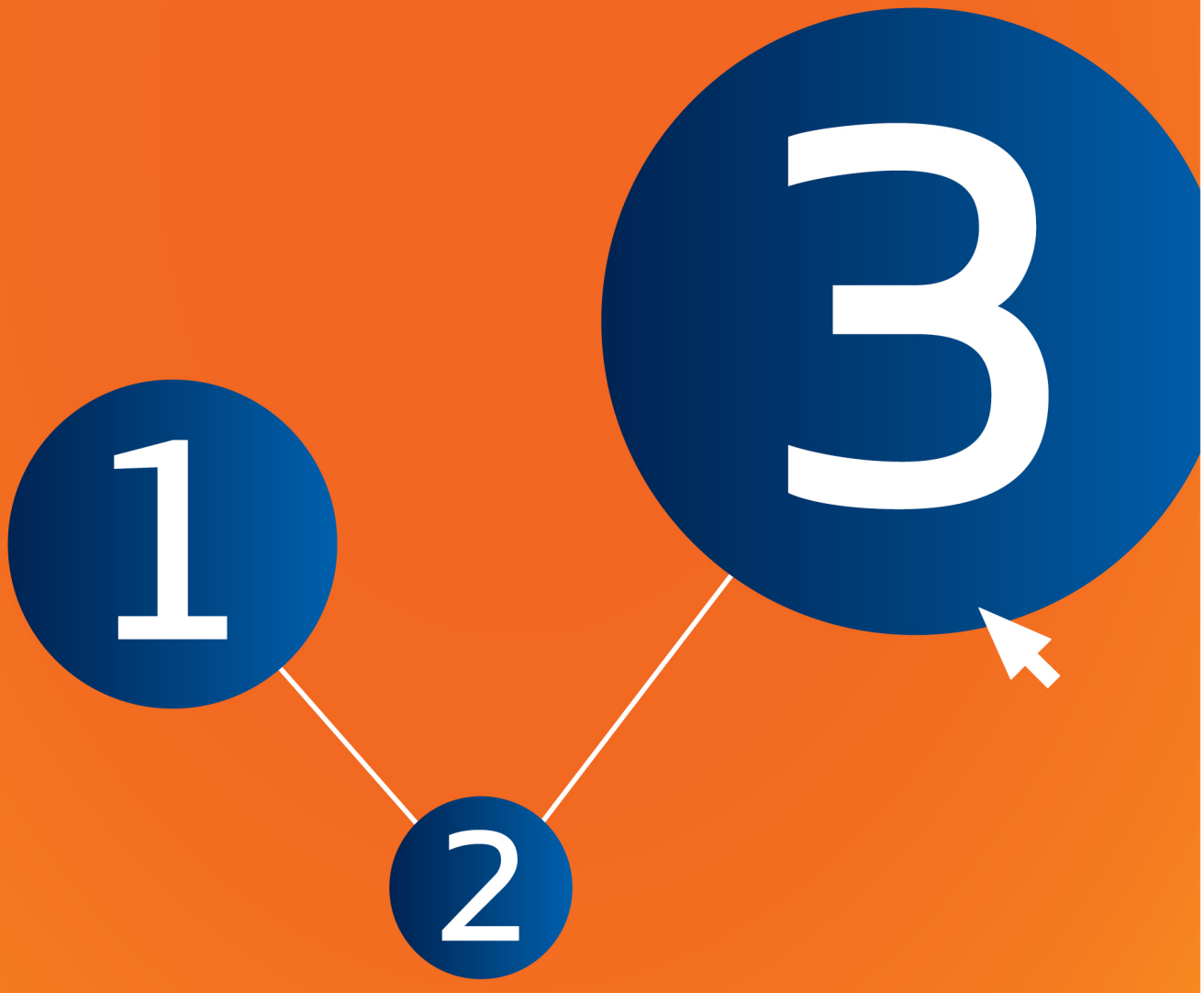
ECHA
EUROPEAN CHEMICALS AGENCY

MANUAL

Data Submission Manual

Part 2 - How to prepare and submit an inquiry dossier using IUCLID 5



Version	Changes
2.1	November 2012 Document updated to reflect new automated business rules following the release of the update of REACH-IT. The Co-Registrants page is the new functionaliy for the provision of information after the submission of the inquiry. Editorial changes across the document.
2.0	July 2012 Document updated to reflect changes introduced by IUCLID 5.4 and to inform users of the Technical Completeness Check plug-in (TCC plug-in), which can now be used to check an inquiry dossier before submitting it to ECHA (P 7, 18 and 49). P 8: Added clarification on cases where an inquiry is not necessary.
1.4	March 2010 Description of the dossier submission process using REACH-IT 2.0 and IUCLID 5.2.
1.3	December 2009 Minor textual revisions. P 8: Text on Legal Entities updated. Document in new layout.
1.2	December 2008: P 34-35: Text amended to explain how to indicate the inquiry is based on Article 12(2). P 45: Text amended to read as follows: “Step 5: In the field “Name” please type the substance name the inquiry relates to and in the “Dossier submission remark” field type “Inquiry dossier”. If your inquiry is as a result of an update of your registration due to a tonnage band increase (Article 12(2) of the REACH Regulation) in this field type “Inquiry as a result of an update of a registration”. If your substance is a non-phase-in substance legally on the market before June 2008 (see 9th of June ECHA press release (ECHA/PR/08/12) available on the ECHA website in the “Dossier submission remark” field type “Inquiry dossier for non-phase-in substance legally on the market before June 2008”.

	In this field you must also give a justification as to why such placing on the market was considered lawful." P 50: Text deleted in reference to submission using temporary procedures.

Part 2 - How to prepare and submit an inquiry dossier using IUCLID 5

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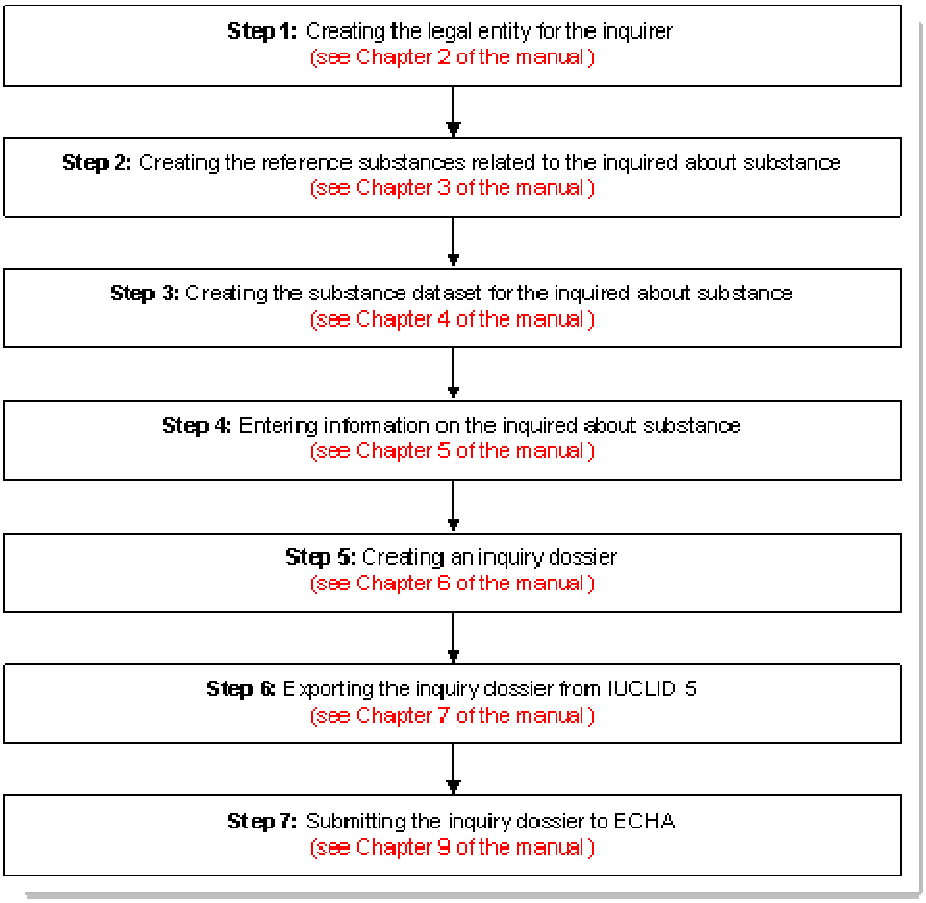
1. Introduction

The purpose of this manual is to assist in the preparation of an inquiry dossier using IUCLID 5. The manual assumes that IUCLID 5 has been installed and that you have a user account assigned to the Legal entity created during the installation of IUCLID 5. If IUCLID 5 has not yet been installed, please consult the IUCLID 5 website available at http://iuclid.echa.europa.eu/. On this website, you can download the software free of charge, and also find more comprehensive guidance about the use of IUCLID 5.

This manual provides a stepwise approach for the preparation and submission of an inquiry dossier as shown in Figure 1.

Figure 1: Steps for creating an inquiry dossier



An IT tool has been developed to provide further assistance on how to prepare an inquiry dossier. This tool is called "Substance Identity check" and it is available as a feature of the "Technical Completeness Check (TCC) plug-in". This IUCLID plug-in can be downloaded via IUCLID 5 website (http://iuclid.echa.europa.eu/).

The tool assists in identifying the IUCLID fields of an inquiry dossier that should be filled in or that deserve particular attention. It is recommended to use the TCC plug-in on the substance dataset and on the final dossier before submitting. For further information on how to use the TCC plug-in, please refer to the "IUCLID 5 Technical Completeness Check Plug-in User Manual" that is available with the downloaded TCC plug-in.

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

Are you a potential registrant?

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

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

(1) at the latest six months after your manufacturing, importing or using the substance exceeds the one-tonne per year threshold and

(2) at least 12 months before the relevant deadline for your registration in Article 23 REACH.

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

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

Are you already a registrant?

According to Article 12(2) of Regulation (EC) No 1907/2006 ("the REACH Regulation") a registrant of a substance reaching the next tonnage threshold shall inform ECHA of the additional information required for updating the registration. If additional information is **not** required, it is not necessary to inform ECHA of your intention to update your registration for the next tonnage band and therefore to submit an inquiry. In such case the inquiry dossier will not be accepted for processing.

2. Legal entities

All information created or imported in a IUCLID installation, e.g. a Substance dataset is associated to one company/organisation which is the owner of the dataset. The information describing a company/organisation is maintained in a specific IUCLID element called a Legal entity. In order to submit an inquiry dossier, you need to have an official legal entity.

The creation of an official legal entity can be done either via the official IUCLID 5 website http://iuclid.echa.europa.eu/ or directly in REACH-IT. Information regarding how to create an official legal entity can be found in the REACH-IT Industry User Manual Part 2 – Sign-up and account management' available on the ECHA website (http://www.echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals).

3. Creating and updating reference substances

To correctly identify the substance you wish to inquire about, it is important to understand the concept of substance, Substance dataset and Reference substance in IUCLID 5.

The inquiry dossier is prepared for a substance (a substance is defined under Article 3(1) of the REACH Regulation).

In IUCLID 5, the substance dataset contains all the information related to a specific substance (such as the identity of the substance, its consituents, the specific composition, etc.).

To create the Substance dataset, you will need to use reference substances. A reference substance enables you to store in a central place identification information on a given substance or a given constituent of a substance, such as chemical names (EC name, CAS name, IUPAC name, synonyms, etc), numerical identifiers (e.g. EC number, CAS number), molecular and structural information. The Reference substance inventory is directly maintained by you, in your local installation and can then be re-used in other datasets without having to retype the information.

To extend the number of entries in your Reference substance inventory, it is recommended to download the ca. 70,000 pre-filled Reference substances from the IUCLID 5 website and import them to your local installation (unless already done so during the IUCLID 5 installation). These pre-defined Reference substances have been prepared to improve data quality and minimise data entry.

In addition, you should also download the EC inventory from the IUCLID 5 website (unless already done during the IUCLID 5 installation). The EC inventory consists of a list of substance identities which is based on a combination of the following EU inventories: EINECS, ELINCS and NLP-list. When creating a new Reference substance with an EC number, first extract the data from the EC inventory to minimise data entry and ensure data quality.

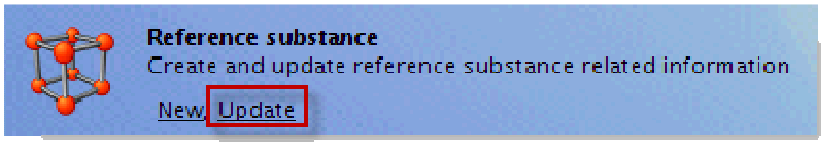
In this chapter of the manual, you will find the procedure to be followed for searching, updating and creating the Reference substances to be assigned to your substance directly from the main task panel.

⚠ It is also possible to create a Reference substance directly from the Substance dataset (chapter 5).

3.1. Querying and updating Reference substances

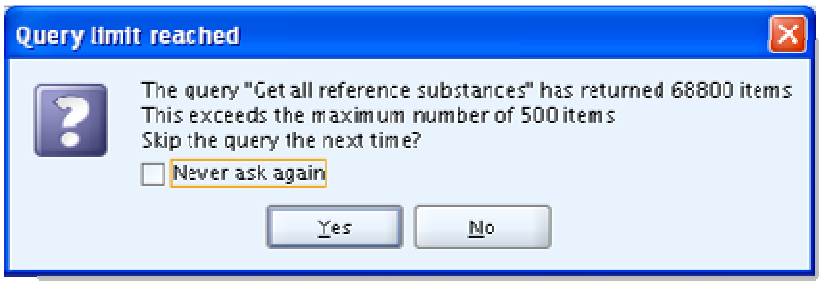
To start click "Update" under "Reference substance" on the main IUCLID task panel (Figure 2).

Figure 2: Update link under the reference substance



If during the installation of IUCLID 5 you chose to download and install the Reference substance inventory, you will have approximately 70,000 Reference substances stored in your computer. A warning will appear, indicating that the default query limit is 500 items (Figure 3).

Figure 3: Query limit reached

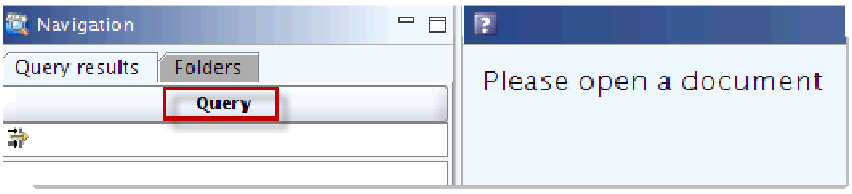


If you answer "Yes", the query for all Reference substances will be skipped the next time you update the inventory.

If you answer "No", IUCLID will retrieve the full list of Reference substances the next time you choose to update the Reference substance inventory. Either way, you will be redirected to the Reference substances screen (Figure 4).

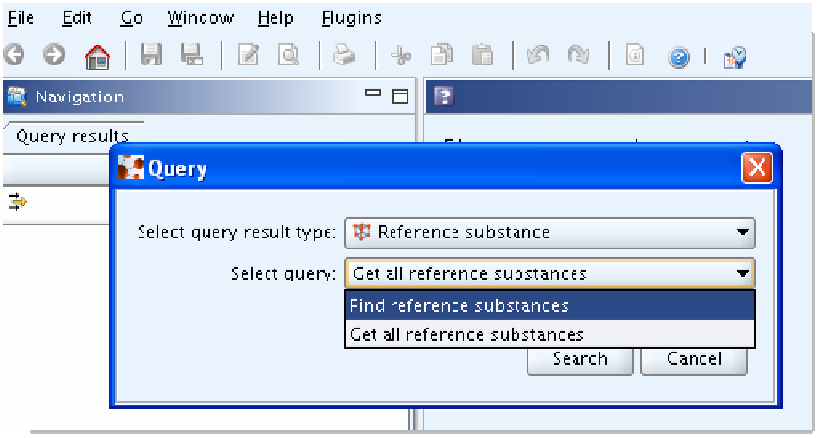
On the Reference substance screen, click on <Query>.

Figure 4: Query button



A dialogue box will appear. Select from "Select query result type" the "Reference substance" and "Find Reference substances" from the "Select query" drop-down-list (Figure 5).

Figure 5: Query drop-down-list

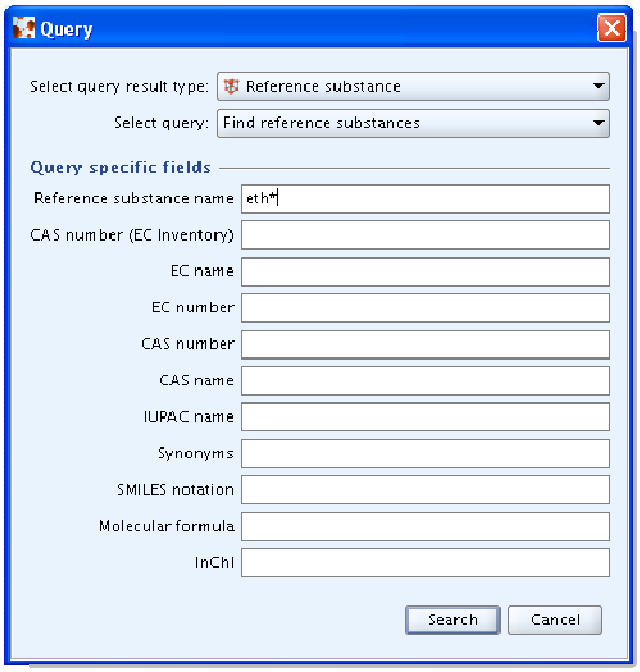


Type the search criteria for the substance you are looking for and click on <Search>. You can use the asterisk (*) as a wild card.

For example, to get all the substances starting with "phenol", type "phenol*". To get all the substances ending in "amine", type "*amine". To get all substances that include "eth" in their nametype "*eth*" (Figure 6).

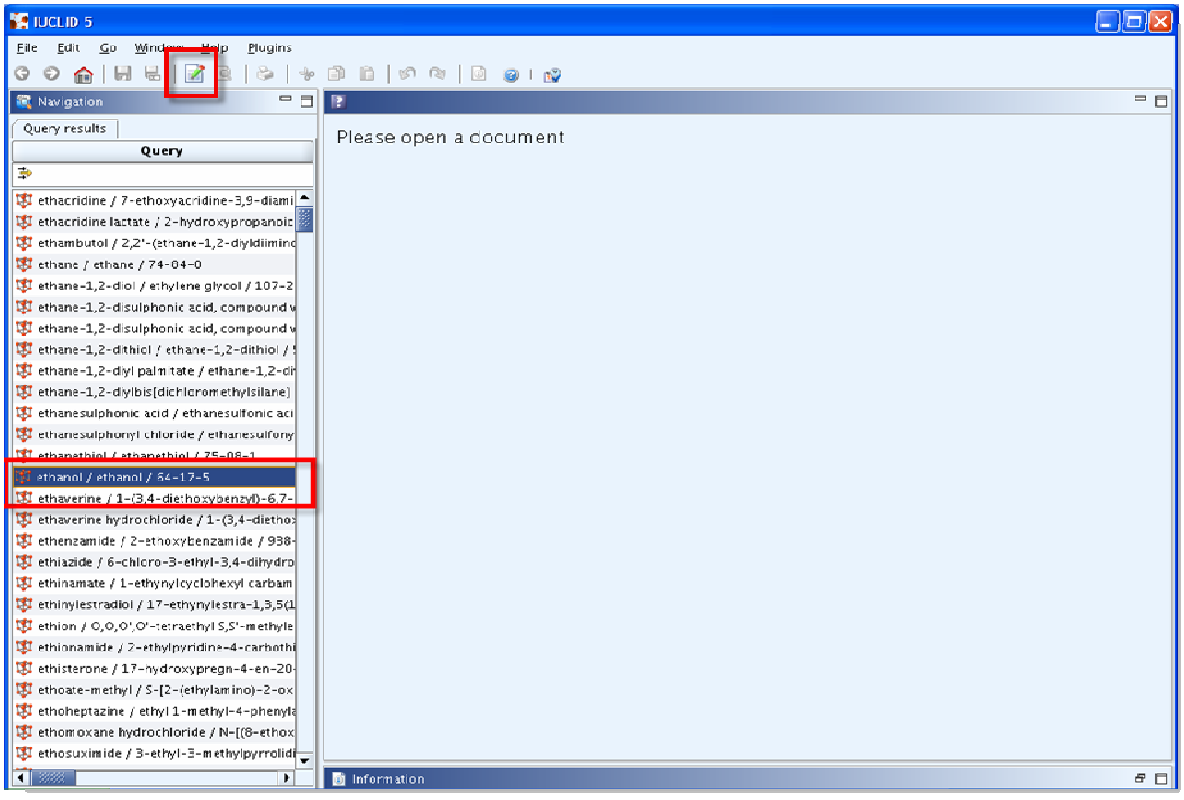
Only 2000 search results can be shown, so your search should be sufficiently specific.

