

GUIDANCE ON COMPLETION OF SECTIONS 1 AND 3 OF THE IUCLID 5 DOSSIER: IRON SINTER [EINECS NUMBER 265-997-9, CAS NUMBER 65996-66-9]

INTRODUCTION

This document details the information submitted by the Lead Registrant for Iron Sinter and is intended as a guide to member registrants for completion of the necessary fields of sections 1 and 3 of their IUCLID 5.2 dossiers for Iron.

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 Practical Guide 9: How to do a registration 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.

This document contains two types of information:

- that which will be common to all dossiers which are part of the Joint Submission for Sinter - 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.

In order to input data to fields, please click on the EDIT button or select Control-E.



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 5.2 TCC plug-in tool [don't forget to update this plug-in].



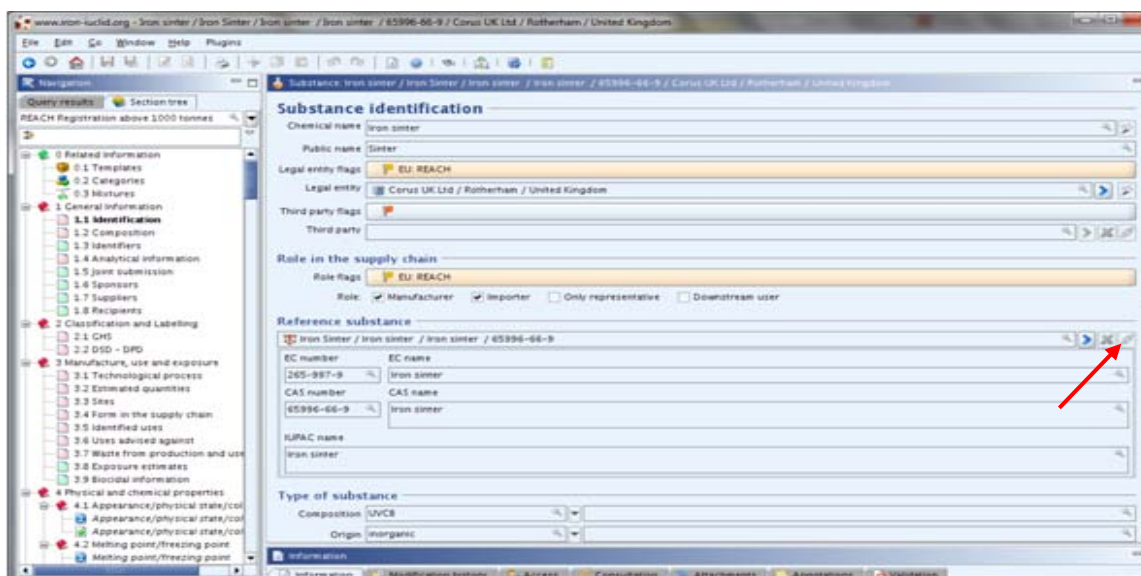
If confidentiality is required, the registration fee will be more expensive and a justification has to be provided! Note that ECHA has very recently issued a [guidance document on confidentiality claims](#) - this can be downloaded from the ECHA website or from the Library page of the Iron Platform website via the link in this sentence. A fee calculator plug in for IUCLID 5.2 will soon be available.

Information on the creation of a new substance is available on the Iron Platform website in the [SLIDES FROM IUCLID AND REACH-IT WEBINAR 08/07/2010](#) [slides 14-20]. Member registrants will have to import all IUCLID files [reference substances and the file containing the uses] provided by the Iron Platform before creating their substance files. A guidance document "How to import an i5z file into IUCLID 5.2" is available on the Iron Platform website.


An IUCLID 5.2 dissemination plug-in tool is available. This allows a registrant to preview or simulate the information from its registration dossier that ECHA will make available via the internet.



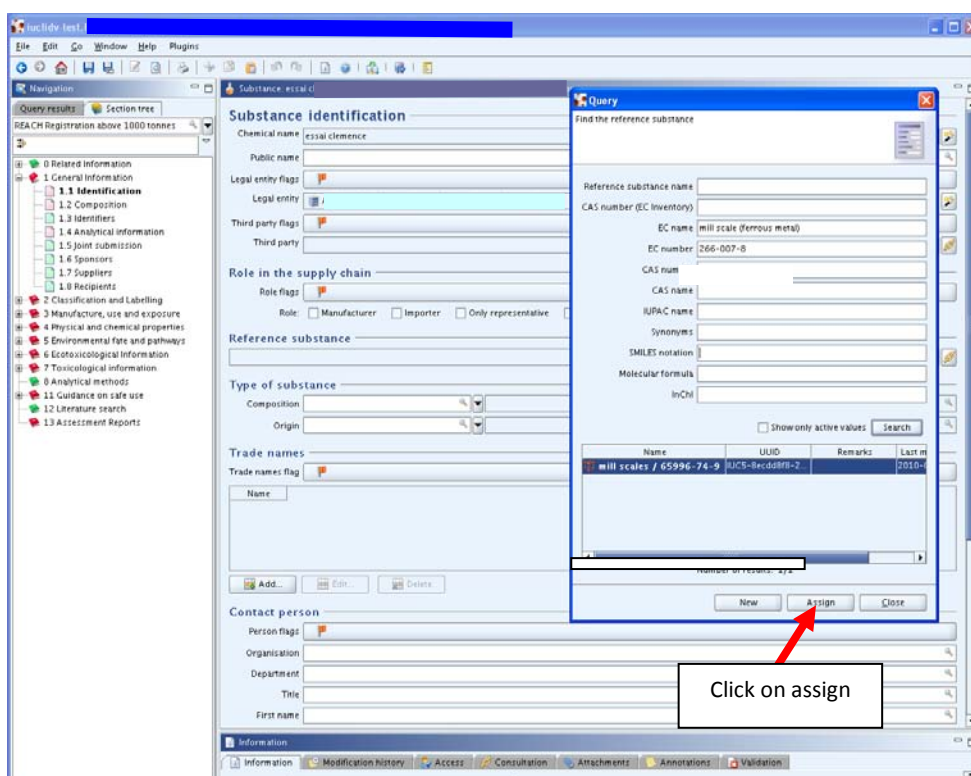
1.1 IDENTIFICATION



ITEM	TEXT TO BE ADDED	EXPLANATION
Substance identification	Heading only	
Chemical name	Iron Sinter	
Public name		Enter the generic name by which you describe your substance, e.g. sinter
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 the appropriate box[es]. Note: <ul style="list-style-type: none"> If "manufacturer" is selected, a production site is needed in section 3.3 "downstream user" cannot be selected if the submission covers only intermediates If "downstream user" is selected, "substance in article" must be ticked in section 3.4 "only representative" cannot be selected together with "manufacturer" or "importer"
Role 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		Leave blank or select EU: REACH.
Reference substance	Iron sinter / 65996-66-9	<p>To locate the reference substance from the IUCLID data base, click on this icon [see red arrow in screenshot above].</p>  <p>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].</p> <p>Two problems may arise:</p> <ul style="list-style-type: none"> • 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 inactive, right mouse click and set to “active reference substance.” <p>In order to simplify matters, the Iron Platform will provide reference substance files which member registrants can import into their IUCLID dossiers.</p>
EC number / name		This information is automatically provided when the reference substance is assigned.
CAS number		This information is automatically provided when the reference substance is assigned
IUPAC name		This information is automatically provided when the reference substance is assigned.
Description	The thermally agglomerated substance formed by heating a variable mixture of finely divided coke, iron ore, blast furnace dust, steelmaking dust, mill scale, other miscellaneous iron-bearing materials, limestone, and dolomite at 1315°C to 1482°C (2400°F to 2700°F).	
Synonyms	sinter	
Molecular & Structural information	Heading only	
Molecular formula	Not available	
Molecular weight range		Leave blank
SMILES notation	Not available	
InChI	Not available	
Structural formula		Leave blank

