**Template #29: Biodegradation in water and sediment: simulation tests *(Version [9.5]-[July 2023])***

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

| **Line no.** | **Field name** | **Field type****Display type** | **Picklist****Freetext template** | **Help text** | **Remarks** **Guidance** **Cross-reference** |
| --- | --- | --- | --- | --- | --- |
|  | **Administrative data** | **Header 1** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  |  |  |
|  | Endpoint | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- biodegradation in water: simulation testing on ultimate degradation in surface water- biodegradation in water: sediment simulation testing- biodegradation in water: sewage treatment simulation testing- biodegradation in water and sediment: simulation testing, other | From the picklist select the relevant endpoint addressed by this study summary. In some cases there is only one endpoint title, which may be entered automatically depending on the software application.If multiple study types are covered by the same data entry form, the specific study type should be selected. If none matches, select the more generic endpoint description '<Generic endpoint>, other' (e.g. Skin irritation / corrosion, other) and give an explanation in the adjacent text field. The generic endpoint title reflects the title of the corresponding OECD Harmonised Template (OHT).Please note: For (Q)SAR studies, if an 'in silico' option does not exist, the generic endpoint title should be selected, normally with no need to fill in the adjacent text field, as '(Q)SAR' needs to be indicated in field 'Type of information' and the model should be described in field 'Justification of non-standard information' or 'Attached justification'. A specific endpoint title may be used, if addressed by the (Q)SAR information, i.e. the model behind has been validated by experimental data addressing this endpoint.Note: For the purpose of OHTs, an 'endpoint' is defined in the rather broad sense as an observable or measurable inherent property of a chemical substance which may be specified by the relevant regulatory framework as 'information requirement' (e.g. Boiling point, Sub-chronic toxicity: oral, Fish early-life stage toxicity). In a narrower sense, the term '(eco)toxicity endpoint' refers to an outcome or effect observed in a study. | **Guidance for data migration:**The relevant target phrase is selected as triggered by the value of source field 'Guideline' and 'Inoculum or test system' as a second indicator. As a fallback the generic phrase 'biodegradation in water and sediment: simulation testing' is selected.Note: The generic phrase is only used for migration, but otherwise deactivated in the picklist. For new entries a generic phrase is provided which consists of the OHT title followed by 'other', i.e. <OHT title>, other. |
|  | Type of information | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- experimental study- experimental study planned- experimental study planned (based on read-across)- (Q)SAR- calculation (if not (Q)SAR)- read-across based on grouping of substances (category approach)- read-across from supporting substance (structural analogue or surrogate)- read-across from similar mixture/product- mixture rules calculation- weight of evidence justification/conclusion- not specified- other: | Select the appropriate type of information, e.g. ' experimental study', ' experimental study planned' or, if alternatives to testing apply, '(Q)SAR', 'read-across ...'. In the case of calculated data, the value 'calculation (if not (Q)SAR)' should only be chosen if the study report does not clearly indicate whether it is based on '(Q)SAR'.If the information is taken from a handbook or review article, select the relevant item, e.g. ‘experimental study’, if this is provided in the information source. Otherwise select ‘not specified’. Please note: In field ‘Reference type’ the option ‘review article or handbook’ should be selected. In general, the option 'not specified' should be selected if the submitter lacks the knowledge of the type of information. The option 'other:' can be used if another than a pre-defined item applies.In the case of read-across, follow the instructions related to the relevant legislation, for instance as to whether the (robust) study summary should be entered in a separate data set defined for the read-across (source) substance and referenced in the target substance dataset.If 'experimental study planned' or 'experimental study planned (based on read-across)' is indicated (in some legislations also defined as 'testing proposal' or 'undertaking of intended submission'), the submitter should include as much information as possible on the planned study in order to support the evaluation of the proposal. Typically, this would include at least the test guideline, information on the test material, the species and the route of administration in the corresponding distinct fields, as appropriate.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on whether specific fields should be completed and/or further details should be attached in field 'Attached background material'. |  |
|  | Adequacy of study | List (picklist)Display: Basic | **Picklist values:**- key study- supporting study- weight of evidence- disregarded due to major methodological deficiencies- other information | Indicate the adequacy of a (robust) study summary in terms of usefulness for hazard/risk assessment purposes depending on the relevant legislation.Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'.Explanation: - key study: In general, a key study is the study that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and representativity of data. - supporting study: Any other adequate study that is considered supportive for the key study or key studies. - weight of evidence: A record that contributes to a weight of evidence justification for the non-submission of a particular (adequate) study. The weight of evidence justification is normally endpoint-related, i.e. based on all available records included in the weight of evidence evaluation. A short reasoning for why a given record is used in this respect can be provided in field 'Detailed justification / remarks'. - disregarded due to major methodological deficiencies: study that demonstrates a higher concern than the key study/ies, but is not used as key study because of flaws in the methodology or documentation. This phrase should be selected for justifying why a potentially critical result has not been used for the hazard assessment. The lines of argumentation should be provided in field 'Rationale for reliability incl. deficiencies', accompanied by the appropriate reliability score.- other information: any other non-relevant information which does not need to be flagged specifically as 'disregarded due to major methodological deficiencies'.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. | **Guidance for field condition:**Condition: Field active only if 'Type of information' is not 'experimental study planned' and not ‘experimental study planned (based on read-across)’ and field 'Data waiving' is not populated (except for migrated data) |
|  | Robust study summary | Check boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Robust Study Summary' or in combination with 'Adequacy of study'. Explanation: The term 'Robust Study Summary' is actually used only to describe the technical content of a very detailed summary of an experimental study or of any other relevant information. It is a priori no synonym with the term 'Key study', although a key study should usually be submitted in the form of Robust Study Summary. However, a Robust Summary may also be useful for other adequate studies that are considered supportive of the key study or even for inadequate studies if they can be used for a weight-of-evidence analysis. Also for studies that are flawed, but indicate critical results, Robust Study Summaries highlighting the weaknesses of the studies need to be elaborated. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Used for classification | Check boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Used for classification'.Explanation: In some use cases it may be necessary to indicate those records that are used for the classification of that substance, e.g. according to UN GHS. If not relevant, disregard this field. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Used for SDS | Check boxDisplay: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'SDS information'. Explanation: 'SDS' stands for Safety Data Sheet. In some use cases it may be necessary to indicate those records that are used for the compilation of SDS information. If not relevant, disregard this field. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Study period: start date | DateDisplay: Basic |  | If applicable indicate the period during which the study was conducted, i.e. start and end date. Note: independent of the study period, the in-life period (i.e. the phase of a study following treatment in which the test system is alive/growing) may have to be specified for some toxicology endpoints. |  |
