

# Data Submission Manual

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



Version	Changes
3.2	<p>03/2014</p> <p>The following paragraphs have been updated:</p> <p>Chapter 4.1.2 – Clarification added on how to fill in additive(s) function.</p> <p>Chapter 5.1 – Information on the Validation Assistant plug-in and on the Dossier Quality Assistant. New screenshots added.</p> <p>TCC plug-in replaced by Validation Assistant plug-in throughout the document.</p>
3.1	<p>02/2013</p> <p>The following paragraphs have been updated:</p> <p>Chapter 4.3.2 – Clarifications on how to report the tonnage for registrants of intermediates.</p> <p>Chapter 4.3.5 – Clarifications on how to report uses within a joint submission. New figure added to illustrate the use of the field "Use coverage in CSR".</p> <p>Chapter 4.3.7 – Clarifications and instructions added on waste management. New figure added to illustrate the migration of information in IUCLID 5.4.</p> <p>Chapter 4.4 – Clarifications on filling in the Purpose flag field for adaptations of the standard testing regime.</p> <p>Chapter 4.6 – Added instructions and a figure on how to report on waste from production and use.</p> <p>Chapter 5.1 – Information on the new tool included in the TCC plug-in: the Dossier Quality Assistant.</p> <p>Annex 5 Instructions on how to report uses in IUCLID 5.4 for lead, member and individual registrants.</p>
3.0	<p>07/2012</p> <p>Document updated for the ECHA New Visual Identity and to reflect changes brought about by IUCLID 5.4.</p>
2.9	<p>Included advice in line with DSM12 to include statement "unknown" if affected organs are unknown.</p>
2.8	<p>04/2011</p> <p>Document updated to reflect the changes introduced by the 2nd ATP to the CLP Regulation. How to report C&amp;L within a joint submission: clarification on best practice to follow in case a member has a different C&amp;L than the lead and does not intend to opt-out (Chapter 4.2).</p> <p>A new chapter (Chapter 5, "Technical Completeness Check") has been added to explain the importance of running the TCC plug-in tool to check the completeness of the substance dataset and the final dossier.</p>
2.7	<p>12/2010:</p> <p>Document updated to reflect the changes introduced by the</p>

	<p>amendment of the REACH Regulation foreseen in Article 58 of the CLP Regulation. This amendment entered into force on 1 December 2010:</p> <p>P 24-34. Requirements for classification and labelling have been updated.</p> <p>P 87-88. Annex 3. Text on the fee for confidentiality claims on the IUPAC name has been updated.</p>
2.6	<p>10/2010:</p> <p>P 25. Classification and labelling: Instructions on how to indicate the "Reason for no classification" modified to match Data Submission Manual 12.</p> <p>P 85-86. Annex 3. Clarification on the fee for confidentiality claims on the degree of purity, impurities and additives. New figure 68.</p> <p>P 89-90. Annex 4. Clarification on updating the classification and labelling for NONS.</p>

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

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### European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland

Visiting address: Annankatu 18, Helsinki, Finland

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## 1. Introduction

### 1.1. Objective

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

### 1.2. Background

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

According to Article 20(2) of REACH Regulation (EC) No 1907/2006 the completeness check consists of two parts: the **Technical Completeness Check (TCC)** to check if all the elements required by REACH have been provided and the **Financial Completeness Check (FCC)** to check the payment of the fee if relevant.

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.

It should be noted that 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 an IUCLID 5 plug-in, called **Validation Assistant**, at the IUCLID 5 website at <http://iuclid.echa.europa.eu/>.

Before you submit your dossier, please ensure that you use the **Validation Assistant** plug-in both on the substance dataset and on the final dossier. Using the plug-in in both steps is vital for you to avoid failures. Please refer to chapter 5 "Technical Completeness Check (TCC)" of this User Manual for further details.

