ECHA
EUROPEAN CHEMICALS AGENCY

How to prepare an inquiry dossier

April 2024

ABC

Disclaimer

This document aims to assist users in complying with their obligations under the REACH Regulation. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at:
http://echa.europa.eu/contact

European Chemicals Agency

P.O. Box 400, FI-00121 Helsinki, Finland

Changes to this document

Version	Changes
12.0	April 2024: Editorial changes
11.0	October 2023: Editorial changes
10.0	May 2023: Update to reflect the new functionalities of IUCLID 6.7
9.0	October 2022: Update to reflect the new functionalities of IUCLID 6.6
8.0	October 2021: Update to reflect the new functionalities of IUCLID 6.6
7.0	April 2021: Update to reflect the new functionalities of IUCLID 6.5
6.0	October 2020: Update to reflect the new functionalities of IUCLID 6.5
5.0	April 2020: Update to reflect the new functionalities of IUCLID 6.4 web user interface.
4.0	October 2019: Update to reflect transition from IUCLID 6.3 to IUCLID 6.4, and from the classic user interface to the web user interface.
3.0	October 2018: Removed the mention about the option of late pre-registration.
2.0	January 2017: Links added to translated versions of this document.
1.0	First version

Table of Contents

Table of Figures

1. Introduction

1.1. Objective

The purpose of this manual is to assist in the preparation of an inquiry dossier using IUCLID. The manual provides you with detailed and practical instructions on how to generate a substance dataset and outlines the IUCLID sections to be filled in, in order to prepare a valid dossier that can be submitted to ECHA through REACH-IT.

> 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 *The functionalities of IUCLID*).

Before registering, you have a duty to inquire to ECHA whether a registration has already been submitted for that substance.

Before preparing an inquiry dossier and submitting it to ECHA, please check whether an inquiry is necessary:

Are you a potential registrant?

You are a potential registrant if you:

- manufacture or import a substance in quantities of 1 tonne or more per year,
- use a substance in the context of production of articles or
- import an article containing a substance that would require a registration.

As potential registrant, you should inquire about your substance prior to registration provided by Article 26 of Regulation (EC) No 1907/2006 (the REACH Regulation).

> As of 1 January 2020, the duty to inquire also applies to substances that you have pre-registered before, but not yet registered. If you are planning to register any substance, you must inquire to ECHA if a registration has already been submitted for that substance.

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. To generate a dossier and submit it you have to proceed through the following steps:

Step 1. Sign-up in REACH-IT and create the Legal entity (https://reach-it.echa.europa.eu/).

Step 2. Create the reference substances in IUCLID related to your substance (see chapter *Reference substance*).

Step 3. Create the substance dataset in IUCLID (see chapter How to create a substance dataset).

Step 4. Enter information in a substance dataset in IUCLID (see the relevant sections in chapter *How to create a substance dataset*).

Step 5. Create a dossier in IUCLID (see chapter *How to create a Dossier*).

Step 6. Export a dossier from IUCLID (see chapter *How to export a Dossier*).

Step 7. Submit the dossier to ECHA via REACH-IT (see chapter Submit Dossier).

Upon receipt of your dossier, ECHA will undertake a set of administrative and technical checks of your submission (see chapter *Checks performed by ECHA on the submitted dossiers*).

1.3. Information requested for inquiry

For an inquiry dossier you must provide the following information:

- identity of the inquiry submitter (REACH-IT account),
- identity and composition of the (target) substance (IUCLID section 1.1 Identification, 1.2 Composition),
- analytical data (IUCLID section 1.4 Analytical Information),
- information requirements (IUCLID section 14 Information requirements).
- for a read-across inquiry, in addition to the information indicated above, you will also need to provide the source substance EC/List number (IUCLID section 14 Information requirements).

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
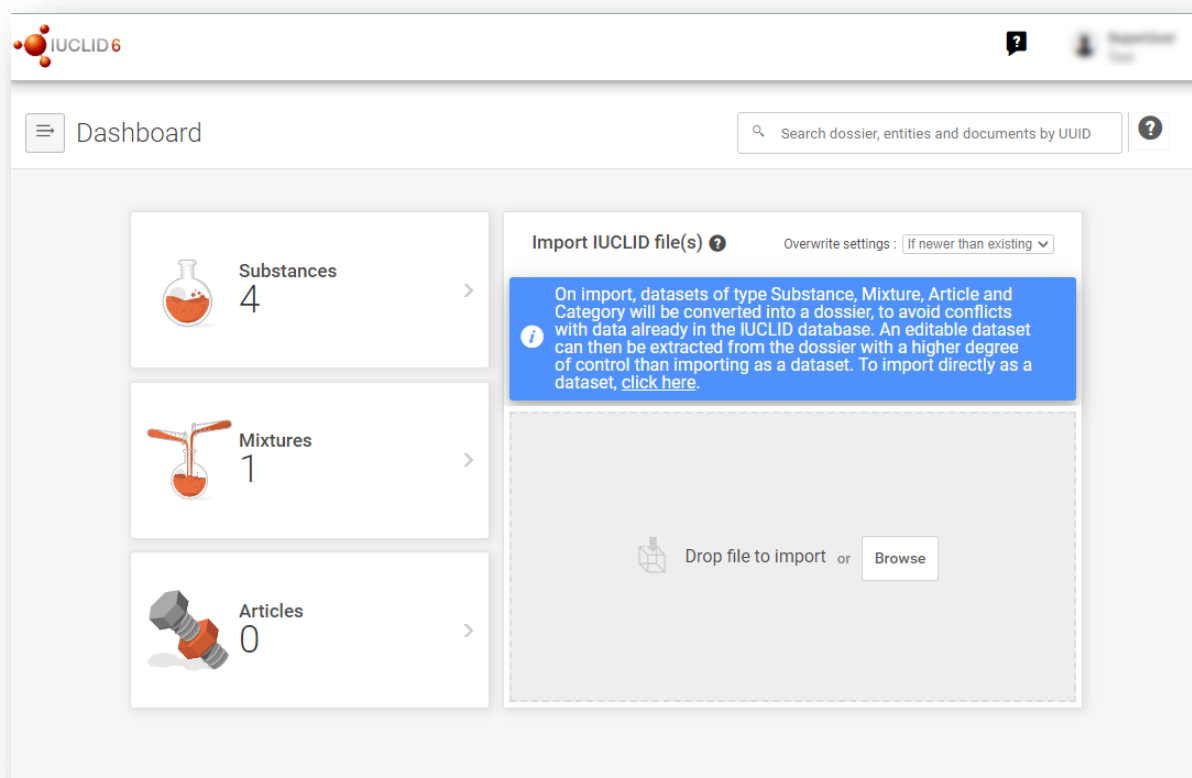
The squared question mark icon allows you to easily access to a list of supporting material

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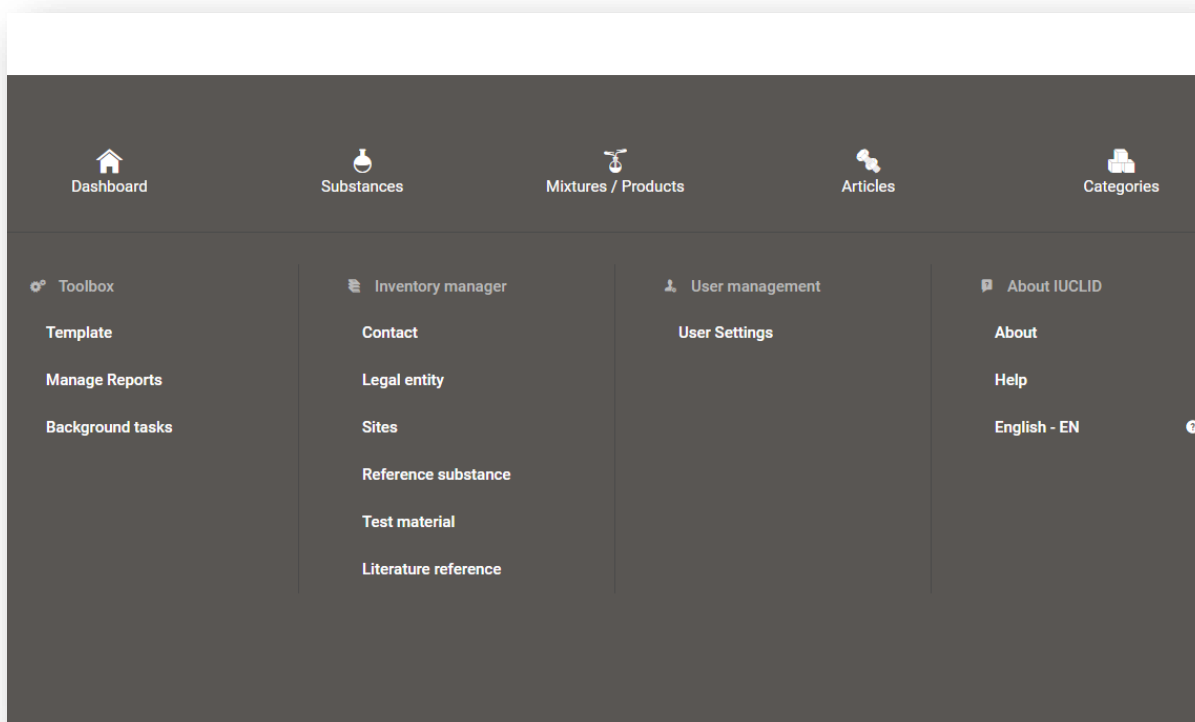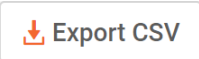
The widgets for *Substance*, *Mixtures* and *Articles* lead to lists of existing substances, mixtures and articles and the option to create new ones. The windows for *Substances*, *Mixture* and *Articles* that open by clicking on the widgets can each display either datasets or dossiers based on these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