|  | End date | DateDisplay: Basic |  |  |  |
|  | Remark | Text (255 char.)Display: Basic |  |  |  |
|  | Reliability | List (picklist)Display: Basic | **Picklist values:**- 1 (reliable without restriction)- 2 (reliable with restrictions)- 3 (not reliable)- 4 (not assignable)- other: | Enter an appropriate reliability score, according to Klimisch et al. (1997):1 = reliable without restrictions: “studies or data [...] generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline [...] or in which all parameters described are closely related/comparable to a guideline method.”2 = reliable with restrictions: “studies or data [...] (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable.”3 = not reliable: “studies or data [...] in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g. non-physiological pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment.”4 = not assignable: “studies or data [...] which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.).”The 'other:' option may be selected if a different scoring system is used. Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field.Note: This field is only applicable (or active) if neither 'waiving of standard information' nor 'experimental study planned' has been selected in field 'Type of information'.Note: The term reliability defines the inherent quality of a test report or publication relating to preferably standardised methodology and the way the method and results are described. More detailed criteria can be selected in field 'Justification'. |  |
|  | Rationale for reliability incl. deficiencies | List sup. (picklist with remarks - 32,000 char.)Display: Basic | **Picklist values:**- guideline study - [Reliability 1]- comparable to guideline study - [Reliability 1]- test procedure in accordance with national standard methods - [Reliability 1]- test procedure in accordance with generally accepted scientific standards and described in sufficient detail - [Reliability 1]- guideline study without detailed documentation - [Reliability 2]- guideline study with acceptable restrictions - [Reliability 2]- comparable to guideline study with acceptable restrictions - [Reliability 2]- test procedure in accordance with national standard methods with acceptable restrictions - [Reliability 2]- study well documented, meets generally accepted scientific principles, acceptable for assessment - [Reliability 2]- accepted calculation method - [Reliability 2]- data from handbook or collection of data - [Reliability 2]- significant methodological deficiencies - [Reliability 3]- unsuitable test system - [Reliability 3]- abstract - [Reliability 4]- secondary literature - [Reliability 4]- documentation insufficient for assessment - [Reliability 4]- results derived from a valid (Q)SAR model and falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 1 or 2]- results derived from a valid (Q)SAR model and falling into its applicability domain, with limited documentation / justification - [Reliability 2, 3 or 4]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 2 or 3]- results derived from a (Q)SAR model, with limited documentation / justification, but validity of model and reliability of prediction considered adequate based on a generally acknowledged source - [Reliability 2 or 3]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, and documentation / justification is limited - [Reliability 3 or 4]- results derived from a (Q)SAR model, with limited documentation / justification - [Reliability 4]- other: | Select an appropriate standard justification from the picklist, e.g. 'Comparable to guideline study with acceptable restrictions'. Additional explanations (e.g. deficiencies observed) can be entered in the related supplementary text field. Particularly if reliability scores 2 or 3 are assigned, indicate the concrete arguments for defending a study or relevant deficiencies.For QSAR results (i.e. 'Type of information' is '(Q)SAR') some pre-defined phrases are provided for indicating if the prediction results are considered reliable based on the scientifically validity of the (Q)SAR model used, its applicability to the query substance, and the adequacy of reporting. Please note: If (Q)SAR results are flagged as key study in field 'Adequacy of study', the relevance of the model used for the regulatory endpoint should be documented in the field where the (Q)SAR model is described, i.e. 'Justification for type of information', 'Attached justification' or 'Cross-reference'. | **Guidance for field condition:**Condition: Field active only if 'Type of information' is not 'experimental study planned' and not ‘experimental study planned (based on read-across)’.Condition 1: If 'Type of information' is not '(Q)SAR':- guideline study - [Reliability 1]- comparable to guideline study - [Reliability 1]- test procedure in accordance with national standard methods - [Reliability 1]- test procedure in accordance with generally accepted scientific standards and described in sufficient detail - [Reliability 1]- guideline study without detailed documentation - [Reliability 2]- guideline study with acceptable restrictions - [Reliability 2]- comparable to guideline study with acceptable restrictions - [Reliability 2]- test procedure in accordance with national standard methods with acceptable restrictions - [Reliability 2]- study well documented, meets generally accepted scientific principles, acceptable for assessment - [Reliability 2]- accepted calculation method - [Reliability 2]- data from handbook or collection of data - [Reliability 2]- significant methodological deficiencies - [Reliability 3]- unsuitable test system - [Reliability 3]- abstract - [Reliability 4]- secondary literature - [Reliability 4]- documentation insufficient for assessment - [Reliability 4]Condition 2: If 'Type of information' = '(Q)SAR':- results derived from a valid (Q)SAR model and falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 1 or 2]- results derived from a valid (Q)SAR model and falling into its applicability domain, with limited documentation / justification - [Reliability 2, 3 or 4]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, with adequate and reliable documentation / justification - [Reliability 2 or 3]- results derived from a (Q)SAR model, with limited documentation / justification, but validity of model and reliability of prediction considered adequate based on a generally acknowledged source - [Reliability 2 or 3]- results derived from a valid (Q)SAR model, but not (completely) falling into its applicability domain, and documentation / justification is limited - [Reliability 3 or 4]- results derived from a (Q)SAR model, with limited documentation / justification - [Reliability 4]- other: |
|  | Data waiving | List (picklist)Display: Basic | **Picklist values:**- study technically not feasible- study scientifically not necessary / other information available- exposure considerations- study waived due to provisions of other regulation- other justification | If appropriate, indicate here that the study has been waived, i.e. not performed. Select the basis from the picklist (e.g. 'study technically not feasible' or 'other justification'). Include a more detailed justification in the field 'Justification for data waiving' and, as needed, in field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference'. Please note: the option 'study scientifically not necessary / other information available' covers cases where it can be justified that performance of a specific study prescribed by the relevant legislation is scientifically not necessary because reliable information is provided in other part(s) of the submission document.The option 'study waived due to provisions of other regulation' can be used for indicating that another, overlapping regulation allows or requires the waiving of a specific information requirement. This should then be detailed in the justification fields.If waiving is based on several lines of argumentation (e.g. ‘exposure considerations’ and ‘study scientifically not necessary / other information available’), create separate records for each.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use data waivers. | **Guidance for field condition:**Condition: Deactivate this field if any of the following fields is populated: 'Type of information', 'Adequacy of study', 'Reliability', 'Rationale for reliability'. |
