



IUCLID Guidance for completion of REACH registration dossier

Version November 9, 2017



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INTRODUCTION

As part of the registration process under the Registration, Evaluation, & Authorisation and Restriction of Chemical Substances (REACH) initiative, registration dossiers must be prepared and submitted to the European Chemicals Agency (ECHA) for all chemicals manufactured in or imported to the European Union (EU) at or above 1 tonne per year.

In order to complete the registration dossiers, information for each chemical must be reviewed, integrated, and recorded in the **International Uniform Chemical Information Database (IUCLID)**. Then each IUCLID file must be submitted to the ECHA portal, REACH-IT. For a general scheme on the process of REACH submission, please refer to Annex 1 of this document.

Although the Secretariat with the support of its consultants has prepared the IUCLID file with all of the data to be shared as part of the joint submission registration dossier, each member of the joint submission will have to complete all required legal entity-specific information individually, prior to submitting their own registration dossier to ECHA.

IUCLID Sections 2, 4-7 and 12-14 will be identical for all members of the joint submission and have been completed for you by the Secretariat and the consultants. These will only be submitted as part of the dossier of the Lead Registrant (LR) (including section 13 (CSR) which will be submitted by the LR on behalf of all members). All members of the joint submission must complete IUCLID Sections 1, 3 and 11 (which will be (partly) pre-completed by the Secretariat in certain cases). IUCLID Sections 2 and 4-7 must be left empty in Co-Registrant dossiers (except in case of an opt-out¹). IUCLID Section 11 is submitted separately for all PMC dossiers and should thus be checked by all PMC members.

Table 1: Overview of IUCLID Sections completed by the PMC Secretariat and/or to be completed by (Lead) Registrants (LR=Lead Registrant).

| | (Partly) completed by PMC Secretariat if relevant | To be completed by each Legal Entity | Not applicable |
|--|---|--------------------------------------|----------------|
| IUCLID Section 1: General Information | (X) | X | |
| IUCLID Section 2: Classification & Labeling and PBT assessment | X | | |
| IUCLID Section 3: Manufacture, Use and Exposure | (X) | X | |
| IUCLID Section 4: Physical and Chemical Properties | X | | |
| IUCLID Section 5: Environmental Fate and Pathways | X | | |
| IUCLID Section 6: Ecotoxicological Information | X | | |
| IUCLID Section 7: Toxicological Information | X | | |
| IUCLID Section 8: Analytical Methods | | | X |
| IUCLID Section 9: Residues in Food and Feedingstuffs | | | X |
| IUCLID Section 10: Effectiveness Against Target Organisms | | | X |
| IUCLID Section 11: Guidance on Safe Use | X | X* | |
| IUCLID Section 12: Literature Search | X | | |
| IUCLID Section 13: Assessment Reports | X | | |
| IUCLID Section 14: Information requirements | X | | |

* Guidance on Safe Use will be pre-filled by the Secretariat but it is the responsibility of each registrant to review this Section and adapt as needed to their company-specific situation.

¹ If a member does not agree on the jointly submitted data, or if the joint submission tonnage band does not cover the member's tonnage, then the member can provide data in sections 4-8 on his own. It is considered opt-out and IUCLID section 14 needs to be filled with the opt-out data. Consequences of an opt-out: dossier will be prioritised for evaluation and there is no joint submission discount for the fee.



This guide includes specific instructions for completing/updating IUCLID Sections 1, 3, 11 and 13 (for the Lead Registrant); it does not provide the text that will go into IUCLID (to be prepared by each registrant and/or provided by the PMC Secretariat in the pre-completed company-specific IUCLID file). In addition, guidance will also be provided on using the Validation Assistant (previously the Technical Completeness Check) and generate your registration dossier from your completed IUCLID file.

Important note for Co-Registrants: Dossier creation in REACH-IT

If you are a co-registrant, there is an alternative to IUCLID: the dossier creation directly in REACH-IT. This functionality can only be used if you are a member of a joint submission and if you have not yet successfully submitted a IUCLID dossier for your substance. In addition, if you wish to report more than one composition in your member registration dossier (e.g. if you have a manufacturing process that leads to substances with different impurities) or if you wish to opt out for some studies provided by the LR and provide your own studies, then creating your dossier with IUCLID is the only available option. It is important to choose the right tool for your particular case.

If you decide to create your dossier directly in REACH-IT, please refer to the ECHA webinar 'REACH 2018: Prepare your registration as a IUCLID dossier':

- <https://www.youtube.com/watch?v=VpwuyStfrXo&feature=youtu.be> : the dossier creation in REACH-IT is explained as from 48:00.

- <https://echa.europa.eu/documents/10162/22840336/Dossier+creation+in+REACH-IT.pdf/e0fd4ecc-f492-42c9-b0c3-135a358e5f05>

Special considerations for intermediate registrants

This guide contains some special considerations for intermediate registrants. Intermediates are a class of substances for which specific provisions have been laid down under REACH for reasons of workability and because of their special nature (recital 41). Non-isolated intermediates are exempt from REACH regulation. On-site and transported isolated intermediates benefit from reduced registration requirements² under REACH, provided their manufacture and use take place under the conditions set in Article 17 and 18 (strictly controlled conditions or SCC). These intermediates are referred to as 'SCC intermediates' in this Guidance.

Intermediate registrants can choose between two registration routes:

- 1) For SCC intermediates, a reduced registration can be done. In this case, information on risk management measures has to be provided in IUCLID Section 11 and 13 (See also Chapter 4 and 5 of this Guidance).
- 2) For isolated intermediates for which SCC cannot be demonstrated (referred to as 'non-SCC intermediates'), a full registration (REACH Article 10) will be required.

Each registrant can/must decide for its individual registration (not for the joint registration which is the consortium's responsibility).

Registrants who can only demonstrate SCC for certain uses, and who wish to report both uses requiring a full registration (Article 10) and uses of intermediates under SCC are advised to submit a combination dossier. In this case, they should clearly report the SCC intermediate tonnage in IUCLID Section 3.2 (see Chapter 3.2), which can be excluded from the exposure assessment.

² Reduced registration requirements for SCC intermediates include identity of the manufacturer/importer, identity of the intermediate, classification of the intermediate, any available existing information on physicochemical, human health or environmental properties of the intermediate, a brief general description of the use, and information on risk management measures applied and recommended to the user. For transported isolated intermediate manufactured/imported in quantities of more than 1000 tonnes per year also data on the intermediate's intrinsic properties as specified in Annex VII must be included.



As stated in Article 2(8) of the REACH Regulation, isolated intermediates are exempted from Authorisation. Since the tonnage of substance used as non-SCC intermediate cannot be reported separately from the tonnage used as regular substance in Section 3.2, it is recommended to report it in Section 3.5 under the specific use (see Chapter 3.5).

For more information on intermediates, please refer to PMC's factsheet on REACH & intermediates (to be obtained through the PMC Secretariat), as well as to the ECHA Guidance on Intermediates (http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf). For more information on SCC, please refer to PMC's factsheet on SCC (to be obtained through the PMC Secretariat).

Note: This guide has been updated for the IUCLID 6 version that was released in June 2016. You will need to install IUCLID 6 to submit your dossier for REACH registration.

More information can be found on this tool at the following ECHA webpage: <https://iuclid6.echa.europa.eu/home>



HOW TO USE THIS IUCLID GUIDE

This IUCLID Guide contains instructions on how to complete/update your IUCLID file for REACH registration; it does not provide the text that will go into IUCLID (to be prepared by each registrant and/or provided by the PMC Secretariat in the pre-completed company-specific IUCLID file). IUCLID screenshots, notes, and suggestions for completing each required data field are provided for clarity. Guidance is provided regarding technical issues as well as content-related issues.

To maximize the usefulness of the IUCLID Guide, please carefully read all instructions, notes, and suggestions.

This guide includes specific instructions for completing IUCLID Sections 1, 3, 11 and 13 (only for Lead Registrant). The remaining IUCLID sections will be identical for all members of the joint submission, will be completed for you by the Secretariat, and will be submitted on behalf of all Co-Registrants by the Lead Registrant.

Note: Throughout IUCLID there are pieces of information that are eligible to be kept confidential upon request. If you wish to keep them confidential, you must submit a confidentiality request to ECHA for each of them. Such requests are submitted by setting the confidentiality flags (🚫) on the piece of information that you wish to claim confidential. It is important to remember that **each time you flag a section as confidential, you need to justify why the information you provided in the IUCLID database is confidential** and why the publication of such information would be harmful to your business. 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. Also be aware that **if you flag sections as confidential, this could trigger additional fees invoiced by ECHA**. You can find more information on a confidentiality requests and dissemination at <https://echa.europa.eu/manuals>.

How You Should Prepare

To complete the IUCLID database for REACH registration (legal entity-specific portion of the joint submission), you should prepare as follows:

- Install the IUCLID software version 6 from the following webpage: <https://iuclid6.echa.europa.eu/home>;
- Download the IUCLID User Manual for reference from the following webpage: <https://iuclid6.echa.europa.eu/documentation>;
- Have the details to access REACH-IT (such as name of the legal entity, pre-registration number, username and password to access REACH-IT account) that were created for pre-registration at hand (the pre-registration leaflet provided by PMC in November 2008 can be of use here);
- Have at hand all the data to complete sections 1 and 3 of IUCLID:
 - For Section 1.1 of IUCLID you should have a list of your substance Trade name(s) at hand;
 - For Section 1.1 of IUCLID you should decide on a contact person to provide in your IUCLID file and have all its contact details at hand;
 - For Section 1.2 of IUCLID, have your substance-specific composition(s) information readily available as listed below or as described in more detail in each one of PMC's substance ID Cards:















- Degree of purity;
 - Typical concentration and concentration range of main constituent(s);
 - Typical concentration and concentration range of impurities;
 - Function and typical concentration and concentration range of additive(s).
- For section 1.4 of IUCLID, have your substance-specific analytical information readily available (for all substance compositions) as listed below or as described in more detail in each one of PMC's substance ID Cards:
 - Description of analytical methods or spectral data used for substance identity; including method to determine granulometry. Optical activity is optional;
 - Description of analysis results (include granulometry data);
 - For powders, the below recommended characterisation should be performed by each legal entity:
 - Determine particle size: DLS/laser diffraction + number based distribution (can theoretically be calculated from the volume based distribution);
 - Determine surface area: BET for dry powders. For suspensions, estimate surface area on the basis of particle size distribution (if shape of particles is more or less spherical);
 - Report detailed morphology: Digital light microscopic images AND either TEM or REM to qualitatively describe the shape and the agglomeration behaviour of the particles.
 - For Section 3 of IUCLID, have at hand your legal entity-specific information;
 - For Only Representatives, you need to provide:
 - Name of the non-EU manufacturer you represent;
 - Contract or letter appointing you as Only Representative;
 - List of the importers in the same supply chain who are covered by the Registration;
- Have the IUCLID .i6z file for the joint submission of your precious metal or rhenium substance as provided by the Secretariat readily available.






ICONS

In the interface, icons, menu items, and buttons that contain links to functions can be shown in three different states. Dark grey means that the link is active. A very pale grey means that the link is not active either because the function is not relevant, or is blocked for security reasons. The colour orange indicates that the mouse pointer is currently hovering over at item so that a primary/left click follows the link. In some cases, right-click gives access to a menu.

IUCLID contains several icons that you should familiarize yourself with.

-  (house): Home icon
-  (beaker): Substance icon
-  (import): Import icon
-  (factory): legal entity icon
-  (arrowhead pointing right): Expand All icon; expands components of Substance Section tree
-  (arrowhead pointing down): Collapse All icon; condenses components of Substance Section tree
-  (black arrowhead pointing down): Drop-down or Pick-list icon; lists pre-selected options
-  (filter): Find or Filter icon; this is a search tool
-  (book with red asterix): Required IUCLID data point
-  (book): Optional IUCLID section(s)
-  (plus sign): Add icon; provides the option to add additional information or details
-  (arrow pointing right): Go To icon; opens windows with additional data fields
-  (arrow pointing down): Unfold icon; opens data fields within Substance subsections
-  (arrow pointing up): Fold icon; condenses data fields within Substance subsections
-  (link): Add Reference icon
-  (three points): Edit icon; allows changes to be made within the various data fields and tables
-  (disk): Save icon; saving regularly is recommended; IUCLID will automatically prompt for saving before leaving an entry
-  (X): Delete icon
-  (paper clip): Attachment icon
-  (bullet): Study Record icon; identifies individual study records for effects data



-  (flag): Confidentiality Flag icon; specifies level of confidentiality requested for displayed data (see note on Page 7 above)
-  (three check marks): Validation Assistant icon; opens the plug-in tool that checks an IUCLID file includes the required information for the submission template selected
-  (question mark): Help icon; use to search thousands of pages of IUCLID guidance for help with clarifying content needed in specific IUCLID sections



CHAPTER 1: STARTING WITH IUCLID

The information in this chapter is a quick tutorial on importing IUCLID .i6z files, manoeuvring through IUCLID to begin working with your files, and creating IUCLID files.

To begin, create an account on the IUCLID homepage to be able to download latest releases, documentation and support information. A login can be obtained via <https://iuclid6.echa.europa.eu/> by selecting “Sign In” at the top right of the screen and then “Create Account” at the bottom left of the screen.


After that, you should prepare as follows (unless already done as per recommendations provided above):

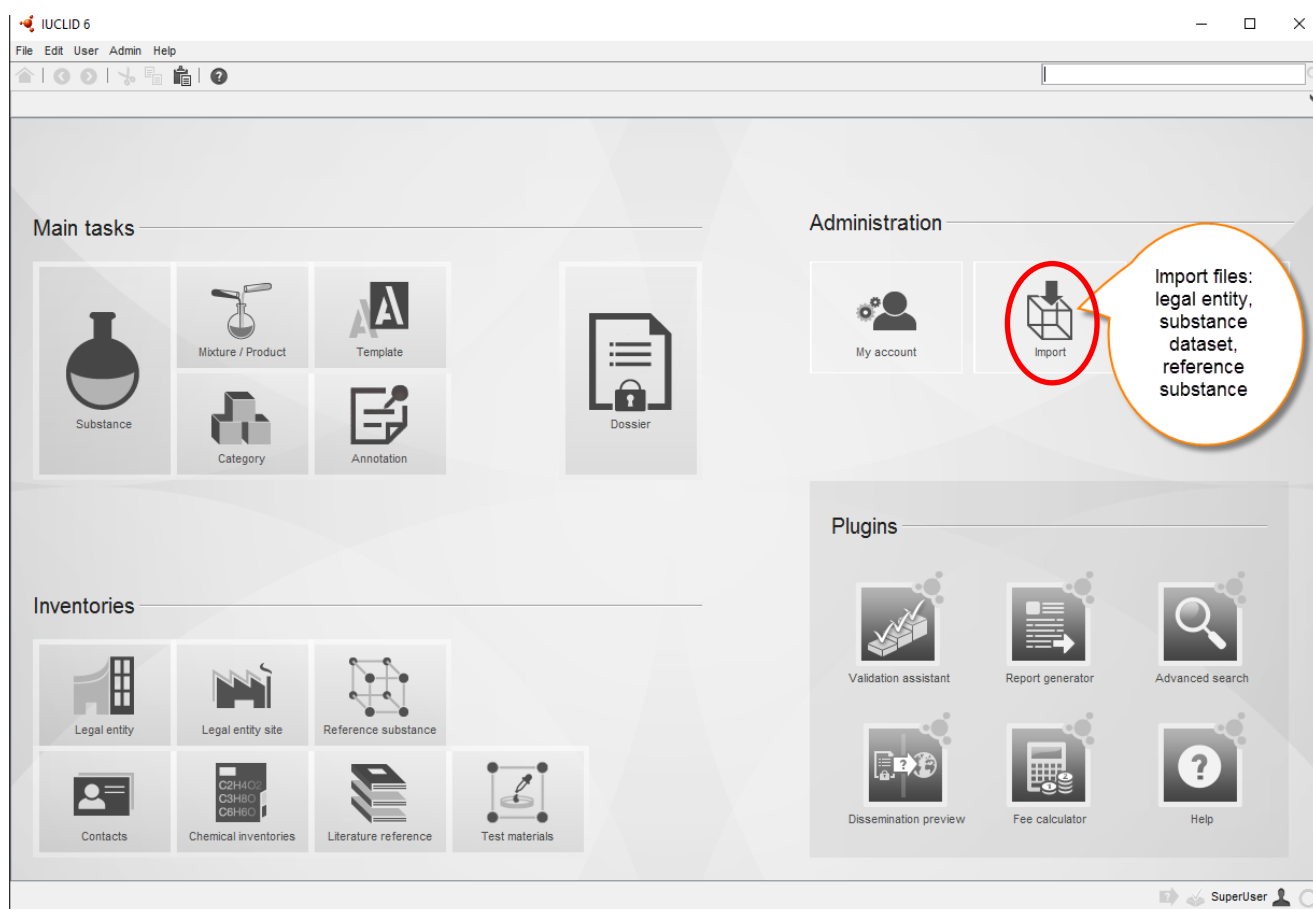
- Download IUCLID 6 from the following webpage: <https://iuclid6.echa.europa.eu/download>;
- Download and import the EC Inventory from the following webpage: <https://iuclid6.echa.europa.eu/get-iuclid-data>;
- Download the IUCLID Guidance and Support: End User Manual for reference from the following webpage: <https://iuclid6.echa.europa.eu/documentation>;
- Have the IUCLID .i6z file for the joint submission of your precious metal or rhenium substance (provided by the Secretariat) readily available. **Note:** IUCLID .i6z files finalized in IUCLID 6 can only be opened in IUCLID version 6; they will not open in older IUCLID versions, so you will need to make sure that you installed IUCLID 6 prior to this point and back-up any previous files.