1.5.2.   The Substances list page

Figure 3: The Substances list page
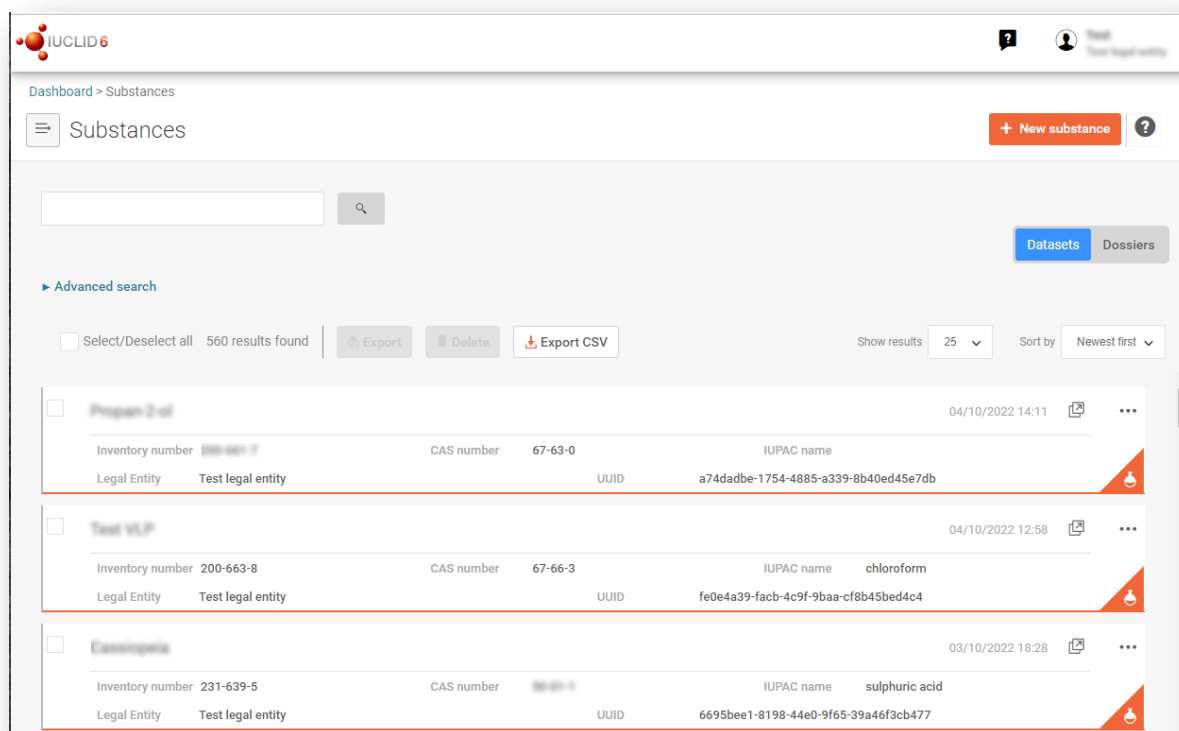
[Datasets][Dossiers] This button displayed in the *Substances*, *Mixtures* and *Articles* list pages allows switching between the display of datasets and dossiers.

[Export CSV] 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.

test 2   By selecting the checkbox next to the datasets you will be able to export or delete

the selected dataset. More than one dataset can be selected in one instance.

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

1.5.3.   The Dataset page

Figure 4: The Dataset page of a Substance dataset with the working context (submission type) "REACH Registration above 1000 tonnes"
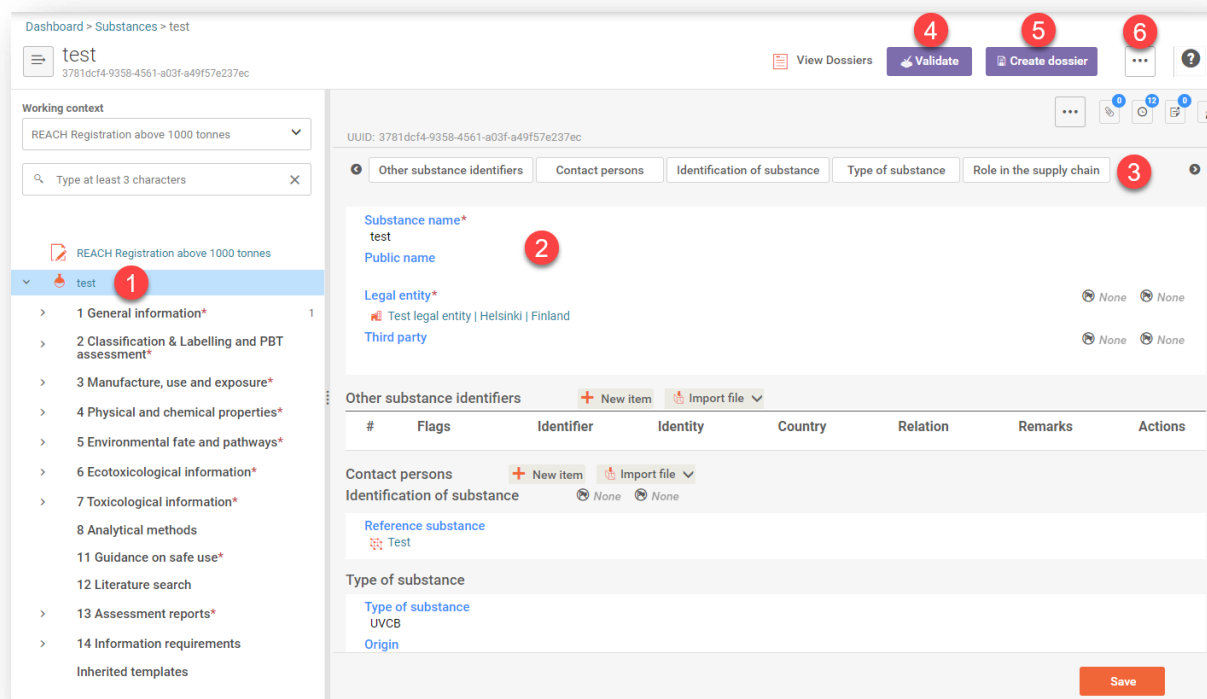
Depending on the *working context* (submission type) selected, IUCLID automatically displays the table of contents containing all sections that are relevant. The table of content is displayed as a navigation panel on the left hand side of the screen (1).

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

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

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

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

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

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

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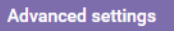
📄 Create dossier Dossier creation is started by clicking on the button *Create dossier* (5).

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

1.5.4.   The Dossier header

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

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

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 7: Add more legal entities from the main menu
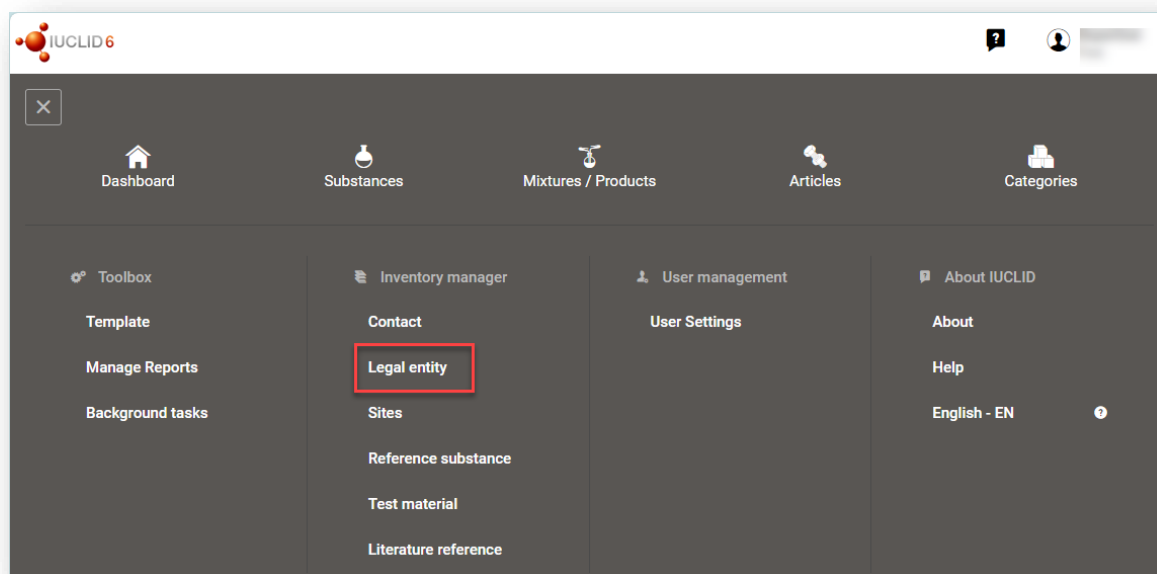
2. From the point where the *Legal entity* is referred to in a dataset.