Figure 6: Searching for a reference substance



Once you found it, double click the Reference substance to display the related data (Figure 7).

Figure 7: Displaying data



Check the data on the Reference substance. To update/add any information on the Reference substance, click on <Edit item> (Figure 7) in the toolbar on the top of the screen.

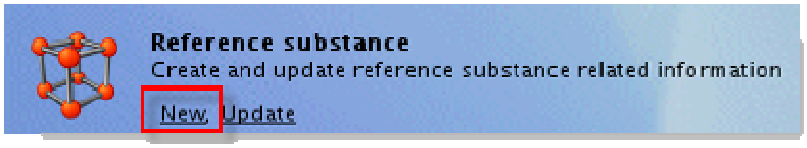
Edit the information on the Reference substance, and save the changes.

3.2. Creating a new Reference substance

If you do not find your Reference substance from the Reference substance inventory, you can create it following the steps below.

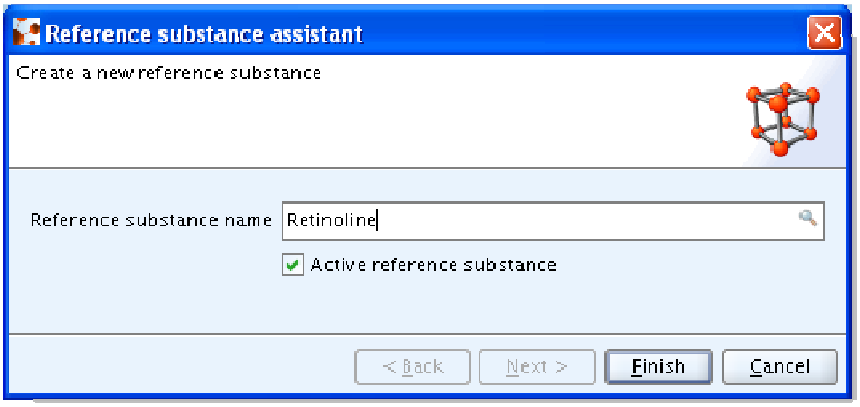
In the main screen click "New" under "Reference substance" (Figure 8).

Figure 8: New link under the reference substance



Type the name of the Reference substance in the "Reference substance assistant" pop-up window. Tick the box "Active Reference substance", as only Reference substances marked as "active" can be used during the creation of a Substance dataset (Figure 9).

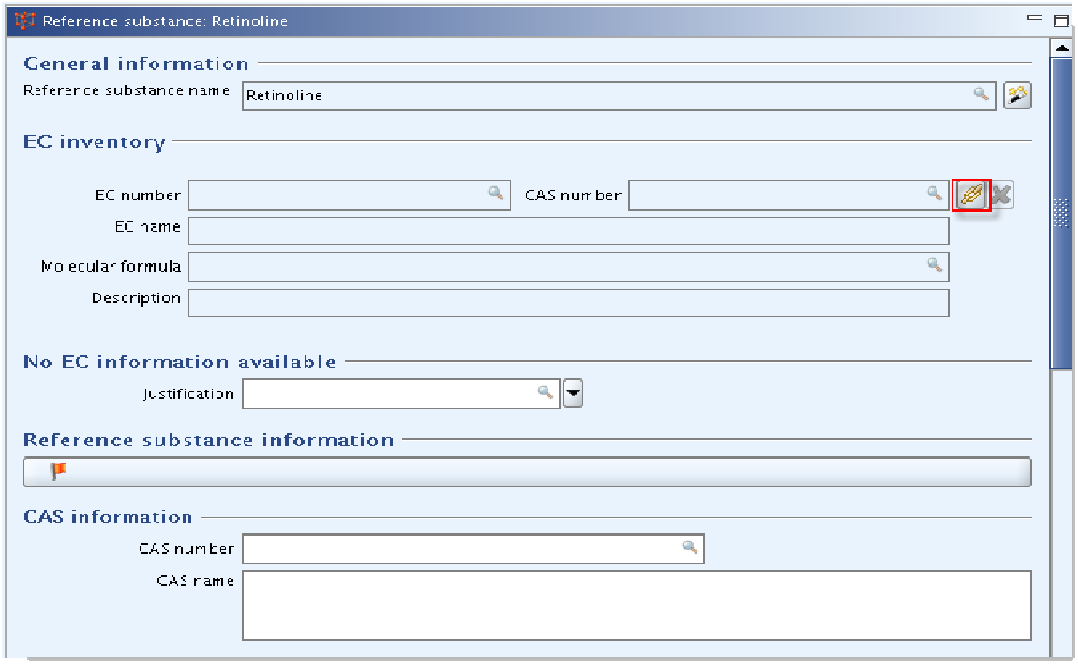
Figure 9: Adding reference substance name



The Reference substance is created, and an empty Reference substance section appears.

If the Reference substance is listed in the EC inventory, the relevant entry can be assigned to it by clicking the chain button as shown in Figure 10.

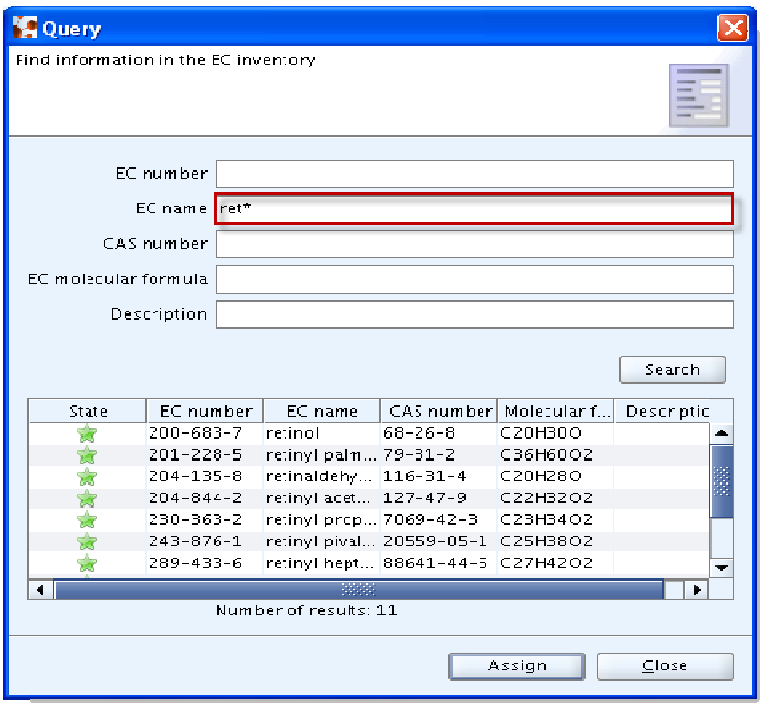
Figure 10: Reference substance section



The query dialogue appears in which EC inventory entries can be searched (Figure 11):

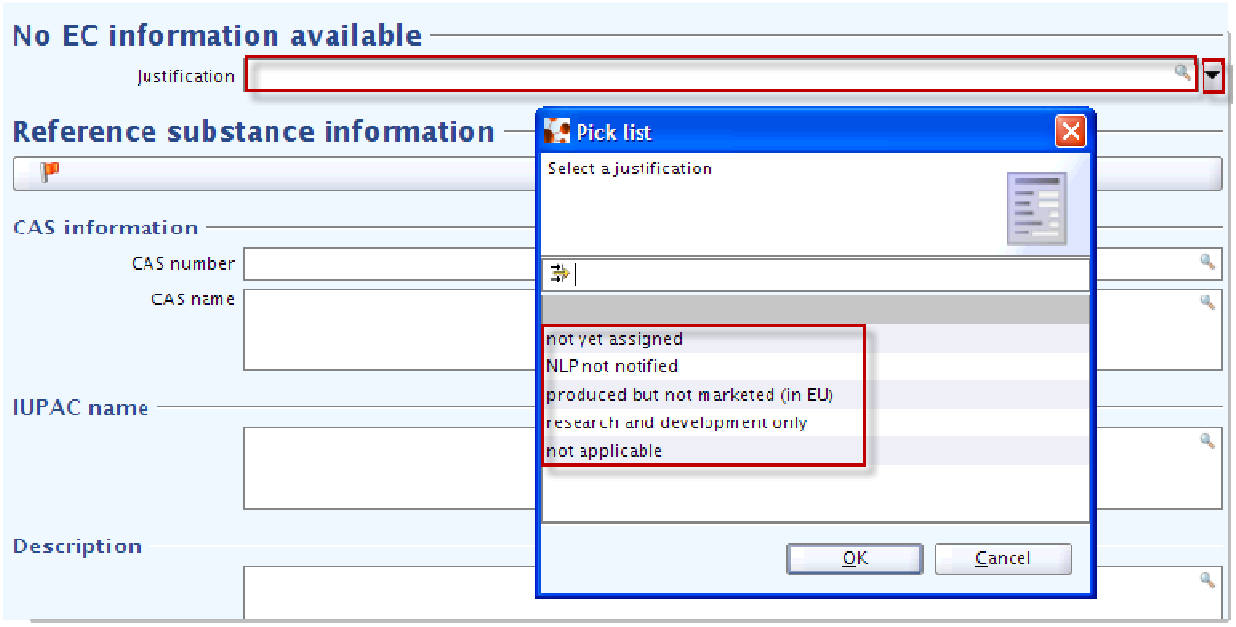
- Search by using any of the criteria listed, such as the EC name of the substance. Again, you can use "*" as a wild card (Figure 11).
- Click the entry that matches your Reference substance (the entry is highlighted).
- Click on <Assign>. The information available for this Reference substance will be included in your new Reference substance.

Figure 11: Searching for a reference substance



If your Reference substance is not listed in the EC inventory, select a justification from the drop-down-list proposed under the "No EC information available" section.

Figure 12: Justification field

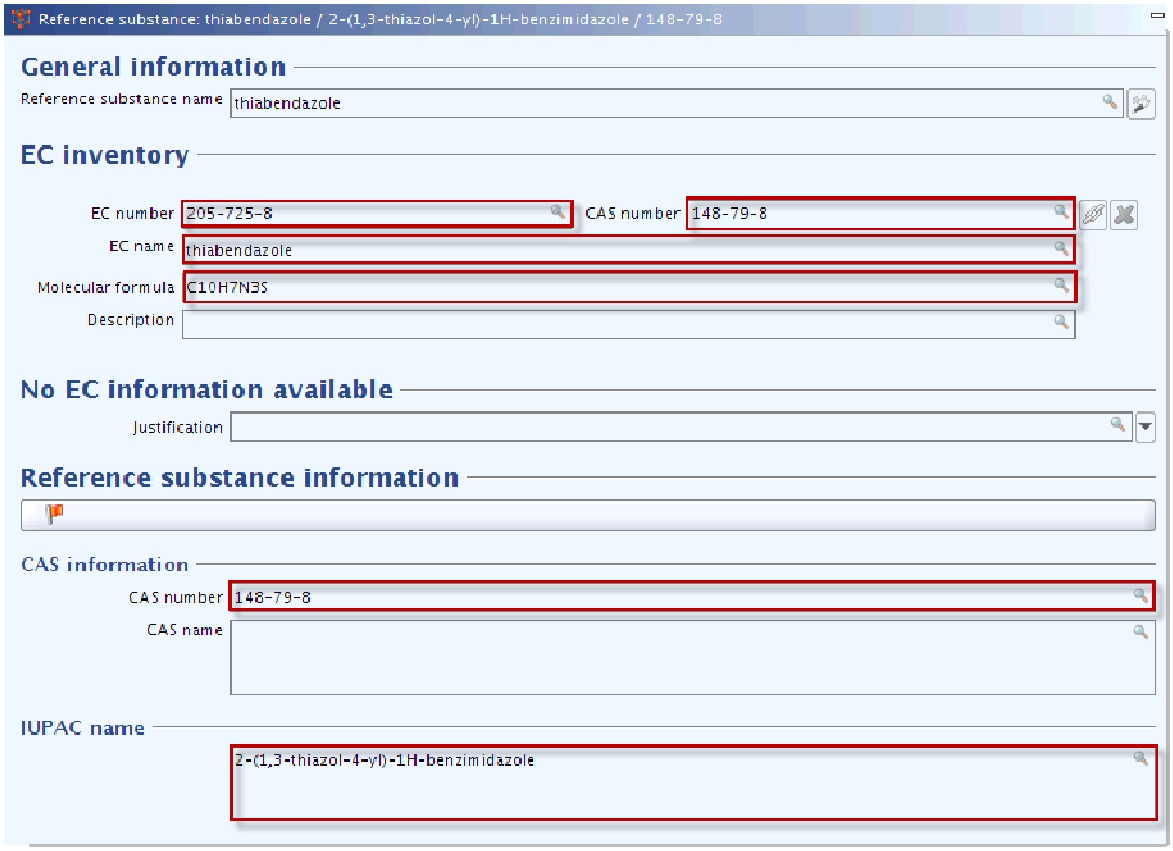


Complete as far as possible the fields to define your Reference substance (see example in Figure 13).

You should provide the following:

- EC number and EC name (if available);
- CAS number and CAS name (if available);
- IUPAC name;
- Description (specify any additional information relevant for the description of the Reference substance in this field);
- Molecular formula (if a molecular formula cannot be derived from the Reference substance, a justification should be indicated in the "Remarks" field at the bottom of the screen);
- Molecular weight range (if applicable);
- SMILES notation (if applicable);
- InChI (if applicable);
- Structural formula (if applicable).

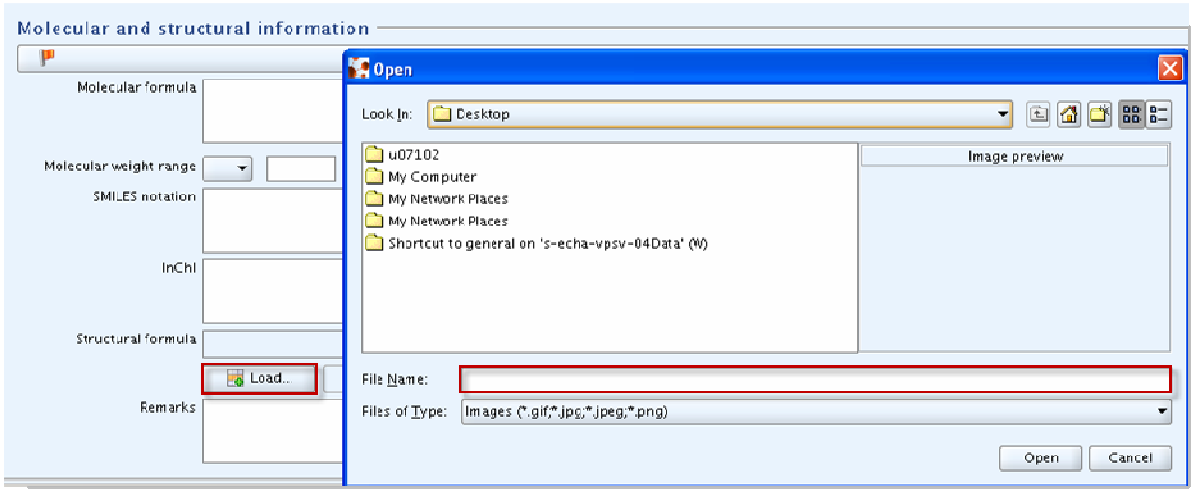
Figure 13: Completed reference substance



In order to include the structural formula, go to "Structural formula", under "Molecular and structural information" and click on <Load>. You can then upload an image file with the structural formula (Figure 14).

A reference substance needs to be prepared for the substance and for each constituent (main constituent, impurity, additive) your substance contains.

Figure 14: Uploading the structural formula

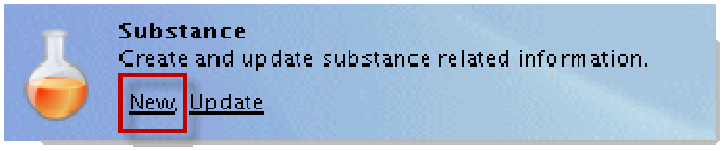


4. Creating a substance dataset

To create an inquiry dossier in IUCLID 5, you need first to create a Substance dataset. A Substance dataset is the repository of data, which is used as a basis to create the inquiry dossier to be submitted to ECHA.

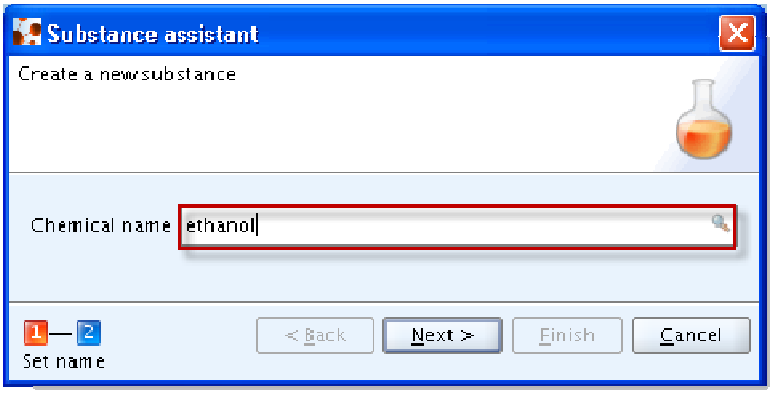
To create a Substance dataset you need to click "New" on the IUCLID 5 task panel, under tasks (Figure 15).

Figure 15: Link for creating a new substance dataset



Type the name of the substance you wish to inquire about. The name can be anything, but please use an identifier that you are familiar with (e.g. a trade name or chemical name (Figure 16).

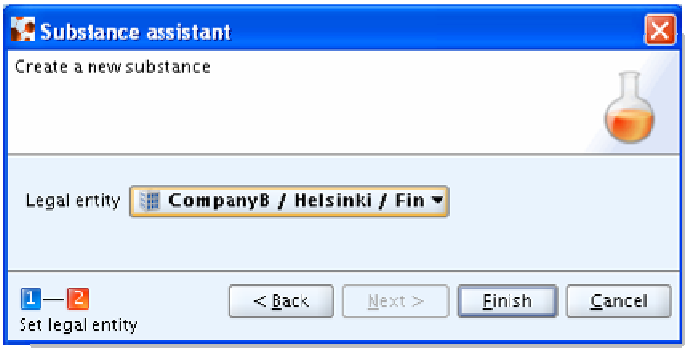
Figure 16: Name of your substance



Click on <Next> and select the legal entity to be assigned in the Substance dataset

(Figure 17).

