**Template #66-1: Skin sensitisation *(Version [12.2]-[July 2023])***

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

| **Line no.** | **Field name** | **Field type**  **Display type** | **Picklist**  **Freetext template** | **Help text** | **Remarks**  **Guidance**  **Cross-reference** |
| --- | --- | --- | --- | --- | --- |
|  | **Administrative data** | **Header 1** |  |  |  |
|  |  | Confidentiality  Display: Basic |  |  |  |
|  | Endpoint | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - skin sensitisation: in vitro - skin sensitisation: in chemico - skin sensitisation: in silico - skin sensitisation: in vivo (LLNA) - skin sensitisation: in vivo (non-LLNA) - skin sensitisation, 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).  Select 'skin sensitisation: in silico' for e.g. a (Q)SAR model. '(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', 'Type of study' and 'Guideline'. For instance all test guidelines describing an LLNA test can be used to trigger the relevant Endpoint phrase. The EPA guidelines cannot serve this purpose as they cover both LLNA and non-LLNA methods. In such cases the indication given in field 'Type of method' is used as trigger. As a fallback the generic phrase 'skin sensitisation' is selected, with default supplementary text = value of 'Type of method'. 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 box  Display: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Robust Study Summary' or in combination with 'Adequacy of study'.   Explanation: The term 'Robust Study Summary' is actually used only to describe the technical content of a very detailed summary of an experimental study or of any other relevant information. It is a priori no synonym with the term 'Key study', although a key study should usually be submitted in the form of Robust Study Summary. However, a Robust Summary may also be useful for other adequate studies that are considered supportive of the key study or even for inadequate studies if they can be used for a weight-of-evidence analysis. Also for studies that are flawed, but indicate critical results, Robust Study Summaries highlighting the weaknesses of the studies need to be elaborated.   Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Used for classification | Check box  Display: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'Used for classification'.  Explanation: In some use cases it may be necessary to indicate those records that are used for the classification of that substance, e.g. according to UN GHS. If not relevant, disregard this field.   Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Used for SDS | Check box  Display: Basic |  | Set this flag if relevant for the respective regulatory programme or if otherwise useful as filter for printing or exporting records flagged as 'SDS information'.   Explanation: 'SDS' stands for Safety Data Sheet. In some use cases it may be necessary to indicate those records that are used for the compilation of SDS information. If not relevant, disregard this field.   Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Study period: start date | Date  Display: 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 | Date  Display: 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 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) - [study scientifically not necessary / other information available] - the study does not need to be conducted because the substance is classified as skin corrosion (Category 1, 1A, 1B or 1C) - [study scientifically not necessary / other information available] - an in vitro skin sensitisation 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 skin sensitisation study was conducted - [study scientifically not necessary / other information available] - an in vitro skin sensitisation study does not need to be conducted because adequate data from an in vivo skin sensitisation 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 template  Display: Basic | **Freetext template:  Option 1 Type 'Waiving of standard information'** JUSTIFICATION FOR DATA WAIVING [Specific explanation in addition to field 'Justification for data waiving'] **Option 2 Type 'Experimental study planned / Testing proposal on vertebrate animals'** TESTING PROPOSAL ON VERTEBRATE ANIMALS [Please provide information for all of the points below. The information should be specific to the endpoint for which testing is proposed. Note that for testing proposals addressing testing on vertebrate animals under the REACH Regulation this document will be published on the ECHA website along with the third party consultation on the testing proposal(s).]  NON-CONFIDENTIAL NAME OF SUBSTANCE: - Name of the substance on which testing is proposed to be carried out - Name of the substance for which the testing proposal will be used [if different from tested substance]  CONSIDERATIONS THAT THE GENERAL ADAPTATION POSSIBILITIES OF ANNEX XI OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION [please address all points below]: - Available GLP studies - Available non-GLP studies - Historical human/control data - (Q)SAR - In vitro methods - Weight of evidence - Grouping and read-across - Substance-tailored exposure driven testing [if applicable] - Approaches in addition to above [if applicable] - Other reasons [if applicable]  CONSIDERATIONS THAT THE SPECIFIC ADAPTATION POSSIBILITIES OF ANNEXES VI TO X (AND COLUMN 2 THEREOF) OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION: - [free text]  FURTHER INFORMATION ON TESTING PROPOSAL IN ADDITION TO INFORMATION PROVIDED IN THE MATERIALS AND METHODS SECTION: - Details on study design / methodology proposed [if relevant] **Option 3 Type 'QSAR prediction'** 1. SOFTWARE  2. MODEL (incl. version number)  3. SMILES OR OTHER IDENTIFIERS USED AS INPUT FOR THE MODEL  4. SCIENTIFIC VALIDITY OF THE (Q)SAR MODEL [[Explain how the model fulfils the OECD principles for (Q)SAR model validation. Consider attaching the QMRF and/or QPRF or providing a link] - Defined endpoint: - Unambiguous algorithm: - Defined domain of applicability: - Appropriate measures of goodness-of-fit and robustness and predictivity: - Mechanistic interpretation:  5. APPLICABILITY DOMAIN [Explain how the substance falls within the applicability domain of the model] - Descriptor domain: - Structural domain: - Mechanistic domain: - Similarity with analogues in the training set: - Other considerations (as appropriate):  6. ADEQUACY OF THE RESULT [Explain how the prediction fits the purpose of classification and labelling and/or risk assessment] **Option 4 Type 'Read-across (analogue)'** REPORTING FORMAT FOR THE ANALOGUE APPROACH [Please provide information for all of the points below. