

How to prepare a classification and labelling notification

April 2024

ABC

Changes to this document

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11.0	April 2024: Chapter 5.2.1: New CLP hazard classes and information on the new field 'Reason for classification' added.
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2.0	January 2017: Links added to translated versions of this document.
1.0	First version

Disclaimer

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1. Introduction

1.1. Objective

The purpose of this manual is to assist in the preparation of a IUCLID Classification and Labelling (C&L) notification dossier under the CLP Regulation (EC) No 1272/2008. More particularly it outlines the IUCLID sections and fields to be filled-in in order to prepare a complete C&L notification dossier according to Article 40(1) of the CLP Regulation.

The aim of this users' manual is to help the notifiers to identify which of the numerous IUCLID fields are of prime importance for a successful submission of a C&L notification.

This IUCLID C&L notification dossier can then be submitted to the European Chemicals Agency (ECHA) using the REACH-IT application.

For more details on your duties regarding C&L notification under the CLP Regulation, you can consult the CLP FAQ available at: <https://echa.europa.eu/support/gas-support/browse/-/qa/70Qx/view/topic/CLP>.

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*). The manual also assumes that you have all relevant information available.

1.2. Overview of the preparation and the submission of a dossier

A IUCLID dossier is non-editable snapshot file of a substance dataset, containing the information to be submitted to ECHA. The steps below indicate the approach for the preparation of a C&L notification dossier in IUCLID:

- Step 1.** Sign-up in REACH-IT and create the *Legal entity* of the notifier (<https://reach-it.echa.europa.eu/>).
- Step 2.** Create the *reference substance* in IUCLID (see chapter *Reference substance*).
- Step 3.** Create the *substance dataset* in IUCLID for the notified substance (see chapter *How to create a substance dataset*).
- Step 4.** Enter the information requested by the CLP Regulation in the *substance dataset* in IUCLID (see relevant subsections of chapter *How to create a substance dataset*).
- Step 5.** Create a C&L notification dossier in IUCLID (see chapter *How to create a Dossier*).
- Step 6.** Export the C&L notification dossier from IUCLID (see chapter *How to export a Dossier*).
- Step 7.** Submit the C&L notification dossier to ECHA via *REACH-IT* (see chapter *Submit Dossier*).

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

1.3. Information required for C&L notification

The information to be included in the Substance dataset is described in the CLP Regulation (Article 40(1)).

The requested information comprises the following (the corresponding IUCLID section is indicated in brackets):

- identity of the notifier, i.e. name, contact details (provided in the REACH-IT account);
- contact person of the notifier (section 1.1);
- identity of the notified substance as specified in section 2.1 to 2.3.4 of Annex VI to REACH (sections 1.1, 1.2, and 1.4);
- in case you flag the IUPAC name confidential in the C&L inventory: an alternative name to the IUPAC name of the notified substance for publication, and the relevant justification (section 1.1);
- classification of the substance according to the criteria set in the CLP Regulation (section 2.1);
- reason for no classification in case a substance is classified in some but not all hazard classes or differentiations (section 2.1);
- specific concentration limits or M-factors where applicable (section 2.1), together with a justification using the relevant parts of sections 1, 2 and 3 of Annex I to REACH (section 13);
- label elements, i.e. hazard pictograms, signal words and hazard statements (section 2.1).

1.3.1. Confidentiality requests

You can flag the IUPAC name of your substance confidential in the C&L inventory ONLY if your substance is:

- a non-phase in substance;
- a substance only used as one or more of the following: as intermediate, in scientific research and development, in product and process orientated research and development.

ECHA can process the IUPAC names flagged confidential in the C&L inventory ONLY upon the following conditions:

- a confidentiality flag is assigned to the IUPAC name;
- an alternative name is given for the publication on ECHA website;
- a justification is attached.

If one of the requested information is missing, the confidentiality claim cannot be processed.

Confidentiality on a IUPAC name in the C&L inventory is different from an alternative name in a Safety Data Sheet or on the label for substance in a mixture (Article 24 of the CLP Regulation).

If you want to use an alternative name in your Safety Data Sheet or on the label, you need to make a request for an alternative name according to Article 24 of the CLP Regulation.

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

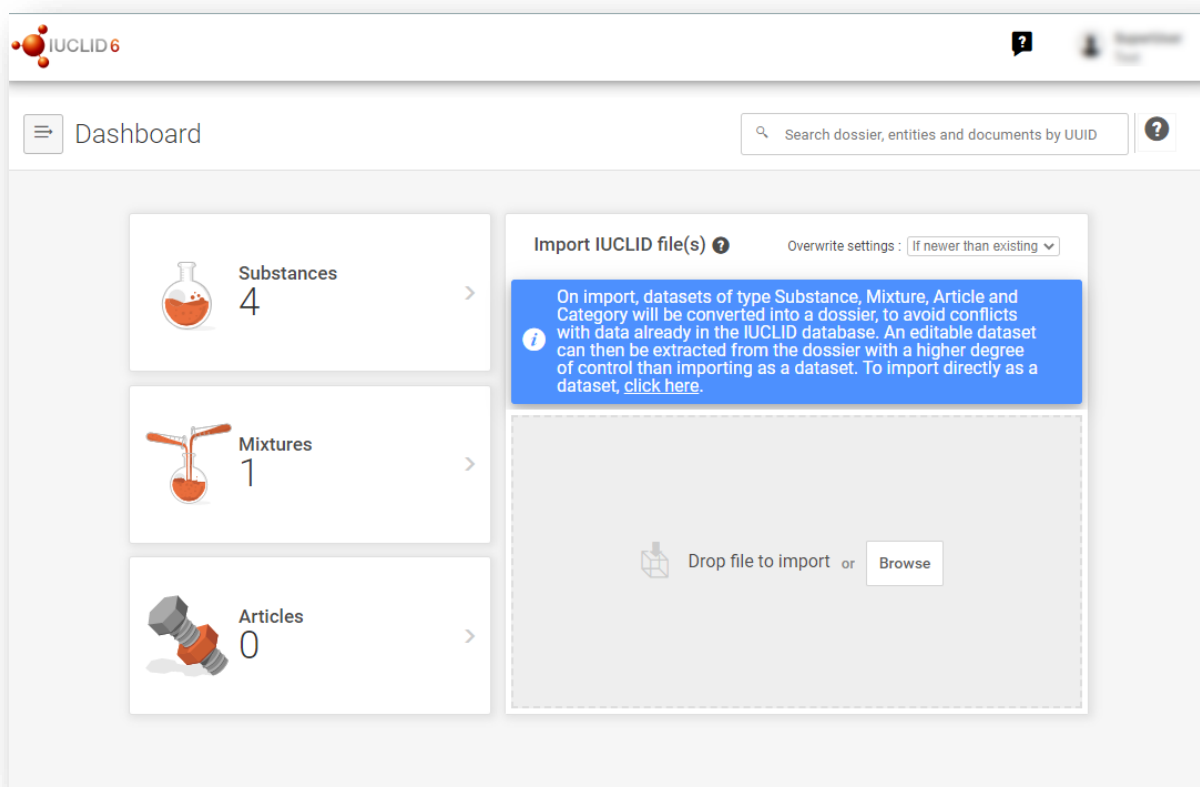
In this chapter an overview of the IUCLID web user interface's main new features is presented.

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.