Figure 17: Assigning a legal entity

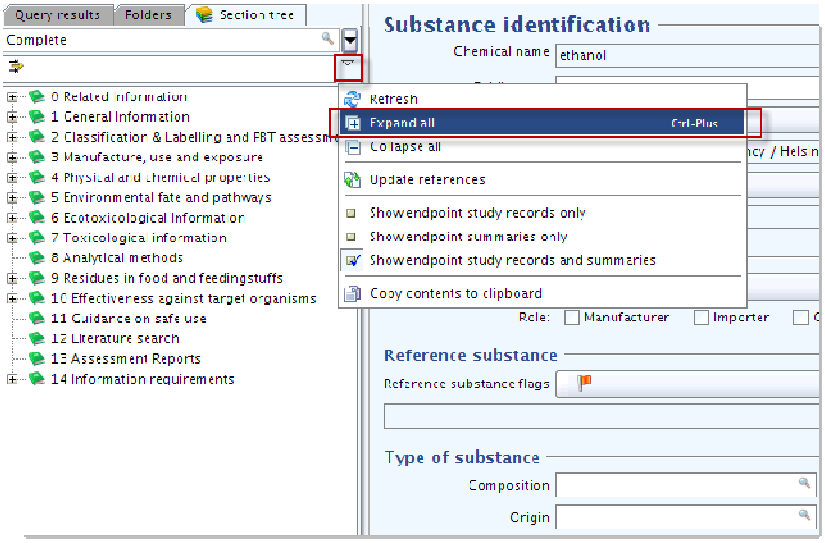


If the legal entity to be linked to the Substance dataset is not available from the drowp-down-list, a new Legal entity should be assigned to the user. Please refer to the instructions provided on the IUCLID 5 website and in the REACH-IT Industry User Manual 'Part 2 – Sign-up and account management' available on the ECHA website (http://www.echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals).

Click on <Finish>: you have created a Substance dataset.

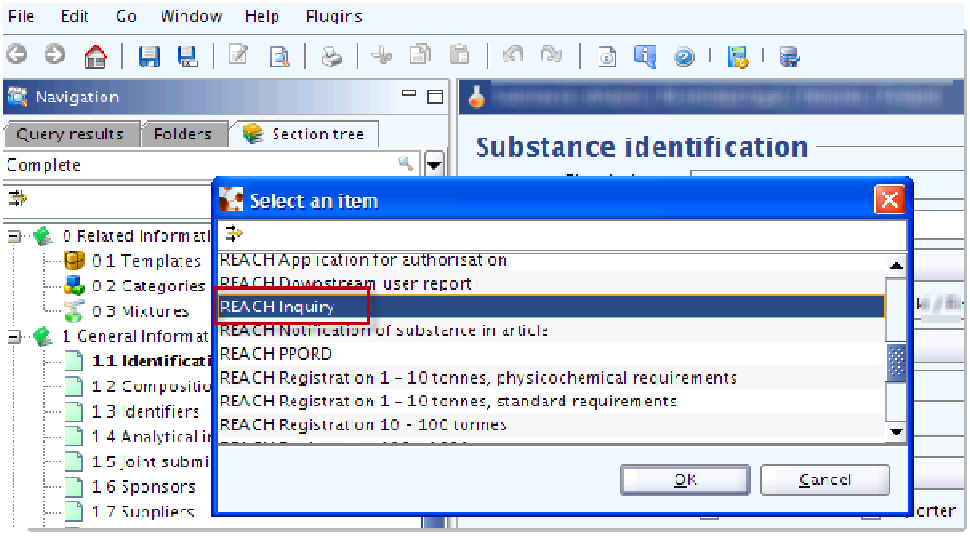
The section tree of your Substance dataset is displayed in the navigation pane of the screen (to see the complete tree view click the white arrow button and select "Expand all" from the pop-up menu) (Figure 18).

Figure 18: Expanding the section tree



IUCLID 5 offers the possibility of highlighting sections that are mandatory for specific dossier types in order to assist the user in the preparation of various types of dossiers. For inquiry dossiers choose "REACH Inquiry" as a type of a dossier by clicking the black arrow button and select "REACH Inquiry" from the drop-down-list.

Figure 19: Selecting the template from the drop-down-list



After selecting "REACH Inquiry" as a dossier type, the mandatory sections are marked with red in IUCLID 5 and optional sections are shown in green.

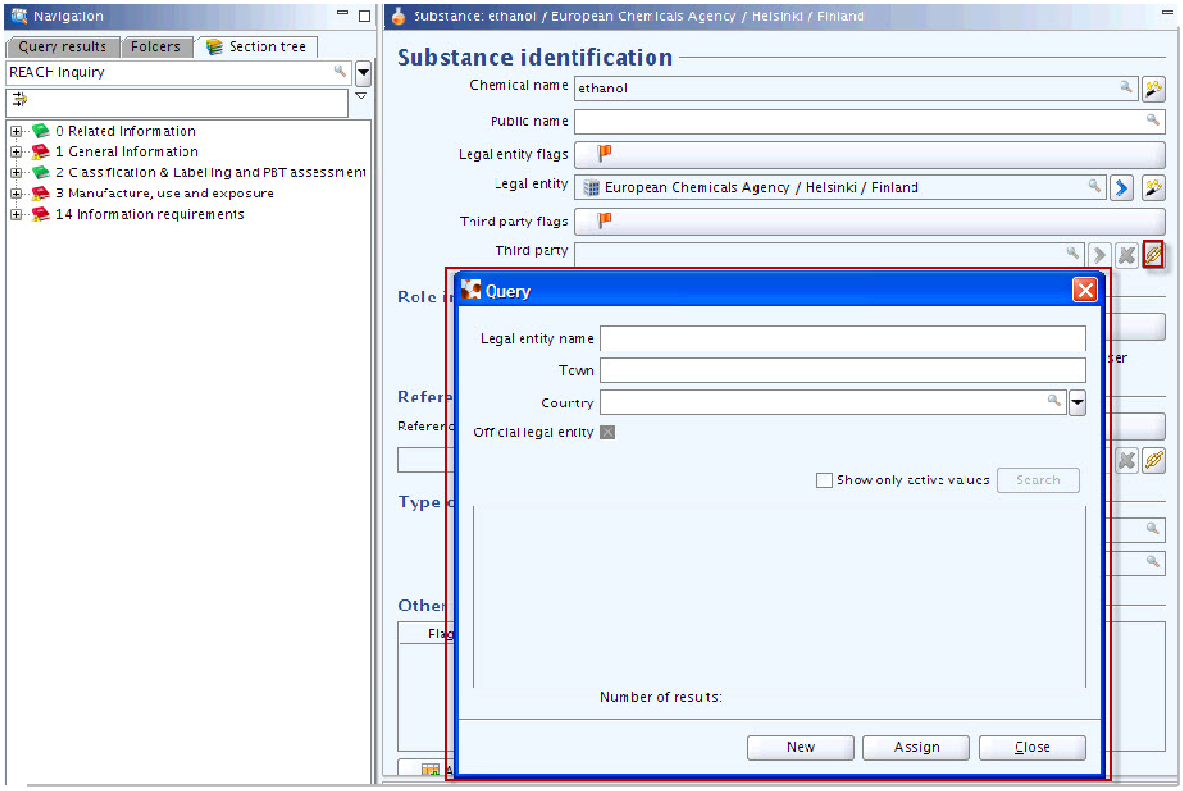
4.1. Assigning a third party representative

It is not compulsory to indicate a third party representative. However if a third party representative (TPR) has been appointed according to Article 4 of REACH, the legal entity of this TPR must also be provided in the block "Substance identification". In order to assign a TPR, you need to get from your TPR their company UUID (official legal entity).

For further information regarding how to create and/or import official legal entities, see IUCLID 5 website and the REACH-ITIndustry User Manual 'Part 2 – Sign-up and account management' available on the ECHA website (http://www.echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals).

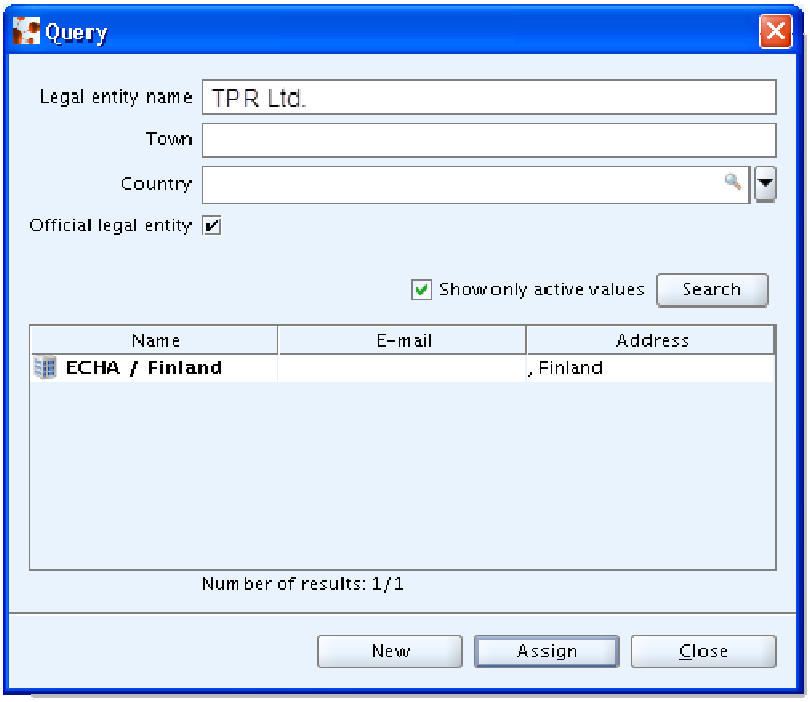
Once you obtained the company UUID of your TPR in your local IUCLID 5, it can be assigned to your Substance dataset. Click the chain button next to the TPR (Figure 20). A "query" dialogue appears. Ensure that the "Official legal entity" and "Show only active values" checkboxes are ticked.

Figure 20: Querying third party representatives



Type the search criteria and click on <Search>. You can use the asterisk (*) as a wild card. Click the TPR you wish to assign to your Substance datase (it is highlighted) and click on <Assign>: TPR has now been assigned (Figure 21).

Figure 21: Assigning a third party to your inquiry



5. Entering information in the substance dataset

Once you have created a Substance dataset for the substance for which you want to make an inquiry, you can enter data regarding the substance in this dataset. The information required to be included in the Substance dataset is described in the REACH Regulation (Article 26(1)) and the associated Data Sharing guidance available on the ECHA website (http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach).

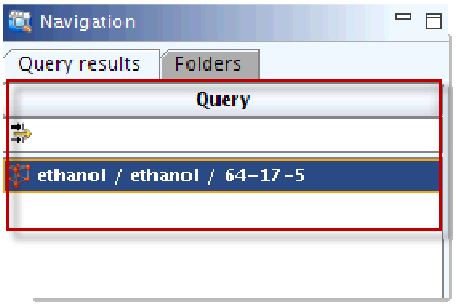
Remember that further information on the description of substances in IUCLID 5 is available in the Guidance for Identification and Naming of substances under REACH and CLP. This guidance is also available on the ECHA website (http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach).

To retrieve the Substance dataset you have already created, click "Update" under "Substance" in the main task panel, and select your substance from the list by double clicking it.

To facilitate the retrieval of your Substance dataset, you may either use the filtering system by typing the name (or part of it) of the substance in the query field or use the query system by clicking on<Query>).

Once the substance is displayed in the data entry pane (Figure 22), expand the section tree (by clicking the "Section tree" tab; see Figure 17).

Figure 22: Displaying a substance in query field



Double-click on each section to display it, and click on<Edit item> in the upper part of the screen (Figure 23) to complete the fields.

Figure 23: Edit button in tool bar

5.1. Section 1 - General information

You need to provide information (in the various IUCLID sections) pertaining to the substance identification.

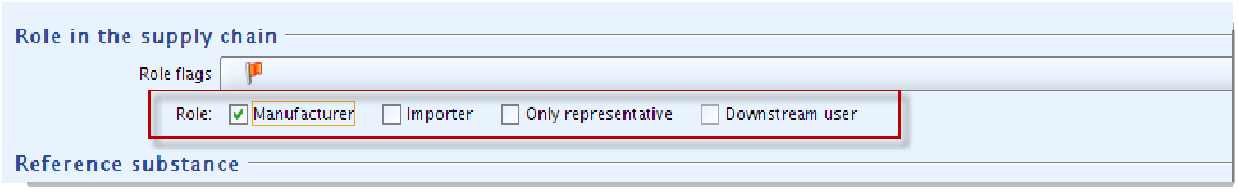
5.1.1. Section 1.1 – Substance identification

This section covers identity of the substance, your role in the supply chain and the contact details.

5.1.1.1. Role in the supply chain

Please use the appropriate tickbox to indicate your role in the supply chain (Figure 24).

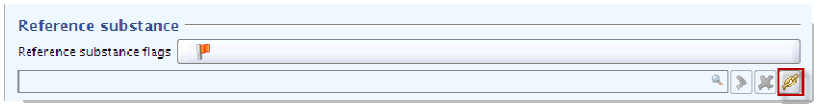
Figure 24: Role in the supply chain



5.1.1.2. Reference substance

In "Reference substance" click the chain button to assign a "Reference substance" to your substance (Figure 25).

Figure 25: Chain button



A query dialogue appears (Figure 26). Search for your "Reference substance". Highlight the Reference substance from the result list and click on <Assign> (Figure 27).

Figure 26: Query dialogue box

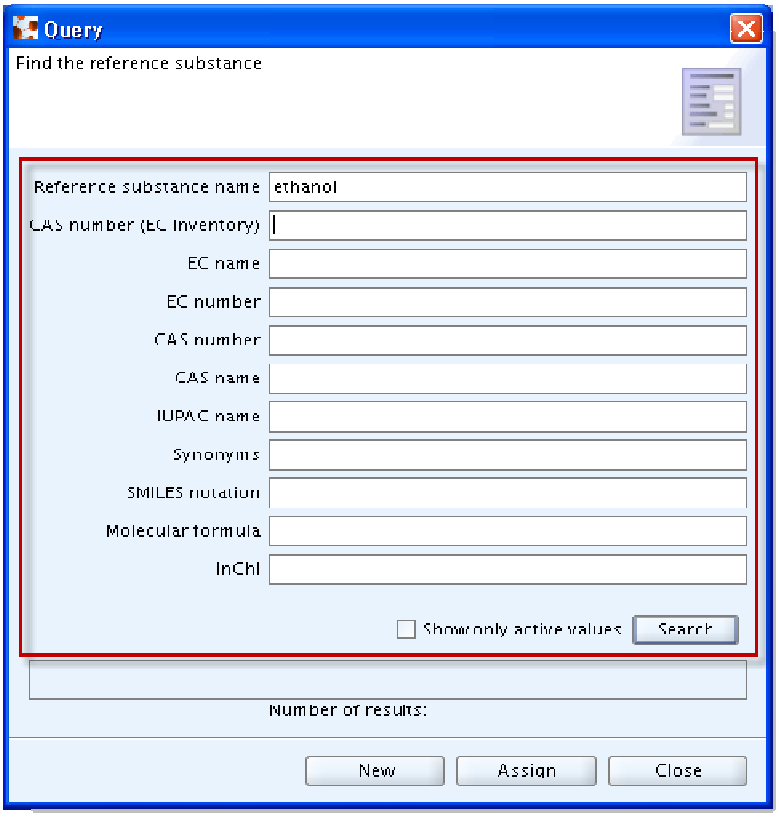
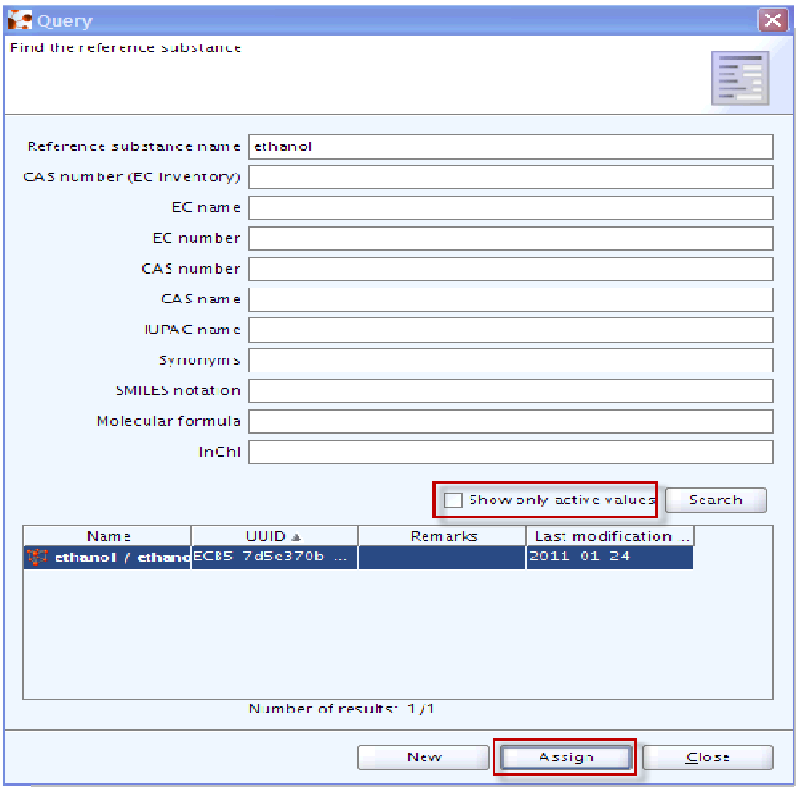


Figure 27: Assigning the reference substance



It is possible that the Reference substance already exists, but you have not set it as "Active". In this case, un-tick the "Show only active values" checkbox to display both active and inactive Reference substances. Right click the non activated reference substance you want to assign and click the "Active reference substance" to activate it. Then click on <Assign>.

If you cannot find your Reference substance, it means that the Reference substance has not been created. Go back to create a new Reference substance by following the instructions given in chapter 3.2 or by taking the following steps:

- Click "New" to create a new Reference substance (Figure 28).
- You will be redirected to the "Reference substance assistant".
- Type the name of the Reference substance you need to create and click the "Finish" button (Figure 29).
- To specify the information on the new Reference substance, click the blue arrow button (Figure 30).
- You will be redirected to the screen for the new Reference substance. Complete all the possible fields as described in the chapter 3- Creating and updating reference substances.
- Click on <Save>.
- Click back arrow button ( ) to go back to the substance (save when requested).

