

How to prepare a request for use of an alternative chemical name for a substance in a mixture

October 2023

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Changes to this document

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11.0	October 2023: Section 5.4 and 5.5: Editorial changes
10.0	May 2023: Update to reflect the new functionalities of the IUCLID 6.7.
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1.0	First version

Disclaimer

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1. Introduction

1.1. Objective

Under the CLP Regulation, substances and mixtures placed on the market shall be well identified.

However, a manufacturer (M), importer (I) or downstream user (DU) may be concerned that disclosure of the chemical identity of one or several substances contained in the mixture(s), on the label and/or on the Safety Data Sheet (SDS), puts the confidential nature of their business, in particular intellectual property rights, at risk.

In such cases, the CLP Regulation allows the M/I/DU to submit a request to use an alternative chemical name which refers to that substance in a mixture (either by means of a name that identifies the most important functional chemical groups or by means of an alternative designation). The criteria for approving such a request are defined in the CLP Regulation (Part 1 of Annex I, point 1.4.1).

Note that if an M/I/DU wants to request the use of an alternative chemical name for several substances in the same mixture(s), a separate request must be prepared for each substance.

Please note that *no updates are allowed*, when a request has been submitted and the fee has been paid, *unless specifically requested by the European Chemicals Agency (ECHA)*. This includes e.g. adding new mixtures, revising the alternative chemical name, or the name of (a) mixture(s). Please always make sure that you include all relevant mixtures for which the alternative chemical name is to be used, and that you use the trade name that will be used for each mixture when put on the market, both in the IUCLID dossier and in the mixture SDS. Any later request for the use of the alternative chemical name, e.g. if you want to add other mixtures, or in case you want to revise the alternative chemical name or the name(s) of a mixture(s), will be a new request for which ECHA will levy another fee. Also note that only an M/I/DU based in the EU can submit a request, and that it is not possible to appoint a 'Third Party Representative' or an 'Only Representative' to submit a request for use of an alternative chemical name.

Where a justification claiming confidentiality of the IUPAC name (for substances listed in Articles 119(2)(f) and (g) in accordance with Article 10(a)(xi) of the REACH Regulation) has been accepted as valid by ECHA, the M/I/DU may use the name that is made publicly available over the internet, on the ECHA website, also on the label and in the SDS of the mixture(s) (Article 24(8), CLP Regulation). However, for substances in a mixture where Article 119(2)(f) or (g) of the REACH Regulation no longer applies, the M/I/DU may submit a request to use an alternative chemical name to ECHA.

The purpose of this manual is to assist in the preparation of such a request and its submission to ECHA. For example, it outlines the required information, and the IUCLID sections and fields to be filled in to prepare a request according to Article 24 of the CLP Regulation.

This manual assumes that IUCLID has been installed, that you are using the web user interface and that you have a valid ECHA account. Please note that the classic user interface (IUCLID client) is being phased-out. Instructions in how to run the classic user interface are provided in the IUCLID website at: <https://iuclid6.echa.europa.eu/>.

More information about the different functionalities in IUCLID web user interface and how to use those functionalities can be found in the help system of IUCLID (see chapter *The 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

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 IUCLID dossier is a non-editable snapshot of the substance dataset at a certain moment. The information in the dossier cannot be modified, but any modifications need to be done in the substance dataset. The IUCLID dossier contains 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/find the *reference substance* in IUCLID for the substance for which an alternative chemical name is requested (see chapter *Reference Substance*).
- Step 3.** Create the *substance dataset* in IUCLID (see chapter How to create a substance dataset).
- Step 4.** Enter the required information in the *substance dataset* in IUCLID (see relevant subsections of chapter *How to create a substance dataset*).
- Step 5.** Create a IUCLID dossier (see chapter *How to create a dossier*).
- Step 6.** Export the dossier from IUCLID (see chapter *How to export a dossier*).
- Step 7.** Submit the dossier to ECHA via *REACH-IT* (see chapter *Submit dossier*).

1.3. Information required for alternative name request dossier

Before you start preparing your alternative chemical name request dossier in IUCLID, make sure that you have the required information available. The required information comprises the following:

- Identity of the request submitter, i.e. name, contact details (ECHA account);
- The proposed alternative chemical name (IUCLID section 1.1);
- Identity and composition of the substance (IUCLID sections 1.1, 1.2);
- Information on the classification and labelling of the substance (IUCLID section 2.1);
- The SDS of the substance for which an alternative chemical name is requested (IUCLID section 13.2);

- A justification for non-disclosure of the actual substance name, i.e. a justification demonstrating that the request submitter has a commercial interest worthy of protection (IUCLID section 13.2);
- A justification demonstrating that the use of the alternative chemical name meets the need to provide enough information for necessary health and safety precautions to be taken in the workplace, and that the risks from handling the mixture can be controlled (IUCLID section 13.2);
- The trade name(s) of the mixture(s) containing the substance for which an alternative chemical name is requested (IUCLID section 14);
- The SDS(s) of the mixture(s) containing the substance (IUCLID section 14).

1.4. Checks performed by ECHA on the submitted dossiers

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

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

For more information on the business rules check refer to the Annex 1 of this manual: *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

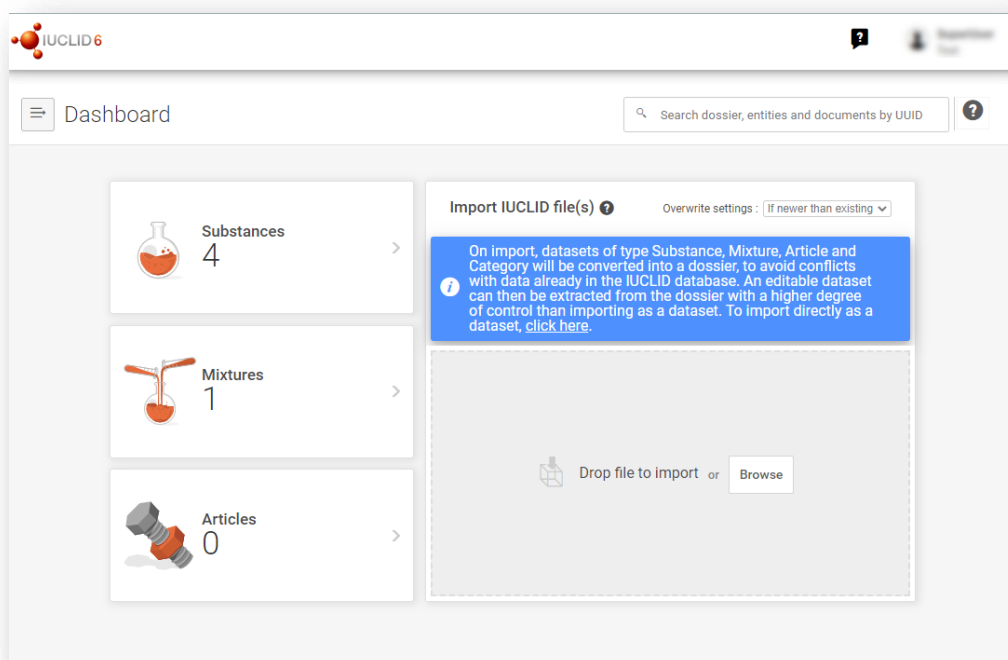
In this chapter an overview of the IUCLID web user interface's main new features is presented.

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.

