

How to prepare a downstream user report

May 2023

ABC

Changes to this document

| Version | Changes |
|---------|--|
| 10.0 | May 2023: Update to reflect the new functionalities of the IUCLID 6.6 |
| 9.0 | October 2022: Update to reflect the new functionalities of the IUCLID 6.6 |
| 8.0 | October 2021: Update to reflect the new functionalities of the IUCLID 6.6 |
| 7.0 | April 2021: Update to reflect how/where a downstream user can report info on nanoforms. |
| 6.0 | October 2020: Update to reflect the new functionalities of the IUCLID 6.5. |
| 5.0 | April 2020: Update to reflect the new functionalities of the IUCLID 6.4 web user interface. |
| 4.0 | October 2019: Update to reflect transition from IUCLID 6.3 to IUCLID 6.4, and from the classic user interface to the web user interface. |
| 3.0 | October 2018: Registration number (IUCLID section 1.3) and site (IUCLID section 3.3) are mandatory information. Only the role 'Downstream user' is allowed (IUCLID section 1.1). |
| 2.0 | January 2017: Links added to translated versions of this document. |
| 1.0 | First version |

Disclaimer

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Title: How to prepare a downstream user report

Reference: ECHA-16-B-17-EN

ISBN: 978-92-9247-931-2

Cat. Number: ED-04-16-347-EN-N

DOI: 10.2823/519547

Publ.date: May 2023

Language: EN

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1. Introduction

1.1. Objective

The purpose of this manual is to assist in the preparation of a IUCLID Downstream User Report under the REACH Regulation (EC) No 1907/2006. More precisely it outlines the IUCLID sections and fields to be filled-in in order to prepare a complete DU Report according to Article 38 of the REACH Regulation.

This manual assumes that IUCLID has been installed, that you are using the web user interface and that you have a valid ECHA account.

More information about the different functionalities in IUCLID and how to use those functionalities can be found in the help system of IUCLID (see chapter *Functionalities of IUCLID*).

Persuant to Article 38 of the REACH Regulation there are 2 situations in which a downstream user (DU) has to report to the European Chemicals Agency (ECHA):

1. The DU has to prepare a chemical safety report in accordance with Article 37(4), or is relying on the exemptions in Article 37(4)(c) or (f). Article 38(2) lists the information that the downstream user shall report to ECHA.
2. The DU classifies a substance, and the classification is different from that of all of the suppliers.

For more information on how to submit go to the ECHA website:

<http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/downstream-user-report>

For more details on your duties regarding downstream user reports under the REACH Regulation, you can consult the ECHA Guidance for downstream users available at:

<http://echa.europa.eu/guidance-documents/guidance-on-reach>

1.2. Overview of the preparation and the submission of a DU Report

A DU Report in IUCLID is a non-editable snapshot file of the substance dataset. It contains the information to be submitted to ECHA.

The steps below indicate the approach for the preparation of a IUCLID dossier for a DU Report:

- Step 1.** Sign-up in REACH-IT and create the *Legal entity* for the downstream user (<https://reach-it.echa.europa.eu/>).
- Step 2.** Create in IUCLID the *reference substances* related to the reported substance (see chapter *Reference substance*).
- Step 3.** Create in IUCLID the *substance dataset* for the reported substance (see chapter *How to create a substance dataset*).
- Step 4.** Enter information on the reported substance in the substance dataset (see chapter *How to create a substance dataset*).

- Step 5.** Create a downstream user report *dossier* in IUCLID (see chapter *How to create a Dossier*).
- Step 6.** Export the downstream user report dossier from IUCLID (see chapter *How to export a Dossier*).
- Step 7.** Submit the downstream user report dossier to ECHA via *REACH-IT* (see chapter *Submit Dossier*).

The details of the information required to complete each of these steps is explained later in this manual.

1.3. Information requested for a DU Report

The information to be included in the Substance dataset is described in the REACH Regulation (Article 38(2) and Article 38(4) for the two different types of DU report).

For the **DU report on the preparation of a chemical safety report** (or relying on exemptions), under Article 38(2) the requested information comprises the following (the corresponding IUCLID section is indicated in brackets):

- Identity of the downstream user, i.e. name, contact details (REACH-IT account and IUCLID section 1.1 Identification);
- Identity of the substance as specified in section 2.1 to 2.3.4 of Annex VI to REACH (IUCLID sections 1.1 Identification and 1.2 Composition)
- The registration number(s) as communicated to the DU by their suppliers (IUCLID section 1.3 Identifiers);
- Identity of the manufacturer(s), importer(s) or other supplier, i.e. name, contact details (IUCLID section 1.7 Suppliers);
- Site(s) of use (IUCLID section 3.3 Sites);
- A brief general description of the use(s) (IUCLID section 3.5 Life Cycle description) including the information on the conditions of use(s);
- If appropriate according to Article 38(2)(f), a proposal for additional testing on vertebrate animals (relevant endpoint study record(s) in IUCLID section 5-7);
- An indication of the type of report (including any exemptions relied upon), and an explanation for why the report was required, including why the issue could not be resolved through the supplier (IUCLID Section 14).

For the **DU report on classification difference**, under Article 38(4) the requested information comprises the following (the corresponding IUCLID section is indicated in brackets):

- Identity of the downstream user, i.e. name, contact details (REACH-IT account and IUCLID section 1.1 Identification);
- Identity of the substance as specified in section 2.1 to 2.3.4 of Annex VI to REACH (IUCLID sections 1.1 Identification and 1.2 Composition)
- The registration number(s) as communicated to the DU by their suppliers (IUCLID section 1.3 Identifiers);
- Identity of the manufacturer(s), importer(s) or other supplier, i.e. name, contact details (IUCLID section 1.7 Suppliers);
- The classification according to the CLP Regulation (IUCLID section 2.1 GHS);
- Site(s) of use (IUCLID section 3.3 Sites);
- An indication of the type of report (IUCLID Section 14).

1.4. Checks performed by ECHA on the submitted dossiers

All dossiers submitted to ECHA undergo initial technical and administrative checks in order to ensure that they can be handled properly and that the subsequent required regulatory processes can be successfully carried out. Such checks are called business rules (BR).

A dossier can be accepted for processing only if all of the relevant business rules, such as format verification and availability of administrative information are satisfied.

For more information on the business rules check refer to the Annex: [Overview of the business rules checks performed by ECHA on the submitted dossiers](#).

1.4.1. The Validation assistant

The *Validation assistant* (VA) has been developed to enable you to perform some checks on the dossier before you submit it to ECHA via REACH-IT.

Therefore, before the submission, we strongly advise you to use the *Validation assistant* in two steps:


- i. To check your substance dataset (before the IUCLID dossier is created) to be able to correct any failures reported at this level.
- ii. To check the final IUCLID dossier and address any issues identified in this step.

Using the *Validation assistant* in both steps is vital for you to minimise any unnecessary failures and potential rejection of your submission.

For instructions on how to run the *Validation assistant*, refer to the help system of IUCLID.

1.5. The main features of the IUCLID web user interface

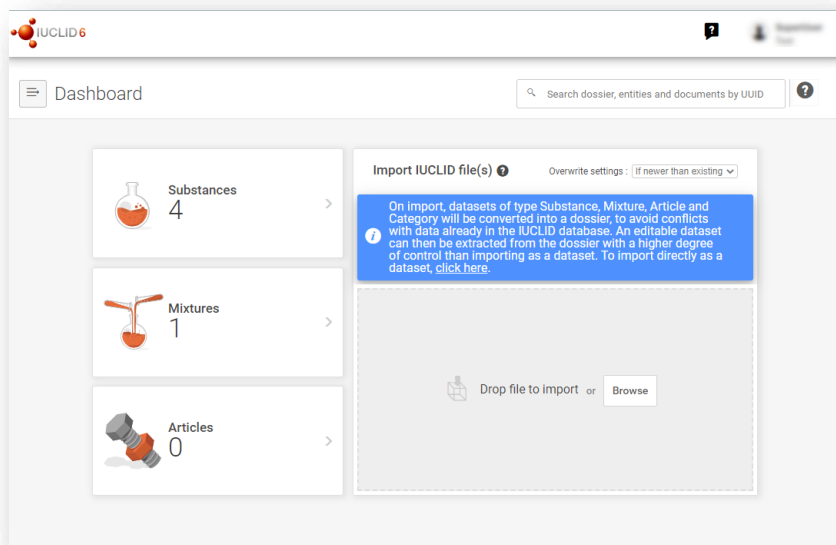
In this chapter an overview of the IUCLID web user interface's main new features is presented.

Please note that the features introduced here below are not an exhaustive representation of the IUCLID web user interface. Only the most used features of the web interface for preparing dossiers for submissions to ECHA are covered. For an overview of all the features included in the IUCLID web user interface please refer to the help system of IUCLID that can be accessed from anywhere in the application by clicking the round question mark icon  displayed in the top-left corner of the screen (see chapter *The functionalities of IUCLID*).

1.5.1. The Dashboard

The *Dashboard* is the page shown upon starting IUCLID with the web interface.

Figure 1: The Dashboard and its icons



The squared question mark icon allows you to easily access to a list of supporting material for IUCLID such as manuals, Q&As and video tutorials.

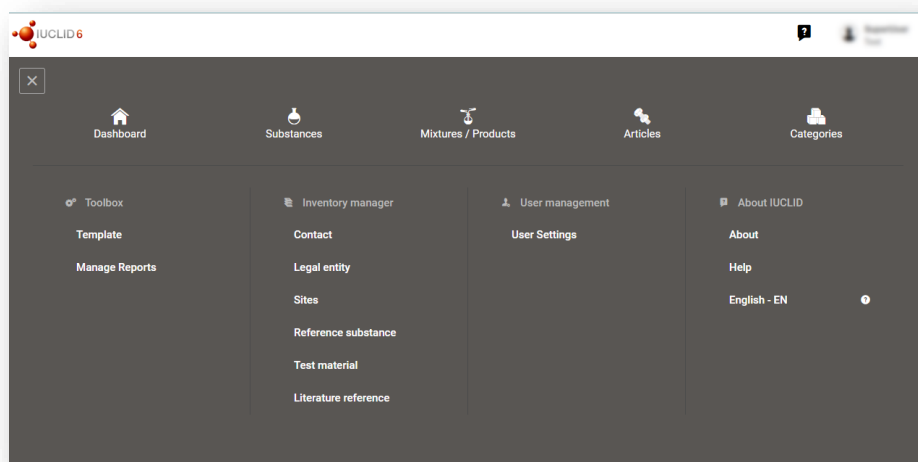


The round question mark icon next to the search bar opens the help system of IUCLID, a user manual presenting in detail the functionalities of IUCLID in the web interface.



The three dashes icon is the link to the Main menu, which contains direct links to list of entities and to functionalities that do not necessarily need the context provided by the data window.

Figure 2: View of the main menu

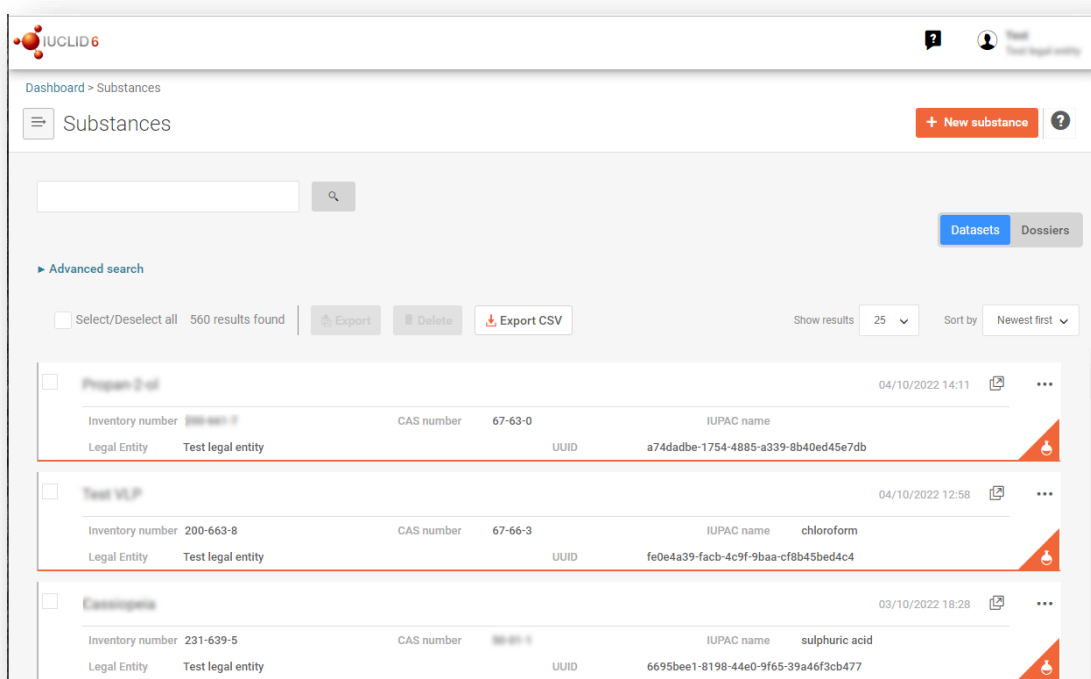




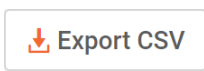
The widgets for *Substance*, *Mixtures* and *Articles* lead to lists of existing substances, mixtures and articles and the option to create new ones. The windows for *Substances*, *Mixture* and *Articles* that open by clicking on the widgets can each display either datasets or dossiers based on these entities.

1.5.2. The Substances list page


Figure 3: The Substances list page




This button displayed in the *Substances*, *Mixtures* and *Articles* list pages allows switching between the display of datasets and dossiers.



This button allows you to export the full list of results in the substances list page as a CSV file.

 In the *Substances* and *Mixtures* and *Articles* list pages, the orange icon with a bottle indicates datasets. The datasets represent the editable data related to a particular substance, mixture or article from which a dossier can be created.

 The purple icon with a lock instead indicates dossiers. Dossiers represent the data related to a particular substance, mixture or article at a snapshot in time. Dossiers cannot be edited and are the format in which the data is submitted to ECHA.

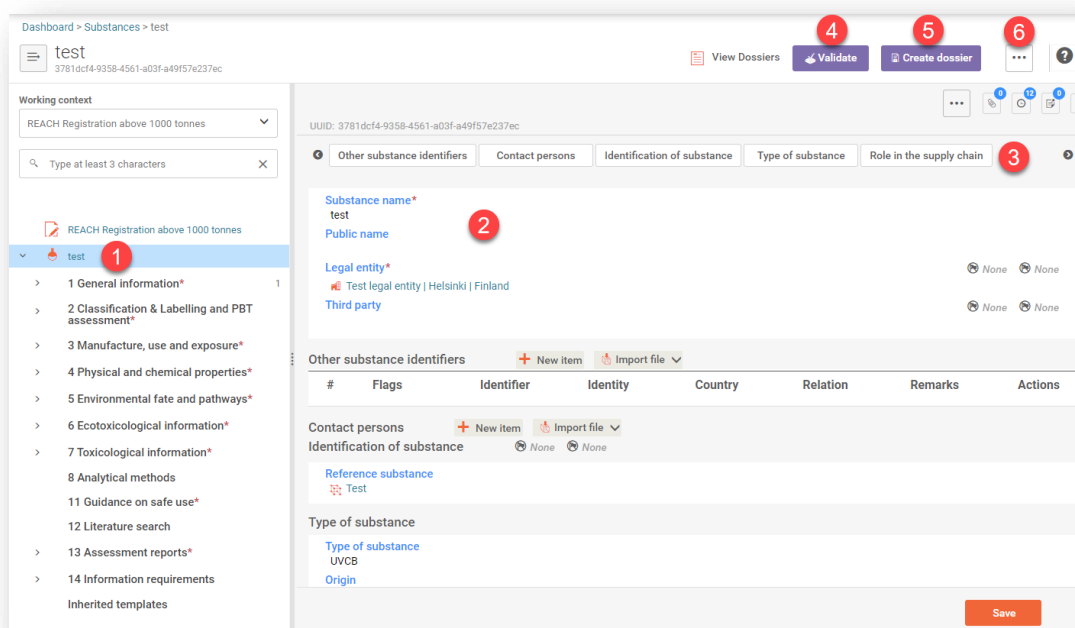
... The button labelled with three dots allows deleting and cloning an entity (substance, mixture or article) from the list. Please note that another button labelled with three dots is also displayed in the top of each *Dataset page*. For the functionalities included in the three dotted button of the *Dataset page* please see the following subchapter.

test 2 By selecting the checkbox next to the datasets you will be able to export or delete the selected dataset. More than one dataset can be selected in one instance.