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]  1. HYPOTHESIS FOR THE ANALOGUE APPROACH [Describe why the read-across can be performed (e.g. common functional group(s), common precursor(s)/breakdown product(s) or common mechanism(s) of action]  2. SOURCE AND TARGET CHEMICAL(S) (INCLUDING INFORMATION ON PURITY AND IMPURITIES) [Provide here, if relevant, additional information to that included in the Test material section of the source and target records]  3. ANALOGUE APPROACH JUSTIFICATION [Summarise here based on available experimental data how these results verify that the read-across is justified]  4. DATA MATRIX **Option 5 Type 'Read-across (category)'** REPORTING FORMAT FOR THE CATEGORY APPROACH [Please provide information for all of the points below addressing endpoint-specific elements that were not already covered by the overall category approach justification made available at the category level. Indicate if further information is included as attachment to the same record, or elsewhere in the dataset (insert links in 'Cross-reference' table)]  1. HYPOTHESIS FOR THE CATEGORY APPROACH (ENDPOINT LEVEL) [Describe why the read-across can be performed]  2. CATEGORY APPROACH JUSTIFICATION (ENDPOINT LEVEL [Summarise here based on available experimental data how these results verify that the read-across is justified] **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 406 (Skin Sensitisation) - OECD Guideline 429 (Skin Sensitisation: Local Lymph Node Assay) - OECD Guideline 442A (Skin Sensitization: Local Lymph Node Assay: DA) - OECD Guideline 442B (Skin Sensitization: Local Lymph Node Assay: BrdU-ELISA) - [before 27 June 2018] - OECD Guideline 442B (Skin sensitisation: Local Lymph Node Assay: BrdU-ELISA or –FCM) - [from 27 June 2018] - OECD Guideline 442C (In Chemico Skin Sensitisation Assays addressing the Adverse Outcome Pathway key event on covalent binding to proteins) - [from 18 June 2019] - OECD Guideline 442C (In Chemico Skin Sensitisation: Direct Peptide Reactivity Assay (DPRA)) - [before 18 June 2019] - OECD Guideline 442D (In Vitro Skin Sensitisation: ARE-Nrf2 luciferase KeratinoSens™ test method) - [from 25 June 2018] - OECD Guideline 442D (In Vitro Skin Sensitisation: ARE-Nrf2 Luciferase Test Method) - [before 25 June 2018] - OECD Guideline 442E (In Vitro Skin Sensitisation assays addressing the key event on activation of dendritic cells on the Adverse Outcome Pathway for skin sensitisation) - [from 9 October 2017] - OECD Guideline 442E (In Vitro Skin Sensitisation: human Cell Line Activation Test (h-CLAT)) - [before 9 October 2017] - OECD Guideline 497 (Deﬁned Approaches on Skin Sensitisation) - EPA OPP 81-6 (Skin Sensitisation) - EPA OPPTS 870.2600 (Skin Sensitisation) - EPA OTS 798.4100 (Skin Sensitisation) - EU Method B.42 (Skin Sensitisation: Local Lymph Node Assay) - EU Method B.50 (Skin Sensitisation: Local Lymph Node Assay: DA) - EU Method B.51 (Skin Sensitisation: Local Lymph Node Assay: BrDU-ELISA) - EU Method B.59 (In Chemico Skin Sensitisation: Direct Peptide Reactivity Assay (DPRA) - EU Method B.6 (Skin Sensitisation) - EU Method B.71 (In vitro Skin Sensitisation assays addressing the Key Event on activation of dendritic cells on the Adverse Outcome Pathway (AOP) for Skin Sensitisation - EU Method: B.60 (In Vitro Skin Sensitisation: ARE-Nrf2 Luciferase Test Method) - other: | Select the applicable test guideline, e.g. 'OECD Guideline xxx'. If the test guideline used is not listed, choose 'other:' and specify the test guideline in the related text field. Information on the version and date of the guideline used and/or any other specifics can be entered in the next field 'Version / remarks'.  If no test guideline can be specified, this should be indicated in the preceding field 'Qualifier'. The method used should then be shortly described in the field 'Principles of method if other than guideline', while details can be given in other distinct fields.  Please note: Test guidelines used for the validation of (Q)SAR models should be reported in the description of the relevant model in field 'Justification for type of information' or 'Attached justification'. | **Guidance for field condition:** Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Version / remarks | Text (2,000 char.)  Display: Basic |  | In this text field, you can enter any remarks as applicable, particularly:  - To include any other title of the test guideline draft used, a subtitle, another version or update number and the year of update (For instance, different titles and/or numbers may exist for a given EU test guideline);  - To indicate if the study was performed prior to the adoption of the test guideline specified;  - To indicate if the methodology used was based on an extension of the test guideline specified;  - To indicate what protocol was followed for methods that allow the optional determination of more than one parameter if this cannot be indicated in a distinct field of the Materials and methods section. | **Guidance for field condition:** Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | Deviations | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - yes - no - not applicable - not specified | In case a test guideline or other standardised method was used, indicate if there are any deviations. Briefly state relevant deviations in the supplementary remarks field (e.g. 'other test system used', 'different exposure duration'); details should be described in the respective fields of the section MATERIALS AND METHODS. | **Guidance for field condition:** Condition: Field active only if 'Qualifier' is not 'no guideline ...' |
|  | **Test guideline** | **Block of fields (repeatable) End** |  |  |  |
|  | Principles of method if other than guideline | Text template  Display: Basic | **Freetext template:  Option 1 Method of non-guideline study** - Principle of test: - Short description of test conditions: - Parameters analysed / observed: **Option 2 (Q)SAR** - Software tool(s) used including version: - Model(s) used: - Model description: see field 'Justification for non-standard information', 'Attached justification' and/or 'Cross-reference' - Justification of QSAR prediction: see field 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' | If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. As appropriate use either of the pre-defined freetext template options for 'Method of non-guideline study' or '(Q)SAR'. Delete / add elements and edit text set in square brackets [...] as appropriate.  For a non-guideline experimental study a high-level freetext template can be used for summarising the principle of test, test conditions and parameters analysed / observed.   If the freetext template for (Q)SAR is selected, indicate the QSAR model(s) or platform including version and the software tool(s) used. Detailed justification of the model and prediction should be provided in field(s) 'Justification for type of information', 'Attached justification' and/or 'Cross-reference' as appropriate.  Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate. |  |
|  | GLP compliance | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - yes (incl. QA statement) - yes - no - not specified | Indicate whether the study was conducted following Good Laboratory Practice or not. In case 'yes’ is selected, a Quality Assurance (QA) statement must be provided with the report. You can give an explanation in the supplementary remarks field, e.g. for explaining why GLP was not complied with or for specifying which (national) GLP was followed. |  |
|  | Type of study | List (picklist)  Display: Basic | **Picklist values:** - amino acid derivative reactivity assay (ADRA) - ARE-Nrf2 luciferase KeratinoSens™ test method - ARE-Nrf2 luciferase LuSens test method - Buehler test - direct peptide reactivity assay (DPRA) - Draize test - Freund's complete adjuvant test - guinea pig maximisation test - human Cell Line Activation Test (h-CLAT) - Interleukin-8 Reporter Gene Assay (IL-8 Luc assay) - intracutaneous test - in silico (Derek Nexus) - in silico (OECD QSAR Toolbox) - kinetic direct peptide reactivity assay (kinetic DPRA) - Maurer optimisation test - mouse ear swelling test - mouse local lymph node assay (LLNA) - mouse local lymph node assay (LLNA): BrdU-ELISA - mouse local lymph node assay (LLNA): BrdU-FCM - mouse local lymph node assay (LLNA): DA - open epicutaneous test - patch test - reduced LLNA - reduced LLNA: BrdU-ELISA - reduced LLNA: BrdU-FCM - reduced LLNA: DA - skin painting test - split adjuvant test - U937 cell line activation test (U-SENS™) - not specified - other: | Select type of study as appropriate. If another than the LLNA test system was used, a justification may be required in the following field.  If the study was performed as part of an OECD TG 497 DA, justification can be provided as text template in the justification field, e.g. “Study is part of 2-out-3-approach/ ITSv1 according to OECD TG 497”. | **Guidance for field condition:** Condition: Field active only if field ‘Type of information' is not '(Q)SAR' or 'estimated by calculation (if not (Q)SAR)' |
