**Template #301: Manufacture - OHT *(Version [6.0]-[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** |
| --- | --- | --- | --- | --- | --- |
|  | Manufacture | Tab |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  |  |  |
|  | Manufacture name | Text (2,000 char.)Display: Basic |  | The name of the reported manufacturing can be entered here. The name is important to uniquely label the nature and scope of the activities covered. Further details can be provided in the brief description of manufacturing process and the contributing activity / technique names. If an exposure assessment has been carried out, the manufacture name forms the 'Exposure scenario name' in the relevant section when this use section and the exposure scenario section are linked. Please note: If manufacturing takes place under a variety of conditions it may be necessary to report more than one set of entries under this life cycle stage. |  |
|  | Further description of the manufacturing process | Text (rich-text area)Display: Basic |  | Describe the technological process used for the manufacture of the substance. It might include specification of the type of system in which the substance is processed (continuous/batchwise), duration and frequency of processing, maximum capacity per time-unit, pressure and temperature during processing, solvents used, processing efficiency). The information provided here should be both concise and sufficiently concrete to support the understanding of readers who are not familiar with the details of the technologies in the sector. |  |
|  | Tonnage of substance manufactured (tonnes/year) | Numeric range (decimal)Display: Basic | **Lower numeric field [xx]:**- >- >=- ca.**Upper numeric field [xx]:**- <- <=- ca. | Enter the tonnage per year for this use\*). Provide further details in the next field to support the interpretation of the value provided here. (Consult the relevant legislation-specific guidance on what kind of information is expected). The tonnage value should be entered preferably as single value. If a range is provided, in context of safety assessment, the upper value may be considered as the relevant one depending on the regulatory framework. \*) The term 'use' is applied in a generic manner, regardless of the life cycle stage it refers to. Depending on the regulatory framework more specific terms may be required. | **Remarks:**The field type Numeric range includes a generic help text which guides the user to enter a single value |
|  | Details on tonnage reported | Text (32,768 char.)Display: Basic |  | Additional information on the tonnage figure can be entered in field 'Details on tonnage reported', e.g. source of information and method for generating this tonnage (e.g. market survey by sector), the calendar year, regional reference, historical data and information on sites. It may also important to indicate whether or not the tonnage relates to a total market volume for that use (across all manufacturers and importers). |  |
|  | **Contributing activity / technique for the environment** | **Block of fields (repeatable) Start** |  |  |  |
|  | Name of activity / technique | Text (2,000 char.)Display: Basic |  | Enter a name here for an activity / technique contributing to the use described.A use may consist of one or more contributing activities, processes, tasks or unit operations. From the environmental perspective the focus is on the type of technique(s) operated at a site from a potential release perspective. If an exposure assessment has been carried out, each contributing scenario is related to a specific contributing activity / technique. |  |
|  | Environmental release category (ERC) | List multi. (multi-select list)Display: Basic | **Picklist values:**- ERC1: Manufacture of the substance | A category can be assigned to the type of process described, providing a generic characterisation from the environmental perspective. |  |
|  | **Contributing activity / technique for the environment** | **Block of fields (repeatable) End** |  |  |  |
|  | **Contributing activity / technique for workers** | **Block of fields (repeatable) Start** |  |  |  |
|  | Name of activity / technique | Text (2,000 char.)Display: Basic |  | Enter a name here for an activity / technique contributing to the use described. A use may consist of one or more contributing activities, processes, tasks or unit operations. From the environmental perspective the focus is on the type of technique(s) operated at a site from a potential release perspective. For example textile dyeing/finishing may be carried out with two different types of water based techniques by a textile finisher. These techniques lead to different emission factors and potentially require different types of environmental RMM. If an exposure assessment has been carried out, each contributing scenario is related to a specific contributing activity / technique. |  |
|  | Process category (PROC) | List multi. (multi-select list)Display: Basic | **Picklist values:**- PROC 1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions- PROC 2: Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions- PROC 3: Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment conditions- PROC 4: Chemical production where opportunity for exposure arises- PROC 5: Mixing or blending in batch processes- PROC 6: Calendering operations- PROC 7: Industrial spraying- PROC 8a: Transfer of substance or mixture (charging and discharging) at non-dedicated facilities- PROC 8b: Transfer of substance or mixture (charging and discharging) at dedicated facilities- PROC 9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)- PROC 10: Roller application or brushing- PROC 11: Non industrial spraying- PROC 12: Use of blowing agents in manufacture of foam- PROC 13: Treatment of articles by dipping and pouring- PROC 14: Tabletting, compression, extrusion, pelletisation, granulation- PROC 15: Use as laboratory reagent- PROC 16: Use of fuels- PROC 17: Lubrication at high energy conditions in metal working operations- PROC 18: General greasing / lubrication at high kinetic energy conditions- PROC 19: Hand-mixing with intimate contact and only PPE available.