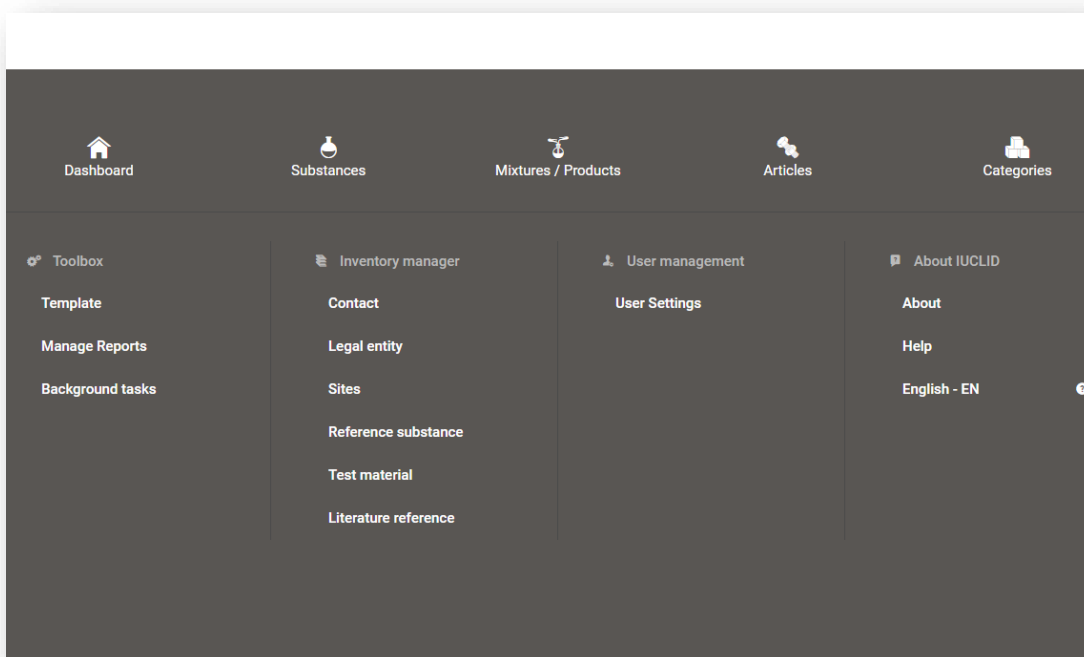


The round question mark icon next to the search bar opens the help system of IUCLID, a user manual presenting in detail the functionalities of IUCLID in the web interface.



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.

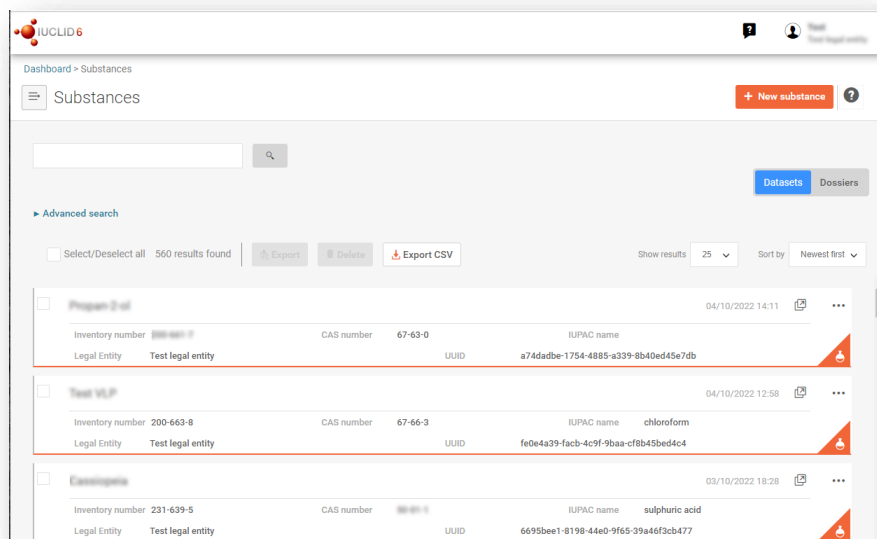
Figure 2: View of the main menu



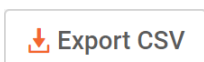
The widgets for *Substance*, *Mixtures* and *Articles* lead to lists of existing substances, mixtures and articles and the option to create new ones. The windows for *Substances*, *Mixture* and *Articles* that open by clicking on the widgets can each display either datasets or dossiers based on these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

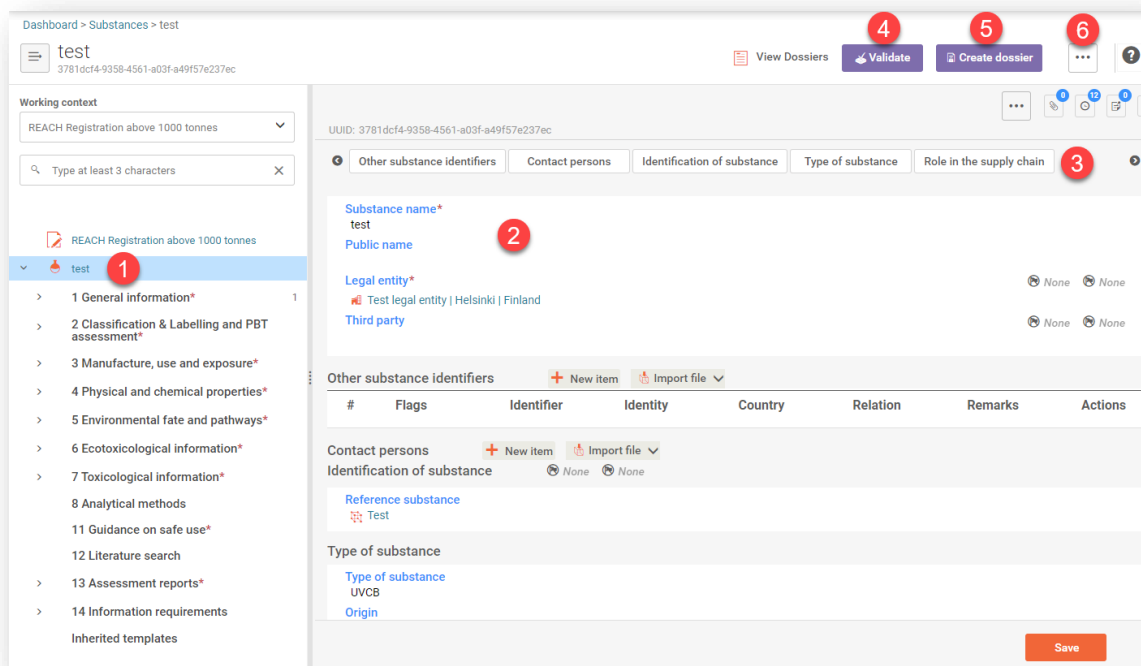


By selecting the checkbox next to the datasets you will be able to export or delete the selected dataset. More than one dataset can be selected in one instance.

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 **A** Insert existing templates **v**.

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

#	Flags	IT system	Remarks	Actions
1				

Validate

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.



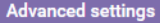
Dossier creation is started by clicking on the button *Create dossier* (5).



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

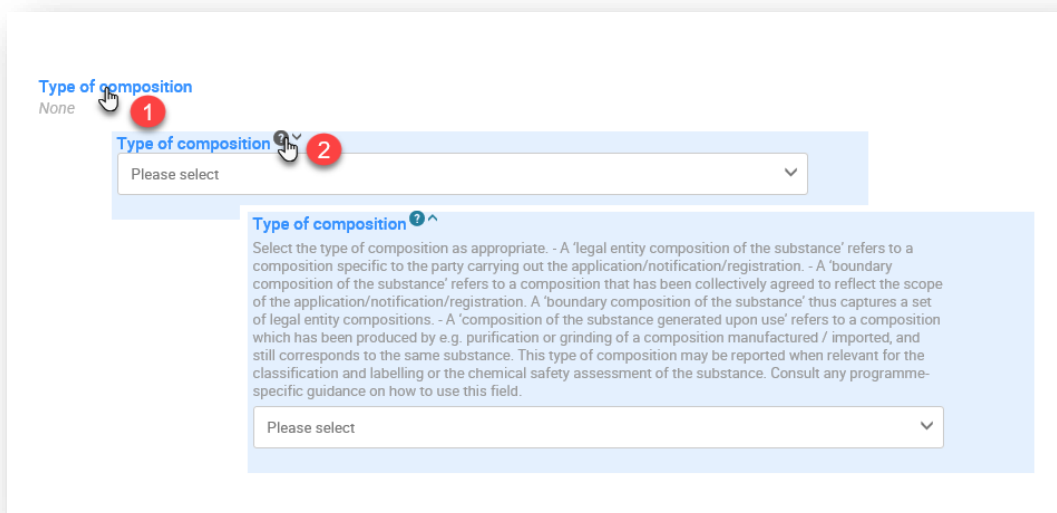
The functionalities of IUCLID are described in detail in the help document *Functionalities of IUCLID in the web interface*. To access the *Functionalities of IUCLID* document, click the icon