From the *Substances*, *Mixtures* and *Articles* list you can access both datasets and dossiers. To open a dataset click on the selected substance among those displayed in the list. The page that opens up is the Substance dataset page (see Figure below).

1.5.3. The Dataset page

Figure 4: The Dataset page of a Substance dataset with the working context (submission type) "REACH Registration above 1000 tonnes"



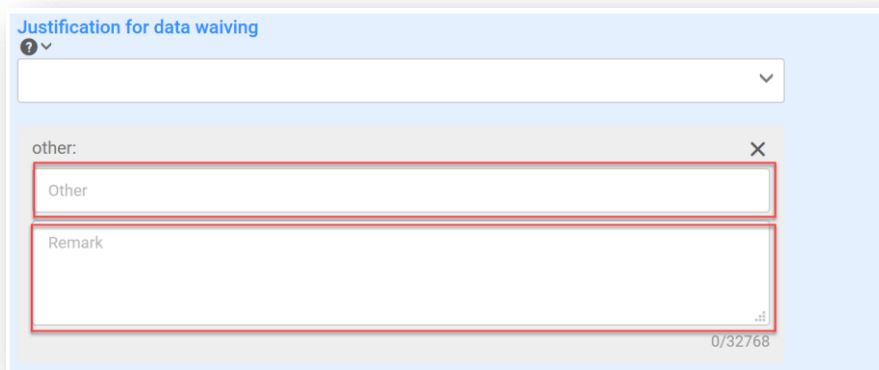
Depending on the *working context* (submission type) selected, IUCLID automatically displays the table of contents containing all sections that are relevant. The table of content is displayed as a navigation panel on the left hand side of the screen (1).

The content of the dataset can be modified by filling the data of the fields of the various sections (2). The tabs at the top of the dataset page help to navigate through the dataset page taking you to directly to the section indicated on the tab (3).

The fields to be filled in are either free-text fields or picklist fields.

Some picklist fields - when the option 'other' is selected - the possibility to add a *remark* (See figure below).

Figure 5: Add a remark to a Justification for deviation field



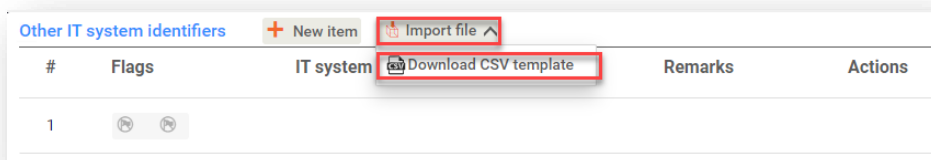
In certain free-text fields it is possible to insert a template containing suggestions on the information required for the field. To open the free-text template, click on the icon that shows the letter A with an arrow at the bottom right, displayed above the selected field



Repeatable blocks such *Other IT system identifiers* in figure 6 can be filled in:

1. By clicking the **+ New item** button, clicking on the generated row and manually fields in the pop up window.
2. By downloading the CSV template for that specific repeatable block, filling in the excel file with your data and importing the excel file in the repeatable block. This option is recommended for those cases in which many rows need to be created.

Figure 6: Filling in repeatable blocks by downloading and importing CSV files



The Validation assistant on a dataset is run by clicking on the button labelled *Validate* (4), which is shown at the upper right of the substance dataset page. The validation assistant can be run also on a dossier by clicking the Validate button on the dossier page.

Create dossier

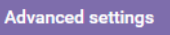
Dossier creation is started by clicking on the button *Create dossier* (5).



With the button labelled with three dots (6) at the right top of the Dataset page the following functions can be accessed: *Export to i6z*, *Create document PDF/RTF*, *Create component PDF/RTF*, *Generate report*, *Compare*, *Clone and Copy data from* and *Bulk Deleting*.

1.5.4. The Dossier header

The page opening when clicking the *Create dossier* button is the *Dossier header*.

From the *Dossier header* page you can either use default settings and create your dossier by clicking on *Create dossier* at the foot of the page or access the *Advanced settings* for dossier creation by clicking on the related button  displayed next to *Create dossier*. The *Advanced settings* allow for example to include or exclude the *Legal entity* that is attached to the *Substance*, *Mixture* or *Articles*, or to select the documents to be included in the dossier outside of the default based on the submission type.

1.5.5. Confidentiality flags

A flag icon to the left of the name of a field or section indicates whether a flag can be set, whether it has been set, and whether it involves confidentiality or is a regulatory programme flag for filtering information. The icons are described here below.



No flag is set;



A regulatory programme flag is set which does not involve confidentiality;



A flag is set that involves confidentiality.

1.6. The functionalities of IUCLID

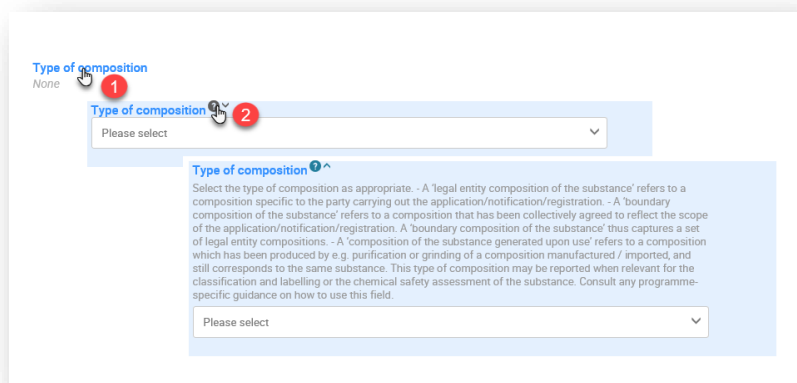
The functionalities of IUCLID are described in detail in the help document *Functionalities of IUCLID in the web interface*. To access the *Functionalities of IUCLID* document, click the icon



displayed on the top right corner of any page inside the interface and you will be able to open the IUCLID user manual. From there it is possible to navigate to the specific help required.

For specific support on how fields should be filled in within IUCLID, click on the question mark icons next to the field headers. Please note that the question mark icon will appear only after hovering with the cursor over the selected field, as shown here below.

Figure 7: Field specific help



2. Legal entity

Submissions to ECHA are done by *Legal entities* which have to be defined including contact details prior to submission. The contact details of the company are stored as a *Legal Entity Object (LEO)*. You can create a LEO both in IUCLID and in the *ECHA accounts* available at <http://idp.echa.europa.eu/ui/>

Note that ECHA will use only the contact details of the legal entity that you have registered in the ECHA accounts or in REACH-IT.

You have already created one legal entity when you installed IUCLID. You can add more legal entities either:

1. By clicking on *Legal entities* from the main Menu.
2. From the point where the *Legal entity* is referred to in a dataset.

However, ECHA will not enforce the consistency between the IUCLID legal entity and the ECHA accounts legal entity.

Please note that by the default settings the legal entity is not included in the dossier. If you wish to include the legal entity in your dossier, you can change the default settings during the dossier creation (see chapter *How to create a Dossier*).

If you include a legal entity in the dossier which will be submitted to ECHA it may be beneficial to check if the legal entities in IUCLID and REACH-IT are the same. For further information on how to create a Legal Entity Object (LEO) and how to synchronise it between IUCLID and REACH-IT, refer to the next chapter.

2.1. How to update and synchronise the LEO information

To register your legal entity, you should sign-up into the *ECHA accounts* where you can enter and administer your legal entity information.

When you create a LEO, a numeric identifier called Universal Unique Identifier (UUID) is

generated. Example of a legal entity UUID: *IUC5-a620a92d-32c6-426a-b6ee-fc338cde0932*.

The UUID is different for each LEO, even within the same company in case the company has several LEOs.

You can synchronise the legal entity between IUCLID and REACH-IT by exporting your LEO from ECHA accounts or REACH-IT. You can then import the file into IUCLID. It may be beneficial that the UUID is identical between all the applications where the company identity appears (IUCLID, REACH-IT, any web forms submitted to ECHA). Alternatively, if you have not yet created your ECHA account, you may export the LEO from IUCLID and import the file to ECHA accounts when you create an account. Note that a LEO can be imported to ECHA accounts only while you create an account, and not to an existing ECHA account.

To compare the UUIDs between the applications, you can find them inside each application by following the below paths:

- IUCLID: Main Dashboard menu > Legal entity > find your legal entity.
- ECHA Accounts: Legal Entity tab > General information > Legal Entity UUID
- REACH-IT: Menu > Company information > General information > UUID

For more information on the ECHA account management refer to the ECHA accounts manual available at <https://echa.europa.eu/manuals>.

3. Legal entity sites (Sites)

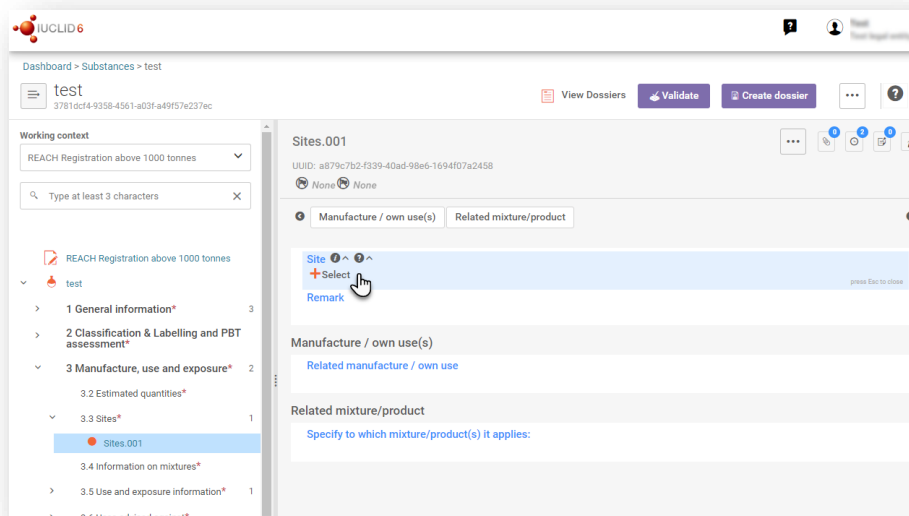
A *Legal entity site (Site)* is an entity where you can indicate the site where manufacture or own use of your substance takes place. This information includes the name of the site, the address and other contact details of the site, and the possibility to include the identifiers of the site under *Other IT system identifiers*. The *Legal entity site* belongs to only one *Legal entity owner*.

Note that it is not possible to create a *Legal entity site* without linking it to a legal entity, but it is possible to modify the link between a *Site* and its legal entity owner by selecting another legal entity from your inventory. More than one *Site* can be associated with the same legal entity.

The creation and editing of a site is done either:

1. from the list page of *Sites* which can be accessed from the main menu;
2. from the point where the *Site* is referred to in a dataset. To create a new site from the point where the *Site* is referred to in a dataset click on *Select* in the *Site* field as shown below. The link will take you to the *Site* inventory.

Figure 8: Link to Sites inventory from within the dataset

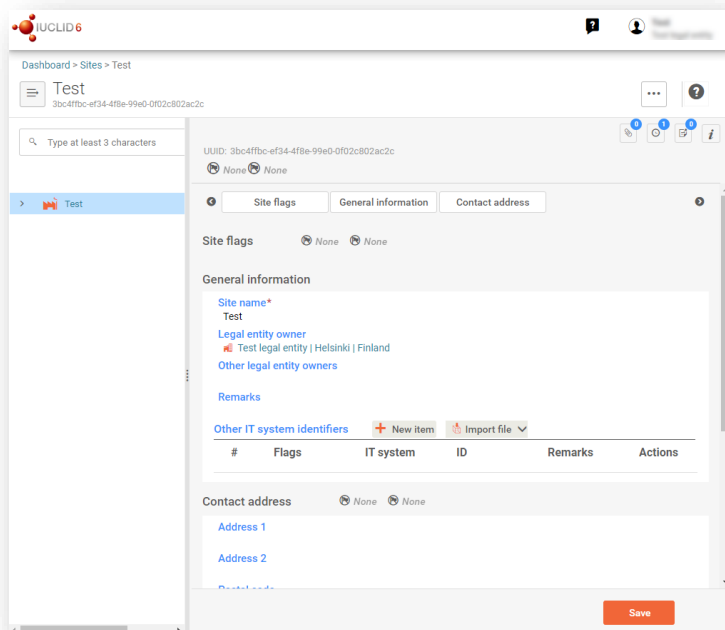


3.1. Creating a Legal entity site

To create a new site:

- Step 1.** In the pop-up window click on *New site / Create*.
- Step 2.** Complete as many fields as possible under *General information* and *Contact address*. The minimum data required is the *Country* where the site is located.
- Step 3.** Click *Save*.

Figure 9: Create a new Legal entity site



4. Contact

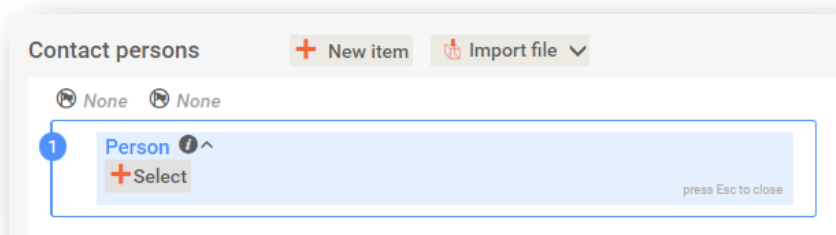
In the Contact inventory you can insert the contact details of the relevant competent persons, such as person responsible for the safety data sheet (SDS), toxicologist, etc, which can be attached to the IUCLID dossier. This person may be contacted to provide assistance or ask about the information submitted.

Information on the contact person responsible for your submission must be specified and managed in REACH-IT.

A *Contact* can be either edited or created either from:

1. from the list page of *Contacts* which can be accessed from the main Menu;
2. from the place where the *Contact* is referred to in a dataset. Typically, a link can be made to more than one *Contact* from the same place. To create a new contact from the place where the *Contact* is referred to in a dataset, click on *Select* within the link as shown below. The link will take you to the *Contacts* inventory.

