# How to prepare a substance in articles notification

April 2024

# Changes to this document

| Version | Changes |
|---------|---------|
| 12.0 | April 2024<br><br>Chapter 6.2.1: New CLP hazard classes and information on the new field 'Reason for classification' added. |
| 11.0 | October 2023:<br><br>Information regarding specific exemptions added to section 1.1.<br><br>Editorial corrections in the text. |
| 10.0 | April 2023:<br><br>Update to reflect the new functionalities of the IUCLID 6.6.<br><br>Deletion of chapter 6 and changes introduced in chapters 5 and 7 due to the discontinuation of publication of IUCLID datasets in the Candidate List of substances of very high concern for Authorisation. The chapters 7 and followings were renumbered. |
| 9.0 | October 2022:<br><br>Update to reflect the new functionalities of the IUCLID 6.6. |
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| 4.0 | October 2019:<br><br>Update to reflect transition from IUCLID 6.3 to IUCLID 6.4, and from the classic user interface to the web user interface. |
| 3.0 | October 2018:<br><br>Changes in Annex I (business rules). Role in the supply chain is mandatory information. |
| 2.0 | January 2017:<br><br>Links added to translated versions of this document. |
| 1.0 | First version |

**Disclaimer**

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

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

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# 1.  Introduction

## 1.1.  Objective

The purpose of this manual is to assist forthcoming notifiers in the preparation of a IUCLID Substance in Articles (SiA) notification dossier under the REACH Regulation (EC) No 1907/2006. More precisely, it outlines the IUCLID sections and fields to be further filled-in after downloading the *Reference substance* from the website of the European Chemicals Agency (ECHA) and creating a dataset, in order to prepare a complete SiA notification dossier according to Article 7(2) of the REACH Regulation and submit it successfully.

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This manual assumes that IUCLID has been installed, that you are using the web user interface and that you have a valid ECHA account.

More information about the different functionalities in IUCLID and how to use those functionalities can be found in the help system of IUCLID (see chapter *Functionalities of IUCLID*).

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In principle, producers and importers of articles are required to prepare a SiA notification when all conditions of Article 7(2) of REACH are met:

- The substance is included in the Candidate List of Substances of Very High Concern (SVHC) for authorisation (hereafter referred to as Candidate List);
- The substance is present in articles produced and/or imported above a concentration of 0.1% w/w;
- The total amount of the substance present in all articles produced and/or imported, which contain more than 0.1% w/w of the substance exceeds 1 tonne per producer and/or importer per year.

Two specific exemptions can apply to the notification of substance in articles:

- exemption based on exclusion of exposure [REACH Article 7(3)] and
- exemption for substances already registered for that use [REACH Article 7(6)].

A Substance in Articles notification shall be made no later than 6 months after the substance has been included in the Candidate List. This obligation has been applicable since 1 June 2011 for substances included in the Candidate List before 1 December 2010.

Once a notification has been submitted, notifiers are strongly encouraged to keep their notification up-to-date. The notification can be updated in case the notified information changes (see chapter *Update dossier*).

One notification should concern one substance on the Candidate List. If articles you import or produce contain more than one of the substances on the Candidate List, you need to submit a separate notification for each substance. If several articles contain the same substance, you need to include them all in one notification.

For more information on Substance in Article (SiA) notifications (Article 7(2) of REACH), please consult the dedicated ECHA webpage at http://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles

and the *Guidance on requirements for substances in articles* at: http://echa.europa.eu/guidance-documents/guidance-on-reach

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

A SiA notification IUCLID dossier is a non-editable snapshot file of the substance dataset for the Candidate List substance contained in your article. It contains the information to be submitted to ECHA.

The steps below indicate the approach for the preparation of a IUCLID dossier for your SiA notification:

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

**Step 2.** Download the Reference substance from ECHA's website (see chapter *Reference substance*).

**Step 3.** Import the Reference substance into IUCLID (see chapter *Reference substance*).

**Step 4.** Create a substance dataset in IUCLID (see chapter *How to create a substance datase*).

**Step 5.** Create a REACH notification of Substance in Article dossier in IUCLID (see *How to create a Dossier*).

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

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

## 1.3.    Information requested for a Substance in Article notification

The information to be included in the notification is described in the REACH Regulation (Article 7(4)). The requested information comprises the following (the corresponding IUCLID section is indicated in brackets):

- identity of the notifier (i.e. the producer or importer of articles), i.e. name and contact details (REACH-IT account and IUCLID section 1.1);
- identity of the notifier and role in the supply chain (IUCLID section 1.1);
- identification of the substance (IUCLID sections 1.1 and 1.2);
- the registration number of the Candidate List substance, if available (IUCLID section 1.3);
- classification of the Candidate List substance according to the CLP criteria (IUCLID section 2.1);
- the production site of the notifier, to be filled-in only by producers of articles, not by importers of articles (IUCLID section 3.3);
- a brief description of the use(s) of the substance(s) in the article [technical function(s)] and of the uses of the article(s) (IUCLID section 3.5);

- the tonnage band of the substance contained in the article(s), i.e. 1-10 tonnes, 10-100 tonnes, 100-1000 tonnes or ≥1000 tonnes (IUCLID dossier header).

Chapter 6. *How to create a dataset* describes in detail how you can create and complete a Substance in Article notification in order to fulfil your obligations under Article 7(2) of the REACH Regulation.


## 1.4.    Checks performed by ECHA on the submitted dossiers

All dossiers submitted to ECHA undergo initial technical and administrative checks. Such checks are called business rules (BR).

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

For more information on the business rules check refer to the Annex 1: *Overview of the business rules checks performed by ECHA on the submitted dossiers*.


### 1.4.1.    The Validation assistant

The *Validation assistant* (VA) has been developed to enable you to perform some checks on the dossier before you submit it to ECHA via REACH-IT.

Therefore, before the submission, we strongly advise you to use the *Validation assistant* in two steps:

  i.  To check your substance dataset (before the IUCLID dossier is created) to be able to correct any failures reported at this level.

  ii.  To check the final IUCLID dossier and address any issues identified in this step.


Using the *Validation assistant* in both steps is vital for you to minimise any unnecessary failures and potential rejection of your submission.

For instructions on how to run the *Validation assistant*, refer to the help system of IUCLID.

## 1.5. The main features of the IUCLID web user interface

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

Please note that the features introduced here below are not an exhaustive representation of the IUCLID web user interface. Only the most used features of the web interface for preparing dossiers for submissions to ECHA are covered. For an overview of all the features included in the IUCLID web user interface please refer to the help system of IUCLID that can be accessed from anywhere in the application by clicking the round question mark icon ❓ displayed in the top-left corner of the screen (see chapter *The functionalities of IUCLID*).

### 1.5.1. The Dashboard

The *Dashboard* is the page shown upon starting IUCLID with the web interface.

**Figure 1: The Dashboard and its icons**
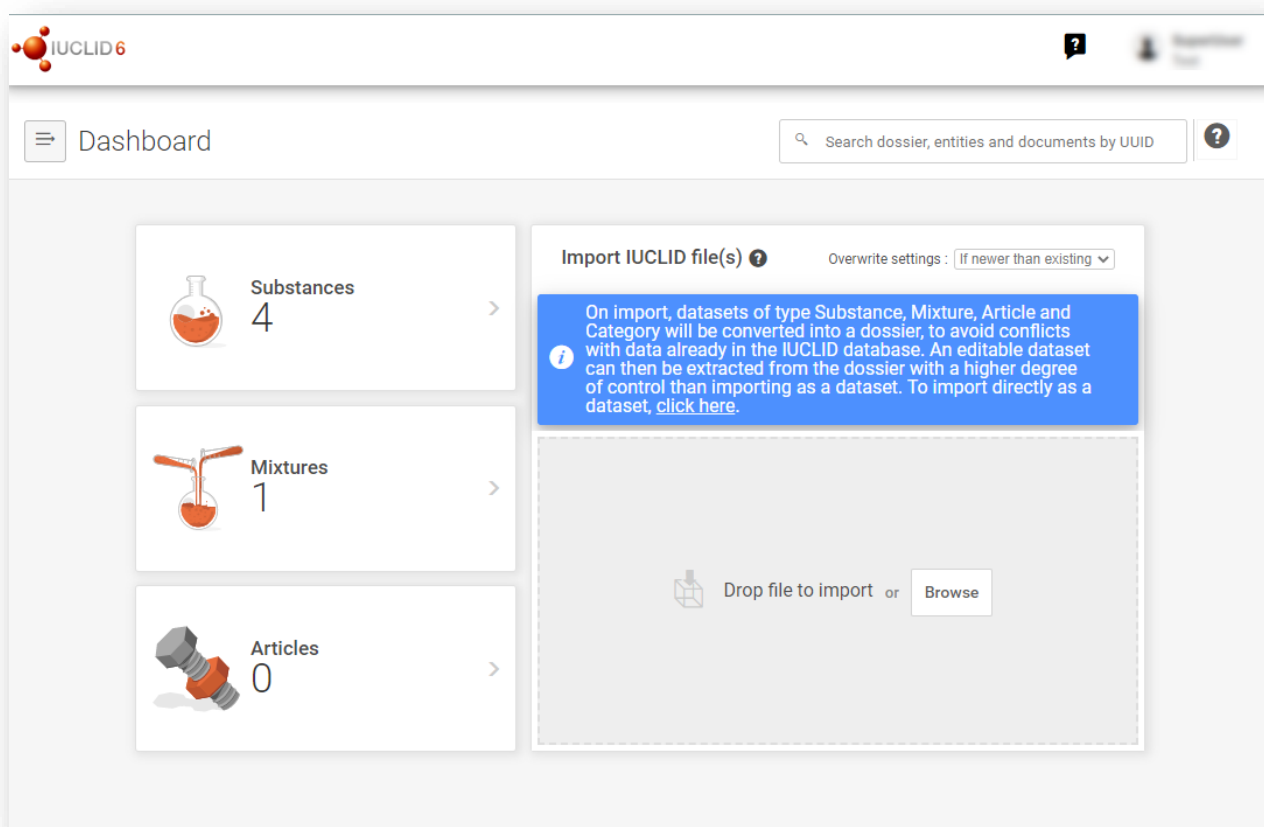


The squared question mark icon allows you to easily access to a list of supporting material for IUCLID such as manuals, Q&As and video tutorials.

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

The three dashes icon is the link to the Main menu, which contains direct links to list of entities and to functionalities that do not necessarily need the context provided by the data window.

**Figure 2: View of the main menu**
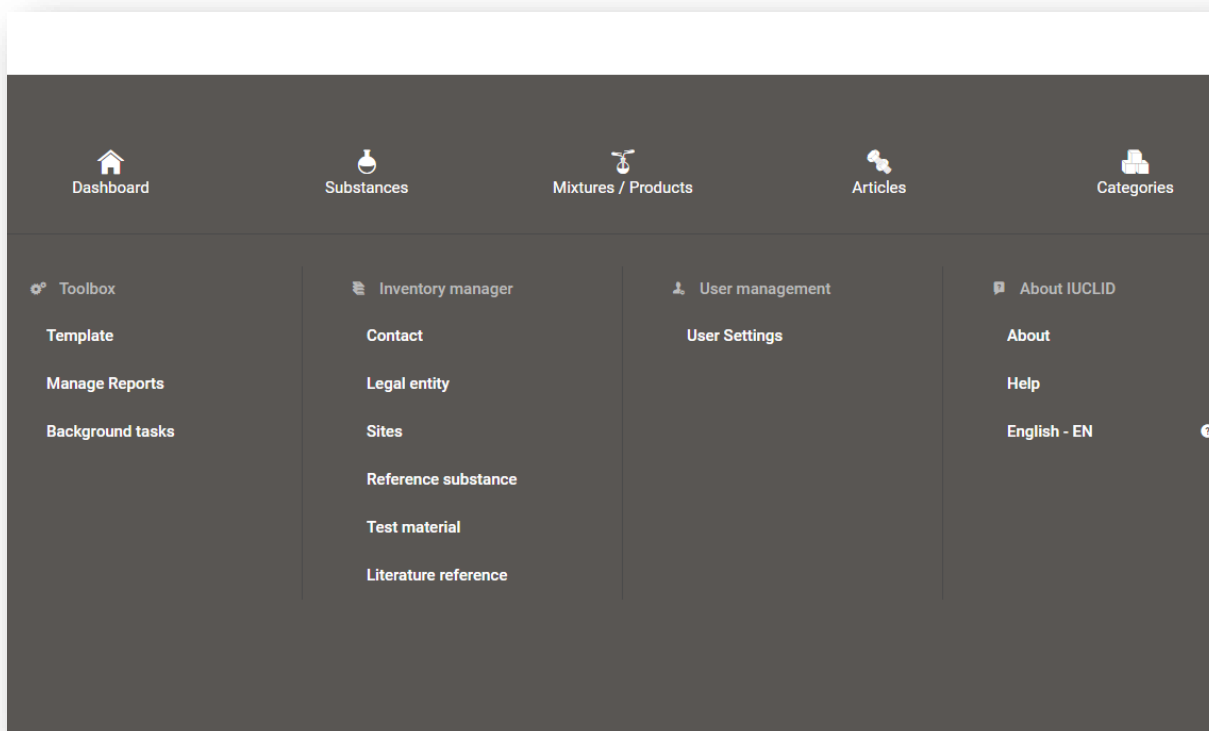


The widgets for *Substance*, *Mixtures* and *Articles* lead to lists of existing substances, mixtures and articles and the option to create new ones. The windows for *Substances*, *Mixture* and *Articles* that open by clicking on the widgets can each display either datasets or dossiers based on these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

