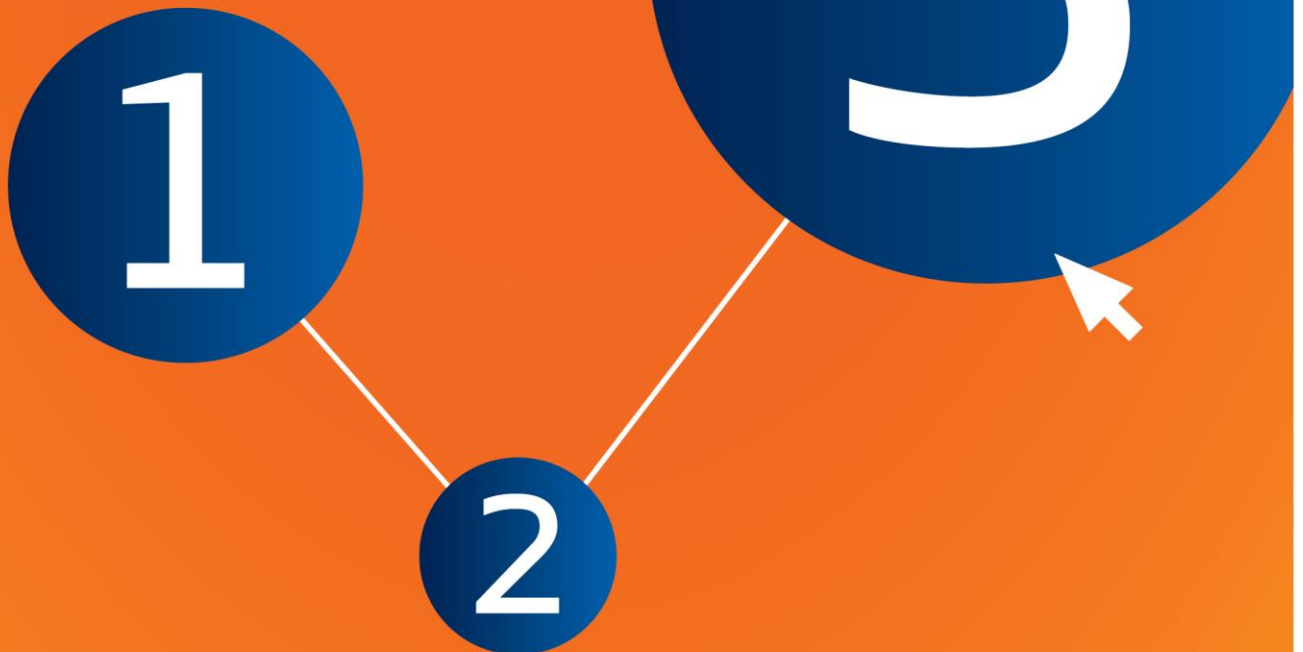


How to prepare a downstream user report



Changes to this document

Version	Changes
2.0	January 2017: Links added to translated versions of this document.
1.0	First version

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1. Introduction

1.1. Objective

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

This manual assumes that IUCLID has been installed and you have the valid ECHA account. More information about the different functionalities in IUCLID and how to use those functionalities can be found in the help system built-in IUCLID (see chapter *Functionalities of IUCLID*).

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

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

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

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

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

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

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

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

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

- Step 1.** Sign-up in REACH-IT and create the *Legal entity* for the downstream user (<https://reach-it.echa.europa.eu/>).
- Step 2.** Create in IUCLID the *reference substances* related to the reported substance (see chapter 6)
- Step 3.** Create in IUCLID the *substance dataset* for the reported substance (see chapter 7)
- Step 4.** Enter information on the reported substance in the substance dataset (see chapter 7)
- Step 5.** Create a downstream user report *dossier* in IUCLID (see chapter 8)
- Step 6.** Export the downstream user report dossier from IUCLID (see chapter 9)
- Step 7.** Submit the downstream user report dossier to ECHA via *REACH-IT* (see chapter 10)

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

1.3. Information requested for a DU Report

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

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

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

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

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

1.4. Checks performed by ECHA on the submitted dossiers

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

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

For more information on the business rules check refer to the Annex: *Overview of the business rules checks performed by ECHA on the submitted dossiers.*

1.4.1. The Validation assistant

The *Validation assistant* (VA) plugin 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* plugin in two steps:

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

Using the plugin 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 functionalities of IUCLID


The functionalities of IUCLID are described in detail in the help that is built in to the IUCLID application. To view the help, press the F1 key anywhere inside the application. The help system will try to display the most relevant part of the help content. From there it is possible to navigate to the specific help required. For example, if the export wizard of the application is open, pressing F1 should open the help content at a description of the *Export* functionality. As an alternative to pressing F1, there are links to help in the application interface, wherever there is a help icon in the form of a question mark.

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://echa.europa.eu/support/helpdesks/echa-helpdesk/echa-accounts>.

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 by right clicking on *Legal entity*  on the IUCLID home page. 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 in the dossier creation wizard (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. Then you can import the file to your local IUCLID installation. 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 your IUCLID installation 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: Home page > *Legal entity* > double click your legal entity. The UUID of the company is displayed in the *Information Panel* at the bottom of the IUCLID window.
- ECHA Accounts: Legal Entity tab > General details > 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 <http://echa.europa.eu/support/helpdesks/echa-helpdesk/echa-accounts>.

3. Legal entity site

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

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

3.1. Creating a Legal entity site



- Step 1.** To create a new site right-click on *Legal entity site*  on the home page and select *New*.
- Step 2.** Provide a name for the site and assign it to the *Legal entity owner* by clicking on the  button.
- Step 3.** Fill as many fields as possible under the *General information and Contact address*. The minimum data required is the *Country* where the site is located.
- Step 4.** To save the legal entity site information click on  from the main menu.

4. Contact

In the *Contacts 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.