How to Get Started with IUCLID and Import Files

You may have IUCLID already installed on your workstation from when you (pre-)registered. However, you will need to install IUCLID 6 as described above (and migrate your data from IUCLID 5.6).

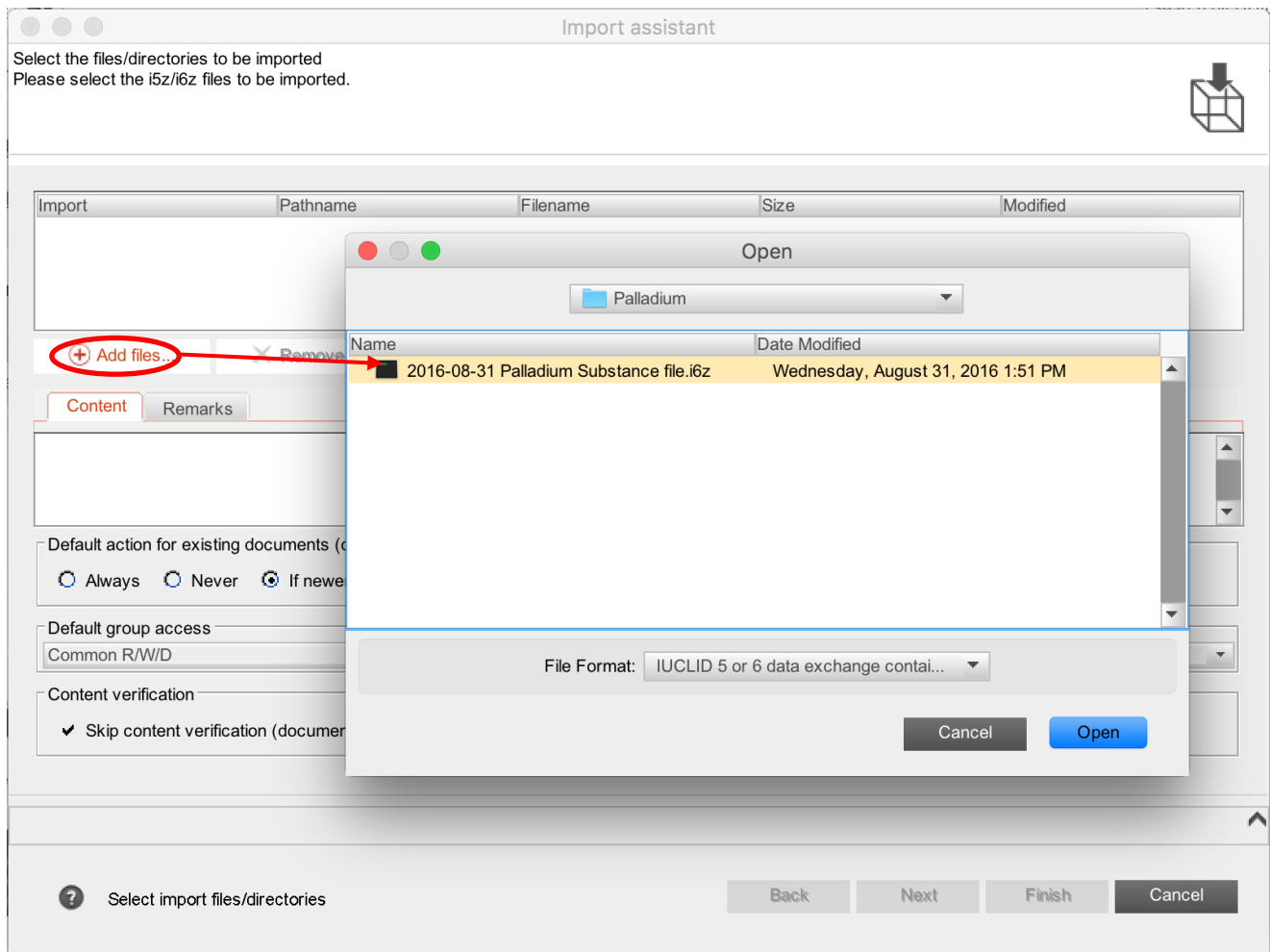
Avoid doing more than one manoeuvre on your computer at the same time and make sure each step is properly followed. While working in IUCLID, preferably close any other program that may limit the resources of your computer.

When you open IUCLID, you should see the Home page (as shown below). To begin working with the IUCLID file provided by the Secretariat, click on “Import” () on the Home page screen.

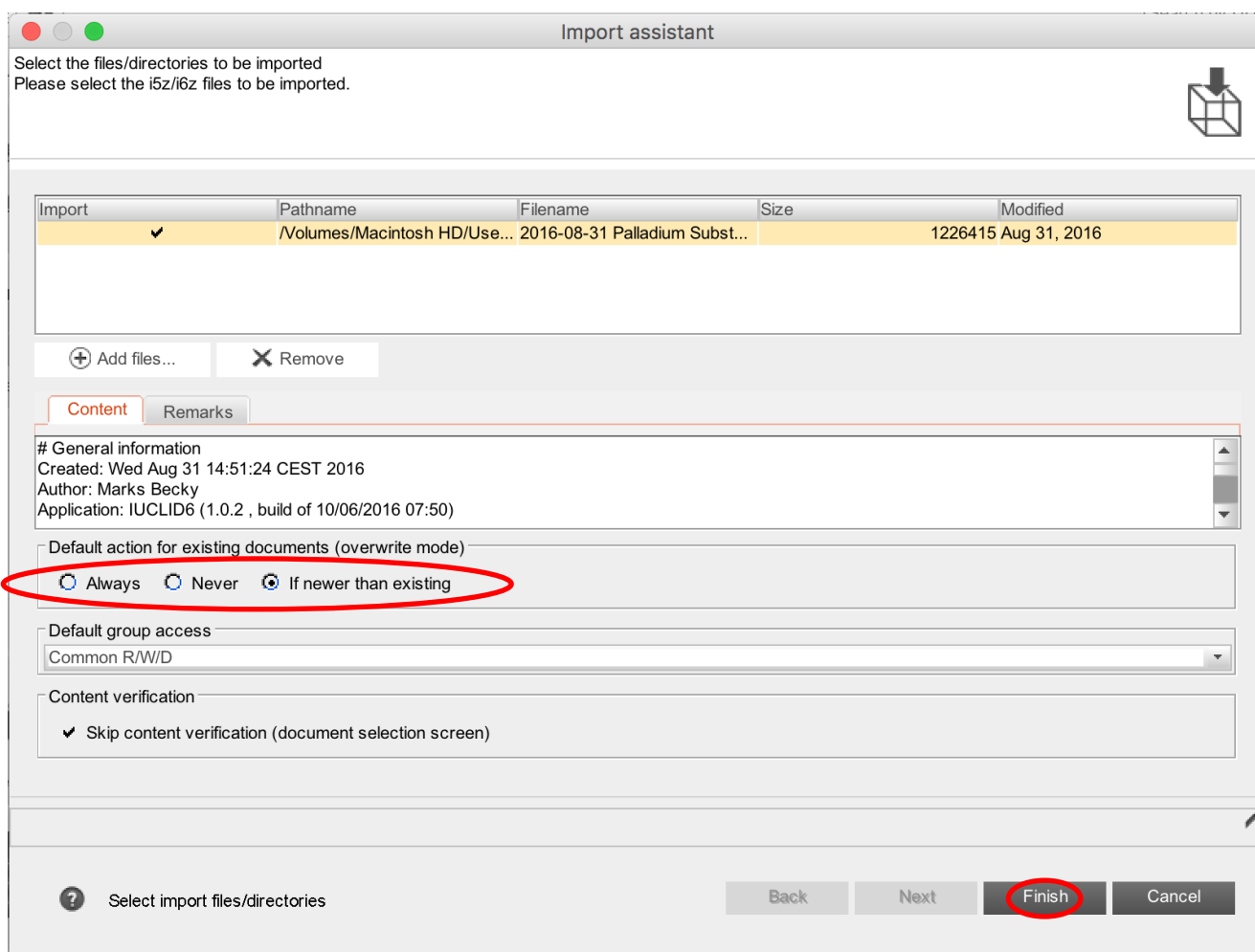


Make sure you have the latest version of the IUCLID .i6z file provided by the Secretariat. It is always best to delete previous versions (substance **and** template file) before importing the updated version to avoid confusion between various drafts of a specific .i6z file. The newest version does not always overwrite the previous version and you may proceed with the older version unknowingly.



In the next window (see screen shot example below), click on the plus sign (+) to open one or more IUCLID .i6z files. Select the IUCLID .i6z file(s) made available to you by the Secretariat and click "Open".



You may keep the default action for “Overwrite mode” (“if newer than existing”) or you may select differently. Keep the default action for “Content verification”. Finally, click “Finish”.



Then the files will begin to copy in IUCLID. This step may take several minutes and up to 40 minutes for very large files. Initially, the program will not appear to start the copying process, but it may take several minutes before you begin to see progress. To verify that the copy process has started, you should see a flashing red hollow circle in the lower right corner of the screen. You can click on the flashing red hollow circle to check the status of the import.

You are now ready to begin working with the PMC files. Click “Substance” () to see your imported IUCLID .i6z file, and double-click on the newly imported file to open it. You may use the filter option () if you have a lot of files.



Main tasks

- Substance
- Mixture / Product
- Template
- Category
- Annotation
- Dossier

Administration

- My account
- Import

Invenories

- Legal entity
- Legal entity site
- Reference substance
- Contacts
- Chemical inventories
- Literature reference
- Test materials

Plugins

- Validation assistant
- Report generator
- Advanced search
- Dissemination preview
- Fee calculator
- Help

SuperUser

Navigation panel: Search, TOC, Annotations

Result type: Substance
Query type: Get all substances
Ownership: [dropdown]
Group: [dropdown]

Search: [button] Search: [button]

| Chemical name | Legal entity name | Reference subst... | Last modification... |
|--------------------------|-------------------|--|----------------------|
| Palladium dinitrate | WCA Environmen... | palladium dinitrate / palladium(2+) dinitrate / 10102-05-3 / 233-265-8 | 2016-07-05T11:1... |
| Palladium | WCA Environmen... | palladium / palladium(2+) / 7440-05-3 / 231-115-6 | 2016-08-09T09:5... |
| Tetraamineper dichloride | WCA Environmen... | Tetraamineper dichloride / 13E 237-489-7 | 2016-06-06T14:4... |

Substance name*: Palladium
Public name: [dropdown]
Legal entity flags: [dropdown]
Legal entity*: WCA Environment ltd / Faringdon / United Kingdom
Third party flags: [dropdown]
Third party: [dropdown]
Role in the supply chain ^
Role flags: [dropdown]

Information panel: Information, Clipboard manager, Attachments, Modification history, Annotations

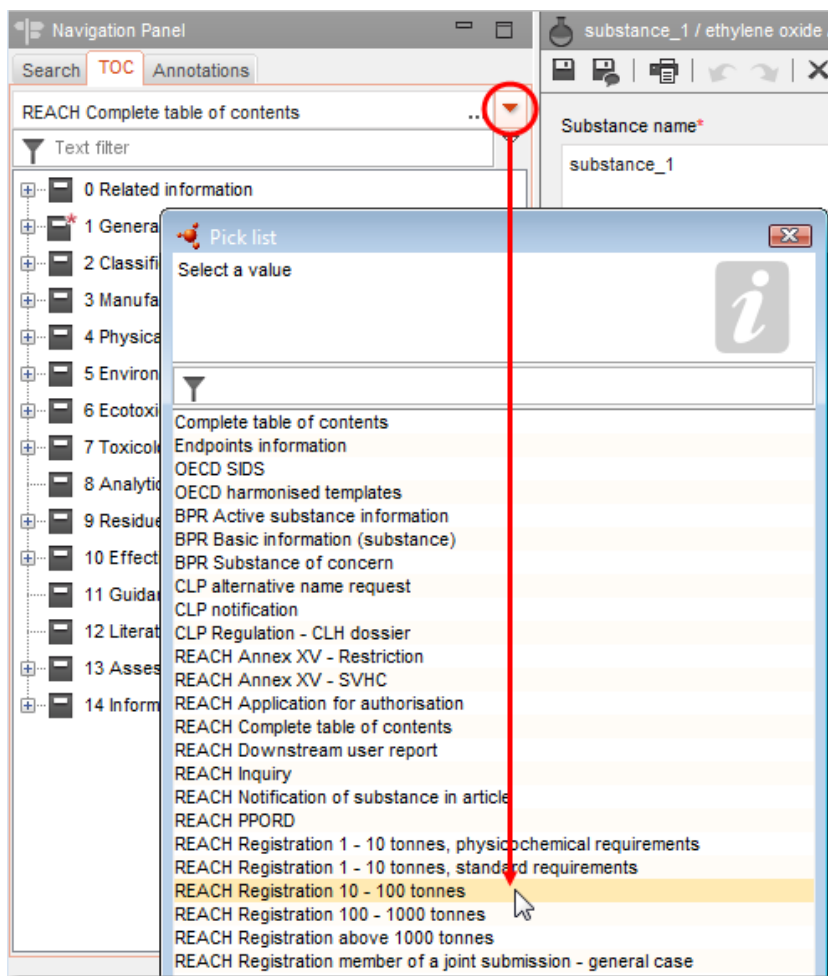






How to manoeuvre through IUCLID

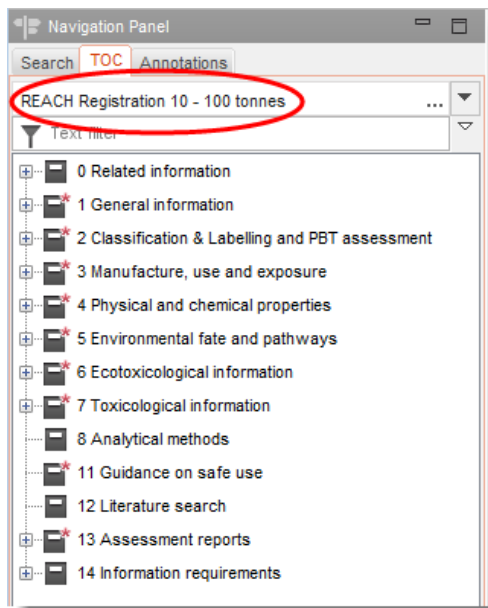
To display the table of content of the dataset, click on the “TOC” (Table of Content) tab in the navigation panel. By default, the view is “REACH Complete table of contents”. To see which sections and subsections within the IUCLID file are required versus those that are optional, you need to change the type of view.

The screenshot shows the IUCLID 6 interface. The 'Navigation panel' on the left has the 'TOC' tab selected, showing a list of 14 sections. The main window displays the 'REACH Complete table of contents' view. The right-hand side shows the 'Substance name' field with 'Member_900-468-4', 'Public name' field, 'Legal entity flags' field, 'Legal entity' field with 'Example Company 1 / Example city / Finland', 'Third party flags' field, 'Third party' field, 'Role in the supply chain' section with 'Role flags' field and 'Manufacturer' checkbox.


