Data Submission Manual

Part 05 - How to complete a technical dossier for registrations and PPORD notifications

Document history

Version	Changes
2.8	04/2011 Document updated to reflect the changes introduced by the 2nd ATP to the CLP Regulation. How to report C&L within a joint submission: clarification on best practice to follow in case a member has a different C&L than the lead and does not intend to opt-out (Chapter 4.2) A new chapter (Chapter 5, Technical Completeness Check') has been added to explain the importance of running the TCC plugin tool to check the completeness of the substance dataset and the final dossier.
2.7	12/2010: Document updated to reflect the changes introduced by the amendment of the REACH Regulation foreseen in Article 58 of the CLP Regulation. This amendment entered into force on 1 December 2010: P 24-34. Requirements for classification and labelling have been updated. P 87-88. Annex 3. Text on the fee for confidentiality claims on the IUPAC name has been updated.
2.6	10/2010: P 25. Classification and labelling: Instructions on how to indicate the 'Reason for no classification' modified to match Data Submission Manual 12 P 85-86. Annex 3. Clarification on the fee for confidentiality claims on the degree of purity, impurities and additives. New figure 68. P 89-90. Annex 4. Clarification on updating the classification and labelling for NONS
2.5	05/2010: P 20. 'Section 1.5 - Joint submission' information requirements has changed. P 26. 'Section 2.1 – GHS' now has direct link to Data Submission Manual 12 in ECHA website. P 35. Figure 38 'Estimated quantities' has been updated to reflect the changes brought about by IUCLID 5.2

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http://echa.europa.eu/help/echahelp_en.asp

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1 Introduction

The purpose of this manual is to provide guidance relating to the preparation of registration and PPORD dossiers. It outlines the IUCLID 5 sections/fields to be filled in, in order to prepare a complete technical dossier according to Article 20 of REACH.

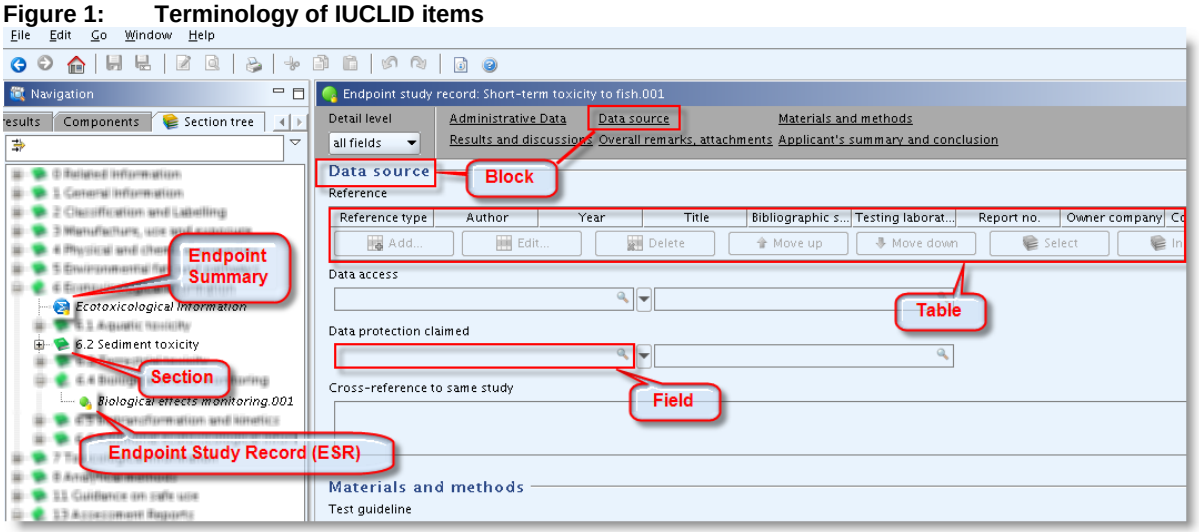
ECHA will undertake a technical completeness check for registration dossiers (including registration dossiers for isolated intermediates, dossiers for substances in articles) and PPORD notifications and their subsequent updates.

Technical completeness check: according to Article 20(2) of Regulation (EC) No 1907/2006 (the REACH Regulation), the completeness check includes two components: the technical completeness check (to check if all the elements required by the Regulation have been provided) and the financial completeness check (the payment of the fee if relevant).

It should be noted that the aim of this guidance is to help the potential registrants/notifiers to identify which of the numerous IUCLID 5 fields are of prime importance in relation to the technical completeness check. In addition to this guidance, **IT software has been developed in order to offer the possibility to registrants/notifiers to check by themselves the completeness of their dossiers before submitting them to ECHA**. This IT software is available as a IUCLID plugin ("Technical Completeness Check Plugin") at the IUCLID website: http://iuclid.echa.europa.eu/. Before you submit your dossier, please ensure that you use the technical completeness check plugin on both the substance dataset and on the final dossier. Using the tool in BOTH steps is vital for you to avoid failures. Please refer to chapter 5 'Technical Completeness Check (TCC)' in this User Manual for further details.

The terminology used to describe IUCLID 5 items within this document is as indicated in Figure 1 below.

Figure 1: Terminology of IUCLID items



2 General principles

During the creation of the IUCLID 5 dossier (including the creation of the IUCLID 5 Substance dataset and the IUCLID 5 Legal entity) one must follow the following general rules, described in the below chapters.

2.1 Range fields

For every field where two entries can be provided (range or single data), at least one of the two fields must be filled in (first or second one):

Figure 2: Range fields

2.2 Unit fields

When there is a unit field related to a value field, then a unit must always be selected from the unit dropdown list:

Figure 3: Unit fields

2.3 Selection of other

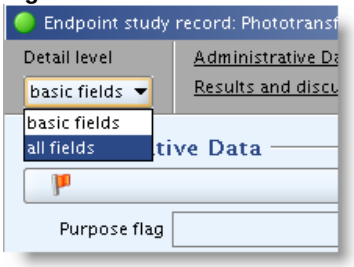
Every time “other:” is selected from a dropdown list then information must be provided in the adjacent field:

Figure 4: Selection of other in a list

2.4 Detail level of the endpoint study records

In IUCLID 5 sections 4 to 10, the selection of “all fields” in the “Detail level” dropdown list displays more fields than the “basic fields” selection (Figure 5). Therefore it is recommended to select the “all fields” option when filling in the endpoint study records. For more information please consult the IUCLID 5 user manual - section D.4.7.6 which is available from: http://iuclid.echa.europa.eu/index.php?fuseaction=home.documentation

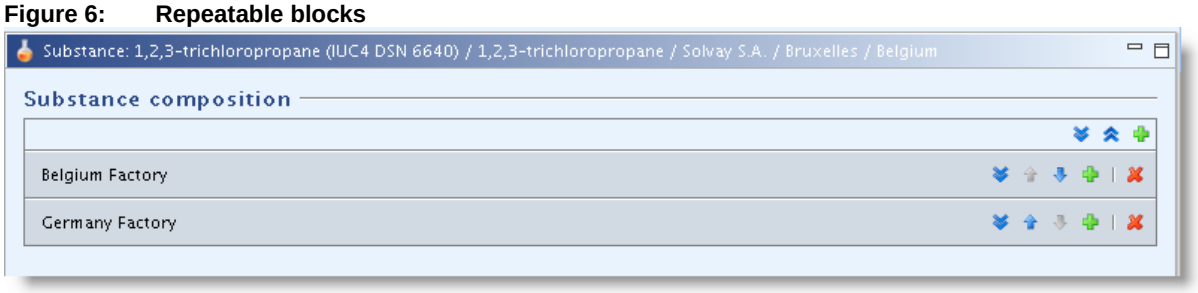
Figure 5: Detail level of endpoint study record



2.5 Repeatable blocks

In case of multiple repeatable blocks (as depicted in Figure 6), it must be noted that information will be checked for all the blocks created:

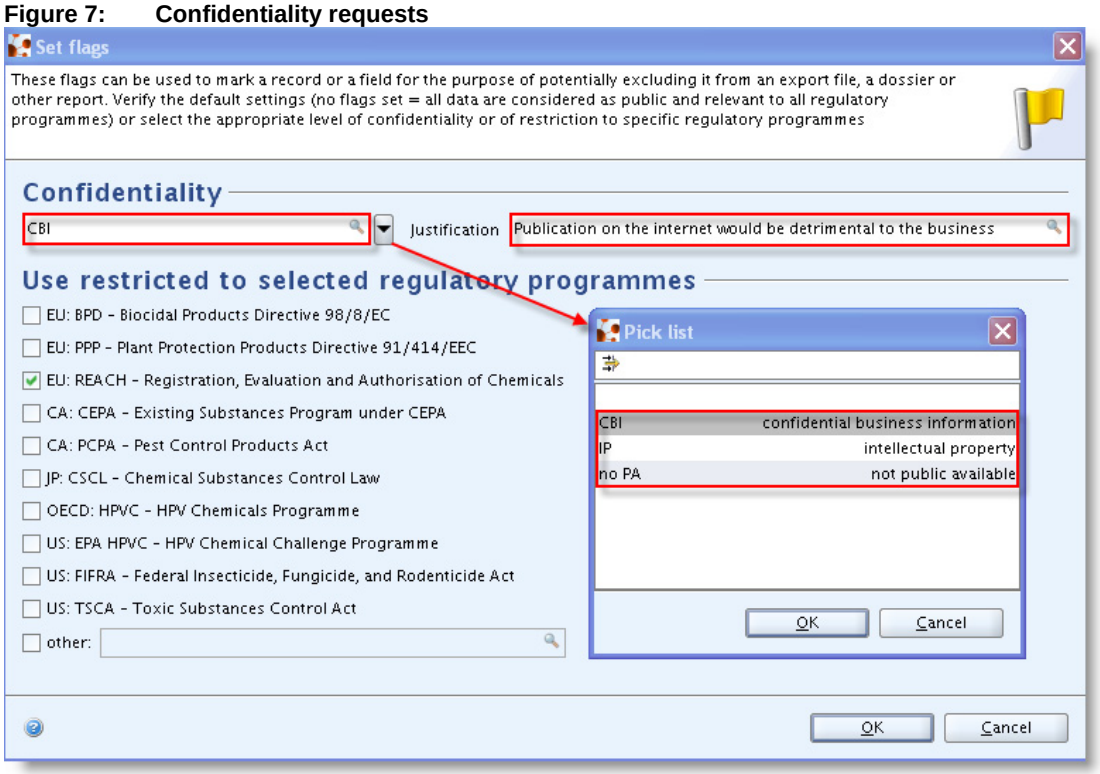
Figure 6: Repeatable blocks



2.6 Confidentiality requests

Any time a flag for confidentiality is indicated (CBI, IP or no PA) the justification as to why publication on the internet could be harmful must be provided in the adjacent field. Vice-versa, any time justification for confidentiality is indicated then a confidentiality flag must be indicated (Figure 7).

Figure 7: Confidentiality requests



Please note that some records migrated from IUCLID 4 contains the text “IUCLID 4” in the field “Justification”. This text should be deleted because if it is not removed and there is no flag for confidentiality (CBI, IP or no PA) then the automatic Technical Completeness Check (TCC) would consider this “Justification” as an incomplete confidentiality request.

Confidentiality requests that fall under Article 119(2) of the REACH Regulation and Annex IV of Regulation EC/340/2008 (the Fee Regulation) will require a fee payment. Further information on how to request confidentiality in IUCLID 5 and the links between confidentiality requests and fees is provided in Annex 3 of this document.

2.7 IUCLID 4 and SNIF file format migrated to IUCLID 5

Keep in mind that dossiers based on substance datasets migrated from IUCLID 4 or from the SNIF file format to IUCLID 5, as such, do not contain all information needed to pass the completeness check. There will be information missing in some fields/sections. Thus, registrants have to carefully check and complete their IUCLID 5 file for all the migrated dossiers in order to fulfil the completeness check requirements described in this document.

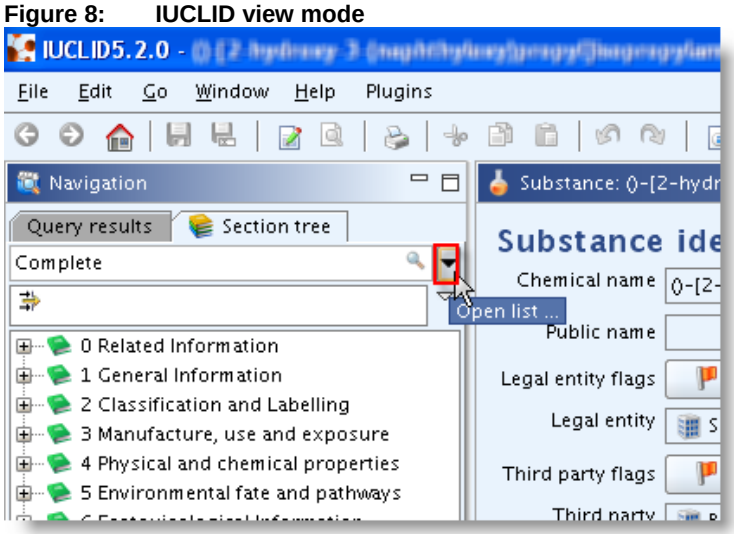
Particular attention should be paid to the classification and labelling (IUCLID section 2), the confidentiality flags, and the endpoint study records (IUCLID sections 4 to 8). Annex 4 of this document details the minimum information required in your dossier when updating a registration that was previously a notification under Directive 67/548/EEC. You can find detailed information on how to update your registration that was previously a notification under Directive 67/548/EEC (NONS) in the document “Questions and answers for the registrants of previously notified substances” (chapter 4) available at:

http://echa.europa.eu/doc/reachit/prev_not_sub_registrants_qa.pdf

2.8 IUCLID 5 view mode selector

When the substance dataset is opened, one can select a specific view mode by clicking on the black arrow indicated in Figure 8.

Figure 8: IUCLID view mode



Once the desired view mode is selected in the drop-down list then the section tree changes in such a way that the leaf or book symbols preceding the IUCLID 5 sections are coloured in red for required sections or in green for optional sections.

Keep in mind that this view mode selector is merely a tool to help in determining which sections to fill in. However, the present manual and the TCC plugin prevails upon this view mode selector regarding the completeness check requirements under REACH.

3 Different dossier types

REACH specifies four types of dossier which require a completeness check to be carried out. These are indicated below:

- Registration dossiers for substances alone or in preparations.
- Registration dossiers for on-site isolated intermediates and transported isolated intermediates.
- PPORD notifications (notification of a PPORD is hereafter included in the term 'registration' unless specified otherwise).
- Registration of substances in articles (either intended release or where ECHA requests registration).

Updates of these dossiers are also subject to a completeness check. These registrations should be submitted as a IUCLID 5 dossier.

The corresponding IUCLID 5 types of registration dossier (also called "Dossier templates") are indicated below:

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

The sections of the IUCLID 5 file that will be checked for completeness vary between the different dossier types. In addition the information to be provided within a section could also differ between the different dossier types. Some of these variations are described in the following special rules for joint submission, intermediates and PPORD dossiers.

3.1 Special rules for joint submission dossiers

A distinction is made between the information to be submitted by the lead registrant and that to be submitted by non-lead registrants, i.e. members of the joint submission.

The IUCLID 5 sections 2, 4, 5, 6 and 7 (the C&L and the endpoints sections) of the lead registrant dossier should be complete.

The IUCLID 5 sections 2, 4, 5, 6 and 7 (the C&L and the endpoints sections) of the member dossier should be empty. If information is submitted in a member dossier in one of these sections then this information will be considered as an opt-out. The study/information opted out will be checked for completeness in the member dossier.

For detailed information on how to fill in the IUCLID dossier header please read “Data Submission Manual 4: How to Pass Business Rules Verification” available on the ECHA website at: http://echa.europa.eu/doc/reachit/how_pass_business_verification.pdf. Moreover, some specific rules for dossiers of members of a joint submission are described in IUCLID section 2 “Classification and labelling”, IUCLID section “11 Guidance on safe use” and IUCLID section “13 Assessment report” of this manual.

3.2 Special rules for isolated intermediate dossiers

For dossiers of isolated intermediates the sections “1.4 Analytical information”, “3.1 Technological process”, “3.4 Form in the supply chain”, “3.6 Uses advised against”, “3.7 Waste from production and use” and “13 Assessment report” will not be checked for completeness. In addition section “3.2 Estimated quantities” will not be checked for completeness, however it is recommended to fill in the field “Year”, at least one of the “Total tonnage” fields and as much as possible the fields under “Details on tonnages”.

The registrants of isolated intermediates have to provide information on risk management measures and their efficiency (articles 17 and 18). This information must be entered in section “11 Guidance on safe use” (see chapter 4.5 “11 Guidance on safe use” of this manual).

For dossiers of intermediates, the registrant must agree to comply with Art. 17 for on-site isolated intermediates or with Art. 18 for transported isolated intermediates by ticking the box “Production and use under strictly controlled conditions” in the IUCLID 5 dossier header. In addition, for transported isolated intermediates at least one of the two following boxes must be selected: “Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18(4)” or “Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18(4)”. These tickboxes must be indicated during dossier creation.

3.3 Special rules for PPORD dossiers

For PPORD the sections “2 Classification and labelling”, “3.1 Technological process”, “3.2 Estimated quantities”, “3.4 Form in the supply chain”, “3.5 Identified uses and exposure scenarios”, “3.6 Uses advised against”, “3.7 Waste from production and use”, “11 Guidance on safe use” and “13 Assessment report” and the confidentiality requests (if indicated) will not be checked for completeness. However, section “1.8 Recipients” and section “1.9 PPORD” will be checked for completeness.

Further information on the completion of a PPORD notification is available in the Data Submission Manual 1: “How to prepare and submit a PPORD notification” available at:

http://echa.europa.eu/doc/reachit/how_to_prep_sub_ppord_en.pdf

4 IUCLID 5 sections to complete

This chapter outlines which information must be provided through the different sections of the IUCLID 5 tree and within the dossier header.

4.1 Section 1 - General information

IUCLID section 1 requires information on the identification of the substance, its composition, identifiers, analytical information, suppliers, recipients, PPORD and classification and labelling. Each of them will be discussed in the following chapters.

4.1.1 Section 1.1 - Identification

Section 1.1 in IUCLID deals with the identification of the substance, role in the supply chain and type of (reference) substance, each called a block.

4.1.1.1 Block 'Substance identification'

The field "Public name" must be filled in if there are confidentiality concerns about the substance name. A generic name, which appropriately describes the substance being registered, should be indicated in this field. The field "Public name" will be made publicly available on the ECHA website, together with the other information required by Article 119 of REACH.

Although the Legal entity is available in REACH-IT as part of the sign-up process, it is also necessary to indicate a Legal entity in the IUCLID dossier to comply with the XML format. This information must be provided in the block "Substance identification" (Figure 9).

Figure 9: Legal entity and third party in the substance identification block

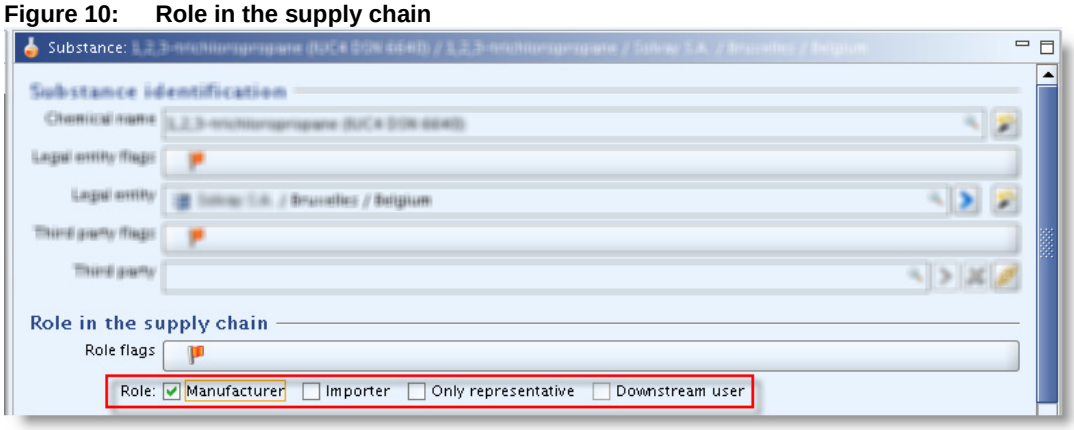
It is not compulsory to indicate a third party; however if a third party representative has been appointed according to Art. 4 of REACH, then the Legal entity of this third party must also be provided in the block "Substance identification".

The information that will be checked is whether the Legal entity (Legal entity of the registrant/notifier and, if available, Legal entity of the third party) has already signed up in REACH-IT (synchronised Company Universal Unique Identifier (UUID)).

4.1.1.2 Block 'Role in the supply chain'

At least one role has to be selected. If the checkbox "Manufacturer" is selected (Figure 10) then information must also be provided on the technological process(es) and the site(s) of production (IUCLID 5 Sections 3.1 and 3.3). If the checkbox "Only representative" is selected then you are advised to provide the specific information described in IUCLID section "1.7 Suppliers".

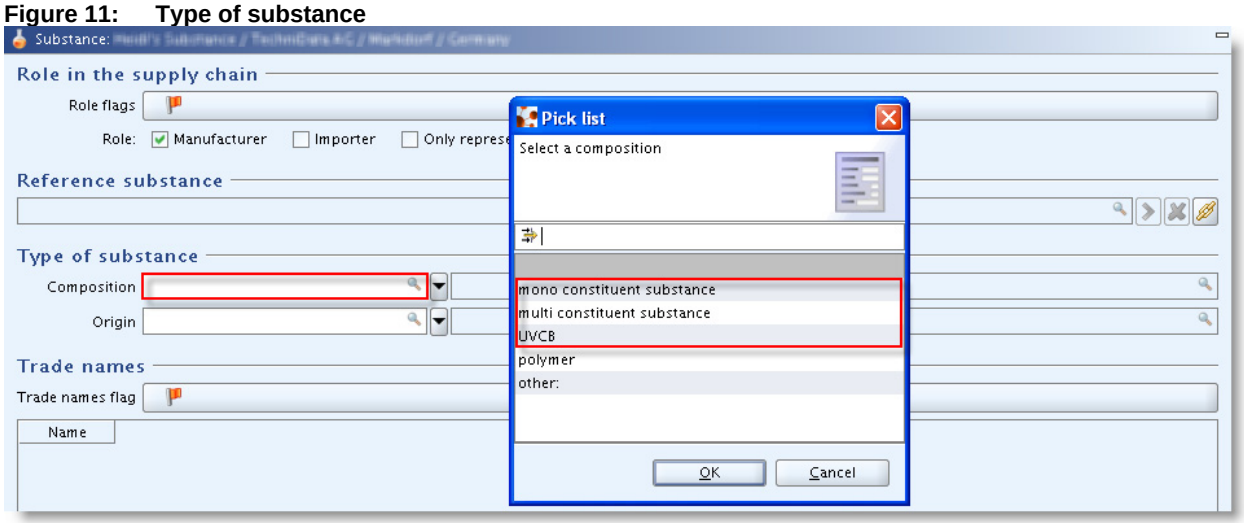
Figure 10: Role in the supply chain



4.1.1.3 Block 'Type of substance'

"Mono constituent substance", "multi constituent substance" or "UVCB" must be selected in the pick list "Composition" (Figure 11).

Figure 11: Type of substance



- Composition "polymer" must not be selected because the monomers contained in the polymer should be registered but not the polymer itself.
- "other" must not be selected, as the substances under REACH should be defined as mono constituent, multI constituent or UVCB.

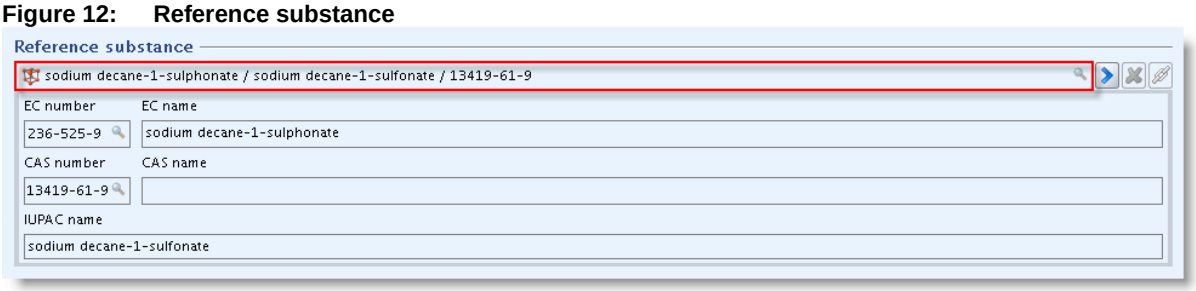
4.1.1.4 Block Reference substance

In this block, a Reference substance must always be attached (even if the substance does not have an EC number, is a non phase-in substance or a UVCB). In case of a mono constituent substance, the Reference substance must be attached in this section 1.1 and the same Reference substance should also be attached in the block "Constituents" of IUCLID section "1.2 Composition".

Substance identifier

For the Reference substance indicated in this block (Figure 12), either EC number or CAS number (with CAS name) or IUPAC name must be given (Figure 13).

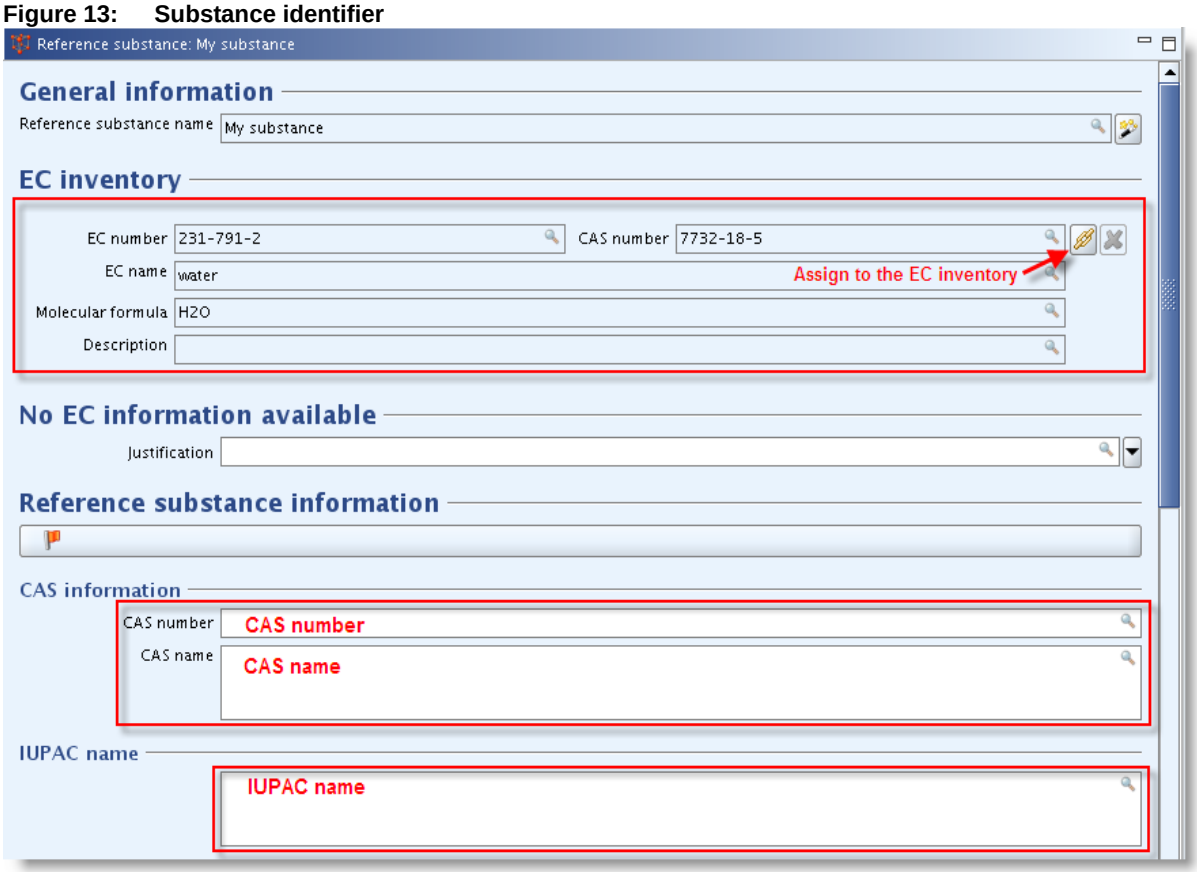
Figure 12: Reference substance



For multi constituent substances (named as a reaction mass of the main constituents e.g. Reaction mass of A and B), you are advised to indicate the name in the field “IUPAC name” of the reference substance assigned in Section 1.1. The individual constituents should be indicated in the IUCLID section “1.2 Composition“.

For UVCB substances you are advised to indicate the name of the UVCB substance in the field “IUPAC name” while the process description, refinement process, etc. should be indicated in the field “Description”.

Figure 13: Substance identifier



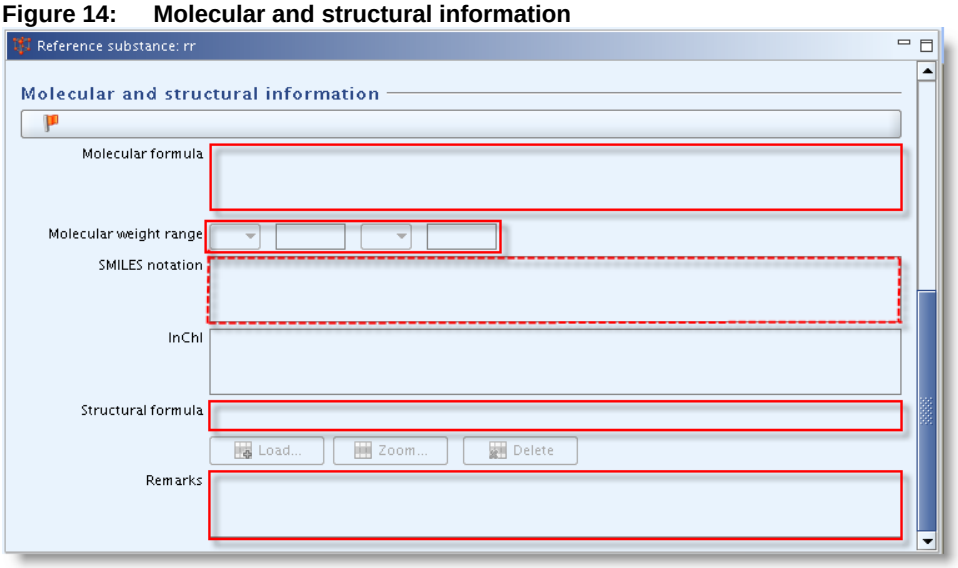
Molecular and structural information

- If you select "mono constituent substance" in section 1.1 under "Type of substance/Composition", then the “Molecular formula”, “Molecular weight” and “Structural formula” of the reference substance must be provided (Figure 14).

- If you indicate "multi constituent substance" in section 1.1 under "Type of substance/Composition", then the “Molecular formula”, “Molecular weight” and “Structural formula” of the reference substance must be provided or a justification for not providing this information must be given in the “Remarks” field (Figure 14).
- If you indicate "UVCB" in section 1.1 under "Type of substance/Composition", then the “Molecular formula” and “Molecular weight” of the reference substance must be provided or a justification for not providing this information must be given in the “Remarks” field (Figure 14).

In addition the “SMILES notation” should also be provided if available.