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

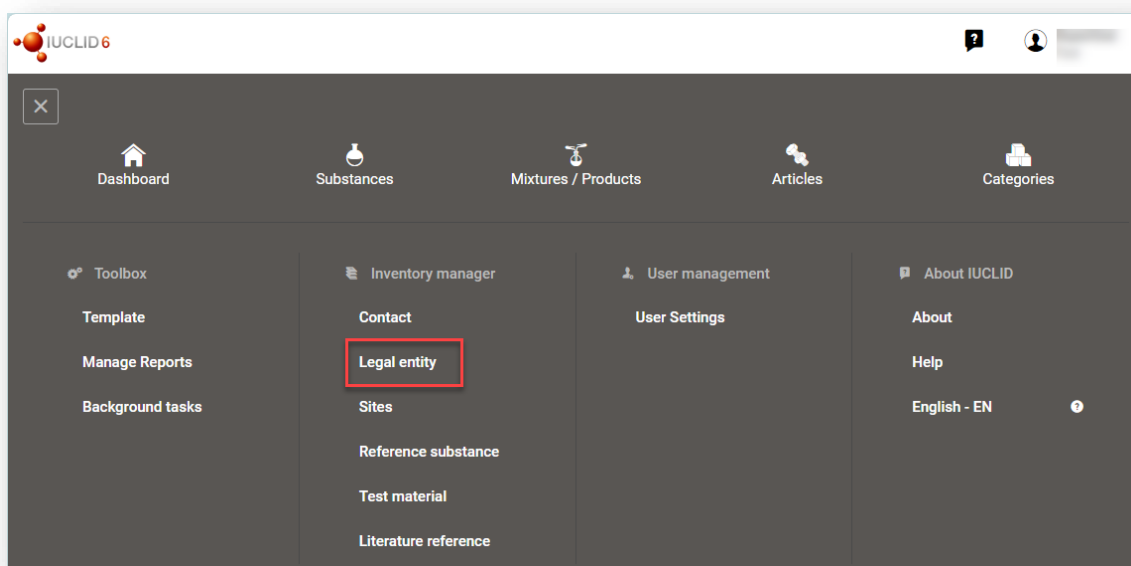
Submissions to ECHA are done by *Legal entities* which have to be defined including contact details prior to submission. The contact details of the company are stored as a *Legal Entity Object (LEO)*. You can create a LEO both in IUCLID and in the *ECHA accounts* available at <http://idp.echa.europa.eu/ui/>.

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:

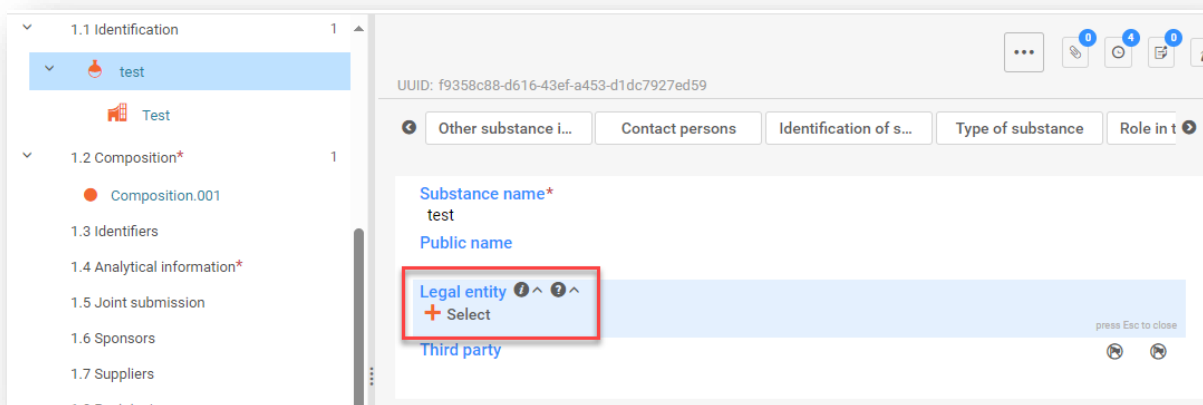
1. By clicking on *Legal entities* from the main Menu.

Figure 8: Add more legal entities from the main menu



2. From the point where the Legal entity is referred to in a dataset.

Figure 9: Add more legal entities from the 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. Contact

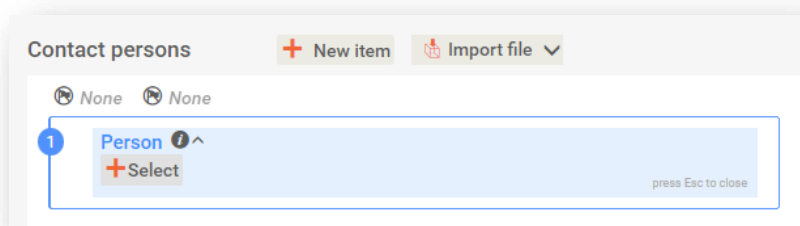
In the Contact inventory you can insert the contact details of the relevant competent persons, such as person responsible for the safety data sheet (SDS), toxicologist, etc, which can be attached to the IUCLID dossier. This person may be contacted to provide assistance or ask about the information submitted.

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 (for example in section 1.1). 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

