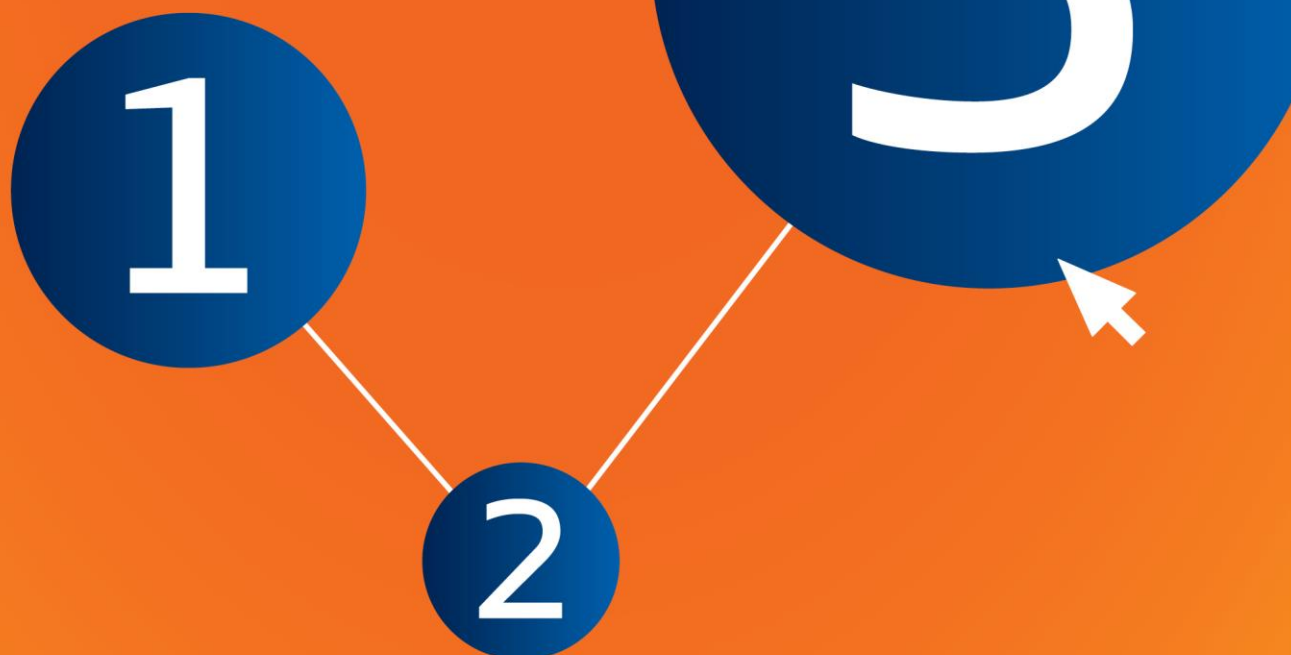


How to prepare an inquiry dossier



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

This manual assumes that IUCLID has been installed and you have a valid ECHA account. More information about the different functionalities in IUCLID and how to use those functionalities can be found in the help system built-in IUCLID (see chapter 1.5 *Functionalities of IUCLID*).

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

Are you a potential registrant?

If you are manufacturing or importing for the first time a phase-in substance in quantities of 1 tonne or more per year or use for the first time a phase-in substance in the context of production of articles or import for the first time an article containing a phase-in substance that would require registration, after 1 December 2008, you may use the late pre-registration option provided by Article 28(6) of the REACH Regulation instead of inquiring about your substance.

To benefit from the late pre-registration option you must **pre-register**:

- at the latest six months after your manufacturing, importing or using the substance exceeds the one-tonne per year threshold and
- at least 12 months before the relevant deadline for your registration in Article 23 REACH.

As a first-time manufacturer, importer or producer of articles (less than 100 tonnes per year) you will need to submit your late pre-registration before 31 May 2017. Manufacture or import for the first time means, manufacture or import for the first time from the entry into force of REACH Regulation.

After the pre-registration of a substance, there is no legal basis to inquire about the same substance before registration. In such cases the inquiry dossier will not be accepted for processing. Therefore if you have already pre-registered a substance (and not yet registered it), you should discuss your information requirements and the availability of data within the Substance Information Exchange Forum (SIEF) created for your substance.