Remarks	Iron Sinter is a thermally agglomerated substance formed by heating a variable mixture of finely divided coke, iron ore, blast furnace dust, steelmaking dust, mill scale, other miscellaneous iron-bearing materials, limestone, and dolomite at 1315°C to 1482°C (2400°F to 2700°F). Therefore it is not possible to give a 'Molecular Formula' and the 'Molecular Weight'.	
Type of substance:	Heading only	
composition	UVCB	Select from pick list
origin	inorganic	Select from pick list
Trade names	Heading only	
Trade names flag:		Click on the flag if you want to assign confidentiality and programme restrictions.
confidentiality		If confidentiality is required, a justification has to be provided. Leave blank or select the right level of confidentiality.
programme restrictions		Select EU: REACH from pick list.
Name		If you have trade name[s] for your substance, add it/them here
Contact person		These fields are for your own company information. The details entered should correspond with the information contained in REACH-IT



Reference substance: Iron Sinter / Iron sinter / Iron sinter / 65996-66-9

Add... View... Delete

Group / category information

Molecular and structural information

EU: REACH

Molecular formula: not available

Molecular weight range: [] []

SMILES notation: not available

InChI: not available

Structural formula

Load... Zoom... Delete

Remarks: Iron Sinter is a thermally agglomerated substance formed by heating a variable mixture of finely divided coke, iron ore, blast furnace dust, steelmaking dust, mill scale, other miscellaneous iron-bearing materials, limestone, and dolomite at 1315°C to 1482°C (2400°F to 2700°F). Therefore it is not possible to give a 'Molecular Formula' and the 'Molecular Weight'.

Information

Information Modification history Access Consultation Attachments Annotations Validation

www.eurochem-lucid.org - Iron sinter / Iron Sinter / Iron sinter / Iron sinter / 65996-66-9 / Corus UK Ltd / Rotherham / United Kingdom

Substance: Iron sinter / Iron Sinter / Iron sinter / Iron sinter / 65996-66-9 / Corus UK Ltd / Rotherham / United Kingdom

Add... View... Delete

EU: REACH

Person flags

Organization

Department

Title

First name

Last name

Phone

Mobile

Fax

E-mail

Address

Address

Postal code

Town

Region / State

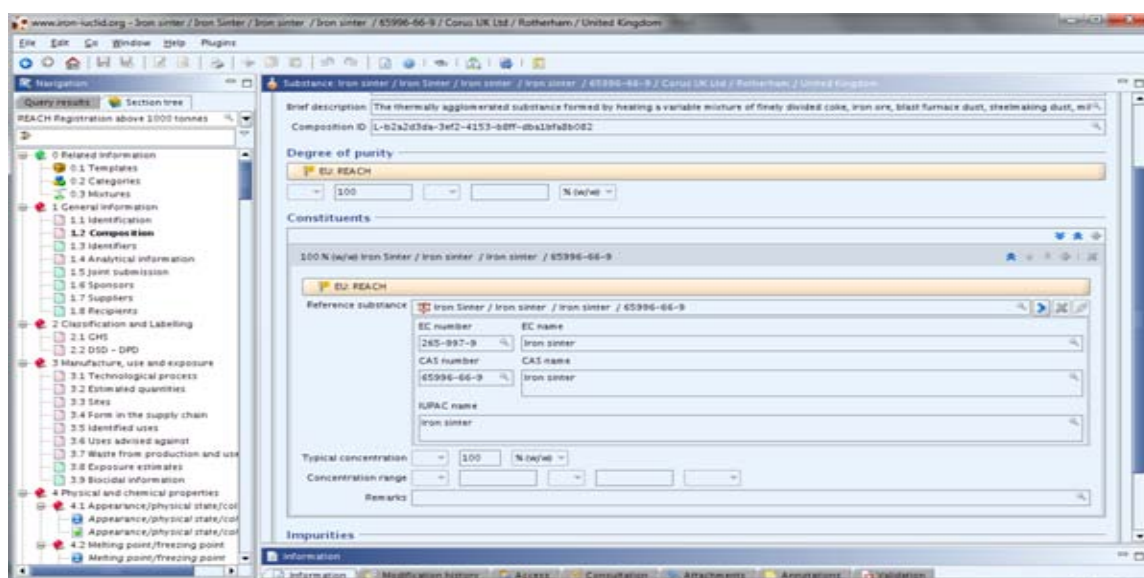
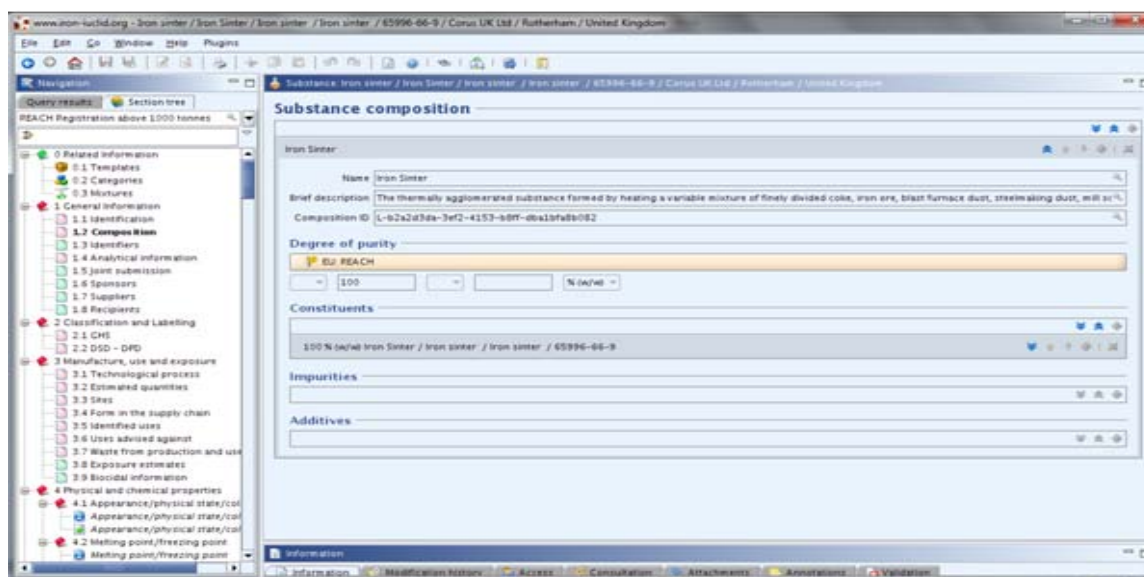
Country

Remarks


Information

Information Modification history Access Consultation Attachments Annotations Validation