## 1.5.2.    The Substances list page

**Figure 3:  The Substances list page**
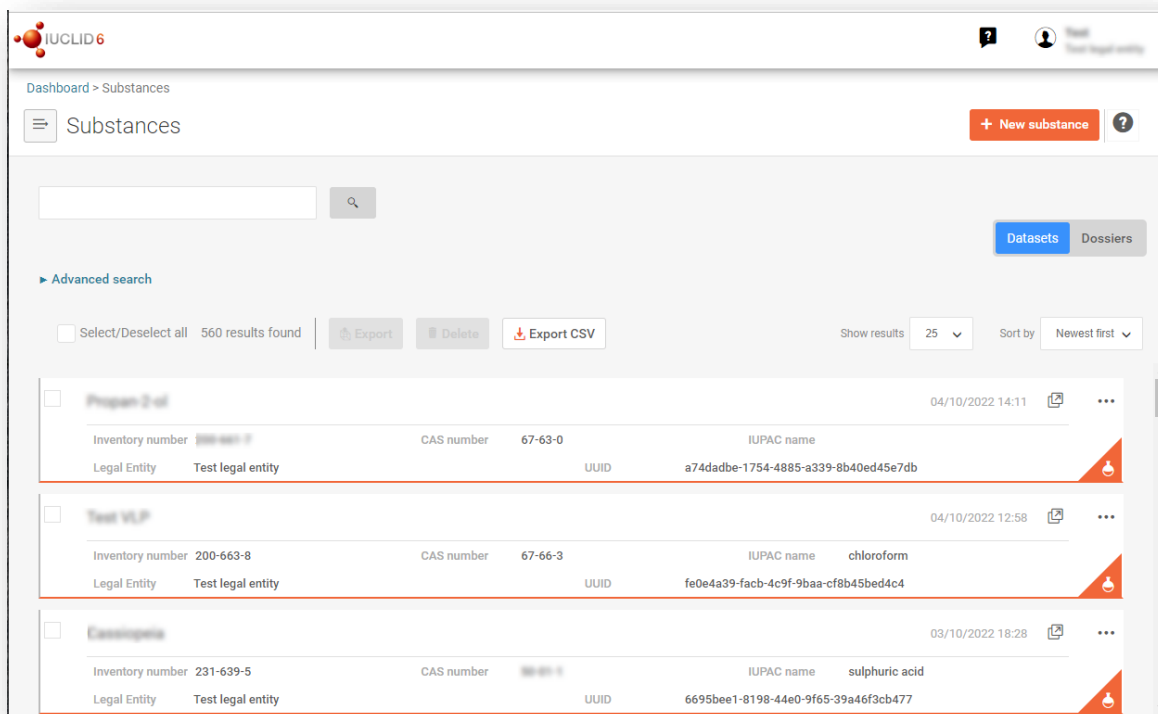


 This button displayed in the *Substances, Mixtures* and *Articles* list pages allows switching between the display of datasets and dossiers.

 This button allows you to export the full list of results in the substances list page as a CSV file.

 In the *Substances* and *Mixtures* and *Articles* list pages, the orange icon with a bottle indicates datasets. The datasets represent the editable data related to a particular substance, mixture or article from which a dossier can be created.

 The purple icon with a lock instead indicates dossiers. Dossiers represent the data related to a particular substance, mixture or article at a snapshot in time. Dossiers cannot be edited and are the format in which the data is submitted to ECHA.

 The button labelled with three dots allows sharing, deleting and cloning an entity (substance, mixture or article) from the list. Please note that another button labelled with three dots is also displayed in the top of each *Dataset page*. For the functionalities included in the three dotted button of the *Dataset page* please see the following subchapter.

☑ test 2          By selecting the checkbox next to the datasets you will be able to export or delete the selected dataset. More than one dataset can be selected in one instance.

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

### 1.5.3.    The Dataset page

**Figure 4: The Dataset page of a Substance dataset with the working context (submission type) "REACH Registration above 1000 tonnes"**
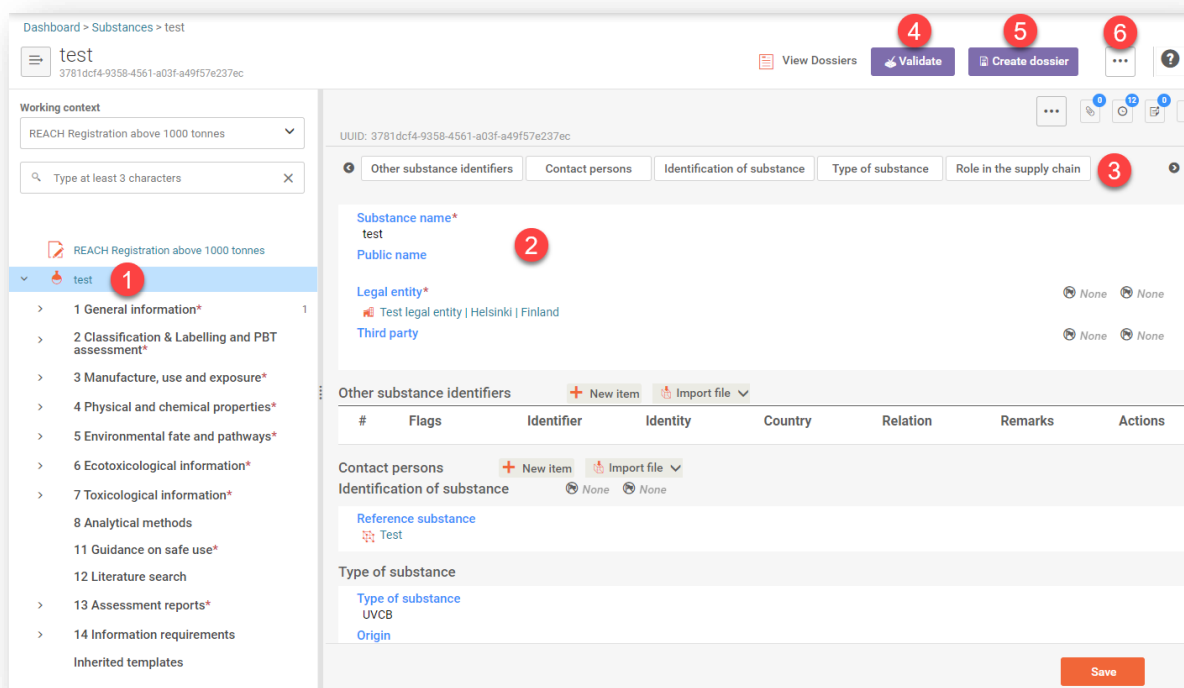


Depending on the *working context* (submission type) selected, IUCLID automatically displays the table of contents containing all sections that are relevant. The table of content is displayed as a navigation panel on the left hand side of the screen (1).

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

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

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

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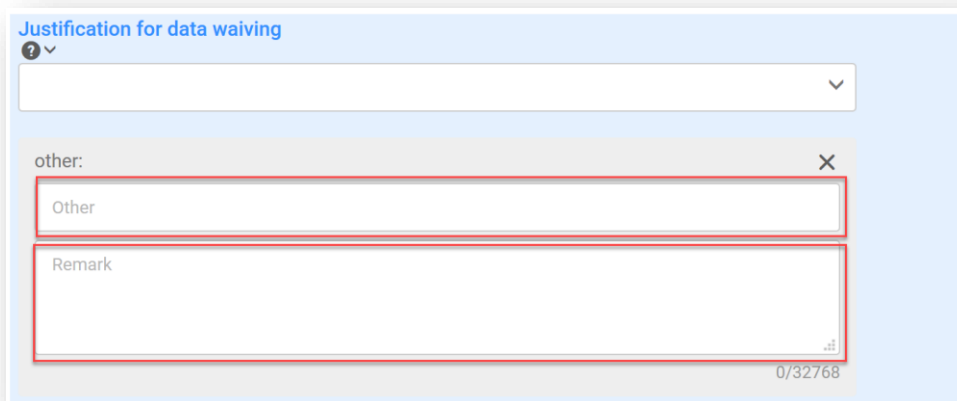


In certain free-text fields it is possible to insert a template containing suggestions on the information required for the field. To open the free-text template, click on the icon that shows the letter A with an arrow at the bottom right, displayed above the selected field
.

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

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

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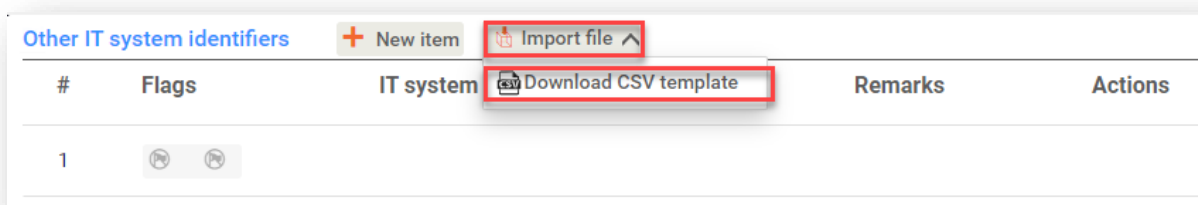


![Validate] The Validation assistant on a dataset is run by clicking on the button labelled *Validate* (4), which is shown at the upper right of the substance dataset page. The validation assistant can be run also on a dossier by clicking the *Validate* button on the dossier page.
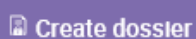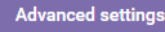
**Create dossier**     Dossier creation is started by clicking on the button *Create dossier* (5).

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

### 1.5.4.     The Dossier header

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

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

### 1.5.5.     Confidentiality flags

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

No flag is set;

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

A flag is set that involves confidentiality*.*

## 1.6.     The functionalities of IUCLID

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

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

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

**Figure 7: Field specific help**
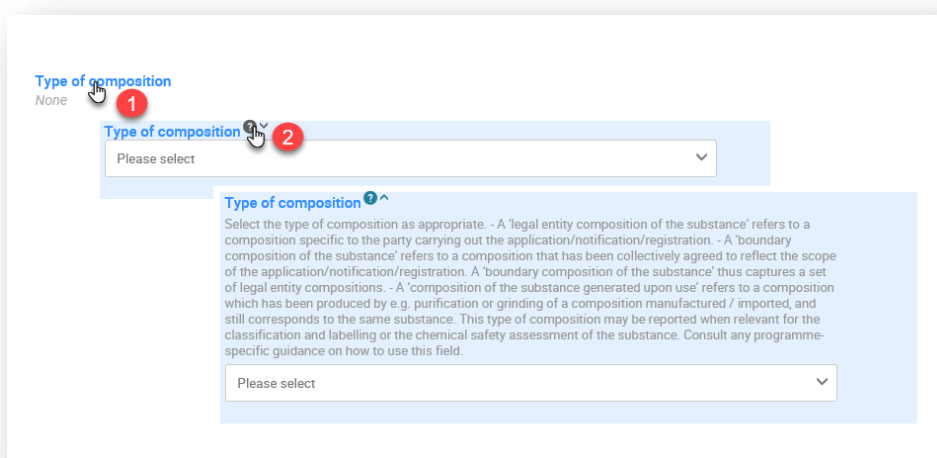


## 2. Legal entity

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

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

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

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

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

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

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

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

# 3. Legal entity sites (Sites)

Only producers of articles which produce their articles in the European Union will have to enter their production sites. Article importers do not need to fill in this information. A *Legal entity site* is an entry where you, as a producer of articles can indicate the site where production of your article 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.