To change the type of view in the TOC, click on the solid black arrowhead icon at the right of the name of the view, and then select the appropriate registration dossier type you intend to submit (according to the tonnage you intend to register for), as shown in the example below. If you are not the Lead Registrant, make sure you select one of the options stating “member of a joint submission” (“REACH registration member of a joint submission – general case” or “REACH registration member of a joint submission – intermediates”, as the case may be). Then click “OK”.

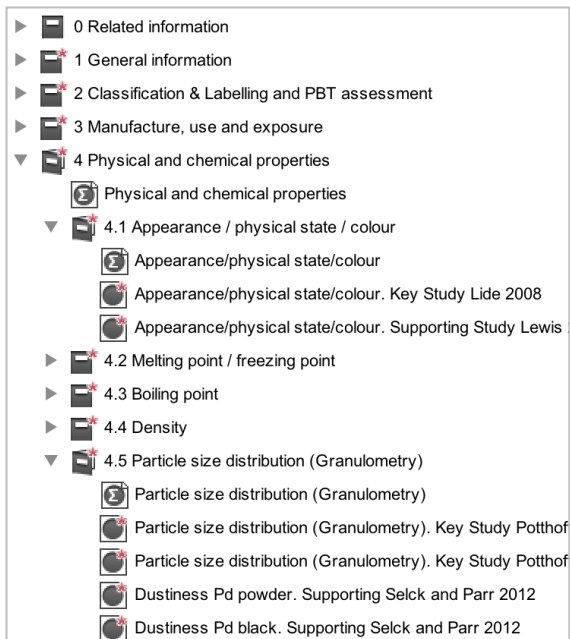


Once the appropriate dossier is selected, you will see book icons with () and without () a red asterix. The  indicate mandatory sections for the selected dossier type. The  indicate optional sections for the selected dossier type. However, these are indicative only.



If you are Lead Registrant, to see the data inserted in the IUCLID file that was provided by the Secretariat, click on the various sections and subsections within your IUCLID file. Sections 4-13 (and subsections if applicable) that contain data are usually denoted by a ► on the left of the section name and when the section is open, the symbol changes to ▼.

To open individual study records for effects data (denoted by ) , click on the study record name and summary information for the study will appear on the right side of the screen. Sections or subsections without data will not have a ► on the left of the section name.



Sections 4-8 and 12-13 will not be completed in the files to be submitted by the Co-Registrants. In the Lead Registrant's file, IUCLID Sections 2 and 4-8 and 12-13 may be locked for editing by anyone other than the Secretariat (those sections should remain identical for all members of the joint submission).



You are now ready to complete your IUCLID file by entering/updating
your legal entity-specific information!



CHAPTER 2: GENERAL INFORMATION (IUCLID SECTION 1)

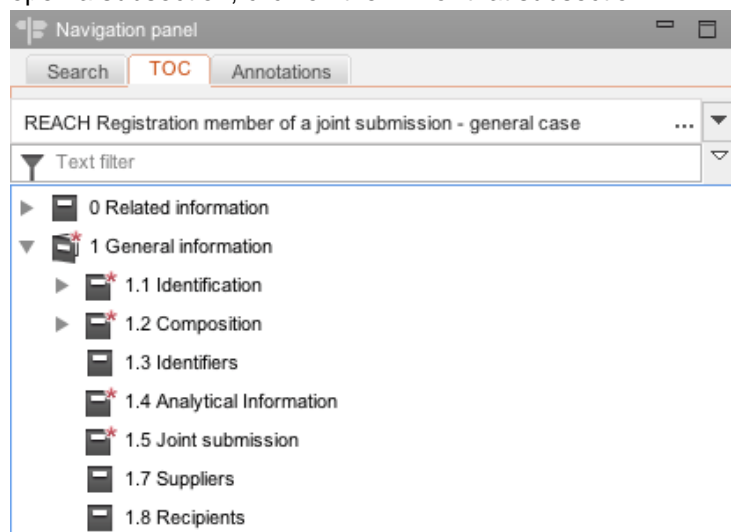
The information needed to complete this IUCLID section is legal entity-specific information on identification, composition, identifiers, analytical information, and joint submission. Information on your sponsors, suppliers, and recipients is optional. Please read through the information provided in Section 1 of the IUCLID .i6z file provided to you by the Secretariat. It is your responsibility to provide the necessary information, to ensure it is accurate, and to make sure that it is correctly entered into your IUCLID file.

Completion of Sections 1.1 to 1.4 is mandatory for substances (on their own or in preparations such as alloys) and for non-SCC intermediates. For SCC intermediates, all of these sections except Section 1.4 are mandatory. If mandatory, this information must be entered into IUCLID.

Instructions are provided on how to manoeuvre through IUCLID to complete the remaining information needed for IUCLID Section 1.

How to complete Section 1: General Information



To see the sections of the IUCLID file, click on "TOC". To open Section 1, click on the ► for that section in the Table of Contents on the left. This will show the Section 1 subsections as shown in the screen shot below. To open a subsection, click on the ► for that subsection.



1.1 Identification

Completion of Section 1.1 is mandatory for substances (on their own or in preparations such as alloys) and isolated intermediates. Some information (substance name, identification of substance, type of substance) will already be included in the IUCLID file you received from the Secretariat. You must enter additional information into IUCLID:



- 1) Assign / replace³ a legal entity to your substance dataset by clicking on the  button next to “Legal entity”.
- 2) If applicable, you can indicate a Third party representative.
- 3) Select at least one checkbox in the “Role in the supply chain” section. If you select “Manufacturer”, you must complete Sections 3.3 later. Please note, that if you are an “Only Representative”, as well as one of the other options, you must submit a separate dossier as an “Only Representative”. If you are not an “Only Representative”, you may select more than one box if applicable.
- 4) You can add your substance trade name(s) into the “Other identifiers” field under “Type of substance” by clicking  Add... and selecting “trade name” from the drop-down list.
- 5) Please add the name and contact information of your designated contact person into the “Contact persons” field that is located under “Type of substance”.

The remainder of Section 1.1 will have been pre-completed by the Secretariat.

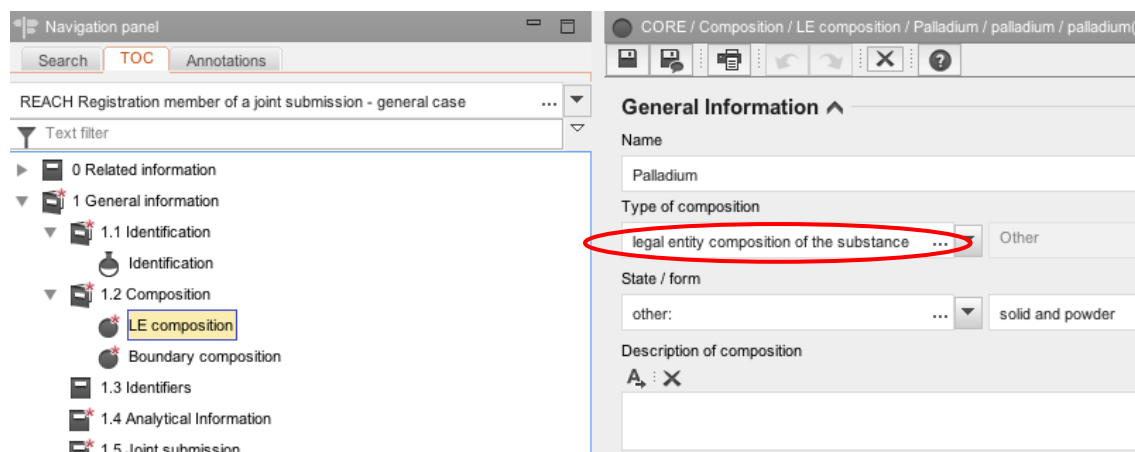
1.2 Composition

Completion of Section 1.2 is mandatory for substances (on their own or in preparations such as alloys) and isolated intermediates.

This Section offers the possibility to provide several composition descriptions of your substance. The generic composition(s) or “**boundary composition(s)**” approved by the relevant PMC project experts’ work group and reflected in the PMC ID card of the substance (one per classification/classification cluster, if relevant) will have been completed by the Secretariat. This composition must be left unchanged. **Each legal entity (including the Lead Registrant) must complete their legal entity-specific composition (“LE composition”) in Section 1.2** even if the LE composition is very similar or the same as the boundary composition.

Note: First check how the boundary composition was entered in IUCLID before completing the LE composition, to ensure consistent reporting and to check if your LE composition is covered by the boundary composition(s).

To complete the LE composition, click on “LE composition” and check that the type of composition is set to “legal entity composition of the substance”



The screenshot displays the IUCLID interface for editing a substance dataset. On the left, a navigation panel shows a tree view with '1.2 Composition' expanded to 'LE composition'. The main window shows the 'General Information' section for 'Palladium'. The 'Type of composition' dropdown menu is highlighted with a red circle, and 'legal entity composition of the substance' is selected. Other options include 'Other'. The 'State / form' dropdown is set to 'solid and powder'.

³ Note that there will be a dummy legal entity assigned to the file sent by the Secretariat; make sure that you replace it by your own.



Complete the following information:

- 1) Under “Degree of purity”, report the purity range of your substance.
- 2) Under “Constituents”, report the typical concentration and the concentration range of the main constituents. The Secretariat will have already selected the correct reference substance(s). **Do not add new constituents under this section.**
- 3) Under “Impurities”, report the typical concentration and the concentration range of the impurities. The Secretariat will have already selected the correct reference substance(s) for those impurities that are present in the boundary composition. **Do not add new impurities under this section.**
- 4) If applicable, under “Additives”, report the typical concentration and the concentration range of the additives. The Secretariat will have already selected the correct reference substance(s) for those additives that are present in the boundary composition. **Do not add new additives under this section.**

The screenshot shows the IUCLID interface for a substance entry. The browser address bar indicates the path: CORE / Composition / LE composition / Palladium / palladium / palladium(2+) / 7440-05-3. The IUCLID logo is visible in the top right corner of the application window.

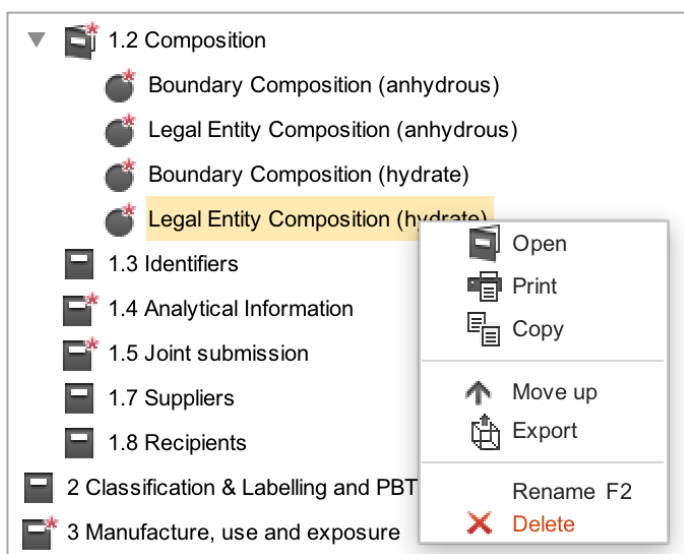
The 'Degree of purity' section is expanded, showing a dropdown menu and a text input field with a unit selector set to '% (w/w)'. A red circle highlights this input area.

The 'Constituents' section is also expanded, showing a table of reference substances. The first entry is 'palladium / palladium(2+) / 7440-05-3 / 231-115-6, % (w/w), >= - <= % (w/w)'. Below the table, the 'Reference substance' field is populated with 'palladium / palladium(2+) / 7440-05-3 / 231-115-6'. A table below this shows the following details:

| Inventory | Inventory number | Inventory name |
|---------------|------------------|----------------|
| EC | 231-115-6 | palladium |
| CAS number | CAS name | |
| 7440-05-3 | | |
| IUPAC name | | |
| palladium(2+) | | |

Below the table, the 'Typical concentration' field is highlighted with a red circle, showing a dropdown menu and a text input field with a unit selector set to '% (w/w)'. The 'Concentration range' field is also highlighted with a red circle, showing dropdown menus for '>=' and '<=' operators, text input fields, and a unit selector set to '% (w/w)'. The 'Remarks' field is visible at the bottom of the section.

If one of the Legal Entity compositions indicated by the Secretariat is not applicable to you (e.g. hydrate/anhydrous form), you can remove it by right-clicking the composition and selecting “Delete”. (hydrate/anhydrous).



Do not remove any of the Boundary compositions indicated by the Secretariat.

Table 2: Definition of constituents, additives and impurities.

| | |
|--------------------------|--|
| Main constituent* | A constituent, not being an additive or impurity, in a substance that makes a significant part of that substance and is therefore used in substance naming and detailed substance identification. A mono-constituent substance only contains one main constituent; a multi-constituent substance contains more than one main constituent. Concentration ≥ 80 % (w/w) for mono-constituent substances; ≥ 10 % (w/w) and < 80 % (w/w) for multi-constituent substances. |
| Additive | A substance that has been intentionally added to stabilise the substance and which cannot be removed without changing the chemical nature to which it is added. To be reported if concentration ≥ 1 % (or lower if contributing to the hazard). |
| Impurity* | An unintended constituent present in a substance, as produced. It may originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While impurities are present in the final substance, they were not intentionally added. All constituents (except additives) which are not the main constituent(s) in the mono-constituent substance or multi-constituent substance are considered to be impurities. To be reported if concentration ≥ 1 % (or lower if potentially influencing the classification of the substance). |

* For UVCBs (substances of Unknown or Variable composition, Complex reaction products or Biological materials), due to the lack of differentiation between constituents and impurities, the terms “main constituent” and “impurity” should not be regarded as relevant. A UVCB can only contain constituents (concentration ≥ 10 % (w/w) or lower if relevant for classification) and additives.

A typical concentration and concentration range should be included for all constituents, impurities, and additives. Any additional information on your reference substance(s) should be provided in the “Remarks” section.

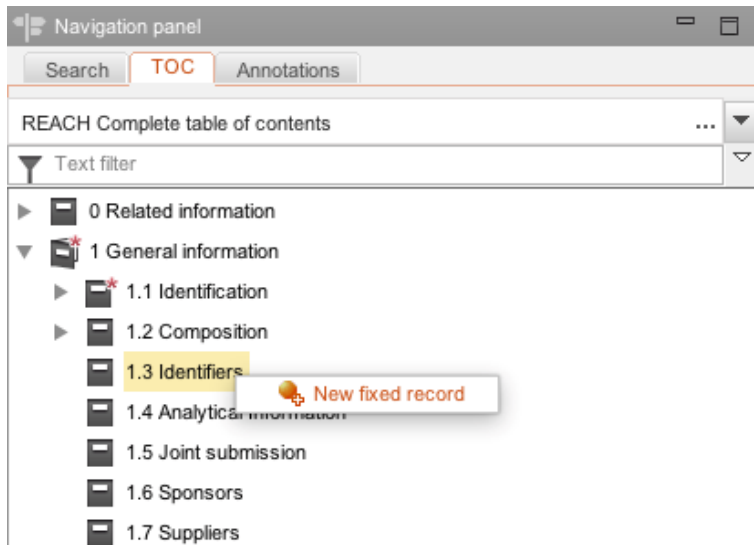
1.3 Identifiers

Completion of Section 1.3 is mandatory for substances (on their own or in preparations such as alloys) and isolated intermediates. This section identifies your company as legitimate and links your registration to your pre-registration information.