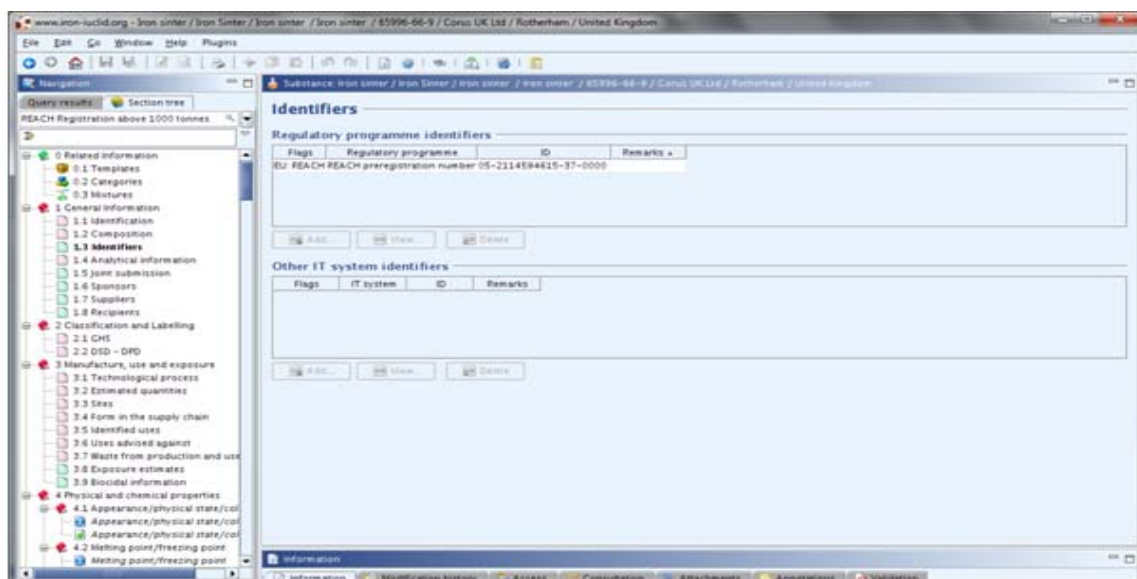
1.2 COMPOSITION



ITEM	TEXT TO BE ADDED	EXPLANATION
Substance composition	Heading only	Create a block here
Name	Iron Sinter	
Brief description	The thermally agglomerated substance formed by heating a variable mixture of finely divided coke, iron ore, blast furnace dust, steelmaking dust, mill scale, other miscellaneous iron-bearing materials, limestone, and dolomite at 1315°C to 1482°C.	Text from Lead Registrant.
Composition ID		Automatically filled by IUCLID.
Degree of purity flags		
confidentiality		Leave blank or select the right level of confidentiality. If confidentiality is required, a

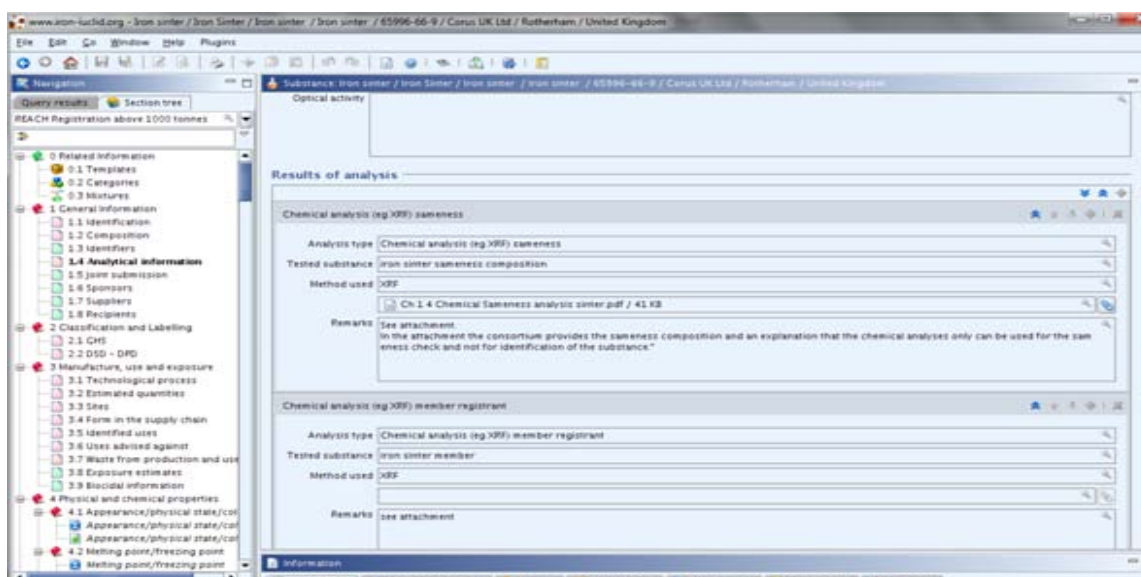
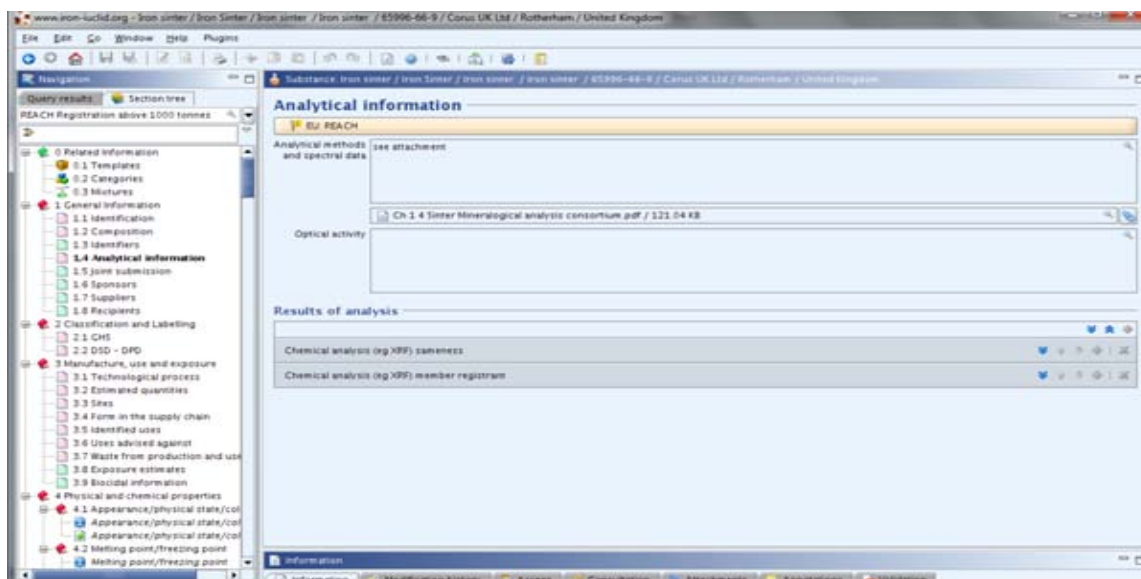
		justification has to be provided.
programme restrictions		Select EU: REACH from pick list.
Degree of purity	100% and % [w/w]	
Constituents	Iron sinter / 65996	
Reference substance	Iron sinter / 65996	<p>To locate the reference substance from the IUCLID data base, click on this icon [see section 1.1 above].</p>  <p>Select your substance from the database by typing in the name, EC or CAS number, click SEARCH, select the substance name and click Assign.</p> <p>Two problems may arise:</p> <ul style="list-style-type: none"> • 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 inactive, right mouse click and set to "active reference substance." <p>In order to simplify matters, the Iron Platform will provide reference substance files which member registrants can import into their IUCLID dossiers.</p>
Typical concentration	100% w/w	
Concentration range	100% w/w	
Remarks	Due to the lack of differentiation between constituents and impurities, the terms "main constituents" and "impurities" should not be regarded as relevant for UVCB substances (Ref. ECHA - Guidance for identification and naming of substances under REACH - Section 4.3.1.1 Information on chemical composition)	Suggested text.
Impurities		Do not create a block here - leave blank.
Additives		Do not create a block here - leave blank.