The creation and editing of a site is done either:

1. from the list page of *Sites* which can be accessed from the main Menu;

2. from the point where the *Site* is referred to in a dataset.

## 3.1.    Creating a Legal entity site

**Step 1.**   To create a new site from the point where the *Site* is referred to in a dataset click on *Select* in the *Site* field (1).

**Step 2.**   In the pop-up window click on *Create* (2). The link will take you to the *Sites* inventory.

**Step 3.**   Fill as many fields as possible under *General information* and *Contact address.* The minimum data required is the *Country* where the site is located (3).

**Step 4.**    click *Save* (4).

**Figure 8: Create a new Legal entity site (1)**
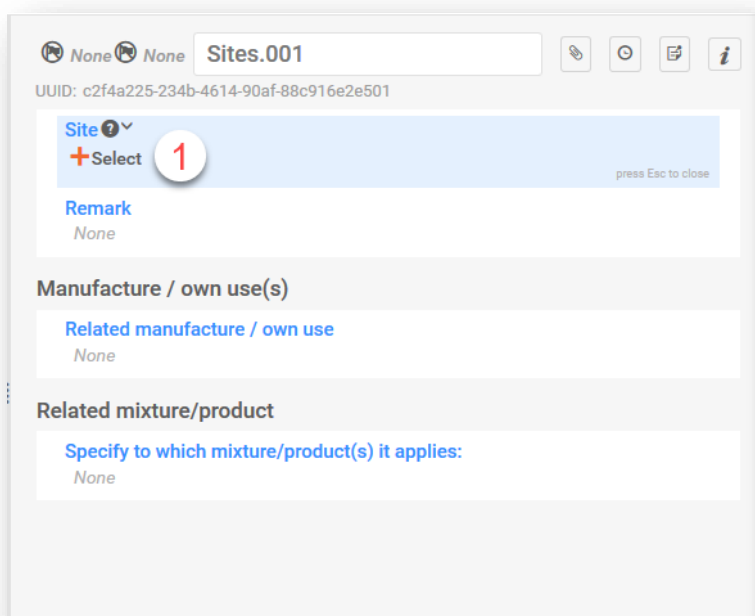
**Figure 9: Create a new Legal entity site (2)**
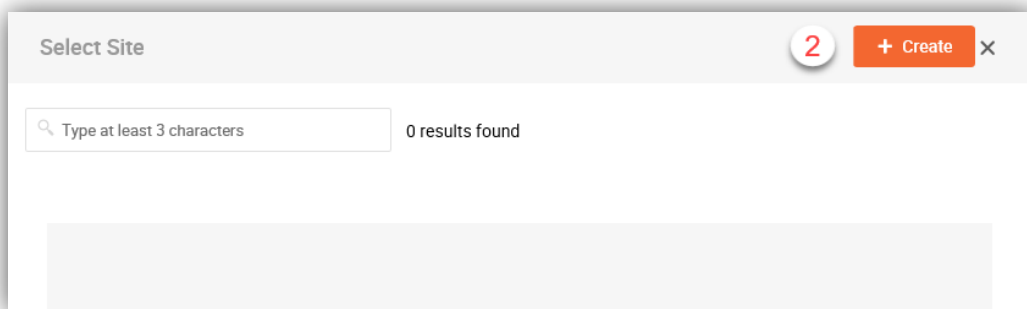


**Figure 10: Create a new Legal entity Site (3)**
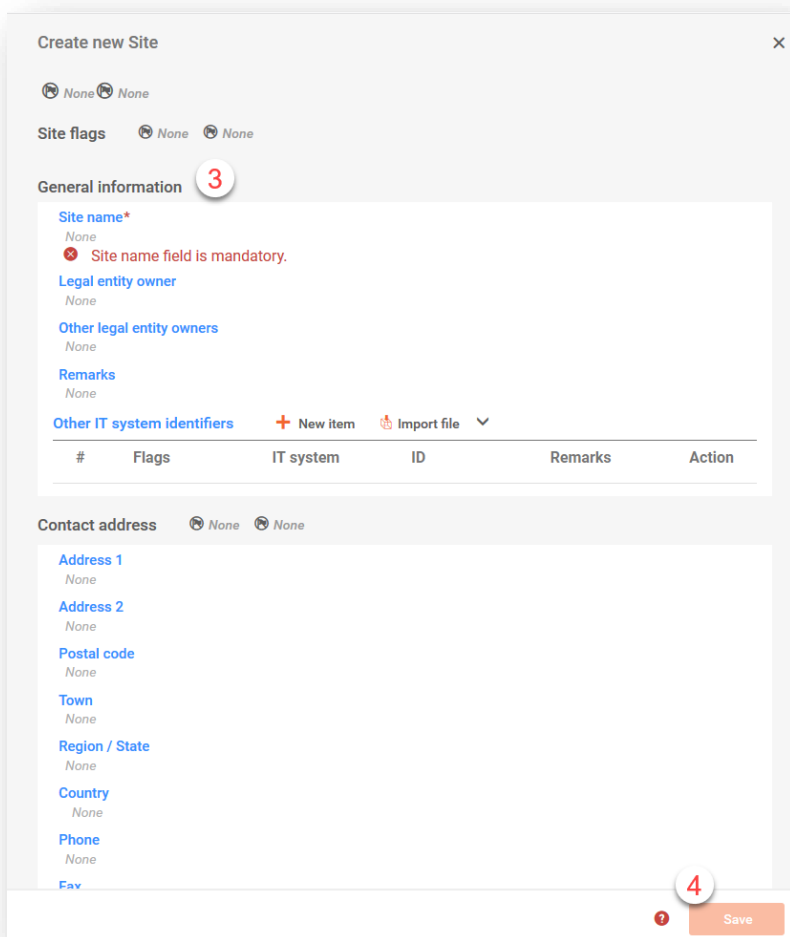
# 4. Contact

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

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

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

1. from the list page of *Contacts* which can be accessed from the main Menu;

2. from the place where the *Contact* is referred to in a dataset. Typically, a link can be made to more than one *Contact* from the same place. To create a new contact from the place where the *Contact* is referred to in a dataset, click on *Select* within the link as shown below. The link will take you to the *Contacts* inventory.
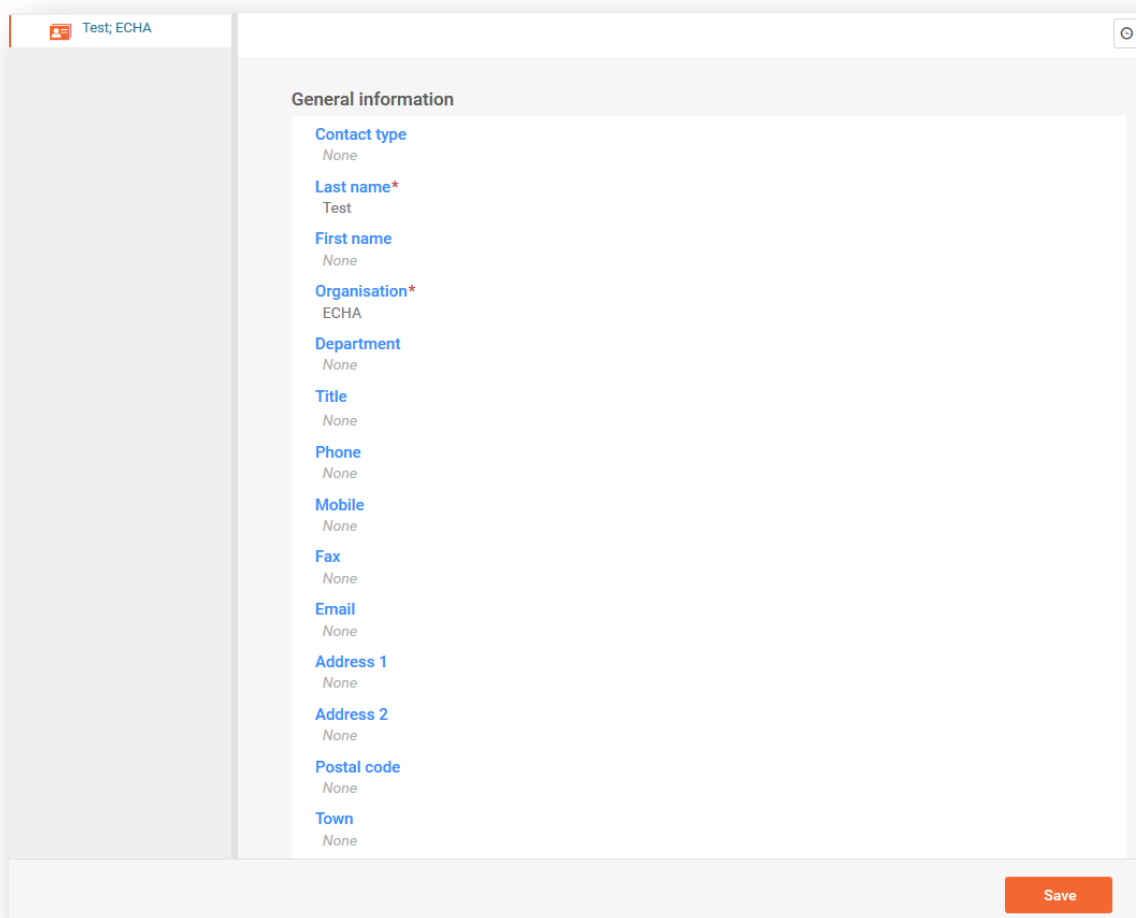
**Figure 11:  Link to Contact inventory from within the dataset**
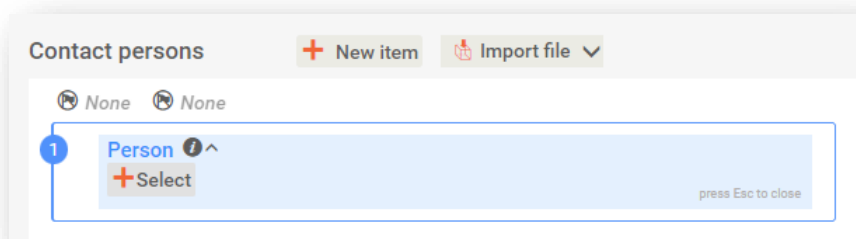


## 4.1. Creating a contact

To create a new contact:

**Step 1.**  Click on *New contact / Create*.

**Step 2.**  Provide the '*Last name*' and the '*Organisation*' (Fields marked with the red asterisk are mandatory) and complete as many fields as possible under *General Information*.

**Step 3.**  Click *Save*.

**Figure 12: Create a new Contact**



## 5. Reference substance

A Substance in Article notification dossier is prepared for a substance, as defined under Article 3(1) of the REACH Regulation, which is included in the Candidate List of substances of very high concern for Authorisation (Candidate List substance). The information related to the Candidate List substance you want to notify, such as the identity of the substance and its composition (*Reference substance*), is available to download on ECHA's website.

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.

ECHA publishes the *Candidate List reference substances package* to support notifiers of a Substance in Articles (SiA) notification.

Please proceed as follows to download a *Reference substance* for the Candidate List substance you want to notify:

**Step 1.**   Go to the "Candidate List Package" in the SCIP webpage (under Tools to prepare and submit notifications > Candidate List Package) on ECHA's website at http://echa.europa.eu/candidate-list-package

**Step 2.**   Under the content of the Candidate List package, click over the compilation (ZIP) file for "individual reference substance datasets" or the compilation (ZIP) file for the "delta package reference substance datasets" depending of the Candidate List substance you want to notify. The "individual reference substance datasets package" contains all Candidate List substances datasets (.i6z), while the "delta package" contains only new or updated reference substances datasets from one version to another. The *Reference substances* (.i6z files) can be imported individually or together into IUCLID (see chapter 6).

**Step 3.**   Download and save the selected compilation (.zip) file to your computer. Extract the *Reference substances* (.i6z files) to a selected folder on your computer.