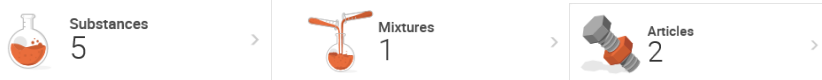
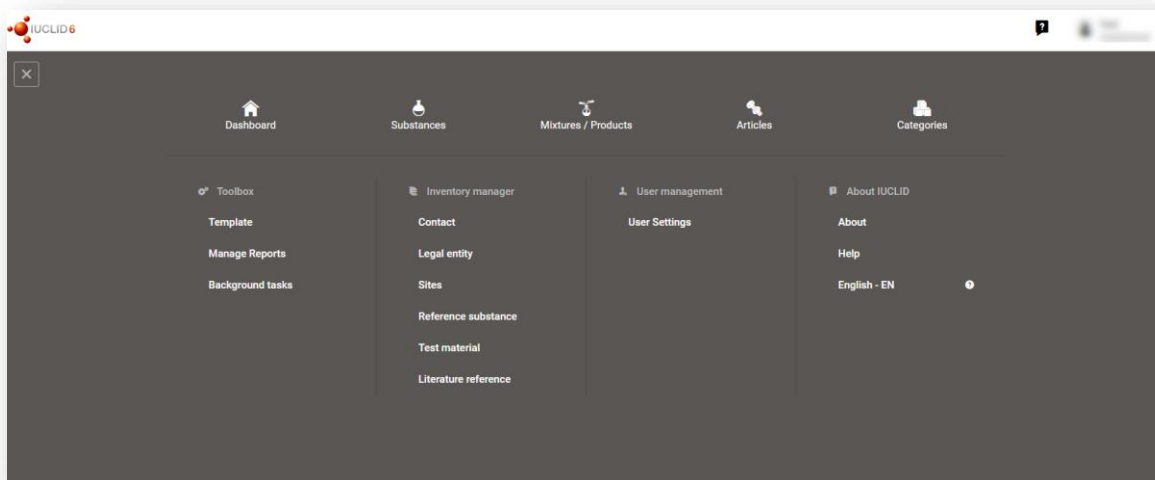


The round question mark icon next to the search bar opens the help system of IUCLID, a user manual presenting in detail the functionalities of IUCLID in the web interface.



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.

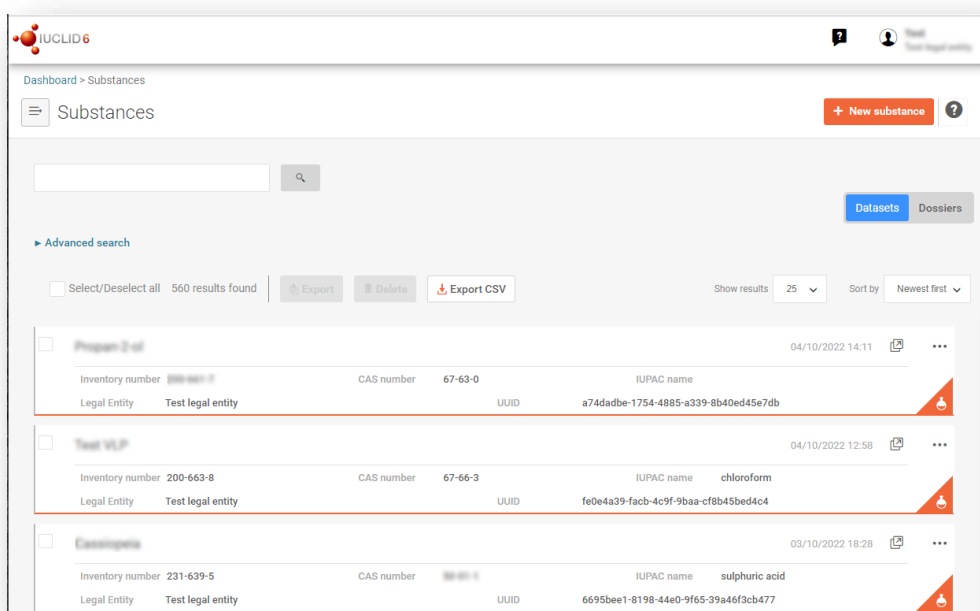
Figure 2: View of the main menu



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.

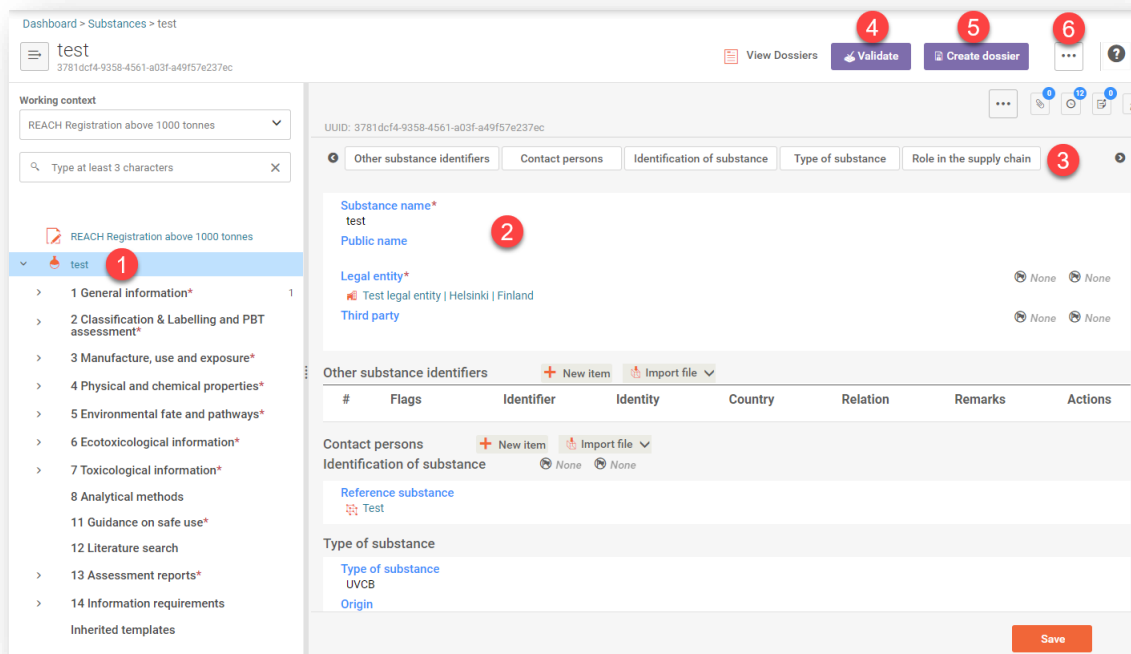
test 2

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”



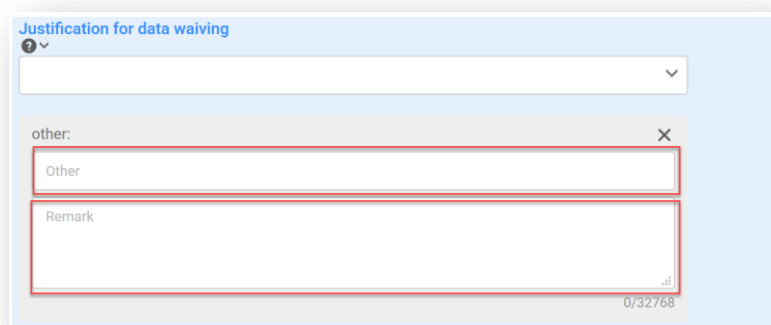
Depending on the *working context* (submission type) selected, IUCLID automatically displays the table of contents containing all sections that are relevant. The table of content is displayed as a navigation panel on the left hand side of the screen (1).