Figure 8: Add more legal entities from the dataset
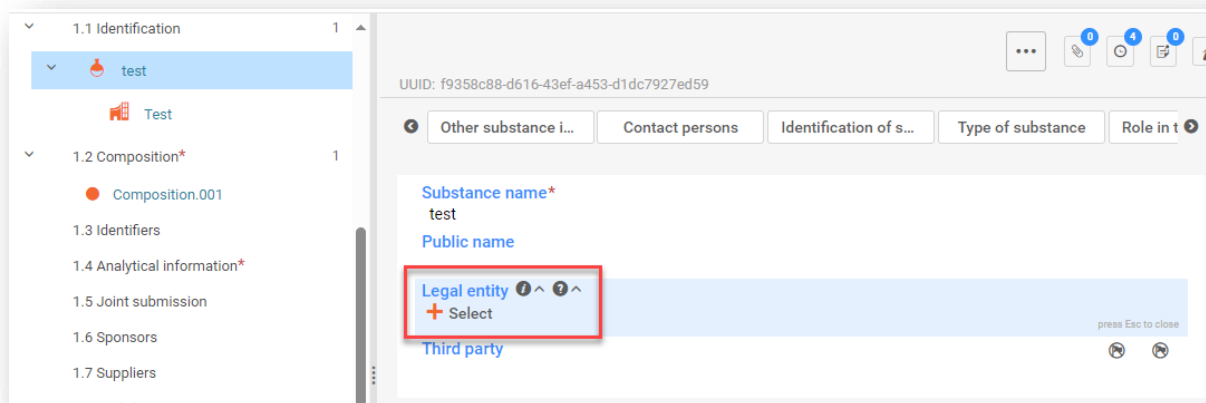
However, ECHA will not enforce the consistency between the IUCLID legal entity and the ECHA accounts legal entity.

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. Legal entity sites (Sites)

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

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

The creation and editing of a *site* is done either:

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

Figure 9: Link to Sites inventory from within the dataset
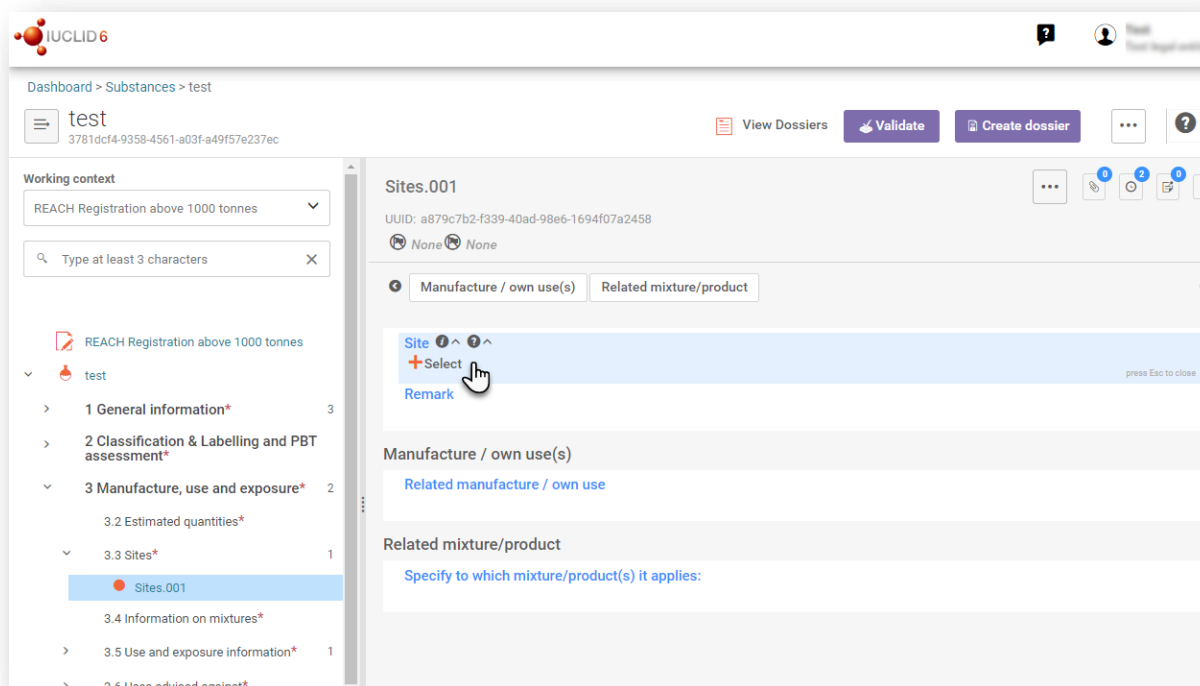
3.1.   Creating a Legal entity site

To create a new site:

Step 1.   In the pop-up window click on *New site / Create*.

Step 2.   *Complete* as many fields as possible under *General information* and *Contact address*.
The minimum data required is the *Country* where the site is located.

Step 3.   Click *Save*.

Figure 10: Create a new Legal entity site
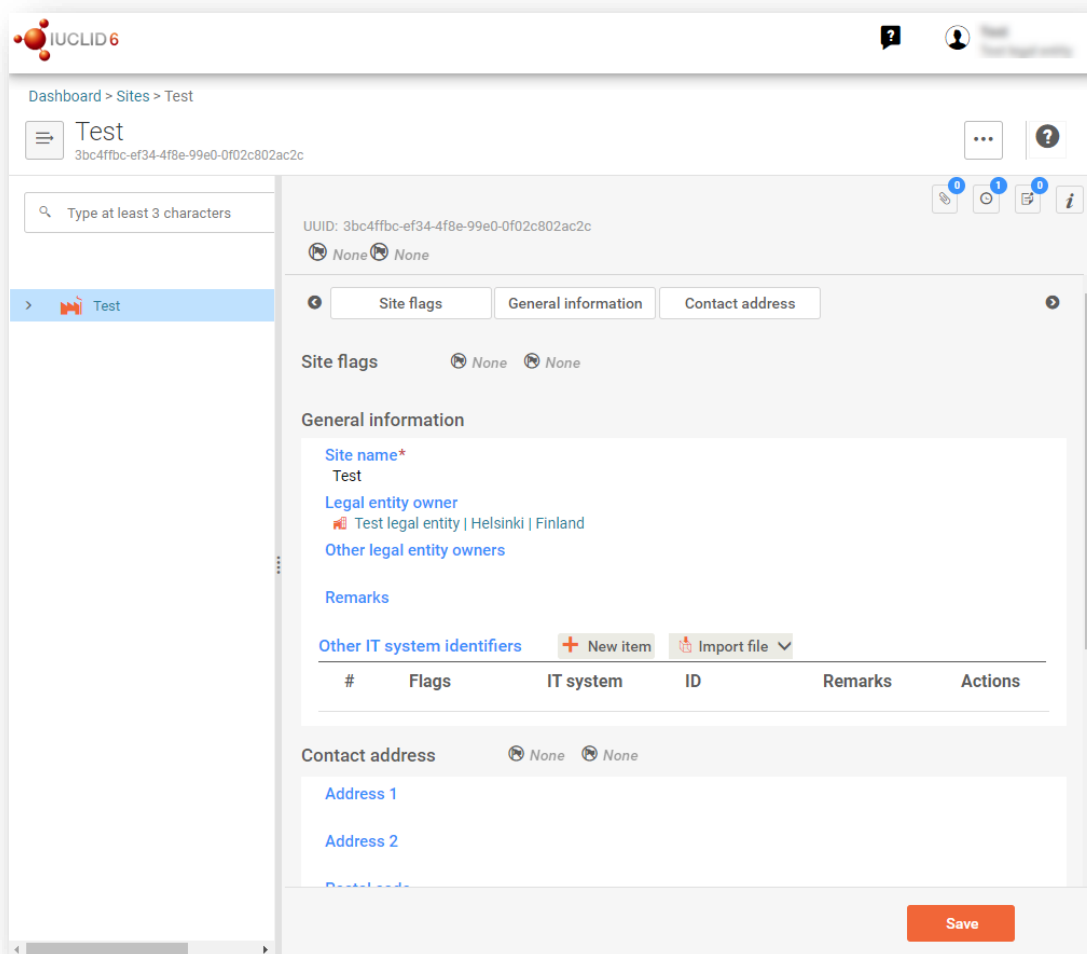
4.   Contact