After downloading and saving to your computer the compilation (.zip) file and extracting the contained *Reference substances* (.i6z files), you need to import the *Reference substance* for the Candidate List substance you are going to notify into IUCLID to create your Substance in Articles notification dossier. To identify the *Reference substance* (.i6z file) for the Candidate List substance you are going to notify, you may wish to consult the "List of reference substances" (XLSX file) on the webpage given under Step 1. You can identify the reference substance (.i6z file) through the CAS number, EC number or ECHA Substance ID if no CAS and EC numbers are available for the substance.

The steps below show how to import the downloaded *Reference substance* (.i6z file) for the Candidate List substance you want to notify to IUCLID:

**Step 4.**   On the IUCLID Dashboard, click on *Browse* in the *Import IUCLID file(s)* box.

**Step 5.**   Select the relevant *Reference substance* (.i6z) file from the folder to which you have extracted the *Reference substances* (.i6z) files during the download process in your hard drive (Step 3). Then, click on the *Open* button. Alternatively, you can also drag and drop the (.i6z) file in the *Import IUCLID file(s)* box.

Alternatively, you may wish to import all the extracted *Reference substances* (.i6z) files from the folder to which you have extracted them, by selecting all of them after clicking on *Browse* (step 1), or by draging and dropping all the (.i6z) files in the *Import IUCLID file(s)* box.

**Step 6.**   When the import is complete a ✅ symbol appears in the *Import IUCLID file(s)* box, next to the name(s) of the file(s).

> For more information on Import function refer to the help system of IUCLID.

The *Reference substances* made available for Candidate List substances on ECHA's website are provided as a support for companies preparing notifications for Substances in Articles. The notifying company remains, however, solely responsible for the appropriateness and correctness of the information submitted in the notification.

A *Substance dataset* is a repository of administrative and scientific data for a substance. The information in the *Substance dataset* can be modified: you can add, remove or change information in the dataset. You can find more detailed information on reference substance and on how to manage a substance dataset in the Manual *How to prepare registration and PPORD dossiers* available at http://echa.europa.eu/manuals.

# 6.  How to create a substance dataset

This chapter outlines which information you must provide through the different sections of IUCLID to prepare a Substance in Articles notification dossier.

When entering your data you can use the help system of IUCLID that can be opened by clicking on the round question mark icon 🔘 on the top-right corner of the screen.

For further support and to read specific help text that explains how each field should be used, click on a question mark icon to the right to the field header. Please note that the question mark icon will appear only after clicking on the selected field.

**Figure 13: How to get further support on the use of fields**
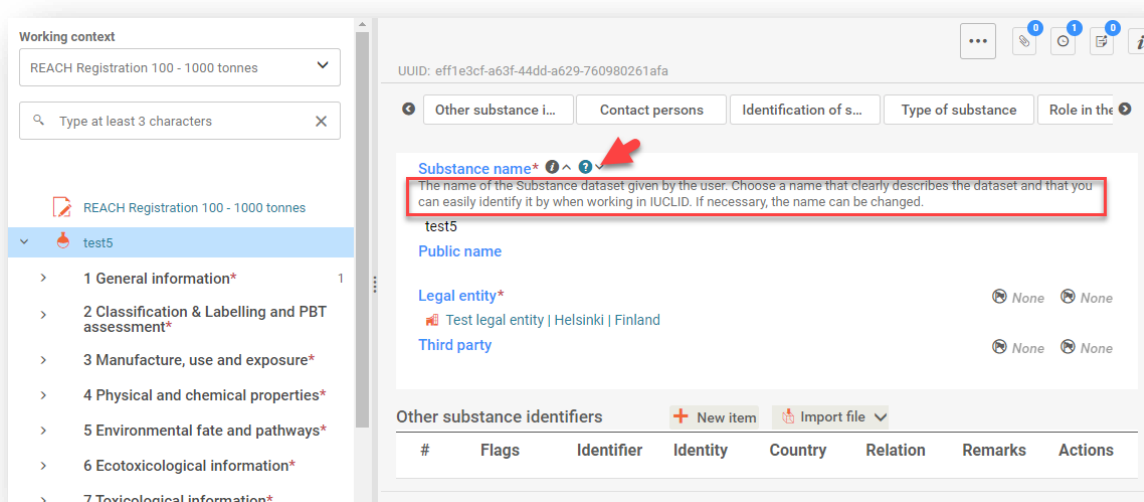


To create a IUCLID **dossier**, you first need to create a substance **dataset**. A substance dataset is a repository of administrative and scientific data for a substance. The information in the dataset can be modified: you can add, remove or change information in the dataset. **The dataset is used as basis for the dossier.** The dossier is a snapshot of the dataset at a certain moment; the information in the dossier cannot be modified.

**To create a dataset:**

**Step 1.**  Click on the button entitled *Substances* in the IUCLID Dashboard and then click *New substance* in the top right-hand corner of the screen. A *New substance* pop up window will appear.

**Step 2.**  Since you have imported the *Reference substance(s)* into IUCLID (see steps 4 to 6 in chapter 5), under 'Reference substance', please click on *select* button ➕ Select . Find your substance in the list of substances displayed in the 'Select Reference substance' window.

**Step 3.** Click on it. The selected substance appears under the 'Reference substance' field, and the name of the substance appears automatically in the 'Name' field. If you have selected the wrong substance from the list of substances, click on the ✕ button in 'Reference substance' field and delete the name of the substance in the 'Name' field.

**Step 4.** Click *Create*.

**Step 5.** Once you receive the message that the substance has been successfully created, click *Open*.

**Step 6.** After opening the Substance dataset, to view the Table of contents (TOC) that is relevant for the SiA notification dossier, click on the *Working context* field in the top of the left hand column of the page; Then click *New working context.*

**Step 7.** Select the *REACH Notification of substance in article* option from the picklist of different submission types and then click *Apply*;

**Figure 14:  Selecting the REACH Notification of substance in article template from the picklist**
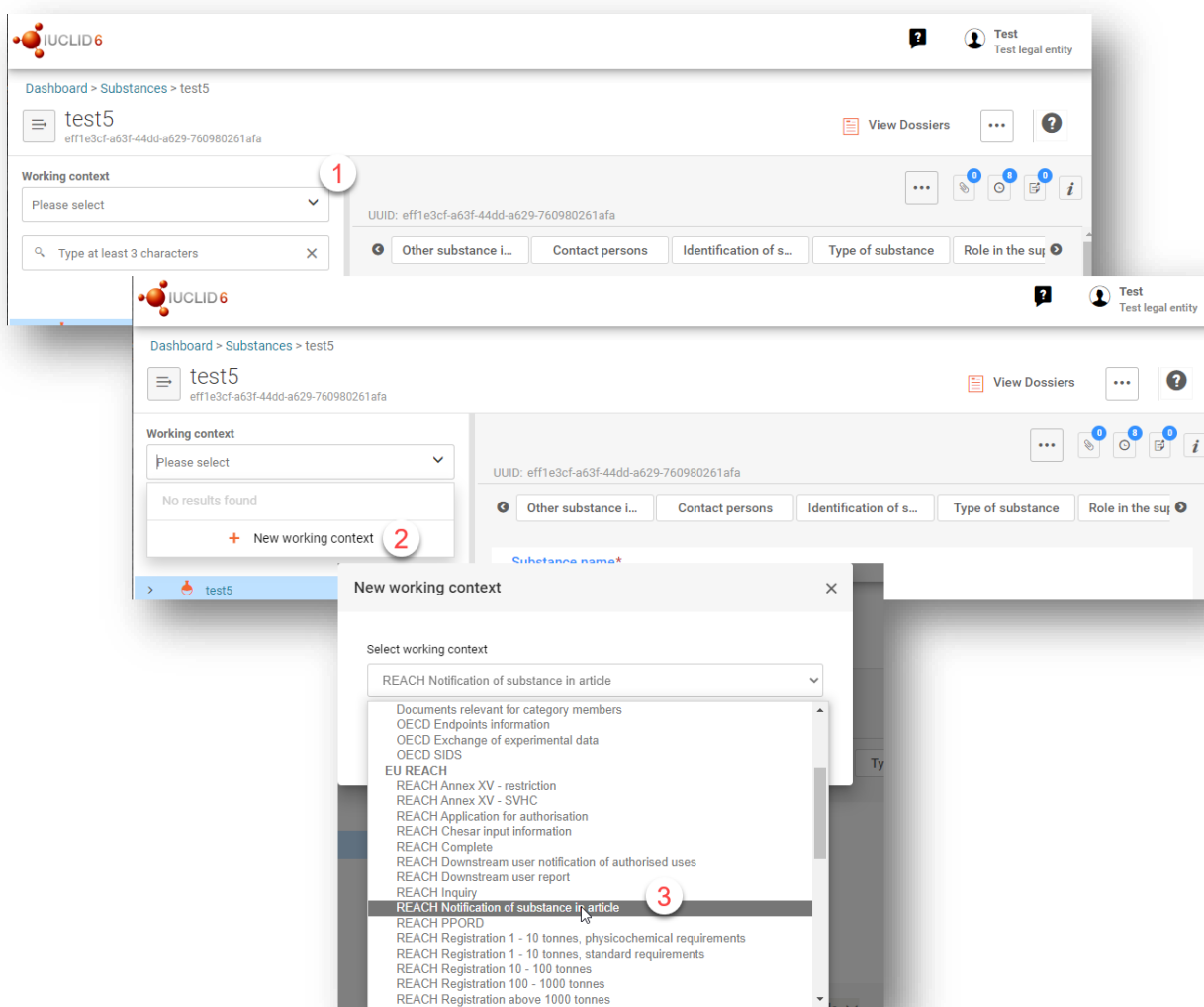
**Step 8.** The sections relevant for a SiA notification dossier are displayed in the navigation panel on the left column of the screen by clicking on the > icon. Then, click on *Save*.

**Step 9.** Complete the Substance dataset by checking and entering the required information for a SiA notification in this dataset, into each section of IUCLID, as described in detail in the next sections of this chapter. The sections are shown with their name and the numbering used in IUCLID.

---

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

---

## 6.1.     Section 1 General information

In section 1, *General information*, of IUCLID specify the information on substance identification and the identity of the notifier, as required under Article 7(4) of the REACH Regulation, as explained below.

### 6.1.1.     Section 1.1 Identification

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

To complete this section, follow the steps:

**Step 1.** By default, the name of the Candidate List substance for which you are preparing the SiA notification dossier should appear automatically in the *Substance name* field (see step 3 in chapter 7). If not, please type the name of the Candidate List substance as it appears in the Candidate List of substances of very high concern for Authorisation (https://echa.europa.eu/candidate-list-table).

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

---

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

---

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

---

You can NOT appoint a *Third party representative* for a notification of substances in articles.

---

**Role in the supply chain:**

**Step 4.** Select the checkbox *Manufacturer* (for producer of articles), *Importer* (of articles) or *Only representative* in this section according to your role in the supply chain. If you

are both a producer and an importer of articles containing the same Candidate List substance then tick both boxes: *Manufacturer* and *Importer*.

**Identification of substance:**

**Step 5.** By default, the *Identification of substance* section is automatically filled with your selected *Reference substance.* If needed, by clicking *Select* in the *Identification of substance* section you can identify your *Reference substance*.

---

Information on substance identification is pre-filled in the imported *Reference substance* that you downloaded. The information given is sufficient to identify the substance and there is no need to provide any further information. The field *Reference substance* is filled with the name of the reference substance and the EC Number/EC name and/or CAS number/CAS name and/or the IUPAC name. In addition to these minimum requirements, you have the possibility to also provide all the information specified in section 2.1 to 2.3.4 of Annex VI to the REACH Regulation as mentioned in REACH Article 7(4)c.

Please make sure you agree with the pre-filled information, if not, please add or change that information. You can find more detailed information on reference substance and on how to manage a substance dataset in the Manual *How to prepare registration and PPORD dossiers* available at http://echa.europa.eu/manuals.

---

An update of a notification successfully submitted (i.e. the notification has received a reference number) must always specify an EC number in the *Reference substance* section of IUCLID section 1.1. Please use the EC number or provisional EC number granted to your previous successful notification submission for this substance.

**Type of substance:**

**Step 6.** Under the section *Type of Substance* select the appropriate *Type of substance* from the picklist. For SiA notifications under REACH, you can only select between mono-constituent substance, multi-constituent substance and UVCB (the options polymer, microorganism and other: are not relevant).