Figure 14: Molecular and structural information



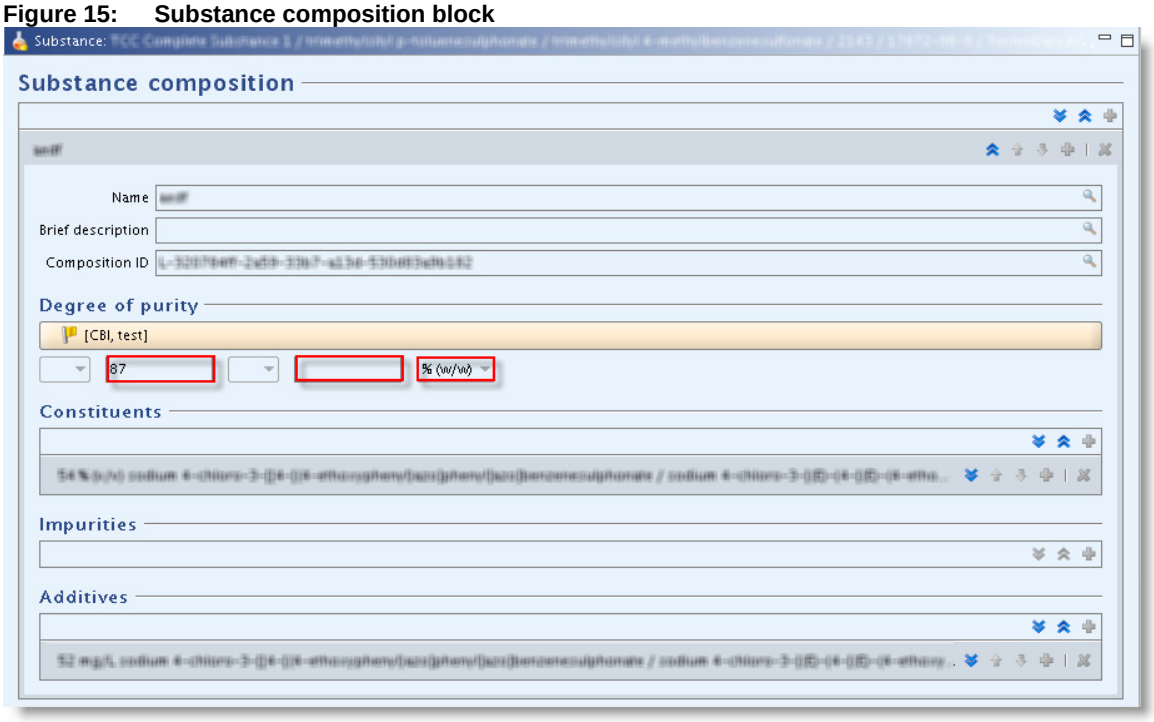
4.1.2 Section 1.2 - Composition

At least one composition must be indicated (normally, one composition should be sufficient). If several “Substance composition” blocks are created then every block must be completed.

The degree of purity shall be specified (Figure 15). It means that at least one of the two boxes should be filled in and that the unit should be selected.

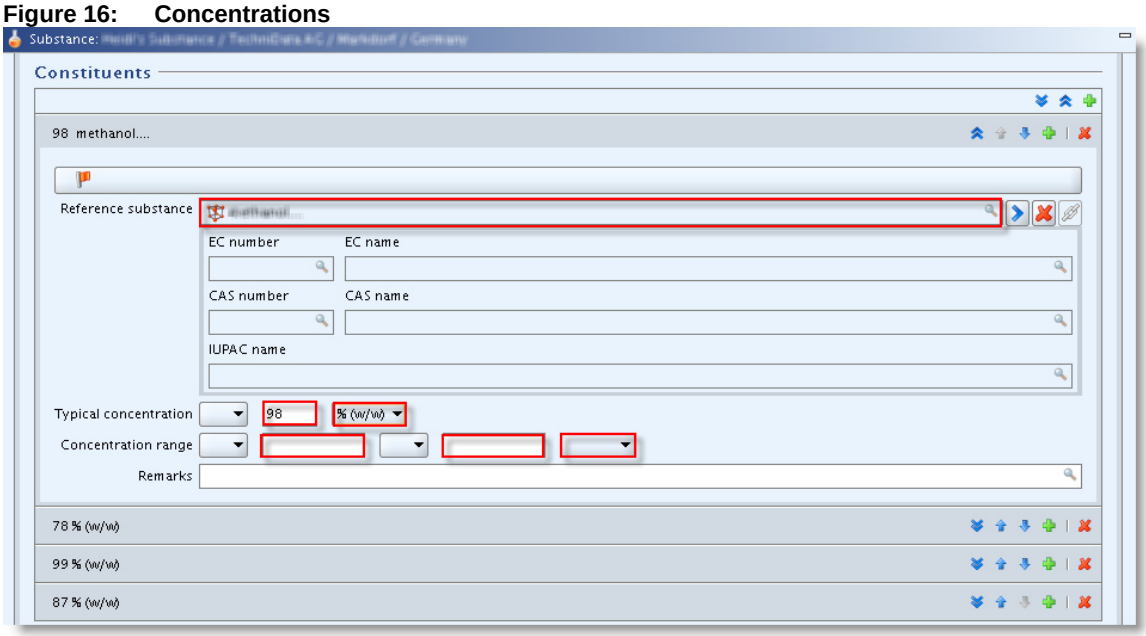
At least one constituent should be indicated for each composition.

Figure 15: Substance composition block



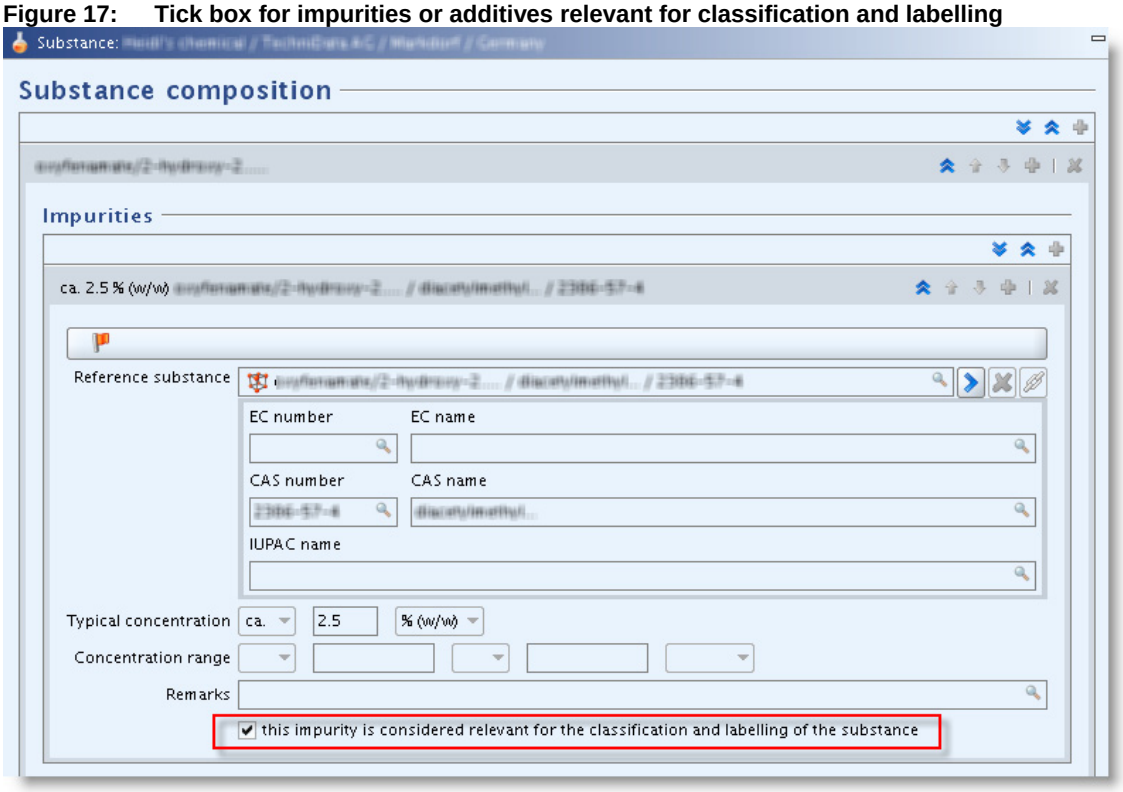
In addition, for each constituent, impurity or additive, a check will be carried out to ensure that a Reference substance is attached and that either the “Typical concentration” or the “Concentration range” has been filled in and that the unit has been selected (Figure 16).

Figure 16: Concentrations



If an impurity or additive is considered relevant for classification and labelling of a substance, the relevant checkbox should be ticked (Figure 17).

Figure 17: Tick box for impurities or additives relevant for classification and labelling



Substance identifier

Each reference substance attached as a constituent, impurity or additive should at least contain either EC number (or CAS number and CAS name) or IUPAC name.

In case of unknown impurities, you need to create a reference substance and state in the IUPAC name field "Unknown impurities" and provide either the typical concentration (with unit) or concentration range (with unit).

Molecular and structural information

Concerning the molecular and structural information, the following information must be provided in the reference substances of IUCLID section 1.2.

For constituents:

- If you indicate "mono constituent substance" or "multi constituent substance" in section 1.1 under "Type of substance/Composition", then the “Molecular formula”, “Molecular weight” and “Structural formula” must be provided.
- If you indicate "UVCB" in section 1.1 under "Type of substance/Composition", then the “Molecular formula” and “Molecular weight” must be provided or a justification for not providing this information must be given in the “Remarks” field.

For additives:

As a minimum, the “Molecular formula”, “Molecular weight” and “Structural formula” must be provided. The function of the additive should also be provided in the field ‘Function’. Note, if you select ‘Other’ in this field, then the adjacent free text must be filled.

For impurities:

The “Molecular formula”, “Molecular weight” and “Structural formula” (if available) must be provided.

In case of unknown impurities, you should specify the number of these unknown impurities in the "Remarks" field and provide either the typical concentration (with unit) or concentration range (with unit).

In addition the “SMILES notation” should also be provided for constituents, additives and impurities if available.

4.1.3 Additional considerations in Sections 1.1 and 1.2

REACH is based on the principle that a registration may only cover one individual substance. For this reason, as part of the Technical Completeness Check, ECHA also checks whether sections 1.1 and 1.2 of the registration dossier contain all the elements required under Article 10(a)(ii) and Annex VI(2) and thus identify the substance to be covered by the registration.

Please also note that the TCC plugin cannot perfectly simulate the checks undertaken to verify completeness of the information on the substance identity.

Registrants are advised to carefully check before the submission of the dossier that the information provided for in section 1.1 and section 1.2 is sufficient to clearly identify the substance covered by the registration. In particular, this information should not be so generic that it may potentially describe more than one substance. The substance identification in the dossier should follow the “Guidance for identification and naming of substances under REACH” (http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf) Any deviation from the guidance should be properly documented in the dossier. Detailed and illustrative technical assistance in how to report and structure the substance identification in a IUCLID dossier is available in “Data Submission Manual 18: How to report the substance identity in IUCLID 5 for registration under REACH” (http://echa.europa.eu/doc/reachit/dsm18/substance_id_report_iuclid_en.pdf)

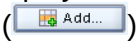
4.1.4 Section 1.3 - Identifiers

IUCLID section 1.3 requires input on identifiers of regulatory programmes.

4.1.4.1 Block Regulatory programme identifiers

In IUCLID section 1.3, indicate the following identifiers, where appropriate:

- The REACH pre-registration number,
- The REACH inquiry number,
- For a dossier update, the registration number (or the PPORD notification number) associated to the initial dossier (it should be available for all spontaneous updates),
- For an update of a notified substance according to Directive 67/548/EEC, the NCD notification number and the registration number.

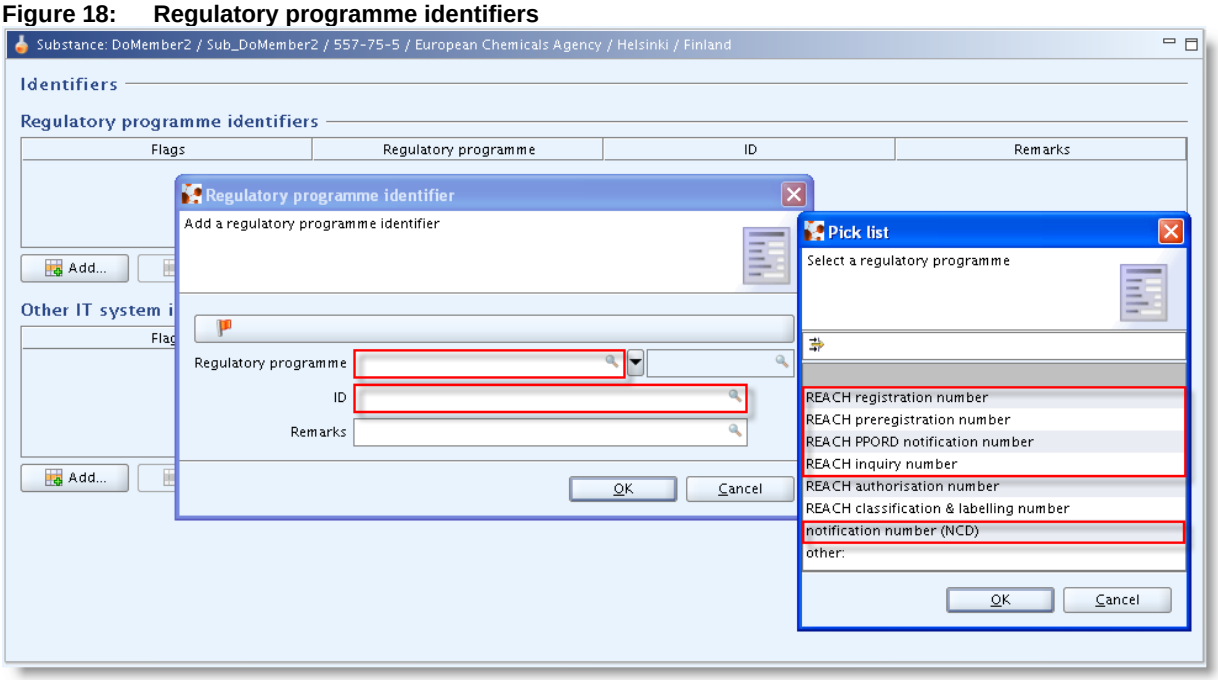
In order to indicate these numbers, you must make a selection in the field “Regulatory programme” and provide the number itself in the field “ID” (Figure 18). If you need to provide two numbers (e.g. a REACH inquiry number and a REACH registration number) you should click twice on the ”Add” button (

).

Please remember that, to fulfil REACH requirements relating to data sharing, a registration should be preceded by either a pre-registration (for a phase-in substance)

or an inquiry (for a non phase-in substance or for a phase-in substance which was not pre-registered).

Figure 18: Regulatory programme identifiers



4.1.5 Section 1.4 - Analytical information

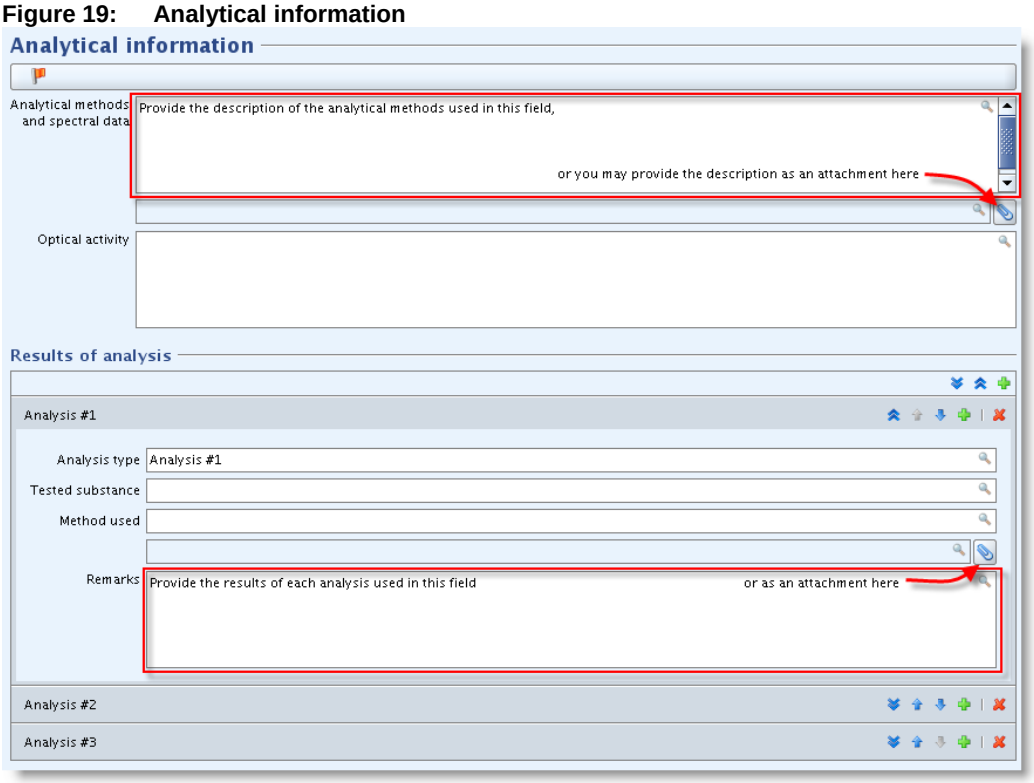
The following information referred in Annex VI of the REACH Regulation must be provided in IUCLID section 1.4:

- 2.2.2 Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)
- 2.3.5 Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)
- 2.3.6 High pressure liquid chromatogram, gas chromatogram
- 2.3.7 Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced

If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items above, the reasons shall be clearly stated. For substances for which any of the items above are not suitable, data from a suitable characterisation method should be included.

The description of the analytical methods must be provided either in the “Analytical methods and spectral data” field or as an attachment under this field (by clicking the paperclip button, indicated in Figure 19). The analytical results used to characterise the substance must be provided in the repeatable blocks under “Results of analysis” as an attachment (by clicking the paperclip button) or in the “Remarks” field (Figure 19).

Figure 19: Analytical information

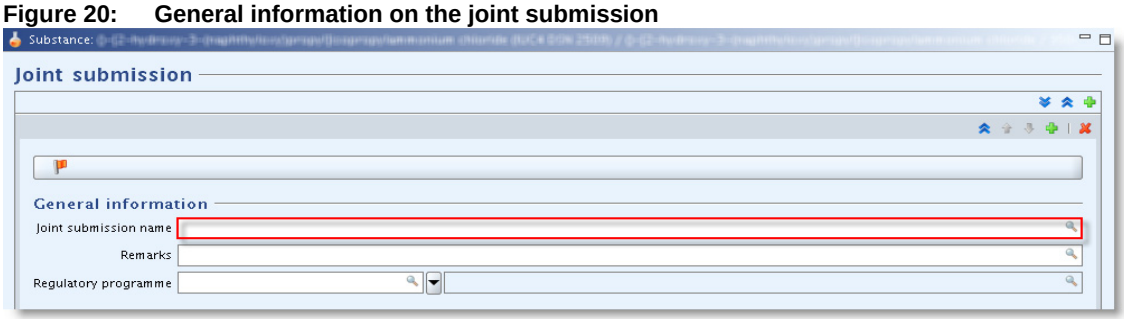


Remember that you can create additional blocks by using the green key.

4.1.6 Section 1.5 - Joint submission

The lead registrant and the members of a joint submission may wish to indicate for their own administrative purposes, the name of their joint submission in the related field in this section (Figure 20). This section is not checked for technical completeness as all the information concerning the joint submission will already have been provided in REACH-IT. For dossiers that are not part of a joint submission, this section must be left empty.

Figure 20: General information on the joint submission

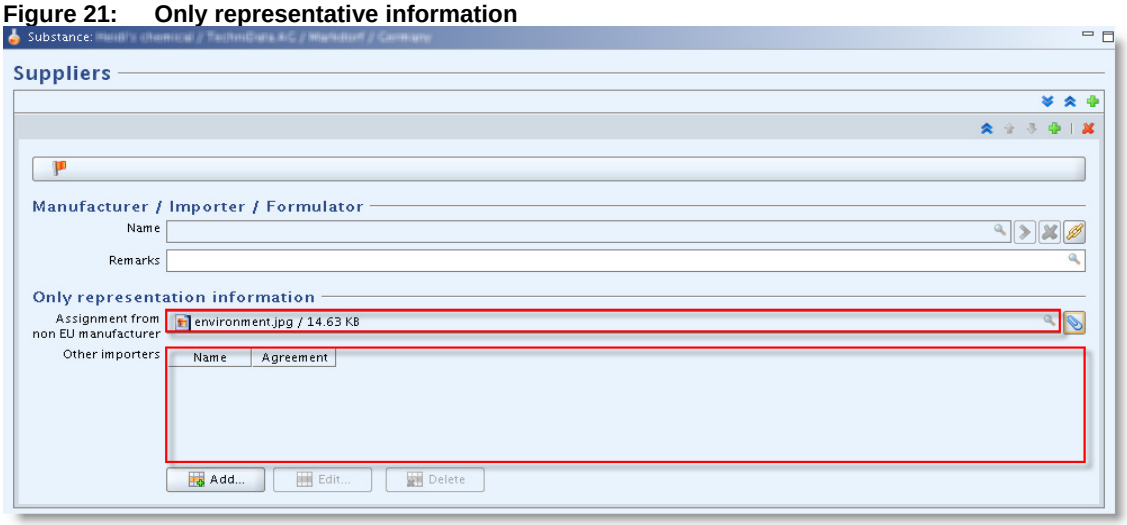


4.1.7 Section 1.7 - Suppliers

If the box “Only representative” is ticked in IUCLID section “1.1 Identification”, then you are advised to attach clear documentation of the appointment of the Only Representative (e.g. a copy of the appointment letter which was sent to importers) in the field “Assignment from non

EU manufacturer". In this case, you are also advised to indicate the list of the importers' names covered by the registration in the field "Other importers" (Figure 21).

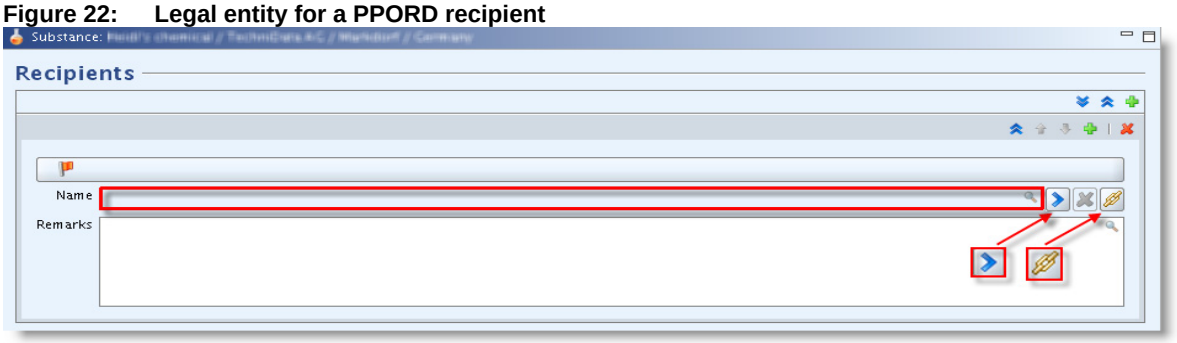
Figure 21: Only representative information



4.1.8 Section 1.8 - Recipients

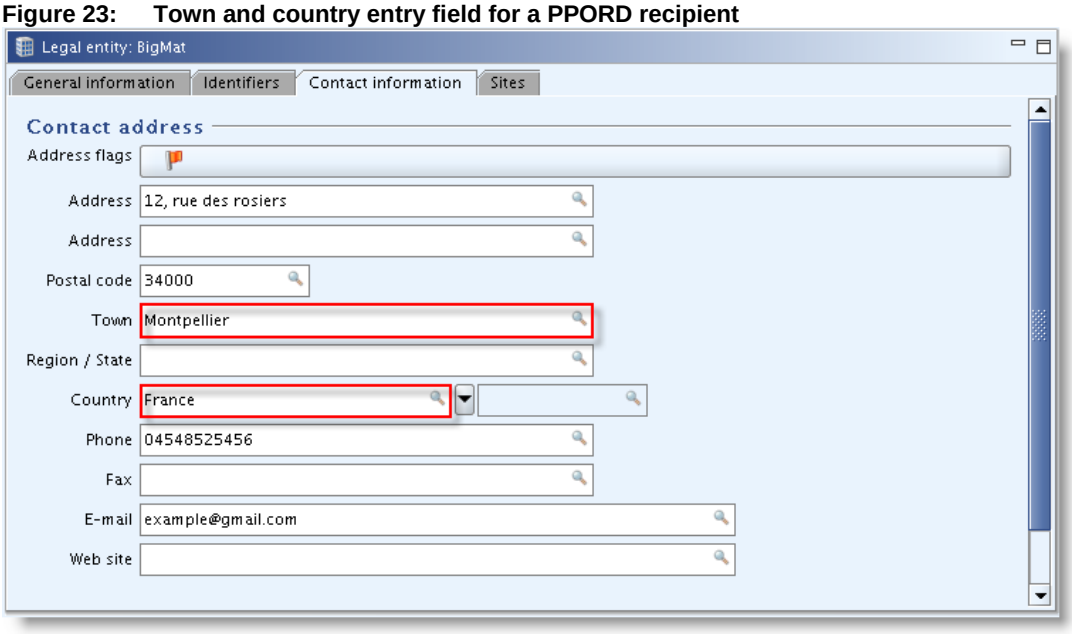
This IUCLID 5 section needs only to be checked for PPORD notification dossiers. If the field "Name" is filled in, the Legal entity related to this name must also be provided (Figure 22).

Figure 22: Legal entity for a PPORD recipient



This information must be provided by linking a Legal entity to the repeatable block (press the chain button (as shown in Figure 22) to link the legal entity or create a new one) and filling the information in the tab "Contact information" (press the arrow button (as shown in Figure 22) to go to the Legal entity information). The minimum information to provide in the tab "Contact information" is the "Town" and the "Country" (Figure 23).

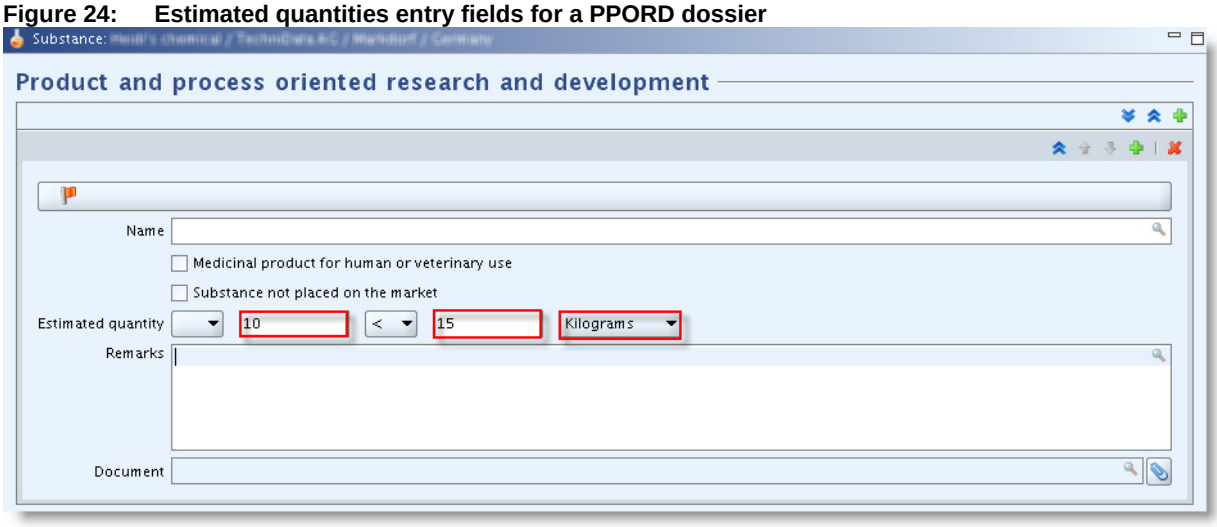
Figure 23: Town and country entry field for a PPORD recipient



4.1.9 Section 1.9 - Product and process oriented research and development

This IUCLID 5 section needs only to be checked for PPORD notification dossiers. The fields "Estimated quantity" must be filled in, together with the appropriate unit (Figure 24).

Figure 24: Estimated quantities entry fields for a PPORD dossier



4.2 Section 2 - Classification and labelling

There are two blocks for entering information relating to classification and labelling (C&L) in IUCLID 5; section "2.1 GHS" and section "2.2 DSD – DPD". The requirements for each are outlined in more details below.

GHS is the abbreviation for the United Nations' **G**lobally **H**armonised **S**ystem. The CLP Regulation introduces throughout the EU a new system for classifying and labelling chemicals, based on the GHS.

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

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

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation) will replace DSD and DPD in a stepwise approach. Further information on CLP is available on our website at http://echa.europa.eu/clp_en.asp

According to the CLP Regulation, substances must be classified, labelled and packaged in accordance with the criteria specified in Annex I of the CLP Regulation from 1 December 2010. Prior to this date, this information was only optional. Therefore, registration dossiers submitted to ECHA **from 1 December 2010** will need to include the C&L information in section "2.1 GHS". Inclusion of the C&L information in section "2.2 DSD-DPD" according to Directive 67/548/EEC (DSD) will be optional from that date.

Please be aware that it is not possible to submit a separate notification if you have already submitted a registration dossier.

If you want to update the C&L information from your registration dossier, you shall submit an update of your registration dossier.

Completeness check rules are applicable to CLP and DSD (IUCLID sections 2.1 and 2.2, respectively).

Here below are listed some principles to follow for completing both IUCLID sections 2.1 and 2.2.

When the substance is "not classified" you should tick the box "Not classified" but also justify why no classification is given for each endpoint, hazard class or differentiation (Annex VI 4.1 of the REACH Regulation) and this must be done by filling in the fields "Reason for no classification".

The reason for no classification should be selected according to the following principles:

- "data lacking" should be selected if you do not have relevant data or other adequate and reliable information that can be compared with the classification criteria;
- "inconclusive" should be selected if you have data or other information but which is not reliable (e.g. data of poor quality) or if you have several equivocal study results or information. The available data/information can not be regarded as a firm basis for classification;
- "conclusive but not sufficient for classification" should be selected in cases where a substance is tested with the appropriate high quality study or where other high quality information is available, and based on that, it is concluded that the classification criteria are not fulfilled. This reason for no classification should also be selected in case a hazard category does not apply for your substance (e.g. "Flammable gases" for a solid substance).

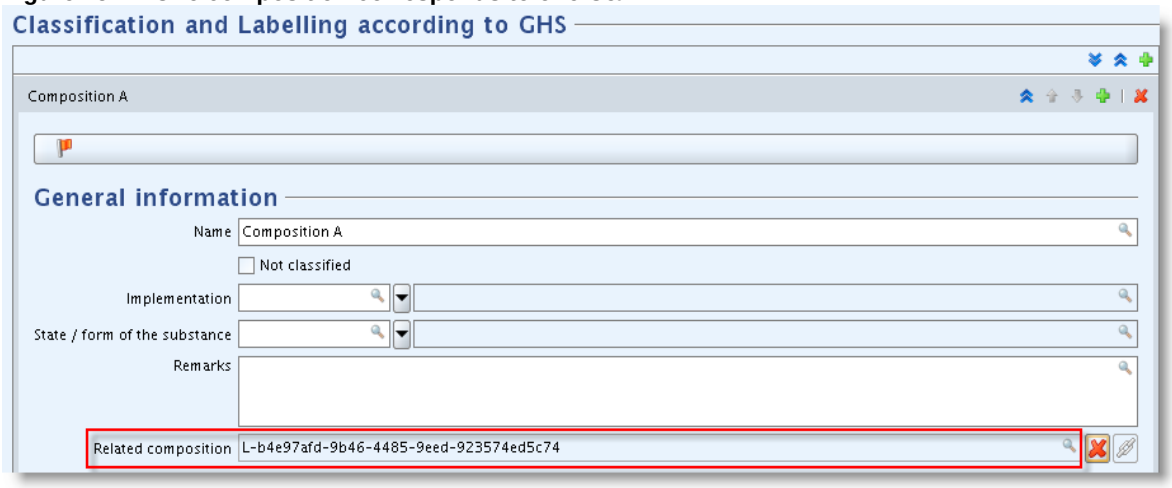
In IUCLID 5 the fields "Reason for no classification" are pre-filled indicating "data lacking" by default. You can change this default setting to another appropriate reason such as "Inconclusive" or "conclusive but not sufficient for classification" or you can also set the

"Reason for no classification" to the "empty field" and then specify a "Hazard category" and a "Hazard statement".

If multiple repeatable blocks are created in IUCLID sections 2.1 and 2.2 then all of these blocks must be complete.

If you have several compositions (several blocks in IUCLID section 1.2) and each composition corresponds to a different C&L then you are advised to link each C&L block to its related composition by using the field "Related composition" (Figure 25).

