**GUIDANCE ON COMPLETION OF SECTIONS 1 AND 3 OF THE IUCLID 6 DOSSIER:**

**BORON [EINECS number 231-151-2, CAS number 7440-42-8]**

**as boron powder**

**and**

**as elemental boron contained in alloys in massive form or powder form**

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**INTRODUCTION**

This document details the information submitted by the Lead Registrant for boron with respect to **boron powder** and **elemental boron contained in alloys in massive or powder form**. It is intended as a guide to member registrants for completion of the necessary fields of sections 1 and 3 of their IUCLID 6 substance and dossier.

Note however that the text of REACH Regulation is the only authentic legal reference and the information contained in this document does not constitute legal advice. It is therefore recommended that member registrants should read all relevant ECHA Guidance documents, for example [How to prepare registrations and PPORD dossiers](http://www.boron-consortium.org/assets/files/boronconsortium/ECHA/ECHA_manual_regis_and_ppord_en.pdf) (May 2017) and visit the [joint submission member support](http://echa.europa.eu/joint-submission-member) page to find the relevant manuals for creating, checking and submitting IUCLID dossiers using REACH-IT as a member of a joint submission.

Member registrants should make themselves aware of all new updates of the IUCLID software and its plug-ins ([IUCLID installation kit](https://iuclid6.echa.europa.eu/)).

This document contains different types of information:

* That which will be common to all dossiers which are part of the Joint Submission for boron - the cells for which in this document are highlighted in orange;
* That which is particular to your company - the cells for which in this document are highlighted in blue;
* Cells highlighted in grey relate to headings only and have no content.

Do not forget to save data entered by clicking on the save button.



Do not forget to check your substance and dossier files with the IUCLID 6 Validation Assistant (VA) plug-in tool.



If confidentiality is required, the registration fee will be more expensive and a justification has to be provided! Note that ECHA has issued in April 2016 a [guidance document on confidentiality claims](http://echa.europa.eu/documents/10162/13653/dsm_16_confidentiality_claims_en.pdf) - this can be downloaded from the ECHA website - [Data submission manuals](https://echa.europa.eu/manuals) or from the Library page of the Iron Platform website. A [fee calculator plug-in](https://iuclid6.echa.europa.eu/fee-calculation-plug-in) is available. This plug-in assists Legal Entities in calculating fees associated to REACH or CLP dossiers.

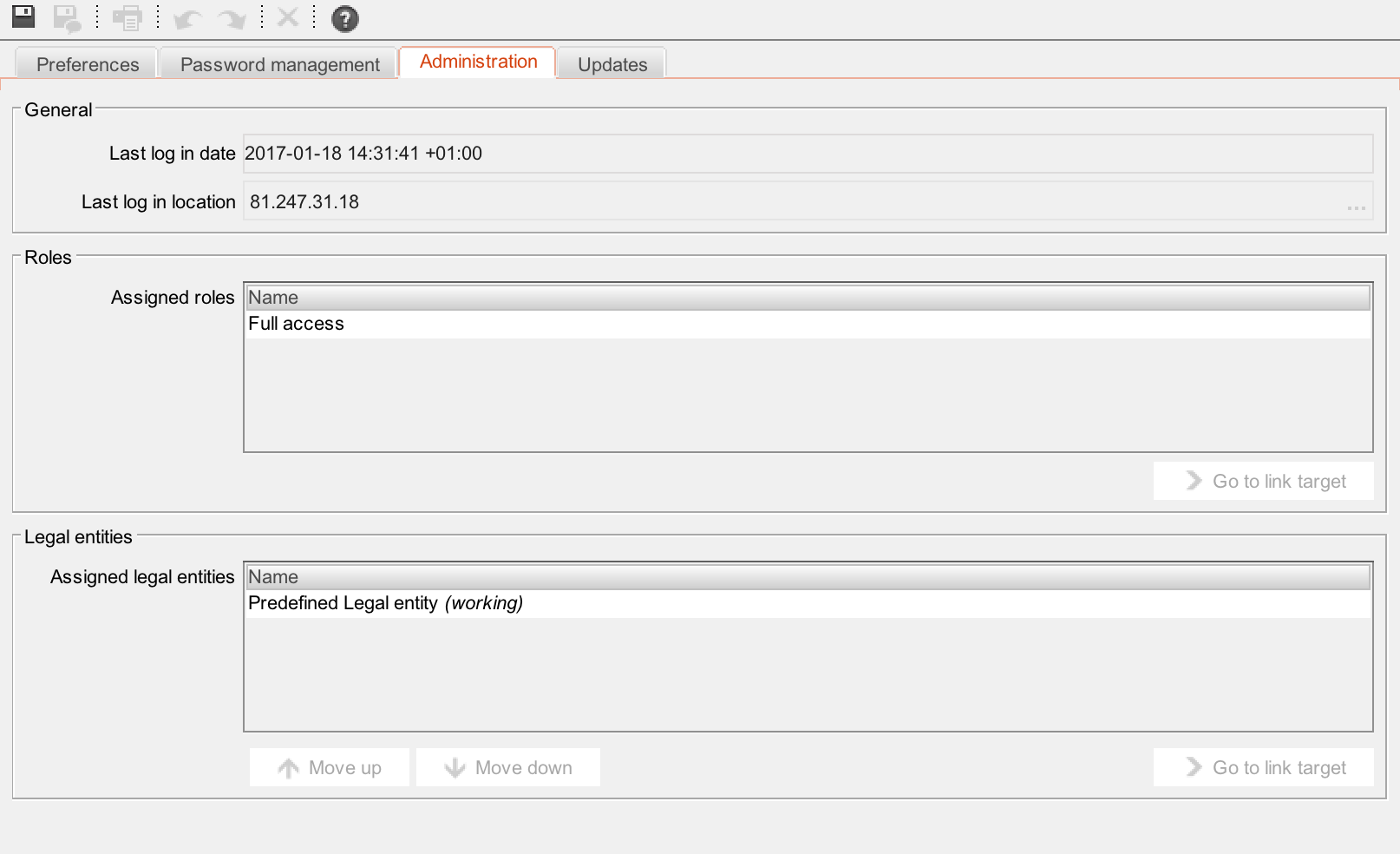


Member registrants will have to import all IUCLID files [reference substances and the file containing the uses] provided by the REACH Boron consortium before creating their substance files. Click [here](http://www.boron-consortium.org/iuclid-files-for-download.html) to download all i6z files.

An IUCLID 6 dissemination preview plug-in is available. This allows a registrant to preview or simulate the information from its registration dossier that ECHA will make available via the internet. You can find more information on disseminated data in the ECHA [Dissemination and confidentiality under REACH regulation (April 2016)](http://www.boron-consortium.org/assets/files/boronconsortium/ECHA/ECHA_manual_dissemination_en.pdf) and its [Transition to the new IT tools](http://www.boron-consortium.org/assets/files/boronconsortium/ECHA/ECHA_it_tools_transition_en.pdf) (March 2016).

**Important**: Before starting to complete the IUCLID 6 file, go to the User management and ensure under Administration that the Legal Entity corresponds to the one registering the substance and is assigned as *“(working)”* [See screenshot]. 





**SUBSTANCE RELATED INFORMATION**

**1. GENERAL INFORMATION**

**1.1 Identification**



| **ITEM** | **TEXT TO BE ADDED** | **EXPLANATION** |
| --- | --- | --- |
| **Identification** | Heading only |  |
| **Substance name** | Boron |  |
| **Public name** |  | Enter the generic name by which you describe your substance, e.g. boron powder  In case of elemental boron contained in alloys, we suggest that “Elemental boron in alloys” be entered in this field. |
| **Legal entity or third party flags:** |  | Click on the flag if you want to assign confidentiality and programme restrictions. |
| Confidentiality |  | Leave blank or select the right level of confidentiality. If confidentiality is required, a justification has to be provided. |
| Programme restrictions |  | Select EU: REACH from pick list. |
| **Role in the supply chain** |  | Choose your role and tick appropriate box. Note:  If “manufacturer is selected, a production site is needed in section 3.3  Note that “only representative” cannot be selected together with “manufacturer” or “importer” |
| **Role flags** |  | Click on the flag if you want to assign confidentiality and programme restriction |
| Confidentiality |  | Leave blank or select the right level of confidentiality. If confidentiality is required, a justification has to be provided. |
| Programme restrictions |  | Select EU: REACH from pick list. |
| **Identification of substance** | Heading only |  |
| **Reference substance flag** |  | Click on the flag if you want to assign confidentiality and programme restrictions. |
| Confidentiality |  | Leave blank or select the right level of confidentiality. If confidentiality is required, a justification has to be provided. |
| Programme restrictions |  | Select EU: REACH from pick list. |
| **Reference substance** | boron / Boron / 7440-42-8 / 231-151-2 | To locate the reference substance from the IUCLID data base, click on this icon [see red arrow in screenshot above].    Select your substance from the database by typing in the name, EC or CAS number, click SEARCH, select the substance name and click Assign [see screenshot below].  Two problems may arise:  • If no entry is found, you have first to import the substance from the EC inventory to the reference substance inventory.  • If an entry is found but is inactive, right mouse click and set to “active reference substance.”  In order to simplify matters, the REACH Boron Consortium has provided reference substance files which member registrants can import into their IUCLID (see Note 1 below) |
| Inventory / number / name |  | This information is automatically provided when the reference substance is assigned. |
| CAS number / name |  | This information is automatically provided when the reference substance is assigned. |
| IUPAC name |  | This information is automatically provided when the reference substance is assigned. |
| **Type of substance:** | Heading only |  |
| Type of substance | mono constituent substance | Select from the pick list |
| Origin | element | Select from the pick list |
| **Other identifiers** | Heading only | Click on |
| Flags**:** |  | Click on the flag if you want to assign confidentiality and programme restriction |
| Confidentiality |  | Leave blank or select the right level of confidentiality. If confidentiality is required, a justification has to be provided. |
| Programme restrictions |  | Select EU: REACH from pick list. |
| Identifier |  | Select trade names, if you have trade name[s] for your substance. |
| Identity |  | If you have trade name[s] for your substance, add it/them here |
| Country |  | Select countries, were the trade names are being used. |
| **Contact person** |  | These fields are for your own company information. The details entered should correspond with the information contained in REACH-IT. Several contacts can be provided. Click on  to add one. |