|  | Justification for non-LLNA method | Text (2,000 char.)  Display: Detailed |  | Provide a justification for the use of another than the LLNA test system (if in vivo), if the relevant legislation so requires. For instance it could be argued that the LLNA method was not available yet by the time the study was conducted or that the LLNA test is not suitable for that substance or that an appropriate guinea pig maximisation test is available which would not justify conducting an additional LLNA due to animal welfare. Refer to the relevant legislation-specific guidance document. | **Guidance for field condition:** Condition: Field active only if 'Type of study' is '\*non-LLNA\*' |
|  | **Test material** | **Header 2** |  |  |  |
|  | Test material information | Link to entity (single)  Display: Basic |  | Select the appropriate Test Material Information (TMI) record. If not available in the repository, create a new one. You may also copy (clone) an existing TMI record, edit it and store it as new TMI.  To change the link to an existing TMI, click the Delete button, then the Link button and proceed as described above.  Depending on the purpose of the reporting or data submission, the information that must be provided may change. As a minimum, the chemical name, identifier and/or CAS number and molecular weight must be provided. | **Cross-reference:** TEST\_MATERIAL\_INFORMATION |
|  | Additional test material information | Link to entity (multiple)  Display: Basic |  | Select additional Test material information record if relevant. For example, in longer terms studies more than one batch of test material can be needed or there may be differences between the labelled and unlabelled test materials. | **Cross-reference:** TEST\_MATERIAL\_INFORMATION |
|  | Specific details on test material used for the study | Text template  Display: Basic | **Freetext template:** SOURCE OF TEST MATERIAL - Source (i.e. manufacturer or supplier) and lot/batch number of test material: - Purity, including information on contaminants, isomers, etc.:  RADIOLABELLING INFORMATION (if applicable) - Radiochemical purity: - Specific activity: - Locations of the label: - Expiration date of radiochemical substance:  STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL - Storage condition of test material: - Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage: - Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis: - Solubility and stability of the test material in the solvent/vehicle and the exposure medium: - Reactivity of the test material with the incubation material used (e.g. plastic ware):  TREATMENT OF TEST MATERIAL PRIOR TO TESTING - Treatment of test material prior to testing (e.g. warming, grinding): - Preliminary purification step (if any): - Final concentration of a dissolved solid, stock liquid or gel: - Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):  FORM AS APPLIED IN THE TEST (if different from that of starting material) - Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:  INFORMATION ON NANOMATERIALS - Chemical Composition: - Density: - Particle size & distribution: - Specific surface area: - Isoelectric point: - Dissolution (rate):  TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable) - Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:  OTHER SPECIFICS - Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.  Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.  If applicable, relevant available information on the following items should be given:  SOURCE OF TEST MATERIAL  - Source and lot/batch No. of test material  - Expiration date of the lot/batch  - Purity test date: provide if available  RADIOLABELLING INFORMATION  - Radiochemical purity  - Specific activity  - Locations of the label  - Expiration date of radiochemical substance  STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL  - Storage condition of test material  - Stability under test conditions  - Solubility and stability of the test substance in the solvent/vehicle  - Reactivity of the test substance with the solvent/vehicle or the cell culture medium  TREATMENT OF TEST MATERIAL PRIOR TO TESTING  - Treatment of test material prior to testing (e.g. warming, grinding)  - Preliminary purification step  - Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used  - Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)  FORM AS APPLIED IN THE TEST (if different from that of starting material)  Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.  FORMULATED PRODUCT (for biocides/pesticides)  Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.  OTHER SPECIFICS  Provide any other relevant information needed for characterising the tested material. |  |
|  | Specific details on test material used for the study (confidential) | Text template  Display: Basic (Confidential) | **Freetext template:** SOURCE OF TEST MATERIAL - Source (i.e. manufacturer or supplier) and lot/batch number of test material: - Purity, including information on contaminants, isomers, etc.:  RADIOLABELLING INFORMATION (if applicable) - Radiochemical purity: - Specific activity: - Locations of the label: - Expiration date of radiochemical substance:  STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL - Storage condition of test material: - Stability and homogeneity of the test material in the vehicle/solvent under test conditions (e.g. in the exposure medium) and during storage: - Stability in the medium, i.e. sensitivity of the test material to hydrolysis and/or photolysis: - Solubility and stability of the test material in the solvent/vehicle and the exposure medium: - Reactivity of the test material with the incubation material used (e.g. plastic ware):  TREATMENT OF TEST MATERIAL PRIOR TO TESTING - Treatment of test material prior to testing (e.g. warming, grinding): - Preliminary purification step (if any): - Final concentration of a dissolved solid, stock liquid or gel: - Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle):  FORM AS APPLIED IN THE TEST (if different from that of starting material) - Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution:  INFORMATION ON NANOMATERIALS - Chemical Composition: - Density: - Particle size & distribution: - Specific surface area: - Isoelectric point: - Dissolution (rate):  TYPE OF BIOCIDE/PESTICIDE FORMULATION (if applicable) - Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application; formulated product seed treatment; solution in organic solvent seed treatment:  OTHER SPECIFICS - Other relevant information needed for characterising the tested material, e.g. if radiolabelled, adjustment of pH, osmolality and precipitate in the culture medium to which the test chemical is added: | Use this field for reporting specific details on the test material as used for the study if they differ from the starting material specified under 'Test material information'. This can include information on the pre-defined items, but not all or additional ones may be relevant.  Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.  If applicable, relevant available information on the following items should be given:  SOURCE OF TEST MATERIAL  - Source and lot/batch No. of test material  - Expiration date of the lot/batch  - Purity test date: provide if available  RADIOLABELLING INFORMATION  - Radiochemical purity  - Specific activity  - Locations of the label  - Expiration date of radiochemical substance  STABILITY AND STORAGE CONDITIONS OF TEST MATERIAL  - Storage condition of test material  - Stability under test conditions  - Solubility and stability of the test substance in the solvent/vehicle  - Reactivity of the test substance with the solvent/vehicle or the cell culture medium  TREATMENT OF TEST MATERIAL PRIOR TO TESTING  - Treatment of test material prior to testing (e.g. warming, grinding)  - Preliminary purification step  - Final dilution of a soluble solid, stock liquid, or gel (e.g., neat liquid, stock diluted liquid, or dissolved solid) to final concentration and the solvent(s) used  - Final preparation of a solid (e.g. stock crystals ground to fine powder using a mortar and pestle)  FORM AS APPLIED IN THE TEST (if different from that of starting material)  Specify the relevant form characteristics if different from those in the starting material, such as state of aggregation, shape of particles or particle size distribution.  FORMULATED PRODUCT (for biocides/pesticides)  Description of the formulation, e.g. formulated product for foliar application; formulated product soil application; solution in organic solvent for soil application: formulated product seed treatment; solution in organic solvent seed treatment.  OTHER SPECIFICS  Provide any other relevant information needed for characterising the tested material. |  |