- PROC 20: Use of functional fluids in small devices- PROC 21: Low energy manipulation of substances bound in materials and/or articles- PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting- PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature- PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles- PROC 25: Other hot work operations with metals- PROC 26: Handling of solid inorganic substances at ambient temperature- PROC 27a: Production of metal powders (hot processes)- PROC 27b: Production of metal powders (wet processes)- PROC28: Manual maintenance (cleaning and repair) of machinery- PROC 0: Other: |  |  |
|  | **Contributing activity / technique for workers** | **Block of fields (repeatable) End** |  |  |  |
|  | Remarks | Text (rich-text area)Display: Basic |  |  |  |
|  | **Use takes place under rigorously contained conditions** | **Header 1** |  |  |  |
|  | Rigorously contained system with strict control for manual interventions | Check boxDisplay: Basic |  | Select the checkbox if the use by workers takes place under rigorous containment conditions (by technical means) or equivalent conditions leading to negligible exposure (including strict controls for short and/or infrequent manual interventions), e.g. sampling).Making a claim here enables description of such conditions in other fields. |  |
|  | Rigorously contained system with minimisation of release to the environment | Check boxDisplay: Basic |  | Select the checkbox if (residual) environmental releases from the contained system are minimised to the technically possible extent (e.g. advanced treatment of extract air or purging liquids).Making a claim here enables description of such conditions in other fields. |  |
|  | Description of non-technical means for strict control | Text templateDisplay: Basic | **Freetext template:**• Management controls• Process monitoring• Worker monitoring• Monitoring of environmental releases• Procedures for cleaning and maintenance• Procedures to respond to accident and incidents | Describe the non-technical means for strict controls at workplace, such as training, supervision and documentation. The organisational measures described are meant to support the technical means for rigorous containment. | **Guidance for field condition:**Condition: Only active if check box 'Rigorously contained system with strict control for manual interventions' is selected or if check box 'Rigorously contained system with minimisation of release to the environment' is selected or if the field 'Registration/ Notification status for the use' is 'use registered according to REACH Article 17/18'. |
|  | Contributing scenario for the environment (related to workers activities) | Tab |  |  |  |
|  | **Contributing scenario for the environment (related to workers activities)** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  |  |  |
|  | Linked contributing activity | Link to repeatable entryDisplay: Basic |  |  |  |
|  | **Conditions of use for the environment** | **Header 1** |  |  |  |
|  | **Product (article) characteristic** | **Header 2** |  |  |  |
|  |  | **Block of fields (repeatable) Start** |  |  |  |
|  | Product (article) characteristic | Text (32,768 char.)Display: Basic |  | Describe the product or article characteristic that impact on the release to the environment. |  |
|  |  | **Block of fields (repeatable) End** |  |  |  |
|  | **Amounts used, frequency and duration of use (or from service life)** | **Header 2** |  |  |  |
|  | Daily use amount at a site (tonnes/day) | Numeric (decimal)Display: Basic |  | Quantify the amount of substance used per day. This amount can refer to a use taking place at industrial site or to the use taking place in a municipality (by professionals).This amount, together with the emission factor enables determining the release rate. Note that for closed processes with reservoirs and long residence time of the substance (e.g. baths to treat surfaces) the rele-vant release value per day may be driven by the event when exchanging the bath rather than the every-day losses. In such case the use amount to be reported may be different than the daily use amount. Please pro-vide explanations in the field 'Details on daily use amount'.The amount for the generic municipality may be calculated from the market tonnage for this use (see Life cycle section) by determining the fraction proportional to a certain number of inhabitants, assuming equal spatial and annual distribution. |  |
|  | Details on daily use amount | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the information on the daily amount. For example: use amount based on statistics of generic sites carrying such use or amount corresponding to the maximum daily amount that can be safely used under the other conditions reported. |  |
|  | Annual use amount at a site (tonnes/year) | Numeric (decimal)Display: Basic |  | Quantify the amount of substance used per year at a site. Such an amount cannot be more than 365 times the daily use amount at the site. |  |
|  | Details on annual use amount | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the information on the annual amount. |  |
|  | Number of emission days (days/year) | Numeric (decimal)Display: Basic |  | For industrial sites the emission can be equally distributed over the year, or the emission can be limited to a few days spread over the year or cumulated in a certain period of time (e.g. in case of production campaigns).As a determinant of environmental exposure, the number of emissions may play a role in the following context:• The number of emission days may be so small (and so spread over the year as an additional condition) that the ecosystem can recover after the short single emission event. • The number of emission days can be used to calculate the annual amount/release from the daily amount/release. |  |