---

If you need clarifications about the type of your substance, further information on the type of the substances of very high concern included in the Candidate List is available in the respective "Support document", included under details (eye icon:  ), for each entry of the Candidate List of substances of very high concern for Authorisation available at https://echa.europa.eu/candidate-list-table.

---

Relevant substance types:

**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.

**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.[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.

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

**Contact person:**

**Step 7.** You can add information of the contact person(s) for that specific substance in the *Contact persons* field from the previously defined contacts (see chapter *Contact*). To enter your data click on the *New item* button.

**Step 8.** Click on the *Person* field and then on *Select* to assign a contact from your inventory.

**Step 9.** To save the information click *Save*.

### 6.1.2.    Section 1.2 Composition

Section 1.2 of IUCLID is used for describing the identity of the substance at a compositional level. This section should indicate the identity, degree of purity and concentration of the constituents in the substance, including any impurities and additives. The state and form of the substance must also be specified in this section.

Use this section to specify some of the information requested under Article 7(4) of the REACH Regulation, on the identity of the substance to be notified at a compositional level that you may have available.

Each substance dataset must contain at least one composition which refers to the substance to be notified. Each composition is a new record in IUCLID.

---

[1] 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".

---

The following information is usually needed to be filled, but you may set the default values recommended below, which is sufficient for the effect of submitting a SiA notification:

- The fields *Name*, *Type of composition* and *State/form* must contain the information regarding the name and type of the composition, as well as the physical state or form.
- The field *Degree of purity* may be filled as ≤ 100 %.

Under the section *Constituents*:

- The field *Reference substance* may be filled with the imported reference substance that you have downloaded (see chapter 5).
- The field *Typical concentration* field may be filled as ≤ 100%.
- The field *Concentration range* may be filled as: ≥ 80 % and ≤ 100% .

You are free to provide more detailed information, if that would be available to you. Information on the composition of the substances of very high concern included in the Candidate List is available in the respective "Support document", included under details (eye icon: 👁 ), for each entry of the Candidate List of substances of very high concern for Authorisation available at https://echa.europa.eu/candidate-list-table.

---

Follow the steps below to create a new record and fill in the information on your substance.

To create a new record:

**Step 1.** Click on the ✚ button displayed in the navigation tree next to *1.2 Composition.*

**Step 2.** Fill in the composition as described below.
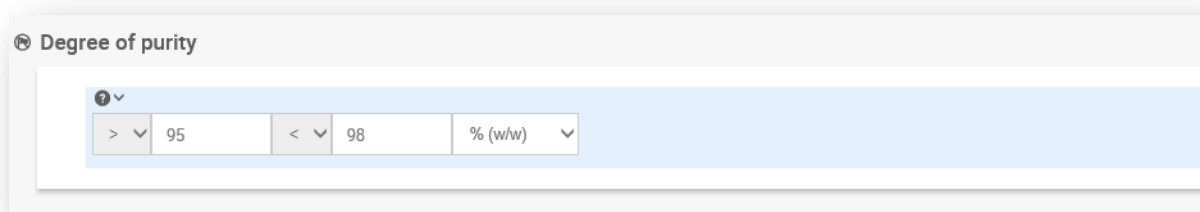
**General information:**

**Step 1.** Provide a descriptive *Name* for the composition.

**Step 2.** The default selection in the *Type of composition* field is *legal entity composition of the substance*. We recommend to to change it. You may wish to 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. If case your composition covers nanoforms, you must select the value '*solid: nanoform'* in order to be able to insert their characterisation below (For more information please refer to the manual *How to prepare registration dossiers covering nanoforms* at https://echa.europa.eu/manuals). You can give more detailed information on the composition under the *Description field*. In the *Justification for deviations* field, provide where relevant, the justification for deviating (e.g. 'SiA notification') from the rules for reporting the composition of substances as specified in the legal text and indicated in the *Guidance for identification and naming of substances under REACH and CLP* available at https://www.echa.europa.eu/web/guest/guidance-documents/guidance-on-reach. You can provide supporting attachments under the *Attached description/ Justification.*

**Degree of purity:**

**Step 3.** 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.

**Figure 15: Degree of purity**



**Constituents:**

**Step 4.** Include the constituents for the composition. Each composition must have, as a minimum, one constituent. If you follow our recommendation in the box above, you may report as the only constituent under the *Constituents* in section 1.2, by assigning the same reference substance for this constituent as in section 1.1 (see step 7).

If you have more detailed information on the composition, you may wish to provide it. The number of constituents to be reported will depend on the type of substance. To add more constituents, click on *New item*, and then the new rows will appear.

**Step 5.** Assign a *reference substance* to the newly created constituent. Search for the appropriate reference substance by clicking *Select*. Once you have found the appropriate reference substance (the one that you have downloaded and imported into IUCLID – see chapter 5) click on it to select it. In case you wish to provide more detailed information, alternatively, create a new reference substance to specify the constituent (see chapter 5 of the Manual *How to prepare registration and PPORD dossiers* available at http://echa.europa.eu/manuals).

**Step 6.** Indicate the *Typical concentration* and the *Concentration range* (minimum and maximum values, and unit of measurement) for every constituent. You may wish to report the values recommended in the box above by default.

Alternatively, you can add constituents by uploading a CSV file.

**Figure 16: Reporting constituent**
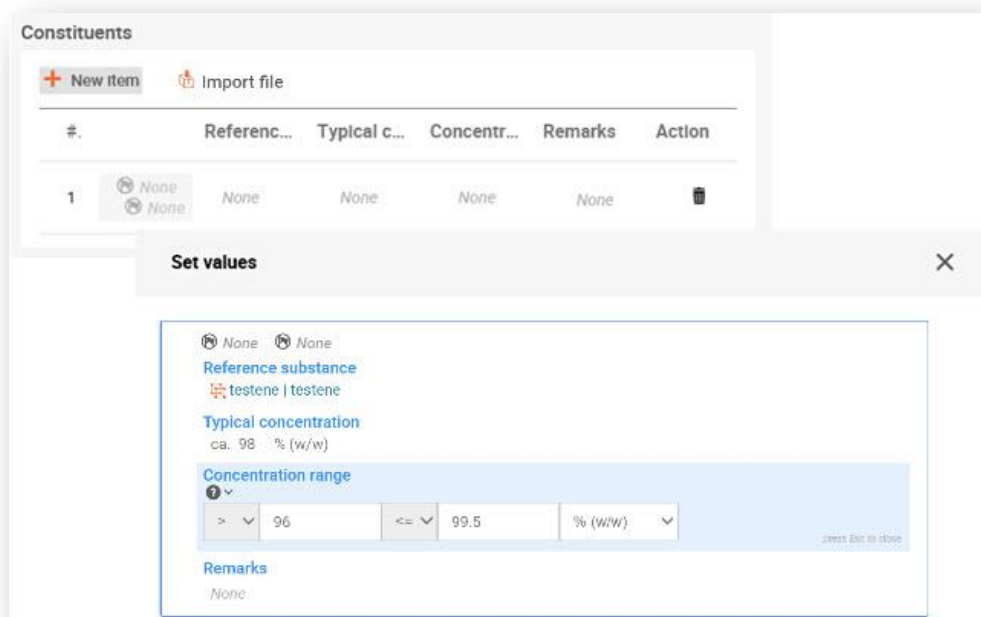


**Impurities and additives:**

**Step 7.** If you wish, you can also provide more detailed information on impurities and additives. To complete the information regarding *Impurities* and *Additives* follow the same procedure.

**Step 8.** Where the impurity or additive is considered relevant for classification and labelling of the substance, the relevant checkbox must be selected.

**Step 9.** The function of each *additive* may be provided by making a selection in the picklist *Function*. Only selections beginning with the word *stabiliser* are applicable under REACH and CLP.

For more detailed information on how to to create a new record and fill in the information on your substance composition, please refer to the Manual *How to prepare registration and PPORD dossiers*.

---

**Reporting the characterisation of nanoforms**

For information on how to report the characterisation for nanoforms please see the manual *How to prepare registration and PPORD dossiers.*

---

## 6.1.3. Section 1.3 Identifiers

In this section you can insert identifiers for regulatory programmes. In particular, this section should be used to report the following identifiers when available: REACH registration number and REACH substance in article notification number (in case of notification update, see below).

To enter your data, you must first create a new record by clicking on the ➕ button displayed in the navigation panel next to *1.3 Identifiers.* Then click *New document.*

**Step 1.**   Press the *New item* button to add a new identifier to the *Regulatory programme identifiers* table.

**Step 2.**   Click on the generated row and, 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, the REACH registration number has the following format: 01-XXXXXXXXX-CC-XXXX.

**Step 4.**   Click on *Save.*

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

---

Importers of articles may not have access to a registration number of the substances in the article. Producers of articles, incorporating the Candidate List substance into the article themselves, should normally have access to the registration number via the Safety Data Sheet (SDS) of the substance. However, in that case the article producer should verify that his use is covered by the registration, in which case he is exempted from the notification obligation.

---

**For notification updates:**

In this section you should add the reference number (notification number) that has been already granted to your substance, in case you want to submit a Substance in Articles notification update, by following the steps above, taking into account the following:

- From the *Regulatory programme* picklist, select *REACH substance in article notification number*;
- Please note that a notification number has the following format: 03-XXXXXXXXX-CC-XXXX.

## 6.2.   Section 2 C&L and PBT assessment

There is one section in IUCLID for entering information relating to classification and labelling: 2.1 GHS. In addition, the section 2.3 PBT assessment will allow you to store the outcome of the PBT assessment performed under the REACH Regulation.

---

**GHS** is the abbreviation for the United Nations Globally Harmonised System.

**The CLP Regulation** is the Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation), which implements the GHS in the EU. Further information on CLP is available on our website at Understanding CLP - ECHA (europa.eu).

---

The subchapter below contains relevant information for your SiA notification on the section 2.1 GHS of IUCLID. For more information on this section and its subsections in IUCLID, please refer to the Manual *How to prepare registration and PPORD dossiers.*

---

According to REACH Article 7(4), the classification of the Candidate List substance according to the CLP criteria must be provided in a SCIP notification.

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It must contain at least the information available in the respective "Support document", included under details for each entry of the Candidate List of substances of very high concern for Authorisation available at https://echa.europa.eu/candidate-list-table. To access the document, click the Details button 👁 in the specific substance row of the webpage of the Candidate List. The classification and labelling information can also be found in Annex VI to the CLP Regulation, where available, at http://echa.europa.eu/regulations/clp/legislation.

### 6.2.1.    Section 2.1 GHS

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

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

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

To create a new record:

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

**Step 2.**    A new record to report the classification and labelling information is created.

A CLP Annex VI Harmonised classification has to be respected and you should report those harmonised hazard classes/differentiations accordingly. Exception is made when there is a "minimum classification" in Annex VI, marked with an asterisk. In this case, if there is data on which a stricter classification (hazard classes and/or differentiations) could apply, you should use that. If there is data available for a stricter classification, but the one in Annex VI to CLP is not such a "minimum classification", you should report it to your relevant Member State competent authority. Please see further information in point **Re-assessment of the harmonised classification** at https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling.

Note that all other hazard classes not listed in an Annex VI entry must also be assessed, and if the data shows that additional hazard classes apply, you should report them in the same record with the harmonised classification. Please also remember that your substance may be covered by one or more group entry in Annex VI that may not come up in a search for the name and identity numbers of the substance.

To complete each created record, follow the steps:

**General information:**

**Step 1.**    Enter a descriptive *Name* for the GHS record. This is particularly relevant in the case that multiple GHS records are created, to easily distinguish the different records.

**Step 2.** If you submit a dossier for a substance which is not classified, you should select the checkbox *Not classified.* In this case, you should not enter any *Hazard category* or *Hazard statement* in the GHS record.

**Step 3.** Specify the *Implementation* by selecting from the picklist.

**Step 4.** In the field *Type of classification*, indicate whether the reported classification corresponds to a harmonised classification as per Annex VI of the CLP regulation, or to a self-classification. Note that if for the same composition or form of the substance certain hazard classes are based on a harmonised classification and others are self-classified, you should report all classifications in the same record and select *harmonised classification* in the field *Type of classification*.

**Step 5.** Enter any additional information in the *Remarks* field.

**Step 6.** Select a composition(s) in the *Related composition* field for which the GHS record is relevant by clicking the *Select* button.