### 1.3. Conventions and terminology

The following icons will be used throughout this manual:



Useful information, guidance, assistance



Very important note, especially in order to pass the TCC

The following text conventions will be used throughout this manual:

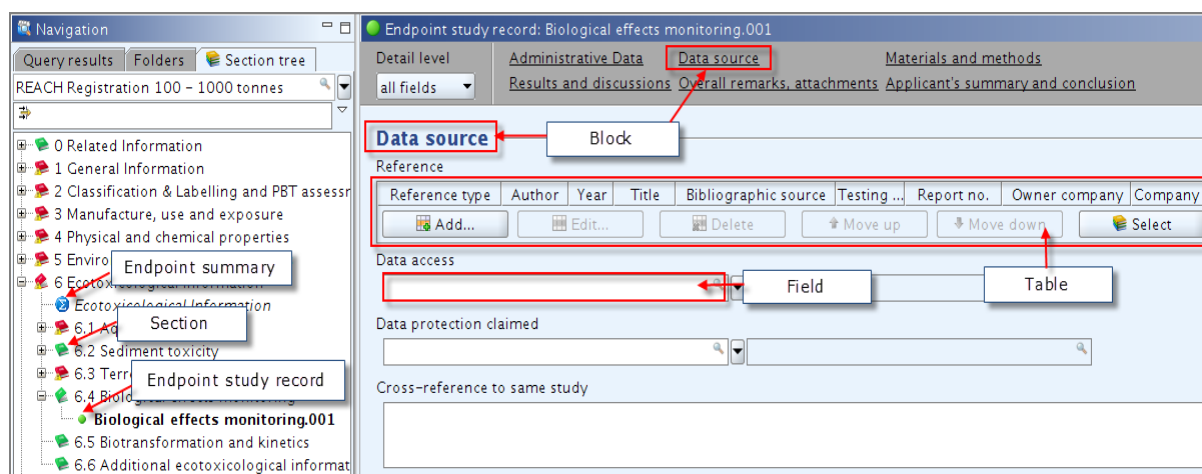
CLP                      Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

CSR                      Chemical Safety Report

C&L	Classification and Labelling
ECHA	European Chemicals Agency
PBT	Persistent, Bioaccumulative and Toxic
PPORD	Product and Process Orientated Research and Development
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH-IT	An online platform to submit data and dossiers on chemicals
TCC	Technical Completeness Check

The terminology used to describe IUCLID 5 items is described in Figure 1.

**Figure 1: Terminology of IUCLID 5 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 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 (Figure 2):

**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 drop-down list (Figure 3):

**Figure 3: Unit fields**



## 2.3. Selection of other

Every time "other:" is selected from a drop-down list then information must be provided in the adjacent field (Figure 4):

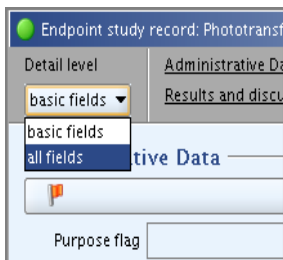
**Figure 4: Selection of other in a list**



## 2.4. Detail level of the endpoint study records

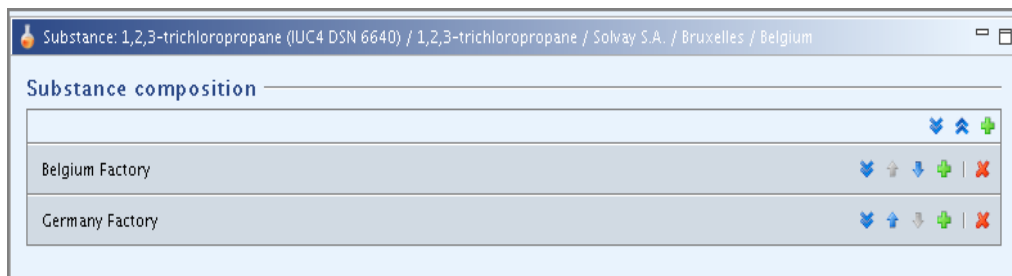
In IUCLID 5 sections 4 to 10, the selection of "all fields" in the "Detail level" drop-down list displays more fields than the "basic fields" selection (Figure 5). Therefore it is recommended to select the "all fields" option when filling in the endpoint study records. For more information please consult the IUCLID 5 End User Manual - section D.4.7 available at: <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 (Figure 6), it must be noted that information will be checked for all the blocks created:

**Figure 6: Repeatable blocks**

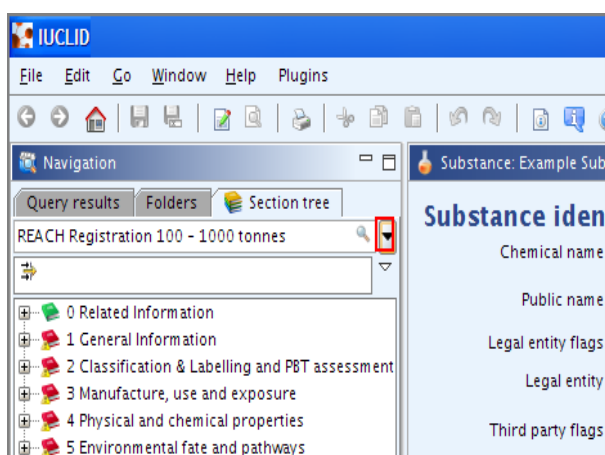
## 2.6. Confidentiality requests

Confidentiality requests that fall under Article 119(2) of the REACH Regulation and Annex IV of the Fee Regulation EC/340/2008 will require a fee payment. Any time a confidentiality flag is indicated (CBI, IP or no PA) for such a confidentiality request, 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. These confidentiality requests will be checked in order for your dossier to be accepted for processing. Confidentiality claim flags are not subject to the TCC.

- ❗ For further information on confidentiality claims and dissemination of information please see Annex 3 of this manual.

## 2.7. 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 7. The view mode corresponds to the various dossier types detailed in paragraph 3 of this manual.

**Figure 7: IUCLID 5 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 symbols preceding the IUCLID 5 sections are coloured in red for required sections or in green for optional sections. An obligatory section with no entries yet is marked with the sign "No Entry" .

- ! This view mode selector is merely a tool to assist in determining which IUCLID 5 sections to fill in for the desired dossier type. However, the present manual and the Validation Assistant plug-in prevail upon this view mode selector regarding the completeness check requirements under REACH.

### 3. Different dossier types

REACH specifies four types of dossiers which require 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. All registrations should be submitted in IUCLID 5 dossier format.

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 2.1, 2.2, 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.

Moreover, some specific rules for dossiers of members of a joint submission are described in IUCLID 5 section 2 "Classification & Labelling and PBT assessment", IUCLID 5 section 11 "Guidance on safe use" and IUCLID 5 section 13 "Assessment Reports" of this manual.

- ❗ For detailed information on how to fill in the IUCLID 5 dossier header please read Data Submission Manual 4 "How to Pass Business Rules Verification" available at: <http://echa.europa.eu/web/guest/support/dossier-submission-tools>.

### 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 "Information on mixtures", 3.6 "Uses advised against" and 13 "Assessment Reports" 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 (REACH Article 17 and 18). This information must be entered in section 11 "Guidance on safe use" (chapter 4.5).

For dossiers of intermediates, the registrant must agree to comply with Article 17 for on-site isolated intermediates or with Article 18 for transported isolated intermediates by selecting the tickbox "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 tickboxes 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 notifications the sections 2 "Classification & Labelling and PBT assessment", 3.1 "Technological process", 3.2 "Estimated quantities", 3.4 "Information on mixtures", 3.5 "Life Cycle description", 3.6 "Uses advised against", 3.7 "Exposure Scenarios, exposure and risk assessment", 11 "Guidance on safe use" and 13 "Assessment Reports" 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 can be found in the Data Submission Manual 1 "How to prepare and submit a PPORD notification" available at:  
<http://echa.europa.eu/web/guest/support/dossier-submission-tools>.

### 3.4. Special rules for notifications made under Directive 67/548/EEC (NONS)

According to Article 24 of the REACH Regulation all notifications made under Directive 67/548/EEC (NONS) are considered registrations under the REACH Regulation at the relevant tonnage band. These registrations need to be updated if at least one of the cases described in Article 22 or Article 24(2) of the REACH Regulation applies.

When preparing the update of a NONS registration, keep in mind that substance datasets migrated from IUCLID 4 or from the SNIF file format to IUCLID 5, do not contain all information needed to pass the technical 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 and PBT assessment (IUCLID 5 section 2), the confidentiality flags, and the endpoint study records (IUCLID 5 sections 4 to 8). Annex 4 of this document outlines 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" available at:  
<http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/nons>.

## 4. IUCLID 5 sections to complete

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

### 4.1. Section 1 - General information

For completeness, IUCLID 5 section 1 requires that information is provided on the identification of the substance, its composition, identifiers, analytical information, and PPORD (if relevant). Each of them will be discussed in the following chapters.