|  | Details on number of emission days | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the information on the emission days. |  |
|  | **Other conditions** | **Block of fields (repeatable) Start** |  |  |  |
|  | Other conditions related to amounts, frequency and duration of use characteristic | Text (32,768 char.)Display: Basic |  | Any other conditions of use impacting on exposure can be reported here. |  |
|  | **Other conditions** | **Block of fields (repeatable) End** |  |  |  |
|  | **Technical and organisational conditions and measures** | **Header 2** |  |  |  |
|  |  | **Block of fields (repeatable) Start** |  |  |  |
|  | Technologies to minimise emissions | Text (32,768 char.)Display: Basic |  | Describe conditions of use that are meant to minimise residual emissions to the environment occurring from rigorously contained systems. 'Minimisation' means applying the best technical means available to achieve release close to zero.When describing such conditions refer to the sources of residual release (generated although rigorous containment is in place) and explain the minimisation measures to be taken regarding emission to air and water. Include residues from cleaning and maintenance operations if relevant. | **Guidance for field condition:**Only active if the check box 'Rigorously contained system with minimisation of release to the environment' is selected. |
|  |  | **Block of fields (repeatable) End** |  |  |  |
|  | **Other technical and organisational conditions** | **Block of fields (repeatable) Start** |  |  |  |
|  | Technical and organisational conditions and measures not related to biological sewage treatment | Text (32,768 char.)Display: Basic |  | Describe conditions of use controlling releases to the environment that are not related to biological sewage treatment plants, such as wet/dry scrubbing, exhaust air incineration, onsite waste water oxidation, onsite pre-treatment by precipitation. For each measure the affected release route should be indicated, and (if relevant) an assumed or required effectiveness may be reported for each. If the measure is effective for more than one route, report each route separately. |  |
|  | **Effectiveness** | **Block of fields (repeatable) Start** |  |  |  |
|  | Effectiveness (%) | Numeric (decimal)Display: Basic |  | Indicate the typical effectiveness of the measure for the selected route. |  |
|  | Route affected | List (picklist)Display: Basic | **Picklist values:**- water- air | Select the route for which the effectiveness has been reported. |  |
|  | Details on effectiveness | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the information on effectiveness. |  |
|  | **Effectiveness** | **Block of fields (repeatable) End** |  |  |  |
|  | **Other technical and organisational conditions** | **Block of fields (repeatable) End** |  |  |  |
|  | **Conditions and measures related to Biological Sewage Treatment Plant** | **Header 2** |  |  |  |
|  | Biological Sewage Treatment Plant (STP) | List (picklist)Display: Basic | **Picklist values:**- no- municipal biological STP- site specific biological STP- site specific and municipal biological STP | Select type of biological sewage treatment applied. If no biological sewage treatment is foreseen select 'no'. In case a biological STP for which the 'settings' are standard (not use specific) is foreseen, then select 'municipal biological STP'. In case a biological STP with specific settings is foreseen, then select 'site specific biological STP'. Some setting of the site specific STP can be provided in the Field 'Details on site specific biological sewage treatment' as well as in further structured fields such as the discharge rate and whether sludge is intended to be applied to agricultural soil. |  |
|  | Details on site specific biological STP | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the information regard-ing biological sewage treatment. |  |
|  | Discharge rate of the site specific biological STP (m³/day) | Numeric (decimal)Display: Basic |  | Report the daily amount of waste-water treated and discharged into surface water from the site specific biological STP. | **Guidance for field condition:**Condition: Field only active if 'Biological Sewage Treatment Plant (STP)' contains any picklist item starting with 'Site-specific ...' |
|  | Details on discharge rate of the site specific biological STP | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the information regard-ing discharge rate. | **Guidance for field condition:**Condition: Field only active if 'Biological Sewage Treatment Plant (STP)' contains any picklist item starting with 'Site-specific ...' |
|  | Application of site specific biological STP sludge on agricultural soil | List (picklist)Display: Basic | **Picklist values:**- yes- no | Select whether or not the application of the site specific STP sludge on agricultural soil takes place, and thus has to be accounted for in the exposure estimation to soil. | **Guidance for field condition:**Condition: Field only active if Biological Sewage Treatment Plant (STP) contains any picklist item 'Site-specific ...' |
|  | Details on application of site-specific biological STP sludge | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the information regard-ing application of the site-specific STP sludge. | **Guidance for field condition:**Condition: Field only active if Biological Sewage Treatment Plant (STP) contains any picklist item 'Site-specific ...' |
|  | **Other conditions of use** | **Block of fields (repeatable) Start** |  |  |  |