Are you already a registrant?

According to Article 12(2) of Regulation (EC) No 1907/2006 (the REACH Regulation) a registrant of a substance reaching the next tonnage threshold shall inform ECHA of the additional information required for updating the registration. If additional information is not required, it is not necessary to inform ECHA of your intention to update your registration for

the next tonnage band and therefore to submit an inquiry. In such case the inquiry dossier will not be accepted for processing.

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

A IUCLID dossier is non-editable snapshot file of a substance dataset, containing the information to be submitted to ECHA. To generate a dossier and submit it you have to proceed through the following steps:

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

Upon receipt of your dossier, ECHA will undertake a set of administrative and technical checks of your submission (see chapter 1.4 *Checks performed by ECHA on the submitted dossiers*).

1.3. Information requested for inquiry

For inquiry dossier you must provide the following information:

- identity of the requested submitter (REACH-IT account),
- identity and composition of substance (IUCLID section 1.1 Identification, 1.2 Composition),
- analytical data (IUCLID section 1.4 Analytical Information),
- information requirements (IUCLID section 14 Information requirements).

1.4. Checks performed by ECHA on the submitted dossiers

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

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

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

1.4.1. The Validation assistant

The *Validation assistant* (VA) 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.

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.

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.

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:


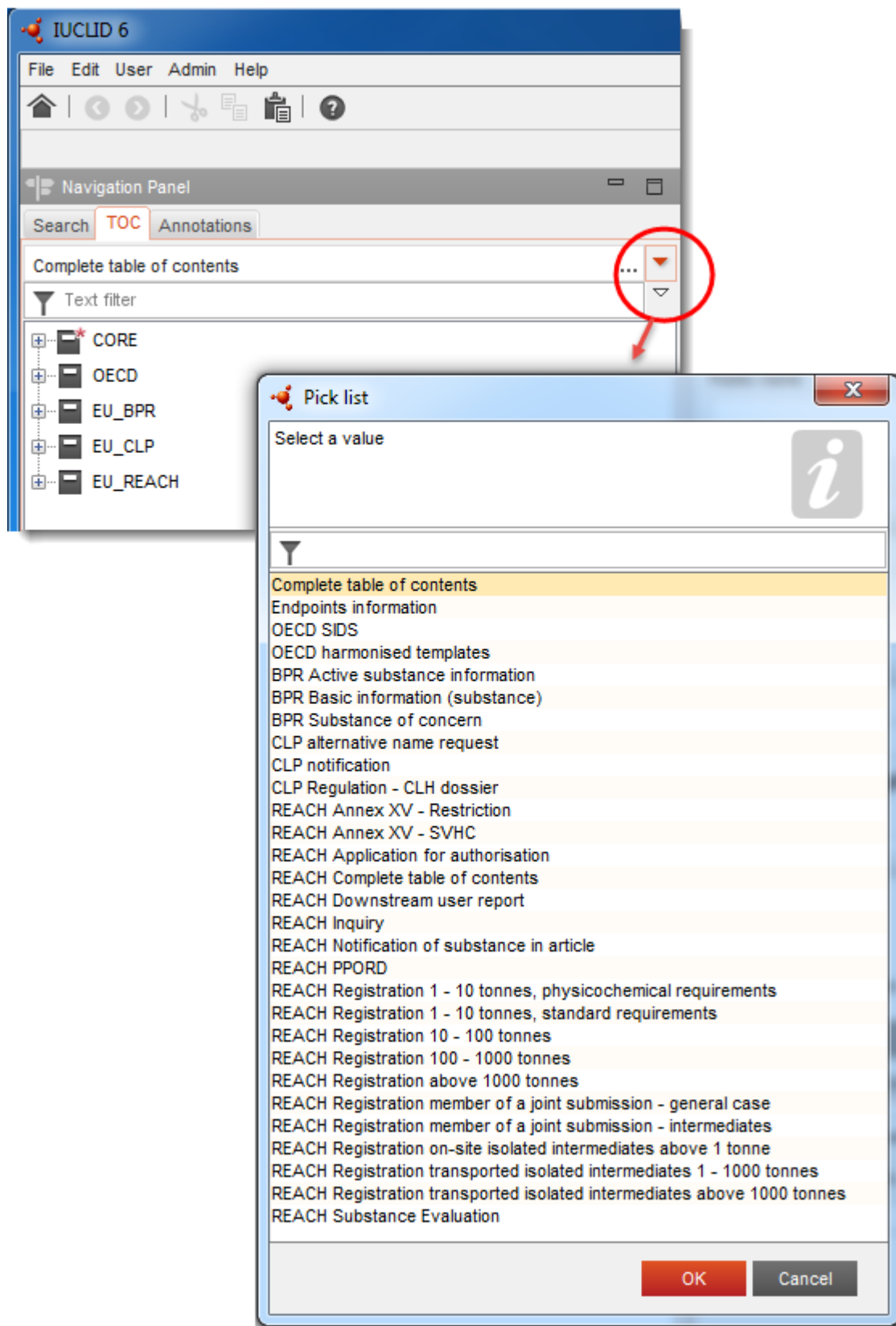

- Step 1.** Once your substance dataset is created it is displayed in the navigation panel on the left part of the screen.
- Step 2.** To open your dataset double-click or right-click and select *Open*.
- Step 3.** When the dataset is open the *Table of contents* (TOC) tab is displayed in the navigation 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 the substance identity.


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:**

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.

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.

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.

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:

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**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.


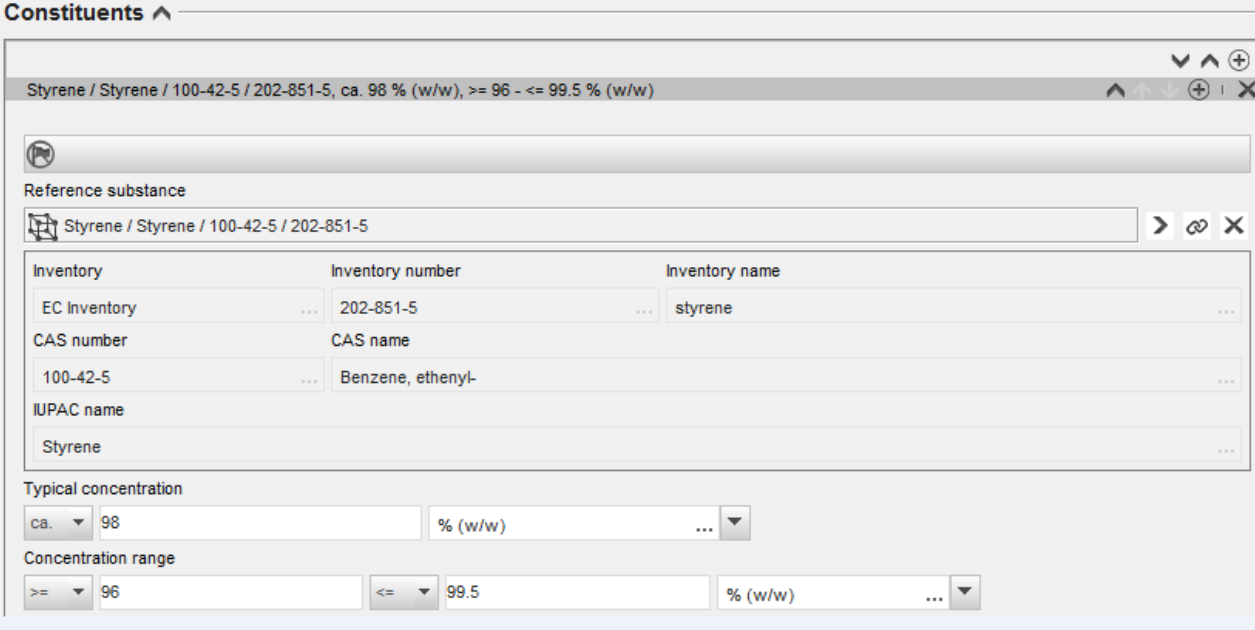
- Step 9.** Assign a *reference substance* to the newly created constituent by clicking the  button. Search for the appropriate reference substance and add it by selecting it and clicking *Assign*; alternatively, create a new reference substance to specify the constituent (see *Reference substance*). 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



Constituents ^

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	Inventory number	Inventory name
EC Inventory	202-851-5	styrene
CAS number	CAS name	
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

Impurities ^

Unknown impurities / Unknown impurities, ca. 0.05 % (w/w), >= 0.04 - <= 0.08 % (w/w)

Reference substance
Unknown impurities / Unknown impurities

Inventory	Inventory number	Inventory name
...