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

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

**Classification:**

Under this header you can select a *Hazard category*, *Hazard statement and Reason for classification* for each hazard class or differentiation. Otherwise, you must fill in the *Reason for no classification*.

Note that when reporting hazards, the fields *Reason for no classification* have the default selection *Data lacking*. The fields to report hazard categories are only available for editing when the option *Not classified* is unticked, and when the field *Reason for no classification* is cleared of a selection.

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

- If a harmonised classification based on Annex VI of the CLP regulation exists for the hazard class, you should always select *EU harmonised classification* as the *Reason for classification*.

- If there is no harmonised classification but you are self-classifying based on the available data, specify if the classification is driven by a particular component of the substance (constituent/impurity/additive), by a particular physical state, size or form of the substance, or by the substance itself.

---

**IUCLID 6 v.8 includes new CLP hazard classes**

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

-   ED HH in Category 1 and Category 2 (Endocrine disruption for human health)

-   ED ENV in Category 1 and Category 2 (Endocrine disruption for the environment)

-   PBT (persistent, bioaccumulative, toxic), vPvB (very persistent, very bioaccumulative)

-   PMT (persistent, mobile, toxic), vPvM (very persistent, very mobile)

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

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

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

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If no classification is reported for a specific hazard class, the *Reason for no classification* should be selected according to the following principles:

-   *data lacking* should be selected if you do not have relevant data or other adequate and reliable information that can be compared with the classification criteria;

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

-   *data conclusive but not sufficient for classification* should be selected in cases where a substance has been tested with the appropriate high quality or where other high quality information is available, and based on that, it is concluded that the classification criteria are not fulfilled.

-   *hazard class not applicable* should be selected in cases where a substance has a physical state which is not compatible with the physical hazard class under evaluation (e.g. Flammable Solid when the substance is placed on the market as a liquid).

-   *hazard class not assessed* can be selected if the hazard class has not been assessed yet, e.g. if a transition period applies to the hazard class.

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

4.13   Flammable

4.14   Explosives

4.15   Oxidising properties

6       Ecotoxicological information

7.2     Acute Toxicity

7.3     Irritation / corrosion

7.4     Sensitisation

7.5     Repeated dose toxicity

7.6     Genetic toxicity

7.7     Carcinogenicity

7.8     Toxicity to reproduction

7.9.1   Neurotoxicity

7.9.2   Immunotoxicity.

---

**The CLP regulation foresees certain waivers:**

If a substance is classified for certain physical hazards, it does not need to be classified for certain others. For example: explosives, organic peroxides, self-reactive substances, and mixtures as well as pyrophoric or oxidising solids should not be considered for classification as flammable solids since flammability is an intrinsic hazard in these classes.

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

**and interconnections:**

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

---

**Classification - Physical hazards:**

**Step 7.**  Specify the *Hazard category* (e.g. Expl. Div. 1.1), *Hazard statement* (e.g. H201: Explosive; mass explosion hazard) and Reason for classification (e.g. based on the substance itself) for the *Physical hazards* by selecting the appropriate values from the picklists.

The CLP Regulation implements the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). However, not all the hazard categories and corresponding hazard statements from the GHS have been implemented in the CLP Regulation. Therefore, please note

when populating IUCLID section 2.1 - GHS that not all the available entries are relevant for CLP (e.g. Flammable liquids/Flammable liquid 4/H227: Combustible liquid).

**Classification - Health hazards:**

**Step 8.** Specify *Hazard category* (e.g. Acute Tox. 1), *Hazard statement* (e.g. H300: Fatal if swallowed) and Reason for classification (e.g. EU harmonised classification) for the *Health hazards* by selecting the appropriate values from the picklists.

The nature of *Reproductive toxicity* effects (i.e. *damage to fertility and/or the unborn child*), should be indicated in the field *Specific effect* by including the appropriate additional *Hazard statement* code(s).

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

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

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

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

**Figure 17: Specify the nature and the route of exposure for reproductive toxicity**

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

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

**Figure 18: Specify the hazard of carcinogenity via inhalation**



**Step 9.** For the following hazard class or differentiation: *Specific target organ toxicity - single exposure (STOT SE)* and *Specific target organ toxicity - repeated exposure (STOT RE)* you should fill in *Hazard category*, *Hazard statement, Reason for classification* and *Affected organs*. Otherwise, the field *Reason for no classification* should be filled in.

For practical reasons, it is not recommended to include more than three primary target organs. If more target organs are affected, it is recommended that the overall systemic damage should be reflected by the phrase *damage to organs*.

If the affected organ is unknown, indicate *unknown* in the field *Affected organs*. For these and other classes/differentiations, you are also advised to indicate the *Route of exposure*, where applicable.

You can specify more than one *STOT SE / STOT RE* by adding additional entries. To add additional entries, click *New item*.

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

**Figure 19: 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 have not been transposed to CLP.

| Hazard class | Hazard category | Hazard statement |
|---|---|---|
| Acute toxicity - oral | Acute Toxicity 5 | H303 |
| Acute toxicity - dermal | Acute Toxicity 5 | H313 |
| Acute toxicity - inhalation | Acute Toxicity 5 | H333 |
| Skin corrosion / irritation | Skin Mild Irritation 3 | H316 |
| Serious eye damage / eye irritation | Eye Irritation 2A<br>Eye Irritation 2B | H320 |
| Aspiration hazard | Asp. Toxicity 2 | H305 |
| Germ cell mutagenicity | Muta. 1* | * |
| Carcinogenicity | Carc. 1* | * |
| Reproductive toxicity | Repr. 1* | * |

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

**Classification - Specific concentration limits:**

**Step 10.** If your substance has harmonised *Specific concentration limits*, you need to specify them by filling in at least one of the two range fields in the *Concentration range (%)*. In addition, you also need to indicate the relevant *Hazard categories*.

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

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

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

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

## Figure 20: Specific concentration limits
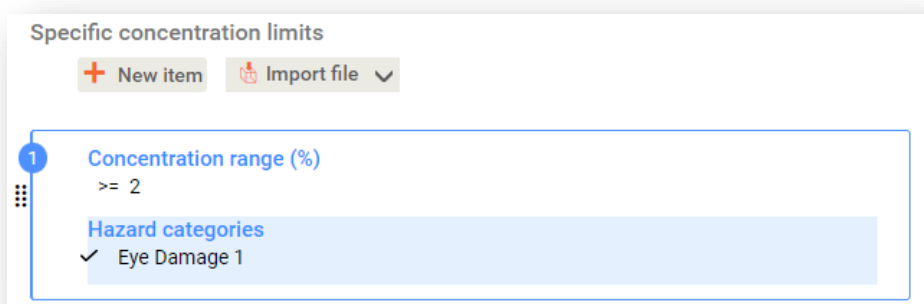


The CLP Regulation implements the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). However, not all the hazard categories and corresponding hazard statements from the GHS have been implemented into the CLP regulation. Therefore, please note when populating IUCLID section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

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

| Chemicals under pressure 1, 2 and 3 |
|---|

## Classification – Acute Toxicity Estimates (ATE)

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

## Classification - Environmental hazards:

**Step 12.** Specify *Hazard category* (e.g. Aquatic Acute 1), *Hazard statement* (e.g. H400: Very toxic to aquatic life) and *Reason for classification* (e.g. EU harmonised classification) for the *Environmental hazards* by selecting the appropriate values from the picklists.

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

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

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

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

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

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

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

**Figure 21: Specify the Environmental hazards**



**Classification – Ozone layer:**

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

You can specify *Additional hazard classes* in the free text fields *Additional hazard classes* and *Additional hazard statements*.

**Labelling:**

**Step 14.** Specify the *Signal word* by selecting the appropriate value from the picklist. If no signal word applies to your substance, then you need to select *No signal word* from the picklist.

**Step 15.** If applicable, please select a *Hazard pictogram* from the picklist. You can select more than one pictogram by adding a *New item*.

**Step 16.** You should select at least one *Hazard statement* from the picklist and provide *Additional text* where applicable. If no hazard statement applies to your substance, then you need to select *No hazard statement*.

You can always specify more than one hazard statement for the labelling by adding a *New item*.

**Figure 22: Labelling for section 2.1**



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

According to Art. 27 of CLP Regulation, some hazard statements are not required in the label as they would be redundant. A few examples are listed below. For additional information please consult the Guidance on the application of the CLP criteria.

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

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

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

**Step 17.** If applicable, please select a *Precautionary statements* from the picklist.

**Step 18.** If applicable, please specify the *Additional labelling requirements*. These include supplemental CLP hazard statements and additional labelling elements resulting from the application of CLP Article 25. Please consult the CLP Regulation and Guidance for further information on the additional labelling requirements.

**Notes (EU CLP)**

**Step 19.** If applicable, you can select *note(s)* from the picklist. These *notes* are mandatory for harmonised classifications listed in Annex VI to CLP. If your substance has a harmonised classification, and the entry has any of them, you need to include them in your dossier

More information on how to fill in Section 2.1 of IUCLID can be found in the Manual *How to prepare registration and PPORD dossiers.*

## 6.3.    Section 3 Manufacture use and exposure

### 6.3.1.    Section 3.2 Estimated quantities

In this section you have the possibility to provide information on the tonnage of the Candidate List substance present in the article.

To insert information on the tonnage, please proceed through the following steps:

**Step 1.** Create a new record by clicking on the + button displayed in the navigation panel next to *3.2 Estimated quantities*.

**Step 2.**   Fill in the *Year* field with the calendar year for which the tonnage calculation has been made.

**Step 3.**   Under *Tonnages relevant for registration/notification of substances in articles*, please provide information on tonnage (tonnes/year) that is relevant to your articles:

- tonnage of the Candidate List substance contained in the imported articles in the field *Tonnage imported in articles*

       and/or

- tonnage of the Candidate List substance contained in the produced articles in the field *Tonnage in produced articles*.

You can calculate and provide (for both cases mentioned above) the total tonnage of the Candidate List contained in the articles. The *Guidance on requirements for Substances in Articles* available at http://echa.europa.eu/guidance-documents/guidance-on-reach gives you some advice on how to carry out the calculations.

**Step 4.**   To save the information click *Save*.

---

For articles which have been produced/imported for at least three consecutive years, the tonnage to be reported should correspond to the average tonnage produced/imported during these three full years (or average of two full years if the article has been produced/imported for two full years). Otherwise the tonnage will be calculated based on the previous calendar year only and no averaging will be made.

In case production/import of the article starts in the current year and it is expected that the article producer/importer will fall under the notification obligation (the 1 tonne threshold has been or will be exceeded) you are advised to notify as soon as the 1 tonne threshold has been reached. In that case, please indicate an expected tonnage for the whole year.

---

You have the possibility to indicate the tonnage that you have provided in this section as confidential. In that case a justification has to be provided, please proceed as follows:

**Step 5.**   To add confidentiality to the flag of this section, on the top of the page, click on the 'no flag is set' button    .

**Figure 23: 'No flag is set' button**
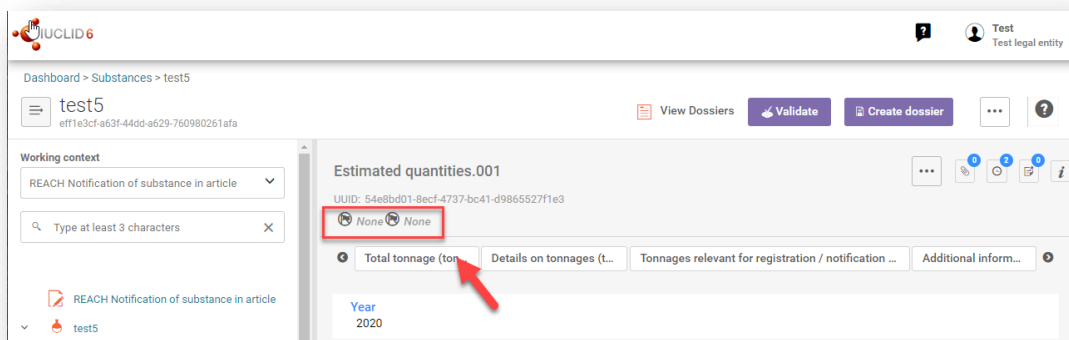
**Step 6.** On the set flags window under *Confidentiality*, select from the picklist one of the reasons for confidentiality: *CBI*.