1.3 IDENTIFIERS






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.
Regulatory programme identifiers		Select REACH Pre-registration number or REACH Inquiry number from the pick list.
ID		Enter your pre-registration or inquiry number.
Remarks		Leave blank
Other IT system identifiers		Leave blank


1.4 ANALYTICAL INFORMATION



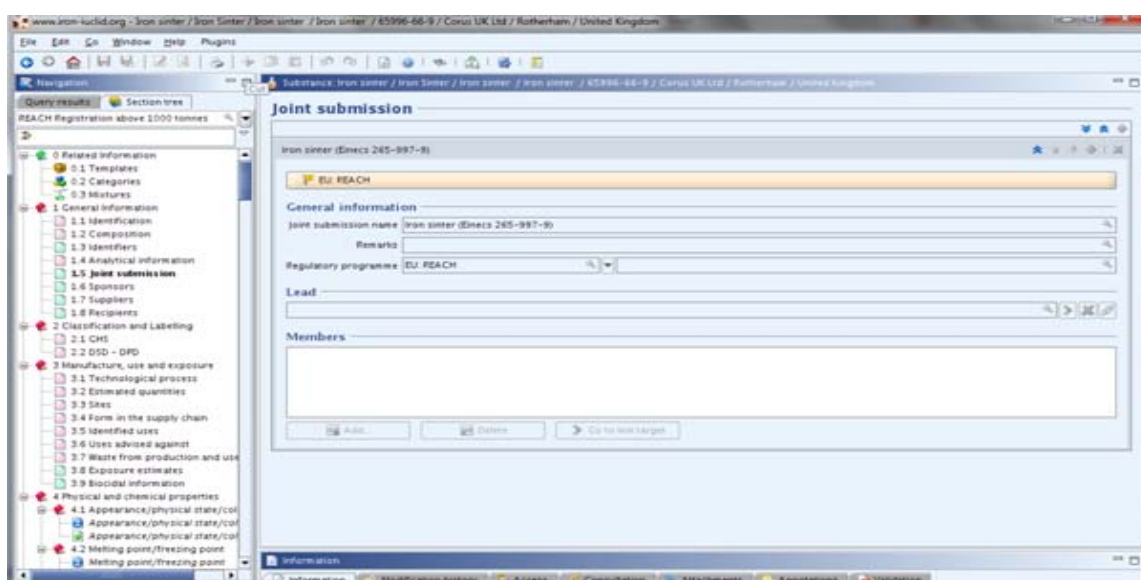
For guidance on the analytical methods to use, please refer to our guidance document on [Composition and Analysis for Sinter](#).

ITEM	TEXT TO BE ADDED	EXPLANATION
Analytical information 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.
Analytical methods and spectral data		 Attach a document describing the analytical methods used.

Optical activity	Not applicable for inorganic substances.	
Results of analysis - chemical analysis	Heading only	Create a new block here.
Analysis type	Chemical analysis to prove sameness.	
Tested substance		Identify the substance tested, e.g. sinter from
Analysis results		 Attach a file with your chemical analysis data. The name of the file will automatically appear in this field.
Method used		Specify the analysis method and standard in accordance with which the analysis has been carried out, e.g. XRF in accordance with ISO ...
Remarks	The sameness composition for Iron Sinter is as follows: Fe_2O_3 : >55% FeO : <23% SiO_2 : 2-11% Al_2O_3 : <3% CaO : 4-20% MgO : <5% Other elements [Zn, Ti, K_2O , Cr, Mn]: <5% Free moisture: \leq 6% Particle size: \geq 85% in range 5-70 mm	Recommended text. NB: the full sameness specification for particle size distribution could be added: -8 mm: \geq 16% -10 mm: \geq 26% -20 mm: \geq 60% -30 mm: \geq 75% -50 mm: \geq 90% -70 mm: \geq 99%
Results of analysis - spectral analysis X-Ray diffraction [XRD]		Create a new block here.
Analysis type		Specify the name of the method used for this analysis, e.g. "spectral analysis X-Ray Diffraction."
Tested substance		Identify the substance tested, e.g. sinter from.....
Analysis results		 Attach a file with your analysis data. The name of the file will automatically appear in this field.
Method used		Specify your analysis method, e.g. "spectral analysis X-Ray Diffraction."
Remarks		You may wish to insert a summary of the conclusion from your XRD analysis, e.g. "The diffractogram shows that Iron is mainly present in Iron Sinter as Iron oxides (wüstite, hematite)."
Results of analysis - particle size distribution		Create a new block here.

Analysis type		Specify the name of the method used for this analysis, e.g. "screen analysis."
Tested substance		Identify the substance tested, e.g. sinter from.....
Analysis results		 Attach a file with your analysis data. The name of the file will automatically appear in this field.
Method used		Specify your analysis method, e.g. "screen analysis carried out in accordance with ... standard."
Remarks		If you wish to add any remarks about your screen analysis results, enter them in this field.

1.5 JOINT SUBMISSION



ITEM	TEXT TO BE ADDED	EXPLANATION
Joint submission name	Iron sinter (Einecs 265-997-9)	
Joint submission 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.
Lead		Leave blank
Members		Leave blank

1.6 SPONSORS

Registrants can 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.

The screenshot displays a web-based interface for REACH registration. On the left, a navigation pane shows a tree structure with categories such as '0 Related Information', '1 General Information', '2 Classification and Labelling', and '13 Assessment Reports'. The '1.6 Sponsors' section is highlighted. The main content area is titled 'Sponsors' and contains a form with the following fields:

- Name
- Type
- Contact information:
 - Address
 - Address
 - Postal code
 - Town
 - Region / State
 - Country
 - Phone
 - Fax
 - E-mail
 - Web site
- Contact persons

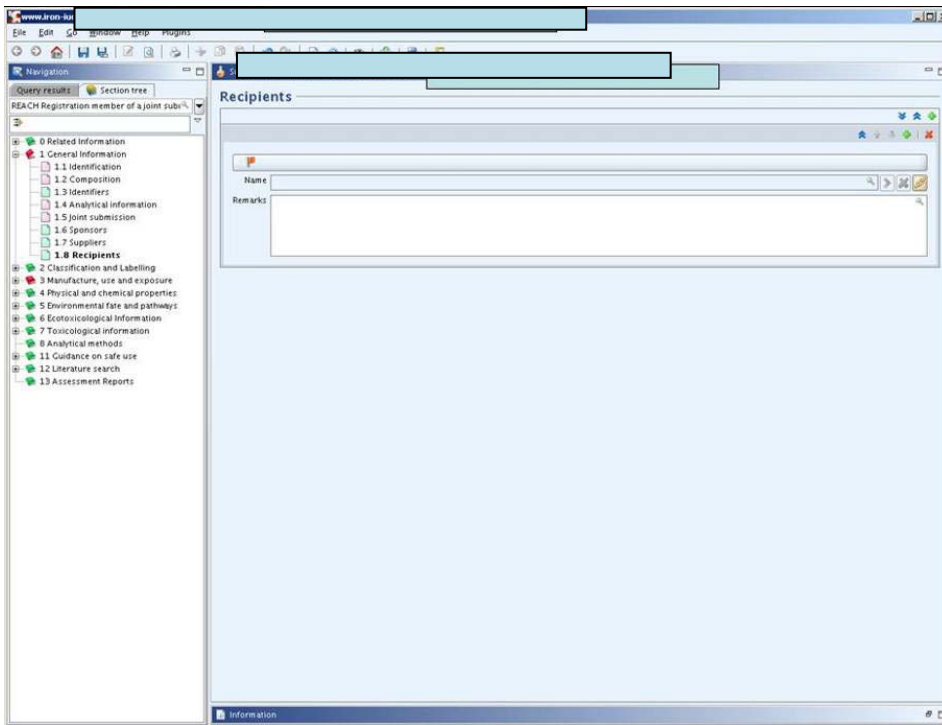
1.7 SUPPLIERS

Leave this section blank unless you are 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 Iron Platform strongly advises Only Representatives to follow ECHA's recommendation.

