2** |  |  |  |
|  | Bioaccessibility (or Bioavailability) testing results | Text (32,768 char.)  Display: Basic |  | Indicate the results of the bio-accessibility (or bio-availability) tests, if applicable. |  |
|  | **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.  In case of in vitro clearance test, the Annex 2 of TG 319A and TG 319B provide template tables for reporting information on fish hepatocytes.  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 - 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** |  |  |  |
|  | Illustration (picture/graph) | Image upload  Display: Basic |  | Upload file by clicking the upload icon. As appropriate, enter any additional information, e.g. language. The file name is displayed after uploading the document. |  |
|  | **Applicant's summary and conclusion** | **Header 1** |  |  |  |
|  | Conclusions | Text (32,768 char.)  Display: Basic |  | Enter any conclusions if applicable in addition to the information given in fields 'Key results' and 'Interpretation of results' (if any). | **Guidance for data migration:** Target field for removed field 'Interpretation of results' |
|  | 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. |  |