**Template #30: Biodegradation in soil *(Version [7.2]-[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:** - biodegradation in soil: simulation testing - biodegradation in soil, 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 specific target phrase 'biodegradation in soil: simulation testing' is selected if source field 'Guideline' contains either 'OECD Guideline 307 (Aerobic and Anaerobic Transformation in Soil)' or 'EU Method C.23 (Aerobic and Anaerobic Transformation in Soil)'. Otherwise the generic phrase 'biodegradation in soil' 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:** - the study does not need to be conducted because the substance is readily biodegradable - [study scientifically not necessary / other information available] - the study does not need to be conducted because direct and indirect exposure of soil is unlikely - [exposure considerations] - 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** |  |  |  |
|  | **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 304 A (Inherent Biodegradability in Soil) - OECD Guideline 307 (Aerobic and Anaerobic Transformation in Soil) - EU Method C.23 (Aerobic and Anaerobic Transformation in Soil) - EPA OPPTS 835.3300 (Soil Biodegradation) - EPA OPPTS 835.4100 (Aerobic Soil Metabolism) - EPA OPPTS 835.4200 (Anaerobic Soil Metabolism) - EPA OPPTS 885.5200 (Microbial Pesticide, Expression in a Terrestrial Environment) - EPA OTS 796.3400 (Soil Biodegradation) - ISO/DIS 17556.2 (Plastics - Determination of the Ultimate Aerobic Biodegradability in Soil by Measuring the Oxygen Demand in a Respirometer or the Amount of Carbon Dioxide Evolved) - 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 type | List (picklist)  Display: Basic | **Picklist values:** - field trial - laboratory - other: - not specified | Indicate whether the study was a field trial or laboratory study. |  |
|  | **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 - 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'. |  |
|  | **Study design** | **Header 2** |  |  |  |
|  | Oxygen conditions | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - aerobic - aerobic/anaerobic - anaerobic - other: - not specified | Indicate whether test was performed under aerobic or anaerobic conditions. Include any explanations in the supplementary remarks field as appropriate. |  |
|  | Soil classification | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - Canadian System of Soil Classification - DIN 19863 (Deutsche Industrie-Norm) - NF X31-107 (Norme francaise) - USDA (US Department of Agriculture) - WRB (World Reference Base for Soil Resources) - other: - not specified | Select as cited in the study report. If not available from picklist, select 'other:' and specify. |  |
|  | Year | Numeric (integer)  Display: Basic |  | Enter year of study report or publication. For a study report this field should be completed to include it in any searches, regardless of whether the complete date is given in field 'Report date'. |  |
|  | **Soil properties** | **Block of fields (repeatable) Start** |  | Repeat this block of fields for each different soil used as indicated by the Soil No. Enter soil type as cited in the study report and the respective soil properties. |  |
|  | Soil no. | List (picklist)  Display: Basic | **Picklist values:** - #1 - #2 - #3 - #4 - #5 - #6 - #7 - #8 - #9 - #10 - #11 - #12 - #13 - #14 - #15 - #16 - #17 - #18 - #19 - #20 | Select a consecutive soil number from drop-down list if more than one soil types were used. |  |
|  | Soil type | List (picklist)  Display: Basic | **Picklist values:** - Alfisol - Andisol - Aridsol - Brunisol - Chernozem - clay - clay loam - Cryosol - Entisol - Gleysol - Histosol - Inceptisol - loam - loamy sand - Luvisol - Mollisol - Organic - Oxisol - Podzol - Regosol - sand - sandy clay loam - sandy loam - sandy clay - Silt - silt loam - silty clay - silty clay loam - Solonetzic - Spodsol - Ultisol - Vertisol - other: | Select from drop-down list. |  |
|  | % Clay | Numeric range (decimal)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. | 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. |  |
|  | % Silt | Numeric range (decimal)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. | 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. |  |
|  | % Sand | Numeric range (decimal)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. | 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. |  |
|  | % Org. C | Numeric range (decimal)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. | 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. |  |
|  | pH | Numeric range (decimal)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. | 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. |  |
|  | CEC | Numeric range (decimal with picklist)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. **Picklist values:** - meq/100 g soil d.w. - other: - not specified | 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. |  |
|  | Bulk density (g/cm³) | Numeric range (decimal)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. | 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. |  |