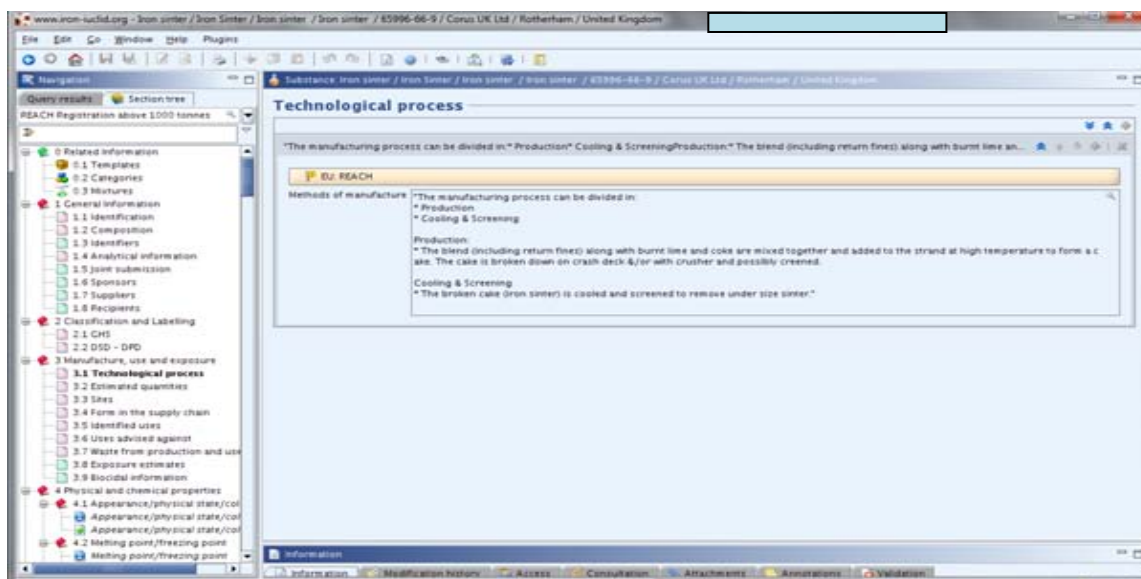
The screenshot displays the Iron Platform software interface. On the left is a navigation pane with a tree view showing sections such as '0 Related Information', '1 General Information', '1.1 Identification', '1.2 Composition', '1.3 Identifiers', '1.4 Analytical information', '1.5 Joint submission', '1.6 Sponsors', '1.7 Suppliers', '1.8 Recipients', '2 Classification and Labeling', '3 Manufacture, use and exposure', '4 Physical and chemical properties', '5 Environmental fate and pathways', '6 Ecotoxicological information', '7 Toxicological information', '8 Analytical methods', '11 Guidance on safe use', and '13 Assessment Reports'. The '1.7 Suppliers' section is selected. The main content area shows the 'Suppliers' form. It includes a 'Manufacturer / Importer / Formulator' section with 'Name' and 'Remarks' fields. Below this is the 'Only representation information' section, which has an 'Assignment from non EU manufacturer' field and an 'Other importers' table. The table has columns for 'Name' and 'Agreement'. A red arrow points to an 'Add' button located to the right of the table. At the bottom of the form are 'Add...', 'Edit...', and 'Delete' buttons. The bottom status bar shows 'Information', 'Modification history', 'Access', 'Consultation', 'Attachments', 'Annotations', and 'Validation'.

1.8 RECIPIENTS

A recipient can be a Downstream user, Distributor or Customer [e.g. in the context of Product and Process Orientated Research and Development (PPORD)] being supplied with a Substance, Mixture or Article. These definitions never include consumers.

