

# How to prepare registration and PPORD dossiers

October 2020

# ABC

## Changes to this document

Version	Changes
9.0	<p>October 2020: Update to reflect the new functionalities of IUCLID 6.5</p>
8.0	<p>April 2020: Update to reflect the new functionalities of IUCLID 6.4 web user interface. Annex 8: New TCC rules added</p>
7.0	<p>October 2019: Update to reflect transition from IUCLID 6.3 to IUCLID 6.4, and from the classic user interface to the web user interface. Annex 8: New annex added with information specific to nanoforms</p>
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## 1. Introduction

### 1.1. Objective

The purpose of this manual is to assist in the preparation of REACH registration and PPORD (product and process oriented research and development) dossiers using IUCLID. The manual provides you with detailed and practical instructions on how to generate a substance dataset and outlines the IUCLID sections to be filled in, in order to prepare a valid dossier that can be submitted to ECHA through REACH-IT.

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

More information about each field, the different functionalities in IUCLID and how to use those functionalities can be found in the help system of IUCLID (see chapter 1.8 *Functionalities of IUCLID*).

The manual also assumes that you have decided on your registration approach and have all relevant information available. Please consult the Guidance documents for support on the information requirements for registration: <https://echa.europa.eu/support/guidance>.

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

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

- Step 1.** Sign-up in REACH-IT and create the *Legal entity* (<https://reach-it.echa.europa.eu/>).
- Step 2.** Create the *reference substances* in IUCLID related to your substance (see chapter 5 *Reference substance*).
- Step 3.** Create the *substance dataset* in IUCLID (see chapter 8 *How to create a substance dataset*).
- Step 4.** Enter information in the substance dataset in IUCLID (see the relevant sections of chapter 8 *How to create a substance dataset*).
- Step 5.** Include the chemical safety report (CSR) for all substances manufactured or imported above 10 tonnes unless exempted by REACH article 14(2)<sup>1</sup>.

Note that a Report generator is available in IUCLID to support you generating your CSR. It compiles the information from your IUCLID dataset and generates a formatted document covering the CSR chapters 1 to 8. You may also use Chesar to perform your CSA. In this case, the full CSR can be generated from Chesar. To generate a report click on the three dots button at the top of the substance dataset page and then select *Generate report* (See chapter 1.6.3 *The Dataset page*). More information on Chesar is available on the Chesar website: <https://chesar.echa.europa.eu/>.

- Step 6.** Create a *dossier* in IUCLID (see chapter 9 *How to create a Dossier*).

<sup>1</sup> Note that when you are exempted of CSA by Article 14(2) you have to provide an explanation in section 13 of IUCLID

**Step 7.** Export a dossier from IUCLID (see chapter 10 *How to export a Dossier*).

**Step 8.** Submit a dossier to ECHA via REACH-IT (see chapter 11 *Submit a Dossier*).

Upon receipt of your dossier, ECHA will undertake a set of administrative and technical checks of your submission before providing you with a registration number (see chapter 1.5 *Checks performed by ECHA on the submitted dossiers*).

ECHA will also disseminate on its website information from the registration dossier. For more information on what is disseminated and possibilities to claim some information confidential, see chapter 1.7 *Confidentiality requests and publication of information*.

### 1.3. IUCLID dossier templates

Before creating a dossier from a substance dataset you have to select the appropriate template for the type of dossier that you need to submit from the types indicated below<sup>2</sup>:

REACH Registration 1 - 10 tonnes, physicochemical requirements;  
REACH Registration 1 - 10 tonnes, standard requirements;  
REACH Registration 10 – 100 tonnes;  
REACH Registration 100 – 1000 tonnes;  
REACH Registration above 1000 tonnes;  
REACH Registration member of a joint submission – general case;  
REACH Registration member of a joint submission – intermediates;  
REACH Registration on-site isolated intermediates above 1 tonne;  
REACH Registration transported isolated intermediates 1 – 1000 tonnes;  
REACH Registration transported isolated intermediates above 1000 tonnes;  
REACH PPORD.

The information requirements for a registration dossier depend on the registered tonnage band and type of registration dossier prepared (Article 10 vs. 17/18; joint submission member vs. lead). This means that the information in the IUCLID dossier that will be checked for completeness varies depending the type of submission. This manual gives a section-by-section overview of the information that is required for registration and PPORD dossiers. In addition, a summary of the completeness check rules applied can be found in the Annex 2 *Overview of the completeness check performed by ECHA on the submitted dossiers*.

#### Registration or PPORD notification dossier?

The most common type of dossier is the registration dossier. However, where your substance is subject to product and process oriented research and development (PPORD) in quantities of one tonne or more per year, you can submit a **PPORD dossier** in order to be exempted from the obligation to register for a period of five years.

For more information specific provisions under REACH for substances manufactured, imported or used in scientific Research and Development (SR&D) and Product and Process Orientated Research and Development (PPORD), consult the corresponding guidance available at <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

<sup>2</sup> Tonnage bands referred to are per year.

### Individual registration or joint submission?

The REACH Regulation requires parties manufacturing/importing a substance to submit one registration for this substance (the so-called "One substance - one registration", or OSOR principle). Registrants of a substance are put in contact with other (potential) registrants after they submit to ECHA an inquiry. The registrants of the same substance have the collective responsibility to identify the substance, generate/collect relevant information according to the Annexes VI-X of REACH, and ultimately submit it in IUCLID format in fulfilment of the obligations.

This manual assumes that joint submission obligations have been determined by the submitting party and that all relevant information has been generated/collected and is available.

For more information on data sharing and joint submission obligations refer to the *Guidance on data sharing* and *Guidance on registration* available at <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

### On-site isolated intermediate or transported isolated intermediate?

If you are a manufacturer or importer of an isolated intermediate in quantities of one tonne or more per year, you may benefit from reduced registration requirements. Note that the requirements for registration vary depending on whether the isolated intermediate is an on-site or a transported intermediate.

For more information on obligations related to registration of intermediates refer to the *Guidance on registration* available at <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

### Notification made under Directive 67/548/EEC (NONS)?

According to Article 24 of the REACH Regulation all notifications made under Directive 67/548/EEC (NONS) are considered registrations under the REACH Regulation at the relevant tonnage band. These registrations need to be updated if at least one of the cases described in Article 22 or Article 24(2) of the REACH Regulation applies.

You can find detailed information on how to update your registration that was previously a notification under Directive 67/548/EEC (NONS) in the Annex 4 *Minimum information required for updating a registration under previous Directive 67/548/EEC* of this manual as well as the document *Questions and answers for the registrants of previously notified substances* available at:  
<https://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/nons-registrantsofpreviouslynotifiedsubstances>

## 1.4. Information requested for registration and PPORD notification

Registrants of the same substance have to share data and submit information jointly to ECHA. A distinction is made between information to be submitted by the **lead registrant** and that to be submitted by the other **members of the joint submission**.

Each registrant (manufacturer, importer or only representative) has the obligation to submit his

own **dossier** as a part of the joint registration. If you are preparing a dossier as the only registrant for that substance, and no joint submission exists, you need to provide all the information in your own dossier.

The table below shows the information that is submitted by the lead registrant on behalf of all members of the joint submission (joint information<sup>3</sup>) and the information that is submitted by each registrant in his own dossier (individual information).

**Table 1: Information requirements for registration and PPORD dossiers**

Information requirements	Lead dossier		Member dossier	PPORD
	Joint information	Individual information	Individual information	
identity of the registrant (ECHA account)		X	X	X
identity and composition of substance referred in Annex VI of REACH Regulation (IUCLID section 1.1, 1.2)		X	X	X
analytical information of substance referred in Annex VI of REACH Regulation (IUCLID section 1.4)		X	X	X
information on the classification and labelling of the substance referred in Annex VI of the REACH Regulation (IUCLID section 2)	X			X
information on manufacture and uses of the substance referred in Annex VI of REACH Regulation (IUCLID section 3)		X	X	if applicable section 3.3 Sites
information on exposure for substance registered in quantities between 1 and 10 tonnes per year referred in Annex VI of REACH Regulation (IUCLID section 3)		X	X	
scientific studies referred in Annexes VII to X of the REACH Regulation (IUCLID sections 4-8)	X			if applicable
guidance on safe use of the substance registered in the quantities of 10 tonnes or more per year referred in Annex VI of the REACH Regulation (IUCLID section 11)	upon agreement	upon agreement	upon agreement	if applicable
assessment reports referred in Article 14 of REACH Regulation, Chemical Safety Report (IUCLID section 13)	upon agreement	upon agreement	upon agreement	
a confidentiality claim request for the information in Article 119(2) of REACH which should be considered as confidential if any, including a justification	if applicable	if applicable	if applicable	

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

All dossiers submitted to ECHA undergo initial technical and administrative checks in order to ensure that they can be handled properly and that the subsequent required regulatory processes

<sup>3</sup> Article 11 of REACH Regulation allows members of the joint registration to opt-out for some of the information submitted jointly for a number reasons. More information on opt-out and its consequences is available in the guidance on data sharing here: <http://echa.europa.eu/guidance-documents/guidance-on-reach>

can be successfully carried out. Such checks are called business rules (BR).

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

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

After successfully passing the business rules step, registration and PPORD dossiers undergo the completeness check required by Article 20 of the REACH Regulation to ensure that the required information is provided.

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

In addition, as part of the completeness check, certain data in the dossier will be checked manually to ensure that the required elements are present.

You can find more information on the manual verification at <https://echa.europa.eu/manuals>.

### 1.5.1. 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.

Please note that as of 21 June 2016 the technical completeness check includes additional verifications of the registration dossier by ECHA staff. These checks cannot be replicated using the Validation Assistant plug-in; the related completeness issues cannot be displayed by the tool. Information on the areas of the additional **manual** verifications can be found at <https://echa.europa.eu/manuals>.

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

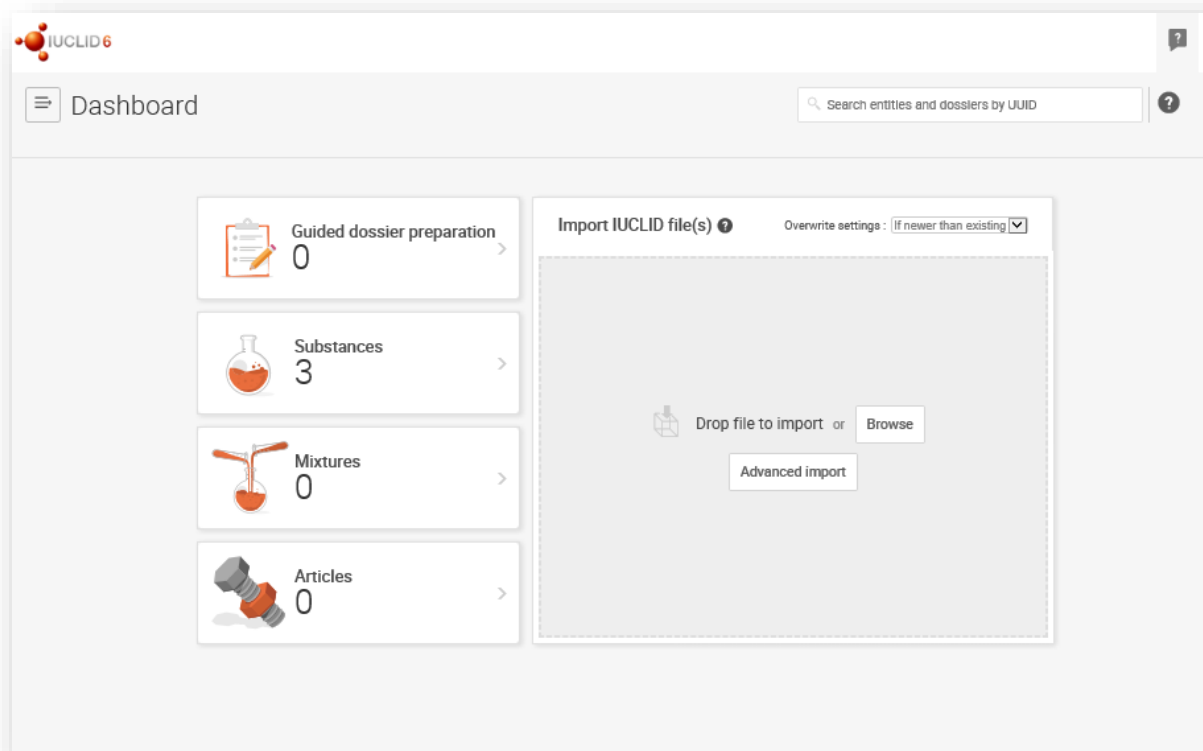
In this chapter an overview of the IUCLID web user interface's main new features is presented. The overview is intended both for new IUCLID users and for users who are already familiar with the classic version.

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 1.8 *The functionalities of IUCLID*).

### 1.6.1. 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.

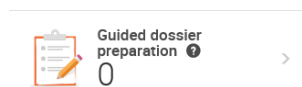
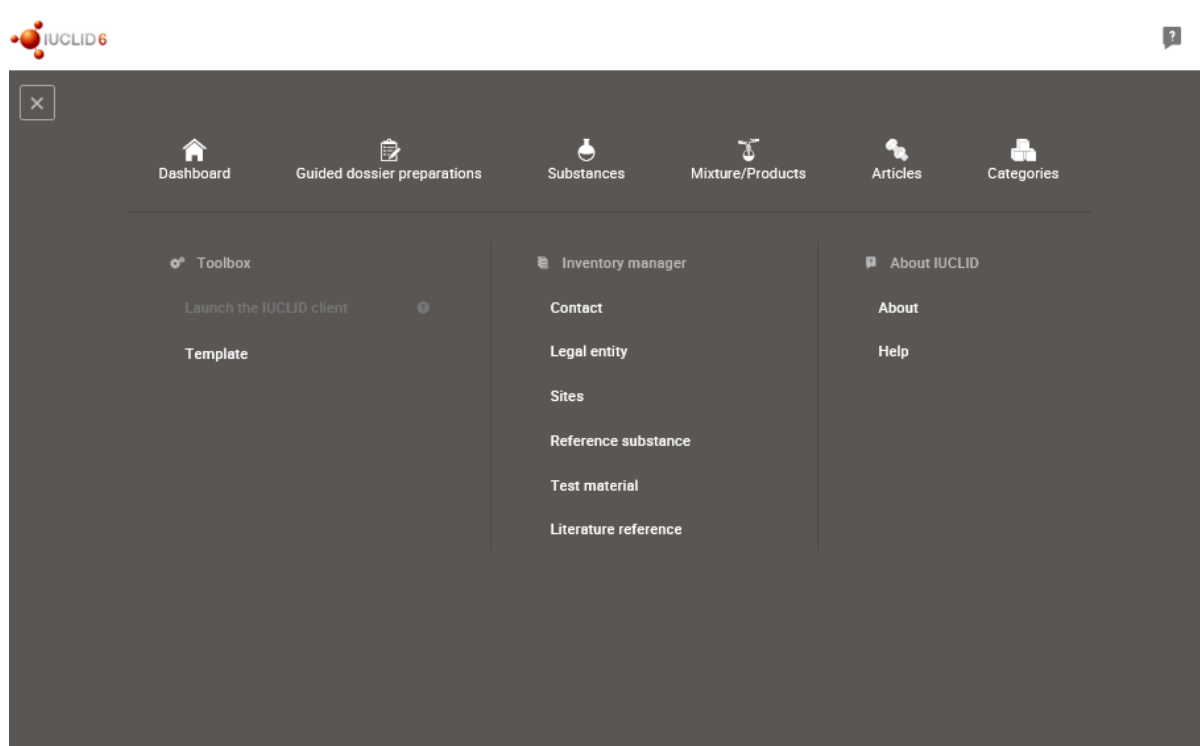


The round question mark icon opens the help system of IUCLID, a user manual presenting in details the functionalities of IUCLID in the web interface.



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**



This widget leads to the *Guided dossier preparation*. The *Guided dossier preparation* is a functionality that helps users to create a Dossier for submission under a particular regulatory programme. Currently, the *Guided dossier preparation* functionality is aimed for creating CLP Poison centres notification dossiers. It can also be used in the creation of REACH Registration dossiers of a limited scope; however the new web user interface offers a similar user experience with a broader set of functionalities.

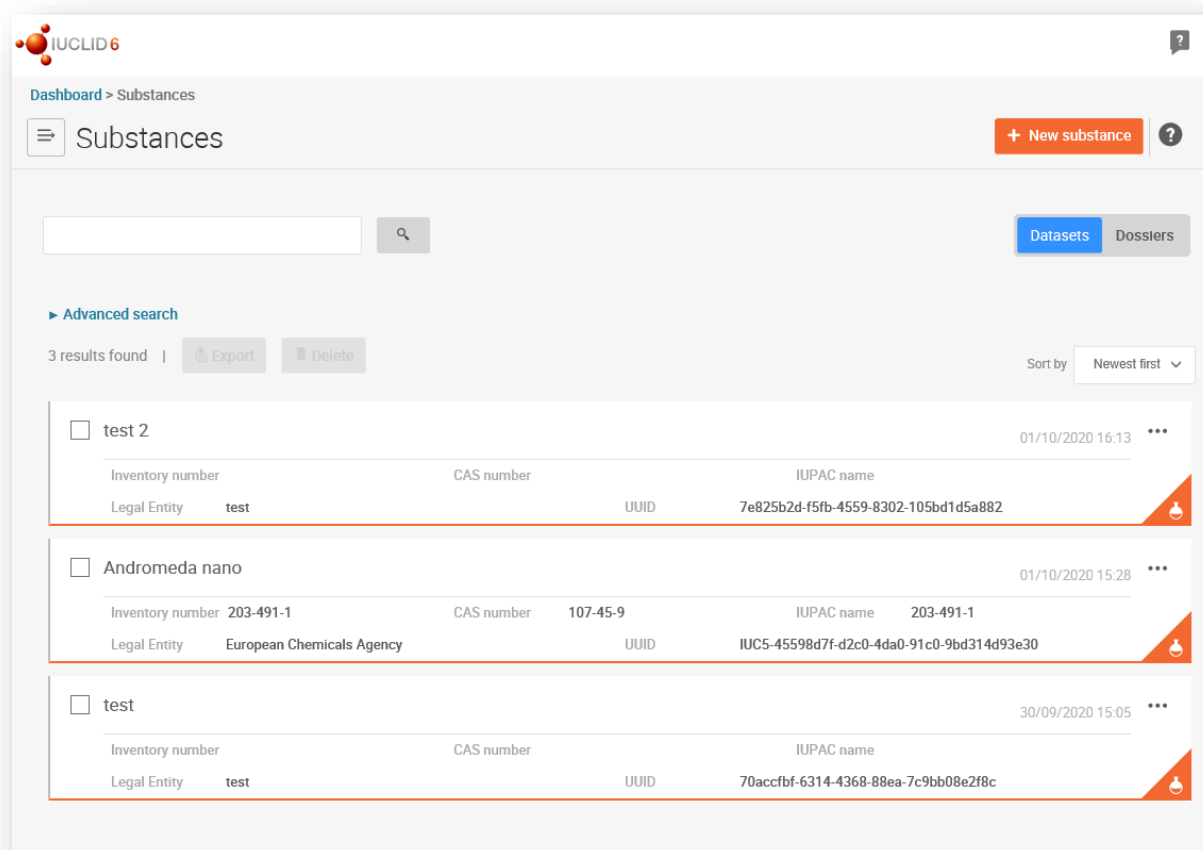


The widgets for *Substance*, *Mixtures* and *Articles* lead to lists of existing substances, mixtures and articles and the option to create new ones. The windows for Substances, Mixture and Articles that open by clicking on the widgets can each display either datasets or dossiers based on these entities.





## 1.6.2. The Substances list page

Figure 3: The Substances list page



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

 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.

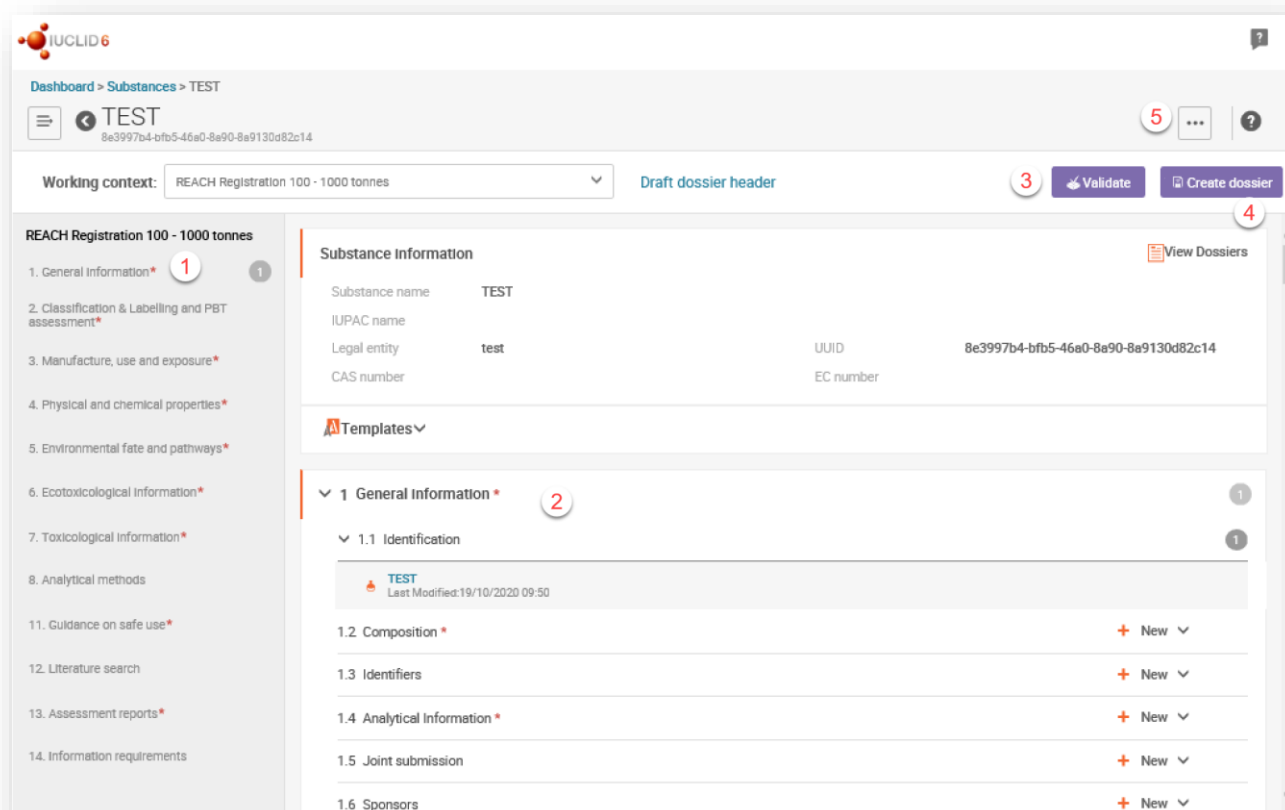
... The button labelled with three dots allows deleting or cloning an entity (substance, mixture or article) from the list. Please note that another button labelled with three dots is also displayed in the top of each Dataset page. For the functionalities included in the three dotted button of the Dataset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

### 1.6.3. The Dataset page


**Figure 4: The Dataset page of a Substance dataset with the working context (submission type) "REACH Registration 100-1000 tonnes"**



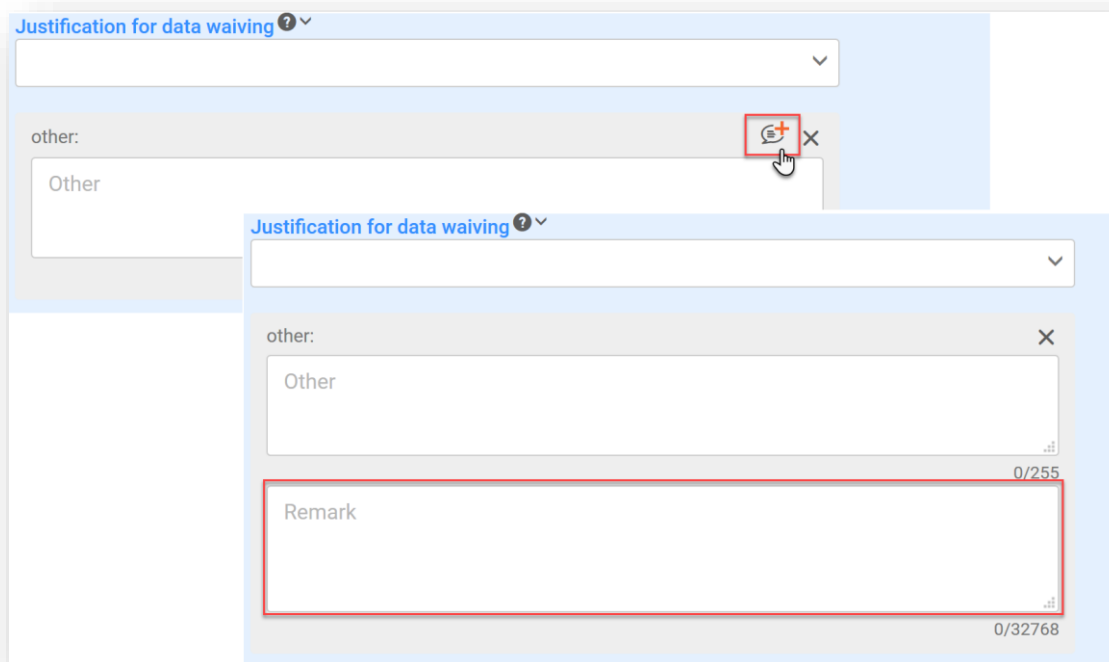
Depending on the working context (submission type) selected, IUCLID automatically displays the table of contents containing all sections that are relevant. The table of content is displayed on the left hand side of the screen (1).


The content of the dataset can be modified by filling the data of the fields of the various sections (2).

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

Some picklist fields - when the option 'other' is selected - has the possibility to add a remark by clicking on this icon  that appears above the selected field as shown in the figure below.

**Figure 5: How to 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 .

 **Validate**

The *Validation assistant* on a dataset is run by clicking on the button labelled *Validate* (3), 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* (4).



With the button labelled with three dots (5) at the right top of the Dataset page the following functions can be accessed: *Export to i6z*, *Create PDF*, *Generate report*, *Clone* and *Copy data from*.

### 1.6.4. The Dossier header

The page opening up 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 purple three dotted button  displayed next to *Create dossier*. The *Advanced settings* allow for example to include or exclude the Legal entity that is attached to the *Substance*, *Mixture* or *Articles*, or to select the documents to be included in the dossier outside of the default based on the submission type.

### 1.6.5. 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.

## 1.7. Confidentiality requests and publication of information

Certain IUCLID data can be flagged as confidential. If you wish to flag a document field, a section of a document, or an entire document as confidential, you must use the IUCLID *confidentiality request* flag for each request. Such requests are flagged by setting the confidentiality flags (  ) on the field, section or document that you wish to claim as confidential and providing a justification for the claim, explaining in detail why the publication of such information would be harmful to your business. You are strongly advised to use the justification template which appears after clicking the icon  **Insert existing templates** . There is no difference in the treatment of the confidentiality requests flagged as *Confidential business information* (CBI), *Intellectual property* (IP) or *Not publicly available* (no PA). The selected type is for information purposes only.

You can find more information on confidentiality requests and publication at <http://echa.europa.eu/manuals> or in the guide [How to protect your confidential business information](#)

Any confidentiality requests on information falling under **REACH Article 119(1)** are disregarded, as such information is always published.

In case of confidentiality requests relating to the information covered by **REACH Article 119(2)** a fee is incurred. Such requests must be accompanied by a full justification. In case of flags referring to information not covered by REACH Article 119(2), no fee is incurred.

To calculate the costs of confidentiality requests, you can use the Fee calculator. The Fee calculator is run from the application bar located at the top of the record for a Dossier. Click on the button labelled with three dots, and then select Calculate Fee. For more information on the Fee calculator, refer to the help system of IUCLID.


### 1.7.1. The Dissemination preview

The *Dissemination preview* has been developed in order to offer you a possibility to check which information from your dossier will be made publicly available on the ECHA website. It is strongly recommended to use the *Dissemination preview* before submitting your dossier to simulate which information will be published.

The *Dissemination preview* is run from the application bar located at the top of the record for a *Dossier*. Click on the button labelled with three dots, and then select *Dissemination preview*. For more instructions on the *Dissemination preview* refer to the help system of IUCLID.

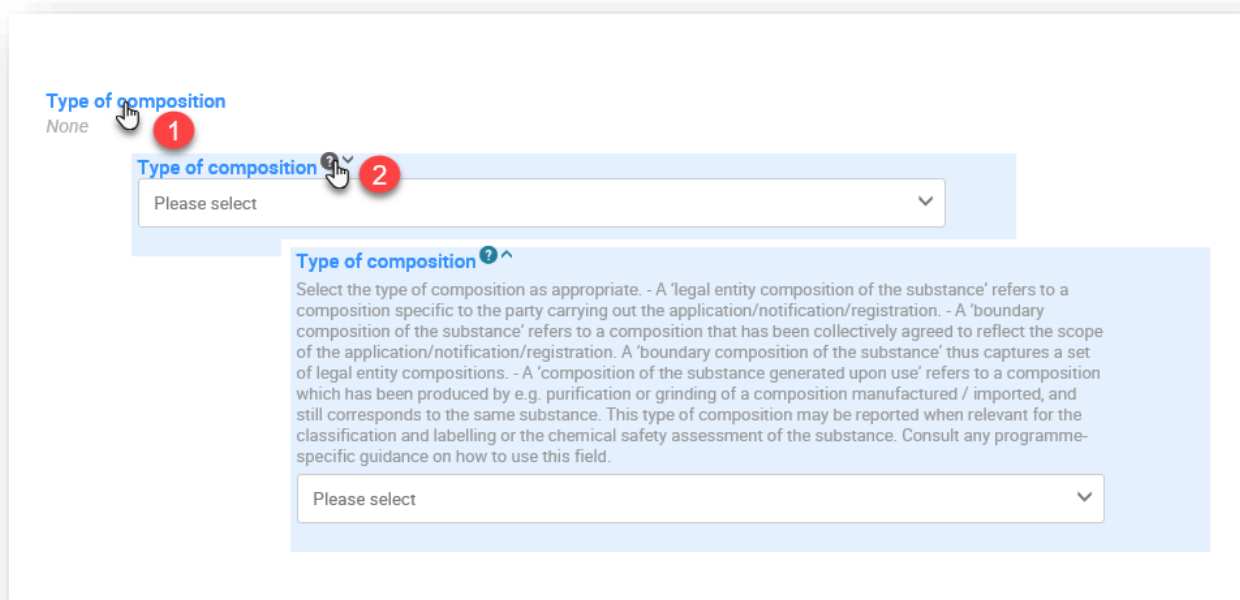
## 1.8. The functionalities of IUCLID

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 you have clicked on the selected field, as shown here below.

**Figure 6: 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 <https://ulem-web.echa.europa.eu/ulem-industry/views/selfregister/index.xhtml>.

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

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

entities either:

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

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

Please note that by the default settings the legal entity is not included in the dossier. If you wish to include the legal entity in your dossier, you can change the default settings during the dossier creation (see chapter 9 *How to create a Dossier*).

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

## 2.1. How to update and synchronise the LEO information

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

When you create a *LEO* a numeric identifier called Universal Unique Identifier (UUID) is generated. Example of a legal entity UUID: *IUC5-a620a92d-32c6-426a-b6ee-fc338cde0932*. The UUID is different for each *LEO*, even within the same company in case the company has several *LEOs*.

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

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

- IUCLID: Main Dashboard menu > Legal entity > find your legal entity.
- ECHA Accounts: *Legal Entity tab* > *General details* > *Legal Entity UUID*
- REACH-IT: *Menu* > *Company information* > *General information* > *UUID*

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

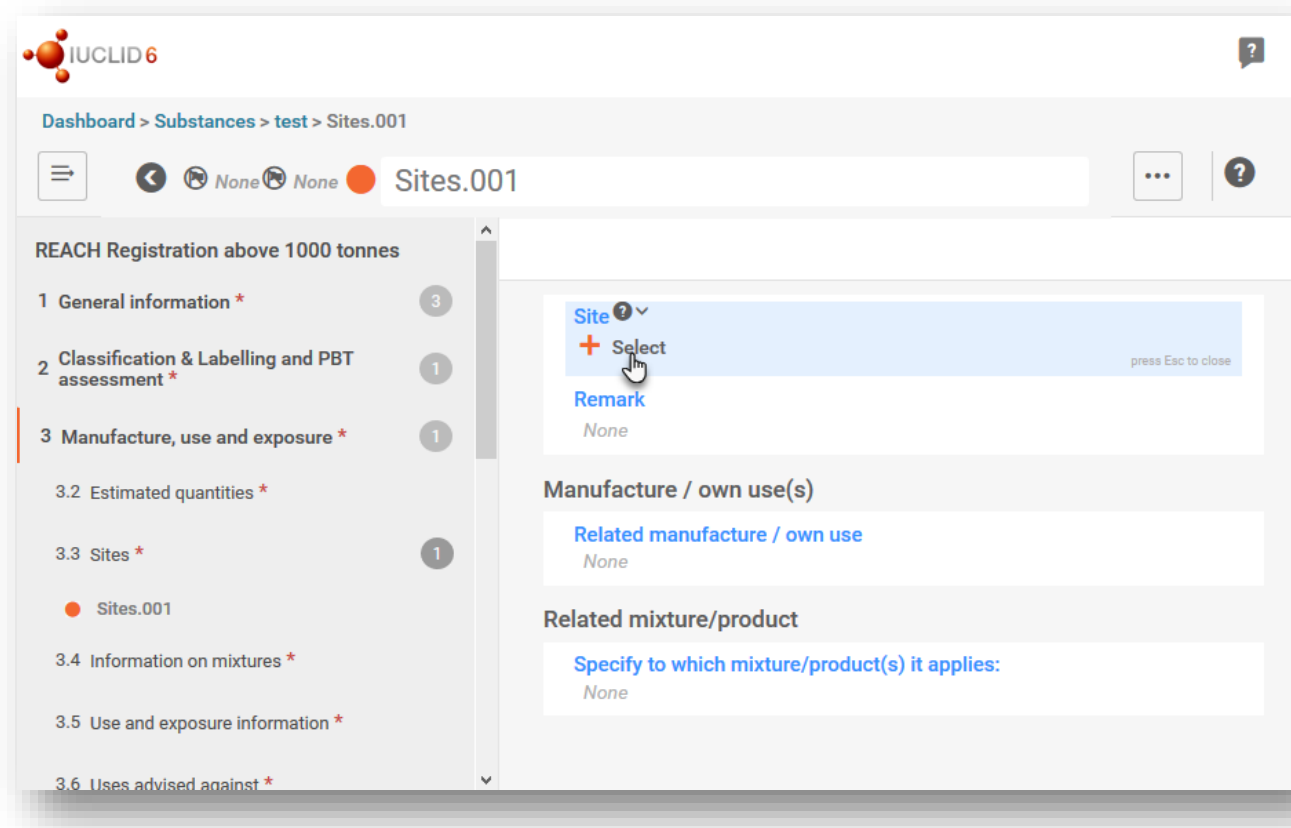
## 3. Legal entity sites (Sites)

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

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

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

**Figure 7: Link to Sites inventory from within the dataset**

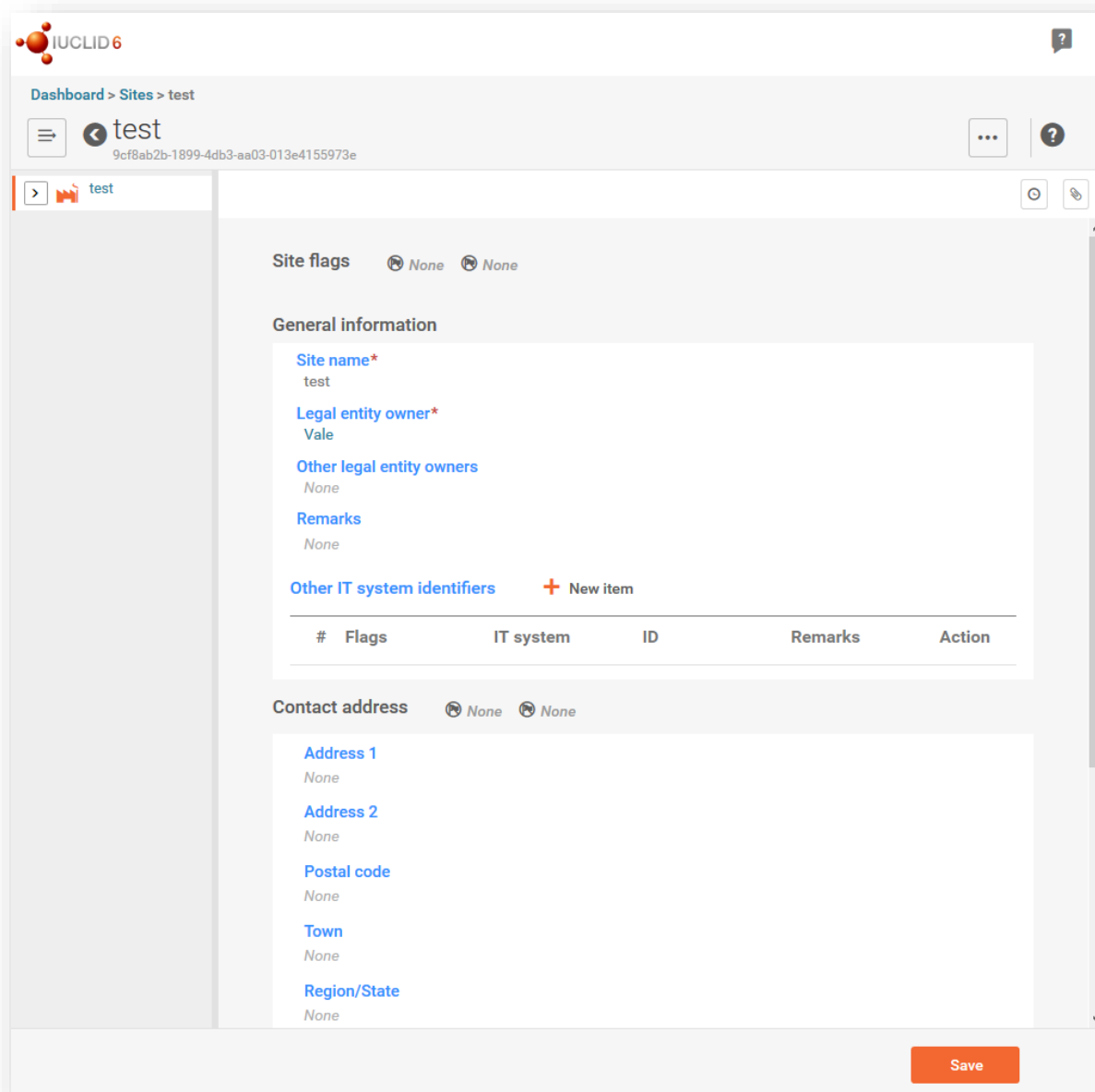


### 3.1. Creating a Legal entity site

To create a new site:

- Step 1.** In the pop-up window click on *New site / Create*.
- Step 2.** Complete as many fields as possible under the *General information* and *Contact address*. The minimum data required is the *Country* where the site is located.
- Step 3.** click *Save*.

Figure 8: Create a new Legal entity site





## 4. Contact

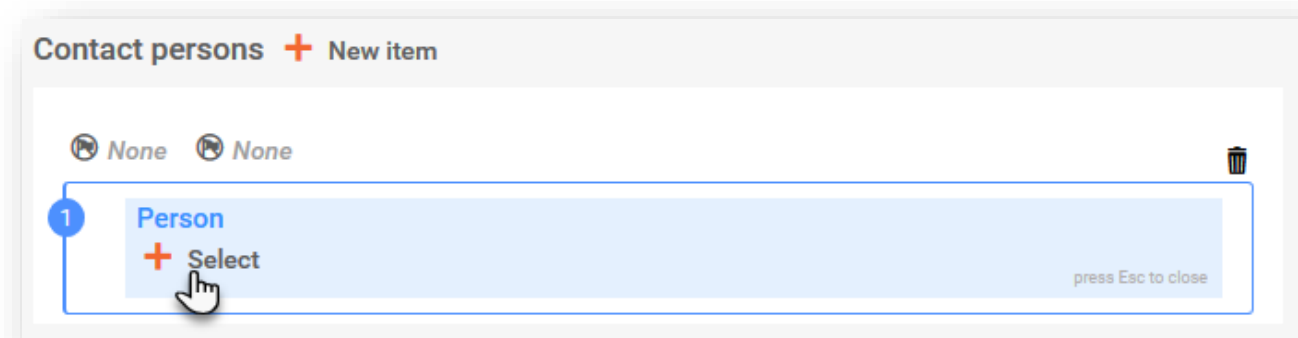
In the *Contact* inventory you can insert the contact details of the relevant competent persons, such as person responsible for the safety data sheet (SDS), toxicologist, etc, which can be attached to the IUCLID dossier. This person may be contacted to provide assistance or ask about the information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

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

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

1. from the list page of *Contacts* which can be accessed from the main Menu;
2. from the place where the *Contact* is referred to in a dataset. 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 9: 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 10: Create a new Contact**

The screenshot shows a web form for creating a new contact. The form is titled "General information" and is part of a window labeled "Test; ECHA". The form contains the following fields, each with a dropdown menu showing "None":

- Contact type
- Last name\*
- First name
- Organisation\*
- Department
- Title
- Phone
- Mobile
- Fax
- Email
- Address 1
- Address 2
- Postal code
- Town

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

## 5. Reference substance

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

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

To extend the number of entries in your inventory, you can search, download and import

available reference substances from the IUCLID website under the section *Support / Get Reference Substances* to your IUCLID web user interface. These pre-defined reference substances have been prepared to improve data quality and minimise data entry.

## 5.1. Creating a reference substance

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

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

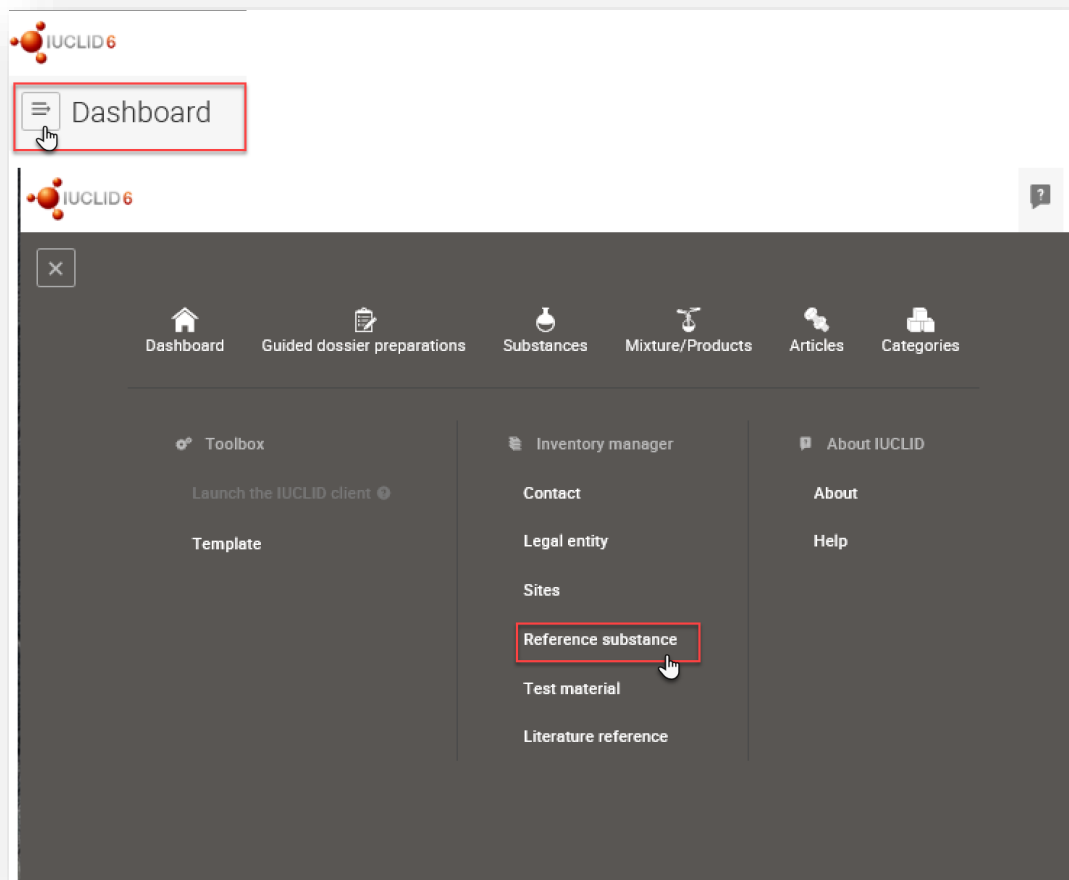
1. Information **specific** to the *reference substance*: such information exactly corresponds to the substance/constituent(s) covered by that reference substance;
2. Information **related** to the *reference substance*: this information does not accurately correspond to the substance/constituent(s) covered by that reference substance for any of the following reasons:
  - The information is generic as it also covers other substances/constituents;
  - The information only covers some of the constituents of a reference substance for a substance or a group of constituents;
  - The information refers to a similar constituent/substance;
  - The information is not the latest available information to identify the substance/constituent(s)

Related information should be reported under the *Identifiers of related substances* as it may create an ambiguity on the identity of substance or constituent(s) which a reference substance corresponds to.

The creation and editing of a *Reference substance* can be done from the point where the *Reference substance* is referred to in a dataset, or from the list page of *Reference substances*. Here below you find instructions on how to create a *Reference substance* from the inventory list page.

To open the list page for Reference substances click on the menu button in the top left corner of the Dashboard, and then click on *Reference substance* in the main menu as shown below.

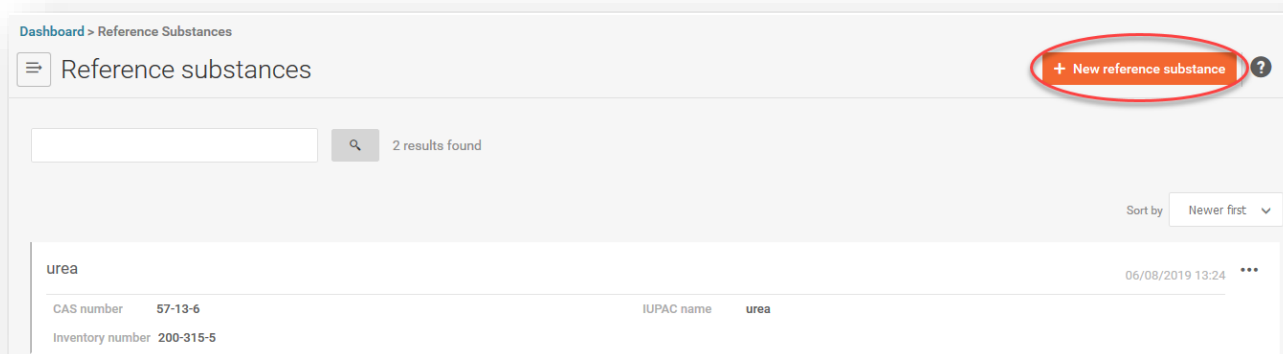
**Figure 11: Open the list page for Reference substances**



To create a new Reference substance:

**Step 1.** Click on *New reference substance*.

**Figure 12: The list page for Reference substances**



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

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

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

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

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

- *EC Inventory number*
- *CAS number and CAS name,*
- *IUPAC name (Note that, if a name following the IUPAC nomenclature cannot be derived, you should still provide a name defining the chemical nature of the substance or the constituents/impurities /additive which the reference substance describes),*
- *Description (Specify any additional information relevant for the description of the reference substance in this field. This is important especially when the reference substance does not correspond to a well-defined chemical substance. Attached files can be added if necessary.),*
- *Synonyms,*
- *Identifiers of related substances,*
- *Molecular formula (if a molecular formula cannot be derived from the reference substance, a justification should be indicated in the Remarks field at the bottom of the section);*
- *Molecular weight range,*
- *SMILES notation,*
- *InChI,*
- *Upload an image file with the Structural formula.*

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

## 6. Literature reference

In *Literature references* inventory you can insert and store different types of the bibliographic references, such as publications and the study reports which serve as the literature basis for the endpoint study records. Each literature reference stored in your inventory can be linked to the endpoint study records of sections 4 to 10 in IUCLID.