CAS number	CAS name
...	...

IUPAC name
Unknown impurities

Typical concentration
ca. 0.05 % (w/w)

Concentration range
>= 0.04 <= 0.08 % (w/w)

Remarks
3 unknown organic impurities for which the individual concentration does not exceed 0.03% according to the HPLC analysis (see section 1.4). Based on the fragmentation pattern in the HPLC-MS analysis (see also section 1.4), the structure of these impurities might include one chlorine and two bromine atoms

Figure 5: Additive

4-tert-butylbenzene-1,2-diol / 4-tert-butylbenzene-1,2-diol / 98-29-3 / 202-653-9, ca. 0.01 % (w/w), >= 0.005 - <= 0.02 % (w/w)

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

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 Other

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.

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.

- Do not report any constituent under the *Impurities* header of the composition (impurities are not considered relevant for UVCBs).
- 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 1.4 Analytical information

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

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

- Step 1.** Right-click on *1.4 Analytical information* 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 analytical information is created.

To complete this section, follow the steps:

Methods and results of analysis:

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

- Step 1.** Click on the *Add* button and then the pop-up window appears.
- Step 2.** Fill in the information on the analytical methods and results.

For each analytical determination: enter the purpose for which the analysis was carried out, select the *Analysis type* (e.g. spectral, chromatographic), *Type of information provided*, and any *Remark* you consider relevant. For each method, you should attach the file containing the

method and the result of the analysis. If you cannot provide results for the indicated analysis type, select the reason from the picklist *Rationale for no results* and fill in the explanation in the *Justification* field. Note that several analysis types can be reported for one determination.

You can choose to enter *identification* or *quantification* as purpose of an analysis. Both identification and quantification analyses are expected to be submitted to verify the composition of a substance.

Identification refers to any analysis carried out to establish the identity of the constituents, including their chemical functionalities, present in the composition of a substance. Examples of analyses used for identification are spectroscopic analyses such as UV, IR, NMR, MS or XRD.

Quantification refers to any analysis carried out to establish the concentration of the constituents in the composition. Examples of analyses used for quantification are chromatographic analyses, elemental analyses, titration.

Some analyses may be carried out both for identification and quantification purposes.

Figure 6: Analytical determination

Analytical information ^

Methods and results of analysis ^

Analytical determination

Purpose of analysis	Analysis type	Type of information ...	Attached methods/r...	Rationale for no res...	Justification	Remarks
quantification	chromatography – HPLC, chromatography –	methods and results	Analytical report_chromatographic analyses.pdf /			
identification	other: HPLC-MS, UV/Vis, NMR, IR	methods and results	Analytical report_spectroscopic analyses.pdf / 1.245			

+ Add... Edit... X Delete ↑ Move up ↓ Move down

Step 3. Indicate whether your substance is optically active by selecting the appropriate value from the picklist.

Step 4. Provide information on the optical activity, whenever applicable in the *Remarks* field.

Figure 7: Optical activity

Optical activity

yes ...

Remarks

The specific rotation has in this case been recorded on a diluted sample (c 2.0, CHCl₃)
Specific rotation: $[\alpha] = -30.0^\circ$ (20°C, 589 nm)

Related composition(s):


Step 5. You can link the reported analytical information to the relevant *Composition* from *section 1.2* by clicking the *Add* button. This is especially relevant when you have reported several compositions in *section 1.2*.

7.2. Section 3 Manufacture use and exposure

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

7.2.1. Section 3.3 Sites

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

To report the data 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. Section 14 Information requirements

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

Step 6. Create a *New record* by right click on *Inquiry*.

Step 7. Re-name the new record as "Request for Information" by right-clicking on it.

Step 8. Specify the *Type of inquiry* by selecting the appropriate option from the picklist.

There are four types of inquiry:

- *Type 1: Inquiry for non-phase-in substance*

This is an inquiry for a non-phase-in substance in accordance with Article 26 of the REACH Regulation for which none of the other inquiry types apply.