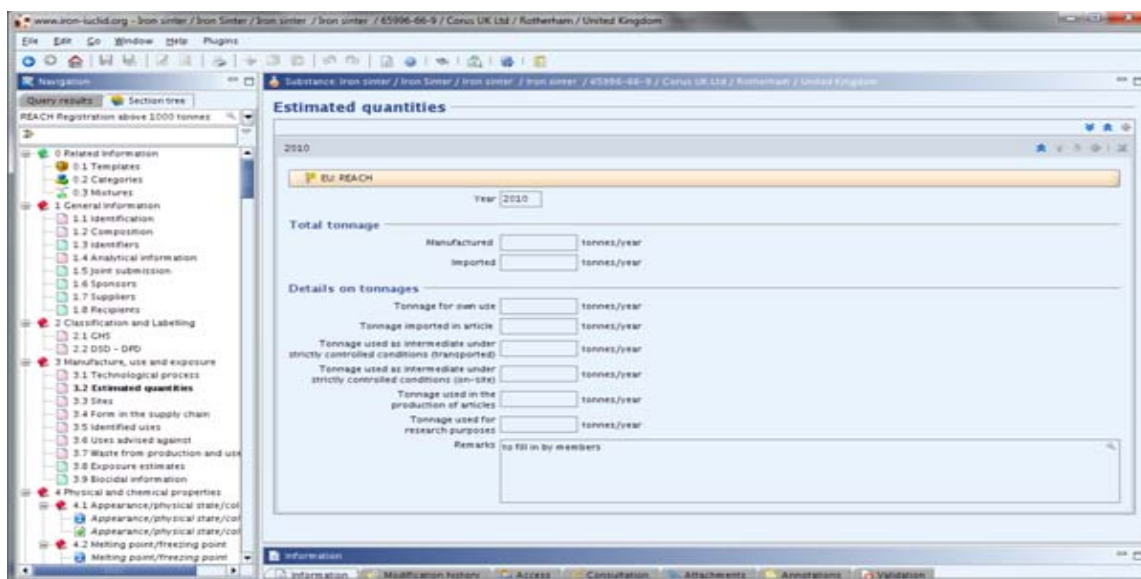


3.1 TECHNOLOGICAL PROCESS



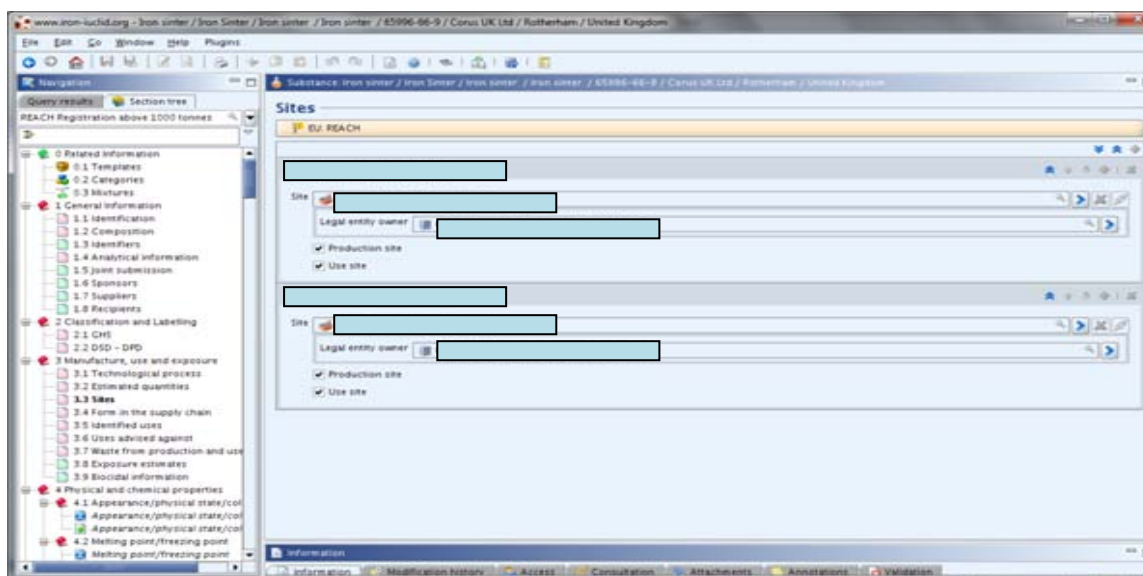
ITEM	TEXT TO BE ADDED	EXPLANATION
Technological process flags		Click on the flag if you want to assign confidentiality and programme restrictions.
confidentiality		Leave blank or select the right level of confidentiality. If confidentiality is required, a justification has to be provided.
programme restrictions		Select EU: REACH from pick list.
Methods of manufacture	<p>The manufacturing process can be divided in:</p> <ul style="list-style-type: none"> * Production * Cooling & Screening <p>Production:</p> <ul style="list-style-type: none"> * The blend (including return fines) along with burnt lime and coke are mixed together and added to the strand at high temperature to form a cake. The cake is broken down on crash deck &/or with crusher and possibly screened. <p>Cooling & Screening</p> <ul style="list-style-type: none"> * The broken cake (iron sinter) is cooled and screened to remove under size sinter. 	<p>If you are an importer or Only Representative enter as the case may be "Importer/Only Representative - not relevant."</p> <p>This is the text submitted by the Lead Registrant - we suggest that EU manufacturers copy it unless it does not cover the method of manufacture, in which case amend or re-draft as appropriate.</p>

3.2 ESTIMATED QUANTITIES



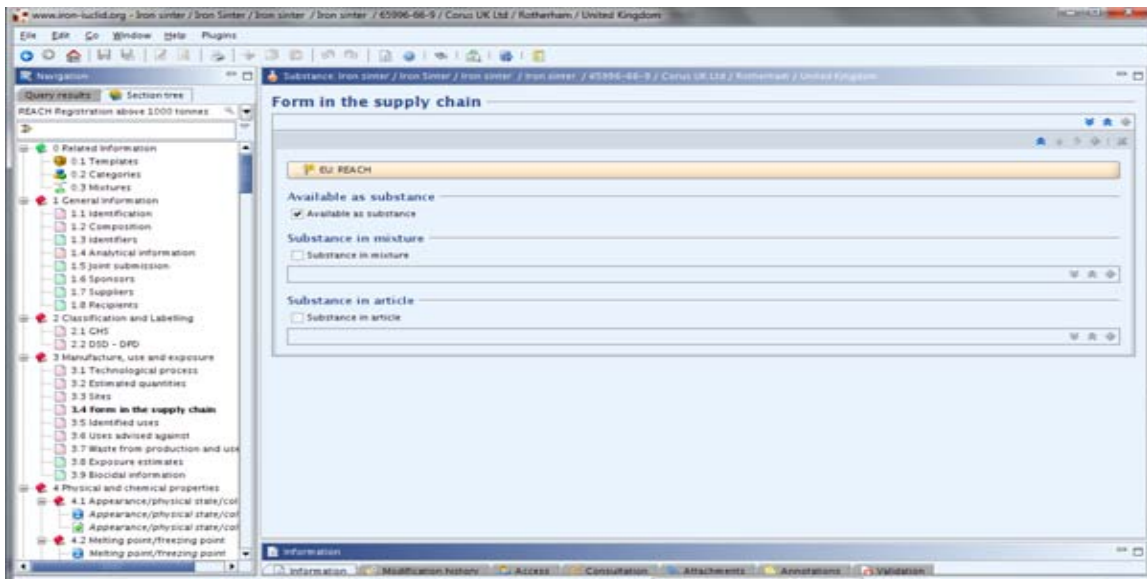
ITEM	TEXT TO BE ADDED	EXPLANATION
Year	2010	
Estimated quantities flags		Click on the flag if you want to assign confidentiality and programme restrictions.
confidentiality		Leave blank or select the right level of confidentiality. If confidentiality is required, a justification has to be provided.
programme restrictions		Select EU: REACH from pick list.
Total tonnage		Enter the estimated tonnage to be manufactured or imported in 2010. If you cannot estimate your tonnage for 2010, use the average of the three prior years, 2007/8/9, assuming that these were representative years.
Details on tonnages		This would normally be left blank. If you feel the need to provide an explanation for the basis of your tonnage, include it here.