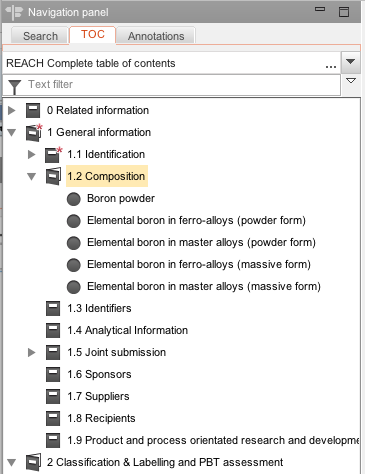
Note 1

The reference substance for boron (boron / Boron / 7440-42-8 / 231-151-2) developed by the Lead Registrant contains the following data. It can be downloaded on the Boron Consortium website (by clicking [here](http://www.boron-consortium.org/iuclid-files-for-download.html)) and directly imported into your IUCLID database:

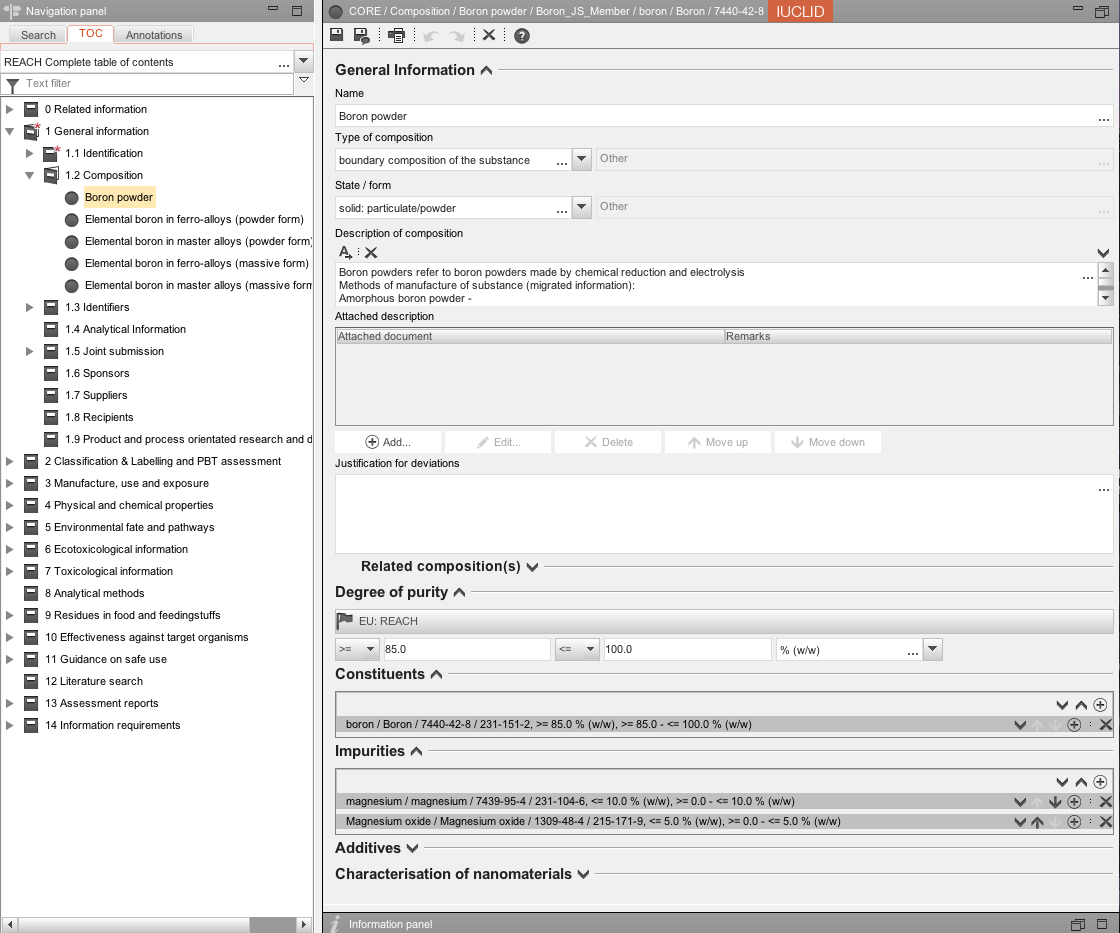
|  |  |
| --- | --- |
| **General information** | Heading only |
| Reference substance name | Boron |
| **Inventory** | Heading only |
| Inventory number | EC / 231-151-2 / boron / 7440-42-8 / B |
|  |  |
| **Reference substance information** | Heading only |
| Reference substance flag | EU: REACH |
| IUPAC name | Boron |
| Description | Leave blank |
| Synonyms | Boron |
| CAS number | 7440-42-8 |
| CAS name | Boron |
| IUPAC name | Boron |
| Identifiers of related substances | Leave blank |
| Group / category information | DSL Category: Inorganics |
| **Related CAS information** | Leave blank |
| **Group / category information** | Leave blank |
| **Molecular & Structural information** | Heading only |
| Molecular formula | B |
| Molecular weight range | 10.81 |
| SMILES notation | [B] |
| InChl | InChl=1/B |
| Structural formula | B |
| Remarks | Leave blank |

**1.2 Composition**

The records containing the boundary compositions for boron powder, elemental boron in ferro-boron (massive form/powder form), elemental boron in master alloys (massive form/powder form) are already included. No adaptations should be made to these records. To include the legal entity composition of the forms of boron you intend to register, you can make a copy of the corresponding boundary composition files by right clicking and copying the record and adjust as described below: boron powder, elemental boron in ferro-boron (massive form/powder form), elemental boron in master alloys (massive form/powder form).