|  | Justification for data waiving | List multi. (multi-select list with remarks - 32,000 char.)Display: Basic | **Picklist values:**- the study does not need to be conducted because the substance is highly insoluble in water - [study technically not feasible]- 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 sediment 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 templateDisplay: Basic | **Freetext template:Option 1 Type 'Waiving of standard information'**JUSTIFICATION FOR DATA WAIVING[Specific explanation in addition to field 'Justification for data waiving']**Option 2 Type 'Experimental study planned / Testing proposal on vertebrate animals'**TESTING PROPOSAL ON VERTEBRATE ANIMALS[Please provide information for all of the points below. The information should be specific to the endpoint for which testing is proposed. Note that for testing proposals addressing testing on vertebrate animals under the REACH Regulation this document will be published on the ECHA website along with the third party consultation on the testing proposal(s).]NON-CONFIDENTIAL NAME OF SUBSTANCE:- Name of the substance on which testing is proposed to be carried out- Name of the substance for which the testing proposal will be used [if different from tested substance]CONSIDERATIONS THAT THE GENERAL ADAPTATION POSSIBILITIES OF ANNEX XI OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION [please address all points below]:- Available GLP studies- Available non-GLP studies- Historical human/control data- (Q)SAR- In vitro methods- Weight of evidence- Grouping and read-across- Substance-tailored exposure driven testing [if applicable]- Approaches in addition to above [if applicable]- Other reasons [if applicable]CONSIDERATIONS THAT THE SPECIFIC ADAPTATION POSSIBILITIES OF ANNEXES VI TO X (AND COLUMN 2 THEREOF) OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION:- [free text]FURTHER INFORMATION ON TESTING PROPOSAL IN ADDITION TO INFORMATION PROVIDED IN THE MATERIALS AND METHODS SECTION:- Details on study design / methodology proposed [if relevant]**Option 3 Type 'QSAR prediction'**1. SOFTWARE2. MODEL (incl. version number)3. SMILES OR OTHER IDENTIFIERS USED AS INPUT FOR THE MODEL4. SCIENTIFIC VALIDITY OF THE (Q)SAR MODEL[[Explain how the model fulfils the OECD principles for (Q)SAR model validation. Consider attaching the QMRF and/or QPRF or providing a link]- Defined endpoint:- Unambiguous algorithm:- Defined domain of applicability:- Appropriate measures of goodness-of-fit and robustness and predictivity:- Mechanistic interpretation:5. APPLICABILITY DOMAIN[Explain how the substance falls within the applicability domain of the model]- Descriptor domain:- Structural domain:- Mechanistic domain:- Similarity with analogues in the training set:- Other considerations (as appropriate):6. ADEQUACY OF THE RESULT[Explain how the prediction fits the purpose of classification and labelling and/or risk assessment]**Option 4 Type 'Read-across (analogue)'**REPORTING FORMAT FOR THE ANALOGUE APPROACH[Please provide information for all of the points below. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]1. HYPOTHESIS FOR THE ANALOGUE APPROACH[Describe why the read-across can be performed (e.g. common functional group(s), common precursor(s)/breakdown product(s) or common mechanism(s) of action]2. SOURCE AND TARGET CHEMICAL(S) (INCLUDING INFORMATION ON PURITY AND IMPURITIES)[Provide here, if relevant, additional information to that included in the Test material section of the source and target records]3. ANALOGUE APPROACH JUSTIFICATION[Summarise here based on available experimental data how these results verify that the read-across is justified]4. DATA MATRIX**Option 5 Type 'Read-across (category)'**REPORTING FORMAT FOR THE CATEGORY APPROACH[Please provide information for all of the points below addressing endpoint-specific elements that were not already covered by the overall category approach justification made available at the category level. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]1. HYPOTHESIS FOR THE CATEGORY APPROACH (ENDPOINT LEVEL)[Describe why the read-across can be performed]2. CATEGORY APPROACH JUSTIFICATION (ENDPOINT LEVEL[Summarise here based on available experimental data how these results verify that the read-across is justified]**Option 6 Type 'Weight of Evidence justification'**JUSTIFICATION FOR WEIGHT OF EVIDENCE- Relevance (including coverage) and reliability of each source of information compared with the study normally required for the information requirement.- Weighing of the sources of information (including overall coverage) to reach an overall conclusion for the information requirement.- Assessment of the uncertainty in the conclusion compared with the study normally required for the information requirement. | This field can be used for entering free text. As appropriate, one of the freetext templates can be selected (e.g. Justification for read-across (analogue)) to use pre-defined headers and bulleted elements. Delete/add elements as appropriate.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on what should be taken into account when providing justifications or whether specific reporting formats should be used.Explanations:Option 1: Type 'Waiving of standard information':This field should be used for entering any further lines of argumentation, if necessary, in addition to those provided in the field 'Justification for data waiving'.Option 2: Type 'Experimental study planned / Testing proposal':Further details can be entered here on the study design / methodology proposed in addition to details given in the distinct fields on test guideline, test material, species, route of administration and other relevant fields.Option 3: Type 'QSAR prediction':For describing a (Q)SAR model it is recommended to provide the QMRF as attachment instead of using the free text template.The QSAR Model Reporting Format (QMRF) is a harmonised template for summarising and reporting key information on QSAR models, including the results of any validation studies. The information is structured according to the OECD validation principles and can be compiled using the QMRF editor application.The JRC QSAR Model Database is intended to help to identify valid (Q)SARs (e.g. for the purpose of REACH). It provides information on the validity of QSAR models and can be browsed for published QMRFs.Based on this freetext template details on the QSAR model used can be given, in addition to the information provided in field 'Principles of method if other than guideline'.Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature.Option 4: Type 'Read-across (analogue)' and Option 5: Type 'Read-across (category)'This freetext template can be used and modified as appropriate for providing a justification for read-across, particularly if it is endpoint-specific.Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature. |  |
|  | **Attached justification** | **Block of fields (repeatable) Start** |  | The Attached justification feature can be used in case the justification is best provided in form of attached document(s).Copy this block of fields for attaching more than one file.Refer to the relevant legislation-specific guidance document as to the recommended use of the Attached justification feature. |  |
|  | Attached justification | Attachment (single)Display: Basic |  | Upload file by clicking the upload icon. |  |
|  | Reason / purpose | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- data waiving: supporting information- exposure-related information- read-across: supporting information- (Q)SAR model reporting (QMRF)- (Q)SAR prediction reporting (QPRF)- (Q)SAR model and prediction reporting (QMRF/QPRF)- (Q)SAR: supporting information- weight of evidence: supporting information- justification, other: | Indicate the reason for / purpose of the attached document. Select the relevant item from the picklist or, if none applies, select 'justification, other:' and specify. |  |
|  | **Attached justification** | **Block of fields (repeatable) End** |  |  |  |
|  | **Cross-reference** | **Block of fields (repeatable) Start** |  | The cross-reference feature can be used to refer to related information that is provided in another record of the dataset. This can be done either by entering just free text in the 'Remarks' field or by creating a link to the relevant record. The field 'Reason / purpose' allows for selecting a standard reason from the picklist and optionally to add free text explanation in the related supplementary text field.Refer to the relevant legislation-specific guidance document as to the recommended use of cross-references. |  |