|  | % Moisture content | Numeric range (decimal)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. | Moisture content of the soil (at pF 2 or at Maximum Water Holding Capacity). 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. |  |
|  | **Soil properties** | **Block of fields (repeatable) End** |  |  |  |
|  | Details on soil characteristics | Text template  Display: Detailed | **Freetext template:** SOIL COLLECTION AND STORAGE  - Geographic location:   - Pesticide use history at the collection site:   - Collection procedures:   - Sampling depth (cm):   - Storage conditions:   - Storage length:   - Soil preparation (e.g., 2 mm sieved; air dried etc.):     PROPERTIES OF THE SOILS (in addition to defined fields)  - Moisture at 1/3 atm (%):   - Bulk density (g/cm3): | For each soil type, specify soil collection and storage and properties of the soil as far as not indicated in the defined fields.  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. |  |
|  | **Duration of test (contact time)** | **Block of fields (repeatable) Start** |  | Specify duration of test in terms of contact time. Repeat block for each soil type. If different test runs have different durations, enter lower and upper value in respective subfields. |  |
|  | Soil No. | List (picklist)  Display: Basic | **Picklist values:** - #1 - #2 - #3 - #4 - #5 - #6 - #7 - #8 - #9 - #10 - #11 - #12 - #13 - #14 - #15 - #16 - #17 - #18 - #19 - #20 | Select a consecutive soil number from drop-down list if more than one soil types were used. |  |
|  | Duration | Numeric range (decimal with picklist)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. **Picklist values:** - s - min - h - d - wk - mo - yr | 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. |  |
|  | **Duration of test (contact time)** | **Block of fields (repeatable) End** |  |  |  |
|  | **Initial test substance concentration** | **Block of fields (repeatable) Start** |  | Specify the initial test concentration applied. If different concentrations were used in different test runs, copy this block of fields accordingly. If a range of concentrations is reported, include the lower and upper values in the numeric range field.  If appropriate copy this block of fields for indicating different parameters the initial concentration is based on (e.g. COD and test substance). |  |
|  | Soil No. | List (picklist)  Display: Basic | **Picklist values:** - #1 - #2 - #3 - #4 - #5 - #6 - #7 - #8 - #9 - #10 - #11 - #12 - #13 - #14 - #15 - #16 - #17 - #18 - #19 - #20 | Select a consecutive soil number from drop-down list if more than one soil types were used. |  |
|  | Initial conc. | Numeric range (decimal with picklist)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. **Picklist values:** - CFU/g - CFU/ha dw - CFU/kg - CFU/kg soil dw - IU/g - IU/ha dw - IU/kg - IU/kg soil dw - OB/g - OB/ha dw - OB/kg - OB/kg soil dw - g/ha d.w. - g/kg soil d.w. - kg/ha d.w. - mg/kg soil d.w. - ppm - spores/g - spores/kg - spores/kg soil dw - spores/ha dw - 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:** - COD - DOC - IC (inorganic carbon) - ThCO2 - ThOD - ThIC - TOC - test mat. - act. ingr. - formulation - other: - not specified | From drop-down list, select the parameter on which the initial concentration is based. |  |
|  | **Initial test substance concentration** | **Block of fields (repeatable) End** |  |  |  |
|  | Parameter followed for biodegradation estimation | List multi. (multi-select list with remarks)  Display: Basic | **Picklist values:** - CH4 evolution - CO2 evolution - DOC removal - inorg. C analysis - O2 consumption - radiochem. meas. - test mat. analysis - TOC removal - other: - not specified | Indicate the parameter used to measure biodegradation. Copy field for more than one parameter as appropriate. In supplementary remarks field, give relevant details on the method. For radiochemical measurement or test substance analysis use freetext template in field 'Details on analytical methods'. |  |
|  | Details on analytical methods | Text template  Display: Detailed | **Freetext template:** DETAILS ON PRETREATMENT  - Digestion (acid used, method: e.g. micro-oven):   - Extraction (solvent used, method: e.g. liquid-liquid, SPE):   - Total 14C measurement:   - Clean up method:e.g. chemical used for chemistry method (Cu, Hg, ...) or phase and solvent used for SPE method:   - Derivatisation method if used:   - Concentration (method):     IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND  - Separation method (e.g. HPLC, GC):   - Conditions (column, mobile phase, etc.):   - Detection method (e.g. ECD, UV, MS, ICP-AES, ICP-MS):   - Detection limits (LOD, LOQ) (indicate method of determination/calculation):   - Reproducibility in % (indicate method of evaluation; should be given for stated concentration levels):   - Linearity range:   - Internal or external calibration:   - Extraction recovery (indicate if results are corrected or not for recoveries):   - Recovery ratio of test material from inoculated vs. blank samples:   - Method of confirmation of identity of measured compound:     IDENTIFICATION AND QUANTIFICATION OF TRANSFORMATION PRODUCTS | If the amount of test material in the test solutions was monitored, enter any details on the analytical methods used. Use freetext template and delete/add elements as appropriate. Copy any subheading(s) under IDENTIFICATION AND QUANTIFICATION OF PARENT COMPOUND to include the respective information for transformation products and/or non-extractable residues. |  |