The creation and editing of A *Literature reference* is done either:

1. from the list page of *Literature reference* which can be accessed from the main Menu;
2. from the point where the *Literature reference* is referred to in a dataset.

### 6.1. Creating a literature reference

To create a new literature reference from the point where the *Literature reference* is referred to in a dataset (like an endpoint study record), click on *Select* in the *Reference* field under *Data source* (1). The link will take you to the Literature reference inventory. In the pop-up window click on *Create /New Literature reference* (2). Fill in the fields in the pop-up window (3) and click *Save* (4).

Figure 13: Create a new Literature reference (1)

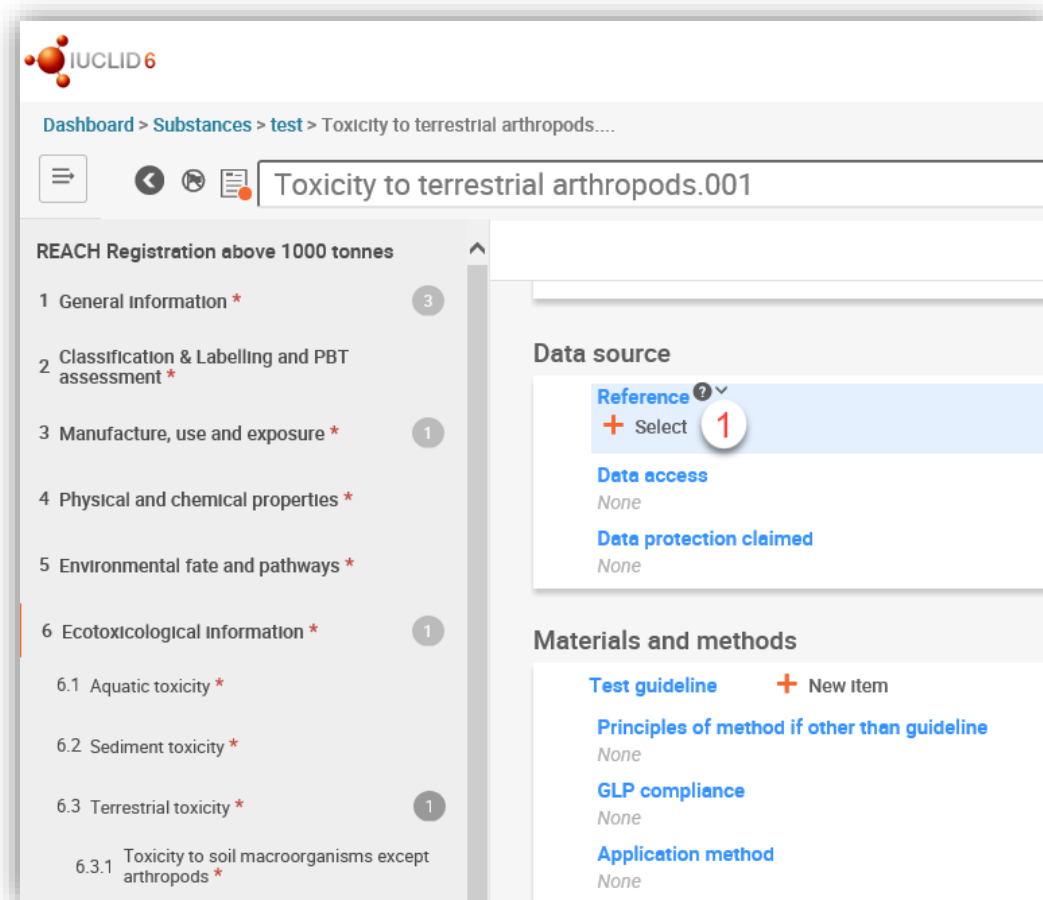
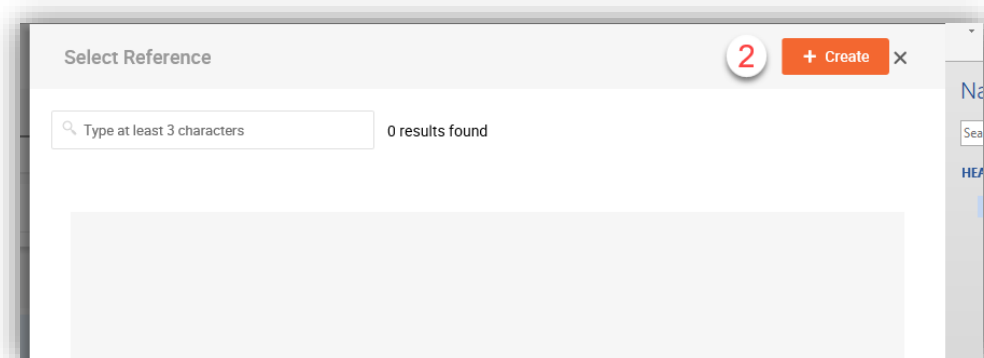


Figure 14: Create a new Literature reference (2)



**Figure 15: Create a new Literature reference (3)**

## 7. Test material

In the *Test material* record you can insert information on the identity of the material(s) used in the study(ies) reported in your dossier. Test material records stored in the inventory can be reused in each record where the same test material was used. A link can be made to a *Test material* entity from within an endpoint study record. In this way, the test material information can be centrally prepared and managed, and linked to the relevant endpoint study records.

Each Test material entry consists of a *Composition* to report the different constituents of the test material, similar to the information used to define a *Substance*. In addition, under *Other characteristics* the form of the test material can be provided as well as additional details on the test material such as and the possibility to provide.

The creation and editing of a test material is done either:

1. from the list page of *Test material* which can be accessed from the main Menu;
2. from the point where the *Test material* is referred to in a dataset. The link will take you to the Test material inventory.

## 7.1. Creating a test material


To create a new test material from the place where the *Test material* is referred to in a dataset:

- Step 1.** Click *Select* in the Test material information field. Then click *Create / New test material*.
- Step 2.** Enter the same *Name* which is given in the study record where the test on the material has been performed.
- Step 3.** Use the table under the *Composition* to report the *constituents, impurities, additives* of the test material. Identify the reported components by linking the corresponding *Reference substance* and insert their *Concentration*. To insert a new entry under the *Composition* click on *New item*.
- Step 4.** If the details on the purity of the composition are not known, you can provide a qualitative statement by selecting the appropriate value from the *Composition / purity: other information* picklist.
- Step 5.** When the Test material is used to identify the chemical structure used in a (Q)SAR prediction, information on the concentration is not relevant. Instead, the value *not applicable for in silico study* should be selected under *Composition / purity: other information* in addition to the specified *Composition*.
- Step 6.** Under the *Other characteristics* you should insert information about the form of the test material and more details as appropriate.
- Step 7.** To save the test material click on *Save*.



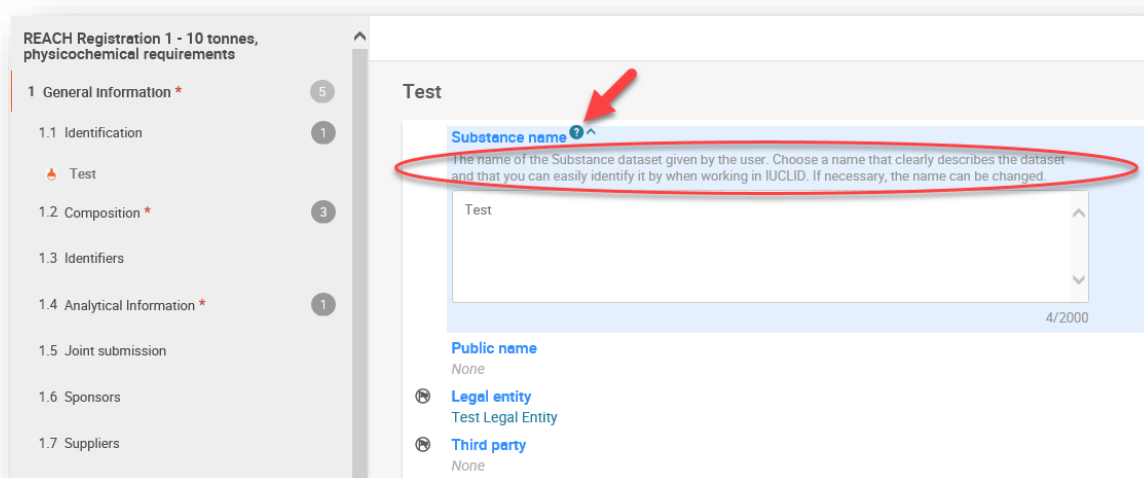
## 8. How to create a substance dataset

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

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

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

**Figure 16: How to get further support on the use of fields**



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

### To create a dataset:

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

**Step 2.** Fill in the field *Name* for your new substance. Especially if your IUCLID contains several datasets, ensure to enter a name that you can easily use to distinguish the substance. Then click *Create*.

**Step 3.** Once you receive the message that the substance has been successfully created, click *Open*.

**Step 4.** You are now presented with a view of your substance dataset with the *Complete table of contents* displayed on the left-hand side of the screen.

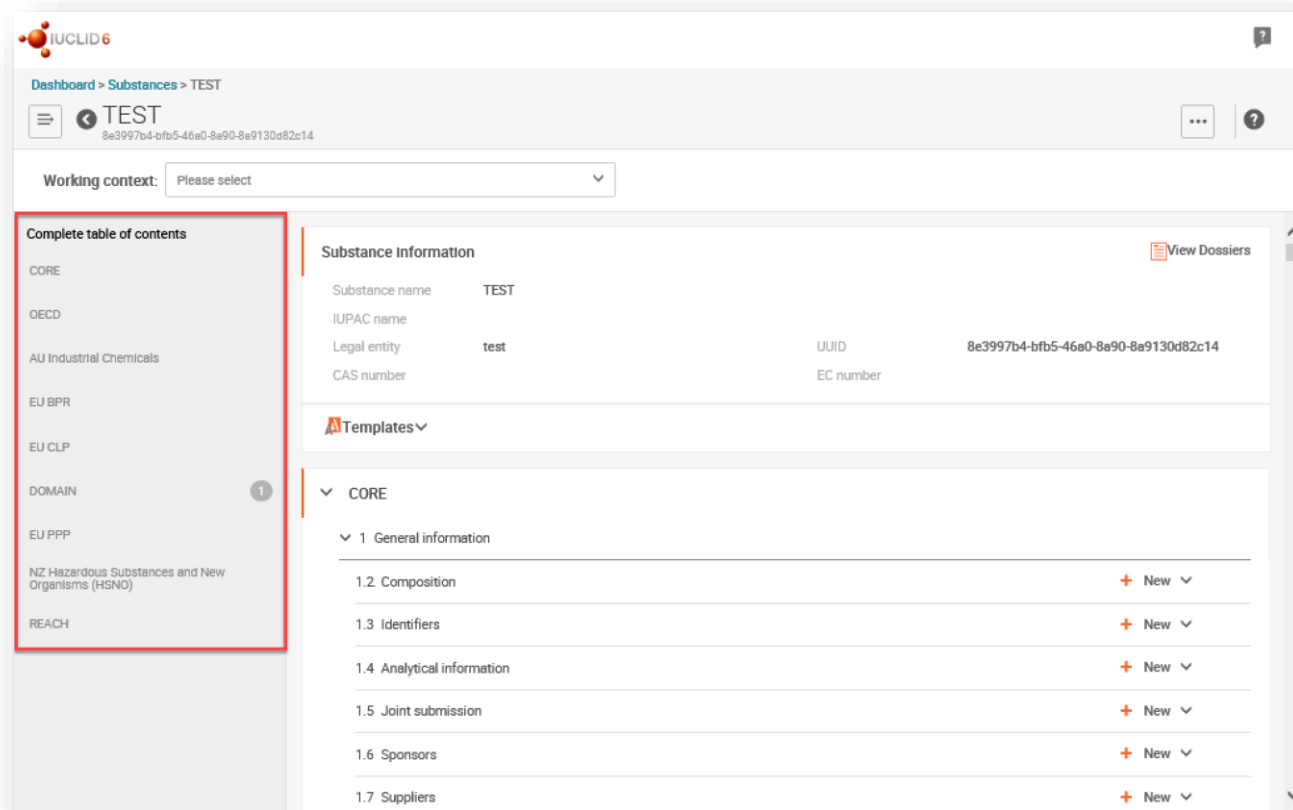
Please note that all the datasets that you have created (or imported) can be accessed from the Substances page. To open a substance dataset click on the selected substance among those displayed in the list. In case you have several dataset, you can search the substance you wish to view by typing into the query box either the substance name, the CAS or EC number of the substance, or its IUPAC name. Alternatively, the *Advanced search* can be used.

**Figure 17: Substances page - list of substances**

The screenshot shows the IUCLID6 Substances page. At the top, there is a search bar and a '+ New substance' button. Below the search bar, there are tabs for 'Datasets' and 'Dossiers'. A section for 'Advanced search' is visible, showing '3 results found' and buttons for 'Export' and 'Delete'. The results are sorted by 'Newest first'. The list contains three entries:

Substance Name	Inventory number	CAS number	IUPAC name	Legal Entity	UUID	Date
test 2				test	7e825b2d-f5fb-4559-8302-105bd1d5a882	01/10/2020 16:13
Andromeda nano	203-491-1	107-45-9	203-491-1	European Chemicals Agency	IUC5-45598d7f-d2c0-4da0-91c0-9bd314d93e30	01/10/2020 15:28
test				test	70accfbf-6314-4368-88ea-7c9bb08e2f8c	30/09/2020 15:05

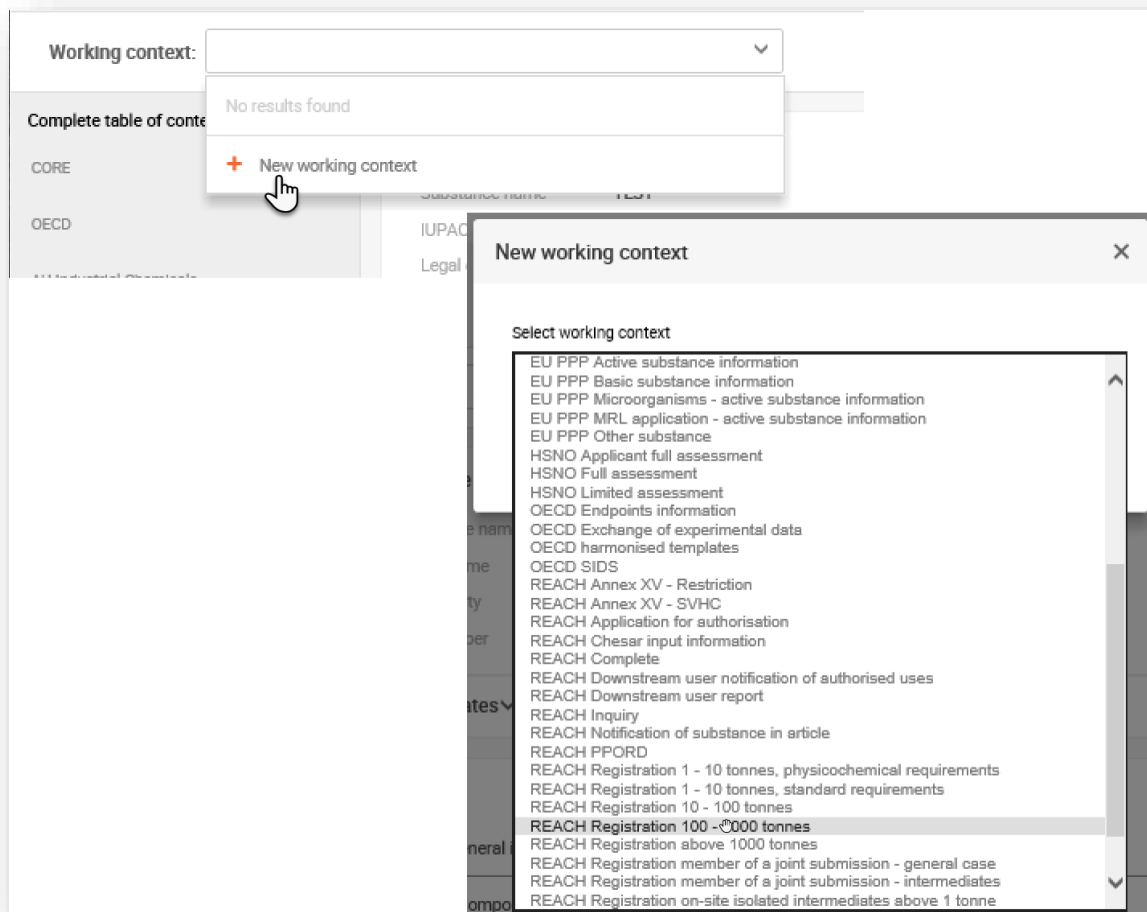
**Figure 18: View of substance dataset with complete table of content (TOC)**



**Step 5.** To view the table of contents that is relevant for the type of dossier that you are preparing, click on the *Working context* query box and then click on *New working context*.

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

**Figure 19:** An example of selecting the working context from the picklist



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

For information on how to fill the data in the *Dossier header*, please see the dedicated section under the chapter 9 *How to create a Dossier*.

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

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

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

## 8.1. Templates

A *Template* allows data from multiple sections to be copied or linked to a *Substance* dataset all at once without having to manually recreate all sections and to retype the data. Its structure is very similar to that of a substance dataset. Templates can be accessed from the *Main menu*.

A template can be used in two different ways:

**Inherit:** in this case a link is established between a substance and a template. The data managed in the template can only be edited in the template itself but is visible in the substance dataset together with the other data. When modifications are made in the template, they are immediately reflected in the substance dataset to which the template is linked. The same template can be linked to different substances which then share a common set of data.

**Copy:** in this case the documents part of the template are copied to the substance dataset. There is no link between the documents in the template and the documents copied in the substance. After the copy, the documents in the template and in the substance dataset are not synchronised anymore. A document copied in this way can be modified in the substance to which it was copied. Even if the template is completely deleted the data in the substance dataset are not affected.

For more information on *Templates* refer to the help system of IUCLID.

## 8.2. Categories

For the substances whose physicochemical and toxicological properties are similar or follow a regular pattern as a result of structural similarity, a *Category* in IUCLID can be created and included in the dossier. These structural similarities may create a predictable pattern in any or all of the following parameters: physicochemical properties, environmental fate and environmental effects and human health effects.

Grouping the chemicals in terms of their similarity could be based on the following:

- common functional group (e.g. aldehyde, epoxide, ester, metal ion, etc.);
- common precursors or breakdown products (e.g. the "metabolic pathway approach" of examining related chemicals such as acid/ester/salt);
- incremental and constant change across the category (e.g. a chain-length category);
- common constituents or chemical class.

A chemical category is defined by a list of chemicals (the category members) and by a set of properties and/or effects for which experimental and or estimated data are available or can be generated (the category endpoints). For each category member, a separate substance dataset in IUCLID has to be created, in which all relevant data are entered.

Data gaps in a chemical category can be filled by using various approaches, including simple read-across, trend analysis (interpolation and extrapolation) and computational methods based on SARs, QSARs or QAARs.

More information on how to use these methods to fill data gaps is available on the ECHA website: <https://echa.europa.eu/practical-guides>, <https://echa.europa.eu/support/grouping-of-substances-and-read-across> and <https://echa.europa.eu/support/oecd-qsar-toolbox>.

For all information needed on how to create a dossier based on category refer to the help system built-in IUCLID.

### 8.3. Section 1 General information

In section 1, *General information*, enter information on substance identity and the submitting party in the different sections as explained below.

#### 8.3.1. Section 1.1 Identification

Section 1.1 contains the identification of the substance, role in the supply chain and the type of (reference) substance. To complete this section, follow the steps:

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

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

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

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

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

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

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

#### Identification of substance:

**Step 5.** Click in the *Reference substance* field under *Identification of substance* and then click *Select* to identify your reference substance.

**Step 6.** Search for your reference substance and click on it.

If you cannot find your reference substance because it has not been created yet, click *Create*

and create it (see chapter 5 *Reference substance*).

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

- **Mono-constituent substances:**

A **mono-constituent substance** is a **well-defined substance** for which one constituent is present at a concentration of at least 80 % (w/w). This constituent is the main constituent of the substance. The substance is named according to the chemical name of that main constituent.

If your substance is a **mono-constituent** substance, assign the *reference substance*<sup>4</sup> corresponding to the main constituent in section 1.1.

- **Multi-constituent substances:**

A **multi-constituent substance** is a **well-defined** substance for which more than one constituent is present at a concentration between 10 % and 80 % (w/w). These constituents are the main constituents of the substance. A multi-constituent substance is normally named as a *reaction mass* of the main constituents.<sup>5</sup>

If your substance is a **multi-constituent** substance, assign the *reference substance*<sup>6</sup> corresponding to the reaction mass of the main constituents of your substance in section 1.1.

- **UVCB substances:**

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

If your substance is a **UVCB** substance, assign a *reference substance*<sup>7</sup> corresponding to the UVCB substance in section 1.1.

### Type of substance:

**Step 7.** Select the appropriate *Type of substance* from the picklist. For submissions of registrations under REACH, you can only select between mono-constituent substance, multi-constituent substance and UVCB (the options *polymer* and *other:* are not relevant).

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

**Step 8.** Select the *Origin*, e.g. organic or inorganic, from the picklist.

<sup>4</sup> Note that for the reference substance: *Molecular formula*, *Molecular weight range* and *Structural formula* must be provided. In addition, the *SMILES notation* should also be provided if available.

<sup>5</sup> 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".

<sup>6</sup> Note that the chemical name of the multi-constituent substance must be reported in the IUPAC name field of the reference substance. This applies even if the naming convention "reaction mass of" does not follow the IUPAC nomenclature. Note also that the *Molecular formula*, *Molecular weight range* and *Structural formula* of the reference substance must be provided or a justification for not providing this information must be given in the *Remarks* field. In addition, the *SMILES notation* should also be provided if available.

<sup>7</sup> Note that the chemical name of the UVCB substance must be reported in the IUPAC name field of the reference substance. This applies even if the naming conventions for UVCB substances do not follow the IUPAC nomenclature. Note also that the *Molecular formula*, *Molecular weight range* and *Structural formula* of the reference substance must be provided or a justification for not providing this information must be given in the *Remarks* field. In addition, the *SMILES notation* should also be provided if available.

**Step 9.** If relevant, you can include additional identifiers for your substance under *Other substance identifiers*. Such identifiers may include Trade names of the substance, identifiers by which the substance was previously known but have later been replaced/refined, or identifiers which are used to identify the substance under other regulatory schemes. Chemical (scientific) synonyms should not be listed here, but should be indicated in the reference substance information.

**Step 10.** You can add information of the contact person(s) for this substance from the previously defined contacts (see chapter 4 *Contact*). A new contact can also be created by clicking *Select* on the *Person* field and then *Create*. An example of a contact to be added here is the competent person responsible for the Safety Data Sheet (SDS) of the registered substance.

#### **Role in the supply chain:**

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

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

### **8.3.2. Section 1.2 Composition**

In this section, you will report the identity and concentration of the constituents of the composition, including any impurities and additives. The state and form of your composition(s) is reported in this section.

Additionally, in this section you can indicate if your registration dossier cover nanoforms and fill in information on their characterisation parameters. For more information please refer to the manual *How to prepare registration dossiers covering nanoforms* at <https://echa.europa.eu/manuals>.

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

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

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

**Step 1.** Click on the *New* button displayed on the right-hand side of the screen, in the row corresponding to *1.2 Composition*.

**Step 2.** Click on *New document*.

**Step 3.** Fill in the composition as described below.

#### **General information:**

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



For more information on how to name the substance, please refer to the *Guidance for identification and naming substances under REACH and CLP* available at: <https://echa.europa.eu/guidance-documents/guidance-on-reach>

- Step 2.** The default selection in the *Type of composition* field is *legal entity composition of the substance*. This refers to a composition manufactured, imported or used by the registrant/notifier/applicant. Each dataset should contain at least one composition of this type. Only modify this value where you intend to report a composition with a different purpose. For more information on what composition types that can be reported for that submission please refer to the specific instructions for the submission type that you are preparing, you can find more explanations below.
- Step 3.** You must 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.
- Step 4.** You can give more detailed information on the composition under the *Description* field. This is particularly important when several compositions are reported in order to clarify the differences between them. Providing further considerations on how the composition has been defined is also advisable when the composition covers wide concentration ranges or polymorphs or isomers. For substances that cannot be described with well-defined and quantified constituents (e.g. UVCB substances), further information to identify the composition is provided in this field, including the identity of the starting materials and a description of the production process used to manufacture the substance (see Table 2).

**Table 2: Example of the manufacturing process of a UVCB substance that should be reported in the 'Description' field**

Description	
<b>Identity and ratio of starting materials</b>	Soybean oil (EC#232-274-4) and methanol (EC# 200-659-6, purity 99%) are used in a molar ratio of 1:4 respectively.
<b>Description of the relevant manufacturing steps in the order they occur (including information on the reaction steps/mechanisms)</b>	Step 1: loading of the reactants in the batch reaction vessel Step 2: loading of the catalyst in the batch reaction vessel Step 3: transesterification reaction Step 4: extraction with water Step 5: distillation of the organic phase Step 6: collection of the residue from the distillation process.  Please see the attached process workflow.
<b>The relevant operating parameters applied to control the composition (e.g. temperature, pressure, solvent, catalysis type...)</b>	Step 1: no relevant parameter Step 2: the catalyst used is sodium hydroxide (EC# 215-185-5) Step 3: the reaction is carried out at 50oC and is monitored every 5 hours by gas chromatography (GC-FID). The reaction is stopped when the concentration in the methyl esters formed during the reaction represents at least 75% (w/w) of the reaction medium. Step 4: the extraction is carried out until the glycerol is removed in full. It involves a drying step of the organic phase. The drying method does not contaminate the

	<p>organic fraction.</p> <p>Step 5: the distillation is carried out under vacuum (0.05 bars). Several distillates are collected. The last distillate fraction from the distillation column boils in the range corresponding to 335-350°C at atmospheric pressure. The residue from this process is the registered substance</p> <p>Step 6: no relevant parameter.</p>
<b>Extraction/isolation steps (if applicable)</b>	The registered distillation residue is directly isolated from the distillation equipment.
<b>Clean-up/purification steps (if applicable)</b>	Not relevant. The substance is a waxy solid that is not further purified.

**Step 5.** In the *Justification for deviations* field, provide where relevant, the justification for deviating from the rules for reporting the composition of substances as specified in the legal text and indicated in the *Guidance for identification and naming of substances under REACH and CLP* available at <https://www.echa.europa.eu/web/guest/guidance-documents/guidance-on-reach>.

**Step 6.** You can provide supporting attachments under the *Attached description/ Justification*. Note that under *Attached description/ Justification* you can attach information that complements the description of the manufacturing process for a UVCB substance, for example reaction schemes and process workflows. Additionally, you can attach information that complements justifications for deviating from standard requirements for reporting your substance. However, in this case please pay attention that the rationale must be provided in the *Justification for deviations* field.

## Types of composition

In IUCLID 6, the composition record contains the field *Type of composition*. This field allows users to indicate more precisely the nature of the composition they are providing. The field will be automatically populated with the value *legal entity composition of the substance* during migration or when creating a new record. This type of composition is expected to reflect the composition of the registered substance as manufactured/imported by the registrant and is an information requirement subject to completeness check. The first legal entity composition record will be used by REACH-IT to determine the substance identity of the registration.

Other composition types available are *boundary composition of the substance* (see below for more information), and *composition of the substance generated upon use*.

A *composition generated upon use* is a composition/form of the registered substance generated in the supply chain by processes other than manufacture such as purification or generation of nanoform from bulk form by mechanical process. This composition generated upon use should only be reported when it refers to the same substance. Identifying such compositions/forms enables transparent reporting of the properties of the various compositions (classification and labelling, fate and hazard assessment) when those are different. You may use assessment entities for that (see chapter 8.3.9 *Assessment approach*). It also enables clear identification of the uses relevant for each composition. See also paragraph on connecting the compositions to the hazard information below.

- **Boundary composition of the substance for lead registrants**

IUCLID 6 enables registrants in a joint submission to report the substance identity information that should be common to the legal entity compositions for which they are jointly submitting the Annex VII-X information and the related classification and assessments. This information is reported in the format of a so-called *boundary composition of substance*. This type of

composition is also known as the Substance identification profile (SIP, as published by Cefic<sup>8</sup>). The number of boundary compositions provided in one dossier will depend on the variability of the compositions registered by the different joint submission participants and the fate and hazard profiles of these compositions. If one information profile (physicochemical, fate and hazard information) covers all the compositions reported in **section 1.2 by all the participants of the joint submission**, it is sufficient that one *boundary composition* is defined in the lead registrant dossier, covering all the legal entity compositions in the joint submission.

Boundary compositions should be reported in the lead registrant dossier. Information provided in boundary composition records is extracted to the REACH-IT Joint submission page and displayed to participants of the joint submission. Boundary compositions are subject to certain business rule checks during submission, which verify that minimum information is present: at least one constituent must be provided, and for each constituent, impurity and additive a reference substance with identifiers, and a concentration range must be given. For UVCB substances, a description of the starting material and process that defines the UVCB composition must be indicated.

Registration dossiers for joint submission member registrants, or dossiers for a substance with no joint submission, are not expected to contain boundary compositions.

### Related composition:

**Step 7.** Provide related compositions whenever relevant.

This *Related composition* functionality enables you to define the logic links existing between the compositions reported in a registration:

- If you are the **lead registrant**, for each legal entity composition you report, select the relevant boundary composition in the *Related composition* field by clicking the *Select* button.
- If you are a **member registrant**, for each legal entity composition you report, include the Name of the relevant boundary composition submitted by the lead registrant in the *Reference to related composition(s)* field.

The *Name* of a boundary composition submitted by the lead registrant is extracted to the REACH-IT Joint submission page and displayed to participants of the joint submission.

Please refer to the help system of IUCLID for more information on this section.

### Degree of purity:

**Step 8.** 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.

**Step 9.** Note: The degree of purity should correspond to the overall concentration of the (main) constituents in the composition.

<sup>8</sup> <http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/>

**Figure 20: Degree of purity**

**Constituents:**

**Step 10.** Include the *constituents* for the composition. Each composition must have, as a minimum, one constituent. The number of constituents to be reported will depend on the type of substance. To add more constituents, click on *New item*, and then the new rows will appear.

**Step 11.** Assign a *reference substance* to the newly created constituent. Search for the appropriate reference substance by clicking *Select*. Once you have found the appropriate reference substance click on it to select it; alternatively, create a new reference substance to specify the constituent (see chapter 5 *Reference substance*). Ensure that the reference substance contains a chemical name in the IUPAC name field, and the appropriate EC and CAS identifiers, as available. To create a new reference substance click *Create*.

**Step 12.** Indicate the *Typical concentration* and the *Concentration range* (minimum and maximum values, and unit of measurement) for every constituent.

**Figure 21: Reporting constituent**

### Impurities and additives:

**Step 13.** To complete the information regarding *Impurities* and *Additives* follow the same procedure.

**Step 14.** Where the impurity or additive is considered relevant for classification and labelling of the substance, the relevant checkbox must be selected.

**Step 15.** The function of each *additive* has to be provided by making a selection in the picklist *Function*. Only selections beginning with the word *stabiliser* are applicable under REACH and CLP.

To report **unknown impurities**, create a generic reference substance (see chapter 5 *Reference substance*) and insert in the *IUPAC name* field the phrase *unknown impurities*. In the *Remarks* field of the impurity block, specify the nature, number and relative amounts of the impurities as far as possible. Also provide the *Typical concentration* (with unit of measurement) and *Concentration range* (with unit of measurement) for the *unknown impurities*.

**Figure 22: Reporting unknown impurities**

The screenshot shows a web interface titled 'Impurities'. At the top left, there is a '+ New Item' button. Below it, a form entry is displayed with a blue border and a close button (X) at the top right. The form contains the following fields:

- Reference substance:** Unknown impurities
- Typical concentration:** ca. 0.05 % (w/w)
- Concentration range:** >= 0.04 <= 0.08 % (w/w)
- Remarks:** 3 unknown organic impurities for which the individual concentration does not exceed 0.03% according to the HPLC analysis (see section 1.4). Based on the fragmentation pattern in the HPLC-MS analysis (see also section 1.4), the structure of these impurities might include one chlorine and two bromine atoms
- This impurity is considered relevant for the classification and labelling of the substance

**Figure 23: Reporting additive**

The screenshot shows a web interface titled 'Additives'. At the top left, there is a '+ New Item' button. Below it, a form entry is displayed with a blue border and a close button (X) at the top right. The form contains the following fields:

- Reference substance:** 4-tert-butylbenzene-1,2-diol / 4 tert-butylbenzene-1,2-diol / 98-29-3 / 202-653-9
- Typical concentration:** ca. 0.01 % (w/w)
- Concentration range:** >= 0.005 <= 0.02 % (w/w)
- Function:** stabiliser: inhibitor
- Details of function in composition:** The stabiliser is added to styrene in order to prevent its polymerisation
- Remarks:** None
- This additive is considered relevant for the classification and labelling of the substance

When reporting information on the composition, where there is any deviation from the rules for identifying a mono-constituent, multi-constituent or UVCB substance, you will need to provide explanations for the deviations in the field *Justification for deviations*. Such deviations include, for example, reporting a mono-constituent composition that includes a main constituent with a concentration of less than 80 %.

The composition to be reported depends on the substance type:

### **Mono-constituent substances:**

**For mono-constituent** substances, you have to complete the following information:

- Report only the main constituent under the *Constituents* in section 1.2. Assign the same reference substance for this constituent as in section 1.1;
- Report individually any impurities under the *Impurities* in section 1.2;
- Report any additive necessary to stabilise your composition under the Additives in section 1.2. Specify the stabilising function of the additive from the picklist Function;
- Report the concentration range (both minimum and maximum values) and the typical concentration for the main constituent, any impurity and any additive;  
Note: The typical concentration and concentration range values reported for the main constituent of a mono-constituent substance should normally not be less than 80% (w/w)<sup>9</sup>;
- Report a degree of purity for your composition corresponding to the concentration range of the main constituent.

### **Multi-constituent substances:**

For **multi-constituent** substances, you have to complete the following information:

- Report the main constituents under the *Constituents* in section 1.2.  
Note: The main constituents should be the same for all compositions reported;
- Report any other constituent below 10% under *Impurities* in section 1.2;
- Report any additive necessary to stabilise your composition under *Additives* in section 1.2. Specify the stabilising function of the additive from the picklist *Function*;
- Report the *concentration range* (both minimum and maximum values) and the *typical concentration* for the main constituents, any impurity and any additive. Note: The typical concentration and concentration range values of each main constituent should normally be  $\geq 10$  and  $< 80\%$ <sup>10</sup>;
- Report a *degree of purity* for the composition corresponding to the overall concentration range of the main constituents.

<sup>9</sup> Any deviation from the "80% rule" should not be applied, unless a valid justification is provided. This justification should be provided in the Justification for deviations field for each composition where such a deviation is applied.

<sup>10</sup> Any deviation from the "80% rule" should not be applied, unless a valid justification is provided. This justification should be provided in the Justification for deviations field for each composition where such a deviation is applied.

### **Registration of individual constituents of a multi-constituent substance:**


Under specific circumstances (see the *Guidance for identification and naming of substances under REACH and CLP*), you may register the individual constituents of multi-constituent substances instead of the multi-constituent substance itself.

In this case, select mono-constituent in the field *Type of substance*, and proceed as follows:

- Assign a reference substance corresponding to the constituent you are registering in section 1.1;
- For technical reasons, report the composition of the corresponding mono-constituent substance as the first composition with the composition type *legal entity composition* in section 1.2;
- If you also manufacture or import such a mono-constituent substance, you should report the composition of that substance as the first composition;
- If you do not manufacture or import such a mono-constituent substance, you still need to report a composition corresponding to the mono-constituent substance as the first composition in section 1.2. In this case we recommend you to report a theoretical composition where the main constituent is reported at a typical concentration of 100%(w/w). Select *legal entity composition* of the substance as the *type of composition*. Insert in the field *Description* the considerations for using the approach to register the multi-constituent substance through its individual constituents, as well as the following statement: "This composition is neither manufactured nor imported. It is only reported for technical reasons because the registration of the multi-constituent substances through their individual constituents is applied";
- Report all the multi-constituent compositions that you manufacture/import where the constituent, to which the registration dossier refers, is present. Include the following statement in the field *Justification for deviations*: "Composition of a multi-constituent substance covered by the registration of its individual constituents".

### **UVCB substances:**

For **UVCB** substances, you have to complete the following information:

- Report the description of the manufacturing process, as well as other information relevant for the substance identification, in the field *Description*;  
Note: To facilitate the reporting of the manufacturing process, suggestions as to what to enter are provided in free text templates for the field *Description*. To open the free text templates, click on the icon that shows the letter A with an arrow at the bottom right,  **Insert existing templates**. A pop-up window appears. Click *Option 2: Composition of a UVCB substance* or *Option 6: Composition of a petroleum UVCB substance* depending on the type of your UVCB substance. The text should then be edited so that it contains only the relevant data;
- Report the appropriate individual constituents or groups of constituents under *Constituents*. To provide compositional information, you must not reuse, in section 1.2, the reference substance already assigned for your substance in section 1.1, but report individual constituents or groups of generic constituents based on their chemical nature.

- Do not report any constituent under the *Impurities* of the composition (impurities are not considered relevant for UVCBs);
- Report any additive necessary to stabilise your composition under *Additives*. Specify the stabilising function of the additive;
- Report the concentration values of the individual constituents, groups of constituents and any additive as a concentration range (both minimum and maximum values) and typical concentration.
- Report the appropriate degree of purity for your UVCB substance (the degree of purity should normally be 100% for UVCBs which do not include any additive, as the concept of *impurity* is not considered relevant for these substances).

### **Reporting the characterisation of nanoforms:**

This sub-section is filled in when 'solid: nanoform' has been selected in the *State/form* picklist for that composition. It includes fields to report key characteristics of compositions that are nanoforms. For more information on how to fill in this section please to the manual *How to prepare registration dossiers covering nanoforms* at <https://echa.europa.eu/manuals>.

### **Reporting the characterisation of polymers:**

This sub-section should not be filled under REACH regulation at present.

### **Connecting the composition(s) to the hazard information when several fate/hazard profile are covered by the registration.**

When more than one composition is reported in section 1.2, it is important to clarify whether they correspond to one or more fate/hazard profiles (properties of the substance reported in sections 2 and 4 to 7 of the IUCLID dossier).

If the registration covers more than one fate/hazard profile, in order to transparently report the properties for the various compositions, it is strongly recommended to define assessment entities (see chapter 8.3.9 *Assessment approach – assessment entities*). In addition, in such case, it is important that you create the relevant links between the various IUCLID records to make clear which fate/hazard data are relevant for which compositions. For that you should link the following records to the composition:

- A Classification and Labelling record in section 2.1;
- A PBT summary in section 2.3 (if a CSR is required);
- One or more assessment entity records in section 1.10.

For joint submissions several boundary compositions should be defined in the lead dossier, each covering those legal entity compositions sharing the same fate/hazard profile. The links mentioned above have to be made to the boundary compositions.

For individual submissions, those links have to be made to the legal entity compositions.

If a composition generated upon use is part of a substance dataset those links have to be made to it as for the cases above.

### **8.3.3. Section 1.3 Identifiers**

In this section you can insert identifiers for regulatory programmes. In particular, this section should be used to report the following identifiers when available: REACH registration number,



REACH pre-registration number, REACH inquiry number, notification number (NCD), CLP notification number.

To enter your data:

- Step 1.** Click the *New item* button under *Regulatory programme identifiers* and then click on the generated row.
- Step 2.** Depending on the type of submission, select the appropriate identifier from the *Regulatory programme* picklist.
- Step 3.** Enter the relevant number in the *ID* field.
- Step 4.** If you need to provide more than one programme identifier, create a new item by repeating the previous steps.
- Step 5.** To save the information click *Save*.

### 8.3.4. Section 1.4 Analytical information

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

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

- Step 1.** In the row corresponding to *1.4 Analytical information* click on *New* button displayed on the right-hand side of the screen.
- Step 2.** Click on *New document*.

To complete this section, follow the steps:

#### Methods and results of analysis:

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

- Step 3.** Fill in the information on the analytical methods and results.

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

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

Identification refers to any analysis carried out to establish the identity of the constituents,

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

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

**Figure 24: Analytical determination**

Analytical determination <span style="float: right;">+ New Item</span>							
#.	Purpose of analysis	Analysis type	Type of Information p...	Attached methods/re...	Rationale for no results	Justification	Remarks
1	identification and/or quantification	✓ other.migrated information	methods	None	other: fgbfgfg	bbgbgfb	None
2	identification and/or quantification	✓ other.migrated information	results	None	other: bgfbgf	bgfbgf	None
3	quantification	✓ ion chromatography	methods	<a href="#">Doc3_second test.doc</a>	None	None	None
4	identification	✓ NMR	methods and results	<a href="#">Doc4_second test.docx</a>	None	None	None

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

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

#### Related composition(s):

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

In addition, in this section you can provide analytical data for nanoforms under the heading *Analytical determination for nanoforms*, for more information refer to the manual *How to prepare registration dossiers covering nanoforms* at <https://echa.europa.eu/manuals>.

### 8.3.5. Section 1.5 Joint submission

In this section you (regardless if you are the lead or a member of a joint submission) may wish to indicate, for your own administrative purposes, the name and some further details of the joint submission that this substance refers to in the corresponding fields. To enter your data, you must first create a new record.

### 8.3.6. Section 1.7 Suppliers

If the checkbox *Only representative* is selected in section 1.1 Identification, then you are advised

to attach clear documentation of your appointment as the only representative (e.g. a copy of the appointment letter which was sent to importers) in the field *Assignment from non EU manufacturer*. In this case, you are also advised to indicate the list of the importers' names covered by your registration in the field *Other importers*. To enter your data, you must create a new record.

### 8.3.7. Section 1.8 Recipients

This section only needs to be provided for **PPORD notification dossiers**. You can indicate the identity of all the customers in the PPORD activity, including their names and addresses. To enter your data, you must create a new record.

### 8.3.8. Section 1.9 PPORD

This section only needs to be provided for **PPORD notifications dossiers**. When you are creating a dataset for PPORD notification you must create a new record and fill in the following information:

- Step 1.** Enter the *Name* for the PPORD activities for which the notification is prepared.
- Step 2.** Report the *Estimated quantity* of the substance to be manufactured, imported or used in the production of an article for the purpose of PPORD for the calendar year of the notification.
- Step 3.** This estimation can be provided as an exact or approximate tonnage, or as a tonnage range. However, it is important to provide as specific tonnage information as possible.
- Step 4.** In the *Remarks* field you can provide additional information you consider relevant for the PPORD notification dossier, such as the Research and Development programme or other relevant information (as information related to requirements under Article 9.4 provided because of a request decision or spontaneously provided).
- Step 5.** You can provide an attachment for any other information you consider relevant for the PPORD notification dossier. For example, you can attach a document justifying the request for extension of a PPORD.

### 8.3.9. Section 1.10 Assessment approach (assessment entities)

To prepare your registration dossier you need to have an understanding on the properties and the life cycle of your substances in order to determine your assessment approach. This is particularly relevant if you are registering a substance above 10 tonnes per year, and therefore you have to perform a Chemical Safety Assessment. In a standard safety assessment, the fate and effect properties of a substance are characterised by one set of values. However, there are cases where more than one set of values for the fate and effect properties may be needed (for more details see the *Guidance on Chemical Safety Assessment part D*, chapter D.2). If several sets of properties are needed to assess your substance, then to transparently report the information in your registration dossier you are advised to create assessment entities (see *Annex 5: Assessment entities in IUCLID 6* for more information). For that:

- Step 1.** Open *section 1.10 Assessment approach (assessment entities)*.
- Step 2.** Provide information on the assessment approach to fate/hazard followed, describing the overall reasoning used for the definition of the assessment entities.

**Step 3.** Select the relevant type(s) of assessment entity and create a new record. Provide all necessary information and links to better understand your substance.

In any case, you are advised to provide information in the field *Approach to fate/hazard assessment* in section 1.10 even if no assessment entities need to be created. Such information will be reported in section 1 of the CSR.

**The following chapters provide you with information on the different sections of IUCLID relevant for a registration dossier.**

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

There are two sections in IUCLID for entering information relating to classification and labelling, 2.1 GHS and section 2.2 DSD - DPD. 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 Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) introduces throughout the EU system for classifying, labelling and packaging chemicals, based on GHS.

**DSD** is the abbreviation for Dangerous Substances Directive (Directive 67/548/EEC).

**DPD** stands for Dangerous Preparations Directive (Directive 1999/45/EC).

The **CLP Regulation** has replaced DSD and DPD in a stepwise approach. Further information on CLP is available on our website at [https://echa.europa.eu/clp\\_en.asp](https://echa.europa.eu/clp_en.asp).

Note that when reporting hazards, the fields have a default selection in the field *Reasons for no classification* as *Data lacking*, in order to report a hazard category, the selection needs to be changed to the blank entry to allow the editing of the other fields.

### 8.4.1. Section 2.1 GHS

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

It is highly recommended to consult Annex I of the CLP Regulation for the classification criteria and the following guidance document for more detailed instructions on the application of the C&L criteria available at <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp>.

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

To create a new record:

- Step 1.** In the row corresponding to 2.1 GHS, click on the *New* button displayed on the right-hand side of the screen.
- Step 2.** From the picklist select *New document*.
- Step 3.** A new record to report the classification and labelling information is created.

Harmonised classification has to be respected and you should not modify any of those harmonised hazard classes/differentiations. Exception is made in the case that there is data based on which a stricter classification (hazard classes and/or differentiations) could apply. Therefore, if your substance has a harmonised classification for some hazard classes/differentiations, you should classify for other hazards according to available and reliable data and upgrade the harmonised classification towards a stricter classification, if necessary.

To complete this section, follow the steps:

#### **General information:**

- Step 1.** Enter a descriptive *Name* for the GHS record. This is particularly relevant in the case that multiple GHS records are created, to easily distinguish the different records.
- Step 2.** If you submit a dossier for a substance which is not classified you should select the checkbox *Not classified*. In this case, you should not enter any *Hazard category* or *Hazard statement* in the GHS record.
- Step 3.** 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 it refers to a self-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 must select a *Hazard category* and *Hazard statement* for each hazard class of differentiation, otherwise, you must fill in the *Reason for no classification*.

Note that the fields 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.