3.3 SITES



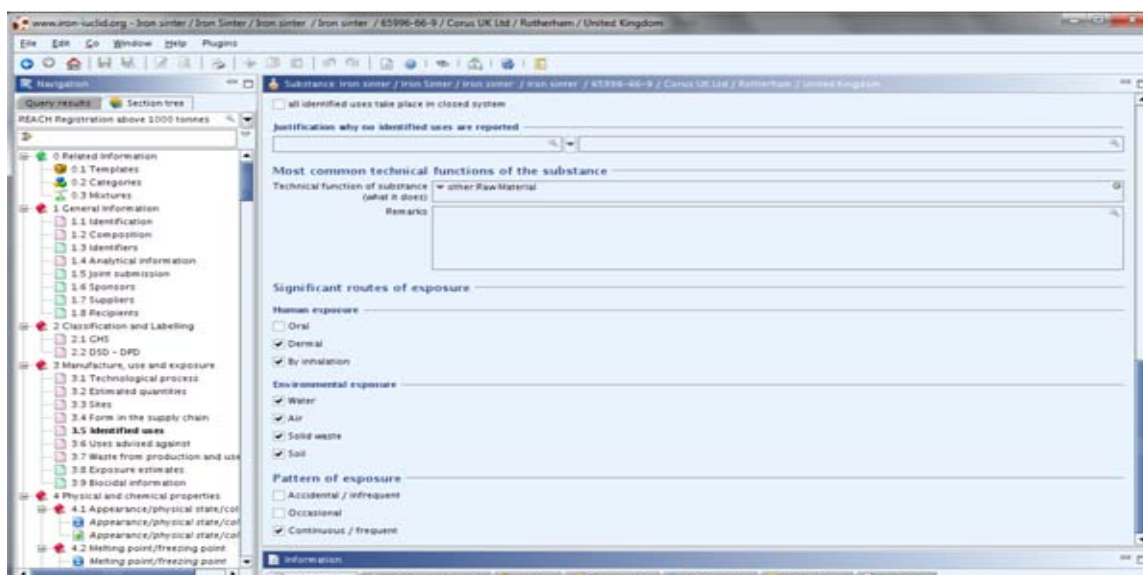
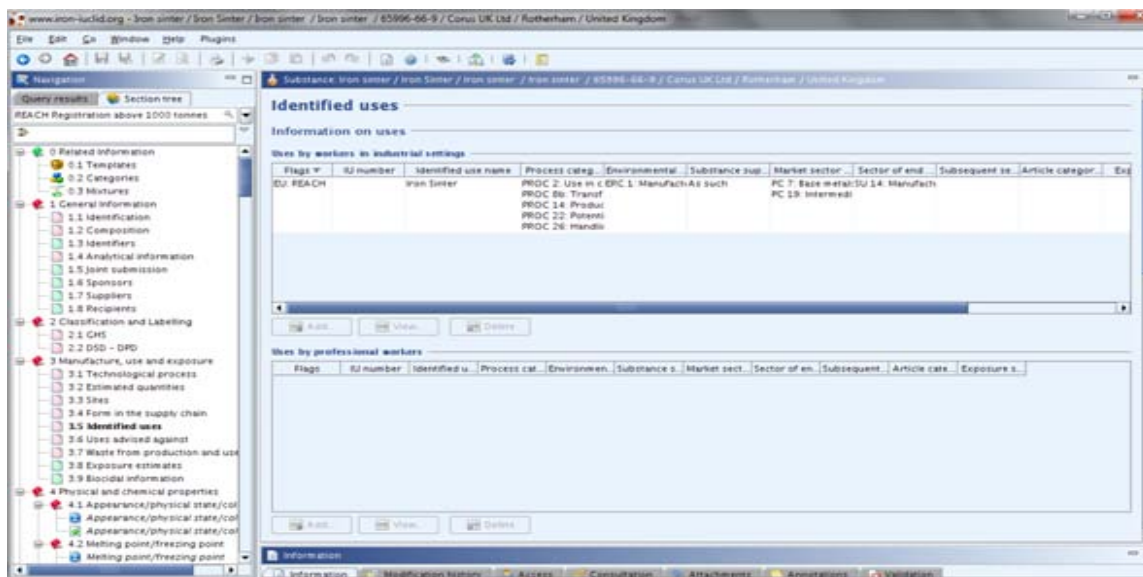
ITEM	TEXT TO BE ADDED	EXPLANATION
Site		<p>Enter the name and location of your site[s]. The minimum contact address information is town/city and country, but ECHA recommends filling all address fields.</p> <p>An Only Representative or Importer can assign a site, but this is not mandatory.</p> <p>If “Manufacturer” is selected in section 1.1, at least one production site must be entered in section 3.3.</p>
Site 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.
Legal entity owner		Assign the name of the legal entity which owns the site from the drop down list.
Type of site		Tick the appropriate box.

3.4 FORM IN THE SUPPLY CHAIN



ITEM	TEXT TO BE ADDED	EXPLANATION
Form 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.
Available as a substance		Tick this box
Substance in mixture		Do not tick this box
Substance in article		Do not tick this box

3.5 IDENTIFIED USES

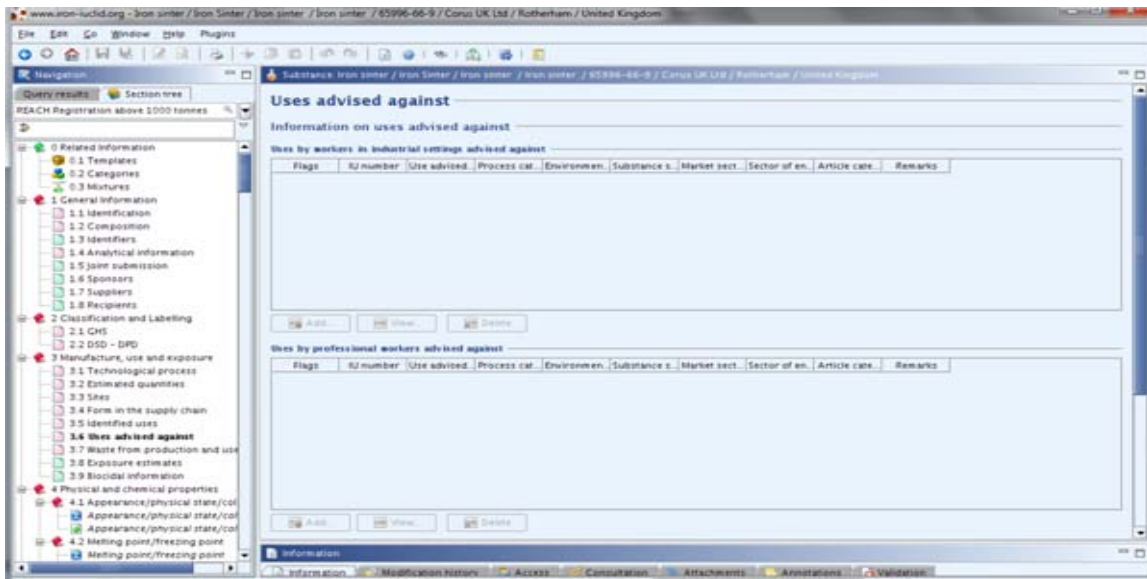


ITEM	TEXT TO BE ADDED	EXPLANATION
Information on uses	Heading only	
Uses by workers in industrial settings		<p>There is conflicting advice as to whether member registrants should select only certain uses or should select them all - the advice of the Iron Platform is to select them all so as not to have to modify the dossier in the future when a new use is entered into.</p> <p>The text in the fields below is what was entered by the Lead Registrant. If you wishes to specify only certain uses, create a block here by clicking on the "Add"</p>

		button and tick the relevant options.
IU number		Leave blank
Identified use name	Iron Sinter	
Process category	PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 14: Production of preparations or articles by tableting, compression, extrusion, pelletisation PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting PROC 26: Handling of solid inorganic substances at ambient temperature	Entered by the Lead Registrant.
Environmental release category	ERC 1: Manufacture of substances	Entered by the Lead Registrant.
Substance supplied to that use in form of	As such	Entered by the Lead Registrant.
Market sector by type of product	PC 7: Base metals and alloys PC 19: Intermediate	Entered by the Lead Registrant.
Sector of end use	SU 14: Manufacture of basic metals, including alloys	Entered by the Lead Registrant.
Substance service life relevant for that use?	No	Select "No" from drop down list.
Article category related to subsequent service life?		Leave blank
Exposure scenario reference in the CSR		Leave blank
Uses by professional workers		This is not relevant in this case so do not create a block here and leave this section blank.
Uses by consumers		This is not relevant in this case so do not create a block here and leave this section blank.
Closed system		This box should be ticked when the substance is used in a closed system, such as the use of liquids in hydraulic systems, cooling liquids in refrigerators and lubricants in engines and dielectric fluids in electric transformers and oil in heat exchangers.
Justification why no identified uses are reported		Leave blank.
Most common technical function of substance	Heading only	
Technical function	Other: raw material	
Remarks		Leave blank