|  | **Experimental conditions** | **Block of fields (repeatable) Start** |  | For each soil type, indicate the environmental conditions during the test if available or assumed in the model, if estimated. |  |
|  | Soil No. | List (picklist)  Display: Basic | **Picklist values:** - #1 - #2 - #3 - #4 - #5 - #6 - #7 - #8 - #9 - #10 - #11 - #12 - #13 - #14 - #15 - #16 - #17 - #18 - #19 - #20 | Select a consecutive soil number from drop-down list if more than one soil types were used. |  |
|  | Temp. | Text (255 char.)  Display: Basic |  | Specify test temperature including mean and range values during test if available or temperature assumed in the model, if estimated. Use °C; convert other units and indicate original data in parentheses if applicable. |  |
|  | Humidity | Text (255 char.)  Display: Basic |  | Indicate soil humidity in % moisture content or g water/100g soil dry weight. |  |
|  | Microbial biomass | Text (255 char.)  Display: Basic |  | Indicate initial and final microbial biomass / microbial population of control and treated soil, if provided. Specify unit, e.g., mg biomass/100 g soil dry weight or µg C/g soil. |  |
|  | **Experimental conditions** | **Block of fields (repeatable) End** |  |  |  |
|  | Details on experimental conditions | Text template  Display: Detailed | **Freetext template:** 1. PRELIMINARY EXPERIMENTS:    2. EXPERIMENTAL DESIGN  - Soil preincubation conditions (duration, temperature if applicable):   - Soil condition: air dried/fresh  - Soil (g/replicate):  - Control conditions, if used (present differences from other treatments, i.e., sterile/non-sterile, experimental conditions):  - No. of replication controls, if used:  - No. of replication treatments:  - Test apparatus (Type/material/volume):  - Details of traps for CO2 and organic volatile, if any:  - If no traps were used, is the system closed/open:  - Identity and concentration of co-solvent:    Test material application  - Volume of test solution used/treatment:  - Application method (e.g. applied on surface, homogeneous mixing etc.):  - Is the co-solvent evaporated:    Any indication of the test material adsorbing to the walls of the test apparatus:    Experimental conditions (in addition to defined fields)  - Moisture maintenance method:  - Continuous darkness: Yes/No    Other details, if any:    3. OXYGEN CONDITIONS (delete elements as appropriate)  - Methods used to create the an/aerobic conditions:  - Evidence that an/aerobic conditions were maintained during the experiment (e.g. redox potential):    4. SUPPLEMENTARY EXPERIMENTS:    5. SAMPLING DETAILS  - Sampling intervals:  - Sampling method for soil samples:  - Method of collection of CO2 and volatile organic compounds:  - Sampling intervals/times for:  > Sterility check, if sterile controls are used  > Moisture content:  > Redox potential/other:  > Sample storage before analysis:  - Other observations, if any: | Include Soil No. in parentheses if conditions were not identical for all soil types tested. 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. |  |
|  | **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** |  |  |  |
|  | **Material (mass) balance** | **Block of fields (repeatable) Start** |  | If applicable, indicate mean total recovery of test material as percentage of applied amount +/- standard deviation. Copy this block of fields for each soil type as appropriate. |  |
|  | Soil No. | List (picklist)  Display: Basic | **Picklist values:** - #1 - #2 - #3 - #4 - #5 - #6 - #7 - #8 - #9 - #10 - #11 - #12 - #13 - #14 - #15 - #16 - #17 - #18 - #19 - #20 | Select a consecutive soil number from drop-down list if more than one soil types were used. |  |
|  | Sampling date | Date  Display: Basic |  |  |  |
|  | Sampling day(s) | Numeric (decimal including unit)  Display: Basic | **Unit [xx]:** - d | Enter sampling time in days. |  |
|  | % Total extractable | Numeric range (decimal)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. | 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. |  |
|  | % Non extractable | Numeric range (decimal)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. | 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. |  |
|  | % CO2 | Numeric range (decimal)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. | 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. |  |
|  | % Other volatiles | Numeric range (decimal)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. | 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. |  |
|  | % Recovery | Numeric (decimal)  Display: Basic |  | Enter numeric value. |  |
|  | St. dev. | Numeric (decimal)  Display: Basic |  | Enter numeric value. |  |
|  | Remarks on result | List sup. (picklist with remarks - 2,000 char.)  Display: Basic | **Picklist values:** - not determinable - not determinable because of methodological limitations - not measured/tested - other: | This field can be used for:  - giving a qualitative description of results in addition to or if no numeric value(s) were derived;  - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or  - entering any additional information by selecting 'other:' |  |