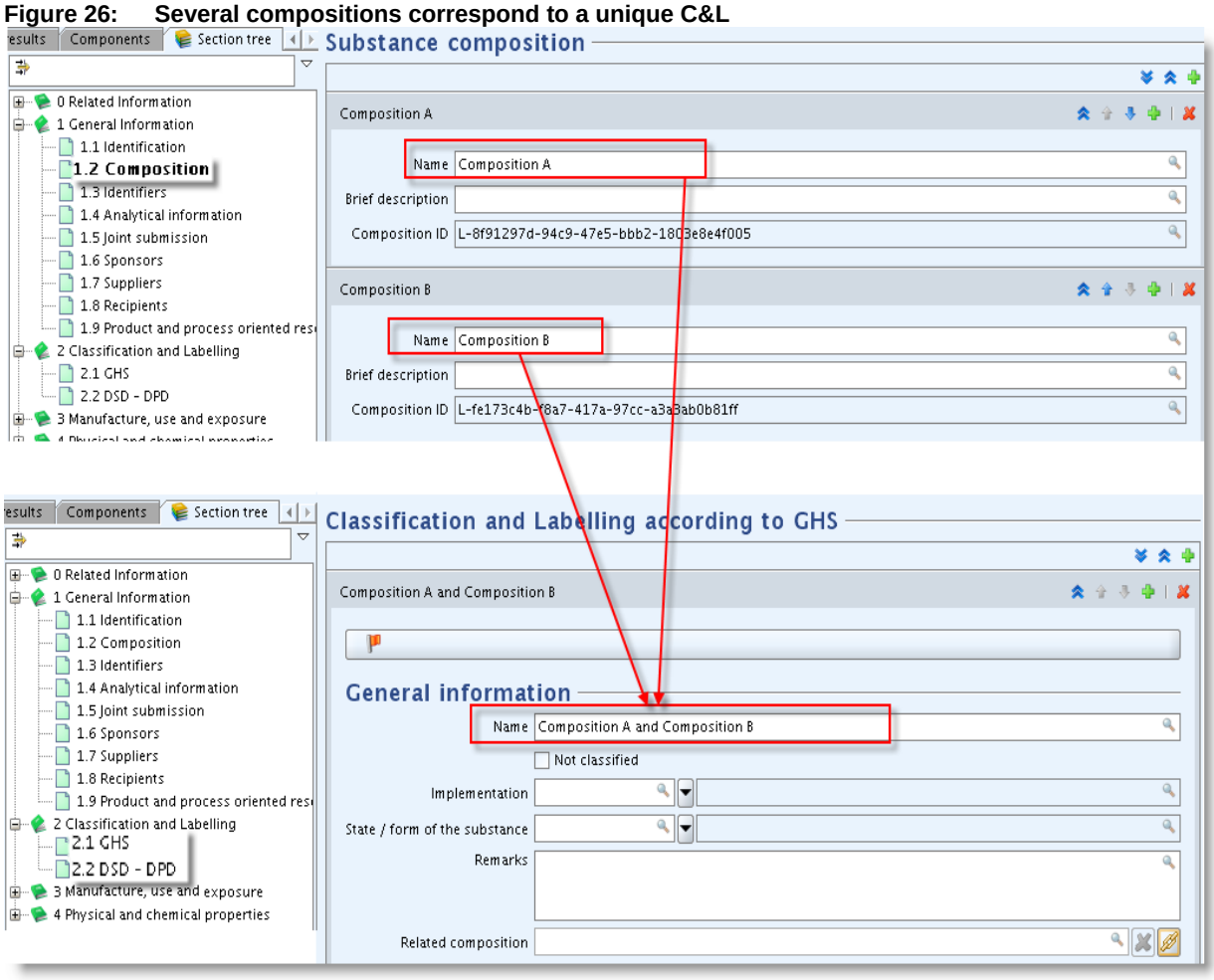
Figure 25: One composition corresponds to one C&L



If you have several compositions linked with the same C&L then you are advised to let the field "Related composition" blank and to indicate in the field "Name" of IUCLID section 2.1 and 2.2 the composition name to which your C&L refer to (Figure 26).

This advice is nevertheless valid only if your registration dossier contains multiple C&L and only one composition in section 1.2.

Figure 26: Several compositions correspond to a unique C&L



How to report the classification and labelling within a joint submission

The dossiers of the lead and the members of a joint submission have to be clear and transparent as to which classification belongs to which composition. There are different ways of achieving this. A best practice of how this could be achieved is described in the following section.

The lead registrant should always provide at least one C&L in its dossier, while for members there are three different scenarios to fulfil their C&L requirements:

1) The member has the same C&L as the lead: In this case, the member should not provide any information in sections 2.1 and 2.2 of its IUCLID dossier.

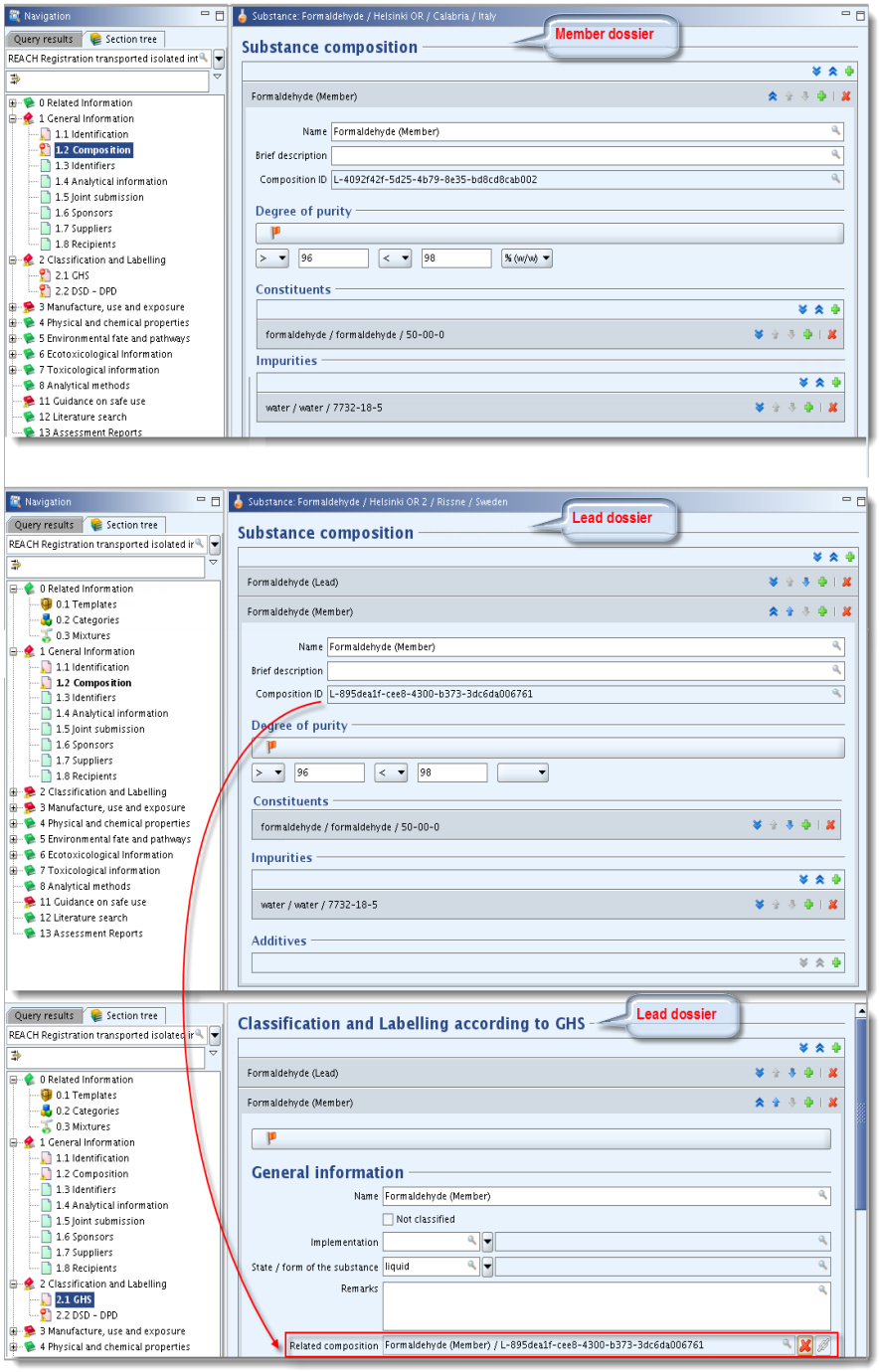
2) The member opts out from the C&L information: If the member decides to submit a separate C&L (as described in REACH Article 11(3)) then the member should provide a C&L in at least section 2.1 of his own IUCLID dossier.

3) The member has a different C&L than the lead but does not want to opt out

If a member has a different C&L than the lead and the member is willing to have its C&L submitted by the lead on his behalf, the member should still provide the composition in IUCLID section 1.2 but should leave the IUCLID sections 2.1 and 2.2 empty in the dossier.

In this specific case, the lead should add the composition of the member and the C&L of the member in his own dossier. The composition of the member should then be linked in at least section 2.1 of the lead dossier. In addition, it is recommended to indicate in the field “Name” of sections 2.1 (and 2.2 if relevant) of the lead dossier the same name as the composition name provided in section 1.2 of the member dossier (Figure 27).

Figure 27: Linking the composition and C&L of a Member (not opting out) and Lead of a joint submission



4.2.1 Section 2.1 - GHS

As indicated in the previous chapter, from 1 December 2010 it is compulsory to include the information on classification and labelling according to the CLP Regulation in all registration dossiers (except for members of a joint submission). Therefore, if no repeatable block has been created in section 2.1 this will be a reason for considering the dossier as incomplete.

When a repeatable block is created in section “2.1 GHS”, all the requested fields of this repeatable block will be checked for completeness.

With the entry into force of the CLP Regulation, title XI of the REACH Regulation has been repealed. Therefore, you need to use section 2.1 of IUCLID to specify the C&L information requested under Article 40(1- c, d, e and f) of the CLP Regulation.

More detailed information concerning C&L can be found in the Data Submission Manual 12: ‘How to Prepare and Submit a Classification and Labelling Notification Using IUCLID’ available from the ECHA website at:

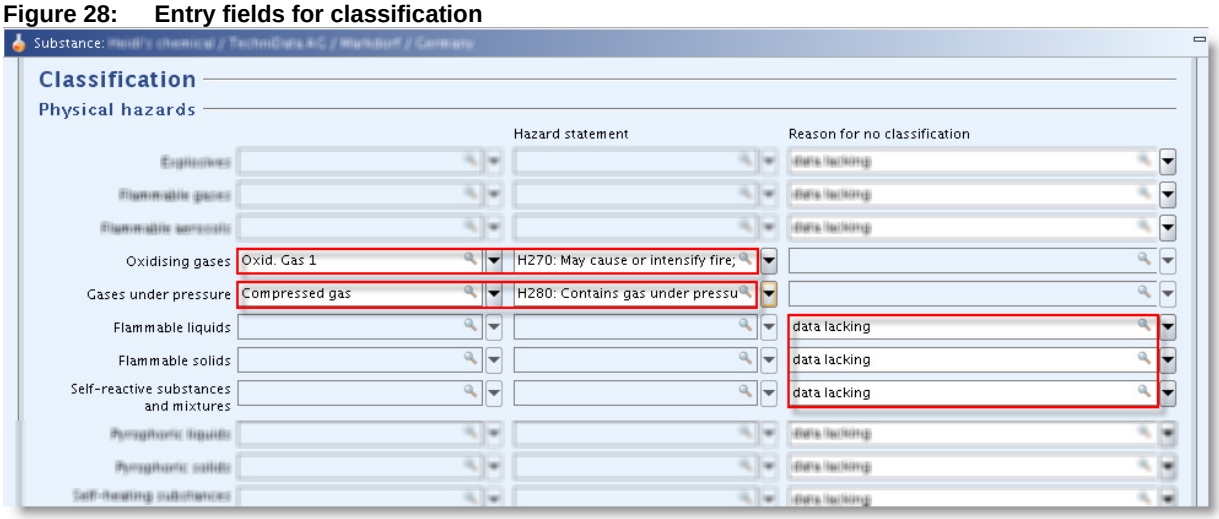
http://echa.europa.eu/doc/reachit/data_submission_manual_12_c&l.pdf

In addition, it is highly recommended to consult Annex I of the CLP Regulation for the classification criteria and the following guidance document for more detailed instructions on the application of the C&L rules: http://guidance.echa.europa.eu/docs/guidance_document/clp_introductory_en.pdf

4.2.1.1 Classification

- For each hazard class or differentiation either the two fields, “Hazard category” and “Hazard statement” must be indicated, otherwise, the field “Reason for no classification” must be filled in (Figure 28). Note that the ‘Reason for no classification’ is prefilled to ‘Data lacking’ by default.

Figure 28: Entry fields for classification



It is not compulsory to make a selection in the field “State/form of the substance” above the block “Classification”, however this information may be useful to justify a classification.

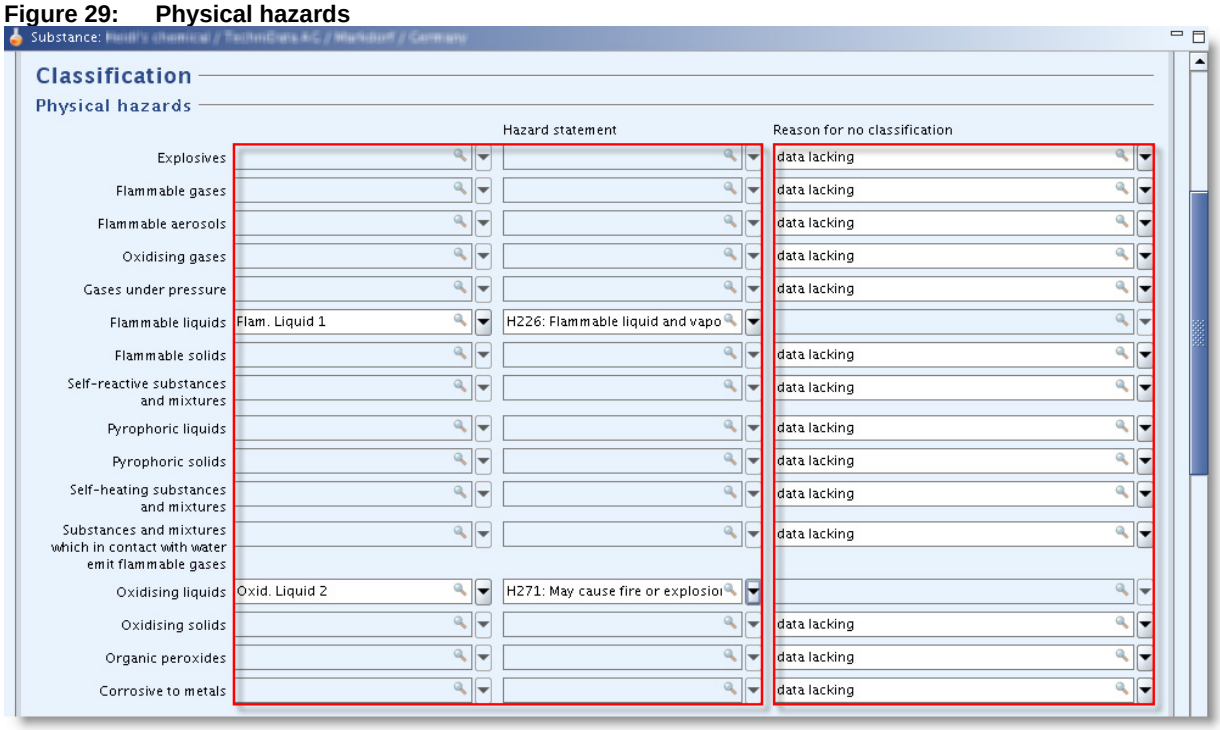
Some hazard categories and hazard statements do not exist in the CLP Regulation and shall therefore not be selected in your registration dossier. These categories/statements are listed in Chapter 5.7 of Data Submission Manual 12.

4.2.1.2 Block ‘Physical hazards’

For all hazard classes indicated in the block “Physical hazards”, either the two first fields (i.e. the field “Hazard category” (e.g. Flam. Liquid 1) and the field “Hazard statement” (e.g. H226:

Flammable liquid and vapour)) should be filled in, or the field “Reason for no classification” should be filled in (Figure 29).

Figure 29: Physical hazards



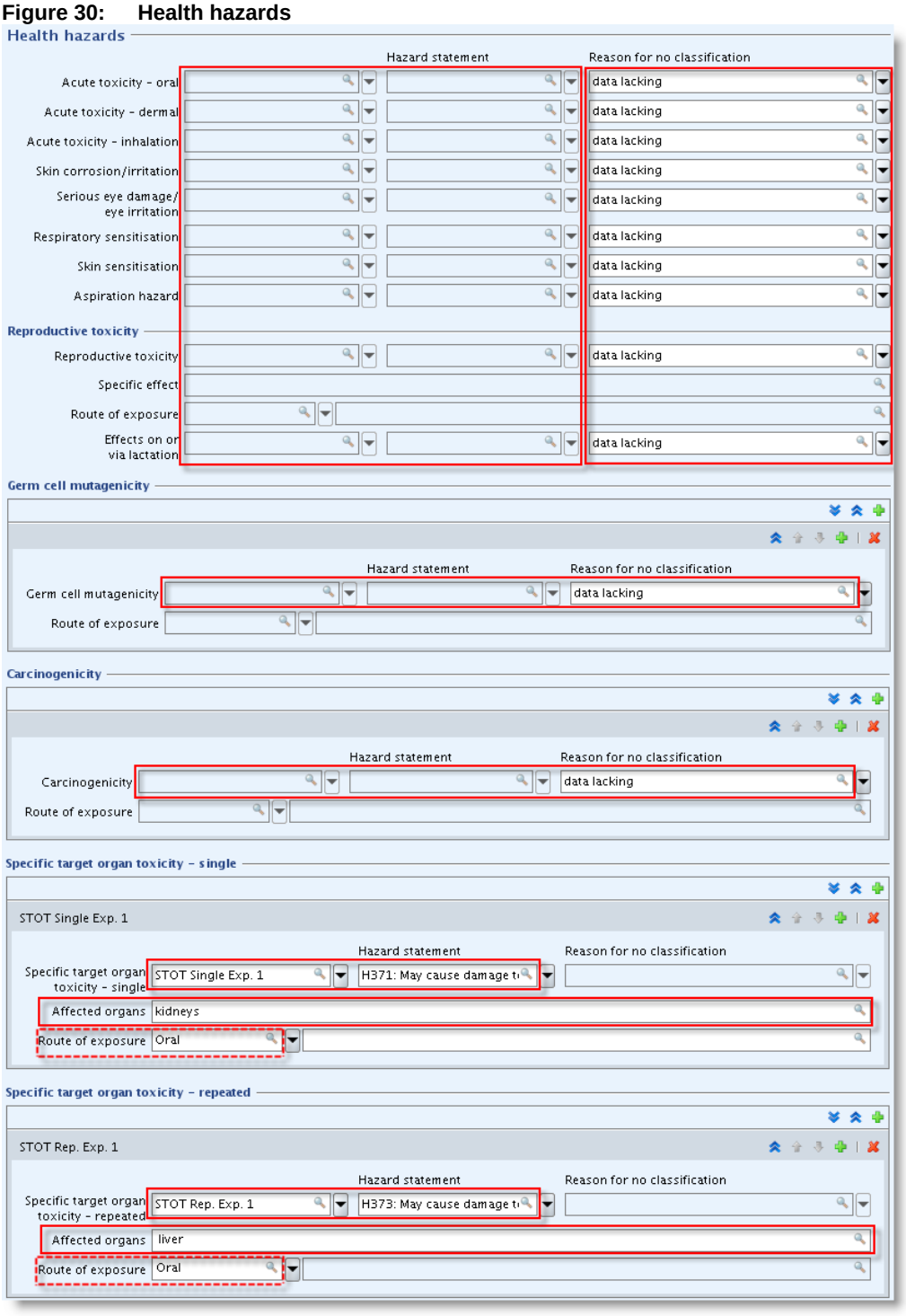
4.2.1.3 Block ‘Health hazards’

For all hazard classes and differentiations indicated in the block “Health hazards”, either the first two fields (i.e. fields “Hazard category” and “Hazard statement”) should be filled in or the field “Reason for no classification” should be filled in (Figure 30).

If a substance is classified for either “Specific target organ toxicity – single” (STOT-single) or for “Specific target organ toxicity – repeated” (STOT-repeated) then you are required to fill in also the field “Affected organs” (Figure 30). Failure to do so will be recognised at the technical completeness check stage. For these and other hazard classes/differentiations, you are also advised to indicate the “Route of exposure”.

In keeping with the rules imposed under the CLP regulation (GHS), the field “Affected organs” is now compulsory to pass the completeness check if the substance has been classified STOT-single or STOT-repeated.

Figure 30: Health hazards

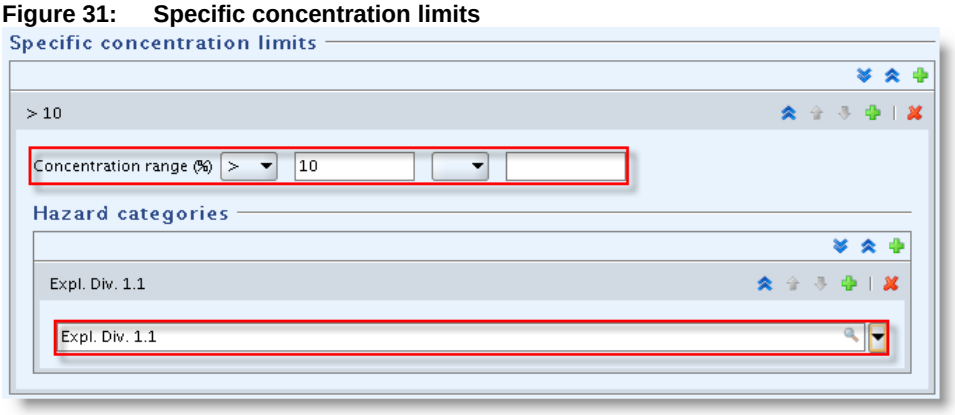


4.2.1.4 Block 'Specific concentration limits'

In case there is/are specific concentration limit(s), you need to indicate it/them by filling in at least one of the two fields for "Concentration range (%)" and in addition, you also need to select a "Hazard category" (Figure 31).

If data is entered in the block "Specific concentration limits", it will be checked for technical completeness. If a block has been created both "Concentration range (%)" and "Hazard category" should be provided otherwise a failure will be recognised at the technical completeness check stage.

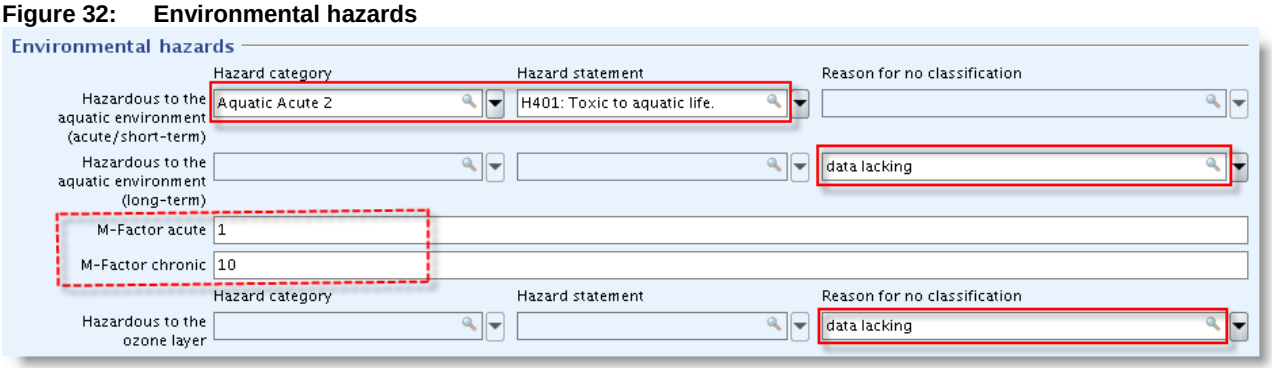
Figure 31: Specific concentration limits



4.2.1.5 Block Environmental hazards

For all hazard classes indicated in the block "Environmental hazards", either the two first fields (i.e. fields "Hazard category" and "Hazard statement") should be filled in or the field "Reason for no classification" should be filled in (Figure 32).

Figure 32: Environmental hazards



Further recommendations on how to fill in the block "Environmental hazards" including M-Factors are provided in Chapter 5.7 of Data Submission Manual 12 at:

http://echa.europa.eu/reachit/inventory_notification/notification_how_en.asp .

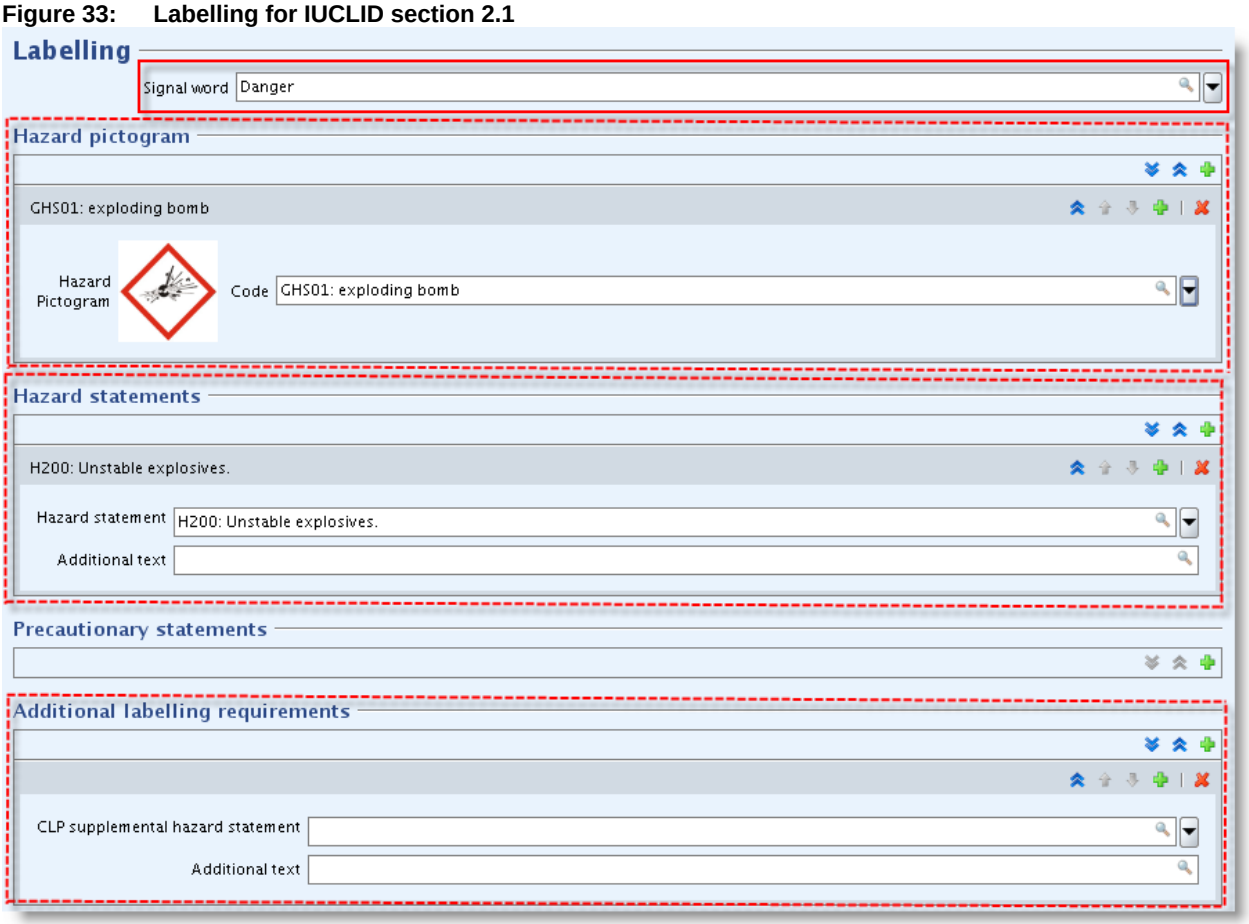
4.2.1.6 Labelling for section 2.1

A selection is required in the field “Signal word” (“Danger”, “warning” or “no signal word”).

In addition, if at least one hazard class or differentiation is classified as hazardous then at least one hazard statement should be indicated in this “Labelling” block (Figure 33).

If applicable, you are also advised to indicate the “Hazard pictogram” and the “CLP supplemental hazard statement”.

Figure 33: Labelling for IUCLID section 2.1



In the case where there is no valid hazard statement(s) from the pick-list, you may select a CLP supplemental hazard statement from the pick-list.

For dossiers of isolated intermediates, this “Labelling” block will not be checked for completeness.

4.2.2 Section 2.2 - DSD - DPD

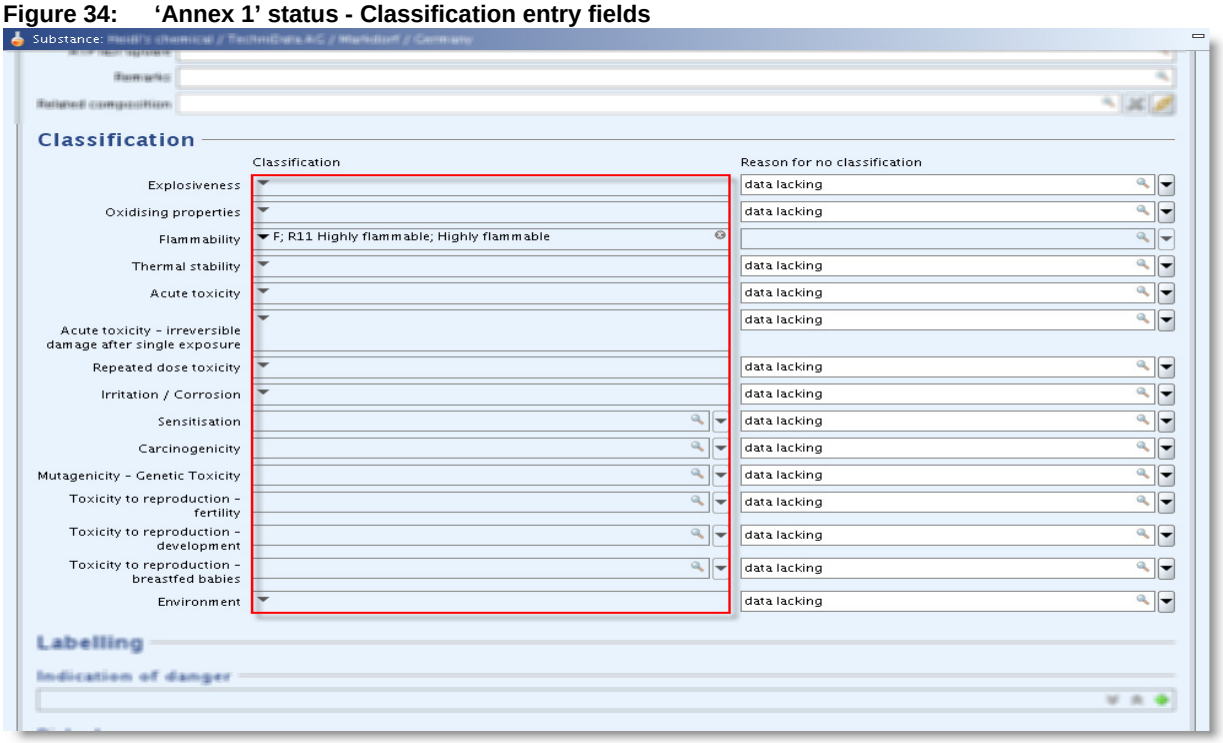
4.2.2.1 Classification

With the entry into force of the CLP Regulation (GHS), the C&L information provided in section “2.2 DSD-DPD” according to Directive 67/548/EEC (DSD) is only optional from 1

December 2010. However, if a block is created in section '2.2 – DSD-DPD', then it must be technically complete. For technical completeness, you must select either '67/548/EEC annex 1¨', or '67/548/EEC self classification' or 'other:' in the 'Status' field. Depending on this selection, the requirements vary and as such, you are advised to follow the instructions as indicated below:

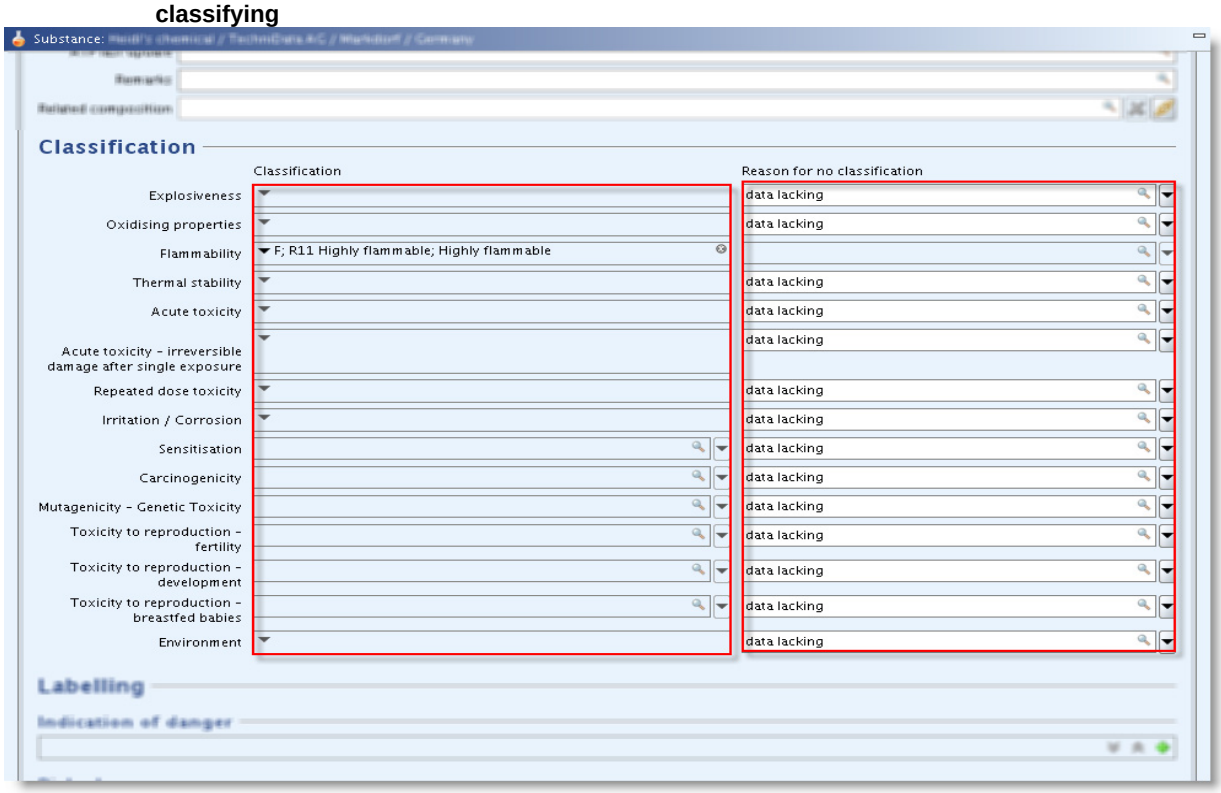
- If '67/548/EEC annex 1' is selected in the field 'Status', then at least one classification field must be filled in (explosiveness, oxidising properties …) (Figure 34). Note that the 'Reason for no classification' is prefilled to 'Data lacking' by default.