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

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

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

1. from the list page of *Contacts* which can be accessed from the main Menu;
2. from the place where the *Contact* is referred to in a dataset (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 11: Link to Contact inventory from within the dataset
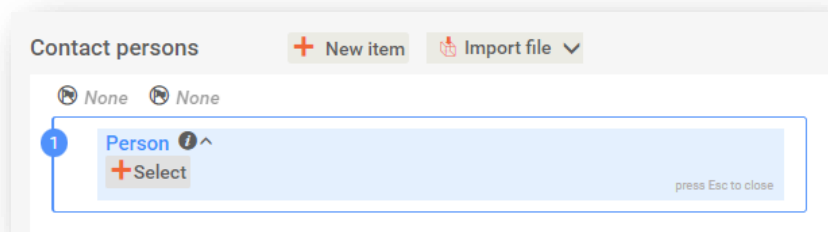
4.1.   Creating a contact

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 12: Create a new Contact
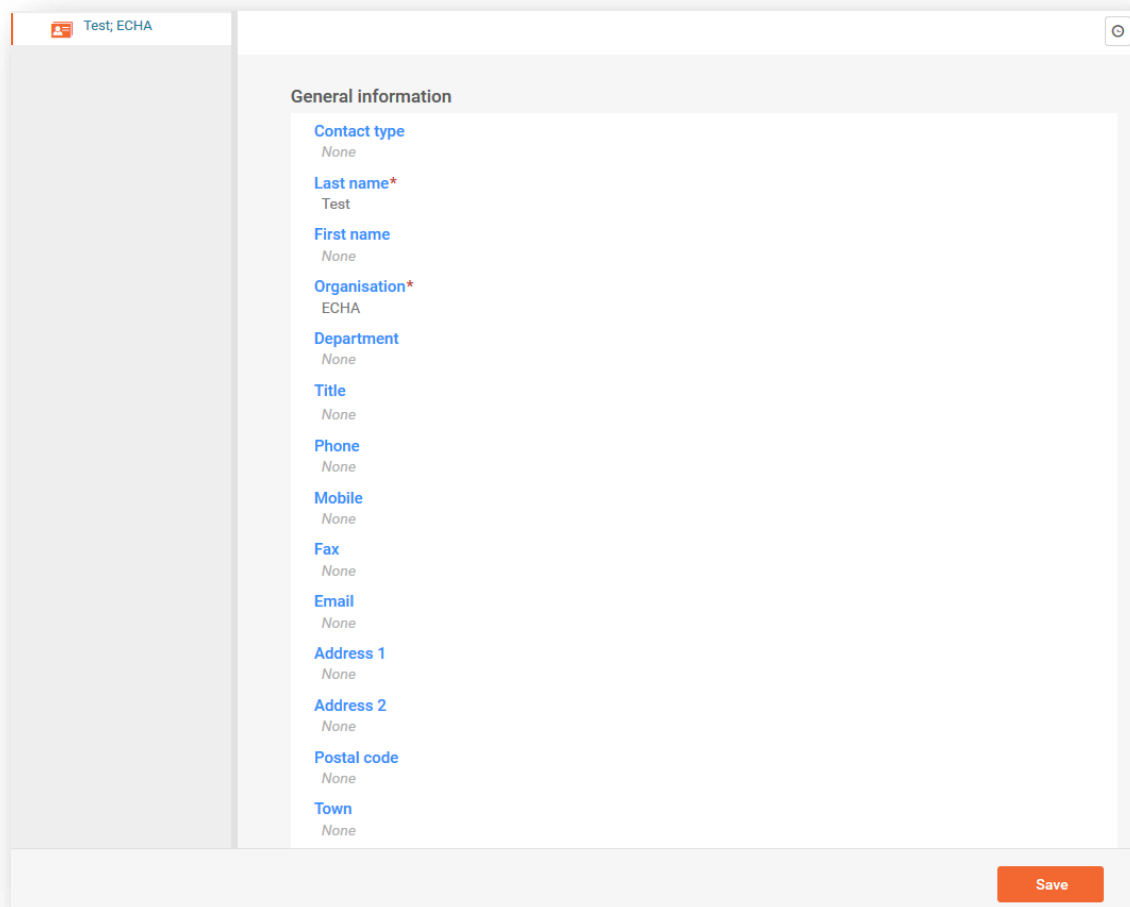
5.   Reference substance

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

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

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

5.1.   Creating a reference substance

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

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

1. Information **specific** to the *reference substance*: such information exactly corresponds to the substance/constituent(s) covered by that reference substance;

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 13: Open the list page for Reference substances
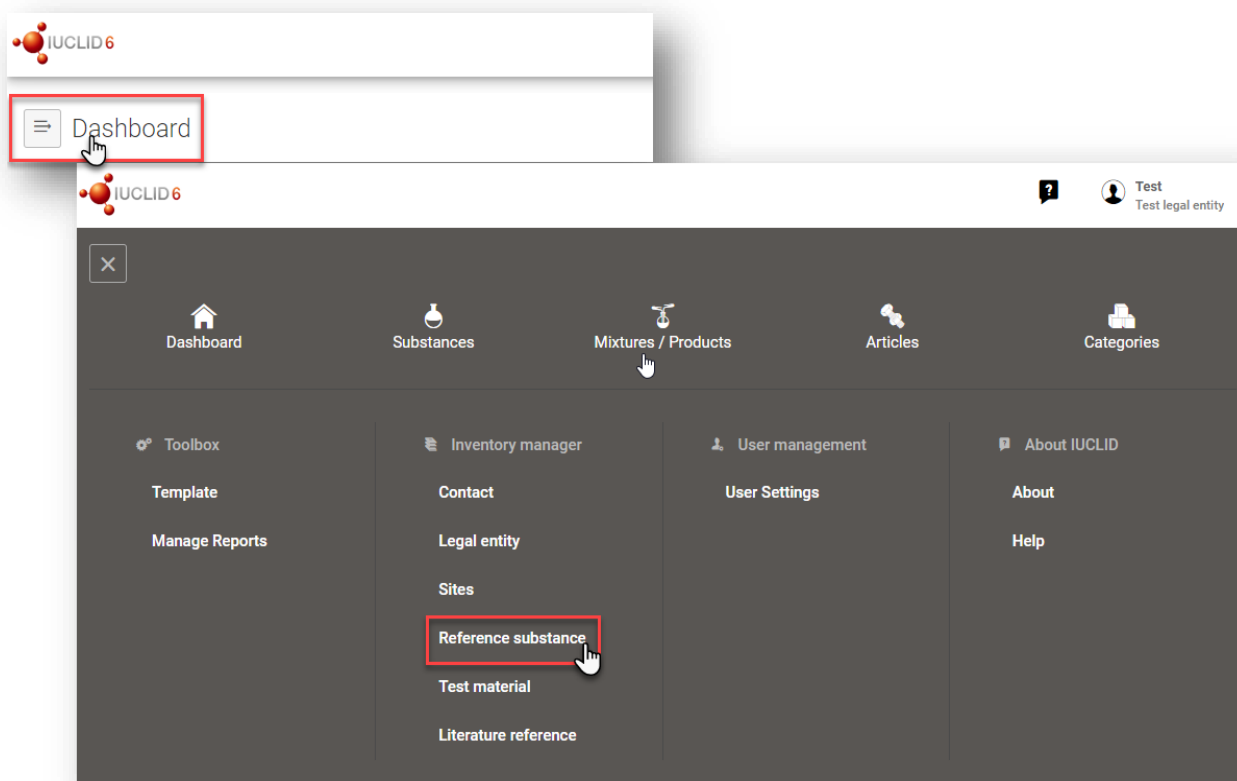
To create a new *Reference substance*:

Step 1.   Click on *New reference substance*.

Figure 14: The list page for Reference substances
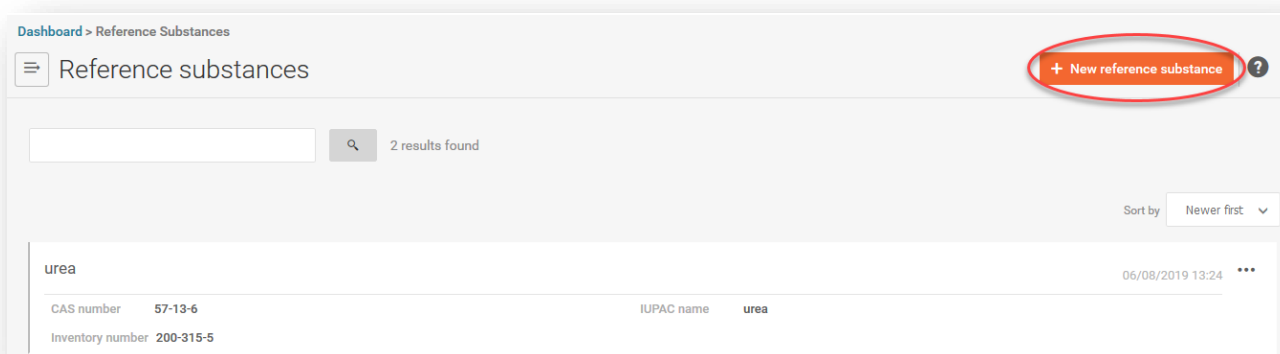
Step 2.   Enter a name for your new *Reference substance* and click *Create*. Once you receive the message that your *Reference substance* has been created click *Open*.