|  | **In vitro test system** | **Header 2** |  |  | **Guidance for field condition:** Condition: Show and activate fields under this heading if 'Endpoint' is '\*in vitro' |
|  | Details of test system | List (picklist)  Display: Basic | **Picklist values:** - Keratinoses transgenic cell line [442D] - Lusens transgenic cell line [442D] - THP-1 cell line [442E] - THP-G8 cell line [442E] - U-937 cell line [442E] - other: | If standard cell lines not used, please select 'other:' and specify in the freetext field exact details of the cell line used. |  |
|  | Details on the study design | Text template  Display: Detailed | **Freetext template:** 442D  PREPARATION OF TEST SOLUTIONS - Preparation of the test chemical stock solution - Preparation of the test chemical serial dilutions - Preparation of the positive controls - Preparation of the solvent, vehicle and negative controls - Stable dispersion obtained - Other:  DOSE RANGE FINDING ASSAY: - Highest concentration used - Solubility in solvents - Solubility in incubation medium - Cytotoxicity assessment performed - Final concentration range selected on basis of: [describe]  APPLICATION OF THE TEST CHEMICAL AND CONTROL SUBSTANCES - Number of replicates - Number of repetitions - Test chemical concentrations - Application procedure - Exposure time - Study evaluation and decision criteria used - Description on study acceptance criteria - Other:  SEEDING AND INCUBATION - Seeding conditions (passage number and seeding density) - Incubation conditions - Washing conditions - Precipitation noted - Other:  LUCIFERASE ACTIVITY MEASUREMENTS - Choice of luminometer with demonstration of appropriate luminescence measurements based on control test - Plate used - Lysate preparation - Other:  DATA EVALUATION - Cytotoxicity assessment - Prediction model used - Other:  442E  PREPARATION OF TEST SOLUTIONS - Preparation of the test chemical stock solution - Preparation of the test chemical serial dilutions - Preparation of the positive controls - Preparation of the solvent, vehicle and negative controls - Stable dispersion obtained - Log Kow of the test chemical - Other:  DOSE RANGE FINDING ASSAY: - Highest concentration used - Solubility in solvents - Solubility in incubation medium - Results of selecting appropriate concentration and determination of cytotoxicity e.g. CV75 - Final concentration range selected on basis of: [describe]  APPLICATION OF THE TEST CHEMICAL AND CONTROL SUBSTANCES - Number of replicates - Number of repetitions - Test chemical concentrations - Application procedure - Exposure time - Study evaluation and decision criteria used - Description on study acceptance criteria - Other:  SEEDING AND INCUBATION - Seeding conditions (passage number and seeding density) - Incubation conditions - Washing conditions - Other:  MEASUREMENT OF CELL SURFACE EXPRESSION/LUCIFERASE ACTIVITY For h-CLAT and USENS - Flow cytometry used - Plate used - Propidium iodide staining/cytotoxicity measurements - Preparation for CD54 and/or CD86 expression measurements/cell staining - Other:  For IL8-Luc: - Luminometer used with demonstration of appropriate luminescence measurements based on control test - Plate used - Other:  DATA EVALUATION - Cytotoxicity assessment - Prediction model used - Other: | PREPARATION OF TEST SOLUTIONS: describe how test solutions were prepared to obtain suitable concentration including specific substance details on the materials used (EC/CAS, purity, treatment of the material) etc. If stable dispersion is not obtained and the test solution is still used, add an explanation why this is not considered to affect the validity of the study.  DOSE RANGE FINDING ASSAY: describe the highest concentration used for the dose range finding assay and how appropriate doses were selected taking solubility and cytotoxicity into account. Specify which solvents were used and finally selected and how cytotoxicity assessment was performed.  APPLICATION OF THE TEST CHEMICAL AND CONTROL SUBSTANCES: describe the application of test chemical and control substance exposure conditions in detail.  SEEDING AND INCUBATION: describe the seeding and incubation conditions and whether precipitation was noted.  MEASUREMENT OF CELL SURFACE EXPRESSION/LUCIFERASE ACTIVITY: describe the steps taken to ensure the suitability of the cell surface marker expression/luciferase activity measurements for the test chemical, including solvents used  LUCIFERASE ACTIVITY MEASUREMENTS: describe the steps taken to ensure the suitability of the luciferase activity measurements for the test chemical, including solvents used  DATA EVALUATION: report the cytotoxicity measurements taken and the prediction model to be used. |  |
|  | Vehicle / solvent control | List (picklist)  Display: Basic | **Picklist values:** - cell culture medium - DMSO - saline [442E] - water - X-VIVO 15 [442E] - other: | Select the vehicle/solvent as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent. |  |
|  | Negative control | List (picklist)  Display: Basic | **Picklist values:** - DL-Lactic acid - not applicable - other: | Select the negative control as appropriate. If no negative control required (Keratinosens), select 'not applicable'. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent. |  |
|  | Positive control | List (picklist)  Display: Basic | **Picklist values:** - 4-nitrobenzyl bromide (4-NBB) [442E] - cinnamic aldehyde [442D] - dinitrochlorobenzene (DNCB) [442E] - EGDMA (120 M) [442D] - nickel sulfate [442E] - picrylsulfonic acid/2,4,6-trinitro-benzene-sulfonic acid (TNBS) [442E] - other: | Select the positive control as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard positive control. |  |
|  | **In chemico test system** | **Header 2** |  |  | **Guidance for field condition:** Condition: Show and activate fields under this heading if 'Endpoint' is '\*in chemico' |
|  | Details of test system | List multi. (multi-select list with remarks)  Display: Basic | **Picklist values:** - cysteine derivative NAC - cysteine peptide, (Ac-RFAACAA-COOH) - lysine derivative NAL - lysine peptide (Ac-RFAAKAACOOH) - other: | Indicate the purity of the peptides used in the 'remarks' field.  If standard peptides are not used, please select ‘other:’ and specify in the freetext field the exact details of the peptide used and supporting information on the scientific validity of their use. |  |