4.1. Creating a contact

- Step 1.** To create a *new contact* right-click on the *Contacts*  on the home page and select *New*.
- Step 2.** Complete as many fields as possible under the *General information*.
- Step 3.** To save the contact information click on  from the main menu.

5. Chemical inventories

The *Chemical inventories* contains chemical identifiers, which serve as the basis for defining the *reference substances*. The term *inventory* is used to compile all the different chemical inventories that can be available in IUCLID. Currently, the **EC Inventory** is the only inventory used in IUCLID.

The EC Inventory is a combination of three individual inventories:

- **EINECS** (European Inventory of Existing Commercial Chemical Substances) includes substances that were deemed to be on the European Community market between 1st January 1971 and 18th September 1981.
- **ELINCS** (European List of Notified Chemical Substances) includes substances notified under Directive 67/548/EEC, the Dangerous Substances Directive Notification of New Substances (NONS) and placed on the market after 18th September 1981.
- **NLP-list** (No-Longer Polymers list) includes substances that have been on the European Community market between 18th September 1981 and 31st October 1993, and were

considered to be polymers under the reporting rules for EINECS but were no longer considered to be polymers according to the 7th amendment of Dir 67/548/EEC.

The entries in the EC Inventory consist of a chemical name and a number (EC name and EC number), a CAS number¹ (if available), molecular formula (if available) and description (for certain types of substances).

6. 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 to 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 local installation. Each *reference substance* can be linked to an unlimited number of *substance* or *mixture/product* 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 to your local installation. These pre-defined reference substances have been prepared to improve data quality and minimise data entry.

6.1. 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.

¹ In the case of substances listed in the EC inventory with an EC number starting with 4, there may be no CAS number published even though a CAS number may exist for that substance. This is because under the notification scheme for new substances which existed under the previous legislation the CAS number could be claimed confidential and therefore was not published.

To create a reference substance:



- Step 1.** Right-click on the *Reference substance* on the home page and select *New*.
- Step 2.** Enter the name of the reference substance.
- Step 3.** If the **reference substance is listed in the EC inventory** you can assign that entry by clicking the *Add* button.
- 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*.
- 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 all the known constituents and additives:

- *EC Inventory* information,
- *CAS number* and *CAS name*,
- *IUPAC name*,
- *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*,
- *InChI*,
- Upload an image file with the *Structural formula*.

- Step 6.** To save the reference substance click on  from the main menu.




7. How to create a Substance dataset

This chapter outlines which information you have to provide through 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 which is built inside the application. To view the help, press the F1 key anywhere inside the application and the most relevant information will be displayed in the help window.

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.** Right-click on the *Substance*  on the IUCLID home page and then select *New*.
- Step 2.** Fill in the field *Substance name*. Especially if your IUCLID installation contains several datasets, ensure to enter a name that you can easily use to distinguish the substance.
- Step 3.** Assign an existing *legal entity* to the dataset by clicking on the  button. A new window opens where you can search for legal entities within your IUCLID installation. Enter the search criteria, select the appropriate legal entity from the list, and assign it to the substance dataset.
- Step 4.** Save the information by clicking the  icon in the main menu.

For more information on how to fill in the fields in this view, see section 1.1 *Identification*.

To complete a dataset:


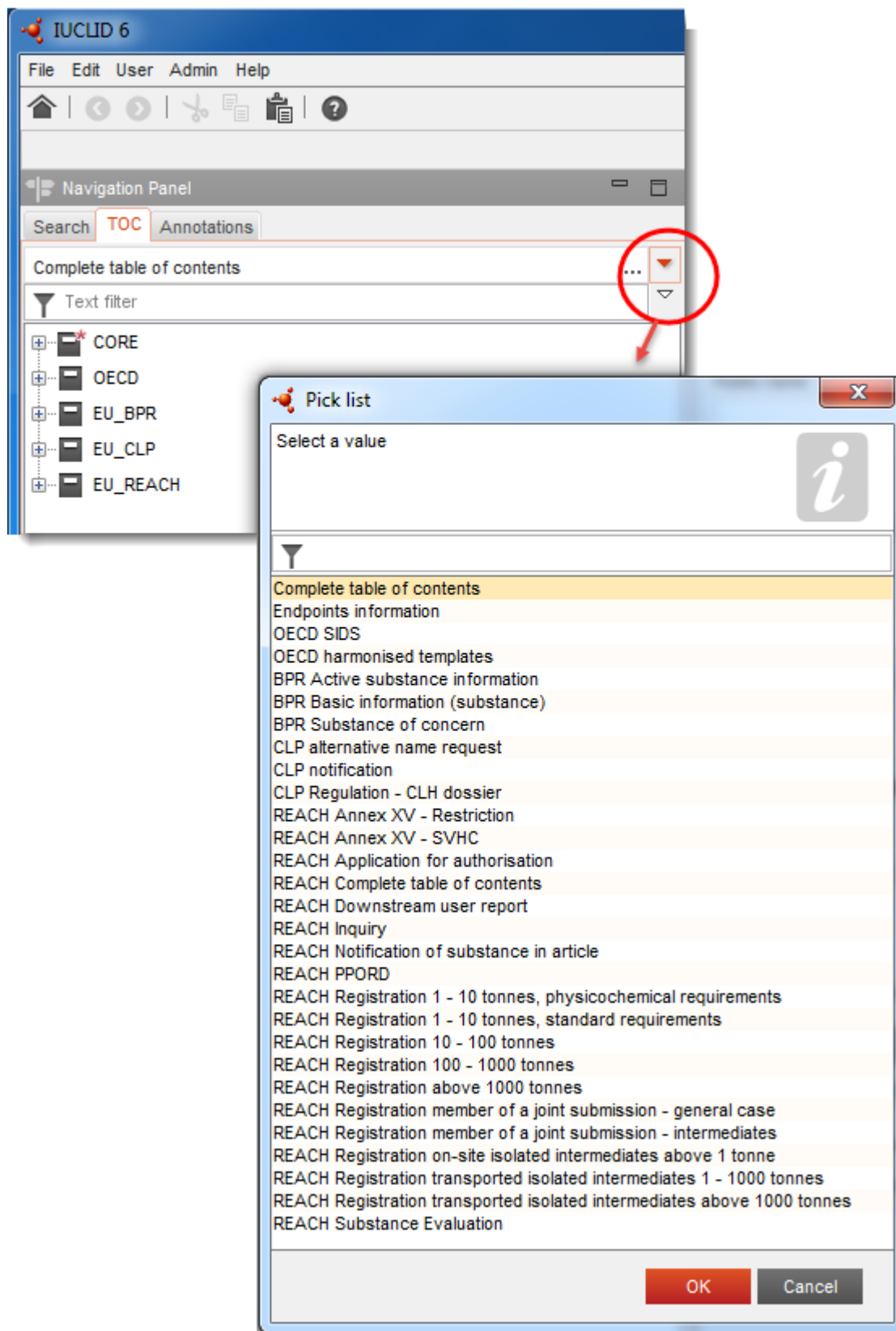

- Step 1.** Once your substance dataset is created it is displayed in the navigation panel on the left part of the screen.
- Step 2.** To open your dataset double-click or right-click and select *Open*.
- Step 3.** When the dataset is open the *Table of contents* (TOC) tab is displayed in the navigation part of the screen.
- Step 4.** To view the table of contents that is relevant for the type of dossier that you are preparing, click on the filled downward arrow () in the TOC tab.
- Step 5.** A list of different submission types appears. Select the specific type of submission from the list.

Figure 1: An example of selecting the template from the picklist



Step 6. The sections relevant for the 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 table of contents*. This will display the table of contents containing all sections that are relevant under the REACH Regulation.

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 adjacent text field marked with 'Other' must be completed,
- when a field is associated with a unit, this must be filled in.

7.1. Section 1 General information

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

7.1.1. Section 1.1 Identification


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

To complete this section, follow the steps:

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

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

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

Step 3. Assign a *Legal entity* to your substance dataset by clicking on the  button (see chapter *Legal entity*).

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

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

Role in the supply chain:

Step 5. Select at least one checkbox in this section according to your role in the supply chain with regards to this substance.

Identification of substance:

Step 6. Click the  button to assign a *reference substance* to your substance dataset.

Step 7. A query dialog appears. Search for your reference substance. Click *Assign*.

If you cannot find your reference substance because it has not been created yet, click *New* 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*² 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.³

If your substance is a **multi-constituent** substance, assign the *reference substance*⁴ corresponding to the reaction mass of the main constituents of your substance in section 1.1.

- **UVCB substances:**

² 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.

³ 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".

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.

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*⁵ corresponding to the UVCB substance in section 1.1.

Type of substance:

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

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

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

Step 10. If relevant, you can include additional identifiers for your substance under *Other identifiers*. Such identifiers may include Trade names of the substance, identifiers by which the substance was previously known but have later been replaced/refined, or identifiers which are used to identify the substance under other regulatory schemes. Chemical (scientific) synonyms should not be listed here, but should be indicated in the reference substance information.

Step 11. You can add information of the contact person(s) for this substance from the previously defined contacts (see chapter *Contact*).

Step 12. To save the information click  from the main menu.

7.1.2. Section 1.2 Composition

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:

⁵ 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 1.** Right-click on the *1.2. Composition* in the *TOC* from the navigation panel on the left part of the screen.
- Step 2.** From the picklist select *New record*.
- Step 3.** A new record to report a new composition is created.

Next, fill in the information on your substance composition.

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 of composition*. This is particularly important when several compositions are reported in order to clarify the differences between the compositions. 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 the *Attached description*.
- 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 <http://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 2: Degree of purity

The screenshot shows a software interface for setting the degree of purity. It features a title bar 'Degree of purity' and a search icon. Below, there are two input fields: the first contains '95' with a '>=' operator, and the second contains '98' with a '<=' operator. To the right, there is a unit dropdown menu set to '% (w/w)' and an ellipsis menu.

Constituents:

- Step 8.** Include the *constituents* for the composition by clicking the button. Each composition must have, as a minimum, one constituent. The number of constituents to be reported will depend on the type of substance. To add more constituents, click the , and then the new repeatable blocks will appear.
- Step 9.** Assign a *reference substance* to the newly created constituent by clicking the button. Search for the appropriate reference substance and add it by selecting it and clicking *Assign*; 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.
- Step 10.** Indicate the *Typical concentration* and the *Concentration range* (minimum and maximum values, and unit of measurement) for every constituent.

Figure 3: Constituent

The screenshot shows the 'Constituents' window with a title bar and a search icon. The main content area displays the following information:

- Header: Styrene / Styrene / 100-42-5 / 202-851-5, ca. 98 % (w/w), >= 96 - <= 99.5 % (w/w)
- Reference substance: Styrene / Styrene / 100-42-5 / 202-851-5
- Inventory table:

Inventory	Inventory number	Inventory name
EC Inventory	202-851-5	styrene
CAS number	100-42-5	Benzene, ethenyl-
IUPAC name	Styrene	
- Typical concentration: ca. 98 % (w/w)
- Concentration range: >= 96 <= 99.5 % (w/w)

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 box must be ticked.

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 4: Unknown impurities

The screenshot displays the 'Impurities' software interface. The title bar reads 'Impurities ^'. The main window title is 'Unknown impurities / Unknown impurities, ca. 0.05 % (w/w), >= 0.04 - <= 0.08 % (w/w)'. The interface includes a 'Reference substance' section with a search field containing 'Unknown impurities / Unknown impurities'. Below this is a table with columns for 'Inventory', 'Inventory number', and 'Inventory name'. Further down are fields for 'CAS number', 'CAS name', and 'IUPAC name', with 'Unknown impurities' entered in the latter. The 'Typical concentration' is set to 'ca. 0.05 % (w/w)'. The 'Concentration range' is defined as '>= 0.04 <= 0.08 % (w/w)'. The 'Remarks' field contains the text: '3 unknown organic impurities for which the individual concentration does not exceed 0.03% according to the HPLC analysis (see section 1.4). Based on the fragmentation pattern in the HPLC-MS analysis (see also section 1.4), the structure of these impurities might include one chlorine and two bromine atoms'.