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*.

6.   How to create a substance dataset

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

When entering your data you can use the *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 15: How to get further support on the use of fields
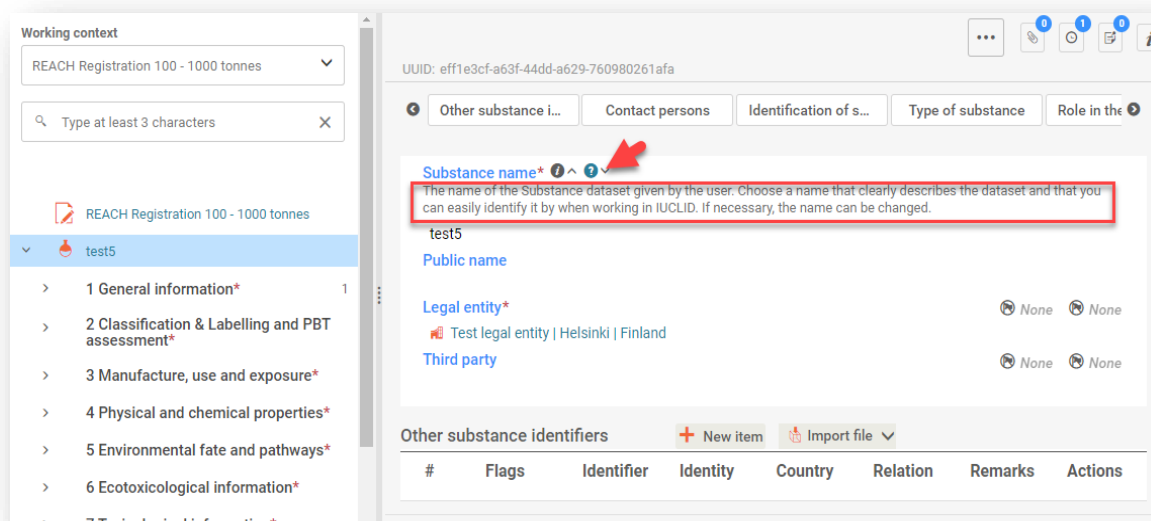
To create a IUCLID **dossier**, you first need to create a substance **dataset**. A substance dataset is a repository of administrative and scientific data for a substance. The information in the dataset can be modified: you can add, remove or change information in the dataset. **The dataset is used 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 16: Substances page - list of substances

Figure 17: View of substance dataset with complete table of content (TOC)
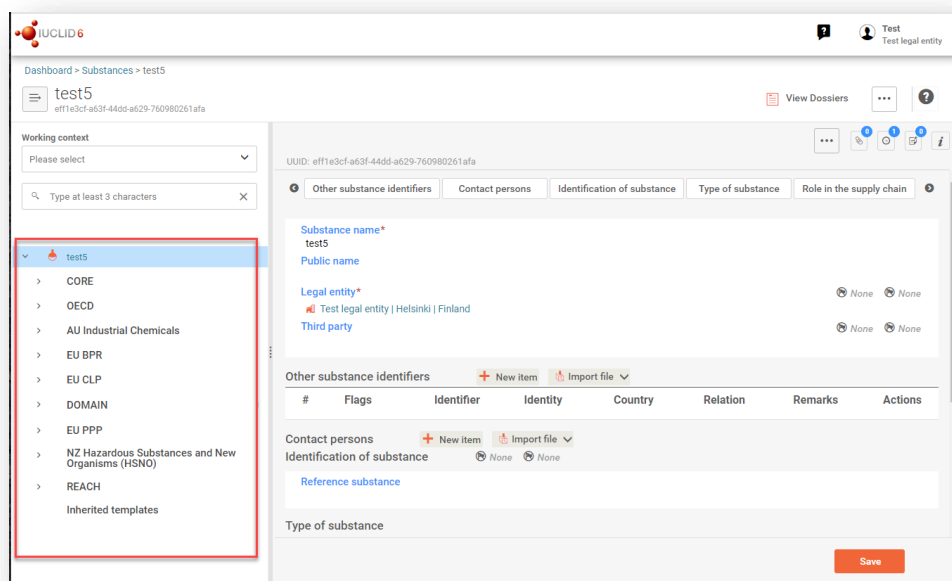
Step 5.   To view the table of contents that is relevant for the type of *dossier* that you are preparing, click on the *Working context* query box and then click on *New working context.*

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

Figure 18:   An example of selecting the template from the picklist
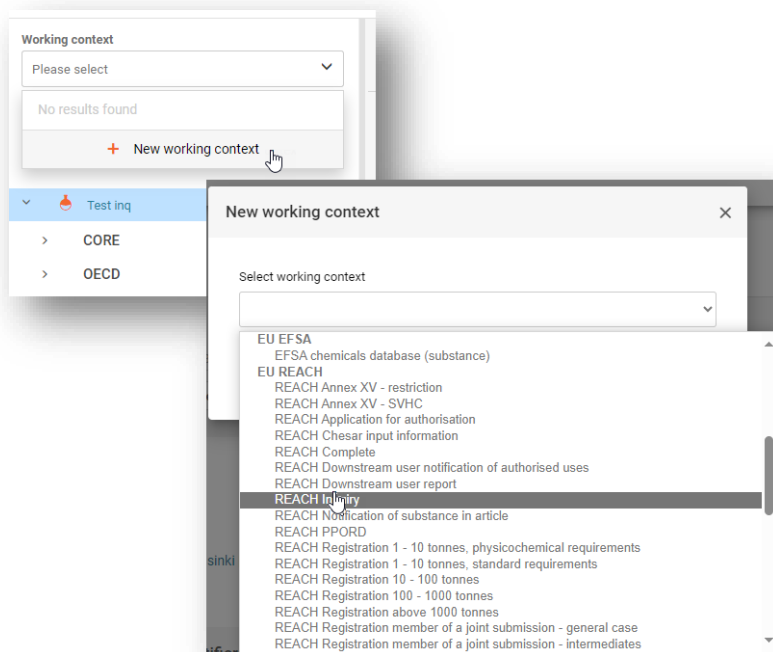
Step 7.   The sections relevant for the *working context* (submission type) are now displayed. Sections including mandatory information to complete are marked with the asterisk. Note that if you are creating a dataset but do not yet know the exact REACH dossier type that will be prepared, you can select the option *REACH Complete*. This will display the table of contents containing all sections that are relevant under the REACH Regulation.

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

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

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

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

6.1.   Section 1 General information

In section 1, *General information*, enter information on the substance identity.

6.1.1.   Section 1.1 Identification

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

To complete this section, follow the steps:

Step 1.   In the *Substance name* field type a name for the substance which you are preparing the dossier for.

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

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

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

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

Step 4. For REACH registration, Inquiry and PPORD dossiers you can indicate a *Third party representative (TPR)*.

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

---

Other substance identifiers and Contact persons:

Step 5. 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 6. You can specify other identifiers by clicking *New item*, then on the generated row and filling out the *Other substance identifiers* fields that are shown in the window. Alternatively you can import a CSV file.

Step 7. You can add information of the contact person(s) for this substance from the previously defined. A new contact can also be created by clicking on *New Item* (See chapter *Contacts*).

Identification of substance:

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

<u>**Mono-constituent substances:**</u>

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.

<u>**Multi-constituent substances:**</u>

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]

---

[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".

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

UVCB substances:

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

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

Step 8. By clicking *Select* in the *Identification of substance* section you can identify your *Reference substance*.

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

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

Type of substance:

Step 9. Under the section *Type of Substance* select the appropriate *Type of substance* from the picklist. For submissions of registrations under REACH, you can only select between mono-constituent substance, multi-constituent substance and UVCB (the options polymer, microorganism and other: are not relevant).

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

Step 10. Select the *Origin,* e.g. organic or inorganic, from the picklist.

Role in the supply chain:

Step 11. Select at least one checkbox in this section according to your role in the supply chain with regards to this substance and this submission context.

Step 12. To save the information click on *Save*.

---

[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.

6.1.2.   Section 1.2 Compositions

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

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

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

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

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

Step 2.   Fill in the composition as described below:

General Information:

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

Step 2.   The default selection in the *Type of composition* field is *legal entity composition of the substance*. This refers to a composition manufactured, imported or used by the registrant/notifier/applicant. Each dataset should contain at least one composition of this type. Only modify this value where you intend to report a composition with a different purpose. For more information on what composition types that can be reported for that submission please refer to the specific instructions for the submission type that you are preparing.

Step 3.   Indicate the physical *State/form* of the composition by selecting the appropriate value in the picklist. Where the substance covers different physical states or forms, a separate composition should be created for each of them.

Step 4.   You can give more detailed information on the composition under the *Description*. This is particularly important when several compositions are reported in order to clarify the differences between them. Providing further considerations on how the composition has been defined is also advisable when the composition covers wide concentration ranges or polymorphs or isomers. For substances that cannot be described with well-defined and quantified constituents (e.g. UVCB substances), further information to identify the composition is provided in this field, including the identity of the starting materials and a description of the production process used to manufacture the substance.