#### 4.1.1. Section 1.1 - Identification

Section 1.1 in IUCLID 5 contains the identification of the substance, role in the supply chain and the type of (reference) substance, each called a block.

##### 4.1.1.1. Block "Substance identification"

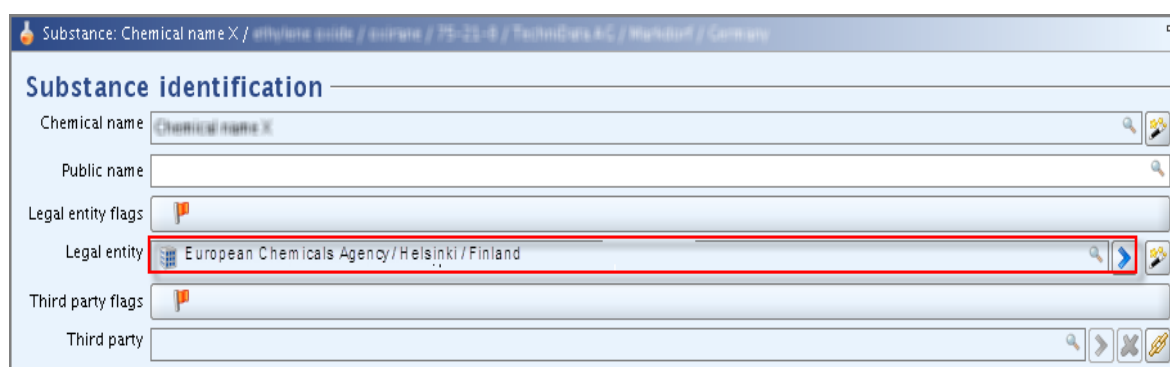
The field "Public name" must be filled in if there are confidentiality concerns about the substance name. A generic name, which appropriately describes the substance being

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.

- ❗ Guidelines on how to derive an adequate public name are provided in Data Submission Manual 17 "How to derive a Public Name for a substance for use under the REACH Regulation" available at: <http://echa.europa.eu/web/guest/support/dossier-submission-tools>.

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 5 dossier to comply with the XML format. This information must be provided in the block "Substance identification" (Figure 8).

**Figure 8: Legal entity and third party in the substance identification block**



The screenshot shows a web interface for 'Substance identification'. The fields are as follows:

- Chemical name: Chemical name X
- Public name: (empty)
- Legal entity flags: (empty)
- Legal entity: European Chemicals Agency / Helsinki / Finland (highlighted with a red box)
- Third party flags: (empty)
- Third party: (empty)

It is not compulsory to indicate a third party; however if a third party representative has been appointed according to Article 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. The check is done using the 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 tickbox "Manufacturer" is selected (Figure 9) 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 tickbox "Only representative" is selected then you are advised to provide the specific information described in IUCLID 5 section 1.7 "Suppliers".



**Figure 9: Role in the supply chain**

Substance: 1,2,3-trichloropropane (ECHA DPN 0040) / 1,2,3-trichloropropane / Other: U.K. / Bruxelles / Belgium

Substance identification

Chemical name: 1,2,3-trichloropropane (ECHA DPN 0040)

Legal entity flags: [Flag]

Legal entity: Other: U.K. / Bruxelles / Belgium

Third party flags: [Flag]

Third party: [Field]

Role in the supply chain

Role flags: [Flag]

Role:  Manufacturer  Importer  Only representative  Downstream user

#### 4.1.1.3. Block "Type of substance"

"Mono constituent substance", "multi constituent substance" or "UVCB" must be selected in the drop-down list "Composition" (Figure 10).

**Figure 10: Type of substance**

Substance: Substance / Example Company / Helsinki / Finland

Role in the supply chain

Role flags: [Flag]

Role:  Manufacturer  Importer  Only

Reference substance

Reference substance flags: [Flag]

Type of substance

Composition: [Dropdown menu]

Origin: [Dropdown menu]

Other names

Flags	Name Type	Name	Country	Remarks

Pick list dialog: Select a composition

- mono constituent substance
- multi constituent substance
- UVCB
- polymer
- other:

Buttons: OK, Cancel

**!** 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 5 section 1.2 "Composition". The reference substance details can be edited by entering the reference substance object using the blue arrow (Figure 11).

### Substance identifier

For the Reference substance indicated in this block (Figure 11), either an EC number or a CAS number (with a CAS name) or a IUPAC name must be given (Figure 12). Please note, that for the registration dossiers it is checked at the Business Rule step that the IUPAC name has been provided.