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 is tested with the appropriate high quality reflected in the study or where other high quality information is available, and based on that, it is concluded that the classification criteria are not fulfilled.
- *hazard class not applicable* should be selected in cases where a substance has a physical state (e.g. liquid) which is not compatible with the physical hazard class under evaluation (e.g. Flammable Solid).

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

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

**Note that the CLP regulation foresees certain waivers:**

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

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

**and interconnections:**

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

### Classification - Physical hazards:

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

The CLP Regulation implements the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). However, not all the hazard categories and corresponding hazard statements from the GHS have been implemented into the CLP regulation. Therefore, please note when populating IUCLID section 2.1 - GHS that not all the available entries are relevant for CLP (e.g. Flammable liquids/Flammable liquid 4/H227: Combustible liquid).

### Classification - Health hazards:

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

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

Reproductive toxicity  
Reproductive toxicity

**Hazard category**  
Repr. 1A

**Hazard statement**  
H360: May damage fertility or the unborn child <state specific effect if known > <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

**Reason for no classification**  
data lacking

**Specific effect**  
H360F May damage fertility

**Route of exposure**  
Oral

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 *Add 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 26: Specify the hazard of carcinogenicity via inhalation**

Carcinogenicity  
Carcinogenicity

**Hazard category**  
Carc. 1A

**Hazard statement**  
H350: May cause cancer <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.

**Reason for no classification**  
data lacking

**Route of exposure**  
Inhalation

H350



**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 and Affected organs, otherwise, the field Reason for no classification should be filled in.

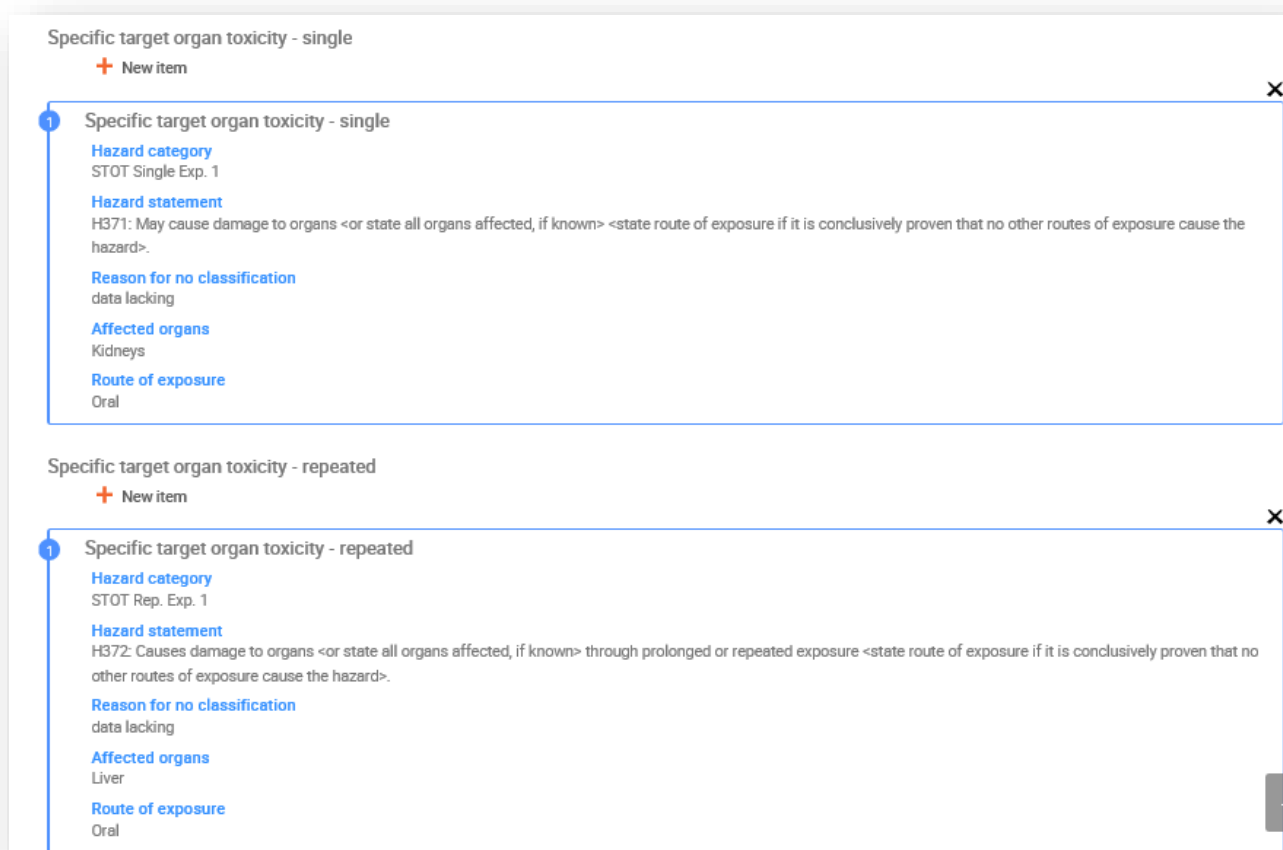
For practical reasons, it is not recommended to include more than three primary target organs. If more target organs are affected it is recommended that the overall systemic damage should be reflected by the phrase 'damage to organs'.

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 section 13 (unless it is already specified in Annex VI to the CLP Regulation).

**Figure 27: 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 Eye Irritation 2B	H320
Aspiration hazard	Asp. Toxicity 2	H305
Germ cell mutagenicity	Muta. 1*	*
Carcinogenicity	Carc. 1*	*
Reproductive toxicity	Repro. 1*	*

\* Please note that for the purposes of classification the CLP regulation requires the hazard categories Muta. 1, Carc. 1 and Repro. 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 (%)* and in addition, you also need to indicate the relevant *Hazard categories*.

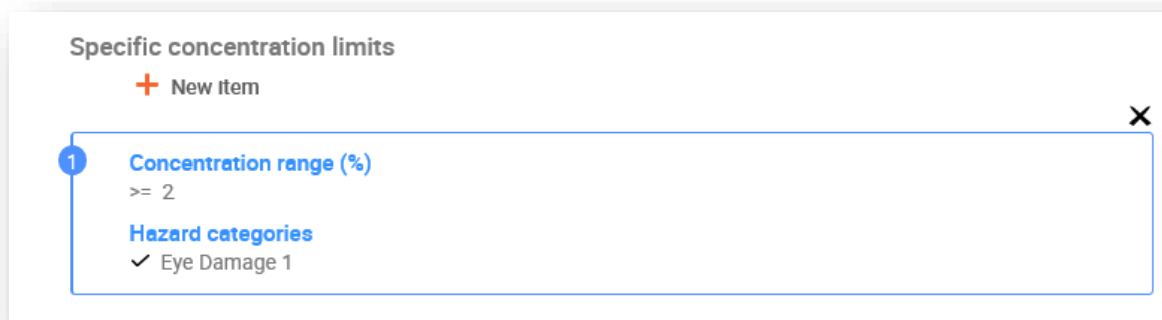
You can specify more than one concentration limit by adding additional entries. To add additional entries click *New item*.

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

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 28: 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 - Environmental hazards:**

**Step 11.** Specify *Hazard category* (e.g. Aquatic Acute 1) and *Hazard statement* (e.g. H400: Very toxic to aquatic life) for the *Environmental hazards* by selecting the appropriate values from the picklists.

The CLP Regulation implements the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). However, not all the hazard categories and corresponding hazard statements from the GHS have been implemented into the CLP regulation. Therefore, please note when populating IUCLID section 2.1 - GHS that the following entries under the environmental hazards 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 29: Specify the Environmental hazards

#### Environmental hazards

##### Aquatic environment

##### Hazardous to the aquatic environment (acute / short-term)

###### Hazard category

Aquatic Acute 1

###### Hazard statement

H400: Very toxic to aquatic life.

###### Reason for no classification

data lacking

##### Hazardous to the aquatic environment (long-term)

###### Hazard category

Aquatic Chronic 1

###### Hazard statement

H410: Very toxic to aquatic life with long lasting effects.

###### Reason for no classification

data lacking

#### M factor

##### M-Factor acute

10

##### M-Factor chronic

100

### Classification – Ozone layer:

**Step 12.** Select *Hazardous to the ozone layer 1* in the field *Hazard category* and the *Hazard statement H420* if the substance is classifiable as such.

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

### Labelling:

**Step 13.** 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 14.** If applicable, please select a *Hazard pictogram* from the picklist. You can select more than one pictogram by adding a *New item*.

**Step 15.** You should select at least one *Hazard statement* from the picklist and provide *Additional text* where applicable or, if no hazard statement applies to your substance, then you need to select *No hazard statement*.

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

**Figure 30: Labelling for section 2.1**

**Labelling**

**Signal word**  
Danger

**Hazard pictogram**  
+ New item

1 **Code**  
GHS01: exploding bomb

**Hazard statements**  
+ New item

1 **Hazard statement**  
H200: Unstable explosives.  
**Additional text**  
None

TOP

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

According to Art. 27 of CLP Regulation, some hazard statements are not required in the label 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.

<b>Hazard classification</b>	<b>Associated hazard statement(s)</b>	<b>Associated hazard statement that should appear on the label</b>
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.

<b>Hazard statement (in Labelling section):</b>
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 16.** If applicable, please select a *Precautionary statements* from the picklist.

**Step 17.** If applicable, please specify the *Additional labelling requirements*. These include supplemental CLP hazard statements and additional labelling elements resulting from

the application of CLP Article 25. Please consult the CLP Regulation and Guidance for further information on the additional labelling requirements.

**Notes:**

**Step 18.** If applicable, you can select note(s) from the picklist.

#### **8.4.1.1. C&L within a joint submission**

The dossiers of the lead and the members of a joint submission have to be clear and transparent as to which classification belongs to which composition.

The lead registrant dossier contains the information on the collectively registered substance, namely information on the intrinsic properties of the substance, and the resulting classification and labelling agreed among the members. The lead dossier also contains the boundary composition(s) of the substance, outlining the compositions and forms of the substance covered by the joint registration. It is therefore expected, that in the lead dossier, the C&L information is related to the boundary composition(s).

When multiple C&L records exist in section 2.1, and multiple compositions (of any type) exist in section 1.2, then the relations between these must be made explicit by linking them.

Joint submission member dossiers, where the forms and compositions registered by the member fall within the boundary compositions of the lead dossier, and therefore are covered by the agreed classification provided by the Lead, are not expected to contain C&L information.

There may be situations where joint submission participants (member or lead) wish to provide C&L information that is not in line with that agreed by the members and provided in the lead dossier for the collectively registered substance. In this case, the party wishing to provide the differing C&L should provide it in his own dossier as opted-out information (see chapter 8.9.2 *Opt-out information for REACH registration*), and link each of the C&L records to the particular composition(s) it relates to. Such a composition would be of the type *legal entity composition of the substance*, if it is a particular composition manufactured or imported by that registrant, but not covered by the boundary composition of the substance. In specific cases, it could also be a *composition of the substance generated upon use*, if the composition is not manufactured/imported, but subsequently produced by e.g. purification or physical processing of the substance.

#### **8.4.2. Section 2.2 DSD-DPD**

After entry into force of the CLP Regulation (GHS) on December 1, 2010, providing classification information in section 2.2 according to Directive 67/548/EEC (DSD) is optional. However, if you do include this section in your dossier, the information in it must be complete. For more information refer to the Annex 2 *Overview of the completeness check performed by ECHA on the submitted dossiers* of this manual.

#### **8.4.3. Section 2.3 PBT assessment**

In this section a persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment of the substance should be provided by all registrants who need to conduct a chemical safety assessment (CSA) and report the relevant scientific data in the chemical safety report (CSR) (see chapter 8.8 *Assessment reports*).

The PBT endpoint study record (●) is the place where to report the assessment of the PBT properties of the substance itself, or of one or a group of constituents or a transformation product

if relevant. To report a PBT assessment for any of the above a new record has to be created:

**Step 1.** In the row corresponding to *2.3 PBT assessment* click on *New* button displayed on the right-hand side of the screen.

**Step 2.** Select *Endpoint study record*. A new record to report a new PBT assessment is created. You have to repeat the operation if you need to create several records for several (group of) constituents/impurities/additives or transformation products.

When filling in the endpoint study record please ensure that the conclusions reported for each individual property (P,B and T) are consistent with the conclusion reported for the substance (or (group of) constituents or transformation product) assessed in the record. In case the conclusion is that the substance is not PBT then ensure that there is at least the justification that one of the criteria is not met (e.g. the substance is not persistent).

In case PBT assessment does not apply for that substance (e.g. inorganic substances), there is no need to create an endpoint study record but to report this in an endpoint summary (see below).

The final conclusion on the PBT assessment is to be reported and summarised in the endpoint summary (2).

**Step 3.** In the row corresponding to *2.3 PBT assessment* click on *New* button displayed on the right-hand side of the screen.

**Step 4.** Select *Endpoint summary*. A new record to report a new PBT summary is created.

In the endpoint summary, you must select the appropriate option from the *PBT status* picklist. If you select option *PBT assessment does not apply*, then you must provide the relevant information in the *Justification* field.

In case you select the option *the substance is PBT/vPvB* or *the substance is handled as if it were a PBT/vPvB substance* it is important to remember that the next step of the PBT assessment is to characterise the emissions and demonstrate minimisation of releases in your CSR. Also the likely routes of exposure by which humans and environment are exposed to the substances should be summarised in the field *Likely routes of exposure*.

Ensure that the final conclusion reported in the endpoint summary takes into account and is consistent with the conclusions for the substance itself, for all the constituents or transformation products when relevant, reported in the endpoint study record(s).

When different compositions have different PBT status, several PBT summaries can be created. A link from the PBT summary to the composition record is then to be made to clearly identify the PBT status of the various compositions (see also the section 8.3.2 on composition).

The objective of the PBT Section 2.3 in IUCLID is not to repeat information already provided in other IUCLID sections and therefore a reference to other sections can be made in the justification fields for the various criteria.

In case of a joint submission, the PBT assessment (records and summary) should be submitted by the lead registrant on behalf of the members, unless the Chemical safety report is not submitted by the lead on behalf of (some of the) members of the joint submission. In that case each member should submit the PBT assessment. When submitted in the lead dossier, the PBT information is to be related to the boundary composition(s).



More information on the different fields of this section is available in the help system of IUCLID.

## 8.5. Section 3 Manufacture, use and exposure

This chapter contains information on how to report the manufacture and uses of the substance as well as information on conditions of use in a IUCLID dossier as specified under section 3 of Annex VI of REACH Regulation. Each section of IUCLID is explained in a separate subchapter including practical instructions.

When preparing a **PPORD notification dossier** you can use this section to indicate the *Sites* where the PPORD activity of the notifier takes place.

### 8.5.1. Section 3.2 Estimated quantities

Use this section to report the information of the tonnage manufactured, imported and used as such or in articles that is a subject to registration per calendar year.

To enter your data, you must create a new record per each calendar year that you want to report.

You can refer to the help system of IUCLID for more explanation on what each tonnage field means.

Where you are a part of a **joint submission** for the substance, you cannot submit a dossier for a higher tonnage band than the maximum tonnage band of the joint submission (defined by the template of the lead dossier) unless you opt-out from the tonnage band of the joint submission. To increase the tonnage band of the joint submission, the lead has to update the lead dossier.

The estimated quantities reported in this section 3.2 should be consistent with the tonnages reported for each use in section 3.5 and the tonnages in the dossier header (tonnage bands) for both the tonnage requiring a full registration (Article 10) and the tonnage registered under article 17/18. More information on reporting tonnages is available in Annex 6 *Overview of tonnage fields in IUCLID*.

#### 8.5.1.1. Special considerations for intermediate use(s)

Please note that uses of intermediates for which strictly controlled conditions in the meaning of REACH Articles 17 and 18 cannot be demonstrated, should be reported as any other use in a full registration (REACH Article 10) in both IUCLID sections 3.2 *Estimated quantities* and 3.5 *Use and exposure information* and should also be accounted for in the exposure assessment and risk characterisation in the Chemical Safety Report. Hence, the fields *Tonnage used as intermediate under strictly controlled conditions (transported)* and *Tonnage used as intermediate under strictly controlled conditions (on-site)* in IUCLID section 3.2 should only be filled with the tonnage of the intermediate used under the conditions as set out in Articles 17 and 18.

If you have decided to cover in the same dossier both uses requiring a full registration (Article 10) and uses of intermediates under strictly controlled conditions (Articles 17 and 18) it is very important that the different uses are clearly identified in the field *Registration/notification status for this use*. You are also expected to report a tonnage for use as intermediate in IUCLID section 3.2 and, additionally, exclude the intermediate tonnage under strictly controlled conditions from the exposure assessment. More aspects to consider when submitting one dossier covering intermediate and non-intermediate uses, are explained in the chapter 9 *How to create a dossier*.

### 8.5.1.2. Special considerations for PPORD use

If part of the tonnage is used for the purpose of **PPORD** and covered by **PPORD notification dossier** it should not be included here. If it is not covered by a PPORD notification, it should be reported as part of the total tonnage manufactured or imported, and included in the tonnage used for the determination of the information requirements.

### 8.5.2. Section 3.3 Sites

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

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

List all the sites where your legal entity manufactures or uses the registered substance. If the legal entity site is not yet available in the inventory, create a new legal entity site by clicking *Select* in the *Site* field and then *Create* in the pop-up window.

The uses taking place at the site can be specified by linking them using the *Select* button under *Manufacture / own use(s)*. Uses previously created in section 3.5 are displayed and can be selected.

If you indicated in section 1.1 that your *Role in the supply chain* is *Manufacturer*, then you must provide at least one production site in this section. To this end, you must create a record and link it using the field *Related manufacture/own use* to at least one manufacture use in section 3.5.1. For manufacturing sites, the country of the site is normally expected to be the same as the country of the submitting legal entity.

**Figure 31: Linking the manufacture use to the manufacturing site**

The screenshot shows a form titled "Sites.001" with three main sections:

- Site:** A text field containing "Example site". Below it is a "Remark" field containing "None".
- Manufacture / own use(s):** A section with a "Related manufacture / own use" field containing "Manufacturer".
- Related mixture/product:** A section with a "Specify to which mixture/product(s) it applies:" field containing "None".

Note that in IUCLID sites are connected to legal entities. If you change the legal entity in section 1.1 Identification of the substance dataset, any site(s) linked in section 3.3 that belonged to that legal entity will be removed from the substance dataset. After changing the legal entity in section 1.1, you need to go to section 3.3 and manually link the appropriate sites of the new legal entity.

### 8.5.3. Section 3.4 Information on mixtures

This section can be used to report information on mixtures including the substance, which is subject to the registration. To enter your data, you must create a new record for each mixture you wish to report. You can then indicate the information on the mixture such as trade name or the typical concentration of the substance in the mixture.

### 8.5.4. Section 3.5 Use and exposure information relevant for all uses

According to Annex VI section 3.5 of the REACH Regulation, registrants have to provide a brief general description of their identified use(s). This information on manufacture and use of the substance is to be reported in this section.

For substances > 10 t/a and which are meeting the criteria to be classified as hazardous or being considered a PBT/vPvB, an exposure assessment is required to be submitted to ECHA as part of the CSR document (see chapter 8.8 *Assessment reports*). You can also report information on the exposure assessment of each of the identified uses here in this section. This option will be particularly useful if you intend to demonstrate that the uses and the conditions of use of your substance do not give rise to any concern and thus no action by authorities would be needed.

Use and exposure information (including tonnage) is used by Authorities to assess the need for further regulatory actions for a given substance under REACH and to support corresponding priority setting. Having use and exposure information correctly reflected in the registration dossier ensures that decisions can be made on well-founded basis. ECHA advises you to ensure in particular that:

- the uses reported reflect your current market situation (ceased uses or uses from other members of the joint submission should not be reported);
- each use is correctly assigned to the appropriate life-cycle stage;
- tonnage information, if available, is provided (in particular tonnage per use);
- uses having specific regulatory status (e.g. intermediate), uses taking place in a limited number of sites and uses taking place in rigorously contained conditions are reported as explained below.

Note that if Chesar is used for carrying out the CSA, the IUCLID fields for use and exposure information can be directly populated via export from Chesar.

#### 8.5.4.1. Overview (section 3.5.0)

In this section you can report use and exposure information that is relevant across all uses.

In the rare case where no uses are reported, select a justification in the field *Justification for no uses reported*.

If no exposure assessment has been performed for any of the uses reported, select the justification in the field *Justification for no exposure assessment*. If you do so, you would not need to specify it in each use.

Note that if you are exempted from performing a CSA by REACH Article 14(2), you should indicate here that no assessment has been performed and you still need to provide information in section 13 of IUCLID (see chapter 8.8 *Assessment reports*)

In this section you can also report the cumulative tonnages of the substance in each of the

following Life cycle stages: *Uses at industrial site*, *Widespread uses by professional workers*, *Consumer uses* or *Service life*. The overall tonnage per Life cycle stage may be of particular relevance if you want to demonstrate that the amounts ending up in widespread uses and/or articles are very low. Cumulative tonnages can be reported here as ranges in tonnes/year. If the cumulative tonnage represents the EU tonnage for the substance (and not just your own individual tonnage), you should select the checkbox *Cumulative EU tonnage* where relevant. Details such as the source of the values reported or the methods used to estimate the volumes can be indicated in the fields *Details on cumulative tonnages*.

Where information on the tonnage for each individual use is available, we advise you to report it in the dedicated fields available in section 3.5., rather than reporting the cumulative tonnage in this section only.

More information on the fields to report tonnage information is available in Annex 6 *Overview of tonnage fields in IUCLID*.

#### **8.5.4.2. Report uses and select regulatory status of each use (sections 3.5.1 to 3.5.6)**

You need to describe the identified uses in section 3.5.1. to 3.5.6. For each use, you have create a record under the corresponding Life cycle stage:

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

Depending on the Life cycle stage under which you have created a record, a set of fields will be displayed for describing the use. This set includes general fields (relevant for all Life-cycle stages) and fields that are only relevant for some Life-cycle stages.

The current IUCLID manual is meant to provide an overview of the information in this section, for more detailed explanation consult the help system of IUCLID, which provides an explanation of which type of information is expected for each field. To access the field specific help click on the question mark icons next to the field headers. Please note that the question mark icon will appear only after you have clicked on the selected field.

To report a new use:

- Step 1.** Click on the *New* button corresponding to the relevant life cycle stage where you want to add a new use.
- Step 2.** Select *New document* and provide an intuitive name for the record so that you can easily recognise it later. This name can be the same as the use name or at least consistent with it.
- Step 3.** Provide a use name which should be representative for the use; in case an exposure assessment is performed, the use name becomes the exposure scenario name in the Chemical Safety Report (CSR) and Exposure Scenario (ES).
- Step 4.** Report further details in the field *Further description of [use]* to further explain the process(es) covered by the use, or the type of product(s) in the case of a consumer use.

**Step 5.** Select the *Registration/Notification status for the use* from the picklist. This selection will determine the type of fields provided for entering information. You will still see the non-relevant fields, visually identified as non-editable.

The Registration/Notification status can be:

- *use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant.* For use at industrial site it is possible to specify that the use is *as intermediate* (see explanation in the later section);
- *use registered according to REACH Article 10; total tonnage manufactured/imported <10tonnes/year per registrant.* For use at industrial site it is possible to specify that the use is *as intermediate* (see explanation in the later section);
- *use registered according to REACH Article 17/18.*

Further explanation on the relevant fields for these three types of registration status is provided in the chapters below.

### Linking use information

There are a number of relationships (links) among fields which can be reported in a IUCLID dataset i.) between uses and other information in the dossier, namely the composition and manufacture/use site and ii.) between uses of different life cycle stages.

- i. Link between uses and other information in the dossier

When describing a use, you may link it to a certain composition, reported in section 1.2 of IUCLID under *Related composition(s)*. This may be particularly relevant if the composition supplied to one use has a hazard profile different from the compositions in other uses e.g. most hazardous compositions are not supplied to consumer uses.

You can also link a use to one of the sites listed in the IUCLID section 3.3. (see chapter 8.5.2 *Sites* for more information).

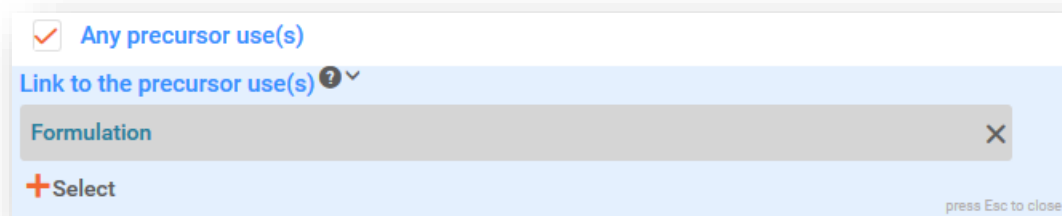
- ii. Link between uses of different life cycle stages

There are several situations where links between uses apply:

- The first situation is when an end use leads to the inclusion of the substance in a matrix, this use should be linked to the relevant subsequent service life. To enable this linking, select *yes* in the picklist *Subsequent service life relevant for this use* to flag whether the substance is included into an article during the use. Then set a link to the relevant subsequent use(s) described in the section 3.5.6 *Service life* once they have been created;
- The second situation is when the *registration/notification status* of a use at industrial site has been set to *use registered according to REACH Article 17/18*, it is possible to link this use to use records in earlier life-cycle stages that have led to this intermediate use e.g. previous formulation step. To enable such linking you need to select the checkbox *Any precursor use(s)* and then select the relevant use(s) as shown in the figure below;
- The third situation is when the use is registered under article 10, and has a particular *regulatory status* that impacts on the required use and exposure information e.g. the chemical safety assessment of cosmetic uses does not need to address human health. The regulatory status of a *use at industrial site*, *Use by professional workers* and *Consumer uses* may trigger a particular status of uses in previous Life cycle stages that

have led to this use e.g. formulation of the cosmetic use. To enable such linking you need to check the box *Any precursor use(s)* and then select the relevant use(s) at earlier Life cycle stages.

**Figure 32: Reporting precursor use(s)**

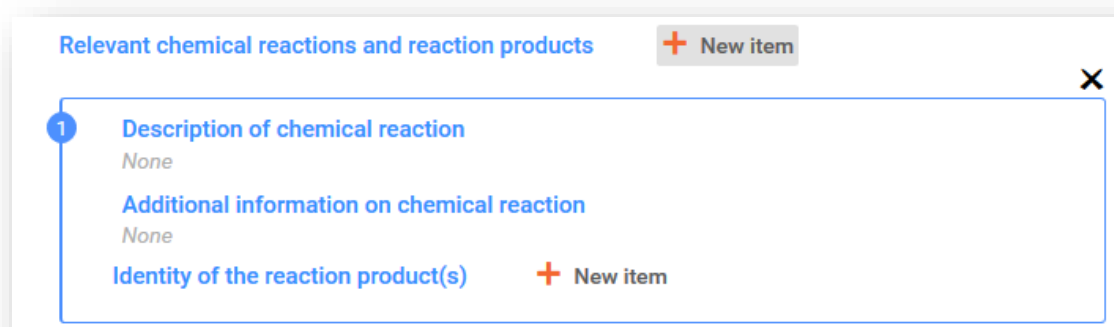


### 8.5.4.3. Describe uses of Article 10 substances for 10 t/a and more

For uses in some Life Cycle stages, you can select, if applicable, a *Regulatory status* from the picklist and provide a justification in the *Explanation for the regulatory status* field. Otherwise, do not select any item in the picklist *Regulatory status*.

For a use at industrial site, if the *registration/notification status for the use is use as intermediate registered according to REACH Article 10; total tonnage manufactured/imported > = 10 tonnes/year*, you need to confirm the intermediate status with providing information under the heading *Relevant chemical reactions and reaction products*. Create one block per chemical reaction in which the substance is involved as intermediate. Create then one block per each product or residue resulting from the chemical reaction.

**Figure 33: Describing chemical reaction and its reaction products**



Additional information such as schemas or structures can be provided as an attachment in the field *Additional information on chemical reaction*.

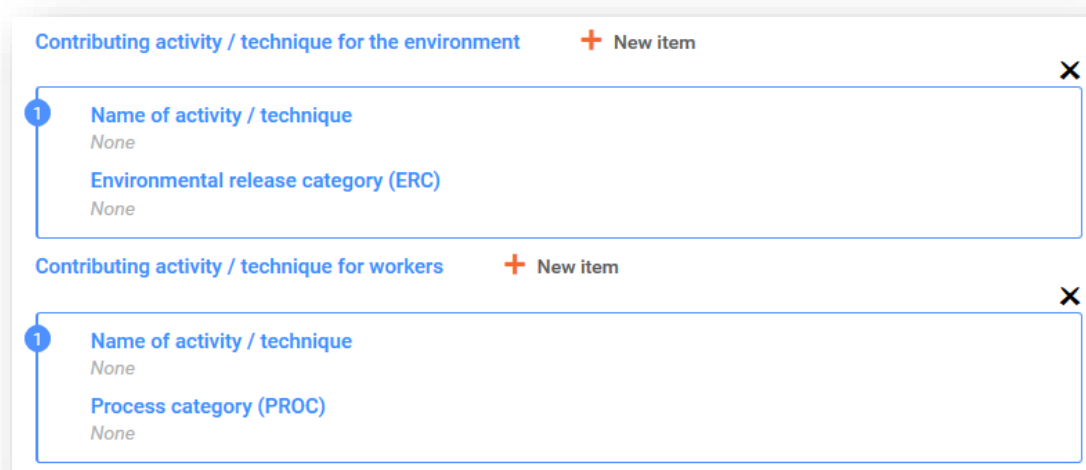
### Describe the use in more detail

A use may consist of one or more contributing activities describing processes, tasks or unit operations. Such contributing activities are to be defined from environmental perspective and from the human health perspective. Each use needs to include as a minimum a *Contributing activity / technique for the environment* and a *Contributing activity /technique for workers or*

*consumers* (depending on the Life cycle stage to which the use belongs to). Each contributing activity needs to have as a minimum a use descriptor assigned e.g. PROC, ERC.

**Note:** a use is usually characterised by one (more broad) contributing activity for the environment and a set of contributing activities for workers (defined by tasks) or for consumers (defined by specific product types).

**Figure 34: Contributing activities / techniques for environment and workers**



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

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

When you describe a **worker use**, complete the description of the use by adding (repeatable) blocks of information for *Contributing activity / technique for worker*:

- Provide a *Name of the activity/technique*, to facilitate the understanding of the task or process step carried out by a worker. Standard names may be available from downstream sector organisations via use maps. In case an exposure assessment is performed, this name becomes also the *contributing scenario name*;
- Select a suitable *Process category (PROC)* from the picklist;
- Add further *contributing activity/technique for worker* if relevant. **Note:** the same PROC may be assigned to more than one activity. In this case, the contributing activity name can provide further specificity.

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

- Provide a *Name of the activity/technique*, to facilitate the understanding on the type of product the consumer uses. Standard names may be available from downstream sector

organisations via use maps. In case an exposure assessment is performed, this name becomes also the *contributing scenario name*;

- Select a suitable *Product category (PC)* [or suitable Article Category for Service life by consumers] from the picklist;
- Add further *contributing activity/technique for consumer* if relevant. **Note:** the same PC may be assigned to various (sub)product types. In this case, the contributing activity name can provide further specificity.

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

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

- Provide more information on the market where the use takes place by selecting one or more relevant use descriptor(s) in the following fields, where applicable: *Product category used, Sector of end use*. This information may also be available from downstream user organisations via use maps;
- If the substance has a particular technical function during a use, select one or more entries in the picklist *Technical function of the substance during use*. If the substance has no specific technical function during this particular use, select *No technical function* which is the last entry in the picklist;
- Select *substance supplied to this use in form of: as such or in a mixture*.

**Note:** the fields for characterising the market (Product Category used (PC), Sector of end use (SU), Article Category (AC)), the technical function of the substance during use, the form of supply and the relevance of subsequent service life are not available for all Life cycle stages, as this information is not always relevant for each stage e.g. Sector of end use is not relevant for consumer uses as the "sector" is the general public.

### Add information on the extent of the use

Information on the extent of the use, such as the tonnage or the number of sites where the substance is used, provides (together with other criteria<sup>11</sup>) an indication on the wide-depressiveness of the use. For example, uses with low tonnage and/or low number of sites may not be of concern for authorities when prioritising substances for further scrutiny or regulatory action. At the same time, tonnage information is also an input to the environmental exposure assessment.

Quantify the *tonnage of substance for this use (tonnes/year)* and provide some explanation in the two related fields, enabling the interpretation of the tonnage figure. If the tonnage represents the EU tonnage for the substance (and not just your own individual tonnage), you should select the checkbox *Total EU tonnage for this use*. Details, such as the source of the values reported or the methods used to estimate the volumes, can be indicated in the fields *Details on tonnage reported*.

If the use only takes place in a limited number of sites in the EU, select the checkbox *Limited number of sites for this use* and provide any justification on why this number is limited in the field *Details on limited number of sites*. This option is only available in the Life cycle stages

<sup>11</sup> The guidance on use description R.12 provides further explanation on the concept of wide-dispersive uses: <http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>



*Formulation and Uses at industrial sites.*

**Figure 35: Reporting on the extent of the use**

The screenshot shows a form with the following content:

- Tonnage of substance for this use (tonnes/year)**  
> 300 < 400
- Details on tonnage reported**  
Tonnage based on information on overall EU market figures available in the website xxxx
- Total EU tonnage for this use**
- Limited number of sites for this use**
- Details on limited number of sites**  
The use only takes place in three sites in the EU because

### **Add information on related exposure assessment**

Indicate in the field *Related assessment* whether or not an exposure assessment has been carried out for this use. If an exposure assessment has been carried out, select among the available options whether this assessment:

- is part of the CSR submitted by the lead registrant on behalf of all the co-registrants;
- is part of the CSR submitted by the lead registrant on behalf of all the co-registrants but it is not relevant to the lead registrant;
- is only part of your own CSR submitted with your registration dossier.

If no exposure assessment is carried out for any use, you can flag that under section 3.5.0. Otherwise you should specify *Use not assessed* in the *Related assessment* field for each use.

### **Demonstrate that the use takes place under rigorously contained conditions**

You may want to demonstrate that the *use takes place under rigorously contained conditions*, and thus that the potential for exposure is negligible. This may be relevant for adapting information requirements or for convincing authorities that the use is not of priority concern for regulatory action. If you want to make such claim, select the relevant checkboxes:

- *Rigorously contained system with strict control for manual interventions;*
- *Rigorously contained system with minimisation of release to the environment.*

You can then describe the *non-technical means for strict control* (measures supporting the implementation of the rigorously contained system which are related to non-technical aspects such as management controls, monitoring and procedures).

Describe the *technologies to minimise emissions* and the *technical means for rigorous containment* in each contributing scenario as they may be specific to each activity (see section below).

### **Particular information only relevant for uses under Life cycle stage service life**

For uses reported under service life (section 3.5.6) the following particularities exist:

- In the field *Article used by* you need to specify whether the use describes the use of articles by workers or by consumers. Depending on this choice the use description fields are displayed with different options e.g. if article is used by workers, the relevant use descriptor for the contributing activity is the PROC;
- You also need to flag whether *the substance is intended to be released from articles*. "Intended" means that it is not only foreseeable, but also that the release is intended to deliver the technical function of the substance during the use.

#### 8.5.4.4. Provide exposure information for Article 10 substances > 10 t/a

##### General structure of exposure information

If the use is subject to **exposure assessment**, information on conditions of use and the related release/exposure estimates can be reported for each contributing activity. This information should correspond to a risk characterisation concluding that the risks resulting from the use are adequately controlled.

##### Notes:

- This manual does not provide support on how to perform a chemical safety assessment, but rather how to report the outcome of it. For more information on CSA, please refer to the guidance: <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>
- The risk characterisation itself as documented in the CSR is not reported in IUCLID.

There are two *Contributing Scenarios* available for each use:

- *Contributing scenario for the environment (related to workers [consumers] activities)* for reporting the conditions of use driving the release to the environment during a use by workers [consumers];
- *Contributing scenario for the workers [consumers]* for reporting the conditions of use driving the direct exposure of workers [consumers].

**Figure 36: Contributing scenarios for workers**

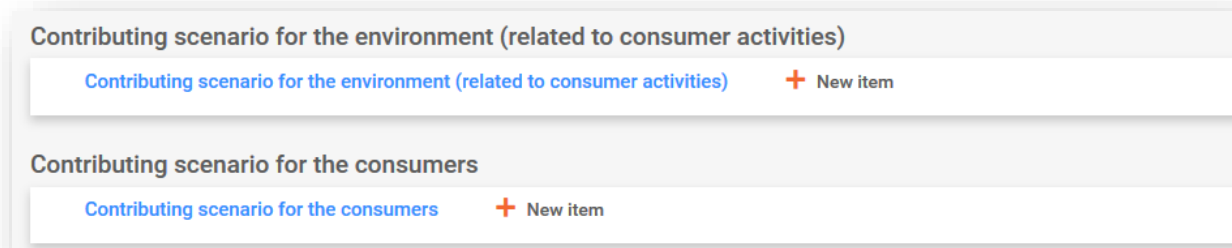
##### Contributing scenario for the environment (related to workers activities)

Contributing scenario for the environment (related to workers activities) + New item

##### Contributing scenario for the workers

Contributing scenario for the workers + New item

**Figure 37: Contributing scenarios for consumers**



Create a *contributing scenario for the environment (related to workers [consumer] activities)* under the relevant heading by clicking the *New item* button. Link to the corresponding contributing activity to which this contributing scenario refers to by clicking on the *Linked contributing activity field* selecting among the previously defined contributing activities for environment.

Create also a *contributing scenario for the workers [consumers]* under the relevant heading by clicking the *New item* button. Link with the contributing activity to which this contributing scenario refers to by clicking on the *Linked contributing activity field* and selecting among the previously defined contributing activities for workers [consumers]. Repeat the operation to create as many contributing scenarios as needed.

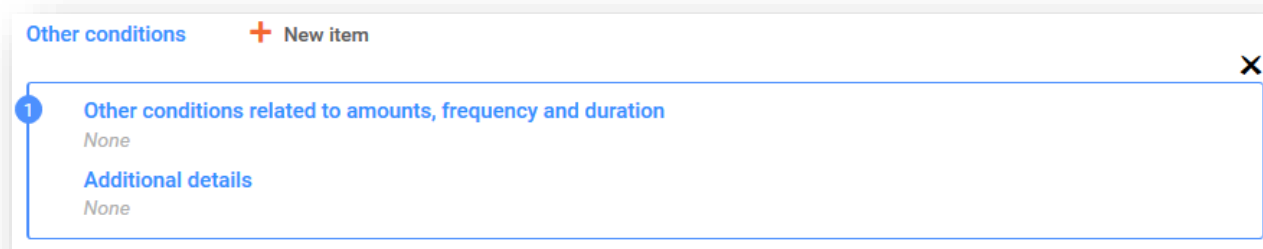
Each of the contributing scenarios consists of different parts such as the conditions of use (operational conditions or risk management measures), the related releases (environment) and the exposure estimates.

A few conditions of use are pre-defined (fixed) e.g. *Percentage (w/w) of substance in the mixture/article*, or *Place of use* so that you can only select among or insert some relevant values. If there are other relevant conditions of use you need to define them by yourself, or report them as documented in sector use maps and/or in the exposure estimation tools you apply.

The conditions of use are grouped under fixed subheadings. For more explanation on these sub headings consult the *Guidance Part D: Framework for Exposure Assessment* available at <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

Where the pre-defined conditions are listed under a subheading, usually also a field *Other conditions* is available to allow you to report as many relevant conditions of use as relevant for your assessment. IUCLID provides you with repeatable blocks of information for that.

**Figure 38: Example of section to report other conditions of use not suitable to report elsewhere**



For all the *conditions of use* a field *Additional details* is available. Here you can enter explanation to assist the recipient of the dossier (e.g. ECHA) in understanding the information provided.

For risk management measures (i.e. conditions of use aiming to limit release/exposure) the effectiveness of the measure (i.e. reduction of release/exposure in %) and the route of release/exposure affected by the measure as well as some explanations can be reported.

**Figure 39: Reporting effectiveness of a measure for a particular exposure route**

The screenshot shows a software window titled "Effectiveness" with a "+ New item" button in the top right. The main content area is divided into sections: "Effectiveness (%)" with the value "90", "Route affected" with the value "inhalation", and "Details on effectiveness" which is a text input field containing the text "This effectiveness of this measure for inhalation is based on the study...". At the bottom right of the window, there is a character count "74/32768" and the instruction "press Esc to close".

The release to the environment and the corresponding exposure estimates are to be reported per release route and per subsequently exposed compartment. For each estimate the applied method and tool used should be selected.

When a substance consists of various constituents, forms, or transformation products occur during use, the release or exposure estimates may be related to certain constituents or transformation products. If relevant for the assessment, link the release and/or exposure data-set to a certain assessment entity (see chapter 8.3.9 *Assessment approach (assessment entities)*) via the field *Release [exposure] related to*.

For more information *on exposure assessment*, please refer to *Guidance on information requirements and chemical safety assessment part D* at <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

The next sections explain in more detail how to report exposure information such as conditions of use, releases or exposure estimates.

### Conditions of use driving the environmental release

**Note:** The type of conditions driving the environmental release are different between workers and consumers. *Technical and organisational conditions and measures* limiting releases to the environment are usually not available for consumer uses. The same applies for particular *conditions and measures related to Biological Sewage Treatment Plant*. Therefore, the corresponding sub-headlines or pre-defined conditions are not displayed for consumer uses.

Report *Product (article) characteristics* having an impact on environmental releases. Information

to be reported here includes concentration of the substance in the product used, package design affecting releases, etc. Create a block by clicking *New item* for each of the *Product (article) characteristics*, provide a short description in the corresponding field and give any additional details in the *Additional details* field.

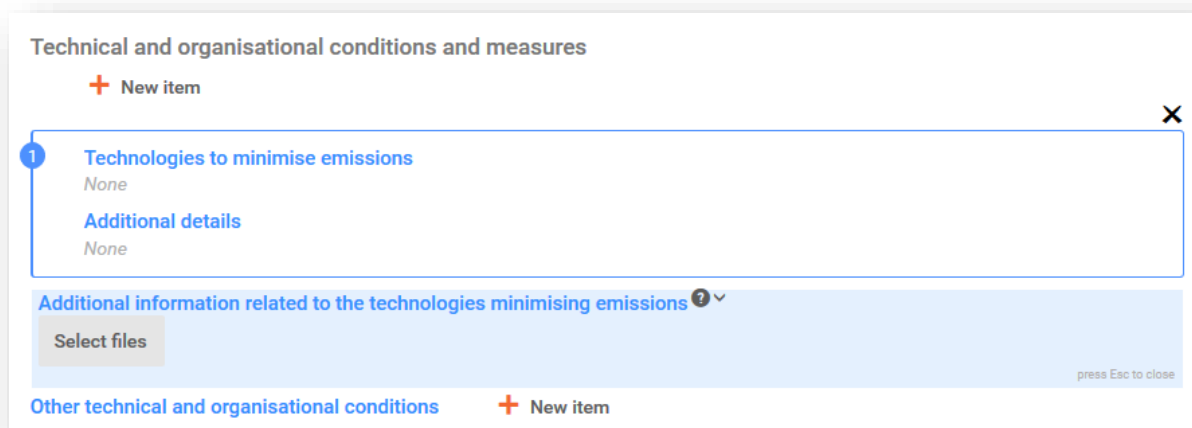
Report *Amounts used, frequency and duration of use*: The *Daily [annual] use amount at a site* is the highest amount of substance used in a day [year] at a generic site (industrial site or standard town with 10,000 inhabitants for widespread uses by workers or consumers). Together with the emission factors, they determine the release rate to the local[regional] environment. You can also indicate the *Number of emission days*. Note that you should always provide an explanation on how the number of emission days is taken into account in the assessment.

Report the *Technical and organisational conditions and measures* limiting or minimising releases to the environment by clicking *New item*. This should include i) any process design and/or organisation that has an impact on environmental releases and ii) any treatment of exhaust air, waste water or waste before release, except for Biological waste water treatment (which is reported in a section on its own).

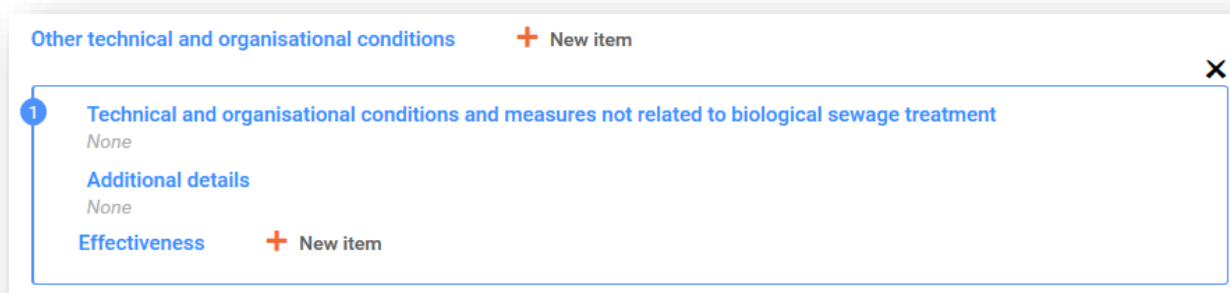
If you claim the use to take place under strictly controlled conditions (checkbox *Rigorously contained system with minimisation of releases* selected) you need to describe the process design and integrated measures, including containment in the field *Technologies to minimise emissions*. To activate this field click on *New item* under the heading *Technical and organisational conditions and measures*

The field *Additional information related to the technologies minimising emissions* provides an opportunity for an attachment (e.g. to report process schemes).

**Figure 40: Reporting technologies to minimise emissions**



Otherwise, add your information in *Other technical and organisational conditions*. In this block any measure to control release except for those related to biological sewage treatment can be reported including its effectiveness on one or more routes.

**Figure 41: Reporting other technical and organisational conditions**

Other technical and organisational conditions + New item

1 Technical and organisational conditions and measures not related to biological sewage treatment  
None

Additional details  
None

Effectiveness + New item

Report *Conditions and measures related to Biological Sewage Treatment Plant*. In this set of pre-defined fields you can report the relevant information from your assessment regarding the biological waste water treatment.

Report *Conditions and measures related to external treatment of waste*: You can provide any particular considerations on the waste treatment operations by selecting among the options in the picklist. If the substance properties and/or the use pattern do not call for a particular assessment of the waste life stage, select *no*, and explain the reasoning in *Details on waste treatment*. Examples for such reasoning can be found in the *Guidance on environmental assessment* R.16 available in <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>.

Report any *Other conditions of use affecting environmental exposure* that do not fit under any of the fixed subheadings. This section includes two pre-defined conditions: *Place of use* (indoor or outdoor with implications on potential direct release to soil or water) and the *receiving surface water flow rate* (which may be set to a site-specific value if relevant for the assessment).

## Environmental release and exposure

Report the *Releases to waste and the environment* predicted or measured for the reported conditions of use. Click on *New item* to open a repeatable block. When a substance consists of various constituents or forms transformation products during use, the release may be related to certain constituents or transformation products. If relevant for the assessment, link the release dataset to the previously defined assessment entity to which the releases relate to via the field *Release related to*.

Report the *Release to the environment* for each release route separately by clicking on the *New item* button under the *Release to the environment* heading. Start with selecting a release route in the field *Release from site to* and then enter the relevant information in the pre-defined fields. **Note:** The *Release factor from site after on-site risk management* refers to releases before biological sewage treatment (regardless whether this takes place onsite or in the municipal STP). Repeat the reporting for each relevant release route.