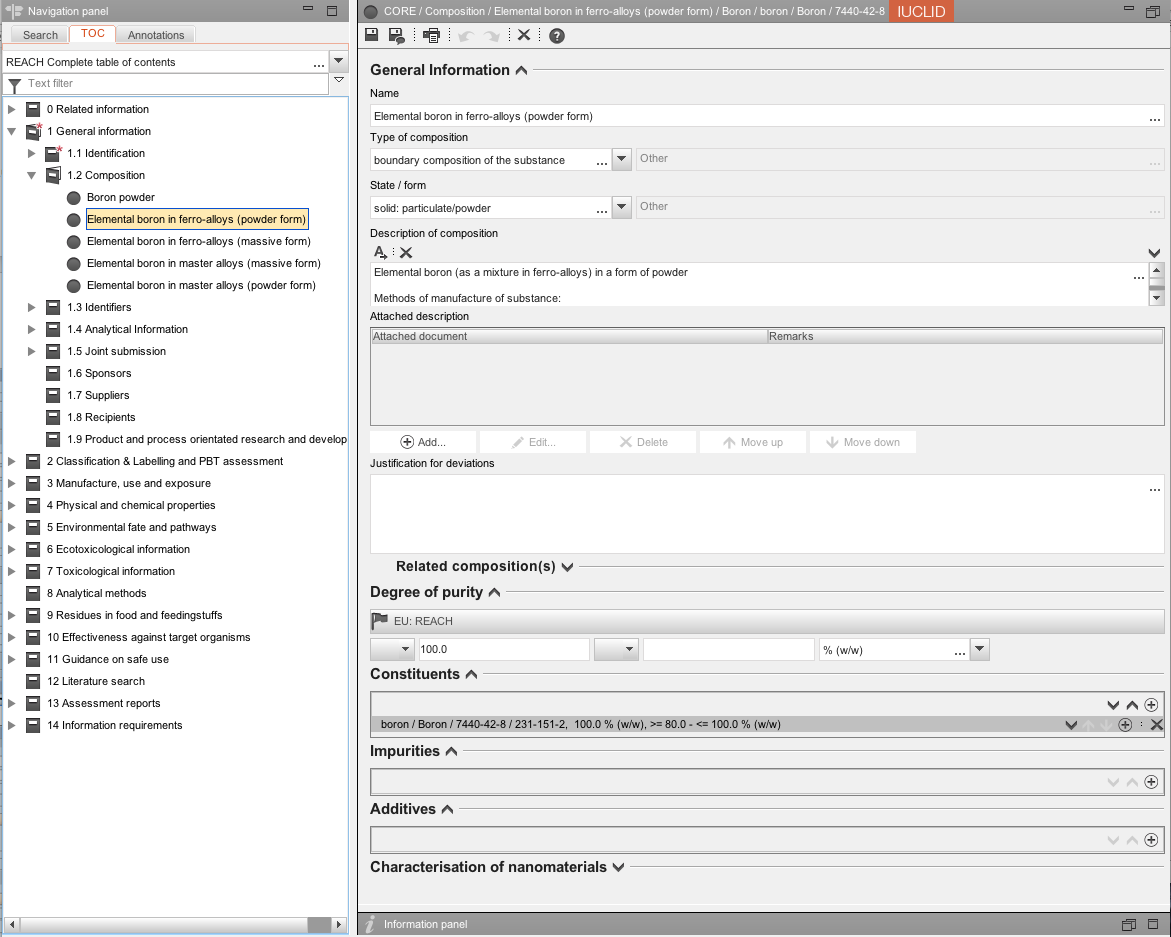
**1.2.1 Boron powders**



| **ITEM** | **TEXT TO BE ADDED** | **EXPLANATION** |
| --- | --- | --- |
| **General information** | Heading only |  |
| Name | Boron powder |  |
| Type of composition | Legal entity composition |  |
| State / form | Solid: particulate/powder |  |
| Description of composition | Boron powders refer to boron powders made by chemical reduction and electrolysis  Methods of manufacture of substance:  Amorphous boron powder -  Amorphous boron is produced in a Moisson process from boron oxide and magnesium. Both raw materials are mixed and ignited to start the strongly exothermic reaction. An excess of boron oxide is used as reaction moderator. The reaction block is cooled in a water basin and then crushed in a jaw breaker and a roller crusher. Hydrochloric acid is used to remove remaining magnesium oxide and incompletely reduced boron oxide from the raw boron. The excess of boron oxide is collected as boric acid. The boron is dried in fluidized bed driers to get boron with boron with 86%. Using a higher excess of boron oxide another grade with 90% boron content is obtained.  The 86% boron grade can be cleaned further in a thermal treatment step with fluorides to convert insoluble by-products into soluble compounds which are again removed by washing with hydrochloric acid to obtain boron with 95-97% boron content.  The resulting powders are mixed homogeneously, analyzed and packed in drums.  Crystalline boron powder -  Crystalline boron is produced from amorphous boron by re-crystallization in vacuum induction furnaces at temperatures of typically 2000°C. The reaction block is crushed and milled to obtain the specialty product crystalline boron. | Enter the description of the registered boron powder |
| Attached descriptions | Leave blank |  |
| Justification for deviations | Leave blank |  |
| Related compositions | Leave blank |  |
| **Degree of purity flags:** | Heading only | Click on the flag if you want to assign confidentiality and programme restriction |
| Confidentiality |  | Leave blank or select the right level of confidentiality. If confidentiality is required, a justification has to be provided. |
| Programme restrictions |  | Select EU: REACH from pick list. |
| **Degree of purity** | >= 85 <= 100 % [w/w] | This purity is by default the same for all boron powders. |
| **Constituents** | Heading only |  |
| Reference substance | boron / Boron / 7440-42-8 / 231-151-2 | To locate the reference substance from the IUCLID data base, click on this icon [see red arrow in screenshot above].    Select your substance from the database by typing in the name, EC or CAS number, click SEARCH, select the substance name and click Assign [see screenshot below].  Two problems may arise:  • If no entry is found, you have first to import the substance from the EC inventory to the reference substance inventory.  • If an entry is found but is inactive, right mouse click and set to “active reference substance.”  In order to simplify matters, the REACH Boron Consortium has provided reference substance files which member registrants can import into their IUCLID dossiers (see Note 1 on page 6 above). |
| Typical concentration |  | Enter the typical concentration of boron in your registered boron powder(s) |
| Concentration range | ≥ 85 ≤ 100 % [w/w] | This is per the sameness specification agreed by the SIEF. |
| Remarks |  | Boron powder: Enter any comments that you may wish to make with respect to the concentration level or range of your substance here. |

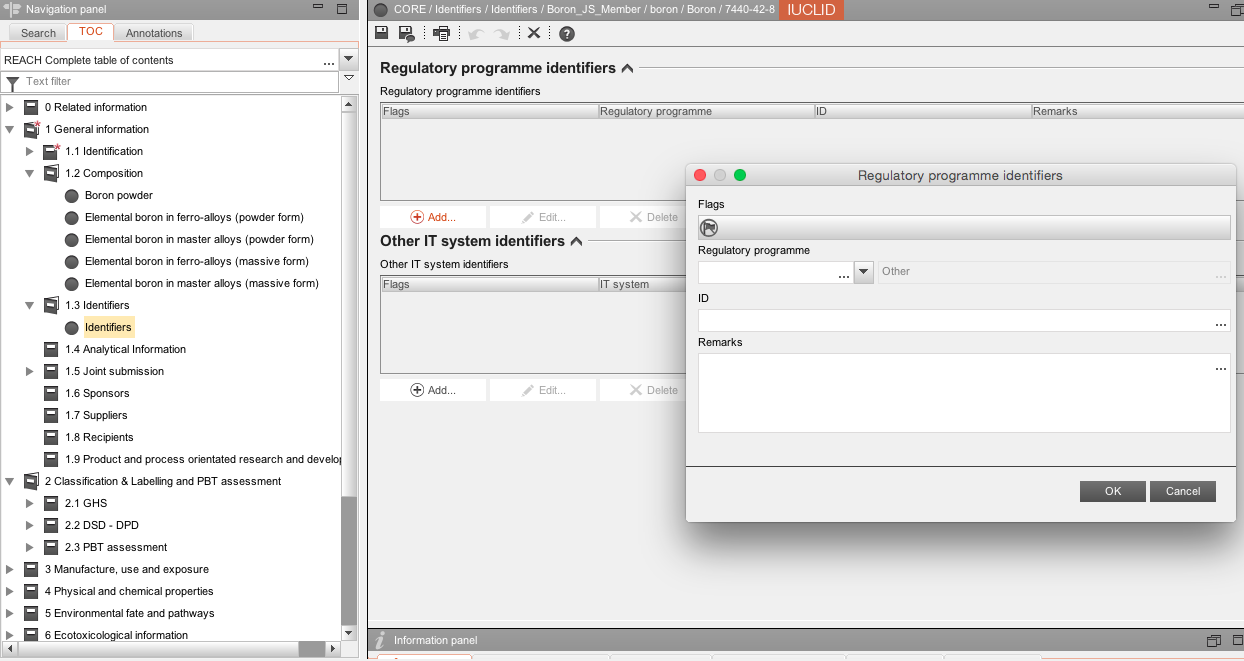
|  |  |  |
| --- | --- | --- |
| **Impurities** | Heading only | For boron powder, enter relevant compounds that do not induce any classification for the substance.  Add a block for each impurity by clicking on . |
| Reference substance | magnesium / magnesium / magnesium / 7439-95-4 | To locate the reference substance from the IUCLID data base, click on this icon  In order to simplify matters, the REACH Boron Consortium has provided reference substance files which member registrants can import into their IUCLID dossiers (see Note 1 on page 6 above). |
| Typical concentration |  | Enter the concentration level or range for your substance here. |
| Concentration range | ≥ 0 ≤ 10 % [w/w] | This is per the sameness specification included in the Chemical Safety Report for Boron. |
| Remarks |  | Enter any comments that you may wish to make with respect to the concentration level or range of your substance here. |
| Do not tick : “this impurity is considered relevant for the classification and labelling of the substance” | | |
| **Impurities** | Heading only |  |
| Reference substance | Magnesium oxide / Magnesium oxide / Magnesium oxide / 1309-48-4 | To locate the reference substance from the IUCLID data base, click on this icon  In order to simplify matters, the REACH Boron Consortium has provided reference substance files which member registrants can import into their IUCLID dossiers (see Note 1 on page 6 above). |
| Typical concentration |  | Enter the concentration level or range for your substance here. |
| Concentration range | ≥ 0 ≤ 5 % [w/w] | This is per the sameness specification included in the Chemical Safety Report for Boron. |
| Remarks |  | Enter any comments that you may wish to make with respect to the concentration level or range of your substance here. |
| Do not tick : “this impurity is considered relevant for the classification and labelling of the substance” | | |
| **Additives** | Heading only | Do not create a block here |
| **Characterisation of nanomaterial** | Heading only | Not applicable, leave all items under nanomaterials blank |