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

 Insert existing templates ▾

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


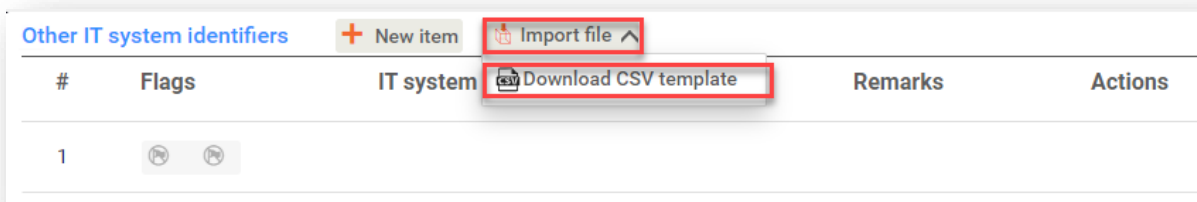



1. By clicking the  **New item** button, clicking on the generated row and manually fields in the pop up window.
2. By downloading the CSV template for that specific repeatable block, filling in the excel file with your data and importing the excel file in the repeatable block. This option is recommended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

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



#	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.

 **Create dossier**

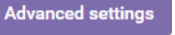
Dossier creation is started by clicking on the button *Create dossier* (5).



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

1.5.4. The Dossier header

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

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

1.5.5. Confidentiality flags

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



No flag is set;



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



A flag is set that involves confidentiality.

1.6. The functionalities of IUCLID

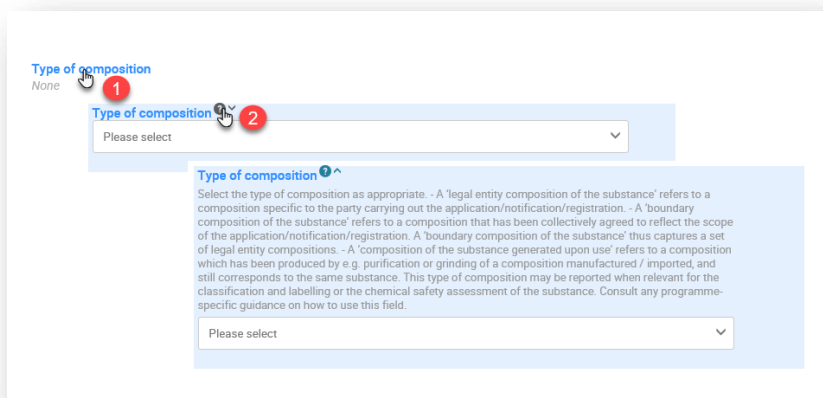
The functionalities of IUCLID are described in detail in the help document *Functionalities of IUCLID in the web interface*. To access the *Functionalities of IUCLID* document, click the icon



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

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

Figure 7: Field specific help



2. Legal entity

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

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

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

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

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

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

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

2.1. How to update and synchronise the LEO information

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

When you create a LEO, a numeric identifier called Universal Unique Identifier (UUID) is generated. Example of a legal entity UUID: IUC5-a620a92d-32c6-426a-b6ee-fc338cde0932.

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

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

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

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

- REACH-IT: Menu > Company information > General information > UUID

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

3. Contact

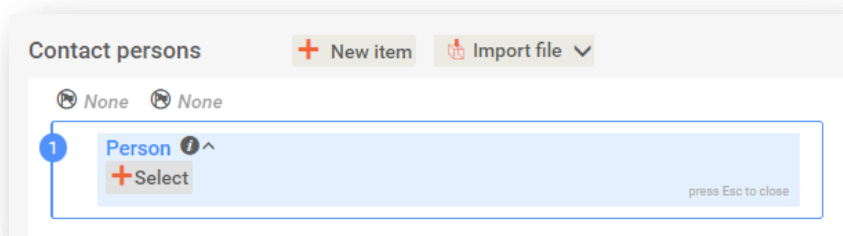
In the Contact inventory you can insert the contact details of the relevant competent persons, such as person responsible for the safety data sheet (SDS), toxicologist, etc, which can be attached to the IUCLID dossier. This person may be contacted to provide assistance or ask about the information submitted.

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

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

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

Figure 8: 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 9: Create a new Contact

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

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

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

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:

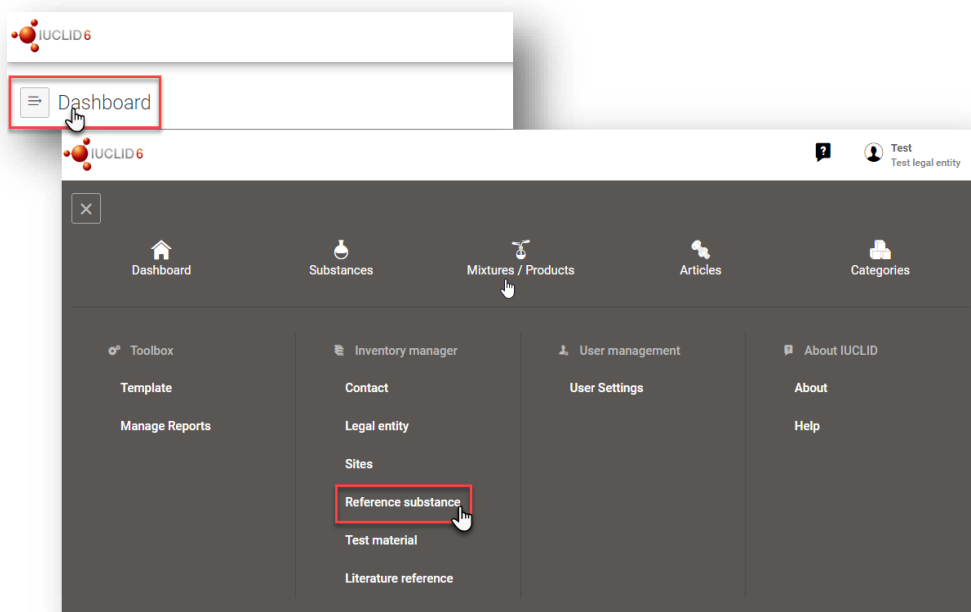
1. Information **specific** to the reference substance: such information exactly corresponds to the substance/constituent(s) covered by that reference substance;
2. Information **related** to the reference substance: this information does not accurately correspond to the substance/constituent(s) covered 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.

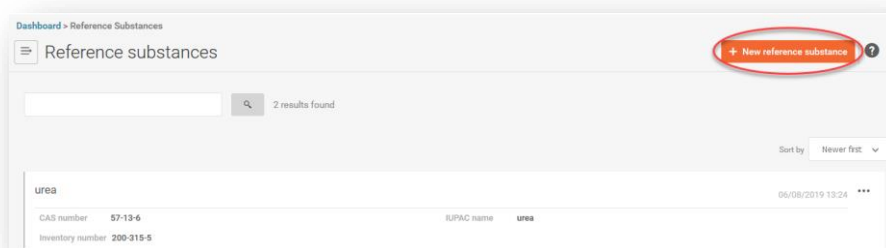
Figure 10: Open the list page for Reference substances



To create a new Reference substance:

Step 1. Click on *New reference substance*.