|  | Details on the study design | Text template  Display: Detailed | **Freetext template:** PREPARATION OF TEST SOLUTIONS - Preparation of the peptide/derivative stock solutions - Preparation of the test chemical solutions - Preparation of the positive controls, reference controls and co-elution controls  INCUBATION - Incubation conditions - Precipitation noted  DETECTION For ADRA and DPRA:PREPARATION OF THE HPLC - Standard calibration curve for both Cys- and Lys-peptide or NAC and NAL, as appropriate - Verification of the suitability of the HPLC for test chemical and control substances  DATA EVALUATION - Cys and Lys peptide detection wavelength, as appropriate For the kDPRA: Fluorescent probe used Excitation and emission wavelength used Analysis of potential fluorescence interference with the test agent | PREPARATION OF TEST SOLUTIONS: describe how test solutions were prepared to obtain suitable concentration including specific substance details on the materials used (EC/CAS, purity, treatment of the material) etc.  INCUBATION: describe the incubation conditions and whether precipitation was noted.  PREPARATION OF THE HPLC: describe the steps taken to ensure the suitability of the HPLC for the test chemical, including solvents used  DATA EVALUATION: report the UV wavelength used for peptide/derivative detection.  Describe whether mBrB was used or an alternative fluorescent probe.  Indicate whether Fluorescent interaction was noted based on the measures described in the SOP. |  |
|  | Vehicle / solvent | List (picklist)  Display: Basic | **Picklist values:** - 1:1 mix, acetone:acetonitrile - 1:1 mix, water:acetonitrile - acetone - acetonitrile - isopropanol - mix DMSO:acetonitrile - water - other: | Select the vehicle/solvent as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard vehicle/solvent. |  |
|  | Positive control | List (picklist)  Display: Basic | **Picklist values:** - cinnamic aldehyde - [CAS 104-55-2] - phenylacetaldehyde - [CAS 122-78-1] - other: | Select the positive control as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard positive control. |  |
|  | **In silico test system** | **Header 2** |  |  | **Guidance for field condition:** Condition: Show and activate fields under this heading if 'Endpoint' is '\*in silico' |
|  | Details of test system | List multi. (multi-select list with remarks)  Display: Basic | **Picklist values:** - ITSv1: Derek Nexus - ITSv2: OECD QSAR Toolbox - other: | Select the test system as appropriate. If not available from the picklist, select 'other:' and provide detailed justification for not using a standard test system. |  |
|  | Details on the study design | Text template  Display: Basic | **Freetext template:** TEST PROTOCOL - Derek Nexus: Skin sensitisation predictions according to OECD TG 497 (Annex 2): - OECD QSAR Toolbox: Skin sensitisation predictions according to OECD TG 497 (Annex 2): - other: | Based on this freetext template further details on the QSAR model or deviations can be given (if needed).  In silico predictions have to cover the whole composition of the registered substance, i.e. that more than one structure might need to be predicted:  - For mono-constituent substances, in addition to the main constituent, individual predictions have to be run for eventual impurities and/or additives present at significant concentrations in the composition of the substance-  - For multi-constituent substances, all constituents have to be predicted individually.  - For UVCB substances, one or more representative substances have to be selected and individually predicted. The selection has to be justified. |  |
|  | **In vivo test system** | **Header 2** |  |  | **Guidance for field condition:** Condition: Show and activate fields under this heading if 'Endpoint' is not '\*in vitro' or '\*in chemico' or '\*in silico' |
|  | **Test animals** | **Header 3** |  |  |  |
|  | Species | List (picklist)  Display: Basic | **Picklist values:** - guinea pig - mouse - rabbit - other: | Select as appropriate. For in vitro tests, indicate the species used as source of the test system. If not available from picklist, select 'other' and specify.  NOTE: Human data should be reported in an appropriate subsection of section 'Exposure related observations', particularly subsection 'Sensitisation data'.  It can be useful to document, in section 'Skin sensitisation', that human data are provided by creating a record and referring to the human data in field '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:** - Abyssinian - [guinea pig] - AKR - [mouse] - Angora - [rabbit] - B6C3F1 - [mouse] - Balb/c - [mouse] - Belgian Hare - [rabbit] - C3H - [mouse] - C57BL - [mouse] - CAF1 - [mouse] - Californian - [rabbit] - CB6F1 - [mouse] - CBA - [mouse] - CBA/Ca - [mouse] - CBA:J - [mouse] - CBA:JN - [mouse] - CD-1 - [mouse] - CF-1 - [mouse] - Chinchilla - [rabbit] - DBA - [mouse] - DBF1 - [mouse] - Dunkin-Hartley - [guinea pig] - Dutch - [rabbit] - Flemish Giant - [rabbit] - FVB - [mouse] - Hartley - [guinea pig] - Himalayan - [rabbit] - ICL-ICR - [mouse] - ICR - [mouse] - New Zealand Black - [rabbit] - New Zealand Red - [rabbit] - New Zealand White - [rabbit] - NMRI - [mouse] - Nude - [mouse] - Nude Balb/cAnN - [mouse] - Nude CD-1 - [mouse] - Peruvian - [guinea pig] - Pirbright-Hartley - [guinea pig] - Polish - [rabbit] - San Juan - [rabbit] - Sencar - [mouse] - Shorthair - [guinea pig] - SIV 50 - [mouse] - SKH/HR1 - [mouse] - Strain A - [mouse] - Swiss - [mouse] - Swiss Webster - [mouse] - Tif:MAGf - [mouse] - Vienna White - [rabbit] - other: - not specified | Select strain as appropriate. If not available from picklist, select 'other' and specify. In the supplementary remarks field, also specify the substrain if not specified by picklist item. Provide rationale for choice of strain and substrain if deviating from the ones recommended by the test guideline used. |  |
|  | Sex | List (picklist)  Display: Basic | **Picklist values:** - female - male - male/female - not specified | Select as appropriate. If females were used, indicate in field “Details on test animals and environmental conditions” whether nulliparous and non-pregnant. |  |
|  | Details on test animals and environmental conditions | Text template  Display: Detailed | **Freetext template:** TEST ANIMALS - Source: - Females (if applicable) nulliparous and non-pregnant: [yes/no/not specified] - Microbiological status of animals, when known: - Age at study initiation: - Weight at study initiation: - Housing: - Diet (e.g. ad libitum): - Water (e.g. ad libitum): - Acclimation period: - Indication of any skin lesions:  ENVIRONMENTAL CONDITIONS - Temperature (°C): - Humidity (%): - Air changes (per hr): - Photoperiod (hrs dark / hrs light): - IN-LIFE DATES: From: To: | Use freetext template and delete/add elements as appropriate. Enter any details that could be relevant for evaluating this study summary or that are requested by the respective regulatory programme. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof.  Explanations:  - Diet: Describe type of diet (e.g. conventional laboratory diet / caloric restriction) and whether it was provided ad libitum.  - Water: Describe type (e.g. drinking water) and whether it was provided ad libitum.  - 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). |  |
|  | **Study design: in vivo (non-LLNA)** | **Header 3** |  |  | **Guidance for field condition:** Condition: Show and activate fields under this heading if 'Endpoint' is '\*in vivo (non-LLNA)' |
|  | **Induction** | **Block of fields (repeatable) Start** |  | Record the vehicle, test substance concentrations used for induction exposure(s), the total amount of substance applied and the day(s) and duration of the induction. Copy this block of fields as appropriate. |  |
|  | Route | List (picklist)  Display: Basic | **Picklist values:** - epicutaneous, open - epicutaneous, occlusive - epicutaneous, semiocclusive - intradermal - intradermal and epicutaneous - other: | Indicate the route of induction exposure. |  |