|  | Other conditions of use related to biological sewage treatment plant | Text (32,768 char.)Display: Basic |  | Any other conditions of use impacting on environmental release can be reported here. |  |
|  | **Other conditions of use** | **Block of fields (repeatable) End** |  |  |  |
|  | **Conditions and measures related to external treatment of waste (including article waste)** | **Header 2** |  |  |  |
|  | Particular considerations on the waste treatment operations | List (picklist)Display: Basic | **Picklist values:**- no- dedicated re-collection infrastructure required- biological treatment not appropriate- incineration not appropriate- prevent formation of hazardous break down products in thermal destruction- treatment under rigorous containment conditions required- other: | Select one of the specific considerations if appropriate. For example, particularly hazardous metals in batteries would require a dedicated re-collection system, or biological treatment would not be appropriate for persistent substances. If substance properNties and use pattern do not call for particular considerations for the waste life stage of the sub-stance, select 'no'. If other specific concerns for waste treatment are to be reported, select 'other' and explain in “Details on waste treatment” which particular measures regarding waste treatment are needed.Note: Waste treatment includes operations aiming at recovery or disposal. |  |
|  | Details on waste treatment | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the information regard-ing waste treatment. |  |
|  | **Other conditions of use** | **Block of fields (repeatable) Start** |  |  |  |
|  | Other conditions of use related to waste treatment | Text (32,768 char.)Display: Basic |  | Any other conditions of use impacting on environmental release can be reported here. |  |
|  | **Other conditions of use** | **Block of fields (repeatable) End** |  |  |  |
|  | **Other conditions affecting environmental exposure** | **Header 2** |  |  |  |
|  | Place of use | List (picklist)Display: Basic | **Picklist values:**- indoor- indoor (room 100-1000 m³)- indoor (room >1000 m³)- outdoor | Select type of use condition. Outdoor use implies that direct release to soil (e.g. loss of lubricants for machinery in agriculture and forestry) or water (e.g. construction work at bridges, releases from boat/ship surface) can take place. Also releases from articles may be increased due to outdoor weathering conditions. |  |
|  | Details on place of use | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the information regarding indoor/outdoor use |  |
|  | Receiving surface water flow rate (m³/day) | Numeric (decimal)Display: Basic |  | Report receiving water flow rate assumed to be available for diluting the local release to water. For site specific data sets this can be the river flow rate at a specific location. For the generic assessment a river flow rate, consistent with the other assumptions (e.g. number of inhabitants in the generic municipality and discharge rate of the STP), is to be assumed. |  |
|  | Details on surface water flow rate | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the information regarding surface water flow rate. |  |
|  | **Other conditions of use** | **Block of fields (repeatable) Start** |  |  |  |
|  | Other conditions of use impacting on environmental exposure | Text (32,768 char.)Display: Basic |  | Any other conditions of use impacting on environmental exposure can be reported here. |  |
|  | **Other conditions of use** | **Block of fields (repeatable) End** |  |  |  |
|  | **Releases to waste and the environment** | **Header 1** |  |  |  |
|  |  | **Block of fields (repeatable) Start** |  |  |  |
|  | **Release to the environment** | **Header 2** |  |  |  |
|  |  | **Block of fields (repeatable) Start** |  |  |  |
|  | Release from the site to: | List (picklist)Display: Basic | **Picklist values:**- wastewater- surface water- ambient air- non-agricultural soil- agricultural soil- underground | Select the route to which the release is reported in this block of fields. The releases reported should correspond to releases from the site, i.e. before potential treatment in a (standard) 'Municipal biological sewage treatment plant'. |  |
|  | Release estimation method | List sup. (picklist with remarks)Display: Basic | **Picklist values:**- ERC- SpERC- measured release rate- estimated release factor | The release to the environment can be estimated by different release estimation models or based on measured releases. Select the method used for estimating the release used in the risk assessment.Provide explanations in the field 'Details on release estimates'. For example explain the source of the information (e.g. referring to an OECD Emission Scenario Document when Estimated release factor is the method selected). |  |
|  | Release factor from the site after on-site risk management (%) | Numeric (decimal)Display: Basic |  | This is the release factor corresponding to the overall release factor from the site, after all on-site risk management measures have been applied. |  |
|  | Local release rate from the site (kg/day) | Numeric (decimal)Display: Basic |  | The release rate is expressed in kg/day and corresponds to the amount of substance released over the day. When a release factor is provided the release rate is equal to the release factor multiplied by the daily tonnage. |  |
|  | Details on release estimates | Text templateDisplay: Basic | **Freetext template:**MONITORING STUDY DESIGN AND DESCRIPTION OF SCENARIO MONITORED- Study's design:- Scope:- Objectives and scenario being monitored:SAMPLING AND ANALYTICAL METHODS- Media Sampled:- Sampling:- Method/ Procedure:RESULTSREMARKS | Details on release estimates can be entered in this field as free text both for modelled estimates or monitoring.For monitoring information a freetext template can be uploaded and edited as an option. As appropriate delete/add elements. |  |