|  | Reason / purpose for cross-reference | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- adverse outcome pathway (AOP)- assessment report- data waiving: supporting information- defined approach- exposure-related information- method used in study- read-across source- (Q)SAR model reporting (QMRF)- read-across: supporting information- reference to other assay used for intermediate effect derivation- reference to other study- reference to same study- weight of evidence source- other: | Select the appropriate reason of the cross-reference, i.e.- adverse outcome pathway (AOP) (in case the information is related to a key event that is part of an AOP). Consult the AOP wiki at: https://aopwiki.org) and provide the reference in the remarks field- assessment report (for referring to a record that contains an assessment report as attachment)- data waiving: supporting information (for referring to a record containing relevant endpoint information that is used to justify a data waiver)- defined approach for combining with results from another methods (in vitro, in chimico, in silico) - exposure-related information (for referring to a record containing exposure-related information that is used for instance to justify a data waiver)- read-across source (for linking to another study summary used for read-across. This can be useful in cases where results are derived from one or several read-across sources and recorded in a separate (target) study summary.)- read-across supporting information (for linking to another record which contains read-across justification that applies also for the current study summary)- (Q)SAR model reporting (QMRF) (for referring to a record containing the relevant model description. Note: The (Q)SAR prediction should be reported specifically for each endpoint in the field 'Justification for type of information'.)- reference to other assay used for intermediate effect derivation (for optional indication in a study summarising 'intermediate effects' if reference is made to the outcome of another assay)- reference to same study (e.g. if different species were tested and the results recorded in different records), - reference to other study (e.g. if another study is considered relevant in the interpretation of the test results), - other: (to be specified). |  |
|  | Related information | Link to endpoint (single)Display: Basic |  | As appropriate, select the record containing the related information, thus creating a link. | **Cross-reference:**AllSummariesAndRecords |
|  | Remarks | Text (32,768 char.)Display: Basic |  | This field can be used for including any remarks. |  |
|  | **Cross-reference** | **Block of fields (repeatable) End** |  |  |  |
|  | **Data source** | **Header 1** |  |  |  |
|  | Reference | Link to lit. reference (multiple)Display: Basic |  | Indicate the bibliographic reference of the study report or publication the study summary is based on. Provide general information such as Title, Author, Year, Bibliographic source, Testing Facility, Report Number, Study number, Report date etc., as requested in the core template for literature search (https://www.oecd.org/ehs/templates/Generic%20elements%20for%20all%20OHTs.zip). Always enter the primary reference in the first block of fields or sort it to the first position, if there are more than one reference to be cited. Copy this block of fields for specifying any other references related to this record (e.g. report of a preliminary study or other documentation). If results of a study report have been published, indicate the full citation of that publication(s) in addition to the reference of the original study. |  |
|  | Data access | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- data submitter is data owner- data submitter has Letter of Access- data no longer protected- data published- data submitter has permission to refer- not applicable- other: | Select appropriate indication for data access. Enter 'Not applicable' if the summary consists of information that is commonly accessible such as guidance on safe use.Select 'data submitter has permission to refer' if the information requirement can be covered based on a permission to refer to old data as issued by the relevant regulatory agency. In addition, provide, in the adjacent free-text field, the statement according to instructions you received from the relevant regulatory authority together with the permission to refer. |  |
|  | Data protection claimed | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- yes, but willing to share- yes, but not willing to share | Indicate as appropriate. Note: 'yes' should be selected only if 'Data submitter is data owner' or 'Data submitter has Letter of Access'. Options 'yes, but willing to share' or 'yes, but not willing to share' may be relevant for specific regulatory programmes where the submitter is requested to indicate whether he is willing to share studies conducted (e.g. with vertebrates).In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. 'for justification see attached document X') |  |
|  | **Materials and methods** | **Header 1** |  |  |  |
|  | **Test guideline** | **Block of fields (repeatable) Start** |  | Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'.Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline). |  |
|  | Qualifier | List (picklist)Display: Basic | **Picklist values:**- according to guideline- equivalent or similar to guideline- no guideline followed- no guideline available- no guideline required | Select appropriate qualifier, i.e.- 'according to guideline' (if a given test guideline was followed);- 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline);- 'no guideline followed' (if none of above qualifiers apply. If so, fill in field 'Principles of method if other than guideline');- 'no guideline available' (if so, fill in field 'Principles of method if other than guideline').- 'no guideline required' (if so, fill in field 'Principles of method if other than guideline'). |  |
|  | Guideline | List (picklist)Display: Basic | **Picklist values:**- OECD Guideline 303 A (Simulation Test - Aerobic Sewage Treatment. A: Activated Sludge Units)- OECD Guideline 303 B (Simulation Test - Aerobic Sewage Treatment. B. Biofilms)- OECD Guideline 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems)- OECD Guideline 309 (Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test)- OECD Guideline 314 A (Simulation Tests to Assess the Biodegradability of Chemicals in Wastewater. A: Biodegradation in a Sewer System)- OECD Guideline 314 B (Simulation Tests to Assess the Biodegradability of Chemicals in Wastewater. B: Biodegradation in Activated Sludge)- OECD Guideline 314 C (Simulation Tests to Assess the Biodegradability of Chemicals in Wastewater. C: Mineralization and Transformation in Anaerobic Digester Sludge)- OECD Guideline 314 D (Simulation Tests to Assess the Biodegradability of Chemicals in Wastewater. D: Biodegradation in Treated Effluent-Surface Water Mixing Zone)- OECD Guideline 314 E (Simulation Tests to Assess the Biodegradability of Chemicals in Wastewater. E: Biodegradation in Untreated Wastewater-Surface Water Mixing Zone)- EU Method C.10 (Biodegradation: Activated Sludge Simulation Test)- EU Method C.10-A (Simulation Test Aerobic Sewage Treatment: Activated Sludge Units)- EU Method C.10-B (Simulation Test Aerobic Sewage Treatment: Biofilms)- EU Method C.24 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems)- EPA OPPTS 835.3160 (Biodegradability in Sea Water)- EPA OPPTS 835.3180 (Sediment / Water Microcosm Biodegradation Test)- EPA OPPTS 835.3190 (Aerobic Mineralisation in Surface Water - Simulation Biodegradation Test)- EPA OPPTS 835.3220 (Porous Pot Test)- EPA OPPTS 835.3240 (Simulation Test - Aerobic Sewage Treatment: A. Activated Sludge Units)- EPA OPPTS 835.3260 (Simulation Test - Aerobic Sewage Treatment: B. Biofilms)- EPA OPPTS 835.4300 (Aerobic Aquatic Metabolism)- EPA OPPTS 835.4400 (Anaerobic Aquatic Metabolism)- EPA OPPTS 835.5154 (Anaerobic Biodegradability in the Subsurface)- EPA OPPTS 885.5000 (Microbial Pesticide, Background for Microbial Pesticides Testing)- EPA OPPTS 885.5300 (Microbial Pesticide, Expression in Freshwater Environment)- EPA OPPTS 885.5400 (Microbial Pesticide, Expression in a Marine or Estuarine Environment)- EPA OTS 795.54 (Anaerobic Biodegradability in the Subsurface)- EPA Subdivision N Pesticide Guideline 162-3 (Anaerobic Aquatic Metabolism)- EPA Subdivision N Pesticide Guideline 162-4 (Aerobic Aquatic Metabolism)- ISO 11733 Water quality - Determination of the elimination and biodegradability of organic compounds in an aqueous medium - Activated sludge simulation test- ISO 11734: Water quality - Evaluation of the "ultimate" anaerobic biodegradability of organic compounds in digested sludge - Method by measurement of the biogas production- ISO 14592-1 (Water quality - Evaluation of the aerobic biodegradability of organic compounds at low concentrations - Part 1: Shake-flask batch test with surface water or surface water/sediment suspensions)- ISO 14592-2 (Water quality - Evaluation of the aerobic biodegradability of organic compounds at low concentrations - Part 2: Continuous flow river model with attached biomass)- other: | Select the applicable test guideline, e.g. 