|  | Vehicle | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - unchanged (no vehicle) - acetone/olive oil (4:l v/v) - arachis oil - beeswax - carbowaxe - castor oil - CMC (carboxymethyl cellulose) - coconut oil - corn oil - cotton seed oil - N,N-dimethylformamide - DMSO - hydrogenated vegetable oil - lecithin - macrogel ester - maize oil - methyl ethyl ketone - olive oil - paraffin oil - peanut oil - petrolatum - physiological saline - poloxamer - polyethylene glycol - propylene glycol - silicone oil - sorbitan derivative - soya oil - theobroma oil - vegetable oil - water - other: - not specified | Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. If the vehicle used is not from the list provided in the test guideline, a rationale should be provided. |  |
|  | Concentration / amount | Text (2,000 char.)  Display: Basic |  | Provide the test substance concentrations used for induction exposures and the total amount of substance applied (i.e. undiluted, %, % active substance, FCA, mg, g). Provide justification for dose selection (including results from pre-screen test, if conducted). |  |
|  | Day(s)/duration | Text (255 char.)  Display: Basic |  | Indicate the day number(s) on which the induction took place and as appropriate the duration (e.g. day 5-7 and day 6-8). |  |
|  | Adequacy of induction | List (picklist)  Display: Basic | **Picklist values:** - highest concentration used causing mild-to-moderate skin irritation and well-tolerated systemically - highest technically applicable concentration used - non-irritant substance, but skin pre-treated with 10% SDS - not specified - other: | Indicate if the test concentration used for the induction exposure was well-tolerated systemically and the highest to cause mild-to-moderate skin irritation, or if the highest technically applicable concentration used. If the substance is a non-irritant, indicate in field 'Details on study design' the appropriate pre-treatment applied for causing local irritation. |  |
|  | **Induction** | **Block of fields (repeatable) End** |  |  |  |
|  | **Challenge** | **Block of fields (repeatable) Start** |  | Record the vehicle, test substance concentrations used for challenge exposure(s), the total amount of substance applied and the day(s) and duration of challenge. Copy this block of fields as appropriate. Consecutive numbers can be entered in the subfield "No." for indicating multiple challenges. |  |
|  | No. | List (picklist)  Display: Basic | **Picklist values:** - #1 - #2 - #3 - #4 - #5 - #6 - #7 - #8 - #9 - #10 - #11 - #12 - #13 - #14 - #15 - #16 - #17 - #18 - #19 - #20 | For indicating multiple challenges or rechallenge select a consecutive number from drop-down list. |  |
|  | Route | List (picklist)  Display: Basic | **Picklist values:** - epicutaneous, open - epicutaneous, occlusive - epicutaneous, semiocclusive - intradermal - intradermal and epicutaneous - other: | Indicate the route of challenge exposure. |  |
|  | Vehicle | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - unchanged (no vehicle) - acetone/olive oil (4:l v/v) - arachis oil - beeswax - carbowaxe - castor oil - CMC (carboxymethyl cellulose) - coconut oil - corn oil - cotton seed oil - N,N-dimethylformamide - DMSO - hydrogenated vegetable oil - lecithin - macrogel ester - maize oil - methyl ethyl ketone - olive oil - paraffin oil - peanut oil - petrolatum - physiological saline - poloxamer - polyethylene glycol - propylene glycol - silicone oil - sorbitan derivative - soya oil - theobroma oil - vegetable oil - water - other: - not specified | Select 'unchanged (no vehicle)' if none was used or select vehicle used if any. Further information can be given in the supplementary remarks field. If the vehicle used is not from the list provided in the test guideline, a rationale should be provided. |  |
|  | Concentration / amount | Text (2,000 char.)  Display: Basic |  | Provide the test substance concentrations used for challenge exposures and the total amount of substance applied (i.e. undiluted, %, % active substance, FCA, mg, g). Provide justification for dose selection (including results from pre-screen test, if conducted). |  |
|  | Day(s)/duration | Text (255 char.)  Display: Basic |  | Indicate the day number(s) on which the induction took place and as appropriate the duration (e.g. day 5-7 and day 6-8). |  |
|  | Adequacy of challenge | List (picklist)  Display: Basic | **Picklist values:** - highest non-irritant concentration - not specified - other: | Indicate if the test concentration used for the challenge exposure was the highest non-irritation dose. |  |
|  | **Challenge** | **Block of fields (repeatable) End** |  |  |  |
|  | No. of animals per dose | Text (2,000 char.)  Display: Basic |  | Provide number of animals per dose or range if different numbers were used, e.g. '10 (controls), 10-20 (in test groups)'. |  |
|  | Details on study design | Text template  Display: Detailed | **Freetext template:** RANGE FINDING TESTS:     MAIN STUDY  A. INDUCTION EXPOSURE  - No. of exposures:   - Exposure period:   - Test groups:   - Control group:   - Site:   - Frequency of applications:   - Duration:   - Concentrations:     B. CHALLENGE EXPOSURE  - No. of exposures:   - Day(s) of challenge:   - Exposure period:   - Test groups:   - Control group:   - Site:   - Concentrations:   - Evaluation (hr after challenge):     OTHER: | For in vivo non-LLNA sensitisation tests, describe any range finding tests (pilot study) and for the main study the induction and challenge procedures including the type of information given in the freetext template. 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.  Example for Freund's Complete Adjuvant (FCA) test (partly adopted from OECD 406):  - A. INDUCTION EXPOSURE  - No. of exposures: 5  - Exposure period: -  - Test groups: TS in FCA  - Control group: FCA only  - Site: R flank  - Frequency of applications: every 2nd day  - Duration: 0-8 d  - Concentrations: same throughout  B. CHALLENGE EXPOSURE  - No. of exposures: 2  - Day(s) of challenge: 22 & 35  - Exposure period: -  - Test groups: TS  - Control group: TS  - Site: L flank  - Concentrations: 4 different  - Evaluation (hr after challenge): 24, 48, 72 |  |
|  | Challenge controls | Text (2,000 char.)  Display: Detailed |  | Discuss the use of a challenge (i.e. naive) control group: number and sex of animals, dose for challenge application. |  |
|  | Positive control substance(s) | List sup. (picklist with remarks)  Display: Detailed | **Picklist values:** - yes - no - not specified - not required | Indicate if positive control substance(s) was/were used. If yes, describe the positive control(s) in supplementary field as appropriate. If no, describe any periodic or historic positive control(s). |  |
|  | **Study design: in vivo (LLNA)** | **Header 3** |  |  | **Guidance for field condition:** Condition: Show and activate fields under this heading if 'Endpoint' is '\*in vivo (LLNA)' |
|  | Vehicle | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - unchanged (no vehicle) - acetone/olive oil (4:1 v/v) - dimethyl sulphoxide - dimethylformamide - methyl ethyl ketone - propylene glycol - 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. If the vehicle used is not from the list provided in the test guideline, a rationale must be provided. |  |
|  | Concentration | Text (2,000 char.)  Display: Basic |  | Describe dose selection, i.e. at least 3 consecutive concentrations (100%, 50%, 25% 10%, 5%, 2.5%, 1%, 0.5% etc.) of the test substance. Adequate scientific rationale should accompany the selection of the concentration series used. |  |
|  | No. of animals per dose | Text (2,000 char.)  Display: Basic |  | Provide number of animals per dose or range if different numbers were used. |  |
