**Template #65: Eye irritation *(Version [10.1]-[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:**- eye irritation: in vitro / ex vivo- eye irritation: in vivo- eye irritation, 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(s) of source fields 'Type of method', 'Guideline' and 'Interpretation of results'. As a fallback the generic phrase 'eye irritation' is selected and the Type of method is entered in the supplementary remarks field.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 classified as skin irritation and the available information indicates that it should be classified as eye irritation (Category 2) - [study scientifically not necessary / other information available]- the study does not need to be conducted because the substance is classified as skin corrosion, leading to classification as serious eye damage (Category 1) - [study scientifically not necessary / other information available]- the study does not need to be conducted because the substance is spontaneously flammable in air or in contact with water or moisture at room temperature - [study technically not feasible]- the study does not need to be conducted because the substance is a strong acid (pH <= 2.0) or base (pH => 11.5) and the available information indicates that it should be classified as serious eye damage (Category 1) - [study scientifically not necessary / other information available]- an in vitro eye irritation study does not need to be conducted because the available in vitro test methods are not applicable for the substance and therefore an in vivo eye irritation study was conducted - [study scientifically not necessary / other information available]- an in vitro eye irritation study does not need to be conducted because adequate data from an in vivo eye irritation study are available - [study scientifically not necessary / other information available]- other: | In addition to the more generic justification selected in the preceding field 'Data waiving', it is highly recommended to provide a detailed justification. To this end you can either select one or multiple specific standard phrase(s) if it/they give an appropriate rationale of the description given in the preceding field 'Data waiving' or 'other:' and enter free text. Additional specific explanations should be provided if the pre-defined phrase(s) do no sufficiently describe the justification.More details can be provided using the following fields:- Text field adjacent to this field 'Justification for data waiving' (available after selecting any picklist item in this field);- Field 'Justification for type of information';- Field 'Attached justification';- Cross-reference (for referencing / linking to a justification or information referred to in the justification which is stored in another record, e.g. a record describing physico-chemical properties information used to support a data waiver)Please note: The pre-defined phrases are not necessarily exhaustive and may not always apply. Consult the guidance documents and waiving options in the relevant regulatory frameworks. If no suitable phrase is available from the picklist, enter a free text justification using the 'other:' option. | **Guidance for field condition:**Condition: Deactivate this field if any of the following fields is populated: 'Type of information', 'Adequacy of study', 'Reliability', 'Rationale for reliability'. |
|  | Justification for type of information | Text templateDisplay: Basic | **Freetext template:Option 1 Type 'Waiving of standard information'**JUSTIFICATION FOR DATA WAIVING[Specific explanation in addition to field 'Justification for data waiving']**Option 2 Type 'Experimental study planned / Testing proposal on vertebrate animals'**TESTING PROPOSAL ON VERTEBRATE ANIMALS[Please provide information for all of the points below. The information should be specific to the endpoint for which testing is proposed. Note that for testing proposals addressing testing on vertebrate animals under the REACH Regulation this document will be published on the ECHA website along with the third party consultation on the testing proposal(s).]NON-CONFIDENTIAL NAME OF SUBSTANCE:- Name of the substance on which testing is proposed to be carried out- Name of the substance for which the testing proposal will be used [if different from tested substance]CONSIDERATIONS THAT THE GENERAL ADAPTATION POSSIBILITIES OF ANNEX XI OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION [please address all points below]:- Available GLP studies- Available non-GLP studies- Historical human/control data- (Q)SAR- In vitro methods- Weight of evidence- Grouping and read-across- Substance-tailored exposure driven testing [if applicable]- Approaches in addition to above [if applicable]- Other reasons [if applicable]CONSIDERATIONS THAT THE SPECIFIC ADAPTATION POSSIBILITIES OF ANNEXES VI TO X (AND COLUMN 2 THEREOF) OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION:- [free text]FURTHER INFORMATION ON TESTING PROPOSAL IN ADDITION TO INFORMATION PROVIDED IN THE MATERIALS AND METHODS SECTION:- Details on study design / methodology proposed [if relevant]**Option 3 Type 'QSAR prediction'**1. SOFTWARE2. MODEL (incl. version number)3. SMILES OR OTHER IDENTIFIERS USED AS INPUT FOR THE MODEL4. SCIENTIFIC VALIDITY OF THE (Q)SAR MODEL[[Explain how the model fulfils the OECD principles for (Q)SAR model validation. Consider attaching the QMRF and/or QPRF or providing a link]- Defined endpoint:- Unambiguous algorithm:- Defined domain of applicability:- Appropriate measures of goodness-of-fit and robustness and predictivity:- Mechanistic interpretation:5. APPLICABILITY DOMAIN[Explain how the substance falls within the applicability domain of the model]- Descriptor domain:- Structural domain:- Mechanistic domain:- Similarity with analogues in the training set:- Other considerations (as appropriate):6. ADEQUACY OF THE RESULT[Explain how the prediction fits the purpose of classification and labelling and/or risk assessment]**Option 4 Type 'Read-across (analogue)'**REPORTING FORMAT FOR THE ANALOGUE APPROACH[Please provide information for all of the points below. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]1. HYPOTHESIS FOR THE ANALOGUE APPROACH[Describe why the read-across can be performed (e.g. common functional group(s), common precursor(s)/breakdown product(s) or common mechanism(s) of action]2. SOURCE AND TARGET CHEMICAL(S) (INCLUDING INFORMATION ON PURITY AND IMPURITIES)[Provide here, if relevant, additional information to that included in the Test material section of the source and target records]3. ANALOGUE APPROACH JUSTIFICATION[Summarise here based on available experimental data how these results verify that the read-across is justified]4. DATA MATRIX**Option 5 Type 'Read-across (category)'**REPORTING FORMAT FOR THE CATEGORY APPROACH[Please provide information for all of the points below addressing endpoint-specific elements that were not already covered by the overall category approach justification made available at the category level. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]1. HYPOTHESIS FOR THE CATEGORY APPROACH (ENDPOINT LEVEL)[Describe why the read-across can be performed]2. CATEGORY APPROACH JUSTIFICATION (ENDPOINT LEVEL[Summarise here based on available experimental data how these results verify that the read-across is justified]**Option 6 Type 'Weight of Evidence justification'**JUSTIFICATION FOR WEIGHT OF EVIDENCE- Relevance (including coverage) and reliability of each source of information compared with the study normally required for the information requirement.- Weighing of the sources of information (including overall coverage) to reach an overall conclusion for the information requirement.- Assessment of the uncertainty in the conclusion compared with the study normally required for the information requirement. | This field can be used for entering free text. As appropriate, one of the freetext templates can be selected (e.g. Justification for read-across (analogue)) to use pre-defined headers and bulleted elements. Delete/add elements as appropriate.Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on what should be taken into account when providing justifications or whether specific reporting formats should be used.Explanations:Option 1: Type 'Waiving of standard information':This field should be used for entering any further lines of argumentation, if necessary, in addition to those provided in the field 'Justification for data waiving'.Option 2: Type 'Experimental study planned / Testing proposal':Further details can be entered here on the study design / methodology proposed in addition to details given in the distinct fields on test guideline, test material, species, route of administration and other relevant fields.Option 3: Type 'QSAR prediction':For describing a (Q)SAR model it is recommended to provide the QMRF as attachment instead of using the free text template.The QSAR Model Reporting Format (QMRF) is a harmonised template for summarising and reporting key information on QSAR models, including the results of any validation studies. The information is structured according to the OECD validation principles and can be compiled using the QMRF editor application.The JRC QSAR Model Database is intended to help to identify valid (Q)SARs (e.g. for the purpose of REACH). It provides information on the validity of QSAR models and can be browsed for published QMRFs.Based on this freetext template details on the QSAR model used can be given, in addition to the information provided in field 'Principles of method if other than guideline'.Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature.Option 4: Type 'Read-across (analogue)' and Option 5: Type 'Read-across (category)'This freetext template can be used and modified as appropriate for providing a justification for read-across, particularly if it is endpoint-specific.Please note: Any information that can be re-used for several study summaries can be entered once and then assigned to the relevant studies using either the 'Attached justification' or 'Cross-reference' feature. |  |
|  | **Attached justification** | **Block of fields (repeatable) Start** |  | The Attached justification feature can be used in case the justification is best provided in form of attached document(s).Copy this block of fields for attaching more than one file.Refer to the relevant legislation-specific guidance document as to the recommended use of the Attached justification feature. |  |
|  | Attached justification | Attachment (single)Display: Basic |  | Upload file by clicking the upload icon. |  |
|  | Reason / purpose | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- data waiving: supporting information- exposure-related information- read-across: supporting information- (Q)SAR model reporting (QMRF)- (Q)SAR prediction reporting (QPRF)- (Q)SAR model and prediction reporting (QMRF/QPRF)- (Q)SAR: supporting information- weight of evidence: supporting information- justification, other: | Indicate the reason for / purpose of the attached document. Select the relevant item from the picklist or, if none applies, select 'justification, other:' and specify. |  |
|  | **Attached justification** | **Block of fields (repeatable) End** |  |  |  |
|  | **Cross-reference** | **Block of fields (repeatable) Start** |  | The cross-reference feature can be used to refer to related information that is provided in another record of the dataset. This can be done either by entering just free text in the 'Remarks' field or by creating a link to the relevant record. The field 'Reason / purpose' allows for selecting a standard reason from the picklist and optionally to add free text explanation in the related supplementary text field.Refer to the relevant legislation-specific guidance document as to the recommended use of cross-references. |  |
|  | Reason / purpose for cross-reference | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- adverse outcome pathway (AOP)- assessment report- data waiving: supporting information- defined approach- exposure-related information- method used in study- read-across source- (Q)SAR model reporting (QMRF)- read-across: supporting information- reference to other assay used for intermediate effect derivation- reference to other study- reference to same study- weight of evidence source- other: | Select the appropriate reason of the cross-reference, i.e.- adverse outcome pathway (AOP) (in case the information is related to a key event that is part of an AOP). Consult the AOP wiki at: https://aopwiki.org) and provide the reference in the remarks field- assessment report (for referring to a record that contains an assessment report as attachment)- data waiving: supporting information (for referring to a record containing relevant endpoint information that is used to justify a data waiver)- defined approach for combining with results from another methods (in vitro, in chimico, in silico) - exposure-related information (for referring to a record containing exposure-related information that is used for instance to justify a data waiver)- read-across source (for linking to another study summary used for read-across. This can be useful in cases where results are derived from one or several read-across sources and recorded in a separate (target) study summary.)- read-across supporting information (for linking to another record which contains read-across justification that applies also for the current study summary)- (Q)SAR model reporting (QMRF) (for referring to a record containing the relevant model description. Note: The (Q)SAR prediction should be reported specifically for each endpoint in the field 'Justification for type of information'.)- reference to other assay used for intermediate effect derivation (for optional indication in a study summarising 'intermediate effects' if reference is made to the outcome of another assay)- reference to same study (e.g. if different species were tested and the results recorded in different records), - reference to other study (e.g. if another study is considered relevant in the interpretation of the test results), - other: (to be specified). |  |