Figure 11: The list page for Reference substances



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

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

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

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


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

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

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

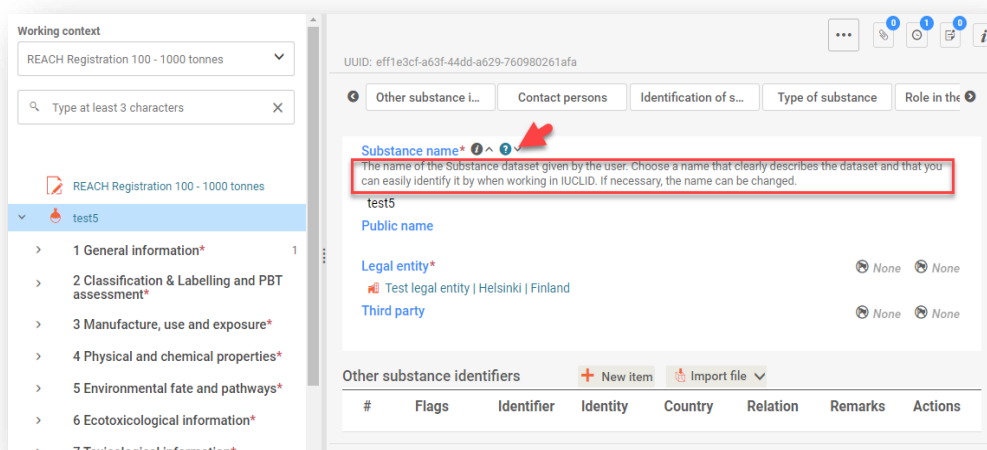
5. How to create a substance dataset

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 help system of IUCLID that can be opened by clicking on the round question mark icon  on the top-right corner of the screen.

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

Figure 12: 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 13: Substances page - list of substances

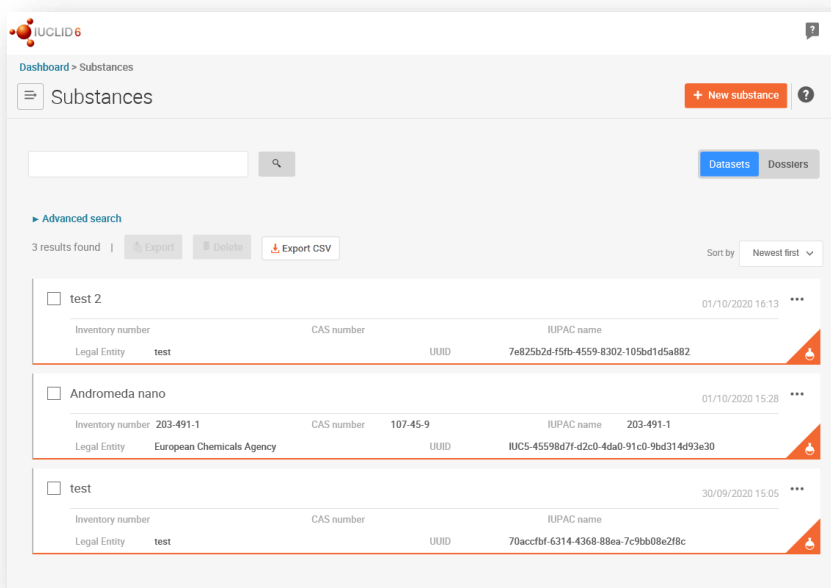
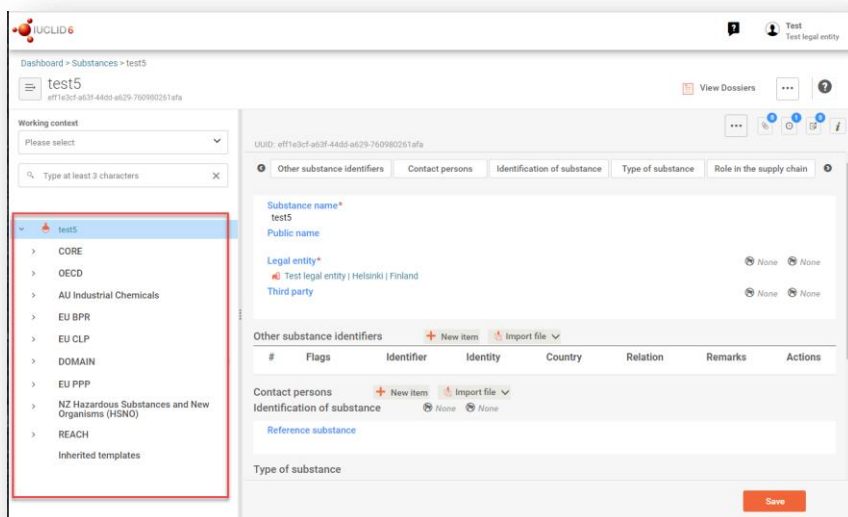
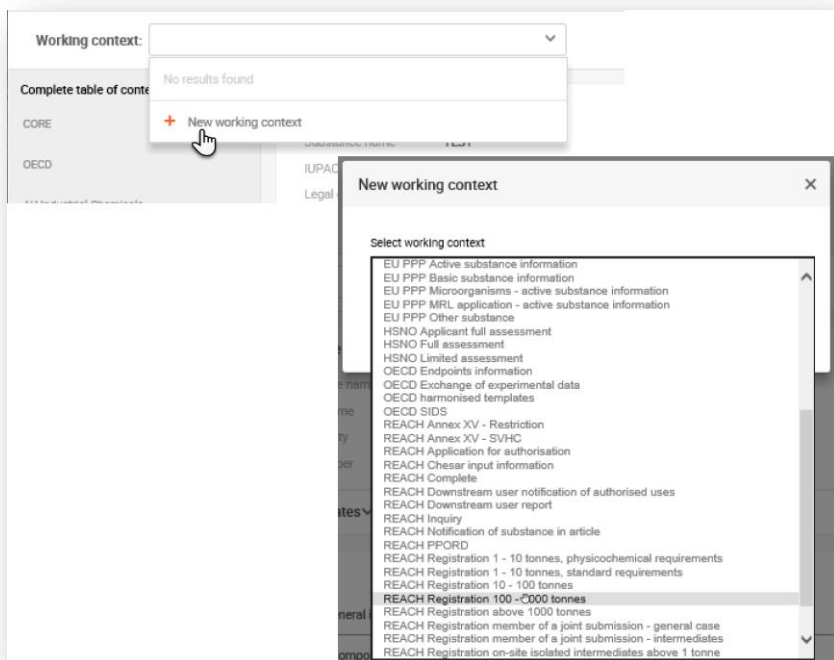


Figure 14: View of substance dataset with complete table of content (TOC)



- 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 15: 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. Copy/update from registered Substance dataset

If a *Substance dataset* has already been submitted for a registration it may contain information also relevant for the alternative chemical name request. Thus, the request submitter may take advantage of this by copying an existing registration *Substance dataset* to a newly created *Substance dataset* for an alternative chemical name request. For instance, sections 1.1 *Identification*, 1.2 *Composition*, 2.1 *GHS*, and 13 *Assessments reports*, might benefit to be automatically imported from an existing registration *Substance dataset*.

The request submitter may then proceed to the appropriate refinement of information specifically related to the alternative chemical name request (e.g. not all documents required for an alternative chemical name request are in place in section 13 of a registration *Substance dataset*).