Figure 28: Button for creating a new reference substance

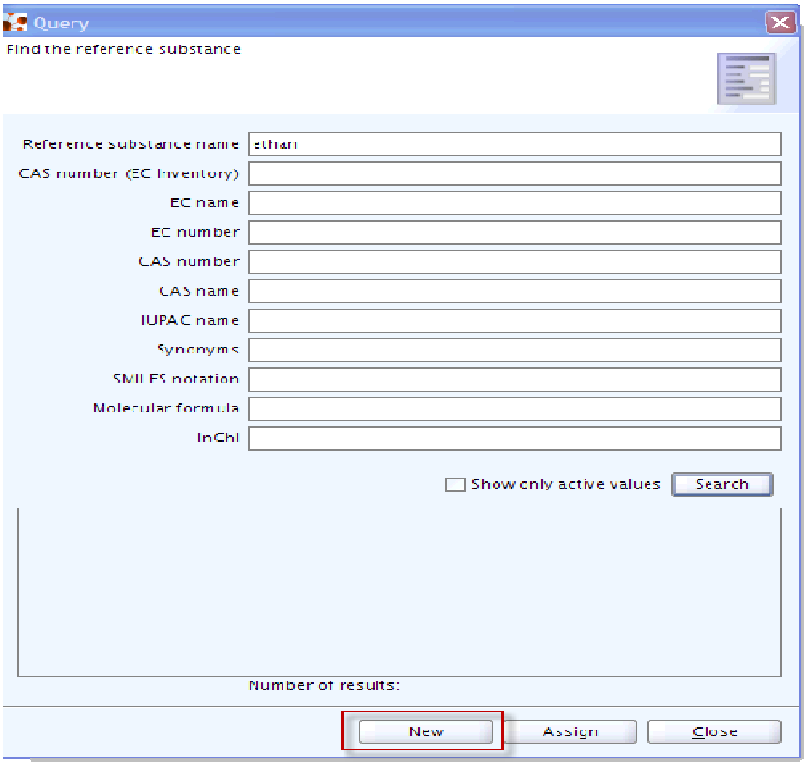


Figure 29: Name of the reference substance

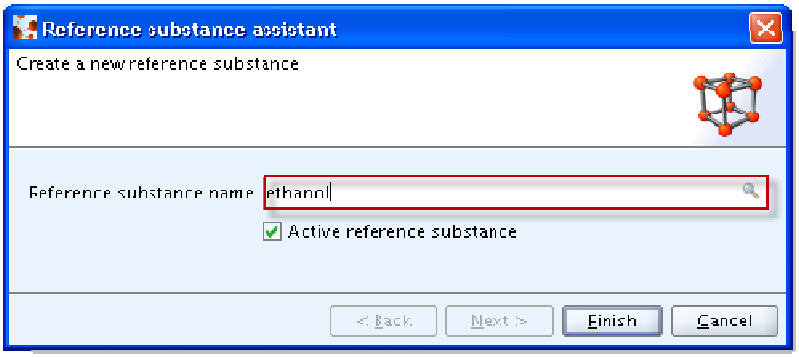
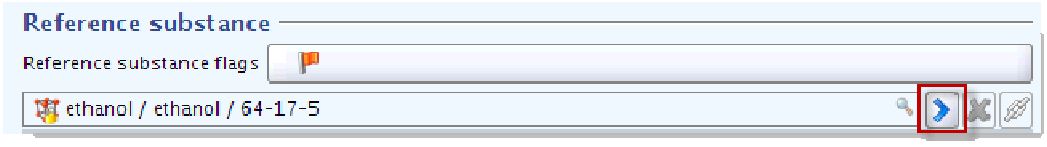


Figure 30: Blue arrow button



Fill in manually all the fields related to the Reference substance (again, complete as many fields as possible).

5.1.1.3. Type of the substance

Information regarding the type of the substance can be included by clicking the down arrow buttons (▼) next to "Composition" and "Origin" and by choosing the relevant item from the drop-down-lists (Figure 31 and Figure 32).

Figure 31: Composition of a substance

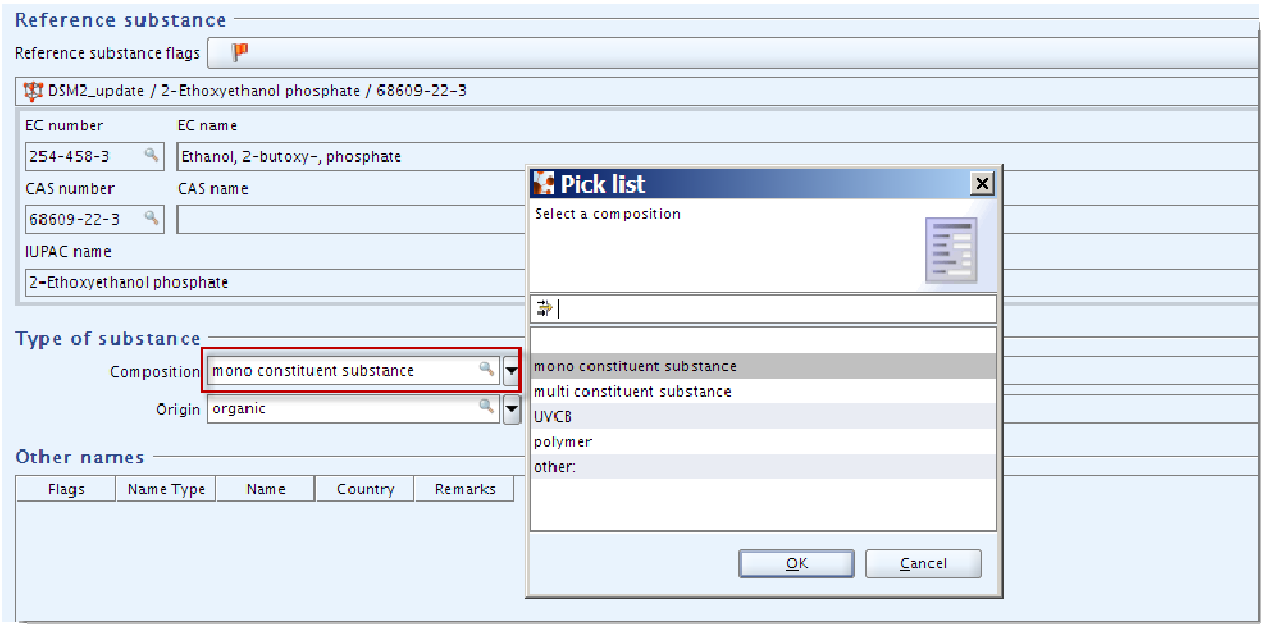
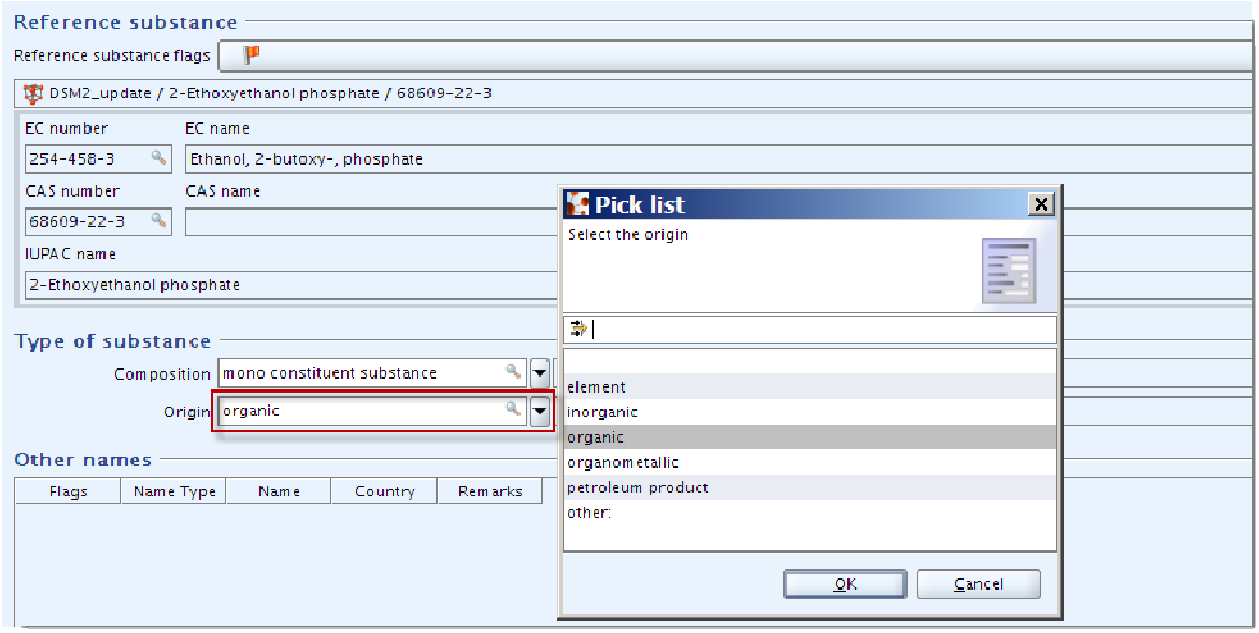


Figure 32: Origin of a substance

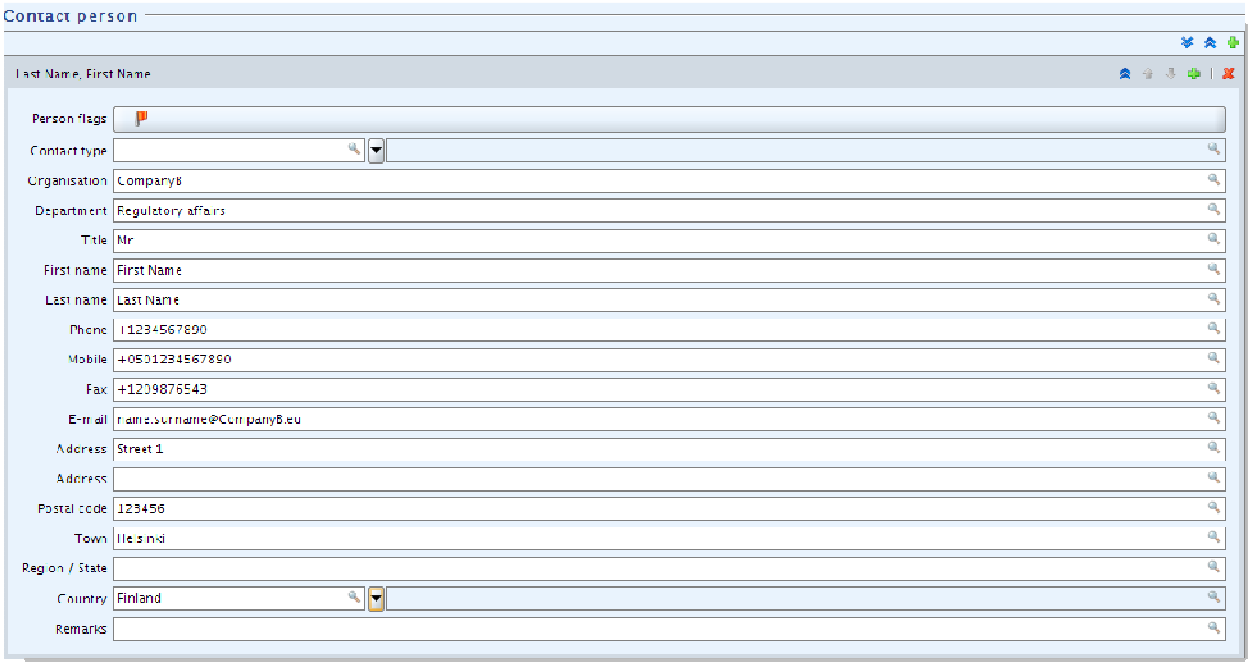


Futhermore the button "Add" (Add...) under "other names" allows you to create additional repeatable blocks, if you want to add alternative names or trade names for your substance.

5.1.1.4. Contact person

Although the contact details of your company are specified in the "legal entity", you can also indicate the details of the contact person for a specific substance. Complete as many of the fields as possible (Figure 33).

Figure 33: Contact details fields

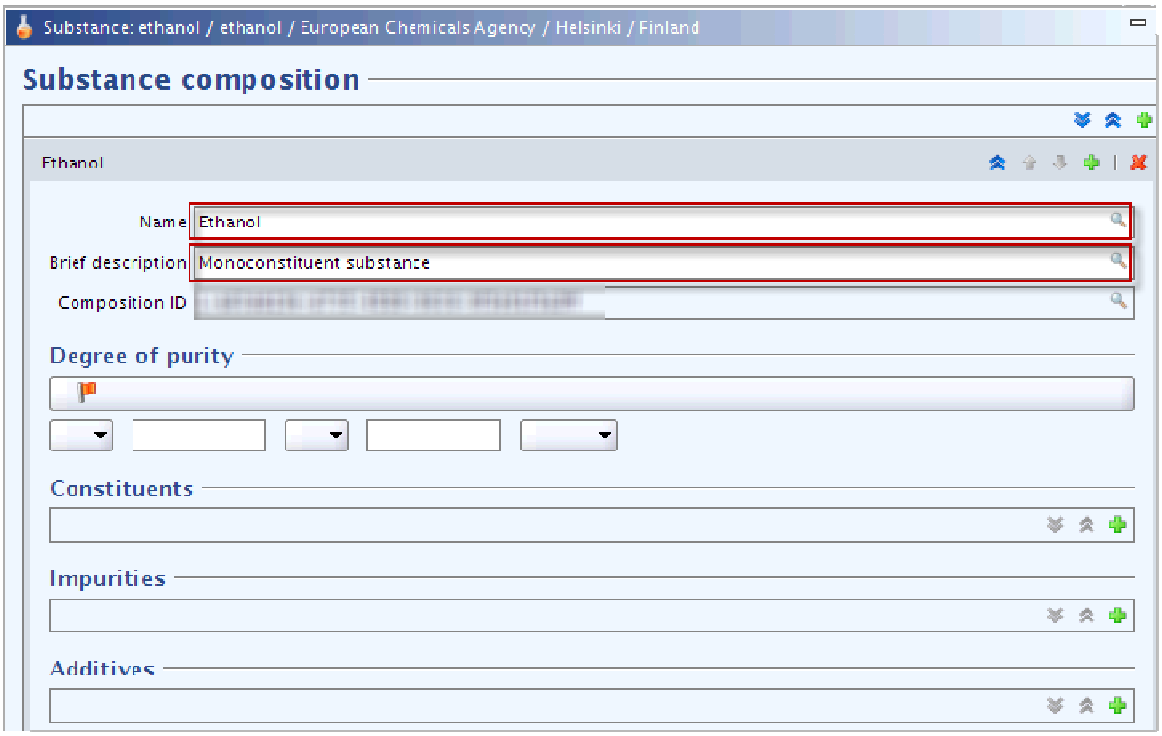


5.1.2. Section 1.2 - Composition

In order to include information regarding the composition of the substance, double click section "1.2 Composition" and click on <Edit item> (Figure 23). Click the green cross "Add" button (Figure 37).

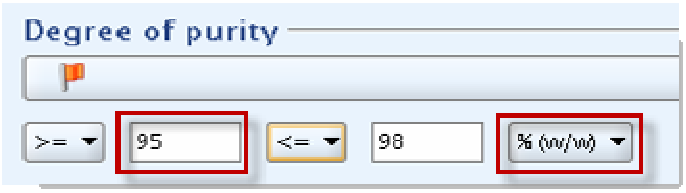
Write the name and a brief description of your substance (Figure 34).

Figure 34: Name of substance



Complete the "Degree of purity" section. The degree of purity to be specified must correspond to the concentration of the main constituent(s) of your substance. The drop-down list allows you to pick symbols or units from a list, and the boxes allow you to type numbers. In this part, give the typical range of purity for the substance (Figure 35).

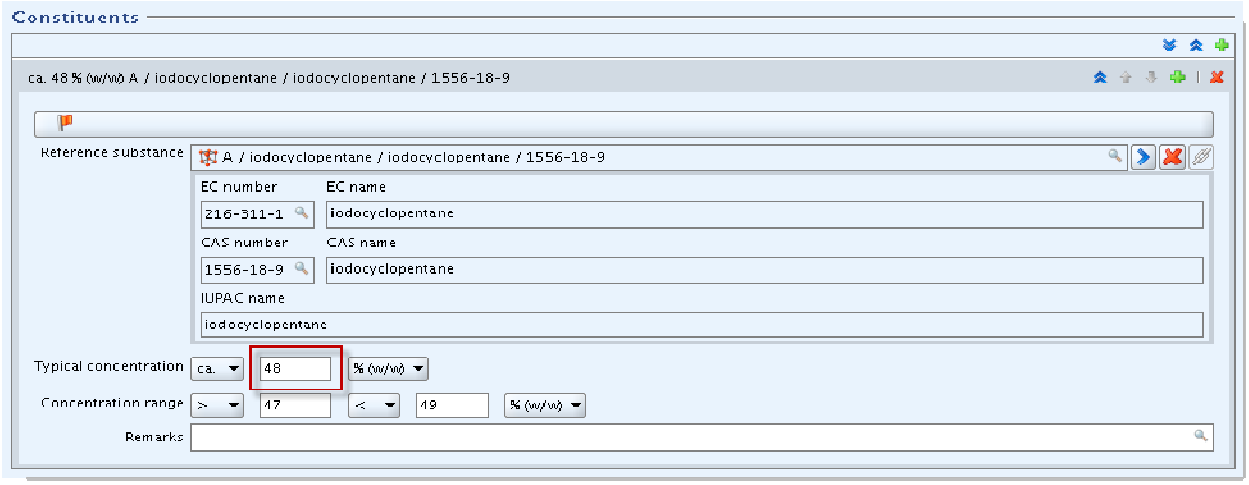
Figure 35: Degree of purity



You can include the constituents by clicking on <Add> button as shown in Figure 37. Assign a "Reference substance" to each constituent by clicking the chain button (Figure 25). Search for the appropriate Reference substance (as described in chapter 5.1.1.2) and add it by selecting it and clicking on <Assign>. If the Reference substance does not exist yet, create a new one (as described in chapter 3.2).

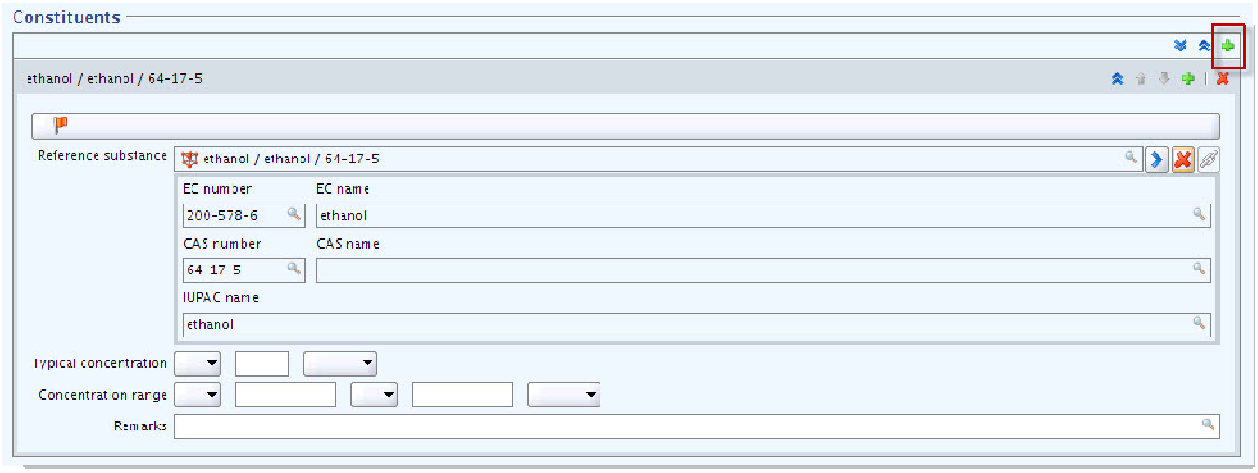
Indicate the typical concentration and the concentration range (minimum and maximum values) for every constituent (Figure 39) in the same manner as indicated above for the degree of purity.