|  | Related information | Link to endpoint (single)Display: Basic |  | As appropriate, select the record containing the related information, thus creating a link. | **Cross-reference:**AllSummariesAndRecords |
|  | Remarks | Text (32,768 char.)Display: Basic |  | This field can be used for including any remarks. |  |
|  | **Cross-reference** | **Block of fields (repeatable) End** |  |  |  |
|  | **Data source** | **Header 1** |  |  |  |
|  | Reference | Link to lit. reference (multiple)Display: Basic |  | Indicate the bibliographic reference of the study report or publication the study summary is based on. Provide general information such as Title, Author, Year, Bibliographic source, Testing Facility, Report Number, Study number, Report date etc., as requested in the core template for literature search (https://www.oecd.org/ehs/templates/Generic%20elements%20for%20all%20OHTs.zip). Always enter the primary reference in the first block of fields or sort it to the first position, if there are more than one reference to be cited. Copy this block of fields for specifying any other references related to this record (e.g. report of a preliminary study or other documentation). If results of a study report have been published, indicate the full citation of that publication(s) in addition to the reference of the original study. |  |
|  | Data access | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- data submitter is data owner- data submitter has Letter of Access- data no longer protected- data published- data submitter has permission to refer- not applicable- other: | Select appropriate indication for data access. Enter 'Not applicable' if the summary consists of information that is commonly accessible such as guidance on safe use.Select 'data submitter has permission to refer' if the information requirement can be covered based on a permission to refer to old data as issued by the relevant regulatory agency. In addition, provide, in the adjacent free-text field, the statement according to instructions you received from the relevant regulatory authority together with the permission to refer. |  |
|  | Data protection claimed | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- yes, but willing to share- yes, but not willing to share | Indicate as appropriate. Note: 'yes' should be selected only if 'Data submitter is data owner' or 'Data submitter has Letter of Access'. Options 'yes, but willing to share' or 'yes, but not willing to share' may be relevant for specific regulatory programmes where the submitter is requested to indicate whether he is willing to share studies conducted (e.g. with vertebrates).In the supplementary remarks field, include an explanation as appropriate, i.e. justification for denial of sharing the corresponding study or refer to a document attached that provides justification (e.g. 'for justification see attached document X') |  |
|  | **Materials and methods** | **Header 1** |  |  |  |
|  | **Test guideline** | **Block of fields (repeatable) Start** |  | Indicate according to which test guideline the study was conducted. If no test guideline was explicitly followed, but the methodology used is equivalent or similar to a specific guideline, you can indicate so in the 'Qualifier' subfield preceding the field 'Guideline'.Copy this block of fields for specifying more than one guideline (e.g. US EPA in addition to OECD guideline). |  |
|  | Qualifier | List (picklist)Display: Basic | **Picklist values:**- according to guideline- equivalent or similar to guideline- no guideline followed- no guideline available- no guideline required | Select appropriate qualifier, i.e.- 'according to guideline' (if a given test guideline was followed);- 'equivalent or similar to guideline' (if no test guideline was explicitly followed, but the methodology is equivalent or similar to a specific guideline);- 'no guideline followed' (if none of above qualifiers apply. If so, fill in field 'Principles of method if other than guideline');- 'no guideline available' (if so, fill in field 'Principles of method if other than guideline').- 'no guideline required' (if so, fill in field 'Principles of method if other than guideline'). |  |
|  | Guideline | List (picklist)Display: Basic | **Picklist values:**- EPA OPP 81-4 (Acute Eye Irritation)- EPA OPPTS 870.2400 (Acute Eye Irritation)- EPA OTS 798.4500 (Acute Eye Irritation)- EU Method B.5 (Acute Toxicity: Eye Irritation / Corrosion)- EU method B.47 (Bovine corneal opacity and permeability test method for identifying ocular corrosives and severe irritants)- EU method B.48 (Isolated chicken eye test method for identifying occular corrosives and severe irritants)- OECD Guideline 405 (Acute Eye Irritation / Corrosion)- OECD Guideline 437 (Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants) - [before 26 July 2013]- OECD Guideline 437 (Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage) - [from 26 July 2013]- OECD Guideline 438 (Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants) - [before 26 July 2013]- OECD Guideline 438 (Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage) - [from 26 July 2013]- OECD Guideline 460 (Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants)- OECD Guideline 491 (Short Time Exposure In Vitro Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage)- OECD Guideline 492 (Reconstructed Human Cornea-like Epithelium (RhCE) Test Method for Identifying Chemicals Not Requiring Classification and Labelling for Eye Irritation or Serious Eye Damage)- OECD Guideline 494 (Vitrigel-Eye Irritancy Test Method for Identifying Chemicals Not Requiring Classification and Labelling for Eye Irritation or Serious Eye Damage)- other: | Select the applicable test guideline, e.g. 'OECD Guideline xxx'. If the test guideline used is not listed, choose 'other:' and specify the test guideline in the related text field. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'. The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields.Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Version / remarks | Text (2,000 char.)Display: Basic |  | In this text field, you can enter any remarks as applicable, particularly:- To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline);- To indicate if the study was performed prior to the adoption of the test guideline specified;- To indicate if the methodology used was based on an extension of the test guideline specified;- To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Deviations | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes- no- not applicable- not specified | In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS. | **Guidance for field condition:**Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | **Test guideline** | **Block of fields (repeatable) End** |  |  |  |