'OECD Guideline xxx'. If the test guideline used is not listed, choose 'other:' and specify the test guideline in the related text field. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'. The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields.Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Version / remarks | Text (2,000 char.)Display: Basic |  | In this text field, you can enter any remarks as applicable, particularly:- To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline);- To indicate if the study was performed prior to the adoption of the test guideline specified;- To indicate if the methodology used was based on an extension of the test guideline specified;- To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Deviations | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- no- not applicable- not specified | In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | **Test guideline** | **Block of fields (repeatable) End** |  |  |  |
|  | Principles of method if other than guideline | Text templateDisplay: Basic | **Freetext template:Option 1 Method of non-guideline study**- Principle of test:- Short description of test conditions:- Parameters analysed / observed:**Option 2 (Q)SAR**- Software tool(s) used including version:- Model(s) used:- Model description: see field 'Justification for non-standard information', 'Attached justification' and/or 'Cross-reference'- Justification of QSAR prediction: see field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' | If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate use either of the pre-defined freetext template options for 'Method of non-guideline study' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate.For a non-guideline experimental study a high-level freetext template can be used for summarising the principle of test, test conditions and parameters analysed / observed. If the freetext template for (Q)SAR is selected, indicate the QSAR model(s) or platform including version and the software tool(s) used. Detailed justification of the model and prediction should be provided in field(s) 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' as appropriate.Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate. |  |
|  | GLP compliance | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes (incl. QA statement)- yes- no- not specified | Indicate whether the study was conducted following Good Laboratory Practice or not. In case 'yes’ is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed. |  |
|  | **Test material** | **Header 2** |  |  |  |
|  | Test material information | Link to entity (single)Display: Basic |  | Select the appropriate Test Material Information (TMI) record. If not available in the repository, create a new one. You may also copy (clone) an existing TMI record, edit it and store it as new TMI.To change the link to an existing TMI, click the Delete button, then the Link button and proceed as described above.Depending on the purpose of the reporting or data submission, the information that must be provided may change. As a minimum, the chemical name, identifier and/or CAS number and molecular weight must be provided. | **Cross-reference:**TEST\_MATERIAL\_INFORMATION |
|  | Additional test material information | Link to entity (multiple)Display: Basic |  | Select additional Test material information record if relevant. For example, in longer terms studies more than one batch of test material can be needed or there may be differences between the labelled and unlabelled test materials. | **Cross-reference:**TEST\_MATERIAL\_INFORMATION |
|  | Specific details on test material used for the study | Text templateDisplay: Basic | **Freetext template:**SOURCE OF TEST MATERIAL- Source (i.e. manufacturer or supplier) and lot/batch number of test material:- Purity, including information on contaminants, isomers, etc.:RADIOLABELLING INFORMATION (if applicable)- Radiochemical purity:- Specific activity:- Locations of the label:- Expiration date of radiochemical substance:STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material:- Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage:- Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis:- Solubility and stability of the test material in the solvent/vehicle and the exposure medium:- Reactivity of the test material with the incubation material used (e.g. plastic ware):TREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding):- Preliminary purification step (if any):- Final concentration of a dissolved solid, stock liquid or gel:- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):FORM AS APPLIED IN THE TEST (if different from that of starting material)- Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:INFORMATION ON NANOMATERIALS- Chemical Composition:- Density:- Particle size & distribution:- Specific surface area:- Isoelectric point:- Dissolution (rate):TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable)- Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:OTHER SPECIFICS- Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.If applicable, relevant available information on the following items should be given:SOURCE OF TEST MATERIAL- Source and lot/batch No. of test material- Expiration date of the lot/batch- Purity test date: provide if availableRADIOLABELLING INFORMATION (repeat for multiple radio labels)- Radiochemical purity- Specific activity- Locations of the label- Expiration date of radiochemical substanceSTABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material- Stability under test conditions- Solubility and stability of the test substance in the solvent/vehicle- Reactivity of the test substance with the solvent/vehicle or the cell culture mediumTREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding)- Preliminary purification step- Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)FORM AS APPLIED IN THE TEST (if different from that of starting material)Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.FORMULATED PRODUCT (for biocides/pesticides)Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.OTHER SPECIFICSProvide any other relevant information needed for characterising the tested material. |  |
|  | Specific details on test material used for the study (confidential) | Text templateDisplay: Basic (Confidential) | **Freetext template:**SOURCE OF TEST MATERIAL- Source (i.e. manufacturer or supplier) and lot/batch number of test material:- Purity, including information on contaminants, isomers, etc.:RADIOLABELLING INFORMATION (if applicable)- Radiochemical purity:- Specific activity:- Locations of the label:- Expiration date of radiochemical substance:STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material:- Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage:- Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis:- Solubility and stability of the test material in the solvent/vehicle and the exposure medium:- Reactivity of the test material with the incubation material used (e.g. plastic ware):TREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding):- Preliminary purification step (if any):- Final concentration of a dissolved solid, stock liquid or gel:- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):FORM AS APPLIED IN THE TEST (if different from that of starting material)- Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:INFORMATION ON NANOMATERIALS- Chemical Composition:- Density:- Particle size & distribution:- Specific surface area:- Isoelectric point:- Dissolution (rate):TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable)- Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:OTHER SPECIFICS- Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.If applicable, relevant available information on the following items should be given:SOURCE OF TEST MATERIAL- Source and lot/batch No. of test material- Expiration date of the lot/batch- Purity test date: provide if availableRADIOLABELLING INFORMATION (repeat for multiple radio labels)- Radiochemical purity- Specific activity- Locations of the label- Expiration date of radiochemical substanceSTABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material- Stability under test conditions- Solubility and stability of the test substance in the solvent/vehicle- Reactivity of the test substance with the solvent/vehicle or the cell culture mediumTREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding)- Preliminary purification step- Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)FORM AS APPLIED IN THE TEST (if different from that of starting material)Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.FORMULATED PRODUCT (for biocides/pesticides)Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.OTHER SPECIFICSProvide any other relevant information needed for characterising the tested material. |  |