Figure 34: 'Annex 1' status - Classification entry fields



If the field "Status" indicates "67/548/EEC self classification" or "other:" then information must be provided for all the endpoints (Figure 35).

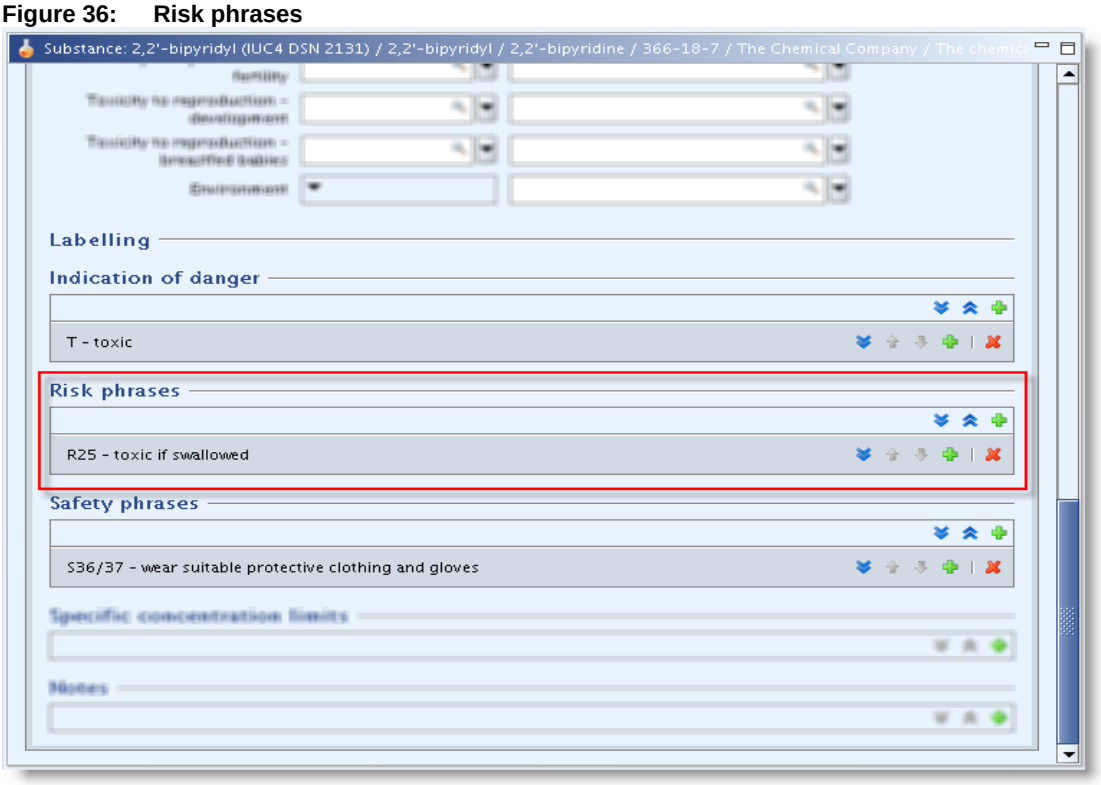
Figure 35: 'Self classification' or 'Other' status - Classification entry fields and reason for not classifying



4.2.2.2 Labelling for section 2.2

If at least one classification has been indicated for an endpoint, then at least one "Risk phrase" must be indicated. A "Safety phrase" should also normally be provided in this case (see Figure 36).

Figure 36: Risk phrases



For dossiers of isolated intermediates, this “Labelling” block will not be checked for completeness.

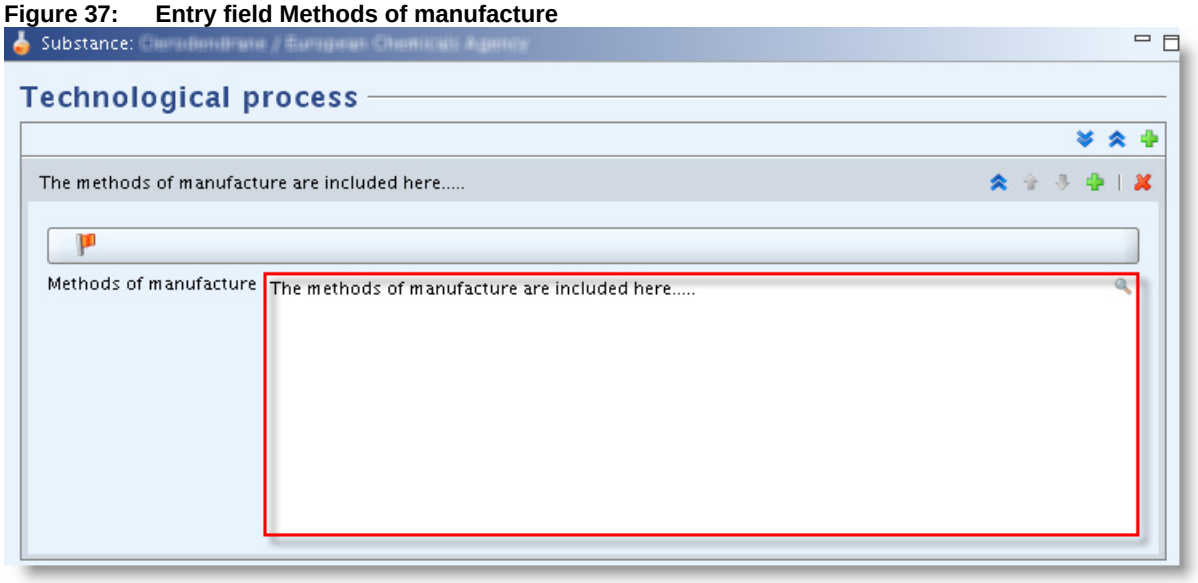
4.3 Section 3 - Manufacture, use and exposure

This chapter provides information on how to provide data in IUCLID on the technological processes used, estimated quantities, site(s), form in the supply chain, identified use and exposure, advice against the use of the chemical, and waste from the production and use. Each topic will be presented in a separate chapter.

4.3.1 Section 3.1 - Technological process

Following the requirement of section 3.2 of Annex VI of REACH, if the box “Manufacturer” is ticked in section “1.1 Identification”, then information must be provided in the field “Methods of manufacture” as shown in Figure 37.

Figure 37: Entry field Methods of manufacture



4.3.2 Section 3.2 - Estimated quantities

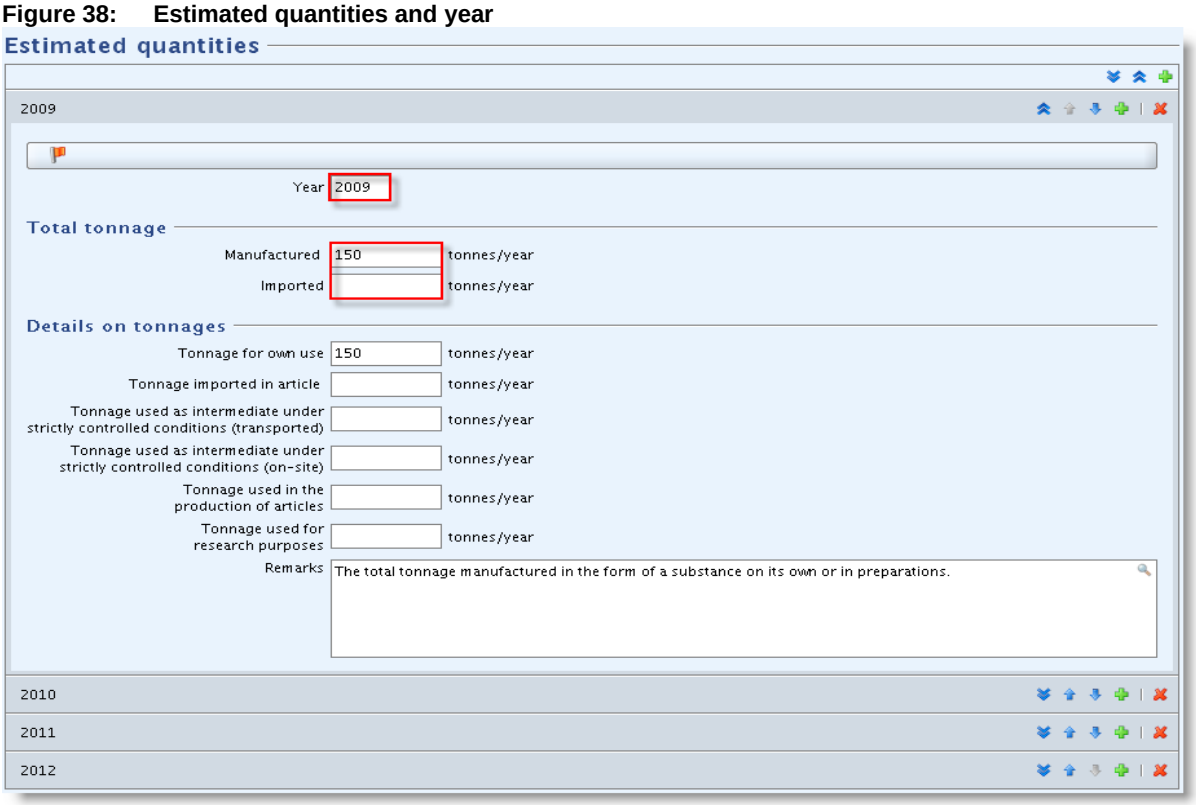
Manufacturers/importers of a substance and producers of an article have to give information on their tonnage (manufactured, imported and/or used in articles) per year that is subject to registration (Annex VI of REACH, sections 3.1) and also an indication of the tonnage used for their own use(s) (Annex VI of REACH section 3.3). This corresponds to section “3.2 Estimated quantities” and it will be checked that the fields “Year” and “Total tonnage” (manufactured and/or imported) are completed Figure 38.

If several blocks are created in this section, all of them have to be completed.

Information to provide in the field “Tonnage” is the total tonnage manufactured or imported in the form of a substance on its own or in preparations, including “intermediate” uses. It should not include the tonnage of the substance imported in articles. For further information see chapter 1.6.2 ‘Calculation of the volume to be registered’ found in the “Guidance on registration“ available at:

http://guidance.echa.europa.eu/docs/guidance_document/registration_en.pdf

Figure 38: Estimated quantities and year

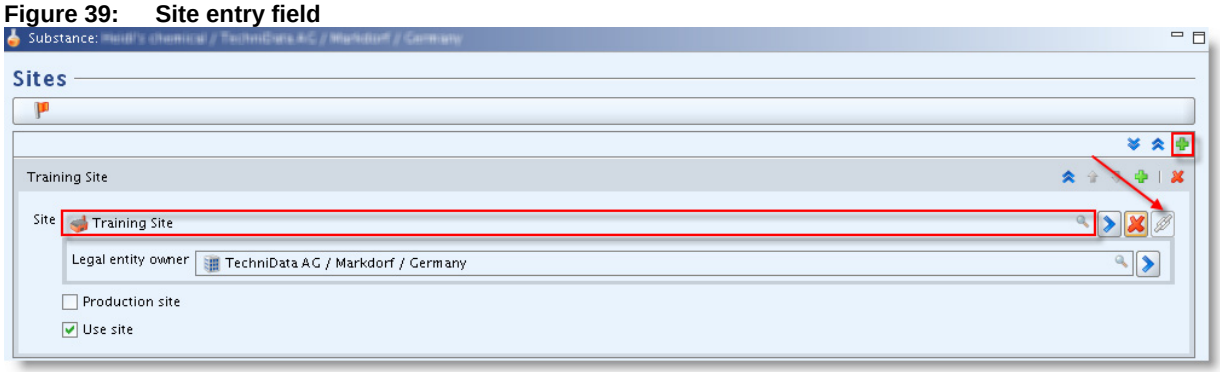


In addition to these rules, it is also recommended to fill in the fields under “Details on tonnages” where relevant (e.g. for dossiers which include tonnages of isolated intermediates or substances in articles).

4.3.3 Section 3.3 - Sites

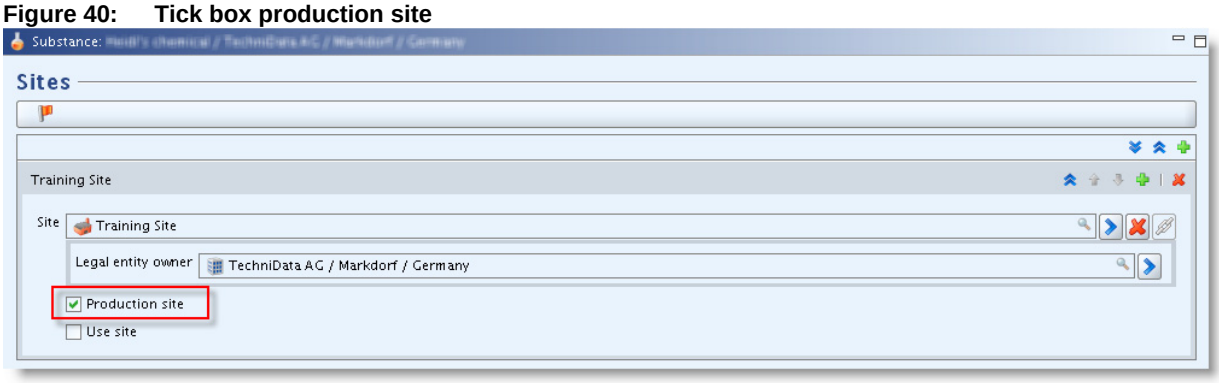
As specified in section 1.1.3 of Annex VI of REACH, the location of the registrant’s production and own use site(s) must be provided, as appropriate. Therefore, every site created by clicking on the green cross button (Figure 39) must have a site linked to it (to do so one should click on the chain button (Figure 39)).

Figure 39: Site entry field



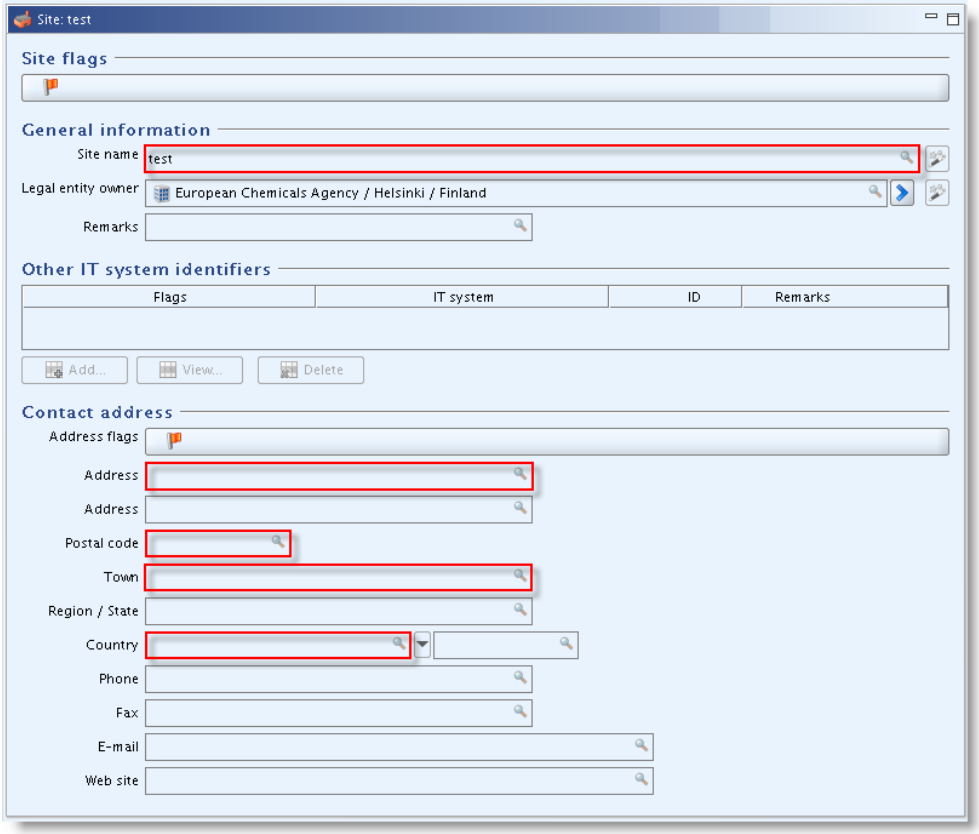
If the box “Manufacturer” is ticked in IUCLID section “1.1 Identification”, then at least one production site must be provided, i.e. one site should have the box “Production site” ticked (Figure 40)

Figure 40: Tick box production site



In addition, for each site created at least one of the two boxes “Production site” or “Use site” must be ticked. In addition, the fields that must be filled in for each site are the “Site name”, “Address”, “Postal code”, “Town” and “Country” as shown in Figure 41.

Figure 41: Site name and contact address



4.3.4 Section 3.4 - Form in the supply chain

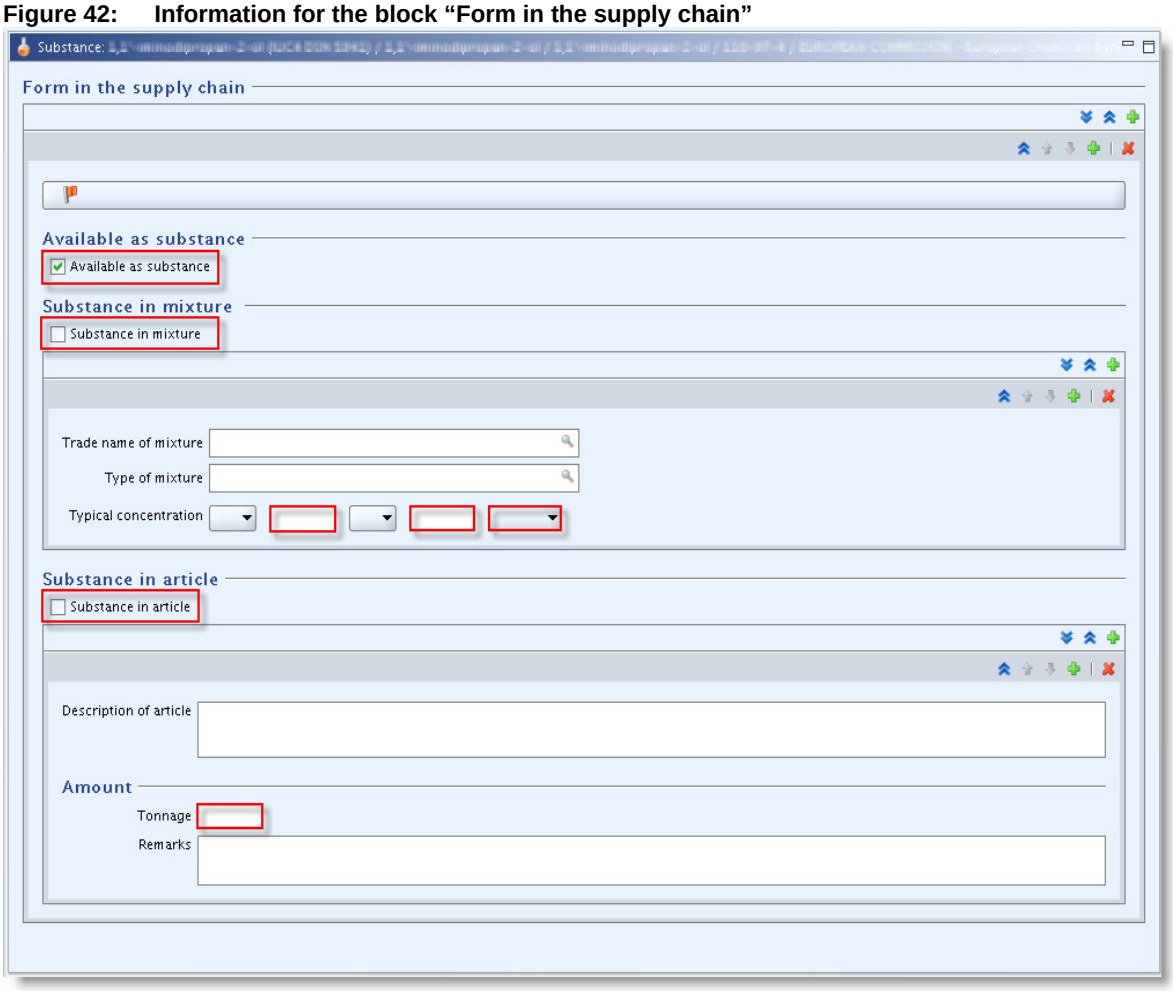
This information is required in Annex VI section 3.4 of the REACH Regulation. Therefore at least one of the following must be done:

- either the checkbox “available as substance” is ticked,
- or the checkbox “substance in mixture” is ticked and a value is given in the field “typical concentration” (with its unit),

- or the checkbox “substance in article” is ticked and a value is given in the field “tonnage”.

Figure 42 shows the entry fields discussed above.

Figure 42: Information for the block “Form in the supply chain”



4.3.5 Section 3.5 - Identified uses

This chapter provides information on the identified use and overall use and exposure of a chemical.

4.3.5.1 Information on uses

According to Annex VI section 3.5 of the REACH Regulation, registrants have to provide a brief general description of their identified use(s). Therefore, this section has to contain at least one of the following (Figure 43):

- either a complete row for "Uses by workers in industrial settings": ("Identified use name", "Process category", "Environmental Release Category" and "Subsequent service life relevant for that use?" are filled in) OR ("Identified use name", "Process category" and "Sector of end use" are filled in),

- or a complete row for "Uses by professional workers": ("Identified use name", "Process category ", "Environmental Release Category" and "Subsequent service life relevant for that

use?" are filled in) OR ("Identified use name", "Process category" and "Sector of end use" are filled in),

- or a complete row for "Uses by consumers": ("Identified use name" and "Subsequent service life relevant for that use?" are is filled in) OR ("Identified use name" and "Sector of end use" are filled in),

- or a selection in the Pick-list "Justification why no identified uses are reported". In case "Other" is selected as justification then the adjacent free text field must be filled in.

When completing this section, please note the following:

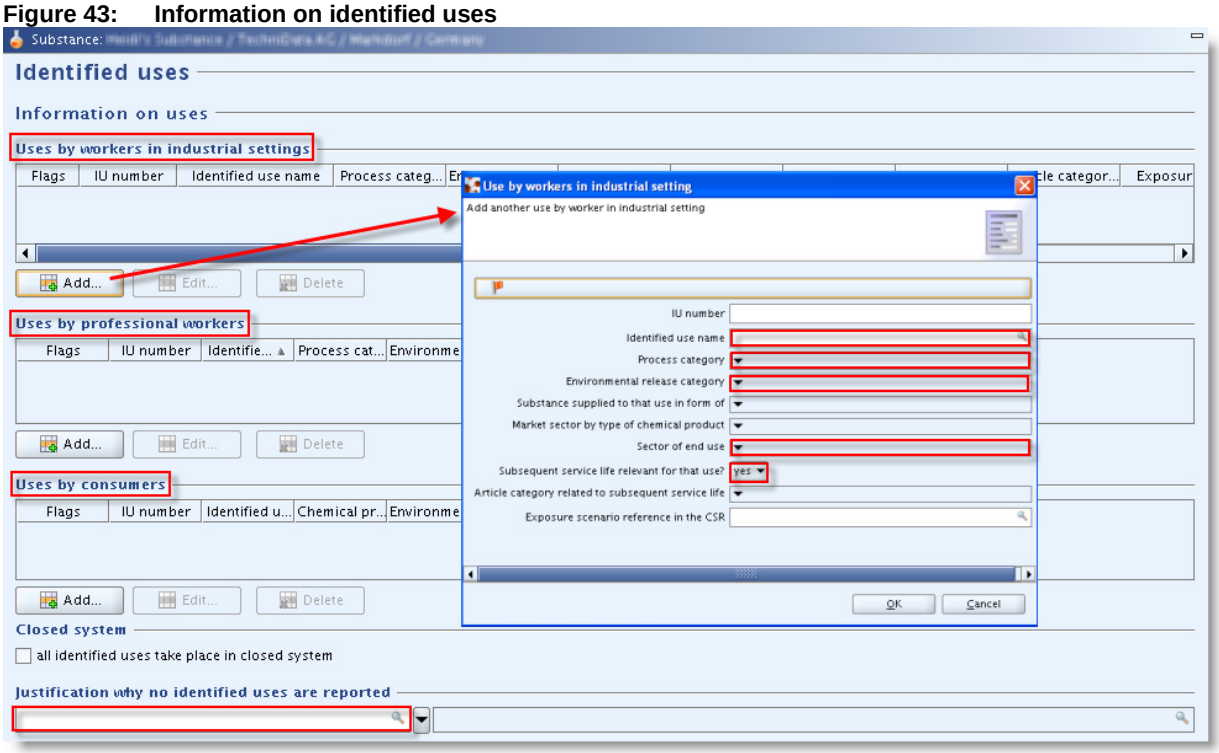
- If several rows are created in a table then all of these rows have to be complete (e.g. if there are two rows under "Uses by professional workers" then both rows have to be complete).

- If rows are created in more than one table then all of these rows have to be complete (e.g. if there is one row under "Uses by professional workers" and one row under "Uses by consumer" then both rows have to be complete).

- The field “Subsequent service life relevant for that use?” is filled in by default with a “yes” if you are using IUCLID version 5.2.2 or later. Therefore, you should change this value appropriately.

- If "Other:" is selected in any of the pick-lists then the adjacent free text field must be filled in.

Figure 43: Information on identified uses



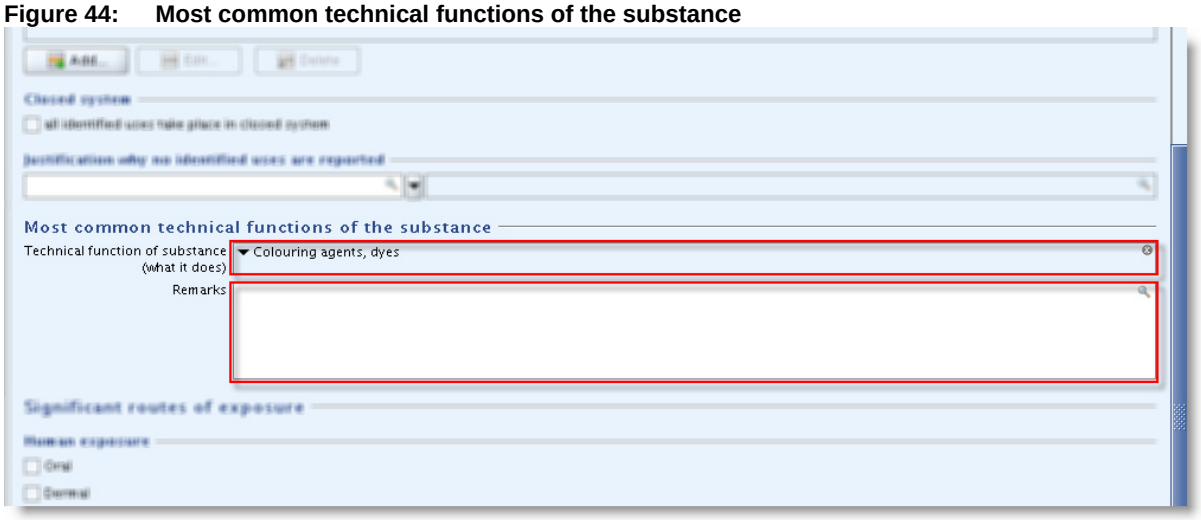
For substances registered at more than 10 tonnes, the information provided in this block must also be indicated in the CSR.

For substances registered between 1 to 10 tonnes, exposure information as specified in section 6 of REACH Annex VI must be provided. However the requirements listed in this section 6 will be considered as fulfilled if the rules mentioned above have been followed. As a consequence it means that there are no additional TCC checks done on IUCLID section 3.5 for substances registered between 1 to 10 tonnes.

4.3.5.2 Most common technical functions of the substance

A selection must be done in the Pick-list "Technical function of substance" or a description of the function/use of the substance must be provided in the "Remarks" field (Figure 44).

Figure 44: Most common technical functions of the substance



4.3.6 Section 3.6 - Uses advised against

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

If no uses advised against have been identified then you should not enter any information in IUCLID Section “3.6 Uses advised against”.

If you have identified use(s) advised against, then you must add a row for each use advised against and fill in as a minimum the field “Used advised against name” or the field “Remarks”.

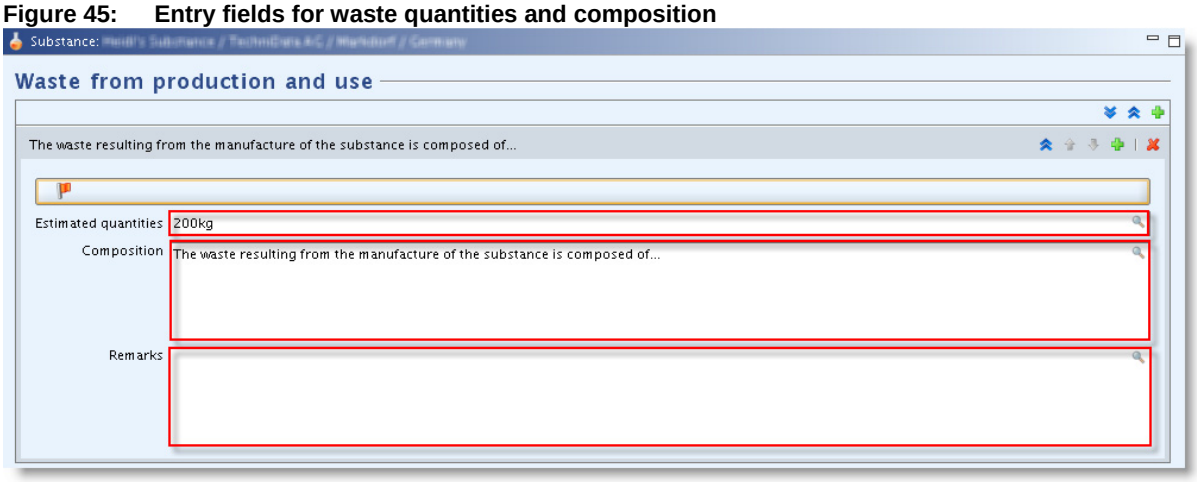
4.3.7 Section 3.7 - Waste from production and use

According to Annex VI section 3.6 of the REACH Regulation, registrants have to provide information on waste quantities and composition of waste.

If no waste has been identified then you should not create any repeatable blocks in IUCLID Section “3.7 Waste from production and use”.

If you have identified waste then you must create a repeatable block for each waste type and fill in at least one of the fields of this block: “Estimated quantities”, “Composition” or “Remarks” (Figure 45).

Figure 45: Entry fields for waste quantities and composition



4.4 Sections 4, 5, 6, 7 and 8 - Endpoint sections

This chapter discusses several endpoint sections in IUCLID and provides some background, a description of the approach to be followed, data waiving, testing proposals, how to deal with study results and PNEC/DNEL data.