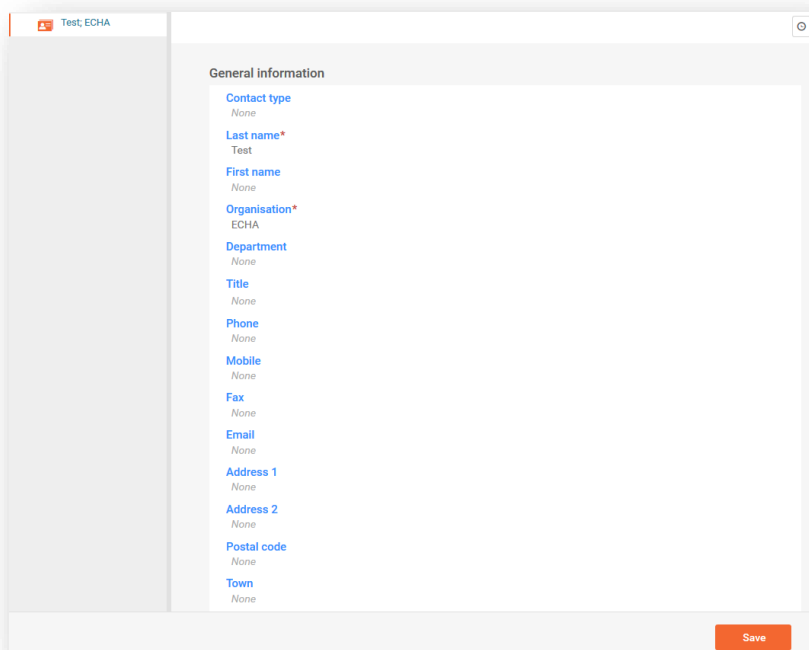
Figure 10: Link to Contact inventory from within the dataset



4.1. Creating a contact

To create a new contact:

- Step 4.** Click on *New contact / Create*.
- Step 5.** Provide the 'Last name' and the 'Organisation' (Fields marked with the red asterisk are mandatory) and complete as many fields as possible under *General Information*.
- Step 6.** Click *Save*.

Figure 11: Create a new Contact

The screenshot shows a web form for creating a new contact. The form is titled "General information" and contains the following fields:

- Contact type: None
- Last name*: Test
- First name: None
- Organisation*: ECHA
- Department: None
- Title: None
- Phone: None
- Mobile: None
- Fax: None
- Email: None
- Address 1: None
- Address 2: None
- Postal code: None
- Town: None

A "Save" button is located at the bottom right of the form.

5. Reference substance

A *Reference substance* enables you to store identification information on a given substance or a given constituent of a substance, such as chemical names (EC name, CAS name, IUPAC name, synonyms, etc.), identity codes (EC number, CAS number), molecular and structural information.

The *Reference substance inventory* gives the possibility to use the same information for the same chemical identity avoiding re-type it and to ensure that the data is centrally managed and updated. The *Reference substance inventory* is directly maintained by you, in your IUCLID web user interface. Each *reference substance* can be linked to an unlimited number of *substance* or *mixture* datasets. For updating the information in a *reference substance*, you can open the *Reference substance inventory*, search for the relevant *reference substance* and update it. The modifications will impact every single dataset linked to that *reference substance*.

To extend the number of entries in your inventory, you can search, download and import available reference substances from the IUCLID website under the section [Support ->Get IUCLID data -> Reference substances](#) to your IUCLID web user interface. These pre-defined reference substances have been prepared to improve data quality and minimise data entry.

5.1. Creating a reference substance

If you do not find a reference substance in the *Reference substance* inventory, you can create a new reference substance.

There are two types of information that can be reported in a *reference substance*:

1. Information **specific** to the *reference substance*: such information exactly corresponds to

the substance/constituent(s) covered by that reference substance;

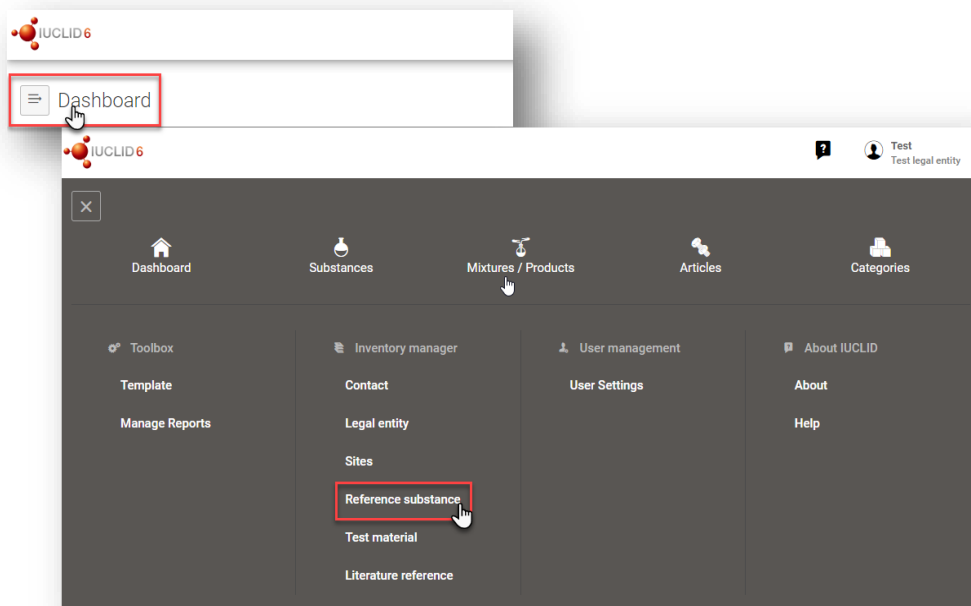
- Information **related** to the *reference substance*: this information does not accurately correspond to the substance/constituent(s) covered by that reference substance for any of the following reasons:
 - The information is generic as it also covers other substances/constituents;
 - The information only covers some of the constituents of a reference substance for a substance or a group of constituents;
 - The information refers to a similar constituent/substance;
 - The information is not the latest available information to identify the substance/constituent(s)

Related information should be reported under the *Identifiers of related substances* as it may create an ambiguity on the identity of substance or constituent(s) which a reference substance corresponds to.

The creation and editing of a *Reference substance* can be done from the point where the *Reference substance* is referred to in a dataset, or from the list page of *Reference substances*. Here below you find instructions on how to create a *Reference substance* from the inventory list page.

To open the list page for *Reference substances* click on the menu button in the top left corner of the *Dashboard*, and then click on *Reference substance* in the main menu as shown below.

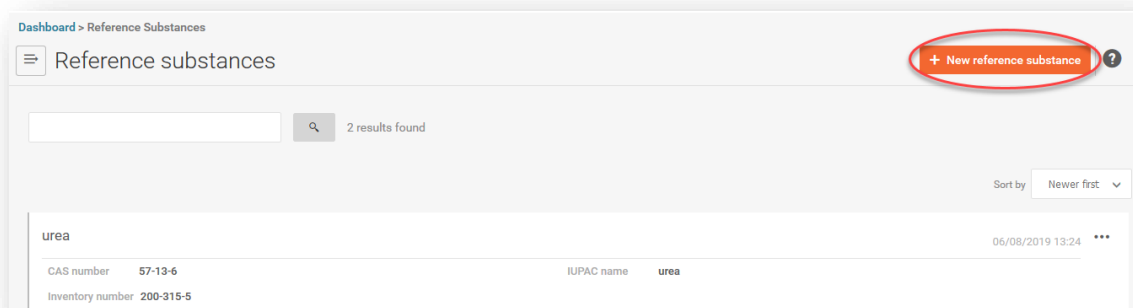
Figure 12: Open the list page for Reference substances



To create a new Reference substance:

Step 1. Click on *New reference substance*.

Figure 13: The list page for Reference substances



Step 2. Enter a name for your new *Reference substance* and click *Create*. Once you receive the message that your Reference substance has been created click *Open*.

Step 3. If the **reference substance is listed in the EC inventory** you can assign that entry by filling the *Inventory number* field.

Step 4. If your **reference substance is not listed in the EC inventory**, select a justification from the picklist proposed under the *No inventory information available - Justification*.

Step 5. Complete as far as possible the remaining fields of the reference substance.


The following information, if available and/or applicable, should be submitted for the substance and any of the constituents, impurities and additives required to be reported:

- *EC Inventory number*,
- *CAS number* and *CAS name*,
- *IUPAC name* (Note that, if a name following the IUPAC nomenclature cannot be derived, you should still provide a name defining the chemical nature of the substance or the constituents/impurities/ which the reference substance describes),
- *Description* (Specify any additional information relevant for the description of the reference substance in this field. This is important especially when the reference substance does not correspond to a well-defined chemical substance. Attached files can be added if necessary.),
- *Synonyms*,
- *Identifiers of related substances*,
- *Molecular formula* (if a molecular formula cannot be derived from the reference substance, a justification should be indicated in the Remarks field at the bottom of the section);
- *Molecular weight range*,
- *SMILES notation* (the text must be limited to the SMILES notation itself. Do not include any other text in this field. Further information on the nomenclature is available at e.g. <https://www.daylight.com/dayhtml/doc/theory/theory.smiles.html>. SMILES translators are available from different websites such as <https://cactus.nci.nih.gov/translate/> and <https://pubchem.ncbi.nlm.nih.gov/edit3/index.html>)
- *InChI* (the text must be limited to the InChI itself. Do not include any other text in this field. Further information on the nomenclature and a software to generate InChI are available at <https://iupac.org/who-we-are/divisions/division-details/inchi/>).
- Upload an image file with the *Structural formula*.

Step 6. To save the Reference substance click on *Save*.

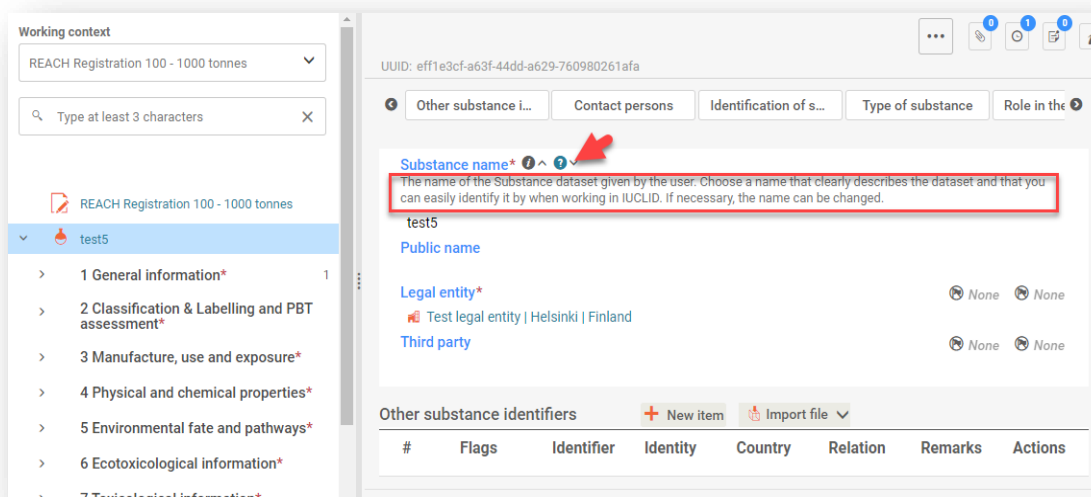
6. How to create a substance dataset

This chapter outlines which information you have to provide in different sections of IUCLID, which depends on the type of submission that you wish to do via a IUCLID dossier.

When entering your data you can use the help system of IUCLID that can be opened by clicking on the round question mark icon  on the top-right corner of the screen.

For further support and to read specific help text that explains how each field should be used, click on a question mark icon displayed next to the field heading. Please note that the question mark icon will appear only after hovering with the cursor over the selected field.

Figure 14: How to get further support on the use of fields



To create a IUCLID **dossier**, you first need to create a substance **dataset**. A substance dataset is a repository of administrative and scientific data for a substance. The information in the dataset can be modified: you can add, remove or change information in the dataset. **The dataset is used as basis for the dossier**. The dossier is a snapshot of the dataset at a certain moment; the information in the dossier cannot be modified.

To create a dataset:

- Step 1.** Click on the button entitled *Substances* in the IUCLID Dashboard and then click *New substance* in the top right-hand corner of the screen.
- Step 2.** Fill in the field *Name* for your new substance. Especially if your IUCLID contains several datasets, ensure to enter a name that you can easily use to distinguish the substance. Then click *Create*.
- Step 3.** Once you receive the message that the substance has been successfully created, click *Open*.

Step 4. You are now presented with a view of your substance dataset with the *Complete table of contents* displayed as a navigation tree on the left-hand side of the screen.

Please note that all the datasets that you have created (or imported) can be accessed from the *Substances page*. To open a substance dataset, click on the selected substance among those displayed in the list. In case you have several datasets, you can search the substance you wish to view by typing into the query box either the substance name, the CAS or EC number of the substance, or its IUPAC name. Alternatively, the *Advanced search* can be used.

Figure 15: Substances page - list of substances

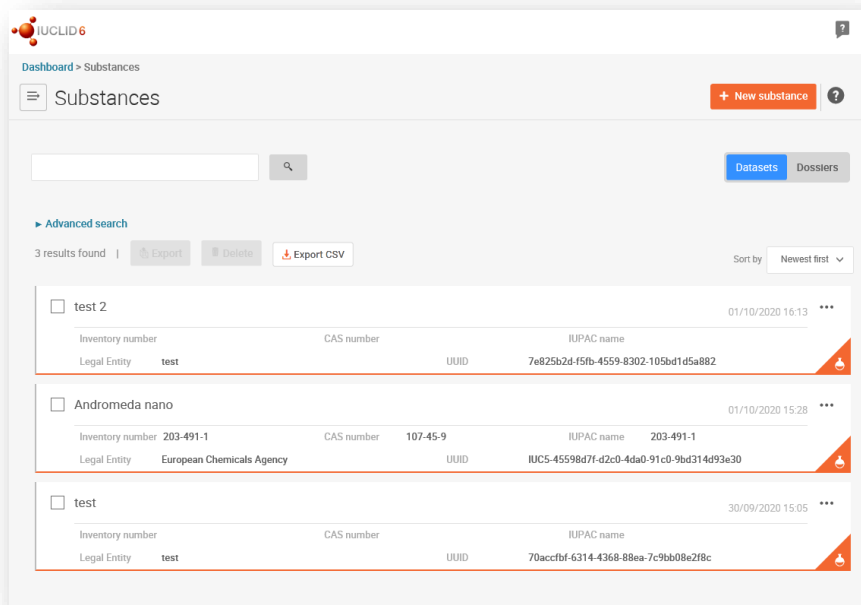
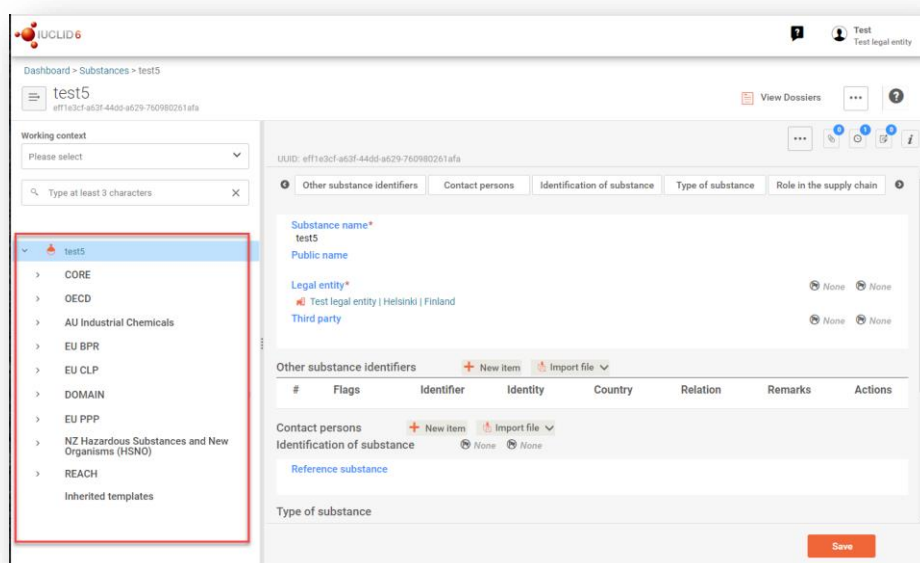


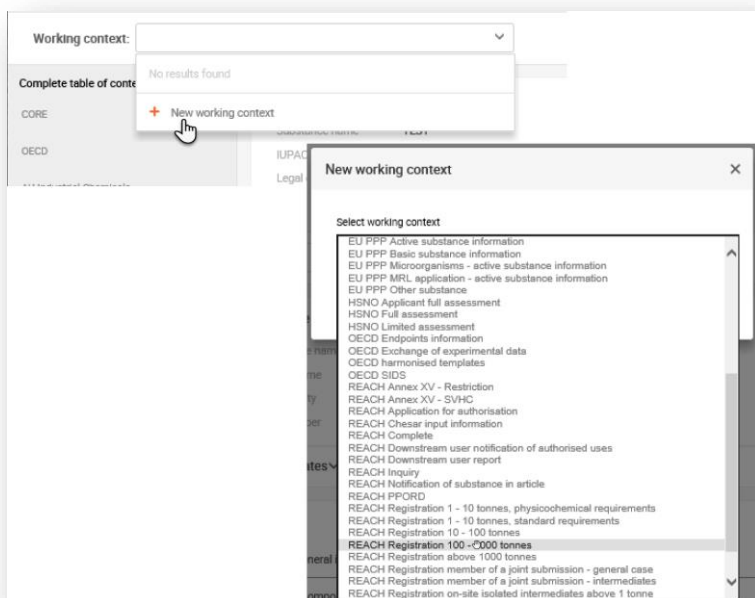
Figure 16: View of substance dataset with complete table of content (TOC)



Step 5. To view the table of contents that is relevant for the type of *dossier* that you are preparing, click on the *Working context* query box and then click on *New working context*.