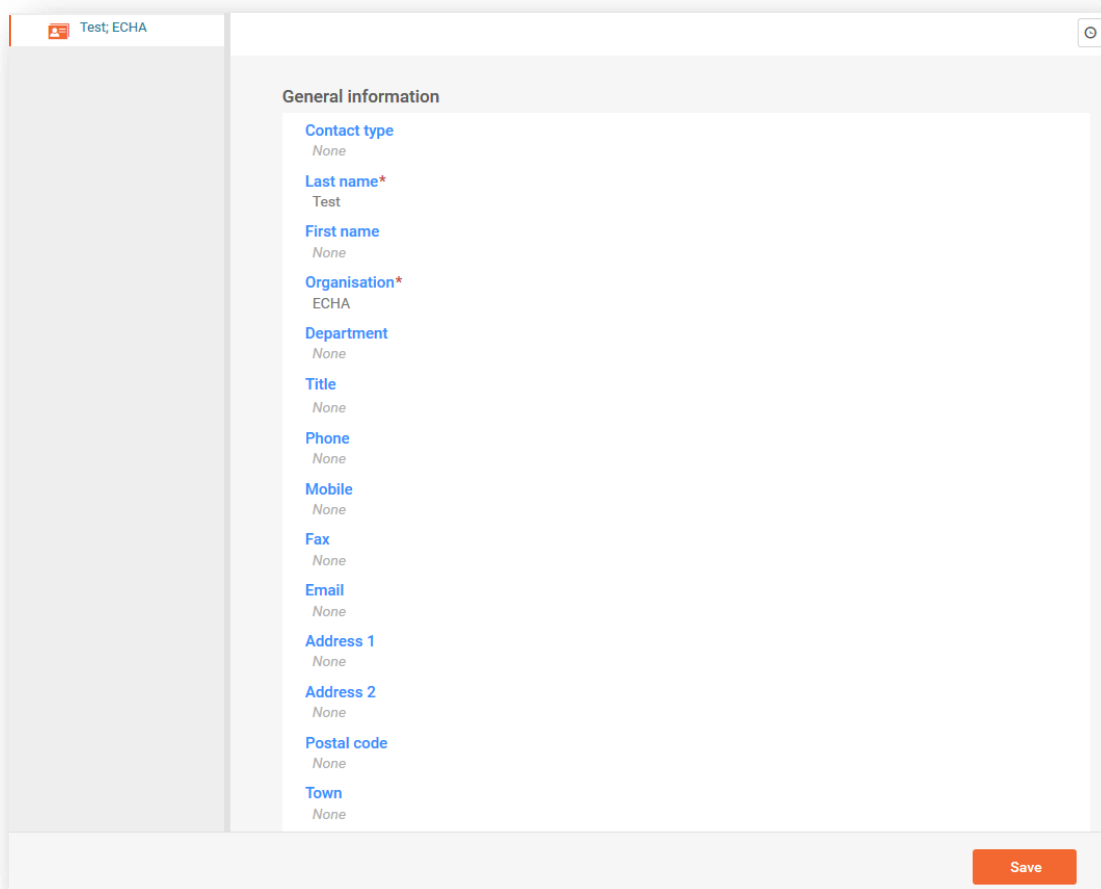


3.1. Creating a contact

To create a new contact:

- Step 1.** Click on *New contact / Create*.
- Step 2.** 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 3.** Click *Save*.

Figure 11: Create a new Contact



4. 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.

4.1. 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;
2. 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)

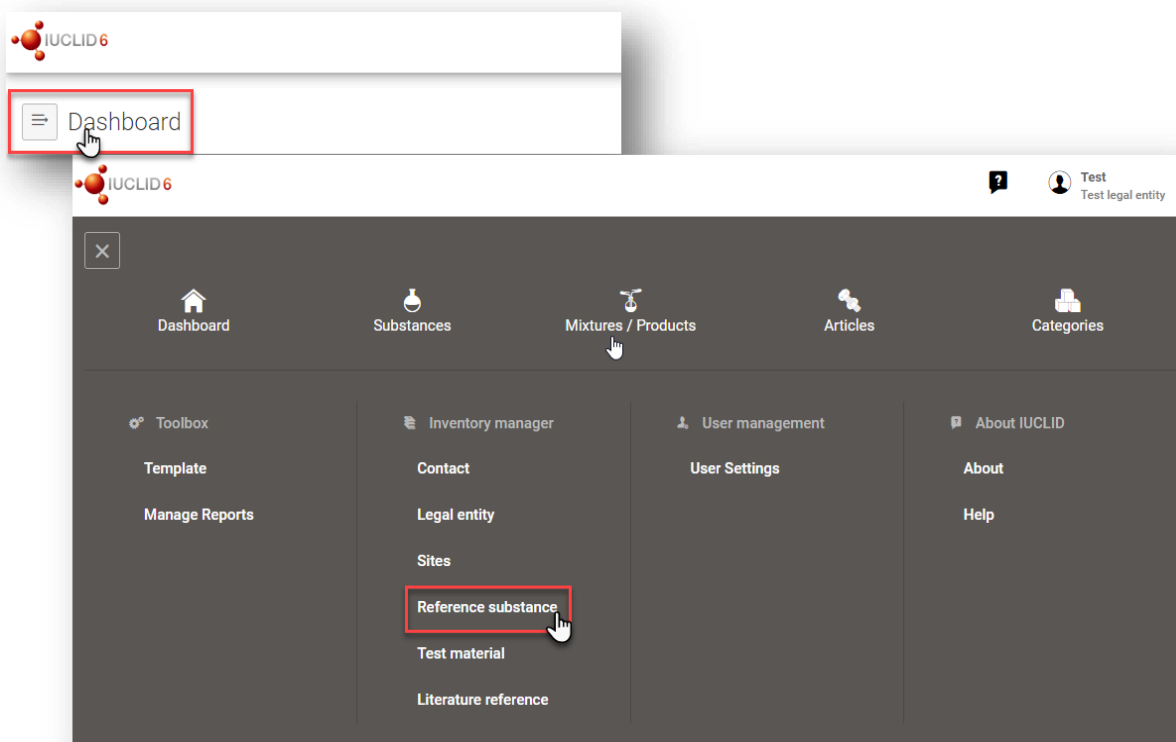
Related information should be reported under the *Identifiers of related substances* as it may create an ambiguity on the identity of substance or constituent(s) which a reference substance corresponds to.

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.

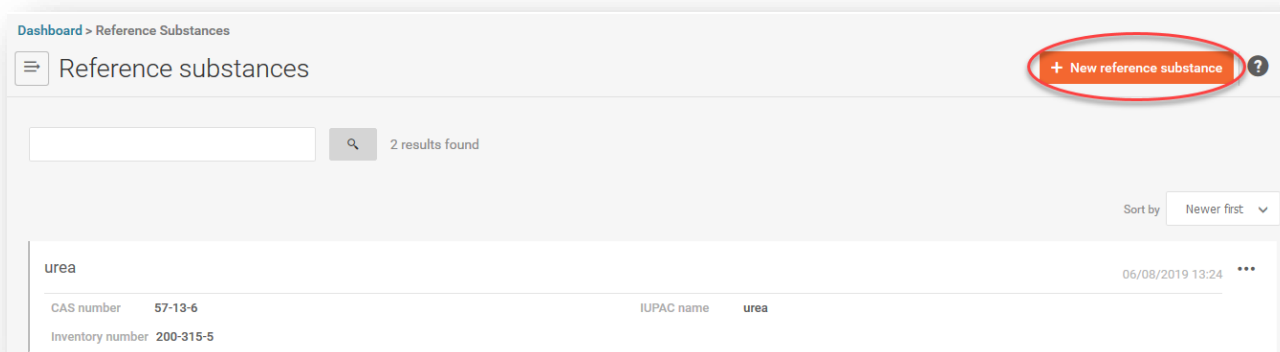
Figure 12: Open the list page for Reference substances



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** or if it is described by an existing List number you can assign that numerical entry by filling the *Inventory number* field.
- Step 4.** If your **reference substance is not listed in the EC inventory** and **no List number exists**, 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:

- *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*.

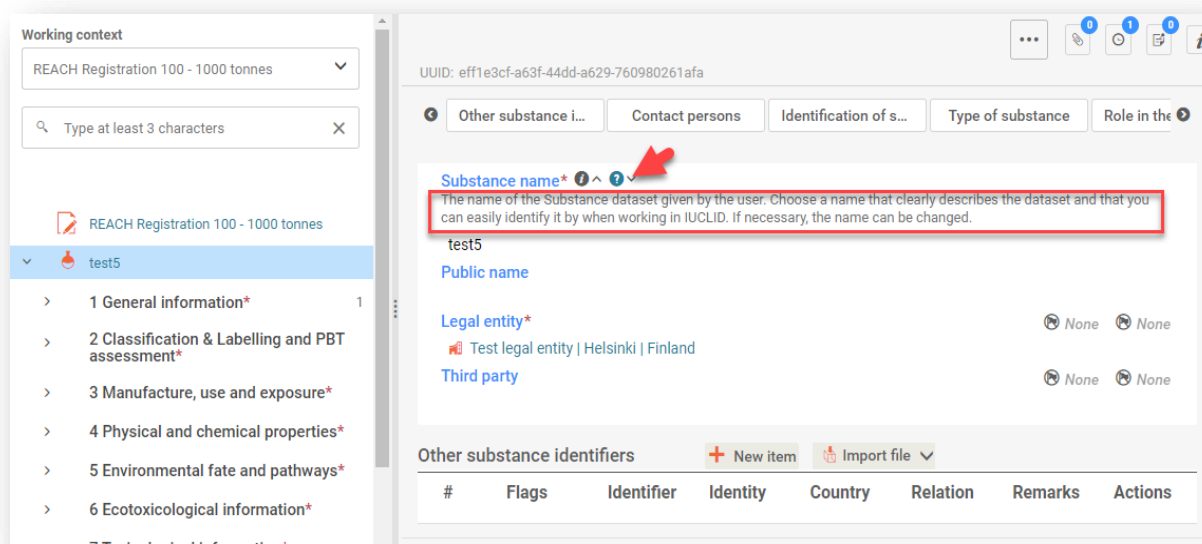
5. How to create a substance dataset

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 *IUCLID User Manual* 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.