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

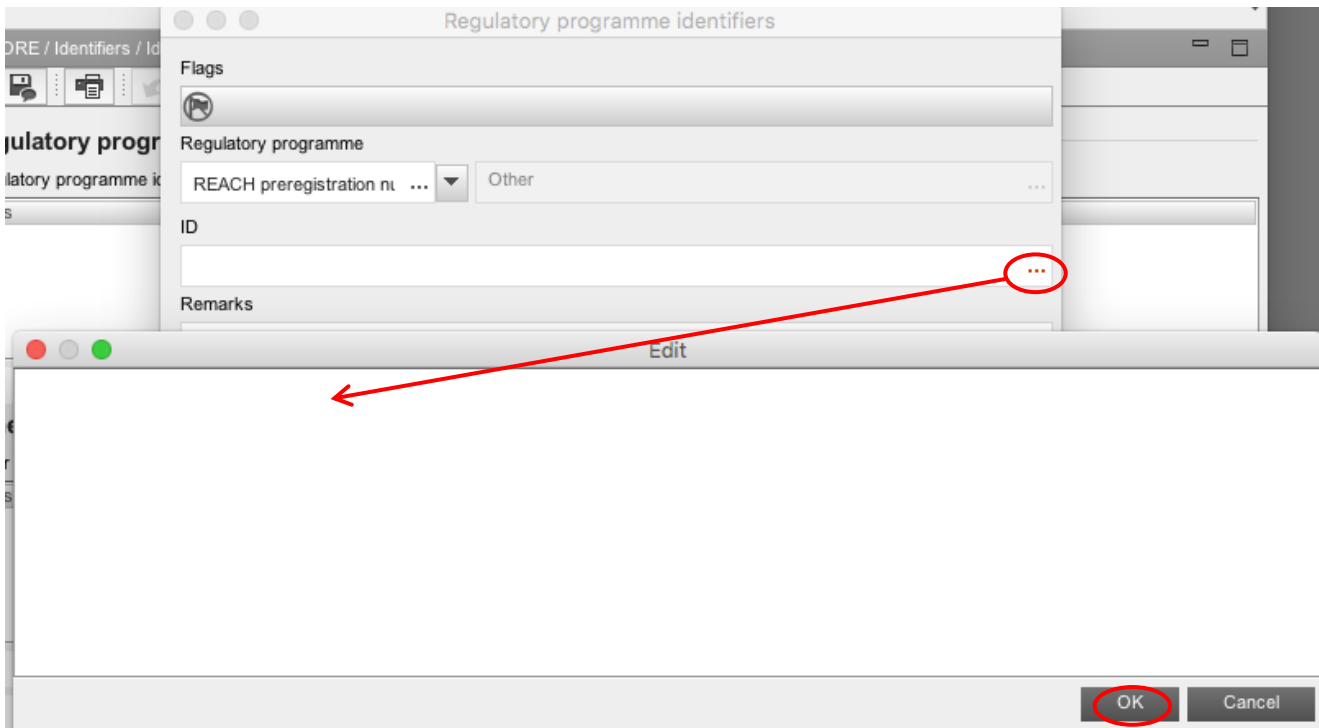
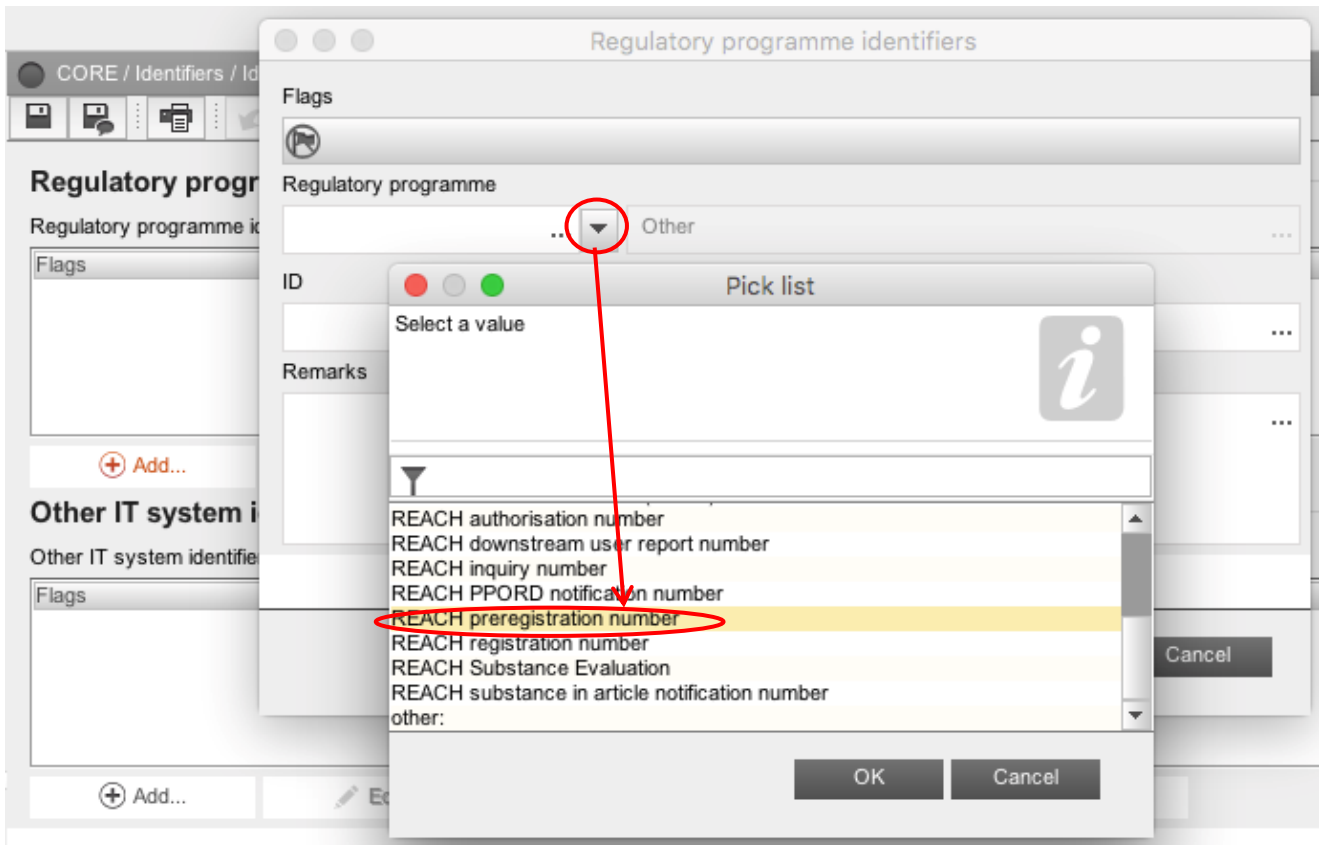


fixed record”.



Under “Regulatory programme identifiers,” click on “Add” and select “REACH preregistration number” under the “Regulatory programme” picklist, then add your pre-registration number in the “ID” data field. Click on “OK” and the added regulatory programme identifiers will appear in the table.





If you pre-registered e.g. two different EINECS numbers which will be registered as a single substance (following the identification and sameness discussion with the other Co-Registrants), it is recommended to list both pre-registration numbers under this field (repeat the above steps twice or once for each pre-registration number you wish to add).



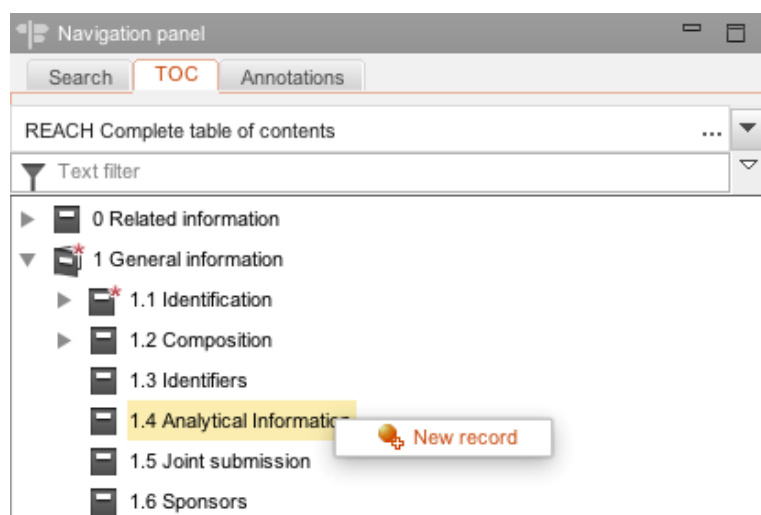
In the same context, for those who have pre-registered the “wrong” EINECS, it is recommended to include the pre-registration number linked to this “wrong” EINECS in the registration dossier for the “correct” EINECS agreed upon by all Co-Registrants during the identification and sameness discussion.

If there is a difference between the EINECS number(s) used during pre-registration and registration for the same substance, it is worthwhile adding the following sentence to the ‘Remarks’ field: “*Registration approach agreed upon by Co-Registrants following identification and sameness discussions*”.

1.4 Analytical information

Completion of Section 1.4 is mandatory for substances (on their own or in preparations such as alloys) and non-SCC intermediates; not mandatory for SCC intermediates. This section is for the analytical information of your substance.

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, right-click on the section name and select “New record”. A new record to report the analytical information is created.



Provide a description of analytical method(s) for substance identification, chromatogram, and spectral data for your substance in the “Methods and results of analysis” field as recommended by PMC in the ID Card of the substance you are registering.

Under the table “Analytical determination”, click on “Add” and then the pop-up window appears.



The screenshot displays the 'Analytical information' section of the REACH-IT software. A modal window titled 'Analytical determination' is open, allowing users to enter details for an analysis. The modal includes fields for 'Purpose of analysis', 'Analysis type', 'Type of information provided', 'Remarks', 'Attached methods/results', 'Rationale for no results', and 'Justification'. A red circle highlights the '+ Add...' button in the background interface.

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

You may also provide optical activity for your substance in the “Optical activity” field. The completion of this section is optional.

1.5 Joint Submission

Completion of Section 1.5 is not mandatory for REACH registration. The information of the Joint Submission is completely derived from REACH-IT and any information in Section 1.5 is not taken into account / not checked for technical completeness. You may wish to indicate, for your own administrative purposes, the name of the joint submission in the related field in this section but it is important to note that the consistency of any information in this section of IUCLID will not be verified against the information derived from REACH-IT.

To enter your data, you must first create a new record.



1.6 Sponsors

Section 1.6 is not mandatory for REACH registration.


1.7 Suppliers

Section 1.7 is mandatory for Only Representatives. The following information is required for Only Representatives:

- Name of the non-EU manufacturer you represent (only one non-manufacturer per IUCLID file).
- Contract or letter appointing you as the Only Representative – As an Only Representative, you must be able to document who you are representing and you are advised to attach a document (in IUCLID Section 1.7) from the “Non EU manufacturer” assigning you as an Only Representative, as stated in the ECHA Guidance on Registration.
- List of the importers in the same supply chain who are covered by the Registration.

1.8 Recipients

Section 1.8 is not mandatory for REACH registration.

Please save all of your changes, additions, or deletions to IUCLID Section 1 by clicking the save button () at the top of the screen.

This completes IUCLID Section 1: General Information!



CHAPTER 3: MANUFACTURE, USE AND EXPOSURE (IUCLID SECTION 3)

The information provided in this IUCLID section is site-specific information on technological processes, tonnage, form in the supply chain, and exposure, etc... In addition, this section contains all identified uses that are relevant along your supply chain with their associated use descriptors.

Section 3 will have been pre-completed by the Secretariat. Instructions are provided on how to manoeuvre through IUCLID to complete the remaining information needed for IUCLID Section 3.

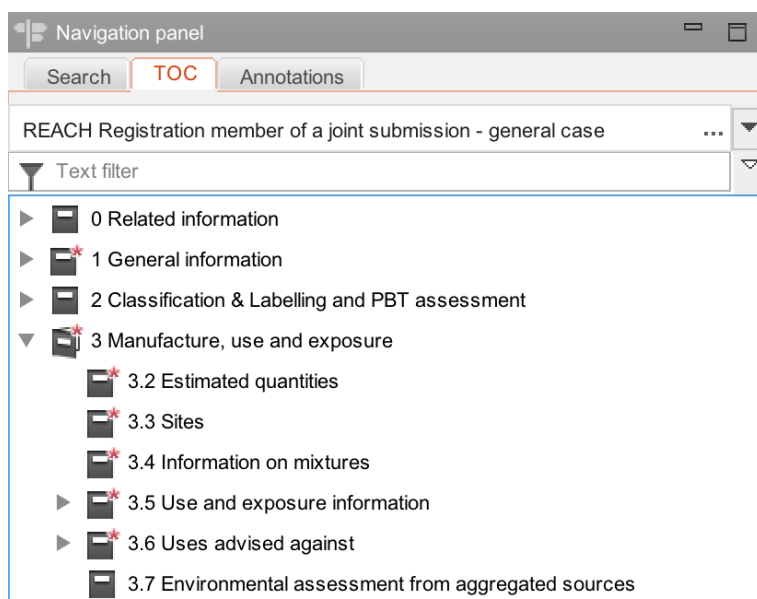
How to Complete Section 3: Manufacture, use and exposure

Please use the table below to determine which subsections must be completed based on your role in the supply chain.

Table 3: IUCLID subsections to be completed based on role in the supply chain.

| IUCLID subsection | Role in the Supply Chain | |
|---|--------------------------|-------------------------------------|
| | Manufacturer (M) | Importer/Only Representative (I/OR) |
| 3.2. Estimated quantities | Mandatory | Mandatory |
| 3.3. Sites | Mandatory | Not relevant |
| 3.4. Information on mixtures | Mandatory (if relevant) | Mandatory (if relevant) |
| 3.5. Use and exposure information | Mandatory | Mandatory |
| 3.6. Uses advised against | Mandatory (if relevant) | Mandatory (if relevant) |
| 3.7. Environmental assessment from aggregated sources | Not mandatory | Not mandatory |

To see the sections of the IUCLID file, click on "TOC". To open Section 3, click on the ► for that section in the Table of Contents on the left. This will show the Section 3 subsections as shown in the screen shot below. To open a subsection, click on the ► for that subsection.



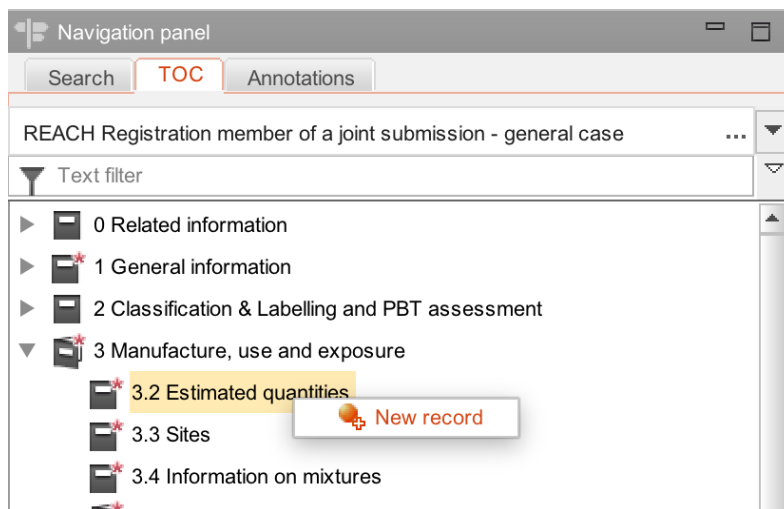


Note: Information from the previous IUCLID 5.6 section 3.1 (Technological process) has been migrated into Section 3.5.1 - Exposure information for manufacture.

3.2 Estimated quantities (for all registrants)

Completion of Section 3.2 is mandatory for dossiers of substances (on their own or in preparations such as alloys) and non-SCC intermediates; and not mandatory for dossiers of SCC intermediates but highly recommended (see special considerations for intermediate registrants below).

To enter your data, you must create a new record per each calendar year that you want to report. E.g. if you are planning to submit your dossier in 2018, you must report estimated quantities for 2015, 2016 and 2017. To create a new record, right-click on the section name and select “New record”. A new record to report the estimated quantities is created.



You can also create additional records if reporting more than one form of the substance (e.g., in massive form, in powder form, in solution form, etc.) in the same IUCLID file. PMC Secretariat recommends registering legal entities to be as complete and transparent as possible in reporting the different forms manufactured/imported and/or placed on the EU market of each substance, and to individually report the amounts of massive material (> 1 mm), powder material (< 1 mm and down to 100 nm), suspended material, material in mixture or alloys, etc. relevant for the registrant as applicable.



CORE / Estimated quantities / Estimated quantities.001 / Hexachloroplatinic acid / hexachloroplatinic acid / 16941-12-1 IUCLID

Year

Total tonnage (tonnes / year) ^

Manufactured

Imported

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 conditions (on-site)

Tonnages relevant for registration / notification of substances in articles ^

Tonnage imported in articles

Tonnage in produced articles

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

Please note:

- For a substance that is considered a **“substance in mixture”**: Only include the tonnage of your substance; not the tonnage of the mixture (e.g., a silver-gold-copper alloy, provide the tonnage of the precious metal or rhenium substance you are registering only; not the complete tonnage of the alloy).
- For **multi-constituent substances**, use the overall tonnage of the multi-constituent substance and not the tonnage of the constituent.
- Registrants who produce both the **anhydrous** and the **hydrated** form of a substance need to add up the quantities of the anhydrous form and the different hydrated forms when determining their tonnage band (but excluding the water which is attached to the parent molecule).
- For **solutions** where the solvent can be separated without affecting the stability of the substance or changing its composition, the solvent does not need to be considered in the tonnage calculations.