4.4.1 Background

This part of the document deals with the general rules for the scientific studies submitted following Annexes VII to XI of the REACH Regulation, which are to be presented in sections 4 to 8 of IUCLID 5 as follows:

- IUCLID Section “4 Physical and chemical properties”
- IUCLID Section “5 Environmental fate and pathways”
- IUCLID Section “6 Ecotoxicological information”
- IUCLID Section “7 Toxicological information”
- IUCLID Section “8 Analytical information”

The particular studies that are required in a dossier are dependant on the type of registration and on the tonnage band of the dossier (see Annex 1). Once you have determined which studies need to be provided in the dossier, the content of each study must be provided. The following chapter indicates the rules for completing the content of each study.

The rules only apply to those studies listed in column 1 of REACH Annexes VII to X, i.e. studies not listed in these columns will not be checked for completeness. However, testing proposals must be always complete regardless of the endpoint.

For each endpoint study record, the same fields have to be checked for the administrative data, the data source and the materials and methods blocks (except some additional fields for few endpoints in the block “Material and methods”). On the other hand the block “Results and discussions” is more endpoint-specific and, therefore, the fields to be filled in vary from one endpoint to the other.

In addition it should be noted that an endpoint study record could be a study summary or a robust study summary (i.e. a detailed summary of a full study report). In cases where no test data is submitted for the registered substance, an endpoint study record could be a

calculated estimation, read-across, (Q)SAR, testing proposal (experimental study planned) or a data waiver.

4.4.2 Description of the approach to follow

The approach to follow in order to complete the set of endpoint studies required under the REACH Annexes VII to X is the following:

- Each requirement indicated in columns 1 of REACH Annexes VII-X must correspond to at least one complete endpoint study record in IUCLID.
- If no data waiver, no testing proposal, no key study and no weight of evidence study are provided for a required endpoint, then the endpoint will be considered as incomplete.
- All data waivers, testing proposals, weight of evidence and key studies must be complete. As a consequence, if there is more than one key study per endpoint then all of these key studies must be complete.
- Data waiving: If the study has been waived according to (i) the specific rules for adaptation in Annexes VII-X, or, (ii) Annex XI principles, then this must be identified in the endpoint study record, and a justification must be entered in the appropriate field. In this case, no further information is required in the endpoint study record.
- Testing proposal: If, for the information requirements in Annexes IX and X, a testing proposal has been submitted instead of a study result then, as a minimum, information about the guideline/method and the time schedule must be provided.
- Weight of evidence and Key study: If no data waiving or testing proposal is provided for an endpoint, then at least one record flagged as key study or as weight of evidence must be provided. A key study and a weight of evidence are endpoint study records for which the “Purpose flag” field is respectively set to “key study” or to “weight of evidence”. For weight of evidence and key studies certain minimum information is required in the “Administrative data”, “Data source”, “Materials and methods” and “Results and discussions” blocks. These requirements are detailed in the following sections, based on the rationale that for the majority of study types it is possible to identify certain basic fields that must normally be completed in order to be able to draw conclusions from the study (and indeed to use the results for later evaluation and dissemination of information).
- An endpoint study record cannot be at the same time a data waiving, a testing proposal and/or a study summary. As a consequence you should not at the same time provide information for waiving the data (i.e. fill in the fields “Data waiving” and “Justification for data waiving”), select "Experimental study planned" in the field "Study result type" and/or do a selection in the field "Purpose flag".
- A particular information requirement in REACH can be indicated in more than one endpoint in IUCLID 5 (e.g. the section 8.6.1 of Annex VIII of REACH requires a short term repeated dose toxicity which could be in IUCLID 5 sections 7.5.1, 7.5.2 or 7.5.3 depending on the likely route of human exposure). In other cases, the opposite applies and one endpoint study in IUCLID 5 (e.g. section “7.3.1 skin irritation/corrosion”) could be used to meet more than one REACH data requirement (see Annex 1). Therefore one IUCLID section could correspond to two or three REACH Annex numbers and one REACH Annex number could correspond to two or three IUCLID sections:

- If one IUCLID section corresponds to two or three REACH Annex numbers then one endpoint study record in this IUCLID section could be enough to cover the two or three REACH requirements.

⚠ This rule is true except for dossiers above 10 tonnes for which at least 2 endpoint study records must be provided in IUCLID section 7.6.1.

- If one REACH Annex number corresponds to two or three IUCLID sections then one endpoint study record in one of these IUCLID sections is enough to cover this REACH requirement.

⚠ For the specific case of the endpoint acute toxicity (section 7.2.1, 7.2.2 and 7.2.3 of IUCLID), in case of dossier for tonnage band over 10 tons, Annex VIII of REACH establishes that in addition to the oral route, for substances other than gases, acute toxicity tests should be provided for at least one other route. This means that the three sections “7.2.1 Acute Toxicity: oral”, “7.2.2 Acute toxicity: inhalation” and “7.2.3 Acute toxicity: dermal” will be checked for completeness. If one of them is not relevant, this should be indicated by creating a data waiver for the non-relevant route(s).

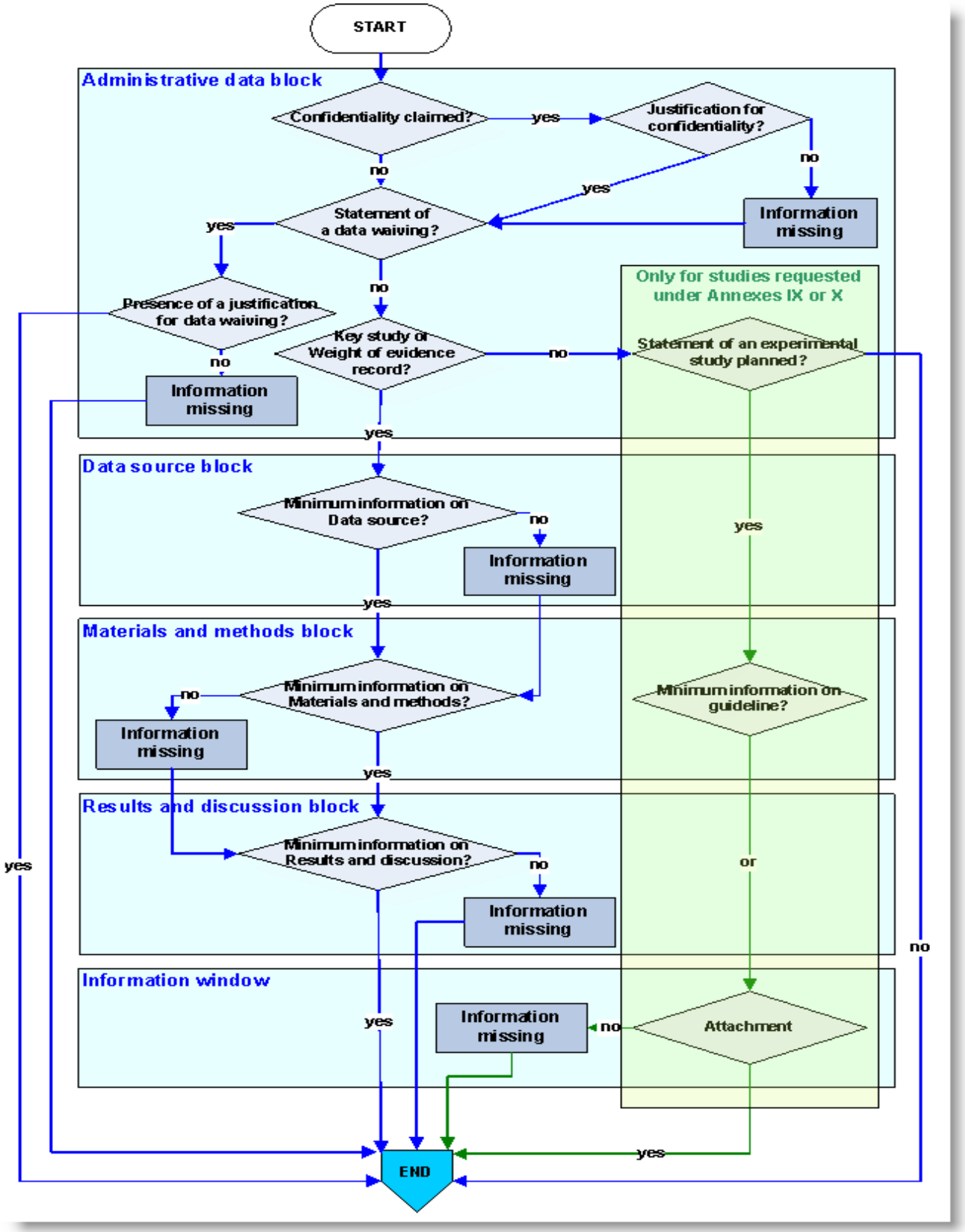
Further information on this IUCLID-REACH endpoint study mapping is provided in Annex 1 of this document (see column “Specific rules for IUCLID-REACH relationships different to a one to one relationship”).

In addition please note that in cases where more than one study is provided for one endpoint then an endpoint summary can be created to summarise and highlight the main points of your endpoint study records. These endpoint summaries can be created by making a right click on the specific IUCLID 5 endpoint (creation of a blue ball sigma sign summary). However please note that these endpoint summaries will not be checked for completeness except the general one for section 6 “Ecotoxicological information” and the general one for section 7 “Toxicological information” (i.e. where the PNEC and DNEL should be reported). Further information on how to complete these two endpoint summaries is provided in the “PNECs and DNELs” chapter 4.4.6 of this document.

⚠ Please note that the generation of a Chemical Safety Report (CSR) by means of the CSR plugin can only be accomplished if appropriate endpoint summaries are provided.

The approach described above results in the following practical scheme (see Figure 46).

Figure 46: General scheme to check the completeness of an endpoint study record



4.4.3 Adaptation of the standard testing regime

This chapter discusses adaptations from the standard testing regime for information requirements under Annexes VII to X.

In case there is a deviation from the standard testing regime, the fields indicated below are the minimum to be filled-in in order to pass the Technical Completeness Check. However, in addition to these, all the other fields under “Data sources”, “Materials and methods” and “Results and discussion” can be used to provide any other relevant information about the study.

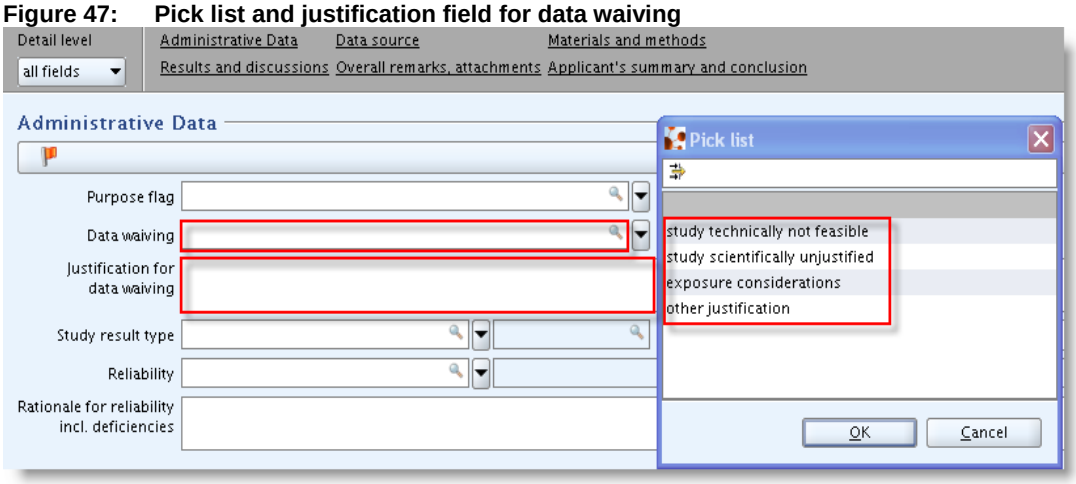
When the information provided in an endpoint study record comes from a study sufficiently adequate and reliable to fulfil information requirements on its own, this should be flagged as key study. If the information comes from a source of information less reliable or adequate (e.g. an experimental study with deviations from the guidelines) it should normally be flagged as “weight of evidence” and be used in combination with other sources of information (that should be included in other endpoint study records). For more information on the concepts of “key study” and “weight of evidence”, check section 8.2.2.6 “Information requirements on inherent properties” found in “Guidance on registration” available at:

http://guidance.echa.europa.eu/docs/guidance_document/registration_en.pdf

If handbook data are used in an endpoint study record and that there is no information about the study result type then the flag “study result type” should not be set to “experimental study” but instead to “no data” or “other:”.

In general, when a record contains data waiving information (i.e. a selection in the “Data waiving” pick list and a justification written in the “Justification for data waiving” free text field), it is recommended to sort it in such a way that it appears as the first record of the respective section. It should also be noted that an individual data waiving record should stand alone and not be mixed with other data such as existing study summaries. These should be summarised in separate Endpoint Study Records. A check will be carried out to ascertain whether a data waiving has been submitted instead of data as this means that no further checking is then required for the endpoint study record. In cases where a reason for data waiving has been selected in the pick list “Data waiving” then the only further field that will need to be filled-in in the endpoint study record is the field “Justification for data waiving” (Figure 47).

Figure 47: Pick list and justification field for data waiving



A) Specific adaptation from column 2 of REACH Annexes VII to X:

- Purpose flag: empty
- Data waiving: a selection must be done in the pick list (Note: "other justification" can be selected if none of the other options are adequate)
- Justification for data waiving: reference to the appropriate REACH Annex (e.g. in accordance with column 2 of REACH Annex VIII, the in-vivo skin irritation study (required in section 8.1.1) does not need to be conducted as the substance is a strong acid (pH<2))
- Study result type: empty
- Reliability score: empty

B) Last introductory paragraph of the REACH Annexes VII to X:

This paragraph states that "When, for certain endpoints, information is not provided for other reasons than those mentioned in column 2 of this Annex or in Annex XI, this fact and the reasons shall also be clearly stated." The approach to be followed in this case is:

- Purpose flag: empty
- Data waiving: "other justification"
- Justification for data waiving: appropriate justification
- Reliability score: empty
- Study result type: empty

C) General adaptation from section 1, REACH Annex XI: Testing does not appear scientifically necessary

1. Use of existing data

Existing data can be used on its own, in case they are sufficiently adequate and reliable to fulfil the information requirements for a given endpoint (key study) or as part of a weight of evidence approach.

Option 1:

- Purpose flag: key study

- Data waiving: empty
- Justification for data waiving: empty
- Other fields in the blocks “administrative data” (such as “study result type” and “reliability”), “data source”, “materials and methods” and “results and discussion” must be filled in as described for study results (see chapter 4.4.5 of this manual)

Option 2:

- Purpose flag: weight of evidence
- Data waiving: empty (although if a selection is done in this field this will not result in a Technical Completeness Check failure)
- Justification for data waiving: empty
- Other fields in the blocks “administrative data” (such as “study result type” and “reliability”), “data source”, “materials and methods” and “results and discussion” must be filled in as described for study results (see chapter 4.4.5 of this manual)

Option 3:

This option should be considered only if existing data are used to fulfil the information requirements and for which even the minimum fields required for a standard study summary could not be filled in:

- Purpose flag: empty
- Data waiving: study scientifically not justified
- Justification for data waiving: provide explanation as to why the existing data make unnecessary from the scientific point of view to perform the test
- Other fields in the blocks “administrative data” (such as “study result type” and “reliability”), “data source”, “materials and methods” and “results and discussion” should be filled in as much as possible as described for study results (see chapter 4.4.5 of this manual)

2. Weight of evidence

In general for a weight of evidence approach you should provide:

- Several endpoint study records with the purpose flag “weight of evidence”
- An endpoint summary to give an appraisal of all the information provided in the different endpoint study record flagged as “weight of evidence” and a rationale for using this evidence instead of standard testing

Option 1

(Standard option for studies considered as less adequate/reliable or for studies based on newly developed test methods):

- Purpose flag: weight of evidence
- Data waiving: empty (although if “study scientifically not justified” is indicated, it will not be considered a Technical Completeness Check failure)
- Justification for data waiving: empty (since it is already indicated in the purpose flag that the endpoint study records is part of a weight of evidence approach)

- Other fields in the blocks “administrative data” (such as “study result type” and “reliability”), “data source”, “materials and methods” and “results and discussion” must be filled in as described for study results (see chapter 4.4.5 of this manual)

Option 2

(This option should be considered only in the rare cases of information used for a weight of evidence approach for which even the minimum fields required for a standard study summary could not be filled in):

- Purpose flag: weight of evidence
- Data waiving: study scientifically not justified
- Justification for data waiving: when the information does not come from a test report, and the minimum fields required cannot be filled in then it must be indicated in this free text field
- Other fields in the blocks “administrative data” (such as “study result type” and “reliability”), “data source”, “materials and methods” and “results and discussion” should be filled in as much as possible as described for study results (see chapter 4.4.5 of this manual)

3. QSAR

A QSAR can be used on its own in case it is sufficiently adequate and reliable or as part of a weight of evidence approach.

Option 1:

- Purpose flag: Key study
- Data waiving: empty
- Justification for data waiving: empty
- Study result type: (Q)SAR
- Reliability score must be provided
- Other fields in the blocks “data source”, “materials and methods” and “results and discussion” must be filled in as described for study results (see chapter 4.4.5 of this manual)
- Other information: the (Q)SAR model reporting format (QMRF) and the (Q)SAR prediction reporting format (QPRF) should be attached to this endpoint study record (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r6_en.pdf?vers=20_08_08)

Option 2

- Purpose flag: weight of evidence
- Data waiving: empty ((although if “study scientifically not justified” is indicated, it will not be considered a Technical Completeness Check failure)
- Justification for data waiving: empty, since it is already indicated in the purpose flag that the ESR is part of a weight of evidence approach
- Study result type: (Q)SAR
- Reliability score must be provided

- Other fields in the blocks “data source”, “materials and methods” and “results and discussion” must be filled in as described for study results (see chapter 4.4.5 of this manual)
- Other information: the (Q)SAR model reporting format (QMRF) and the (Q)SAR prediction reporting format (QPRF) should be attached to this endpoint study record (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r6_en.pdf?vers=20_08_08). An endpoint study summary could be created for the concerned endpoint (see point 2. ’Weight of evidence’)

4. In vitro

An in-vitro study can be used on its own in case it is sufficiently adequate and reliable (key study) or as part of a Weight of evidence approach.

Option 1:

- Purpose flag: key study
- Data waiving: empty
- Justification for data waiving: empty
- Study result type: experimental study
- Reliability score must be provided
- Other fields in the blocks “data source”, “materials and methods” and “results and discussion” must be filled in as described for study results (see chapter 4.4.5 of this manual)

Option 2:

- Purpose flag: weight of evidence
- Data waiving: empty (although if “study scientifically not justified” is indicated, it will not be considered a Technical Completeness Check failure)
- Justification for data waiving: empty, since it is already indicated in the purpose flag that this record is part of a weight of evidence approach
- Study result type: experimental study
- Reliability score must be provided
- Other fields in the blocks “data source”, “materials and methods” and “results and discussion” must be filled in as described for study results (see chapter 4.4.5 of this manual)
- Other information: an endpoint study summary could be created for the concerned endpoint (see point 2. ‘Weight of evidence’).

5. Grouping and read-across

If a substance is part of a category then a IUCLID category should be created and added to the dossier. Inherited templates could be used.

Endpoint study records in an inherit template which link to a category will be checked for completeness.

Endpoint study records in category members will not be checked for completeness.

Endpoint study records provided in the substance dataset of the registered substance must follow the approach mentioned below.

Option 1:

- Purpose flag: key study
- Data waiving: empty
- Justification for data waiving: empty
- Study result type: read-across based on grouping of substances (category approach) or read-across from supporting substance (structural analogue or surrogate).
- Reliability score must be provided
- Other fields in the blocks “data source”, “materials and methods” and “results and discussion” must be filled in as described for study results (see chapter 4.4.5 of this manual)
- Other information: category reporting format should be attached (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r6_en.pdf?vers=20_08_08)

Option 2:

- Purpose flag: weight of evidence
- Data waiving: empty (study scientifically not justified can be indicated)
- Justification for data waiving: empty, since it is already indicated in the purpose flag that the endpoint study record is part of a weight of evidence approach
- Study result type: read-across based on grouping of substances (category approach) or read-across from supporting substance (structural analogue or surrogate)
- Reliability score must be provided
- Other fields in the blocks “data source”, “materials and methods” and “results and discussion” must be filled in as described for study results (see chapter 4.4.5 of this manual)
- Other information: category reporting format should be attached (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r6_en.pdf?vers=20_08_08). An endpoint study summary could be created for the concerned endpoint (see point 2. ‘Weight of evidence’)

D) General adaptation from section 2, REACH Annex XI: Testing is technically not possible

- Purpose flag: empty
- Data waiving: study technically not possible
- Justification for data waiving: explanation as to why it is not possible to perform the test
- Study result type: empty
- Reliability score: empty

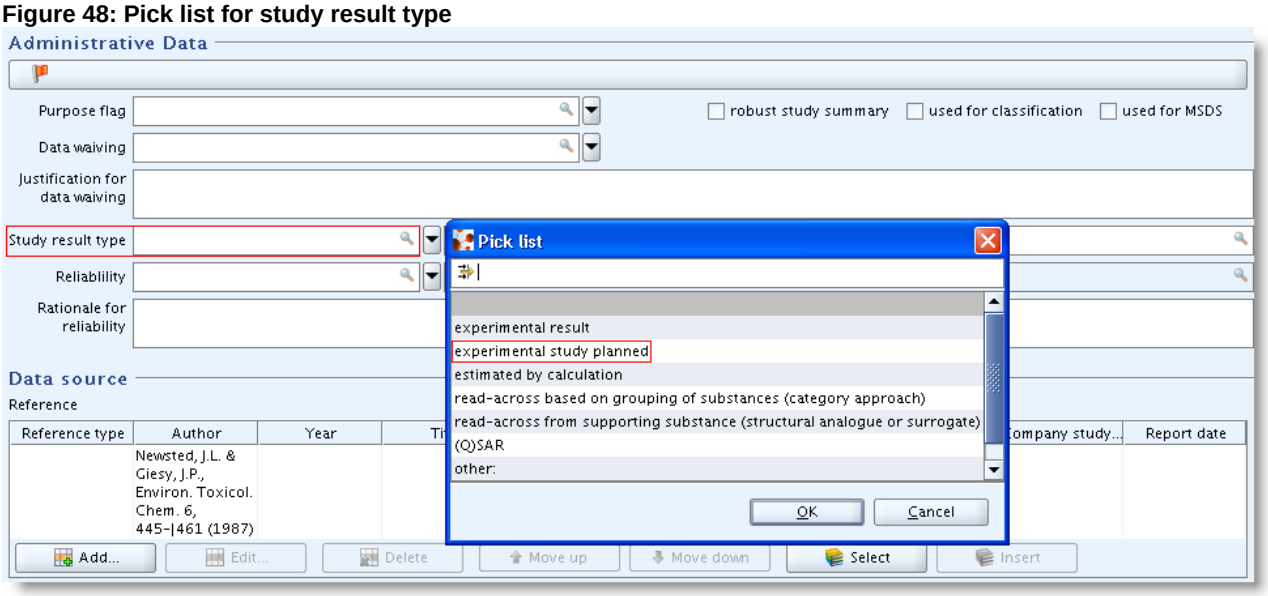
E) General adaptation from section 3, REACH Annex XI: Substance-tailored exposure-driven testing

- Purpose flag: empty
- Data waiving: exposure considerations
- Justification for data waiving: explanation as to why this is applicable and reference to the relevant section of the CSR
- Study result type: empty
- Reliability score: empty
- Other information: not strictly necessary in the endpoint study record, but this type of adaptation should be properly documented in the CSR

4.4.4 Testing proposals

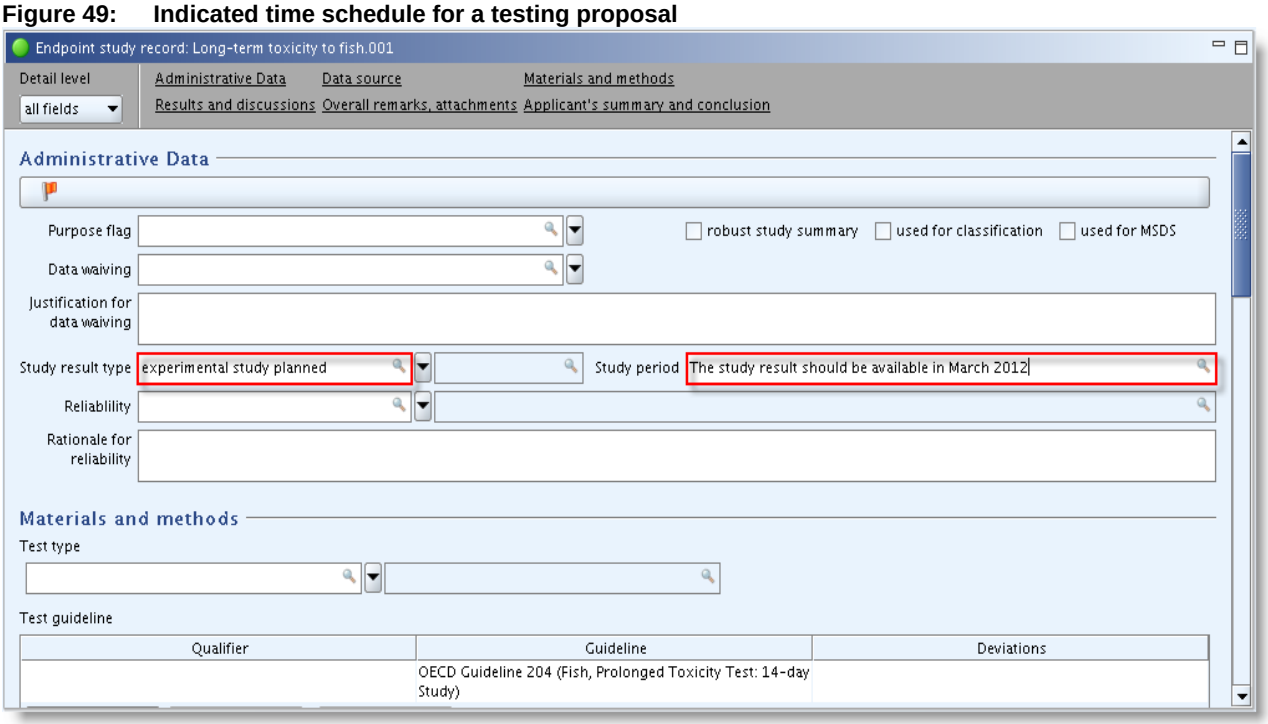
For studies requested under REACH Annexes IX and X (see Annex 1 of the present document, third column), a testing proposal has to be submitted if a valid test result is not available. This testing proposal must be identified in the endpoint study record by selecting "experimental study planned" in the field "study result type" (Figure 48).

Figure 48: Pick list for study result type



In this case, information must be provided about the time schedule in the field "Study period" (Figure 49).

Figure 49: Indicated time schedule for a testing proposal



Moreover, information about the guideline/method must be provided either in the field “Guideline” or in the field “Principles of method if other than guideline” (Figure 50) or an attachment must be present in the field “Attached background material” (Figure 51).

Figure 50: Guideline and method used

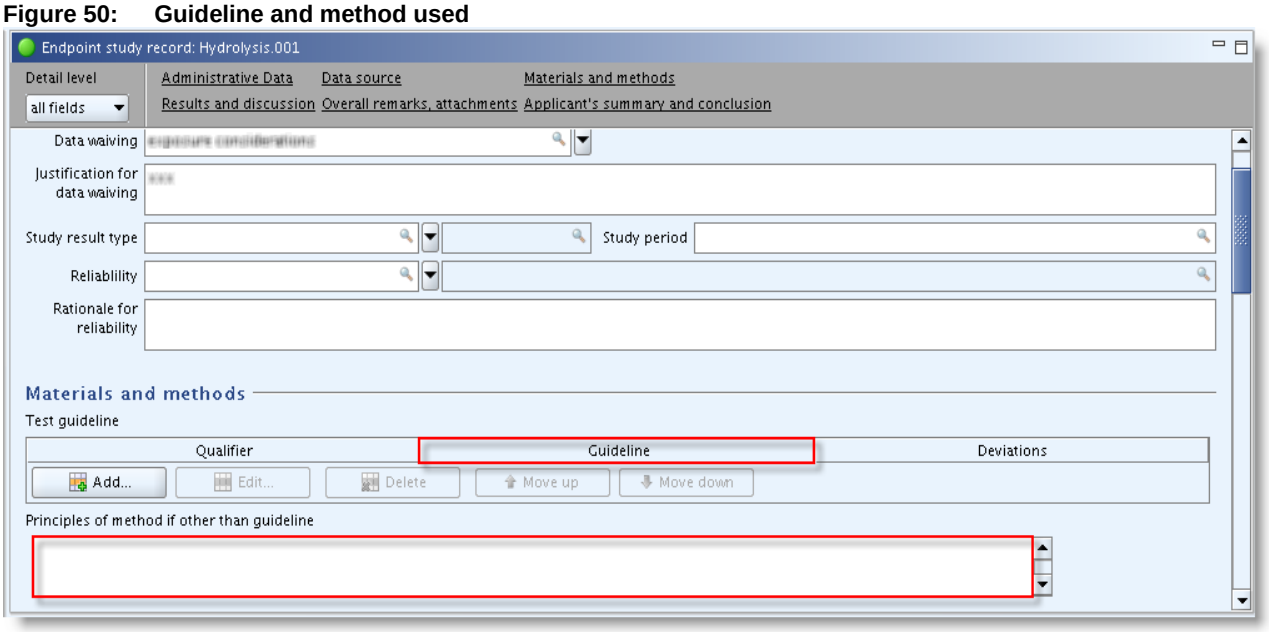
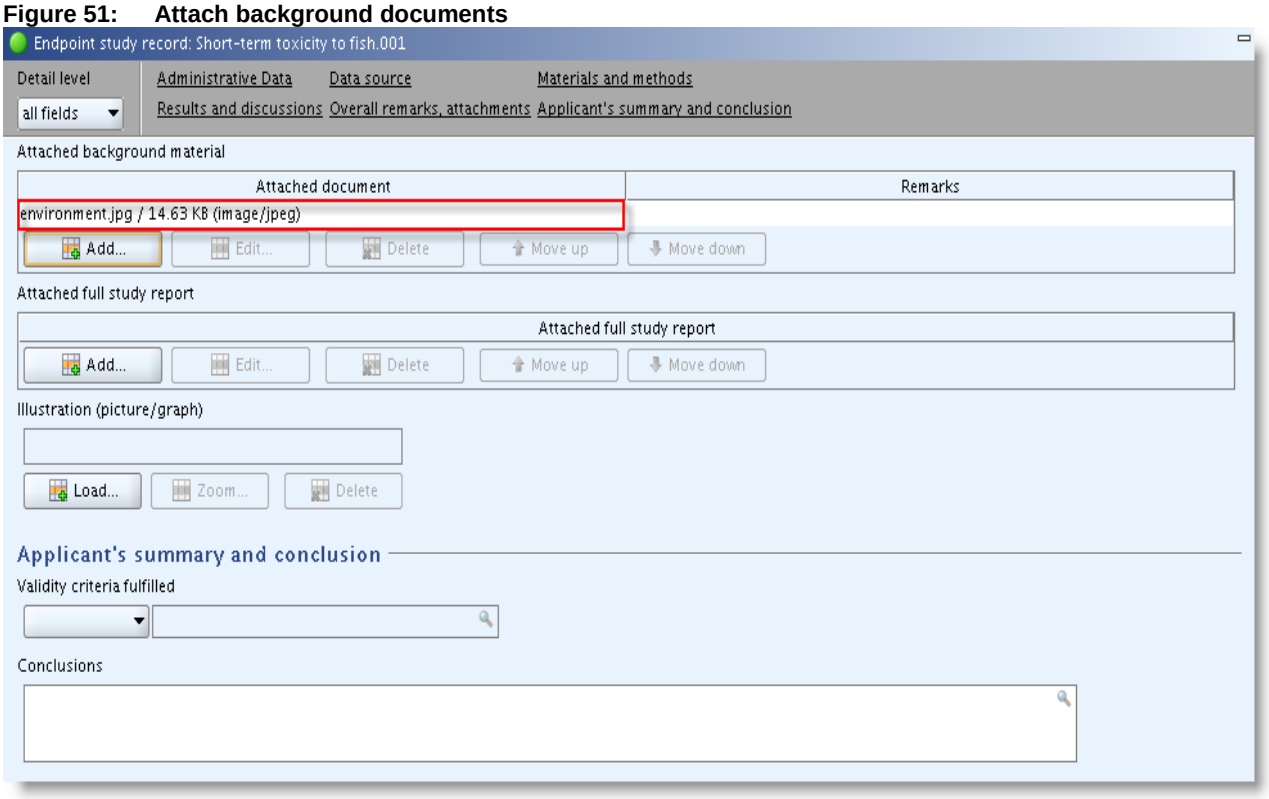


Figure 51: Attach background documents



4.4.5 Study results

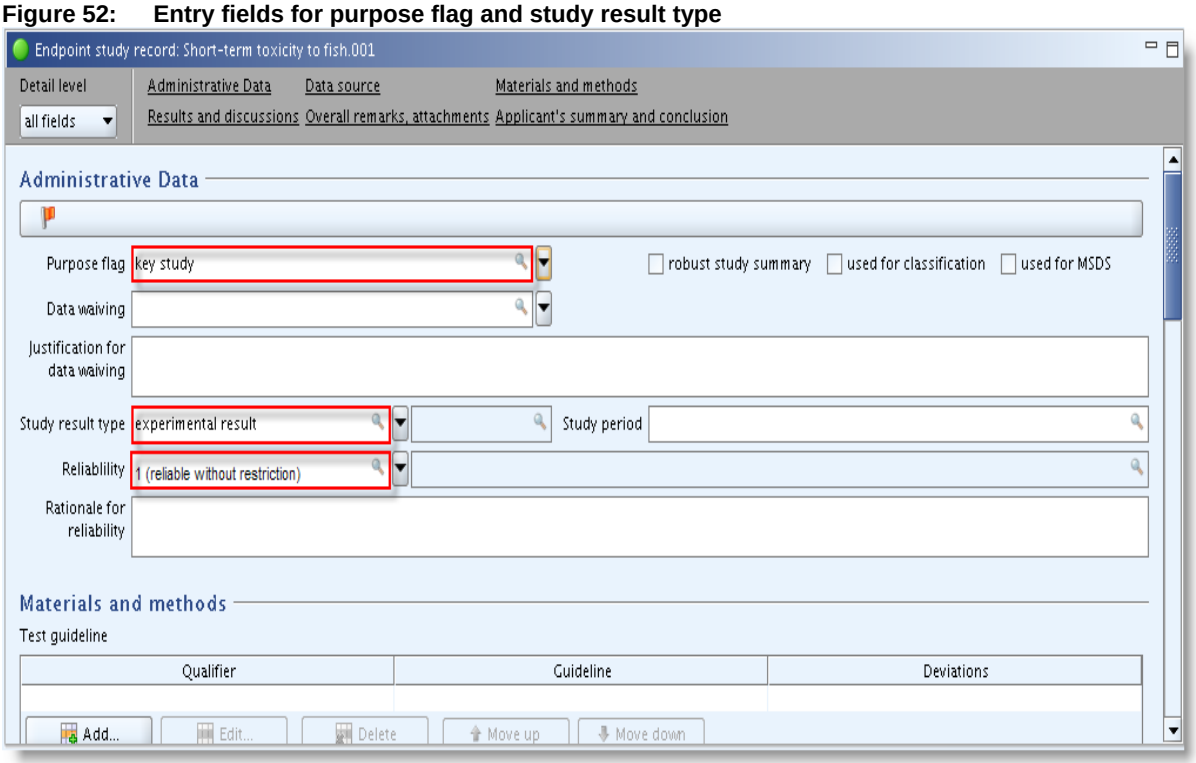
This chapter provides information on how to enter administrative data, the data sources, material and methods used and how to enter results and discussions.