|  | **Material (mass) balance** | **Block of fields (repeatable) End** |  |  |  |
|  | **% Degradation** | **Block of fields (repeatable) Start** |  | For each soil type, indicate percentage of degradation of test substance including standard deviation at the end of the study period. Also indicate on what parameter the degradation rate is based on (e.g. 'radiochemical measurement'). If required, copy block of fields to include values based on different parameters. |  |
|  | Parent/product | List (picklist)  Display: Basic | **Picklist values:** - parent - product |  |  |
|  | Name or code for product | Link to entity (single)  Display: Basic |  | Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one. | **Cross-reference:** REFERENCE\_SUBSTANCE |
|  | 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. |  |
|  | Soil No. | List (picklist)  Display: Basic | **Picklist values:** - #1 - #2 - #3 - #4 - #5 - #6 - #7 - #8 - #9 - #10 - #11 - #12 - #13 - #14 - #15 - #16 - #17 - #18 - #19 - #20 | Select a consecutive soil number from drop-down list if more than one soil types were used. |  |
|  | Sampling date | Date  Display: Basic |  |  |  |
|  | % Degr. | Numeric range (decimal)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. | 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. |  |
|  | St. dev. | Numeric (decimal)  Display: Basic |  | Enter numeric value. |  |
|  | Parameter | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - CH4 evolution - CO2 evolution - DOC removal - inorg. C analysis - O2 consumption - radiochem. meas. - test mat. analysis - TOC removal - other: - not specified | From drop-down list, select the parameter on which the percentage is based. Further information can be given in the supplementary remarks field. |  |
|  | Sampling time | Numeric (decimal including unit)  Display: Basic | **Unit [xx]:** - s - min - h - d - wk - mo - yr | Enter numeric value. |  |
|  | Remarks on result | List sup. (picklist with remarks - 2,000 char.)  Display: Basic | **Picklist values:** - not determinable - not determinable because of methodological limitations - not measured/tested - other: | This field can be used for:  - giving a qualitative description of results in addition to or if no numeric value(s) were derived;  - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or  - entering any additional information by selecting 'other:' |  |
|  | **% Degradation** | **Block of fields (repeatable) End** |  |  |  |
|  | **Half-life / dissipation time of parent compound** | **Block of fields (repeatable) Start** |  | For each soil type, include value (or range if reported so) of half-life and indicate the type of half-life (For first order kinetics DT50 = half-life). | **Guidance for field condition:** Half-life / dissipation time of parent compound |
|  | 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. |  |
|  | Soil No. | List (picklist)  Display: Basic | **Picklist values:** - #1 - #2 - #3 - #4 - #5 - #6 - #7 - #8 - #9 - #10 - #11 - #12 - #13 - #14 - #15 - #16 - #17 - #18 - #19 - #20 | Select a consecutive soil number from drop-down list if more than one soil types were used. |  |
|  | DT50 | Numeric range (decimal with picklist)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. **Picklist values:** - s - min - h - d - wk - mo - yr | 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. |  |
|  | St. dev. | Numeric (decimal)  Display: Basic |  | Enter numeric value. |  |
|  | Type | List (picklist)  Display: Basic | **Picklist values:** - (pseudo-)first order (= half-life) - second order - zero order - other: - not specified | Select from drop-down list. |  |
|  | Temp. | Numeric range (decimal with picklist)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. **Picklist values:** - °C - K - °F | 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 result | List sup. (picklist with remarks - 2,000 char.)  Display: Basic | **Picklist values:** - not determinable - not determinable because of methodological limitations - not measured/tested - other: | This field can be used for:  - giving a qualitative description of results in addition to or if no numeric value(s) were derived;  - giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or  - entering any additional information by selecting 'other:' |  |
|  | **Half-life / dissipation time of parent compound** | **Block of fields (repeatable) End** |  |  |  |
|  | Transformation products | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - no - not measured - yes - not specified | Indicate whether transformation products occurred. If yes, provide the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'. |  |
|  | **Identity of transformation products** | **Block of fields (repeatable) Start** |  | Indicate the identity of the transformation products using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. Copy this block of fields for each relevant substance.  Any further details on transformation products can be provided in field 'Any other information on materials and methods incl. tables'. |  |