Figure 36: Typical concentrations for each constituent



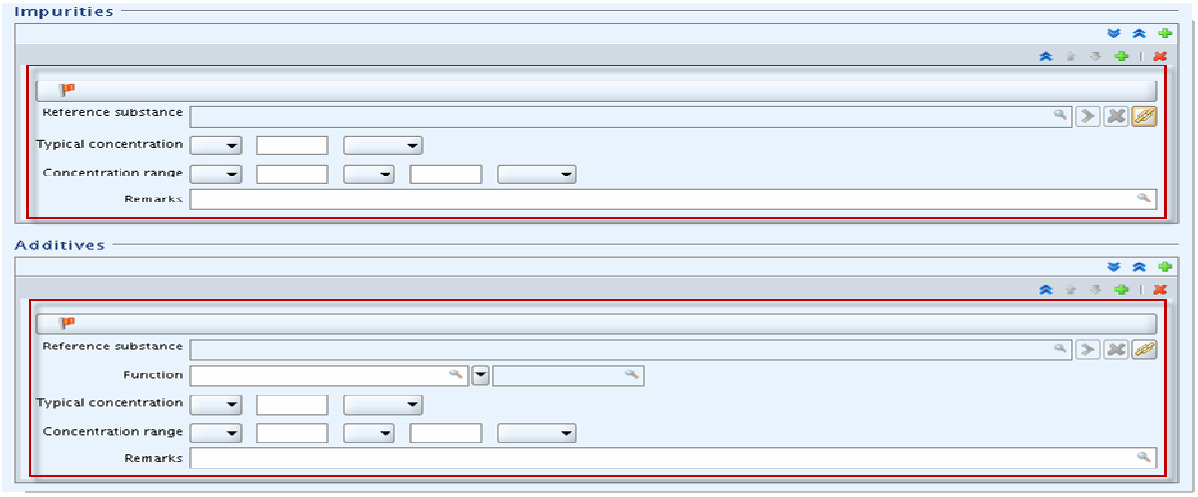
If you need to specify more than one constituent, click on<Add> (Figure 37) in the relevant section, and a new repeatable block will appear.

Figure 37: Green cross add button for additional boxes



Follow the same procedure to complete information regarding impurities and additives fields (Figure 38).

Figure 38: Additional boxes for the impurities and additives

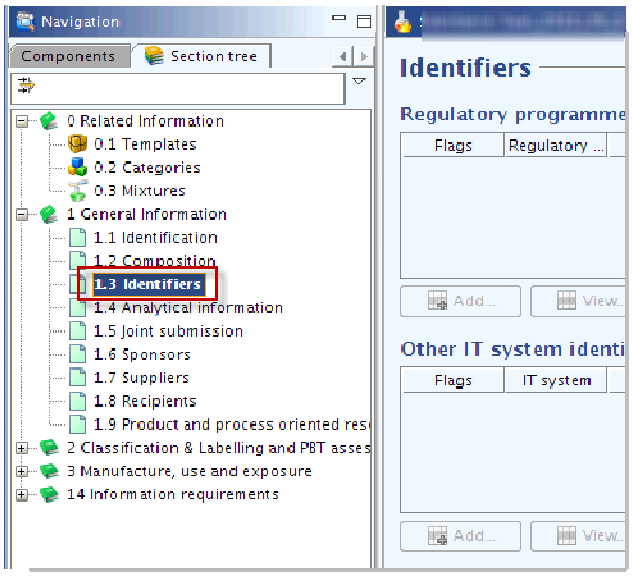


5.1.3. Section 1.3 – Identifiers

In this section, if applicable, you can add identifiers related to other regulatory programmes or IT systems. In particular, indicate your PPORD number if the substance has previously been subject to a product and process orientated research and development (PPORD) notification. If you are subitting an inquiry based on Article 12(2) of the REACH Regulation, indicate your registration number and (if relevant) the notification number in this section.

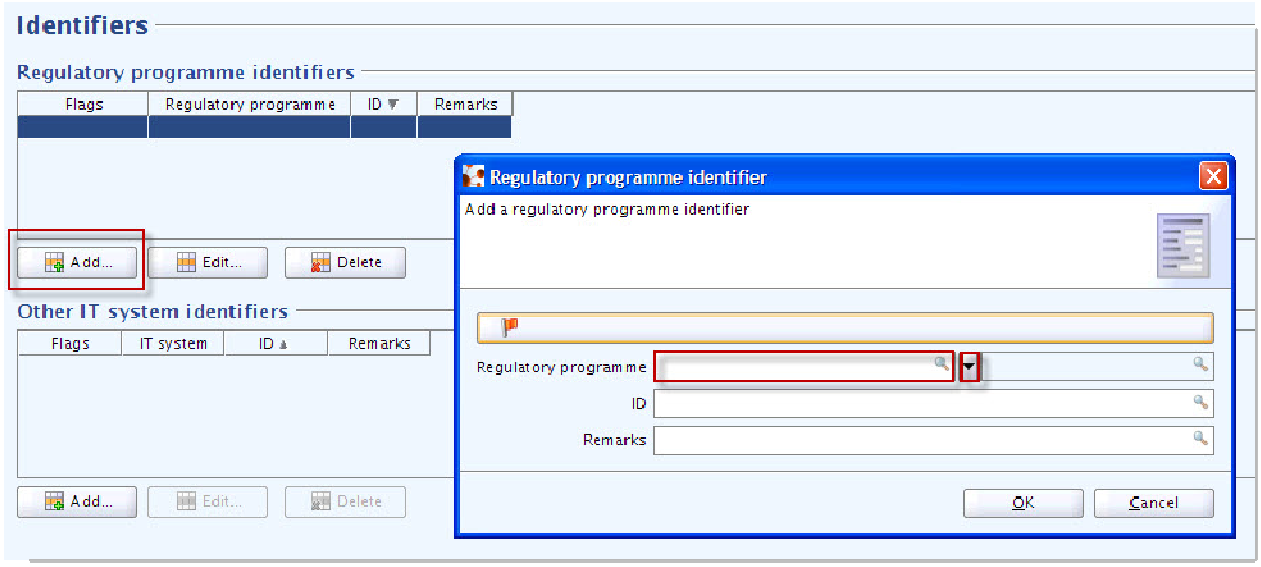
Open section 1.3 of the IUCLID 5 Substance dataset by double-clicking on "1.3 Identifiers" from the section tree and click on <Edit item> (Figure 39).

Figure 39: Opening section 1.3 in IUCLID



In the "Regulatory programme identifiers", select <Add> to edit the list of identifiers. A pop-up window entitled "Regulatory programme identifier" appears on the screen (Figure 40).

Figure 40: Pop-up window



Choose first the relevant option from the drop-down-list ("REACH PPORD notification number" or "notification number (NCD)" or "REACH registration number") and enter then the relevant number in the "ID" field.

Click on <OK> in the "Regulatory programme identifier" window and the regulatory identifiers will appear as a list.

5.1.4. Section 1.4 – Analytical information

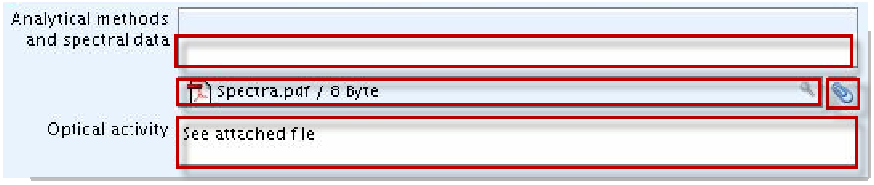
In the section tree of your Substance dataset, double click the section "1.4 Analytical information" and click on <Edit item> (Figure 23).

Under the "Analytical methods and spectral data" field, describe the analytical methods used to characterise your substance, and where appropriate, its impurities and additives. You can also attach such information by clicking the paperclip button ( ).

You can only attach one file in each field.

Under the "Optical activity" field, provide information on the optical activity and typical ratio of (stereo) isomers, whenever applicable (Figure 41).

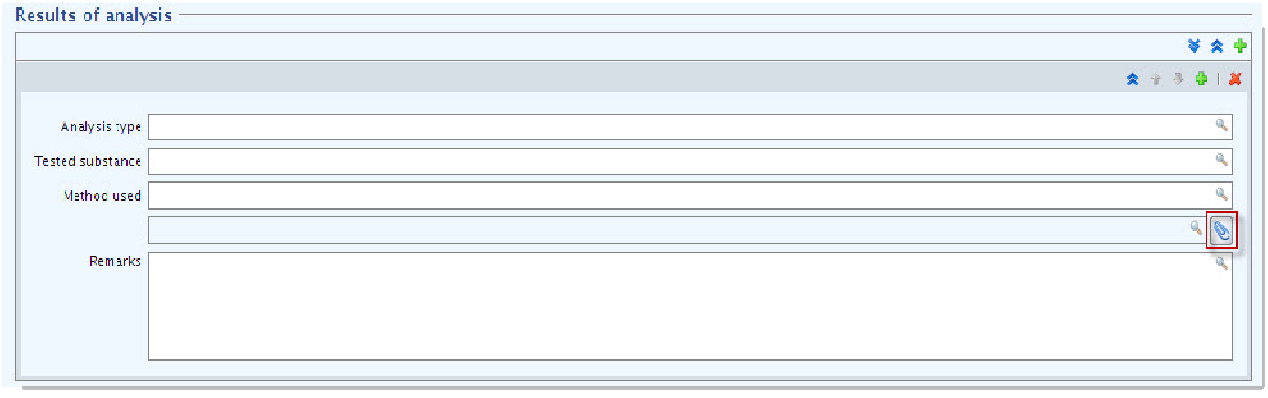
Figure 41: Entering analytical methods and spectral data



The analytical results used to characterise the substance, such as spectral data (UV, IR, NMR, MS, etc.), chromatographic data, etc. are to be provided under "Results of analysis".

For each analytical result, click the green cross button to add a new repeatable block (as shown in Figure 37), and enter the analysis type, the test substance, the method used and any remark you consider relevant. For each analysis you must attach a file containing result(s) of this analysis by clicking the paperclip button (Figure 42).

Figure 42: Entering results of analysis



if no attachment is added in this section, the dossier will not be accepted for processing.

5.2. Section 3 – Manufacture, use and exposure

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

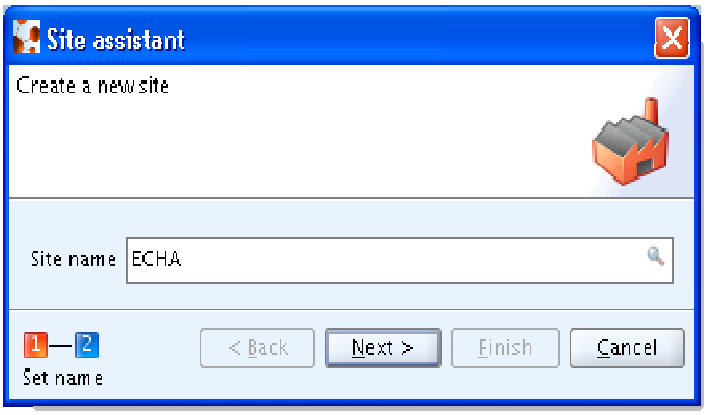
5.2.1. Section 3.3 - Sites

Use this section to indicate the Site where **production** or **use** of your substance takes place. Where needed, you should create those Sites in the relevant section of the main task panel.

5.2.1.1. Creating a site

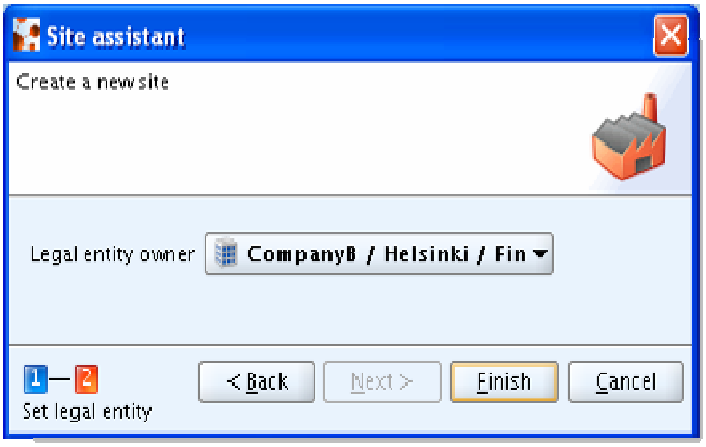
On the main task panel, click on <New> under "Legal entity site". The Site assistant will appear and you can type the name of your site (Figure 43).

Figure 43: Entering name of a site



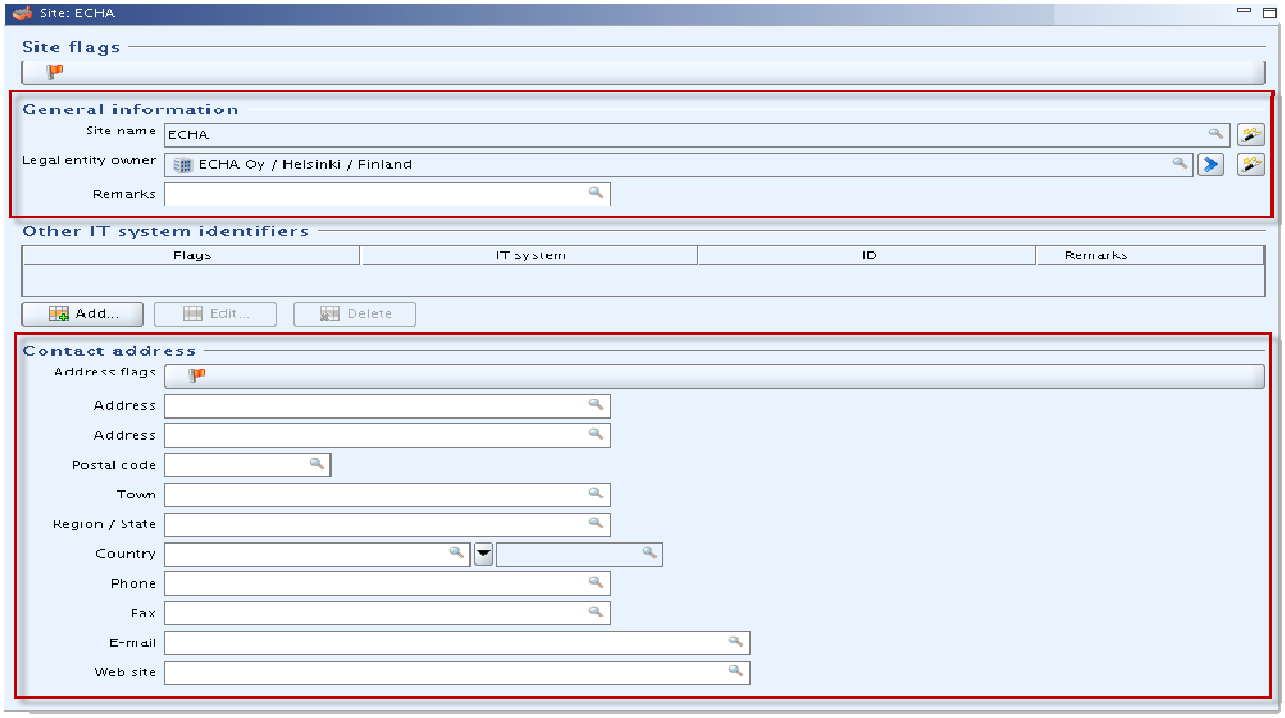
Assign the Legal entity owner to the Site and click on <Finish> (Figure 44).

Figure 44: Assigning the legal entity



The legal entity screen will appear. Indicate the address of your Site, as well as the contact details and other IT identifiers (Figure 45).

Figure 45: Legal entity screen with contact details

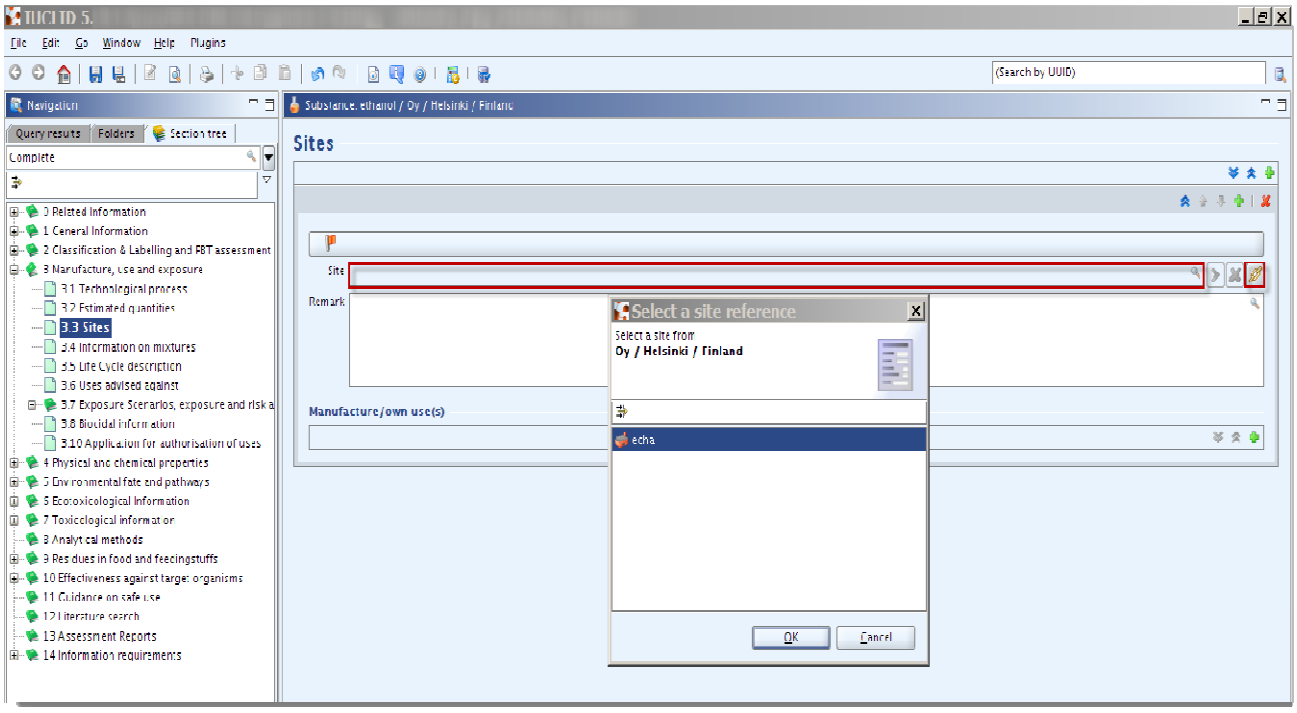


Click on <Save>: you have now created a site which can be linked to the substance dataset.

5.2.1.2. Assigning a site

In the section tree of the Substance dataset, double click "3.3 Sites" and click on <Edit item> (as shown in Figure 23). Create a new repeatable block clicking the green cross button (as shown in Figure 37). The fields where the information on the production/use site can be specified are now displayed. Click the chain button (as shown in Figure 25) to link the Sites assigned to your Legal entity. Select the site and click on <OK> (Figure 46).

Figure 46: Linking the site with the legal entity



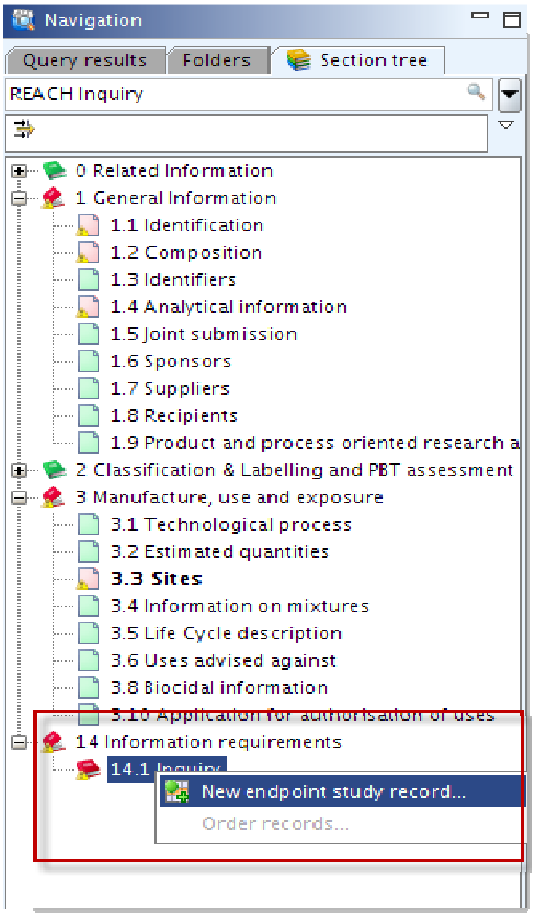
5.3. Section 14 – Information requirements

You need to provide which information requirements you may have.