4.4.5.1 Block Administrative data

A selection must be done in the pick list “Purpose flag” (“key study”, “weight of evidence”, “supporting study” or “disregarded study”) (Figure 52).

- A key study is the study that has been identified as most suitable to describe an endpoint from the perspective of quality, completeness and representativity of data. As indicated in REACH, robust summaries will be required of all key data (key studies) used in the hazard assessment.
- A weight of evidence is a record that contributes to a weight of evidence justification for the non-submission of a particular (adequate) study. The weight of evidence justification is normally endpoint-related, i.e. is based on all records flagged that way.
- A supporting study provides some additional information to support the conclusions from the key study(ies) or the weight of evidence approach.
- A disregarded study is a study which was available to the registrant, but was not taken into account in the risk assessment of the substance because of lack of quality or reliability.

Figure 52: Entry fields for purpose flag and study result type



It should be kept in mind that all studies flagged as “key study” or as “weight of evidence” will be checked for completeness. Studies flagged as “supporting study”, “disregarded study” or for which no selection is done in the pick list “Purpose flag” will not be checked for completeness.

For instance if you submit twenty endpoint study records for an endpoint, two of them are flagged as key study and all others are flagged as “supporting study” then only the two key studies will be checked for completeness. Therefore this rule does not prevent the registrants from providing all available studies. However it should be kept in mind that all the endpoint

study records provided should be filled in as much as possible for the purpose of the following processes: fee calculation, dissemination, priority setting, dossier evaluation.

It also means that if, for instance, a 1-10 tonnes registration dossier contains a key study (or a weight of evidence) in IUCLID section 6.1.4 “long-term toxicity to aquatic invertebrates”, this key study (or weight of evidence) should be complete even if this requirement is “only” listed in REACH Annex IX. It should be noted that if this 1-10 tonnes registration dossier would not contain any endpoint study record at all in section 6.1.4 or only a study summary with a empty “Purpose flag” field in this section 6.1.4 then this section would not fail the completeness check.

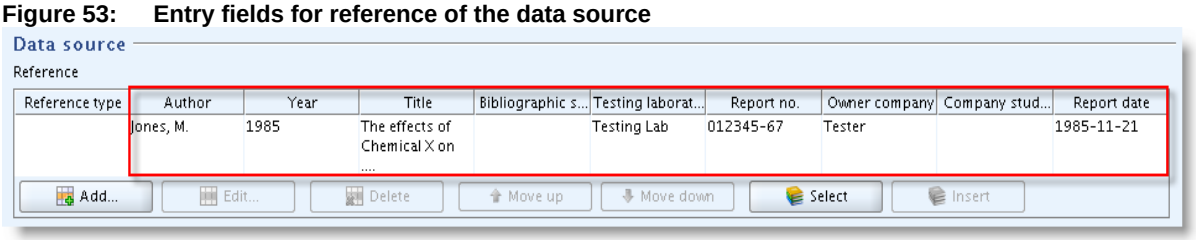
In addition, a selection must be made from the pick list “Study result type” (experimental result, estimated by calculation, read across, QSAR) and from the pick list “Reliability” (1, 2, 3, 4 or other). Afterwards further information must be provided in the blocks “Source data”, “Materials and methods” and “Results and discussion”.

4.4.5.2 Block Data source

The full reference has to be provided under the heading reference. Therefore you are advised to complete as much as possible this reference table. Many combinations are considered as a complete reference. As a minimum, the field “Year” or the field “Report date” must be completed. In addition other fields must be completed depending on the data source. For instance, if the data is:

- From a literature source, the field “Bibliographic source” should be provided.
- From a testing laboratory, the field “Testing laboratory” should be completed. Full address of the testing laboratory (including city and country) should be provided. In addition either “Report no.”, “Company study no” or “Title” should be provided.
- From a company, either the field “Report no.” should be provided (with also information in “Author”, “Owner company” or “Title”) or the field “Company study no.” should be provided (with also information in “Author”, “Owner company” or “Title”) (Figure 53).

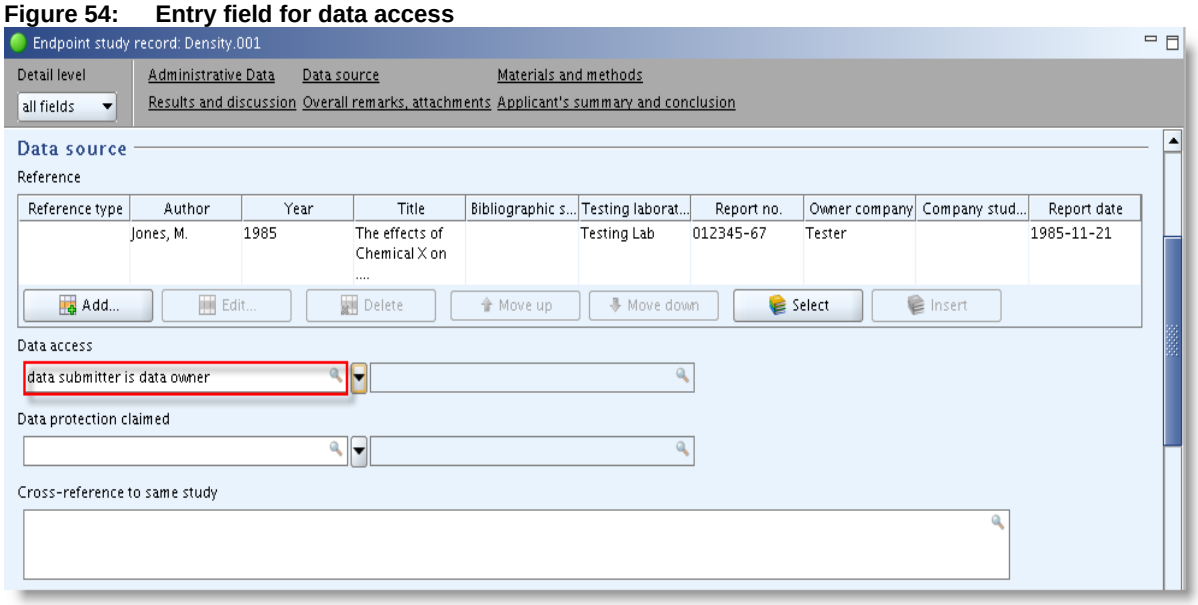
Figure 53: Entry fields for reference of the data source



Note that the CSR plugin captures the fields "Author" and "Year" for specifying the bibliographic citations in the overview tables. To avoid any manual intervention, it is recommended to complete these fields in relevant records. If no individuals are cited as authors, enter name of company or organisation or 'Anon.' as appropriate.

In addition, a value must be selected for the field “Data access” in this IUCLID block “Data source” (Figure 54).

Figure 54: Entry field for data access

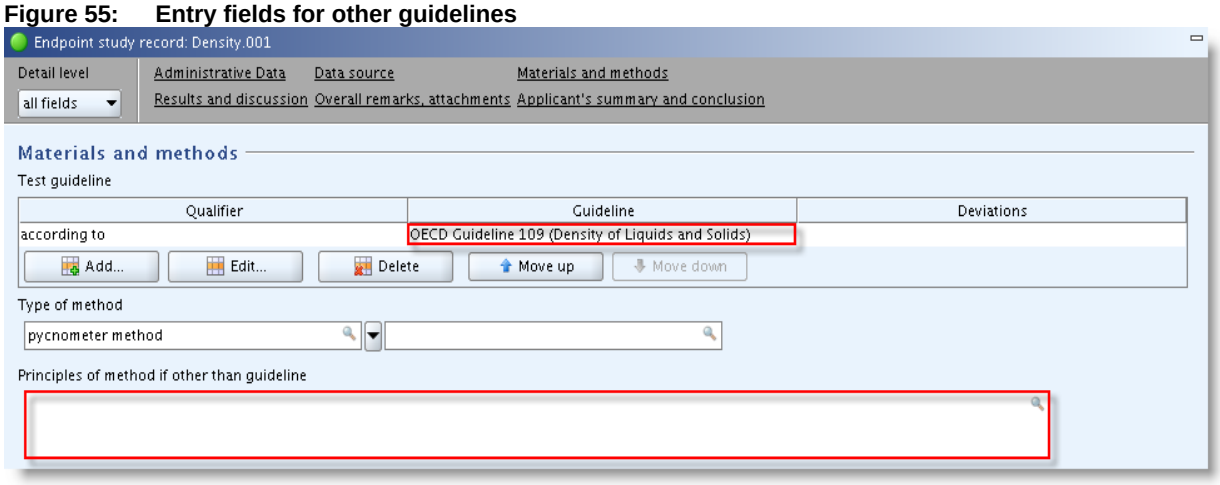


4.4.5.3 Block Materials and methods

Guideline

The endpoint study record is considered complete if sufficient information as to the method used (e.g. OECD guideline) is provided. Therefore a check will be carried out as to whether information on the method is provided in the field “Guideline” of the table “Test guideline” or in the field “Principles of method other than guideline” as there might be cases where a specific method will have to be developed for a substance (Figure 55).

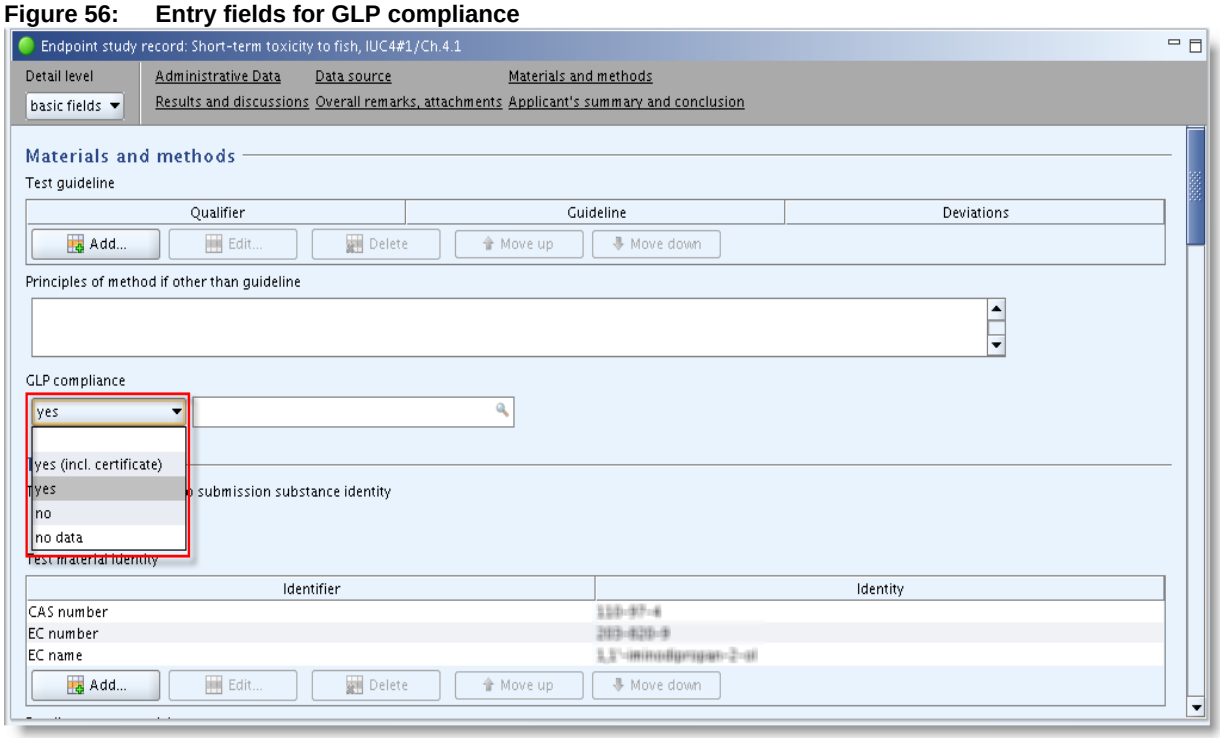
Figure 55: Entry fields for other guidelines



GLP

For the endpoint study records that are indicated as an “experimental result”, “read-across based on grouping of substances (category approach)” or “read-across from supporting substance (structural analogue or surrogate)” in IUCLID 5 sections “5 Environmental fate and pathways”, “6 Ecotoxicological information” and “7 Toxicological information”, it must be indicated whether the study is GLP compliant or not by selecting one of the following options: “yes (incl. certificate)”, “yes”, “no” or “no data” from the Pick-list “GLP compliance” (Figure 56).

Figure 56: Entry fields for GLP compliance



It should be noted that if “yes (incl. certificate)” or “yes” is selected then the field “Testing laboratory” in the table “Reference” of the IUCLID block “Data source” must be filled in.

Note that the full contact details of the laboratory (name, address, country) should be indicated in this “Testing laboratory” field. In addition it should also be noted that, pursuant to REACH Article 13(4), (eco)toxicological tests shall be carried out according to GLP, therefore tests carried out after 1 June 2008 should be GLP compliant.

Test material

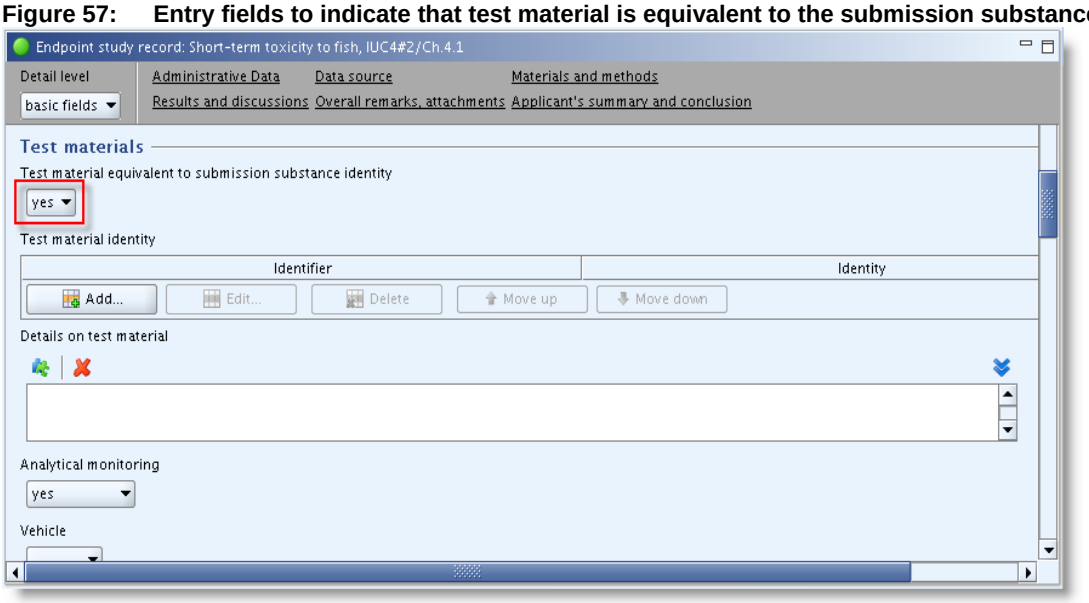
A check will be carried out to ascertain whether there is sufficient information provided about the test material.

There are three options for completing this section. These three alternatives are described below:

- To select “Yes” in the field “Test material equivalent to submission substance identity”. In this case it is only optional to provide further information in the table “Test material identity” and in the field “Details on test material” (Figure 57).

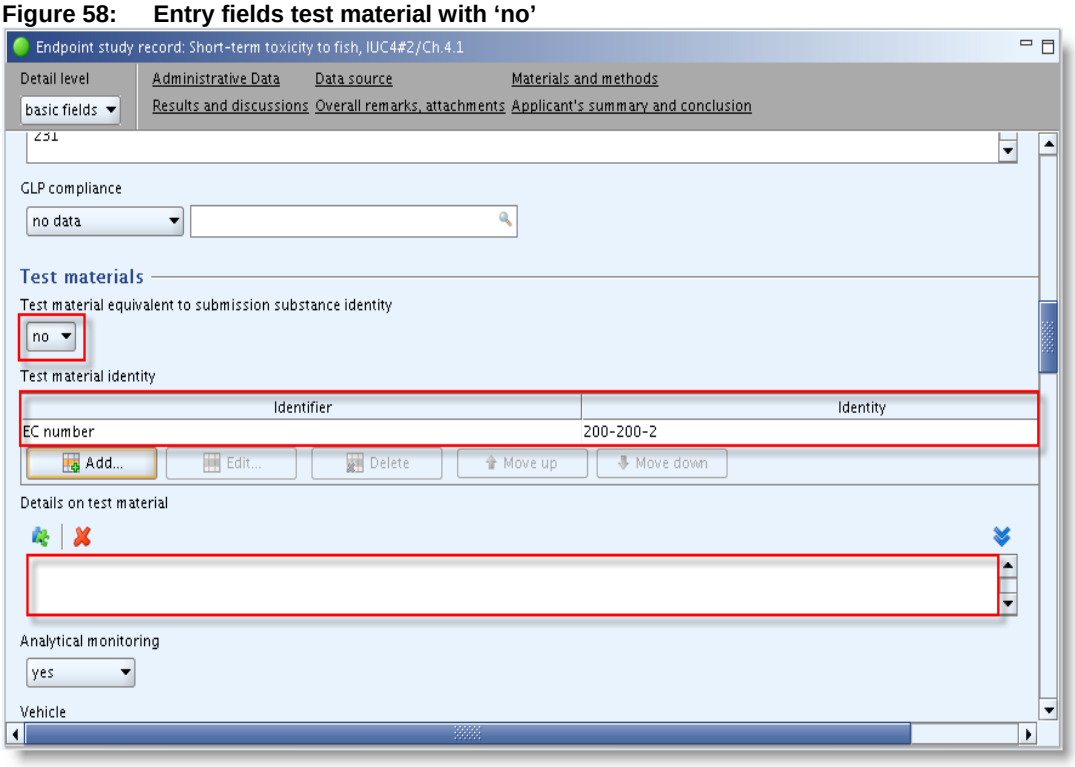
Note that this option is not valid for referenced records and for endpoint study records included in an inherit template. For these types of records information should compulsorily be given either in the table “Test material identity” or in the field “Details on test material”.

Figure 57: Entry fields to indicate that test material is equivalent to the submission substance identity



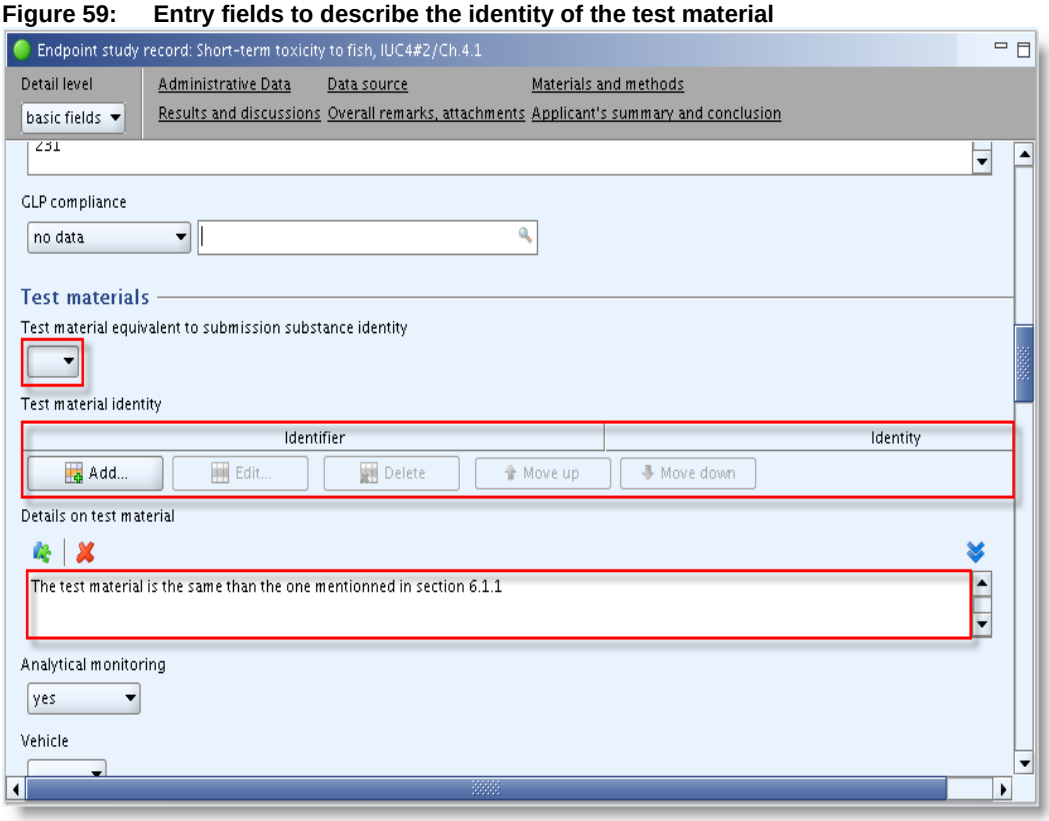
- To select “No” in the field “Test material equivalent to submission substance identity”. In this case either the table “test material identity” (“identifier” and “identity”) or the field “Details on test material” must be filled in (Figure 58).

Figure 58: Entry fields test material with ‘no’



- In rare cases where a selection in the field “Test material equivalent to submission substance identity” would not be relevant then this field should be let blank. In this case either the table “test material identity” (“identifier” and “identity”) or the field “Details on test material” must be filled in (Figure 59).

Figure 59: Entry fields to describe the identity of the test material



In addition to these general rules for this block “materials and methods”, some additional fields must be filled in for some specific endpoints. The fields to be filled in are the following:

- The field “test type” must be filled in for studies provided under sections 5.2.1, 6.3.5, 7.5.1, 7.5.2, 7.5.3 and 7.8.1.
- The field “test duration type” must be filled in for studies provided under sections 6.2, 6.3.1, 6.3.2 and 6.3.3.
- The field “type of method” must be filled in for studies provided under sections 7.3.1, 7.3.2 and 7.4.1.
- The field “type of study” must be filled in for studies provided under sections 7.4.1 and 7.6.1.

It has to be noted that if “other:” is selected then information must be provided in the adjacent free text field.

4.4.5.4 Block Results and discussion

For this block, the fields to be filled in vary from one endpoint to the other. In order to summarise the general rules applied to this block for all physico-chemical, fate and behaviour, ecotoxicological and toxicological endpoints, the main points are listed below. As a general rule, all information considered to form part of the result is checked. Therefore, depending on the endpoint section, the following information will have to be provided:

- The specific endpoint, effect type/level, the value as well as the unit (e.g. EC50 (48h) = 0.20 mg/L)

- The parameter measured (e.g. CO2, DOC in the case of a screening biodegradability test) or the sex of the animals tested if relevant (e.g. toxicity to reproduction)
- Relevant information on parameters applied during the testing phase (e.g. temperature, pH, concentration)
- The duration of testing if relevant
- Etc.

Consequently the fields that must be filled in are specific for each endpoint. Annex 2 of this manual indicates the minimum fields to be filled in. In rare cases where these basic fields can not be completed, explanatory text must be provided under the field “Any other information on results incl. tables” (NB: take care not to confuse this free text field with the field named “Overall remarks”). Alternatively, for the cases in which there is a “Remarks” field at the end of the table for reporting the results, it is possible to provide the text in this field.

However it should be kept in mind that as much as possible information must be put under the specific fields of IUCLID 5 for reporting a result and that this field “Any other information on results incl. tables” should be used only in exceptional cases when for example it is not possible to report a numerical value in the field due to difficulties during the testing.

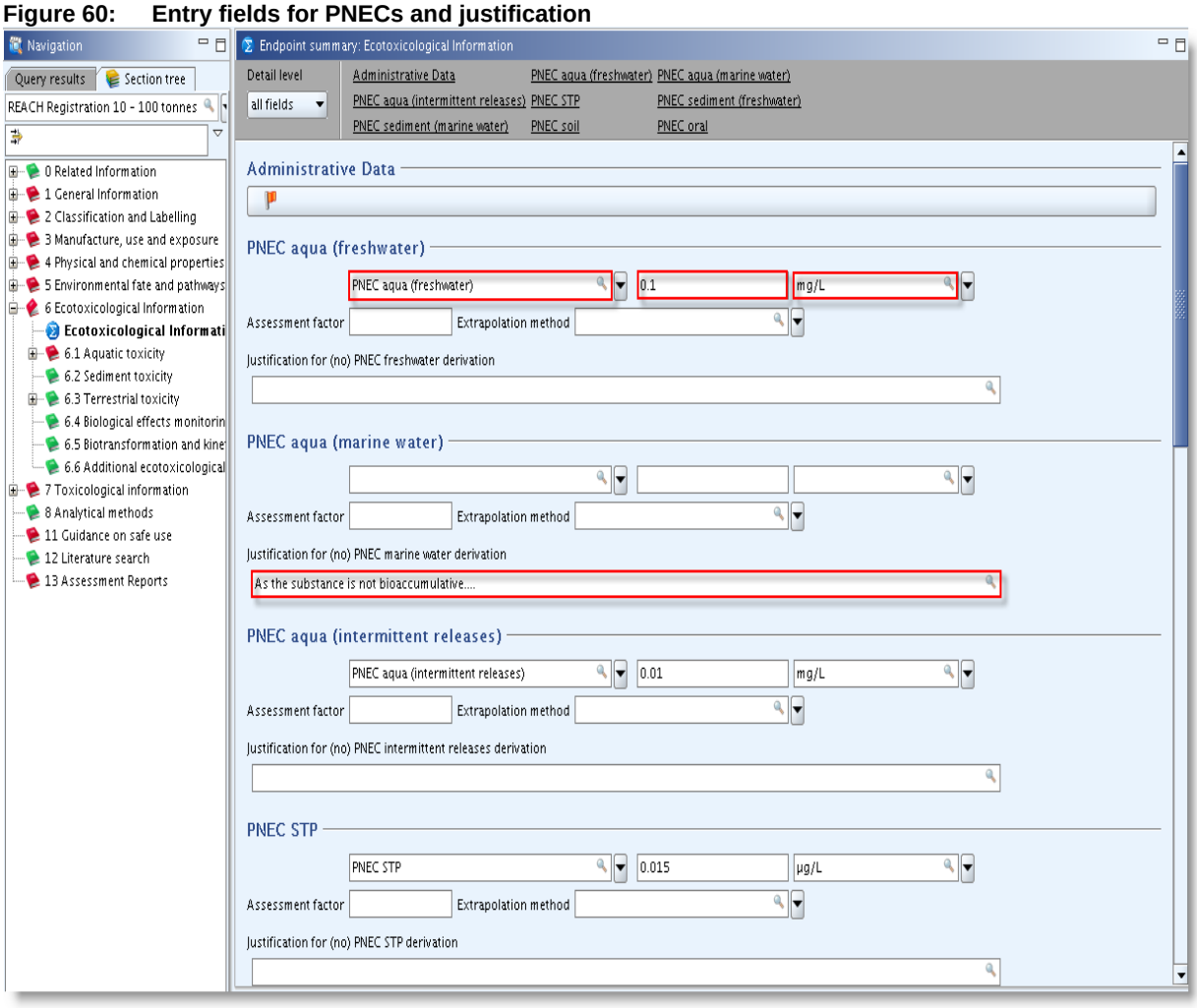
4.4.6 PNECs and DNELs

For dossiers with a tonnage above 10 tonnes, a CSR must be provided. This CSR should contain relevant PNECs and DNELs (as mentioned in REACH Annex II, 8.1). These PNECs and DNELs must be included in IUCLID 5 by creating an endpoint summary in section “6 Ecotoxicological information” and another one in section “7 Toxicological information” (by making a right click on IUCLID 5 sections 6 and 7). The information provided in these two endpoint summaries will be checked for completeness for all dossiers above 10 tonnes (except for intermediates and PPORD).

4.4.6.1 PNECs

In the endpoint summary of section “6 Ecotoxicological information”, for each of the eight PNECs, a selection has to be made in the PNEC field, a numerical value has to be given and a unit has to be selected. In case a PNEC is not available then a justification for not deriving a PNEC must be provided in the related field “Justification for no PNEC derivation”. Therefore all the PNECs (PNEC aqua (freshwater), PNEC aqua (marine water) … PNEC oral) must be provided. If one or more PNECs could not be derived then a justification for not providing these PNECs must be written in the related free text field “Justification of PNEC …” below the PNEC field (Figure 60).