|  | Reliability score of measured data set | List (picklist)Display: Basic | **Picklist values:**- 1 (reliable without restriction)- 2 (reliable with restrictions)- 3 (not reliable)- 4 (not assignable)- other: | Describe the reliability of the release estimate by selecting the appropri-ate reliability score. The 'other:' option may be selected if a different scoring system is used.Consult the relevant legislation -specific guidance on how to use this field. | **Guidance for field condition:**Condition: Field only active if the item 'measured release rate' has been selected in field 'Release estimation method' |
|  | Details on reliability score | Text (32,768 char.)Display: Basic |  | Provide an explanation of the reason why this score was selected. | **Guidance for field condition:**Condition: Field only active if the item 'measured release rate' has been selected in field 'Release estimation method' |
|  |  | **Block of fields (repeatable) End** |  |  |  |
|  |  | **Block of fields (repeatable) End** |  |  |  |
|  | **Release to external waste** | **Header 2** |  |  |  |
|  | Release factor to external waste (%) | Numeric (decimal)Display: Basic |  | The release to external waste is the sum of• the fraction released from the process itself (including the fraction left in a packaging when relevant) as far as not treated on site and• the fraction moved to external waste by the on-site risk management measures (applied to waste water or exhaust air).It refers to the submission substance. |  |
|  | Details on release to external waste | Text (32,768 char.)Display: Basic |  |  |  |
|  | **Exposure of the environment** | **Header 1** |  |  |  |
|  |  | **Block of fields (repeatable) Start** |  |  |  |
|  | **Predicted exposure concentration** | **Block of fields (repeatable) Start** |  |  |  |
|  | Exposed compartment | List (picklist)Display: Basic | **Picklist values:**- freshwater- sediment (freshwater)- marine water- sediment (marine water)- predators' prey (freshwater)- predators' prey (marine water)- top predators' prey (marine water)- sewage treatment plant- air- agricultural soil- non-agricultural soil- predators' prey (terrestrial)- vegetation- other: | Select the compartment for which exposure is reported in this block of fields.Note: Only the exposure information that is to be used in the risk as-sessment should be reported. |  |
|  | Predicted exposure concentration | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- ng/L- µg/L- mg/L- g/L- ng/kg ww- µg/kg ww- mg/kg ww- g/kg ww- ng/kg dw- µg/kg dw- mg/kg dw- g/kg dw- ng/m³- µg/m³- mg/m³ | Report the exposure concentration which is to be used for characterising the risks.In field 'Details on exposure estimates', additional information can be given, e.g. measured data or case-specific modifications of modelled predictions. This may also include information on bioavailability. | **Guidance for field condition:**Conditional picklist depending on compartment selected can be implemented |
|  | Exposure estimation method | List (picklist)Display: Basic | **Picklist values:**- exposure estimation tool- measured data- other: | The exposure to the environment can be estimated by different expo-sure estimation models or based on measured concentration in the environment. Select the method used. | **Remarks:**An option ‘Apply to all’ may be implemented in any software tool (as planned for IUCLID 6) which adopts the recording of the exposure esti-mation method / tool and measured data (if applicable) to all com-partments in one go. This auto-completion should not apply if the relevant fields have been populated manually. Any editing should also be possible for each compartment. |
|  | Exposure estimation tool name | List (picklist)Display: Basic | **Picklist values:**- EUSES- CHARM- ChemCAN- ChemSTEER- SCREEN3- AERSCREEN- AIR MOD- other: | Select which exposure estimation tool has been used. | **Guidance for field condition:**Condition: Field only active if 'Exposure estimation method' is 'Exposure estimation tool' |
|  | Version of exposure estimation tool | Text (255 char.)Display: Basic |  | Provide the version number and additional details relating to the ver-sion (e.g. date or specific model or algorithm used in the case that several options are provided by the tool). | **Guidance for field condition:**Condition: Field only active if 'Exposure estimation method' is 'Exposure estimation tool' |
|  | Number of measured data points | Numeric (decimal)Display: Basic |  | Report the number of data points that have been used to derive the exposure concentration. | **Guidance for field condition:**Condition: Field only active if 'Exposure estimation method' is 'measured data' |
|  | Geometric standard deviation | Numeric (decimal)Display: Basic |  | Report the geometric standard deviation calculated from the series of available measured data points that have been used to derive the exposure concentration. | **Guidance for field condition:**Condition: Field only active if 'Exposure estimation method' is 'measured data' |
|  | Details on exposure estimates | Text templateDisplay: Basic | **Freetext template:**MONITORING STUDY DESIGN AND DESCRIPTION OF SCENARIO MONITORED- Study's design:- Scope:- Objectives and scenario being monitored:SAMPLING AND ANALYTICAL METHODS- Media Sampled:- Sampling:- Method/ Procedure:RESULTSREMARKS | Details on exposure estimates can be entered in this field as free text both for modelled estimates or measured data. This may include details on bioavailability.For monitoring information a free-text template can be uploaded and edited as an option. As appropriate delete/add elements. |  |