**1.2.2 Elemental boron in ferro- and master alloys (massive form / powder form)**



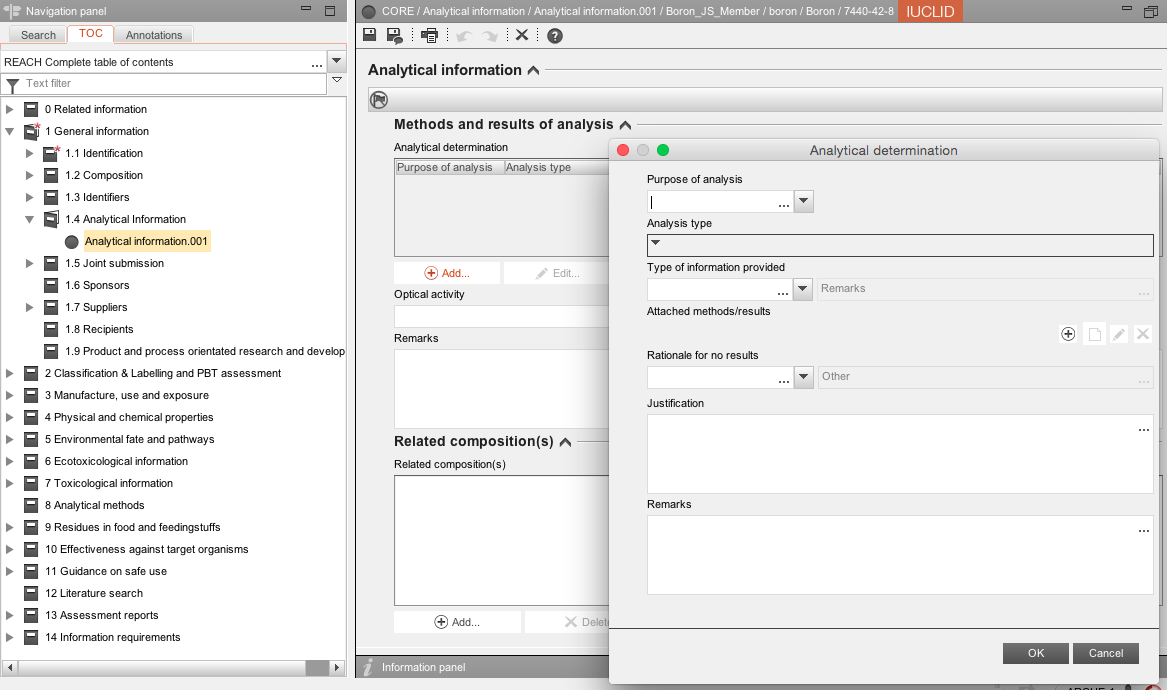
| **ITEM** | **TEXT TO BE ADDED** | **EXPLANATION** |
| --- | --- | --- |
| **General information** | Heading only |  |
| Name | Elemental boron in ferro-boron (powder form) |  |
| Elemental boron in ferro-boron (massive form) |
| Elemental boron in master alloys (powder form) |
| Elemental boron in master alloys (massive form) |
| Type of composition | Legal entity composition |  |
| State / form | Solid: particulate/powder |  |
| Description of composition | Elemental boron (as a mixture in ferro alloys) in a form of powder  Methods of manufacture of substance:  Elemental boron in ferro-alloys (massive and powder forms) by carbothermic processes -    Ferro-boron is produced by the carbothermic reduction of boric acid/boric oxide together with low carbon steel It is melted in a single phase arc furnace. Each melt produces an ingot which is crushed to lump or powder. Sizes range from 10 mm down. Packaging is steel drums. | Enter an appropriate description of your substance as placed on the market, e.g. elemental boron contained in ferro-alloys or master alloys |
| Elemental boron (as a mixture in ferro alloys) in massive form  Methods of manufacture of substance:  Elemental boron in ferro-alloys (massive and powder forms) by carbothermic processes -    Ferro-boron is produced by the carbothermic reduction of boric acid/boric oxide together with low carbon steel It is melted in a single phase arc furnace. Each melt produces an ingot which is crushed to lump or powder. Sizes range from 10 mm down. Packaging is steel drums. |
| Elemental boron (as a mixture in master alloys) in a form of powder  Elemental boron in master alloys (massive forms) -  Boron-aluminium alloys are manufactured by reacting molten aluminium with potassium tetrafluoroborate salts in a high frequency induction furnace. The product is cast into bar, continuous rod or waffle plate.  Elemental boron in Chromium alloys (massive and powder forms) by carbothermic processes -  Chromium Boron is produced by the carbothermic reduction of boric acid/boric oxide together with chromium powder. It is melted in a single phase arc furnace. The melt is allowed to cool in the furnace. It is then removed and crushed to lump or powder. Sizes range from 10 mm down. Packaging is steel drums.  Elemental boron in Nickel alloys (massive and powder forms) by carbothermic processes -  Nickel Boron is produced by the carbothermic reduction of boric acid/boric oxide together with Nickel powder. It is melted in a single phase arc furnace. Each melt produces an ingot which is crushed to lump or powder. Sizes range from 10 mm down. Packaging is steel drums. |
| Elemental boron (as a mixture in master alloys) in massive form  Elemental boron in master alloys (massive forms) -  Boron-aluminium alloys are manufactured by reacting molten aluminium with potassium tetrafluoroborate salts in a high frequency induction furnace. The product is cast into bar, continuous rod or waffle plate.  Elemental boron in Chromium alloys (massive and powder forms) by carbothermic processes -  Chromium Boron is produced by the carbothermic reduction of boric acid/boric oxide together with chromium powder. It is melted in a single phase arc furnace. The melt is allowed to cool in the furnace. It is then removed and crushed to lump or powder. Sizes range from 10 mm down. Packaging is steel drums.  Elemental boron in Nickel alloys (massive and powder forms) by carbothermic processes -  Nickel Boron is produced by the carbothermic reduction of boric acid/boric oxide together with Nickel powder. It is melted in a single phase arc furnace. Each melt produces an ingot which is crushed to lump or powder. Sizes range from 10 mm down. Packaging is steel drums. |
| **Degree of purity flags:** | Heading only | Click on the flag if you want to assign confidentiality and programme restriction |
| Confidentiality |  | Leave blank or select the right level of confidentiality. If confidentiality is required, a justification has to be provided. |
| Programme restrictions |  | Select EU: REACH from pick list. |
| **Degree of purity** | 100% [w/w] | For all types of alloys (massive / powder forms), elemental boron contained in alloys is considered 100% pure. |
| **Constituents** | Heading only |  |
| Reference substance | boron / Boron / 7440-42-8 / 231-151-2 | To locate the reference substance from the IUCLID data base, click on this icon [see red arrow in screenshot above].    Select your substance from the database by typing in the name, EC or CAS number, click SEARCH, select the substance name and click Assign [see screenshot below].  Two problems may arise:  • If no entry is found, you have first to import the substance from the EC inventory to the reference substance inventory.  • If an entry is found but is inactive, right mouse click and set to “active reference substance.”  In order to simplify matters, the REACH Boron Consortium has provided reference substance files which member registrants can import into their IUCLID dossiers (see Note 1 on page 6 above). |
| Typical concentration | 100 % [w/w] | For all types of alloys (massive / powder forms), in order to be consistent with the approach taken by the Lead Registrant 100% [w/w%] should be entered in this field. |
| Concentration range | ≥ 80 ≤ 100 % [w/w] | This is per the sameness specification agreed by the SIEF. |
| Remarks | Alloys (REACH Article 3(41)) are special type of mixture ‘special mixture’ (Recital 31, Annex I and Annex II). Only the individual substances (here metals) require registration (REACH article 6) and not the alloys themselves.  As the substance is part of the chemical matrix of an alloy, impurities cannot be meaningfully assigned to the substance.  Thus, the purity of the substance is 100%. | Recommended text for all types of alloys (massive / powder forms). |
| **Impurities** | Heading only | For all types of alloys (massive / powder forms), do not create a block here |
| **Additives** | Heading only | Do not create a block here |
| **Characterisation of nanomaterial** | Heading only | Not applicable, leave all items under nanomaterials blank |

**1.3 Identifiers**



| **ITEM** | **TEXT TO BE ADDED** | **EXPLANATION** |
| --- | --- | --- |
| **Regulatory programme identifiers** | Heading only | Click on |
| **Flag** | Heading only | Click on the flag if you want to assign confidentiality and programme restrictions. |
| **Regulatory programme** |  | Select REACH Pre-registration number and/or REACH registration number from the pick list. |
| **ID** |  | Enter your pre-registration and/or registration number. |
| **Remarks** | We have updated our pre-registration as producers and importers of boron-containing mixtures [alloys] will register boron [EINECS number 231-151-2, CAS number 7440-42-8] and the other alloying elements separately as components of a mixture [alloy]. | In the case that you did not pre-register boron [EINECS number 231-151-2, CAS number 7440-42-8], but for example you pre-registered for instance iron boride or di-iron boride, please add this remark. |
| **Other IT system identifiers** |  | Leave blank |

**1.4 Analytical information**



**1.4.1 Boron powders**

| **ITEM** | **TEXT TO BE ADDED** | **EXPLANATION** |
| --- | --- | --- |
| **Analytical information flags:** |  | Click on the flag if you want to assign confidentiality and programme restriction |
| Confidentiality |  | Leave blank or select the right level of confidentiality. If confidentiality is required, a justification has to be provided. |
| Programme restrictions |  | Select EU: REACH from pick list. |
| **Methods and results of analysis** | Heading only |  |
| Analytical determination | Heading only | Click on |
| Purpose of analysis |  | You must analyse your boron powder to confirm sameness. Select the appropriate end result from the performed analytics |
| Analysis type |  | Select the analysis method used |
| Type of information provided |  | Select the type of information |
| Attached methods/results |  | Attach a document describing your analysis method and/or results here. |
| Rationale for no results | Leave blank |  |
| Justification | Leave blank |  |
| Remarks |  | If you feel the need to provide an explanation on the results of the analysis, include it here. |
| Optical activity | Not applicable |  |
| Remarks |  | If you feel the need to provide an explanation on the results of the analysis, include it here. |
| **Related composition(s)** | Heading only | Create a block for each type of boron you wish to register by clicking on. |

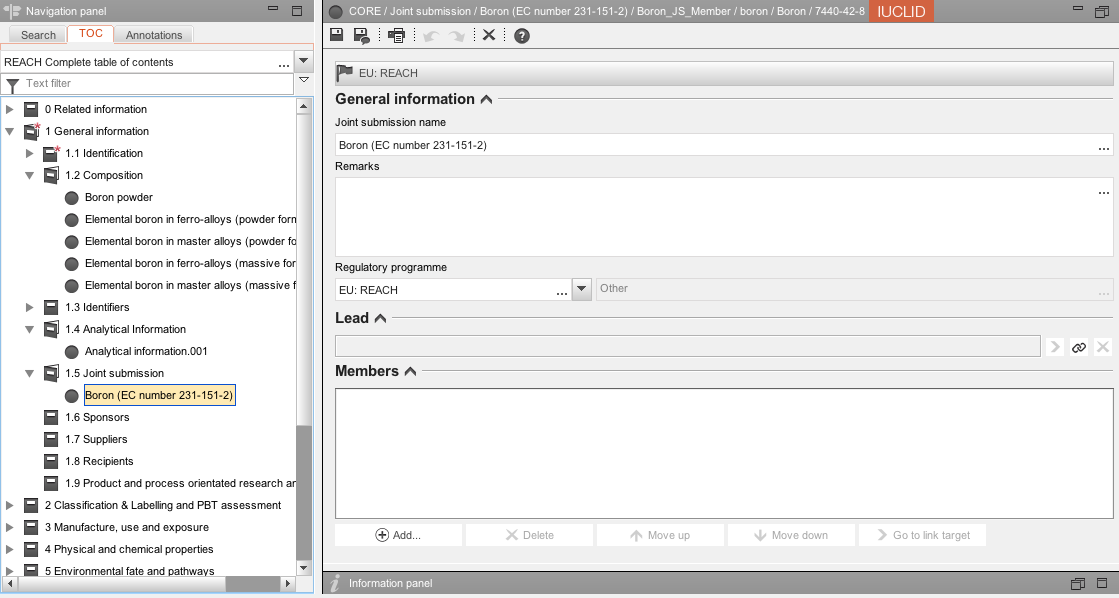
**1.4.2 Elemental boron in ferro- and master alloys (massive form / powder form)**