|  | Principles of method if other than guideline | Text templateDisplay: Basic | **Freetext template:Option 1 Method of non-guideline study**- Principle of test:- Short description of test conditions:- Parameters analysed / observed:**Option 2 (Q)SAR**- Software tool(s) used including version:- Model(s) used:- Model description: see field 'Justification for non-standard information', 'Attached justification' and/or 'Cross-reference'- Justification of QSAR prediction: see field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' | If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate use either of the pre-defined freetext template options for 'Method of non-guideline study' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate.For a non-guideline experimental study a high-level freetext template can be used for summarising the principle of test, test conditions and parameters analysed / observed. If the freetext template for (Q)SAR is selected, indicate the QSAR model(s) or platform including version and the software tool(s) used. Detailed justification of the model and prediction should be provided in field(s) 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' as appropriate.Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate. |  |
|  | GLP compliance | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- yes (incl. QA statement)- yes- no- not specified | Indicate whether the study was conducted following Good Laboratory Practice or not. In case 'yes’ is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed. |  |
|  | **Test material** | **Header 2** |  |  |  |
|  | Test material information | Link to entity (single)Display: Basic |  | Select the appropriate Test Material Information (TMI) record. If not available in the repository, create a new one. You may also copy (clone) an existing TMI record, edit it and store it as new TMI.To change the link to an existing TMI, click the Delete button, then the Link button and proceed as described above.Depending on the purpose of the reporting or data submission, the information that must be provided may change. As a minimum, the chemical name, identifier and/or CAS number and molecular weight must be provided. | **Cross-reference:**TEST\_MATERIAL\_INFORMATION |
|  | Additional test material information | Link to entity (multiple)Display: Basic |  | Select additional Test material information record if relevant. For example, in longer terms studies more than one batch of test material can be needed or there may be differences between the labelled and unlabelled test materials. | **Cross-reference:**TEST\_MATERIAL\_INFORMATION |
|  | Specific details on test material used for the study | Text templateDisplay: Basic | **Freetext template:**SOURCE OF TEST MATERIAL- Source (i.e. manufacturer or supplier) and lot/batch number of test material:- Purity, including information on contaminants, isomers, etc.:RADIOLABELLING INFORMATION (if applicable)- Radiochemical purity:- Specific activity:- Locations of the label:- Expiration date of radiochemical substance:STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material:- Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage:- Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis:- Solubility and stability of the test material in the solvent/vehicle and the exposure medium:- Reactivity of the test material with the incubation material used (e.g. plastic ware):TREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding):- Preliminary purification step (if any):- Final concentration of a dissolved solid, stock liquid or gel:- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):FORM AS APPLIED IN THE TEST (if different from that of starting material)- Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:INFORMATION ON NANOMATERIALS- Chemical Composition:- Density:- Particle size & distribution:- Specific surface area:- Isoelectric point:- Dissolution (rate):TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable)- Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:OTHER SPECIFICS- Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.If applicable, relevant available information on the following items should be given:SOURCE OF TEST MATERIAL- Source and lot/batch No. of test material- Expiration date of the lot/batch- Purity test date: provide if availableRADIOLABELLING INFORMATION- Radiochemical purity- Specific activity- Locations of the label- Expiration date of radiochemical substanceSTABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material- Stability under test conditions- Solubility and stability of the test substance in the solvent/vehicle- Reactivity of the test substance with the solvent/vehicle or the cell culture mediumTREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding)- Preliminary purification step- Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)FORM AS APPLIED IN THE TEST (if different from that of starting material)Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.FORMULATED PRODUCT (for biocides/pesticides)Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.OTHER SPECIFICSProvide any other relevant information needed for characterising the tested material. |  |
|  | Specific details on test material used for the study (confidential) | Text templateDisplay: Basic (Confidential) | **Freetext template:**SOURCE OF TEST MATERIAL- Source (i.e. manufacturer or supplier) and lot/batch number of test material:- Purity, including information on contaminants, isomers, etc.:RADIOLABELLING INFORMATION (if applicable)- Radiochemical purity:- Specific activity:- Locations of the label:- Expiration date of radiochemical substance:STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material:- Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage:- Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis:- Solubility and stability of the test material in the solvent/vehicle and the exposure medium:- Reactivity of the test material with the incubation material used (e.g. plastic ware):TREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding):- Preliminary purification step (if any):- Final concentration of a dissolved solid, stock liquid or gel:- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):FORM AS APPLIED IN THE TEST (if different from that of starting material)- Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:INFORMATION ON NANOMATERIALS- Chemical Composition:- Density:- Particle size & distribution:- Specific surface area:- Isoelectric point:- Dissolution (rate):TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable)- Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:OTHER SPECIFICS- Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.If applicable, relevant available information on the following items should be given:SOURCE OF TEST MATERIAL- Source and lot/batch No. of test material- Expiration date of the lot/batch- Purity test date: provide if availableRADIOLABELLING INFORMATION- Radiochemical purity- Specific activity- Locations of the label- Expiration date of radiochemical substanceSTABILITY AND STORAGE CONDITIONS OF TEST MATERIAL- Storage condition of test material- Stability under test conditions- Solubility and stability of the test substance in the solvent/vehicle- Reactivity of the test substance with the solvent/vehicle or the cell culture mediumTREATMENT OF TEST MATERIAL PRIOR TO TESTING- Treatment of test material prior to testing (e.g. warming, grinding)- Preliminary purification step- Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used- Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)FORM AS APPLIED IN THE TEST (if different from that of starting material)Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.FORMULATED PRODUCT (for biocides/pesticides)Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.OTHER SPECIFICSProvide any other relevant information needed for characterising the tested material. |  |