|  | Reliability score of measured data set | List (picklist)Display: Basic | **Picklist values:**- 1 (reliable without restriction)- 2 (reliable with restrictions)- 3 (not reliable)- 4 (not assignable)- other: |  | **Guidance for field condition:**Condition: Field only active if the item 'measured release rate' has been selected in field 'Release estimation method' |
|  | Details on reliability score | Text (32,768 char.)Display: Basic |  |  | **Guidance for field condition:**Condition: Field only active if 'Exposure estimation method' is 'measured data' |
|  | **Predicted exposure concentration** | **Block of fields (repeatable) End** |  |  |  |
|  |  | **Block of fields (repeatable) End** |  |  |  |
|  | Attachment | Attachment (multiple)Display: Basic |  | Documents can be attached here, for example export files of exposure estimation tools. |  |
|  | **Exposure of humans via the environment** | **Header 1** |  |  |  |
|  |  | **Block of fields (repeatable) Start** |  |  |  |
|  | Daily intake via food consumption | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- ng/kg bw/day- µg/kg bw/day- mg/kg bw/day | Report the dose of substance to which man is exposed via food within a day. The related food items and populations are either i) determined by the modelling tool applied, or ii) can be further specified under 'Details on exposure estimates' if measured data are reported. |  |
|  | Exposure estimation method | List (picklist)Display: Basic | **Picklist values:**- exposure estimation tool- measured data- other: | The exposure to the environment can be estimated by different exposure estimation models or based on measured concentration in the environment. Select the method used. | **Remarks:**An option ‘Apply to all’ may be implemented in any software tool (as planned for IUCLID 6) which adopts the recording of the exposure estimation method / tool and measured data (if applicable) to all compartments in one go. This auto-completion should not apply if the relevant fields have been populated manually. Any editing should also be possible for each compartment. |
|  | Exposure estimation tool name | List (picklist)Display: Basic | **Picklist values:**- EUSES- other: | Select which exposure estimation tool has been used. | **Guidance for field condition:**Condition: Field only active if 'Exposure estimation method' is 'Exposure estimation tool' |
|  | Version of exposure estimation tool | Text (255 char.)Display: Basic |  | Provide the version number and additional details relating to the version (e.g. date or specific model or algorithm used in the case that several options are provided by the tool). | **Guidance for field condition:**Condition: Field only active if 'Exposure estimation method' is 'Exposure estimation tool' |
|  | Details on exposure estimates | Text templateDisplay: Basic | **Freetext template:**MONITORING STUDY DESIGN AND DESCRIPTION OF SCENARIO MONITORED- Study's design:- Scope:- Objectives and scenario being monitored:SAMPLING AND ANALYTICAL METHODS- Media Sampled:- Sampling:- Method/ Procedure:RESULTSREMARKS | Details on exposure estimates can be entered in this field as free text both for modelled estimates or measured data. This may include details on bioavailability. For monitoring information a free-text template can be uploaded and edited as an option. As appropriate delete/add elements. |  |
|  | Reliability score of measured data set | List (picklist)Display: Basic | **Picklist values:**- 1 (reliable without restriction)- 2 (reliable with restrictions)- 3 (not reliable)- 4 (not assignable)- other: | Describe the reliability of the release estimate by selecting the appropriate reliability score. The 'other:' option may be selected if a different scoring system is used. Consult the relevant legislation -specific guidance on how to use this field. | **Guidance for field condition:**Condition: Field only active if 'Exposure estimation method' is 'measured data' |
|  | Details on reliability score | Text (32,768 char.)Display: Basic |  | Provide an explanation of the reason why this score was selected. | **Guidance for field condition:**Condition: Field only active if 'Exposure estimation method' is 'measured data' |
|  |  | **Block of fields (repeatable) End** |  |  |  |
|  | **Contributing scenario for the environment (related to workers activities)** | **Block of fields (repeatable) End** |  |  |  |
|  | Contributing scenario for the workers | Tab |  |  | **Remarks:**IT implementation issue: The section subsumed under this heading should only be active for workers uses, i.e. relation to manufacture, formulation, uses at industrial site, uses by professional workers or service life for workers. |
|  | **Contributing scenario for the workers** | **Block of fields (repeatable) Start** |  |  |  |
|  |  | ConfidentialityDisplay: Basic |  |  |  |
|  | Linked contributing activity | Link to repeatable entryDisplay: Basic |  |  |  |
|  | **Conditions of use for workers** | **Header 1** |  |  |  |
|  | **Product (article) characteristics** | **Header 2** |  |  |  |
|  | Percentage (w/w) of substance in mixture/article | Numeric (decimal)Display: Basic |  | Indicate the concentration of the substance in the mixture to which the set of described use conditions refers to. If the substance is used as such, potentially 100% is to be entered. |  |
|  | Details on the percentage of substance in mixture/article | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the concen-tration value provided. |  |