5.2. Section 1 General information

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

To fulfil your obligation under Article 24 of the CLP Regulation, Section 1.1 of your IUCLID dossier must contain the following minimum information:

The suggested alternative chemical name of the substance in the mixture(s); AND

- A Reference substance with an EC number; OR
- A Reference substance with a CAS number; OR
- A Reference substance with a IUPAC name AND a Molecular formula AND Molecular weight range AND Structural formula; OR
- A Reference substance with a IUPAC name and Remarks; OR
- A Reference substance with a IUPAC name and SMILES notation.

How to fill in the suggested alternative chemical name for the substance:

Specify in the *Public name* field in section 1.1, the alternative chemical name you are requesting to use for the substance in the mixture(s). It is recommended to indicate the alternative chemical name in English, if possible. The alternative chemical name can be a name referring to the most important functional chemical groups of the substance or an alternative designation.

The Lexicon guide (Annex VIII, Part B to the Dangerous Preparations Directive; <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31999L0045>) is recommended to be used for establishing the alternative chemical name. It is however not mandatory to use this guide.

In all cases the names chosen must provide enough information to ensure that the mixture(s) can be handled without risk and that necessary health and safety precautions can be taken in the workplace.

In case the substance for which an alternative chemical name is requested is marketed in more than one EU country, it is recommended to add the alternative chemical name in the language(s) of the additional country(-ies) as well, under *Other substance identifiers*:

- Step 1.** Click the *New item* button next to *Other substance identifiers* and then in the row appearing in the table.
- Step 2.** In the box appearing, first choose *CLP alternative name* in the picklist under *Identifier*, then add the alternative chemical name in the additional language in the *Identity* field, and finally choose the respective country in which the substance is marketed in the *Country* picklist. Click then *Close* and the inserted data will appear in the table;
- Step 3.** Repeat the same procedure for any other additional country/name.
- Step 4.** Choose the type of substance for which the alternative chemical name is requested in the *Type of substance* picklist.

For guidance on how to identify substance type, and how to complete the relevant information in section 1.1 and 1.2 for each substance type, see sections below.

5.2.1. 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 the name of the substance for which you are preparing the dossier.
- Step 2.** 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. (see chapter *Legal entity*).

Role in the supply chain:

- Step 3.** Select at least one checkbox in this section according to your role in the supply chain with regards to this substance.

Please note that only a manufacturer, importer or downstream user of a substance in (a) mixture(s) based in the EU, may submit an alternative chemical name request (cf. Art. 24(1) of the CLP Regulation). It is not possible to appoint a *Third party representative* or an *Only Representative* to submit a request for use of an alternative chemical name in (a) mixture(s).

If you are a non-EU manufacturer who wishes to keep certain substance identity details confidential to the EU importer of your mixture(s), please contact the ECHA Helpdesk for further information (<https://echa.europa.eu/contact>) .

Identification of substance:

- Step 4.** Click in the *Reference substance* field and then on the *Select* button to assign a *reference substance* to your substance dataset.

Step 5. 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 create it (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 and provide the description of the manufacturing process in the description field in section 1.2.

Type of substance:

Step 6. 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>.

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.

- Step 7.** Select the *Origin*, e.g., organic or inorganic, from the picklist.
- Step 8.** You can include additional identifiers for your substance under *Other substance identifiers*.
- Step 9.** You can add information of the contact person(s) for this substance from the previously defined contacts (see chapter *Contact*).
- Step 10.** To save the information click *Save* at the bottom of the page.


5.2.2. 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*.

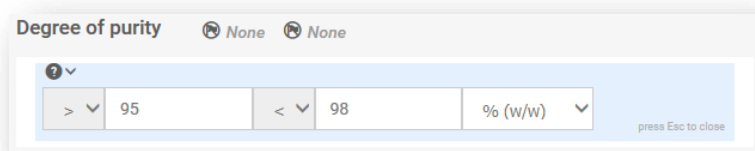
Step 6. In the *Justification for deviations* field provide, where relevant, the justification for deviating from the rules for reporting the composition of substances as specified in the legal text and indicated in the *Guidance for identification and naming of substances under REACH and CLP* available 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 16: Degree of purity



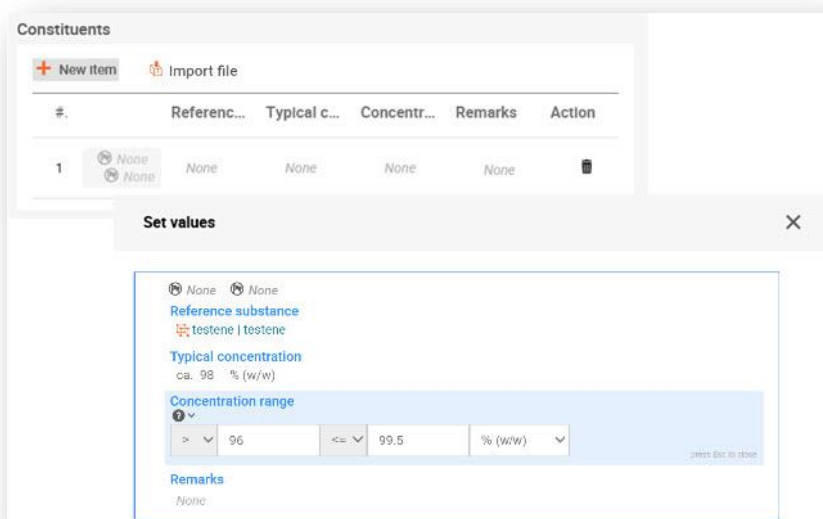
Constituents:

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 17: 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 18: Unknown impurities

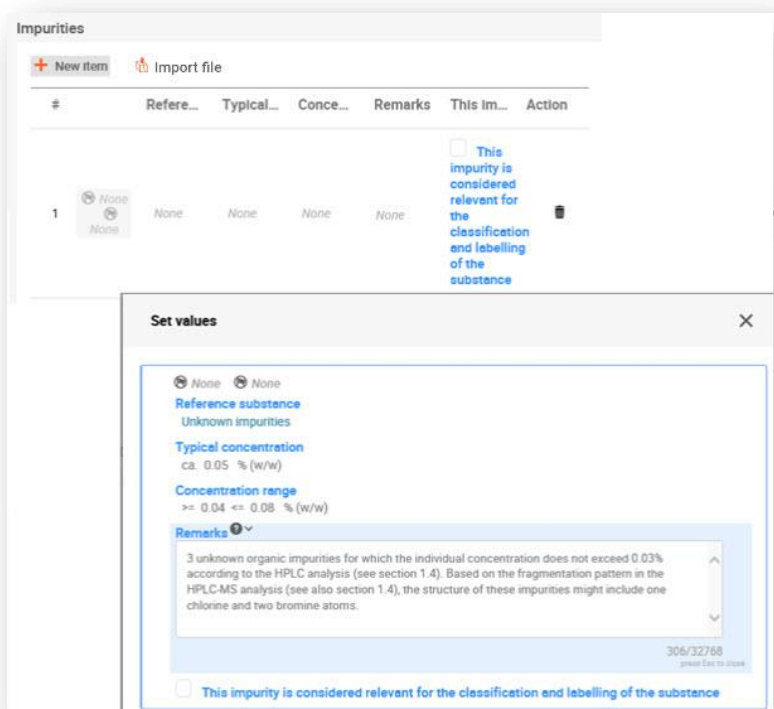
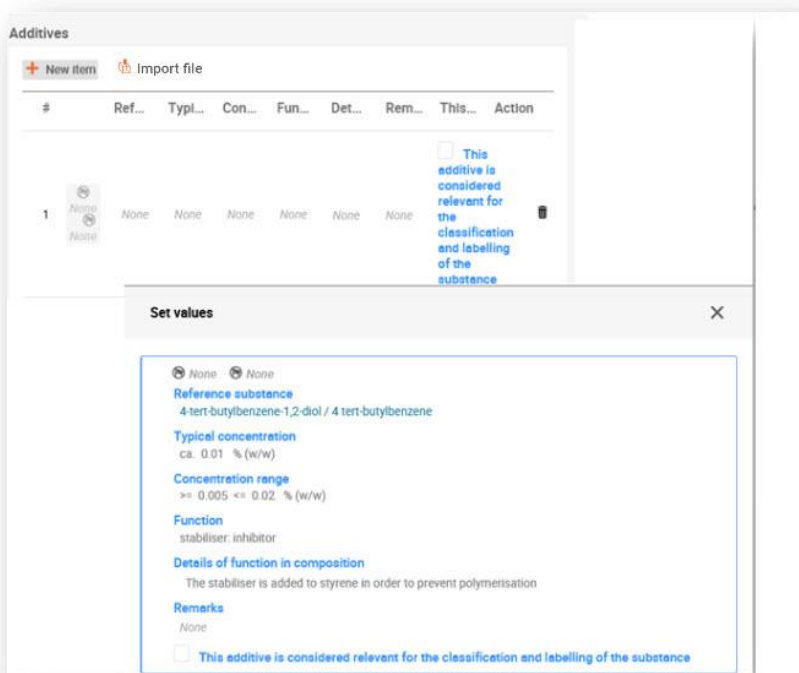