Figure 5: Additive

The screenshot shows the 'Additives' window with the following details:

- Reference substance:** 4-tert-butylbenzene-1,2-diol / 4-tert-butylbenzene-1,2-diol / 98-29-3 / 202-653-9
- Inventory table:**

Inventory	Inventory number	Inventory name
EC Inventory	202-653-9	4-tert-butylpyrocatechol
CAS number	CAS name	
98-29-3	1,2-Benzenediol,4-(1,1-dimethylethyl)-	
IUPAC name		4-tert-butylbenzene-1,2-diol
- Typical concentration:** ca. 0.01 % (w/w)
- Concentration range:** >= 0.005 - <= 0.02 % (w/w)
- Function:** stabiliser: inhibitor
- Details of function in composition:** This stabiliser is added to styrene in order to prevent its polymerisation

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).⁶

- 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 $< 80\%$.⁷
- 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 of the composition*.
Note: To facilitate the reporting of the manufacturing process, suggestions as to what to enter are provided in a free text template for the field *Description of composition*. To open the free text template, click on the icon that shows the letter A with an arrow at the bottom right, . A pop-up window appears. Click *Option 2: composition of a UVCB substance*. To copy the text from the template to the field, click on the button labelled *Insert*. 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 the *Impurities* header of the composition (impurities are not considered relevant for UVCBs).



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.

⁷ 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 any additive necessary to stabilise your composition under the *Additives* header. 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 nanomaterials:

This sub-section is filled in when *solid: nanomaterial* has been selected in the *State/form* picklist for that composition. It includes fields to report key characteristics of compositions that are nanoforms.

- Step 14.** Select the *Shape* of the nanoform from the available options in the picklist.
- Step 15.** Provide size ranges for the three *Dimensions* *x*, *y*, *z* and the unit of measurement (e.g. nm). Provide the *Percentile* (e.g. D50) of the size distributions to which the size ranges refer to. Additional information on shape of the nanoform can be provided in the *Remarks* field.
- Step 16.** Provide the ranges of specific surface areas of the nanoform, together with the unit.
- Step 17.** Under *Surface treatment applied*, indicate whether surface treatment was applied, and the type of treatment as relevant.
- Step 18.** Where surface treatment was applied, provide information on the treatment. Click on the  button to create a surface treatment block and indicate a name for the surface treatment.
- Step 19.** Next, in the table *Surface treatment* report the identity of the surface treatment agents layer-by-layer. Click on the *Add* button to create a new row for each layer. This action will open a dialogue window, where you indicate the layer number, and link a reference substance that describes the surface treatment agent applied by clicking the  button.
- Step 20.** Indicate the nature of the *External layer* by selecting one of the options available in the picklist. Provide the % (w/w) *Total fraction of core particle* that is representative of this nanoform. This value refers to the weight fraction of the core particle relative to the total weight of the surface-treated particle. Any supporting information, such as illustrations of the particle structure can be attached.

Note that several surface treatment blocks can be created within the same composition. This refers to the situation where several nanoforms with similar surface treatment exist, but where the dossier submitter has determined that this does not impact the chemical identity or the hazard profile of this composition.


When the nanoforms of the substance vary significantly in shape, specific surface area or surface treatment applied, then separate composition records are created to reflect these differences.

- Step 21.** To save the information click  from the main menu.

7.1.3. Section 1.3 Identifiers



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

To enter your data, you must first create a new record by right-clicking on the section name and selecting a *new fixed record*.

- Step 1.** Press *Add* button to add a new identifier to the *Regulatory programme identifiers* table.
- 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.** Click on *OK* and the added regulatory programme identifiers will appear in the table.
- Step 5.** If you need to provide more than one programme identifier, create a new row by repeating the previous steps.
- Step 6.** To save the information click  from the main menu.

7.1.4. Section 1.7 Suppliers

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

- Step 1.** To create a new supplier right-click on 1.7 Suppliers and select *New record*.
- Step 2.** Click the  button to search existing legal entities.
- Step 3.** Click the *New* button if you cannot find your supplier in the existing legal entities (this may be because your supplier is a distributor).
- Step 4.** Fill as many fields as possible under the *General information* and *Contact address*.
- Step 5.** To save the suppliers information click on  from the main menu.

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

7.2. Section 2 C&L and PBT assessment

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

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

If you classify a substance, and your classification is different from that of all of your suppliers (as communicated in the safety data sheet under Section 2 for a substance as

such, or Section 3 for the substance as a component of a mixture), you must report your classification to ECHA (if you use the substance in quantities of 1 tonne/year or more). How to report the classification is described in this section.

7.2.1. Section 2.1 GHS

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

It is highly recommended to consult Annex I of the CLP Regulation for the classification criteria and the following guidance document for more detailed instructions on the application of the C&L criteria 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.** Right-click on the section *2.1 GHS* in the *TOC* from the navigation panel on the left part of the screen.
- Step 2.** From the picklist select *New record*.
- Step 3.** A new record to report the classification and labelling information is created.

Harmonised classification has to be respected and you should not modify any of those harmonised hazard classes/differentiations, unless you have data based on which a stricter classification (hazard classes and/or differentiations) applies. Therefore, if your substance has a harmonised classification for some hazard classes/differentiations, you should classify for other hazards according to available and reliable data and upgrade the harmonised classification towards a stricter classification, if necessary.