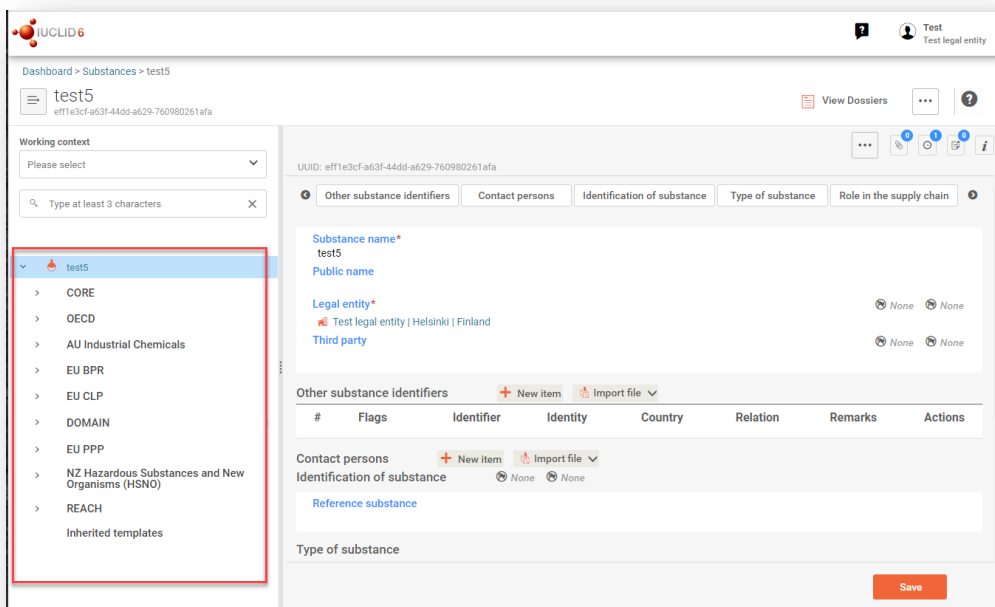
Figure 15: Substances page - list of substances

The screenshot displays the IUCLID 6 Substances page. At the top, there is a search bar and a '+ New substance' button. Below the search bar, there are tabs for 'Datasets' and 'Dossiers'. A section for 'Advanced search' shows '3 results found' and buttons for 'Export', 'Delete', and 'Export CSV'. The main content area lists three substances:

Substance Name	Inventory number	CAS number	UUID	IUPAC name	Date
test 2					01/10/2020 16:13
Andromeda nano	203-491-1	107-45-9		203-491-1	01/10/2020 15:28
test					30/09/2020 15:05

Each substance entry includes a checkbox, a table of metadata (Inventory number, CAS number, UUID, IUPAC name, Legal Entity), and a 'Burn' icon in the bottom right corner.

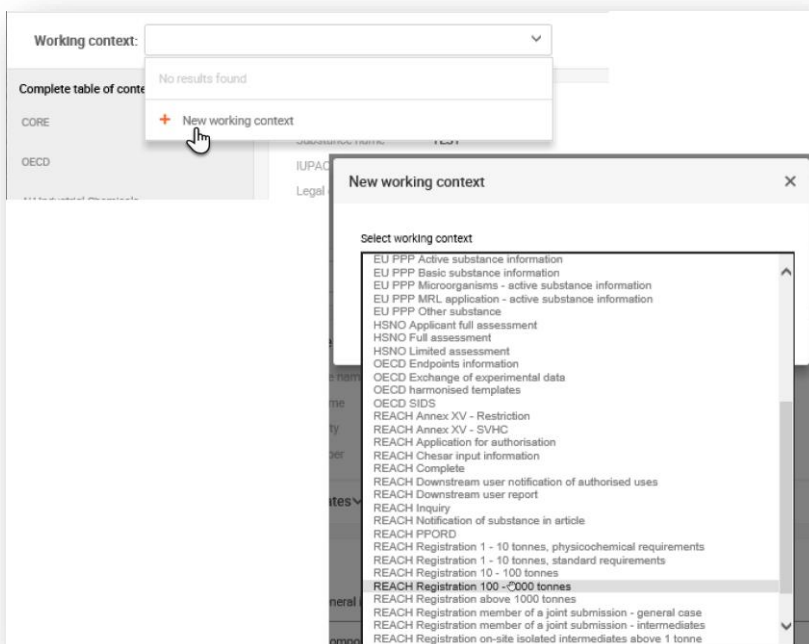
Figure 16: View of substance dataset with complete table of content (TOC)



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.

5.1. Section 1 General information

In section 1, *General information*, enter information on substance identity and on the dossier submitter. According to the data requirement for a C&L notification, IUCLID sections 1.1 to 1.3 shall be completed by the notifier.

5.1.1. 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.

More information on how to derive a *public name* for a substance for use under the REACH Regulation, you can find at <http://echa.europa.eu/manuals>.

Step 3. Make sure that the pre-set *Legal entity* is correct. Please note that the legal entity you created when you installed IUCLID has automatically been attached to your substance dataset (see chapter *Legal entity*).

Role in the supply chain:

Step 4. Select at least one checkbox in this section according to your role in the supply chain with regards to this substance.

Identification of substance:

Step 5. Click in the *Reference substance* field and then on the *Select* button to assign a *reference substance* to your substance dataset.

Step 6. A window with a list of reference substances appears. Search for your reference substance and click on it.

If you cannot find your reference substance because it has not been created yet, click *Create* and fill in the data (see chapter *Reference 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.

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.

Type of substance:

Step 7. Select the appropriate *Type of substance* from the picklist.

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

Step 8. Select the *Origin*, e.g. organic or inorganic, from the picklist.

Step 9. 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 10. You can add information of the contact person(s) for this substance from the previously defined contacts (see chapter *Contact*).

Step 11. To save the information click *Save* at the bottom of the page.


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

Step 4. 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 5.** 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 6.** 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 7.** You can provide supporting attachments under *Attached description / justification*.
- Step 8.** 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 9.** 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

Degree of purity

% (w/w)

Constituents:

- Step 10.** 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 11.** 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 12.** Indicate the *Typical concentration* and the *Concentration range* (minimum and maximum values, and unit of measurement) for every constituent.

Figure 19: Constituent

The screenshot shows the 'Constituents' management interface. At the top, there are buttons for 'New item' and 'Import file'. Below is a table with the following columns: '#', 'Referenc...', 'Typical c...', 'Concentr...', 'Remarks', and 'Action'. The first row contains the number '1', two 'None' buttons, 'None', 'None', 'None', 'None', and a trash icon.