Report the *Release to external waste*. Report the *Release factor to external waste*. This is the percentage of the use amount leaving the site as waste for external treatment (disposal or recovery). This figure is, together with other information, the basis for determining whether a particular assessment for the waste life stage is required.

Report the *Exposure of the environment*. When a substance consists of various constituents,

forms, or transformation products occur during use, link the exposure dataset to the previously defined assessment entity to which the exposure relates to via the field *Exposure related to* as explained for the release.

Report the Exposure to the environment for each compartment separately. Start with clicking on the *New item* button next to the field *Predicted exposure concentration* and then selecting the *Exposed compartment*. Then enter the *predicted exposure concentration*, select the correct *unit* and provide information related to the exposure estimation method. This may include attaching documents such as export files of exposure estimation tools<sup>12</sup>. For measured exposure the number of measured points, standard deviation and reliability scores should be provided in the relevant fields. Repeat the reporting for each relevant compartment.

Report *Exposure to human via the environment*. When relevant, link the exposure data-set to the previously defined assessment entity to which the exposure relates to via the field *Exposure related to* as for the exposure to the environment. Enter a value for the *daily intake via food consumption* and select the right unit. For each estimate, the applied method/tool used should be selected.

### **Conditions of use related to workers activities driving human exposure**

Report the relevant *Product (article) characteristics* having an impact on workers' exposure. This includes the *Percentage (w/w) of the substance in the mixture/article*, and the *Physical form of the used product* during the contributing activity. If the used mixture is *solid*, select the relevant level of dustiness from the picklist in the field *Physical form of the used product*. Note: The form of the used product is not necessarily identical with the physical state of the substance as derived from manufacture (e.g. solid substances may be dissolved or dispersed in liquids). Also, forms may change during use, and this may significantly have an impact on the exposure (e.g. milling of granules into powder).

Report *Amounts used (or contained in articles) frequency and duration of use/exposure*. This includes the duration of each contributing activity (in hours/day) as assumed for the exposure estimate and risk characterisation. If this duration is shorter than 8h, you may provide under *Details on duration of activity* whether the shorter duration is required to control risks for a worker.

Report the *Technical and organisational conditions and measures* limiting or minimising exposure to workers:

- If you claim the use to take place under strictly controlled conditions (check box *Rigorously contained system with strict control for manual intervention* selected) you need to describe how the technical equipment ensures rigorous containment. Provide this information in the field *Technical means for rigorous containment and strict control for manual intervention*. The field *Additional details* provides an opportunity for supporting information.
- Otherwise, report under the heading *Technical and organisational conditions and measures*, any process design or engineering controls having an impact on workers' exposure e.g. local exhaust ventilation, technical barriers for dermal protection, etc. The organisational measures that support the implementation of these technical measures should be described here as well e.g. maintenance of the equipment.

Report *Conditions and measures related to personal protection, hygiene and health evaluation*, such as respiratory protective equipment or dermal protective equipment. The organisational measures necessary to achieve the reported effectiveness when using the protective equipment should be described as well e.g. training.

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<sup>12</sup> Export files from exposure estimation tools may also be attached to section 13 if covering more than one use

Report *Other conditions affecting workers exposure*. This includes two pre-defined conditions *The Place of use* (indoor, outdoor) and *the operating temperature*.

### **Conditions of use related to consumers activities driving human exposure**

Report *Product (article) characteristics* having an impact on consumers' exposure. This includes the *Percentage (w/w) of the substance in the mixture/article*, and the physical form of the used product during the contributing activity. If the used mixture is *solid*, select the relevant level of dustiness from the picklist in the field *Physical form of the used product*. Note: The form of the used product is not necessarily identical with the physical state of the substance as derived from manufacture (e.g. solid substances may be dissolved or dispersed in liquids).

Report *Amounts used (or contained in articles) frequency and duration of use/exposure*. This may include the amount of product used per event, the duration of exposure event or the frequency of use.

Report *Information and behavioural advice for consumers*, required to ensure safe use. This includes for example instructions on safe use and in very exceptional cases also personal protective measures.

Report *Other conditions affecting consumers exposure*. These can include information on the place of use (indoor/outdoor), or room size assumed in the assessment.

### **Exposure of workers or consumers**

Report the *Exposure of workers* predicted or measured for the reported conditions of use.

When a substance consists of various constituents, forms, or transformation products occur during use, the exposure may be related to certain of these constituents or transformation products. If relevant for the assessment, link the exposure data-set to the previously defined assessment entity to which the exposure relates to via the field *Exposure related to*.

Report the *Exposure estimation* for each *type of exposure* separately by creating several blocks. To create a block click on *New item*. Start with selecting a type of exposure, enter the *Exposure estimate* and select the correct *unit* and provide information on the method/tool used to generate the exposure estimation.

For measured exposure estimates the *number of measured data points, geometric standard deviation and reliability scores of measured data set* should be provided in the relevant fields.

#### **8.5.4.5. Describe uses for Article 10 substances below 10 t/a**

For substances manufactured or imported up to a volume of 10 tonnes per year a few particularities apply regarding the reporting of use and exposure information. Otherwise follow the explanation in section above (Describe uses for Article 10 substances above 10 t/a).

- There is no need to indicate the *related assessment* as no exposure assessment is required in this tonnage band. This should be indicated in section 3.5.0 in the field *Justification for no exposure assessment*.
- You can demonstrate that a use takes place under rigorously contained conditions, by filling in the three text-fields available in the use description: *Description of non-technical means for strict controls, Technologies to minimise emissions, Technical means for rigorous containment and strict control for manual intervention*. This may be relevant



for convincing authorities that the use is not of priority concern for regulatory action.

- To claim that exposure via one or more routes of release/exposure is insignificant, a set of particular fields is available for this tonnage band: *Insignificant exposure via the following route* and *Insignificant release via the following route*. These fields can be used both when a substance is not used under rigorous containment, but nevertheless you consider the exposure is negligible for other reasons, or to provide quantification of residual releases in case of use in rigorous containment. In this case, select for which route(s) insignificant exposure (or release) is expected for this use. Provide explanations supporting the selection in the subsequent field.

#### 8.5.4.6. Describe uses for Article 17/18 intermediates

An intermediate substance under REACH is a substance that is manufactured/imported for and consumed in chemical processing, in order to be transformed into another substance. Intermediates being manufactured and used under strictly controlled conditions can benefit from a particular registration regime as described in REACH Article 17 and 18.

For uses with a *Registration/Notification status for the use registered according to REACH Article 17/18*, information needs to be given to support both the intermediate status (details on chemical reactions and reaction products) as well as to support the strictly controlled conditions. Note that you can only claim the status of intermediates for uses of the registered substance in the life cycles that describe the manufacture (if your registration covers the manufacture of the intermediate substance), the formulation or re-packing of the intermediate (if such activity takes place) and the chemical process where the substance is transformed into another substance. These uses should be reported in IUCLID sections:

##### 3.5.1 Manufacture

##### 3.5.2 Formulation on re-packaging

##### 3.5.3 Uses at industrial sites

In addition, for uses at industrial sites, a checkbox appears to give the possibility to further specify the type of intermediate registration. Select the checkbox if the use is *Use as on-site isolated intermediate registered according to REACH Article 17(3)*. This is important as on-site intermediates are exempted from Evaluation and Authorisation.

**Step 1.** Confirm the intermediate status by providing information under the heading *Relevant chemical reactions and reaction products*. Create one block per chemical reaction in which the substance is involved as intermediate by clicking on *New item*.

**Step 2.** Create also one block per product or residue resulting from the chemical reaction. Additional information such as schemas or structures can be provided as an attachment in the field *Additional information on chemical reaction*.

**Figure 42: Describing chemical reaction and its reaction products**

The screenshot shows a software window titled "Relevant chemical reactions and reaction products" with a "+ New item" button. The window is divided into two main sections:

- Description of chemical reaction:** This section has a "None" value and a sub-section titled "Additional information on chemical reaction" with a "Select file" button and a "press Esc to close" instruction.
- Identity of the reaction product(s):** This section has a "+ New item" button and contains several fields:
  - Product or residue:** Value is "None".
  - Is the product registered under REACH?:** Value is "None".
  - Details on registration of product:** Value is "None".
  - REACH Regulatory status of product:** Value is "None".

**Step 3.** For all uses registered under Article 17/18 you may define the *contributing activities/techniques for workers* to describe which activities take place with the substance. This will be useful to confirm the fact that the use takes place under strictly controlled conditions. Describing the contributing activities includes giving the activity an intuitive name and assigning a suitable process category (PROC).

**Figure 43: Defining contributing activities techniques for workers**

The screenshot shows a software window titled "Contributing activity / technique for workers" with a "+ New item" button. The window contains the following fields:

- Name of activity / technique:** Value is "None".
- Process category (PROC):** Value is "None".

**Step 4.** You may also specify the sector of industry (*sector of end use*) in which the intermediate is used.

**Note:** This would be usually a sector where manufacturing of substances takes place. If not, please cross check whether your substance indeed fulfils the criteria for being treated under REACH as an intermediate.

**Step 5.** Select whether the substance is supplied: as such or in a mixture under Substance supplied to that use in form of.

- Step 6.** Quantify the *Tonnage of substance for this use* and provide some explanation in the related field enabling the interpretation of the tonnage figure. If the tonnage represents the EU tonnage for the substance (and not just your own individual tonnage), you should select the checkbox *Total EU tonnage*. Details such as the source of the values reported or the methods used to estimate the volumes can be indicated in the fields *Details on tonnage reported*.
- Step 7.** Next, you need to describe the strictly controlled conditions for both the conditions at workplace and the conditions related to environmental release. This information is to be entered under the header *Use takes place under rigorously contained conditions*. For the *Technical means for rigorous containment including strict control for manual intervention* provide such descriptions per process step or task.
- Step 8.** You may want to provide some additional information supporting the description in the textboxes (e.g. graphical schemes, flow charts). You can attach documents in the field *Additional information on the conditions of strict control*.
- Step 9.** Finally, you should provide *contact details of the downstream users*, who have confirmed intermediate use and strictly controlled conditions to you under Article 18.4, unless you have already described their uses and conditions in the following fields:
- *Chemical reactions and reaction products;*
  - *Use takes place under rigorously contained conditions.*

For more information on registration of intermediates refer to the *Practical Guide on how to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID* available at <https://echa.europa.eu/practical-guides>.

### 8.5.5. Section 3.6 Uses advised against

According to Annex VI section 3.7 of the REACH Regulation, registrants have to provide information of their uses advised against.

If no uses advised against have been identified then you should not enter any information in this section.

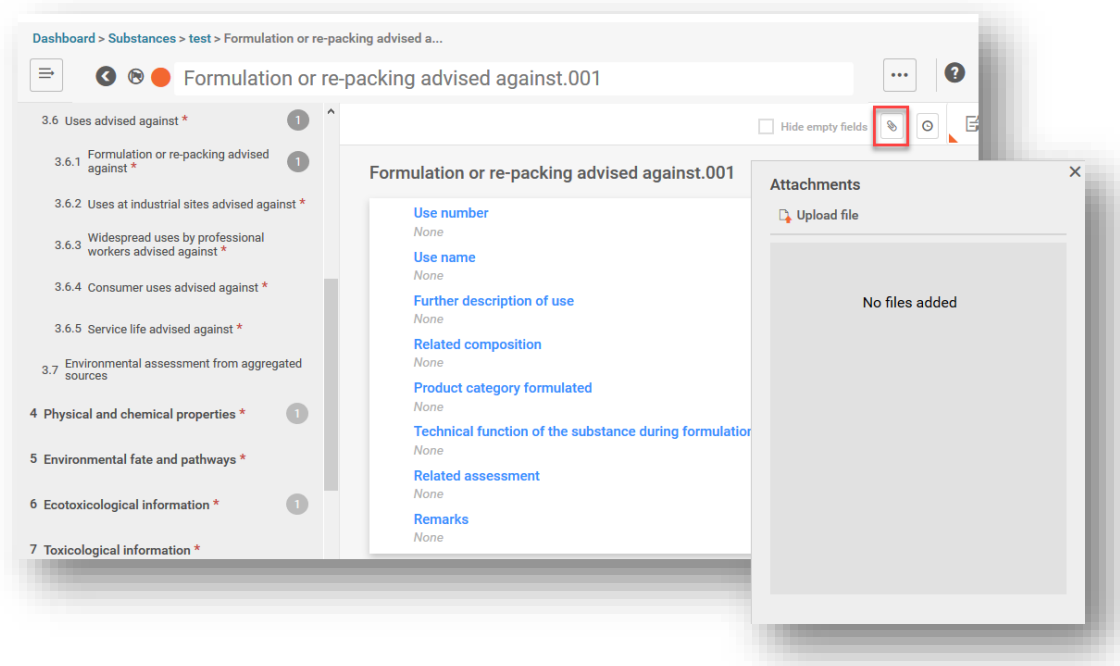
If you have identified use(s) advised against, then you must add a record for each use advised against in the corresponding Life cycle stage subsections:

- 3.6.1 Formulation or re-packing advised against;
- 3.6.2 Uses at industrial sites advised against;
- 3.6.3 Widespread uses by professional workers advised against;
- 3.6.4 Consumer uses advised against;
- 3.6.5 Service life advised against.

The fields in this section are similar to the ones described above for other uses, however the number of fields is lower to report uses in this section. Please refer to the explanations above and IUCLID for support.

Registrants should also report the justification why the use(s) are advised against. Provide such justification in the *Remarks* field per use. Additional details can be provided as an attachment by clicking on the paperclip icon displayed on the top right corner of the record.

**Figure 44: Where to attach further information on uses advised against**



### 8.5.6. Section 3.7 Environmental assessment from aggregated sources

This section is to report exposures aggregated from the different Life cycle stages. The regional exposure consists in the background exposure when taking into account all sources, i.e. all uses in all the life cycle stages. The combined widespread exposure relates to a predicted exposure concentration in a local environment (standard municipal town) when releases from all widespread uses, i.e. consumers uses and uses widespread uses by professionals as well as service life, are taken into account. For more information refer to Guidance R16.

You have to create a record for reporting this information. You may have to create several records if:

- You have created assessment entities for your assessment (see section 9.3.9). In this case, make a reference to the relevant assessment entity in the field *Exposure related to (select an assessment entity if relevant)*;
- You are the lead and you are submitting two CSRs: one joint CSR covering part of the uses in the joint registration and one CSR for your own uses not covered by the joint CSR. In this case select whether the values are corresponding to your own CSA or the joint CSA in the *field Exposure related to (select a CSA type if relevant)*.

Report the total releases to water, air and soil. They correspond to the releases from all the uses at the regional scale, before biological sewage treatment is applied, as this corresponds to a standard output of an environmental assessment using the release estimation tool EUSES.

Report then the Predicted Exposure Concentrations (PEC) regional for each compartment in the subsequent fields. For each PEC, indicate which method has been used to estimate this value.

At the end, report the PECs for water and soil obtained when combining the local releases from all widespread uses.

## 8.6. Sections 4, 5, 6, 7 and 8 - Endpoint sections

This chapter guides you through the most relevant aspects of filling in sections 4 to 8. You will find here instructions to enter information for the scientific studies carried out following Annexes VII to X (and their adaptations according to Annex XI) of the REACH Regulation, into the sections 4 to 8 of IUCLID:

- **Section 4** *Physico-chemical properties;*
- **Section 5** *Environmental fate and pathways;*
- **Section 6** *Ecotoxicological information;*
- **Section 7** *Toxicological information;*
- **Section 8** *Analytical methods.*

### Further information

- For further support on the different fields and sections of IUCLID, access the help system in IUCLID by pressing the question mark icon to the right of a field heading, which will allow you to:
  - i. read the field-specific help text that explains how each field should be used;
  - ii. find information on the different functionalities of IUCLID that relate to these sections, such as the literature reference and test material inventories.
- To see the endpoint requirements per REACH Annex (tonnage band) and the information verified during the completeness check, please refer to the Annexes *Overview of the completeness check performed by ECHA on the submitted dossiers* and *Overview of endpoints and information requirements* of this manual.
- In addition, you can find detailed description of the information requirements under REACH in:
  - i. *Guidance on information requirements and chemical safety assessment:* (<https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>);
  - ii. Practical guides: (<https://echa.europa.eu/web/guest/practical-guides>).
- If your registration dossier cover nanoforms, please refer to the manual *How to prepare registration dossiers covering nanoforms* at <https://echa.europa.eu/manuals> for more information.

### 8.6.1. Concepts

REACH prescribes that the registration dossier must contain in the form of study summaries or robust study summaries the physicochemical, ecotoxicological and toxicological information that results from the application of Annexes VII-X, as well as all relevant available information. In IUCLID, (robust) study summaries are reported in electronic formats called endpoint study records, which are based on the harmonised templates developed by the OECD. The following concepts will be used throughout this chapter:

### *Robust study summary (RSS)*<sup>13</sup>

A robust study summary is a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study, minimising the need to consult the full study report.

### *Study summary*<sup>14</sup>

A study summary is a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study.

### *Endpoint study record* ●

An endpoint study record is a IUCLID document that stores the information from a robust study summary or study summary, or the proposal or waiving of a test.

### *Endpoint summary* 📄

An endpoint summary is the IUCLID document that summarises the information from endpoint study records to give an appraisal of all data compiled in a given endpoint section.

## **8.6.2. How to complete endpoint study records**

The IUCLID endpoint study records provide a structured way to fill in the information for each endpoint. Depending on the approach chosen to fulfil the information requirements under REACH Annexes VII-X, and the available data, different parts of the endpoint study record may be relevant. As a starting point, three types of approaches can be identified:

*Study, including alternative methods:* The information requirement is fulfilled by one or more study summary/ies or robust study summary/ies that either directly or indirectly (through an adaptation) provide information on the endpoint.

*Testing proposal:* For studies required under REACH Annexes IX and X, a testing proposal has to be submitted if a valid test result is not available. Whenever testing proposals on vertebrate animals are submitted, to demonstrate the use of animal testing as a last resort, the considerations for adaptations according to Column 2 of the REACH Annexes on information requirements, and Annex XI must be provided.

*Data waiving:* For studies that have been waived according to the specific rules for adaptation in Annexes VII-X or Annex XI, section 2 and 3 principles. Data waiving usually relates to a property of the substance, or its use and exposure information, that should be demonstrated in the same or a different section of the registration dossier. Please note that it is not enough to refer in your data waiving justification to information provided elsewhere in the dossier. The main argument of your justification for data waiving must be reported in the field *Justification for data waiving*. Additional information can be reported in the field *Justification for type of information*.

Each information requirement must be fulfilled by one of the above approaches. Table 3 shows the relevant parts of the endpoint study record that need to be filled in for each approach.

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<sup>13</sup> Article 3(28) of REACH

<sup>14</sup> Article 3(29) of REACH

Each endpoint study record must correspond to exactly one of the above approaches; it is not possible to combine several approaches in one record. However, it is possible that more than one endpoint study record is required for an endpoint, e.g. when the information is provided using a read-across.

**Table 3: Relevant parts of endpoint study record per approach**

	Endpoint study record	Study summary	Data waiving	Testing proposal
<b>i</b>	Administrative data	X	X	X
<b>ii</b>	Data source	X		
<b>iii</b>	Materials and methods	X		X
<b>iv</b>	Test material	X		X
<b>v</b>	Results and discussion	X		
<b>vi</b>	Overall remarks, attachments	X		
<b>vii</b>	Applicant’s summary and conclusion	X		

For reporting of read-across refer to chapter 8.6.3 *How to report read-across in IUCLID*.

**Administrative data**

The Administrative data part of the endpoint study record is used to summarise the purpose of the record – whether it contains information from a study, it is a testing proposal or a data waiving – and the main contextual information for the chosen approach. Table 4 shows the fields in the Administrative data part and their relevance to the approaches outlined in Table 3.

Conditional formatting of the fields will prevent major inconsistencies; e.g. if the endpoint study record has been indicated as a study, the fields for reporting data waiving become inactive.

**Table 4: Relevant fields under Administrative data, per approach**

	Study summary	Data waiving	Testing proposal
<b>Endpoint</b>	X	X	X
<b>Type of information</b>	X		X
<b>Adequacy of study</b>	X		
<b>Robust study summary</b>			
<b>Used for classification</b>	X		
<b>Used for SDS</b>			
<b>Study period</b>	X		
<b>Reliability</b>	X		
<b>Rationale for reliability incl. deficiencies</b>	X		
<b>Data waiving</b>		X	
<b>Justification for data waiving</b>		X	



Justification for type of information	X	X	X
Attached justification	X	X	X
Cross-reference	X	X	

For reporting of read-across refer to chapter 8.6.3 *How to report read-across in IUCLID*.

### Endpoint

For all endpoint study records created, whether they represent study summaries, data waiving or testing proposals, you must indicate the *Endpoint* that is addressed. Several IUCLID sections cover more than one information requirement under REACH; this field allows referring to the particular information requirement in the REACH Annexes.

### Type of information

The field *Type of information* is used to specify what kind of information the (robust) study summary reported in the endpoint study record is based on: experimental data, read-across or QSAR, for example. The field is also used to indicate if the endpoint study record refers to a testing proposal; to this end you should select *experimental study planned* or *experimental study planned (based on read-across)*, as appropriate.

### Adequacy of study

Use the picklist field *Adequacy of study* to indicate how the (robust) study summary reported in the endpoint study record is used in terms of fulfilling the information requirements for the registered substance and the subsequent hazard assessment. To this end, you have to select one of the following:

- *key study* is a study that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and representativeness of data. A key study is expected to correspond to a robust study summary that is used in the hazard assessment. When several results are available for a given information requirement there can also be several key studies. For substances with more than one study available, the study/ies giving rise to the highest concern should normally be used as the key study/ies for the assessment of the substance. In case another study is used as key study the reasons should be clearly documented (see selection *disregarded due to major methodological deficiencies*).
- *supporting study* provides some additional information to support the conclusions from the key study/ies.
- *weight of evidence* is selected to indicate that an endpoint study record contributes to a weight of evidence approach. A weight of evidence approach relies on the submission of multiple endpoint study records for the same endpoint. Using weight of evidence implies that no single study of sufficient quality and reliability exists, and that information from several independent sources is required to be able to reach a conclusion on a particular property of the substance. A short reasoning for why a given record is used in this respect can be provided in the field *Justification for type of information*. When using a *weight of evidence* approach you should provide as a minimum two separate endpoint study records for an endpoint (REACH Annex XI, 1.2).
- *disregarded due to major methodological deficiencies* is a study that demonstrates a higher concern than the key study/ies, but is not used as key study because of flaws in the methodology or documentation. This picklist value should be selected for justifying

why a potentially critical result has not been used for the hazard assessment. The lines of argumentation should be provided in field *Rationale for reliability incl. deficiencies*, accompanied by the appropriate reliability score.

- *other information* is other available information which does not directly contribute to the conclusions for the endpoint, and which does not fall under the criteria for *disregarded due to major methodological deficiencies*, e.g. because the disregarded study does not demonstrate a higher concern than the key study/ies.

All endpoint study records in sections corresponding to the REACH Annexes that are indicated as key study or as weight of evidence are subject to a full completeness check. Other types of study summaries should be filled in as much as possible to support the assessment of the endpoint.

#### *Reliability and Rationale for reliability incl. deficiencies*

Indicate in the field *Reliability for reliability incl. deficiencies* the reliability score for the (robust) study summary reported in the endpoint, and support the selection by providing the Rationale for reliability.

#### *Data waiving*

If you waive the information requirement according to the provisions of REACH Annexes VII-X or Annex XI (sections 2 or 3), you need to indicate this in the field *Data waiving*.

Select the rationale for waiving from the picklist, e.g. *study technically not feasible* when the nature of the substance does not allow it to be tested for that endpoint; or *study scientifically not necessary / other information available* when information exists that suggest that the study is not needed/relevant.

You then need to provide in the picklist field *Justification for data waiving* the detailed justification(s) as to why the study was not performed. The picklist contains standard phrases to justify data waiving, which are endpoint-specific and mostly based on the specific rules of column 2 under REACH Annexes VII-X. It is important to bear in mind that the availability of standardised phrases does not mean that a data waiving justification in the picklist is necessarily applicable to your particular case. The phrases are provided to assist you in documenting your decision. It is always up to the registrant to analyse their situation and decide whether waiving is applicable.

If you consider that data waiving is possible for a certain information requirement, but a suitable standard phrase is not available, the *Justification for data waiving* picklist also includes the option *other:*. When choosing this option, ensure to clearly document the basis for the waiving in accordance with the REACH regulation in the text field below.

If you intend to waive based on Annex XI, section 2 (testing is technically not possible), the omission of testing should be thoroughly justified and the technical limitations explained in the field *Justification for data waiving* under the picklist option *other:*. The data waiving justification needs to include the test method that has been attempted and the property of the substance that has impeded the testing. This property must be relevant for the endpoint.

#### *Justification for type of information*

Use the field *Justification for type of information* and the subsequent *Attached justification* field to store documentation specifically relevant for the type of information provided. The field provides free text templates that help the user in addressing the relevant points. In particular,

the field is expected to be populated when the *Type of information* of the endpoint study record is the following:

- *experimental study planned*: in the case of proposing a test on vertebrates, mandatory considerations for adaptation possibilities. Note that this information will always be published.
- *experimental study planned (based on read-across)*: endpoint-specific documentation on the read-across approach.
- *(Q)SAR*: endpoint-specific documentation on the prediction.
- *read-across based on grouping of substances (category approach)*: endpoint-specific documentation on the read-across approach.
- *read-across from supporting substance (structural analogue or surrogate)*: endpoint-specific documentation on the read-across approach.

In addition, for an endpoint study record where *Adequacy of study* has been set to *weight of evidence*, a short reasoning for why a given record is used in this respect can be provided in this field.

#### *Cross-reference*

Use the field *Cross reference* to link the endpoint study record to other records in the same IUCLID section, or to other sections that belong to the same dataset. For example, use the field:

- in a data waiving record to refer to the endpoint study record which provides the relevant information that is used as a basis for the data waiving (Data waiving: *study scientifically not necessary / other information available*). Note that the main argument of a data waiving must be reported in the field *Justification for data waiving* in the IUCLID section that is being waived.
- to link a read-across target record to the source record (Type of information: *read-across from supporting substance (structural analogue or surrogate)*, see chapter 8.6.3 *How to report read-across in IUCLID*).

**The following basic conventions apply when completing endpoint studies provided under the REACH Annexes VII to XI:**

- Each requirement indicated in columns 1 of REACH Annexes VII-X must correspond to at least one complete endpoint study record in IUCLID;
- If no data waiving, no testing proposal, no key study and no weight of evidence study are provided for a required endpoint, then the endpoint will be considered as incomplete;
- All data waiving, testing proposals, weight of evidence and key studies must be complete. As a consequence, if there is more than one key study or weight of evidence records per endpoint then all of these records must be complete; this applies even if the endpoint is not required for that Annex;
- An endpoint study record cannot be at the same time a data waiving, a testing proposal and/or a study summary.

### **Data source**

The Data source part of the endpoint study record captures information on the bibliographic reference of the data and on the data access (see also chapter 6 *Literature reference*).

#### *Reference*

To insert a *Reference*, click on the *Reference* field and then click the button *Select*.

- i. This action will open a dialogue window, where you can search for existing references in your IUCLID database by entering search criteria, such as Author, or Report date in the open dialogue or by typing at least three characters in the search field. Select the relevant reference in the list of search results.
- ii. Alternatively, you can create a new reference by clicking the *Create* button at the top of the window, entering the information and clicking *Save*.

Ensure to provide sufficient information about the reference to enable it to be verified.

#### *Data access*

Use the field *Data access* to indicate your relation with the provided study information; e.g. whether you are the data owner, or you have a Letter of Access to the information. If you select *data submitter has permission to refer*, then you must provide in the *Remark* field below the statement according to instructions you received from ECHA together with the permission to refer.

### **Materials and methods**

The information on the materials and methods is relevant for (robust) study summaries and testing proposals.

### *Test guideline*

Both for endpoint study records that represent (robust) study summaries and testing proposals, the test guideline (to be) used in the study must be indicated in the *Guideline* field under the table *Test guideline*. If no test guideline can be specified (e.g. because the study is a non-guideline study, or (Q)SAR was applied), or if you deviate from the indicated guideline, a description of the principles of the test protocol or the method must be provided in the field *Principles of method if other than guideline*. Templates are available to support entering the information.

### *GLP compliance*

For the endpoint study records that have the *Type of information* indicated as experimental study in sections 5 *Environmental fate and pathways*, 6 *Ecotoxicological information* and 7 *Toxicological information*, it must be indicated whether the study is compliant or not with the principles of Good Laboratory Practice (GLP) provided for in Directive 2004/10/EC. This is done by selecting one of the following options: *yes (incl. QA statement)*, *yes*, *no* or *not specified* from the picklist *GLP compliance*.

Note that according to REACH Article 13(4), ecotoxicological and toxicological tests performed after 1 June 2008 for REACH purposes should be carried out in compliance with GLP.

For each endpoint study record where the study has been indicated as GLP compliant, the contact details of the testing laboratory must be provided. To this end, at least one entry under *Reference* under *Data source* heading must contain information on the name, address and country in the *Testing facility* field.

*Type of method*, *Test type*, *Type of study*, *Type of assay*, *Type of study / information*, *Application method*, (section-dependent)

Report in these fields the specific type of method used, or test performed.

## **Test material**

The fields below the sub-heading *Test material* are relevant for endpoint study records that represent (robust) study summaries and testing proposals.

The field *Test material information* is a link field where a test material corresponding to the test material that was used in the study is linked (or is planned to be used in a proposed study)(see chapter 7 *Test material*).

The information provided in the test material record should cover the test material as it was used in the study as starting material for the test system, prior to any preparatory steps to convert it to the form actually used in the experiment. For the purposes of each experiment, the test material may have been further processed before used or administered to test animals. The details of this further processing are study specific and should therefore be given in the corresponding endpoint study record, in the field *Specific details on test material used for the study* or the relevant fields related to study design.

To link a test material information record:

Click the button *Select* in the *Test material information* field.

- i. This action will open a dialogue window, where you can search for existing test material

records in your IUCLID database by entering search criteria or by typing at least three characters in the search field. Select the relevant test material information record in the list of search results.

- ii. Alternatively, you can create a new test material information record by clicking the *Create* button at the top of the window, entering the information and clicking *Save*.

The test material record consists of a table in which to report the composition of the test material by using linked reference substances and concentration range fields. It also contains fields to report the test material form, and the details on the test material.

The test material should be reported to the level of detail available and relevant; however as a minimum, at least one constituent must be provided by linking a reference substance containing standard identifiers (EC, CAS and/or IUPAC).

- For an *experimental robust study summary*, it is expected that detailed compositional information on the test material exists and is provided, while for a *study summary based on handbook information*, less details on the test material may be available.
- When reporting the results for a *QSAR study*, the test material should correspond to the structure for which the prediction was made. QSAR predictions are typically made with discrete molecular structures and hence there is no need to define the concentration range. Instead, the registrant may indicate in the field *Composition / purity: other information* that the purity concept is *not applicable for an in silico study*. Moreover, in the case of QSAR studies typically only one reference substance would be expected to be linked to the test material. This reference substance should contain the *SMILES notation* or *InChI* with which the prediction was carried out.
- For a *read-across target record* (see chapter 8.6.3 *How to report read-across in IUCLID*), the test material should refer to the target of the read-across approach (i.e, the registered substance). The experimentally tested material(s) should be identified in the source study summary record (analogue) or in the category member substance records (category).
- For a record corresponding to a *testing proposal* the test material should be identified to the extent known.

It is important to note that any deviations in the test material from the registered substance should be listed (e.g. different amount of impurities). Moreover, all possible effects that such a deviation may have on the obtained test results should be analysed and reported under the *Overall remarks, attachments* heading of the endpoint study record.

Use the field *Specific details on test material used for the study* to report any study-specific information on the test material, such as the batch number and treatment of the test material prior to testing.

Use the field *Specific details on test material used for the study (confidential)* to report any study-specific confidential information on the test material.

Provide all available information on the study design, test animals, test systems and other sub-headings of the *Materials and methods* heading.

## Results and discussions

The *Results and discussion* part should be filled in for all endpoint study records that correspond to a (robust) study summary. The structure of the results part varies depending on the endpoint section; in general it consists of one or more tables where the results are summarised, together with fields that capture other observations related to the particular endpoint.

As a general rule, you must always fill in the results table; the minimum fields required for each section can be seen in the Annex 2. *Overview of the completeness check performed by ECHA on the submitted dossiers*, of this manual. Whenever a result was determined in the test, this should be provided, together with the relevant information on the parameters and test conditions, such as pH and temperature. When the test was performed (i.e. the information requirement was not waived), but a result could not be determined, this should be explained in the field *Remarks on result*.

**Figure 45: Example of filling in results table for flammable solids in section 4.13 – Flammability, when a result was determined in the test**

Flammable solids						
+ New item						
#	Key result	Test procedure	Burning time	Moisture (wt %)	Remarks on result	Action
1	<input checked="" type="checkbox"/> Key result	burning rate test: preliminary screening test	> 90.0 < 95.0 s	None	None	✘

**Figure 46: Example of filling in results table for flammable solids in section 4.13 – Flammability, when no result could be determined in the test**

Flammable solids						
+ New item						
#	Key result	Test procedure	Burning time	Moisture (wt %)	Remarks on result	Action
1	<input checked="" type="checkbox"/> Key result	burning rate test: preliminary screening test	None	None	substance does not ignite and propagate combustion either by burning with flame or smouldering along 200 mm of the powder train within the 2 minutes test period	✘

Report in the field *Any other information on results incl. tables* further information on the results,

e.g. the individual measurements behind the reported key result, and when relevant, any concentration/dose response relationship.

All results of the study are to be provided under *Results and discussion* heading. The information should not include interpretation of the obtained results, or analysis for the purposes of classification etc.

### Overall remarks, attachments

Under this heading, provide the interpretation or analysis of the obtained results, e.g. due to deviations in the test guideline, relationship of the substance properties to the applicability boundaries of the test method, or other factors that may have influenced the obtained results or their quality. Include an explanation on the reasoning for which the test results need to be interpreted in a particular way. Additional information may be provided under the table *Attached background material*.

### Applicant's summary and conclusion

Report the main conclusions from the study under *Applicant's summary and conclusion* heading. Use the field *Interpretation of results* (section-dependent), where available, to indicate how any effects observed in the study relate to classification and labelling criteria. Depending on the section, explain how the results impact the distribution of the test material in the environment and body (e.g. surface tension), and their influence on the risk assessment. In the field *Validity criteria fulfilled* (section-dependent), state whether the validity (or quality/repeatability) criteria of the applied testing method were fulfilled as per the OECD and EC test guideline used; note that the details included in the endpoint study record should support the selection.

### 8.6.3. How to report read-across in IUCLID

The approach of read-across implies that endpoint information from one or several chemicals (**source**) is used to predict information for another chemical (**target**) for the same endpoint, when the properties of the chemicals are considered to be similar. Using read-across to fulfil an information requirement requires the reporting of both the experimental information on the source chemical(s), as well as the outcome of the read-across prediction on the target chemical.

In IUCLID, the **source records** are normally endpoint study records with the *Type of information* selection *experimental study*. They must be provided as directly linked to the substance dataset (analogue approach), or as part of category member datasets (category approach). Endpoint study records indicated with the *Type of information* field to be *read-across based on grouping of substances (category approach)* or *read-across from supporting substance (structural analogue or surrogate)* are considered to be **target records**. The target records document the outcome of reading across from the source substance(s) (analogue approach) or from the chemical group (category approach).


Both target and source information must be present in a IUCLID dossier containing a read-across approach<sup>15</sup>. Below, instructions are given for the reporting of category and analogue read-across,

<sup>15</sup> As reporting of read-across in IUCLID 5 did not strictly follow the analogue or category approach, and as analogue read-across has so far been reported with a mix of source and target information in the same record, existing read-across records are migrated to IUCLID 6 with an indication in the *Type of information* field that the value was migrated from a previous version of IUCLID. In line with this, migrated read-across



and for the completion of read-across target records.

#### *Read-across based on grouping of substances (category approach)*

- **Target data:** You must indicate each endpoint study record linked to the registered substance, which documents the outcome of reading across information from the category to the registered substance, with the *Type of information* set to *read-across based on grouping of substances (category approach)*. See below for more detailed instructions on how to fill in a target endpoint study record.
- **Source data:** To provide the source information for the read-across, you must include at least one category object in the dossier, and ensure that all reported category objects are complete:
  - i. Provide information on the category hypothesis, applicability domain and category justification in the field *Category rationale (insert existing templates  Insert existing templates )* or attached in the table *Reports*.
  - ii. Link the *Category members*, i.e. the substance datasets that form part of the chemical category underlying the read-across, to the category object. The category member substance datasets that are not in scope of the registration should contain as a minimum all the relevant information on substance identification and property/endpoint data to support the category approach.
  - iii. In addition, you must list the *Category documents* that are used in the read-across approach.

#### *Read-across from supporting substance (structural analogue or surrogate)*

- **Target data:** You must indicate each endpoint study record, which documents the outcome of reading across information from the analogue to the registered substance, with the *Type of information* set to *read-across from supporting substance (structural analogue or surrogate)*. See below for more detailed instructions on how to fill in a target endpoint study record in the IUCLID web user interface.
- **Source data:** For each such target record, you must include at least one source record in the same IUCLID section. The source endpoint study record (ESR) should consist of a (robust) study summary of the experimental study done on the source substance. It should be filled in as any other ESR that documents an experimental study, and will be subject to full completeness check. Endpoint study records that are used as source documentation for read-across are expected to be reliable (1 or 2) studies and should therefore be reported with the *Adequacy of study* set to *key study* (exceptionally, the adequacy could be set to *weight of evidence*, if justified).

#### *Read-across target records*

Target endpoint study records are subject to a limited completeness check as it is not meaningful for the target record to contain information related to an experimental study, such as the guideline or reliability. Table 5 shows an example of how to fill in a target record for read-across from a supporting substance. Target records must be filled in as follows:

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records will be checked according to general completeness check rules for endpoint study records, and will not require the source-target approach described above. It is however advisable, for the sake of transparency and consistency, to adapt the read-across reporting to the new approach as soon as feasible.

### Administrative data:

- *Endpoint*: Indicate the endpoint as appropriate; generally it is the same as in the source study/ies
- *Adequacy of study*: Indicate the adequacy as appropriate, according to how you will use the target information to fulfil the information requirement in the registration dossier. Note that indicating a read-across target endpoint study record with the field *Adequacy of study* flagged as *supporting study*, *other information* or *disregarded due to major methodological deficiencies* means that it is not used to fulfil the information requirement and only provides additional information to the main body of data.
- *Justification for type of information*: Provide here the endpoint-specific justification for the read-across.
  - i. For read-across from a supporting substance it is possible to load a text template that can be further adapted and extended, as needed, to report the necessary justification for the particular read-across hypothesis.
  - ii. For read-across based on category this field should contain endpoint specific considerations, it is possible to load a text template. The category justification should be provided in the category object in the field *Category rationale*. For category read-across: if multiple category objects exist in the dossier, it is also useful to mention the category name supporting this read-across outcome.
- *Cross-reference*: The field is only relevant for analogue read-across; provide here a link to the endpoint study record(s) in the same IUCLID section used as source study/ies for the read-across.

### Materials and methods:

*Test material information*: Specify here the material that is the *target* of the read-across. While the test material information of the read-across target record usually reflects the substance that is in scope of the registration, explicit reporting of the read-across target material is important for the following reasons:

- i. As the registered substance often represents a more wide range of concentrations than a particular test material and as several purity profiles may be covered in the registration, it is essential to indicate the assumed composition of the read-across target material, so that its relevance for the registered substance can be assessed.
- ii. Read-across may also take place from one form of a test material to another. In this case, the form of the read-across target material should be clearly indicated.
- iii. In the case of a multi-constituent or UVCB substances, the target material may also refer to a (group of) constituent of such a substance, depending on what approach the registrant takes in fulfilling the information requirement.
- iv. Read-across may be applied to generate results on another substance than the registered substance (e.g. transformation product), which is relevant for the safety assessment.

### Results and discussion:

- Each IUCLID section has its own structure to report the results of the study. Click *New Item* to create the results table of the read-across target record and provide all the

relevant information on the result as generated through the read-across approach.

- The results in the target record may be identical to the source endpoint study record if read-across is truly one-to-one. However, there may be differences between the source and target chemicals, which influence the numerical result (e.g. molecular weight). In the case of chemical categories, the property to be predicted may not be stable within the chemical group but follows a trend. Therefore, it is important that the result you report in the target endpoint study record corresponds to the value estimated for the read-across target substance after applying any such corrections.
- You should only report results that have been generated by the read-across approach in the target record. The source endpoint study record may also contain results which are not used in the read-across approach; these should not be present in the target endpoint study record.

### Applicant’s summary and conclusion (optional but recommended)

- Present under this heading the main conclusions of the approach.
- The information should reflect the target material; provide an indication of how the estimated effects relate to classification and labelling criteria for the target material, if available in that section, and explain whether the results impact the distribution of the target material in the environment and body.
- In the *Executive summary* field, you may briefly summarise the justification for the read-across approach and the applicability of the result (please refer to the example in Table 8).

Table 5 below highlights the relevant parts of the endpoint study record for read-across source and target records. Mandatory chapters and fields are indicated in bold; parentheses refer to information that may be useful to report depending on the case.

**Table 5: Relevant parts of endpoint study record for read-across source and target records**

	Endpoint study record	Source record	Target record
<b>i</b>	Administrative data	X	X
	Endpoint	X	X
	Type of information	X	X
	Adequacy of study	X	X
	Robust study summary Used for classification Used for SDS	X	X
	Study period	X	
	Reliability	X	
	Rationale for reliability incl. deficiencies	X	
	Data waiving		
	Justification for data waiving		
	Justification for type of information	(X)	X
	Attached justification	(X)	X

	Cross-reference		X (analogue only)
ii	Data source	X	
iii	Materials and methods	X	
iv	Test material	X	X
v	Results and discussion	X	X
vi	Overall remarks, attachments	X	(X)
vii	Applicant's summary and conclusion	x	x

More information on the read-across approach:

- *Read-across Assessment Framework* (<https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across>)
- Guidance document: *QSARs and grouping of chemicals*; Chapter R.6 of the *REACH Guidance on information requirements and chemical safety assessment* (<https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>)
- Practical Guides (<https://echa.europa.eu/web/guest/practical-guides>)
- Video tutorial: How to report read-across using the analogue approach in IUCLID? (<https://www.youtube.com/watch?v=uKk7c0BLCgo&t=1s>)
- Video tutorial: How to report read-across using the category approach in IUCLID? (<https://www.youtube.com/watch?v=sLskhHjgZJU&t=4s>)

#### 8.6.4. How to report testing proposals in IUCLID

For studies required under REACH Annexes IX and X, a testing proposal has to be submitted if a valid test result is not available. A testing proposal is indicated by setting the field *Type of information*, to *experimental study planned*, or *experimental study planned (based on read-across)*, and should be completed as follows:

*Standard testing proposal, where the test is proposed on a test material that corresponds with the registered substance*

- *Endpoint*: Indicate the endpoint to be addressed by the proposed test.
- *Type of information*: Select the value *experimental study planned*.
- *Justification for type of information*: If the proposed test concerns testing on vertebrate animals, load the available text template *Experimental study planned / Testing proposal on vertebrate animals* and fill in the point-by-point considerations for why the different adaptation possibilities provided by the REACH Regulation cannot be used to address the information requirement, and why animal testing is necessary. This information will always be published on the ECHA website and linked to the third party consultation on the testing proposal.
- *Materials and methods*: under *Test guideline* heading, provide information on the *Guideline* and the *Test material* of the proposed test, as described in chapter 8.6.2 *How*

to complete endpoint study records.

- In addition, for testing proposals concerning sections 7.8.1 and 7.8.2, enter information in the fields *Justification for study design* and *Species*, respectively.

*Testing proposal based on read-across, where the test is proposed on a substance different from the registered substance, to be used as a source for read-across to the registered substance*

- *Endpoint*: Indicate the endpoint to be addressed by the proposed test.
- *Type of information*: Select the value *experimental study planned (based on read-across)*.
- *Justification for type of information*: load the available text template '*Read-across (analogue)*' or '*Read-across (category)*' and provide the endpoint-specific justification for the read-across approach (see also chapter 8.6.3 *How to report read-across in IUCLID* for links to further information on the application of read-across to fulfil information requirements).
- *Materials and methods*: *under Test guideline heading, provide information on the Guideline and the Test material of the proposed test, as described in chapter 8.6.2 How to complete endpoint study records.*
- In addition, for testing proposals concerning sections 7.8.1 and 7.8.2, enter information in the fields *Justification for study design* and *Species*, respectively.
- If the substance on which testing is proposed is subject to registration under REACH, ensure to include a standard testing proposal in the corresponding registration dossier according to the above instructions.

Note that if you have received a decision from ECHA requiring you to carry out studies for one or more endpoints, and you have a need to update your dossier before you have available all the information requested by the decision, you should not submit a testing proposal for the ongoing studies. Instead, proceed as follows: For each endpoint requested for which you do not yet have study information available, in the corresponding IUCLID section, create an endpoint study record with the appropriate selection in the field *Endpoint* and indicate the option *other justification* in the field *Data waiving*. Select the checkbox *other:* in the field *Justification for data waiving* and include the following sentence in the text field below "This information will be submitted later based on ECHA decision number TPE/CCH-D-xxxxxxxxxx-xx-xx" (insert the appropriate decision number).

### 8.6.5. Examples of completing endpoint study records

In this chapter you can find examples of how to document in IUCLID different approaches to fulfil the information requirements, i.e. which fields are relevant and the type of information to be filled in. For information on what the different approaches entail and how to use them to fulfil the information requirements, please refer to the following documents:

- *Guidance on information requirements and chemical safety assessment* (<https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>)
- *Practical guides* (<https://echa.europa.eu/web/guest/practical-guides>)

Note that the examples aim at illustrating how to use the IUCLID structure to report certain type of information. They are not exhaustive in content, and do not offer guidance on how to use the different approaches to fulfil the information requirements in a compliant way. The fields indicated below represent the minimum information expected when entering the information in IUCLID; all available information that is relevant for the interpretation of the results should be provided.

### Key study

In order to prepare an endpoint study record corresponding to a key study, detailed information on the applied methodology, test materials, the study results and conclusions has to be provided in the respective fields of IUCLID. An example is given on how to report a key study for section 4.7 – *Partition coefficient*. Note that the fields indicated below represent the minimum information expected when preparing an endpoint study record corresponding to a key study; all available information that is relevant for the interpretation of the results should be provided.