|  | 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- anaerobic- aerobic/anaerobic- aerobic (low dissolved oxygen)- other:- not specified | Indicate whether test was performed under aerobic or anaerobic conditions. Select 'aerobic/anaerobic' if both oxygen conditions occur as in water/sediment studies. If 'aerobic (low dissolved oxygen)' applies, specify in the supplementary remarks field or in the field 'Details on study design' that the O2 concentration was controlled. Include any explanations in the supplementary remarks field as appropriate. |  |
|  | Continuous darkness | Check boxDisplay: Basic |  | Indicate if the study was performed in continuous darkness |  |
|  | Inoculum or test system | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- activated sludge (adaptation not specified)- activated sludge, adapted- activated sludge, domestic (adaptation not specified)- activated sludge, domestic, adapted- activated sludge, domestic, non-adapted- activated sludge, industrial (adaptation not specified)- activated sludge, industrial, adapted- activated sludge, industrial, non-adapted- activated sludge, non-adapted- anaerobic bacteria- anaerobic microorganisms- anaerobic sludge- artificial sediment- digested sludge- effluent/surface water mixture, adapted treated- effluent/surface water mixture, non-adapted treated- effluent/surface water mixture, untreated- irradiated sediment- irradiated water- mixture of sewage, soil and natural water- natural sediment- natural sediment: brackish- natural sediment: freshwater- natural sediment: marine- natural soil- natural water- natural water / sediment- natural water / sediment: brackish- natural water / sediment: freshwater- natural water / sediment: marine- natural water: brackish- natural water: freshwater- natural water: marine- sediment (not specified)- sewage, domestic (adaptation not specified)- sewage, domestic, adapted- sewage, domestic, non-adapted- sewage, industrial (adaptation not specified)- sewage, industrial, adapted- sewage, industrial, non-adapted- sewage, predominantly domestic (adaptation not specified)- sewage, predominantly domestic, adapted- sewage, predominantly domestic, non-adapted- sewage, predominantly industrial (adaptation not specified)- sewage, predominantly industrial, adapted- sewage, predominantly industrial, non-adapted- water (not specified)- other:- not specified | Select the inoculum used. As far as possible, indicate whether any activated sludge or sewage used was adapted or not. If the study report does not give clear information thereof, select '..... (adaptation not specified)', e.g. 'sewage, domestic (adaptation not specified)'. In this case, give further explanation in field 'Details on inoculum', if any. In field 'Rationale for reliability', discuss the impact of this reporting deficiency on the study results.If no inoculum was added in the strictest sense, but natural water and/or sediment was used, indicate the corresponding test system, e.g. 'natural water / sediment'.Note that any simulation tests should be recorded using the corresponding template. |  |
|  | Details on source and properties of surface water | Text templateDisplay: Detailed | **Freetext template:**- Details on collection (e.g. location, sampling depth, contamination history, procedure): - Storage conditions: - Storage length: - Temperature (°C) at time of collection: - pH at time of collection: - Electrical conductivity: - Redox potential (mv) initial/final:  - Oxygen concentration (mg/l) initial/final: - Hardness (CaCO3): - Dissolved organic carbon (%):  - Biomass (e.g. in mg microbial C/100 mg, CFU or other): - Water filtered: yes/no - Type and size of filter used, if any: | Give details on source and properties of surface water used as inoculum if applicable. Use freetext template and delete/add elements as appropriate. |  |
|  | Details on source and properties of sediment | Text templateDisplay: Detailed | **Freetext template:**- Details on collection (e.g. location, sampling depth, contamination history, procedure): - Storage conditions: - Storage length: - Textural classification (i.e. %sand/silt/clay): - pH at time of collection: - Organic carbon (%): - Redox potential (mv) initial/final: - CEC (meq/100 g):  - Bulk density (g/cm³): - Biomass (e.g. in mg microbial C/100 mg, CFU or other):  - Sediment samples sieved: yes/no | Give details on source and properties of sediment used as inoculum if applicable. Use freetext template and delete/add elements as appropriate. |  |
|  | Details on inoculum | Text templateDisplay: Detailed | **Freetext template:Option 1 Option 1: Activated sludge**- Temperature (°C) at time of collection:- pH at time of collection:- Oxygen concentration (mg/l) initial/final:- Dissolved organic carbon (%):- Source of activated sludge (e.g. location, contamination history):- Laboratory culture:- Method of cultivation:- Storage conditions:- Storage length:- Preparation for exposure:- Pretreatment:- Biomass concentration (mg/L) used in test:**Option 2 Option 2: Other**- Source of inoculum wastewater (e.g. location, contamination history)- Storage conditions:- Storage length:- Temperature (°C) at time of collection:- pH at time of collection:- Electrical conductivity:- Redox potential (mv) initial/final:- Oxygen concentration (mg/l) initial/final:- Dissolved organic carbon (%):- Biomass (e.g. in mg microbial C/100 mg, CFU:- Biomass concentration (mg/L) used in test:- Chemical oxygen Demand (COD)- Water filtered: yes/no | Give details on any other inoculum, e.g. wastewater, activated sludge, anaerobic sludge if applicable. Use either freetext template 1 (activated sludge) or 2 (other) and delete/add elements as appropriate. |  |
|  | Duration of test (contact time) | 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. |  |
|  | **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). |  |
|  | Initial conc. | Numeric range (decimal with picklist)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca.**Picklist values:**- µg/L- mg/L- g/L- µmol/L- mmol/L- mol/L- microbial active substances- cells/L- CFU/L- ITU/L- IU/L- OB/L- spores/L- nanoforms- particles/L- surface area/L- 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.The following units should only be used in the case of microbial active substances:- cells- CFU (colony-forming unit)- ITU (International Toxic Unit)- IU (International Unit)- OB (occlusion bodies)- spores |  |
|  | 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 the supplementary remarks field, give relevant details on the method. Indicate if total mineralisation was determined if applicable. Specify if the radioactivity was recovered as parent and/or metabolite or associated with biomass. For further relevant details on radiochemical measurement or test substance analysis use freetext template in field 'Details on analytical methods'. |  |
|  | Details on analytical methods | Text templateDisplay: 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.Specify methods for water and sediment if applicable. |  |
|  | Details on study design | Text templateDisplay: Detailed | **Freetext template:**TEST CONDITIONS - Volume of test solution/treatment:  - Composition of medium:  - Additional substrate:  - Solubilising agent (type and concentration if used):  - Test temperature:  - pH:  - pH adjusted: yes/no  - CEC (meq/100 g):  - Aeration of dilution water:  - Suspended solids concentration:  - Continuous darkness: yes/no  - Any indication of the test material adsorbing to the walls of the test apparatus:  - Other:   TEST SYSTEM  - Culturing apparatus:  - Number of culture flasks/concentration:  - Method used to create aerobic conditions:  - Method used to create anaerobic conditions:  - Method used to control oxygen conditions:  - Measuring equipment:   - Test performed in closed vessels due to significant volatility of test substance:  - Test performed in open system:  - Details of trap for CO2 and volatile organics if used:  - Other:   SAMPLING  - Sampling frequency:  - Sampling method used per analysis type:  - Sterility check if applicable:  - Sample storage before analysis:  - Other:  DESCRIPTION OF CONTROL AND/OR BLANK TREATMENT PREPARATION  CONTROL AND BLANK SYSTEM  - Inoculum blank:  - Abiotic sterile control:  - Toxicity control:  - Other:   STATISTICAL METHODS: | 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. |  |