Step 5.   You can provide supporting attachments under *Attached description / justification*.

Step 6.   In the *Justification for deviations* field provide, where relevant, the justification for deviating from the rules for reporting the composition of substances as specified in the
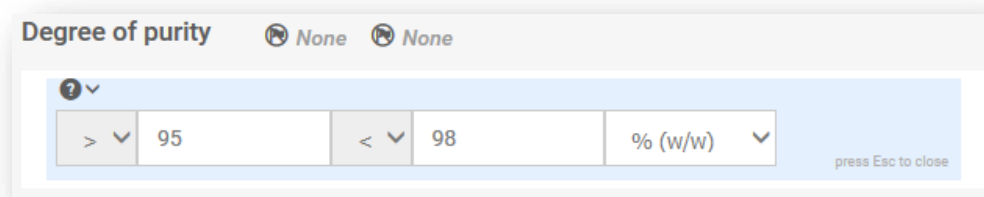
legal text and indicated in the *Guidance for identification and naming of substances under REACH and CLP* available at https://www.echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

Degree of purity:

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

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

Figure 19: Degree of purity

Constituents:

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

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

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

Figure 20: Constituent

Impurities and additives:

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

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

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

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

Figure 21: Unknown impurities

Figure 22: 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];

---

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

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

- Report 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 templates, click on the icon that shows the letter A with an arrow at the bottom right and the text *Insert existing templates.* A pop-up window appears. Click *Option 2: Composition of a UVCB substance* or *Option 6: Composition of a petroleum UVCB substance* depending on the type of your UVCB substance. The text should then be edited so that it contains only the relevant data;

- Report the appropriate individual constituents or groups of constituents under *Constituents*.
  Note: To provide information on the constituents or groups of constituents in your substance, you must not reuse, in section 1.2, the reference substance already assigned for your substance in section 1.1;

- Do not report any constituent under *Impurities* of the composition (impurities are not considered relevant for UVCBs);

- Report any additive necessary to stabilise your composition under *Additives*. Specify the stabilising function of the additive;

- Report the concentration values of the individual constituents, groups of constituents and any additive as a concentration range (both minimum and maximum values) and typical concentration.

- Report the appropriate degree of purity for your UVCB substance (the degree of purity should normally be 100% for UVCBs which do not include any additive, as the concept of *impurity* is not considered relevant for these substances).

6.1.3. Section 1.3 Identifiers

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

To enter your data:

Step 1. Click the *New item* button under *Regulatory programme identifiers* and then click on the generated row.

Step 2. Depending on the type of submission, select the appropriate identifier from the *Regulatory programme* picklist.

Step 3. Enter the relevant number in the *ID* field.

Step 4. If you need to provide more than one programme identifier, create a new item by repeating the previous steps. Alternatively you can import a CSV file.

Step 5. To save the information click *Save*.

6.1.4.   Section 1.4 Analytical information

Section 1.4 is for the inclusion of analytical information such as spectra or chromatograms to enable the identity of your substance to be verified, including the compositions specified in the dossier. It is also the place to include the descriptions of the methods used to generate this information.

In this section you can create several records to include analytical information you consider sufficient to verify the identity of your substance. To create a new record:

Step 1. In the navigation panel click *on* ✛ *next* to *1.4 Analytical information*.

To complete this section, follow the steps:

Methods and results of analysis:

Step 2. Use the table *Analytical determination* to provide analytical information used to verify the identity of the substance.

Step 3. Fill in the information on the analytical methods and results of the analysis.

You can populate the repeatable block content by clicking on 🔖 Import file and uploading a csv file. Alternatively, you can manually create a *New item* for each analytical determination and then click on the generated row: enter the *Purpose of analysis* for which the analysis was carried out, select the *Analysis type* (e.g. spectral, chromatographic), *Type of information provided*, and any *Remark* you consider relevant. For each method, you should attach the file containing the method and the result of the analysis. If you cannot provide results for the indicated analysis type, select the reason from the picklist *Rationale for no results* and fill in the explanation in the *Justification* field. Note that several analysis types can be reported for one determination.

> You can choose to enter *identification* or *quantification* as purpose of an analysis. Both identification and quantification analyses are expected to be submitted to verify the composition of a substance.
>
> *Identification* refers to any analysis carried out to establish the identity of the constituents, including their chemical functionalities, present in the composition of a substance. Examples of analyses used for identification are spectroscopic analyses such as UV, IR, NMR, MS or XRD.

> *Quantification* refers to any analysis carried out to establish the concentration of the constituents in the composition. Examples of analyses used for quantification are chromatographic analyses, elemental analyses, titration.
>
> Some analyses may be carried out both for identification and quantification purposes.

Figure 23 Analytical determination

Step 4. Indicate whether your substance is optically active by selecting the appropriate value from the picklist under *Optical activity*.

Step 5. Provide information on the optical activity, whenever applicable in the *Remarks* field.

Related composition(s):

Step 6. You can link the reported analytical information to the relevant *Composition* from *section 1.4*. This is especially relevant when you have reported several compositions in section 1.2. To link reported analytical information to the relevant *Composition* from *section 1.4* click *Select* in the *Related composition(s)* field. In the pop-up window select the composition among those displayed in the list.

> **Reporting the analytical determination for nanoforms**
>
> For information on how to report the analytical determination for nanoforms please see the manual *How to prepare registration dossiers covering nanoforms.*

6.2.   Section 3 Manufacture use and exposure

You need to provide information in the IUCLID sections to pertaining the manufacture, use and exposure of your substance.

6.2.1.   Section 3.3 Sites

In this section you can specify the information on your substance manufacture and use sites.

To report the data, click *on* the ➕ button in the navigation panel next to 3.3 *Sites* and create an endpoint. You can change the name of the endpoint on the top of the endpoint page. You can create several records and each of them must have one of the existing *Legal entity owner* linked to it.

6.3.   Section 14 Information requirements

In Section 14 you need to provide which information requirements you may have. The following steps describe how to report this information:

Step 1.   Create a new record by clicking on ➕ in the navigation panel next to Inquiry in section 14 Information requirements.

Step 2.   Re-name the new record as "Request for Information" by clicking and typing in the bar at the top of the record as shown below.

Figure 24: Rename the Inquiry record
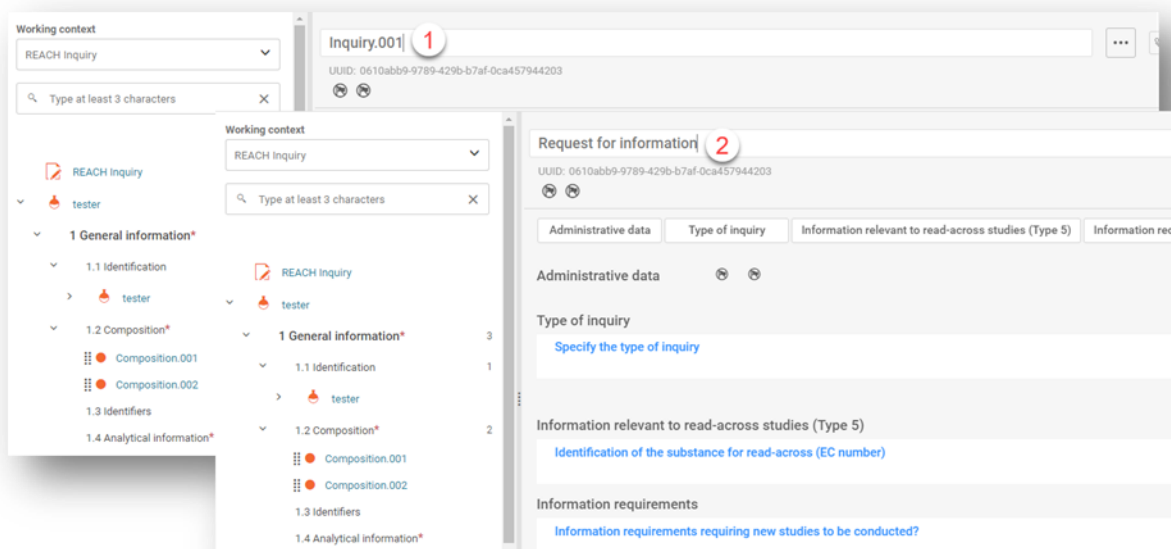
Step 3.   Specify the Type of inquiry by selecting the appropriate option from the picklist.

There are three types of inquiry:

• *Inquiry for a substance before its registration*

This is an inquiry for a substance that has not yet been registered in accordance with Article 26 of the REACH Regulation.

- *Inquiry for tonnage band increase*

Before submitting an update of your registration, due to a tonnage band increase, you are obliged to inform ECHA of the additional information you would require to comply with the information requirements for the new tonnage level (Article 12(2)). You should select this type of inquiry in order to meet your obligations under Article 12(2) of the REACH Regulation.