Step 6. A picklist of different submission types appears. Select the specific type of submission *from the list* and click *Apply*.

Figure 17: An example of selecting the template from the picklist



Step 7. The sections relevant for the working context (submission type) are now displayed. Sections including mandatory information to complete are marked with the asterisk. Note that if you are creating a dataset but do not yet know the exact REACH dossier type that will be prepared, you can select the option REACH Complete. This will display the table of contents containing all sections that are relevant under the REACH Regulation.

For information on how to fill the data in the Dossier header, please see the dedicated section under the chapter 'How to create a Dossier'.

Once you have created a dataset for your substance, you can enter data on the substance in this dataset. The following chapters describe what data should be entered into each section of IUCLID for the specific type of submission that this manual refers to. The sections are shown with their name and the numbering used with the relevant IUCLID table of contents view.

When filling in the different parts of a dataset it is important, that:

- when you create many rows in a table, you must fill in the relevant information in each row,
- when other is selected in a picklist the text field below marked with 'Other' must be completed,
- when a field is associated with a unit, this must be filled in.

6.1. Section 1 General information

In section 1, *General information*, enter information on substance identity. The sections below provide instructions on how to fill in the information on substance identification in IUCLID. Not all the detailed information may be available to you. The main source of information for you is the received safety data sheet (SDS). Make sure that the identifiers and composition you report are consistent with those indicated in the SDS. Refer also to the Annex *Overview of the business rules checks performed by ECHA on the submitted dossiers* to understand what is needed for your submission.

6.1.1. Section 1.1 Identification

Section 1.1 contains the identification of the substance, role in the supply chain and the type of (reference) substance.

To complete this section, follow the steps:

- Step 1.** In the *Substance name* field type a name for the substance which you are preparing the dossier for.
- Step 2.** If you have any confidentiality concerns about the substance name, you need to fill in the *Public name field*. In this field you have to indicate a generic name suitable for publication, which appropriately describes the substance.

For more information on how to derive a *public name* for a substance for use under the REACH Regulation, refer to the manual *Dissemination and confidentiality under the REACH Regulation* available at <http://echa.europa.eu/manuals>.

- Step 3.** Assign a *Legal entity* to your substance dataset.

The legal entity that has subscribed to the web interface has automatically been attached in the IUCLID web interface.

For REACH registration, Inquiry and PPORD dossiers you can indicate a *Third party representative (TPR)*.

Information on the *Third party representative* for your submission must be specified and managed in REACH-IT prior to the submission. For more information on *Third party representatives*, please refer to the Guidance on data sharing available at: <http://echa.europa.eu/guidance-documents/guidance-on-reach>

Other substance identifiers and Contact persons:

- Step 4.** If relevant, you can include additional identifiers for your substance under *Other substance identifiers*. Such identifiers may include Trade names of the substance, identifiers by which the substance was previously known but have later been replaced/refined, or identifiers which are used to identify the substance under other regulatory schemes. Chemical (scientific) synonyms should not be listed here, but should be indicated in the reference substance information.
- Step 5.** You can specify other identifiers by clicking *New item*, then on the generated row and filling out the *Other substance identifier* fields that are shown in the window. Alternatively you can import a CSV file.

Step 6. You can add information of the contact person(s) for this substance from the previously defined. A new contact can also be created by clicking on *New Item* (See chapter *Contacts*).

Identification of substance:

The information to be reported in your reference substance depends on the substance type:

Mono-constituent substances:

A **mono-constituent substance** is a **well-defined substance** for which one constituent is present at a concentration of at least 80 % (w/w). This constituent is the main constituent of the substance. The substance is named according to the chemical name of that main constituent.

If your substance is a **mono-constituent** substance, assign the *reference substance*¹ corresponding to the main constituent in section 1.1.

Multi-constituent substances:

A **multi-constituent substance** is a **well-defined substance** for which more than one constituent is present at a concentration between 10 % and 80 % (w/w). These constituents are the main constituents of the substance. A multi-constituent substance is normally named as a *reaction mass* of the main constituents.²

If your substance is a **multi-constituent** substance, assign the *reference substance*³ corresponding to the reaction mass of the main constituents of your substance in section 1.1.

UVCB substances:

UVCB substances (i.e. substances of Unknown or Variable composition, Complex reaction products or Biological materials) are substances that cannot be sufficiently identified by their chemical composition.

If your substance is a **UVCB** substance, assign a *reference substance*⁴ corresponding to the UVCB substance in section 1.1.

Step 7. By clicking *Select* in the *Identification of substance* section you can identify your *Reference substance*.

If you have many Reference substances in your system we recommend you to start by searching the Reference substance inventory. If you already have the correct Reference substance created and found it, click on it from the list to select it.

¹ Note that for the reference substance: *Molecular formula*, *Molecular weight range* and *Structural formula* must be provided. In addition, the *SMILES notation* should also be provided if available.

² Certain multi-constituent substances corresponding to reaction masses of isomers may sometimes be more conveniently named using a chemical name where the isomeric form is not specified rather than as a "reaction mass".

³ Note that the *Molecular formula*, *Molecular weight range* and *Structural formula* of the reference substance must be provided or a justification for not providing this information must be given in the *Remarks* field. In addition, the *SMILES notation* should also be provided if available.

⁴ Note that the *Molecular formula*, *Molecular weight range* and *Structural formula* of the reference substance must be provided or a justification for not providing this information must be given in the *Remarks* field. In addition, the *SMILES notation* should also be provided if available.

If you do not find a reference substance in the Reference substance inventory, you can create a *New reference substance* by clicking on *Create* in the right top corner of the screen. (See chapter *Reference substance*)

Type of substance:

Step 8. Under the section *Type of Substance* select the appropriate *Type of substance* from the picklist. For submissions of registrations under REACH, you can only select between mono-constituent substance, multi-constituent substance and UVCB (the options polymer, microorganism and other: are not relevant).

We also recommend you to read the *Guidance for identification and naming of substances under REACH and CLP* available at <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

Step 9. Select the *Origin*, e.g. organic or inorganic, from the picklist.

Role in the supply chain:

Step 10. Select at least one checkbox in this section according to your role in the supply chain with regards to this substance and this submission context.

Step 11. To save the information click on *Save*.


6.1.2. Section 1.2 Compositions

Section 1.2 is used for describing the identity of your substance at a compositional level. In this section, you will report the identity and concentration of the constituents of the composition, including any impurities and additives. The state and form of your composition(s) is reported in this section.

You are advised to ensure that the information included in IUCLID section 1.1 and section 1.2 is sufficient to clearly report your substance identity and is consistent between both sections. In particular, this information reported may not be so generic that it would describe more than one substance.

Each substance dataset must contain at least one composition record which refers to the composition manufactured, imported or used by the registrant/notifier/applicant. Depending on the type of substance and dossier to be prepared, it may be necessary to report more than one composition. This is in particular the case where compositional differences affect the hazard profile and classification of the substance.

Each composition is reported as a record in IUCLID. To create a new record:

Step 1. In the navigation panel on the left hand side of the screen click on  next to *1.2 Composition*.

Step 2. Fill in the composition as described below:

General Information:

Step 1. Provide a descriptive *Name* for the composition. This is especially relevant if you report multiple compositions.

- Step 2.** The default selection in the *Type of composition* field is *legal entity composition of the substance*. This refers to a composition manufactured, imported or used by the registrant/notifier/applicant. Each dataset should contain at least one composition of this type. Only modify this value where you intend to report a composition with a different purpose. For more information on what composition types that can be reported for that submission please refer to the specific instructions for the submission type that you are preparing.
- Step 3.** Indicate the physical *State/form* of the composition by selecting the appropriate value in the picklist. Where the substance covers different physical states or forms, a separate composition should be created for each of them.
- Step 4.** You can give more detailed information on the composition under the *Description*. This is particularly important when several compositions are reported in order to clarify the differences between them. Providing further considerations on how the composition has been defined is also advisable when the composition covers wide concentration ranges or polymorphs or isomers. For substances that cannot be described with well-defined and quantified constituents (e.g. UVCB substances), further information to identify the composition is provided in this field, including the identity of the starting materials and a description of the production process used to manufacture the substance.
- Step 5.** You can provide supporting attachments under *Attached description / justification*.
- Step 6.** In the *Justification for deviations* field provide, where relevant, the justification for deviating from the rules for reporting the composition of substances as specified in the legal text and indicated in the *Guidance for identification and naming of substances under REACH and CLP* available at <https://www.echa.europa.eu/web/guest/guidance-documents/guidance-on-reach>.

Degree of purity:

- Step 7.** Provide the *degree of purity* of the composition, together with the unit of measurement. For instance, a substance with a purity of between 95-98% (w/w) will be given as shown below.


Note: The degree of purity should correspond to the overall concentration of the (main) constituents in the composition.

Figure 18: Degree of purity

The screenshot shows a software interface for entering the degree of purity. At the top, the label 'Degree of purity' is followed by two 'None' buttons. Below this is a search icon and a dropdown arrow. The main input area contains a range from 95 to 98, with a unit dropdown set to '% (w/w)'. A 'press Esc to close' button is visible on the right side of the input area.

Constituents:

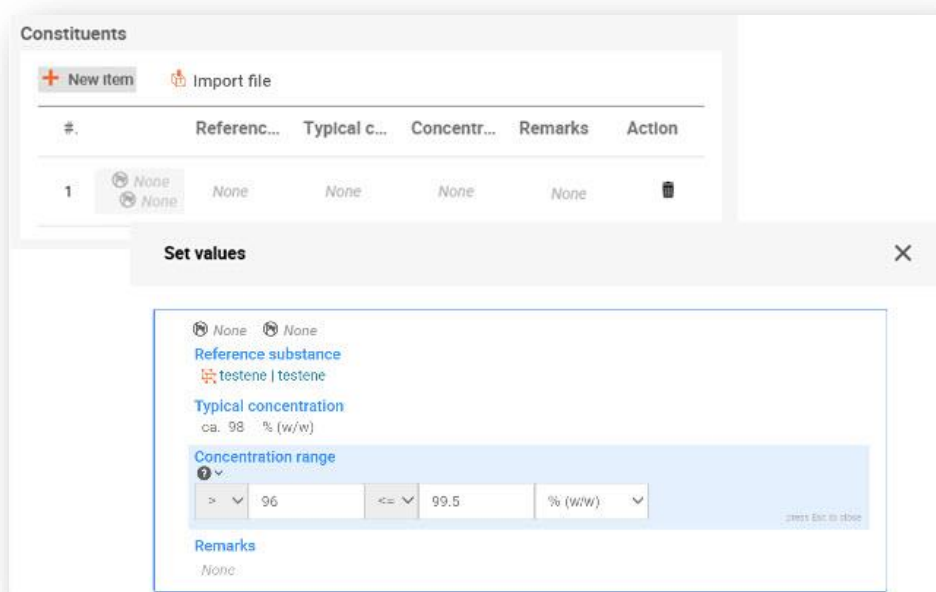
- Step 8.** Include the constituents for the composition. Each composition must have, as a minimum, one constituent. The number of constituents to be reported will depend on the type of substance. Add a *Constituent* by clicking on *New item* and then clicking on the generated row. Provide the requested information in the 'Set values' pop-up

window. Alternatively, you can populate the repeatable block content by clicking on  **Import file** and uploading a csv file.

Step 9. Assign a reference substance to the newly created constituent. Search for the appropriate reference substance by clicking *Select*. Once you have found the appropriate reference substance click on it to select it; alternatively, create a new reference substance to specify the constituent (see *Reference substance*). Ensure that the reference substance contains a chemical name in the IUPAC name field, and the appropriate EC and CAS identifiers, as available. To create a new reference substance click *Create*.

Step 10. Indicate the *Typical concentration* and the *Concentration range* (minimum and maximum values, and unit of measurement) for every constituent.

Figure 19: Constituent



Impurities and additives:

Step 11. To complete the information regarding Impurities and Additives follow the same procedure.

Step 12. Where the impurity or additive is considered relevant for classification and labelling of the substance, the relevant checkbox must be selected.

Step 13. The function of each additive has to be provided by making a selection in the picklist *Function*. Only selections beginning with the word stabiliser are applicable under REACH and CLP.

To report **unknown impurities**, create a generic reference substance (see *Reference substance*) and insert in the *IUPAC name* field the phrase *unknown impurities*. In the *Remarks* field of the impurity block, specify the nature, number and relative amounts of the impurities as far as possible. Also provide the *Typical concentration* (with unit of measurement) and *Concentration range* (with unit of measurement) for the *unknown impurities*.