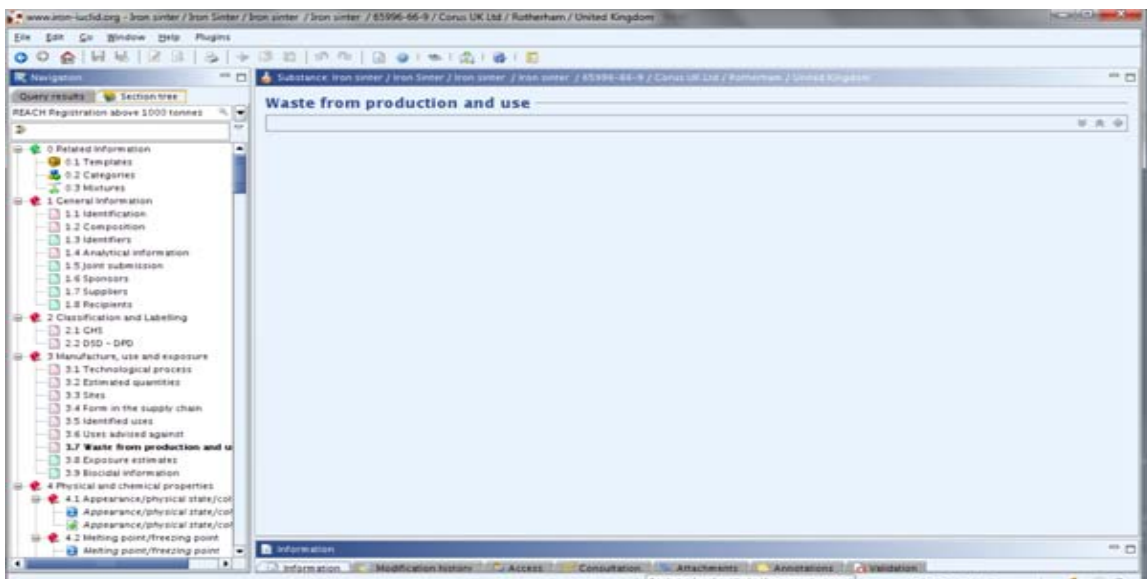
ITEM		
Significant routes of exposure	Heading only	Either include the same list as given by the Lead Registrant or make your own list as appropriate.
Human exposure		The Lead Registrant has ticked the following boxes: <ul style="list-style-type: none"> • Dermal • By inhalation
Environmental exposure		The Lead Registrant has ticked the following boxes: <ul style="list-style-type: none"> • Water • Air • soil
Pattern of exposure		The Lead Registrant has ticked the following boxes: <ul style="list-style-type: none"> • continuous/frequent

3.6 USES ADVISED AGAINST



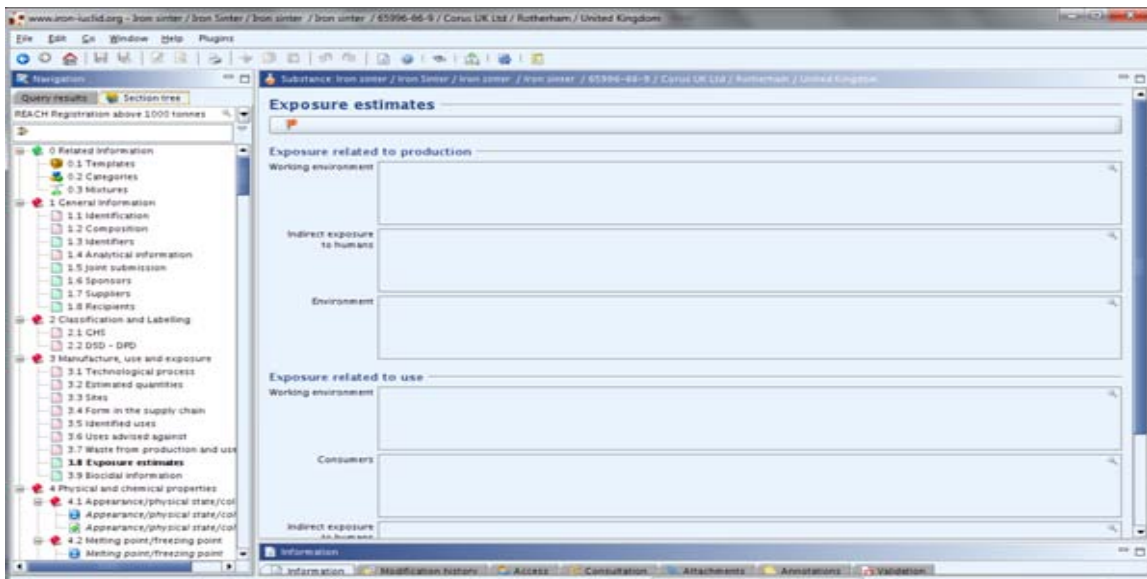
Do not create a block for section 3.6 - leave it blank as there are no uses advised against.

3.7 WASTE FROM PRODUCTION AND USE



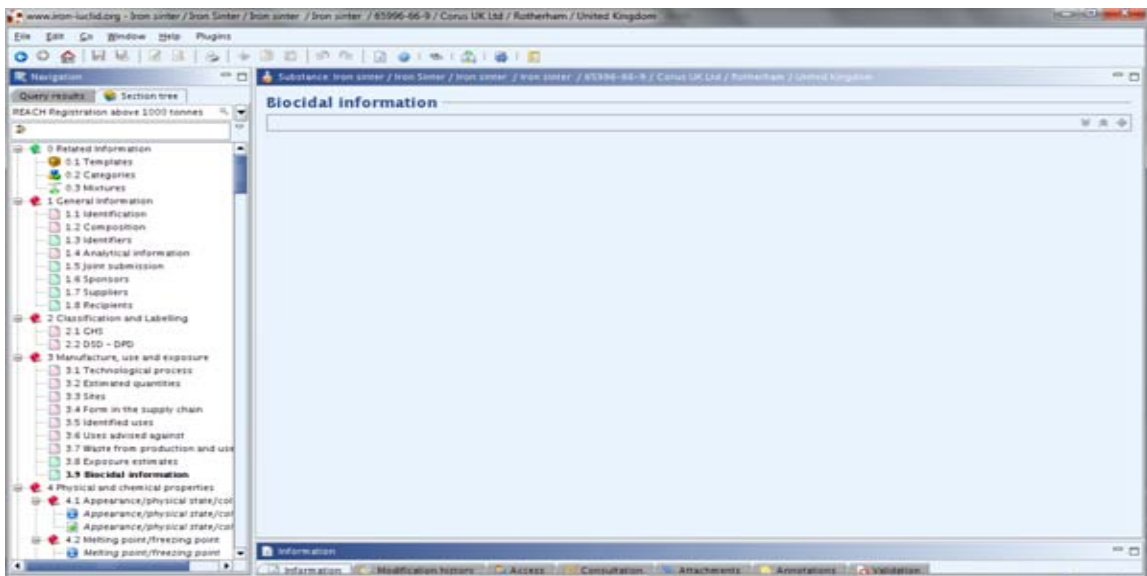
Section 3.7 should be left blank - do not create a block for it.

3.8 EXPOSURE ESTIMATES



Section 3.8 should be left blank as this substance is not classified - do not create a block for it.

3.9 BIOCIDAL INFORMATION



Section 3.9 should be left blank as it is not relevant in this case - do not create a block for it.

Before submitting your dossier, do not forget to:

1. check your substance file with the TCC Tool plug-in:
 - ⇒ If TCC fails, create a new substance file
 - ⇒ If TCC passes, go to the next step
2. create a dossier by right clicking on your substance
3. check your dossier file
 - ⇒ If TCC fails, create a new dossier file
 - ⇒ If TCC passes, go to the next step
4. export your dossier file on your computer by right clicking on the dossier
5. open your account on ECHA REACH-IT
6. 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 REACH-IT message box]
7. follow the prompts to submit your dossier file [for more detailed information, please consult the [ECHA Guidance on submission](#)]

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;
2. take the necessary actions, for example paying the registration fee.

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