**Step 7.** Enter the required justification it into the field *Justification*, which is a free text field. After confidentiality is set, the flag icon in this section will appear as confidentiality flag CBI None .
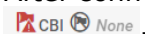
**Step 8.** To save the information click *Save*.

For more information on indicating information as confidential, please refer to manual on confidentiality requests and dissemination available at http://echa.europa.eu/manuals.

## 6.3.2.    Section 3.3 Sites

Only producers of articles will have to enter their articles production sites. Importers of articles do not need to fill in this information.

To enter your data create a new record by clicking on the + button next to *3.3 Sites.* To include a production site in this record, first create a site using the same *Legal entity* that you used for the creation of the dataset (see chapter *Legal entity sites*). To specify the information on your articles production sites, you can create several records (one for each site) and each of them must have one of the existing *Legal entity sites* linked to it. When reporting the production site, the country is expected to be the same as the country of the submitting *Legal entity.*

## 6.3.3.    Section 3.5 Use and exposure information

The section 3.5 is composed of a number of sub-sections corresponding to the different life cycles stages of a substance. In the context of a notification for substance in articles, only the subsection 3.5.6 *Service life* must be completed. In this sub-section you have to describe the article(s) and its use(s).

It is recommended to follow the principles explained in the *Guidance on information requirements and chemical safety assessment,* Chapter R.12: *Use description* (available at https://echa.europa.eu/guidance-documents/guidance-on-reach.

## 6.3.3.1.    Section 3.5.6 Service life

The steps described below show how the different fields should be filled in. Detailed information on the expected content of each field can be accessed clicking the help button, when available.

**Step 1.** Click on the + button next to *3.5.6 Service life.*

**Step 2.** A service life record is then created. When creating a new record you can re-name it by clicking on the bar at the top of the page and inserting, as needed (cf. examples below) the name assigned to each article or each use of the article you wish to describe.

You can create several service life records if needed.

In general it is advised to describe separately (i.e. in different *Service life* records) the different articles containing the same Candidate List substance. Similar articles should however be grouped together and the information provided only in one record. To this aim you should decide which articles are similar enough to be described together. This can be done based, namely, on all the following conditions:

- the articles have the same use/function; and
- the Candidate List substance has the same technical function; and
- the Candidate List substance is located in the same (integral) part/material of the article; and
- the use conditions of the articles can be expected to be similar.

**Example 1**: The Candidate List substance is contained in the single seat and back rest piece of chairs. The seat and back rest piece is an article made of a plastic material. This article exists in different designs, sizes and colours. These variants should however all be considered as the same 'type of article'. Articles that only differ in design, size or colour, can be grouped together in the same *Service life* record.

**Example 2**: The Candidate List substance is used as waterproofing agent in textile fabrics made of polyester fibres. In one case the substance is used in very low concentration in the fabrics for everyday clothing, where frequent skin contact and regular cleaning with releases to the environment, e.g. during washings, are expected . In the other case the substance is used in high concentration for fabrics used to produce boat sails, where limited skin contact and no frequent cleaning are expected. However, during use there are releases to the environment. These articles should not be grouped in the same *Service life* record, because their uses/functions and use conditions are different which means that not all conditions above are met.

The following (types of) articles, where relevant, should be described in separate *Service life* records:

- articles only used by workers;
- articles with high potential release of the Candidate List substance during use.

**Step 3.**  Under *Registration/Notification status for the use*, choose from the picklist: *use of substance in articles notified according to REACH Article 7(2)*.

**Step 4.**  Provide a *Service life number* for the service life record, if deemed useful for your own purpose.

**Step 5.**  Provide the service life name (or name/use of your article). Insert, in the *Service life name* field, a short name. The name should be concise but descriptive of the specific article you are describing and of its use, e.g. insulation element, computer cables etc.

**Step 6.**  Provide further description of the article and of its use(s). In the field *Further description of use*, provide more information on the article and its use(s).

Please fill in this section, for example, by including the information below:

- description of the article and its different (integral) parts/materials, when applicable;
- information in which part(s)/materials the Candidate List substance is present and its maximum concentration (w/w); precise technical function of the Candidate List substance in the article or part(s)/materials of the article;
- description of all the different foreseen 'uses' during the service life (e.g. processing into finished article (for semi-finished articles), installation, maintenance and use of the finished article, disposal). Highlight to the extent possible where releases can be expected;

- Indicate if the article is intended to be used by vulnerable populations (e.g. babies, children, pregnant women);
- In the case you are grouping similar articles, we advise you to describe the different characteristics of those articles.

**Example 3**: Single seat and back rest plastic piece of a chair

The article is a single seat and back rest piece of a chair made of polypropylene (PP). It contains 3% w/w of a Candidate List substance used as a flame retardant. The chair, and therefore its seat and back rest piece, is mainly for indoor use, but there may be some outdoor use. When sitting on the chair, this plastic article will come into contact with skin or clothing.

If the article is exposed to heat or a flame, the PP used can burn and melt and generates a highly exothermic combustion reaction. The Candidate List substance is added to PP, in order to disrupt its combustion.

**Example 4**: Sewer pipe

The article is a sewer pipe made of Polyvinyl chloride (PVC). The PVC sewer pipe contains 1% w/w of a Candidate List substance, which was used as heat stabiliser in the production of the pipe. The pipe will be handled and mounted by workers. It is foreseen for outdoor use. The pipe comes into contact with the soil and with sewage water from homes/buildings and industrial sites and therefore the Candidate List substance can be released to the environment.

The Candidate List substance is used to prevent thermal degradation of PVC during manufacture and when processed.

**Example 5**: Semi-finished textile fabric

The article is a semi-finished textile fabric made of polyester fibres. It contains 3% w/w of a Candidate List substance, used as flame retardant. The fabric will be further processed in finishing activities, including washing processes and/or curing processes under elevated temperature. Releases to the environment from these processes are expected, as well as inhalation of vapours and particles by workers.

The finished fabric is used for the production of clothes and home textile articles. Further releases to the environment are expected during washings of these final articles. Contact with skin while wearing the clothing article can be expected. Inhalation of released particles or vapours during use of the final article, in particular from home textiles with large surface areas.

**Example 6**: Insulated electric wires in a TV

The articles are insulated electric wires contained in an imported TV. The insulated electric wires were made by insulating the copper wire, through extrusion, using a PVC liquid mixture containing 10% w/w of the Candidate List substance. The Candidate List substance is used as plasticiser and its maximum concentration in the insulated wires is 4% w/w.

The insulated wires containing the Candidate List substance in the TV were grouped together because they are similar, even if having different diameters, code colours, and being bundled in cables.

When disposed, the TV should be treated as electronic waste, which includes the insulated electric wires in it.

**Step 7.** Where several compositions of the Candidate list substance are reported in the section 1.2 (see subchapter *Section 1.2 Composition*), you can link the compositions that are

related to this particular use in the table *Related composition* by clicking on *Select* and selecting the relevant composition(s).

**Step 8.** Indicate by whom the article is foreseen to be used. In the field *Article used by*, please indicate if the article is foreseen to be used by *workers*, or by *consumers* (i.e. by the general public) by selecting from the picklist. You should not select both *workers* and *consumers* within one service life record.

Article foreseen to be used by consumers (e.g. screw, hammer) can also be used by workers. It is enough to report these articles as article used by consumers if the use conditions are generally the same.

**Step 9.** In the field *Article category (AC)*, you should select the type of article(s) into which the Candidate List substance has been incorporated from a list of standard articles categories (e.g. wood articles, plastic articles). In case of an article with various (integral) parts/materials (e.g. painted paper clip), please choose the article category describing the part of the article where the Candidate List substance is present. Select the article category (AC) from the picklist.

The Article Categories (AC) are listed in the Table R.12-14 in the Appendix R.12.4. of the *Guidance on information requirements and chemical safety assessment*, Chapter R.12: *Use description*. The Table also includes explanations and examples, as well as suitable TARIC chapters, for some AC.

If you cannot identify a suitable article category (or you wish to be more specific), please select *AC0: Other* and provide explanation in the field below. If applicable, you can select a code (and the corresponding phrasing) from the TARIC system (http://ec.europa.eu/taxation_customs/dds2/taric/taric_consultation.jsp) – e.g. by clicking 'Browse the Nomenclature'.

In principle, articles that are assembled or joined together remain articles, therefore, articles categories AC1 to AC3 are recommended to be used in combination with the relevant material-based article categories AC4 to AC13 or AC0.

**Step 10.** Describe the use of the articles from the perspective of release to the environment.

    i. Create one *Contributing activity / technique for the environment*, by clicking the *New item* button. Alternatively, you can import a CSV file.

    ii. Under the field *Name of activity / technique* briefly characterise with your own words the use of the articles from an environmental perspective.

    iii. Under *Environmental release category (ERC)*, select from the standardised list of environmental release categories (ERCs) the one(s) that best describe the use of the articles, by selecting from the picklist. It is possible to choose several ERCs, if appropriate.

You will find the list of ERCs together with explanation and examples in the Tables R.12-12 and R.12-13 of the *Guidance on information requirements and chemical safety assessment, Chapter R.12: Use description* (see Appendix R.12.4.). Please also refer to the figure R.12.7 in this appendix for a decision tree for the ERC assignment.

If the articles described within a use have different conditions of uses from an environmental perspective, this can be indicated by creating several *contributing activities/techniques for the environment*. Additional contributing activities can be created by clicking on the *New item* button. Alternatively, you can import a CSV file.

**Step 11.** Describe the use of the articles from the human health exposure perspective.

- If you have indicated that your **article is used by consumers** in the field *Article used by*, you will have the possibility to create *Contributing activity / technique for consumers*;

- If you have indicated that your **article is used by workers** in the field Article used by, you will have the possibility to create Contributing activity / technique for workers.

Contributing activities/techniques are created by clicking the *New item* button.

    i.  Under the field *Name of activity / technique* briefly characterise with your own words the specific use of the article from an human health exposure perspective.

    ii.  If you have selected *consumers* under *article used by*: under *Article category (AC)*, select from the standardised list of articles categories in the picklist menu the one(s) that best characterise the article from an exposure perspective (e.g. *AC6a –leather articles, large surface area articles*). If you cannot identify a suitable article category please select *AC0: Other* and provide explanation in the field below.

    iii.  If you have selected *workers* under *article used by*: under *Process categories (PROC)*, select from the standardised list of process categories available in the picklist menu the appropriate one(s), e.g.*PROC 21:Low energy manipulation of substances bound in materials and/or articles*.

    iv.  If none of the specific PROC categories seems applicable, you can tick the box *PROC0: Other* and describe in the field below, the foreseen tasks, application techniques or process types in your own words.

A process category for articles used by workers describes the tasks, application techniques or process types defined from the occupational perspective. You can find the name, explanation and examples of these PROCs in Table R.12-11 in the Appendix R.12.4. to the *Guidance on information requirements and chemical safety assessment,* Chapter R.12: *Use description*.

    v.  In the field *Percentage (w/w) of substance in mixture / article (%)*, please provide the concentration (% w/w) of the Candidate List substance present in the article as imported or produced. In the field *Details on the percentage of substance in a mixture / article*, you can provide more detailed information on the concentration reported. The obligation to notify applies when this concentration is above 0.1 % (w/w). This concentration threshold applies to each article of an imported object made up of more than one article, which were joined or assembled together.

If the articles described within a use have different conditions of uses from a human health exposure perspective, this can be indicated by creating several contributing activities / techniques. Additional contributing activities can be created by clicking on the *New item* button. Alternatively, you can import a CSV file.

**Step 12.** Provide a description of the use(s) – as technical function - of the Candidate List substance in your article.

Under *Technical function of the substance during use* select the appropriate technical function of the substance in the article from the picklist. If the substance remains in the article from a preceding life cycle stage, and does not have any function in the article, you can select from the picklist *no technical function*. Further explanation can be provided in the field *Further description of use* (see step 5).

The technical function (TF) of the substance in the article describes the role that the substance fulfils when it is used (what it actually does in an article). The technical function is therefore focused on substances, and it is not meant to convey information on the type of article.

The list of specific TFs are listed in Table R.12-15 in the Appendix R.12.4. to the *Guidance on information requirements and chemical safety assessment,* Chapter R.12*: Use description*. If none of the listed technical functions (TF) seems applicable, you may describe it in your own words, instead of assigning a specific available TF. In that case you should tick the box *Other* and provide the relevant description in the field below.