Figure 60: Entry fields for PNECs and justification

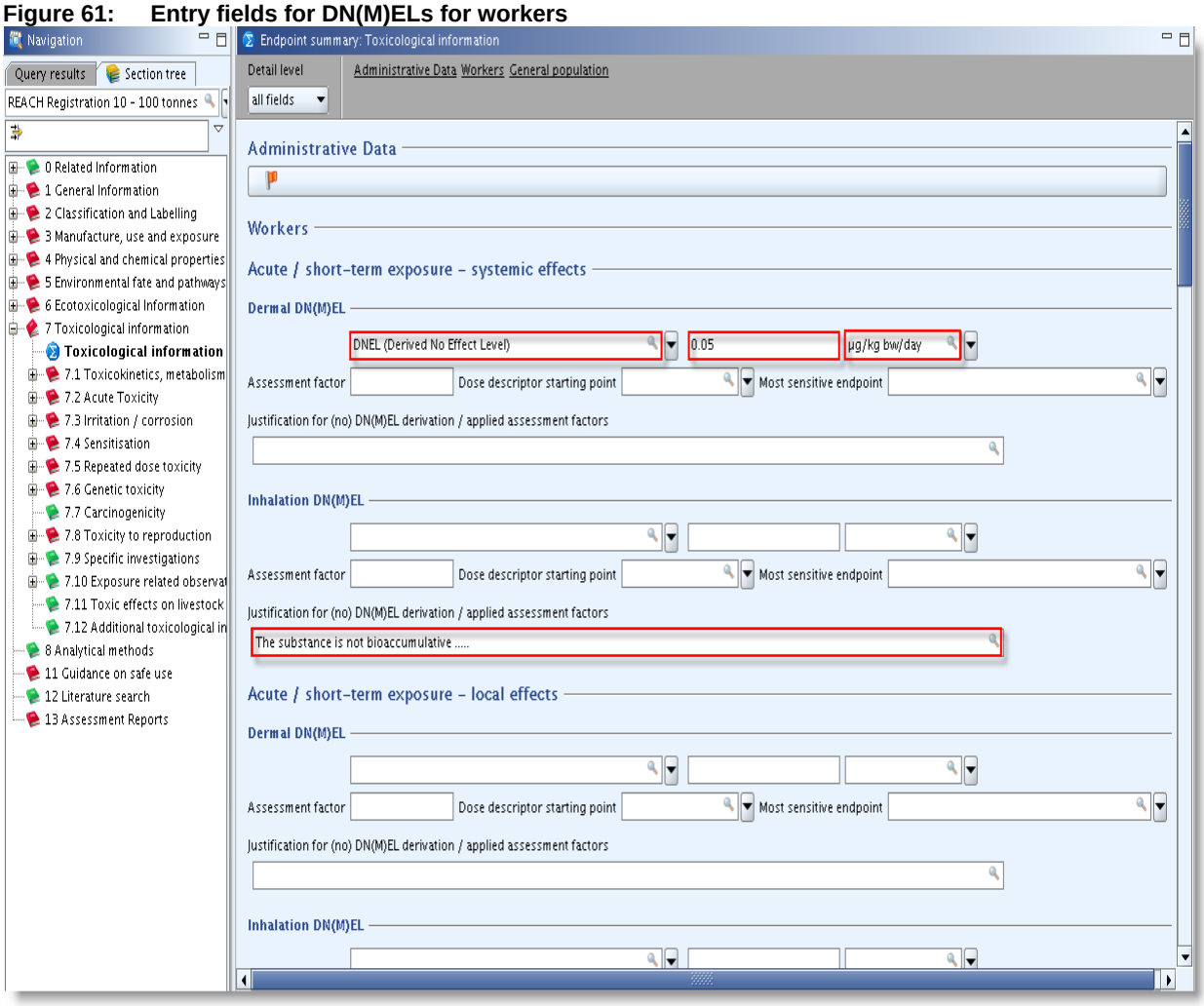


4.4.6.2 DN(M)ELs

In the endpoint summary of section “7 Toxicological information”, information in the blocks “Workers” and “General population” must be provided.

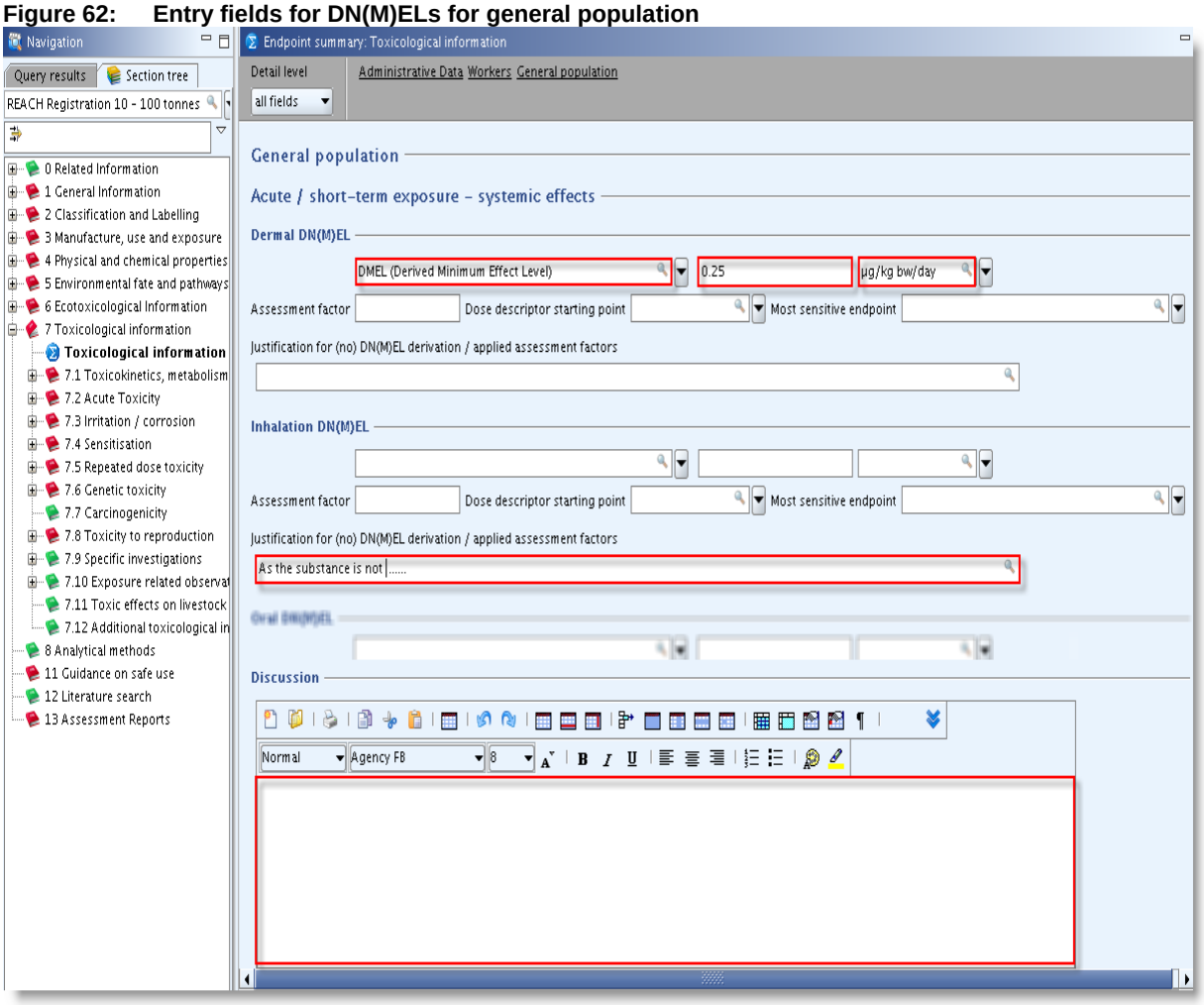
In the block “Workers”, for each one of the eight DN(M)ELs, either the value “DNEL" or “DMEL” must be selected from the Pick-list, a numerical value must be given, and a selection must be done in the adjacent unit field. Alternatively, in case a DN(M)EL is not available then a justification must be provided in the field “Justification for no DN(M)EL derivation” (Figure 61) or in the field “Discussion”.

Figure 61: Entry fields for DN(M)ELs for workers



In the block “General population”, for each one of the ten DN(M)EL either the value “DNEL" or “DMEL” must be selected in the Pick-list, a numerical value must be given, and a selection must be done in the adjacent unit field. Alternatively, in case a DN(M)EL is not available then a justification must be provided in the field “Justification for no DN(M)EL derivation” or in the field “Discussion” (Figure 62).

Figure 62: Entry fields for DN(M)ELs for general population



4.5 Section 11 - Guidance on safe use

Under Section 5 of Annex VI it is necessary to provide guidance on safe use. Therefore, for all dossiers, information will have to be provided as a minimum in all of the following fields:

- “First aid measures”
- “Fire-fighting measures”
- “Accidental release measures”
- “Handling and storage”

In addition, where a CSR is not required (REACH registration 1-10 tonnes dossiers: REACH Registration 1 – 10 tonnes, physicochemical requirements; REACH Registration 1 – 10 tonnes, standard requirements), information will also have to be provided in the following fields:

- “Exposure controls / personal protection”
- “Stability and reactivity”
- “Disposals considerations” (as IUCLID 5 has no fields related to information on recycling and methods of disposal for industry and for the public (Annex VI, 5.8.2 and

5.8.3) then this information should also be provided in this “Disposals considerations” field).

However there are some specific rules for some types of dossiers:

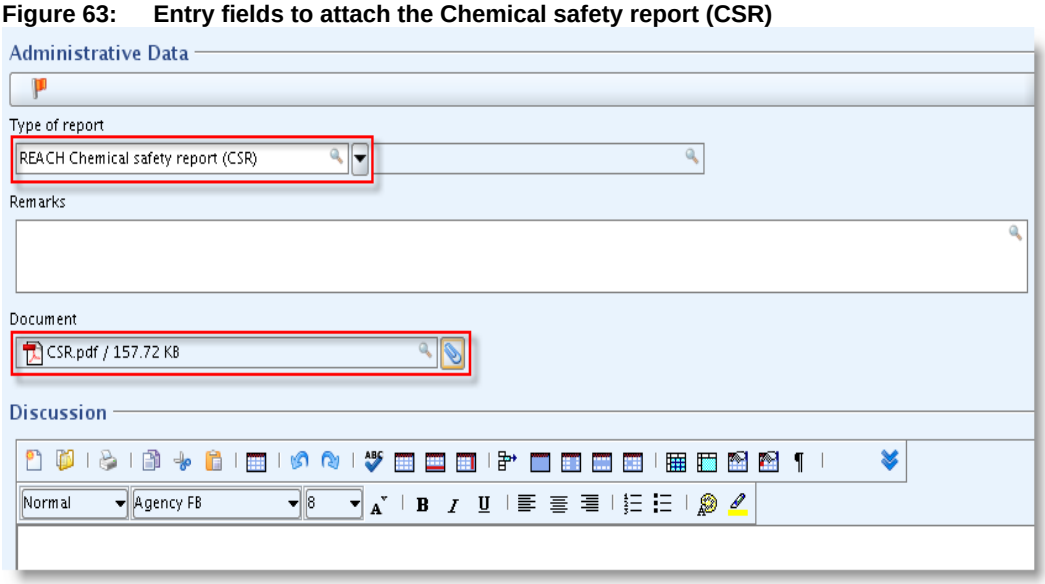
- For joint submissions, the guidance on safe use can be provided jointly or separately (Article 11(1) (paragraph 4)). Therefore if the lead of the joint submission indicated that the guidance on safe use is provided separately then the member dossiers must contain this guidance on safe use.
- For intermediates dossiers, the rules mentioned above for this section “11 Guidance on safe use” do not apply. However for intermediates the registrants have to provide information on risk management measures and their efficiency (Articles 17 and 18). Therefore this information must be provided in this section 11, preferably in the fields “Handling and storage” or “Exposure controls/personal protection”
- Note that in case of intermediate dossiers belonging to a joint submission the information on risk management measures applied (i.e. Section 11 of the IUCLID dossier) cannot be provided by lead. Therefore this information needs to be submitted always separately in each intermediate dossier participating as a member of the joint submission

4.6 Section 13 - Assessment report

For substances manufactured or imported at more than 10 tonnes per year Article 14 requires a chemical safety assessment to be carried out. Therefore for dossiers above 10 tonnes, it will be checked that (for at least one of the assessment reports provided):

- In field “Type of report”, “REACH Chemical safety report (CSR)” is selected
- AND that the CSR is attached in the field “Document” or that information is provided in the field “Remarks” or in the field “Discussion” (e.g. justification for not submitting a CSR based on Article 14(2)) (Figure 63).

Figure 63: Entry fields to attach the Chemical safety report (CSR)



However it has to be noted that there is a specific rule for the member dossiers. Indeed for joint submissions the CSR can be provided jointly or separately (Article 11(1) (paragraph 4)).

Therefore if the lead of the joint submission indicated that the CSR is provided separately then the member dossiers must contain this CSR. Detailed information on how to submit a CSR as part of a joint submission is available in the Data Submission Manual 19 available at http://echa.europa.eu/doc/reachit/dsm_19_how_joint_csr_en.pdf

4.7 Dossier Header

During the IUCLID 5 dossier creation procedure, the dossier creation wizard requests the user to "Enter additional administrative information concerning your dossier" in step 6. This information will then be contained in what is called the "IUCLID 5 dossier header" (Figure 64).

To create a dossier in IUCLID 5, you should start from the IUCLID 5 substance dataset, select the template corresponding to your submission (for ex. REACH Registration 10 - 100 tonnes, REACH PPORD, …), follow the dossier creation wizard guide, export the dossier and save it in on your PC (from where you can submit it to ECHA via REACH-IT).

For dossier creation containing a category, the wizard step related to the dossier header is step 7.

The dossier header is a crucial part of the registration dossier because it contains information which allows ECHA to determine the type of dossier (e.g. new registration or update), and is used to ensure that the dossier can be accepted for further processing. Many of the fields also impact on the registration fee.

Full information on how to complete the IUCLID 5 dossier header depending on your submission type is available in the Data Submission Manual 4: "How to pass business rules verification" (http://echa.europa.eu/doc/reachit/how_pass_business_verification.pdf)

The checkbox "**Joint submission**" has to be ticked only if your dossier will be submitted as the lead dossier of a joint submission. In that case you will also have to indicate which information you are providing on behalf of the members (Chemical safety report, Guidance on safe use, Review by an assessor).

In the field "**Tonnage band(s)**" you then have to select your own tonnage band (the tonnage band of the joint submission is established by the type of dossier template that you have selected in step 1 of the wizard). In case that you are creating a dossier as a member of a joint submission you have to select one of the two member templates at step 1 ("member of a joint submission – general case"; or "member of a joint submission – intermediates" as appropriate). In this case you have to indicate at step 6 which information the lead is providing on your behalf. In the field "Tonnage band" you have to indicate your own tonnage band.

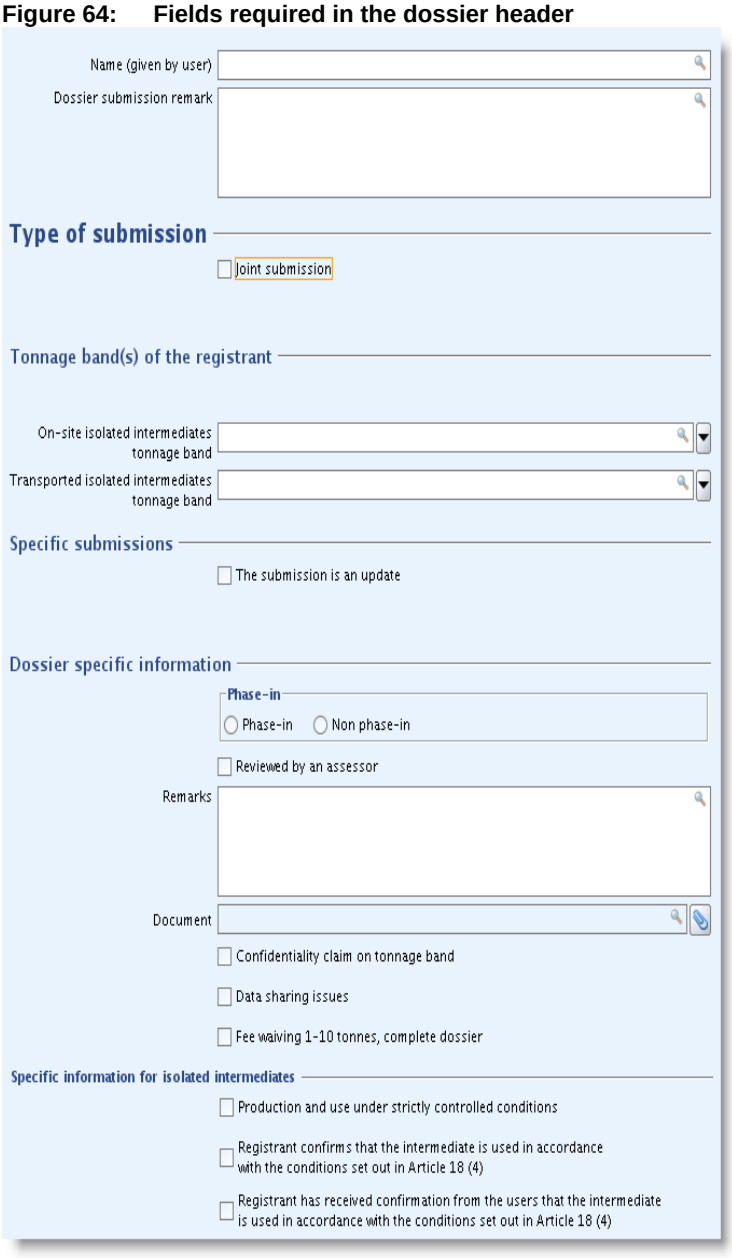
In case your submission is an **update**, then the "**Specific submissions**" part of the dossier header should be completed.

As a general rule for the dossier header, when one of the checkboxes under "**Dossier specific information**" (reviewed by an assessor, confidentiality claim on tonnage band, data sharing issues…) is selected, then the associated free text fields below the checkbox must be filled in. If one checkbox is ticked, and its associated free text field is empty, this is considered a TCC failure. In the same manner, if free text is written in any of these fields but the associated checkbox is not ticked, this is considered a TCC failure.

Indicate the **phase-in status** of your substance by selecting the radio button "Phase-in" or "Non phase-in".

The checkbox "**Reviewed by an assessor**" is not compulsory, but if the dossier, or parts of it, have been reviewed by an assessor (in accordance to Art. 10 (a) (viii)), it must be indicated here. If your dossier has not been reviewed by an assessor you can leave empty the checkbox "Reviewed by an assessor" and this will not be considered a TCC failure. If the box "Reviewed by an assessor" is ticked then the field "Remarks" should be filled in or a document should be attached. Vice-versa, if the field "Remarks" is filled in or a document is attached then the box "Review by an assessor" should be ticked.

Figure 64: Fields required in the dossier header



The checkbox "**Confidentiality claim on tonnage band**" and its "Justification" field only need to be filled in case you want to claim the relevant tonnage band confidential (see Annex 3 of this document as well as the Data Submission Manual 4: "How to Pass Business Rules Verification" (http://echa.europa.eu/doc/reachit/how_pass_business_verification.pdf). Leaving the two checkboxes un-ticked and the free text empty does not lead to a TCC failure.

The checkbox "**Data sharing issues**" and its "Justification" field only need to be filled-in in case there is some problem that has risen during the data sharing process for the dossier. Leaving both the checkbox and the field empty does not lead to a TCC failure.

The checkbox "**Fee waiving 1-10 tonnes, complete dossier**" only need to be filled-in in case you can request a fee waiver for a dossier in the tonnage band 1-10 tonnes for which all the information listed in REACH Annex VII has been submitted. If you tick this specific checkbox it is not compulsory to fill in its "Justification" field below. Leaving the checkbox un-ticked does not lead to a TCC failure.

The checkboxes under "**Specific information for isolated intermediates**" only need to be ticked as appropriate, when your dossier covers a registration for intermediates. In that case, the box "Production and use under strictly controlled conditions" must be ticked. If your dossier covers a registration for transported isolated intermediates then one or both of the boxes referring to the conditions of use in accordance with article 18(4) have to be ticked.

5 Technical Completeness Check (TCC)

5.1 The TCC plugin

As mentioned in chapter 1 of this manual, IT software has been developed in order to offer you the possibility to check the completeness of your registration/notification before you submit it to ECHA via REACH-IT. This IT software is available as a IUCLID plugin and can be downloaded via your IUCLID 5 website account (http://iuclid.echa.europa.eu/). You can use the plugin to check both your substance dataset before you create the dossier (Figure 64) in addition to checking the final dossier (complete with dossier header) (Figure 64). To run the tool on the substance dataset ( ) and the final dossier ( ), see the screenshots below.

Note that it is important for you to run on both the substance dataset and the final dossier before you submit to avoid any unnecessary failures and potential rejection if the submission is for a requested update.

If you are in any doubt about how to present the information in your dossier or how to run the tool, please contact the ECHA Helpdesk. ECHA will then provide you with more specific advice on how to proceed.

Figure 65: Running the TCC plugin on the substance dataset

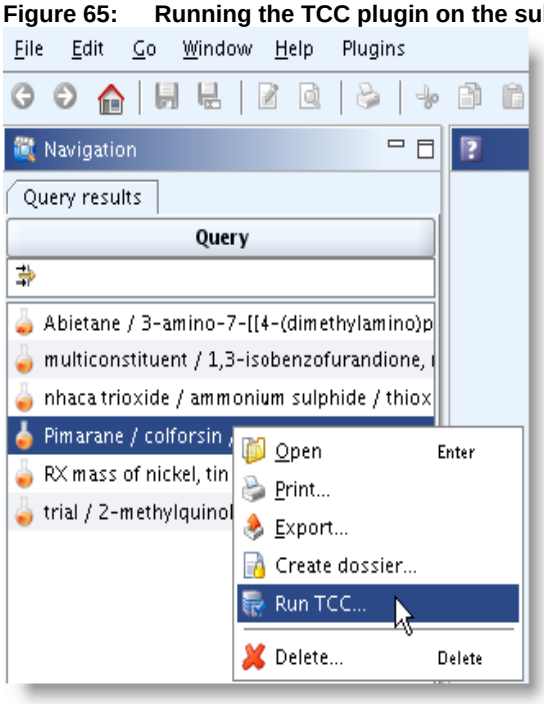
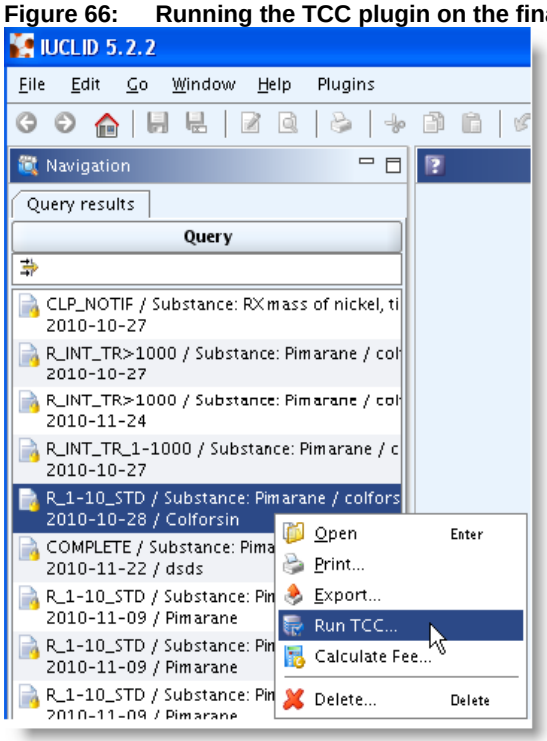


Figure 66: Running the TCC plugin on the final dossier



Annex 1 – Dossier endpoint matrix

NB: **r** means that an endpoint study record is required for this endpoint. **o** means that endpoint study records are optional for this endpoint.

IUCLID 5 tree view	Section Name	REACH Annex	REACH Number	Specific rules for IUCLID-REACH relationships different to a 1 to 1 relationship	1 – 10T, physicochemical requirements, Annex 7	1 – 10T, standard requirements, Annex 7	10 – 100T, Annex 8	100 – 1000T, Annex 9	above 1000T, Annex 10	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex 7	PPORD
4	**Physical and chemical properties**												
4.1	Appearance / physical state / colour	7	7.1		r	r	r	r	r	o	o	r	o
4.2	Melting point / freezing point	7	7.2		r	r	r	r	r	o	o	r	o
4.3	Boiling point	7	7.3		r	r	r	r	r	o	o	r	o
4.4	Density	7	7.4		r	r	r	r	r	o	o	r	o
4.5	Particle size distribution (Granulometry)	7	7.14		r	r	r	r	r	o	o	r	o
4.6	Vapour pressure	7	7.5		r	r	r	r	r	o	o	r	o
4.7	Partition coefficient	7	7.8		r	r	r	r	r	o	o	r	o
4.8	Water solubility	7	7.7		r	r	r	r	r	o	o	r	o
4.10	Surface tension	7	7.6		r	r	r	r	r	o	o	r	o
4.11	Flash point	7	7.9		r	r	r	r	r	o	o	r	o
4.12	Auto flammability	7	7.12		r	r	r	r	r	o	o	r	o
4.13	Flammability	7	7.10		r	r	r	r	r	o	o	r	o
4.14	Explosiveness	7	7.11		r	r	r	r	r	o	o	r	o
4.15	Oxidising properties	7	7.13		r	r	r	r	r	o	o	r	o

IUCLID 5 tree view	Section Name	REACH Annex	REACH Number	Specific rules for IUCLID-REACH relationships different to a 1 to 1 relationship	1 – 10T, physicochemical requirements, Annex 7	1 – 10T, standard requirements, Annex 7	10 – 100T, Annex 8	100 – 1000T, Annex 9	above 1000T, Annex 10	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex 7	PPORD
4.17	Stability in organic solvents and identity of relevant degradation products	9	7.15		o	o	o	r	r	o	o	o	o
4.21	Dissociation constant	9	7.16		o	o	o	r	r	o	o	o	o
4.22	Viscosity	9	7.17		o	o	o	r	r	o	o	o	o
5	**Environmental fate and pathways**												
5.1.2	Hydrolysis	8	9.2.2.1		o	o	r	r	r	o	o	o	o
5.2.1	Biodegradation in water: screening tests	7	9.2.1.1		o	r	r	r	r	o	o	r	o
5.2.2	Biodegradation in water and sediment: simulation tests	9	9.2.1.2 (water) 9.2.3	For 100-1000T and >1000T, REACH requires 2 data (a test for REACH 9.2.1.2 and a test for 9.2.1.4). However, a single study (a water/sediment test) could cover both requirements. Therefore to be complete this IUCLID section 5.2.2 needs only to contain 1 complete endpoint study record.	O	o	o	r	r	o	o	o	o
		9	9.2.1.4 (sediment) 9.2.3		o	o	o	r	r	o	o	o	o
5.2.3	Biodegradation in soil	9	9.2.1.3 9.2.3		o	o	o	r	r	o	o	o	o

IUCLID 5 tree view	Section Name	REACH Annex	REACH Number	Specific rules for IUCLID-REACH relationships different to a 1 to 1 relationship	1 – 10T, physicochemical requirements, Annex 7	1 – 10T, standard requirements, Annex 7	10 – 100T, Annex 8	100 – 1000T, Annex 9	above 1000T, Annex 10	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex 7	PPORD
5.3.1	Bioaccumulation: aquatic / sediment	9	9.3.2		o	o	o	r	r	o	o	o	o
5.4.1	Adsorption / desorption	8	9.3.1		o	o	r	r	r	o	o	o	o
6	**Ecotoxicological Information**												
6.1.1	Short-term toxicity to fish	8	9.1.3		o	o	r	r	r	o	o	o	o
6.1.2	Long-term toxicity to fish	9	9.1.6		o	o	o	r	r	o	o	o	o
6.1.3	Short-term toxicity to aquatic invertebrates	7	9.1.1		o	r	r	r	r	o	o	r	o
6.1.4	Long-term toxicity to aquatic invertebrates	9	9.1.5		o	o	o	r	r	o	o	o	o
6.1.5	Toxicity to aquatic algae and cyano-bacteria	7	9.1.2	A complete endpoint study record must be provided either in 6.1.5 or in 6.1.6	o	r	r	r	r	o	o	r	o
6.1.6	Toxicity to aquatic plants other than algae	na	not req.		o	o	o	o	o	o	o	o	o
6.1.7	Toxicity to micro-organisms	8	9.1.4		o	o	r	r	r	o	o	o	o
6.2	Sediment toxicity	10	9.5.1		o	o	o	o	r	o	o	o	o

IUCLID 5 tree view	Section Name	REACH Annex	REACH Number	Specific rules for IUCLID-REACH relationships different to a 1 to 1 relationship	1 – 10T, physicochemical requirements, Annex 7	1 – 10T, standard requirements, Annex 7	10 – 100T, Annex 8	100 – 1000T, Annex 9	above 1000T, Annex 10	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex 7	PPORD
6.3.1	Toxicity to soil macro-organisms except arthropods	9	9.4.1 (short-term)	For 100-1000T, 1 short-term or long-term test must be provided either in 6.3.1 or in 6.3.2 For >1000T, 1 long-term test must be provided either in 6.3.1 or 6.3.2	o	o	o	r	r	o	o	o	o
		10	9.4.4 (long-term)		o	o	o	o	r	o	o	o	o
6.3.2	Toxicity to terrestrial arthropods	9	9.4.1 (short-term)		o	o	o	r	r	o	o	o	o
		10	9.4.4 (long-term)		o	o	o	o	r	o	o	o	o
6.3.3	Toxicity to terrestrial plants	9	9.4.3 (short-term)	For 100-1000T, 1 short-term or long-term test must be provided. For >1000T, 1 long-term test must be provided.	o	o	o	r	r	o	o	o	o
		10	9.4.6 (long-term)		o	o	o	o	r	o	o	o	o
6.3.4	Toxicity to soil microorganisms	9	9.4.2		o	o	o	r	r	o	o	o	o
6.3.5	Toxicity to birds	10	9.6.1		o	o	o	o	r	o	o	o	o
7	**Toxicological information**												
7.2.1	Acute toxicity: oral	7	8.5.1		o	r	r	r	r	o	o	r	o

IUCLID 5 tree view	Section Name	REACH Annex	REACH Number	Specific rules for IUCLID-REACH relationships different to a 1 to 1 relationship	1 – 10T, physicochemical requirements, Annex 7	1 – 10T, standard requirements, Annex 7	10 – 100T, Annex 8	100 – 1000T, Annex 9	above 1000T, Annex 10	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex 7	PPORD
7.2.2	Acute toxicity: inhalation	8	8.5.2		o	o	r	r	r	o	o	o	o
7.2.3	Acute toxicity: dermal	8	8.5.3		o	o	r	r	r	o	o	o	o
7.3.1	Skin irritation / corrosion	7	8.1 (in vitro skin corrosion)	For 1-10T standard requirements and transported isolated intermediates above 1000T, 1 endpoint study record must be provided (1 in-vivo or 1 in-vitro with a possible new guideline that covers corrosion and irritation) For >10T, 1 in-vivo endpoint study record must be provided.	o	r	r	r	r	o	o	r	o
		7	8.1 (in vitro skin irritation)		o	r	r	r	r	o	o	r	o
		8	8.1.1 (in vivo skin irritation)		o	o	r	r	r	o	o	o	o
7.3.2	Eye irritation	7	8.2 (in vitro)	For 1-10T standard requirements and transported isolated intermediates above 1000T, 1 in-	o	r	r	r	r	o	o	r	o

IUCLID 5 tree view	Section Name	REACH Annex	REACH Number	Specific rules for IUCLID-REACH relationships different to a 1 to 1 relationship	1 – 10T, physicochemical requirements, Annex 7	1 – 10T, standard requirements, Annex 7	10 – 100T, Annex 8	100 – 1000T, Annex 9	above 1000T, Annex 10	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex 7	PPORD
		8	8.2.1 (in vivo)	vitro or 1 in vivo endpoint study record must be provided. For >10T: 1 in-vivo endpoint study record must be provided.	o	o	r	r	r	o	o	o	o
7.4.1	Skin sensitisation	7	8.3 (in-vivo)		o	r	r	r	r	o	o	r	o
7.5.1	Repeated dose toxicity: oral	8	8.6.1 (short-term)	For 10-100T, 1 endpoint study record (short-term) must be provided either in 7.5.1 or 7.5.2 or 7.5.3 For >100T, 1 sub-chronic test must be provided either in 7.5.1 or 7.5.2 or 7.5.3	o	o	r	r	r	o	o	o	o
		9	8.6.2 (sub-chronic)		o	o	o	r	r	o	o	o	o
7.5.2	Repeated dose toxicity: inhalation	8	8.6.1 (short-term)		o	o	r	r	r	o	o	o	o
		9	8.6.2 (sub-chronic)		o	o	o	r	r	o	o	o	o
7.5.3	Repeated dose toxicity: dermal	8	8.6.1 (short-term)		o	o	r	r	r	o	o	o	o
		9	8.6.2 (sub-		o	o	o	r	r	o	o	o	o

IUCLID 5 tree view	Section Name	REACH Annex	REACH Number	Specific rules for IUCLID-REACH relationships different to a 1 to 1 relationship	1 – 10T, physicochemical requirements, Annex 7	1 – 10T, standard requirements, Annex 7	10 – 100T, Annex 8	100 – 1000T, Annex 9	above 1000T, Annex 10	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex 7	PPORD
			chronic)										
7.6.1	Genetic toxicity: in vitro	7	8.4.1 (in vitro gene mutation in bacteria)	For 1-10T standard requirements and transported isolated intermediates above 1000T, 1 study must be provided. For >10T: This IUCLID section corresponds to 3 REACH Annex numbers. However only 2 studies are sufficient for completeness (as a gene mutation mammalian cell overrides a gene mutation bacteria).	o	r	r	r	r	o	o	r	o
		8	8.4.2 (in vitro cytogenicity in mammalian cells or in vitro micronucleus)		o	o	r	r	r	o	o	o	o
		8	8.4.3 (in vitro gene mutation in mammalian cells)		o	o	r	r	r	o	o	o	o
7.8.1	Toxicity to reproduction	8	8.7.1 (screening)	For 10-100T, 1 screening study must be provided.	o	o	r	r	r	o	o	o	o

IUCLID 5 tree view	Section Name	REACH Annex	REACH Number	Specific rules for IUCLID-REACH relationships different to a 1 to 1 relationship	1 – 10T, physicochemical requirements, Annex 7	1 – 10T, standard requirements, Annex 7	10 – 100T, Annex 8	100 – 1000T, Annex 9	above 1000T, Annex 10	on-site isolated intermediates above 1T	transported isolated intermediates 1 – 1000T	transported isolated intermediates above 1000T, Annex 7	PPORD
		9	8.7.3 (two-generation)	For >100T, 1 two-generation study must be provided.	o	o	o	r	r	o	o	o	o
7.8.2	Developmental toxicity / teratogenicity	9	8.7.2		o	o	o	r	r	o	o	o	o

Annex 2 – Information to provide in the block “Results and discussions”

In order to complete the blocks “Results and discussion” of the study summaries it is important to keep in mind the following general principles:

- Any provided value must come with a unit.
- If you create several rows or blocks (because several results are derived from a study) then all of them must be completed as described in the table below.
- In rare cases where the field(s) indicated in the table below could not be completed then explanatory text must be provided in the field “Any other information on results incl. tables”.