To complete this section, follow the steps:

General information:

- Step 1.** Enter a descriptive *Name* for the GHS record. This is particularly relevant in the case that multiple GHS records are created, to easily distinguish the different records.
- Step 2.** If you submit a dossier for a substance which is **not classified** you should select the checkbox *Not classified*. In this case, you should not enter any hazard category or hazard statement in the GHS record.
- Step 3.** Select a composition(s) in the *Related composition* field for which the GHS record is relevant by clicking the *Add* button.

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

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

Classification:

In this block you must select a *Hazard category* and *Hazard statement* for each hazard class of differentiation, otherwise, you must fill in the *Reason for no classification*.

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;
- *inconclusive* should be selected if you have data or other information which is not reliable (e.g. data of poor quality) or if you have several equivocal study results or information. In these cases, the available data/information cannot be regarded as a firm basis for classification;
- *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.

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

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

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 *conclusive, but not sufficient for classification* as a reason for no classification.

and interconnections:

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

Classification - Physical hazards:

Step 4. Specify the *Hazard category* (e.g. Expl. Div. 1.1) and *Hazard statement* (e.g. H201: Explosive; mass explosion hazard) for the *Physical hazards* by selecting the appropriate values from the picklists.

The CLP Regulation implements the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). However, not all the hazard categories and corresponding hazard statements from the GHS have been implemented 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 5. Specify *Hazard category* (e.g. Acute Tox. 1) and *Hazard statement* (e.g. H300: Fatal if swallowed) for the *Health hazards* by selecting the appropriate values from the picklists.

In case you have conclusive data which enables you to specify the nature of *Reproductive toxicity* effects (i.e. damage to fertility and/or the unborn child), you should indicate that in the field *Specific effect* by including the appropriate additional *Hazard statement* code(s).

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

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

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

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

Figure 6: Specify the nature and the route of exposure for reproductive toxicity

Reproductive toxicity ^			
	Hazard category	Hazard statement	Reason for no class
Reproductive toxicity	Repr. 1A ... ▼	H360: May damage ferti ... ▼	
Specific effect	H360F May damage fertility		
Route of exposure	Oral ... ▼	Remarks	
Effects on or via lactation	... ▼	... ▼	

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

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


Figure 7: Specify the hazard of carcinogenicity via inhalation

Carcinogenicity ^			
	Hazard category	Hazard statement	Reason for
Carcinogenicity	Carc. 1A ... ▼	H350: May cause cancer <state r ... ▼	
Route of exposure	Inhalation ... ▼	H350	

Step 6. For the following hazard class or differentiation: *Specific target organ toxicity - single exposure (STOT SE)* and *Specific target organ toxicity - repeated exposure (STOT RE)* you should fill in *Hazard category*, *Hazard statement* and *Affected organs*, otherwise, the field *Reason for no classification* should be filled in.

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 STOT SE /STOT RE by adding additional blocks by clicking on the  symbol.

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

Figure 8: Specify the affected organ


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 are not relevant for 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
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Classification - Specific concentration limits:

Step 7. 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*.

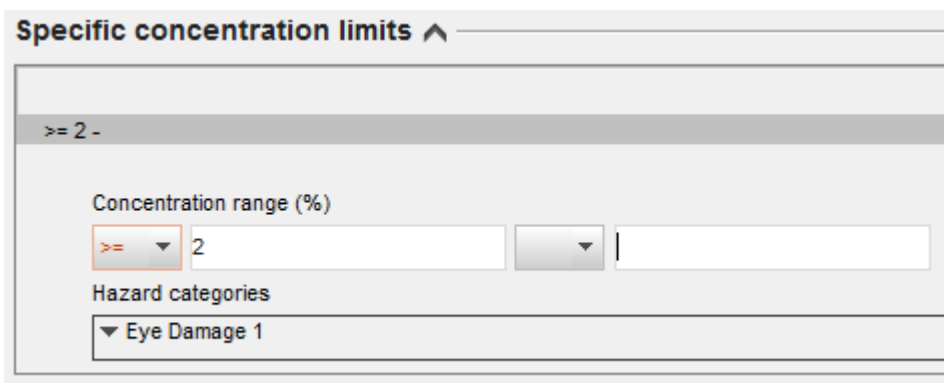
You can specify more than one concentration limit by adding additional blocks by clicking on the  symbol.

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

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

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

Figure 9: Specific concentration limits



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

Hazard category
Flammable Liquid 4
Acute Toxicity 5
Skin Mild Irritation 3
Eye Irritation 2A
Eye Irritation 2B
Asp. Toxicity 2

Classification - Environmental hazards:

Step 8. Specify *Hazard category* (e.g. Aquatic Acute 1) and *Hazard statement* (e.g. H400: Very toxic to aquatic life) for the *Environmental hazards* by selecting the appropriate values from the picklists.

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

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

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

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

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

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

Figure 10: Specify the Environmental hazards

The screenshot shows the 'Aquatic environment' section of the IUCLID software. It contains a table with two columns: 'Hazard category' and 'Hazard statement'. The first row shows 'Aquatic Acute 1' and 'H400: Very toxic to aquatic life.' The second row shows 'Aquatic Chronic 1' and 'H410: Very toxic to aquatic life with long-term effects'. Below the table, there are two input fields for 'M factor'. The 'M-Factor acute' field contains the value '10', and the 'M-Factor chronic' field contains the value '100'.