| **ITEM** | **TEXT TO BE ADDED** | **EXPLANATION** |
| --- | --- | --- |
| **Analytical information flags:** |  | Click on the flag if you want to assign confidentiality and programme restriction |
| Confidentiality |  | Leave blank or select the right level of confidentiality. If confidentiality is required, a justification has to be provided. |
| Programme restrictions |  | Select EU: REACH from pick list. |
| **Methods and results of analysis** | Heading only |  |
| Analytical determination | Heading only | Click on |
| Purpose of analysis |  | You must analyse your boron alloy. Select the appropriate end result from the performed analytics |
| Analysis type |  | Select the analysis method used |
| Type of information provided |  | Select the type of information |
| Attached methods/results |  | Attach a document describing your analysis method and/or results here. |
| Rationale for no results | Leave blank |  |
| Justification | Leave blank |  |
| Remarks | The constituent substances are bound in a chemical matrix. Methods such as XRF, XRD and ICP are appropriate techniques. While it may provide structural information concerning the alloy, XRD is unlikely to yield sameness information. | If you feel the need to provide an explanation on the results of the analysis, include it here. |
| Optical activity | Not applicable |  |
| **Remarks** | The registered substance is inorganic and a constituent of an alloy, where the constituent substances are bound in the chemical matrix. GC, HPLC, IR, NMR, MS and UV are not appropriate spectral techniques for alloys. Methods such as XRF, XRD and ICP are more appropriate techniques for the provision of the required structural and compositional information for this type of inorganic substance and a usual practice in the metals industry. However, while it may provide structural information concerning the alloy, XRD is unlikely to yield information useful for the determination of the sameness of the constituent and reference substances. This is due to the influence of the relative atomic size of the constituents, which determine the crystal structure adopted by the alloy, the extent of lattice strain and the range of solid solubility as well as the position taken up by individual atoms either in the lattice itself or in the interstice. In addition, the cooling rate as well as the thermal and mechanical history has a profound influence on the crystal structure of the alloy. | Include this remark |
| **Related composition(s)** | Heading only | Create a block for each type of boron you wish to register by clicking on. |

**Note for registrants of elemental boron in master alloys:**

Data on physical and chemical properties of ferro-boron such as water solubility, flammability and auto-flammability are included in the Lead Registrant dossier (part 4) which covers elemental boron in alloys. Nevertheless, data on physical and chemical properties of master alloys are not included in the Lead Registrant dossier since some experimental results performed on master alloys and the associated boron chemistry are complex and not fully understood. Hence for the moment, member registrants registering boron contained in master alloys may add their own specific data on physical and chemical properties of master alloys such as water solubility, flammability and auto-flammability in their own section 1.4 “Analytical information” by creating another block in the “Results of analysis” part.

**1.5 Joint submission**



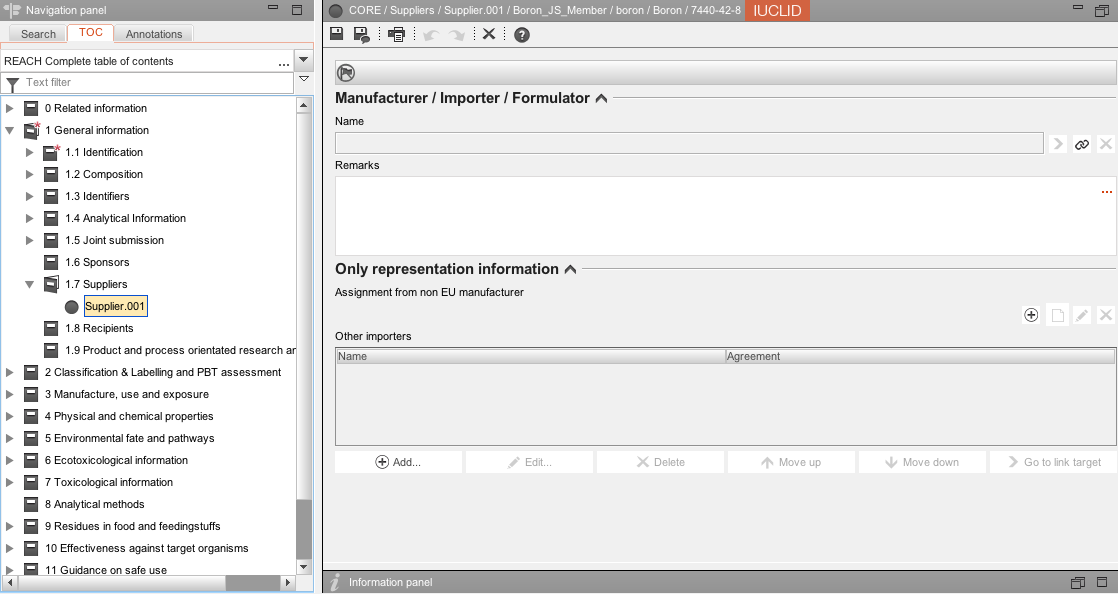
| **ITEM** | **TEXT TO BE ADDED** | **EXPLANATION** |
| --- | --- | --- |
| **Joint submission** | Heading only |  |
| **Joint submission flags:** |  | Click on the flag if you want to assign confidentiality and programme restriction |
| confidentiality |  | Leave blank or select the right level of confidentiality. If confidentiality is required, a justification has to be provided. |
| programme restrictions |  | Select EU: REACH from pick list. |
| **General information** |  |  |
| Joint submission name | Boron (EC number 231-151-2) |  |
| Remarks |  | Leave blank |
| Regulatory programme |  | Select EU: REACH. |
| **Lead** | Heading only | Leave blank |
| **Members** | Heading only | Leave blank |

**1.6 Sponsors**

It enables to specify different Sponsor organisations, e.g. a Competent Authority in the context of the OECD HPV Chemicals programme or a Company in the context of the US EPA HPV Challenge programme. Otherwise leave this section blank.

**1.7 Suppliers**

Leave this section blank unless you are an Only Representative. Although not mandatory, ECHA recommends that as an Only Representative you should attach clear documentation of your appointment as Only Representative, for example a copy of the appointment letter sent to importers. In this case you are also advised to indicate the list of importers’ names covered by the registration in the field “Other importers”. The REACH Boron Consortium strongly advises Only Representatives to follow ECHA’s recommendation.

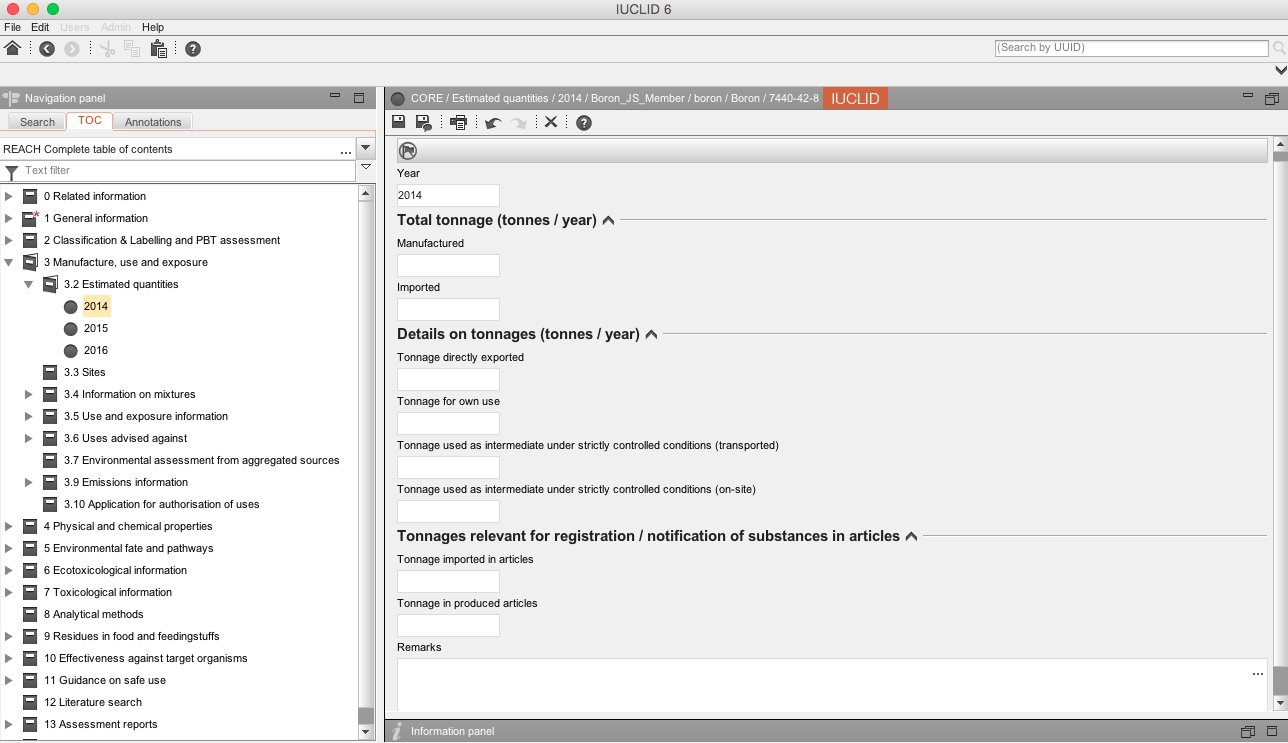


**1.8 Recipients**

A recipient can be a Downstream user, a Distributor or a Customer (e.g. in the context of Product and process orientated research and development (PPORD)) being supplied with a Substance, or a Mixture or an Article. These definitions never include consumers.