The year and total tonnage fields (either Manufactured, Imported, or both) are **required** to pass the Validation Assistant check.

It is also recommended to fill in the “Own use” (tonnes per year used by the registrant), “Use as intermediate under strictly controlled conditions (on-site)” and “use as intermediate under strictly controlled conditions (transported)” fields for dossiers which include tonnages of isolated intermediates under strictly controlled conditions.



Special considerations for intermediate registrants

Technically, section 3.2 is not mandatory for dossiers of isolated intermediates handled under SCC (i.e. it is not checked for completeness) but it is recommended to fill in the field "Year", at least one of the "Total tonnage" fields and as much as possible the fields under "Details on tonnages". This will allow authorities to have a faithful picture of the proportion of the substance that is used as an intermediate across all registrants, and decide upon whether Authorisation/Restriction requirements may or not apply (if the substance is mainly used as an intermediate it should not be picked up for Authorisation/Restriction)

It is important to note that only the tonnage used as intermediate under SCC can be reported separately in Section 3.2. This because the reduced registration requirements laid down under REACH for isolated intermediates **ONLY** apply to intermediates manufactured and used under SCC. Hence, the registrant has to report separately the tonnage for own use (including both uses as an SCC intermediate, non-SCC intermediate and as regular substance), the tonnage manufactured for use as on-site intermediate under SCC and the tonnage manufactured / imported for use as transported isolated intermediate under SCC. This way, the quantity of a substance used as intermediate under SCC will be easily identifiable in the registration dossier.

Please note that uses of intermediates for which SCC 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 (Life Cycle description) and should also be accounted for in the exposure assessment and risk characterisation in the Chemical Safety Report. As stated in Article 2(8) of the REACH Regulation, isolated intermediates are exempted from Authorisation. Since the tonnage of substance used as non-SCC intermediate cannot be reported separately from the tonnage used as regular substance in Section 3.2, it is recommended to report it in Section 3.5 under the specific use (see 3.5).


Registrants who wish to report both uses requiring a full registration (Article 10) and uses of intermediates under SCC are advised to submit a combination dossier. Only in this case they are expected to report a tonnage for use as intermediate under SCC in IUCLID section 3.2 and, additionally, are allowed to exclude the intermediate tonnage under SCC from the exposure assessment. The tonnages reported for each use in IUCLID section 3.5 should be consistent with the estimated quantities in IUCLID section 3.2 and should not exceed the tonnages in the dossier header (tonnage bands) for both the tonnage requiring a full registration (Article 10) and the isolated intermediate tonnage.

3.3 Sites (for Manufacturers only)


Completion of Section 3.3 is mandatory for substances (on their own or in preparations such as alloys) and isolated intermediates.

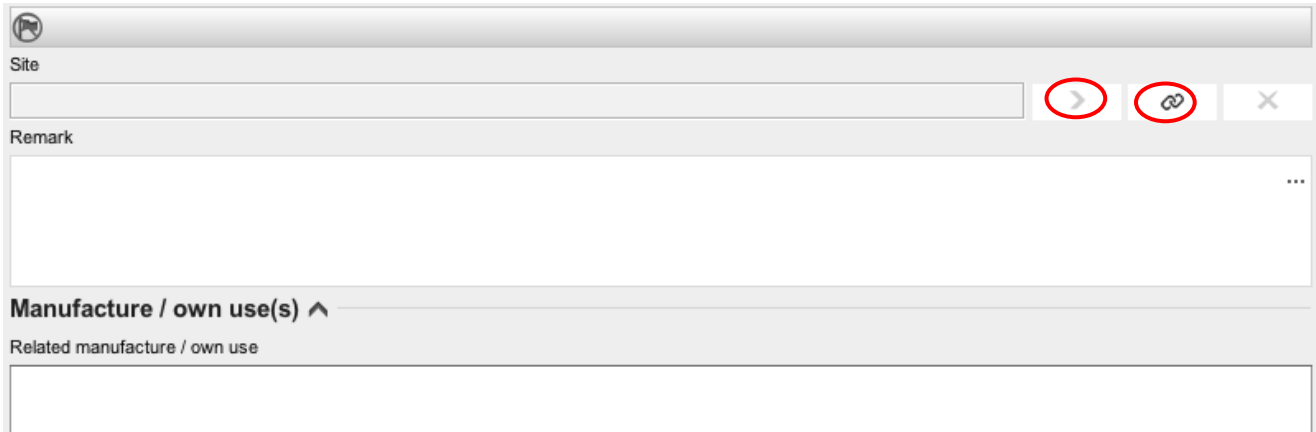
In Section 1.1, if you selected "Manufacturer" as your role in the supply chain, you must complete Section 3.3. However, if you are an "Only Representative", you may leave this section empty.

To enter your data, you must create a new record per Legal Entity site where the substance is produced and/or used. To create a new record, right-click on the section name and select "New record". A new record to report a site is created.

Click the  to the right of the "Site" data field to select your own site reference from the drop down list. If the legal entity site is not yet available in the inventory, create a new legal entity site by clicking New in the query window.



If the “Site” data field is already populated, click on the  to the right to open the site information and verify that the required information has been filled out correctly. The “Site name”, “Town”, “Country” and “Legal entity owner” fields are required to pass the Validation Assistant Check.



Note: The sites listed should only be the sites “associated” with the Legal Entity for which the Registration is prepared.

Each site created must be linked to at least one “Related manufacture/own use” in Section 3.5. To this end, the corresponding uses must first be reported in the appropriate tables in Section 3.5. Click on the “Add” button below “Manufacture/own use(s)” to display and select uses previously created in section 3.5 and to assign the link to the site. Add as many uses as necessary to list all uses at this site. For each “Site” created, the “Related manufacture/own use” field must be checked to pass the Validation Assistant check.



Note: For distributors only, no manufacture/own use should be linked to the site.

[3.4 Information on mixtures](#)

Completion of Section 3.4 is mandatory for substances in mixtures such as alloys. It is not mandatory for SCC intermediates.

To enter your data, you must create a new record per mixture. To create a new record, right-click on the section name and select “New record”. A new record to report a site is created.



The screenshot shows a form with three main sections: 'Trade name of mixture' with a text input field and a search icon; 'Type of mixture' with a text input field and a search icon; and 'Typical concentration' with three input fields, each preceded by a dropdown arrow, and a search icon.

In the free text boxes provided, add the trade name of the mixture, type of the mixture (e.g. granulate, paste, solution) and the typical concentration of your substance in the mixture as made available to downstream users. For example, if registering a silver-copper alloy, provide the typical concentration of the silver in the alloy.

3.5 Use and exposure information

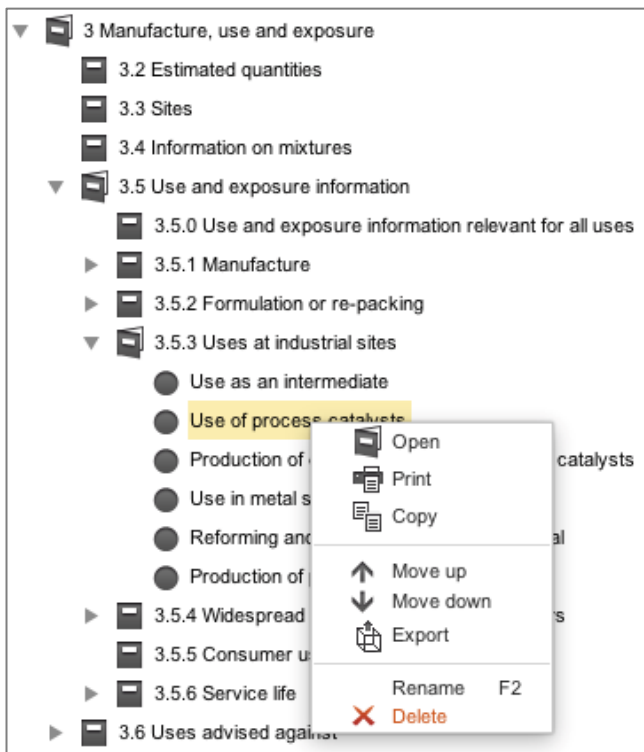
Completion of Section 3.5 is mandatory. This section enables the generation of a systematic overview of uses relevant during the life cycle of a substance.

Section 3.5 will have been completed by the Secretariat.

It is the recommendation of the Secretariat that each legal entity removes non-applicable uses. This is especially relevant if you register the substance ONLY as an SCC intermediate (see boxed text below). **Do not add any uses⁴.**

To remove a use, right-click on it and select "Delete".

⁴ unless you are declaring confidential uses. Note that if you add confidential uses for substances requiring a CSA/CSR, you need to cover that use with a separate Exposure Scenario. In this case, please contact the Secretariat for information/guidance.



Special considerations for intermediate registrants

If the joint submission covers both intermediate and non-intermediate use, and only intermediate use is applicable to your site, you should make sure to delete non-intermediate uses from Section 3.5. In addition, if you are registering an SCC intermediate, you should make sure to delete all use descriptors that are incompatible with SCC from Section 3.5.

It is important to note that for non-SCC intermediates, Section 3.5 is the only section in IUCLID to indicate that your substance is by definition still an intermediate (even though not strictly controlled). The identified uses in Section 3.5 should therefore clearly show intermediate use if applicable, so it would be obvious that the substance is an intermediate should the dossier be looked at in depth in the compliance check. It is also suggested to report the tonnage of substance used as non-SCC intermediate under the specific use in Section 3.5.



Uses at industrial sites | Contributing scenario for the environment (related to workers activities) | Contributing scenario for the workers

Substance supplied to that use in form of
▼ as such
in a mixture

Subsequent service life relevant for this use
no

Subsequent service life name

+ Add... | X Delete | ↑ Move up | ↓ Move down | > Go to link target

Tonnage of substance for this use (tonnes/year)

Details on tonnage reported

3.6 Uses advised against


If applicable, completion of Section 3.6 is mandatory for substances (on their own or in preparations such as alloys) and non-SCC intermediates; not mandatory for SCC intermediates.

Section 3.6 will have been completed by the Secretariat.

For most PMC substances, no use will have been reported as advised against (i.e. do not be surprised if this section is left empty).

3.7 Environmental assessment from aggregated sources

Completion of Section 3.7 is not mandatory for substances (on their own or in mixtures such as alloys) and isolated intermediates.

Please save all of your changes, additions, or deletions to IUCLID Section 3 by clicking the save button () at the top of the screen.

This completes IUCLID Section 3: Manufacture, Use and Exposure.



CHAPTER 4: GUIDANCE ON SAFE USE (IUCLID SECTION 11)

Completion of Section 11 is mandatory for substances (on their own or in preparations such as alloys) and for isolated intermediates.

Section 11 will have been completed by the Secretariat for substance dossiers but it is the responsibility of each registrant to review this Section and adapt as needed to their company-specific situation.

All registrants should decide whether the Guidance on Safe Use as pre-filled by the Secretariat is applicable to their specific situation (based on their SDS) or whether they need to adjust the Guidance on Safe Use in their company-specific registration. The Secretariat could not be considered as liable for the information provided under this section.



Administrative data ^

First-aid measures ^

INHALATION
If inhaled, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention.

INGESTION
Do not induce vomiting unless directed to do so by a medical personnel. Never give anything by mouth to an unconscious person. If potentially dangerous quantities of this material have been swallowed, call a physician immediately.

Fire-fighting measures ^

EXTINGUISHING MEDIA
- Suitable: Use an extinguishing agent suitable for the surrounding fire.
- Not suitable: None known
- Special exposure hazards: No specific fire or explosion hazard. Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire.
- Hazardous combustion products: Decomposition products may include metal oxide(s)

Accidental release measures ^

PERSONAL PRECAUTIONS
No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material.

ENVIRONMENTAL PRECAUTIONS
Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused

Handling and storage ^

HANDLING
Put on appropriate personal protective equipment. Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking.

STORAGE
Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible

Transport information v

Exposure controls / personal protection ^

PALLADIUM OCCUPATIONAL EXPOSURE LIMITS
ACGIH TLV (United States, 1/2009)
TWA: 10 mg/m³ 8 hours. Form: inhalable, particulates (insoluble) not otherwise specified (PNOS)

Stability and reactivity ^

- Stability: The product is stable
- Possibility of hazardous reactions: under normal conditions of storage and use, hazardous reactions will not occur
- Hazardous decomposition products: under normal conditions of storage and use, hazardous reactions will not occur

Disposal considerations ^

METHODS OF DISPOSAL
The generation of waste should be avoided or minimised wherever possible. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

EUROPEAN WASTE CATALOGUE (EWC)

As you update this section with relevant information from your updated SDS, please keep in mind that your updated SDS should correlate with the Chemical Safety Report (CSR) content and include the following:

- all new information gathered during the REACH process;
- the most recent CLP classifications (the CLP classifications should align with IUCLID Section 2 as it has been filled out in the IUCLID file provided by the Secretariat);
- new risk management measures, if applicable.


Since the Guidance on Safe Use is provided separately by each registrant (i.e. not by the LR on behalf of all members), the corresponding tickbox in the dossier header indicating that this information is provided by the Lead Registrant should be left empty (as further explained in Chapter 7 of this Guidance).

Special considerations for intermediate registrants



Registrants of SCC intermediates have to provide information on risk management measures and their efficiency (REACH Article 17 and 18). This information must be entered in IUCLID Section 11, either in the field "Handling and storage" or "Exposure controls/personal protection"

Note that in case of SCC intermediate dossiers belonging to a joint submission the information on risk management measures applied (i.e. Section 11 of the IUCLID dossier) cannot be provided by the Lead Registrant on behalf of Co-Registrants. Therefore this information needs to be submitted always separately in each registrant's SCC intermediate dossier.

Please save all of your changes, additions, or deletions to IUCLID Section 11 by clicking the save button () at the top of the screen.

This completes IUCLID Section 11: Guidance on Safe Use!



CHAPTER 5: CHEMICAL SAFETY REPORT (APPLICABLE TO LEAD REGISTRANTS ONLY) (IUCLID SECTION 13)


Completion of Section 13 is mandatory for substances (on their own or in preparations such as alloys). It will contain the Chemical Safety Report as well as other reports referred to elsewhere in previous sections of IUCLID. Section 13 is an endpoint study record-type section in which different assessment reports can be attached covering information not documented in other IUCLID sections.

Section 13 will have been completed by the Secretariat for substance dossiers.

This section will be submitted in the Lead Registrant file only. Co-Registrants shall leave this section empty (unless they register SCC intermediates - see below).

Special considerations for intermediate registrants

For SCC intermediates, information on details of the risk management measures applied at the manufacturing site and recommended to the user in order to achieve SCC, have to be included in the registration dossier. Existing legislative frameworks or industry standards can be referred to when documenting such risk management measures. The format in the ECHA Guidance on Intermediates (http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf) Appendix 3 is recommended to explain the risk management measures in the registration dossier. It should be attached by each registrant to the IUCLID Section 13 with the file name 'RMM_details'.

Please save all of your changes, additions, or deletions to IUCLID Section 13 by clicking the save button () at the top of the screen.

This completes IUCLID Section 13: Assessment Reports!



CHAPTER 6: Validation Assistant

To check that your IUCLID file is complete and that required IUCLID fields have been filled in correctly, you should use the Validation Assistant (previously called the Technical Completeness Check or TCC). In this chapter, instructions are provided on how to use the Validation Assistant to check your IUCLID file or dossier.

The Validation Assistant was used to check those sections completed by the Secretariat and consultants; you should not have any errors for these sections if you properly imported the file provided by the Secretariat. If the Validation Assistant reports errors for these sections, please contact the Secretariat for further assistance.