Labelling:



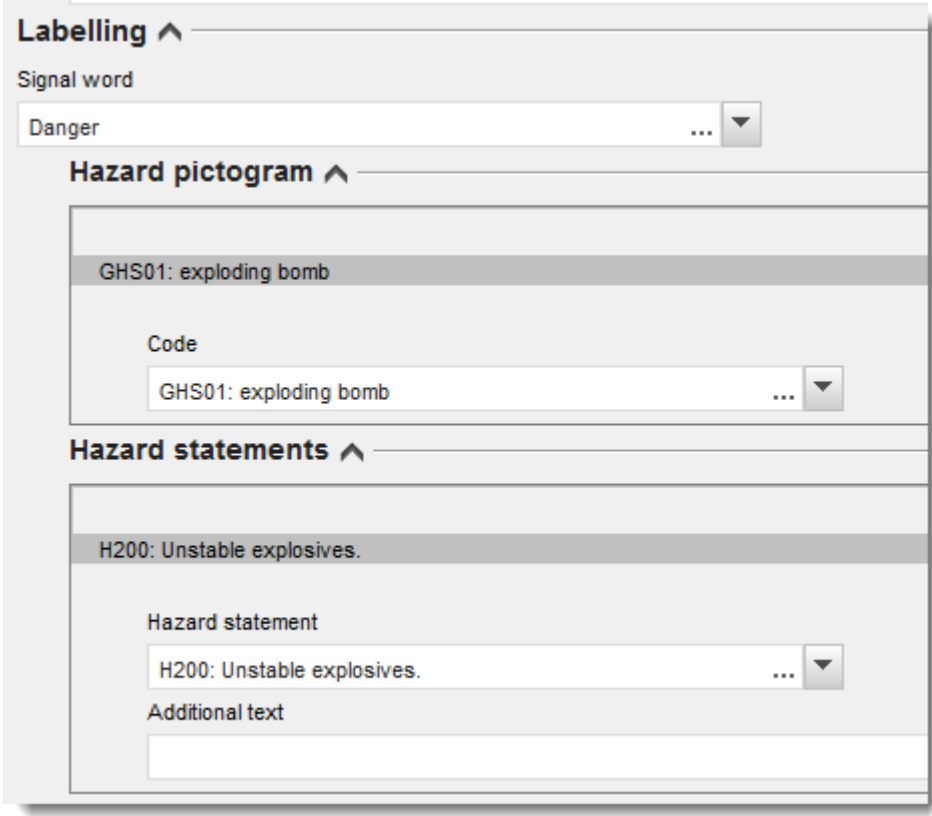
- Step 9.** Specify the *Signal word* by selecting the appropriate value from the picklist. If no signal word applies to your substance, then you need to select *No signal word* from the picklist.
- Step 10.** If applicable, please select a *Hazard pictogram* from the picklist. You can select more than one pictogram by clicking on .
- Step 11.** 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 clicking on .

Figure 11: Labelling for section 2.1

The screenshot shows a web form titled "Labelling" with three main sections:

- Signal word:** A dropdown menu with "Danger" selected.
- Hazard pictogram:** A list of options with "GHS01: exploding bomb" selected. Below it is a "Code" dropdown menu also set to "GHS01: exploding bomb".
- Hazard statements:** A list of options with "H200: Unstable explosives." selected. Below it is a "Hazard statement" dropdown menu also set to "H200: Unstable explosives." and an empty "Additional text" input field.

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

According to Art. 27 of CLP Regulation, some hazard statements are not required in the label because of redundancy. A few examples are listed below. For additional information please consult the guidance on the application of the CLP criteria.

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

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

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

Step 12. If applicable, please select a *Precautionary statements* from the picklist.

Step 13. If applicable, please specify the *Additional labelling requirements*. These include supplemental CLP hazard statements and additional labelling elements resulting from the application of CLP Article 25. Please consult the CLP Regulation and Guidance for further information on the additional labelling requirements.


Notes:

Step 14. If applicable, you can select note(s) from the picklist.

7.3. Section 3 Manufacture use and exposure

7.3.1. Section 3.3 Sites

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

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

7.3.2. Section 3.5 Life cycle description

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

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

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

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

Depending on the life cycle stage under which you have created a record, a set of relevant fields will be displayed for describing the use. The help-text in IUCLID provides an explanation of which type of information is expected for each field. Therefore, the current IUCLID manual is meant to provide an overview on the information, for more detailed explanation please consult the help-text.

To report a new use:

- Step 1.** Right-click on the relevant life cycle stage where you want to add a new use.
- Step 2.** Select *New record* and provide an intuitive name for the record so that you can easily recognise it later. This name can be the same as the use name or at least consistent with it.
- Step 3.** Select *use reported by Downstream user according to REACH Article 38* from the picklist in the *Registration/Notification status for the use*. This selection will determine the type of fields provided for entering information. You will still see the non-relevant fields, visually identified as non-editable.

Step 4. Provide a *use name* which should be representative for the use; in case an exposure assessment is performed for the contributing activities in this use, the use name becomes the exposure scenario name in the Downstream User Chemical Safety Report (DU CSR) and Exposure Scenario (ES).

Step 5. Report further details in the field *Further description of use* to further explain the process(es) covered by the use, or the type of product(s) in the case of a consumer use.

After having created a use, you can also make a link from the site in the IUCLID section 3.3. to this use (see chapter 7.3.1 for more information). This is relevant when reporting your own uses. If the dossier includes uses from your downstream users, they are not linked to sites. You will see the link(s) before continue with the further description of the use.

Describe the use in more detail

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

Figure 12: Contributing activities / techniques for environment and workers

The image shows two overlapping software windows. The top window is titled "Contributing activity / technique for the environment" and contains a text input field labeled "Name of activity / technique" and a dropdown menu labeled "Environmental release category (ERC)". The bottom window is titled "Contributing activity / technique for workers" and contains a text input field labeled "Name of activity / technique" and a dropdown menu labeled "Process category (PROC)". Both windows have standard window controls (minimize, maximize, close) in the top right corner.

Start the description of the use with adding (repeatable) blocks of information for each *Contributing activity / technique for the environment*:

- Provide a *Name of the activity/technique*, to facilitate the understanding on the process, technique, product or article addressed in this contributing activity. Standard names may be available from downstream sector organisations via use maps. In case an exposure assessment is performed this name becomes also the *contributing scenario name*.
- Select a suitable *Environmental release category (ERC)* from the picklist. Only relevant ERCs for the Life cycle stage are available.