**Figure 11: Reference substance**

Reference substance	
Reference substance flags	
water / water / 7732-18-5	
EC number	EC name
231-791-2	water
CAS number	CAS name
7732-18-5	
IUPAC name	
water	

- ❗ 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 5 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 12: Substance identifier**

Reference substance: My substance

**General information**

Reference substance name My substance

**EC inventory**

EC number 231-791-2 CAS number 7732-18-5

EC name water Assign to the EC inventory

Molecular formula H2O

Description

**No EC information available**

Justification

**Reference substance information**

**CAS information**

CAS number CAS number

CAS name CAS name

**IUPAC name**

IUPAC name

### 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 range" and "Structural formula" of the reference substance must be provided (Figure 13).
- If you indicate "multi constituent substance" in section 1.1 under "Type of substance/Composition", then the "Molecular formula", "Molecular weight range" 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 13).
- If you indicate "UVCB" in section 1.1 under "Type of substance/Composition", then the "Molecular formula" and "Molecular weight range" of the reference substance must be provided or a justification for not providing this information must be given in the "Remarks" field (Figure 13).

In addition, the "SMILES notation" should also be provided if available.

**Figure 13: Section 1.1 Molecular and structural information**

Reference substance: □ □ □

**Molecular and structural information**

Molecular formula

Molecular weight range

SMILES notation

InChI

Structural formula

Remarks

#### 4.1.2. Section 1.2 - Composition

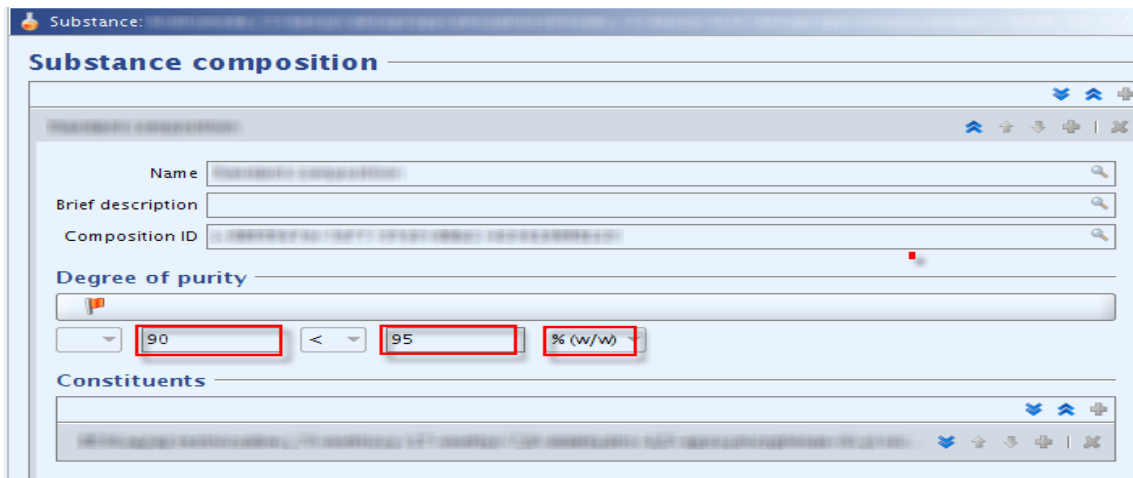
At least one composition must be indicated. Normally, one composition should be sufficient. If several "Substance composition" blocks are created then every block must be complete.

- ⓘ Depending on your specific case several compositions may be necessary. More information on how to report the compositions in a IUCLID 5 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/web/guest/support/dossier-submission-tools>.

The degree of purity shall be specified (Figure 14). It means that at least one of the two boxes must be filled in and that a unit has to be selected.

- ⓘ In most cases full range should be specified for the degree of purity and it should correspond to the substance as manufactured/imported.