Figure 20: Unknown impurities

The screenshot shows the 'Impurities' management interface. At the top, there are buttons for 'New item' and 'Import file'. Below is a table with columns: '#', 'Refere...', 'Typical...', 'Conce...', 'Remarks', 'This Im...', and 'Action'. The table contains one row with the following data:

| # | Refere... | Typical... | Conce... | Remarks | This Im... | Action |
|---|-----------|------------|----------|---------|---|--------|
| 1 | None | None | None | None | <input type="checkbox"/> This impurity is considered relevant for the classification and labelling of the substance | |

A 'Set values' dialog box is open over the table. It contains the following fields:

- Reference substance:** Unknown impurities
- Typical concentration:** ca. 0.05 % (w/w)
- Concentration range:** >= 0.04 <= 0.08 % (w/w)
- Remarks:** 3 unknown organic impurities for which the individual concentration does not exceed 0.03% according to the HPLC analysis (see section 1.4). Based on the fragmentation pattern in the HPLC-MS analysis (see also section 1.4), the structure of these impurities might include one chlorine and two bromine atoms.
- Footer:** 306/32768 (printed: Dec 19, 2024)
- Checkbox:** This impurity is considered relevant for the classification and labelling of the substance

Figure 21: Additive

The screenshot shows the 'Additives' management interface. At the top, there are buttons for 'New item' and 'Import file'. Below is a table with columns: '#', 'Ref...', 'Typi...', 'Con...', 'Fun...', 'Det...', 'Rem...', 'This...', and 'Action'. The table contains one row with the following data:

| # | Ref... | Typi... | Con... | Fun... | Det... | Rem... | This... | Action |
|---|--------|---------|--------|--------|--------|--------|---|--------|
| 1 | None | None | None | None | None | None | <input type="checkbox"/> This additive is considered relevant for the classification and labelling of the substance | |

A 'Set values' dialog box is open over the table. It contains the following fields:

- Reference substance:** 4-tert-butylbenzene-1,2-diol / 4 tert-butylbenzene
- Typical concentration:** ca. 0.01 % (w/w)
- Concentration range:** >= 0.005 <= 0.02 % (w/w)
- Function:** stabiliser, inhibitor
- Details of function in composition:** The stabiliser is added to styrene in order to prevent polymerisation
- Remarks:** None
- Checkbox:** This additive is considered relevant for the classification and labelling of the substance

When reporting information on the composition, where there is any deviation from the rules for identifying a mono-constituent, multi-constituent or UVCB substance, you will need to provide explanations for the deviations in the field *Justification for deviations*. Such deviations include, for example, reporting a mono-constituent composition that includes a main constituent with a concentration of less than 80 %.

The composition to be reported depends on the substance type:

Mono-constituent substances:

For mono-constituent substances, you have to complete the following information:

- Report only the main constituent under the *Constituents* in section 1.2. Assign the same reference substance for this constituent as in section 1.1;
- Report individually any impurities under the *Impurities* in section 1.2;
- Report any additive necessary to stabilise your composition under the *Additives* in section 1.2. Specify the stabilising function of the additive from the picklist *Function*;
- Report the concentration range (both minimum and maximum values) and the typical concentration for the main constituent, any impurity and any additive;
Note: The typical concentration and concentration range values reported for the main constituent of a mono-constituent substance should normally not be less than 80% (w/w)⁵;
- Report a degree of purity for your composition corresponding to the concentration range of the main constituent.

Multi-constituent substances:

For **multi-constituent** substances, you have to complete the following information:

- Report the main constituents under the *Constituents* in section 1.2.
Note: The main constituents should be the same for all compositions reported;
- Report any other constituent below 10% under *Impurities* in section 1.2;
- Report any additive necessary to stabilise your composition under *Additives* in section 1.2. Specify the stabilising function of the additive from the picklist *Function*;
- Report the concentration range (both minimum and maximum values) and the typical concentration for the main constituents, any impurity and any additive.
Note: The typical concentration and concentration range values of each main constituent should normally be ≥ 10 and $< 80\%$ ⁶;
- Report a degree of purity for the composition corresponding to the overall concentration range of the main constituents.

UVCB substances:

For **UVCB** substances, you have to complete the following information:

⁵ Any deviation from the "80% rule" should not be applied, unless a valid justification is provided. This justification should be provided in the *Justification for deviations* field for each composition where such a deviation is applied.

⁶ Any deviation from the "80% rule" should not be applied, unless a valid justification is provided. This justification should be provided in the *Justification for deviations* field for each composition where such a deviation is applied.

- Report the description of the manufacturing process, as well as other information relevant for the substance identification, in the field *Description*;
Note: To facilitate the reporting of the manufacturing process, suggestions as to what to enter are provided in free text templates for the field *Description*. To open the free text templates, click on the icon that shows the letter A with an arrow at the bottom right and the text *Insert existing templates*. A pop-up window appears. Click *Option 2: Composition of a UVCB substance* or *Option 6: Composition of a petroleum UVCB substance* depending on the type of your UVCB substance. The text should then be edited so that it contains only the relevant data;
- Report the appropriate individual constituents or groups of constituents under *Constituents*.
Note: To provide information on the constituents or groups of constituents in your substance, you must not reuse, in section 1.2, the reference substance already assigned for your substance in section 1.1;
- Do not report any constituent under *Impurities* of the composition (impurities are not considered relevant for UVCBs);
- Report any additive necessary to stabilise your composition under *Additives*. Specify the stabilising function of the additive;
- Report the concentration values of the individual constituents, groups of constituents and any additive as a concentration range (both minimum and maximum values) and typical concentration.
- Report the appropriate degree of purity for your UVCB substance (the degree of purity should normally be 100% for UVCBs which do not include any additive, as the concept of *impurity* is not considered relevant for these substances).

6.1.3. Section 1.3 Identifiers

In this section you can insert identifiers for regulatory programmes. In particular, this section should be used to report the following identifiers when available: REACH registration number, REACH pre-registration number, REACH inquiry number, notification number (NCD), CLP notification number.


To enter your data:

- Step 1.** Click the *New item* button under *Regulatory programme identifiers* and then click on the generated row.
- Step 2.** Depending on the type of submission, select the appropriate identifier from the *Regulatory programme* picklist.
- Step 3.** Enter the relevant number in the *ID* field.
- Step 4.** If you need to provide more than one programme identifier, create a new item by repeating the previous steps. Alternatively you can import a CSV file.
- Step 5.** To save the information click *Save*.

6.1.4. Section 1.7 Suppliers

This section is used to identify the manufacturer(s) or the importer(s) or other supplier as requested under Article 38(2)(d) of the REACH Regulation. Firstly existing legal entities should be searched, and if you cannot find your supplier in the list, there is an option to create a new legal entity for them (which may be required, for example, for distributors).

To complete this section, follow the steps:

- Step 1.** To create a new supplier click on the  button displayed in the navigation panel next to *1.7 Suppliers*.
- Step 2.** Click on *Select* in the *Name* field to search existing legal entities.
- Step 3.** Click the *Create* button if you cannot find your supplier in the existing legal entities (this may be because your supplier is a distributor).
- Step 4.** Fill as many fields as possible under the *General information* and *Address*.
- Step 5.** To save the suppliers information click on *Save*.

If you have more than one supplier, then create a new record for each supplier in section 1.7, and provide the abovementioned information for all of them.

6.2. Section 2 C&L and PBT assessment

There are two sections in IUCLID for entering information relating to classification and labelling (C&L), 2.1 GHS and section 2.2 DSD - DPD. In addition, the section 2.3 PBT assessment allows to store the outcome of the PBT assessment performed under the REACH Regulation.

The subchapter below contains relevant information for your DU Report on the section 2.1 GHS of IUCLID.

If you classify a substance, and your classification is different from that of all of your suppliers (as communicated in the safety data sheet under Section 2 for a substance as such, or Section 3 for the substance as a component of a mixture), you must report your classification to ECHA (if you use the substance in quantities of 1 tonne/year or more). How to report the classification is described in this section.


6.2.1. Section 2.1 GHS

Use this section to specify the Classification and Labelling (C&L) information of your substance resulting from the application of the criteria of the CLP Regulation (1272/2008).

It is necessary to consult Annex I of the CLP Regulation for the classification criteria and the following guidance documents for more detailed instructions on its application. The Guidance documents are available at <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp>.

In this section you can create several records to indicate more than one C&L for different compositions and forms of a substance. Note that when a new record is created you must fill in the data in all requested fields.

To create a new record:

Step 1. In the navigation tree on the left-hand side of the screen click on the  button next to *2.1 GHS*.

Step 2. A new record to report the classification and labelling information is created.

Harmonised classification has to be respected and you should not modify any of those harmonised hazard classes/differentiations. Exception is made when there is a "minimum classification" in Annex VI, marked with an asterisk. In this case, if there is data on which a stricter classification (hazard classes and/or differentiations) could apply, you should use that. If there is data available for a stricter classification, but the one in Annex VI to CLP is not such a "minimum classification", you should report it to your relevant Member State competent authority. Please see further information in point **Re-assessment of the harmonised classification** at <https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling>.

Note that all other hazard classes not listed in an Annex VI entry must also be assessed, and if the data shows that additional hazard classes apply, you should report them in the same record with the harmonised classification. Please also remember that your substance may be covered by one or more group entry in Annex VI that may not come up in a search for the name and identity numbers of the substance.

To complete this section, follow the steps:

General information:

Step 1. Enter a descriptive *Name* for the GHS record. This is particularly relevant in the case that multiple GHS records are created, to easily distinguish the different records.

Step 2. If you submit a dossier for a substance which is not classified you should select the checkbox *Not classified*. In this case, you should not enter any *Hazard category* or *Hazard statement* in the GHS record.

Step 3. Specify the *Implementation* by selecting from the picklist.

Step 4. In the field *Type of classification*, indicate whether the reported classification corresponds to a harmonised classification as per Annex VI of the CLP regulation, or to a self-classification.

Step 5. Enter any additional information in the *Remarks* field.

Step 6. Select a composition(s) in the *Related composition* field for which the GHS record is relevant by clicking the *Select* button.

If you have several compositions (several records in section 1.2) and several GHS records (i.e. several classification and labelling pairs), then it is mandatory that you link each GHS record to the related composition(s) by using the *Related composition* field.

Several compositions can be linked to the same C&L record if they have the same classification.

Classification:

Under this header you must select a *Hazard category* and *Hazard statement* for each hazard class or differentiation. Otherwise, you must fill in the *Reason for no classification*.

Note that when reporting hazards, the fields have a default selection in the field *Reasons for no classification* as *Data lacking*. The fields to report hazard categories are only available for editing when the option *Not classified* is unticked, and when the field *Reason for no classification* is cleared of a selection.

The *Reason for no classification* should be selected according to the following principles:

- *data lacking* should be selected if you do not have relevant data or other adequate and reliable information that can be compared with the classification criteria;
- *data inconclusive* should be selected if you have data or other information which is not reliable (e.g. data of poor quality) or if you have several equivocal study results or information. In these cases, the available data/information cannot be regarded as a firm basis for classification;
- *data conclusive but not sufficient for classification* should be selected in cases where a substance has been tested with the appropriate high quality or where other high quality information is available, and based on that, it is concluded that the classification criteria are not fulfilled.
- *hazard class not applicable* should be selected in cases where a substance has a physical state which is not compatible with the physical hazard class under evaluation (e.g. Flammable Solid when the substance is placed on the market as a liquid).
- *hazard class not assessed* should be selected if the hazard class has not been assessed and the justification cannot be covered by any of the other options.

For each of the classifications, or the reasons for no classifications, reported in this section, a justification should be provided in the field *Justification for (no) classification*. This field is available in the endpoint summary for some specific endpoints:

- 4.13 Flammable
- 4.14 Explosives
- 4.15 Oxidising properties
- 6 Ecotoxicological information
- 7.2 Acute Toxicity
- 7.3 Irritation / corrosion
- 7.4 Sensitisation
- 7.5 Repeated dose toxicity
- 7.6 Genetic toxicity
- 7.7 Carcinogenicity
- 7.8 Toxicity to reproduction
- 7.9.1 Neurotoxicity
- 7.9.2 Immunotoxicity.

The CLP regulation foresees certain waivers:

If a substance is classified for certain physical hazards, it does not need to be classified for certain others. For example: explosives, organic peroxides, self-reactive substances, and mixtures as well as pyrophoric or oxidising solids should not be considered for classification as flammable solids since flammability is an intrinsic hazard in these classes.

In case the above classification waivers apply, you should select conclusive, but not sufficient for classification as a reason for no classification.

and interconnections:

If a substance is classified for Skin corrosion Cat.1, the risk of severe damage to eyes is considered implicit (but not *vice versa*). In this case, the substance should be classified also for serious eye damage 1.

Classification - Physical hazards:

Step 7. Specify the *Hazard category* (e.g. Expl. Div. 1.1) and *Hazard statement* (e.g. H201: Explosive; mass explosion hazard) for the *Physical hazards* by selecting the appropriate values from the picklists.

The CLP Regulation implements the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). However, not all the hazard categories and corresponding hazard statements from the GHS have been implemented in the CLP Regulation. Therefore, please note when populating IUCLID section 2.1 - GHS that not all the available entries are relevant for CLP (e.g. Flammable liquids/Flammable liquid 4/H227: Combustible liquid).

Classification - Health hazards:

Step 8. Specify *Hazard category* (e.g. Acute Tox. 1) and *Hazard statement* (e.g. H300: Fatal if swallowed) for the *Health hazards* by selecting the appropriate values from the picklists.

The nature of *Reproductive toxicity* effects (i.e. damage to fertility and/or the unborn child), should be indicated in the field *Specific effect* by including the appropriate additional *Hazard statement* code(s).

The following additional codes are specified in Annex VI, 1.1.2.1.2: to the CLP Regulation:

- H360F - May damage fertility.
- H360D - May damage the unborn child.
- H360FD - May damage fertility. May damage the unborn child.
- H360Fd - May damage fertility. Suspected of damaging the unborn child.
- H360Df - May damage the unborn child. Suspected of damaging fertility.
- H361f - Suspected of damaging fertility.
- H361d - Suspected of damaging the unborn child.
- H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

For more instructions on the selection of these codes, please consult the Guidance on the application of the CLP criteria available at <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp>.

The route of exposure for Reproductive toxicity should only be specified if it is conclusively proven that no other routes of exposure cause the hazard. Supporting evidence should be attached in section 13 (unless it is already specified in Annex VI to the CLP Regulation).

Figure 22: Specify the nature and the route of exposure for reproductive toxicity

Reproductive toxicity
 Reproductive toxicity
Hazard category
 Repr. 1A
Hazard statement
 H360: May damage fertility or the unborn child <state specific effect if known > <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
Reason for no classification
Specific effect
 H360F May damage fertility
Route of exposure
 ✓ oral

In case you have conclusive data which enables you to explicitly specify the hazard of *Carcinogenicity* via inhalation (or it is specified in Annex VI to the CLP Regulation) you should include the corresponding additional hazard statement code (H350) in the free text field *Remark*.

The route of exposure for Carcinogenicity should only be specified if it is conclusively proven that no other route of exposure causes the hazard. Supporting evidence should be attached in section 13 (unless it is already specified in Annex VI to the CLP Regulation).

Figure 23: Specify the hazard of carcinogenicity via inhalation

Carcinogenicity
 Carcinogenicity
Hazard category
 Carc. 1A
Hazard statement
 H350: May cause cancer <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
Reason for no classification
Route of exposure
 inhalation
 H350
 4/255

Step 9. For the following hazard class or differentiation: *Specific target organ toxicity - single exposure (STOT SE)* and *Specific target organ toxicity - repeated exposure (STOT RE)* you should fill in *Hazard category*, *Hazard statement* and *Affected organs*. Otherwise, the field *Reason for no classification* should be filled in.

For practical reasons, it is not recommended to include more than three primary target organs. If more target organs are affected, it is recommended that the overall systemic damage should be reflected by the phrase *damage to organs*.

If the affected organ is unknown, indicate *unknown* in the field *Affected organs*. For these and other classes/differentiations, you are also advised to indicate the *Route of exposure*, where applicable.

You can specify more than one STOT SE /STOT RE by adding additional entries. To add additional entries, click *New item*.

The route of exposure should only be specified if it is conclusively proven that no other route of exposure causes the hazard. Supporting evidence should be attached in section 13 (unless it is already specified in Annex VI to the CLP Regulation).

Figure 24: Specify the affected organ

The screenshot displays two entries in the IUCLID interface for Specific Target Organ Toxicity (STOT). Each entry is shown in a separate card with a 'New item' button at the top left.