|  | **Test animals / tissue source** | **Header 2** |  |  |  |
|  | Species | List (picklist)Display: Basic | **Picklist values:**- cattle- chicken- guinea pig- hamster- hamster, Armenian- hamster, Chinese- hamster, Syrian- human- monkey- mouse- pig- rabbit- rat- other: | Select as appropriate. For in vitro / ex vivo tests, indicate the species used as source of the test system. If not available from picklist, select 'other' and specify.Use of other than the species recommended by the test guideline is to be considered as deviation from guideline and should be noted and justified in the respective fieldsNOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Direct observations: clinical cases, poisoning incidents and other'.It can be useful to document, in section Irritation / corrosion', that human data are provided by creating a record and referring to the human data in block 'Cross-reference'. This could be relevant if lack of animal experiments is defended by the availability of data on experience with human exposure.Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) as to whether human data should be referenced in the appropriate endpoint summary record. |  |
|  | Strain | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- AKR - [mouse]- Abyssinian - [guinea pig]- Angora - [rabbit]- B6C3F1 - [mouse]- Balb/c - [mouse]- Beagle - [dog]- Belgian Hare - [rabbit]- Brown Norway - [rat]- C3H - [mouse]- C57BL - [mouse]- CAF1 - [mouse]- CB6F1 - [mouse]- CBA - [mouse]- CD-1 - [mouse]- CF-1 - [mouse]- Californian - [rabbit]- Chinchilla - [rabbit]- Crj: CD(SD) - [rat]- DBA - [mouse]- DBF1 - [mouse]- Dunkin-Hartley - [guinea pig]- Dutch - [rabbit]- FVB - [mouse]- Fischer 344 - [rat]- Fischer 344/DuCrj - [rat]- Flemish Giant - [rabbit]- Hartley - [guinea pig]- Himalayan - [rabbit]- ICL-ICR - [mouse]- ICR - [mouse]- Lewis - [rat]- Long-Evans - [rat]- Macaca fascicularis - [monkey]- Marmoset - [monkey]- Mulatta arctoides - [monkey]- NMRI - [mouse]- New Zealand Black - [rabbit]- New Zealand Red - [rabbit]- New Zealand White - [rabbit]- Nude - [mouse]- Nude Balb/cAnN - [mouse]- Nude CD-1 - [mouse]- Osborne-Mendel - [rat]- Peruvian - [guinea pig]- Pirbright-Hartley - [guinea pig]- Polish - [rabbit]- Rainbow trout - [fish]- SIV 50 - [mouse]- SKH/HR1 - [mouse]- San Juan - [rabbit]- Sencar - [mouse]- Sherman - [rat]- Shorthair - [guinea pig]- Sprague-Dawley - [rat]- Strain A - [mouse]- Swiss - [mouse]- Swiss Webster - [mouse]- Tif:MAGf - [mouse]- Vienna White - [rabbit]- Wistar - [rat]- Wistar Kyoto (WKY) - [rat]- Zucker - [rat]- not specified- other: | Select strain as appropriate. If not available from picklist, select 'other' and specify. |  |
|  | Details on test animals or tissues and environmental conditions | Text templateDisplay: Basic | **Freetext template:Option 1 In vivo test method**TEST ANIMALS- Source:- Age at study initiation:- Weight at study initiation:- Housing:- Diet (e.g. ad libitum):- Water (e.g. ad libitum):- Acclimation period:ENVIRONMENTAL CONDITIONS- Temperature (°C):- Humidity (%):- Air changes (per hr):- Photoperiod (hrs dark / hrs light):IN-LIFE DATES: From: To:**Option 2 Ex vivo test method (BCOP) and ex vivo test method (ICE)**SOURCE OF COLLECTED EYES- Source:- Number of animals:- Characteristics of donor animals (e.g. age, sex, weight):- Storage, temperature and transport conditions of ocular tissue (e.g. transport time, transport media and temperature, and other conditions):- Time interval prior to initiating testing:- Indication of any existing defects or lesions in ocular tissue samples:- Indication of any antibiotics used:- Selection and preparation of corneas:- Quality check of the isolated corneas:**Option 3 In vitro test method**- Justification of the test method (e.g. ICE, EIT, RhCE) and considerations regarding applicability:- Description of the cell system used, incl. certificate of authenticity and the mycoplasma status of the cell live:- Cell line used, its source, passage number and confluence of cells used for testing:- RhCE tissue or hCE cell construct used, including batch number:- For hCE cell: passage number and confluence of cells used, time and date of sub-culturing, duration of tripsinization, dilution ratio: | Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.Explanations:- Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum.- Water: Describe type (e.g. drinking water) and whether it was provided ad libitum.- Food quality and water quality: provide analytical information on the nutrient and dietary contaminant levels. Similarly provide analytical information on the drinking water used in the study.- IN-LIFE DATES: If required, specify the in-life dates (i.e. the phase of a study following treatment in which the test system is alive/growing). |  |
|  | **Test system** | **Header 2** |  |  |  |
|  | Vehicle | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- unchanged (no vehicle)- physiological saline- water- Hank's balanced salt solution- other:- not specified | Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. |  |
|  | Controls | List multi. (multi-select list with remarks)Display: Basic | **Picklist values:**- not required- yes- yes, concurrent no treatment- yes, concurrent vehicle- yes, concurrent positive control- yes, concurrent negative control- no- not specified- other: | Indicate whether and what type of concurrent control groups were used or select 'not required' if applicable.In the supplementary remarks field, specify the name of the control substance and other identifiers (e.g. CAS number, the physical state, lo/batch No. including expirations date, purity and any other relevant information.Multiple selection is possible if more than one type of control was used, e.g. a concurrent positive control and a concurrent negative control. |  |
|  | Amount / concentration applied | Text templateDisplay: Detailed | **Freetext template:**TEST MATERIAL - Amount(s) applied (volume or weight with unit): - Concentration (if solution):  VEHICLE - Amount(s) applied (volume or weight with unit): - Concentration (if solution): - Lot/batch no. (if required):  - Purity: | Give the amount(s) of substance / controls applied (volume or weight with unit) and the concentration of the substance, controls and vehicle (if used) in the test solution. Specify if different doses were applied. Use freetext template and delete/add elements as appropriate. |  |