Figure 19: Additive



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).

Reporting the characterisation of nanoforms

For information on how to report the characterisation for nanoforms please refer to the manual *How to prepare registration dossiers covering nanoforms* at <https://echa.europa.eu/manuals>.

5.2.3. 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*.

5.2.4. (Optional) 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 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 20 Analytical determination

Analytical determination							+ New item
#.	Purpose of analysis	Analysis type	Type of information p...	Attached methods/re...	Rationale for no results	Justification	Remarks
1	identification and/or quantification	✓ other:migrated information	methods	None	other: fgfbgfg	bbgfbgfb	None
2	identification and/or quantification	✓ other:migrated information	results	None	other: bgfbgf	bgfbgf	None
3	quantification	✓ ion chromatography	methods	Doc3_second test.doc	None	None	None
4	identification	✓ NMR	methods and results	Doc4_second test.docx	None	None	None

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.

5.3. Section 2 Classification & Labelling and PBT assessment


5.3.1. 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.

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

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

To create a new record:

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

Step 2. Fill in the GHS section as described below:

Harmonised classification has to be respected and you should not modify any of those harmonised hazard classes/differentiations. Therefore, if your substance has a harmonised classification for some hazard classes/differentiations, you should self-classify for other hazards according to available and reliable data.

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. Select a composition(s) in the *Related composition* field for which the GHS record is relevant by clicking on the *Related composition* field. Then click *Select*.

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 the *Classification* header you must select a *Hazard category* and *Hazard statement* for each hazard class (and differentiation, if applicable). If the substance is not classified for a certain hazard, you must fill in the *Reason for no classification* field.

Special attention should be given to Part 1.4 of the Annex I to the CLP Regulation, where specific criteria for “requests for use of an alternative chemical name under Article 24” are illustrated.

Requests for the use of an alternative chemical name under Article 24 of the CLP Regulation may be granted when the substance is exclusively classified as one or more of the hazard categories listed below:

Hazard class or differentiation	Hazard category	Hazard statement
Physical Hazard classes	All	All
Acute toxicity - oral	Category 4	H302: Harmful if swallowed
Acute toxicity - dermal	Category 4	H312: Harmful in contact with skins
Acute toxicity - inhalation	Category 4	H332: Harmful if inhaled
Skin corrosion/irritation	Category 2	H315: Causes skin irritation
Serious eye damage/eye irritation	Category 2	H319: Causes serious eye irritation
Specific target organ toxicity – Single exposure	Category 2	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>

Specific target organ toxicity – Single exposure	Category 3	H335: May cause respiratory irritation
Specific target organ toxicity – Single exposure	Category 3	H336: May cause drowsiness or dizziness
Specific target organ toxicity – Repeated exposure	Category 2	H373: May cause 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>
Hazardous to the aquatic environment – Chronic	Category 3	H412: Harmful to aquatic life with long lasting effects
Hazardous to the aquatic environment – Chronic	Category 4	H413: May cause long lasting harmful effects to aquatic life

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 and 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 is tested with the appropriate high quality reflected in the study 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 (e.g. liquid) which is not compatible with the physical hazard class under evaluation (e.g. Flammable Solid).
- *hazard class not assessed* should be selected if the hazard class has not been assessed and the justification cannot be covered by any of the other options.

Note that 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.

If a substance has a particular physical state, e.g. it is a gas, it does not need to be classified for hazards that are only associated with other physical states, e.g. as an oxidising solid or corrosive to metals.

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

and interconnections:

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

Classification - Physical hazards:

Step 3. Specify the *Hazard category* (e.g. Expl. 1.1) and *Hazard statement* (e.g. H201: Explosive; mass explosion hazard) for the *Physical hazards* by selecting the appropriate values from the picklists.

The CLP Regulation implements the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). However, not all the hazard categories and corresponding hazard statements from the GHS have been implemented into 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 4. Specify *Hazard category* (e.g. Acute Tox. 4) and *Hazard statement* (e.g. H302: Harmful if swallowed) for the *Health hazards* by selecting the appropriate values from the picklists.

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>.

Step 5. For the following hazard class or differentiation: *Specific target organ toxicity - single exposure (STOT SE)* and *Specific target organ toxicity - repeated exposure (STOT RE)* you should fill in *Hazard category*, *Hazard statement* and *Affected organs*.

It is recommended to include no more than three primary target organs for practical reasons and because the classification is for *specific* target organ toxicity. 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 target organ for *STOT SE/STOT RE* by adding additional entries by clicking on *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 can be attached in section 13.2 (unless it is already specified in Annex VI to the CLP Regulation).

Figure 21: Specify the affected organ

The screenshot shows the IUCLID interface for configuring Specific Target Organ Toxicity (STOT). It is divided into two main sections: 'Specific target organ toxicity - single (STOT-SE)' and 'Specific target organ toxicity - repeated (STOT-RE)'. Each section has a '+ New item' button and a numbered list icon. The 'STOT-SE' section shows 'Hazard category' as 'STOT Single Exp. 1', 'Hazard statement' as '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>', and 'Reason for no classification' as empty. Under 'Affected organs', 'kidney' is checked. Under 'Route of exposure', 'oral' is checked. The 'STOT-RE' section shows 'Hazard category' as 'STOT Rep. Exp. 1', 'Hazard statement' as '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>', and 'Reason for no classification' as empty. Under 'Affected organs', 'liver' is checked. Under 'Route of exposure', 'oral' is checked.