5.3.1. New endpoint study record

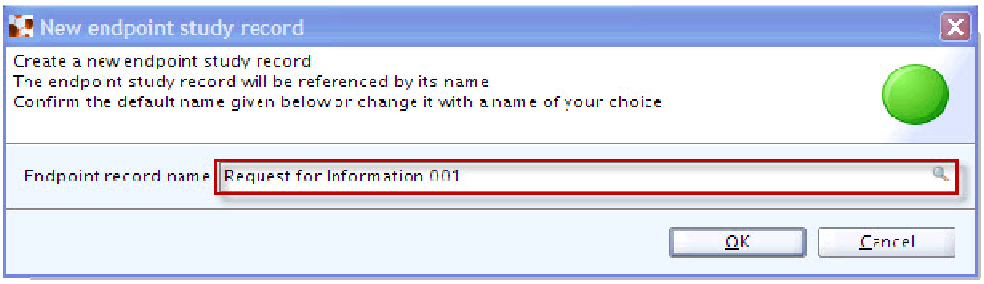
Click on section "14.1 Inquiry" to create a "New endpoint study record" (Figure 47).

Figure 47: Adding new endpoint study record



A "New endpoint study record" section appears. Re-name this new endpoint study record as "**Request for Information**" (Figure 48) and click the "OK" button".

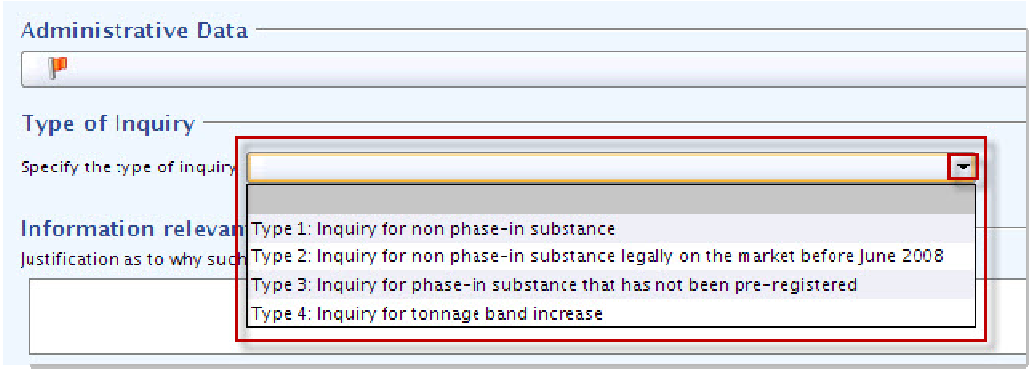
Figure 48: Name for the endpoint study record



5.3.2. Select inquiry type

First select the type of the inquiry and information requirements which would require new studies to be carried out from the drop-down-list under "Type of Inquiry" (Figure 49).

Figure 49: Selecting the inquiry type



There are four types of inquiry to choose from.

Type 1 – Inquiry for non-phase-in substance

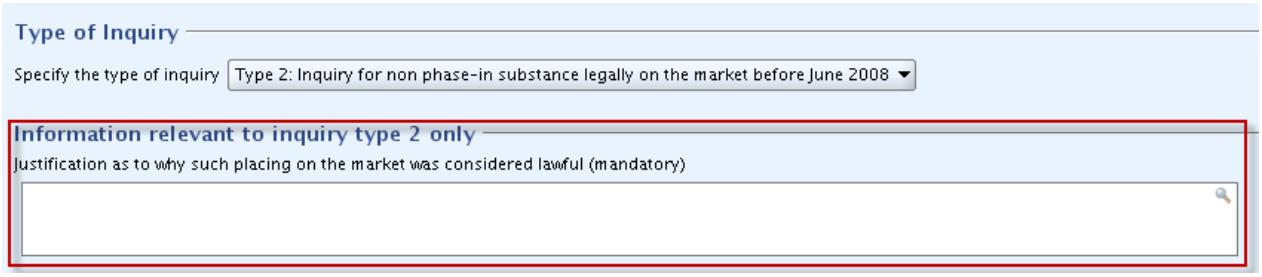
This is an inquiry for a non-phase-in substance in accordance with Article 26 of the REACH Regulation for which none of the other inquiry types apply.

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

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

If you select "Type 2", you must provide the justifications why placing on the market was considered lawful (Figure 50)

Figure 50: Type 2 inquiries



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

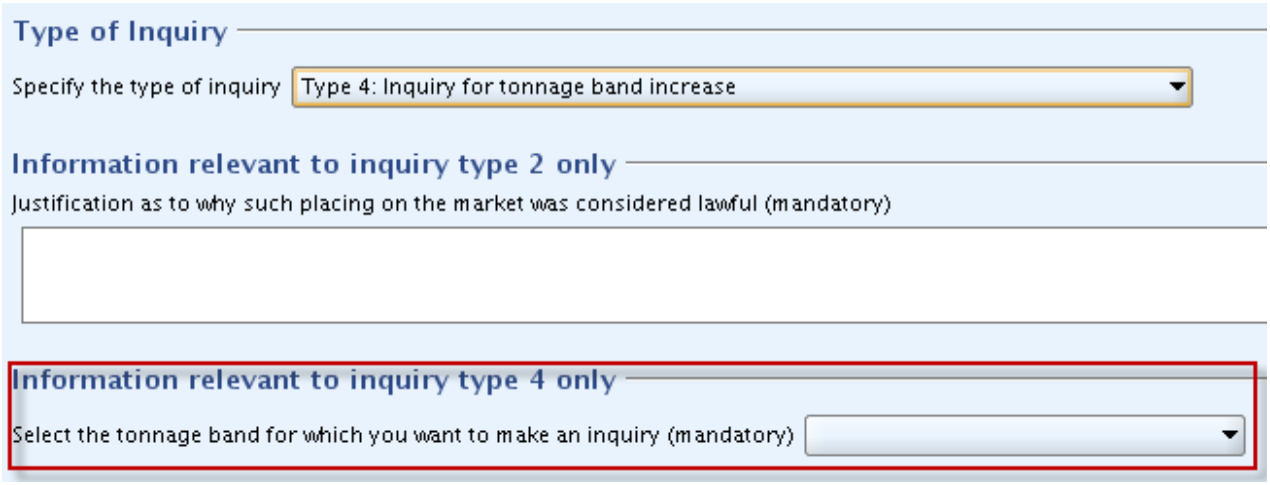
Inquiry for a phase-in substance (that was not pre-registered) in accordance with Article 26 of the REACH Regulation for which none of the other inquiry types apply.

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

Type 4 – Inquiry for tonnage band increase

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

Figure 51: Type 4 inquiries



If you select "Type 4" you need to select the tonnage band for which your inquiry refers to (Figure 51).

If you have not yet successfully registered the substance you are inquiring about and you select "Type 4" as type of your inquiry, your inquiry will not be accepted for processing.

If additional information are **not** requested, there is no reason to submit an inquiry to ECHA. Type 4 inquiries for which additional information are not requested will not be accepted for processing.

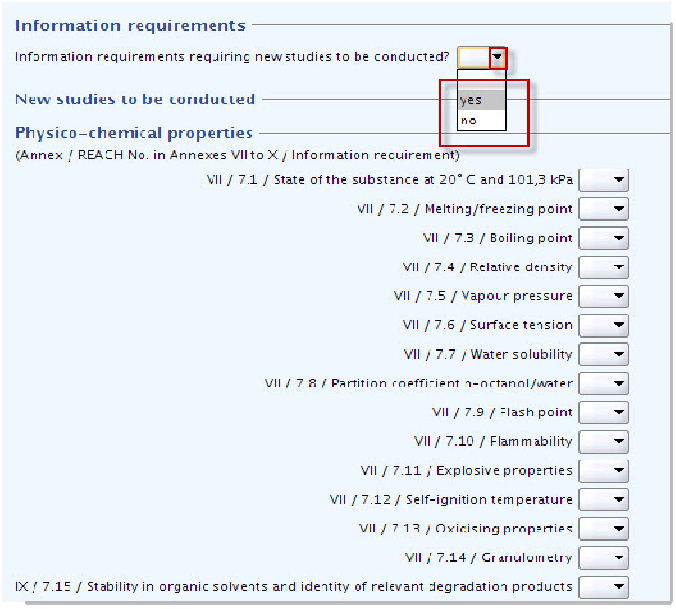
5.3.3. Specify information requirements

Indicate in "Information requirements" whether you have information requirements that would require new studies to be conducted. Select either "yes" or "no" from the drop-down-list that appears (Figure 52).

Please note that the sections "Information requirements" and "New studies to be conducted" shall be filled in a consistent way.

Dossiers filled in an inconsistent way will not be accepted for processing.

Figure 52: Specifying information requirements



If you select "yes" under "Information requirements" specify your information requirements by selecting "yes" for one or more relevant endpoint listed in the section "New studies to be conducted" and under "Physico-chemical properties", "Toxicological information", "Ecotoxicological information" and "Methods of detection and analysis".

If you do not have any information requirements, select "no" under "Information requirements", and do not fill in anything under "Physico-chemical properties", "Toxicological information", "Ecotoxicological information" and "Methods of detection and analysis".

Figure 53: Selecting the relevant end points

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

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

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

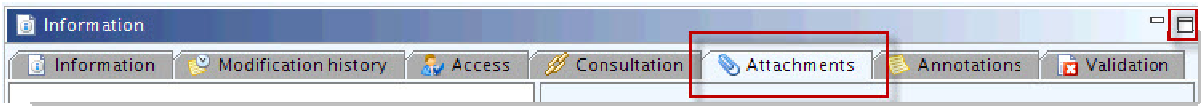
* Information can thus not be requested

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

5.4. Attaching files as additional information

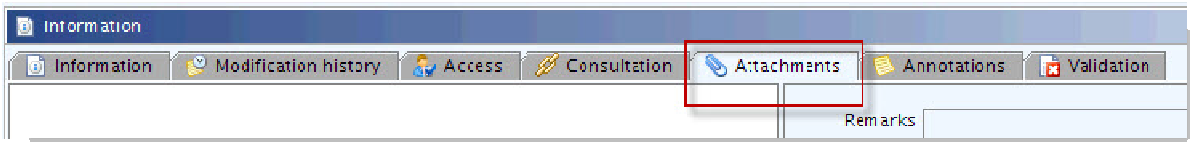
If you want to attach files containing additional information, this can be done via the "Information" window at the bottom of the Substance dataset screen(Figure 54). This window is minimised by default and can be used by clicking on the button on the right to maximise it.

Figure 54: Maximising information window



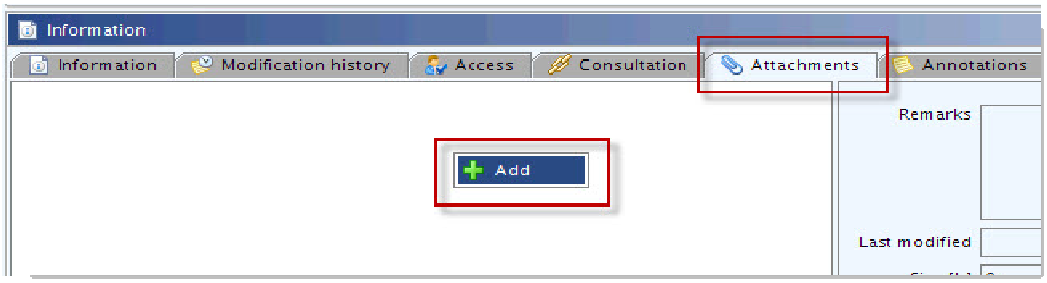
The information screen will appear. Click the tab "Attachments" (Figure 55).

Figure 55: Information screen with attachment tab



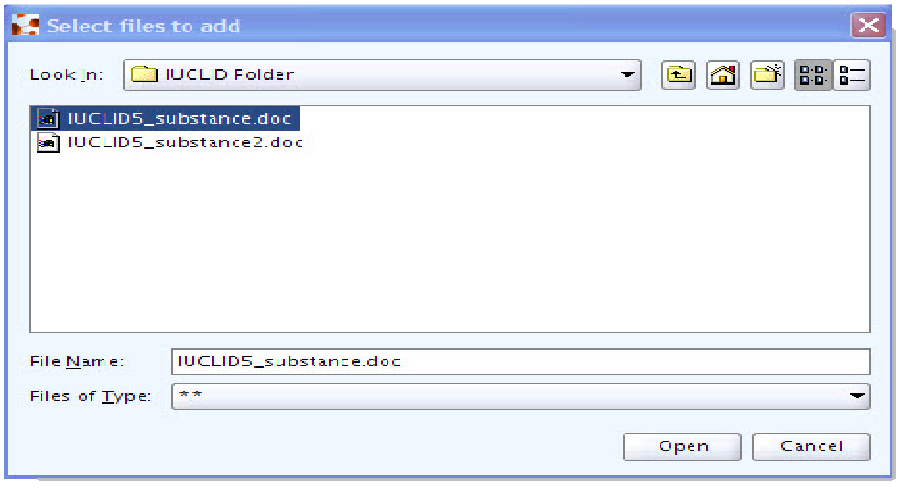
To add an attachment, click on <Edit item> button, right click the white left field and select <Add> (Figure 56).

Figure 56: Attaching a document via the add button



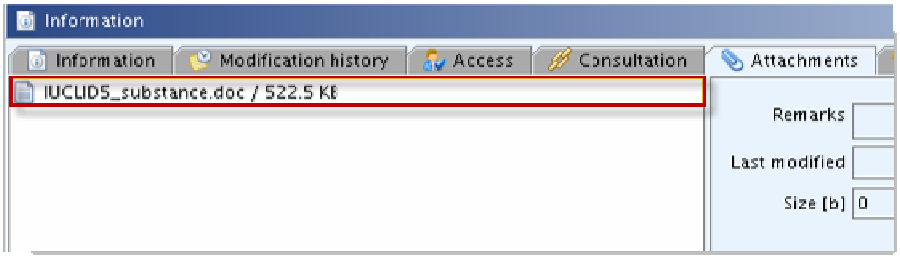
The system will ask you whether you wish to save the working document. Click on <Accept>, and the browsing box will appear. Select the file to attach and click on <Open> (Figure 57).

Figure 57: Browsing box with selected file to attach



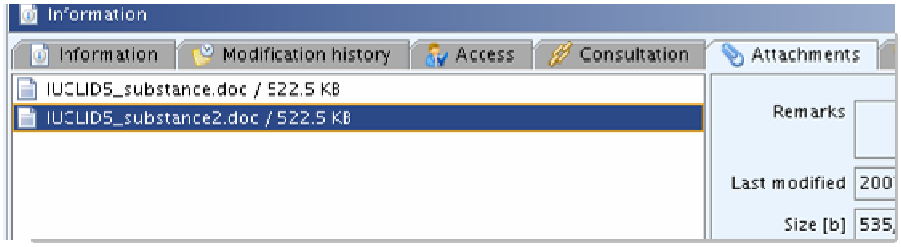
Write remarks on the file if you wish, and click on <Save>. The attached file will appear in the list (Figure 58).

Figure 58: List of attached documents



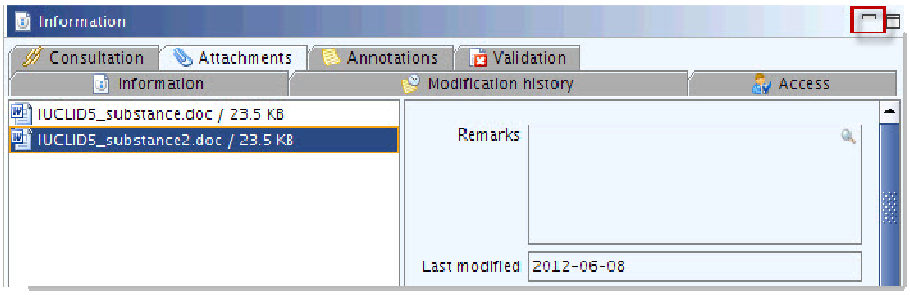
If you wish to attach more than one file, repeat the previous steps (Figure 59).

Figure 59: Additional documents attached



Once you added the necessary attachments to the Substance dataset, click on <Minimise> button to visualise the Substance dataset entry data pane (Figure 60).

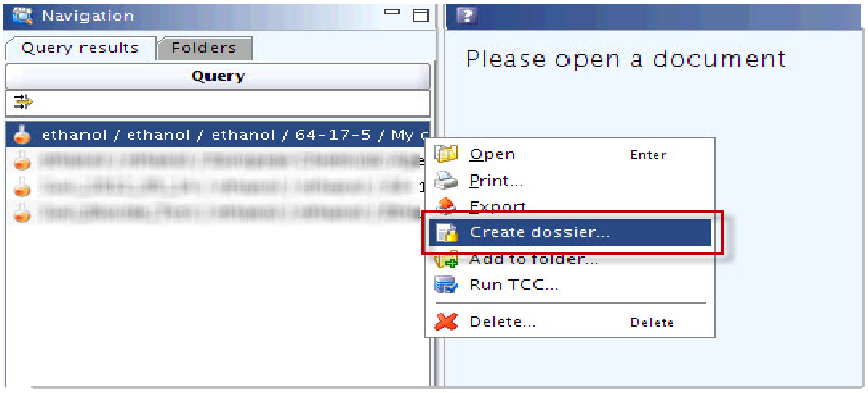
Figure 60: Minimise button



6. Creating an inquiry dossier

On the IUCLID 5 task panel, select "Update" from Substance. All available substances are displayed and you can select the substance for which you want to create the Inquiry dossier. Right click a substance in the query results list and select from the pop-up menu "Create Dossier" (Figure 61).