**Table 6: Key study record in section 4.7 – Partition coefficient**

Administrative data	
Endpoint	partition coefficient
Type of information	experimental study
Adequacy of study	key study
Robust study summary	<checked>
Reliability	1 (reliable without restriction)
Rationale for reliability incl. deficiencies	guideline study
Data Source	
Reference	<Link to a Literature reference record.>
Data access	data submitter is data owner
Materials and methods	
Test guideline	EU Method A.8 (Partition coefficient – Shake Flask Method)
Other quality assurance	ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories)
Type of method	flask method
Partition coefficient type	octanol-water
Test material information	[The example substance is a mono-constituent substance, tested with a representative sample.] <Link to test material record:> -Composition: Type 'Constituent'; <link to reference substance describing test material with standard identifiers (EC/CAS/chemical name)>; Concentration: ca 98.5 % (w/w) -Test material form: solid: flakes
Specific details on test material used for the study	- Batch nr: xxxx - Storage conditions: xxxx
Analytical method	high-performance liquid chromatography
Results and discussion	
Key result	<checked>

Type	log Pow
Partition coefficient	3.3
Temp.	20.0°C
pH	7.0
Any other information on results incl. tables	RESULTS TABLE: - Concentrations, phase 1 - Concentrations, phase 2 - Calculated partition coefficients P (mean + SD)
<b>Overall remarks, attachments</b>	
Overall remarks	The test was carried out according to the guideline, without deviations. The test material is representative of the registered substance, and no significant differences in the purity profile exist.
<b>Applicant's summary and conclusion</b>	
Conclusions	The partition coefficient (log Pow) of the test item was determined to be 3.3 at 20°C and pH 7.
Executive summary	The partition coefficient was determined using the Shake-flask method according to the EU A.8 test guideline and using HPLC as the analytical method. The partition coefficient was determined in triplicate, at 20°C and pH 7, obtaining a mean value (log Pow) of 3.3 and a standard deviation of 0.1.  <Include, in addition, any known implication for ENV/HH studies>

## Weight of evidence

When using a *weight of evidence* approach you should provide as a minimum two separate endpoint study records for the endpoint (REACH Annex XI, 1.2). You can provide in the field *Justification of type of information* an explanation on how the information in the particular endpoint study record contributes to the weight of evidence. In addition, you should create an endpoint summary (see chapter 8.6.7 *How to complete endpoint summaries*) to give an appraisal summary of all the information provided in the different endpoint study records, and a rationale for using this evidence instead of standard testing in the field *Description of key information*. The endpoint summary should link all endpoint study records that contribute to the weight of evidence.

Below you can see an example on two different weight of evidence records for section 4.7 – *Partition coefficient*. As above, the fields indicated below represent the minimum information expected when preparing weight of evidence records; all available information that is relevant for the interpretation of the results should be provided.

**Table 7: Weight of evidence record #1 in section 4.7 – Partition coefficient: (Q)SAR**

<b>Administrative data</b>	
Endpoint	partition coefficient
Type of information	(Q)SAR
Adequacy of study	weight of evidence
Reliability	2 (reliable with restrictions)
Rationale for reliability incl. deficiencies	results derived from a valid (Q)SAR model and falling into its applicability domain, with adequate and reliable documentation/justification
Justification for type of information	Load the available text template 'QSAR prediction': 1. SOFTWARE:

	<p>2. MODEL (incl. version number):</p> <p>3. SMILES OR OTHER IDENTIFIERS USED AS INPUT FOR THE MODEL:</p> <p>4. SCIENTIFIC VALIDITY OF THE (Q)SAR MODEL:</p> <p>5. APPLICABILITY DOMAIN:</p> <p>6. ADEQUACY OF THE RESULT:</p> <p>This endpoint study record is part of a Weight of Evidence approach comprising a QSAR (this study) and a read-across. Both data sources agree in the estimated value of log Pow and are sufficient to fulfil the information requirements as further explained in the provided endpoint summary.</p>
<b>Attached justification</b>	<Attached QMRF>
<b>Data source</b>	
<b>Reference</b>	<Link to a Literature reference record.>
<b>Data access</b>	data submitter is data owner
<b>Materials and methods</b>	
<b>Principles of method if other than guideline</b>	<details/references for the (Q)SAR model>
<b>Test material information</b>	<p>[The example substance is a mono-constituent substance; the prediction is done on the constituent.]</p> <p>&lt;Link to test material record&gt;:</p> <p>-Composition: Type 'Constituent'; &lt;link to the reference substance of the structure used as input for the prediction; include standard identifiers (EC/CAS/chemical name) and the SMILES notation or InChI.&gt;</p> <p>- Composition / purity: other information: not applicable for in silico study</p>
<b>Results and discussion</b>	
<b>Key result</b>	<checked>
<b>Type</b>	log Pow
<b>Partition coefficient</b>	3.0
<b>Temp.</b>	<Indicate value, if known. Otherwise, leave the field empty and state in the field Remarks on results of the same table row that the temperature value is not specified by the QSAR model.>
<b>pH</b>	<Indicate value, if known. Otherwise, leave the field empty and state in the field Remarks on results of the same table row that the pH value is not specified by the QSAR model.>
<b>Any other information on results incl. tables</b>	<When using QSAR for multi-constituent and UVCB substances, provide a detailed analysis of the estimations leading to the result.>
<b>Overall remarks, attachments</b>	
<b>Overall remarks</b>	(Q)SAR model is a valid model for this endpoint and it has been used within its applicability domain. The substance used for the prediction is representative of the registered substance.
<b>Applicant's summary and conclusion</b>	
<b>Conclusions</b>	The partition coefficient (log Pow) of the test item was estimated to be 3.0.
<b>Executive summary</b>	The partition coefficient was estimated using the (Q)SAR model X. This is a valid model for this substance which falls into its applicability domain as explained in the attached reports. The partition coefficient was estimated to be 3.0.



**Table 8: Weight of evidence record #2 in section 4.7 – Partition coefficient: target record for read-across from supporting substance**

Administrative data	
Endpoint	partition coefficient
Type of information	read-across from supporting substance (structural analogue or surrogate)
Adequacy of study	weight of evidence
Justification for type of information	<p>Load the available text template 'Read-across (analogue)':</p> <ol style="list-style-type: none"> <li>1. HYPOTHESIS FOR THE ANALOGUE APPROACH</li> <li>2. SOURCE AND TARGET CHEMICAL(S)</li> <li>3. ANALOGUE APPROACH JUSTIFICATION</li> <li>4. DATA MATRIX</li> </ol> <p>This endpoint study record is part of a Weight of Evidence approach comprising a read-across (this study) and a QSAR prediction. Both data sources agree in the estimated value of log Pow and are sufficient to fulfil the information requirements as further explained in the provided endpoint summary.</p>
Cross-reference	<Under 'Related information' heading, select 'Endpoint Study Record' and link to section 4.7 endpoint study record that contains the source study; indicate the Reason/purpose of the link as read-across source>
Materials and methods	
Test material information	<p>[The example substance is a mono-constituent substance; the read-across target is the constituent.]</p> <p>&lt;Link to test material record&gt;:</p> <p>-Composition: Type 'Constituent'; &lt;link to the reference substance corresponding to the target of the read-across; include standard identifiers (EC/CAS/chemical name).&gt;</p> <p>-&lt;provide further information on the read-across target material, such as form and concentration, as relevant.&gt;</p>
Results and discussion	
Key result	<checked>
Type	log Pow
Partition coefficient	2.8
Temp.	20.0°C
pH	7.0
Overall remarks, attachments	
Overall remarks	<as relevant>
Applicant's summary and conclusion	
Conclusions	The partition coefficient (log Pow) of the constituent indicated in the test material information was estimated to be 2.8 at conditions of 20°C and pH 7.
Executive summary	The partition coefficient was estimated to be 2.8 at 20°C and pH 7 from the partition coefficient of source study X. As explained in the justification for type of information, the differences in molecular structure between the target and the source are unlikely to lead to differences in the partition coefficient that are higher than the typical experimental error of the test method.

## Data waiving

Note that data waiving records should not contain information on study results; any supporting information on the data waiving should be provided in separate endpoint study records and indicated with the appropriate selection in the *Adequacy of study* field.

**Table 9: Data waiving in section 4.13 –Flammability, based on that the study is not technically feasible due to that the substance is a liquid**

Administrative data	
Endpoint	flammable liquids: obsolete as covered by section 'Flash point'
Data waiving	study technically not feasible
Justification for data waiving	the study does not need to be conducted because the substance is a liquid
Cross-reference	<Under 'Related information' heading, select 'Flexible record' and link to section 1.2 composition record describing the registered substance to be a liquid. Select 'Endpoint Study Record' and link to section 4.11 endpoint study record (key study or weight of evidence records) for results of the flash point – the corresponding endpoint for liquids.>

**Table 10: Data waiving in section 5.1.2 – Hydrolysis, based on that the study is not technically feasible due to high insolubility in water**

Administrative data	
Endpoint	hydrolysis
Data waiving	study technically not feasible
Justification for data waiving	the study does not need to be conducted because the substance is highly insoluble in water
Cross-reference	< Under 'Related information' heading, select 'Endpoint Study Record' and link to section 4.8 endpoint study record (key study or weight of evidence records) that demonstrate low water solubility.>

**Table 11: Data waiving in section 7.3.1 – Skin irritation/corrosion, based on the fact that an in vitro study is not scientifically necessary due to existing results from an in vivo study. Applicable when the in vivo study has been carried out under Annex VIII prior to the amendment to the REACH Annexes that makes the in vitro study the standard information requirement at all Annexes**

Administrative data	
Endpoint	skin irritation: in vitro / ex vivo
Data waiving	study scientifically not necessary / other information available
Justification for data waiving	an in vitro skin irritation study does not need to be conducted because adequate data from an in vivo skin irritation study are available
Cross-reference	< Under 'Related information' heading, select 'Endpoint Study Record' and link to section 7.3.1 endpoint study record (key study or weight of evidence records) for in vivo skin irritation.>

**Table 12: Data waiving in section 7.3.2 – Eye irritation based on the fact that the study is not scientifically necessary due to existing classification**

Administrative data	
Endpoint	eye irritation: in vitro / ex vivo
Data waiving	study scientifically not necessary / other information available
Justification for data waiving	other: "the study need not be conducted because the substance is classified as irritating to eyes with risk of serious damage to eyes" [free text to be entered by registrant]
Cross-reference	< Under 'Related information' heading, select 'Flexible record' and link to section 2.1 GHS record that includes the relevant classification.>

**Table 13: Data waiving in section 7.8.1 – Toxicity to reproduction based on the fact that the study is not necessary as the 28-day or 90-day repeated dose toxicity study indicates no adverse effects on reproductive organs or tissues. Applicable for information required at Annex IX only**

Administrative data	
Endpoint	extended one-generation reproductive toxicity – basic test design (Cohorts...)
Data waiving	study scientifically not necessary / other information available
Justification for data waiving	other: "the study does not need to be conducted because results from a 28/90-day study indicates no adverse effects on reproductive organs or tissues" [free text to be entered by registrant]
Cross-reference	< Under 'Related information' heading, select 'Endpoint Study Record' and link to section 7.5.X Repeated dose toxicity endpoint study record(s) that demonstrate absence of effects on reproductive organs or tissues.>

## Testing proposal

For studies required under REACH Annexes IX and X, a testing proposal has to be submitted if a valid test result is not available. In some cases, the need to submit a testing proposal may be also triggered by results of tests performed at a lower tonnage band. The fields indicated below represent the minimum information needed to submit a testing proposal; any further information relevant to support the testing proposal should be provided in the relevant fields. For testing proposals in sections 7.8.1 and 7.8.2, additional information in the fields *Justification for study design* and *Species*, respectively, are required. (see example below).

**Table 14: Testing proposal in section 7.8.2 – Developmental toxicity**

Administrative data	
Endpoint	developmental toxicity
Type of information	experimental study planned
Justification for type of information	<Include considerations for why this test is necessary and why adaptation possibilities are not adequate to generate the necessary information. Load the text template available for this field in IUCLID and ensure to address all points listed.> Note that this information will always be published on the ECHA website.
Materials and methods	
Test guideline	EU Method B.31 (Prenatal Developmental Toxicity Study)
Test material information	<Identify as far as possible the test material planned to be used in the test.>
Test animals	

Species	<Indicate the species on which the test will be performed.>
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### 8.6.6. Section specific advice - transformation product(s)

The identification of the transformation products must be provided for under section 5.1.2 Hydrolysis, section 5.2.2 Biodegradation in water and sediment: simulation tests, section 5.2.3 Biodegradation in soil, and section 5.4.1 Adsorption / desorption).

A selection must be made in the field *Transformation products*. If *yes* was selected, the transformation product(s) must be identified under *Identity of transformation products* heading by linking the appropriate reference substance(s) in the field *Reference substance*. The reference substance is expected to be identified by at least one of the following standard identifiers: EC number, CAS number and/or IUPAC name. If these information are not available, a spectrum can be attached in the field *Attached document*, under *Attached background material* heading.

In case of data waiving record for the above IUCLID sections, it is advisable to report the available information about the transformation product(s) in the data waiving record following the advice given above.

### 8.6.7. How to complete endpoint summaries

Endpoint summaries are created by clicking *New* next to the corresponding IUCLID sections inside the dataset, on the right of the screen. Except for the case where several sets of data are relevant for the assessment of the substance (see chapter 8.3.9 *Assessment approach - assessment entities* or Annex 5 *Assessment Entities in IUCLID 6*), there should normally not be more than one endpoint summary per type of record.

In the context of REACH, the endpoint summaries are very important, as the information compiled in them is used by the IUCLID Report generator for generating the Chemical safety report (CSR). In addition, selected key values are intended to serve as input parameters to feed specific software used for assisting in the risk assessment process, e.g. any exposure estimation tool or the REACH-specific ECHA Chemical Assessment and Reporting Tool (Chesar).

Endpoint summaries are available for all endpoints in IUCLID. There are three types of endpoint summaries:

- **Endpoint summaries at endpoint level** (e.g. section 6.1.1 Short-term toxicity to fish), to identify and justify what is(are) the key study(ies) to be used for the further assessment. Hence, an endpoint summary addresses, in a very condensed form, the most relevant and reliable data. The summary may be confined to the highlights of one key study, if only one is available, or give a justification as to why the results of a given study are considered as key data in case several studies are available. The same holds true, where an endpoint requires a weight of evidence evaluation based on several studies (guide on what needs to be considered in a WoE approach can be found in the "Weight of Evidence/uncertainty" template available at: <https://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats>).

Endpoint summaries at endpoint level include a number of data entry fields, which are further explained later in this chapter.

- **Endpoint summaries for main sections**, in which no endpoint data can be entered

directly. For instance, Endpoint sections 6.1.1 Short-term toxicity to fish, 6.1.2 Long-term toxicity to fish, 6.1.3 Short-term toxicity to aquatic invertebrates, etc., are grouped in section 6.1 Aquatic toxicity. The template for such endpoint summary usually only consist of two rich text fields: *Description of key information* and *Additional information*, which are included at the beginning of CSR sections as a conclusion on an endpoint. In some cases, a field for justifying the classification and labelling is also included (see chapter 8.4.1 *Section 2.1 GHS*);

- Hazard conclusions for the environment and for human health.** At the main heading level of section 6 *Ecotoxicological Information* and section 7 *Toxicological information* specific fields are provided for recording more integrated information, on hazard assessment conclusion, e.g. PNECs, DNELs respectively, including relevant input parameters but also more qualitative hazard conclusions. The fields for the hazard conclusion summary are further explained later in this chapter. Note that a DNEL calculator has been implemented in IUCLID to support registrants in deriving long term systemic DNELs (see chapter 8.6.7.1 *The IUCLID DNEL calculator*).

The next paragraphs explain the different endpoint summaries types in more detail.

### Endpoint summaries at endpoint level

Endpoint summaries at endpoint level are meant to identify the key information from the endpoint for the assessment. They consist of a set of information:

#### *Link to relevant study record(s)*

Provide here the link to the most relevant study (or studies) from which the key value for chemical safety assessment is extrapolated.

#### *Description of key information*

Provide here a short summary of the relevant values for the endpoint with some contextual information on the origin of the value. In particular, you can provide here the information which cannot be reported in the more structured fields under the section *Key value for chemical safety assessment*. Also, several key studies can be referenced as applicable. You may provide some information on the uncertainty of the key value used for the chemical safety assessment (for example including potentially ranges for the value). You may also provide qualitative characterisation of some properties (e.g. fully soluble). This text is mainly used for the CSR as a short summary of the data. For the physico-chemical properties reported in IUCLID sections 4 the description of key information corresponds to the information reported in the CSR section 1 by the Report generator. However, the characterisation of the endpoint data should be kept as concise as possible.

**Table 15: Examples of what could be reported in the *Description of key information* field of different summaries for different IUCLID sections**

Melting point	54.6-55.8 °C at 1,013 hPa (EEC Guideline A.1: Thermal analyses (Differential scanning calorimetry (DSC))partition coefficient)
Water solubility	completely miscible (EEC Guideline A.6)
Phototransformation in air	T1/2 = 9.32 x 10 <sup>-2</sup> yr (sensitizer: OH radical) (AOP Win v 1.86)
Biodegradation in water: screening test	Not readily biodegradable: 0 - 8% (BOD) in 28 days, 0 - 1% (HPLC) in 28 days (OECD TG 301C)
Explosiveness	Lower explosion limit: 3% by volume of air
Short-term toxicity to fish	LC50 (96h) < 100 mg/l for Pimephales promelas (OECD TG 203, static)
Repeated dose toxicity	Subchronic (90-day) study oral (gavage), rat (Sprague-Dawley) m/f (OECD guideline 408, GLP): NOAEL: 700 mg/kg bw/day (nominal) (male)

	Subacute (28-day) study oral (gavage), rat (Wistar) m/f (OECD guideline 408, GLP): NOAEL: >1000 mg/kg bw/day (actual dose received) (male/female)
<b>Genetic toxicity in vitro</b>	Gene mutation (Bacterial reverse mutation assay / Ames test): <i>S. typhimurium</i> TA 100: positive with and without metabolic activation; TA 1535: positive without metabolic activation (equivalent to OECD TG 471)
<b>Genetic toxicity in vivo</b>	Chromosome aberration (micronucleus assay): negative (similar to OECD TG 474; 3 concentrations (2 x 100, 2 x 200 and 2 x 400 µg/kg bw) orally administered to mice)

#### *Key value for chemical safety assessment.*

The information is foreseen for identifying the key value(s) that may subsequently be used in the chemical safety assessment as input parameters for exposure estimation or for deriving (eco)toxicological hazard conclusions, classification and labelling. In order to enable the use of any specific software, only a minimum number of structured fields are provided. Key values are intended to condense the data summarised in field *Description of key information* to one single numeric value or a concluding remark (e.g. negative / positive) chosen from a picklist. Where a numeric field is provided, only a value can be entered, that is, no range and no less than or greater than qualifiers. Conversion to a predefined unit or temperature may be required, if indicated in the field label (e.g. Koc at 20 °C), although in most cases the unit can be specified in a separate unit field.

If the key value identified from the study data is not a single value, but a range, or preceded by <, <=, >, or >=, you may have to provide the value that you consider most appropriate for the subsequent use of the value as input to the exposure assessment process. Indeed, assessment tools such as Chesar depend on the availability of key values entered in IUCLID endpoint summaries (e.g. molecular weight, vapour pressure, water solubility, biodegradability). The rationale for any user-derived values should be described in the rich text field *Additional information* for the sake of transparency.

- For physico-chemical and environmental fate properties, the key value mainly consists in a value which may be used for the estimation of a deterministic exposure value. Therefore select the value leading to a realistic worst case exposure estimate; As an example of user-derived parameter, if for water solubility the substance is completely miscible: enter an appropriate concentration value (e.g. 1 g/L) which falls in the highest solubility category used in the relevant assessment tool;
- For environmental hazard endpoints, the key value usually consists in a dose descriptor (e.g. LC50 or NOEC) which may be used for the derivation of a PNEC. Therefore, select the lowest relevant value.  
As an example of user-derived parameter, if for aquatic long-term toxicity to fish a LOEC of 1 mg/L is available (corresponding to >10% and <20% effect): calculate NOEC as LOEC/2 and enter 0.5 mg/L in the field for NOEC;
- For human health endpoints, the key value is further differentiated into a set of structured data which may be used for the derivation of a DNEL (therefore select the lowest relevant value) or a qualitative conclusion (e.g. irritant). The structure may vary depending on the endpoint. The following information can be reported as it is useful to identify the appropriate assessment factors for the derivation of a DNEL when relevant:
  - i. Endpoint conclusion: adverse effect observed/no adverse effect observed/no study available/ no study available (further information necessary)
  - ii. Endpoint selection enabling reference to an endpoint study record

- iii. Justification of selection to document why the selected study is considered as appropriate for concluding on the hazard for that endpoint
- iv. Effect level (when appropriate) to report the effect level from the selected study
- v. Test type (when appropriate) to report the test type from the selected study
- vi. Species (when appropriate) to report the species on which the selected study has been performed
- vii. Quality of the whole database described by different factors such as to what extent does the available information meets the tonnage driven data requirement of REACH (the completeness of the database), and the reliability and consistency across different studies (the quality of the testing method, the size and statistical power of the study design, the biological plausibility, the dose-response relationships and the statistical testing).

*Justification for classification or non-classification*

Available for some endpoints (see chapter 8.4.1 *Section 2.1 GHS*).

*Additional information*

In this rich text field, describe the interpretation of the key information you have made for the given endpoint. This includes for example:

- Conclusions for the hazard assessment for the endpoint. For example for physicochemical properties linked to physical hazards to human health, the inherent capacity of the substance to cause adverse effects is characterised.
- Discussion on the potential data gaps.
- Relevance of the results for the risk assessment. For example for human health, the extent to which the results from an animal study are relevant.
- The rationale for the choice of the key study(ies) and the choice of the key value that, according to your judgment, characterises the endpoint. This includes a discussion of the most relevant information identified and in some instances of studies which are considered to be unreliable, but give critical results. A discussion as to why they were discarded in favour of other studies should then be included. Vice versa, a weight of evidence analysis based on less reliable data or use of published data, the reliability of which cannot be judged because of limited reporting, should be justified.
- If several studies were identified to be relevant for the assessment, discuss possible reasons for differing results if any, e.g. differences in purity / impurities of the test substance used, differences in the methods and test conditions, etc. Such discussion may not be needed for simple endpoints in standard situation, for example water solubility.

**Table 16: Examples of what could be reported in the *Additional information* field**

Physicochemical properties mainly influencing the distribution and fate of the substance	
<b>Biodegradation</b>	The test item must be regarded as not readily biodegradable. However, as the substance still degraded between 40-60% in CO2 Evolution test, it is a clear indication that extensive primary biodegradation has occurred. The REACH Guidance on Information Requirements R.7b states 'When results of ready biodegradability tests indicate that the pass level

	critterion is almost fulfilled (i.e. ThOD slightly below 60%) such results can be used to prove inherent biodegradability.'. Therefore the substance is considered to be inherently biodegradable.
<b>Physicochemical properties linked to physical hazard for human health</b>	
<b>Flammability</b>	The flammable liquid has its flashpoint at 13 °C. The lower and upper explosion/flammability limits are between 3 and 19% by volume of air. The substance vapours are heavier than air. Due to its high vapour pressure (...) significant evaporation from liquid phase is expected. Auto ignition and decomposition may occur at temperature above 300 degrees.

In addition, for a few endpoints for human health (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) you may report an analysis of the mode of action of your registered substance in the field *Mode of action analysis / human relevance framework*. In order to properly complete this field, it is advised to refer to the templates based on the WHO/IPCS Mode of Action Framework published at <https://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats>. In particular it is recommended to make use of the HTML formats of these template which is already suitable for inclusion in the related IUCLID toxicological endpoint summaries.

### Hazard assessment conclusions<sup>16</sup>

For dossiers with a tonnage above 10 tonnes, a CSR must be provided (Annex I of REACH). This CSR should contain a hazard assessment where PNECs and DNELs should be derived when possible. In case the substance meets the classification criteria for at least one hazard, or is assessed as being PBT or vPvB, an exposure assessment is to be carried out. In this case the scope of exposure assessment under REACH and the type or risk characterisation to be carried out can be deducted from the hazard assessment conclusion for each protection target for the environment and each route and type of effect for human health:

- If the conclusion is that there is no hazard identified, then there is no need to carry out an exposure assessment;
- If a PNEC or a DNEL has been derived, a quantitative risk characterisation has to be carried out;
- If a DMEL or another toxicological threshold has been derived, a semi quantitative assessment has to be carried out;
- In all the other cases a qualitative risk characterisation is to be carried out.

For more information refer to Guidance Part D: Framework for Exposure Assessment available at <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

### Hazard conclusion for the environment (including PNECs)

In the endpoint summary of section 6 *Ecotoxicological information*, for each protection target (e.g. *Freshwater, Marine water, STP, Sediment (freshwater), Sediment (marine water), Air, Soil, Secondary poisoning*), a selection must be made in the picklist *Hazard assessment conclusion*.

<sup>16</sup> Guidance available at: <http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>



Based on the outcome of the hazard assessment, either a PNEC must be selected providing a numerical value and a unit, or a reason why no PNEC is available must be chosen from the list. If a PNEC was derived, provide additional information on the PNEC derivation in the fields *Assessment factor* and *Extrapolation method*.

When no PNEC is derived an explanation should be provided in the field *Explanation for hazard conclusion*.

### **Hazard conclusion for human health (including DN(M)ELs)**

In the endpoint summary of section 7 *Toxicological information*, for each hazard under *Workers* and *General population*, a selection must be made in the picklist *Hazard assessment conclusion*. The conclusions include:

- Derivation of DNELs or DMELs from the dose descriptors giving rise to the highest concern (usually the lowest NOAEL/LOAEL) per route of exposure and type of effect;
- Derivation of a qualitative description of the level and type of hazard (low, medium or high hazard) for threshold effects like irritation or sensitisation if no dose descriptor is available. This also applies for non-threshold effects for which no DMEL can be derived (e.g. mutagenicity);
- The statement *no hazard identified* for a route of exposure and type of effect, if no adverse effects have been observed at the limit dose in the reported studies;
- Statements related to the conclusion that the available information does not support a conclusion on the hazards of the substance for a certain route of exposure or type of effect. This may include two assessment cases:
  - i. *Hazard unknown but no further hazard information necessary as no exposure expected*: this is to be selected when the generation of hazard information is waived on the basis that no exposure is expected. In such case the exposure assessment should describe the use conditions under which exposure is prevented;
  - ii. *Insufficient hazard data available (further information necessary)*: to report that testing is proposed.

If a DNEL was derived, provide additional information on the DNEL derivation under *DNEL related information*.

When a deviation from a standard assessment factor is made your justification should specify how the following factors in REACH Annex I, Section 1.4.1. have been taken into account:

- the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
- the nature and severity of the effect;
- the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
- and that the DNELs reflect the likely route(s), duration and frequency of exposure.

Read the field-specific help text in IUCLID for more information.

### 8.6.7.1. The IUCLID DNEL calculator

IUCLID 6 includes a *DNEL calculator* functionality. The aim of the IUCLID DNEL calculator is to support the derivation of Workers and General Population Derived No-Effect Levels for long-term systemic effects for oral, dermal and inhalation routes based on the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.8.

The current version of the *DNEL calculator* only supports the derivation of DNELs for long-term systemic effect based on dose-dependent effects on repeated dose toxicity or reproductive toxicity. It does not support the calculation of DNELs for acute toxicity or local effects, nor the use of human data and the derivation of DNEL for threshold carcinogens. Finally, the *DNEL calculator* does not support the calculation of Derived Minimal Effect Levels (DMELs) for non-threshold hazards.

The *DNEL calculator* is available by clicking on the *Calculate DNEL* button in the endpoint summary under section '7 Toxicological information' in a substance data set or template. The *DNEL calculator* will calculate default DNEL values based on the data provided in the data set in the endpoint summaries of section 7.1, 7.5 and 7.8. The registrant can modify some parameters of the default calculations if needed, providing a justification. The outcome is automatically reported in the endpoint summary of section 7. The hazard conclusions for local effects and for acute effects have to be manually reported by the registrant directly in the endpoint summary of section 7.

For more information on the IUCLID *DNEL calculator*, refer to the help system of IUCLID.

### 8.6.7.2. The IUCLID PNEC calculator

IUCLID 6 includes a *PNEC calculator* functionality. The aim of the IUCLID PNEC calculator is to support the derivation of Predicted No-Effect Concentration for the aquatic, sediment and terrestrial environmental protection targets based on the ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.10.

The current version of the *PNEC calculator* does not support the calculation of PNECs for microorganisms in sewage treatment plants and the PNEC oral used for the assessment of secondary poisoning.



The *PNEC calculator* is available by clicking on the PNEC button in the endpoint summary under section '6 Ecotoxicological information' in a substance data set or template. The *PNEC calculator* will calculate default PNEC values based on the data provided in the dataset in the endpoint summaries of section 5.4.1 (Adsorption / desorption), 6.1.1 to 6.1.6 (Aquatic toxicity), 6.2 (Sediment toxicity) and 6.3.1 to 6.3.4 (Terrestrial toxicity). The registrant can modify some parameters of the default calculations if needed, providing a justification. The outcome is automatically reported in the endpoint summary of section 6. The hazard conclusions for microorganisms in sewage treatment plants and for the secondary poisoning have to be manually reported by the registrant directly in the endpoint summary of section 6.

For more information on the IUCLID *PNEC calculator*, refer to the help system of IUCLID.

## 8.7. Section 11 Guidance on safe use

According to section 5 of Annex VI of REACH Regulation you need to provide a guidance on safe use with the following information:

- *First aid measures;*
- *Fire-fighting measures;*
- *Accidental release measures;*
- *Handling and storage;*
- *Transport information.*

You can load the available text templates to support you to fill in these fields with the expected information. To load the templates click on the fields and then on the *Insert existing templates* icon (  Insert existing templates  ).

In cases, where CSR is not required, you need to report the additional information, such as:

- *Exposure controls / personal protection;*
- *Stability and reactivity;*
- *Disposal considerations.*

For joint submissions, the guidance on safe use can be provided jointly by the Lead registrant on behalf of all members, or separately by each member individually.

The reported information must be consistent with that in the safety data sheet (SDS), where an SDS is required.

## 8.8. Section 13 Assessment reports

This is the section where the chemical safety report is attached, if needed. Article 14 of the REACH Regulation requires a chemical safety assessment (CSA) and its documentation in a chemical safety report (CSR). This applies to the substances manufactured or imported at more than 10 tonnes per year with some exemptions listed in Article 14.2.

### 8.8.1. Section 13.1 Chemical Safety Report (CSR)

To attach a CSR:

**Step 1.** Create a record in section 13.1.

**Step 2.** Select the *Type of CSR*: if you are a lead registrant, select whether it is a *Joint CSR (joint uses)* that you submit on behalf of all members, or if it is an *Own CSR (own uses)*. You can also indicate if your own CSR is based on a jointly prepared CSR *Own CSR initially prepared jointly within the consortium*.

**Step 3.** Select the content of the attached CSR in the picklist *CSR contains* i.e. whether the CSR contains part A, or part B section 1 to 8 with hazard assessment, or part B section 9 and 10 with exposure assessment, or a combination of them.

**Step 4.** Indicate the type of tool used for performing the CSA and generating the CSR in the field *Chemical safety assessment/report tool used* (e.g. if you have used Chesar).

**Step 5.** Attach the CSR in the field *Chemical safety report (CSR)*.

**Step 6.** If you used a tool for performing your assessment and generating the report, you can also attach the export file from this tool in the field *Export file (safety assessment / exposure estimation tool)*.

**Step 7.** In the subsequent fields you can provide additional details on the attached files (for example if you attach an assessment tool export file, you may want to indicate the version used) or other explanations.

#### *Joint chemical safety report*

In case of a joint submission, the members can agree that the lead registrant submits a joint CSR on behalf of some or all of the members of the joint registration. The hazard assessment should always be done collectively within the joint submission. Submitting a joint CSR is also advised in case the exposure assessment is expected for the substance to be registered. The lead registrant dossier should include in section 3.5 all the uses covered by the joint CSR, and document, using the section 3.5.X field *Related assessment*, whether those uses:

- i. are assessed in the joint CSR, or
- ii. are assessed in the joint CSR but are not the lead's own uses

The member registrants include their uses in section 3.5, and indicate in section 3.5.X field *Related assessment*, that the uses are assessed in the joint CSR. The joint CSR should be submitted by the lead only. It is advisable that the lead provides a documentation to the members detailing how the uses covered in the joint CSR have been described in IUCLID section 3.5. The document could be provided as an export file from IUCLID.

In addition, the lead and member registrants may report and assess particular uses relevant only to themselves. In this case, they can submit a partial CSR Part B, containing only chapter 1, 2, 9 and 10, and add the corresponding uses in section 3.5. In the *Related assessment* field it should be flagged that the use are assessed in an own CSR.

It is essential that each registrant reports for each use in section 3.5.X whether it is assessed in a joint CSR or an own CSR, or is exempted from assessment.

If a CSR including exposure assessment is provided by the lead on behalf of the members, each member registrant should still provide part A of the CSR, where the member certifies that he applies the identified risk management measures at his own site, and has also communicated the required risk management measures relevant to his customers.

#### *Waiving the chemical safety report*

Article 14(2) of REACH specifies certain conditions under which a chemical safety assessment does not need to be conducted. If your substance fulfils the conditions under Article 14(2), in order for the dossier to be considered complete, you must create a record in section 13.1 and justify the absence of a CSR by including an explanation in the field *Discussion*. In the justification, you must clearly document how the substance fulfils the conditions in Article 14(2), i.e. that the substance is imported in a mixture or material where it is present at a value below the cut-off value relevant for that substance. The justification must be specific to the registered substance; a generic reference to Article 14(2) is not sufficient to omit the CSR.

- If you apply the derogation offered by Article 14(2) on the special case of a monomer imported in a polymer, you need to, in addition to the above, demonstrate that the

substance does not reoccur (i.e. is not released from the polymer) during its life cycle or after release into the environment.

### *IUCLID Report generator*

If you provide information under CSR Part A in section 13.1 *Chemical Safety Report (CSR)*, the IUCLID Report generator will use this information to complete part A of your CSR. This part includes the following three text fields:

- A summary of risk management measures: there is no need to repeat the description of the risk management measures included in the part B. A reference to the relevant exposure scenarios in Part B should be sufficient.
- The declaration that these measures have been implemented: this refers to the registrant's manufacture and own uses.
- The declaration that these measures have been communicated to customers via the extended safety data sheets.

Once the CSR has been generated with the IUCLID Report generator, it must be attached to section 13.1, as explained above. For information on how to access the Report generator see chapter 1.6.3 *The Dataset page*.

## **8.8.2. Section 13.2 Other assessment reports**

This section allows the attachment of different reports, other than the chemical safety report. For example, reports in response to dossier evaluation or measured exposure data reports can be attached here.

To attach a report:

**Step 1.** Create a record in section 13.2.

**Step 2.** Select the *Type of report*.

**Step 3.** Attach the report in the field *Document/report*.

**Step 4.** Provide additional information on the report in the *Further information on the attachment / remarks* field, as relevant.

## **8.9. Section 14 Information requirements**

### **8.9.1. Section 14 Annex III criteria**

The standard information requirements for the 1-10 tonnes/year registrations under REACH are defined in REACH Annex VII, which is divided into two types of information:

- Information on physicochemical properties required for all 1-10 tonnes/year substances; and
- Information on toxicological and eco-toxicological properties for all substances that do

not meet the criteria of a phase-in substance, and those phase-in substances that fulfil the Annex III criteria of REACH.

If you are registering a substance at 1-10 tonnes/year which meets the criteria of a phase-in substance according to REACH Article 3(20), and which does not have any properties of concern as described in REACH Annex III, you can benefit from the reduced information requirements and submit your registration dossier with physicochemical information only (see also the Annex *Overview of endpoints and information requirements*). In this scenario, you will need to fill in *Annex III criteria under Section 14 Information requirements* in IUCLID to justify your approach. This is applicable for individual, lead and member dossiers relying only on physicochemical information:

**Step 1.** Click on the *New* button in the row corresponding to *Annex III criteria*.

**Step 2.** Click on *New document*.

**Step 3.** A new record with a set of questions is created.

The questions/points appearing in the record will guide you, in a step by step mode, to the different possibilities for a substance falling under REACH Annex III, in order for you to demonstrate the non-applicability of its criteria to your substance. You will need to reply to all of the questions choosing *Yes* or *No* from the respective picklists. You will be able to justify your conclusion by a free text explanation and by attaching supporting documents, if necessary.

In order to support registrants' efforts in considering whether their substance meets the REACH Annex III criteria or not, ECHA has generated an inventory of substances for which there is evidence that they would possibly fulfil these criteria. The inventory, together with illustrative examples on how to use it, is available at <https://echa.europa.eu/information-on-chemicals/annex-iii-inventory>. In addition, ECHA has developed support material outlining an effective step by step procedure for companies to consider REACH Annex III in the context of their registration. For more information please visit the Annex III dedicated webpage at <https://echa.europa.eu/support/registration/what-information-you-need/reduced-information-requirements>.

### 8.9.2. Section 14 Opt-out information for REACH registration

In this section you indicate that you submit all or part of the registration dossier data separately, i.e., opt-out the commonly agreed data of the joint submission (REACH Article 11(3) or 19(2)).

There are two scenarios for opting-out from the joint submission of information:

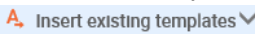
- Firstly, with the agreement of the lead registrant, you can opt-out from the joint submission some (a 'partial opt-out') or all (a 'full opt-out') of the data that is normally submitted jointly. In this case the lead will provide you with a token to sign up to the joint submission in REACH-IT and submit your opt-out dossier.
- Secondly, if you have not reached an agreement with the lead of the joint submission, you have to opt-out all of the data that is normally submitted jointly (a 'full opt-out'). In this case ECHA provides you with a token to sign up to the joint submission in REACH-IT following a data sharing dispute or access request to the joint submission. You can then submit your opt-out dossier.

For a full opt-out, you will need to prepare a dossier where you rely entirely on your own data. This means that your dossier needs to contain all the information required at your tonnage band. For a partial opt-out you will need to provide the information required at your tonnage band for only the sections you are opting-out from.

In order to prepare your dataset for opt-out, first complete all the data in the relevant IUCLID section then:

- Step 1.** Go to section 14 - Information requirements, then in the Opt-out information for REACH registration row click on *New* and then select *New document*.
- Step 2.** Select *New* item next to the Data selected for opt-out heading.
- Step 3.** Click in the *Documents* field and then click *Select*. You can then choose whether you are adding an endpoint study record or a Ghs record. To add a second endpoint study or Ghs record you click on *Select* again and add the chosen record.

Different blocks should be created if the opt-out data is justifiable based on different provisions laid down in REACH Article 11(3) or 19(2). To add additional data blocks click on *New item* again and repeat the steps described here above.

For each block created in that section, both for partial and full opt-out, you must provide a justification for the opt-out that covers all the documents in the block. To help in providing the opt-out justification four text templates are available. These templates are also available in Annex VII of this manual. All points of at least one template must be fully answered using the free text *Justification* field or the attachments tab in the Information panel of section 14 - *Opt-out information for REACH registration*. To open the text template, click in the *Justification* field and then on the *Insert existing template* icon (  ). Choose the template (a, b, c or d) relevant for the set of documents by selecting it from the drop down list. The text should then be edited so it contains only relevant data and all points should be answered.

Note: If you are opting-out to provide available existing information on physicochemical, human health or environmental properties of an intermediate (Article 17(2)(d) or 18(2)(d) of REACH) or other information that is not required by any registrant in the joint submission you should use template 'c'. If opting-out to provide your own classification and labelling data you should use template 'd'.

If you have received an ECHA decision granting the 'permission to refer' related to a data sharing dispute, you do not need to complete templates a, b, c or d for the data you have permission to refer to. Instead, type the following sentence in the field *Justification*: "Permission to refer granted by ECHA based on data sharing dispute DSH-XX-X-XXXX-XXXX." The 'X' characters in the reference DSH-XX-X-XXXX-XXXX must be replaced with the actual number of the dispute. For any additional data submitted separately for which you have not received the 'permission to refer', you must provide a justification for submitting that data separately, answering all of the points of at least one of the templates (a, b, c, d) provided in this section.

All the records linked in section 14 will be automatically included in the dossier. However, depending on the tonnage band, some additional data that is required (such as endpoint summaries) can only be included in your dossier during the dossier creation step. For advice on how to include such data please see section 10.2 of this manual.

More information on the opting out possibilities and mechanisms can be found in the *Guidance on data sharing* available at <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

A Q&A section on the joint submission of data by multiple registrants is available at <https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/Joint+submission+of+data+by+multiple+registrants> (see section Joint submission opt-out).

Additionally, more information on how to create a full and partial opt-out dossier can be found in chapter 9.2 of this manual.

## 9. How to create a Dossier

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

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

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

- Step 1.** To create a dossier open the list of available substance datasets by clicking on the 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.**

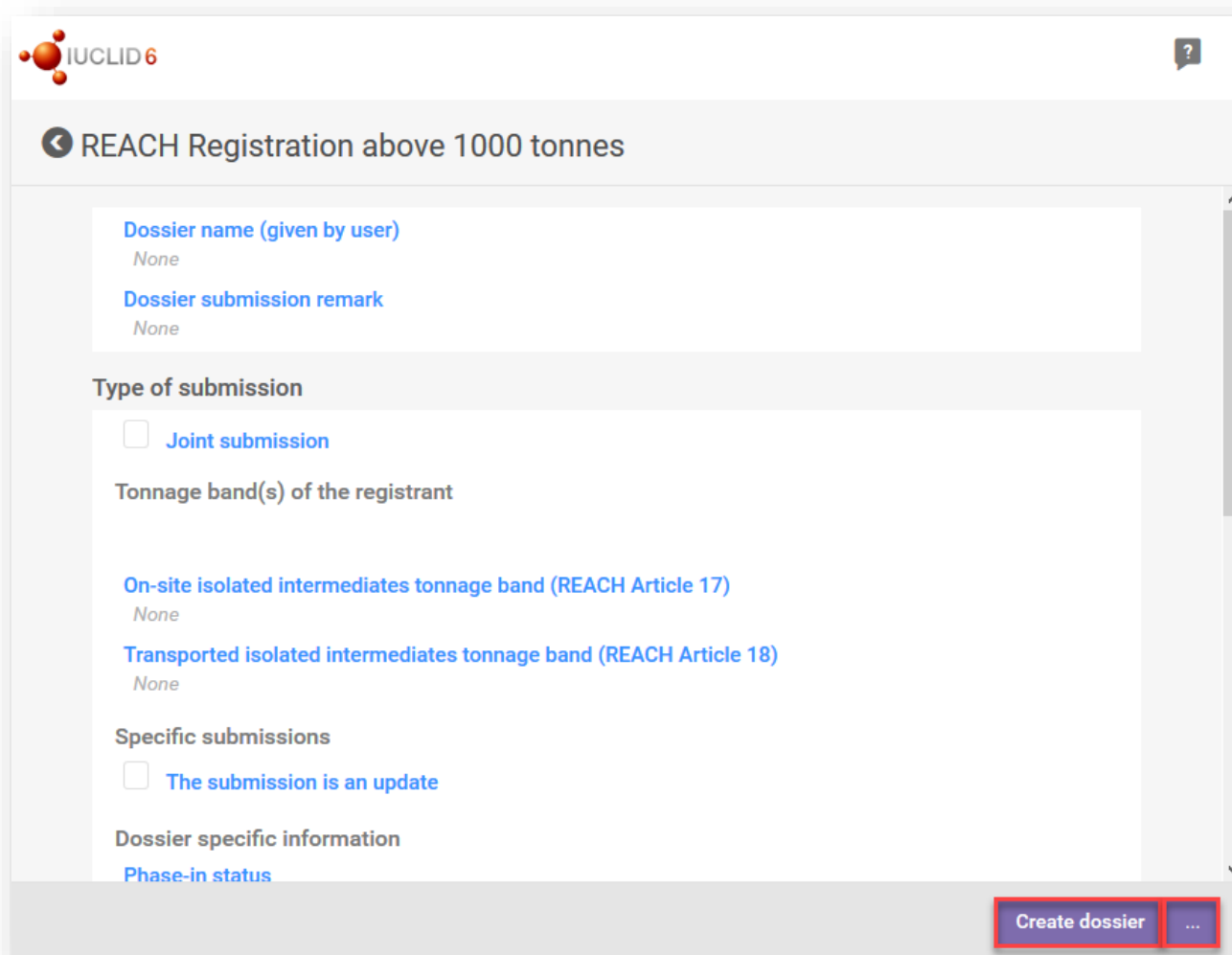
Information contained in the dossier header is crucial for business rules checking when you submit your dossier. Missing or incorrect information can result in that your submission cannot be accepted for further processing and will be automatically removed from the system. In this case you need to create 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 purple three dotted button displayed next to *Create dossier*.

**Figure 47: 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.

## 9.1. Administrative information

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

*Dossier submission remark:* This field is optional and can be used for additional remarks on the submission reasons, e.g. in the case of an update, what motivated it.

### 9.1.1. Type of submission

**Individual registrant:** The checkbox *Joint submission* should not be selected if you are not part of a joint submission with your substance.

**Lead registrant:** The checkbox *Joint submission* should be selected only if your dossier will be submitted as the lead dossier of a joint submission. Select the relevant checkboxes if you are providing information on behalf of the members, such as *Chemical safety report*, *Guidance on safe use* and/or *Review by an assessor*.

**Member registrant:** If you are a member of a joint submission, make sure you have selected one of the two following *Working contexts* (Submission types):

*Member of a joint submission - general case;*  
*Member of a joint submission - intermediates.*

As a member of a joint submission you can indicate in the dossier header if information is provided by the lead on your behalf. This applies to the *Chemical safety report*, *Guidance on safe use* and *Review by an assessor*.

### 9.1.2. Tonnage band

In the field *Tonnage band(s) of the registrant* select your own tonnage band. The tonnage band of the joint submission is established by the type of dossier template that you have selected. If the dossier is a combined submission for non-intermediate and intermediate use, then indicate also the intermediate tonnage bands.

### 9.1.3. Specific submissions

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

An update can be submitted only in the following cases:

- Spontaneous update, when you have successfully registered this particular substance and you wish to update your dossier with new information;
- Requested update, following a failure of the technical completeness check (TCC) in your previous submission, or a request or decision by the Agency.

They are further explained in the next chapters.

### 9.1.3.1. Spontaneous update

Submit a spontaneous update if you wish to update your dossier on your own initiative in order to keep your dossier up to date as per REACH Article 22, or in response to an informal communication from the Agency such as a screening campaign. Indicate in the dossier header that *The submission is an update* and enter the submission number of the last successful submission in the corresponding field. Select the checkbox *Spontaneous update*. Select an appropriate reason for updating from the picklist in the *Justification* field. If you select *other*, then the free text field needs to be filled with an appropriate reason for updating. If you wish to indicate more than one reason for updating the dossier, you should create an additional repeatable block for each reason. Please note that a *Justification* has to be provided in all the blocks.

### 9.1.3.2. Update following a completeness check failure

**Submit a requested update if you are updating your dossier due to a completeness check failure(s) in your previous submission.** Indicate that *The submission is an update* and enter the submission number of the submission that failed the completeness check in the corresponding field. Select the checkbox *Further to a request/decision from regulatory body* and enter the communication number in the field *Number*. The communication number can be found in the completeness check failure letter under the Key documents tab of the Submission page in REACH-IT.

### 9.1.3.3. Update following other request by the Agency

Submit a requested update if it was so requested by the Agency e.g., resulting from a compliance check or confidentiality claim assessment outcome in a letter sent to your REACH-IT account. Indicate in the dossier header that *The submission is an update* and enter the submission number of your last successful submission in the corresponding field. Select the checkbox *Further to a request/decision from a regulatory body* and enter the communication number linked to the request by the Agency that motivated the update in the field *Number*.

### 9.1.4. Dossier specific information

**Reviewed by an assessor:** The checkbox *Reviewed by an assessor* is not compulsory, but in accordance to REACH Article 10 (a) (viii) if the dossier, or parts of it, have been reviewed by an assessor it must be indicated here.