It is very important to pass the Validation Assistant check before submitting your dossier, as this simulates the check that will be conducted automatically as part of your registration process when you submit your dossier through the REACH-IT system. Using the Validation Assistant will minimize the risk of business rules (BR) failures and TCC failures but it will not exclude the possibility of failing BRC or TCC. Therefore, it is important to keep an eye on the tasks and messages in REACH-IT:

- The Validation Assistant shows the business rules that can be checked on IUCLID level but not the ones that depend on REACH-IT, e.g. Joint Submission name, last Submission number, etc.
- The Validation Assistant shows all the automatically checked TCC rules. ECHA will perform additional manual checks.

Important note on manual verification at completeness check

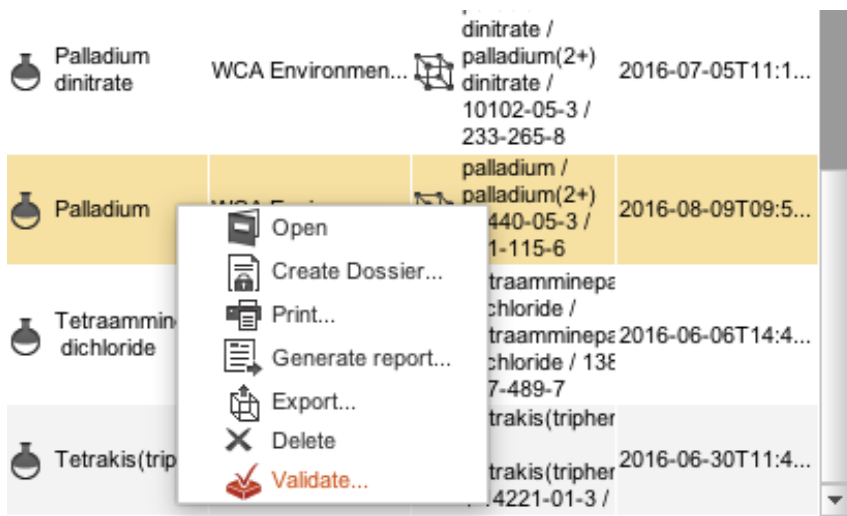
As of 21 June 2016, the automated completeness check is complemented with additional manual checks of certain elements of the registration dossier that cannot be checked automatically, to ascertain that all the information required by the legislation has been included. ECHA will not assess the quality of information at this point – this is performed during dossier evaluation – but rather ensure that the required data is provided i.e. the dossier is complete.

Before you submit your dossier to ECHA, use the Validation Assistant plug-in on your substance dataset as described in this chapter. If the Validation Assistant does not indicate any failures, it is not an automatic confirmation that your dossier is complete, since the technical completeness has been complemented with additional verifications done by ECHA staff that cannot be displayed by the Validation Assistant plug-in. Consequently, ensure that all the information required by the legislation is included in the dossier.

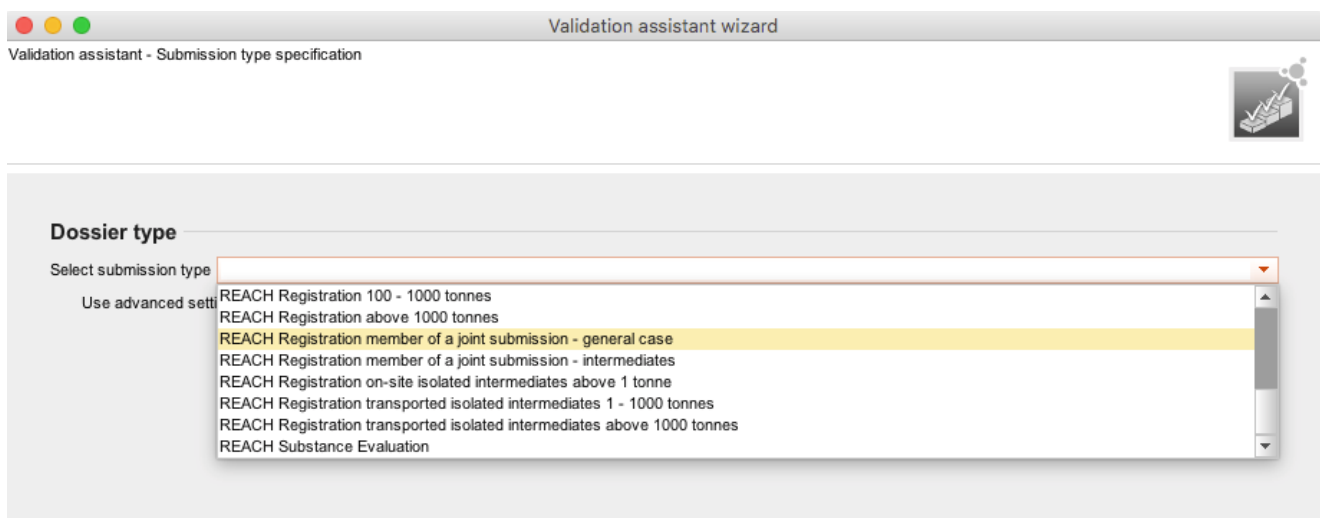
Based on ECHA's experience there are certain areas of the dossiers with regular issues: please refer to Annex 2 of this guidance for further information. Note that the Secretariat has checked the joint sections of the dossier for these regular issues but each registrant should pay particular attention to the company-specific information (e.g. substance identification and analytical information).

How to use the Validation Assistant

To begin, right-click on the dataset and select "Validate". This will open the Validation assistant wizard.



First, select the correct submission type (starting with “REACH Registration”) from the drop-down menu (according to the tonnage / intermediate status of the joint submission). If you are not the Lead Registrant, make sure you select one of the options stating “member of a joint submission”. Then click “Next”.



On the next screen select the appropriate fields as described below.

For the **Lead Registrant** (see screen shot below):

- Tick “Joint submission”.
- Under “Information provided by the lead on behalf of the member(s)”, tick “Chemical safety report”. Do not tick “Guidance on safe use”!
- Under “Tonnage band(s) of the lead registrant”, specify your own tonnage band(s) (i.e. this can be lower than the tonnage of the joint submission indicated in the previous screen). If you indicated intermediates in your tonnage in IUCLID Section 3.2, you must also indicate it here.
- Under “Dossier specific information”, select “Phase-in substance” if this is a pre-registered substance.
- If your fee will be waived, select “Fee waiving (1-10 tonnes, full Annex VII)”. In this case, you are advised to provide a justification.
- Select the “Compulsory information for isolated intermediates under REACH Article 17 and 18” as appropriate.



Then click on “Next”.

Type of submission

Joint submission

Information provided by the lead on behalf of the member(s)

Chemical safety report
Guidance on safe use
Review by an assessor

Tonnage band(s) of the lead registrant

Tonnage band: between 1 to 10 tonnes ...

On-site isolated intermediates tonnage band (REACH Article 17) ...

Transported isolated intermediates tonnage band (REACH Article 18) ...

Specific submissions

The submission is an update

Dossier specific information

Phase-in: phase-in ...

Reviewed by an assessor

Remarks

Document

Confidentiality claim on registration number
Confidentiality claim on tonnage band
Data sharing issues
Fee waiving (1-10 tonnes, full Annex VII)

Compulsory information for isolated intermediates under REACH Article 17 and 18

Production and use under strictly controlled conditions
Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)

Submission type header information

Back Next Finish Cancel

For the **Co-registrant** (see screen shot below):

- Under “Information provided by the lead on behalf of the member(s)”, tick “Chemical safety report”. Do not tick “Guidance on safe use”!
- Under “Tonnage band(s) of the member registrant”, specify your own tonnage band(s). If you indicated intermediates in your tonnage in IUCLID Section 3.2, you must also indicate it here.
- Under “Dossier specific information”, select “Phase-in substance” if this is a pre-registered substance.
- If your fee will be waived, select “Fee waiving (1-10 tonnes, full Annex VII)”. In this case, you are advised to provide a justification.
- Select the “Compulsory information for isolated intermediates under REACH Article 17 and 18” as



appropriate.
Then click on "Next".

Type of submission

Information provided by the lead on behalf of the member(s)

- Chemical safety report
- Guidance on safe use
- Review by an assessor

Tonnage band(s) of the member registrant

Tonnage band: between 1 to 10 tonnes ...

On-site isolated intermediates tonnage band (REACH Article 17): ...

Transported isolated intermediates tonnage band (REACH Article 18): ...

Specific submissions

The submission is an update

Dossier specific information

Phase-in: phase-in ...

Reviewed by an assessor

Remarks:

Document:

- Confidentiality claim on registration number
- Confidentiality claim on tonnage band
- Data sharing issues
- Fee waiving (1-10 tonnes, full Annex VII)

Compulsory information for isolated intermediates under REACH Article 17 and 18

- Production and use under strictly controlled conditions
- Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
- Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)

Submission type header information

In the next window, the tool begins the validation of the business rules and technical completeness check. When it has finished, you will see a log of all the validation warnings and failures associated with your file.



Validation assistant wizard

Validated entity: Palladium / palladium / palladium(2+) / 7440-05-3
Time of validation: 2016/09/20 10:53:23
Validation scenario: SC0002 - Registration, member 1-10 STD, own GSU

Submission checks (7) ! Quality checks (0)

Business rules (0), Completeness check rules (7)

No business rule failures were detected by the Validation assistant. Please note that some of the business rules can only be checked at dossier level. Also note that as the Validation assistant only verifies information within the IUCLID dossier/dataset, it cannot perform all the business rules checks that apply when the dossier is submitted to ECHA.

Re-check Open document Open document Copy report Copy selected row(s) to clipboard Filter: All Rule level: All

| Rule | Section number | Section name | Document name | Message | Rule type | Rule level |
|-------------|----------------|------------------------|----------------|--|--------------------|------------|
| TCC_0101_02 | 1.1 | Identification | Palladium | At least one 'Role in the supply chain' must be selected. | Completeness check | Failure |
| TCC_0102_01 | 1.2 | Composition | LE composition | For each legal entity composition, at least one value and a unit must be provided for the 'Degree of purity'. | Completeness check | Failure |
| TCC_0102_06 | 1.2 | Composition, (1) | LE composition | For each constituent of a legal entity composition, the full 'Concentration range' must be provided (lower and upper value), together with a unit. If you are reporting a provide this value, together with the unit, in the ve the 'Concentration range' fields empty. | Completeness check | Failure |
| TCC_0102_08 | 1.2 | Composition, (1) | LE composition | For each constituent of a legal entity composition, the full 'Concentration range' must be together with a unit. | Completeness check | Failure |
| TCC_0104_01 | 1.4 | Analytical Information | | Section 1.4 is incomplete. You must create at least one record in section 1.4 and fill in the table 'Analytical determination'. In each row created in the table, the 'Purpose of analysis' and the 'Analysis type' fields must be filled in. In addition, either the methods and results of analysis must be attached, or if a result was not determined, a justification must be given using the 'Rationale for no results' and 'Justification' fields, clearly stating the reasons for not providing the information. | Completeness check | Failure |
| TCC_0302_01 | 3.2 | Estimated quantities | | You must provide analytical information to cover at least one identification, and one quantification approach, as indicated in the 'Purpose of analysis' field. 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. | Completeness check | Failure |

Validation assistant - Report

Back Next Finish Cancel

To go to the data field that produced a validation failure, right click on it in the validation log and select “Go to reference document”. This should take you to the IUCLID location in question. Correct the problem, save the file and re-check the Validation Assistant to find out if you have corrected the problem.

Once you have a file that has no validation failures, click on “Finish”.
The file can be confidently submitted through the REACH-IT system.

This completes the Validation Assistant Check!

Quality Checks: In the Validation Assistant, you will see a tab called “Quality checks”. However, the current version of the Validation Assistant does not yet support the checking of Quality rules.



CHAPTER 7: REGISTRATION DOSSIER

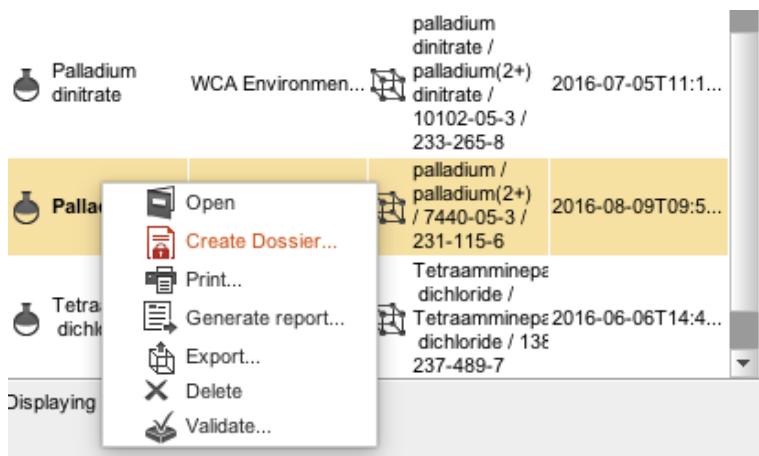
Your registration dossier is composed of the completed IUCLID file (technical dossier). If you are the Lead Registrant, this will include the Chemical Safety Report (CSR). The CSR will be attached to the final IUCLID file that the Lead Registrant receives from the Secretariat. Once you have completed the IUCLID file with your company-specific information, you can convert it to a registration dossier.

In this chapter, instructions are provided on how to create a registration dossier. To complete this process, you should prepare as follows:

- Have your completed IUCLID file containing your company-specific information ready and make sure it has passed the Validation Assistant check;
- Know the exact joint submission name (**case-sensitive**) that was created on the REACH-IT system by the Lead Registrant (**provided by the Secretariat**);
- **Lead Registrants only:** Be sure that the “common” joint submission CSR (unmodified from how you received it from the Secretariat) is attached to Section 13 of your IUCLID file. The CSR will not be included in the dossier of the individual Co-Registrants;
- **Co-Registrants only:** All Sections but Section 1, 3 and 11 should remain empty. The Lead Registrant will submit the remaining sections’ content on behalf of all Co-Registrants.
- **For those Lead or Co-Registrants of SCC intermediates:** Section 11 and 13 should contain the legal entity-specific SCC justification (See Chapter 4 and 5).

How to Create a registration dossier

To begin, right-click on the dataset and select “Create Dossier”. This will open the Dossier creation wizard.



On the next screen, select the appropriate registration dossier type you intend to submit (according to the tonnage you intend to register for). If you are not the Lead Registrant, make sure you select one of the options stating “member of a joint submission”. Then click “Next”.



Dossier creation wizard

Select submission type: Select a submission type, which meets your specific requirements: regulatory programme, type of dossier, tonnage band, member of a joint submission, etc.

The dossier/export template is used to determine which substance or mixture/product documents will be selected by default. The selection can be modified manually in a subsequent step of the dossier creation/export process.
Note that all referenced documents will be automatically detached.

Substance

Select submission type for a Substance

CLP Regulation - CLP Dossier

EU_REACH

- REACH Annex XV - Restriction
- REACH Annex XV - SVHC
- REACH Application for authorisation
- REACH Downstream user report
- REACH Inquiry
- REACH Notification of substance in article
- REACH PPORD
- 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 Substance Evaluation

Use advanced settings

1 Select submission type

Back Next Finish Cancel

On the next screen, complete the dossier header as described below.

For the **Lead Registrant** (see screen shot below):

- Provide a dossier name (e.g., JS_Silver PMC_130429).
- Under the “Dossier submission remark”, include any specific remarks you want to include regarding your dossier (e.g. specific forms of the substance covered or excluded from the joint or individual dossier). You may also add “*This Dossier is a joint Registration Dossier submitted by **NAME OF THE LEAD REGISTRANT** on behalf of the concerned Members of the Precious Metals and Rhenium Consortium, an initiative of the European Precious Metals Federation aisbl (Brussels, Belgium), a member of Eurométaux on **DATE**.*”
- Under “Type of submission”, tick “Joint submission”.
- Under “Information provided by the lead on behalf of the member(s)”, tick “Chemical safety report”. Do not tick “Guidance on safe use”!
- Under “Tonnage band(s) of the lead registrant”, specify your own tonnage band(s) (i.e. this can be lower than the tonnage of the joint submission indicated in the previous screen). If you indicated



intermediates in your tonnage in IUCLID Section 3.2, you must also indicate it here.