|  | Duration of treatment / exposure | Text (2,000 char.)Display: Basic |  | Indicate length of time test material was in contact with animal/cell/tissue including unit, e.g. '4 hours'. Also indicate if different exposure time periods were applied in different tests of this study. |  |
|  | Observation period (in vivo) | Text (2,000 char.)Display: Basic |  | Indicate length of observation period. |  |
|  | Duration of post- treatment incubation (in vitro) | Text (2,000 char.)Display: Detailed |  | Indicate length of post-treatment incubation period as appropriate. |  |
|  | Number of animals or in vitro replicates | Text (2,000 char.)Display: Basic |  | Indicate number of animals used (if in vivo) or, in the case of in vitro tests, the number of replicate tissues used in each treatment / exposure and control group. |  |
|  | Details on study design | Text templateDisplay: Detailed | **Freetext template:Option 1 In vivo test method**REMOVAL OF TEST SUBSTANCE - Washing (if done):  - Time after start of exposure:   SCORING SYSTEM:   TOOL USED TO ASSESS SCORE: hand-slit lamp / biomicroscope / fluorescein**Option 2 Ex vivo test method (BCOP)**NUMBER OF REPLICATESNEGATIVE CONTROL USEDSOLVENT CONTROL USED (if applicable)POSITIVE CONTROL USEDAPPLICATION DOSE AND EXPOSURE TIMETREATMENT METHOD: [closed chamber / open chamber]POST-INCUBATION PERIOD: yes/no. If YES please specify durationREMOVAL OF TEST SUBSTANCE- Number of washing steps after exposure period:- POST-EXPOSURE INCUBATION:METHODS FOR MEASURED ENDPOINTS:- Corneal opacity:- Corneal permeability: passage of sodium fluorescein dye measured with the aid of [UV/VIS spectrophotometry / microtiter plate reader] (OD490)- Others (e.g, pertinent visual observations, histopathology): (please specify)SCORING SYSTEM: In Vitro Irritancy Score (IVIS)DECISION CRITERIA: please specify if the decision criteria as indicated in the TG was used.**Option 3 Ex vivo test method (ICE)**SELECTION AND PREPARATION OF ISOLATED EYESEQUILIBRATION AND BASELINE RECORDINGSNUMBER OF REPLICATESNEGATIVE CONTROL USEDSOLVENT CONTROL USED (if applicable)POSITIVE CONTROL USEDAPPLICATION DOSE AND EXPOSURE TIMEOBSERVATION PERIODREMOVAL OF TEST SUBSTANCE- Volume and washing procedure after exposure period:- Indicate any deviation from test procedure in the GuidelineMETHODS FOR MEASURED ENDPOINTS:- Corneal opacity:- Damage to epithelium based on fluorescein retention:- Swelling: measured with optical pachymeter on a slit-lamp microscope; slit-width setting:- Macroscopic morphological damage to the surface:- Others (e.g, histopathology):SCORING SYSTEM:- Mean corneal swelling (%)- Mean maximum opacity score- Mean fluorescein retention score at 30 minutes post-treatmentDECISION CRITERIA: please specify if the decision criteria as indicated in the TG was used.**Option 4 In vitro test method (FL)**- Preparation of the cellular monolayer- Binding properties of the substance- Calcium concentration in the culture media- Solubility of the test chemical in HBSS- Application of the test chemical and control chemicals: concentrations and method- Number of replicates used for each concentration- Method for quantification of fluorescein leakage and sensitivity of the apparatus**Option 5 In vitro test method (STE)**- Number of repetitions and replicates used- Test chemical concentrations used (if different than the ones recommended)- Justification for choice of solvent for each test chemical- Duration of exposure to the test chemical (if different than the one recommended)- Description of any modifications of the test procedure- Description of evaluation and decision criteria used- Reference to historical positive control mean and Standard Deviation (SD)- Demonstration of proficiency of the laboratory in performing the test method (e.g. by testing of proficiency substances) or demonstration of reproducible performance of the test method over time**Option 6 In vitro test method (EIT)**- Details of the test procedure used- Doses of test chemical and control substances used- Duration and temperature of exposure, post-exposure immersion and post-exposure incubation periods (where applicable)- Justification for the use of a different negative control than ultrapure H2O (if applicable)- Justification for the use of a different positive control than neat methyl acetate (if applicable)- Description of any modifications to the test procedure- Indication of controls used for direct MTT-reducers and/or colouring test chemicals (if applicable)- Number of tissue replicates used per test chemical and controls (positive control, negative control, NSMTT, NSCliving and NSCkilled, if applicable)- For hCE cells: number of runs and of hCE models used within each run- Wavelength and band pass (if applicable) used for quantifying MTT formazan, and linearity range of measuring device (e.g. spectrophotometer)- Description of the method used to quantify MTT formazan, if applicable- For hCE cells: data of QC check for TEER measuring system- Description of the qualification of the HPLC/UPLC-spectrophotometry system (if applicable)- Description of evaluation criteria used including the justification for the selection of the cut-off point for the prediction model- Reference to historical positive and negative control results demonstrating suitable run acceptance criteria- Complete supporting information for the specific RhCE tissue construct or hCE cells used- Reference to historical data of the RhCE tissue construct / hCE cells- Demonstration of proficiency in performing the test method before routine use by testing of the proficiency chemicals- Positive and negative control means and acceptance ranges based on historical data- Acceptable variability between tissue replicates for positive and negative controls- Acceptable variability between tissue replicates for the test chemical | Select freetext template for the respective type of study (i.e. In vivo test method, In vitro test method (BCOP) or In vitro test method (ICE) 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. |  |
|  | High dose level used | List (picklist)Display: Basic | **Picklist values:**- yes- no | Where a test method offers flexibility in the study design, for example in relation to the choice of dose levels, the chosen study design shall ensure that the data generated are adequate for hazard identification and risk assessment. To this end, testing shall be performed at appropriately high dose levels. If dose (concentration) selection is limited by the physicochemical properties or biological effects of the test substance, justification shall be provided. |  |
|  | Justification for deviation from the high dose level | Text templateDisplay: Basic | **Freetext template:**Justification for deviation from the high dose level | Provide a justification for deviating from the high dose level. |  |
|  | **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** |  |  |  |
|  | **In vitro** | **Header 2** |  |  | **Guidance for field condition:**Condition: Show and activate fields under this heading if ‘Endpoint' = '\*in vitro / ex vivo' or '\* other' |