Entry 1: Specific target organ toxicity - single (STOT-SE)

- Hazard category:** STOT Single Exp. 1
- Hazard statement:** H371: May cause damage to organs <or state all organs affected, if known> <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
- Reason for no classification:** (Link)
- System:** (Link)
- Affected organs:** ✓ kidney
- Route of exposure:** ✓ oral

Entry 2: Specific target organ toxicity - repeated (STOT-RE)

- Hazard category:** STOT Rep. Exp. 1
- Hazard statement:** H372: Causes damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
- Reason for no classification:** (Link)
- System:** (Link)
- Affected organs:** ✓ liver
- Route of exposure:** ✓ oral

The CLP Regulation implements the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). However, not all the hazard categories and corresponding hazard statements from the GHS have been implemented into the CLP regulation. Therefore, please note when populating IUCLID section 2.1 - GHS that the following entries under the health hazards have not been transposed to CLP.

| Hazard class | Hazard category | Hazard statement |
|-------------------------------------|--|------------------|
| Acute toxicity - oral | Acute Toxicity 5 | H303 |
| Acute toxicity - dermal | Acute Toxicity 5 | H313 |
| Acute toxicity - inhalation | Acute Toxicity 5 | H333 |
| Skin corrosion / irritation | Skin Mild Irritation 3 | H316 |
| Serious eye damage / eye irritation | Eye Irritation 2A Eye Irritation 2B | H320 |
| Aspiration hazard | Asp. Toxicity 2 | H305 |
| Germ cell mutagenicity | Muta. 1* | * |
| Carcinogenicity | Carc. 1* | * |
| Reproductive toxicity | Repr. 1* | * |

* Please note that for the purposes of classification, the CLP Regulation requires the hazard categories Muta. 1, Carc. 1 and Repr. 1 to be further distinguished on the basis of whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).

Classification - Specific concentration limits:

Step 10. If your substance has harmonised *Specific concentration limits*, you need to specify them by filling in at least one of the two range fields in the *Concentration range (%)*. In addition, you also need to indicate the relevant *Hazard categories*.

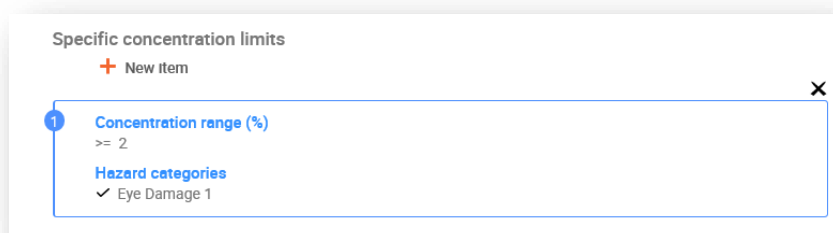
You can specify more than one concentration limit by adding additional entries. To add additional entries, click *New item*.

If you propose to set specific concentration limit(s) under the strict condition of Article 10 of the CLP Regulation, you have to provide a scientific justification in section 13.

For each specific concentration limit (SCL), you should specify:

- a concentration range (at least one of the two range fields);
- at least one hazard statement related to the SCL.

Figure 25: Specific concentration limits



The CLP Regulation implements the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). However, not all the hazard categories and corresponding hazard statements from the GHS have been implemented into the CLP regulation. Therefore, please note when populating IUCLID section 2.1 - GHS that the following hazard categories under the specific concentration limits are not relevant for CLP.

| Hazard category |
|-------------------------------------|
| Flammable Liquid 4 |
| Acute Toxicity 5 |
| Skin Mild Irritation 3 |
| Eye Irritation 2A |
| Eye Irritation 2B |
| Asp. Toxicity 2 |
| Chemicals under pressure 1, 2 and 3 |

Classification - Environmental hazards:

Step 11. Specify *Hazard category* (e.g. Aquatic Acute 1) and *Hazard statement* (e.g. H400: Very toxic to aquatic life) for the *Environmental hazards* by selecting the appropriate values from the picklists.

The CLP Regulation implements the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). However, not all the hazard categories and corresponding hazard statements from the GHS have been implemented into the CLP regulation. Therefore, please note when populating IUCLID section 2.1 - GHS that the following entries under the environmental hazards have not been transposed to CLP.

| Hazard class | Hazard category | Hazard statement |
|--------------------------------------|-----------------|------------------|
| Hazardous to the aquatic environment | Aquatic Acute 2 | H401 |
| | Aquatic Acute 3 | H402 |

If a substance meets the criteria for classification to the aquatic environment as both, Aquatic Acute 1 and Aquatic Chronic 1 (or other category):

- select from the picklist in the field *Hazardous to the aquatic environment (acute / short-term)*, the category *Aquatic Acute 1* and the hazard statement *H400*;
- select from the picklist in the field *Hazardous to the aquatic environment (long-term)*, the category *Aquatic Chronic 1* (or relevant category) and the hazard statement *H410* (or relevant hazard statement).

When a substance is classified as *Aquatic Acute 1* and/or *Aquatic Chronic 1*, multiplying factor(s) (M-factor) has/have to be assigned. Where appropriate, *M-factors* shall be set for acute and long-term hazards separately. This means that there can be two different *M-factors* for one substance.

If you propose to set such M-factors you have to provide a scientific justification in section 13.

Figure 26: Specify the Environmental hazards

| Environmental hazards | | |
|---|---|-------------------------------------|
| Aquatic environment | | |
| Hazardous to the aquatic environment (acute / short-term) | | |
| Hazard category | Hazard statement | Reason for no classification |
| Aquatic Acute 1 | H400: Very toxic to aquatic life. | |
| Hazardous to the aquatic environment (long-term) | | |
| Hazard category | Hazard statement | Reason for no classification |
| Aquatic Chronic 1 | H410: Very toxic to aquatic life with long lasting effects. | |
| M factor | | |
| M-Factor acute | | |
| 10 | | |
| M-Factor chronic | | |
| 100 | | |

Classification – Ozone layer:

Step 12. Select *Hazardous to the ozone layer 1* in the field *Hazard category* and the *Hazard statement H420* if the substance is classified as such.

Step 13. You can specify Additional hazard classes in the free text fields *Additional hazard classes* and *Additional hazard statements*.

Labelling:

Step 14. Specify the *Signal word* by selecting the appropriate value from the picklist. If no signal word applies to your substance, then you need to select *No signal word* from the picklist.

Step 15. If applicable, please select a *Hazard pictogram* from the picklist. You can select more than one pictogram by adding a *New item*.

Step 16. You should select at least one *Hazard statement* from the picklist and provide *Additional text* where applicable. If no hazard statement applies to your substance, then you need to select *No hazard statement*.

You can always specify more than one hazard statement for the labelling by adding a *New item*.

Figure 27: Labelling for section 2.1

Labelling

Signal word
Danger

Hazard pictogram
+ New item Import file

Code
GHS01: exploding bomb

Hazard statements
+ New item Import file

Hazard statement
H200: Unstable explosives.

Additional text
None

The principles of precedence for the hazard pictograms are stated in Art. 26 of CLP Regulation. For example, if the hazard pictogram 'GHS06' applies, the hazard pictogram 'GHS07' should not appear on the label. Please consult CLP Regulation and the Guidance on the application of the CLP criteria to ensure consistency between the classification and labelling sections.

According to Art. 27 of CLP Regulation, some hazard statements are not required in the label as they would be redundant. A few examples are listed below. For additional information please consult the Guidance on the application of the CLP criteria.

| Hazard classification | Associated hazard statement(s) | Associated hazard statement that should appear on the label |
|-------------------------------|---------------------------------------|--|
| Skin Corr. 1B and Eye Dam. 1 | H314; H318 | H314 |
| Aquatic Acute 1 and Chronic 1 | H400; H410 | H410 |
| Aquatic Acute 1 and Chronic 2 | H400; H411 | H410 |

The CLP Regulation implements the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). However, not all the hazard categories and corresponding hazard statements from the GHS have been implemented into the CLP regulation. Therefore, please note when populating IUCLID section 2.1 GHS that the following hazard statements for labelling are not relevant for CLP.

| Hazard statement (in Labelling section): |
|--|
| H227: Combustible liquid |
| H303: May be harmful if swallowed |
| H305: May be harmful if swallowed and enters airways |
| H313: May be harmful in contact with skin |
| H316: Causes mild skin irritation |
| H320: Causes eye irritation |
| H401: Toxic to aquatic life |
| H402: Harmful to aquatic life |
| H303+H313: May be harmful if swallowed or in contact with skin |
| H303+H333: May be harmful if swallowed or if inhaled |
| H313+H333: May be harmful in contact with skin or if inhaled |
| H303+H313+H333: May be harmful if swallowed, in contact with skin or inhaled |
| H315+H320: Causes skin and eye irritation |

Step 17. If applicable, please select a *Precautionary statements* from the picklist.

Step 18. If applicable, please specify the *Additional labelling requirements*. These include supplemental CLP hazard statements and additional labelling elements resulting from the application of CLP Article 25. Please consult the CLP Regulation and Guidance for further information on the additional labelling requirements.

Notes:

Step 19. If applicable, you can select *note(s)* from the picklist. These *notes* are mandatory for harmonised classifications listed in Annex VI to CLP. If your substance has a harmonised classification, and the entry has any of them, you need to include them in your dossier

6.3. Section 3 Manufacture use and exposure

6.3.1. Section 3.3 Sites

In this section you need to specify the information on your use sites. Indicate the site(s) where your own use(s) take place, then complete the information in Section 3.5 for your own use(s), then come back here and link your own use(s) to the site(s) you previously created.

To report the data you can create several records and each of them must have one of the existing Legal entity sites linked to it.

6.3.2. Section 3.5 Use and exposure information

Use this section to provide a brief general description of the use(s), and of the conditions of use(s), as requested under Article 38(2)(e) of the REACH Regulation.

ECHA will accept your dossier provided that you have indicated at least one use in IUCLID section 3.5. Life Cycle description. However, you are encouraged to describe as much as possible your use(s) for which you have to prepare a DU CSR in accordance with Article 37(4) or for which you rely on the exemptions according to Article 37(4)(c) or (f).


You need to describe the identified uses in section 3.5.2. to 3.5.6. For each use, you have create a record under the corresponding Life cycle stage:

- 3.5.2 Formulation or re-packing
- 3.5.3 Uses at industrial site
- 3.5.4 Widespread uses by professional workers
- 3.5.5 Consumer uses
- 3.5.6. Service life

Depending on the life cycle stage under which you have created a record, a set of relevant fields will be displayed for describing the use. The help-text in IUCLID provides an explanation of which type of information is expected for each field. For specific support on how fields should be filled in within IUCLID, click on the question mark icons next to the field headers. Please note that the question mark icon will appear only after you have clicked on the selected field.

Therefore, the current IUCLID manual is meant to provide an overview on the information, for more detailed explanation please consult the help-text.

To report a new use:

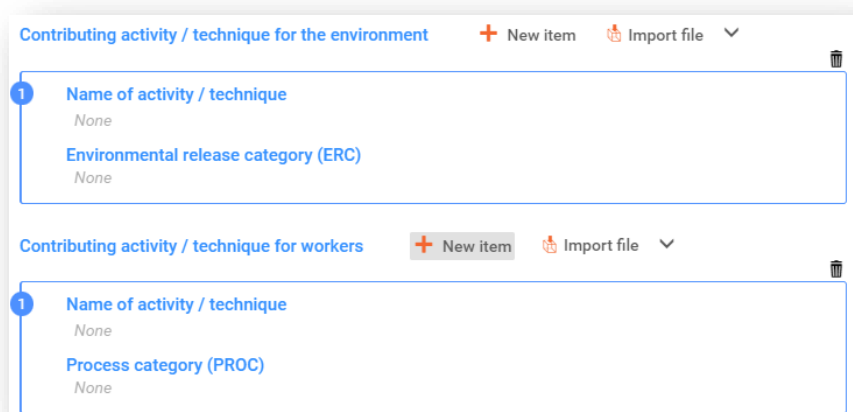
- Step 1.** Click the  button next to the relevant life cycle stage where you want to add a new use.
- Step 2.** Provide an intuitive name for the record so that you can easily recognise it later. This name can be the same as the use name or at least consistent with it.
- Step 3.** Select *use reported by Downstream user according to REACH Article 38* from the picklist in the *Registration/Notification status for the use*.
- Step 4.** Provide a *use name* which should be representative for the use; in case an exposure assessment is performed for the contributing activities in this use, the use name becomes the exposure scenario name in the Downstream User Chemical Safety Report (DU CSR) and Exposure Scenario (ES).
- Step 5.** Report further details in the field *Further description of use* to further explain the process(es) covered by the use, or the type of product(s) in the case of a consumer use.

After having created a use, you can also make a link from the site in the IUCLID section 3.3. to this use (see chapter *Section 3.3 Sites* for more information). This is relevant when reporting your own uses. If the dossier includes uses from your downstream users, they are not linked to sites. You will see the link(s) before continue with the further description of the use.

Describe the use in more detail

A use may consist of one or more contributing activities describing processes, tasks or unit operations. Such contributing activities are to be defined from environmental perspective and from the human health perspective. Each use needs to include as a minimum a *Contributing Activity / technique for the environment* and a *Contributing activity /technique for workers or consumers* (depending on the Life cycle stage to which the use belongs to). Each contributing activity needs to have as a minimum a use descriptor assigned e.g. PROC, ERC. **Please note:** Usually a use will be characterised by one (more broad) contributing activity for the environment and a set of contributing activities for workers (defined by tasks) or for consumers (defined by specific product types).

Figure 28: Contributing activities / techniques for environment and workers



Start the description of the use with adding repeatable blocks of information for each *Contributing activity / technique for the environment*. Alternatively, you can import a CSV file:

- Provide a *Name of the activity/technique*, to facilitate the understanding on the process,

technique, product or article addressed in this contributing activity. Standard names may be available from downstream sector organisations via use maps. In case an exposure assessment is performed this name becomes also the *contributing scenario name*.

- Select a suitable *Environmental release category (ERC)* from the picklist. Only relevant ERCs for the Life cycle stage are available.

Complete the description of the use by adding repeatable blocks of information for *Contributing Activity / technique for worker*. Alternatively, you can import a CSV file:

- Provide a *Name of the activity/technique*, to facilitate the understanding of the task or process step carried out by a worker. Standard names may be available from downstream sector organisations via use maps. In case an exposure assessment is performed, this name becomes also the *contributing scenario name*.
- Select a suitable *Process category (PROC)* from the picklist. In exceptional cases you may select additional categories for the same *Name of activity/technique*, if all tasks are carried out under the same conditions of use. This option may be in particular relevant if a measured data set is applied in the exposure assessment, and this data set integrates exposure across various tasks/process steps.
- Add further *contributing activity/technique for worker* if relevant. Note: The processes covered by the use may be relatively specific, and the same PROC may be assigned to various activities. In this case, the contributing activity name can provide further specificity.

Or (when you describe a consumer use) complete the description of the use by adding repeatable blocks of information for *Contributing activity / technique for consumers*. Alternatively, you can import a CSV file:

- Provide a *Name of the activity/technique*, to facilitate the understanding on the type of product the consumer uses. Standard names may be available from downstream sector organisations via use maps. In case an exposure assessment is performed, this name becomes also the *contributing scenario name*.
- Select a suitable *Product category (PC)* from the picklist.
- Add further *contributing activity/technique for consumer* if relevant. Note: The product types covered by a consumer use may be relatively specific, and the same PC may be assigned to various (sub)product types. In this case the contributing activity name can provide further specificity.

For more information on how to describe a use and the concepts of contributing activity and use descriptors refer to *Guidance on use description (R.12)* and *Guidance Part D: Framework for Exposure Assessment* available at <http://echa.europa.eu/guidance-documents/guidance-on-reach>.