**Confidentiality claims:** *Confidentiality claim on registration number* and *Confidentiality claim on tonnage band* should be selected if you want to claim the relevant data confidential. The claim needs to be followed by a justification. Also, these claims may trigger an invoice.

The confidentiality claim flag in the dossier header needs to be re-introduced every time the dossier is resubmitted. Once you have received the registration number, you can also put the confidentiality flag on the registration number in IUCLID section 1.3. The flag will remain there in the subsequent updates.

The checkbox for the *confidentiality claim on the tonnage band* is the only location in the dossier where you can request confidentiality on your registered tonnage band. The confidentiality flag in IUCLID section 3.2 relates to the actual tonnage manufactured/imported, which is always treated as confidential information.

**Data sharing issues:** When joining a joint submission using a token provided by the Agency, it is mandatory to select the checkbox *Data sharing issues* in the dossier header while creating the dossier. Provide an explanation in the *Justification* field that refers to your enquiry number (INC000000XXXXXX) in case of joint submission access request for submitting a full opt-out dossier, or your Data sharing dispute number (DSH-XX-X-XXXX-XXXX) in case you have received the 'permission to refer' following a Data sharing dispute. The 'X' characters in the reference DSH-XX-X-XXXX-XXXX must be replaced with the actual number of the dispute.

When the checkbox *Data Sharing Issues* in the dossier header is selected, the submission cannot rely on the jointly submitted documents.

**Fee waiving (1-10 tonnes, not fulfilling Annex III criteria and voluntarily providing full Annex VII):** You can claim a fee waiver in the dossier for 1-10 tonnage band (including intermediates) only if you, or the joint submission lead, voluntarily provide the full information indicated in Annex VII of REACH and your substance is phase-in and considered of low risk (i.e. does not meet the Annex III criteria of REACH).

Please see also Chapter 8.9.1 *Section 14 Annex III criteria* of this document for background information.

Note that in order to refer to the full Annex VII data of the lead dossier you need to have a prior agreement with the lead registrant during the data sharing negotiations. If the lead submission does not cover the full Annex VII (e.g. lead dossier with reduced information requirements/physicochemical information only), as a member you can provide the information as an opt-out.

When submitting a registration using the template REACH Registration *1 – 10 tonnes, physicochemical requirements* the registrant is not entitled to waive the fee.

#### 9.1.4.1. Compulsory information for isolated intermediates

If your dossier covers a registration for intermediates then one or both of the checkboxes referring to the conditions of the use in accordance with REACH Article 17 and 18 need to be selected as appropriate.

## 9.2. How to include endpoint summaries in an opt-out dossier

When preparing a full opt-out dossier (see chapter 8.9.2) you should link in section 14 all the information corresponding to sections 2.1 - *GHS* and the endpoint study records in sections 4-7, i.e. the information that is normally submitted jointly as per Article 11 (see chapter 8.9.2 of this manual). When creating a dossier using a joint submission member template most of this information is automatically transferred from your dataset to your dossier, however if you need to include endpoint summary records including section 6 'Ecotoxicological information' and section 7 'Toxicological information' they must be selected manually.

In order to include all relevant information proceed as follows:

**Step 1.** When starting to create your dossier, under *Working context* choose the relevant template and click *Create dossier*.

Select your tonnage band, phase-in status and any other relevant information. If you are accessing the joint submission using a token provided by the Agency following a request to access the joint submission or following a dispute, you need to select the checkbox *Data sharing issues*. Then, add the following sentence in the *Justification* field: 'Opt-out based on token provided by ECHA following the enquiry INC000000XXXX'

or

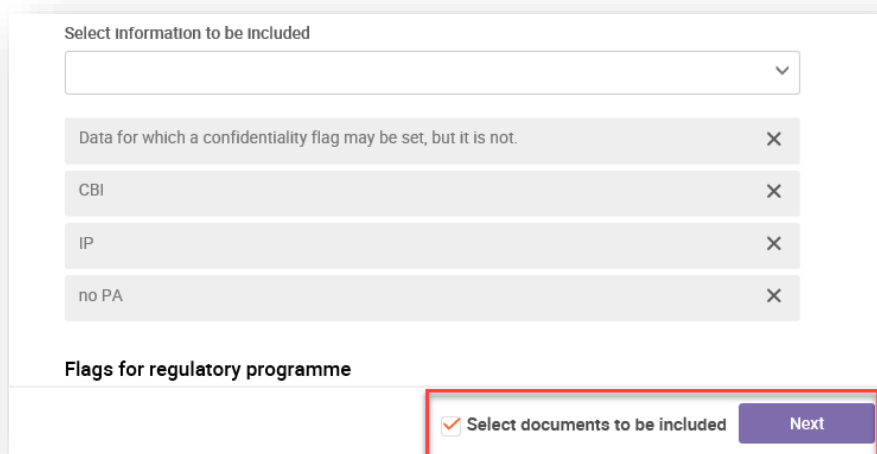
'Opt-out based on token provided by ECHA following Data sharing dispute DSH-XX-X-XXXX-XXXX.'

The 'X' characters in the references INC000000XXXX or DSH-XX-X-XXXX-XXXX must be replaced with the actual number of the inquiry or dispute. Further instructions are included in an annex to your request for joint submission access or data sharing dispute decision.

Some documents are already pre-selected based on the dossier template. These are the default sections for a non opt-out joint submission member dossier and the opt-out sections indicated in section 14. Endpoint summaries are not pre-selected, but need to be manually added. If you need to add endpoint summary records:

- Step 2.** Access the *Advanced settings* for dossier creation by clicking on the purple three dotted button displayed next to *Create dossier*.
- Step 3.** Select the tick box *Select documents to be included* then click *Next*.
- Step 4.** Add the endpoint summary records.

**Figure 48: Dossier creation: Select documents**



- Step 5.** Click *Create dossier*.
- Step 6.** Verify that the additional documents you selected to include are present in the final dossier.

More information on opt-out possibilities and mechanisms can be found in the *Guidance on data sharing* available at <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

IUCLID tutorial videos:

*How to opt-out in IUCLID*


<https://www.youtube.com/watch?v=lhcs270KQg&t=12s>

*How to opt-out in IUCLID Cloud*

<https://www.youtube.com/watch?v=FQIBW5W6dBA>

## 10. 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*.

## 11. 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/https://reach-it.echa.europa.eu/>.

## 12. 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 9 *How to create a Dossier*).

Once a registration dossier has been submitted to ECHA and accepted for processing, any resubmission of the dossier has to be identified as an update for technical reasons and it is the responsibility of registrant. If the information is the part of the joint submission, the lead registrant have to update the registration on behalf of the members.

There are two types of updates for registration dossier: *requested* and *spontaneous update*. When updating a dossier refer to the chapter 9 of this manual.

For more information how to update a registration refer to the *Guidance on registration* available at <https://www.echa.europa.eu/web/guest/guidance-documents/guidance-on-reach>.

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

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

This document will guide you through the basic requirements of creating the substance dataset and the IUCLID dossier header. In addition, it is recommended to use the IUCLID Validation Assistant on the substance dataset and also on the final dossier before exporting it from IUCLID and submitting it to REACH-IT. Click on your substance dataset or on the dossier in the IUCLID navigation panel 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 PPORD and for registration dossiers (full registration, on-site isolated intermediate, transported isolated intermediate)		
Location (IUCLID/REACH-IT)	Rule description	Relevance
<b>IUCLID substance dataset</b>	A REACH dossier must be created from a substance dataset. It cannot be created out of a mixture or product dataset.	All dossier types
<b>IUCLID section 1.1 – Identification</b>	A reference substance must exist in section 1.1	All dossier types
<b>IUCLID section 1.1 – Identification; section 1.2 – Composition</b>	<p>Each reference substance in section 1.1 and 1.2 must contain a substance identifier. An acceptable substance identifier is:</p> <ul style="list-style-type: none"> <li>EC/List number</li> <li>CAS number</li> <li>IUPAC name</li> </ul> <p>Any EC/List number defined in section 1.1 and 1.2 of IUCLID must exist in the REACH-IT EC inventory.</p> <p>If you use a reference substance to report unknown constituents/impurities, they must be “identified” by inserting “Unknown constituent/impurity” in the IUPAC name field.</p> <p>If categories are used, this rule is applied to all the category member substances.</p>	All dossier types

<b>IUCLID section 1.1 – Identification</b>	The reference substance must be marked as one of the following: Mono-constituent substance Multi-constituent substance UVCB	All registration dossiers and PPORD
<b>IUCLID section 1.1 - Identification</b>	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.	All registration dossiers and PPORD
<b>IUCLID section 1.1 - Identification</b>	For an update submission, you must always specify an EC number in the reference substance that is assigned to IUCLID section 1.1. The EC number must correspond to the one used in your previous submissions for this substance. If your initial submission did not contain an EC number, you must use the EC number that REACH-IT has created for this substance. In this case, you need to go to REACH-IT and download the EC entry that REACH-IT created for your substance. Import the EC entry into your IUCLID installation and assign it to your reference substance.	All registration dossiers and PPORD - Updates
<b>IUCLID section 1.2 – Composition</b>	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
<b>IUCLID section 1.2 – Composition</b>	All compositions created in section 1.2 must have the composition type indicated. At least one of the compositions in section 1.2 must reflect the composition of the substance manufactured/imported by the registrant. This composition must be marked as the “Legal entity composition of the substance”.  If the composition type “other” is selected from the list, the relevant information must be provided in the below text field.	All dossier types
<b>IUCLID section 1.1 – Identification; section 1.2 – Composition</b>	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
<b>IUCLID section 1.1 - Identification; section 1.2 – Composition</b>	If the substance is defined as a multi-constituent substance, the reference substance in section 1.1 cannot be identical to any of the constituents defined in the first composition of type ‘legal entity composition of the substance’ in section 1.2.	All dossier types
<b>IUCLID section 1.2 – Composition</b>	All constituents of a multi-constituent or of a UVCB substance must identify distinct reference substances.	All dossier types
<b>IUCLID section 3.3 - Sites</b>	Assign a site for each record in IUCLID section 3.3. You must also provide a contact address for the site; ‘Country’ is the	All registration dossiers and PPORD



	minimum information required.	
<b>IUCLID dossier header</b>	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.	All registration dossiers and PPORD
<b>IUCLID dossier header</b>	Updates can be submitted in the following cases: Following the successful registration / notification of this particular substance, after having received a reference number (spontaneous update). Following a technical completeness check (TCC) failure (requested update). Following a request for further information by the Agency (spontaneous or requested update as specified in the request).  In any other case, an initial submission is required.	All dossier types - Updates
<b>IUCLID dossier header</b>	If you wish to submit a spontaneous update then the following conditions must be fulfilled: In the dossier header select the checkboxes 'The submission is an update' and 'Spontaneous update'. Insert the submission number to the last successful submission as the 'Last submission number'. Select an appropriate justification for updating by first creating a block under 'Spontaneous update' and then making a selection in the pick-list. If you selected 'other:', you are required to give the reason in the below text field.	All registration dossiers and PPORD - Updates
<b>IUCLID dossier header</b>	If you wish to update your dossier following a TCC failure then the below conditions are to be fulfilled: In the dossier header select the checkboxes 'The submission is an update' and 'Further to a request from a regulatory body'. Insert the submission number of the dossier that failed TCC as the 'Last submission number'. Provide the annotation number in the field 'Number'. The annotation number can be found in REACH-IT under the Key documents in the letter that motivated the update.  A requested update following a TCC failure must be submitted within the given deadline. Missing this deadline leads to the decision made on the original submission. No other submission can be made for the given substance until a final decision has been communicated to the registrant.	All registration dossiers and PPORD - Updates
<b>IUCLID dossier header</b>	If you wish to update your dossier following a request by the Agency (except when following a TCC failure) then the below conditions must be fulfilled: In the dossier header select the checkboxes 'The submission is an update' and 'Further to a request from a regulatory body'.	All registration dossiers and PPORD - Updates

	<p>Insert the submission number to the last successful submission as the 'Last submission number'.</p> <p>Provide the annotation number in the field 'Number'. The annotation number can be found in REACH-IT under the Key documents in the letter that motivated the update.</p>	
<b>IUCLID section 1.3 – Identifiers</b>	<p>For an update submission, a reference number must be given in IUCLID section 1.3. If you are updating your dossier because your initial submission failed TCC then there is no reference number available yet.</p>	All registration dossiers and PPORD - Updates
<b>IUCLID dossier template</b>	<p>The dossier template used in IUCLID must correspond with the intended submission type in REACH-IT.</p>	All dossier types
<b>IUCLID dossier header</b>	<p>Legal entity change cannot be performed by submitting and update to the dossier. The 'Legal entity change' module in REACH-IT is to be used to carry out the administrative changes related to ownership of the registration/notification.</p>	All registration dossiers and PPORD - Updates
<b>REACH-IT</b>	<p>Parallel submissions are not allowed for the same annotation number. You cannot submit a dossier quoting the same annotation number while another dossier is still being processed.</p>	All registration dossiers and PPORD - Updates
<b>REACH-IT</b>	<p>A new dossier cannot be submitted when the previous submission for the same substance is still being processed.</p>	All dossier types - Updates
<b>REACH-IT</b>	<p>No submissions can be made from the account of a legal entity, which at the time of submission undergoes the legal entity change (merge) process.</p> <p>Legal entity change functionality is available in REACH-IT.</p>	All dossier types
<b>REACH-IT</b>	<p>The same IUCLID dossier cannot be submitted more than once.</p>	All registration dossiers and PPORD
<p><b>Business rules applicable for the registration dossiers (full registration, on-site isolated intermediate, transported isolated intermediate)</b></p>		
<b>IUCLID section 1.3 - Identifiers</b>	<p>When submitting an update to a previously notified substance (NONS) then both the Registration number and the NCD number must be indicated.</p>	All registration dossiers
<b>IUCLID section 1.1 – Identification; section 3.3 - Sites</b>	<p>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. In addition you must assign at least one manufacture use from section 3.5.1 using the field 'Related manufacture/own use'.</p>	All registration dossiers
<b>IUCLID section 1.1 – Identification; section 1.3 – Identifiers</b>	<p>The EC number indicated in IUCLID section 1.1 has to be in line with the one indicated in the result of your previous inquiry on this substance.</p>	All registration dossier

<b>IUCLID dossier header section 1.1 – Identification</b>	If the reference substance in section 1.1 corresponds to an EINECS or NLP substance (200, 300 or 500 EC number), then the substance must not be indicated as 'non phase-in' in the dossier header.	All registration dossiers
<b>IUCLID substance dataset</b>	If you wish to include a category in the dossier, you need to create the dossier from a substance dataset that has been assigned to the category.	All registration dossiers
<b>IUCLID section 1.1 – Identification</b>	The reference substance in section 1.1 has to have a chemical name provided in the IUPAC name field.	All registration dossiers
<b>IUCLID section 1.2 – Composition</b>	In a lead dossier, at least one of the compositions in section 1.2 must be marked as the 'boundary composition of the substance'. This composition is to describe the collectively agreed boundaries of the substance and correspond to the data submitted on the substance properties.	All registration dossiers
<b>IUCLID section 1.2 – Composition</b>	For UVCB substances, all composition in section 1.2 indicated as 'boundary composition of the substance' must include details on the source material and the type of process used for production in the field 'Description'.	All registration dossiers
<b>IUCLID section 1.2 – Composition</b>	Provide the full concentration range (lower and upper value together with a unit) for each constituent, impurity and additive of a composition indicated as 'boundary composition of the substance'.	All registration dossiers
<b>IUCLID section 1.2 – Composition</b>	All impurities and additives in compositions that are indicated as 'boundary composition of the substance' must be linked to a reference substance. The reference substance must be identified by one of the following: EC/List number CAS number IUPAC name	All registration dossiers
<b>IUCLID section 1.2 – Composition</b>	For compositions indicated as a 'boundary composition of the substance' in IUCLID section 1.2, you must identify each additive by assigning it a reference substance. In the reference substance you must provide information on the EC, CAS and/or IUPAC identifiers, as available, in the designated fields.	All registration dossiers
<b>IUCLID section 1.2 – Composition; section 2.1 - GHS</b>	When you report multiple 'legal entity compositions' in section 1.2 then all of them must be assigned to the corresponding classification and labelling record in section 2.1. This is done through the field 'Related composition' in section 2.1.	All registration dossiers
<b>IUCLID section 2.1 - GHS</b>	The classification and labelling information must be provided in the GHS format in section 2.1.	All registration dossiers
<b>IUCLID</b>	For each 'Specific concentration limit' entry that is created in	All registration dossiers

<p><b>section 2.1 – GHS</b></p>	<p>a C&amp;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'.</p> <p>If no classification is given in a C&amp;L record, the checkbox 'Not classified' should be marked and no specific concentration limits should be indicated in that record.</p>	
<p><b>IUCLID section 2.1 – GHS</b></p>	<p>If the substance is classified, a 'Hazard category' and a 'Hazard statement' must be provided, or a 'Reason for no classification' for each hazard class in IUCLID section 2.1 should be indicated.</p> <p>If the substance is not classified, the checkbox 'Not classified' should be marked and no classification should be provided in that record.</p>	<p>All registration dossiers</p>
<p><b>IUCLID section 2.1 – GHS</b></p>	<p>If the substance is classified, at least one entry for 'Specific target organ toxicity – single (STOT-SE)' and 'Specific target organ toxicity – repeated (STOT-RE)' must be provided in IUCLID section 2.1. For each entry, a 'Hazard category', a 'Hazard statement', and 'Affected organs' must be provided, or indicate a 'Reason for no classification'.</p> <p>If the substance is not classified, the checkbox 'Not classified' should be marked and no classification should be provided in that record.</p>	<p>All registration dossiers</p>
<p><b>IUCLID section 1.2 – Composition; section 2.1 – GHS</b></p>	<p>As lead registrant if you report several classification and labelling (C&amp;L) records in IUCLID section 2.1 then each of these records must be assigned to the corresponding composition of the type 'boundary composition of the substance' in section 1.2. This linking is done through the field 'Related composition' in section 2.1.</p>	<p>All registration dossiers</p>
<p><b>IUCLID section 2.3 – PBT assessment</b></p>	<p>If a Chemical Safety Report (CSR) is required for your dossier, the PBT assessment summary is also to be provided in section 2.3. Make a selection in the field 'PBT status. If the 'PBT assessment does not apply' option is selected, a justification must be provided. If multiple PBT assessment summaries are provided, they all have to be complete.</p>	<p>All registration dossiers</p>
<p><b>IUCLID section 1.2 – Composition; section 2.3 – PBT assessment</b></p>	<p>When multiple PBT assessment summaries are provided, all of them need to be connected to the matching composition of the type 'boundary composition of the substance' through the field 'Assessed composition(s)' in section 2.3.</p>	<p>All registration dossiers</p>
<p><b>IUCLID section 1.2 – Composition; section 2.3 – PBT assessment</b></p>	<p>When multiple compositions are provided in section 1.2, all of them need to be connected to the matching PBT assessment summary through the field 'Assessed composition(s)' in section 2.3.</p>	

<p><b>IUCLID section 14 – Opt-out information for REACH registration</b></p>	<p>If you decide to submit certain or all the data on your own, i.e. opt-out the jointly submitted information, then a data block has to be created in section 14 for each piece of information that you wish to opt-out. A justification for the opt-out has to be given in the designated field, following the provisions of REACH Article 11(3) and 19(2). You are advised to use at least one of the text templates available for the field to ensure that all the relevant information has been provided.</p>	<p>All registration dossiers</p>
<p><b>IUCLID dossier header - ‘Data Sharing Issues’</b></p>	<p>When joining a joint submission using a token provided by the Agency following a ‘Joint submission dispute’, it is mandatory to select the checkbox ‘Data sharing issues’ in the dossier header while creating the dossier. Provide an explanation in the ‘Justification’ field.</p> <p>When the check box ‘Data Sharing Issues’ in the dossier header is marked, the submission cannot rely on the jointly submitted documents (Guidance on Safe Use / Chemical Safety Report).</p>	<p>All registration dossiers</p>
<p><b>IUCLID dossier template; REACH-IT</b></p>	<p>In order to submit a member dossier the submitting legal entity has to be part of a joint submission for that substance.</p>	<p>All registration dossiers</p>
<p><b>IUCLID dossier template</b></p>	<p>The following IUCLID templates are relevant for member registrants only:</p> <p>REACH Registration member of a joint submission – general case.</p> <p>REACH Registration member of a joint submission – intermediates.</p>	<p>All registration dossiers</p>
<p><b>IUCLID dossier template; dossier header</b></p>	<p>When you are a part of a joint submission you cannot submit a dossier for a higher tonnage band than the maximum tonnage band of the joint submission (defined by the template of the lead dossier) unless you opt-out from the joint submission. To increase the joint submission tonnage band the lead has to update his dossier.</p>	<p>All registration dossiers</p>
<p><b>IUCLID dossier template;</b></p>	<p>A lead of a joint submission cannot lower the tonnage band of the joint submission, as members might be relying on the data. If such change is required, contact the Agency.</p>	<p>All registration dossiers</p>
<p><b>IUCLID dossier header; section 11 – Guidance on safe use; section 13 - Chemical Safety Report’</b></p>	<p>As member registrant you can mark the ‘Chemical Safety Report’ and/or ‘Guidance on Safe Use’ provided by the lead only if the lead has confirmed that you have the right to reference them.</p>	<p>All registration dossiers</p>
<p><b>IUCLID dossier header; section 11 – Guidance on safe use; section 13 - Chemical Safety</b></p>	<p>When you update your lead dossier, verify that all the documents that you previously submitted jointly (Chemical Safety Report, Guidance on Safe Use) are correctly marked in the dossier header. If earlier indication of joint submission was done erroneously, contact the Agency.</p>	<p>All registration dossiers</p>

<b>Report'</b>		
<b>IUCLID substance dataset; dossier header</b>	<p>When including a chargeable confidentiality claim in the dossier a justification must be provided in the designated field.</p> <p>If a confidentiality claim is placed on the IUPAC name then the phase-in status must be indicated and cannot be set to "not specified".</p>	All registration dossiers
<b>IUCLID dossier header</b>	A fee waiver for registrations in the 1-10 tonnes full registration tonnage band can only be granted, if all the data required in Annex VII of REACH is voluntarily provided and the substance is considered of low risk (i.e. does not meet the Annex III criteria of REACH). Consequently, if the joint submission does not cover that information threshold, a member cannot request the fee to be waived.	All registration dossiers
<b>IUCLID dossier header</b>	As lead registrant for the given substance you have to select the checkbox 'Joint submission' in the dossier header during the dossier creation wizard.	All registration dossiers
<b>IUCLID dossier header</b>	<p>It is not allowed to modify one or more of the following characteristics, when submitting a requested update following a TCC failure:</p> <p>Dossier template</p> <p>Status within a joint submission (part of a joint submission or not)</p> <p>Tonnage band.</p>	All registration dossiers - Updates
<b>REACH-IT</b>	If you register or update your substance as part of a joint submission then the correct joint submission name must be indicated in the submission wizard in REACH-IT.	All registration dossiers
<b>REACH-IT</b>	If a joint submission exists for your substance and registration type (full or intermediate) then you are expected to submit your dossier (initial or update) as part of that joint submission.	All registration dossiers
<b>REACH-IT</b>	It is not possible to submit a full registration dossier as part of a joint submission that is created for intermediate use only.	All registration dossiers
<b>REACH-IT</b>	You cannot submit a dossier to a joint submission that has expired. A new joint submission has to be created.	All registration dossiers
<b>REACH-IT</b>	You cannot update a dossier that is currently deactivated or has been revoked.	All registration dossiers
<b>Business rules applicable for PPORD notifications</b>		
<b>IUCLID section 1.1 – Identification;</b>	If you indicate in IUCLID section 1.1 that your 'Role in the supply chain' is manufacturer, then you must provide at least one production site in section 3.3. To this end, you must create a	PPORD notifications

<b>section 3.3 - Sites</b>	record in section 3.3 and assign a 'Site' to this record.	
<b>IUCLID Section 1.8 - Recipients</b>	Each record provided in section 1.8 must have a legal entity assigned to it. The legal entity must contain an address with at least a country provided.	PPORD notifications
<b>IUCLID section 1.9 - PPORD</b>	A justification must be provided in section 1.9 when submitting an update notification to request PPORD exemption extension.	PPORD notifications
<b>Business rules applicable for full registration dossiers</b>		
<b>IUCLID dossier template</b>	When submitting an individual registration in the tonnage band of 1-10 tonnes, you are only allowed to use the template 'REACH Registration 1 – 10 tonnes, physicochemical requirements' if the substance meets the criteria of a phase-in substance according to REACH Article 3(20). The phase-in status needs to be indicated in the dossier header.  Non phase-in substances can only be registered at 1-10 tonnes/year with the full Annex VII information of REACH, i.e. it is mandatory to use the 'standard requirements' template.	Full Registration
<b>IUCLID dossier template; dossier header</b>	When submitting a registration using the template 'REACH Registration 1 – 10 tonnes, physicochemical requirements' the registrant is not entitled to waive the fee, therefore the 'Fee waiver' check box cannot be marked.  You can claim a fee waiver in the 1-10 tonnage band only if you voluntarily provide the full information indicated in Annex VII of REACH, and the substance meets the criteria of a phase-in substance and is considered of low risk (i.e. does not meet the Annex III criteria of REACH). The phase-in status needs to be indicated in the dossier header.	Full Registration
<b>IUCLID dossier template; dossier header</b>	You cannot combine the IUCLID dossier template 'REACH Registration 1-10 tonnes, physicochemical requirements' with the tonnage band 'Transported isolated intermediates tonnage band over 1000 tonnes/year'.	Full Registration
<b>IUCLID section 1.1 – Identification; section 3.5.6 – Service life</b>	Downstream users can only submit a registration dossier in case they are producers/importers of articles (detailed criteria in REACH Article 7(1)). When in section 1.1 under the 'Role in the supply chain' 'Downstream user' is the only selection, it is mandatory to provide an identified use under the 'Service life name' in Section 3.5.6.	Full Registration
<b>Business rules applicable for intermediate registration dossiers</b>		
<b>IUCLID dossier template; dossier header</b>	When submitting a dossier with intermediate tonnage band indicated (Art 17 or 18) then 'Downstream user' as the 'Role in the supply chain' cannot be selected.	On-site isolated intermediate registration dossiers;  Transported isolated intermediate registrations

<p><b>IUCLID dossier template; dossier header</b></p>	<p>When submitting an individual registration for transported isolated intermediate the tonnage band selected in the dossier header has to match with the dossier template. The following template and tonnage band combinations are allowed:</p> <p>‘REACH Registration transported isolated intermediate 1 – 1000 tonnes’ template + transported isolated intermediates tonnage band 1 to 10 tonnes/year.</p> <p>‘REACH Registration transported isolated intermediate 1 – 1000 tonnes’ template + transported isolated intermediates tonnage band 10 to 1000 tonnes/year.</p> <p>‘REACH Registration transported isolated intermediate above 1000 tonnes’ template + transported isolated intermediates tonnage band over 1000 tonnes/year.</p>	<p>Transported isolated intermediate registrations</p>
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## Annex 2. Overview of the completeness check performed by ECHA on the submitted dossiers

This Annex compiles the minimum elements to be reported in a registration or PPORD dossier. The checks described below do not provide an indication of the quality or compliance of the dossier.

Also note that the completeness check performed by ECHA may include additional checks than the ones listed below, to ascertain that all the required elements have been provided. These additional checks include manual verification by ECHA staff of certain elements in the dossier that cannot be automatically determined. They could potentially lead to different conclusions from those indicated by this Annex. For more information on the areas of manual verification refer to the document ['Information on manual verification at completeness check'](https://echa.europa.eu/manuals): <https://echa.europa.eu/manuals>

The below checks are included in the IUCLID Validation assistant. The Validation assistant includes some more detailed logic on when certain rules are verified. This is not reflected in the list below as it would increase its complexity. It is strongly recommended to use the Validation assistant when preparing the Substance dataset, and also on the final dossier, before submitting it to ECHA.

The following conventions apply and are not separately stated for each of the checks below:

- Whenever the value *other*: is selected in any picklist field, the below text field displaying the word 'Other' must be provided;
- Wherever a check applies to a repeatable field structure such as a repeatable block or table: each created entry must be complete;
- Whenever a field is associated with a unit, this must be filled in.

You are advised to consult the main part of this manual for further information on how to provide information under REACH for each of the sections listed below.

IUCLID section	Check	Relevance
<b>Substance identification</b>		
<b>1.1 – Identification</b>	At least one 'Role in the supply chain' must be selected.	PPORD and registration
<b>1.1 – Identification</b>	The substance must be identified by linking a reference substance in section 1.1.	PPORD and registration
<b>1.1 – Identification</b>	The reference substance in section 1.1 must be identified. As a minimum, one of the following must be provided: -EC number; -CAS number and CAS name; -IUPAC name.  The identifiers must be inserted in the corresponding fields of the linked reference substance.	PPORD and registration
<b>1.1 – Identification</b>	The reference substance in section 1.1 must contain molecular and structural information.	PPORD and registration

	<p>For a mono-constituent substance, the molecular formula, molecular weight and structural formula of the reference substance must be indicated in the designated fields.</p> <p>For a multi-constituent substance, the molecular formula, molecular weight and structural formula of the reference substance must be indicated in the designated fields or a justification for not providing this information must be given in the 'Remarks' field.</p> <p>For a UVCB substance, the molecular formula and molecular weight of the reference substance must be indicated in the designated fields or a justification for not providing this information must be given in the 'Remarks' field.</p>	
<b>1.2 – Composition</b>	Each substance must be identified by at least one registrant-specific composition. To this end, there must be in section 1.2 at least one composition record of the type 'legal entity composition'. All legal entity compositions will be checked for completeness. Other composition types are not checked, but should be completed as far as possible.	PPORD and registration
<b>1.2 – Composition General information</b>	<p>'State/form' of a composition must be specified by selecting the appropriate value in the picklist.</p> <p>If a substance covers different physical states or forms, a separate composition should be created for each of them.</p> <p>If a composition covers nanoforms, then 'solid: nanoform' must be selected in the picklist. Note that an incorrect indication in this field will not enable to provide the information on nanoforms under the Characterisation of nanoforms heading.</p>	PPORD and registration
<b>1.2 – Composition</b>	Each composition must contain at least one value and a unit for the 'Degree of purity'.	PPORD and registration
<b>1.2 – Composition, Constituents</b>	For each composition at least one constituent must be defined. All constituents must be identified by linking a reference substance.	PPORD and registration
<b>1.2 – Composition, Constituents</b>	<p>Each constituent must be identified by providing as a minimum one of the following:</p> <ul style="list-style-type: none"> <li>-EC number;</li> <li>-CAS number and CAS name;</li> <li>-IUPAC name.</li> </ul> <p>The identifiers must be inserted in the corresponding fields of the section 1.2 constituent reference substance.</p>	PPORD and registration
<b>1.2 – Composition, Constituents</b>	<p>The constituent reference substances in section 1.2 must contain molecular and structural information.</p> <p>For a mono-constituent substance, or a multi-constituent substance, the molecular formula, molecular weight and structural formula of the reference substance must be indicated in the designated fields.</p> <p>For a UVCB substance, the molecular formula and molecular weight of the reference substance must be indicated in the designated fields, or a justification for not providing this information must be given in the related 'Remarks' field.</p>	PPORD and registration
<b>1.2 – Composition, Constituents</b>	For each constituent, the full 'Concentration range' must be provided (lower and upper value), together with a unit. If you are reporting a constituent at exactly 0% or 100%, provide this value, together with the unit, in the field 'Typical concentration' and leave the 'Concentration range' fields empty.	PPORD and registration

<b>1.2 – Composition, Impurities</b>	<p>Each impurity must be identified by providing as a minimum one of the following:</p> <ul style="list-style-type: none"> <li>-EC number;</li> <li>-CAS number and CAS name;</li> <li>-IUPAC name.</li> </ul> <p>For impurities that cannot be identified with any of the above types of identifiers, the phrase "unknown impurities" should be inserted in the 'IUPAC name' field, and the nature, number and relative amounts of the impurities should be specified as far as possible in the 'Remarks' field of the impurity block.</p>	PPORD and registration
<b>1.2 – Composition, Impurities</b>	<p>For each impurity, the full 'Concentration range' must be provided (lower and upper value), together with a unit. If declaring the absence of a specific impurity, link the appropriate reference substance and indicate the value "0", together with the unit, in the field 'Typical concentration'. Leave the 'Concentration range' fields empty.</p>	PPORD and registration
<b>1.2 – Composition, Additives</b>	<p>Each additive must be identified by providing as a minimum one of the following:</p> <ul style="list-style-type: none"> <li>-EC number;</li> <li>-CAS number and CAS name;</li> <li>-IUPAC name.</li> </ul> <p>The identifiers must be inserted in the corresponding fields of the section 1.2 additive reference substance.</p>	PPORD and registration
<b>1.2 – Composition, Additives</b>	<p>The molecular formula, molecular weight and structural formula of each additive reference substance must be indicated in the designated fields, or a justification for not providing this information must be given in the related 'Remarks' field.</p>	PPORD and registration
<b>1.2 – Composition, Additives</b>	<p>For each additive, the full 'Concentration range' must be provided (lower and upper value), together with a unit. If declaring the absence of a specific additive, link the appropriate reference substance and indicate the value "0", together with the unit, in the field 'Typical concentration'. Leave the 'Concentration range' fields empty.</p>	PPORD and registration
<b>1.2 – Composition, Additives</b>	<p>For each additive, the stabilising function must be confirmed by selecting the relevant value starting with 'stabiliser' in the picklist 'Function'. Further details on the mechanism of stabilisation can be provided under 'Details of function in composition'.</p>	PPORD and registration
<b>1.2 – Composition, mono-constituent substance</b>	<p>For a mono-constituent substance, the main constituent is expected to be present in the composition as a minimum at 80%. When deviating from this rule, a justification must be given in the 'Justification for deviations' field, or alternatively, a 'Typical concentration' must be provided, with unit, demonstrating that the main constituent is typically present as a minimum at 80%.</p>	PPORD and registration
<b>1.2 – Composition, mono-constituent substance</b>	<p>For a mono-constituent substance, impurities are expected to be present in the composition as a maximum at 20% (concentration range). When deviating from this rule, a justification must be given in the 'Justification for deviations' field, or alternatively, a 'Typical concentration' must be provided, with unit, demonstrating that the impurity is typically present as a maximum at 20%.</p>	PPORD and registration
<b>1.2 – Composition, mono-constituent substance</b>	<p>For a mono-constituent substance, each composition is expected to contain only one constituent. When deviating from this rule, a justification must be given in the 'Justification for deviations' field.</p>	PPORD and registration
<b>1.2 – Composition, multi-constituent substance</b>	<p>For a multi-constituent substance, the main constituent is expected to be present in the composition as a maximum at 80% (concentration range). When deviating from this rule, a justification must be given in the</p>	PPORD and registration

	'Justification for deviations' field, or alternatively, a 'Typical concentration' must be provided, with unit, demonstrating that each main constituent is typically present as a maximum at 80%.	
<b>1.2 – Composition, multi-constituent substance</b>	For a multi-constituent substance, impurities are expected to be present in the composition as a maximum at 10% (concentration range). When deviating from this rule, a justification must be given in the 'Justification for deviations' field, or alternatively, a 'Typical concentration' must be provided, with unit, demonstrating that the impurity is typically present as a maximum at 10%.	PPORD and registration
<b>1.2 – Composition, multi-constituent substance</b>	For a multi-constituent substance, each composition is expected to contain at least two constituents. When deviating from this rule, a justification must be given in the 'Justification for deviations' field.	PPORD and registration
<b>1.2 – Composition, UVCB substance</b>	For UVCB substances, composition-specific details on the source of the substance and the process used must be provided in the 'Description' field of each legal entity composition. These should include, as appropriate: <ul style="list-style-type: none"> <li>- identity of starting materials/source (and ratio)</li> <li>- reaction steps/mechanisms</li> <li>- plant operating parameters (e.g. temperatures/pressures)</li> <li>- solvents/reagents used</li> <li>- details of any clean-up/purification steps</li> </ul>	PPORD and registration
<b>1.2 – Composition, UVCB substance</b>	For a UVCB substance, it is expected that each composition is described with constituents other than the section 1.1 reference substance. All individual constituents present at >10%, or relevant for C&L and/or PBT assessment, must be reported separately. Other constituents should be identified as far as possible, as separate constituents or as groups of generic constituents. UVCB substances are not considered to contain impurities; all constituents should be reported under the 'Constituents' heading.  If it is not possible to identify separate constituents, a justification must be given in the 'Justification for deviations' field.	PPORD and registration
<b>1.4 – Analytical information</b>	At least one record must be created in section 1.4. under the 'Analytical determination' heading and must contain at least one entry, and each entry created must be filled in as follows: <ul style="list-style-type: none"> <li>- a selection must be made in the 'Purpose of analysis' picklist</li> <li>- at least one selection must be made in the 'Analysis type' picklist</li> <li>- either an attachment must exist in the 'Attached methods/results' field, or a reason for not providing a method/result must be indicated by making a selection in the field 'Rationale for no results' and by inserting a further explanation in the 'Justification' field.</li> </ul> <p>The 'Analysis type' field is a multi-select list; if several selections are made, the corresponding results or justifications for all must be provided in the same entry.</p> <p>Analysis results must be provided for at least one identification, and one quantification approach, as indicated in the 'Purpose of analysis' field.</p>	PPORD; registration except Art. 17/18 intermediates only
<b>PPORD only</b>		
<b>1.8 – Recipients</b>	If the notification is done in cooperation with customers (REACH Article 9), then these shall be indicated in section 1.8. For each Recipient record created in section 1.8, a Legal entity must be linked under the field 'Name'. In the Legal entity tab 'Contact information', the 'Address' must be provided. As a minimum, the recipient 'Country' and 'Town' must be indicated.	PPORD

<b>1.9 – Product and process orientated research and development</b>	At least one record must be provided in section 'Product and process orientated research and development'. For each record, the 'Estimated quantity' must be provided, with unit.	PPORD
<b>Classification and labelling</b>		
<b>2.1 – GHS</b>	At least one record must be created in section 2.1 – GHS.	Registration, individual and JS lead.
<b>2.1 – GHS</b>	Each created GHS record must have a complete 'Classification' part: -For each hazard class or differentiation, a 'Hazard category' and a 'Hazard statement', or a 'Reason for no classification' must be given. -For 'Specific target organ toxicity – single (STOT-SE)' and 'Specific target organ toxicity – repeated (STOT-RE)', if a classification is provided also the 'Affected organs' must be indicated.	Registration
<b>2.1 – GHS</b>	Each created GHS record must have a complete 'Labelling' part: - A selection must be made in the field 'Signal word', under 'Labelling'. - If at least one 'Hazard category' has been indicated under the 'Classification' heading then at least one hazard statement must be indicated under the 'Labelling' heading of the same GHS document. To provide a hazard statement, create an entry under 'Hazard statements' or 'Additional labelling requirements' and select the appropriate 'Hazard statement' or 'CLP supplemental hazard statement'.	Registration except Art. 17/18 intermediates only
<b>Estimated quantities and sites</b>		
<b>3.2 – Estimated quantities</b>	As a minimum the estimated quantities for one year must be provided by creating a record in section 3.2. In each record, the 'Year' and as a minimum, the total tonnage 'Manufactured' or 'Imported' must be provided.	Registration except Art. 17/18 intermediates only
<b>3.3 – Sites</b>	If you indicated in section 1.1 that your 'Role in the supply chain' is 'Manufacturer', then you must provide at least one production site in section 3.3. To this end, you must create a record in section 3.3 and link a 'Site' to it. The contact address of each site must be provided; as a minimum the fields 'Site name', 'Address', 'Town' and 'Country' must be filled in.  Note for registration dossiers: to indicate the site as a production site, you must link it using the field 'Related manufacture/own use' to at least one record created in section 3.5.1 – 'Manufacture'.	PPORD and registration
<b>3.3 – Sites</b>	Each site record created in section 3.3 must contain a linked 'Site'. For each site, the fields 'Address', 'Postal code', 'Town' and 'Country' must be filled in.	PPORD and registration
<b>Life cycle description</b>		
<b>3.5 – Life cycle description</b>	At least one use must be described in any of the following sections: 3.5.2 – Formulation or re-packing 3.5.3 – Uses at industrial sites 3.5.4 – Widespread uses by professional workers 3.5.5 – Consumer uses 3.5.6 – Service life  If there are no uses identified in any of the above sections a selection must be made in section 3.5.0, in the picklist 'Justification for no uses reported'.	Registration except Art. 17/18 intermediates only

<b>3.5.1 – Manufacture</b>	For each record created in section 3.5.1 – ‘Manufacture’ the field 'Manufacture name' must be filled in. In addition, at least one contributing activity / technique for the environment and one contributing activity / technique for workers must be provided, and described with the appropriate 'Environmental release category' and 'Process category' codes.	Registration except Art. 17/18 intermediates only
<b>3.5.2 – Formulation or re-packing</b>	For each record created in section 3.5.2 – ‘Formulation or re-packing’ the fields 'Use name' and 'Technical function of the substance during formulation' must be filled in. In addition, at least one contributing activity / technique for the environment and one contributing activity / technique for workers must be provided, and described with the appropriate 'Environmental release category' and 'Process category' codes.	Registration except Art. 17/18 intermediates only
<b>3.5.3 – Uses at industrial sites</b>	For each record created in section 3.5.3 – ‘Uses at industrial sites’ the fields 'Use name', 'Technical function of the substance during use' and ‘Subsequent service life relevant to this use’ must be filled in. In addition, at least one contributing activity / technique for the environment and one contributing activity / technique for workers must be provided, and described with the appropriate 'Environmental release category' and 'Process category' codes.	Registration except Art. 17/18 intermediates only
<b>3.5.4 – Widespread uses by professional workers</b>	For each record created in section 3.5.4 – ‘Widespread uses by professional workers’ the fields 'Use name', 'Technical function of the substance during use' and ‘Subsequent service life relevant to this use’ must be filled in. In addition, at least one contributing activity / technique for the environment and one contributing activity / technique for workers must be provided, and described with the appropriate 'Environmental release category' and 'Process category' codes.	Registration except Art. 17/18 intermediates only
<b>3.5.5 – Consumer uses</b>	For each record created in section 3.5.5 – ‘Consumer uses’ the fields 'Use name', 'Technical function of the substance during use' and ‘Subsequent service life for that use’ must be filled in. In addition, at least one contributing activity / technique for the environment and one contributing activity / technique for consumers must be provided, and described with the appropriate 'Environmental release category' and 'Product category' codes.	Registration except Art. 17/18 intermediates only
<b>3.5.6 – Service life</b>	For each record created in section 3.5.6 – ‘Service life’ the fields 'Service life name' and 'Technical function of the substance during use' must be filled in. In addition, at least one contributing activity/technique for the environment, and at least one contributing activity/technique for consumers or workers must be provided, and described with the appropriate 'Environmental release category' and 'Article category'/'Process category' codes.	Registration except Art. 17/18 intermediates only
<b>3.5.6 – Service life</b>	If any use record in sections 3.5.1, 3.5.2, 3.5.3, 3.5.4 or 3.5.5 contains a selection ‘yes’ in the field ‘Subsequent service life relevant to this use’, at least one record must be created in section 3.5.6 – ‘Service life’.	Registration except Art. 17/18 intermediates only
<b>3.5.6 – Service life</b>	If any use record in sections 3.5.1, 3.5.2, 3.5.3, 3.5.4 or 3.5.5 contains a contributing activity/technique for the environment which is described with the environmental release category 5 (ERC 5), at least one record must be created in section 3.5.6 – ‘Service life’.	Registration except Art. 17/18 intermediates only
<b>3.5.1, 3.5.2, 3.5.3</b>	<p>If under the heading 'Use takes place under rigorously contained conditions' you have selected the checkbox 'Rigorously contained system with strict control for manual interventions', then further details must be provided to substantiate this claim. To this end, the field 'Description of non-technical means for strict control' must be filled in.</p> <p>In addition, depending on the selection in the field 'Registration/Notification status for the use', the following must be provided:</p> <ul style="list-style-type: none"> <li>- For a 'use (as intermediate) registered according to REACH Article 10;</li> </ul>	Registration except Art. 17/18 intermediates only. Applies to all JS lead dossiers which provide the joint submission.