|  | **Results** | **Block of fields (repeatable) Start** |  | Indicate the overall irritation / corrosion results for the test substance in terms of the relevant endpoints examined (e.g. cornea opacity score) and the overall irritation / corrosion results (specify as appropriate). Copy this block of fields for reporting several scores, e.g. means of individual replicates.In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables". (Q)SAR results can be reported under the appropriate heading, i.e. ‘In vitro’ or ‘in vivo’, depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field ‘Remarks on result’ should be completed by entering the adequate qualitative description of the prediction.Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results. | **Remarks:**A heading 'Ex vivo / in vitro' will be added before this field. For technical reasons related to the field paths this will be done in the next revision. |
|  | 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. |  |
|  | Irritation parameter | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- cornea opacity score- corneal swelling - fluorescein leakage- fluorescein retention score- histopathological observations- in vitro irritation score- mean percent tissue viability - morphological effects- percent corneal swelling- percent tissue viability - TEER value (Transepithelial Electrical Resistance) - other: | Select type of parameter from picklist, if applicable. Further details can be given in the supplementary remarks field. For instance, in the case of morphological effects, specify if and to what severity pitting of corneal epithelial cells, loosening of epithelium, roughening of the corneal surface and sticking of the test substance to the cornea occurred. |  |
|  | Run / experiment | Text (255 char.)Display: Basic |  | Indicate the run / experiment the measurement relates to, if more than one run / experiment was performed and the length of time the test material was in contact with the test system, if different exposure time periods were applied in different test runs of this study. Examples: Run 1 (duration of exposure: 10 min.); Run 1, replicate 1 (duration of exposure: 10 min.), Mean of three runs with two replicates each. |  |
|  | Value | 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. |  |
|  | Vehicle controls validity | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- valid- not valid- not applicable- not examined- not specified- other: | Indicate whether test(s) with vehicle control(s) (i.e. vehicle only without test substance) is/are valid. Relevant remarks can be given in the supplementary remarks field. |  |
|  | Negative controls validity | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- valid- not valid- not applicable- not examined- not specified- other: | Indicate whether test with negative control(s) demonstrated lack of irritation/corrosion of the known non-irritant/non-corrosive substance, and/or that the negative control falls within the acceptance criteria range as described in the TG. Relevant remarks can be given in the supplementary remarks field. |  |
|  | Positive controls validity | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- valid- not valid- not applicable- not examined- not specified- other: | Indicate whether test with positive control(s) demonstrated irritation/corrosive effects of the known irritant/corrosive substance and/or that positive control results fall within the acceptance criteria as described in the TG. Relevant remarks can be given in the supplementary remarks field. |  |
|  | Remarks on result | List sup. (picklist with remarks - 2,000 char.)Display: Basic | **Picklist values:**- no indication of irritation- positive indication of irritation- 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:'. |  |
|  | **Results** | **Block of fields (repeatable) End** |  |  |  |
|  | Other effects / acceptance of results | Text templateDisplay: Detailed | **Freetext template:**OTHER EFFECTS:- Visible damage on test system:DEMONSTRATION OF TECHNICAL PROFICIENCY:ACCEPTANCE OF RESULTS:- Acceptance criteria met for negative control:- Acceptance criteria met for positive control:- Range of historical values if different from the ones specified in the test guideline: | Select freetext template and delete/add elements as appropriate. Provide the following information as appropriate:- OTHER EFFECTS: Describe any other observed effects (e.g. visible damage on test system)- DEMONSTRATION OF TECHNICAL PROFICIENCY: If required according to the test guideline, indicate if and when technical proficiency has been demonstrated using the proficiency chemicals listed in the guideline used. Upload table(s) with data for each individual proficiency chemical in the rich text field 'Any other information on results incl. tables'.- ACCEPTANCE OF RESULTS: Demonstrate that the assay acceptance criteria (for negative and positive control) were met in reference to historical ranges. Indicate the range of historical values if different from the ones indicated in the relevant test guideline.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. |  |
|  | **In vivo** | **Header 2** |  |  | **Guidance for field condition:**Condition: Show and activate fields under this heading if ‘Endpoint' = '\*in vivo' or '\*other' |
|  | **Results** | **Block of fields (repeatable) Start** |  | Indicate the scores of the relevant endpoints examined (e.g. cornea opacity score) and the overall irritation / corrosion results (specify as appropriate). In subfield “Basis of irritation parameter” indicate if the score is an average value (i.e. mean), or for a give animal, or other. Copy this block of fields for reporting several scores, e.g. means or for individual animals.In case of a robust study summary or as requested by the regulatory programme, also provide the raw data of the results (including means and standard deviations) for the test material and all controls used in the field "Irritant/corrosive response data" and/or upload a table in the field "Any other information on results incl. tables".(Q)SAR results can be reported under the appropriate heading, i.e. ‘In vitro’ or ‘in vivo’, depending on the applicability domain of the model behind and based on what kind of data the model was mainly validated. At least the field ‘Remarks on result’ should be completed by entering the adequate qualitative description of the prediction.Note that a separate field "Interpretation of results" is provided in the section "APPLICANT'S SUMMARY AND CONCLUSION" for indicating a classification based on the study results. | **Remarks:**A heading 'In vivo' will be added before this field. For technical reasons related to the field paths this will be done in the next revision. |
|  | 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. |  |
|  | Irritation parameter | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- cornea opacity score- iris score- conjunctivae score- chemosis score- overall irritation score- maximum mean total score (MMTS)- other: | Select type of parameter from picklist. Further details can be given in the supplementary remarks field. |  |