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

- Reference substance: testene | testene
- Typical concentration: ca. 98 % (w/w)
- Concentration range: > 96 <= 99.5 % (w/w)
- Remarks: None

Impurities and additives:

- Step 13.** To complete the information regarding *Impurities* and *Additives* follow the same procedure.
- Step 14.** Where the impurity or additive is considered relevant for classification and labelling of the substance, the relevant checkbox must be selected.
- Step 15.** 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

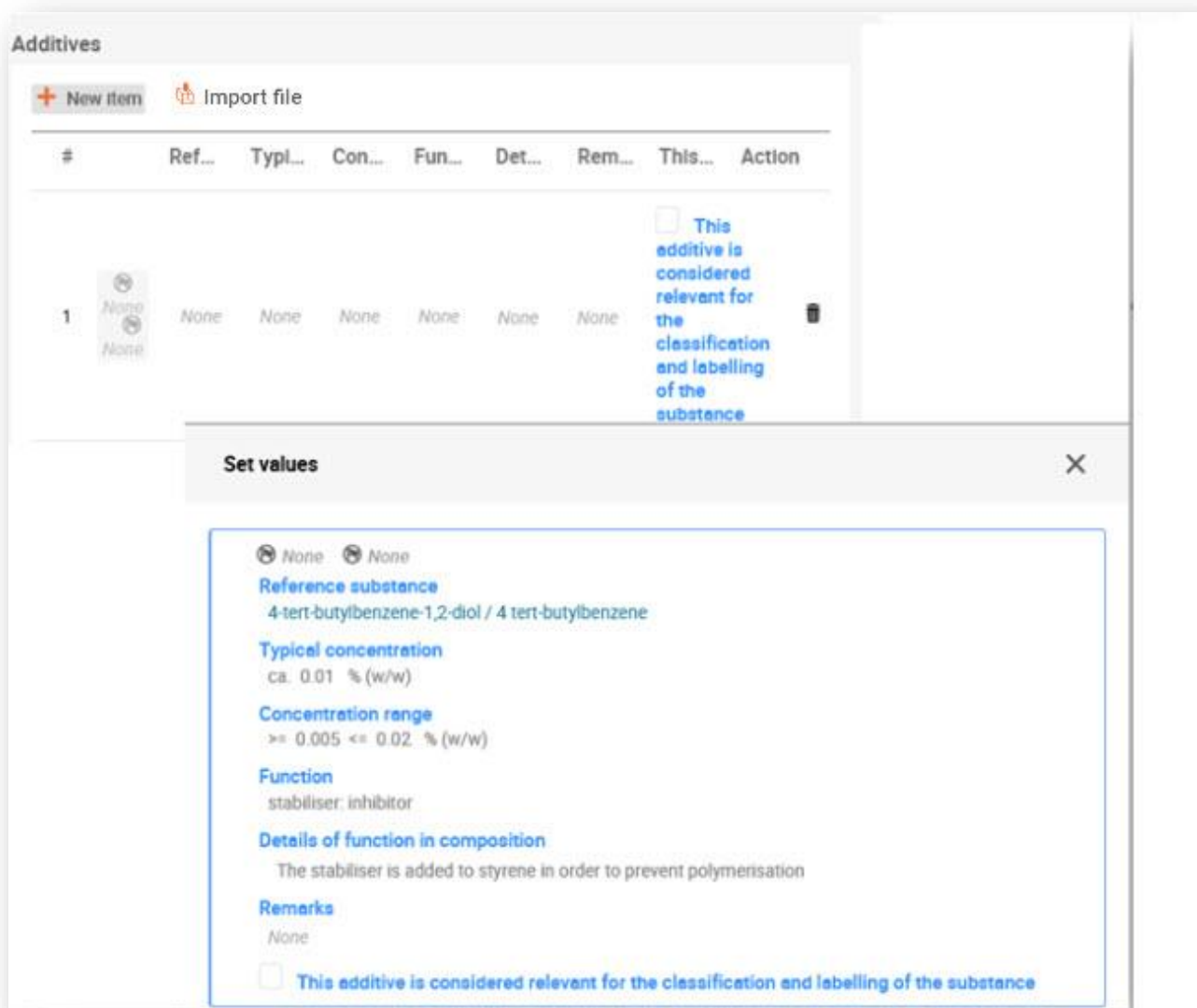
far as possible. Also provide the *Typical concentration* (with unit of measurement) and *Concentration range* (with unit of measurement) for the *unknown impurities*.

Figure 20: Unknown impurities

The screenshot displays 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 entry with 'None' in most fields and a checkbox in the 'This Im...' column.

The 'Set values' dialog box is open, showing the following details for the selected impurity:

- 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.
- Checkbox: This impurity is considered relevant for the classification and labelling of the substance

Figure 21: Additive

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:

- 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

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.

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).

5.1.3. 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*.

5.1.4. Section 1.4 - Analytical information

Use section 1.4 of IUCLID to specify, if available, some of the information requested under Article 40 (1- b) of the CLP Regulation, on the identity of the substance to be notified.

- Step 1.** In the navigation panel click on  next to *1.4 Analytical information*.
- Step 2.** Under the *Optical activity* field, provide information on the existence or not of optical activity.
- Step 3.** In the *Remarks* field, provide information on typical ratio of (stereo) isomers, whenever applicable.

If your substance is optically active you should also specify the value for the specific rotation (in degrees) indicating also the temperature of measurement (in °C) and the wavelength of the incident light source (in nanometres). The direction of rotation should also be specified as either + or -. If a sample solution is used the concentration and solvent name should also be provided.

Typically specific rotation is specified as follows:

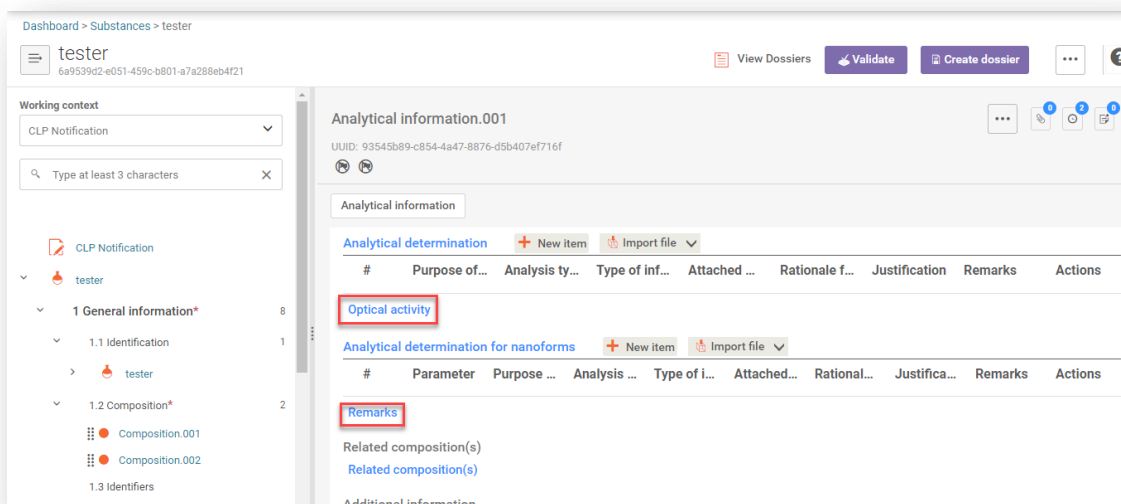
$[α]_t^λ$

Where: $[α]$ = specific rotation

t = temperature in °C

λ = wavelength of incident light; for sodium D lamp (598 nm) this is indicated simply by D.

Figure 22: Optical activity information



Analytical methods and spectral data are not requested in a C&L notification under the CLP Regulation.

5.2. Section 2 C&L and PBT assessment

The information on the substance C&L according to the GHS should be included in IUCLID section 2.1.


5.2.1. 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 CLP 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>.

If your substance has more than one classification, for example, due to different compositions and forms, you can report these by creating several records.

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.

A CLP Annex VI Harmonised classification has to be respected and you should report those harmonised hazard classes/differentiations accordingly. 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 each created record, 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. Note that if for the same composition or form of the substance certain hazard classes are based on a harmonised classification and others are self-classified, you should report all classifications in the same record and select *harmonised classification* in the field *Type of 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 can select a *Hazard category*, *Hazard statement* and *Reason for classification* for each hazard class or differentiation. Otherwise, you must fill in the *Reason for no classification*.

Note that when reporting hazards, the fields *Reason for no classification* have the default selection *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.