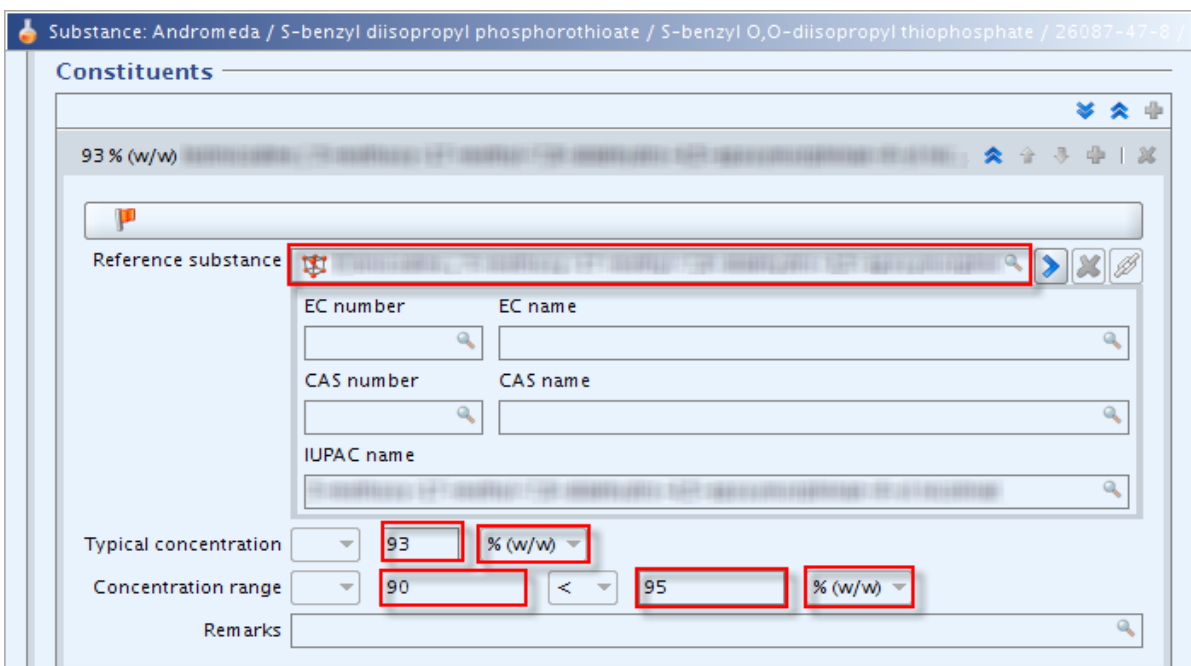
Figure 14: Substance composition block



At least one constituent should be indicated for each composition. For each constituent, impurity or additive, a check will be carried out to ensure that a Reference substance is attached and that as a minimum, either the "Typical concentration" or the "Concentration range" has been filled in and that the unit has been selected (Figure 15).

- While a substance may be in particular cases identified only by a concentration range, normally it is expected to provide full range and typical concentration within the range. Values should correspond with substance as manufactured/imported.

Figure 15: Concentrations



In addition, the function of additives has to be provided by making a selection from the drop-down list "Function". Please note that only additives with a stabilising function are to be reported. If "other" is selected, then the free-text adjacent field must be filled in (Figure 16).

If an impurity or additive is considered relevant for classification and labelling of a substance, the relevant tickbox should be ticked (Figure 16).

**Figure 16: Tickboxes relevant for impurities and/or additives**

The screenshot shows the 'Additives' form with the following details:

- Concentration: 2 % (w/w)
- Reference substance: [Empty field]
- EC number: [Empty field]
- EC name: [Empty field]
- CAS number: [Empty field]
- CAS name: [Empty field]
- IUPAC name: [Empty field]
- Function: stabiliser
- Typical concentration: 2 % (w/w)
- Concentration range: 1 to 3 % (w/w)
- Remarks:  this additive is considered relevant for the classification and labelling of the substance

### Substance identifier

Each reference substance attached as a constituent, impurity or additive should at least contain either an EC number (or a CAS number and a CAS name) or a IUPAC name. Please note, that for the registration dossiers it is checked at the Business Rule step that the IUPAC name has been provided.

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

### Molecular and structural information

Concerning the molecular and structural information, the following information must be provided in the reference substances of IUCLID 5 section 1.2

For constituents (Figure 17):

- 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 (Figure 17):


- As a minimum, the "Molecular formula", "Molecular weight" and "Structural formula" must be provided, or a justification for not providing this information must be given in the "Remarks" field.

For impurities (Figure 17):

- The "Molecular formula", "Molecular weight" and "Structural formula" (if available) must be provided, or a justification for not providing this information must be given in the "Remarks" field.