|  | Basis | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- animal #1- animal #2- animal #3- animal #4- animal #5- animal #6- animal:- mean- other: | Indicate if the score is the mean of all scoring results for the parameter selected on the preceding subfield or based on individual animals, e.g. animal #1. Option 'animal:' allows to enter text/numbers in the related supplementary remarks field, e.g. 'animal: #1, 2 and 3'). |  |
|  | Time point | List (picklist)Display: Basic | **Picklist values:**- 24 h- 48 h- 72 h- 24/48 h- 24/48/72 h- 7 d- 10 d- 14 d- 21 d- other: | Indicate the time point(s) the score relates to by selecting the appropriate value from the picklist, e.g. '24' or '24/48/72 h' (if the same score applies), and in the following field, the unit. |  |
|  | Score | 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. |  |
|  | Max. score | Numeric (decimal)Display: Basic |  | Provide the numeric value of the total possible score depending on the scale used. |  |
|  | Reversibility | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- fully reversible within:- fully reversible- not fully reversible within:- not reversible- other:- not specified | Indicate whether the irritation was reversible or not. As appropriate use supplementary remarks field linked to the picklist item selected for indicating average time for (non-)reversibility. |  |
|  | Remarks on result | List sup. (picklist with remarks - 2,000 char.)Display: Basic | **Picklist values:**- no indication of irritation- positive indication of irritation- probability of weak irritation- probability of mild irritation- probability of moderate irritation- probability of severe irritation- not determinable- not determinable because of methodological limitations- not measured/tested- other: | This field can be used for:- giving a qualitative description of results in addition to or if no numeric value(s) were derived;- giving a pre-defined reason why no numeric value is provided, e.g. by selecting 'not determinable' and entering free text explanation in the supplementary remarks field; or- entering any additional information on the effect level by selecting 'other:'. |  |
|  | **Results** | **Block of fields (repeatable) End** |  |  |  |
|  | Irritant / corrosive response data | Text (32,768 char.)Display: Detailed |  | For robust study summaries or as requested by the regulatory programme, tabulate the raw data for each individual animal at each observation time (unless these data are given in above block of fields 'Irritation / corrosion results'). Upload predefined or other appropriate table(s) if available and tailor it/them to your needs. Use table numbers in the sequence in which you refer to them in the Remarks text (e.g. '... see Table 1').Describe the method of calculation of maximum average score given in the results table.Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof. |  |
|  | Other effects | Text templateDisplay: Basic | **Freetext template:**- Lesions and clinical observations:- Ophthalmoscopic findings:- Histopathological findings:- Effects of rinsing or washing:- Other observations: | Select freetext template and delete/add elements as appropriate. Describe any other relevant results including lesions and clinical observations, ophthalmoscopic and histopathological findings, effects of rinsing or washing if applicable. |  |
|  | **Any other information on results incl. tables** | **Header 2** |  |  |  |
|  |  | Text (rich-text area)Display: Basic |  | In this field, you can enter any other remarks on results. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format.Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry. |  |
|  | **Overall remarks, attachments** | **Header 1** |  |  |  |
|  | Overall remarks | Text (rich-text area)Display: Basic |  | In this field, you can enter any overall remarks or transfer free text from other databases. You can also open a rich text editor and create formatted text and tables or insert and edit any excerpt from a word processing or spreadsheet document, provided it was converted to the HTML format. You can also upload any htm or html document.Note: One rich text editor field each is provided for the MATERIALS AND METHODS and RESULTS section. In addition the fields 'Overall remarks' and 'Executive summary' allow rich text entry. |  |
|  | **Attachments** | **Block of fields (repeatable) Start** |  | Attach any background document that cannot be inserted in any rich text editor field, particularly image files (e.g. an image of a structural formula).Copy this block of fields for attaching more than one file. |  |
|  | Type | List (picklist)Display: Basic | **Picklist values:**- full study report- illustration (picture/graph)- other: | Specify the type of attachment inserted, for example the 'full study report'. |  |
|  | Attached (confidential) document | Attachment (single)Display: Basic (Confidential) |  | An electronic copy of the full study report or other documents can be attached as Word, pdf or other file types. |  |
|  | Attached (sanitised) documents for publication | Attachment (single)Display: Basic |  | An electronic copy of a public (non-confidential) version of the full study report or other relevant documents can be attached. This attachment should be sanitised if needed. |  |
|  | Remarks | Text (255 char.)Display: Basic |  | As appropriate, include remarks, e.g. a short description of the content of the attached document if the file name is not self-explanatory. |  |
|  | **Attachments** | **Block of fields (repeatable) End** |  |  |  |
|  | **Applicant's summary and conclusion** | **Header 1** |  |  |  |
|  | Interpretation of results | List sup. (picklist with remarks - 2,000 char.)Display: Basic | **Picklist values:**- Category 1 (irreversible effects on the eye) based on GHS criteria- Category 2 (irritating to eyes) based on GHS criteria- Category 2A (irritating to eyes) based on GHS criteria- Category 2B (mildly irritating to eyes) based on GHS criteria- study cannot be used for classification- GHS criteria not met- other: | Conclude if the study results fall under relevant classification criteria of the Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS). Further explanations can be entered in the supplementary remarks field.Note that a classification in the strict sense cannot always be based on an individual study, but includes a weight of evidence evaluation of all relevant data. To this end wording such as 'is classified in Category 1' should be used only in the conclusions provided in the relevant classification section. | **Guidance for data migration:**If the source field contains a toxicity category and 'OECD GHS' is indicated in the removed field 'Criteria used for interpretation of results', the matching target phrase is selected. Otherwise the value is migrated as obsolete phrase and the default text 'Migrated information' is entered in the supplementary remarks field. In addition the value of field 'Criteria used for interpretation of results' is preceded by the field label and entered as new line in the remarks field. |
|  | 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. |  |