**3. MANUFACTURE, USE AND EXPOSURE**

**3.2 Estimated quantities**



Make endpoint study records for the last three years by clicking right and selecting new record.

| **ITEM** | **TEXT TO BE ADDED** | **EXPLANATION** |
| --- | --- | --- |
| **Estimated quantities flags:** |  | Click on the flag if you want to assign confidentiality and programme restriction |
| confidentiality |  | Leave blank or select the right level of confidentiality. If confidentiality is required, a justification has to be provided. |
| programme restrictions |  | Select EU: REACH from pick list. |
| **Year** |  | Enter the current year |
| **Total tonnage** |  | If the substance has been imported or manufactured for at least three consecutive years, the volume (tonnes per year) is calculated on the basis of the average tonnage manufactured or imported in the three preceding calendar years. If the substance has not been manufactured or imported for three consecutive years then the tonnes manufactured or imported in a calendar year should be used (see [ECHA guidance on registration](http://www.boron-consortium.org/assets/files/boronconsortium/ECHA/ECHA_registration_en.pdf), November 2016)  To determine the amount of a substance in an article or mixture, see the notes immediately below. |
| **Details on tonnages** |  | If you feel the need to provide an explanation for the basis of your tonnage, include it here. |
| **Tonnages relevant for registration** |  | If you feel the need to provide an explanation for the basis of your tonnage, include it here. |

**Amount of a substance in a mixture**

In order to be able to calculate the amount of a substance in a mixture, the total tonnage of the mixture is multiplied by the fraction of the constituent substance. This value can for example be obtained from the safety data sheet of the mixture. When only a range of concentrations of a substance in a mixture is available, then the maximum tonnage of the substance is calculated using the highest possible content of that substance in the mixture. Without more precise information on the composition, this tonnage should be used for the purpose of registration.

Source: ECHA Guidance: [Guidance on registration](http://www.boron-consortium.org/assets/files/boronconsortium/ECHA/ECHA_registration_en.pdf), version 3.0, November 2016

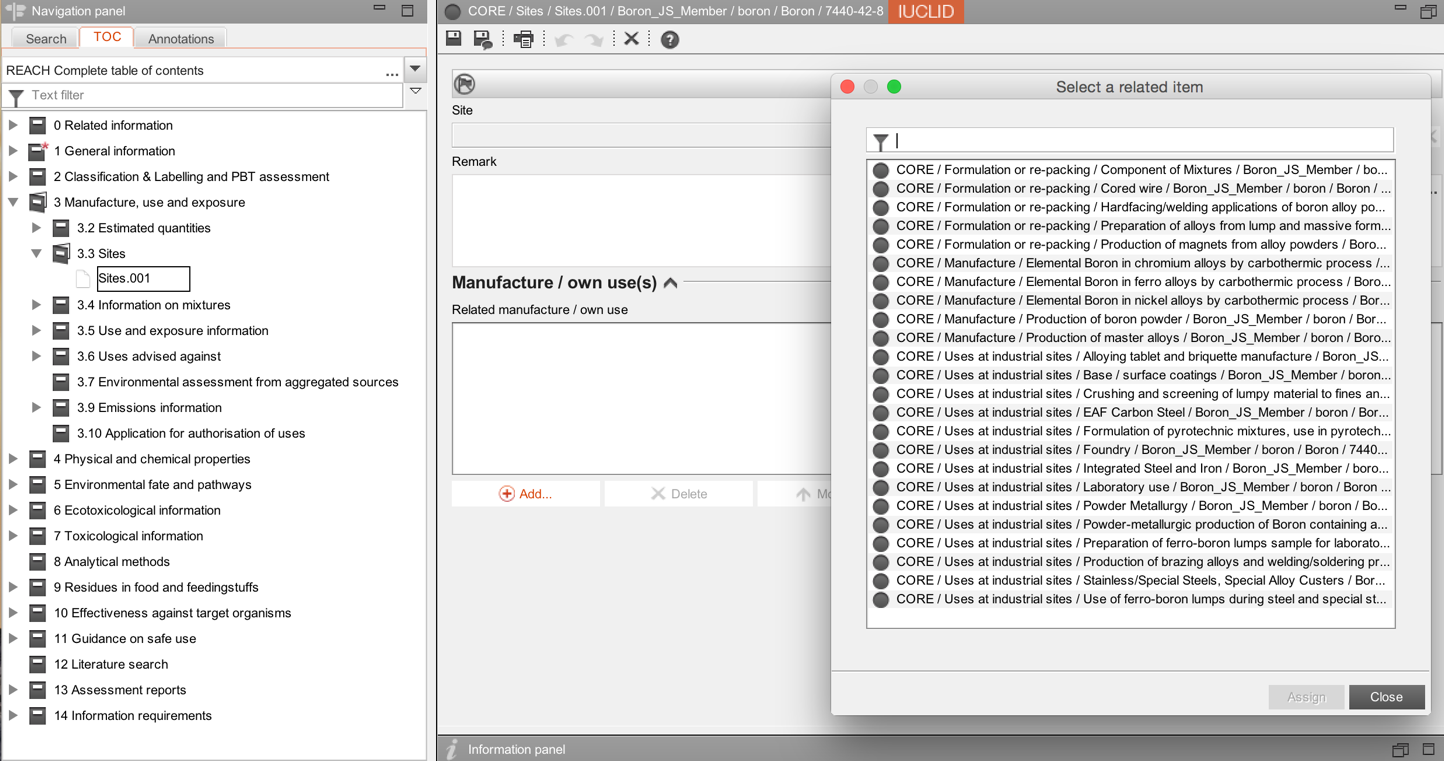
**Amount of a substance in an article**

In the case of articles which contain a substance that is intended to be released under normal or reasonably foreseeable conditions of use, then:

* If the weight by weight content of that substance is known, then this value is multiplied by the total mass of the produced and/or imported article; or
* If the weight of substance per unit article is known then this value is multiplied by the total number of imported articles.

Source: ECHA Guidance: [Guidance on requirements for substances in articles](http://www.boron-consortium.org/assets/files/boronconsortium/ECHA/ECHA_articles_en_1512.pdf), version 3.0, December 2015

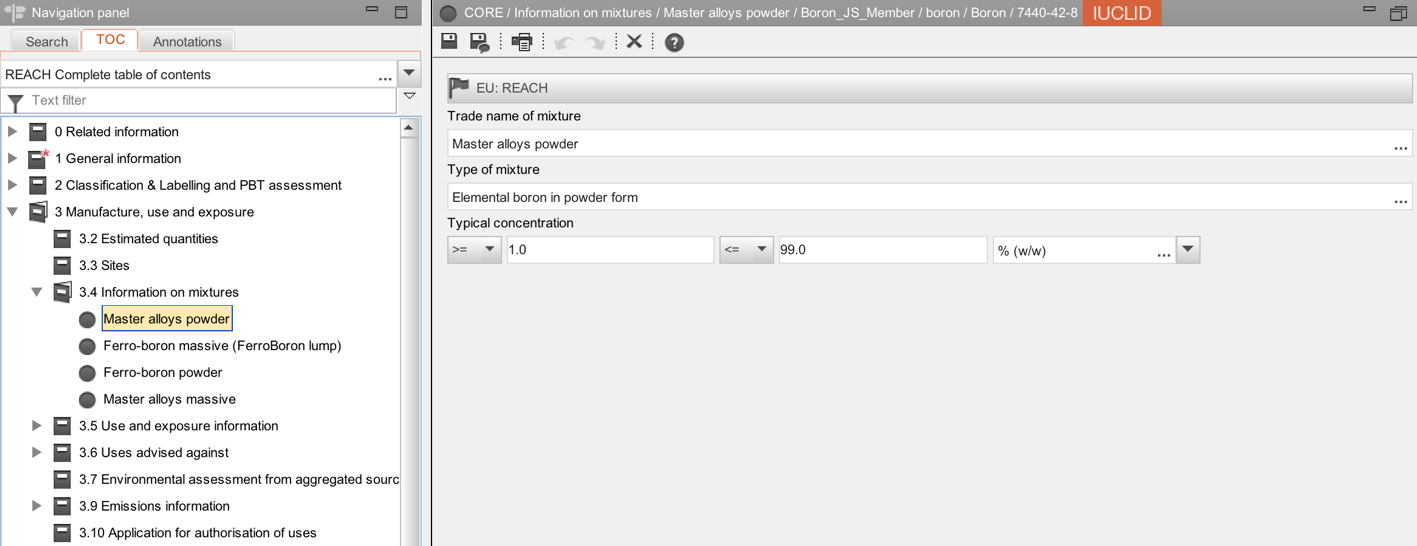
**3.3 Sites**



Create a new record for each production site by clicking right and selecting new record.

| **ITEM** | **TEXT TO BE ADDED** | **EXPLANATION** |
| --- | --- | --- |
| **Site flags:** |  | Click on the flag if you want to assign confidentiality and programme restriction |
| Confidentiality |  | Leave blank or select the right level of confidentiality. If confidentiality is required, a justification has to be provided. |
| Programme restrictions |  | Select EU: REACH from pick list. |
| **Site** |  | Click on  to select an existing site or create a new site  Enter the name and location of your site(s). The minimum contact address information is town/city and country, but ECHA recommends filling all address fields.  An Only Representative or Importer can assign a site, but this is not mandatory.  If “Manufacturer” is selected in section 1.1, at least one production site must be entered in section 3.3. |
| **Manufacture/own use(s)** |  | Create a block. Click on Select appropriate manufacture(s) or use(s) from the section 3.5 Use and exposure information description. |

**3.4 Information on mixtures**



| **ITEM** | **TEXT TO BE ADDED** | **EXPLANATION** |
| --- | --- | --- |
| **Flags** |  | Click on the flag if you want to assign confidentiality and programme restrictions |
| Confidentiality |  | Leave blank or select the right level of confidentiality. If confidentiality is required, a justification has to be provided. |
| Programme restrictions |  | Select EU: REACH from pick list. |
| **Trade name of mixture** |  | Give the name of your alloy[s], e.g. Ferro-boron, etc. |
| **Type of mixture** | State the physical form of your alloy, e.g. massive, powder. |
| **Typical concentration** | Specify the content of boron contained in your alloys[s] - this can be a range or by default the maximum value. Ensure that the content given e.g. for iron is consistent with the value[s] for iron given in other registration dossiers for this alloy. |

### **3.5 Use and exposure information**

Uses covered by the Lead Registrant dossier are available on the REACH Boron consortium website. An i6z file containing the “Use and exposure information” endpoints of the Lead Registrant (LR) can be downloaded from the REACH Boron consortium website by clicking [here](http://www.boron-consortium.org/iuclid-files-for-download.html).