**Figure 17: Section 1.2 Molecular and structural information**

The screenshot shows a software interface titled "Molecular and structural information". It contains several input fields: "Molecular formula", "Molecular weight range" (with two dropdown menus), "SMILES notation", "InChI", "Structural formula", and "Remarks". Below the "Structural formula" field are three buttons: "Load...", "Zoom...", and "Delete". Red rectangular boxes are drawn around the "Molecular formula", "Molecular weight range", "Structural formula", and "Remarks" fields to highlight them.




 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 TCC, 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 Validation Assistant plug-in 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 and CLP": <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach>. 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 5 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/web/guest/support/dossier-submission-tools>.


#### 4.1.4. Section 1.3 - Identifiers


IUCLID 5 section 1.3 requires input on identifiers of regulatory programmes.

##### 4.1.4.1. Block "Regulatory programme identifiers"

In IUCLID 5 section 1.3, indicate the following identifiers, where appropriate:

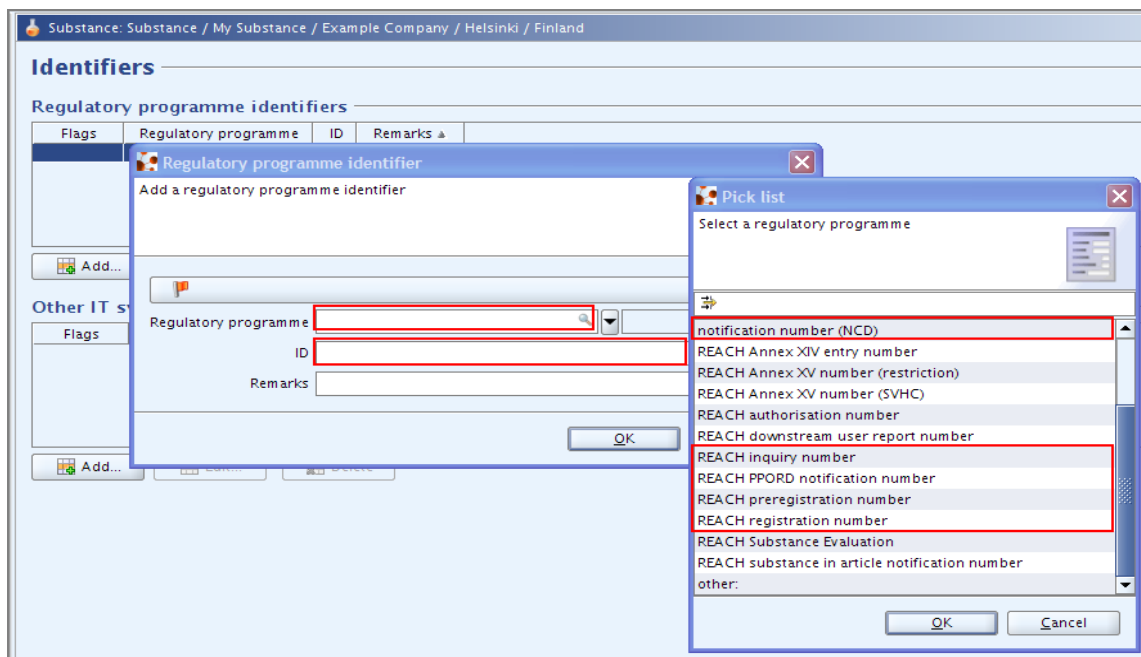
- The REACH pre-registration number;
- The REACH inquiry number;
- For a dossier update, the REACH registration number (or the REACH PPORD notification number) associated to the initial dossier (it should be available for all spontaneous updates);
- For an update of a notified substance according to Directive 67/548/EEC, the notification number (NCD) and the REACH 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 more than one programme identifier (e.g. REACH inquiry number, REACH registration number, etc.) you should click on the "Add" button  .

-  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 5 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 ) (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). Alternatively, a justification for not providing the requested analytical results must be entered in the "Remarks" field (Figure 19).