Complete the description of the use by adding (repeatable) blocks of information for *Contributing Activity / technique for worker*:

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

Or (when you describe a consumer use) complete the description of the use by adding (repeatable) blocks of information for *Contributing activity / technique for consumers*:

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

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

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

- Provide more information on the market where the use takes place by selecting one or more relevant use descriptor(s) in the following fields, where applicable: *Product category used*, *Sector of end use*. Please note: These two fields are not applicable for consumer uses. This information may also be available from downstream user organisations via use maps.
- If the substance has a particular technical function during a use, select one or more entries in the picklist *Technical function of the substance during use*. If the substance has no specific technical function during this particular use, select *No technical function* the last entry in the picklist.
- Select *substance supplied to this use in form of: as such or in a mixture*.
- Select *yes* or *no* in the picklist *Subsequent service life relevant for this use* to flag whether or not the substance is included into an article during the use. If *yes* is selected, set a link to the relevant subsequent use(s) described in the section 3.5.6 *Service life* once they have been created.

Add information on the extent of the use

Provide information on the tonnage of substance assumed/known to enter in this use per year. This information indicates the extent of the use and may serve as supporting the absence of wide-dispersive uses⁸, together with other criteria. Such information may be relevant for authorities when prioritising substances for further scrutiny or regulatory action. At the same time, this information is also an input to the environmental exposure assessment. Quantify the tonnage of substance for this use (tonnes/year) and provide some explanation in the two related fields *Details on tonnage reported* and *Total EU tonnage* for this use enabling the interpretation of the tonnage figure.

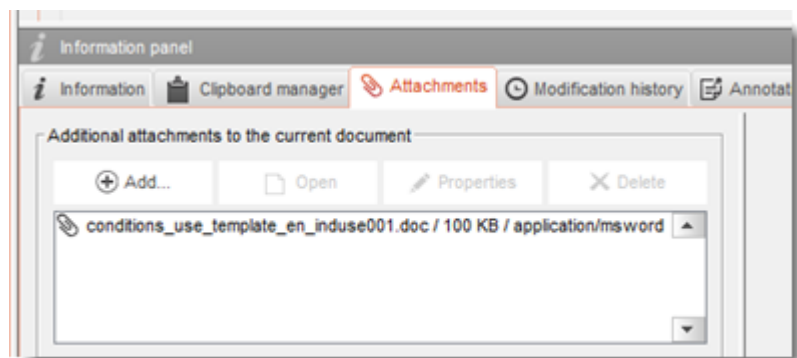
Provide information on conditions of use

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

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

Attach the filled-in template, with the conditions of use for each reported use, in the attachment section of the information panel below.

Figure 13: Attaching the template with conditions of use



7.4. (Optional) Testing proposals

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

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

Step 1. In the *Type of information* select from the picklist *experimental study planned*.


Step 2. Then fill in as much information about the study as possible, in particular the *Study period*.

⁸ The guidance on use description R.12 provides further explanation on the concept of wide-dispersive uses: <http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

Step 3. Information about the guideline must be present in the *Test guideline* or *Principles of method other than guideline* or as an attachment in the field *Attached background material*.

7.5. Section 14 Downstream user report

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


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

8. 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.

This may also be a good time to verify if the quality of the dataset can be improved before creating a dossier, please check the webpage *How to improve your dossier* on the ECHA website: <http://echa.europa.eu/support/how-to-improve-your-dossier>

- Step 1.** To create a dossier open the list of available substance datasets by clicking on the *Substance*  on the IUCLID home page.
- Step 2.** All available substances (within the limits of the search results managed in the user's preferences) are displayed in the navigation panel on the left part of the screen. If a substance does not appear in the list you can search for it using the search panel. If the list is very long, you can also filter by typing (part of) the name of the substance in the filter field.
- Step 3.** Select the substance for which you want to create a dossier.
- Step 4.** Right-click on the substance in the query results list. From the pop-up menu select *Create dossier*.

Step 5. After selecting the *Create dossier* option the dossier creation wizard is displayed. Follow the steps in the dossier creation wizard.

Only two steps are displayed in the dossier creation wizard as the default option: *Select submission type* (1) and *Complete the dossier header* (5). If you wish to change the default settings to have more options you can select the checkbox *Use advanced settings*.

Step 1. Select the submission type. Choosing the correct dossier template by selecting the submission type is essential for a successful submission. Before exporting your dossier you have to make sure that the selected template corresponds with the intended submission.

When the checkbox *Use advanced settings* is selected follow the steps 2-4, if the default settings are kept (recommended approach), go to step 5 directly.

Step 2. 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 'all fields - including confidential test material'. 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 3. Select whether the annotations should be included in the dossier.

Step 4. Verify and select which documents and entities will be included in your dossier. To this end, select in the Entities list the substance entity which will be preceded by . The documents and entities connected to the substance will be listed in the References to window; documents to be included are already checked. 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 select Next and rely on the default settings for that submission type.

Step 5. Complete the dossier header by entering additional administrative information.

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*.

The following subchapters describe how to fill in the administrative information in the dossier header.

8.1. Administrative information

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

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


8.1.1. Specific submissions

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

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

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

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


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

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

8.1.2. Dossier specific information

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

9. How to export a Dossier

To start the export process, first search for the Dossier  in the navigation panel of the IUCLID application. When the Dossier is shown in the list of search results, right-click on its entry, and then *select* Export from the menu.

For details on the export wizard, see the help that is built in to the IUCLID application.

10. 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/>.

11. 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 navigation panel and fill in or update the relevant data. When the dataset is ready you can create a dossier (see chapter *How to create a Dossier*).