Once the use and its contributing activities are defined, further details should/can be added:

- Provide more information on the market where the use takes place by selecting one or more relevant use descriptor(s) in the following fields, where applicable: *Product category used*, *Sector of end use*. Please note: These two fields are not applicable for consumer uses. This information may also be available from downstream user organisations via use maps.
- If the substance has a particular technical function during a use, select one or more entries in the picklist *Technical function of the substance during use*. If the substance has no specific technical function during this particular use, select *No technical function* the last entry in the picklist.
- Select *Substance supplied to this use in form of: as such* or *in a mixture*.
- Select *yes* or *no* in the picklist *Subsequent service life relevant for this use* to flag whether or not the substance is included into an article during the use. If *yes* is selected, set a link to

the relevant subsequent use(s) described in the section 3.5.6 *Service life* once they have been created.

Add information on the extent of the use

Provide information on the tonnage of substance assumed/known to enter in this use per year. This information indicates the extent of the use and may serve as supporting the absence of wide-dispersive uses⁷, together with other criteria. Such information may be relevant for authorities when prioritising substances for further scrutiny or regulatory action. At the same time, this information is also an input to the environmental exposure assessment. Quantify the tonnage of substance for this use (tonnes/year) and provide some explanation in the two related fields *Details on tonnage reported* and *Total EU tonnage for this use* enabling the interpretation of the tonnage figure.

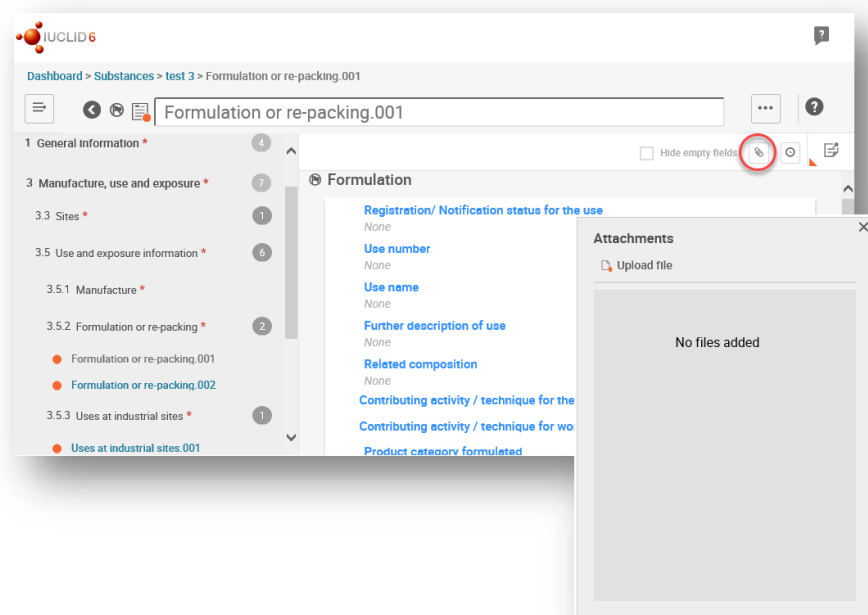
Provide information on conditions of use

According to Article 38.2 (e) the information reported by the DU shall include the conditions of use. In order to describe the conditions of use for the use(s) reported, download the template available on the ECHA website: <http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/downstream-user-report>

Fill in the relevant parts of the form and save it locally. One template is to be filled in for each reported use describing the conditions of use.

Attach the filled-in template, with the conditions of use for each reported use, by clicking on the paperclip icon *Attachments* at the top right of the record.

Figure 29: Attaching the template with conditions of use



⁷ The guidance on use description R.12 provides further explanation on the concept of wide-dispersive uses: <http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

6.4. (Optional) Testing proposals

You may consider that testing on vertebrate animals is necessary to be able to complete your chemical safety assessment. In that case you need to submit a testing proposal to ECHA as indicated under Article 38(2)(f) of the REACH Regulation and wait for the reply before you start testing.

To add a testing proposal, create a new *endpoint study record* in the relevant subsection of IUCLID (Sections 5-7).

- Step 1.** In the *Type of information* select from the picklist *experimental study planned*.
- Step 2.** Then fill in as much information about the study as possible, in particular the *Study period*.
- Step 3.** Information about the guideline must be present in the *Test guideline* or *Principles of method other than guideline* or as an attachment in the field *Attached background material*.

6.5. Section 14 Downstream user report

Provide details on the type of report according to the following steps:

- Step 1.** Create a new record by clicking on the **+** button next to *14 Downstream user report*.
- Step 2.** Under *General information* indicate whether the report is for reporting a classification difference (Article 38(4)) or because the use is not covered Article 38(1)). If it is for classification difference, no other field needs to be completed in this section.
- Step 3.** Select the appropriate box if you are not preparing a chemical safety report (CSR) relying on the exemptions under Article 37(4)(c) or (f) of the REACH Regulation.
- Step 4.** If the report is for a use not covered, describe the reason(s) for submitting downstream user report under *Further information on the reported use(s)*, by selecting the appropriate tick box, e.g. *Our conditions of use are outside the conditions described in the exposure scenario(s)*.
- Step 5.** Please describe the reason why the issue related to this particular use could not be resolved by a discussion with the supplier, e.g. *Confidential Business Information (CBI) reasons*.
- Step 6.** Save the information by clicking *Save*.

7. How to create a Dossier

Once you have included all relevant information in your substance dataset, the next step is to create a dossier.

Before creating a dossier you are advised to check the completeness of your substance dataset by running the *Validation assistant*. For more information on how to run the Validation assistant refer to the help system of IUCLID.

- Step 1.** To create a dossier open the list of available substance datasets by clicking on the button entitled *Substances* in the IUCLID Dashboard.
- Step 2.** All available substances will be displayed in the *Substances* list page. If a substance does not appear in the list you can search for it using the search field.
- Step 3.** Click on the substance for which you want to create a dossier.
- Step 4.** Before creating a Dossier a *Working context* (submission type) must be selected. Click on the *Working context* field and select the right submission type from the picklist. Choosing the correct dossier template by selecting the *Working context* is essential for a successful submission. Before exporting your dossier you have to make sure that the selected template corresponds with the intended submission.
- Step 5.** Click on *Create Dossier* in the top right-hand corner of the screen.

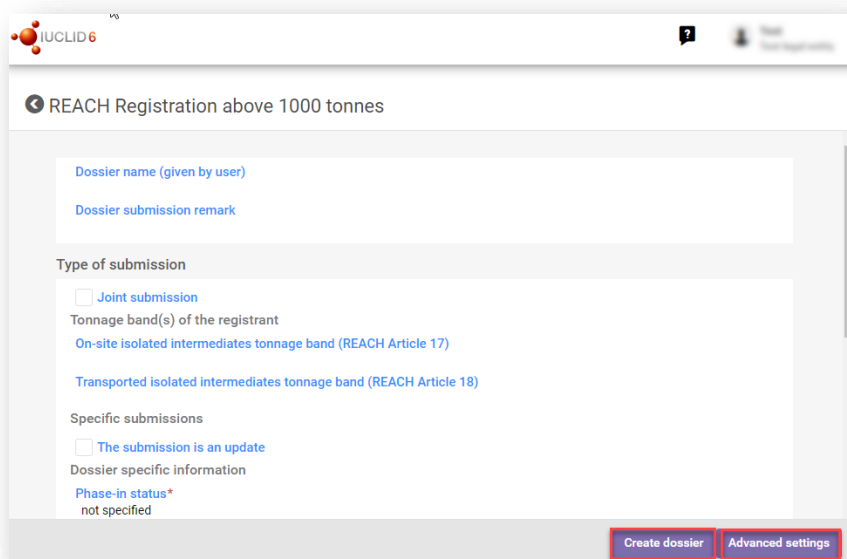
The selection of the *Working context* allows the IUCLID interface to present to the user at the start of *Dossier* creation, either a pre-filled or blank *Dossier header* of the correct type.

For instructions on how to fill the administrative information in the Dossier header, please see the following subchapters.

Information contained in the dossier header is crucial for business rules checking when you submit your dossier. Missing or incorrect information can result in that your submission cannot be accepted for further processing and will be automatically removed from the system. In this case you need to create a new dossier with corrected information and submit it again. For more information refer to the Annex: *Overview of the business rules checks performed by ECHA on the submitted dossiers*.

- Step 6.** From the *Dossier header* page you can either use default settings and create your dossier by clicking on *Create dossier* at the foot of the page, or access the *Advanced settings* for dossier creation by clicking on the *Advanced settings* button.

Figure 30: Dossier header page with 'Create dossier' and 'Advanced settings' buttons.



- Step 7.** From the *Advanced settings* window you can define the confidentiality level by selecting the data protection flags. If you have included any confidentiality or regulatory programme flags in your substance dataset, please make sure that the relevant information is included in your dossier by selecting the appropriate flags in this step. If you are unsure, it is recommended to select the defaults option. ECHA will assess the confidentiality of the information and the justifications provided. You can find more information on the publication of part of the dossier on the ECHA website at <http://echa.europa.eu/manuals>.
- Step 8.** From the *Advanced settings* window you can select whether the annotations should be included in the dossier.
- Step 9.** By ticking the checkbox *Select documents to be included* and clicking *Next* you can verify and select which documents and entities will be included in your dossier. Certain documents, such as section 1.1, will always be included in a dossier, and cannot be excluded in this step. Likewise, depending on the submission type, some documents will not appear in the list and cannot be included as they are not relevant for the selected submission type. If you are unsure of the information to be included, you can rely on the default settings for that submission type.
- Step 10.** To finalise the creation of your dossier click on *Create dossier* at the bottom of the *Advanced settings* window.

7.1. Administrative information

Enter a *Dossier name*, which enables you to easily identify it in your database. You are advised not to use confidential information in the dossier name, as it will be seen by anyone you share the dossier with.

When relevant, enter a *Dossier submission remark*. This remark can include further information on the reason for the submission (e.g. detail which information has been updated).

7.1.1. Specific submissions

Identify whether the dossier should be submitted as an initial submission or as an update of a previous submission.

For your spontaneous update, you must select the checkboxes *The submission is an update* and *Spontaneous update*. Additionally, select an appropriate *Justification* from the picklist, which is reporting the update reasons for a DU report.

When creating an update dossier specify the *Last submission number* (see chapter *Section 1.3 Identifiers*) and the reason for update.

If the reason for the spontaneous update is not listed in the *Justification* picklist, then you are required to select *other* and indicate the information about the reason in the corresponding field.

If you need to indicate more than one reason for updating the dossier, you should create an additional repeatable block for each reason by clicking on the *New item* button. Please note that a *Justification* has to be provided in all the blocks. Alternatively, you can upload a CSV file.

In case that the reported use is ceased, you do not need to submit an update of your IUCLID dossier. You can inform ECHA about it directly in REACH-IT through the "Cease manufacture"


functionality. Similarly, if the use is restarted you can notify ECHA through the "Restart functionality".

7.1.2. Dossier specific information

This part of the dossier header allows giving more general information on the DU report dossier. The checkbox *Reviewed by an assessor* is not compulsory, but if the dossier has been reviewed by an assessor it may be indicated here.

8. How to export a Dossier

To start the export process, first search for the *Dossier* by clicking on *Substances* on the IUCLID Dashboard. In the *Substances* page, click the *Dossiers* button in the top right-hand corner of the screen and then select the relevant dossier among those displayed in the list by clicking on it. A *Dossier* is indicated by a lock icon at the lower right of the entry in the list.

Once your *Dossier* screen is open click on the icon with three dots  displayed in the top right-hand corner of the screen. To export your dossier click *Export to i6z*.

9. Submit Dossier

To submit your dossier to ECHA you must sign-up in REACH-IT with the legal entity details of the submitting entity, and follow the instructions provided there for your specific type of submission.

You can access REACH-IT from ECHA website: <http://www.echa.europa.eu/> or go directly to the REACH-IT website: <https://reach-it.echa.europa.eu/>.

10. Update Dossier

If you need to update your dossier, you do not need to re-type again all your substance data. Instead you can update the information in the *Substance dataset*. To edit the *Substance dataset*, select it from the *Substances list* page and fill in or update the relevant data. When the dataset is ready you can create a dossier (see chapter *How to create a Dossier*).

Annex 1. Overview of the business rules checks performed by ECHA on the submitted dossiers

Business rules are a set of dossier format and administrative pre-requisites that must be fulfilled before ECHA can establish that the dossier can be handled properly and that the required regulatory processes can be successfully carried out. Business rules do not assess the completeness or compliance of the data provided. If the dossier submission fails at the business rule level, the dossier will be automatically removed from the system, and a new submission is required before any regulatory processes can be initiated. You can see the outcome of the business rules check in the submission report in REACH-IT.

This document will guide you through the basic requirements of creating the substance dataset and the IUCLID dossier header. In addition, it is recommended to use the IUCLID Validation Assistant on the substance dataset and also on the final dossier before exporting it from IUCLID and submitting it to REACH-IT. Click on your substance dataset or on the dossier in the Substances / Dossiers list page in IUCLID and select *Validate*. The Validation Assistant will check most of the business rules. However, some of the business rules depend on the information that is stored within the REACH-IT database, and therefore the plug-in cannot simulate all the business rules checked by the Agency.

| Business Rules applicable for Downstream User Reports | | |
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| Location (IUCLID/REACH-IT) | Rule description | Relevance |
| IUCLID substance dataset | A REACH dossier must be created from a substance dataset. It cannot be created out of a mixture or product dataset. | All dossier types |
| IUCLID substance dataset | When creating a dossier where a category will be included, the dossier has to be created out of a substance dataset that is linked to a category. | Downstream User Reports |
| IUCLID section 1.1 – Identification | A reference substance must exist in section 1.1 | All dossier types |
| IUCLID section 1.1 – Identification; section 1.2 – Composition | <p>Each reference substance in section 1.1 and 1.2 must contain a substance identifier. An acceptable substance identifier is:</p> <ul style="list-style-type: none"> EC/List number CAS number IUPAC name <p>Any EC/List number defined in section 1.1 and 1.2 of IUCLID must exist in the REACH-IT EC inventory.</p> <p>If you use a reference substance to report unknown constituents/impurities, they must be “identified” by inserting “Unknown constituent/impurity” in the IUPAC</p> | All dossier types |

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| | <p>name field.</p> <p>If categories are used, this rule is applied to all the category member substances.</p> | |
| IUCLID section 1.1 – Identification | In an update submission, the substance must be identified by an EC/List number. | Downstream User Reports |
| IUCLID section 1.1 – Identification | Only the role 'Downstream user' is allowed when submitting a Downstream User Report. The following roles in the supply chain cannot be selected: 'Only representative', 'Manufacturer' and 'Importer'. | Downstream User Reports |
| IUCLID section 1.1 – Identification | <p>The reference substance must be marked as one of the following:</p> <p>Mono constituent substance</p> <p>Multi constituent substance</p> <p>UVCB</p> | Downstream User Reports |
| IUCLID section 1.2 – Composition | <p>At least one composition must be defined in section 1.2. The following requirements are also to be fulfilled:</p> <p>All created compositions must contain at least one constituent.</p> <p>All constituents must be linked to a reference substance.</p> | All dossier types |
| IUCLID Section 1.2 - Composition | <p>State/form' of a composition must be specified by selecting the appropriate value in the picklist.</p> <p>If a substance covers different physical states or forms, a separate composition should be created for each of them.</p> <p>If a composition covers nanoforms, then 'solid: nanoform' must be selected in the picklist. Note that an incorrect indication in this field will not enable to provide the information on nanoforms under the Characterisation of nanoforms heading.</p> | All dossier types |
| IUCLID section 1.2 – Composition | <p>All compositions created in section 1.2 must have the composition type indicated. At least one of the compositions in section 1.2 must reflect the composition of the substance manufactured/imported by the registrant. This composition must be marked as the "Legal entity composition of the substance".</p> <p>If the composition type "other" is selected from the list, the relevant information must be provided in the free text field below.</p> | All dossier types |
| IUCLID section 1.1 – Identification; section 1.2 – Composition | If the substance is defined as mono-constituent, the first 'legal entity composition of the substance' in section 1.2 has to have a matching substance identity when compared with the reference substance in section 1.1. | All dossier types |
| IUCLID section 1.1 - Identification; | If the substance is defined as a multi-constituent substance, the reference substance in section 1.1 cannot | All dossier types |