- Under “Dossier specific information”, select “Phase-in substance” if this is a pre-registered substance.
- Check any applicable boxes for confidentiality request, data sharing issues, or fee waiving. If you check any of these boxes, you need to be ready to provide a written justification in the dossier header. As soon as you check any of these boxes, a new text box will appear where you can provide legal entity-specific justification for your selection.
- Select the “Compulsory information for isolated intermediates under REACH Article 17 and 18” as appropriate. If you checked the box for “production and use under strictly controlled conditions”, you need to be ready to provide a written justification in the dossier header later (For example you can use the following justification, “*All information related to strictly controlled conditions is available in section 11 and 13 and on-site.*” See ECHA Guidance on Intermediates for details on what should be included in your documentation - http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf). For transported SCC intermediates, you must also check at least one of the boxes regarding intermediate use in accordance with the conditions set out in Article 18(4).

Then click on “Finish”.



Dossier creation wizard

Administrative information: Enter additional information concerning your dossier
Submission type : REACH Registration 1 - 10 tonnes, standard requirements

Dossier name (given by user) ...

Dossier submission remark ...

Type of submission

Joint submission

Information provided by the lead on behalf of the member(s)

Chemical safety report
Guidance on safe use
Review by an assessor

Tonnage band(s) of the lead registrant

Tonnage band ...

On-site isolated intermediates tonnage band (REACH Article 17) ...

Transported isolated intermediates tonnage band (REACH Article 18) ...

Specific submissions

The submission is an update

Dossier specific information

Phase-in ...

Reviewed by an assessor

Remarks

Document

Confidentiality claim on registration number
 Confidentiality claim on tonnage band

? Administrative information Back Next Finish Cancel



For the **Co-registrant** (see screen shot below):

- Provide a dossier name (e.g., JS_Silver PMC_130429).
- Under the “Dossier submission remark”, include any specific remarks you want to include regarding your dossier (e.g. specific forms of the substance covered or excluded from the joint or individual dossier). You may also add “*This Dossier is a joint Registration Dossier submitted by **NAME OF THE LEAD REGISTRANT** on behalf of the concerned Members of the Precious Metals and Rhenium Consortium, an initiative of the European Precious Metals Federation aisbl (Brussels, Belgium), a member of Eurométaux on **DATE**.*”
- Under “Information provided by the lead on behalf of the member(s)”, tick “Chemical safety report”. Do not tick “Guidance on safe use”!
- Under “Tonnage band(s) of the member registrant”, specify your own tonnage band(s). If you indicated intermediates in your tonnage in IUCLID Section 3.2, you must also indicate it here.
- Under “Dossier specific information”, select “Phase-in substance” if this is a pre-registered substance.
- Check any applicable boxes for confidentiality request, data sharing issues, or fee waiving. If you check any of these boxes, you need to be ready to provide a written justification in the dossier header. As soon as you check any of these boxes, a new text box will appear where you can provide legal entity-specific justification for your selection.
- Select the “Compulsory information for isolated intermediates under REACH Article 17 and 18” as appropriate. If you checked the box for “production and use under strictly controlled conditions”, you need to be ready to provide a written justification in the dossier header later (For example you can use the following justification, “*All information related to strictly controlled conditions is available in section 11 and 13 and on-site.*” See ECHA Guidance on Intermediates for details on what should be included in your documentation - http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf). For transported SCC intermediates, you must also check at least one of the boxes regarding intermediate use in accordance with the conditions set out in Article 18(4).

Then click on “Finish”.



Dossier creation wizard

Administrative information: Enter additional information concerning your dossier
Submission type : REACH Registration member of a joint submission - general case

Dossier name (given by user) ...

Dossier submission remark ...

Type of submission

Information provided by the lead on behalf of the member(s)

- Chemical safety report
- Guidance on safe use
- Review by an assessor

Tonnage band(s) of the member registrant

Tonnage band ...

On-site isolated intermediates tonnage band (REACH Article 17) ...

Transported isolated intermediates tonnage band (REACH Article 18) ...

Specific submissions

The submission is an update

Dossier specific information

Phase-in ...

Reviewed by an assessor

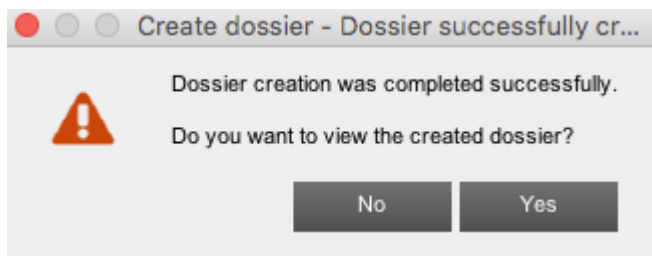
Remarks

Document

- Confidentiality claim on registration number
- Confidentiality claim on tonnage band
- Data sharing issues
- Fee waiving (1-10 tonnes, full Annex VII)

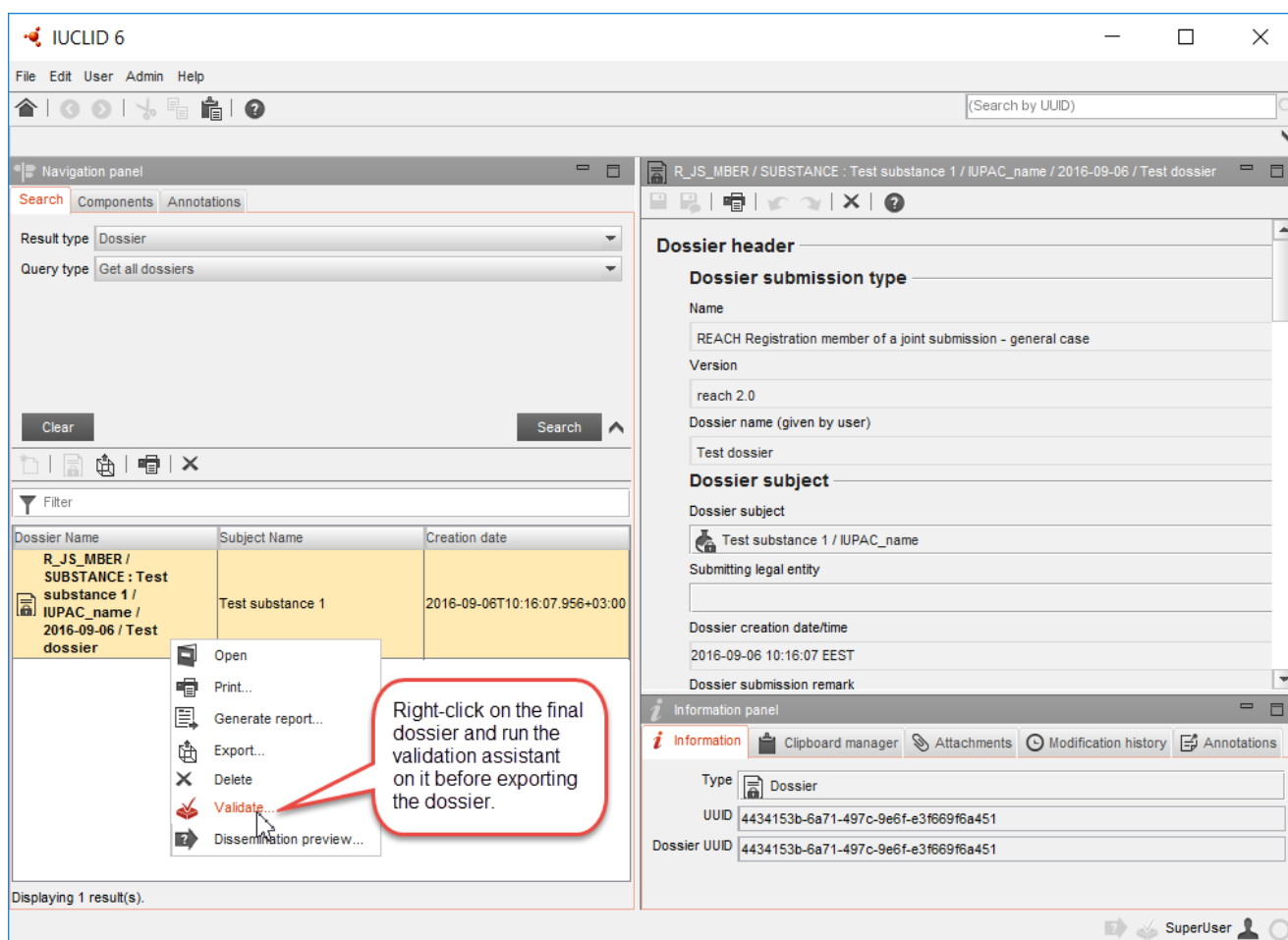
? Administrative information

Once the dossier has been created, you will have the option to view the dossier immediately



Alternatively, you can go to the Home page and click on the Dossier icon to view the dossier. If you then double-click on the dossier, you can see the dossier header.

Now, re-check your dossier with the Validation Assistant (see CHAPTER 6: VALIDATION ASSISTANT for instructions) to verify that your dossier header was properly completed.



The screenshot shows the IUCLID 6 application window. On the left, a navigation panel displays search filters for 'Dossier' and 'Get all dossiers'. Below it, a table lists dossier entries. One entry is highlighted, and a context menu is open over it, with the 'Validate...' option selected. A red callout bubble points to this option with the text: "Right-click on the final dossier and run the validation assistant on it before exporting the dossier." On the right, the 'Dossier header' details are visible, including fields for Name, Version, Dossier name, Dossier subject, and Submission date.

| Dossier Name | Subject Name | Creation date |
|---|------------------|-------------------------------|
| R_JS_MBER / SUBSTANCE : Test substance 1 / IUPAC_name / 2016-09-06 / Test dossier | Test substance 1 | 2016-09-06T10:16:07.956+03:00 |

Dossier header

Dossier submission type

Name: REACH Registration member of a joint submission - general case

Version: reach 2.0

Dossier name (given by user): Test dossier

Dossier subject

Dossier subject: Test substance 1 / IUPAC_name

Submitting legal entity: [Empty field]

Dossier creation date/time: 2016-09-06 10:16:07 EEST

Dossier submission remark: [Empty field]

How to Export a Dossier

Once you have your registration dossier, you will need to export it out of IUCLID so that it can be uploaded to the REACH-IT system when you are ready to submit the dossier for registration. To begin export, right click on the dossier you want to export and select "Export" (as shown in the screen shot below).



The screenshot shows the IUCLID 6 software interface. On the left, a search results table displays one entry:

| Dossier Name | Subject Name | Creation date |
|---|------------------|-------------------------------|
| R_JS_MBER / SUBSTANCE : Test substance 1 / IUPAC_name / 2016-09-06 / Test dossier | Test substance 1 | 2016-09-06T10:16:07.956+03:00 |

A context menu is open over the first row, with the 'Export' option highlighted. A red callout bubble points to the 'Export' option with the text: "Your dossier is ready to be exported."

On the right, the 'Dossier header' information panel is visible, showing details for the selected dossier:

- Dossier submission type:** REACH Registration member of a joint submission - general case
- Version:** reach 2.0
- Dossier name (given by user):** Test dossier
- Dossier subject:** Test substance 1 / IUPAC_name
- Submitting legal entity:** [Empty field]
- Dossier creation date/time:** 2016-09-06 10:16:07 EEST
- Dossier submission remark:** [Empty field]

The bottom right corner shows the user 'SuperUser' and a red status indicator.

On the next screen, you will have to select how much information you wish to include in the dossier you export and then click “Next”. We recommend choosing “Include all related annotations”.

The screenshot shows the 'Export assistant' dialog box. At the top, it says 'Settings: Select the settings that will be applied in the dossier/export'. Below this, under the heading 'Included Annotations', there are three radio button options:

- Include all related annotations
- Do not include annotations
- Export main document's annotations only

Below the options, there is a checkbox labeled 'Skip document selection step'. At the bottom, there are buttons for 'Settings', 'Back', 'Next', 'Finish', and 'Cancel'. The 'Next' button is highlighted.

In the next window, click on “Browse” to select where you would like to store your dossier (as an .i6z file). Then



click "Finish"

Export assistant

Enter additional administrative information concerning your Export.

Export details

/Users/user/40ab1fb0-c799-4b16-80c4-2f96e50c5229.i6z

Modification history

Export modification history

Remarks

Export details

The registration dossier has been exported!



FINAL WORDS

Your registration dossier is complete!!!!

This guide reflects the new IUCLID 6 version that was released in June 2016. Please refer to this guide for completion of dossiers for other substances you intend to register/update by joint submission.

For submission of your registration dossier through the REACH-IT system, please go to <https://reach-it.echa.europa.eu/reach/>. For general guidance on REACH-IT, please refer to https://echa.europa.eu/documents/10162/22308542/discover_reach_it_en.pdf.

The registration dossier is ready for submission to ECHA!



SUGGESTED REFERENCES

Data Submission Manual: How to prepare registration and PPORD dossiers (Version 1.0). 2016. European Chemicals Agency. Available at:

https://echa.europa.eu/documents/10162/22308542/manual_regis_and_ppord_en.pdf

REACH-IT general guidance. European Chemicals Agency. Available at:

https://echa.europa.eu/documents/10162/22308542/discover_reach_it_en.pdf

Guidance for Identification and Naming of Substances under REACH and CLP. Version 1.4. June 2016.

European Chemicals Agency. Available at:

http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf

Guidance on Intermediates. Version 2. December 2010. European Chemicals Agency. Available at:

http://echa.europa.eu/documents/10162/13632/intermediates_en.pdf

Guidance on Registration. Version 2.0. May 2012. European Chemicals Agency. Available at:

http://echa.europa.eu/documents/10162/13632/registration_en.pdf

Functionalities of IUCLID 6. June 2016. European Chemicals Agency. Available at:

https://iuclid6.echa.europa.eu/documents/21812392/22308501/iuclid_functionalities_en.pdf/559b80ad-cef7-4edb-8c2b-ca52e0d511e2

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. 2006. Official Journal of the European Union. Available at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF>.

COMMISSION REGULATION (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V. 2008. Official Journal of the European Journal. Available at:

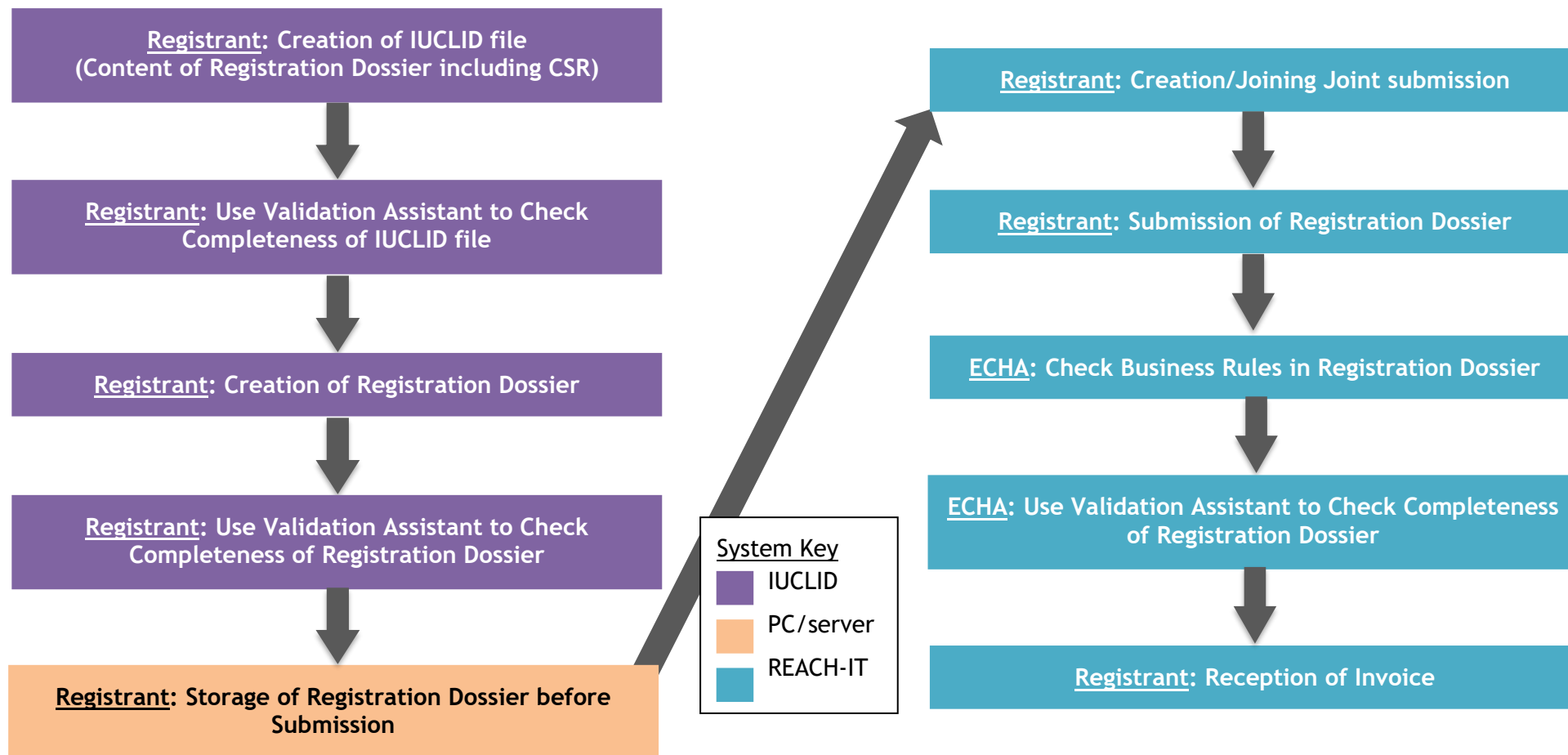
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:268:0014:0019:en:PDF>.