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

Hazard class	Hazard category	Hazard statement
Acute toxicity - oral	Acute Toxicity 5	H303
Acute toxicity - dermal	Acute Toxicity 5	H313
Acute toxicity - inhalation	Acute Toxicity 5	H333
Skin corrosion / irritation	Skin Mild Irritation 3	H316
Serious eye damage / eye irritation	Eye Irritation 2A Eye Irritation 2B	H320
Aspiration hazard	Asp. Toxicity 2	H305

Germ cell mutagenicity	Muta. 1*	*
Carcinogenicity	Carc. 1*	*
Reproductive toxicity	Repr. 1*	*

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

Classification - Specific concentration limits:

Step 6. 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 (%)* and 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 13.2.

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 22: Specific concentration limits

The screenshot shows a window titled "Specific concentration limits" with a "+ New item" button. A single entry is listed with a blue information icon (i) on the left. The entry details are: "Concentration range (%)" with a value of ">= 2", and "Hazard categories" with a checked box next to "Eye Damage 1". A close button (X) is in the top right corner of the window.

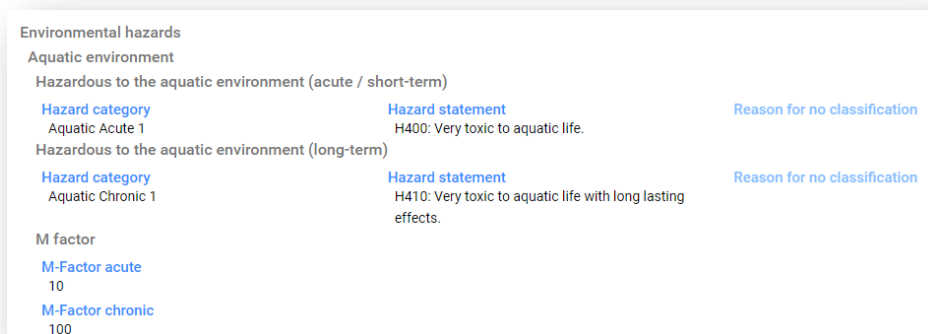
Classification - Environmental hazards:

Step 7. Specify *Hazard category* (e.g. Aquatic Acute 1) and *Hazard statement* (e.g. H400) 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

Figure 23: Specify the Environmental hazards

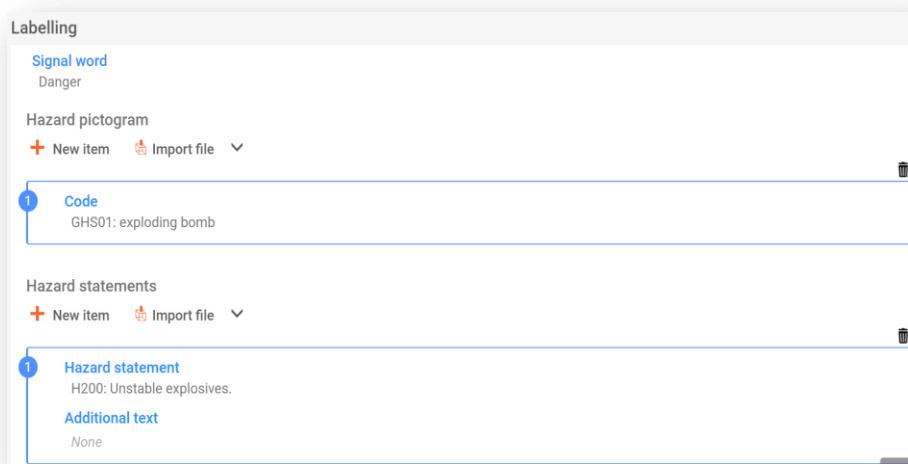


Labelling:

- Step 8.** 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 9.** If applicable, please select a *Hazard pictogram* from the picklist. You can select more than one pictogram by adding a *New item*.
- Step 10.** You should select at least one *Hazard statement* from the picklist and provide *Additional text* where applicable or, 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 24: Labelling for section 2.1



The principles of precedence for the hazard pictograms are stated in Art. 26 of the CLP Regulation, for example, if the hazard pictogram 'GHS06' applies, the hazard pictogram 'GHS07' shall not appear on the label. Please consult the CLP Regulation and/or 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 on the label because of redundancy. For additional information please consult the 'Guidance on the application of the CLP criteria'.

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

Step 12. If applicable, please specify the *Additional labelling requirements*. These include supplemental CLP hazard statements and additional labelling elements resulting from the application of Article 25 of the CLP Regulation. Please consult the CLP Regulation and guidance for further information on the additional labelling requirements.

Notes:

Step 13. If applicable, you can select note(s) from the picklist.

5.4. Section 13.2 Other assessment reports

Section 13.2 is an endpoint study record-type section in which different assessment reports can be attached, covering information not documented in other IUCLID sections. This section should be used by the request submitter to provide some of the required documents for the alternative name request dossier.

The documents that are mandatory to be attached in section 13.2 are:

Safety Data Sheet (SDS) of the substance:

The SDS of the substance for which an alternative chemical name is requested should be attached in this section. The SDS should be in one of the EU/EEA languages (recommended in English, if applicable and possible) and according to the format specified in Annex II to the REACH Regulation.

Commercial interest for requesting an alternative chemical name:

A document demonstrating that the request submitter has a commercial interest worthy of protection should be provided. In the document it should be justified why the disclosure of the actual substance name would cause potential commercial harm to the submitter or to a third party.


Use of the alternative chemical name provides enough information for safe use:

A document demonstrating that the use of the alternative chemical name meets the need to provide enough information for necessary health and safety precautions to be taken in the workplace, and that the risks from handling the mixture can be controlled, should be included in the request (CLP, Annex I, 1.4.1 (II)).

You need to attach the before-mentioned documents in IUCLID as part of the *Substance dataset* as follows:

In the navigation panel click on the  button next to *13.2 Other assessment reports*.

To complete this section follow the steps:

- Step 1.** In the *Type of report* picklist, choose the relevant document type, e.g. *CLP justification for requesting an Alternative name, safety data sheet (SDS)* or *other* (and write "*Justification for safe use*" in the text field below).
- Step 2.** In the *Document/report* field click on *Select file* to attach the relevant document. Use the *Further information on the attachement / remarks* field to specify further the nature of the document. Then click *Save*.
- Step 3.** Repeat the procedure for every required document starting from clicking on the  button.


A separate report entry should be created for each file to be attached.

5.5. Section 14 Information requirements

5.5.1. Alternative name request

In this section the request submitter needs to provide the trade name(s) and the SDS(s) of the mixture(s) in which they request to use an alternative chemical name. You can indicate several mixtures, if the substance for which alternative chemical name is requested is contained in more than one mixture, **by creating a new record for each of them.**

To create a new record:

- Step 1.** In the navigation panel click on the  button next to *Alternative name request* under section 14 *Information requirements*.
- Step 2.** Indicate the name of the mixture in the field *Name or trade name of mixture / product*
- Step 3.** Under *Safety data sheets of mixture / product*, select *New item* to create a row and indicate the required mixture information as instructed here below.
- Step 4.** Click on the *Select file* button in the *Safety data sheet* field to attach the SDS of the mixture (preferably in English language, or, if not available, in any other EU/EEA language) in the same way as done for the SDS of the substance, see *Section 13.2 Other assessment reports*.
- Step 5.** Select the *Country* in which this mixture is marketed from the picklist.
- Step 6.** In the *Remarks* field, indicate the trade name of the mixture in the country in which it is marketed;

In case the mixture is marketed in more than one EU/EEA country, you need to specify the additional country in another row, but in the same table by following the steps above again (*i.e.* do not create a new record). The SDS of the mixture should be attached only once regardless of the number of countries specified in the same table.