|  | Physical form of the used product | List (picklist)Display: Basic | **Picklist values:**- gas- liquefied gas- liquid, including paste/slurry/suspension- molten metal- solid object- solid (material with no or very low dustiness)- solid (material with low dustiness)- solid (material with medium dustiness)- solid (material with high dustiness)- solid (material with very high dustiness) | Select the physical form of the product as used. Note: This is not necessarily identical with the physical state/form of the substance as derived from manufacture. Also the form of the product used is not necessarily identical to the form to which the workers are exposed, as it may be modified during use, for example a liquid may be sprayed and aerosols may be formed.If the product is a solid, determine the level of dustiness by analogy:• if all or significant fraction of substance occurs in form of fine light powders similar to flour, carbon black or chalk dust select 'very dusty'• if all or significant fraction of substance occurs in form of granular solids similar to sugar or detergents select 'medium dusty'• if substance largely occurs as pellets not breaking up or wax, select 'low dusty form' |  |
|  | Details on physical form | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the physical form information. |  |
|  | **Other product (article) characteristics** | **Block of fields (repeatable) Start** |  |  |  |
|  | Other product (article) characteristics | Text (32,768 char.)Display: Basic |  | Other product characteristics impacting on exposure can be reported here. This may for example refer to viscosity of liquid product (to avoid splashes) or size of packaging (to limit amount per application).For article, any characteristics of the article impacting on the release can be reported here such as description of the matrix. |  |
|  | **Other product (article) characteristics** | **Block of fields (repeatable) End** |  |  |  |
|  | **Amounts used (or contained in articles), frequency and duration of use/exposure** | **Header 2** |  |  |  |
|  | Duration of activity (hour/day) | Numeric (decimal)Display: Basic |  | Indicate duration of worker’s activity for the set of conditions described. By default daily use (and hence long-term or re-peated dose exposure) is assumed. If the use however is limited to single short term events, the limited frequency can be reported under 'Other conditions related to amount, duration and frequency'. |  |
|  | Details on duration of activity | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the infor-mation on duration. |  |
|  | **Other conditions** | **Block of fields (repeatable) Start** |  |  |  |
|  | Other conditions related to amount, frequency and duration | Text (32,768 char.)Display: Basic |  | Other conditions related to amount, duration or frequency impacting on exposure can be reported here. This may, for example refer to amount of substance present at the relevant workplaces, and to the duration and/or frequency of use. |  |
|  | **Other conditions** | **Block of fields (repeatable) End** |  |  |  |
|  | **Technical and organisational conditions and measures** | **Header 2** |  |  |  |
|  |  | **Block of fields (repeatable) Start** |  |  |  |
|  | Technical means for rigorous containment and strict control for manual intervention | Text (32,768 char.)Display: Basic |  | Describe how the technical equipment ensures rigorous containment. Address barriers for preventing inhalation and skin exposure. Describe the short and/or infrequent manual interventions (e.g. sampling) if any, and the corresponding measures for strict controls. Describe special technical proce-dures for cleaning and maintenance (e.g. purging). | **Guidance for field condition:**Condition: Only active if the check box 'Rigorously contained system with strict control for manual interventions' is selected |
|  |  | **Block of fields (repeatable) End** |  |  |  |
|  | **Technical and organisational conditions** | **Block of fields (repeatable) Start** |  |  |  |
|  | Technical and organisational conditions and measures | Text (32,768 char.)Display: Basic |  | Describe the technical and organisational conditions (includ-ing measures determining the exposure at workplace), like for example suitable local exhaust ventilation of a certain effectiveness or long-handle tools preventing dermal exposure. An assumed or required effectiveness may be reported for each measure per route. If the measure is effective for more than one route, report each route separately.Measures related to personal protective equipment should not be reported in this section. |  |
|  | **Effectiveness** | **Block of fields (repeatable) Start** |  |  |  |
|  | Effectiveness (%) | Numeric (decimal)Display: Basic |  | Indicate the typical effectiveness of the measure for the selected route. |  |
|  | Route affected | List (picklist)Display: Basic | **Picklist values:**- dermal- inhalation | Select the route for which the effectiveness has been reported. |  |
|  | Details on effectiveness | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the information on effectiveness. |  |
|  | **Effectiveness** | **Block of fields (repeatable) End** |  |  |  |
|  | **Technical and organisational conditions** | **Block of fields (repeatable) End** |  |  |  |
|  | **Conditions and measures related to personal protection, hygiene and health evaluation** | **Header 2** |  |  |  |
|  |  | **Block of fields (repeatable) Start** |  |  |  |
|  | Personal protection equipment | Text (32,768 char.)Display: Basic |  |  |  |
|  | **Effectiveness** | **Block of fields (repeatable) Start** |  |  |  |
|  | Effectiveness (%) | Numeric (decimal)Display: Basic |  |  |  |
|  | Route affected | List (picklist)Display: Basic | **Picklist values:**- dermal- inhalation |  |  |
|  | Details on effectiveness | Text (32,768 char.)Display: Basic |  |  |  |
|  | **Effectiveness** | **Block of fields (repeatable) End** |  |  |  |
|  |  | **Block of fields (repeatable) End** |  |  |  |
|  | **Other conditions affecting workers exposure** | **Header 2** |  |  |  |
|  | Place of use | List (picklist)Display: Basic | **Picklist values:**- indoor- indoor (room 100-1000 m³)- indoor (room >1000 m³)- outdoor | Indicate whether the set of reported conditions refers to outdoor or indoor ventilation conditions. |  |