|  | **Reference substance** | **Block of fields (repeatable) Start** |  | Indicate identity of reference substance(s) used and give details in the supplementary remarks field as appropriate. Repeat field for each substance. |  |
|  | Reference substance | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- aniline- benzoic acid, sodium salt- acetic acid, sodium salt- ethylene glycol- diethylene glycol- laurylsulfonate- other:- not required- not specified | Indicate identity of reference substance(s) used and give details in the supplementary remarks field as appropriate. Repeat field for each substance. |  |
|  | **Reference substance** | **Block of fields (repeatable) End** |  |  |  |
|  | **Any other information on materials and methods incl. tables** | **Header 2** |  |  |  |
|  |  | Text (rich-text area)Display: Basic |  | In this field, you can enter any information on materials and methods, for which no distinct field is available, or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry. |  |
|  | **Results and discussion** | **Header 1** |  |  |  |
|  | Test performance | Text (2,000 char.)Display: Detailed |  | Report on any unusual observations during test or any other information affecting results. Give reasons for any rejection of the test results if applicable.Note that any deviations from test procedure should be briefly stated in field 'Deviations from guideline'. |  |
|  | **Mean total recovery** | **Block of fields (repeatable) Start** |  | If applicable, indicate mean total recovery of test material as percentage of applied amount in water and/or sediment +/- standard deviation. If relevant, also specify 'Total recovery in abiotic control measured at end of test' and 'Total recovery in biologically active treatment at end of test'. |  |
|  | Key result | Check boxDisplay: Basic |  | Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose or for inclusion in the list of endpoints. |  |
|  | Compartment | List (picklist)Display: Detailed | **Picklist values:**- abiotic control measured at end of test- biologically active treatment at end of test- natural water: freshwater- natural water: marine- natural water: brackish- natural water- water- natural water / sediment: freshwater- natural water / sediment: marine- natural water / sediment: brackish- natural water / sediment- natural sediment: freshwater- natural sediment: marine- natural sediment: brackish- natural sediment- artificial sediment- sediment- activated sludge- wastewater- anaerobic sludge- treated effluent: surface water mixing zone- untreated effluent: surface water mixing zone- entire system- other: | Select from drop-down list. |  |
|  | Sampling date | DateDisplay: Basic |  |  |  |
|  | Sampling time | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- s- min- h- d- wk- mo- yr | Enter numeric value. |  |
|  | % 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 residues | 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. |  |
|  | % Mineralisation (% 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: Detailed |  | Enter numeric value. |  |
|  | St. dev. | Numeric (decimal)Display: Detailed |  | Enter numeric value. |  |
|  | Remarks on result | List sup. (picklist with remarks - 2,000 char.)Display: Detailed | **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:' |  |
|  | **Mean total recovery** | **Block of fields (repeatable) End** |  |  |  |
|  | **% Degradation** | **Block of fields (repeatable) Start** |  | Indicate percentage of degradation of test substance including standard deviation at the end of the study period. Indicate the parameter the percentage is based on and the sampling time. Copy this block of fields for recording the percentage values for different parameters.Note that the degradation at different sampling time points (raw data) should be recorded in below field 'Details on results'. |  |
|  | Parent/product | List (picklist)Display: Basic | **Picklist values:**- parent- transformation 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 boxDisplay: Basic |  | Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Compartment | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- water- sediment- total system |  |  |
|  | Sampling date | DateDisplay: Basic |  |  |  |
|  | Sampling time | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- s- min- h- d- wk- mo- yr | Enter numeric value. |  |
|  | % 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. |  |
|  | 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** |  |  |  |
|  | **Disappearance time (DT) of parent compound** | **Block of fields (repeatable) Start** |  | Include value (or range if reported so) of DT50 and indicate the type of the DT50 (For first order kinetics DT50 = half-life). For water-sediment systems repeat this block of fields for each compartment.If relevant, also indicate the DT90 value (or range if reported so) and the DT50 value as normalised to reference conditions. |  |
|  | Key result | Check boxDisplay: Basic |  | Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Compartment | List (picklist)Display: Basic | **Picklist values:**- abiotic control measured at end of test- biologically active treatment at end of test- natural water: freshwater- natural water: marine- natural water: brackish- natural water- water- natural water / sediment: freshwater- natural water / sediment: marine- natural water / sediment: brackish- natural water / sediment- natural sediment: freshwater- natural sediment: marine- natural sediment: brackish- natural sediment- artificial sediment- sediment- activated sludge- wastewater- anaerobic sludge- treated effluent: surface water mixing zone- untreated effluent: surface water mixing zone- entire system- other: | Select from drop-down list. |  |
|  | Parameter | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- DT50- DT50 (normalised)- DT90 | Indicate if you are reporting a DT50 value, a DT50 value normalised to reference conditions or a DT90 value.For the normalised values, you can specify which reference conditions were used and how the normalisation was carried out (e.g. using a Q10 of 2.58 and Walker equation coefficient of 0.7) in the remark field. |  |
|  | Value | 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 of kinetics and method of calculation | List (picklist)Display: Basic | **Picklist values:**- (pseudo-)first order (= half-life)- second order- zero order- other:- not specified | Select the type of kinetics from the drop-down list. You can indicate the kinetics equation used in the remark field (e.g. SFO, DFOP). |  |
|  | Type of value | List (picklist)Display: Basic | **Picklist values:**- degradation time- dissipation time | Select from drop-down list. |  |
|  | Temp. | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- °C- K- °F | Enter numeric value. |  |
|  | Chi-square (χ²) error | Numeric (decimal)Display: Basic |  | Chi-square error of the kinetic model used for deriving the reported DT value. Deviations between observed and calculated values for each separate model relative to the uncertainty of the measurements. |  |
|  | p-value (t-test) | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. | Provide the result of the t-test to evaluate the confidence in the parameter estimates. The parameter is considered significantly different from zero if the probability is smaller than 0.05 (p<0.05), i.e. considering a 5 % significance level. Alternatively, the 95% confidence interval can be reported when kinetic parameters do not allow a t-test to be completed. |  |
|  | Kinetic parameters | Text (2,000 char.)Display: Basic |  | Please provide here the kinetic parameters and their values that are relevant to the kinetic model used for deriving the reported DT value. Depending on the kinetic model, the relevant kinetic parameters could be e.g. alpha, beta, g, k, k1, k2 or tb. |  |
|  | 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:' |  |
|  | **Disappearance time (DT) of parent compound** | **Block of fields (repeatable) End** |  |  |  |
|  | Mineralization rate (in CO2) | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- w-1- d-1- h-1- min-1- other: | Enter Mineralization rate (in CO2) |  |
|  | 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 information on the identified transformation products in following block of fields. Any further details can be entered in field 'Any other information on results incl. tables'. |  |