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| <p>section 1.2 – Composition</p> | <p>be identical to any of the constituents defined in the first composition of type 'legal entity composition of the substance' in section 1.2.</p> | |
| <p>IUCLID substance dataset - section 1.2</p> | <p>All constituents of a multi-constituent or of a UVCB substance must identify distinct reference substances, e.g. it is not allowed to have constituent 1 identified with IUPAC name "formaldehyde" and constituent 2 identified with the EC number 200-001-8 (the EC number of formaldehyde).</p> | <p>All dossier types</p> |
| <p>IUCLID section 1.3 – Identifiers</p> | <p>A REACH Registration number has to be provided in section 1.3.</p> <p>The REACH Registration number provided in section 1.3 has to be a valid number (i.e. exists in REACH-IT) and it has to be for the substance referenced in section 1.1. The number does not have to belong to the submitting legal entity, as it in general should belong to the supplier of the substance.</p> | <p>Downstream User Reports</p> |
| <p>IUCLID section 1.7 - Suppliers</p> | <p>At least one 'Supplier' record must exist in IUCLID section 1.7. For each supplier, a legal entity must be assigned under the field 'Name'. Inside the legal entity under the heading 'Contact information', a 'Contact address' and at least one 'Contact persons' entry must be provided. The following fields for the 'Contact address' and each 'Contact persons' entry (by assigning a 'Person') must be provided:</p> <ul style="list-style-type: none"> Name (first name and last name of a contact person) Phone E-mail Address Postal code Country | <p>Downstream User Reports</p> |
| <p>IUCLID section 3.3 - Sites</p> | <p>At least one production site must be provided in section 3.3.</p> <p>Link a site to all records created in section 3.3.</p> <p>The site contact details must contain at least the country, selected from the pick list. The selection cannot be "Other".</p> | <p>Downstream User Reports</p> |
| <p>IUCLID section 3.5 – Life Cycle description</p> | <p>At least one use has to be provided in one of the following fields:</p> <ul style="list-style-type: none"> Formulation or re-packing (section 3.5.2) Uses at industrial sites (section 3.5.3) Widespread uses by professional workers (section 3.5.4) Consumer uses (section 3.5.5) Service life (section 3.5.6) <p>Each use must be identified with the 'Use name' or</p> | <p>Downstream User Reports</p> |

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| | 'Service life name'. | |
| IUCLID section 2.1 - GHS | At least one classification and labelling record must be provided in CLP/GHS format in section 2.1. | Downstream User Reports |
| IUCLID section 2.1 – GHS | <p>If at least one classification is provided in a C&L record in section 2.1 then:</p> <p>a 'Signal word' must be provided under the 'Labelling' heading of the same record.</p> <p>'Hazard statement' or a 'CLP supplemental hazard statement' must be provided in the 'Additional labelling requirements' heading of the same record.</p> <p>If no classification is provided, the tick box 'Not classified' should be selected and no hazard statements and no signal words should be provided.</p> | Downstream User Reports |
| IUCLID section 2.1 – GHS | <p>If the substance is classified, a 'Hazard category' and a 'Hazard statement' must be provided, or a 'Reason for no classification' for each hazard class in IUCLID section 2.1 should be indicated.</p> <p>If the substance is not classified, the tick box 'Not classified' should be marked and no classification should be provided in that record.</p> | Downstream User Reports |
| IUCLID section 2.1 – GHS | <p>For each 'Specific concentration limit' entry that is created in a C&L record in IUCLID section 2.1, at least one of the two fields under 'Concentration range (%)' must be provided. In addition, at least one selection under 'Hazard categories' has to be made.</p> <p>If no classification is given in a C&L record, the tick box 'Not classified' should be marked and no specific concentration limits should be indicated in that record.</p> | Downstream User Reports |
| IUCLID section 2.1 – GHS | <p>If the substance is classified, at least one entry for 'Specific target organ toxicity - single' and 'Specific target organ toxicity - repeated' must be provided in IUCLID section 2.1. For each entry, a 'Hazard category', a 'Hazard statement', and 'Affected organs' must be provided, or indicate a 'Reason for no classification'.</p> <p>If the substance is not classified, the tick box 'Not classified' should be marked and no classification should be provided in that record.</p> | Downstream User Reports |
| IUCLID section 14 - Downstream User Report | Provide the reason for submitting a downstream user report in a record in section 14, and indicate under 'General information' whether the report is submitted due to a difference in classification and/or due to uses not being covered by the exposure scenarios received from the supplier. | Downstream User Reports |
| IUCLID | If you indicated in section 14 that the uses reported are | Downstream User Reports |

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| <p>section 14 - Downstream User Report</p> | <p>not covered in the exposure scenarios received from the supplier, then you must specify under 'Further information on the reported use(s)' whether the non-coverage is due to differences between the uses or use conditions covered by the supplier, and/or due to unresolved issues with the supplier in relation to CBI or supply chain communication.</p> | |
| <p>IUCLID section 14 - Downstream User Report</p> | <p>If you indicated in section 14 that you are exempted from the requirement to prepare a chemical safety report, then it must be further detailed using the available checkboxes whether the exemption is based on REACH Article 37(4)(c) and/or 37(4)(f).</p> | <p>Downstream User Reports</p> |
| <p>IUCLID section 14 - Downstream User Report</p> | <p>If you indicated in section 14 that the particular uses reported are not covered in the exposure scenarios received from the supplier, then the reasons are to be provided using the available checkboxes. If the selection includes the option 'Other reason(s)', those are to be defined in the below field 'Specify'.</p> | <p>Downstream User Reports</p> |
| <p>IUCLID section 14 - Downstream User Report</p> | <p>If you indicated in section 14 that the issue related to the particular use with the supplier has not been resolved, then the reasons are to be provided by using the available checkboxes. If the selection includes the option 'Other reason(s)', those are to be provided in the below field 'Specify'.</p> | <p>Downstream User Reports</p> |
| <p>IUCLID dossier header</p> | <p>Once a reference number for a registration/notification is granted, it is not allowed to submit another initial submission for the same substance from the same legal entity. If you need to modify/add data, an update submission is required.</p> | <p>Downstream User Reports</p> |
| <p>IUCLID dossier header</p> | <p>Updates can be submitted in the following cases: Following the successful registration / notification of this particular substance, after having received a reference number (spontaneous update). Following a technical completeness check (TCC) failure (requested update). Following a request for further information by the Agency (spontaneous or requested update as specified in the request).</p> <p>In any other case, an initial submission is required.</p> | <p>All dossier types - Updates</p> |
| <p>IUCLID dossier header</p> | <p>If you wish to submit a spontaneous update then the following conditions must be fulfilled: In the dossier header tick the boxes 'The submission is an update' and 'Spontaneous update'. Insert the submission number to the last successful submission as the 'Last submission number'. Select an appropriate justification for updating by first creating a block under 'Spontaneous update' and then making a selection in the pick-list. If you selected 'other:', you are required to give the reason in the adjacent free</p> | <p>Downstream User Reports</p> |

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| | text field. | |
| IUCLID dossier header | If you wish to update your dossier following a request by the Agency then the below conditions must be fulfilled: In the dossier header tick the boxes 'The submission is an update' and 'Further to a request from a regulatory body'. Insert the submission number to the last successful submission as the 'Last submission number'. Provide the annotation number in the field 'Number'. The annotation number can be found in REACH-IT under the Key documents in the letter that motivated the update. | Downstream User Reports |
| IUCLID dossier header | Legal entity change cannot be performed by submitting and update to the dossier. The 'Legal entity change' module in REACH-IT is to be used to carry out the administrative changes related to ownership of the registration/notification. | Downstream User Reports |
| IUCLID dossier template | The dossier template used in IUCLID must correspond with the intended submission type in REACH-IT. | All dossier types |
| REACH-IT | A new dossier cannot be submitted when the previous submission for the same substance is still being processed. | All dossier types - Updates |
| REACH-IT | No submissions can be made from the account of a legal entity, which at the time of submission undergoes the legal entity change (merge) process. Legal entity change functionality is available in REACH-IT. | All dossier types |
| REACH-IT | It is not allowed to submit an update to the Downstream User Report when a registration dossier for the same substance from the same submitting legal entity is currently under processing by the system. | Downstream User Reports |
| REACH-IT | Parallel submissions are not allowed for the same annotation number. You cannot submit a dossier quoting the same annotation number while another dossier is still being processed. | Downstream User Reports |
| REACH-IT | The same IUCLID dossier file cannot be submitted more than once. | Downstream User Reports |
| REACH-IT | If an active registration already exists for the substance by the submitting legal entity, it is not allowed to submit an initial / update notification. | Downstream User Reports |
| REACH-IT | You cannot update a dossier that is currently deactivated or has been revoked. | Downstream User Reports |

| Business Rules applicable for Downstream User Reports covering nanoforms | | |
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| <p>IUCLID Section 1.2 - Composition</p> | <p>If in the field 'State/form' it is indicated that a composition corresponds to a nanoform, then selection in the field 'This nanoform is covered by a registration' must be provided.</p> <p>If the nanoform is covered by a registration the field 'Name of nanoform' must be filled in.</p> <p>Alternatively, if the nanoform is not covered by a registration, the relevant fields under Shape, Particle distribution and range, Crystallinity, Specific surface area, and Surface functionalisation / treatment under the heading 'Characterisation of nanoforms' must be provided.</p> | <p>Downstream user Reports</p> |
| <p>IUCLID Section 1.2 – Composition</p> <p>Shape</p> | <p>At least one entry must be created under the Shape description heading. A selection must be made in the 'Shape category' field and each entry must be filled in as follows:</p> <ul style="list-style-type: none"> -For a nanoform consisting of particles with a single shape, only one entry must be created for the corresponding 'Shape category' with selection of the appropriate 'Shape' and indication 'yes' under 'Pure shape'. -For a nanoform consisting of particles with more than one shape, a separate entry for each shape must be created. Each entry must contain the appropriate 'Shape category', 'Shape', and selection 'no' under 'Pure shape'. In addition, the full 'Range' with unit corresponding to the fraction of particles with that shape must be provided. <p>If for any of the fields available picklist values do not apply, value 'other:' should be selected and the appropriate information provided in the below field.</p> | <p>Downstream User Reports</p> |
| <p>IUCLID Section 1.2 – Composition</p> <p>Particle size distribution and range</p> | <p>At least one entry must be created under the Particle size and distribution heading. A selection must be made in the 'Shape category' field and each entry must be filled in as follows:</p> <ul style="list-style-type: none"> - For each shape category, the percentile parameters must be provided. As a minimum, the values D10, D50 and D90 must be reported as separate entries in the same table under the Percentile heading. In addition, the full range of the 'Fraction of constituent particles in the size range 1-100 nm' with unit must be provided. - For the 'elongated' the full 'Range of length' with unit and the full 'Range of aspect ratio' must be provided. - For the 'platelet' the full ranges of lateral dimension 1 and lateral dimension 2 with units and the full 'Range of aspect ratio' must be provided. | <p>Downstream User Reports</p> |
| <p>IUCLID</p> | <p>At least one entry must be created under the Crystallinity heading. A selection must be made in the</p> | <p>Downstream User Reports</p> |

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| <p>Section 1.2 – Composition</p> <p>Crystallinity</p> | <p>‘Structure’ field and each entry created must be filled in as follows:</p> <p>-For a fully amorphous nanoform, one entry with the ‘Structure’ indicated as ‘amorphous’ and the selection ‘yes’ under ‘Pure structure’ must be provided.</p> <p>-For a fully crystalline nanoform consisting of particles with only one crystal structure one entry with the ‘Structure’ indicated as ‘crystalline’ and the selection ‘yes’ under ‘Pure structure’. In addition, information on the ‘Name’ or the ‘Crystal system’ of the structure, must be provided as a minimum.</p> <p>-For a fully crystalline nanoform consisting of particles with more than one crystal structure, a separate entry for each crystal structure must be created. Each entry must contain indication, ‘crystalline’ under ‘Structure’ and selection ‘no’ under ‘Pure structure’. In addition, as a minimum the ‘Name’ or the ‘Crystal system’ and the full ‘Range’ with unit corresponding to the fraction of particles with that crystal structure in the nanoform must be provided.</p> <p>-For a nanoform consisting of particles with both amorphous and crystalline structures, separate entries for the amorphous and crystalline structure(s) must be created. Each entry must contain indication ‘partially-crystalline’ under ‘Structure’ and selection ‘no’ under ‘Pure structure’ In addition, the full ‘Range’ with unit corresponding to the fraction of particles with that structure must be provided. For the crystalline fraction of the nanoform, a separate entry for each crystal structure and as a minimum the ‘Name’ or the ‘Crystal system’ must be provided for each entry. For the amorphous fraction of the nanoform, ‘amorphous’ as the ‘Name’ should be provided.</p> <p>If for any of the fields the available picklist values do not apply, value 'other:' should be selected and the appropriate information provided in the below field.</p> | |
| <p>IUCLID Section 1.2 – Composition</p> <p>Specific surface area</p> | <p>The specific surface area or the volume specific surface area must be provided with indication of both the range values and the respective units.</p> | <p>Downstream User Reports</p> |
| <p>IUCLID Section 1.2 – Composition</p> <p>Specific surface area</p> | <p>If information on the volume specific surface area is reported, then the ‘Skeletal density’ must be provided with indication of both range values and the applicable unit.</p> | <p>Downstream User Reports</p> |
| <p>IUCLID Section 1.2 - Composition</p> <p>Surface functionalisation/treatment</p> | <p>A selection must be made in the field ‘Surface treatment applied’.</p> | <p>Downstream User Reports</p> |
| <p>IUCLID Section 1.2 - Composition</p> <p>Surface functionalisation/treatment</p> | <p>If ‘Surface treatment’ has been applied, then an entry under the ‘Surface treatment’ heading must be provided for each different surface treatment agent applied.</p> <p>Each created entry must be complete, and contain at least the following:</p> | <p>Downstream User Reports</p> |

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| | <p>- A reference substance linked in the field 'Surface treatment agent' with the IUPAC name, or if not available, another international chemical name of the surface treatment agent given in the field 'IUPAC name'. In addition, if available the EC number and CAS number should be provided.</p> <p>- Both values of the field 'Range of weight-by-weight contribution, % (w/w)' indicating the fraction of each surface treatment agent with respect to the total particle weight.</p> | |
| <p>IUCLID Section 1.2 - Composition</p> <p>Surface functionalisation/treatment</p> | <p>If 'Surface treatment' has been applied, then the 'Description' of the surface treatment process, specifying the process steps and conditions, and the order and concentration of applied surface treatment agents must be provided in the 'Description' field. The text template available for the field should be used to structure the description.</p> | <p>Downstream User Reports</p> |

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