> If you have already successfully registered the substance you are inquiring about and you selected Inquiry for a substance before its registration, your inquiry will not be accepted for processing.

- *Inquiry for read-across studies*

This is an inquiry for obtaining the contact details of the registrants that registered a substance that you do not intend to register (the source substance), but you would like to use their data to register your substance (the target substance).

Step 4. Indicate under *Information requirements requiring new studies to be conducted?* whether you have (or do not have) information requirements that would require new studies to be conducted by selecting the appropriate option from the picklist. If you select *no*, you do not have to fill any of the following sections. If you select *yes*, continue to step 5.

Step 5. For each relevant endpoint that you require new studies to be conducted, select *yes* from the picklist.

> If you have registered a substance according to Article 10 and further request additional information according to Article 12(2), ECHA will process your request in so far that it does not cover endpoints that you have already submitted in your registration dossier.

The studies section in the co-registrants page lists the (robust) study summaries submitted by other registrants, as well as, their contact details. In case any (robust) study summaries are provided to you by ECHA, they are according to the list of endpoints for which you have ticked "yes".

Tonnage band of existing registration	1-10 tpa	10-100 tpa	100-1000 tpa	>1000 tpa
Mandatory information included in the existing registration *	Annex VII	Annexes VII, VIII	Annexes VII, VIII, IX	Annexes VII, VIII, IX, X
If requested and available, information will be provided	Annexes VIII, IX, X	Annexes IX, X	Annex X	This inquiry will not be accepted for processing

*information can thus be requested

The above criteria are not applied if your existing dossier is for the registration of a transported isolated intermediate, a standard registration 1-10 tpa limited to physicochemical requirements, or a notification in accordance with Directive 67/548/EEC that has not yet been updated due to tonnage band increase under Article 24(2) of the REACH Regulation, i.e. all information requests will be taken into account.

7.   How to create a Dossier

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

> Before creating a dossier you are advised to check the completeness of your substance dataset by running the *Validation assistant*. For more information on how to run the Validation assistant refer to the help system of IUCLID.
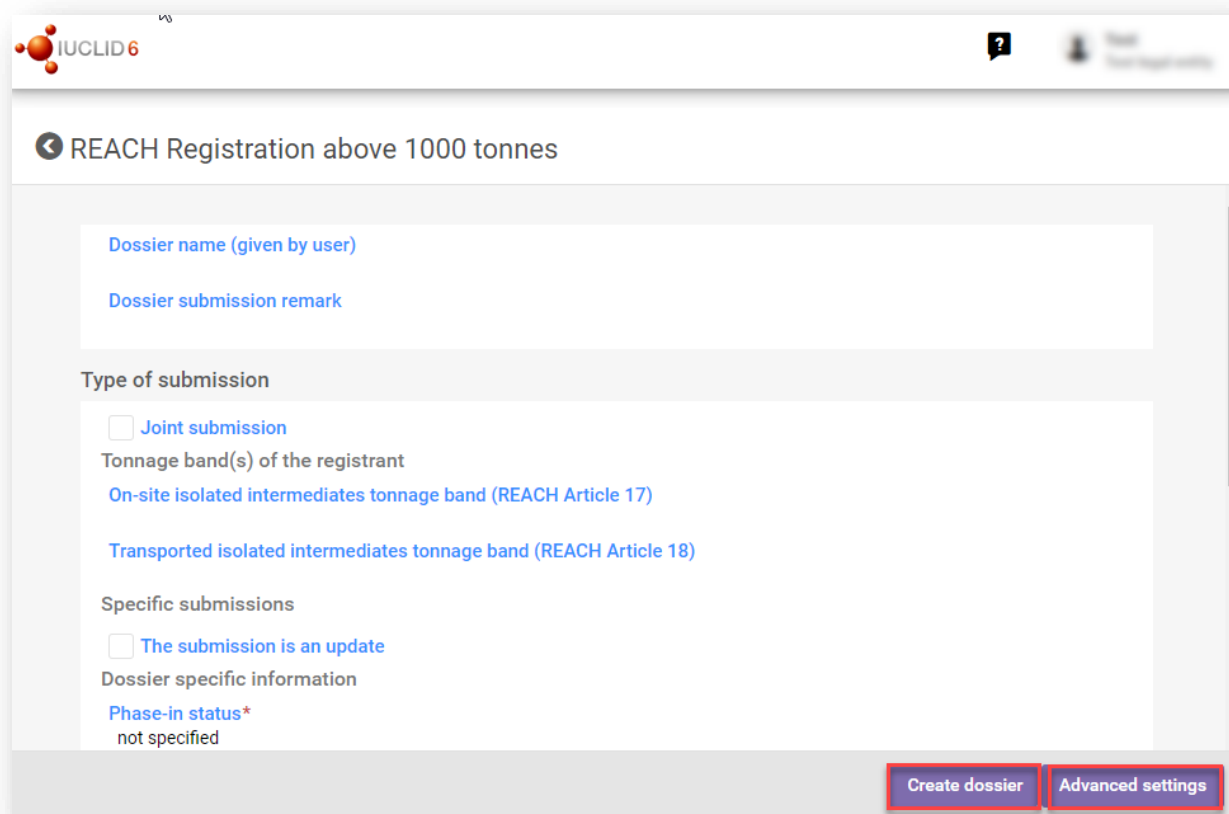
Step 1.   To create a dossier open the list of available subtance datasets by clicking on the button entitled *Substances* in the IUCLID Dashboard.

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

Step 7. From the *Advanced settings* window you can define the confidentiality level by selecting the data protection flags. If you have included any confidentiality or regulatory programme flags in your substance dataset, please make sure that the relevant information is included in your dossier by selecting the appropriate flags in this step. If you are unsure, it is recommended to select the defaults option. ECHA will assess the confidentiality of the information and the justifications provided. You can find more information on the publication of part of the dossier on the ECHA website at http://echa.europa.eu/manuals.

Step 8. From the *Advanced settings* window you can select whether the annotations should be included in the dossier.

Step 9. By ticking the checkbox *Select documents to be included* and clicking *Next* you can verify and select which documents and entities will be included in your dossier. Certain documents, such as section 1.1, will always be included in a dossier, and cannot be excluded in this step. Likewise, depending on the submission type, some documents will not appear in the list and cannot be included as they are not relevant for the selected submission type. If you are unsure of the information to be included, you can rely on the default settings for that submission type.

Step 10. To finalise the creation of your dossier click on *Create dossier* at the bottom of the *Advanced settings* window.

7.1.   Administrative information

Enter a *Dossier name*, which enables you to easily identify it in your database. You are advised not to use confidential information in the dossier name, as it will be seen by anyone you share the dossier with. When relevant you can enter a *Remark* that can include further information on the reason for the submission (e.g. include here a previous inquiry submission number for the same substance, include any relevant communication number related to the submission, etc.)

This can be done either under *Dossier submission remark* field or under the *Dossier specific information* in the *Remarks* field.

8.   How to export a Dossier

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

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

9.   Submit Dossier

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

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

10. Inquiring a second time

If you need to inquire again, 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 new dossier (see chapter *How to create a Dossier*).

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

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

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

Business Rules applicable for Inquiry notifications		
Location **(IUCLID/REACH-IT)**	Rule description	Relevance
IUCLID **substance dataset**	A REACH dossier must be created from a substance dataset. It cannot be created out of a mixture or product dataset.	All dossier types
IUCLID **substance dataset**	Category cannot be used to create an inquiry notification.	Inquiry Notification
IUCLID **section 1.1 – Identification**	A reference substance must exist in section 1.1	All dossier types
IUCLID **section 1.1 – Identification;** **section 1.2 – Composition**	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. If categories are used, this rule is applied to all the category member substances.	All dossier types

IUCLID section 1.1 - Identification	The reference substance in section 1.1 has to have a chemical name provided in the IUPAC name field.	Inquiry Notification
IUCLID section 1.1 - Identification	The reference substance must be marked as one of the following: Mono constituent substance Multi constituent substance UVCB	Inquiry Notification
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	'State/form' of a composition must be specified by selecting the appropriate value in the picklist. If a substance covers different physical states or forms, a separate composition should be created for each of them. If a composition covers nanoforms, then 'solid: nanoform' must be selected in the picklist. Note that an incorrect indication in this field will not enable to provide the information on nanoforms under the Characterisation of nanoforms heading.	All dossier types
IUCLID section 1.2 – Composition	All compositions created in section 1.2 must have the Type of composition 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 type of composition "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, e.g. it is not allowed to have constituent 1 identified with IUPAC name "formaldehyde" and constituent 2 identified with the EC number 200-001-8 (the EC number of formaldehyde).	All dossier types
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 - Composition.	Inquiry Notification