- *Type 2: Inquiry for non-phase-in substance legally on the market before June 2008*

This is an inquiry for a non-phase-in substance in accordance with Article 26 of the REACH Regulation where the substance was legally on the market before June 2008 (see 9 June 2008 ECHA press release ECHA/PR/08/12 available on the ECHA website at <http://echa.europa.eu/web/guest/news-and-events/news-alerts>).

If you select *Type 2*, you must provide the *Justification as to why such placing on the market was considered lawful*.

- *Type 3: Inquiry for phase-in substance that has not been pre-registered*

Inquiry for a phase-in substance (that was not pre-registered) in accordance with Article 26 of the REACH Regulation for which none of the other inquiry types apply.

If you have already successfully registered the substance you are inquiring about and you selected *Type 1*, *Type 2* or *Type 3*, your inquiry will not be accepted for processing.

- *Type 4: Inquiry for tonnage band increase*

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

Step 9. Indicate under *Information requirements* whether you have (or do not have) information requirements that would require new studies to be conducted by selecting the appropriate option from the picklist. If you select *no*, you do not have to fill any of the following sections. If you select *yes*, continue to step 5.

Step 10. For each relevant endpoint that you require new studies to be conducted, select *yes* from the pick list.

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

The list of endpoints that will be provided to you (if available) will follow the criteria described below:

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

* Information can thus not be requested


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

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 you can enter a *Remark* that can include further information on the reason for the submission (e.g. include here a previous inquiry submission number for the same substance, include any relevant communication number related to the submission, etc.)

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

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 plugin cannot simulate all the business rules checked by the Agency.

Business Rules applicable for Inquiry notifications		
Location (IUCLID/REACH-IT)	Rule description	Relevance
IUCLID substance dataset	A REACH dossier must be created from a substance dataset. It cannot be created out of a mixture or product dataset.	All dossier types
IUCLID substance dataset	Category cannot be used to create an inquiry notification.	Inquiry Notification
IUCLID section 1.1 – Identification	A reference substance must exist in section 1.1	All dossier types
IUCLID section 1.1 – Identification; section 1.2 – Composition	Each reference substance in section 1.1 and 1.2 must contain a substance identifier. An acceptable substance identifier is: EC/List number CAS number IUPAC name Any EC/List number defined in section 1.1 and 1.2 of IUCLID must exist in the REACH-IT EC inventory. If you use a reference substance to report unknown constituents/impurities, they must be “identified” by inserting “Unknown constituent/impurity” in the IUPAC name field. If categories are used, this rule is applied to all the category member substances.	All dossier types
IUCLID	The reference substance in section 1.1 has to have a chemical	Inquiry Notification

section 1.1 - Identification	name provided in the IUPAC name field.	
IUCLID section 1.1 - Identification	The reference substance must be marked as one of the following: Mono constituent substance Multi constituent substance UVCB	Inquiry Notification
IUCLID section 1.2 – Composition	At least one composition must be defined in section 1.2. The following requirements are also to be fulfilled: All created compositions must contain at least one constituent. All constituents must be linked to a reference substance.	All dossier types
IUCLID section 1.2 – Composition	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 section 1.2 – Composition	All constituents of a multi-constituent or of a UVCB substance must identify distinct reference substances, e.g. it is not allowed to have constituent 1 identified with IUPAC name "formaldehyde" and constituent 2 identified with the EC number 200-001-8 (the EC number of formaldehyde).	All dossier types
IUCLID section 1.2 - Composition	At least one value and a unit must be provided for the ‘Degree of purity’ for each ‘Legal entity composition of the substance’ in section 1.2 - Composition.	Inquiry Notification
IUCLID section 1.2 - Composition	The full ‘Concentration range’ (lower and upper value together with a unit) must be provided for each constituent, impurity and additive of a ‘Legal entity composition of the substance’ in IUCLID section 1.2 - Composition. When reporting a constituent, impurity or additive at exactly 0% or 100%, provide this value, together with the unit, in the field ‘Typical concentration’ and leave the ‘Concentration range’ fields empty.	Inquiry Notification