COMMISSION REGULATION (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labeling and packaging of substances and mixtures. 2009. Official Journal of the European Journal. Available at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:235:0001:0439:en:PDF>.



ANNEX 1: SCHEME OF GENERAL STEPS FOR SUBMITTING A REACH DOSSIER





ANNEX 2: INFORMATION ON MANUAL VERIFICATION AT COMPLETENESS CHECK

Cf. ECHA document on next pages or via

https://echa.europa.eu/documents/10162/13652/manual_completeness_check_en.pdf/429846b2-3bf3-4d16-b7d4-65b12d7644db for most recent version.

Information on manual verification at completeness check

ECHA performs a completeness check on each incoming registration to ensure that the required information is provided (Article 20 of the REACH Regulation).

As of 21 June 2016, the automated completeness check is complemented with additional manual checks by ECHA staff of certain elements of the registration dossier that cannot be checked automatically, to ascertain that all the information required by the legislation has been included. ECHA will perform a manual verification on both new registrations and updates of existing dossiers.

The manual verification aims at establishing a level playing field between registrants who follow the standard information requirements set out in REACH, and those who waive or deviate from these requirements, by ensuring that the latter provide justifications foreseen by the legislation.

The manual checks are integrated in the completeness check process. Therefore, when the outcome of the manual check is that the data provided in the dossier is not considered complete, ECHA will inform the registrant and request further information within a relevant deadline according to Article 20 to give the registrant the opportunity to make the dossier complete. ECHA will not assess the quality of information at this point – this is performed during dossier evaluation – but rather ensure that the required data is provided i.e. the dossier is complete.

When preparing your dossier, consider that the registration dossier should not only be prepared to pass the completeness check. It should contain all the information on the substance as specified by REACH, including a clear identification of the substance that is being registered, and should aim to demonstrate that the substance is used in a safe manner.

Please note that this document is being regularly updated with new information.

See below our general advice regarding the preparation of a complete registration dossier:

Before you submit your dossier to ECHA, use the IUCLID Validation assistant tool on your substance dataset and if it displays any failures, complete the missing information by following carefully the advice reported in the tool. After you have corrected the failures in the dataset, as a next step, create your dossier and validate before exporting it by completing any missing information identified by the tool.

If the Validation assistant does not indicate any failures, it is not an automatic confirmation of that your dossier is complete, since the technical completeness has been complemented with additional verifications done by ECHA staff that are not displayed in the Validation assistant report. Consequently, ensure that all the information required by the legislation is included in the dossier. Based on our experience there are certain areas of the dossiers with regular issues, therefore pay attention in particular to the four following areas:

We recommend you to watch our [webinar on completeness check](#) on the ECHA website.

1. Substance identification:

A clear substance identification is fundamental for registrants to carry out their registration obligations. Each registrant is responsible for ensuring that they register the substance as part of the correct joint submission, and that they provide the correct substance identification information in their registration dossier. Registrants should not rely on company-specific substance identification information provided by the lead registrant (such as analytical or compositional information). Therefore please take this into account when reporting the substance identity in your dossier.

- **IUPAC name of the registered substances:**

- The IUPAC name of the substance must be provided in the IUPAC name field of IUCLID section 1.1.
- If the IUPAC nomenclature cannot be applied, a chemical name of the substance must be provided in the IUPAC name field.
- For more information on how to fill in the IUPAC name field for multi-constituent substances and UVCB substances, please consult the [Q&A 1197](#) and [Q&A 1196](#) on the ECHA website, respectively.

- **Composition of well-defined substances:**

- When reporting the composition of well-defined substances, the "80%" and "80-10%" rules should be followed. Details of these rules are explained in chapter 4.2 of the [Guidance for identification and naming of substances under REACH and CLP](#). If you deviate from these rules, make sure that the justification is scientifically substantiated and included in the 'Justification for deviations' field in IUCLID section 1.2 of each composition where a deviation takes place. Acceptable deviations are specified in the Guidance.
- The composition of a mono-constituent substance should include one main constituent. The composition of a multi-constituent substance should include more than one constituent. A deviation from these principles is very exceptional and you must include a scientifically fully substantiated justification in the 'Justification for deviations' field in IUCLID section 1.2 of each composition where the deviation takes place.
- You must report the composition of the substance on its own. Do not report the composition of mixtures. For further information, please consult the [Q&A 1200](#) on the ECHA website.

- **Manufacturing process description of UVCB substances**

- For a UVCB substance, a description of the source used and the process applied must be included in the 'Description' field of each legal entity composition in IUCLID section 1.2.
- The manufacturing process information typically consists of the following elements: identity and ratio of starting materials; a description of the relevant manufacturing steps in the order they occur (including information on the

reaction steps/mechanisms); the relevant plant operating parameters applied to control the composition (e.g. temperatures/pressures; solvents; catalysis types...); extraction/isolation steps (if applicable); clean-up/purification steps (if applicable).

- A free text template marked with "A" is available in IUCLID to facilitate the reporting of the information. This template lists those elements that are necessary to address when describing the manufacturing process description. Please do not submit templates "empty", without including the relevant details of your description: such descriptions will not be considered complete.
 - In case you have information that complements the description of the manufacturing process, for example reaction schemes and process workflows, these must be reported in an attachment in IUCLID section 1.2 in the field 'Attached description'.
 - For your information, the 'Description' field of each legal entity composition is not disseminated on the ECHA website.
 - For further information, please consult the [Q&A 1199](#) and [Q&As 1316 to 1320](#) on the ECHA website.
- **Composition of UVCB substances**
 - The constituents for each reported composition of your UVCB substance must be provided in IUCLID section 1.2: all individual constituents present at >10%, or relevant for C&L and/or PBT assessment must be reported separately, while other constituents should be identified as far as possible, as separate constituents or as groups of generic constituents.
 - In very rare cases, if you consider that it is not possible to report constituents or groups of constituents separately, you must include a scientifically fully substantiated justification in the 'Justification for deviations' field in IUCLID section 1.2.
- **Analytical information:**
 - To fulfil the REACH requirement on the analytical data, you must provide the analytical information that enables your substance to be identified, including the compositions specified in section 1.2 of the dossier.
 - Analyses carried out for both identification and quantification purposes must be provided, as identification establishes the chemical identity of the constituents, while quantification is carried out to determine the concentration of the constituents in the composition.
 - To consider your dossier complete in terms of the analytical information, the required analytical reports must be attached in IUCLID section 1.4 (see screenshots below on the possibilities how to attach the reports).
 - In very rare cases, the quantification analysis may not be necessary for verifying the composition required to be reported in your dossier. If your substance belongs to these very rare case, a justification must be provided for

not submitting any quantification in the fields 'Rationale for no results' and 'Justification'. The justification must be scientifically fully substantiated.

IUCLID section 1.4 for reporting analytical data

Methods and results of analysis ^

Analytical determination

| Purpose of analysis | Analysis type | Type of information... | Attached methods/... | Rationale for no re... | Justification | Remarks |
|---------------------|-----------------------|------------------------|---|------------------------|---------------|---------|
| identification | NMR, MS, IR | methods and results | Identification_methods_results.docx / 0 B / | | | |
| quantification | chromatography – HPLC | methods and results | Quantification_methods_results.docx / | | | |

⊕ Add... ✎ Edit... ✕ Delete ⬆ Move up ⬇ Move down

Methods and results of analysis ^

Analytical determination

| Purpose of analysis | Analysis type | Type of information... | Attached methods/ir... | Rationale for no re... | Justification | Remarks |
|-----------------------------------|---------------|------------------------|---|------------------------|---------------|---------|
| identification and quantification | NMR, MS, IR | methods and results | Identification_quantification.docx / 0 B / application/octet-stre | | | |

⊕ Add... ✎ Edit... ✕ Delete ⬆ Move up ⬇ Move down

Further information

For further information consult the supporting documents below on how to provide information on the substance identification under REACH:

[How to prepare registration and PPORD dossiers](#)

[Questions and answers – Substance Identification](#)

[Guidance for identification and naming of substances under REACH and CLP](#)

2. Data waivers:

- For each endpoint study record marked as a 'Data waiving', a valid justification for not fulfilling the standard information requirement must be provided in the field 'Justification for data waiving'.
- Sections 2 and 3 of Annex XI of REACH and Columns 1 and 2 of the relevant endpoint in Annexes VII to X provide the reasons why a study would not need to be submitted in the dossier. If you propose not to provide information for a certain endpoint for other reasons than those mentioned in Columns 1 and 2 of Annexes VII to X or in Annex XI, you must clearly state these reasons and provide a scientifically substantiated justification.
- Adaptations according to Section 1 of Annex XI (use of existing data, weight of evidence, (Q)SAR, in vitro methods, grouping of substances and read-across approach) and testing proposals should not be submitted as data waivers, but reported as study records indicated as 'key study' or as 'weight of evidence'.

- If your reason for data waiving is substantiated by other documentation, for example an expert opinion that you intend to provide as an attachment, ensure to always include a summary of the rationale of the justification in the 'Justification for data waiving' field in line with sections 2 and 3 of Annex XI of REACH and Columns 1 and 2 of the relevant endpoint in Annexes VII to X. Supporting attachments should be provided in the field 'Attached justification'.
- Ongoing studies: If you have already received an ECHA decision or a draft decision requesting you to carry out a test for this endpoint but the information is not yet available, select 'other' from the field 'Justification for data waiving' and type the following sentence in the adjacent text field: "This information will be submitted later based on ECHA communication/decision number TPE/CCH-F-xxxxxxxx-xx-xx", where you replace the "x"-characters with the decision/communication number issued to you by ECHA.
- If the data waiving relies on other information (e.g. a test in another section or a classification), this information must be included in the appropriate section of the dossier. The presence of such information is manually checked.
- Extended one generation reproductive toxicity studies (EOGRTS):
 - o At REACH Annex IX, as indicated in Column 1 of 8.7.3, EOGRTS is a conditional requirement, which depends on the indication of adverse effects from other repeated dose toxicity studies. Therefore, if you are waiving the EOGRTS based on available repeated dose toxicity studies, you must indicate that no adverse effects or concerns have been observed in such studies and refer to these studies in the field 'Justification for data waiving'. If you are still awaiting the results of such test(s), you must follow the advice given in the [Q&A 1324](#) on the ECHA website.
 - o At REACH Annex X, EOGRTS is the standard information requirement to address reproductive toxicity. Unlike at Annex IX (Column 1, section 8.7.3), it cannot be waived based on the results from available repeated dose toxicity studies. If you are waiting for the results of another test (e.g. results from a 90-day study or from a prenatal developmental toxicity study) to decide on the study design of the EOGRTS, you should follow the advice given in [Q&A 1323](#) on the ECHA website.

Pre-natal developmental toxicity studies (PNDT): REACH Annex X requires registrants to provide a second pre-natal developmental toxicity study on a different species. For each of the two species, you need to provide an endpoint study record in section 7.8.2 indicated as key study, weight of evidence, data waiving, or testing proposal. If you fulfil Annex X information requirement related to PNDT studies, please read [Q&A 1437 and 1438](#), and the [newsletter on PNDT tests](#) on the ECHA website.

Further information

For further information consult the supporting documents below on how to provide information on the information requirements in Annexes VII-XI under REACH:

[How to prepare registration and PPORD dossiers](#)

[Endpoint specific guidance R7a, R7b and R7c](#)

[Q&As on preparing registration dossiers in IUCLID](#)**3. Testing proposals on vertebrate animals:**

- Since September 2015, ECHA proactively ensures that registrants have made an effort to consider the potential availability of non-animal testing methods before proposing testing on vertebrate animals ([document here](#)). For this purpose, registrants submitting new testing proposals concerning vertebrate animal tests need to provide their considerations of alternative methods in the registration dossier.
- These considerations of alternatives must be provided in the field 'Justification for type of information' for each proposed vertebrate study to pass the completeness check.
- You are strongly advised to use the text template provided in the field and marked with "A". This template lists those elements that are necessary to be addressed when documenting your considerations. Please do not submit templates "empty", without including the relevant and comprehensive details of your considerations: such considerations will not be considered complete.
- The considerations submitted will be published under the *Information on Chemicals* section of ECHA's website and will be linked to the Third party consultation page; therefore we advise you not to include any confidential information in the form.
- If you have already received an ECHA decision requesting you to carry out a test for an endpoint but the testing has not yet been completed, you should not report the ongoing study as a testing proposal. Instead it must be submitted as a data waiver with a specific justification text. For further details, see the "Data waivers" section of this document.
- It is important that you indicate whether your testing proposal refers to a test on the registered substance, or on another substance than the registered substance from which you intend to read-across. If the proposed test is to be conducted on a material representative of the substance you are registering in this dossier, you should indicate it as 'experimental study planned' in the field 'Type of information'. However, if you propose to test a substance other than the registered substance and read-across from the result to fulfil the information requirement for the registered substance, you should indicate the 'Type of information' as 'experimental study planned based on read-across'. For testing proposals on the registered substance, the full considerations for alternative methods must be provided, whereas for read-across testing proposals, the read-across hypothesis must be given.
- Note that if you have received an adopted implementing decision from the European Commission regarding the amended information requirements of REACH Annexes IX and X, 8.7.3 on reproductive toxicity (IUCLID section 7.8.1), but you are updating the dossier for another reason, please proceed as follows:
 - o Maintain the current testing proposal in IUCLID section 7.8.1
 - o Indicate in the field 'Justification for type of information' the following sentence: "This endpoint will be updated based on the implementing

decision by the European Commission with number <provide number of adopted decision> regarding the amended information requirements of REACH Annexes IX and X, 8.7.3.”

Note that you must update IUCLID section 7.8.1 by the deadline indicated in the European Commission decision according to the approach you have chosen to fulfil the amended information requirements (see instructions sent to you via REACH-IT), and remove the testing proposal submitted to address the previous information requirements.

Further information

For further information consult the supporting documents below on how to provide information on testing proposals under REACH:

[How to prepare registration and PPORD dossiers](#)

[Q&A – Information requirements, test methods and quality of data](#)

[Testing methods and alternatives](#)

4. Chemical safety reports (CSRs):

- If a CSR is not attached, a justification must be provided in line with Article 14(2) of REACH. The justification should explicitly document the conditions of Article 14(2) that the omission of the CSR is based on.
- The justification should be entered in any of the fields ‘Discussion’ or ‘Further information on the CSR attached / remarks’ of the section 13.1 record.

Changes to this document

| Version | Changes |
|---------|---|
| 3.0 | <p>October 2017</p> <ol style="list-style-type: none"> 1. Substance identification: clarifications on how to report the manufacturing process description of UVCB substances 2. Data waivers: clarifications on how to fulfil the information requirements for the extended one generation reproductive toxicity studies (EOGRTS) and the pre-natal developmental toxicity studies (PNDT) 3. Testing proposals: advice for updating your dossier if you have received a decision from the European Commission about the amended information requirements of REACH Annexes IX and X, 8.7.3 on reproductive toxicity 4. New Q&As and useful links added 5. Further editorial changes implemented |
| 2.0 | <p>February 2017</p> <ol style="list-style-type: none"> 1. Detailed description and advice added for each areas of the manual verification, in particular for areas where recurring issues were discovered during the manual checks 2. Q&As and supporting document links added 3. Further editorial changes implemented |
| 1.0 | First version |