**Step 13.** In the field *Tonnage of substance for this use (tonnes/year)*, please report the tonnage (tonnes/year) of the Candidate List substance contained in the article you are describing, e.g. 1.5 (tonnes/year in the sewer pipe). As a minimum requirement, the tonnage range of the Candidate List substance has to be provided in the IUCLID dossier header (Chapter 8 *How to create a Dossier*). In the next field, you have the possibility to provide more detailed information on the tonnage if you so wish.
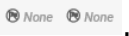
**Step 14.** The field *Details on tonnage reported* can be filled with more detailed information on the tonnage reported in the field above, if necessary, e.g. how the tonnage value has been calculated. Note that the checkbox *Total EU tonnages for this use* is not relevant for the SiA notification and should NOT be selected.

**Step 15.** In the *Remarks* field you can provide additional information you consider relevant for the Substance in Article notification dossier, in particular further information related to exposure resulting from the use of the article (considering the service life of the article including disposal), e.g. results from a chemical safety assessment of article service life. You may also consider to include information for safe and proper use/handling of the article, as well as appropriate instructions for its disposal that you communicate down the supply chain in accordance to Article 33 of REACH Regulation.

**Step 16.** To save the information click *Save*.

If you need to notify more than one type of article or use containing the same Candidate List substance, you need to create several records under the *Service life* following steps 1 to 16 above.

You have the possibility to indicate the information on use that you have provided in this section as confidential. In that case, proceed as follows:

**Step 1.** To add confidentiality to the flag of this section, on the top of the page, click on the 'no flag is set' button ⊗ None ⊗ None .

**Step 2.** On the set flags window under *confidentiality*, select the reasons for confidentiality: *CBI*.

**Step 3.** Enter the required justification it into the field *Justification*, which is a free text field. After confidentiality is set, the flag icon in this section will appear as confidentiality flag CBI ⊗ None .

**Step 4.** To save the information click *Save*.

# 7.  How to create a Dossier

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

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Before creating a dossier you are advised to check the completeness of your substance dataset by running the *Validation assistant*. For more information on how to run the *Validation assistant* refer to the help system of IUCLID.

---

**Step 1.**   To create a dossier open the list of available subtance datasets by clicking on the button entitled *Substances* in the IUCLID Dashboard.

**Step 2.**   All available substances will be displayed in the *Substances* list page*.* If a substance does not appear in the list you can search for it using the search field.

**Step 3.**   Click on the substance for which you want to create a dossier.

**Step 4.**   Before creating a Dossier a *Working context* (submission type) must be selected. Click on the *Working context* field and select the right submission type from the picklist. Choosing the correct dossier template by selecting the *Working context* is essential for a successful submission. Before exporting your dossier you have to make sure that the selected template corresponds with the intended submission.

**Step 5.**   Click on *Create Dossier* in the top right-hand corner of the screen.

The selection of the *Working context* allows the IUCLID interface to present to the user at the start of *Dossier* creation, either a pre-filled or blank *Dossier header* of the correct type.

**For instructions on how to fill the administrative information in the Dossier header, please see the following subchapters**.

---

Information contained in the dossier header is crucial for business rules checking when you submit your dossier. Missing or incorrect information can result in that your submission cannot be accepted for further processing and will be automatically removed from the system. In this case you need to create a new dossier with corrected information and submit it again. For more information refer to the Annex: *Overview of the business rules checks performed by ECHA on the submitted dossiers*.

---

**Step 6.**   From the *Dossier header* page you can either use default settings and create your dossier by clicking on *Create dossier* at the foot of the page, or access the *Advanced settings* for dossier creation by clicking on the *Advanced settings* button.

**Figure 24: Dossier header page with 'Create dossier' and 'Advanced settings' buttons.**



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

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

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

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

Note that In the particular case of SiA notification, you should select **REACH Notification of substance in article** template when creating a Dossier.

## 7.1.    Administrative information

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

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

### 7.1.1.    Specific submissions

By default the dossier is created for an initial submission, in case of an update you should select the checkbox *The submission is un update*.

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 SiA notification.

If the reason for the spontaneous update is not listed in the picklist, then you are required 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 *New item* button. Alternatively, you can import a CSV file. Please note that a *Justification* has to be provided in all the blocks.

See also chapter *Update Dossier*.

### 7.1.2.    Dossier specific information

This part of the dossier header allows giving more general information on the IUCLID SiA notification dossier submitted.

In the field *Tonnage band* you must select your own tonnage band (i.e. 1-10 tonnes, 10-100 tonnes, 100-1000 tonnes or ≥1000 tonnes).

*Confidentiality claim on tonnage band* and its *Justification* fields must to be filled in case you want to claim the relevant data confidential. For tonnage band, this is the only way to request the confidentiality.

The checkbox for the *Confidentiality claim on the tonnage band* is the only location in the dossier where you can request confidentiality on your tonnage band. The confidentiality flag

in IUCLID section 3.2 relates to the actual tonnage manufactured/imported, which is always treated as confidential information.

The checkbox *Reviewed by an assessor* is not required, but if it has been reviewed by an assessor it may be indicated here.

# 8. How to export a Dossier

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

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

# 9. Submit Dossier

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

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

# 10. Update Dossier

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

 It is strongly recommended to keep the SiA notification up to date. You should consider updating your notification if the information you have included in it changes. Reasons for updating could be a change in the tonnage range, in the characteristics of the article produced/imported (description, use(s)) etc. In all these circumstances, updating your notification is strongly recommended. Keeping your notification up to date will help document your REACH compliance towards national enforcement authorities.

Do not forget to specify in section 1.3 of IUCLID the reference number (notification number) that has been already granted to your substance, in case you want to submit a notification for Substance in Articles update (see chapter *Section 1.3 Identifiers*).

# 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. 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. You can see the outcome of the business rules check in the submission report in REACH-IT.

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

| Business Rules applicable for Substance in Article notifications | | |
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| **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. | Substance in Articles 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:<br>- EC/List number<br>- CAS number<br>- IUPAC name<br><br>Any EC/List number defined in section 1.1 and 1.2 of IUCLID must exist in the REACH-IT EC inventory.<br><br>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.<br><br>If categories are used, this rule is applied to all the category member substances. | All dossier types |

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| **IUCLID** **section 1.1 – Identification** | At least one of the following fieldsmust be provided for the reference substance in section 1.1: - EC/List number - CAS number - Molecular formula AND molecular weight AND structural formula - SMILES notation - Remarks | Substance in Articles notification |
| **IUCLID** **section 1.1 – Identification** | In an update submission, the substance must be identified by an EC/List number. | Substance in Articles notification |
| **IUCLID** **section 1.1 – Identification** | The reference substance must be marked as one of the following: - Mono constituent substance - Multi constituent substance - UVCB | Substance in Articles notification |
| **IUCLID** **section 1.1 – Identification;** **section 3.3 - Sites** | When 'Manufacturer' is selected as a role in the supply chain then at least one manufacturing site must be provided in section 3.3. To this end, you must create a record in section 3.3 and assign a 'Site' to this record. | Substance in Articles notification |
| **IUCLID** **section 1.1 – Identification** | You must select a role in the supply chain. You cannot select the role 'Downstream user'. 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. | Substance in Articles 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 'Type of composition' indicated. At least one of the compositions in section 1.2 must reflect the composition of the substance manufactured/imported by the registrant. This composition must be marked as the "Legal entity composition of the substance". If the 'Type of composition "other" is selected from the list, the relevant information must be provided in the free text field below. | All dossier types |
| **IUCLID** **section 1.1 – Identification;** **section 1.2 – Composition** | If the substance is defined as mono-constituent, the first 'legal entity composition of the substance' in section 1.2 has to have a matching substance identity when compared with the reference substance in section 1.1. | All dossier types |
| **IUCLID** | If the substance is defined as a multi-constituent substance, | All dossier types |

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| **section 1.1 - Identification; section 1.2 – Composition** | 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. | |
| **IUCLID section 1.2 – Composition** | All constituents of a multi-constituent or of a UVCB substance must identify distinct reference substances. | All dossier types |
| **IUCLID section 1.2 - Composition** | 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.<br><br>If the substance is not classified, the tick box 'Not classified' should be marked and no classification should be provided in that record. | Substance in Articles notification |
| **IUCLID section 1.2 - Composition** | If the substance is classified, at least one entry for 'Specific target organ toxicity - single' and 'Specific target organ toxicity - repeated' must be provided in IUCLID section 2.1. For each entry, a 'Hazard category', a 'Hazard statement', and 'Affected organs' must be provided, or indicate a 'Reason for no classification'.<br><br>If the substance is not classified, the tick box 'Not classified' should be marked and no classification. | Substance in Articles notification |
| **IUCLID section 1.3 - Identifiers** | When a registration number is provided in section 1.3 it has to refer to the same substance as indicated in section 1.1. | Substance in Articles notification |
| **IUCLID section 1.3 – Identifiers** | For an update submission, a reference number must be given in IUCLID section 1.3. | Substance in Articles notification |
| **IUCLID section 2.1 - GHS** | The classification and labelling information must be provided in the GHS format in section 2.1 - GHS. | Substance in Articles notification |
| **IUCLID section 2.1 - GHS** | If at least one classification is provided in a C&L record in section 2.1 then:<br>- a 'Signal word' must be provided under the 'Labelling' heading of the same record.<br>- a 'Hazard statement' or a 'CLP supplemental hazard statement' must be provided under the 'Additional labelling requirements' heading of the same record.<br><br>If no classification is provided, the tick box 'Not classified' should be selected and no hazard statements and no signal words should be provided. | Substance in Articles notification |
| **IUCLID section 2.1 - GHS** | For each 'Specific concentration limit' entry that is created in a C&L record in IUCLID section 2.1, at least one of the two fields under 'Concentration range (%)' must be provided. In addition, at least one selection must be made under 'Hazard categories'. | Substance in Articles notification |

| | 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. | |
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| **IUCLID**<br>**section 3.3 - Sites** | Assign a site to each record in IUCLID section 3.3. You must also provide a contact address for the site; 'Country' is the minimum information required. | Substance in Articles notification |
| **IUCLID**<br>**section 3.5.6 – Service life** | At least one record in section 3.5.6 has to be included, containing the following information:<br>- 'Service life name'<br>- 'Article used by'<br>- 'Further description of use'<br>- at least one 'Contributing activity / technique for the environment' described with the appropriate 'Environmental release category (ERC)' codes<br>- 'Technical function of the substance during use'<br><br>In addition:<br>- if the article is used by workers, the appropriate 'Article category (AC)' codes must be provided.<br>- if the article is used by consumers, at least one 'Contributing activity / technique for consumers' must be provided described with the appropriate 'Article category (AC)' codes.<br><br>-If 'other:' is selected in any of the picklists then the free text field below must be filled in. | Substance in Articles notification |
| **IUCLID**<br>**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. | Substance in Articles notification |
| **IUCLID**<br>**dossier header** | Updates can be submitted in the following cases:<br>- Following the successful registration / notification of this particular substance, after having received a reference number (spontaneous update).<br>- Following a technical completeness check (TCC) failure (requested update).<br>- Following a request for further information by the Agency (spontaneous or requested update as specified in the request).<br><br>In any other case, an initial submission is required. | All dossier types - Updates |
| **IUCLID**<br>**dossier header** | If you wish to submit a spontaneous update then the following conditions must be fulfilled:<br>- In the dossier header tick the boxes 'The submission is an update' and 'Spontaneous update'.<br>- Insert the submission number to the last successful submission as the 'Last submission number'.<br>- Select an appropriate justification for updating by first | Substance in Articles notification |

| | 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 free text field below. | |
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| **IUCLID dossier header** | 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. | Substance in Articles notification |
| **IUCLID dossier template** | The dossier template used in IUCLID must correspond with the intended submission type in REACH-IT. | All dossier types |
| **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** | 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. | Substance in Articles notification |
| **REACH-IT** | It is not allowed to submit a notification when when a registration dossier for the same substance from the same submitting legal entity is currently under processing by the system. | Substance in Articles notification |
| **REACH-IT** | If an active registration already exists for the substance by the submitting legal entity then it is not allowed to submit a notification. | Substance in Articles notification |
| **REACH-IT** | The same IUCLID dossier cannot be submitted more than once. | Substance in Articles notification |
| **REACH-IT** | It is not allowed to update a dossier that is being deactivated or has been revoked. | Substance in Articles notification |