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

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

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

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

	If categories are used, this rule is applied to all the category member substances.	
IUCLID section 1.1 – Identification	In an update submission, the substance must be identified by an EC/List number.	Downstream User Reports
IUCLID section 1.1 – Identification	The ‘Only representative’ as a role in the supply chain cannot be marked together with ‘Manufacturer’ or ‘Importer’. Separate legal entities and registrations/notifications are required for each non-EU manufacturer represented.	Downstream User Reports
IUCLID section 1.1 – Identification; section 3.3 - Sites	When ‘Manufacturer’ is selected as a role in supply chain (on its own or together with ‘Importer’) in section 1.1, a manufacturing site must be provided in section 3.3.	Downstream User Reports
IUCLID section 1.1 – Identification	The reference substance must be marked as one of the following: Mono constituent substance Multi constituent substance UVCB	Downstream User Reports
IUCLID section 1.2 – Composition	At least one composition must be defined in section 1.2. The following requirements are also to be fulfilled: All created compositions must contain at least one constituent. All constituents must be linked to a reference substance.	All dossier types
IUCLID section 1.2 – Composition	All compositions created in section 1.2 must have the composition type indicated. At least one of the compositions in section 1.2 must reflect the composition of the substance manufactured/imported by the registrant. This composition must be marked as the “Legal entity composition of the substance”. If the composition type “other” is selected from the list, the relevant information must be provided in the adjacent free text field.	All dossier types
IUCLID section 1.1 – Identification; section 1.2 – Composition	If the substance is defined as mono-constituent, the first ‘legal entity composition of the substance’ in section 1.2 has to have a matching substance identity when compared with the reference substance in section 1.1.	All dossier types
IUCLID section 1.1 - Identification; section 1.2 – Composition	If the substance is defined as a multi-constituent substance, the reference substance in section 1.1 cannot be identical to any of the constituents defined in the first composition of type ‘legal entity composition of the substance’ in section 1.2.	All dossier types
IUCLID substance dataset - section 1.2	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	All dossier types

	of formaldehyde).	
IUCLID section 1.3 – Identifiers	<p>A REACH Registration number has to be provided in section 1.3. If no registration number can be provided, the submitter should create an entry in section 1.3 using 'REACH Registration number' as the regulatory programme and provide a justification in the 'Remarks' field.</p> <p>If a REACH Registration number is provided in section 1.3, it has to be a valid number (i.e. exists in REACH-IT) and it has to be for the substance referenced in section 1.1. The number does not have to belong to the submitting legal entity, as it in general should belong to the supplier of the substance.</p>	Downstream User Reports
IUCLID section 1.7 - Suppliers	<p>At least one 'Supplier' record must exist in IUCLID section 1.7. For each supplier, a legal entity must be assigned under the field 'Name'. Inside the legal entity under the tab 'Contact information', a 'Contact address' and at least one 'Contact persons' block must be provided. The following fields for the 'Contact address' and each 'Contact persons' block (by assigning a 'Person') must be provided:</p> <p>Name (first name and last name of a contact person) Phone E-mail Address Postal code Country</p>	Downstream User Reports
IUCLID section 3.3 - Sites	<p>Link a site to all records created in section 3.3.</p> <p>The site contact details must contain at least the country, selected from the pick list. The selection cannot be "Other".</p>	Downstream User Reports
IUCLID section 3.5 – Life Cycle description	<p>At least one use has to be provided in one of the following fields:</p> <p>Formulation or re-packing (section 3.5.2) Uses at industrial sites (section 3.5.3) Widespread uses by professional workers (section 3.5.4) Consumer uses (section 3.5.5) Service life (section 3.5.6)</p> <p>Each use must be identified with the 'Use name' or 'Service life name'.</p>	Downstream User Reports
IUCLID section 2.1 - GHS	At least one classification and labelling record must be provided in CLP/GHS format in section 2.1.	Downstream User Reports
IUCLID section 2.1 – GHS	<p>If at least one classification is provided in a C&L record in section 2.1 then:</p> <p>a 'Signal word' must be provided in the 'Labelling' block</p>	Downstream User Reports

	<p>of the same record.</p> <p>'Hazard statement' or a 'CLP supplemental hazard statement' must be provided in the 'Additional labelling requirements' block of the same record.</p> <p>If no classification is provided, the tick box 'Not classified' should be selected and no hazard statements and no signal words should be provided.</p>	
IUCLID section 2.1 – GHS	<p>If the substance is classified, a 'Hazard category' and a 'Hazard statement' must be provided, or a 'Reason for no classification' for each hazard class in IUCLID section 2.1 should be indicated.</p> <p>If the substance is not classified, the tick box 'Not classified' should be marked and no classification should be provided in that record.</p>	Downstream User Reports
IUCLID section 2.1 – GHS	<p>For each 'Specific concentration limit' block that is created in a C&L record in IUCLID section 2.1, at least one of the two fields under 'Concentration range (%)' must be provided. In addition, at least one selection under 'Hazard categories' has to be made.</p> <p>If no classification is given in a C&L record, the tick box 'Not classified' should be marked and no specific concentration limits should be indicated in that record.</p>	Downstream User Reports
IUCLID section 2.1 – GHS	<p>If the substance is classified, at least one block for 'Specific target organ toxicity - single' and 'Specific target organ toxicity - repeated' must be provided in IUCLID section 2.1. For each block, a 'Hazard category', a 'Hazard statement', and 'Affected organs' must be provided, or indicate a 'Reason for no classification'.</p> <p>If the substance is not classified, the tick box 'Not classified' should be marked and no classification should be provided in that record.</p>	Downstream User Reports
IUCLID section 14 - Downstream User Report	<p>Provide the reason for submitting a downstream user report in a record in section 14, and indicate under 'General information' whether the report is submitted due to a difference in classification and/or due to uses not being covered by the exposure scenarios received from the supplier.</p>	Downstream User Reports
IUCLID section 14 - Downstream User Report	<p>If you indicated in section 14 that the uses reported are not covered in the exposure scenarios received from the supplier, then you must specify under 'Further information on the reported use(s)' whether the non-coverage is due to differences between the uses or use conditions covered by the supplier, and/or due to unresolved issues with the supplier in relation to CBI or supply chain communication.</p>	Downstream User Reports

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

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

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