|  | Details on place of use | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the infor-mation on place of use. |  |
|  | Operating temperature (°C) | Numeric (decimal)Display: Basic |  | Report the typical temperature at which the use takes place. The temperature may impact on exposure as it may change the vapour pressure or the physical state of the substance. |  |
|  | Details on typical operating temperature | Text (32,768 char.)Display: Basic |  | Add explanation as needed for interpretation of the infor-mation on the process temperature. |  |
|  | **Other conditions of use** | **Block of fields (repeatable) Start** |  |  |  |
|  | Other conditions of use affecting workers exposure | Text (32,768 char.)Display: Basic |  | Any other conditions of use impacting on exposure can be reported here. |  |
|  | **Other conditions of use** | **Block of fields (repeatable) End** |  |  |  |
|  | **Exposure of workers** | **Header 1** |  |  |  |
|  |  | **Block of fields (repeatable) Start** |  |  |  |
|  | **Exposure estimation** | **Block of fields (repeatable) Start** |  |  |  |
|  | Type of exposure | List (picklist)Display: Basic | **Picklist values:**- inhalation (external) long-term exposure- inhalation (internal) long-term exposure- inhalation (external) short-term exposure- inhalation (internal) short-term exposure- dermal (external) long-term exposure- dermal (internal) long-term exposure- dermal (external) local concentration on skin- dermal (external) short-term exposure- dermal (internal) short-term exposure- oral (external) long-term intake- oral (internal) long-term intake- oral (external) short-term intake- oral (internal) short-term intake- concentration in tissue or body fluids | Select the type of exposure for which exposure is reported. This block of fields can be repeated.Only the exposure information that is to be used in the risk assessment should be reported.Please note that long-term exposure also covers repeated-dose exposure. Whether the systemic exposure estimate refers to external or internal exposure is determined by the tool/method used for predicting exposure. The corresponding information can be reported in the field 'Details on exposure estimates'. This may also include information on absorption (e.g. through the skin) and bioavailability.The appropriate unit has to be selected. The unit for the systemic expo-sure via dermal route is expressed as daily dose per kg bw. This unit can be used for external exposure and internal exposure.If the exposure estimate refers to concentration in body fluids (e.g. blood or urine) or tissue (e.g. hair), the corresponding item can be selected here. |  |
|  | Exposure estimate | Numeric (decimal including unit)Display: Basic | **Unit [xx]:**- ng/m³- µg/m³- mg/m³- ng/kg bw/day- µg/kg bw/day- mg/kg bw/day- ng/cm²- µg/cm²- mg/cm² | Report the exposure value which is to be used for estimating the risks.In field 'Details on exposure estimates', additional information can be given, e.g. case-specific modifications of modelled predictions. | **Guidance for field condition:**Conditional picklist depending on type of exposure selected can be implemented, see pre-selected units in IUCLID for exp.concentration |
|  | Exposure estimation method | List (picklist)Display: Basic | **Picklist values:**- exposure estimation tool- measured data- negligible exposure- other: | The exposure of workers/consumers can be estimated by different expo-sure estimation models or based on measured data. If uses take place in rigorously contained systems an exposure close to zero (negligible) can also be demonstrated based on qualitative arguments. Select the method used for estimating the exposure. |  |
|  | Exposure estimation tool name | List (picklist)Display: Basic | **Picklist values:**- ART- ChemSTEER- ECETOC TRA workers- EMKG Expo tool- IH MOD- IH SkinPerm- MEASE- Riskofderm- Stoffenmanager- other:- ECPA OWB | Select the tool which has been used for estimating the exposure concentration | **Guidance for field condition:**Condition: Field only active if 'Exposure estimation method' is 'Exposure estimation tool' |
|  | Version of exposure estimation tool | Text (255 char.)Display: Basic |  |  |  |
|  | Number of measured data points | Numeric (decimal)Display: Basic |  | Report the number of data points that have been used to derive the exposure concentration. |  |
|  | Geometric standard deviation | Numeric (decimal)Display: Basic |  | Report the geometric standard deviation calculated from the series of available measured data points that have been used to derive the exposure concentration. |  |
|  | Details on exposure estimates | Text templateDisplay: Basic | **Freetext template:**MONITORING STUDY DESIGN AND DESCRIPTION OF SCENARIO MONITORED- Study's design:- Scope:- Objectives and scenario being monitored:SAMPLING AND ANALYTICAL METHODS- Media Sampled:- Sampling:- Method/ Procedure:RESULTSREMARKS |  |  |
|  | Reliability score of measured data set | List (picklist)Display: Basic | **Picklist values:**- 1 (reliable without restriction)- 2 (reliable with restrictions)- 3 (not reliable)- 4 (not assignable)- other: |  | **Guidance for field condition:**Condition: Field only active if 'Exposure estimation method' is 'measured data' |
|  | Details on reliability score | Text (32,768 char.)Display: Basic |  |  | **Guidance for field condition:**Condition: Field only active if 'Exposure estimation method' is 'measured data' |
|  | **Exposure estimation** | **Block of fields (repeatable) End** |  |  |  |
|  |  | **Block of fields (repeatable) End** |  |  |  |
|  |  | Attachment (multiple)Display: Basic |  | Documents can be attached here, for example export files of exposure estimation tools. |  |
|  | **Contributing scenario for the workers** | **Block of fields (repeatable) End** |  |  |  |