	<p>total tonnage manufactured/imported &lt;10tonnes/year per registrant', the field 'Technical means for rigorous containment and strict control for manual intervention' (under the same heading) must be provided.</p> <p>- For a 'use (as intermediate) registered according to REACH Article 10; total tonnage manufactured/imported &gt;=10tonnes/year per registrant' (or no selection), under the heading 'Contributing scenario for the workers' of the same use record, you must create a contributing scenario entry, and under the heading 'Technical and organisational conditions and measures', create an entry and provide information in the field 'Technical means for rigorous containment and strict control for manual intervention'.</p>	
<b>3.5.1, 3.5.2, 3.5.3</b>	<p>If under 'Use takes place under rigorously contained conditions' you have selected the checkbox 'Rigorously contained system with minimisation of release to the environment', then further details must be provided to substantiate this claim. To this end, the field 'Description of non-technical means for strict control' must be filled in.</p> <p>In addition, depending on the selection in the field 'Registration/Notification status for the use', the following must be provided:</p> <p>- For a 'use (as intermediate) registered according to REACH Article 10; total tonnage manufactured/imported &lt;10tonnes/year per registrant', the field 'Technologies to minimise emissions' (under the same heading) must be provided.</p> <p>- For a 'use (as intermediate) registered according to REACH Article 10; total tonnage manufactured/imported &gt;=10tonnes/year per registrant' (or no selection), under the heading 'Contributing scenario for the environment (related to workers activities)' of the same use record, you must create a contributing scenario entry, and under the heading 'Technical and organisational conditions and measures', create an entry and provide information in the field 'Technologies to minimise emissions'.</p>	<p>Registration except Art. 17/18 intermediates only. Applies to all JS lead dossiers which provide the CSR for the joint submission.</p>
<b>Endpoint study record - general</b>		
<b>4 – 7, Administrative data</b>	The 'Endpoint' addressed by the study record must be indicated.	Registration
<b>4 – 7, Administrative data</b>	<p>Each provided endpoint study record must be indicated either as a study summary, data waiving, or a testing proposal.</p> <p>- If you want to submit a (robust) study summary, make a selection in the field 'Adequacy of study' and fill in all relevant fields under 'Administrative data', 'Data source', 'Materials and methods', and 'Results and discussion' for this endpoint. All endpoint study records in sections corresponding to the REACH Annexes that are indicated as 'key study' or as 'weight of evidence' are subject to a full completeness check. Other types of study summaries should be filled in as much as possible.</p> <p>- If you want to submit a data waiver, make a selection in the field 'Data waiving' and provide a justification in the field 'Justification for data waiving'.</p> <p>- If you want to submit a testing proposal, select 'experimental study planned' or 'experimental study planned (based on read-across)' in the field 'Type of information' and provide information under the 'Test guideline' heading on the 'Guideline' and 'Test material information' of the planned test.</p>	Registration
<b>4 – 7, Administrative data</b>	An endpoint study record cannot be at the same time a data waiving, a testing proposal and/or a study summary. As a consequence, you must not in the same endpoint study record make a selection in the field 'Data waiving', select 'experimental study planned'/'experimental study planned (based on read-across)' in the field 'Type of information' and/or make a selection in the field 'Adequacy of study'.	Registration

<b>4 – 7, Administrative data</b>	If you want to submit a data waiver then the rationale for waiving the information requirement must be indicated in the field 'Data waiving' and an appropriate justification must be selected in the field 'Justification for data waiving'. If none of the available justifications in the picklist apply, select 'other:' and provide the justification in the below free-text field.	Registration: data waiver
<b>4 – 7, Administrative data</b>	As per section 3.1 of REACH Annex XI and per section specific waiving possibilities mentioned in column 2 of REACH Annex VIII, exposure-based waiving can only be submitted for information required in REACH Annexes IX and X, and in sections 8.6 and 8.7 of Annex VIII. Endpoint study records in other endpoints must not have the selection 'exposure considerations' in the field 'Data waiving'.	Registration: data waiver
<b>4 – 7, Administrative data</b>	A testing proposal can only be submitted for information required in Annexes IX and X of REACH.	Registration: testing proposal
<b>4 – 7, Administrative data</b>	A testing proposal on vertebrate animals must document the considerations for why the adaptation possibilities provided by the REACH Regulation cannot be used to address the information requirement. The information must be provided in the field 'Justification for type of information' and will be published on the ECHA website. You are advised to use the text template available for the field to ensure that all the relevant information has been provided.	Registration: testing proposal on the registered substance
<b>4 – 7, Administrative data</b>	'Administrative data' is not complete. For each endpoint study record indicated as 'experimental study planned (based on read-across)' in the field 'Type of information', the endpoint-specific justification for the read-across approach must be provided in the field 'Justification for type of information'. The field contains free-text templates to support the documentation of the justification.	Registration: testing proposal based on read-across
<b>4 – 7, Administrative data</b>	For each endpoint study record marked as 'key study' or 'weight of evidence', the field 'Type of information' must be provided.	Registration: key study or weight of evidence record
<b>4 – 7, Administrative data</b>	For each key study or weight of evidence record with the 'Type of information' indicated as '(Q)SAR', adequate and reliable documentation of the applied method must be provided. The documentation must be inserted in the field 'Justification for type of information' using the available free-text template, or attached in the field 'Attached justification'.  In the case that some parts of the documentation (QMRF) apply to more than one endpoint study record, provide a link to the record in which this common documentation is attached under 'Cross-reference' heading and indicate the type of document in the field 'Reason/purpose'. However, the specific information for each prediction must always be provided separately for each (Q)SAR record.	Registration: key study or weight of evidence record; QSAR
<b>4 – 7, Administrative data</b>	'Administrative data' is not complete. For each key study or weight of evidence record indicated as read-across in the field 'Type of information', the endpoint-specific justification for the read-across approach must be provided in the field 'Justification for type of information'. The field contains free-text templates to support the documentation of the justification.  In addition, further information in support of the read-across approach can be provided in the field 'Attached justification'. To point to supporting documentation elsewhere in the dataset, provide a link to the record(s) containing this information under 'Cross-reference' heading and indicate the type of information linked in the field 'Reason/purpose'.	Registration: key study or weight of evidence record; read-across
<b>4 – 7, Administrative data</b>	For each key study or weight of evidence record indicated as 'read-across from supporting substance (structural analogue or surrogate)' in the field 'Type of information', the source endpoint study record(s) must be	Registration: key study or weight of evidence record;



	<p>provided.</p> <p>To this end, there must exist in the same section at least one other endpoint study record with the 'Adequacy of study' set to 'key study' or 'weight of evidence' which contains the source study that the read-across target record is based on. The read-across record must link to each source endpoint study record under the 'Cross-reference' heading.</p>	read-across
<b>4 – 7, Administrative data</b>	<p>If at least one key study or weight of evidence record has been indicated as 'read-across based on grouping of substances (category approach)' in the field 'Type of information', at least one category object must be linked to the substance. In each category, information on the category hypothesis, applicability domain and category justification must be included, in the field 'Category rationale' or as an attachment under 'Reports'. In addition, the 'Category members' must be linked and the 'Category documents' listed.</p>	Registration: key study or weight of evidence record; read-across
<b>4 – 7, Administrative data</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', the field 'Reliability' must be provided.</p>	Registration: key study or weight of evidence record
<b>4 – 7, Data source</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', at least one entry under 'Reference' must be completed. For each reference, the 'Year' or the 'Report date' must always be indicated. In addition, as a minimum, the following must be provided:</p> <ul style="list-style-type: none"> <li>- If the data is from a study report, the field 'Testing facility' (with the full address of the testing laboratory, including city and country) and either 'Report no.', 'Study no.' or 'Title' must be provided.</li> <li>- If the data is from a company, either the field 'Report no.' or the field 'Study no.' must be provided. In addition, information must be given under 'Author', 'Study sponsor' and/or 'Title'.</li> <li>- If the data is from a literature source, the field 'Bibliographic source' must be provided. Sufficient information should be given to be able to identify the literature source.</li> </ul>	Registration: key study or weight of evidence record
<b>5 – 7, Data source</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence' where the study has been indicated as GLP compliant, the contact details of the testing laboratory must be provided. To this end, at least one entry under 'Reference' must contain information on the name, address and country in the 'Testing facility' field.</p>	Registration: key study or weight of evidence record
<b>4 – 7, Data source</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', the field 'Data access' must be provided.</p> <p>If you select 'data submitter has permission to refer', then you must provide in the below field the statement according to instructions you received from ECHA together with the permission to refer.</p>	Registration: key study or weight of evidence record
<b>4 – 7, Materials and methods</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', or indicated as a testing proposal, the test guideline (to be used in the study) must be indicated in the 'Guideline' field of the 'Test guideline' table. If you add several entries, then the 'Guideline' must be specified for each of them. If the test guideline applied is not found in the picklist, select 'other:' and provide information on the guideline in the below free-text field.</p> <p>If no test guideline can be specified (e.g. because the study is a non-guideline study, or (Q)SAR was applied), a description of the principles of the test protocol or the method must be provided in the field 'Principles</p>	Registration: key study or weight of evidence record, testing proposal

	of method if other than guideline'.	
<b>5 – 7, Materials and methods</b>	For each endpoint study record marked as 'key study' or 'weight of evidence', the field 'GLP compliance' must be provided.	Registration: key study or weight of evidence record
<b>4 – 7, Materials and methods</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', or indicated as a testing proposal, the test material (to be) used in the study must be identified by linking a test material information (TMI) record in the field 'Test material information'.</p> <p>The TMI record should contain sufficient information to allow the understanding of the identity of the tested substance. As a minimum, under 'Composition' at least one 'Constituent' must be reported. Each created component must contain at least one of the following identifiers in the designated fields: EC number, CAS number, IUPAC name.</p> <p>For a read-across target record, the test material information should identify the target substance of the read-across.</p>	Registration: key study or weight of evidence record, testing proposal
<b>Endpoint study record – section 4</b>		
<b>4.2 – Melting point/freezing point</b> <b>4.3 – Boiling point</b> <b>4.4 – Density</b> <b>4.5 – Particle size</b> <b>4.6 – Vapour pressure</b> <b>4.7 – Partition coefficient</b> <b>4.8 – Water solubility</b> <b>4.11 – Flash point</b> <b>4.22 – Viscosity</b>	For each endpoint study record marked as 'key study', under 'Materials and methods' the 'Type of method' must be provided.	Registration: key study
<b>4.1 – Appearance / physical state / colour, Results and discussion</b>	For each endpoint study record marked as 'key study' or 'weight of evidence', the field 'Physical state at 20°C and 1013 hPa' must be filled in. In addition, the field 'Form' should be provided if relevant.	Registration: key study or weight of evidence record
<b>4.2 – Melting point / freezing point, Results and discussion</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', at least one of the fields 'Melting/freezing pt.', 'Decomp. temp.' or 'Subl. temp' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	Registration: key study or weight of evidence record
<b>4.3 – Boiling point, Results and discussion</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', the fields 'Boiling. pt.' and 'Atm. press.', or the fields 'Decomposition' and 'Decomp. temp.' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	Registration: key study or weight of evidence record
<b>4.3 – Boiling point</b>	<p>If the test is waived based on that the substance is explosive you need to, in addition to the data waiving record in section 4.3 include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Explosives'.</p> <p>If the test is waived based on that the substance is self-reactive you need to, in addition to the data waiving record in section 4.3, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Self-reactive substances and mixtures'.</p>	Registration: data waiving

<p><b>4.4 – Density, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', the fields 'Type', 'Density' and 'Temp.' must be provided, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>4.4 – Density, Results</b></p>	<p>If the substance is a gas, the information requirement cannot be waived. Instead, an estimation based on calculation must be provided. To report the information, an endpoint study record must be created in IUCLID section 4.4 of your dossier, where 'key study' or 'weight of evidence' is selected in the 'Adequacy of study' field and 'Type of information' is set to '(Q)SAR' or 'calculation (if not (Q)SAR)'. </p>	<p>Registration: data waiving</p>
<p><b>4.5 – Particle size distribution, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', at least one of the entries 'Particle size' or 'Particle size distribution at different passages' must be filled in.</p> <p>In the table 'Particle size', the fields 'Percentile', 'Mean' and 'St. dev.' must be provided, with unit.</p> <p>In the table 'Particle size distribution at different passages', the fields 'No.', 'Size' and 'Distribution' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result' of the appropriate entry.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>4.6 – Vapour pressure, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', the fields 'Vapour pressure' and 'Temp.' must be given, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>4.6 – Vapour pressure</b></p>	<p>If the test is waived based on that the substance is explosive you need to, in addition to the data waiving record in section 4.6 include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Explosives'.</p> <p>If the test is waived based on that the substance is self-reactive you need to, in addition to the data waiving record in section 4.6, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Self-reactive substances and mixtures'.</p> <p>If the test is waived based on that the substance is an organic peroxide you need to, in addition to the data waiving record in section 4.6, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Organic peroxides'.</p>	<p>Registration: data waiving</p>
<p><b>4.7 – Partition coefficient, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', the fields 'Type', 'Partition coefficient', 'Temp.' and 'pH' must be provided, with unit, if available.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>4.7 – Partition coefficient</b></p>	<p>If the partition coefficient test cannot be performed, a calculation must be provided. To report the information, an endpoint study record must be created in section 4.7, where 'key study' or 'weight of evidence' is selected in the 'Adequacy of study' field and 'Type of information' is set to '(Q)SAR' or 'calculation (if not (Q)SAR)'. </p>	<p>Registration: data waiving</p>
<p><b>4.8 – Water solubility,</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of</p>	<p>Registration: key</p>

<p><b>Results and discussion</b></p>	<p>evidence', at least one of the entries 'Water solubility' or 'Solubility of metal ions in aqueous media' must be filled in.</p> <p>In the table 'Water solubility', the fields 'Water solubility', 'Temp.' and 'pH' must be filled in, with unit. In the table 'Solubility of metal ions in aqueous media', the fields 'Type of test', 'Mean dissolved conc.' and 'Element analysed' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result' of the appropriate entry.</p>	<p>study or weight of evidence record</p>
<p><b>4.8 – Water solubility</b></p>	<p>If the substance appears 'insoluble' in water, a limit test up to the detection limit of the analytical method shall be performed. To report the information, an endpoint study record must be created in section 4.8, where 'key study' or 'weight of evidence' is selected in the 'Adequacy of study' field.</p>	<p>Registration: data waiving</p>
<p><b>4.10 – Surface tension, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', the fields 'Surface tension', 'Temp.' and 'Conc.' must be given, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>4.11 – Flash point, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', the fields 'Flash point' and 'Atm. press.' must be given, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>4.11 – Flash point</b></p>	<p>If the test is waived based on that the substance is explosive you need to, in addition to the data waiving record in section 4.11 include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Explosives'.</p> <p>If the test is waived based on that the substance is pyrophoric you need to, in addition to the data waiving record in section 4.11, include in section 2.1 at least one record where you provide the appropriate classification for either of the hazard classes 'Pyrophoric solids' or 'Pyrophoric liquids'.</p>	<p>Registration: data waiving</p>
<p><b>4.12 – Auto flammability, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', one of the entries 'Auto-ignition temperature (liquids / gases)' or 'Relative self-ignition temperature (solids)' must be filled in.</p> <p>In the table 'Auto-ignition temperature (liquids / gases)', the fields 'Auto-ignition temperature' and 'Atm. press.' must be filled in, with unit. In the table 'Relative self-ignition temperature (solids)', the field 'Relative self-ignition temperature' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result' of the appropriate entry.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>4.12 – Auto flammability</b></p>	<p>If the test is waived based on that the substance is explosive you need to, in addition to the data waiving record in section 4.12 include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Explosives'.</p> <p>If the test is waived based on that the substance is pyrophoric you need to, in addition to the data waiving record in section 4.12, include in section 2.1 at least one record where you provide the appropriate</p>	<p>Registration: data waiving</p>

	classification for either of the hazard classes 'Pyrophoric solids' or 'Pyrophoric liquids'.	
<b>4.13 – Flammability, Results and discussion</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence' the following is checked:</p> <p>For each row created in the table 'Flammable gases (Lower and upper explosion limit)', the field 'Parameter' must be provided, and the 'Value' indicated, with unit. Entries must be created for both the 'lower explosion limit' and 'upper explosion limit' parameters. If other parameters are measured, in addition, select 'other:' and define the parameter in the below field.</p> <p>For each row created in the table 'Flammable solids', the field 'Test procedure' must be provided, and the 'Burning time' indicated, with unit.</p> <p>If for a specified 'Parameter' or 'Test procedure' a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result' of the appropriate entry.</p> <p>Note that for solids and gases, the REACH requirement 7.10 Flammability is reported in section 4.13 - Flammability. Flammability studies on liquids are reported in section 4.11 - Flash point. If the substance is a liquid, you should in section 4.13 select the endpoint for flammable solids or flammable gases, indicate it as a data waiver (study technically not feasible), and select in the field 'Justification for data waiving' the option 'the study does not need to be conducted because the substance is a liquid'.</p>	Registration: key study or weight of evidence record; data waiving
<b>4.13 – Flammability</b>	<p>If the test is waived based on that the substance is explosive you need to, in addition to the data waiving record in section 4.13 include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Explosives'.</p> <p>If the test is waived based on that the substance is self-reactive you need to, in addition to the data waiving record in section 4.13, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Self-reactive substances and mixtures'.</p> <p>If the test is waived based on that the substance is an organic peroxide you need to, in addition to the data waiving record in section 4.13, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Organic peroxides'.</p> <p>If the test is waived based on that the substance is pyrophoric you need to, in addition to the data waiving record in section 4.13, include in section 2.1 at least one record where you provide the appropriate classification for either of the hazard classes 'Pyrophoric solids' or 'Pyrophoric liquids'.</p>	Registration: data waiving
<b>4.14 – Explosiveness, Results and discussion</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', one of the following entries must contain a result:</p> <ul style="list-style-type: none"> <li>- 'Small-scale preliminary tests'</li> <li>- 'Results of test series for explosives'</li> </ul> <p>For each row created in the table 'Small-scale preliminary tests', the field 'Parameter' must be provided, and the 'Value' indicated. For each row created in the table 'Results of test series for explosives', the fields 'Test series', 'Method', 'Parameter', 'Value' and 'Result' must be provided.</p>	Registration: key study or weight of evidence record

	If for a specified 'Parameter' or 'Test series' a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result' of the same entry.	
<b>4.14 – Explosiveness</b>	If the test is waived based on the decomposition energy/temperature of the substance you need to provide further details on these properties in the 'Remarks' field next to the field 'Justification for data waiving', or in the field 'Justification for type of information'.	Registration: data waiving
<b>4.15 – Oxidising properties, Results and discussion</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', one of the following entries must contain a result:</p> <ul style="list-style-type: none"> <li>- Test results (Oxidising gases)</li> <li>- Test results (Oxidising liquids)</li> <li>- Test results (Oxidising solids)</li> </ul> <p>For each row created in the table 'Test result (Oxidising gases)', the field 'Parameter' must be provided, and the 'Result' indicated.</p> <p>For each row created in the table 'Test result (Oxidising liquids)', the field 'Parameter' must be provided, and the 'Sample tested' and 'Result' indicated, with unit.</p> <p>For each row created in the table 'Test result (Oxidising solids)', the field 'Parameter' must be provided, and the 'Sample tested' and 'Result' indicated, with unit.</p> <p>If for a specified 'Parameter' a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	Registration: key study or weight of evidence record
<b>4.15 – Oxidising properties</b>	<p>If the test is waived based on that the substance is explosive you need to, in addition to the data waiving record in section 4.15 include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Explosives'.</p> <p>If the test is waived based on that the substance is an organic peroxide you need to, in addition to the data waiving record in section 4.15, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Organic peroxides'.</p> <p>If the test is waived based on that the substance is pyrophoric you need to, in addition to the data waiving record in section 4.15, include in section 2.1 at least one record where you provide the appropriate classification for either of the hazard classes 'Pyrophoric solids' or 'Pyrophoric liquids'.</p> <p>If the test is waived based on that the substance is flammable you need to, in addition to the data waiving record in section 4.15, include in section 2.1 at least one record where you provide the appropriate classification for either of the hazard classes 'Flammable solids', 'Flammable liquids' or 'Flammable gases and chemically unstable gases'.</p>	Registration: data waiving
<b>4.17 – Stability in organic solvents, Results and discussion</b>	For each endpoint study record marked as 'key study' or 'weight of evidence', the field 'Test substance stable' must be provided.	Registration: key study or weight of evidence record
<b>4.21 – Dissociation constant, Results and discussion</b>	For each endpoint study record marked as 'key study' or 'weight of evidence', the field 'Dissociating properties' must be provided. If the value 'yes' is selected in the picklist, then at least one row must be created in the table 'Dissociation constant' with the fields 'pKa' and 'Temp.' provided, with unit.	Registration: key study or weight of evidence record

	If a quantitative result was not determined for the dissociation constant despite indicating that the substance has dissociating properties, an explanation must be provided in the field 'Remarks on result'.	
<b>4.22 – Viscosity, Results and discussion</b>	For each endpoint study record marked as 'key study' or 'weight of evidence', the fields 'Value' and 'Temp.' must be filled in.  If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.	Registration: key study or weight of evidence record
<b>Endpoint study record – section 5</b>		
<b>5.1.2 – Hydrolysis, Results and discussion</b>	For each endpoint study record marked as 'key study' or 'weight of evidence', the following information must be provided depending on how the study was performed:  - If a preliminary study was carried out, the results should be described in the field 'Preliminary study'. If the preliminary study indicates that the substance is hydrolytically stable and no further study was performed, this should be indicated in the field 'Remarks on result' of the table 'Dissipation DT50 of parent compound' .  - If a full hydrolysis study was carried out, then in the table 'Dissipation DT50 of parent compound' at least one of the fields 'Hydrolysis rate constant' or 'DT50' must be filled in, with unit. If a quantitative result was not determined in the full hydrolysis test, an explanation must be provided in the field 'Remarks on result'.  In addition, a selection must be made in the field 'Transformation products'. If 'yes' was selected, the transformation product(s) must be identified in the table 'Identity of transformation products' by linking the appropriate reference substance(s) in the field 'Reference substance'. The reference substance can be identified by at least one of the following standard identifiers: EC number, CAS number and/or IUPAC name. If not available, a spectrum must be attached in the field 'Attached document', under 'Attached background material' heading.	Registration: key study or weight of evidence record
<b>5.1.2 – Hydrolysis</b>	If the test is waived based on that the substance is highly insoluble in water you need to, in addition to the data waiving record in section 5.1.2, include in section 4.8 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.  If the test is waived based on ready biodegradability of the substance you need to, in addition to the data waiving record in section 5.1.2, include in section 5.2.1 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.	Registration: data waiving
<b>5.2.1 – Biodegradation in water: screening tests</b> <b>5.2.2 – Biodegradation in water and sediment: simulation tests</b>	For each endpoint study record marked as 'key study' or 'weight of evidence', under 'Materials and methods' heading, the field 'Inoculum or test system' must be provided.	Registration: key study or weight of evidence record
<b>5.2.1 – Biodegradation in water: screening tests, Results and discussion</b>	For each endpoint study record marked as 'key study' or 'weight of evidence', in the table '% Degradation' , the fields 'Parameter', 'Value' and 'Sampling time' must be filled in, with unit.  If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.	Registration: key study or weight of evidence record

<p><b>5.2.2 – Biodegradation in water and sediment: simulation tests, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', at least one of the entries '% Degradation' or 'Half-life of parent compound / 50% disappearance time (DT50)' must be filled in.</p> <p>In the table '% Degradation', the fields '% Degr.', 'Parameter' and 'Sampling time' must be filled in, with unit. In the table 'Half-life of parent compound / 50% disappearance time (DT50)', the fields 'Compartment', 'DT50' and 'Temp.' must be filled in, with unit. If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p> <p>In addition, a selection must be made in the field 'Transformation products'. If 'yes' was selected, the transformation product(s) must be identified in the table 'Identity of transformation products' by linking the appropriate reference substance(s) in the field 'Reference substance'. The reference substance can be identified by at least one of the following standard identifiers: EC number, CAS number and/or IUPAC name. If not available, a spectrum must be attached in the field 'Attached document', under 'Attached background material' heading.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>5.2.2 – Biodegradation in water and sediment: simulation tests</b></p>	<p>If the test on ultimate degradation in surface is waived you need to, in addition to the data waiving record in section 5.2.2, include in section 4.8 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.</p> <p>If the test is waived based on ready biodegradability of the substance you need to, in addition to the data waiving record in section 5.2.2, include in section 5.2.1 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.</p>	<p>Registration: data waiving</p>
<p><b>5.2.3 – Biodegradation in soil, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', at least one of the tables '% Degradation' or 'Half-life / dissipation time of parent compound' must be filled in.</p> <p>In the table '% Degradation', the fields '% Degr.', 'Parameter' and 'Sampling time' must be filled in, with unit. In the table 'Half-life / dissipation time of parent compound', the fields 'DT50' and 'Temp.' must be filled in, with unit. If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p> <p>In addition, a selection must be made in the field 'Transformation products'. If 'yes' was selected, the transformation product(s) must be identified in the table 'Identity of transformation products' by linking the appropriate reference substance(s) in the field 'Reference substance'. The reference substance can be identified by at least one of the following standard identifiers: EC number, CAS number and/or IUPAC name. If not available, a spectrum must be attached in the field 'Attached document', under 'Attached background material' heading.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>5.2.3 – Biodegradation in soil</b></p>	<p>If the test is waived based on ready biodegradability of the substance you need to, in addition to the data waiving record in section 5.2.3, include in section 5.2.1 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.</p>	<p>Registration: data waiving</p>
<p><b>5.3.1 – Bioaccumulation: aquatic / sediment, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Bioaccumulation factor', the fields 'Type' and 'Value' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>5.3.1 –</b></p>	<p>If the test is waived based on that the substance has a low potential for</p>	<p>Registration: data</p>



<b>Bioaccumulation: aquatic / sediment</b>	bioaccumulation based on its partition coefficient you need to, in addition to the data waiving record in section 5.3.1, include in section 4.7 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.	waiving
<b>5.4.1 – Adsorption / desorption, Results and discussion</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', at least one of the entries 'Adsorption coefficient' or 'Partition coefficients' must be filled in.</p> <p>In the table 'Adsorption coefficient', the fields 'Type' and 'Value' must be filled in, with unit. If 'Kd' or 'log Kd' was selected under 'Type', then also the field '% Org. carbon' must be filled in. In the table 'Partition coefficients', the fields 'Type' and 'Value' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	Registration: key study or weight of evidence record
<b>5.4.1 – Adsorption / desorption</b>	<p>If the test is waived based on the physicochemical properties of the substance you need to provide further details on these properties and their impact on the adsorption/desorption in the field 'other:' under 'Justification for data waiving'. If needed to further support your justification, the fields 'Remark' and 'Justification for type of information' have longer character limits.</p> <p>If the test is waived based on that the substance decomposes rapidly you need to, in addition to the data waiving record in section 5.4.1, include in section 5.1.2, 5.2.1, 5.2.2 and/or 5.2.3 at least one endpoint study record indicated as "key study' or 'weight of evidence'.</p> <p>If the test is waived based on that the substance has a low octanol water partition coefficient you need to, in addition to the data waiving record in section 5.4.1, include in section 4.7 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.</p>	Registration: data waiving
<b>Endpoint study record &amp; section summary – section 6</b>		
<b>6 – Ecotoxicological information</b>	An endpoint summary must be created under 'Ecotoxicological information', and each created summary must be complete. For each of the hazards, a selection must be made in the 'Hazard assessment conclusion' picklist. If 'PNEC' was selected, the value and unit must be provided in the fields under the conclusion.	Registration: individual and lead over 10 tonnes/year
<b>6 – Ecotoxicological information</b>	If an endpoint summary is created under 'Ecotoxicological information', it must be complete. For each of the hazards, a selection must be made in the 'Hazard assessment conclusion' picklist. If 'PNEC' was selected, the value and unit must be provided in the fields under the conclusion.	Registration: member over 10 tonnes/year
<b>6.1.1 – Short-term toxicity to fish, Results and discussion</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect concentrations', the fields 'Duration', 'Dose descriptor' and 'Effect conc.' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	Registration: key study or weight of evidence record
<b>6.1.1 – Short-term toxicity to fish</b>	<p>If the test is waived based on that the substance is highly insoluble in water you need to, in addition to the data waiving record in section 6.1.1, include in section 4.8 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.</p> <p>If the short-term test is waived based on the availability of a long-term fish toxicity study you need to, in addition to the data waiving record in section 6.1.1, include in section 6.1.2 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.</p>	Registration: data waiving

	<p>If the short-term test is waived based on that a long-term fish toxicity study will be conducted you need to, in addition to the data waiving record in section 6.1.1, include in section 6.1.2 at least one endpoint study record indicated as a testing proposal.</p>	
<b>6.1.2 – Long-term toxicity to fish, Results and discussion</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', under 'Effect concentrations' heading, the fields 'Duration', 'Dose descriptor' and 'Effect conc.' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	Registration: key study or weight of evidence record
<b>6.1.3 – Short-term toxicity to aquatic invertebrates, Results and discussion</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect concentrations', the fields 'Duration', 'Dose descriptor' and 'Effect conc.' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	Registration: key study or weight of evidence record
<b>6.1.3 – Short-term toxicity to aquatic invertebrates</b>	<p>If the test is waived based on that the substance is highly insoluble in water you need to, in addition to the data waiving record in section 6.1.3, include in section 4.8 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.</p> <p>If the short-term test is waived based on the availability of a long-term aquatic invertebrate toxicity study you need to, in addition to the data waiving record in section 6.1.3, include in section 6.1.4 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.</p> <p>If the short-term test is waived based on that a long-term aquatic invertebrate toxicity study will be conducted you need to, in addition to the data waiving record in section 6.1.3, include in section 6.1.4 at least one endpoint study record indicated as a testing proposal.</p>	Registration: data waiving
<b>6.1.4 – Long-term toxicity to aquatic invertebrates, Results and discussion</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect concentrations', the fields 'Duration', 'Dose descriptor' and 'Effect conc.' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	Registration: key study or weight of evidence record
<b>6.1.5 – Toxicity to aquatic algae and cyanobacteria, Results and discussion</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect concentrations', the fields 'Duration', 'Dose descriptor' and 'Effect conc.' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	Registration: key study or weight of evidence record
<b>6.1.6 – Toxicity to aquatic plants other than algae, Results and discussion</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect concentrations', the fields 'Duration', 'Dose descriptor' and 'Effect conc.' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	Registration: key study or weight of evidence record
<b>6.1.7 – Toxicity to microorganisms, Results and discussion</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect concentrations', the fields 'Duration', 'Dose descriptor' and 'Effect conc.' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	Registration: key study or weight of evidence record

<p><b>6.1.7 – Toxicity to microorganisms</b></p>	<p>If the test is waived based on that the substance is highly insoluble in water you need to, in addition to the data waiving record in section 6.1.7, include in section 4.8 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.</p> <p>If the test is waived based on ready biodegradability of the substance you need to, in addition to the data waiving record in section 6.1.7, include in section 5.2.1 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.</p>	<p>Registration: data waiving</p>
<p><b>6.2 – Sediment toxicity, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect concentrations', the fields 'Duration', 'Dose descriptor', 'Effect conc.' and 'Basis for effect' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>6.3.1 – Toxicity to soil macroorganisms except arthropods, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect concentrations', the fields 'Duration', 'Dose descriptor', 'Effect conc.' and 'Basis for effect' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>6.3.2 – Toxicity to terrestrial arthropods, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect concentrations', the fields 'Duration', 'Dose descriptor', 'Effect conc.' and 'Basis for effect' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>6.3.1 – Toxicity to soil macroorganisms except arthropods</b> <b>6.3.2 – Toxicity to terrestrial arthropods</b></p>	<p>If the short-term test is waived based on the availability of a long-term terrestrial organism toxicity study you need to, in addition to the data waiving record, include in section 6.3.1 or 6.3.2 at least one record indicated as 'key study' or 'weight of evidence', with the 'Endpoint' selection corresponding to a long-term study.</p>	<p>Registration: data waiving</p>
<p><b>6.3.3 – Toxicity to terrestrial plants, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect concentrations', the fields 'Duration', 'Dose descriptor', 'Effect conc.' and 'Basis for effect' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>6.3.3 – Toxicity to terrestrial plants</b></p>	<p>If the short-term test is waived based on the availability of a long-term terrestrial plant toxicity study you need to, in addition to the data waiving record, include in section 6.3.3 at least one record indicated as 'key study' or 'weight of evidence', with the 'Endpoint' field set to 'toxicity to terrestrial plants: long-term' or 'toxicity to terrestrial plants: short-term (with study design considered suitable for long-term assessment)'.</p>	<p>Registration: data waiving</p>
<p><b>6.3.4 – Toxicity to soil microorganisms, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect concentrations', the fields 'Duration', 'Dose descriptor', 'Effect conc.' and 'Basis for effect' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>6.3.5 – Toxicity to birds, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect levels', the fields 'Duration (if not bolus)', 'Dose descriptor' and 'Effect level' must be filled in, with unit.</p> <p>If a quantitative result was not determined, an explanation must be</p>	<p>Registration: key study or weight of evidence record</p>

	provided in the field 'Remarks on result'.	
<b>Endpoint study record &amp; section summary – section 7</b>		
<b>7 – Toxicological information</b>	An endpoint summary must be created under 'Toxicological information', and each created summary must be complete. For each of the hazards for 'Workers' and 'General population' a selection must be made in the 'Hazard assessment conclusion' picklist. If 'DNEL', 'DMEL' or 'other toxicological threshold' was selected, the value and unit must be provided in the fields under the conclusion.	Registration: individual and lead over 10 tonnes/year
<b>7 – Toxicological information</b>	If an endpoint summary is created under 'Toxicological information', it must be complete. For each of the hazards for 'Workers' and 'General population' a selection must be made in the 'Hazard assessment conclusion' picklist. If 'DNEL', 'DMEL' or 'other toxicological threshold' was selected, the value and unit must be provided in the fields under the conclusion.	Registration: member over 10 tonnes/year
<b>7.2.1 – Acute toxicity: oral, Results and discussion</b>	For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect levels', the fields 'Dose descriptor' and 'Effect level' must be provided, with unit.  If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.	Registration: key study or weight of evidence record
<b>7.2.1 – Acute toxicity: oral</b>	If the oral acute toxicity test is waived based on the availability of an acute toxicity study by the inhalation route you need to, in addition to the data waiving record in section 7.2.1, include in section 7.2.2 at least one record indicated as 'key study' or 'weight of evidence'.  If the test is waived based on the classification of the substance as corrosive to the skin you need to, in addition to the data waiving record in section 7.2.1, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Skin corrosion / irritation'.	Registration: data waiving
<b>7.2.2 – Acute toxicity: inhalation, Results and discussion</b>	For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect levels', the fields 'Dose descriptor' and 'Effect level' must be provided, with unit.  If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.	Registration: key study or weight of evidence record
<b>7.2.2 – Acute toxicity: inhalation</b>	If the test is waived based on the classification of the substance as corrosive to the skin you need to, in addition to the data waiving record in section 7.2.2, include in section 2.1 at least one record where you provide the appropriate skin corrosiveness classification for the hazard class 'Skin corrosion / irritation'.	Registration: data waiving
<b>7.2.3 – Acute toxicity: dermal, Results and discussion</b>	For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Effect levels', the fields 'Dose descriptor' and 'Effect level' must be provided, with unit.  If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.	Registration: key study or weight of evidence record
<b>7.2.3 – Acute toxicity: dermal</b>	If the test is waived based on the classification of the substance as corrosive to the skin you need to, in addition to the data waiving record in section 7.2.3, include in section 2.1 at least one record where you provide the appropriate skin corrosiveness classification for the hazard class 'Skin corrosion / irritation'.	Registration: data waiving
<b>7.3.1 – Skin irritation / corrosion, Results and</b>	For each endpoint study record marked as 'key study' or 'weight of evidence', the 'Results' table for either 'In vitro' or 'In vivo' must be filled	Registration: key study or weight of

<p><b>discussion</b></p>	<p>in.</p> <p>In the table 'In vitro - Results', the fields 'Irritation / corrosion parameter' and 'Value' must be filled in. In the table 'In vivo - Results', the fields 'Irritation parameter', 'Time point' and 'Score' must be filled in.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result' of the appropriate table.</p>	<p>evidence record</p>
<p><b>7.3.1 – Skin irritation / corrosion</b></p>	<p>If the test is waived based on that the substance is spontaneously flammable in air or in contact with water or moisture (i.e. the substance is pyrophoric) you need to, in addition to the data waiving record in section 7.3.1, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Pyrophoric liquids', 'Pyrophoric solids', or 'Substances and mixtures which in contact with water emit flammable gases'.</p> <p>If the test is waived based on that the substance is classified as acute toxicity by the dermal route (Category 1) you need to, in addition to the data waiving record in section 7.3.1, include in section 2.1 at least one record where you provide the corresponding classification for the hazard class 'Acute toxicity – dermal'.</p> <p>If the test is waived based on findings from an acute toxicity study by the dermal route you need to, in addition to the data waiving record in section 7.3.1, include in section 7.2.3 at least one record indicated as 'key study' or 'weight of evidence'.</p> <p>If the test is waived based on that the substance is classified as corrosive to the skin you need to, in addition to the data waiving record in section 7.3.1, include in section 2.1 at least one record where you provide the appropriate skin corrosiveness classification for the hazard class 'Skin corrosion / irritation'.</p> <p>If the in vitro skin irritation study is waived based on the availability of an in vivo skin irritation study that was carried out before the entry into force of REACH or because the in vitro test methods are not applicable for the substance and therefore an in vivo skin irritation study was conducted, you need to, in addition to the data waiving record, include in section 7.3.1 at least one endpoint study record indicated as 'key study' or 'weight of evidence' with the 'Endpoint' selection 'skin irritation: in vivo'.</p>	<p>Registration: data waiving</p>
<p><b>7.3.2 – Eye irritation, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', the 'Results' table for either 'In vitro' or 'In vivo' must be filled in.</p> <p>In the table 'In vitro - Results', the fields 'Irritation parameter' and 'Value' must be filled in. In the table 'In vivo - Results', the fields 'Irritation parameter', 'Time point' and 'Score' must be filled in.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result' of the appropriate entry.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>7.3.2 – Eye irritation</b></p>	<p>If the test is waived based on the classification of the substance as irritating to the eyes with risk of serious eye damage you need to, in addition to the data waiving record in section 7.3.2, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Serious eye damage / eye irritation'.</p> <p>If the test is waived based on that the substance is spontaneously</p>	<p>Registration: data waiving</p>

	<p>flammable in air or in contact with water or moisture (i.e. the substance is pyrophoric) you need to, in addition to the data waiving record in section 7.3.2, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Pyrophoric liquids', 'Pyrophoric solids', or 'Substances and mixtures which in contact with water emit flammable gases'.</p> <p>If the in vitro eye irritation study is waived based on the availability of an in vivo eye irritation study that was carried out before the entry into force of REACH or because the in vitro test methods are not applicable for the substance and therefore an in vivo eye irritation study was conducted you need to, in addition to the data waiving record, include in section 7.3.2 at least one endpoint study record indicated as 'key study' or 'weight of evidence' with the 'Endpoint' selection 'eye irritation: in vivo'.</p> <p>If the test is waived based on that the available information leads to a classification of the substance as serious eye damage (Category 1) you need to, in addition to the data waiving record in section 7.3.2, include in section 2.1 at least one record where you provide this classification for the hazard class 'Serious eye damage / eye irritation'.</p>	
<p><b>7.4.1 – Skin sensitisation, Materials and methods</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence' the field 'Type of study' must be provided.</p> <p>In addition, if the study addresses the endpoint 'skin sensitisation: in vivo (non-LLNA)', the chosen method must be explained in the field 'Justification for non-LLNA method'.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>7.4.1 – Skin sensitisation, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', the 'Results' table under either 'In vitro / in chemico', 'In vivo (non-LLNA)' or 'In vivo LLNA' must be filled in.</p> <p>In the table 'In vitro / in chemico - Results', the fields 'Parameter' and 'Value' must be provided.</p> <p>In the table 'In vivo (non-LLNA) - Results', the fields 'Reading', 'Dose level', 'No. with + reactions' and 'Total no. in group' must be filled in.</p> <p>In the table 'In vivo LLNA - Results', the fields 'Parameter' and 'Value' must be provided.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result' of the appropriate table.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>7.4.1 – Skin sensitisation</b></p>	<p>If the test is waived based on that the substance is spontaneously flammable in air or in contact with water or moisture (i.e. the substance is pyrophoric) you need to, in addition to the data waiving record in section 7.4.1, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Pyrophoric liquids', 'Pyrophoric solids', or 'Substances and mixtures which in contact with water emit flammable gases'.</p> <p>If the test is waived based on that the substance is classified as corrosive to the skin you need to, in addition to the data waiving record in section 7.4.1, include in section 2.1 at least one record where you provide the appropriate skin corrosiveness classification for the hazard class 'Skin corrosion / irritation'.</p> <p>If the in vitro skin sensitisation study is waived based on the availability of an in vivo skin sensitisation study that was carried out before 2018 or because the in vitro test methods are not applicable for the substance and therefore an in vivo skin sensitisation study was conducted you need to, in addition to the data waiving record, include in section 7.4.1 at least one</p>	<p>Registration: data waiving</p>

	<p>endpoint study record indicated as 'key study' or 'weight of evidence' with the 'Endpoint' selection 'skin sensitisation: in vivo (LLNA)' or 'skin sensitisation: in vivo (non-LLNA)'.</p>	
<p><b>7.5.1 – Repeated dose toxicity: oral</b>  <b>7.5.2 – Repeated dose toxicity: inhalation</b>  <b>7.5.3 – Repeated dose toxicity: dermal, Results and discussion</b></p>	<p>For each endpoint study record in these sections marked as 'key study' or 'weight of evidence', in the table 'Effect levels', the fields 'Dose descriptor', 'Effect level' and 'Basis for effect level' must be provided, with unit.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p> <p>In addition, a selection must be made in the field 'Critical effects observed' on the table 'Target system / organ toxicity'. If 'yes' was selected, then the fields 'Lowest effective dose/conc.', 'System', 'Organ' and 'Treatment related' must be provided, with unit, where applicable.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>7.5.1 – Repeated dose toxicity: oral</b>  <b>7.5.2 – Repeated dose toxicity: inhalation</b>  <b>7.5.3 – Repeated dose toxicity: dermal</b></p>	<p>If the short-term toxicity study by the oral route is waived based on the availability of an appropriate inhalation study you need to, in addition to the data waiving record in section 7.5.1, include at least one endpoint study record indicated as 'key study' or 'weight of evidence' in section 7.5.2.</p> <p>If the short-term toxicity study by the oral route is waived based on the availability of an appropriate dermal study you need to, in addition to the data waiving record in section 7.5.1, include at least one endpoint study record indicated as 'key study' or 'weight of evidence' in section 7.5.3.</p> <p>If the short-term toxicity study is waived based on the availability of a sub-chronic or chronic toxicity study you need to, in addition to the data waiving record, include in section 7.5.1, 7.5.2 or 7.5.3 at least one endpoint study record indicated as 'key study' or 'weight of evidence' with the 'Endpoint' selection 'sub-chronic toxicity: oral/inhalation/dermal' or 'chronic toxicity: oral/inhalation/dermal'.</p> <p>If the short-term toxicity study is waived based on that a sub-chronic or chronic toxicity study will be conducted you need to, in addition to the data waiving record, include in section 7.5.1, 7.5.2 or 7.5.3 at least one endpoint study record indicates as a testing proposal with the 'Endpoint' selection 'sub-chronic toxicity: oral/inhalation/dermal' or 'chronic toxicity: oral/inhalation/dermal'.</p> <p>If the sub-chronic toxicity study by the oral route is waived based on the availability of an appropriate inhalation study you need to, in addition to the data waiving record in section 7.5.1, include at least one endpoint study record indicated as 'key study' or 'weight of evidence' in section 7.5.2 with the 'Endpoint' selection 'sub-chronic toxicity: inhalation' or 'chronic toxicity: inhalation'.</p> <p>If the sub-chronic toxicity study by the oral route is waived based on the availability of an appropriate dermal study you need to, in addition to the data waiving record in section 7.5.1, include at least one endpoint study record indicated as 'key study' or 'weight of evidence' in section 7.5.3 with the 'Endpoint' selection 'sub-chronic toxicity: dermal' or 'chronic toxicity: dermal'.</p> <p>If the sub-chronic toxicity study is waived based on that the substance is unreactive, insoluble, not inhalable and there is no evidence of toxicity from a 28-day 'limit test' and human exposure is limited, then you need</p>	<p>Registration: data waiving</p>

	<p>to, in addition to the data waiving record, include in section 7.5.1, 7.5.2 or 7.5.3 at least one endpoint study record indicated as 'key study' or 'weight of evidence' with the 'Endpoint' selection 'short-term repeated dose toxicity: oral/inhalation/dermal'.</p> <p>If the sub-chronic toxicity study is waived based on the availability of a 28-day study that allows a conclusive decision on classification and NOAEL-90 extrapolation, then you need to, in addition to the data waiving record, include in section 7.5.1, 7.5.2 or 7.5.3 at least one endpoint study record indicated as 'key study' or 'weight of evidence' with the 'Endpoint' selection 'short-term repeated dose toxicity: oral/inhalation/dermal'. In addition, you must include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Specific target organ toxicity – repeated'.</p> <p>If the sub-chronic toxicity study is waived based on the availability of a chronic toxicity study you need to, in addition to the data waiving record, include in section 7.5.1, 7.5.2 or 7.5.3 at least one endpoint study record indicated as 'key study' or 'weight of evidence' with the 'Endpoint' selection 'chronic toxicity: oral/inhalation/dermal'.</p>	
<p><b>7.6.1 – Genetic toxicity in vitro, Materials and methods</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence' the field 'Type of assay' must be provided.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>7.6.1 – Genetic toxicity in vitro, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Test results', the fields 'Species/strain', 'Metabolic activation', 'Genotoxicity' and 'Cytotoxicity / choice of top concentrations' must be provided.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>7.6.1 – Genetic toxicity in vitro</b></p>	<p>If the in vitro cytogenicity / micronucleus study (REACH Annex VIII, 8.4.2.) is waived based on the classification of the substance as a carcinogen (category 1A or 1B), or as a germ cell mutagen (category 1A, 1B or 2) you need to, in addition to the data waiving record in section 7.6.1, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Carcinogenicity' and/or 'Germ cell mutagenicity'.</p> <p>If the in vitro gene mutation study in mammalian cells (REACH Annex VIII, 8.4.3.) is waived based on a positive result from an in vitro cytogenicity in mammalian cells or an in vitro micronucleus study, you need to, in addition to the data waiving record, include in section 7.6.1 at least one endpoint study record indicated as 'key study' or 'weight of evidence' with the 'Endpoint' selection 'in vitro cytogenicity / chromosome aberration study in mammalian cells' or 'in vitro cytogenicity / micronucleus study'.</p> <p>If the in vitro gene mutation study in mammalian cells (REACH Annex VIII, 8.4.3.) is waived based on a positive result from an in vitro gene mutation study in bacteria you need to, in addition to the data waiving record, include in section 7.6.1 at least one endpoint study record indicated as 'key study' or 'weight of evidence' with the 'Endpoint' selection 'in vitro gene mutation study in bacteria'.</p> <p>If the in vitro study/ies is/are waived based on the availability of an in vivo study you need to, in addition to the data waiving record(s) in section 7.6.1, include in section 7.6.2 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.</p>	<p>Registration: data waiving</p>



	<p>If the in vitro study/ies is/are waived based on a proposed in vivo study you need to, in addition to the data waiving record(s) in section 7.6.1, include in section 7.6.2 at least one endpoint study record indicated as a testing proposal.</p>	
<b>7.6.2 Genetic toxicity in vivo</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence' the field 'Type of assay' must be provided.</p>	<p>Registration: key study or weight of evidence record</p>
<b>7.6.2 Genetic toxicity in vivo</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', in the table 'Test results', the fields 'Sex', 'Genotoxicity' and 'Toxicity' must be provided.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p>	<p>Registration: key study or weight of evidence record</p>
<b>7.8.1 – Toxicity to reproduction, Materials and methods</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', or indicated as a testing proposal, which addresses the endpoint extended one-generation reproductive toxicity study (EOGRTS), the chosen study design must be explained in the field 'Justification for study design'.</p>	<p>Registration: key study or weight of evidence record, testing proposal</p>
<b>7.8.1 – Toxicity to reproduction, Results and discussion</b>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', results must be provided for the relevant generations for the selected study design. As a minimum, results for one parental generation (P0, P1) and one offspring generation (F1, F2) must be given. To this end, the corresponding 'Effect levels' entries must be filled in, providing at least the 'Dose descriptor', 'Effect level', 'Sex' and 'Basis for effect level', with unit where applicable.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p> <p>In addition, a selection must be made in the field 'Reproductive effects observed' of the table 'Overall reproductive toxicity'. If 'yes' was selected, then the fields 'Lowest effective dose/conc.', 'Treatment related' and 'Relation to other toxic effects' must be provided, with unit, where applicable.</p>	<p>Registration: key study or weight of evidence record</p>
<b>7.8.1 – Toxicity to reproduction</b>	<p>If the screening test for reproductive toxicity is waived based on other evidence that the substance may be a developmental toxicant you need to, in addition to the data waiving record in section 7.8.1, include in section 7.8.1 or 7.8.2 at least one endpoint study record indicated as 'key study' or 'weight of evidence'.</p> <p>If the screening test for reproductive toxicity is waived based on the availability of an extended one-generation reproductive toxicity study (EOGRTS) you need to, in addition to the data waiving record, include in section 7.8.1 at least one endpoint study record indicated as 'key study' or 'weight of evidence' with the 'Endpoint' selection corresponding to an EOGRTS.</p> <p>If the study is waived based on the availability of a two-, three-, or multi-generation reproductive toxicity study you need to, in addition to the data waiving record, include in section 7.8.1 at least one endpoint study record indicated as 'key study' or 'weight of evidence' with the 'Endpoint' selection corresponding to a two-, three-, or multi-generation study.</p> <p>If the screening test for reproductive toxicity is waived based on the availability of a pre-natal developmental toxicity study you need to, in addition to the data waiving record in section 7.8.1, include in section</p>	<p>Registration: data waiving</p>