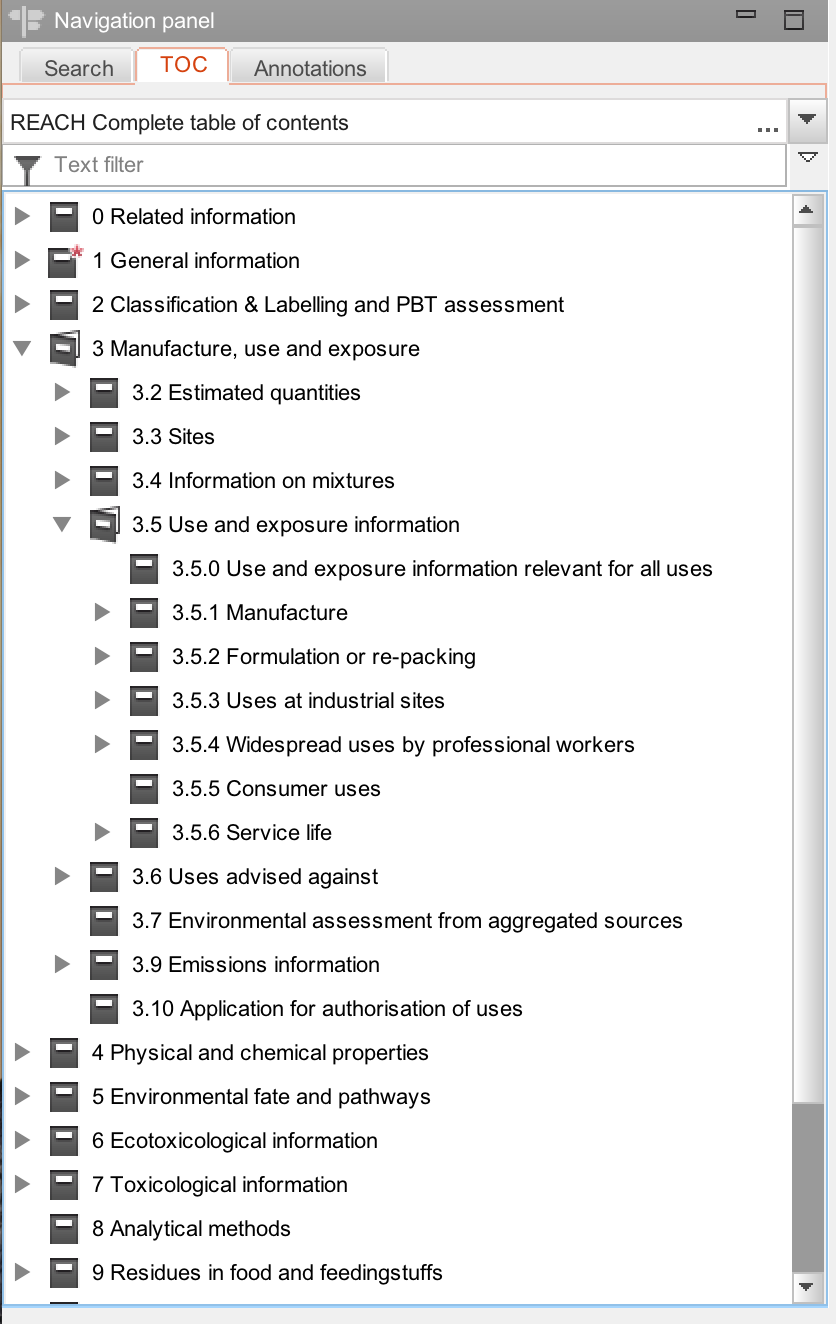
**We recommend you to:**

* **import the i6z file containing the uses covered by the LR dossier into your IUCLID application**
* **copy the full “*3.5 Use and exposure information” endpoints* of the LR to your boron substance dataset**

There is conflicting advice as to whether member registrants should select only certain uses submitted by the Lead Registrant or should select them all. We advise you to select them all to avoid a modification of your dossier if a new use arises in the future.

**Important:**

**All the uses submitted by the Lead Registrant (LR) are included in the joint Chemical Safety Report submitted by the LR on behalf of the members**. If one of your manufacture/uses/service life is not covered in the LR dossier, we strongly advise you to contact the [REACH Boron Consortium](http://www.boron-consortium.org/contact.html) as soon as possible. Note that if you wish to specify uses not included in the LR dossier, you need to carry out your own Chemical Safety Assessment for the uses, conditions of use and related volumes not covered in the joint Chemical Safety Report.

**

**3.6 Uses advised against**

Do not create a record in Section 3.6 and leave it blank as there are no uses advised against.

**3.7** **Environmental assessment for aggregated sources**

Do not create a record in Section 3.7 and leave it blank.

**3.9 Emissions information**

Do not create a record in Section 3.9 and leave it blank.

**3.10 Application for authorisation of uses**

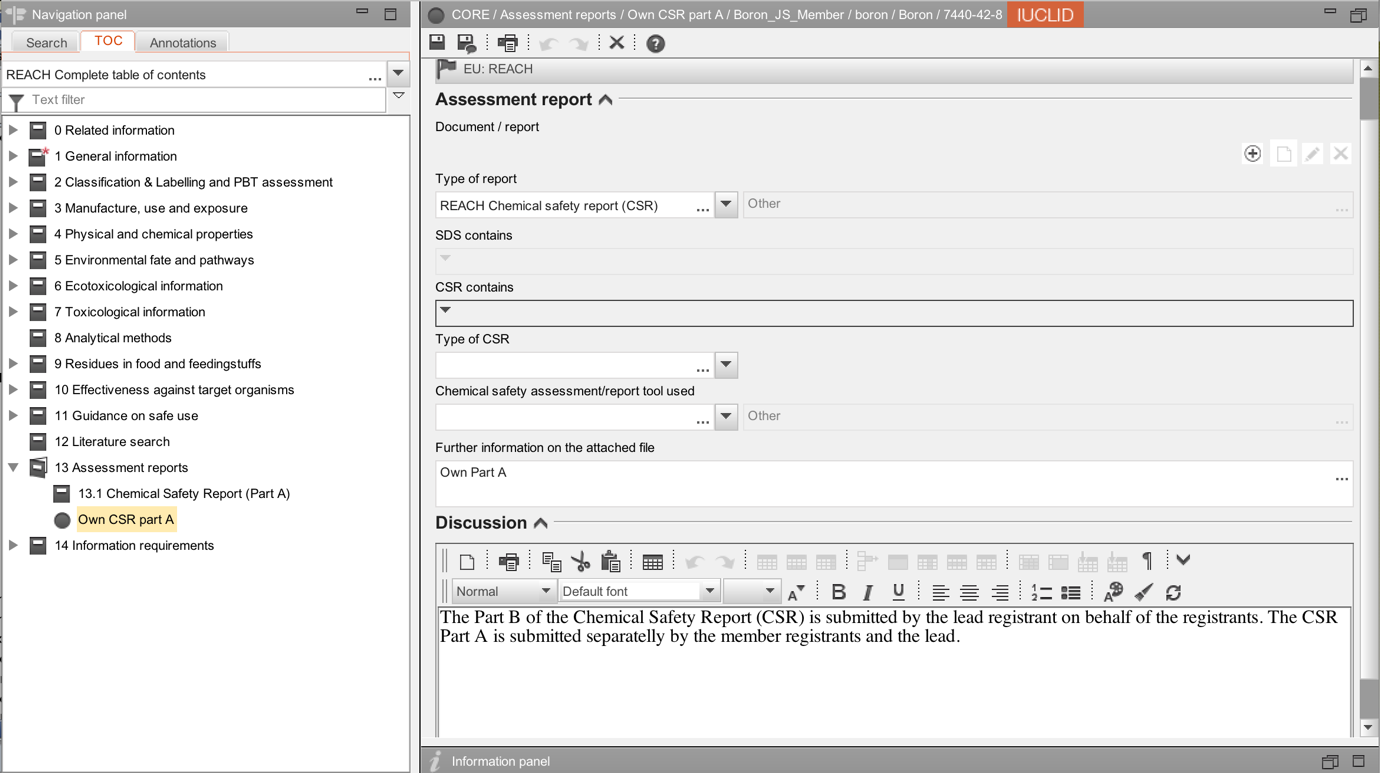
Do not create a record in Section 3.10 and leave it blank.

**11. GUIDANCE ON SAFE USE**

Leave blank; do not create an endpoint. The Guidance on Safe Use is provided by the Lead registrant on-behalf of all member registrants.

**13. ASSESSMENT REPORTS**

The Lead Registrant provided the part B of the CSR on behalf of all member registrants. Member registrants must attach their own part A of the CSR. A [draft of the CSR part A](http://www.boron-consortium.org/guidance.html) can be found on the Consortium website. Review it and amend it accordingly. Create an endpoint named ‘**own CSR part A**’ in the section 13 as recommended by ECHA and attach your part A of the CSR as a pdf file in the section 13.