|  | Details on study design | Text template  Display: Detailed | **Freetext template:** PRE-SCREEN TESTS: - Compound solubility: - Irritation: - Systemic toxicity: - Ear thickness measurements: - Erythema scores:  MAIN STUDY  ANIMAL ASSIGNMENT AND TREATMENT - Criteria used to consider a positive response:  TREATMENT PREPARATION AND ADMINISTRATION: | For LLNA, LLNA:DA or LLNA:BrdU-ELISA, describe details on materials and methods as indicated in the freetext template. 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.  - Details on radio isotope: to be included in field 'Details on test material'  - RANGE FINDING TESTS: Briefly describe compound solubility, irritation and lymph node proliferation response if significant.  - PRE-SCREEN TESTS: Briefly describe compound solubility, irritation, systemic toxicity (changes in: nervous system function, behaviour, respiratory patterns, food and water consumption), ear thickness measurements, erythema scores (0-3 on any day of measurement).  MAIN STUDY  - ANIMAL ASSIGNMENT AND TREATMENT: Indicate name of test method used. Comment on criteria used to consider a positive response.  - TREATMENT PREPARATION AND ADMINISTRATION: Describe dose preparation and administration. (e.g. for LLNA:BrdU-ELISA 25 µl of compound x was applied to the entire dorsal surface of each ear of each mouse. The application was repeated on days 2 and 3). On day 5 an injection of 0.5 ml (5mg/mouse) of BrdU (10 mg/ml) solution was made inter-peritoneally for each experimental mouse. Twenty-four hours later, the draining auricular lymph node of each ear was excised into PBS (indicate individual animal approach or pooled animal approach). A single cell suspension of lymph node cells was prepared from each mouse (describe method of cell suspension). |  |
|  | Positive control substance(s) | List multi. (multi-select list with remarks)  Display: Basic | **Picklist values:** - hexyl cinnamic aldehyde (CAS No 101-86-0) - eugenol (CAS No 97-53-0) - mercaptobenzothiazole (CAS No 149-30-4) - other: - not specified | Indicate the positive control substance(s) used and give additional remarks in supplementary field as appropriate, e.g. the concentration used.  Multiple selection is possible. If not listed, select 'other' and specify. |  |
|  | Statistics | Text (2,000 char.)  Display: Detailed |  | Provide the statistical procedures employed (e.g., linear regression analysis or William’s test to assess dose-response trends; Dunnett's test to make pairwise comparisons). |  |
|  | 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 template  Display: 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** |  |  |  |
|  | Positive control results | Text (2,000 char.)  Display: Detailed |  | Discuss the positive control results and demonstrate that the laboratory has the capability to identify positive dermal sensitizers. |  |
|  | **In vitro / in chemico** | **Header 2** |  |  | **Guidance for field condition:** Condition: Show and activate fields under this heading if 'Endpoint' is '\*in vitro' or '\*in chemico' or generic title 'Skin sensitisation, other' |
|  | **Results** | **Block of fields (repeatable) Start** |  | Indicate the test results. Copy this block of fields as appropriate.  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 "Any other information on results incl. tables".  (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', 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. |  |
|  | Key result | Check box  Display: Basic |  | Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.  Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Group | List (picklist)  Display: Basic | **Picklist values:** - test chemical - other: |  |  |
|  | Run / experiment | List (picklist)  Display: Basic | **Picklist values:** - mean - run/experiment 1 - run/experiment 2 - run/experiment 3 - other: | Indicate the run / experiment the measurement relates to. |  |
|  | Parameter | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - CV70 [442E] - CV75 [442D and 442E] - cysteine depletion - EC 1.5 [442D] - EC150, CD86 [442E] - EC200, CD54 [442E] - IC30 [442D] - IC50 [442D] - Imax [442D] - Ind-IL8LA [442E] - Inh-GAPLA [442E] - logarithm of the maximum kinetic rate constant of cysteine peptide depletion reaction (log kmax) [442C] - lysine depletion - mean cystein depletion - mean lysine depletion - mean NAC depletion - mean NAL depletion - NAC depletion - NAL depletion - nlIL8LA [442E] - RFI CD54>150 [442E] - RFI CD86>200 [442E] - other: | Select type of parameter from picklist, if applicable. Further details can be given in the supplementary remarks field. Please include EC150 and EC200 values, if those can be calculated. |  |
|  | Value | Numeric (decimal including unit)  Display: Basic | **Unit [xx]:** - % - µg/mL - µM - mg/mL - mM - s-1M-1 | Indicate also the unit of measurement e.g. µM, mM, µg/ml, mg/ml etc. |  |
|  | At concentration | Numeric (decimal including unit)  Display: Basic | **Unit [xx]:** - mM - other: |  |  |
|  | Cell viability | Text (32,768 char.)  Display: Basic |  |  |  |
|  | 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. without test substance, with/without solvent) 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) is valid, i.e. substance(s) with known lack of irritation/corrosion in the test conducted. 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) is valid, i.e. substance(s) with known irritation/corrosion in the test conducted. 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 skin sensitisation - no relevant increase - positive indication of skin sensitisation - 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** |  |  |  |
|  | Outcome of the prediction model | List (picklist)  Display: Basic | **Picklist values:** - data inconclusive - high reactivity [in chemico] - low reactivity [in chemico] - moderate reactivity [in chemico] - negative [in vitro/in chemico] - no or minimal reactivity [in chemico] - positive [in vitro/in chemico] - other: | For DPRA, the mean peptide % depletion values have been specified for each reactivity group in the test guideline for each prediction model. |  |
|  | Other effects / acceptance of results | Text template  Display: Basic | **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: - Acceptance criteria met for reference controls A to C: - Acceptance criteria met for co-elution controls (Lysine- and Cysteine-peptide or NAC / NAL, as appropriate): - Acceptance criteria met for variability between replicate measurements: - Range of historical values if different from the ones specified in the test guideline: | Use 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 control, positive control, and variability between replicate measurements) 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 silico** | **Header 2** |  |  | **Guidance for field condition:** Condition: Show and activate fields under this heading if 'Endpoint' is '\*in silico' or generic title 'Skin sensitisation, other' |
|  | **Results** | **Block of fields (repeatable) Start** |  | Indicate the test results. Copy this block of fields as appropriate.  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 "Any other information on results incl. tables".  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. |  |
|  | Key result | Check box  Display: Basic |  | Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.  Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Group | List (picklist)  Display: Basic | **Picklist values:** - test chemical - other: |  |  |
|  | Parameter | List (picklist)  Display: Basic | **Picklist values:** - score - other: |  |  |
|  | Value | List (picklist)  Display: Basic | **Picklist values:** - 0 - 1 | For the in silico prediction, a positive outcome is assigned a score of 1 and a negative outcome is assigned a score of 0. |  |