Figure 61: Selecting create dossier from pop-up menu

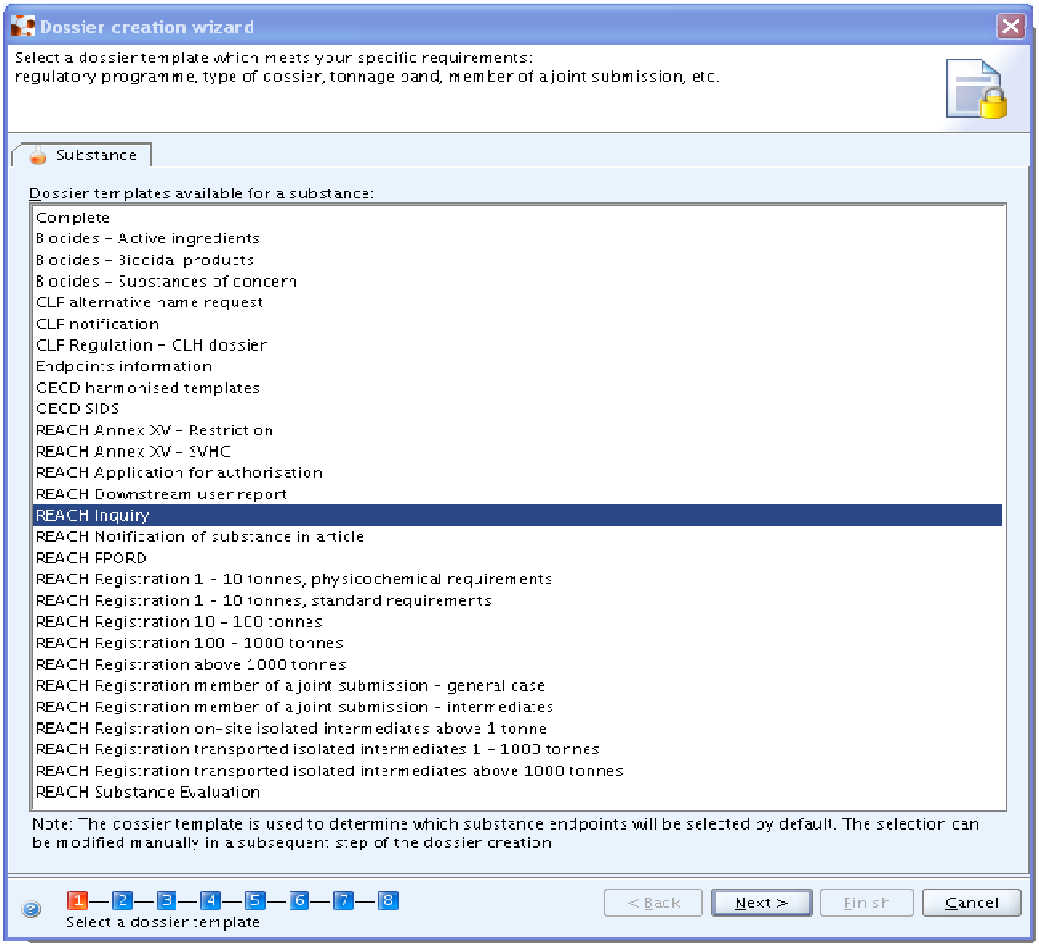


The Dossier creation wizard is displayed. Follow the 8 steps of the wizard, in order to create the inquiry dossier.

Step 1: Select the Dossier template "REACH Inquiry" (Figure 62). Click on <Next>>.

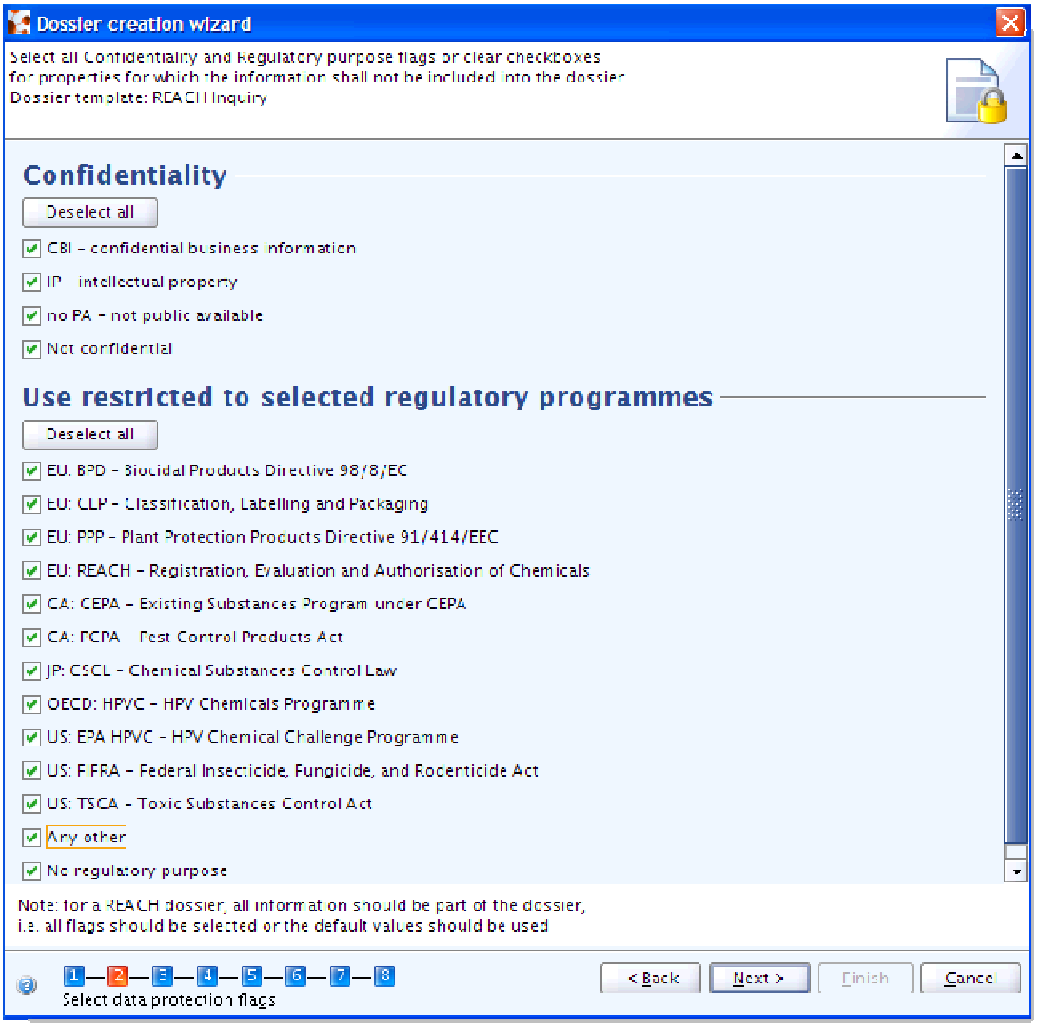
We strongly advise you to run the "TCC plug-in" on your dossier before submitting it to ECHA. The TCC plug-in will identify the fields of your inquiry dossier which deserve particular attention. You are highly advised to correct any failure or relevant warning displayed by the tool. If you fail to do so, your dossier may not be accepted for processing or may not receive any inquiry number.

Figure 62: Selecting the dossier template



Step 2: Click on both <Select all> buttons to select all Confidentiality and Regulatory purpose flags or clear the checkboxes for properties which records shall not be included in the dossier (Figure 63). Click on <Next>>.

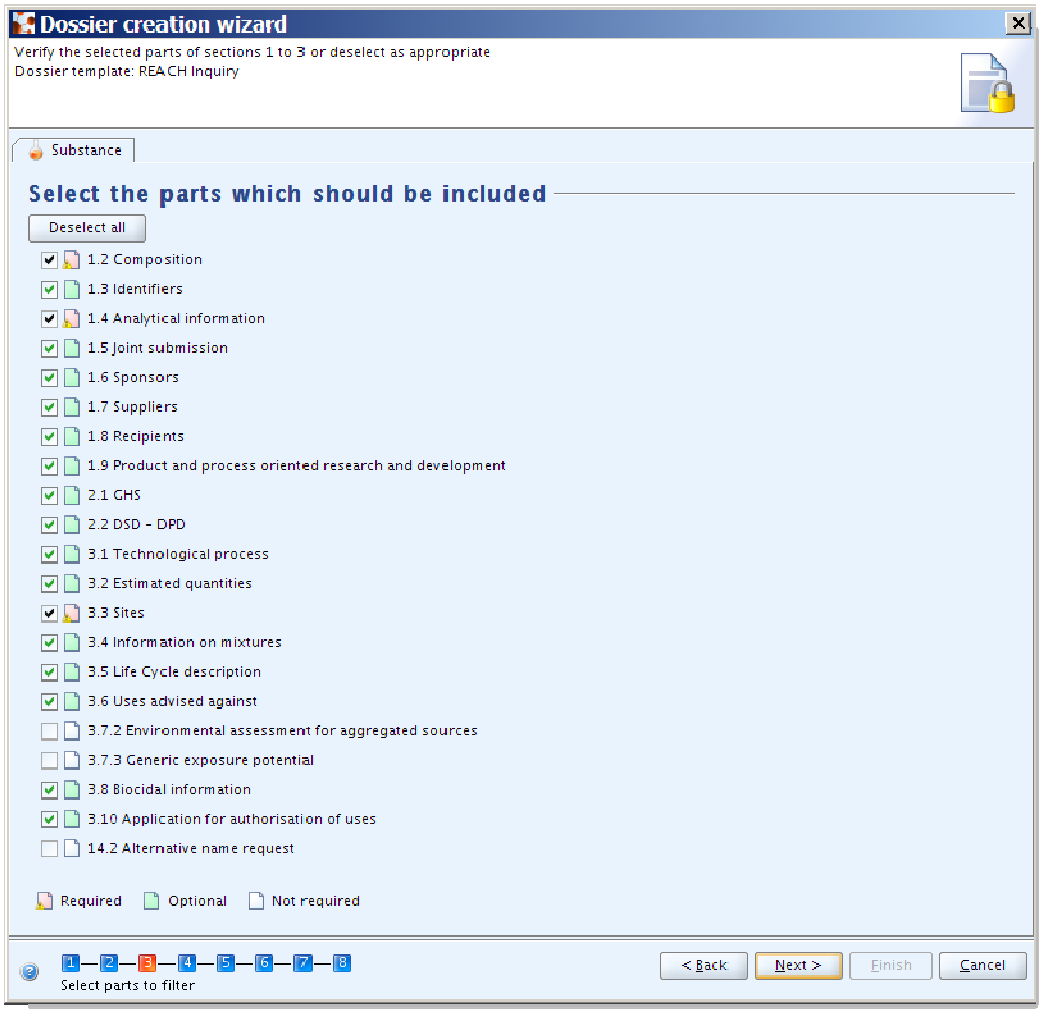
Figure 63: Selecting confidentiality and regulatory purpose flags



Step 3: Select the data to include in the inquiry dossier(Figure 64). Click on <Next> if the default settings apply (i.e. all selected subsections of sections 1-3). Where different settings apply, select/ deselect as appropriate and click on <Next>>.

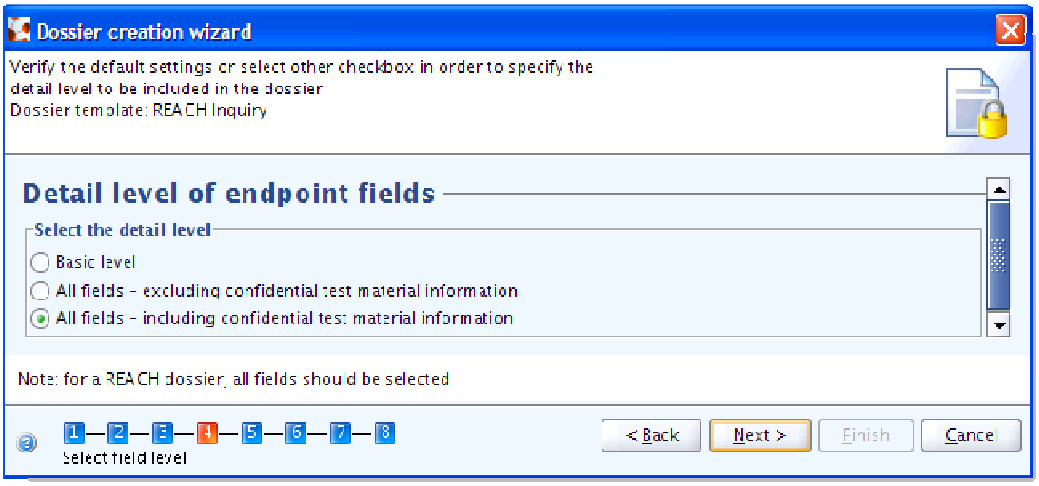
Note that checkboxes with black ticks cannot be deselected

Figure 64: Including data in the dossier



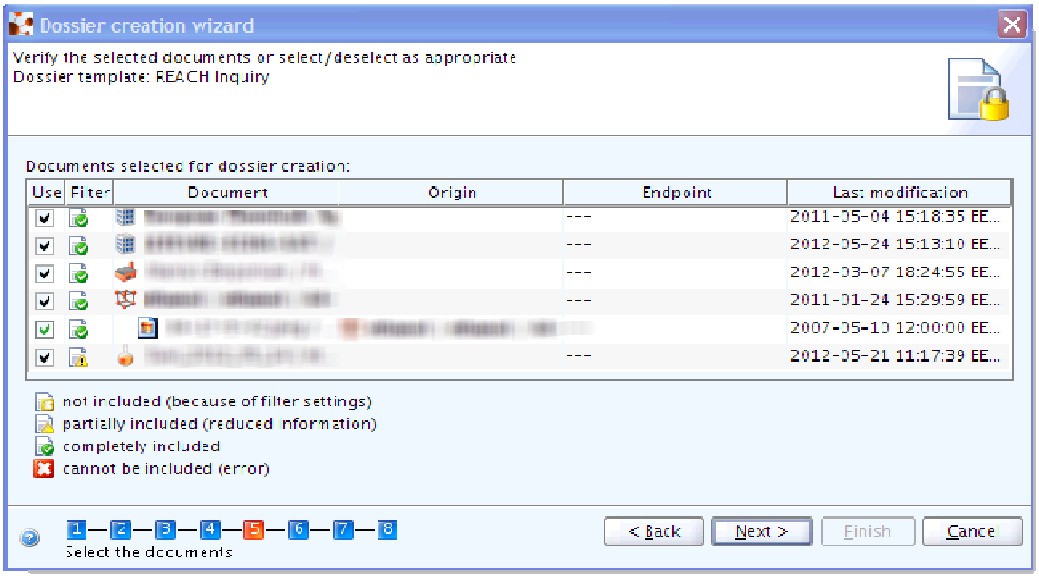
Step 4: If default settings apply Click on <Next>(Figure 65). In order to specify the detail level to be included in the dossierselect other checkbox and click on <Next>>.

Figure 65: Inclusion of detail level in the dossier



Step 5: Verify the selected documents (Figure 66) and click on <Next>.

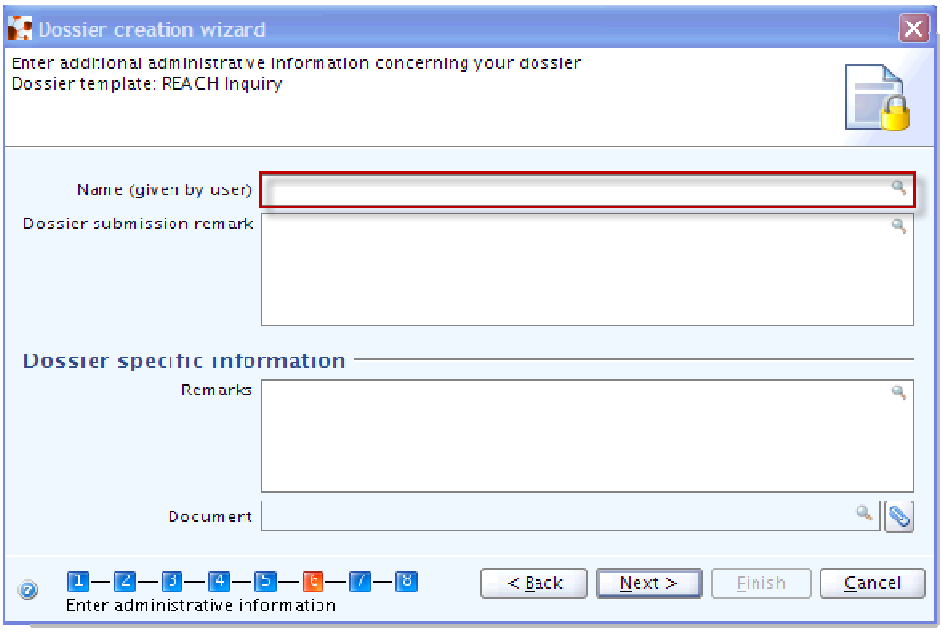
Figure 66: Selection of documents



Step 6: Enter additional administrative data (Figure 67).

In the field "Name", type the substance name the inquiry relates to, and in the "Dossier submission remark" field type "Inquiry dossier" , and click on <Next>>.

Figure 67: Entering administrative data

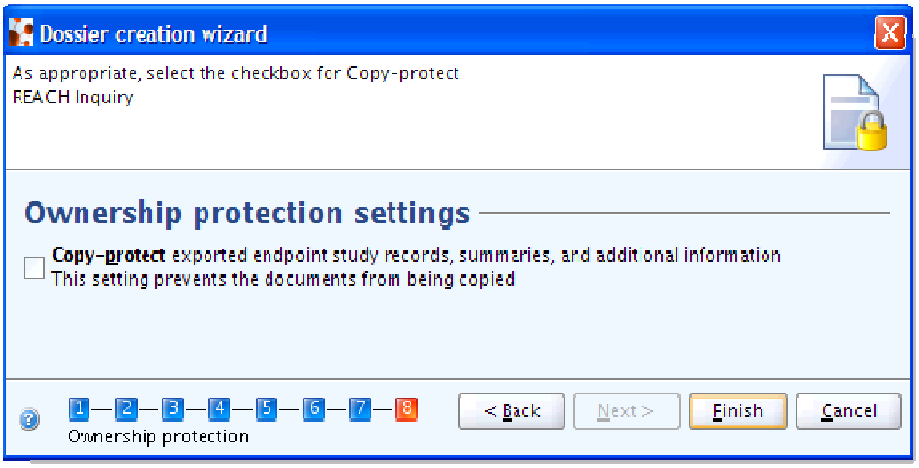


If you are submitting an inquiry due to a tonnage band increase (Article 12(2) of the REACH Regulation), you need to type in the "Dossier submission remark" field "Request for additional information as a result of an tonnage band increase of a registration".

If your substance is a non-phase-in substance legally on the market before June 2008 (see 9th of June ECHA press release (ECHA/PR/08/12) available on the ECHA website at http://echa.europa.eu/web/guest/news-and-events/news-alerts) type "Inquiry dossier for non-phase-in substance legally on the market before June 2008" in the "Dossier submission remark" field. In this field you must also give a justification as to why such placing on the market was considered lawful.

Step 7: Decide on the ownership protection setting (Figure 68).

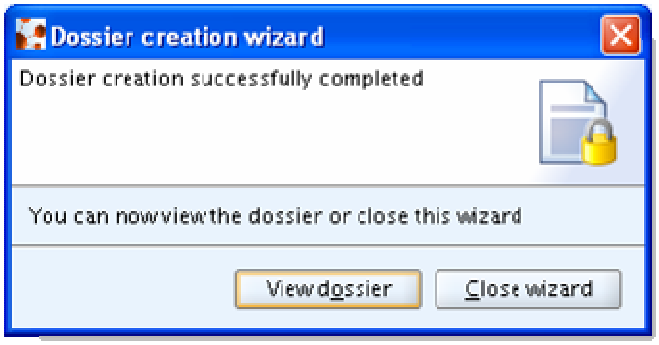
Figure 68: Ownership protection settings



Click on <Finish> in the Ownership protection settings window.

A window informs you about the success of the import (Figure 69).