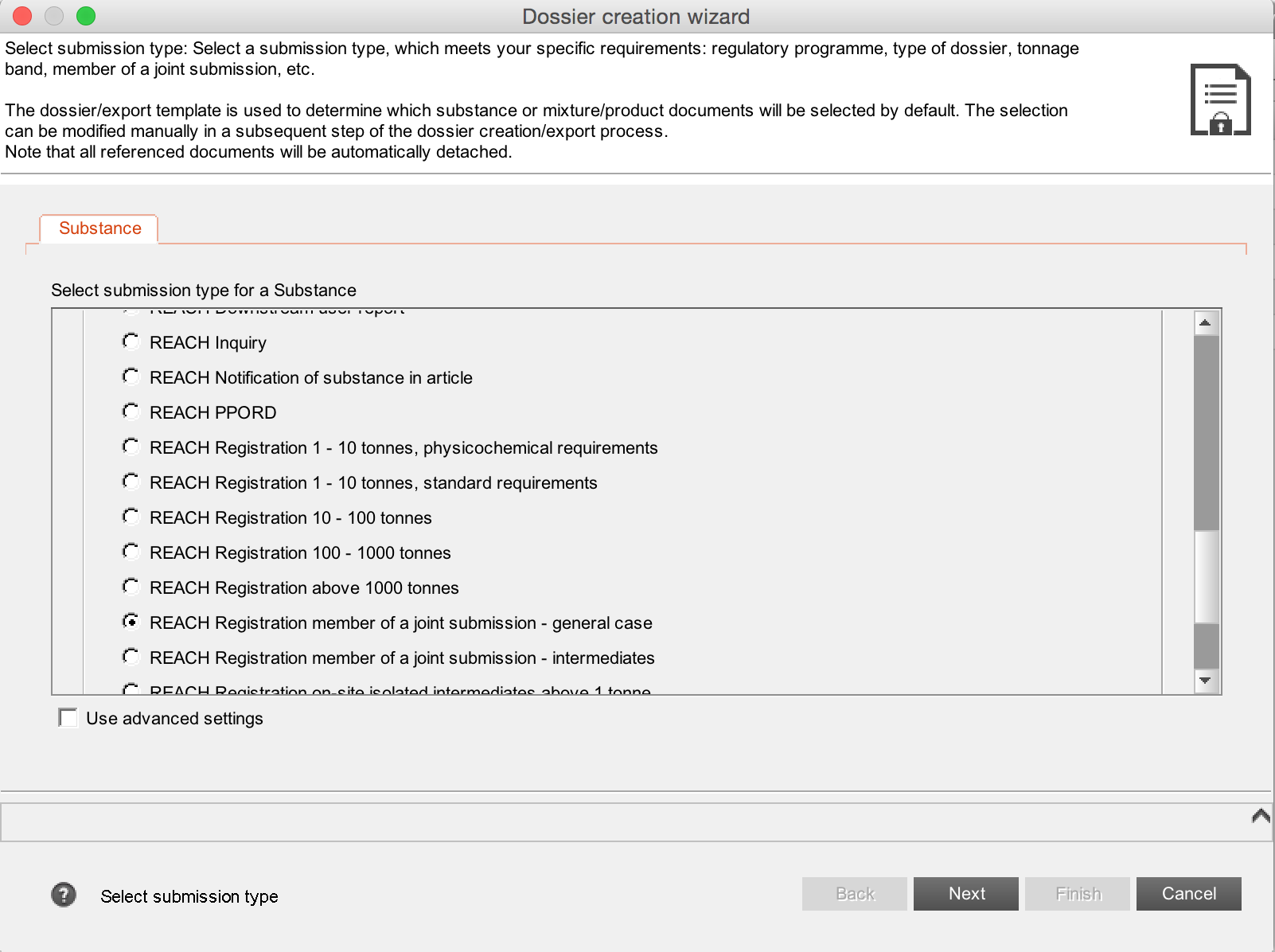
1. **DOSSIER RELATED INFORMATION**

**Important**:

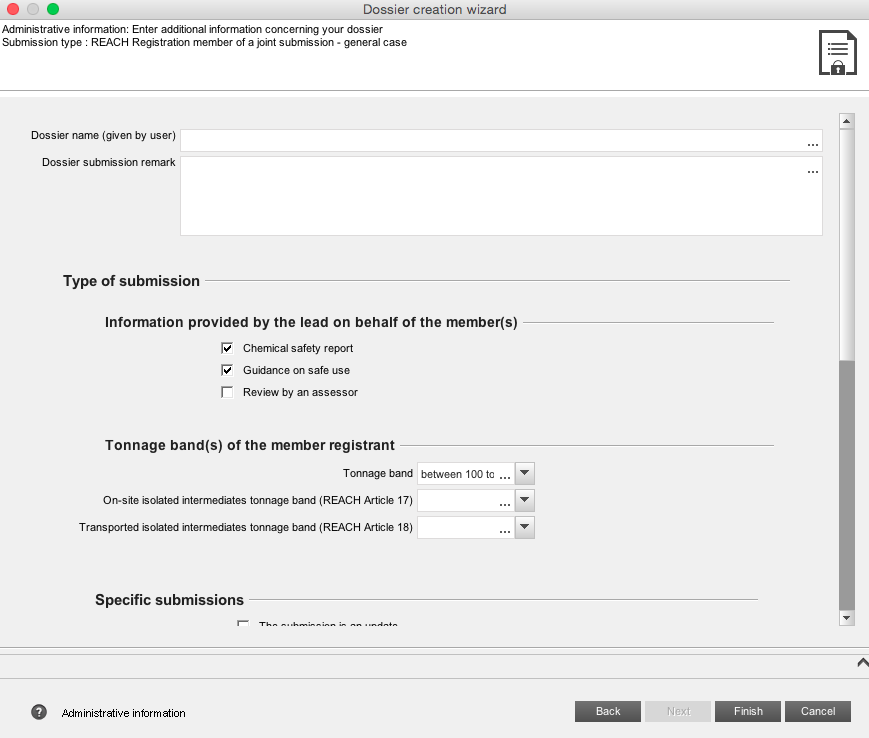
1. Run the Validation Assistant (VA) on your IUCLID substance file:

* If VA fails, correct all mistakes or create a new substance file
* If VA passes, go to the next step

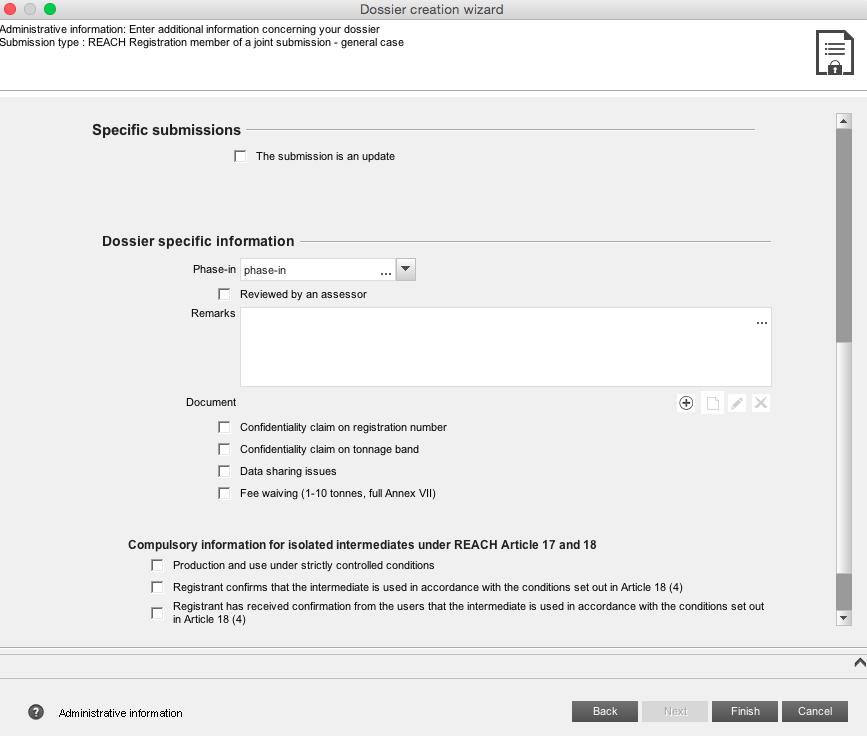
2. Select the appropriate substance, right click and select “Create dossier…” as displayed on the following screenshot and follow the dossier creation wizard guide



**Select the dossier template for member of a Joint Submission**



NOTE: The CSR part B is provided by the Lead Registrant for Boron. **This box should be ticked even if you are submitting your own part A.** See further information in the [ECHA Data Submission Manual 19: How to submit a CSR as part of a joint submission?](http://echa.europa.eu/documents/6362380/7127204/dsm_19_how_joint_csr_en.pdf/233094d2-ac31-48e7-8a13-ec011d965b69) (September 2010)



Tick the box(es) if you wish to claim confidentiality on registration number or tonnage band. Note that this will increase the registration fees.

1. **RECOMMENDATIONS CONCERNING SUBMISSION**

**Before submitting your dossier, do not forget to:**

1. **Run the VA** on your IUCLID dossier file

* If VA fails, create a new dossier file
* If VA passes, go to the next step

1. Export your dossier file on your computer by right clicking on the dossier
2. Login on your ECHA REACH-IT account specific to the Legal Entity
3. If the dossier file size is larger than 20MB => request a large file access code before submission on ECHA REACH-IT [it is normally immediate and you will receive the code in your ECHA REACH-IT message box]
4. Follow the prompts to submit your dossier file [for more detailed information, please consult the [ECHA Guidance on Registration (November 2016)](http://www.boron-consortium.org/assets/files/boronconsortium/ECHA/ECHA_registration_en.pdf)

**After submission:**

1. Check your message box in ECHA REACH-IT to follow progress of ECHA’s 14 dossier examination steps via the submission report. You can define an option in the *User Preferences* to receive an email alert when an email is sent on your REACH-IT mail box.
2. Take the necessary actions, for example paying the registration fee.

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Guidance version

|  |  |
| --- | --- |
| **Date** | **Version - Main changes** |
| December 2012 | Draft |
| March 2013 | First version |
| April 2013 | Revision of the boron powder composition (1.2) |
| May 2017 | Revision for compliance with IUCLID 6 |