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 of the substance' in IUCLID section 1.2 - Composition. 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.	Inquiry Notification
IUCLID **section 1.1 – Identification;** **section 1.2 - Composition**	Molecular formula, molecular weight and structural formula of each reference substance must be provided in section 1.1 - Identification and 1.2. If not possible, a justification must be included in the remarks field.	Inquiry Notification
IUCLID **section 1.2 - Composition**	Each impurity must be identified by a reference substance. In the reference substance information on the EC, CAS and/or IUPAC identifiers must be provided, as available. For impurities that cannot be identified with any of the above identifiers, the phrase "unknown impurities" should be inserted in the 'IUPAC name' field. The nature, number and relative amounts of the impurities should be specified as far as possible in the 'Description' field of the reference substance.	Inquiry Notification
IUCLID **section 1.2 - Composition**	Each additive must be identified by a reference substance. In the reference substance information on the EC, CAS and/or IUPAC identifiers must be provided, as available.	Inquiry Notification
IUCLID **section 1.1 - Identification ;** **section 3.3 – Sites**	If your role in the supply chain is 'Manufacturer' then a manufacturing site must be specified in section 3.3. A site is specified by creating an endpoint record in section 3.3 and linking a site from the field 'Site'.	Inquiry Notification
IUCLID **section 1.2 - Composition**	For UVCB substances, all composition in section 1.2 labelled as 'Boundary composition of the substance' must include details on the source material and the type of process used for production in the field 'Description'.	Inquiry Notification
IUCLID **section 1.2 - Composition**	Provide the full concentration range (lower and upper value together with a unit) for each constituent, impurity and additive of a composition indicated as 'Boundary composition of the substance'.	Inquiry Notification
IUCLID **section 1.2 - Composition**	All impurities and additives in compositions that are labelled as 'Boundary composition of the substance' must be linked to a reference substance. The reference substance must be identified by one of the following: EC/List number CAS number IUPAC name	Inquiry Notification
IUCLID **section 1.2 - Composition**	For compositions indicated as a 'boundary composition of the substance' in IUCLID section 1.2, you must identify each	Inquiry Notification

	additive by assigning it a reference substance. In the reference substance you must provide information on the EC, CAS and/or IUPAC identifiers, as available, in the designated fields.	
IUCLID **section 1.2 - Composition**	For mono- and multi-constituent substances molecular formula, molecular weight and structural formula of the reference substance must be provided. For UVCB substances molecular formula and molecular weight are required. If not possible to provide, justification in the related 'Remarks' field is to be given.	Inquiry Notification
IUCLID **section 1.2 - Composition**	For each additive the molecular weight, molecular formula and structural formula of the reference substance must be provided. Also, the stabilising function must be confirmed by selecting a value starting with 'stabiliser' in the picklist 'Function'. Further details can be provided on the mechanism of stabilisation under 'Details on function'.	Inquiry Notification
IUCLID **section 1.2 - Composition**	For a mono-constituent substance, the main constituent in IUCLID section 1.2 is expected to be present in the composition as a minimum at 80%. When the percentage deviates from this rule, a justification must be given in the 'Justification for deviations' field. Alternatively, a 'Typical concentration' can be provided, with a unit, demonstrating that the main constituent is typically present as a minimum at 80%.	Inquiry Notification
IUCLID **section 1.2 - Composition**	For a mono-constituent substance, each composition is expected to contain only one constituent. When deviating from this rule, a justification has to be provided in the 'Justification for deviations' field.	Inquiry Notification
IUCLID **section 1.2 - Composition**	For a mono-constituent substance, impurities in are expected to be present in the composition as a maximum at 20%. When the percentage deviates from this rule, a justification must be provided in the 'Justification for deviations' field. Alternatively, a 'Typical concentration' can be provided, with unit, demonstrating that the impurity is typically present as a maximum at 20%.	Inquiry Notification
IUCLID **section 1.2 - Composition**	For a multi-constituent substance, the main constituent in IUCLID section 1.2 is expected to be present in the composition as a maximum at 80%. When the percentage deviates from this rule, a justification must be provided in the 'Justification for deviations' field. Alternatively, a 'Typical concentration' can be provided, with a unit, demonstrating that each main constituent is typically present as a maximum at 80%.	Inquiry Notification
IUCLID **section 1.2 - Composition**	For a multi-constituent substance, impurities are expected to be present in the composition as a maximum at 10%. When the percentage deviates from this rule, a justification must be provided in the 'Justification for deviations' field. Alternatively, a 'Typical concentration' can be provided, with unit, demonstrating that the impurity is typically present as a	Inquiry Notification

IUCLID	Content	Type
	maximum at 10%.	
IUCLID **section 1.2 - Composition**	For a multi-constituent substance, each composition is expected to contain more than one constituent. When deviating from this rule, a justification has to be provided in the 'Justification for deviations' field.	Inquiry Notification
IUCLID **section 1.2 - Composition**	In each composition for UVCB substances composition-specific details on the source of the substance and the process used must be provided in the 'Description' field. These should include, as appropriate: identity of starting materials/source (and ratio) reaction steps/mechanisms plant operating parameters (e.g. temperatures/pressures) solvents/reagents used details of any clean-up/purification steps.	Inquiry Notification
IUCLID **section 1.1 – Identification;** **section 1.2 - Composition**	For a UVCB substance, all individual constituents present at >10%, or relevant for C&L and/or PBT assessment must be reported separately. All other constituents should be identified as far as possible, as separate constituents or as groups of generic constituents. Identifying the composition in IUCLID section 1.2 with only one constituent, matching the reference substance in section 1.1, is not allowed. UVCB substances are not considered to contain impurities. All constituents should be reported under the 'Constituents' heading. If it is not possible to identify separate constituents, you must give a justification in the 'Justification for deviations' field.	Inquiry Notification
IUCLID **section 1.3 - Identifiers**	When submitting an update to a previously notified substance (NONS) then both the Registration number and the NCD number must be indicated.	Inquiry Notification
IUCLID **section 1.3 - Identifiers**	When providing a registration and/or an inquiry number in section 1.3, it has to be issued for the substance referenced in section 1.1 - Identification and it has to belong to the submitting legal entity.	Inquiry Notification
IUCLID **section 1.3 - Identifiers**	When submitting an inquiry for a tonnage band update, it is mandatory to have the REACH Registration number provided in section 1.3.	Inquiry Notification
IUCLID **section 1.4 – Analytical information**	At least one record must be created in section 1.4. under the 'Analytical determination' heading and must contain at least one entry, and each entry created must be filled in as follows: - a selection must be made in the 'Purpose of analysis' picklist - at least one selection must be made in the 'Analysis type' picklist - either an attachment must exist in the 'Attached methods/results' field, or a reason for not providing a method/result must be indicated by making a selection in the field 'Rationale for no results' and by inserting a further explanation in the 'Justification' field.	Inquiry Notification

	The 'Analysis type' field is a multi-select list; if several selections are made, the corresponding results or justifications for all must be provided in the same entry. Analysis results must be provided for at least one identification, and one quantification approach, as indicated in the 'Purpose of analysis' field	
IUCLID **section 14 - Inquiry**	Provide the information requirements relevant to the inquiry in IUCLID section 14. Note that only one section 14 record is allowed.	Inquiry Notification
IUCLID **section 14 - Inquiry**	Make a selection in the field 'Information requirements requiring new studies to be conducted?' in section 14. If you answer 'Yes', you must mark at least one study as 'Yes' under 'New studies to be conducted'. If you answer 'No', you must not mark any study under 'New studies to be conducted'.	Inquiry Notification
IUCLID **section 14 - Inquiry**	The type of the inquiry notification in section 14 has to match with the submission context. If the substance is not yet registered by the submitting legal entity, only type 3 is allowed. Following a successful registration, only type 4 inquiry can be submitted.	Inquiry Notification
IUCLID **section 14 - Inquiry**	If you wish to update your dossier due to a tonnage band increase (type 4 inquiry), you shall only inform ECHA of the additional information you need for the prospective tonnage band.	Inquiry Notification
IUCLID **section 14 - Inquiry**	When preparing an inquiry notification, it is mandatory to indicate the inquiry type in section 14.	Inquiry Notification
IUCLID **dossier template**	The dossier template used in IUCLID must correspond with the intended submission type in REACH-IT.	All dossier types
IUCLID **dossier header**	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). In any other case, an initial submission is required.	All dossier types - Updates
REACH-IT	A new dossier cannot be submitted when the previous submission for the same substance is still being processed.	All dossier types - Updates
REACH-IT	No submissions can be made from the account of a legal entity, which at the time of submission undergoes the legal entity	All dossier types

	change (merge) process. Legal entity change functionality is available in REACH-IT.	
REACH-IT	The same IUCLID dossier cannot be submitted more than once.	Inquiry Notification
REACH-IT	It is not allowed to submit an inquiry notification for a substance for which the submitting legal entity has indicated 'Cease manufacture' in REACH-IT.	Inquiry Notification
REACH-IT	If a registration already exists for the same substance, by the same legal entity, it is not allowed to submit an inquiry notification indication no additional data requirements.	Inquiry Notification
REACH-IT	No submissions can be made from the account of a legal entity, which at the time of submission undergoes the legal entity change (merge) process. Legal entity change functionality is available in REACH-IT.	Inquiry Notification
REACH-IT	You cannot update a dossier that is currently deactivated or has been revoked.	Inquiry Notification