As of IUCLID 6 version 8, a new field *Reason for classification* is available to report the reason(s) for classification per each hazard class. In the field, there are several options to select and it is possible to select more than one entry from the picklist.

- If a harmonised classification based on Annex VI of the CLP regulation exists for the hazard class, you should always select *EU harmonised classification* as the *Reason for classification*.
- If there is no harmonised classification but you are self-classifying based on the available data, specify if the classification is driven by a particular component of the substance (constituent/impurity/additive), by a particular physical state, size or form of the substance, or by the substance itself.

IUCLID 6 v.8 includes new CLP hazard classes

The CLP Regulation has been amended in 2023 to introduce the following new hazard classes:

- ED HH in Category 1 and Category 2 (Endocrine disruption for human health)
- ED ENV in Category 1 and Category 2 (Endocrine disruption for the environment)
- PBT (persistent, bioaccumulative, toxic), vPvB (very persistent, very bioaccumulative)
- PMT (persistent, mobile, toxic), vPvM (very persistent, very mobile)

Following the entry into force of the Delegated Regulation different transition periods apply for reporting the new classifications during which manufacturers, importers, downstream users **and distributors are not** yet required to classify or label their substances or mixtures in accordance with [the new hazard classes](#). However, during these periods, the new hazard classes can already be applied on a voluntary basis.

More information on the ECHA website: <https://echa.europa.eu/new-hazard-classes-2023>

Delegated Regulation 2023/707 amending the CLP Regulation (EC) No 1272/2008

If no classification is reported for a specific hazard class, 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* can be selected if the hazard class has not been assessed yet, e.g. if a transition period applies to the hazard class.

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*), *Hazard statement* (e.g. *H201: Explosive; mass explosion hazard*) and *Reason for classification* (e.g. based on the substance itself) 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*), *Hazard statement* (e.g. *H300: Fatal if swallowed*) and *Reason for classification* (e.g. *EU harmonised classification*) 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 23: Specify the nature and the route of exposure for reproductive toxicity

Reproductive toxicity	Hazard statement	Reason for no classification
Reproductive toxicity Hazard category Repr. 1A Specific effect H360F May damage fertility Route of exposure ✓ oral	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>.	

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 24: Specify the hazard of carcinogenicity via inhalation

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

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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*, *Reason for classification* 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 IUCLID section 13 (unless it is already specified in Annex VI to the CLP Regulation).

Figure 25: Specify the affected organ

The screenshot displays two configuration panels for hazard classes. The top panel is for 'Specific target organ toxicity - single (STOT-SE)'. It includes a 'New item' button and a list of fields: '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', 'System', 'Affected organs' (checked: kidney), and 'Route of exposure' (checked: oral). The bottom panel is for 'Specific target organ toxicity - repeated (STOT-RE)'. It also includes a 'New item' button and fields: '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', 'System', 'Affected organs' (checked: liver), and 'Route of exposure' (checked: 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 Irritation 3 Mild	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*.

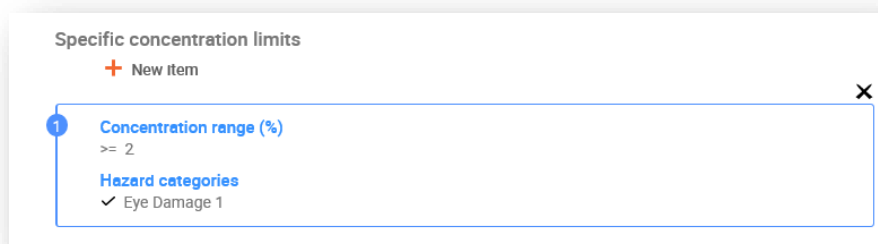
You can specify more than one concentration limit by adding additional entries. To add additional entries, click *New item*.

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 26: 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 – Acute Toxicity Estimates (ATE)

Step 11. If you have reported an acute toxicity hazard classification, provide an acute toxicity estimate for all the relevant routes of exposure. For the calculation, see Table 3.1.1 and notes in Annex I or the CLP regulation.

Classification - Environmental hazards:

Step 12. Specify Hazard category (e.g. Aquatic Acute 1), Hazard statement (e.g. H400: Very toxic to aquatic life) and Reason for classification (e.g. EU harmonised classification) 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 27: Specify the Environmental hazards

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

Classification – Ozone layer:

Step 13. Select *Hazardous to the ozone layer 1* in the field *Hazard category* and the *Hazard statement H420* if the substance is classified as such.

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 28: Labelling for section 2.1

The screenshot shows a 'Labelling' form with the following content:

- 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

5.3. Section 13 Assessment reports

Section 13 can be used to attach the scientific justification requested under Article 40(1e) of the CLP regulation:

- if you want to set specific concentration limit(s) (SCL) or an M-factor under the strict conditions of Article 10 of the CLP Regulation, you have to attach a scientific justification for it,
- for the scientific justification, you should use the relevant parts of the Chemical Safety Report format according to Annex I to REACH. There is no need for a justification if the SCL value is given in Table 3.1 of Annex VI to the CLP Regulation (“the harmonised list”),
- further, this section should be used to demonstrate that a hazard is only caused by specific route(s) of exposure (unless specified in the harmonised list (Annex VI to CLP) or to submit the reasons for Classification and Labelling deviating from existing entries in the C&L inventory (Article 16(1) of the CLP regulation).

Use this section to attach, if needed, the justification requested under Article 16(1).

It should be noted indeed that in case you do not agree with the classification and labelling (excluding the harmonised ones in Table 3.1 of Annex VI) already present in the C&L inventory, you have to provide a reason for this specific hazard class or differentiation. The reason can include for example an:

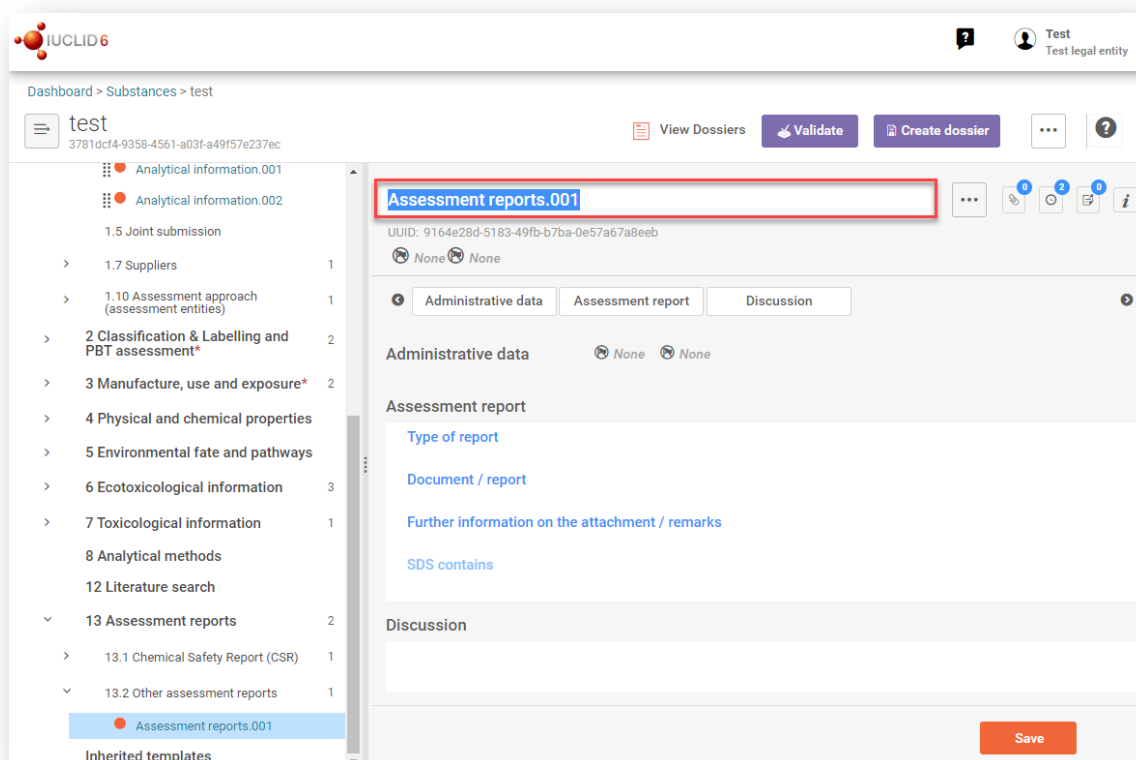
- indication that an impurity/additive has an impact on the C&L; or/and
- indication of the substance form/state; or/and
- indication that you have relevant data/information supporting your classification of the substance.