IUCLID 5 tree view	Minimum fields to be filled in the block "Results and discussion"
4.1	The field "Physical state at 20ºC and 1013 hPa" must be filled in. In addition the field "Form" should be filled in if relevant.
4.2	The fields "Melt/Freez.pt." or "Decomposition temperature" or "Sublimation temperature" must be filled in.
4.3	The fields "Boiling.pt." and "Atm. Pressure" or "Decomposition" and "Decomposition temperature" must be filled in.
4.4	The fields "Type", "Density" and "Temperature" must be filled in.
4.5	All the fields under "Particle size" or under "Particle size distribution at different passages" must be filled in.
4.6	Both "Vapour pressure" and "Temperature" must be given.
4.7	All the fields under "Partition coefficient" must be filled in.
4.8	The fields "Solubility", "Temp" and "pH" must be filled in.
4.10	The fields "Surface tension", "Temp." and "Concentration" must be filled in.
4.11	Both the flash point and the pressure must be given.
4.12	The self-ignition or autoflammability temperature and pressure must be given.
4.13	Either the field "Solid/liquid: ignition on contact with air" or the field “Solid: Burning time (s)" or the fields “Gas” (“Gas: lower explosion limit (%)" and "Gas: Upper explosion limit (%)") must be filled in.
4.14	Either the fields "Explosive under influence of flame", "More sensitive to shock than m-dinitrobenzene" and "More sensitive to friction than m-dinitrobenzene" must be filled in or the field “Explosive (not specified)” must be filled in.
4.15	The measured parameter, its value and unit must be given.
4.17	The field "Test substance stable" must be filled in.
4.21	The field "Dissociating properties" must be filled in.
4.22	A viscosity value and the temperature must be given.

IUCLID 5 tree view	Minimum fields to be filled in the block "Results and discussion"
5.1.2	As a minimum either the field "Preliminary study" or "Hydrolysis rate constant" or "Half-life" must be filled in.
5.2.1	The fields "%Degr.", "Parameter" and "Sampling time" must be filled in.
5.2.2	The fields "%Degr.", "Parameter" and "Sampling time" must be filled in. Alternatively, the fields "Compartment" and "Half-life" can be provided. In addition the fields "Transformation products" and "Identity" of the degradation products must be indicated in any case.
5.2.3	The fields "%Degr.", "Parameter" and "Sampling time" must be filled in. Alternatively, the field "Half-life" can be provided. In addition the fields "Transformation products" and "Identity" of the degradation products must be indicated in any case.
5.3.1	The field "Type" and "Value" under bioaccumulation factor must be filled in.
5.4.1	The field "Adsorption coefficient Koc" or "log Koc" or "Details on results (HPLC method)" or "Adsorption and desorption constants" must be filled in.
6.1.1	At least the fields "Duration", "Endpoint" and "Effect concentrations" must be filled in.
6.1.2	At least the fields "Duration", "Endpoint" and "Effect concentrations" must be filled in.
6.1.3	At least the fields "Duration", "Endpoint" and "Effect concentrations" must be filled in.
6.1.4	At least the fields "Duration", "Endpoint" and "Effect concentrations" must be filled in.
6.1.5	At least the fields "Duration", "Endpoint" and "Effect concentrations" must be filled in.
6.1.6	At least the fields "Duration", "Endpoint" and "Effect concentrations" must be filled in.
6.1.7	At least the fields "Duration", "Endpoint" and "Effect concentrations" must be filled in.
6.2	At least the fields "Duration", "Endpoint" and "Effect concentrations" must be filled

IUCLID 5 tree view	Minimum fields to be filled in the block "Results and discussion"
	in.
6.3.1	At least the fields "Duration", "Endpoint" and "Effect concentrations" must be filled in.
6.3.2	At least the fields "Duration", "Endpoint" and "Effect concentrations" must be filled in.
6.3.3	At least the fields "Duration", "Endpoint" and "Effect concentrations" must be filled in.
6.3.4	At least the fields "Duration", "Endpoint" and "Effect concentrations" must be filled in.
6.3.5	At least the fields "Duration", "Endpoint" and "Effect concentrations" must be filled in.
7.2.1	At least the field "Endpoint" and "Effect level" must be filled in.
7.2.2	At least the field "Endpoint" and "Effect level" must be filled in.
7.2.3	At least the field "Endpoint" and "Effect level" must be filled in.
7.3.1	At least the fields "Irritation parameter", "Time point" and "Score" must be filled in. Reversibility must be provided if relevant.
7.3.2	At least the fields "Irritation parameter", "Time point" and "Score" ('empty' field in table "Overall irritation / corrosion results" of IUCLID 5.0 and IUCLID 5.1) must be filled in. Reversibility must be provided if relevant.
7.4.1	If you select "LLNA" in the field "Type of study" under "Materials and methods" then at least the field "Stimulation index" must be filled in. Otherwise, the fields "Reading", "Dose level", "No. with + reactions" (number of individuals with positive reactions) and "Total no. in group" (number of individuals within the group) must be filled in.
7.5.1	At least the field "Endpoint" and "Effect level" must be filled in.
7.5.2	At least the field "Endpoint" and "Effect level" must be filled in.
7.5.3	At least the field "Endpoint" and "Effect level" must be filled in.

IUCLID 5 tree view	Minimum fields to be filled in the block "Results and discussion"
7.6.1	At least the fields "Species/strain", "Metabolic activation", "Genotoxicity" and "Cytotoxicity" must be filled in.
7.8.1	At least the fields "Endpoint", "Generation", "Sex" and "Effect level" must be filled in.
7.8.2	At least the fields "Endpoint", "Effect type" and "Effect level" must be filled in.

Annex 3 - Confidentiality requests which are subject to a fee

A registrant can request that information that is submitted to ECHA according to Art. 10 of the REACH Regulation is not published on the internet because publication could be harmful to the registrant's or any other concerned party's commercial interests. Article 119 specifies which information requires publication by ECHA.

If the information falls under Article 119(2) of the REACH Regulation and Annex IV of the Fee Regulation, then ECHA will request a fee payment for these confidentiality requests.

Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

You are able to simulate the fee associated to your submission by using the "Fee Calculation Plugin". This IUCLID plugin gives advance information of the likely costs. However, registrants should wait for ECHA to issue an invoice before making their payment.
This software can be downloaded from the IUCLID website free of charge:
http://iuclid.echa.europa.eu/

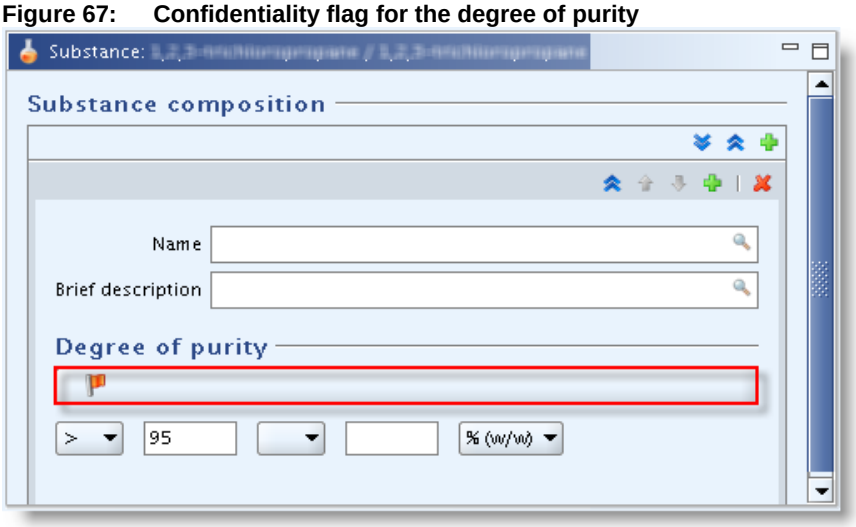
Note that the fee has to be paid for the request but it is up to ECHA to determine whether the reasons given for keeping this information confidential are adequate. If ECHA rejects the request for confidentiality the registrant will be given a future opportunity to justify its request before a final decision is taken as to whether or not the information should be published.

Detailed information on the content and the assessment of confidentiality claims is available in "Data Submission Manual 16: Confidentiality Claims" available at http://echa.europa.eu/doc/reachit/dsm_16_confidentiality_claims.pdf

In order to record your confidentiality requests in IUCLID 5, proceed in the following way:

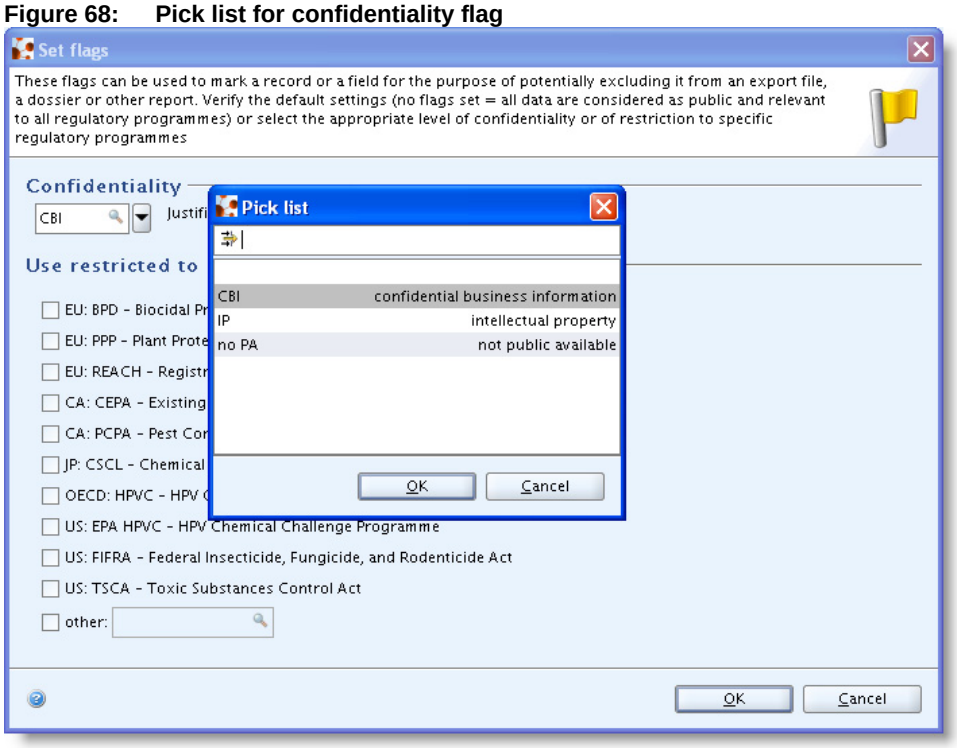
1. **Click on the flag** situated in the block/section you want to request confidential (Figure 67).

Figure 67: Confidentiality flag for the degree of purity



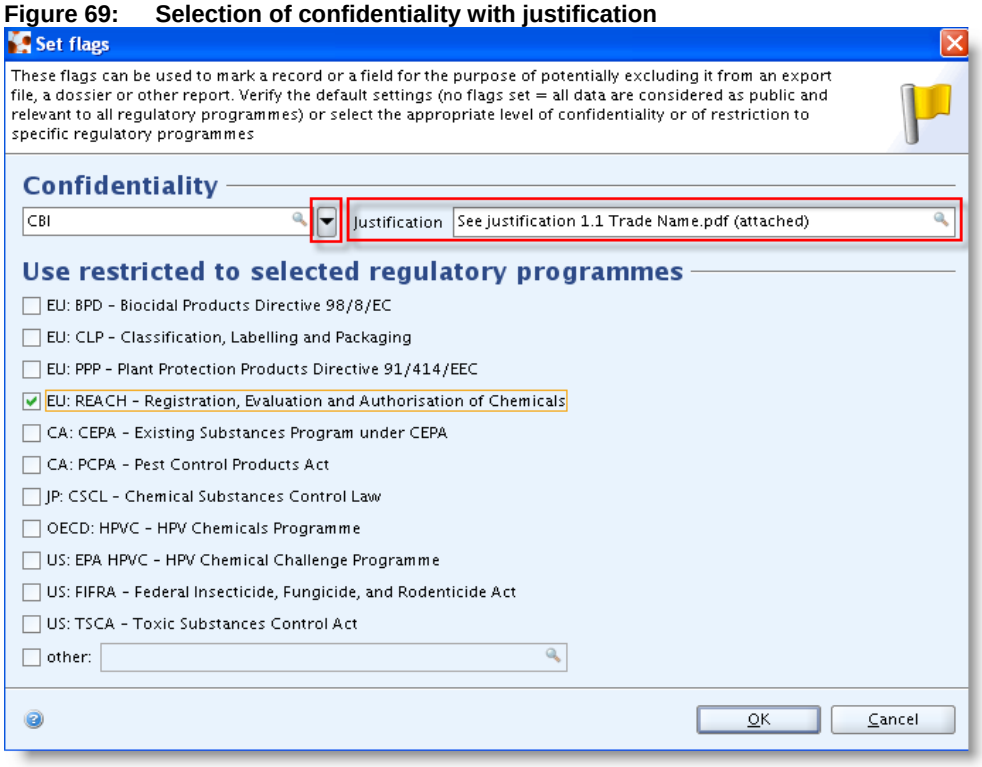
2. **Select a confidentiality flag** from the pick list (CBI: confidential business information; IP: intellectual property; no PA: not public available) (Figure 68).

Figure 68: Pick list for confidentiality flag



3. **Enter a justification** as to why the publication of the information is potentially harmful for the commercial interests of the registrant or any other party concerned (Figure 69). For information falling under REACH Article 119(2) it is strongly recommended to use the justification template described in “Data Submission Manual 16: Confidentiality Claims”.

Figure 69: Selection of confidentiality with justification



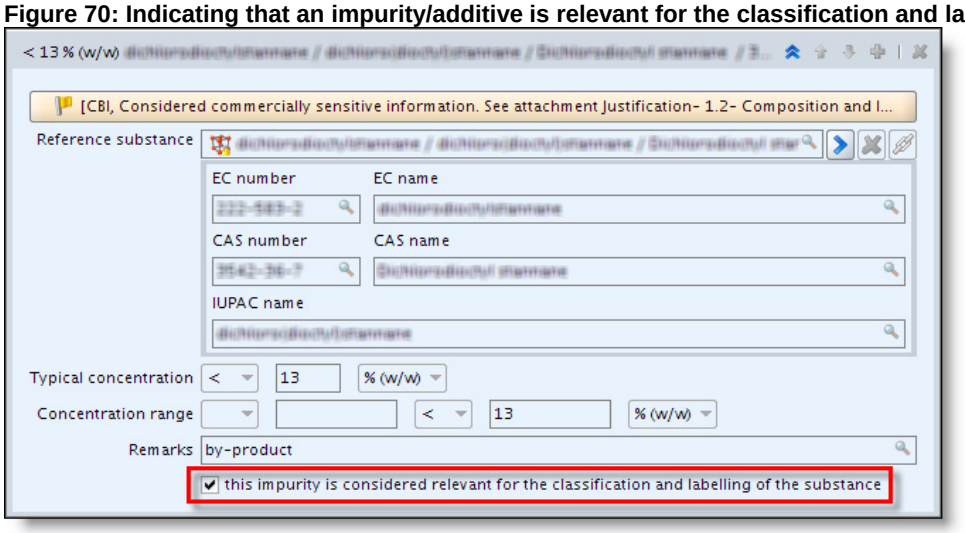
Based on Annex IV of the fee regulation, a fee has to be paid for the following confidentiality requests recorded in IUCLID 5:

- **Degree of purity and/or identity of impurities or additives** (corresponds to Art. 119(2) (a) of REACH). A fee will be charged if a confidentiality request has been recorded in one of the following IUCLID sections:
- Section 1.2: “Degree of purity”
- Section 1.2: Impurities: flag above Reference substance
- Section 1.2: Impurities/Reference substance: flags in a linked reference substances (one or both flags: Reference substance information; Molecular and structural information)
- Section 1.2: Additives: flag above Reference substance
- Section 1.2: Additives/Reference substance: flags in a linked reference substances (one or both flags: Reference substance information; Molecular and structural information).

According with Art. 119(2), the fee for degree of purity is levied if one impurity or additive is essential for the classification and labelling of the substance. For the identity of impurities or additives, the fee is levied if the impurity or additive with a confidentiality claim is essential for the classification and labelling of the substance. This is marked by ticking the corresponding box in the section for the impurity or additive (Figure 70).

One single fee is calculated for this item, it does not matter whether one or more flags in the list above are selected.

Figure 70: Indicating that an impurity/additive is relevant for the classification and labelling



- **Relevant tonnage band** (corresponds to Art. 119(2) (b) of REACH)

Dossier header: Request for the tonnage band (checkbox “Confidentiality claim on tonnage band” is selected and a justification is provided).

- **A study summary or a robust study summary** (corresponds to Art. 119(2) (c) of REACH).

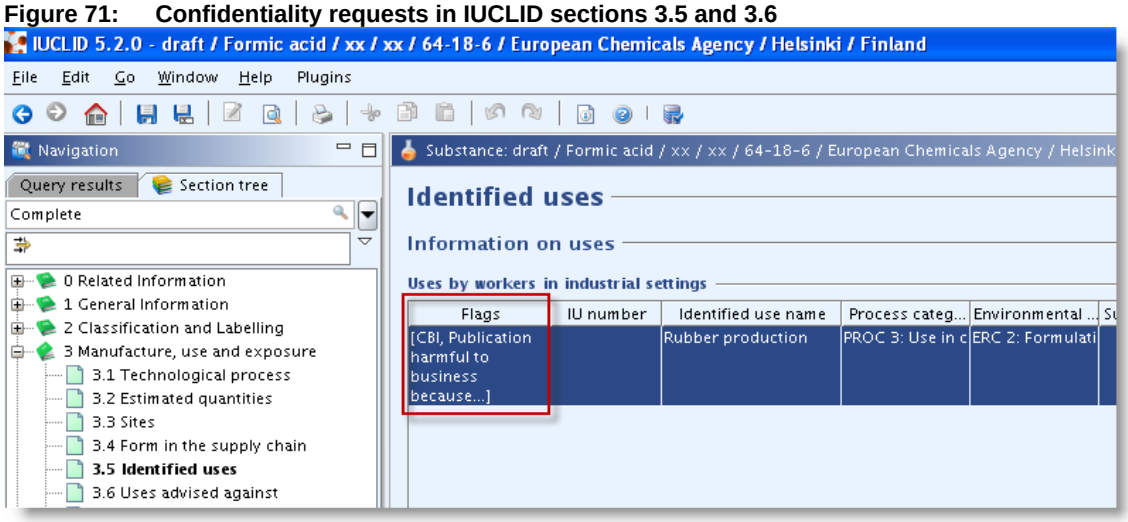
Sections 4 to 7: for each study summary or robust study summary that is flagged as confidential, a fee payment is required.

- **Information in the safety data sheet** (corresponds to Art. 119(2) (d) of REACH).

Sections 3.5 and 3.6: A fee will be charged if confidentiality request has been recorded in one of the Identified uses (3.5) or Uses advised against (3.6).

Confidentiality requests in sections 3.5 and 3.6 should be done in the tables where the uses are reported (Tables “Uses by workers in industrial settings (advised against)”, “Uses by professional workers (advised against)” and “Uses by consumers (advised against)”). (Figure 71)

Figure 71: Confidentiality requests in IUCLID sections 3.5 and 3.6



One single fee is calculated for this item, it does not matter whether one or more flags are selected in sections 3.5 and 3.6.

- **Trade name of the substance** (corresponds to Art. 119(2) (e) of REACH)

Section 1.1: Flag next to the field trade name of the substance.

- **IUPAC name for non-phase in substances that are hazardous** (corresponds to Art. 119(2) (f) of REACH, as amended by Article 58(7) of the CLP Regulation). A fee will be charged if a confidentiality request has been recorded in one of the following IUCLID sections:

Section 1.1: flags in a linked reference substances (one or both flags: Reference substance information; Molecular and structural information)

Section 1.2: Constituents: flag above reference substance

Section 1.2: Constituents/Reference substance: flags in a linked reference substances (one or both flags: Reference substance information; Molecular and structural information)

One single fee is calculated for this item, it does not matter whether one or more flags in the list above are selected. In addition, a fee is applicable only if the substance is a non-phase-in substance and it is reported in Section 2.1 of the dossier that the substance has at least one of the hazardous properties listed in Art. 119(2) (f) of REACH, as amended by Article 58(7) of the CLP Regulation.

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- IUPAC name for hazardous substances used as intermediates, in scientific research and development or product process oriented research and development (corresponds to Art. 119(2) (g) of REACH, as amended by Article 58(7) of the CLP Regulation). A fee will be charged if a confidentiality request has been recorded in one of the following IUCLID sections:

Section 1.1: flags in a linked reference substances (one or both flags: Reference substance information; Molecular and structural information) and/or

Section 1.2: Constituents: flag above reference substance and/or

Section 1.2: Constituents/Reference substance: flags in a linked reference substances (one or both flags: Reference substance information; Molecular and structural information)

One single fee is calculated for this item, it does not matter whether one or more flags in the list above are selected. Moreover, a fee is applicable only if it is reported in Section 2.1 of the dossier that the substance has at least one of the hazardous properties listed in Art. 119(2) (f) of REACH, as amended by Article 58(7) of the CLP Regulation, and it is indicated in the dossier that the substance is used only as an intermediate, in scientific research and development or product process oriented research and development. In practice, the only relevant case will be the use as an intermediate.

Please, remember that you are able to simulate the fee associated to your submission by using the ”Fee Calculation Plugin”. This IUCLID plugin gives advance information of the likely costs. However, registrants should wait for ECHA to issue an invoice before making their payment.
This software can be downloaded from the IUCLID website free of charge:
http://iuclid.echa.europa.eu/

Confidentiality requests in a registration dossier that was previously a notification under Directive 67/548/EEC (NONS)

When updating a registration that was previously a notification under Directive 67/548/EEC (NONS) you should pay attention to the confidentiality requests included in your dossier.

Please note that ECHA will only charge a fee for those confidentiality requests associated with the new information submitted, or new confidentiality requests for the existing information, i.e. there will be no fee for confidentiality requests successfully made under Directive 67/548/EEC, provided that this is confirmed by the registrant in their dossier.

You can find detailed information on the confidentiality requests for registrations that were notifications under Directive 67/548/EEC (NONS) in the document “Questions and answers for the registrants of previously notified substances” (section 4.3) available at http://echa.europa.eu/reachit/nons_en.asp

Annex 4 - Minimum information required for updating a registration under previous Directive

When updating a registration that was previously a notification under Directive 67/548/EEC (NONS) the following two scenarios have to be taken into account:

- Tonnage band update

According to Article 24(2) of the REACH Regulation, the registration dossier for the previously notified substance must be updated as soon as the manufactured/imported quantity reaches the next tonnage threshold (10, 100 or 1000 tonnes). Moreover, an update is required for notified substances produced in quantities below 1 tonne, when reaching the 1 tonne threshold. The update should not only contain the information required by REACH which corresponds to that higher tonnage threshold, but also any information which corresponds to lower tonnage thresholds. In this case the dossier has to be fully in line with REACH requirements in the IUCLID 5 format specified by ECHA, in particular, all of the technical completeness check requirements outlined in this document must be met, without any possibility to make derogations due to the substance being previously notified under 67/548/EEC. Therefore, registrants have to carefully check and complete their IUCLID 5 file in order to fulfil the completeness check requirements as described in chapter 3 of this document.

Please note that in case your update involves a registration at or above the 10 tonnes threshold, a Chemical Safety Report (CSR) should be included in section 13 of your IUCLID 5 dossier, unless not required due to the reasons given in Article 14(2) of the REACH Regulation (in which case a justification should be provided in Section 13 instead).

In addition, as indicated in this manual, all information requirement included in columns 1 of REACH Annexes VII-X, depending on the tonnage, must correspond to at least one complete endpoint study record in IUCLID. Therefore if you are updating a SNIF file migrated to IUCLID 5 then you should be aware that ECHA could consider the endpoint requirement as complete if at least one endpoint study record is complete (Data waiving, testing proposal, weight of evidence or key study).

Testing proposal: Only for the endpoints which refer to an information requirement from Annex IX and X of REACH.

- Other updates

Article 22 of the REACH Regulation lists the cases when the registrant has to update the registration dossier.

This includes also updates to include the classification and labelling according to Article 40 of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation).

It also concerns updates following a decision made according to Article 16(1), 16(2) or 7(2) of Directive 67/548/EEC and now regarded as Agency decisions (Article 135 of REACH).

When updating the registration dossier under any case (excluding a change of tonnage band), certain information in your dossier is not required. However, in order to be considered complete and for REACH-IT to be able to process the dossier, your dossier should include as a minimum the following information:

New information submitted

The new information submitted as a consequence of the update has to meet all of the technical completeness check requirements described in the present manual, with no special exceptions due to the status as a previously notified substance.

If you are updating your dossier to include the classification and labelling according to the CLP Regulation, IUCLID section 2.1 has to be complete.

For any new study and for the studies requested by a MSCA under Directive 67/548/EEC and now regarded as Agency decisions according to Article 135 of the REACH Regulation, robust study summaries have to be provided.

Note that for certain types of update under Article 22 (e.g. new identified use), the relevant sections of your IUCLID 5 dossier should be updated (e.g. Section 3.5 “Identified uses and exposure scenarios”).

Section 1: General Information

The following subsections have to be complete as described in the present manual:

- 1.1 Identification and 1.2 Composition. These sections have to be complete to meet all of the technical completeness check requirements described in the present manual. However structural formulas are only optional as they have been already submitted on paper under Directive 67/548/EEC.
- 1.3 Identifiers. At least the notification number under Directive 67/548/EEC (NCD number), as well as your registration number under the REACH Regulation (the one you received when claiming your registration number via REACH-IT) should be included here.
- 1.7 Suppliers. If you are acting as an “Only representative” you are advised to attach here clear documentation of the appointment of the Only Representative.

Section 2: Classification and Labelling

- 2.1 GHS. The classification and labelling according to the CLP Regulation (GHS) has been only optional until 1 December 2010. From this day forth, it is compulsory to provide this information in section 2.1 of your IUCLID dossier. If you have previously submitted a dossier without section 2.1, you should provide this information in a registration update without undue delay.
- 2.2 DSD-DPD. From 1 December 2010 until 1 June 2015, substances shall be classified in accordance with both Directive 67/548/EEC and the CLP regulation. However, it is only optional to provide information for section 2.2 of your IUCLID dossier from 1 December 2010.

Section 3: Manufacture, use and exposure

The following subsection has to be complete:

- 3.3 Sites. In case that you have indicated in section 1.1 that you are a manufacturer, you have to include here information about your production sites (i.e. tick the boxes “Production site” or “Use site” and for each site fill in the fields “Site name”, “Address”, “Postal code”, “Town” and “Country”)

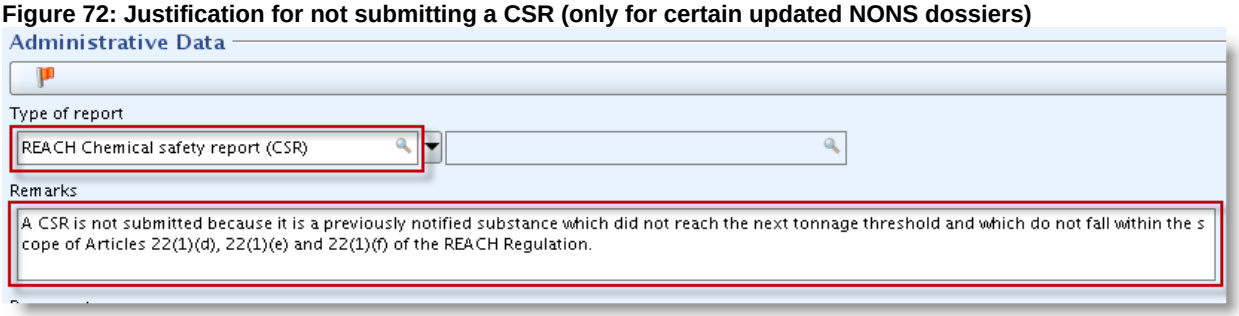
Section 13: Chemical Safety Report (CSR)

When the update does not involve a change in tonnage band the notifier does not normally need to submit a chemical safety report (CSR) unless the updated notification is above 10 tonnes per year and covers new identified uses, new knowledge arises with regard to the risks of the substance to human health and/or the environment which would lead to changes

in the safety data sheet, or there is a change in the classification and labelling of the substance which leads to changes in the safety data sheet. The “Guidance on Registration“ provides in Chapter 9 further details on the necessity to submit a CSR (http://guidance.echa.europa.eu/docs/guidance_document/registration_en.pdf).

Therefore, if you do not need to submit a CSR please proceed in the following way (see also Figure 72 below). In section 13 of your IUCLID 5 dossier select 'REACH Chemical safety report (CSR)' in the field 'Type of report' and provide the justification for not providing the CSR either in the field 'Remarks' or in the field 'Discussion'. This justification sentence should be either “A CSR is not submitted because it is a previously notified substance which did not reach the next tonnage threshold and which do not fall within the scope of Articles 22(1)(d), 22(1)(e) and 22(1)(f) of the REACH Regulation” or “A CSR is not submitted because the substance fulfils the requirements of Article 14(2) of the REACH Regulation.”.

Figure 72: Justification for not submitting a CSR (only for certain updated NONS dossiers)

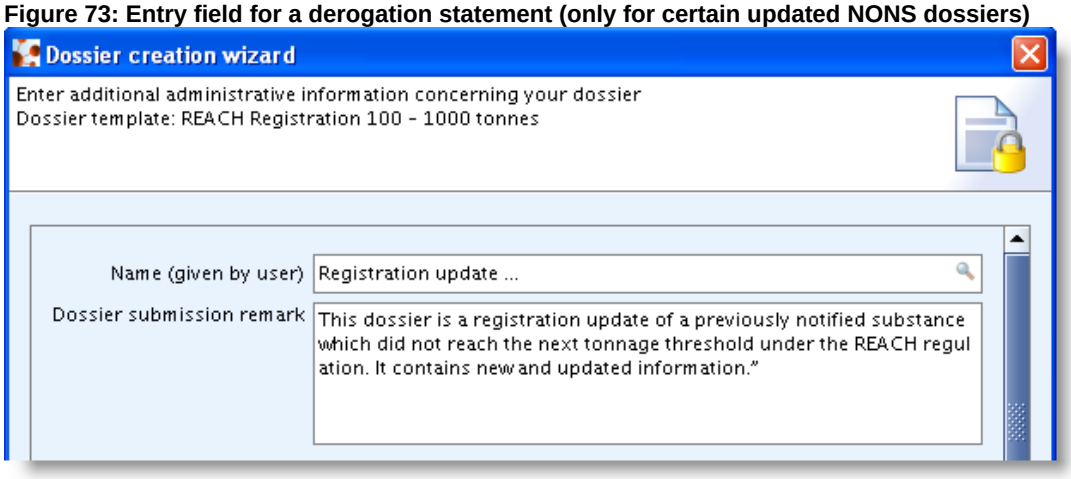


IUCLID dossier header: Derogation statement

You are encouraged to check and complete as much as possible the rest of the information contained in your registration dossier. However, the registration dossier will be acceptable even if there are some gaps provided that you include at least the minimum information detailed above and that you include the following derogation statement in your IUCLID dossier header (in the “Dossier submission remark” field as in Figure 73).

“This dossier is a registration update of a previously notified substance which did not reach the next tonnage threshold under the REACH regulation. It contains new and updated information.”

Figure 73: Entry field for a derogation statement (only for certain updated NONS dossiers)



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