Figure 69: Final message of dossier creation

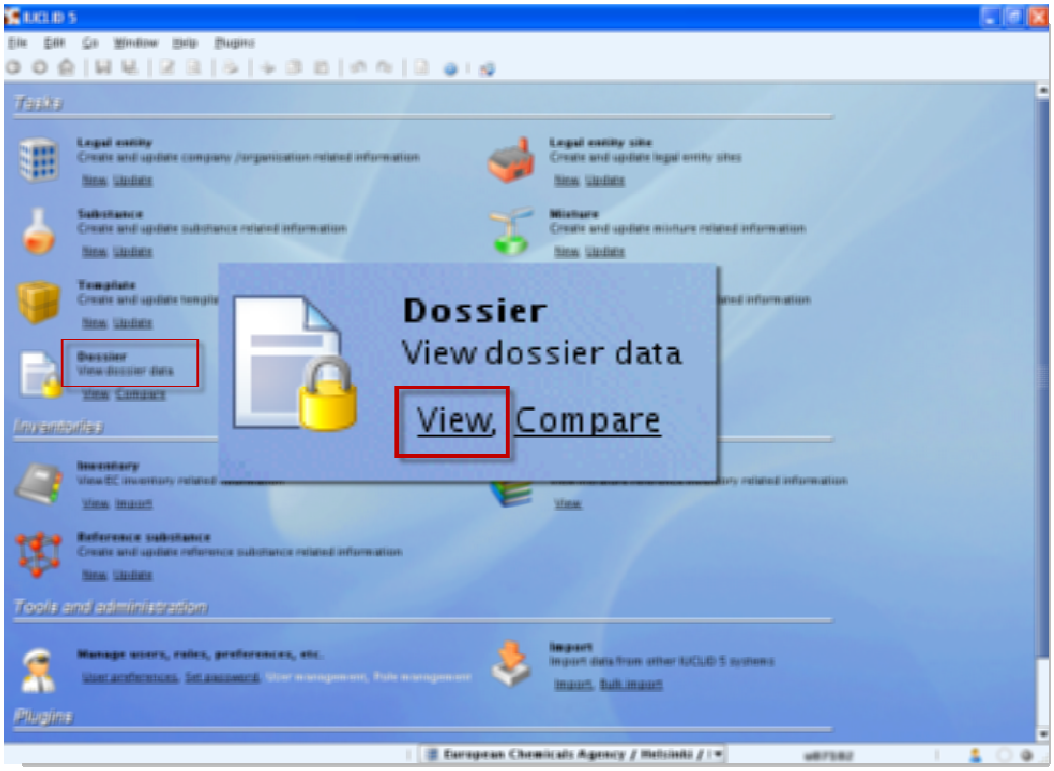


You can either <Close wizard> or <View dossier>. When clicking on <View dossier> button, the dossier will be displayed.

7. Exporting an inquiry dossier

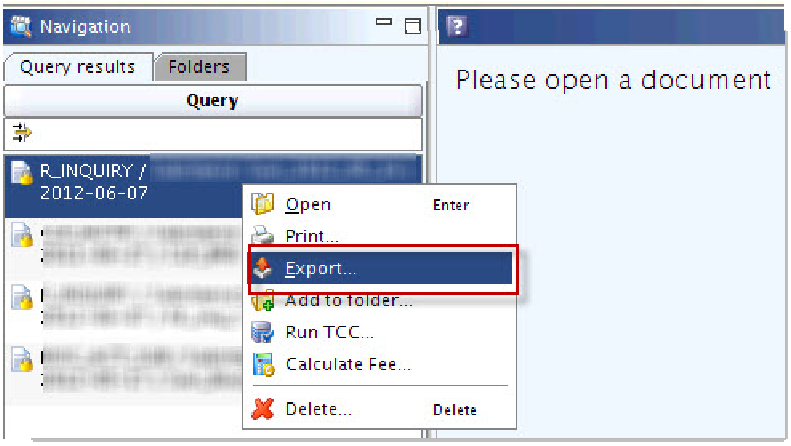
You need to export and store the inquiry dossier on your computer in order to send it to ECHA. Click in the dossier icon or the "View" link in the main task panel (Figure 70).

Figure 70: Viewing a dossier



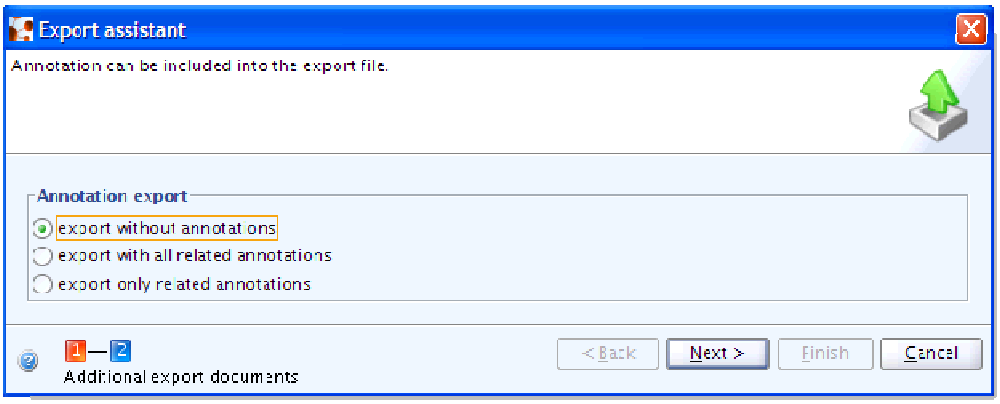
Select your inquiry Dossier, right click it and select "Export" (Figure 71).

Figure 71: Exporting a dossier



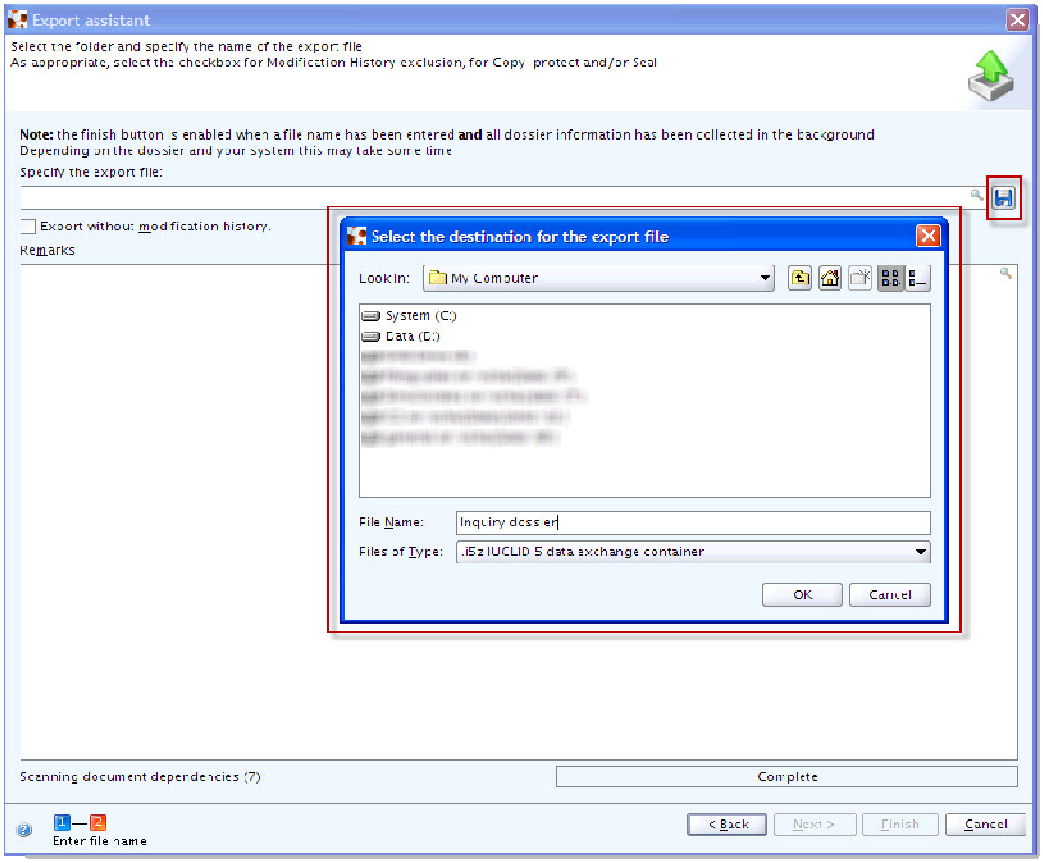
Select "Export without annotations" (unless you have included relevant information as annotations in your dossier) and click on <Next> (Figure 72).

Figure 72: Selection of the annotations in the export



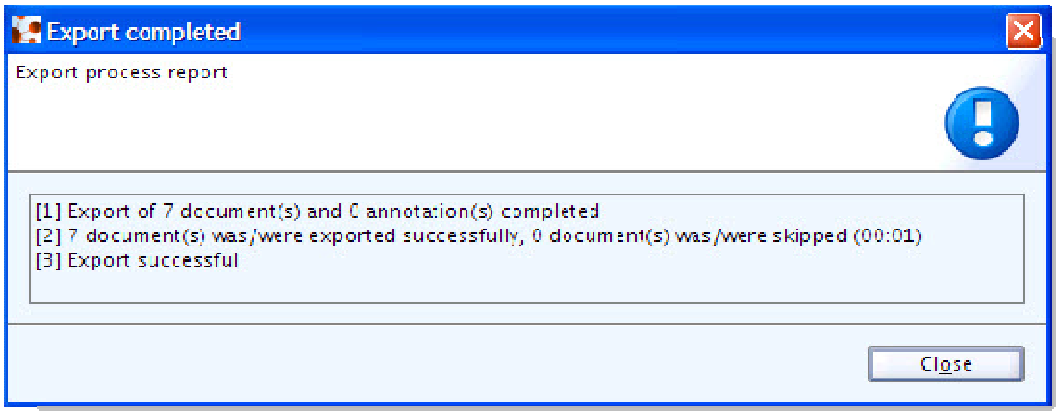
In the next step specify the location where you want to store your dossier by clicking the save button (Figure 73).

Figure 73: Save button and location



Click on <Finish>: the dossier has now been exported to the location you specified. A confirmation message will appear (Figure 74).

Figure 74: Export progress report



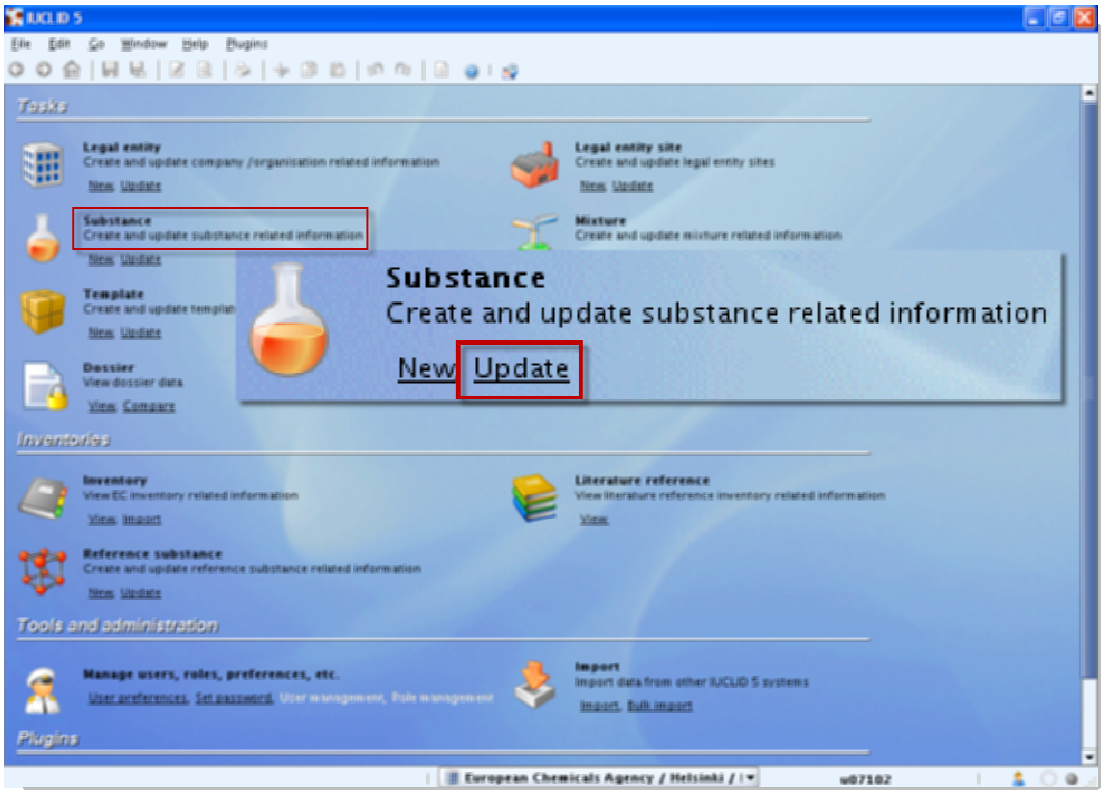
8. Updating a dossier

This chapter provides information on how to update the information contained in your dossier.

If you need to submit further information in your inquiry dossier, be it as a result of missing information, lack of quality or inability to verify the substance identification, you do not need to re-type all your substance data.

In the main task panel, click "Update" under "Substance" (Figure 75).

Figure 75: Selection of update link



Select from the list, the substance for which you wish to submit new information, and double click it. From the Substance dataset tree view, select the section(s) that you wish to update. You can always edit the necessary sections by clicking on <Edit item> (Figure 23).

To create and export the dossier, please refer to Chapters 6 and 7 of this manual.

9. Submitting an inquiry dossier

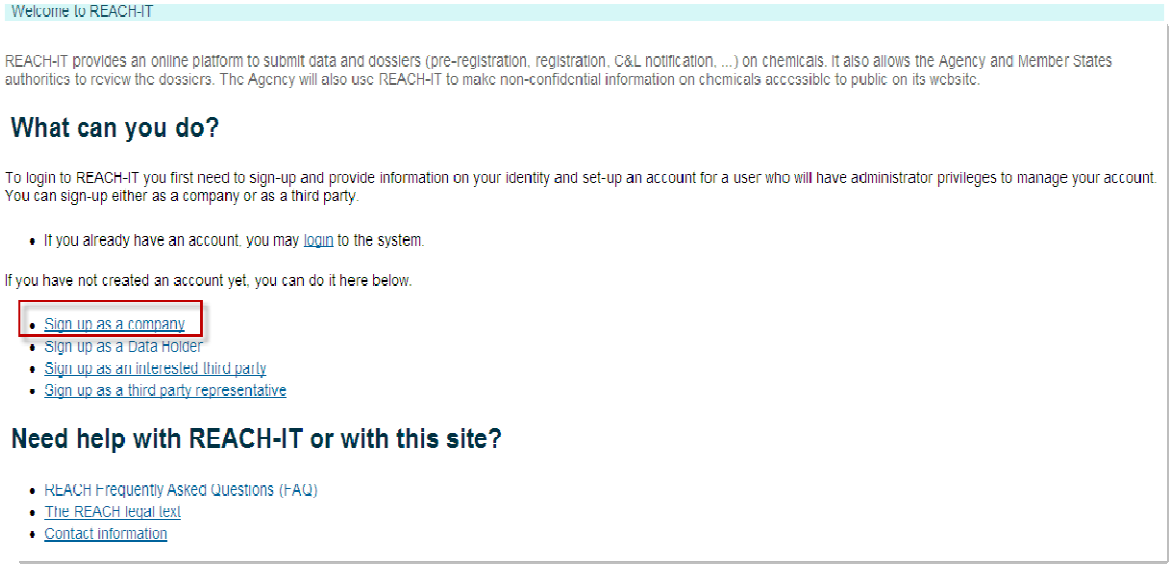
This chapter provides information on how to submit a inquiry dossier to ECHA. First your legal entity need to be signed up in REACH-IT.

9.1. Step 1 - Company sign-up in REACH-IT

If you do not have an account in REACH-IT, refer to the REACH-IT Industry User Manual – Part 02 "Sign-up and account management" available at http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals) or follow the instructions given below:

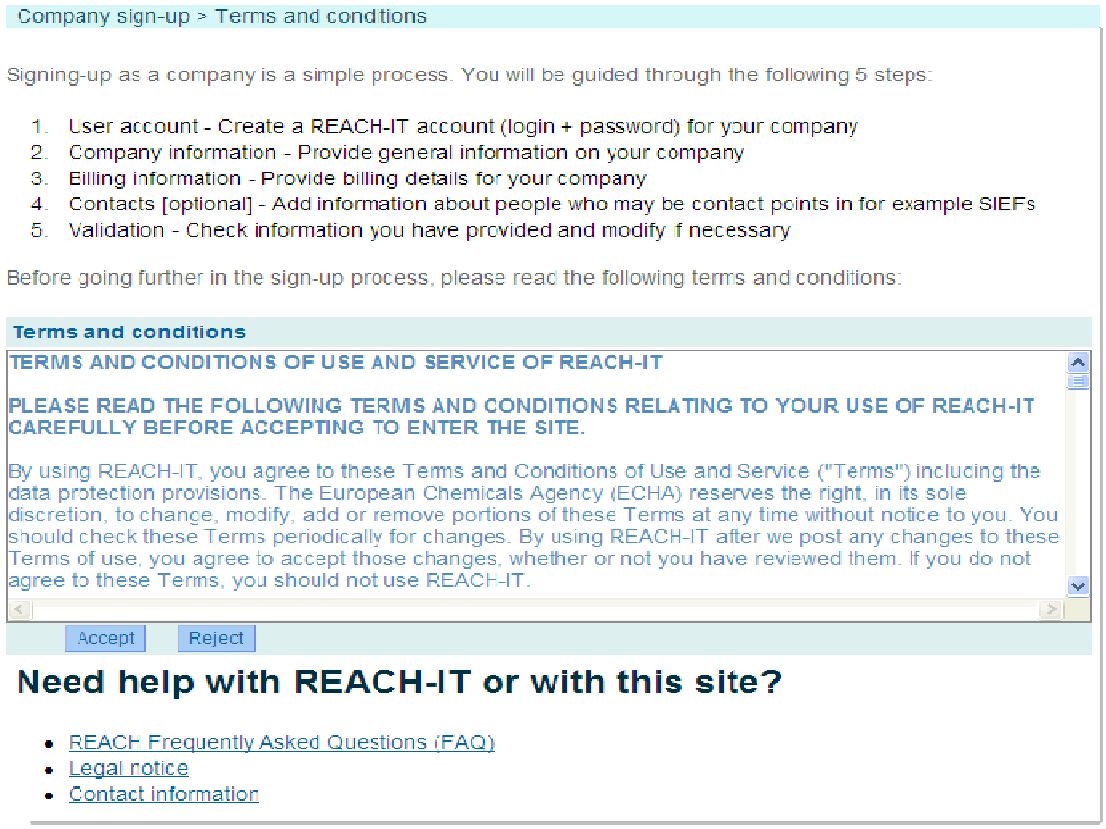
- Go to the ECHA website (http://echa.europa.eu/) to access REACH-IT or go directly to the REACH-IT website (http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals).
- In REACH-IT, click on "sign-up as a company" (Figure 76).

Figure 76: REACH-IT start page



- In the following page, you will be required to accept the terms and conditions in order to proceed with the sign-up procedure. If you agree with the terms and conditions, click on <Accept> (Figure 77).

Figure 77: Sign-up in REACH-IT



Follow the sign-up procedure.

You will be guided through the following 5 steps:

- User account - Create your REACH-IT user account.
- Company information - Provide general information on your company. For consistency, you should import the Legal Entity Object (LEO) created in the IUCLID 5 website, which was linked to the substance for which the IUCLID 5 inquiry dossier was made (see also REACH-IT Industry User Manual - Part 1 and 2, http://www.echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals).
- Billing information - Provide billing details for your company.
- Contacts – In this screen you can specify contact persons for your company.
- Validation - Check the information you have provided and modify if necessary.

9.2. Step 2 - Submitting an IUCLID 5 inquiry dossier

Please refer to the REACH-IT Industry User Manual Part 6 – Dossier Submission, available at http://www.echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals

9.3. Step 3 – Receiving the result of an inquiry dossier

Please refer to the REACH-IT Industry User Manual Part 11 – Online dossier creation and submission for inquires (chapter 4) available at http://www.echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

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