|  | Remarks on result | List sup. (picklist with remarks - 2,000 char.)  Display: Basic | **Picklist values:** - no indication of skin sensitisation - no relevant increase - positive indication of skin sensitisation - 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** |  |  |  |
|  | Outcome of the prediction model | List (picklist)  Display: Basic | **Picklist values:** - data inconclusive - non-skin sensitiser [in silico] - skin sensitiser [in silico] - other: |  |  |
|  | **In vivo (non-LLNA)** | **Header 2** |  |  | **Guidance for field condition:** Condition: Show and activate fields under this heading if 'Endpoint' is '\*in vivo (non-LLNA)' or generic title 'Skin sensitisation, other' |
|  | **Results** | **Block of fields (repeatable) Start** |  | Record the results of in vivo non-LLNA tests at the different readings for each test or control group used. Copy this block of fields as appropriate.  Present the scores from the challenge responses in a table.  (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', 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. |  |
|  | Key result | Check box  Display: Basic |  | Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.  Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Reading | List (picklist)  Display: Basic | **Picklist values:** - 1st reading - 2nd reading - rechallenge - other: | Select from drop-down list. |  |
|  | Hours after challenge | Numeric (decimal)  Display: Basic |  | Enter numeric value. |  |
|  | Group | List (picklist)  Display: Basic | **Picklist values:** - negative control - test chemical - positive control - other: | Select from drop-down list. |  |
|  | Dose level | Text (255 char.)  Display: Basic |  | If more than one concentration was tested at challenge, specify the concentration(s) the reading refers to, e.g. '0.15 g of a 10% aqueous solution'. Several dose levels can be given if the results reported in this block of fields is the same for all challenge groups, e.g. '0.15 or 0.3 g of a 10% aqueous solution'. |  |
|  | No. with + reactions | Numeric (integer)  Display: Basic |  | Enter numeric value. |  |
|  | Total no. in group | Numeric (integer)  Display: Basic |  | Enter numeric value. |  |
|  | Clinical observations | Text (255 char.)  Display: Basic |  | Briefly describe relevant clinical observations. |  |
|  | Remarks on result | List sup. (picklist with remarks - 2,000 char.)  Display: Basic | **Picklist values:** - no indication of skin sensitisation - positive indication of skin sensitisation - 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** |  |  |  |
|  | **In vivo (LLNA)** | **Header 2** |  |  | **Guidance for field condition:** Condition: Show and activate fields under this heading if 'Endpoint' is '\*in vivo (LLNA)' or generic title 'Skin sensitisation, other' |
|  | **Results** | **Block of fields (repeatable) Start** |  | Indicate the cell proliferation results for the test substance, i.e. either ATP (measured adenosine triphosphate content of lymphocytes) or BrdU (measured 5-bromo-2-deoxyuridine content in DNA of lymphocytes) or DPM (incorporated radioactivity as disintegrations per minute) or other. Copy this block of fields as appropriate.  (Q)SAR results can be reported under the appropriate heading, i.e. 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo (LLNA)', 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.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 "Cellular proliferation data / Observations" and/or upload a table in the field "Any other information on results incl. tables".  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. |  |
|  | Key result | Check box  Display: Basic |  | Set this flag for identifying the key information which is of potential relevance for hazard/risk assessment or classification purpose.  Consult any programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) on how to use this field. |  |
|  | Parameter | List sup. (picklist with remarks)  Display: Basic | **Picklist values:** - SI - EC3 - ECt - other: | Select type of parameter from picklist, if applicable, i.e. either SI (stimulation index) or EC3 (estimated concentration of a test substance needed to produce a stimulation index of three) or ECt (estimated concentration of a test substance needed to produce a stimulation index that is indicative of a positive response) or other (specify). Further details can be given in the supplementary remarks field. |  |
|  | Value | Numeric range (decimal)  Display: Basic | **Lower numeric field [xx]:** - > - >= - ca. **Upper numeric field [xx]:** - < - <= - ca. | Provide the numeric value or a range of values if reported so.  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. |  |
|  | Variability | Text (255 char.)  Display: Basic |  | Indicate the standard deviation or other appropriate measure of variability that takes into account the inter-animal variability in both the test substance and control groups when using the individual animal approach. |  |
|  | Test group / Remarks | Text (255 char.)  Display: Basic |  | Indicate the concentration of the test material, the run / experiment number the calculated value relates to and any other relevant information. Examples: Exp. 1 (0%); Exp. 1 (0.5%); Exp. 1 (1%), etc. or Mean of three runs (0%), etc. |  |
|  | Remarks on result | List sup. (picklist with remarks - 2,000 char.)  Display: Basic | **Picklist values:** - no indication of skin sensitisation based on QSAR/QSPR prediction - positive indication of skin sensitisation based on QSAR/QSPR prediction - 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** |  |  |  |
|  | Cellular proliferation data / Observations | Text template  Display: Detailed | **Freetext template:** CELLULAR PROLIFERATION DATA  DETAILS ON STIMULATION INDEX CALCULATION  EC3 CALCULATION  CLINICAL OBSERVATIONS:   BODY WEIGHTS  SIGNS OF TOXICITY (including dermal irritation at the site of administration, if any, e.g. increased ear thickness). | For robust study summaries or as requested by the regulatory programme, tabulate the raw data (unless these data are given in above block of fields 'Stimulation index / EC value') and indicate any relevant observations. Use freetext template and delete/add elements as appropriate.  Alternatively or in addition refer to appropriate table(s), which were uploaded in the rich text field 'Any other information on results incl. tables'. Use predefined table if any or adapt table(s) from study report. Use table numbers in the sequence in which you refer to them (e.g. '... see Table 1').  Provide the results of cellular proliferation measurements (DPM values for conventional LLNA or ATP content values for LLNA: DA or BrdU content values for LLNA: BrdU-ELISA). Comment on dose-response trends and comparisons with the vehicle control group. Give statistical comparisons of group mean measurements compared to control. Indicate whether results are from the individual animals or pooled. Indicate whether the overall result is positive or negative.  Note: Specific tables may be required. Consult the programme-specific guidance (e.g. OECD Programme, Pesticides NAFTA or EU REACH) thereof. |  |
|  | **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 and provide raw data results, You can for example copy the tables from the full study report or use the table templates published on the OECD Harmonised Templates website for this specific template. 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 (skin sensitising) based on GHS criteria - Category 1A (indication of significant skin sensitising potential) based on GHS criteria - Category 1B (indication of skin sensitising potential) 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 'sensitising' or 'not sensitising' 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. |
|  | 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. |  |