|  | No. | List (picklist)  Display: Basic | **Picklist values:** - #1 - #2 - #3 - #4 - #5 - #6 - #7 - #8 - #9 - #10 - #11 - #12 - #13 - #14 - #15 - #16 - #17 - #18 - #19 - #20 | For easier distinction select a consecutive number for each transformation product from drop-down list if more than one transformation product is entered. If the same substance is identified by more than one identifiers (e.g. by CAS name and Common name), make sure that the same number is allocated to these entries. |  |
|  | Reference substance | Link to entity (single)  Display: Basic |  | Click the Link button to navigate to the Substances Inventory and select the relevant substance name. If not available in the inventory, create a new one. | **Cross-reference:** REFERENCE\_SUBSTANCE |
|  | **Identity of transformation products** | **Block of fields (repeatable) End** |  |  |  |
|  | Details on transformation products | Text template  Display: Detailed | **Freetext template:** - Formation and decline of each transformation product during test: - Pathways for transformation: - Maximum occurrence of each transformation product: - Other: | Indicate any relevant supplementary information on transformation products. Use freetext template and delete/add items as appropriate. If useful attach a figure in the corresponding field. |  |
|  | Evaporation of parent compound | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - no - not measured - yes - not specified | Indicate whether evaporation of the parent compound occurred or not. Include any explanations in field 'Details on results' as appropriate. |  |
|  | Volatile metabolites | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - no - not measured - yes - not specified | Indicate whether volatile metabolites were found or not. Include any explanations in field 'Details on results' as appropriate. |  |
|  | Residues | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - no - not measured - yes - not specified | Indicate whether residues were found or not. Include any explanations in field 'Details on results' as appropriate. |  |
|  | Details on results | Text template  Display: Detailed | **Freetext template:** TEST CONDITIONS  - Aerobicity (or anaerobicity), moisture, temperature and other experimental conditions maintained throughout the study: Yes/No  - Anomalies or problems encountered (if yes):     MAJOR TRANSFORMATION PRODUCTS  - Range of maximum concentrations in % of the applied amount and day(s) of incubation when observed:  - Range of maximum concentrations in % of the applied amount at end of study period:  on the - the and -th day of incubation, respectively. At the end of the study period, the corresponding concentrations were - and -- % of the applied amount, respectively.     MINOR TRANSFORMATION PRODUCTS  - Range of maximum concentrations in % of the applied amount and day(s) of incubation when observed:  - Range of maximum concentrations in % of the applied amount at end of study period:    TOTAL UNIDENTIFIED RADIOACTIVITY (RANGE) OF APPLIED AMOUNT:    EXTRACTABLE RESIDUES  - % of applied amount at day 0:  - % of applied amount at end of study period:    NON-EXTRACTABLE RESIDUES  - % of applied amount at day 0:  - % of applied amount at end of study period:    MINERALISATION  - % of applied radioactivity present as CO2 at end of study:    VOLATILIZATION  - % of the applied radioactivity present as volatile organics at end of study:    STERILE TREATMENTS (if used)  - Transformation of the parent compound:  - Formation of transformation products:  - Formation of extractable and non-extractable residues:  - Volatilization:    RESULTS OF SUPPLEMENTARY EXPERIMENT (if any): | Indicate any further relevant details of test results. Use freetext template and delete/add elements as appropriate. As appropriate or requested by the regulatory programme include table(s) with raw data 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 text (e.g. '... see Table 1').  In field 'Attached background material', attach graph(s) with the full degradation or elimination curves.  TEST CONDITIONS: If the test conditions were not maintained, describe any anomalies or problems encountered.  MAJOR / MINOR TRANSFORMATION PRODUCTS: Indicate concentration ranges of the transformation products specified in the defined field 'Identity of transformation products' or specify if no major transformation products were detected. Tabulate comprehensive data and refer to respective table no. (use predefined table if any) or other appropriate table.  STERILE TREATMENTS: If used, report the transformation of the parent, and compare the results with those of the non-sterile treatments:  SUPPLEMENTARY EXPERIMENT: Briefly describe the results of the supplementary experiment, if any. |  |
|  | Results with reference substance | Text (2,000 char.)  Display: Detailed |  | Indicate whether the results with the reference substance(s) are valid. |  |
|  | **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 - 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. |  |
|  | Kinetic evaluation | Attachment (multiple)  Display: Basic |  | Upload Kinetic evaluation (visual and statistical) |  |
|  | **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. |  |