|  | **Transformation products** | **Block of fields (repeatable) Start** |  | Provide information on the transformation products observed in the parent-dosed study. 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'. |  |
|  | Key result | Check boxDisplay: Basic |  | Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose or for inclusion in the list of endpoints. |  |
|  | ID 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- #21- #22- #23- #24- #25- #26- #27- #28- #29- #30- #31- #32- #33- #34- #35- #36- #37- #38- #39- #40- other: | For easier distinction, you can assign consecutive numbers to the test substance (i.e. #1) and to each metabolite (i.e. #2, #3, etc.). |  |
|  | Identity of compound | Link to entity (single)Display: Basic |  | Indicate the identity of the compound (transformation product or test substance) using an appropriate identifier, e.g. CAS number, CAS name, IUPAC name. 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 |
|  | Parent compound(s) | Link to entity (multiple)Display: Basic |  | If the compound is a transformation product, link to the identity of the substance that is characterised as the parent of this metabolite. Link to multiple parent substances if applicable.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 |
|  | Compartment | List (picklist)Display: Basic | **Picklist values:**- abiotic control measured at end of test- biologically active treatment at end of test- natural water: freshwater- natural water: marine- natural water: brackish- natural water- water- natural water / sediment: freshwater- natural water / sediment: marine- natural water / sediment: brackish- natural water / sediment- natural sediment: freshwater- natural sediment: marine- natural sediment: brackish- natural sediment- artificial sediment- sediment- activated sludge- wastewater- anaerobic sludge- treated effluent: surface water mixing zone- untreated effluent: surface water mixing zone- entire system- other: | Select from drop-down list. |  |
|  | Kinetic formation fraction | Numeric (decimal)Display: Basic |  | Indicate the kinetic formation fraction (f. f. kf/kdp) of the transformation product, as derived from the parent-dosed study. |  |
|  | Maximum occurrence (%) | Numeric (decimal)Display: Basic |  | Indicate the maximum occurrence of the transformation product as observed in the parent-dosed study. |  |
|  | Timepoint of maximum occurrence observed in days | Numeric (integer)Display: Basic |  | Indicate the time point in days when the maximum occurrence of the transformation product was observed in the parent-dosed study. |  |
|  | Parameter | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- DT50- DT50 (normalised)- DT90 | Indicate if you are reporting a DT50 value, a DT50 value normalised to reference conditions or a DT90 value. For the normalised values, you can specify which reference conditions were used and how the normalisation was carried out (e.g. using a Q10 of 2.58 and Walker equation coefficient of 0.7) in the remark field. |  |
|  | Value | 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 of kinetics and method of calculation | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- (pseudo-)first order (= half-life)- second order- zero order- other:- not specified | Select the type of kinetics from the drop-down list. You can indicate the kinetics equation used in the remark field (e.g. SFO, DFOP). |  |
|  | Type of value | List (picklist)Display: Basic | **Picklist values:**- degradation time- dissipation time | 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. |  |
|  | Chi-square (χ²) error | Numeric (decimal)Display: Basic |  | Chi-square error of the kinetic model used for deriving the reported DT value. Deviations between observed and calculated values for each separate model relative to the uncertainty of the measurements. |  |
|  | p-value (t-test) | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. | Provide the result of the t-test to evaluate the confidence in the parameter estimates. The parameter is considered significantly different from zero if the probability is smaller than 0.05 (p<0.05), i.e. considering a 5 % significance level. Alternatively, the 95% confidence interval can be reported when kinetic parameters do not allow a t-test to be completed. |  |
|  | Kinetic parameters | Text (2,000 char.)Display: Basic |  |  | **Guidance for field condition:**Please provide here the kinetic parameters and their values that are relevant to the kinetic model used for deriving the reported DT value. Depending on the kinetic model, the relevant kinetic parameters could be e.g. alpha, beta, g, k, k1, k2 or tb. |
|  | **Transformation products** | **Block of fields (repeatable) End** |  |  |  |
|  | Details on transformation products | Text templateDisplay: 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: Detailed | **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: Detailed | **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: Detailed | **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 templateDisplay: 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:- Total extractable residues regarded in DT50 calculation as remaining parent substance:- Total extractable residues regarded in DT50 calculation as remaining transformation product(s): NON-EXTRACTABLE RESIDUES- % of applied amount at day 0:- % of applied amount at end of study period:- Total non-extractable residues measured:- Total non-extractable residues regarded in DT50 calculation as removed (dissipation):- Total non-extractable residues regarded in DT50 calculation as remaining parent substance:- Total non-extractable residues regarded in DT50 calculation as remaining transformation product(s):- Total remobilisable non-extractable residues (type I NER) measured:- Type I NER regarded in DT50 calculation as removed:- Type I NER regarded in DT50 calculation as remaining parent substance:- Type I NER regarded in DT50 calculation as remaining transformation product(s):- Other types of non-extractable residues measured and considered in DT50 calculation:MINERALISATION- % of applied radioactivity present as CO2 at end of study: VOLATILIZATION- % of the applied radioactivity present as volatile organics at end of study:- Total volatile residues regarded in DT50 calculation as removed (dissipation):- Total volatile residues regarded in DT50 calculation as remaining parent substance:- Total volatile residues regarded in DT50 calculation as remaining transformation product(s): 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 or other appropriate table(s) if any, and tailor it/them to your needs. 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- illustration (picture/graph)- other: | Specify the type of attachment inserted, for example the 'full study report'. |  |
|  | Attached (confidential) document | Attachment (single)Display: Basic (Confidential) |  | An electronic copy of the full study report or other documents can be attached as Word, pdf or other file types. |  |
|  | Attached (sanitised) documents for publication | Attachment (single)Display: Basic |  | An electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. This attachment should be sanitised if needed. |  |
|  | Remarks | Text (255 char.)Display: Basic |  | As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory. |  |
|  | **Attachments** | **Block of fields (repeatable) End** |  |  |  |
|  | Kinetic evaluation | Attachment (multiple)Display: Basic |  |  |  |
|  | **Applicant's summary and conclusion** | **Header 1** |  |  |  |
|  | **Validity criteria** | **Block of fields (repeatable) Start** |  | Include any validity criteria from the followed study guidance. |  |
|  | Validity criteria | Text (255 char.)Display: Basic |  | Type in the addressed validity criteria. |  |
|  | Observed value | Text (255 char.)Display: Basic |  | Type in the observation related to the respective validity criteria. |  |
|  | Validity criteria fulfilled | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- no- not specified- not applicable | Indicate whether validity criteria given by test guideline have been fulfilled or not. Use supplementary remarks field for indicating the criteria and entering remarks. If not fulfilled, give justification in field 'Rationale for reliability incl. deficiencies' as to why this study summary is considered reliable. |  |
|  | **Validity criteria** | **Block of fields (repeatable) End** |  |  |  |
|  | Key result | Read-onlyDisplay: Basic |  | This read-only field displays the key results flagged in the corresponding results table(s), if any. |  |
|  | 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. |  |