All alternative name requests must contain at least the following information/fields in IUCLID section *Alternative name request*, for each mixture covered by the request:

- Name of the mixture (*Name or trade name of mixture / product field*):
- At least one row in the table *Safety data sheets of mixture / product*.
- At least one row in each table must contain: *Country* AND mixture SDS attached.
- Remaining rows in the same table (if applicable) must contain at least *Country*.

For every additional mixture included in the request, **you need to create a new record** in the section *Alternative name request* and complete the steps described above. In case you have listed the mixtures also in other documents e.g., in Section 13.2, make sure that the mixture list is comprised of exactly the same mixtures as included in the Section 14 to avoid confusion or the need to clarify the mixtures for which the request was intended.

Please note that the trade name of each mixture, in both the record and the SDS, needs to be the same as the name that will be used when the mixture is put on the market. In case you want to revise the name of any of the mixtures after the request has been submitted and the fee has been paid, this will require a new request to be submitted, and will levv a new fee.

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

The screenshot shows the IUCLID 6 interface for creating a dossier. The title is 'REACH Registration above 1000 tonnes'. The form contains the following elements:

- Input field: Dossier name (given by user)
- Input field: Dossier submission remark
- Section: Type of submission
 - Radio button: Joint submission
- Section: Tonnage band(s) of the registrant
 - Radio button: On-site isolated intermediates tonnage band (REACH Article 17)
 - Radio button: Transported isolated intermediates tonnage band (REACH Article 18)
- Section: Specific submissions
 - Radio button: The submission is an update
- Section: Dossier specific information
 - Radio button: Phase-in status* (not specified)
- Buttons: Create dossier, Advanced settings

- 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. 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).

7.1.1. Specific submissions

If you have received a request for further information from ECHA, when creating an updated dossier, the checkboxes *The submission is an update* and *Further to a request/decision from a regulatory body* must be selected.


The *Last submission number* and the annotation (communication) number in the request letter must be entered in their respective fields.

Do not select *Spontaneous update* for this submission type. This type of update is not allowed and will not be processed by ECHA.

Please note that no updates to a submitted request are allowed unless requested by ECHA in a request for further information. This includes e.g. adding or revising the mixtures covered by the request. Please always make sure that you include all relevant mixtures for which the alternative chemical name is to be used. Any later request for the use of the alternative chemical name in other mixtures will be a new request for which ECHA will levy another fee.

8. How to export a Dossier

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

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

9. Submit Dossier

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

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

10. Update Dossier

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

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

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

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. Click on your substance dataset or on the dossier in the *Substances / Dossiers* page in IUCLID and select *Validate*. The Validation Assistant will check most of the business rules. However, some of the business rules depend on the submission context (e.g., validity of reference number, duplicate submissions, etc.), and therefore the plugin cannot simulate all the business rules checked by ECHA.

Business rules applicable for a request for use of an alternative chemical name for a substance in a mixture (CLP alternative name request)		
Location (IUCLID/REACH-IT)	Rule description	Relevance
IUCLID substance dataset	A CLP alternative name request dossier must be created from a substance dataset. It cannot be created out of a mixture or product dataset.	CLP alternative name request
IUCLID section 1.1 – Identification	Any entry, in the table 'Other substance identifiers' in section 1.1, indicated as 'Alternative name' must contain also the 'Identity' and the 'Country'.	CLP alternative name request
IUCLID section 1.1 – Identification	The field 'Public name' cannot be empty. The requested alternative name has to be provided in this field.	CLP alternative name request
IUCLID section 1.1 – Identification	A reference substance must exist in section 1.1.	CLP alternative name request
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.	CLP alternative name request
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 composition type "other" is selected from the list, the	CLP alternative name request

	relevant information must be provided in the free text field below.	
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 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.	CLP alternative name request
IUCLID section 1.1 – Identification;	The reference substance must be marked as one of the following: Mono-constituent substance Multi-constituent substance UVCB	CLP alternative name request
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.	CLP alternative name request
IUCLID section 1.1 – Identification; section 1.2 – Composition	If the substance is defined as a multi-constituent substance, the reference substance 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.	CLP alternative name request
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).	CLP alternative name request
IUCLID section 1.3 – Identifiers	For an update submission, a reference number must be given in IUCLID section 1.3.	CLP alternative name request
IUCLID section 2.1 – GHS	The classification and labelling information must be provided in the GHS format in section 2.1.	CLP alternative name request
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 alternative name request
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	CLP alternative name request

	<p>under 'Concentration range (%)' must be provided. In addition, at least one selection must be made under 'Hazard categories'.</p> <p>If no classification is given in a C&L record, the tick box 'Not classified' should be marked and no specific concentration limits should be indicated in that record.</p>	
IUCLID section 2.1 - GHS	<p>If the substance is classified, a 'Hazard category' and a 'Hazard statement' must be provided, or a 'Reason for no classification' for each hazard class in IUCLID section 2.1 should be indicated.</p> <p>If the substance is not classified, the tick box 'Not classified' should be marked and no classification should be provided in that record.</p>	CLP alternative name request
IUCLID section 2.1 - GHS	<p>If the substance is classified, at least one entry for 'Specific target organ toxicity - single' and 'Specific target organ toxicity - repeated' must be provided in IUCLID section 2.1. For each entry, a 'Hazard category', a 'Hazard statement', and 'Affected organs' must be provided, or indicate a 'Reason for no classification'.</p> <p>If the substance is not classified, the tick box 'Not classified' should be marked and no classification should be provided in that record.</p>	CLP alternative name request
IUCLID section 13.2 – Assessment reports	<p>The following two documents must be attached to the dossier in section 13.2: Safety Data Sheet (SDS) Justification for the alternative name request (to be included as report type "Other").</p>	CLP alternative name request
IUCLID section 14 - Alternative name request	<p>Information on the mixture must be included in section 14 of the substance dataset.</p>	CLP alternative name request
IUCLID section 14 - Alternative name request	<p>In section 14 of the dossier, each record created under 'Information on mixtures' must contain: the 'Mixture name' at least one row in the table 'Safety data sheets of mixture / product' indicating a trade name, country and an attached document and/or a remark.</p> <p>At least one mixture safety data sheet must be attached in section 14.</p>	CLP alternative name request
IUCLID section 14 - Alternative name request	<p>When submitting a requested update, the number of mixtures indicated in section 14 has to match with the information in the initial submission.</p>	CLP alternative name request
IUCLID dossier template	<p>The dossier template used in IUCLID must correspond with the intended submission type in REACH-IT.</p>	CLP alternative name request

IUCLID dossier header	<p>A CLP alternative name request has to be submitted as an initial submission, unless ECHA has requested an update. In this case the dossier should be marked as a requested update.</p> <p>Spontaneous updates are not valid submission types for CLP alternative name requests.</p>	CLP alternative name request
IUCLID dossier header	<p>When submitting an update following a request for further information from ECHA, the dossier header should contain the following information:</p> <p>The correct last submission number.</p> <p>The correct annotation number indicated in the communication from ECHA.</p>	CLP alternative name request
REACH-IT	The same IUCLID dossier cannot be submitted more than once.	CLP alternative name request
REACH-IT	You cannot submit a CLP alternative name request while another submission is still pending in the system for the same substance.	CLP alternative name request
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.	CLP alternative name request

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