	<p>7.8.2 at least one record indicated as 'key study' or 'weight of evidence'.</p> <p>If the study is waived based on the classification of the substance as a genotoxic carcinogen or a germ cell mutagen you need to, in addition to the data waiving record in section 7.8.1, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Carcinogenicity' or 'Germ cell mutagenicity'.</p> <p>If the study is waived based on the classification of the substance as toxic to reproduction category 1A or 1B you need to, in addition to the data waiving record in section 7.8.1, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Reproductive toxicity'.</p> <p>If the extended one-generation reproductive toxicity study (EOGRTS) is waived based on absence of indications of adverse effects on reproductive organs or tissues from available repeated dose toxicity studies, you need to, in addition to the data waiving record in section 7.8.1, include at least one endpoint study record indicated as a 'key study' or 'weight of evidence' documenting the results of these repeated dose toxicity studies in sections 7.5.1, 7.5.2, 7.5.3, 7.8.1 and/or 7.8.2, as appropriate. This data waiving is only applicable at Annex IX.</p> <p>If the Annex IX information requirements for reproductive toxicity are waived (i.e data waiving for the extended one-generation reproductive toxicity study (EOGRTS) and data waiving for the Developmental toxicity / teratogenicity study), the Annex VIII requirement must be addressed with at least one endpoint study record indicated as a key study, weight of evidence, or data waiving with the 'Endpoint' selection 'screening for reproductive / developmental toxicity'.</p>	
<p><b>7.8.2 – Developmental toxicity / teratogenicity, Materials and methods</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', or indicated as a testing proposal, or as a data waiving, under 'Test animals' a selection must be made in the field 'Species'.</p>	<p>Registration: key study or weight of evidence record, testing proposal, data waiving</p>
<p><b>7.8.2 – Developmental toxicity / teratogenicity, Results and discussion</b></p>	<p>For each endpoint study record marked as 'key study' or 'weight of evidence', results must be provided in the tables 'Effect levels (maternal animals)' and 'Effect levels (fetuses)'. In each table, at least the fields 'Dose descriptor', 'Effect level' and 'Basis for effect level' must be provided, with unit where applicable.</p> <p>If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'.</p> <p>In addition, a selection must be made in the field 'Developmental effects observed' of the table 'Overall developmental toxicity'. If 'yes' was selected, then the fields 'Lowest effective dose/conc.', 'Treatment related' and 'Relation to maternal toxicity' must be provided, with unit, where applicable.</p>	<p>Registration: key study or weight of evidence record</p>
<p><b>7.8.2 – Developmental toxicity / teratogenicity</b></p>	<p>If the test is waived based on the classification of the substance as a genotoxic carcinogen or a germ cell mutagen you need to, in addition to the data waiving record in section 7.8.2, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Carcinogenicity' or 'Germ cell mutagenicity'.</p> <p>If the study is waived based on the classification of the substance as toxic</p>	<p>Registration: data waiving</p>

	to reproduction category 1A or 1B you need to, in addition to the data waiving record in section 7.8.2, include in section 2.1 at least one record where you provide the appropriate classification for the hazard class 'Reproductive toxicity'.	
<b>Guidance on safe use, Chemical safety report, Annex III criteria</b>		
<b>11 – Guidance on safe use</b>	<p>At least one record must be created in section 11. Each record must contain at least the following information related to the guidance on safe use:</p> <ul style="list-style-type: none"> <li>- First-aid measures</li> <li>- Fire-fighting measures</li> <li>- Accidental release measures</li> <li>- Handling and storage</li> </ul> <p>In addition, at Annex VII, where a Chemical safety report is not required, the following additional information must be provided:</p> <ul style="list-style-type: none"> <li>- Exposure controls / personal protection</li> <li>- Stability and reactivity</li> <li>- Disposal considerations</li> </ul> <p>Note for member registrants: if the Guidance on safe use information that applies to your registration has been provided in the joint submission lead dossier, then the corresponding checkbox in the dossier header needs to be selected.</p>	All registration dossiers except Art. 17/18 intermediates only
<b>13.1 – Chemical Safety Report (CSR)</b>	<p>A Chemical safety report (CSR) must be provided, or a justification for why a CSR is not required, must be included.</p> <ul style="list-style-type: none"> <li>- In order to provide a CSR, create a record in section 13.1 and attach the CSR in the field 'Chemical safety report (CSR)'.</li> <li>- In order to provide a justification for why a CSR is not required, create a record in section 13.1 and provide the justification either in the field 'Further information on the CSR attached / remarks' or in the field 'Discussion'. The justification must fall under the reasons listed in Article 14(2) of REACH.</li> </ul> <p>Note that if you are a member of a joint submission, and the lead registrant has provided the Chemical safety report on your behalf, you must indicate this in the dossier header under 'Information provided by the lead on behalf of the member(s)'.</p>	All registration dossiers that require a CSR
<b>13.2 – Other assessment reports</b>	<p>For each record created in section 13.2, the type of assessment report must be indicated in the field 'Type of report'. If none of the available picklist values apply, select 'other:' and provide a description of the type of report provided in the free-text field below. In addition, the report must be attached in the field 'Document / Report', or an explanation for not providing the specified type of report must be inserted either in the field ' Further information on the attachment / remarks' or in the field 'Discussion'.</p>	All registration dossiers
<b>14 – Annex III criteria</b>	<p>For registrants that register a phase-in substance in the tonnage band 1-10 tonnes by applying the possibility provided by REACH Article 12(b) to submit only information on the physicochemical properties specified in Annex VII, section 7:</p> <p>To benefit from the reduced information requirements, you need to create a record in section 14 - 'Annex III criteria' and complete it to demonstrate that you have considered all available information to ensure that the registered substance does not fulfil the REACH Annex III criteria.</p>	All registration dossiers at 1-10 tonnes/year that apply reduced requirements (Annex III)

	<ul style="list-style-type: none"> <li>- Make a selection in question 1 to indicate whether the substance is in the inventory of substances likely to meet the REACH Annex III criteria, published by ECHA.</li> <li>- Make a selection in each of the questions 2–5 to indicate whether any of the available data suggest that the substance is likely to fall under the REACH Annex III(a) criteria.</li> <li>- Make a selection in question 6 to indicate whether wide dispersive or diffuse uses can be excluded. If you indicate ‘no’, then a selection must be made in each of the questions 7–10 to indicate whether any of the available data suggest that the substance is likely to fall under the REACH Annex III(b) criteria.</li> <li>- If you indicate in any of the above questions that there are data available to suggest that the substance meets the Annex III criteria, then you need to provide a justification in the field ‘Justification for disregarding any indication of meeting the criteria of Annex III as declared above’ to explain why you consider that the substance can still be registered according to under REACH Article 12(b).</li> </ul>	
<p><b>14 - Opt-out information for REACH requirement</b></p>	<p>For registrants who opt-out either fully or partially from the joint submission, a justification must be provided by fully completing at least one of the templates in section 14 ‘Information requirements’ under section ‘Opt-out information for REACH registration’ or else by fully answering all points of at least one of the templates in the free text field in the same section.</p> <p>There are three templates available covering disagreement on cost, disclosure of commercially sensitive information and disagreement on the data used. Copies of these templates are available in Annex VII of this manual. You are advised to use at least one of the text templates available for the field to ensure that all the relevant information has been provided.</p>	<p>All registration dossiers opting-out either fully or partially</p>

### Annex 3. Overview of endpoints and information requirements

This table lists the information requirements that depend on the REACH Annex for which the registration is made. The following abbreviations are used: r = required endpoint; o = optional endpoint. Some REACH information requirements do not directly translate to one IUCLID section; for these, additional instructions are provided in the column REACH information requirements which do not have a 1:1 correspondence with a IUCLID section. In addition, note that according to REACH, all relevant physicochemical, ecotoxicological and toxicological information that is available shall always be provided, irrespective of whether it is required at the registered tonnage band.

IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
<b>4</b>	<b>Physical and chemical properties</b>												
4.1	Appearance / physical state / colour	7	7.1		r	r	r	r	r	o	o	r	o
4.2	Melting point / freezing point	7	7.2		r	r	r	r	r	o	o	r	o
4.3	Boiling point	7	7.3		r	r	r	r	r	o	o	r	o
4.4	Density	7	7.4		r	r	r	r	r	o	o	r	o

IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
4.5	Particle size distribution (Granulometry)	7	7.14		r	r	r	r	r	o	o	r	o
4.6	Vapour pressure	7	7.5		r	r	r	r	r	o	o	r	o
4.7	Partition coefficient	7	7.8		r	r	r	r	r	o	o	r	o
4.8	Water solubility	7	7.7		r	r	r	r	r	o	o	r	o
4.10	Surface tension	7	7.6		r	r	r	r	r	o	o	r	o
4.11	Flash point	7	7.9		r	r	r	r	r	o	o	r	o
4.12	Auto flammability	7	7.12		r	r	r	r	r	o	o	r	o
4.13	Flammability	7	7.10	As a minimum, one complete endpoint study record must be provided with the 'Endpoint' selection 'flammable solids' or 'flammable gases'. For liquids, a data waiving record should be provided.	r	r	r	r	r	o	o	r	o
4.14	Explosiveness	7	7.11		r	r	r	r	r	o	o	r	o

IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
4.15	Oxidising properties	7	7.13		r	r	r	r	r	o	o	r	o
4.17	Stability in organic solvents and identity of relevant degradation products	9	7.15		o	o	o	r	r	o	o	o	o
4.21	Dissociation constant	9	7.16		o	o	o	r	r	o	o	o	o
4.22	Viscosity	9	7.17		o	o	o	r	r	o	o	o	o
4.28.8	Dustiness (For nanoforms)	7	7.14bis		r	r	r	r	r	o	o	o	o
<b>5</b>	<b>Environmental fate and pathways</b>												
5.1.2	Hydrolysis	8	9.2.2.1		o	o	r	r	r	o	o	o	o
5.2.1	Biodegradation in water: screening tests	7	9.2.1.1	As a minimum, one complete endpoint study record must be provided with the 'Endpoint'	o	r	r	r	r	o	o	r	o

IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
				selection 'biodegradation in water: ready biodegradability' or 'biodegradation in water: screening test, other'.									
5.2.2	Biodegradation in water and sediment: simulation tests	9	9.2.1.2 (water) 9.2.3	At 100-1000T and >1000T, REACH specifies two information requirements for biodegradation (9.2.1.2 and 9.2.1.4). Therefore, at these tonnages IUCLID section 5.2.2 must contain as a minimum complete endpoint study records for water and sediment compartments.	o	o	o	r	r	o	o	o	o
		9	9.2.1.4 (sediment) 9.2.3		o	o	o	r	r	o	o	o	o
5.2.2	Biodegradation in water and sediment: simulation tests	9	9.2.1.2 (water) 9.2.3	As a minimum, one complete endpoint study record must be provided with the 'Endpoint' selection 'biodegradation in water: simulation testing on ultimate degradation in surface water'.	o	o	o	r	r	o	o	o	o



IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
		9	9.2.1.4 (sediment)  9.2.3	As a minimum, one complete endpoint study record must be provided with the 'Endpoint' selection 'biodegradation in water: sediment simulation testing'.	o	o	o	r	r	o	o	o	o
5.2.3	Biodegradation in soil	9	9.2.1.3  9.2.3		o	o	o	r	r	o	o	o	o
5.3.1	Bioaccumulation: aquatic / sediment	9	9.3.2		o	o	o	r	r	o	o	o	o
5.4.1	Adsorption / desorption	8	9.3.1		o	o	r	r	r	o	o	o	o
<b>6</b>	<b>Ecotoxicological Information</b>												
6.1.1	Short-term toxicity to fish	8	9.1.3		o	o	r	r	r	o	o	o	o
6.1.2	Long-term toxicity to	9	9.1.6		o	o	o	r	r	o	o	o	o

IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
	fish												
6.1.3	Short-term toxicity to aquatic invertebrates	7	9.1.1		o	r	r	r	r	o	o	r	o
6.1.4	Long-term toxicity to aquatic invertebrates	9	9.1.5		o	o	o	r	r	o	o	o	o
6.1.5	Toxicity to aquatic algae and cyano-bacteria	7	9.1.2	As a minimum, one complete endpoint study record must be provided in section 6.1.5 or in 6.1.6.	o	r	r	r	r	o	o	r	o
6.1.6	Toxicity to aquatic plants other than algae	na	not req.		o	o	o	o	o	o	o	o	o
6.1.7	Toxicity to micro-organisms	8	9.1.4		o	o	r	r	r	o	o	o	o
6.2	Sediment toxicity	10	9.5.1	At >1000T, as a minimum one complete endpoint study record must be provided with the 'Endpoint' selection 'sediment toxicity: long-term'.	o	o	o	o	r	o	o	o	o

IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
6.3.1	Toxicity to soil macro-organisms except arthropods	9	9.4.1 (short-term)	At 100-1000T, as a minimum one complete endpoint study record must be provided in section 6.3.1 or in 6.3.2.	o	o	o	r	r	o	o	o	o
		10	9.4.4 (long-term)		o	o	o	o	r	o	o	o	o
6.3.2	Toxicity to terrestrial arthropods	9	9.4.1 (short-term)	At >1000T, as a minimum one complete endpoint study record must be provided in section 6.3.1 with the 'Endpoint' selection 'toxicity to soil macroorganisms except arthropods: long-term', or in section 6.3.2 with the 'Endpoint' selection 'toxicity to terrestrial arthropods: long-term'.	o	o	o	r	r	o	o	o	o
		10	9.4.4 (long-term)		o	o	o	o	r	o	o	o	o
6.3.3	Toxicity to terrestrial plants	9	9.4.3 (short-term)	At 100-1000T, as a minimum one complete endpoint study record must be provided.	o	o	o	r	r	o	o	o	o
		10	9.4.6 (long-term)		o	o	o	o	r	o	o	o	o
				At >1000T, as a minimum one complete endpoint study record must be provided with the									

IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
				'Endpoint' selection 'toxicity to terrestrial plants: long-term' or 'toxicity to terrestrial plants: short-term (with study design considered suitable for long-term assessment)'									
6.3.4	Toxicity to soil micro-organisms	9	9.4.2		o	o	o	r	r	o	o	o	o
6.3.5	Toxicity to birds	10	9.6.1	At >1000T, as a minimum one complete endpoint study record must be provided with the 'Endpoint' selection 'long-term toxicity to birds: reproduction test', 'long-term toxicity to birds', or 'toxicity to birds, other'.	o	o	o	o	r	o	o	o	o
<b>7</b>	<b>Toxicological information</b>												
7.2.1	Acute toxicity: oral	7	8.5.1		o	r	r	r	r	o	o	r	o

IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
7.2.2	Acute toxicity: inhalation	8	8.5.2		o	o	r	r	r	o	o	o	o
7.2.3	Acute toxicity: dermal	8	8.5.3		o	o	r	r	r	o	o	o	o
7.3.1	Skin irritation / corrosion	7	8.1.1 (in vitro skin corrosion)	REACH specifies separate information requirements for in vitro skin corrosion and irritation (8.1.1 and 8.1.2). However, results from one of the two studies may already allow a conclusive decision on the classification of a substance or on the absence of skin irritation potential.	o	r	r	r	r	o	o	r	o
		7	8.1.2 (in vitro skin irritation)	Therefore, in dossiers requiring this endpoint, IUCLID section 7.3.1 must contain as a minimum one complete endpoint study record with the 'Endpoint'	o	r	r	r	r	o	o	r	o

IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
				selection 'skin corrosion: in vitro / ex vivo', 'skin irritation: in vitro / ex vivo', or 'skin irritation / corrosion, other'.									
7.3.2	Eye irritation	7	8.2.1 (in vitro)	As a minimum, one complete endpoint study record must be provided with the 'Endpoint' selection 'eye irritation: in vitro / ex vivo' or 'eye irritation, other'.	o	r	r	r	r	o	o	r	o
7.4.1	Skin sensitisation	7	8.3 (in vitro or in chemico)	As a minimum, one complete endpoint study record must be provided with the 'Endpoint' selection 'skin sensitisation: in vitro', 'skin sensitisation: in chemico', or 'skin sensitisation, other'.	o	r	r	r	r	o	o	r	o
7.5.1	Repeated dose toxicity: oral	8	8.6.1 (short-term)	At 10-100T, as a minimum, one complete endpoint	o	o	r	r	r	o	o	o	o

IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
		9	8.6.2 (sub-chronic)	study record must be provided in section 7.5.1, 7.5.2 or 7.5.3.	o	o	o	r	r	o	o	o	o
7.5.2	Repeated dose toxicity: inhalation	8	8.6.1 (short-term)	At >100T, as a minimum, one complete endpoint study record must be provided in section 7.5.1, 7.5.2 or 7.5.3 with another 'Endpoint' selection than 'short-term repeated dose toxicity: oral/inhalation/dermal'.	o	o	r	r	r	o	o	o	o
		9	8.6.2 (sub-chronic)		o	o	o	r	r	o	o	o	o
7.5.3	Repeated dose toxicity: dermal	8	8.6.1 (short-term)		o	o	r	r	r	o	o	o	o
		9	8.6.2 (sub-chronic)		o	o	o	r	r	o	o	o	o
7.6.1	Genetic toxicity in vitro	7	8.4.1 (in vitro gene mutation in bacteria)		At 1-10T (standard requirements) and >1000T transported isolated intermediates, as a minimum, one complete endpoint study record must be provided.	o	r	r	r	r	o	o	r
		8	8.4.2 (in vitro cytogenicity in mammalian cells or in vitro)	At >10T REACH specifies additionally two information requirements	o	o	r	r	r	o	o	o	o

IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
			micronucleus)	for mutagenicity (8.4.2 and 8.4.3). However, depending on the outcome of the tests, only two of the three requirements may be necessary. Therefore, at >10T IUCLID section 7.6.1 must contain, as a minimum, two complete endpoint study records.									
		8	8.4.3 (in vitro gene mutation in mammalian cells)		o	o	r	r	r	o	o	o	o
7.6.1	Genetic toxicity in vitro	7	8.4.1 (in vitro gene mutation in bacteria)	As a minimum, one complete endpoint study record must be provided with the 'Endpoint' selection 'in vitro gene mutation study in bacteria'.	o	r	r	r	r	o	o	r	o
		8	8.4.2 (in vitro cytogenicity in mammalian cells or in vitro micronucleus)	As a minimum, one complete endpoint study record must be provided with the 'Endpoint' selection 'in vitro cytogenicity / chromosome aberration study in	o	o	r	r	r	o	o	o	o



IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
				mammalian cells' or 'in vitro cytogenicity / micronucleus study'.									
		8	8.4.3 (in vitro gene mutation in mammalian cells)	As a minimum, one complete endpoint study record must be provided with the 'Endpoint' selection 'in vitro gene mutation study in mammalian cells'.	o	o	r	r	r	o	o	o	o
7.6.2	Genetic toxicity in vivo	8	8.4 (in vivo mutagenicity studies)	In case of a positive/ambiguous result in any of the genotoxicity studies in Annex VII or VIII, as a minimum, one complete endpoint study record must be provided.	o	o	r	r	r	o	o	o	o
7.8.1	Toxicity to reproduction	8	8.7.1 (screening)	At 10-100T, as a minimum, one complete endpoint study record must be provided.	o	o	r	r	r	o	o	o	o
		9	8.7.3 (extended one-generation)	At >100T, as a minimum, one complete endpoint	o	o	o	r	r	o	o	o	o

IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
				<p>study record must be provided with the “Endpoint” selection “extended one-generation reproductive toxicity”.*</p> <p>*Also two-, three- or multigeneration studies are considered valid to fulfil the requirement.</p>									
7.8.2	Developmental toxicity / teratogenicity	9	8.7.2 (first species)	At 100-1000T, as a minimum, one complete endpoint study record must be provided.	o	o	o	r	r	o	o	o	o
		10	8.7.2 (second species)	At >1000T, as a minimum, two complete endpoint study record must be provided, for two different species.	o	o	o	o	r	o	o	o	o
7.8.2	Developmental toxicity / teratogenicity	9	8.7.2	First species	o	o	o	r	r	o	o	o	o
		10	8.7.2	Second species (different	o	o	o	o	r	o	o	o	o

IUCLID section number	IUCLID section name	REACH Annex	REACH Column 1 number	REACH information requirements which do not have a 1:1 correspondence with a IUCLID section	1 – 10T, physicochemical requirements, Annex VII	1 – 10T, standard requirements, Annex VII	10 – 100T, Annex VIII	100 – 1000T, Annex IX	above 1000T, Annex X	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex VII	PPORD
				from the first one).									

## **Annex 4. Minimum information required for updating a registration under previous Directive 67/548/EEC**

When updating a registration that was previously a notification under Directive 67/548/EEC (NONS) the following three scenarios have to be taken into account:

Tonnage band update;

Update to become the lead or a member of a joint submission;

Other updates.

Please see the detailed description and the requirements set to these update types below.

### **Tonnage band update**

According to Article 24(2) of the REACH Regulation, the registration dossier for the previously notified substance must be updated as soon as the manufactured/imported quantity reaches the next tonnage threshold (10, 100 or 1000 tonnes). Moreover, an update is required for notified substances produced in quantities below 1 tonne when reaching the 1 tonne threshold.

The update should not only contain the information required by REACH which corresponds to that higher tonnage threshold but also any information which corresponds to all the lower tonnage thresholds. In this case the dossier has to be fully in line with REACH requirements in the IUCLID format specified by ECHA. In particular, all of the completeness check requirements referred to in this document must be met, without any possibility to make derogations due to the substance being previously notified under Directive 67/548/EEC.

If your update involves a registration at or above the 10 tonnes threshold, a Chemical Safety Report (CSR) should be included in section 13 of your IUCLID dossier, unless not required due to the reasons given in Article 14(2) REACH in which case a justification should be provided in section 13.

In addition, all the information requirements included in column 1 of REACH Annexes VII-XI, depending on the tonnage, must correspond to at least one complete endpoint study record in IUCLID. Therefore, if you are updating a SNIF file migrated to IUCLID then ECHA will consider the endpoint complete if at least one endpoint study record is complete, i.e., it includes a data waiving, weight of evidence or a key study. Testing proposals are accepted only for the endpoints which refer to an information requirement from Annex IX and X of REACH.

*Annex Overview of the completeness check performed by ECHA on the submitted dossiers* provides more information on the completeness check performed by ECHA on the submitted dossiers.

### **Update to become the lead or a member of a joint submission**

The joint submission obligation applies also to the previously notified substances. Therefore, when another registrant wants to register the same substance, data must be shared where this is requested, and a joint submission needs to be established according to Article 11 or 19 of REACH, which apply to notified substances too.

In such cases, the previous notifier will need to take one of the following courses of action:

- The previous notifier becomes the lead registrant of the joint submission. Based on Article 11(1) of REACH, the lead registrant must submit all the information that is required to be submitted jointly which is specified in Article 10(a). Accordingly, the previous notifier, as lead registrant will need to create the joint submission in REACH-IT, and submit the joint information with the agreement of the other registrant(s), who will then register as member(s) of the joint submission. In this situation, similar to the case of tonnage band update described above, the lead dossier has to be fully in line with REACH requirements in the IUCLID format specified by ECHA. In particular, all of the completeness check requirements outlined in this manual must be met, without any possibility to make derogations due to the substance being previously notified under Directive 67/548/EEC;
- The previous notifier becomes member of the joint submission. When a new registrant creates a joint submission and becomes the lead of it, the previous notifier will eventually need to join this joint submission as a member registrant. At the latest, this will need to happen when the previous notifier needs to update the dossier. As long as the manufactured/imported quantity of the substance does not reach the next tonnage threshold the previous notifier as member registrant can make derogations due to the substance being previously notified under Directive 67/548/EEC and exempt from some data requirements (see next paragraph for minimum information requirements). As soon as the quantity of the substance reaches the next tonnage threshold the dossier has to be fully in line with REACH requirements (see the previous paragraph for tonnage band update). As for any other registrant, the possibility of opting-out from some or all of the information submitted by the lead applies.

### Other updates

Article 22 of the REACH Regulation lists the cases when the registrant has to update the registration dossier. This includes also updates to include the classification and labelling according to Article 40 of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation).

When updating the registration dossier of a NONS (excluding a change of tonnage band and becoming the lead registrant), certain information in your dossier is not required. However, in order to be considered complete and for REACH-IT to be able to process the dossier, your dossier must include as a minimum the following information<sup>17</sup>:

### New and updated information submitted

The new and the updated information submitted as a consequence of the update has to meet all of the completeness check requirements referred to in the present manual, with no special exceptions due to the status as a previously notified substance, e.g. if you are updating your dossier to include the classification and labelling according to the CLP Regulation, IUCLID section 2.1 has to be complete.

Robust study summaries have to be provided for any new study and for the studies requested by a Competent Authority under Directive 67/548/EEC and now regarded as Agency decisions according to Article 135 of the REACH Regulation.

Certain types of updates under Article 22 require that the relevant sections of your IUCLID dossier are updated, e.g., in order to update the consumer uses the IUCLID section 3.5.5 needs to be updated.

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<sup>17</sup> For more information on how to fill in the specific sections, please refer to the different chapters of this manual

## Section 1 - General Information

**Section 1.1 Identification and 1.2 Composition.** These sections have to be complete to meet all of the completeness check requirements referred to in the present manual. However, structural formulas are only optional as they have been already submitted on paper under Directive 67/548/EEC.

**Section 1.3 Identifiers.** At least the notification number under Directive 67/548/EEC (NCD number), as well as your registration number under the REACH Regulation (that you received when claiming your registration number via REACH-IT) have to be included here.

**Section 1.7 Suppliers.** If you are acting as *Only Representative* you are advised to attach here the documentation regarding your appointment as the *Only Representative*.

## Section 2 – Classification & Labelling and PBT assessment

**Section 2.1 GHS. Classification and labelling** according to the CLP Regulation (GHS) is compulsory in section 2.1 of your IUCLID dossier. If you have previously submitted a dossier without section 2.1, you should provide this information in a registration update without undue delay.

**Section 2.3 PBT assessment.** It consists of an endpoint summary and endpoint study records. If the updated notification is above 10 tonnes per year then you need to create an endpoint summary in section 2.3 PBT assessment (by right clicking on the section number) and make sure that a choice has been made in the picklist PBT status. If *PBT assessment does not apply* is selected, a *Justification* should be provided in the free text field.

## Section 3 - Manufacture, use and exposure

In case you indicated in IUCLID section 1.1 that your *Role in the supply chain* is (also) *Manufacturer* then the following subsection has to be complete:

**Section 3.3 Sites.** If you indicated in section 1.1 that your *Role in the supply chain* is *Manufacturer*, then you must provide at least one production site in this section. To this end, you must create a record in section 3.3; link a *Site* to it; and link it using the field *Related manufacture/own use* to at least one manufacture record in section 3.5.1. For manufacturing sites, the country of the site is normally expected to be the same as the country of the submitting Legal entity.

**Section 3.5.1 Manufacture.** If the checkbox *Manufacturer* is selected in section 1.1 Identification, then at least one record must exist with a manufacture use in section 3.5.1.

## Section 13 - Chemical Safety Report

When the update does not involve a change in tonnage band, the notifier does not normally need to submit a CSR. However, a CSR has to be provided if the updated notification is above 10 tonnes per year and covers new identified uses, or new knowledge arises with regard to the risks of the substance to human health and/or the environment which would lead to changes in the safety data sheet, or there is a change in the classification and labelling of the substance.

If you do not need to submit a CSR, you should select *REACH Chemical safety report (CSR)* from the picklist *Type of report* in IUCLID section 13 and write the justification for not providing the

CSR either in the field *Further information on the attached file* or in the field *Discussion*. Please use the relevant justification from the following examples:

- i. "A CSR is not submitted because it is a previously notified substance which did not reach the next tonnage threshold and which does not fall within the scope of Articles 22(1)(d), 22(1)(e) and 22(1)(f) of the REACH Regulation."
- ii. "A CSR is not submitted because the substance fulfils the requirements of Article 14(2) of the REACH Regulation."

### **Dossier header - Derogation statement**

The following derogation statement in your Dossier header has to be written in the *Dossier submission remark* field:

"This dossier is a registration update of a previously notified substance which did not reach the next tonnage threshold under the REACH regulation. It contains new and updated information."

## Annex 5. Assessment entities in IUCLID 6

### Assessment entity definition

If you conclude that several sets of substance properties are needed for carrying out your assessment (see also considerations in the Guidance on Chemical Safety Assessment part D, chapter D.2) you should create assessment entities in IUCLID in order to transparently report those sets of properties.

An assessment entity is a wrapper [container] for a set of substance property data (phys-chem/fate/hazard) used for assessment purposes. It enables the assessor to define datasets of properties that are relevant for specific compositions/forms (placed on the market or generated upon use). These datasets are then used to assess the substance over its life cycle, reflecting its behaviour (e.g. in terms of fugacity, water solubility, absorption, degradation or transformation) in the different foreseen uses and potential changes in the hazard profile.

There are several types of assessment entity defined by their relation to the registered substance dataset. The possible types are:

1. **Registered substance as such:** it may be useful to create an assessment entity for the registered substance as such when the substance as such and certain constituents or transformation products play a role for the assessment. For example if your substance transforms you may need the properties of both your substance before it transforms and of the transformation product to carry out your assessment. Also for multi constituent substances, it may be that some properties depend on the constituents and impurities but that for some others it is possible to consider the substance as such. It is frequent practice to carry out human health assessment for the full substance (if vapour pressure is similar for the different constituents) but to differentiate the environmental assessment according to groups of constituents (having different physico-chemical properties). In case the registration covers several compositions with different hazard profile, then assessment entity for "specific composition/form" should be defined (see below). The assessment entity type "registered substance as such" should not be created if there is no need to clearly group the substance as such property data.
2. **Specific composition/form of the registered substance:** in case the registration covers compositions with different phys-chem/fate/hazard profile then different assessment entities may be created to group the relevant properties according to those compositions.
3. **(group of) constituent in the registered substance:** when the fate properties of various constituents/impurities lead to a potential exposure of man and/or the environment to a composition different than the composition being used, then one or more sets of properties for (group of) constituents may be relevant for the assessment (for example, if an activity takes place at elevated temperature and the substance is composed of various constituents of various volatilities, the exposure may be to the most volatile constituents). This may also apply if the hazard of e.g. an impurity would drive the assessment. The selection and potential grouping of constituents/impurities is to be well documented.
4. **Transformation product of the registered substance:** the registered substance may transform when used or in the environment. Such transformation may be due to:
  - i. dissociation,
  - ii. biotic or abiotic degradation, hydrolysis, photolysis. (ultimate degradation usually considers that transformation products do not need to be taken into account)
  - iii. reaction during the use (because of the technical function of the substance). When the substance reacts in the manufacturing of another substance which will then be registered



on its own (unless exempted), the reaction products do not need to be assessed. When this is not the case, the transformation products are to be assessed as part of the registration of the original substance (including for service life when only transformation products are remaining in the articles).

### Assessment entity data structure

You should define your assessment approach (assessment entities) by:

- An *assessment name*: Note that this name will not be displayed in the navigation panel. You may re-name the *Assessment entity* by clicking on the bar at the top of the record page.
- An *assessment entity composition* (similar to the way compositions are defined in section 1.2 of IUCLID).
- The composition of the AE is meant to support the understanding of what the assessment entity consists of.

**Table 17: Assessment entity and composition information**

Relationship of the AE to the registered substance	Assessment entity composition
Registered substance as such	Same composition as the substance available in section 1.2
Specific composition/form of the registered substance	One or more composition can be selected from the compositions available in section 1.2
(group of) constituent in the registered substance	One or more constituent/additive/impurity which have been reported in any composition(s) - section 1.2 - can be selected
Transformation product of the registered substance	One or more reference substance can be selected

- A link to the composition(s) reported in section 1.2 (reported in the *Related composition* field). Such link is useful in case several compositions exist, used in different uses, to trace back which assessment entity is relevant for which composition.
- Some *additional information*, when it may be needed to provide more explanation on the assessment entity, for example in case the AE is defined for a group of constituents, the assessor may explain how the grouping had been made.

As the assessment entity is a wrapper for sets of substance properties, reported in endpoint study records and endpoint summaries in IUCLID, you have to set up links to those elements (see sections below).

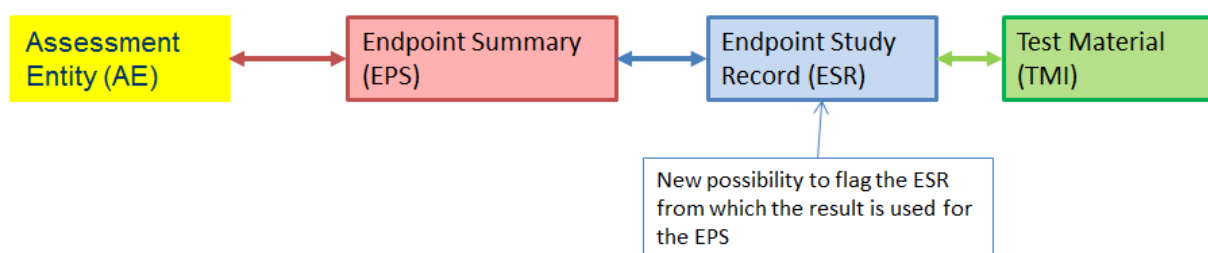
### Relationship between assessment entity, endpoint study records and endpoint summaries

In order to enable transparency and sorting of the information in the IUCLID data set, and to reflect this in the CSR generated by the Report generator, it is essential to indicate for each assessment entity, which endpoint studies records (ESR) and related conclusions (endpoint summary) are available.

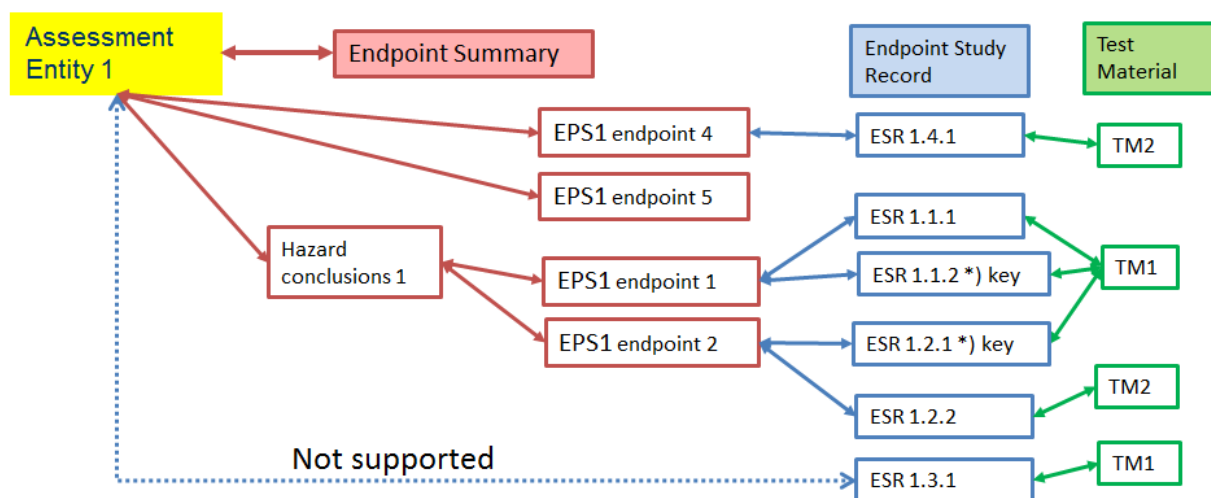
The following links are enabled in IUCLID6:

- Each endpoint study record makes reference to one test material information (TMI);
- All study records considered when assessing a specific endpoint can be linked to the related endpoint summary(EPS);
- Endpoint summaries can be linked to one or more assessment entity. A field exists to explain the link between the endpoint summary(ies) and the AE. In this way it is possible to trace back which study records are relevant for which AE.

**Figure 49: Relations between assessment entity, endpoint summary and endpoint study records**



**Figure 50: More detailed illustration**



It is possible that the dossier contains study records which are not linked to an endpoint summary. This is the case for i) studies reported under the obligation to provide any relevant available information on the substance properties, but not (directly) used in the assessment (e.g. old study where composition is now different), and ii) ESR used to report waiving of information.

### Link between endpoint summaries and assessment entities

You can link endpoint summaries from an AE reported in section 1.10 of IUCLID. You can select several endpoint summaries in one go and link them to the assessment entity. In this case, an explanation valid for all summaries can be added in the note field.

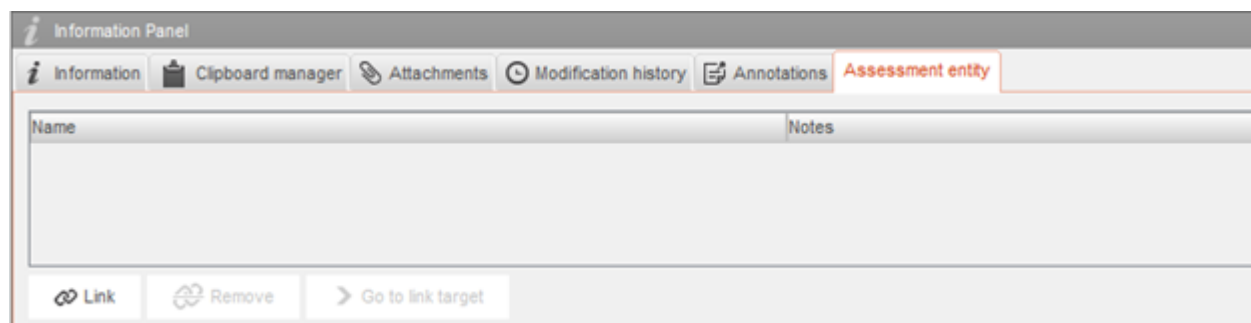
An assessment entity should be linked to only one summary per specific endpoint (for example, one assessment entity should be linked to one boiling point summary only).

The list of summaries linked to the AE is then displayed in the AE itself.

You can also link summaries to AEs from the summary itself\*. A summary can be linked to several assessment entities. This may be the case when for example AEs are defined for different compositions for which differences exist for some endpoints but not for other endpoints. To do so you need to select the *Assessment entity* panel displayed under each endpoint summary of the substance dataset when at least one assessment entity had been defined. Click on *Link* below the table and the list of all the AEs to which the EPS has not yet been linked to is available for selection. A *note* can be entered if additional information needs to be reported to better explain the rationale.

The list of AEs (and the corresponding *notes*) to which the EPS is linked is then displayed in the table.

**Figure 51: Link between endpoint summaries and assessment entities in the classic IUCLID interface**



*\*Please note that this functionality has not been added to the web interface. To link summaries to AEs from the summary itself, please use the classic IUCLID interface.*

### Link between endpoint study records and endpoint summaries

In each endpoint summary it is possible to link all relevant studies (endpoint study records) that contribute to the summary itself. This is particularly needed when assessment entities exist and that several endpoint summaries are created, to ensure transparency on the information basis for the summary.

## Annex 6. Overview of tonnage fields in IUCLID

This Annex provides an overview of the different fields in IUCLID dealing with tonnage information. It describes the field including which kind of tonnage is expected to be reported (individual registrant's tonnage vs EU tonnage) and what is the intended use of the information.

For more information on the fields, consult the help system of IUCLID.

Section	Field(s)	Individual registrant's or total EU tonnage	Explanation	Use of the reported values
<b>3.2 – Estimated quantities</b>	Total tonnage: - manufacture - imported	Individual registrant's	Registrant's tonnage manufactured or imported per year.  Different entries should be created for each year.	By registrants: for calculation of three-year average tonnage which defines the information requirements for registration.  By authorities: - for dissemination after aggregating it to the tonnage of other registrants of the same substance and rounded into tonnage bands; - for screening and priority setting after aggregating it to the tonnage of other registrants.
<b>3.2 – Estimated quantities</b>	Details on tonnages (tonnes/year): - Tonnage directly exported - Tonnage for own use - Tonnage used as intermediate under strictly controlled conditions (transported) - Tonnage used as intermediate under strictly controlled	Individual registrant's	Split the Registrant's tonnage manufactured or imported each year reported above into: how much is (directly) exported, how much is for own use and how much is used as intermediate under SCC (transported or on-site) if relevant.  Additional fields are included in section 3.5 to further describe each individual use (including own uses and uses as intermediate under SCC).  The field 'tonnage per use' in section 3.5 can be	By authorities: for screening and prioritisation.

	conditions (on site)		used to further split the tonnage from 3.2 into different uses if the registrant reports individual tonnages there (see below). Different entries should be created for each year.	
<b>3.2 – Estimated quantities</b>	<p>Details on tonnages (tonnes/year):</p> <ul style="list-style-type: none"> <li>- Tonnage imported in articles</li> <li>- Tonnage in produced articles</li> </ul>	Individual registrant's	<p>In case of registration or notification of substances in articles under article 7; the registrant or notifier should report here the split into how much is brought into the EEA via imported articles and how much is incorporated into produced articles. Different entries should be created for each year.</p>	<p>By registrants: for calculation of three-year average tonnage which defines the information requirements for registration.</p> <p>By authorities:</p> <ul style="list-style-type: none"> <li>- internal statistics and reporting - monitoring the presence of substances of potential concern in articles</li> <li>- screening e.g. for potential new restrictions.</li> </ul>
<b>3.5.0 Use and exposure information relevant for all uses</b>	Cumulative tonnages (tonnes/year)	Individual registrant's or EU (if EU tonnage is reported, the corresponding checkbox should be selected)	<p>The registrant can provide a realistic value of the total tonnage of the substance (per year) that is manufacture or used in each Life cycle stage. When available, reporting the tonnage per use in the sections 3.5.2 to 3.5.6 is preferred (see fields described in rows below).</p> <p>Depending on the information available to him the registrant can report either information from its own supply chain, or information representative of the EU market.</p> <p>If EU tonnage is reported, the corresponding checkbox should be selected.</p> <p>In all cases, details on the tonnage reported (e.g. source of the information) should be provided in the dedicated adjacent field.</p>	<p>By registrants: as basis for environmental assessment.</p> <p>By authorities: for screening or prioritisation e.g. importance of widespread uses.</p>
<b>3.5.1 Manufacture</b>	Tonnage of substance manufactured (tonnes/year)	Individual registrant's or EU (if EU tonnage is reported, the corresponding	<p>The registrant should provide a realistic market value of the total tonnage of the substance that is manufactured every year.</p> <p>Depending on the information available to him the</p>	By registrants: as basis for environmental assessment.

		checkbox should be selected)	<p>registrant can report either information from its own supply chain, or information representative of the EU market.</p> <p>If EU tonnage is reported, the corresponding checkbox should be selected.</p> <p>If individual registrant's tonnage is reported, it should be consistent with the values reported for different years under section 3.2.</p> <p>In all cases, details on the tonnage reported (e.g. source of the information) should be provided in the dedicated adjacent field.</p>	
<p><b>3.5.2 Formulation or re-packing</b></p> <p><b>3.5.3 Uses at industrial site</b></p> <p><b>3.5.4 Widespread uses by professional workers</b></p> <p><b>3.5.5 Consumer uses</b></p> <p><b>3.5.6 Service life</b></p>	Tonnage of substance for this use (tonnes/year)	Individual registrant's or EU (if EU tonnage is reported, the corresponding checkbox should be selected)	<p>The registrant should provide a realistic market value of the total tonnage of the substance that is used every year in each of the reported uses.</p> <p>Depending on the information available to him the registrant can report either information from its own supply chain, or information representative of the EU market.</p> <p>If EU tonnage is reported, the corresponding checkbox should be selected.</p> <p>For uses as intermediate under SCC, if individual registrant's tonnages are reported, it should be consistent with the values reported for different years under section 3.2.</p> <p>In all cases, details on the tonnage reported (e.g. source of the information) should be provided in the dedicated adjacent field.</p>	<p>By registrants: as basis for the CSA if one is done e.g. calculation of 'Daily use amount at a site' or 'Daily use amount' in environmental assessments.</p> <p>By authorities:</p> <ul style="list-style-type: none"> <li>- Internal statistics and reporting;</li> <li>- for screening or prioritisation e.g. tonnage going to uses having specific regulatory status.</li> </ul>

## Annex 7. Opt-out justifications

When opting-out of a joint submission following Article 11(3) or 19(2) of the REACH Regulation you must justify the reason for the opt-out. To facilitate the drafting of the justification four templates are provided in IUCLID section 14 that are also provided below. The four templates cover (a) disagreement on the cost of accessing the joint submission, (b) disclosure of commercially sensitive information, (c) disagreement on the selection of the Annex VII-X information and (d) disagreement on the jointly submitted classification and labelling information. All points of at least one template must be fully answered using the free text *Justification* field of section 14 *Information requirements* under *Opt-out information for REACH registration*. The information should not be provided as an attachment.

The four templates are:

### **Type a: Disproportionately costly to submit this information jointly**

[Article 11(3) and article 19(2) of REACH requires that you submit an explanation as to why the costs would be disproportionate. In order to consider your submission complete, you must answer all the 4 points below.]

1. Provide the cost of access to the jointly submitted data:
  - [amount, currency]
2. Provide the costs of your opt-out:
  - [amount, currency; please remember to take into account also possible internal costs related to the creation of your own dossier]
3. Explain why the cost of submitting the relevant information jointly is disproportionate.
4. Describe the measures taken to agree on the cost of submitting the relevant information jointly.

### **Type b: Disclosure of commercially sensitive information is likely to cause you substantial commercial detriment to submit jointly**

[Article 11(3) and article 19(2) of REACH requires that you submit, along with the dossier, an explanation to why disclosure of information was likely to lead to substantial commercial detriment. In order to consider your submission complete, you must answer you must answer both of the 2 points below.]

1. Specify the information that you consider to be commercially sensitive, which would be disclosed if submitted jointly. Consider that after registration, information from your registration dossier will be made publicly available on ECHA's website in accordance with Article 119 of REACH.  
[Examples of commercially sensitive information:
  - Degree of purity and/or the identity of dangerous impurities or additives
  - Tonnage band
  - Robust study summary and study summaries
  - Uses
  - Trade name
  - Patent-related issues

- Indication of manufacturing process]
  - [free text]
2. Explain the substantial commercial detriment it is likely to cause you:
- [free text]

### **Type c: Disagreement on the selection of the Annex VII-X information**

[Article 11(3) or article 19(2) of REACH requires that you submit, along with the dossier, an explanation on the nature of the disagreement. In order to consider your submission complete, you must answer both of the 2 points below.]

1. Describe the nature of the disagreement with the lead registrant on the selection of the Annex VII-X information. For example;
- Quality (reliability, adequacy) of data
  - Type of data (e.g. bibliographic data or (Q)SARs)
  - Relevance of the data selected by the Lead
  - Substance with specific compositions / impurity profiles
  - Different data is available to fulfil same endpoint
  - Disagreement on testing strategy (use of animal testing, alternative testing methods or selection of representative test substance)
  - [free text]
2. Describe the actions you have taken to include your additional data in the Lead dossier and Justify why it was not possible to include your additional data into the lead dossier:
- [free text]

### **Type d: Disagreement on the jointly submitted classification and labelling information**

[Article 11(3) or article 19(2) of REACH requires that you submit, along with the dossier, an explanation on the nature of the disagreement. In order to consider your submission complete, you must answer all the 3 points below.]

1. Describe the nature of the disagreement with the lead registrant on the jointly submitted classification and labelling information. For example, use the following as a basis for your argumentation:
- Quality (reliability, adequacy) of data used in deriving the classification
  - Difference in interpretation of data for classification
  - Difference in concentrations of constituents / impurities / additives influencing classification
  - Difference in (nano)forms of the substance influencing classification
  - [free text]



2. Outline the differences in the classification and labelling information that you wish to submit separately compared to the jointly submitted information. For each different classification, provide a reference to the data underlying the classification. This reference may be to information submitted in your own dossier as a (robust) study summary, or alternatively, references to publicly available literature may be provided.
3. Describe the actions you have taken to include your classification and labelling in the Lead dossier and explain why it was not possible:
  - [free text]

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