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

	related 'Remarks' field is to be given.	
IUCLID section 1.2 - Composition	<p>For each additive the molecular weight, molecular formula and structural formula of the reference substance must be provided.</p> <p>Also, the stabilising function must be confirmed by selecting a value starting with 'stabiliser' in the picklist 'Function'. Further details can be provided on the mechanism of stabilisation under 'Details on function'.</p>	Inquiry Notification
IUCLID section 1.2 - Composition	For a mono-constituent substance, the main constituent in IUCLID section 1.2 is expected to be present in the composition as a minimum at 80%. When the percentage deviates from this rule, a justification must be given in the 'Justification for deviations' field. Alternatively, a 'Typical concentration' can be provided, with a unit, demonstrating that the main constituent is typically present as a minimum at 80%.	Inquiry Notification
IUCLID section 1.2 - Composition	For a mono-constituent substance, each composition is expected to contain only one constituent. When deviating from this rule, a justification has to be provided in the 'Justification for deviations' field.	Inquiry Notification
IUCLID section 1.2 - Composition	For a mono-constituent substance, impurities in are expected to be present in the composition as a maximum at 20%. When the percentage deviates from this rule, a justification must be provided in the 'Justification for deviations' field. Alternatively, a 'Typical concentration' can be provided, with unit, demonstrating that the impurity is typically present as a maximum at 20%.	Inquiry Notification
IUCLID section 1.2 - Composition	For a multi-constituent substance, the main constituent in IUCLID section 1.2 is expected to be present in the composition as a maximum at 80%. When the percentage deviates from this rule, a justification must be provided in the 'Justification for deviations' field. Alternatively, a 'Typical concentration' can be provided, with a unit, demonstrating that each main constituent is typically present as a maximum at 80%.	Inquiry Notification
IUCLID section 1.2 - Composition	For a multi-constituent substance, impurities are expected to be present in the composition as a maximum at 10%. When the percentage deviates from this rule, a justification must be provided in the 'Justification for deviations' field. Alternatively, a 'Typical concentration' can be provided, with unit, demonstrating that the impurity is typically present as a maximum at 10%.	Inquiry Notification
IUCLID section 1.2 - Composition	For a multi-constituent substance, each composition is expected to contain more than one constituent. When deviating from this rule, a justification has to be provided in the 'Justification for deviations' field.	Inquiry Notification

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

	identification approach and one quantification approach, as indicated in the 'Purpose of analysis' field.	
IUCLID section 14 - Inquiry	Provide the information requirements relevant to the inquiry in IUCLID section 14. Note that only one section 14 record is allowed.	Inquiry Notification
IUCLID section 14 - Inquiry	Make a selection in the field 'Information requirements requiring new studies to be conducted?' in section 14. If you answer 'Yes', you must mark at least one study as 'Yes' under 'New studies to be conducted'. If you answer 'No', you must not mark any study under 'New studies to be conducted'.	Inquiry Notification
IUCLID section 14 - Inquiry	The type of the inquiry notification in section 14 has to match with the submission context. If the substance is not yet registered by the submitting legal entity, only types 1, 2 & 3 are allowed. Following a successful registration, only type 4 inquiry can be submitted.	Inquiry Notification
IUCLID section 14 - Inquiry	If you wish to update your dossier due to a tonnage band increase (type 4 inquiry), you shall only inform ECHA of the additional information you need for the prospective tonnage band.	Inquiry Notification
IUCLID section 14 - Inquiry	When preparing an inquiry notification, it is mandatory to indicate the inquiry type in section 14. If type 2 is selected, then a justification must be provided under 'Information relevant to inquiry type 2 only'.	Inquiry Notification
IUCLID dossier template	The dossier template used in IUCLID must correspond with the intended submission type in REACH-IT.	All dossier types
IUCLID dossier header	Updates can be submitted in the following cases: Following the successful registration / notification of this particular substance, after having received a reference number (spontaneous update). Following a technical completeness check (TCC) failure (requested update). Following a request for further information by the Agency (spontaneous or requested update as specified in the request). In any other case, an initial submission is required.	All dossier types - Updates
REACH-IT	A new dossier cannot be submitted when the previous submission for the same substance is still being processed.	All dossier types - Updates
REACH-IT	No submissions can be made from the account of a legal entity, which at the time of submission undergoes the legal entity change (merge) process. Legal entity change functionality is available in REACH-IT.	All dossier types

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

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