You then need to attach the document containing the justification in IUCLID as part of the substance dataset as follows:

Step 1. In the navigation panel Click on the **+** button next to 13.2 *Other assessment report*.

Step 2. A new endpoint study record section appears. Re-name the new endpoint study record to "Justification for a SCL or M factor in accordance with Article 10 of the CLP Regulation" or "Justification for route of exposure or Reason for not agreeing with a notified C&L (article 16)" and save it. The endpoint can be renamed by clicking on the title field as shown below.

Figure 29: Re-naming the endpoint study record



To complete this section follow the steps:

Step 3. Click in the field *Type of report* and from the picklist choose *other* and fill in the field below.

Step 4. In the *Document/report* field click *Select file*. Find the relevant document, and attach it. Use the *Further information on the attachment / remarks* field to specify further the nature of the document. Then click *Save*.

Repeat the steps if you need to attach more documents in this section.

6. 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.


6.1. Administrative information

Enter an appropriate *Dossier name* which enables you to easily identify the dossier when searching and exporting it from IUCLID.

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. 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*.

8. 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/>.

9. 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 *Validate* in your substance dataset page or on the dossier. 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 plugin cannot simulate all the business rules checked by the Agency.

Business Rules applicable only for the CLP notifications		
Location (IUCLID/REACH-IT)	Rule description	Relevance
IUCLID substance dataset	A dossier must be created from a substance dataset. It cannot be created out of a mixture or product dataset.	All dossier types
IUCLID section 1.1 – Identification	A reference substance must exist in section 1.1.	All dossier types
IUCLID section 1.1 - Identification	At least one of the following fields must be provided for the reference substance in section 1.1: EC/List number CAS number Molecular formula AND molecular weight AND structural formula SMILES notation Remarks	CLP Notifications
IUCLID section 1.1 – Identification; section 1.2 – Composition	Each reference substance in section 1.1 and 1.2 must contain a substance identifier. An acceptable substance identifier is: EC/List number CAS number IUPAC name Any EC/List number defined in section 1.1 and 1.2 of IUCLID must exist in the REACH-IT EC inventory. If you use a reference substance to report unknown constituents/impurities, they must be “identified” by inserting “Unknown constituent/impurity” in the IUPAC name field.	All dossier types

	If categories are used, this rule is applied to all the category member substances.	
IUCLID section 1.1 – Identification	In an update submission, the substance must be identified by an EC/List number.	CLP Notifications
IUCLID section 1.2 - Composition	At least one composition must be defined in section 1.2. The following requirements are also to be fulfilled: All created compositions must contain at least one constituent. All constituents must be linked to a reference substance.	All dossier types
IUCLID section 1.2 – Composition	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”. If the composition type “other” is selected from the list, the relevant information must be provided in the free text field below.	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; section 1.2 - Composition	If the substance is defined as a multi-constituent substance, the reference substance in section 1.1 cannot be identical to any of the constituents defined in the first composition of type ‘legal entity composition of the substance’ in section 1.2.	All dossier types
IUCLID section 1.2 - Composition	All constituents of a multi-constituent or of a UVCB substance must identify distinct reference substances.	All dossier types
IUCLID section 1.1 - Identification; section 1.3 – Identifiers	The EC number assigned to the Inquiry number you have indicated in section 1.3 must match with the EC number linked to the reference substance in Section 1.1	CLP Notifications
IUCLID section 1.2 – Composition	At least one value and a unit must be provided for the ‘Degree of purity’ for each ‘Legal entity composition of the substance’ in section 1.2.	CLP Notifications
IUCLID section 1.2 – Composition	The full ‘Concentration range’ (lower and upper value together with a unit) must be provided for each constituent, impurity and additive of a legal entity composition in IUCLID section 1.2. When reporting a constituent, impurity or additive at exactly 0% or 100%, provide this value, together with the unit, in the field ‘Typical concentration’ and leave the ‘Concentration range’ fields empty.	CLP Notifications
IUCLID section 1.2 - Composition; section 2.1 - GHS	When creating a substance dataset containing multiple compositions of type ‘Legal entity composition of the substance’ in section 1.2, all of them must be linked to a classification and labelling record in section 2.1.	CLP Notifications
IUCLID section 1.2 - Composition;	When you are reporting several compositions in section 1.2 and several records in classification and labelling (C&L) in section 2.1 then each	CLP Notifications

section 2.1 - GHS	composition must be assigned to the corresponding C&L record, through the section 2.1 field 'Related composition'.	
IUCLID section 1.2 - Composition	When submitting CLP notifications, only compositions of type 'Legal entity composition of the substance' are allowed.	CLP Notifications
IUCLID section 1.3 - Identifiers	When submitting an update to a previously notified substance (NONS), it is not enough to provide the Registration number, but the matching NCD number must also be indicated.	CLP Notifications
IUCLID section 2.1 - GHS	At least one set of classification and labelling information must be provided in GHS format under section 2.1.	CLP Notifications
IUCLID section 2.1 - GHS	If at least one classification is provided in a C&L record in section 2.1 then: a 'Signal word' must be provided under the 'Labelling' heading of the same record. a 'Hazard statement' or a 'CLP supplemental hazard statement' must be provided under the 'Additional labelling requirements' heading of the same record. If no classification is provided, the tick box 'Not classified' should be selected and no hazard statements and no signal words should be provided.	CLP Notifications
IUCLID section 2.1 – GHS	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 must be made under 'Hazard categories'. 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.	CLP Notifications
IUCLID section 2.1 – GHS	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. If the substance is not classified, the tick box 'Not classified' should be marked and no classification should be provided in that record.	CLP Notifications
IUCLID section 2.1 – GHS	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'. If the substance is not classified, the tick box 'Not classified' should be marked and no classification.	CLP Notifications
IUCLID dossier header	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.	CLP Notifications

<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 an entry under 'Spontaneous update' and then making a selection in the picklist. If you selected 'other:', you are required to give the reason in the free text field below.</p>	<p>CLP Notifications</p>
<p>IUCLID dossier header</p>	<p>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.</p>	<p>CLP Notifications</p>
<p>IUCLID dossier header</p>	<p>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.</p>	<p>CLP Notifications</p>
<p>IUCLID dossier template</p>	<p>The dossier template used in IUCLID must correspond with the intended submission type in REACH-IT.</p>	<p>All dossier types</p>
<p>REACH-IT</p>	<p>A new dossier cannot be submitted when the previous submission for the same substance is still being processed.</p>	<p>All dossier types - Updates</p>
<p>REACH-IT</p>	<p>It is not allowed to submit a CLP notification while a registration dossier for the same substance is currently undergoing a submission process.</p>	<p>CLP Notifications</p>
<p>REACH-IT</p>	<p>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.</p> <p>Legal entity change functionality is available in REACH-IT.</p>	<p>All dossier types</p>

REACH-IT	It is not allowed to upload a new dossier for the same substance, when the previous submission is still being processed.	CLP Notifications
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.	CLP Notifications
REACH-IT	It is not allowed to submit an initial/update CLP notification, if the substance has already been registered by the submitting legal entity.	CLP Notifications

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