Figure 19: Analytical information

**Analytical information**

Analytical methods and spectral data

Provide a summary of the used analytical methods in this field

or you may provide the description as an attachment in here

Methods.doc / 21.5 KB

Optical activity

To be included if relevant

**Results of analysis**

**Chromatography**

Analysis type: Chromatography

Tested substance: batilol 208-874-7

Method used: HPLC

Provide\_the\_results\_as\_an\_attachment\_in\_here.doc / 21.5 KB

Remarks

**Spectrophotometry**

Analysis type: Spectrophotometry

Tested substance

Method used: IR













































Remarks: Provide a justification why results with the required analytical method is not provided

! 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 since all the information concerning the joint submission has already 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

Substance:                                            

**Joint submission**

**General information**

Joint submission name

Remarks

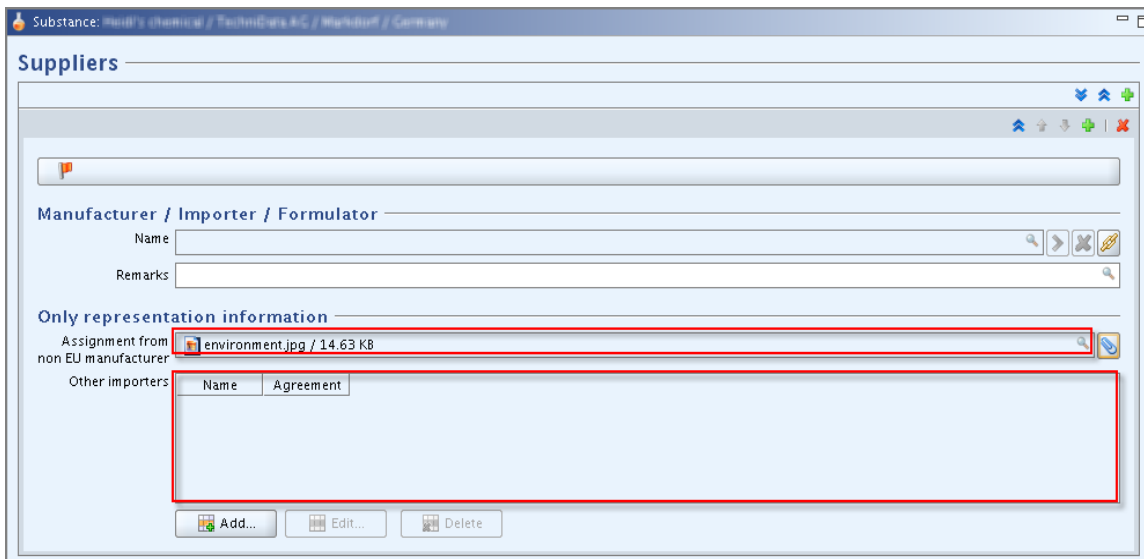
Regulatory programme

#### 4.1.7. Section 1.7 - Suppliers

If the tickbox "Only representative" is ticked in IUCLID 5 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).

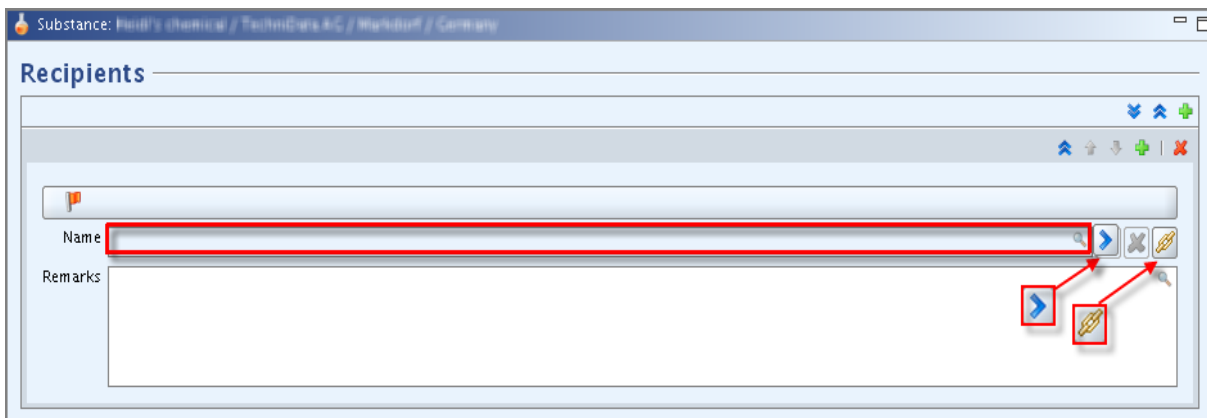
**Figure 21: Only representative information**



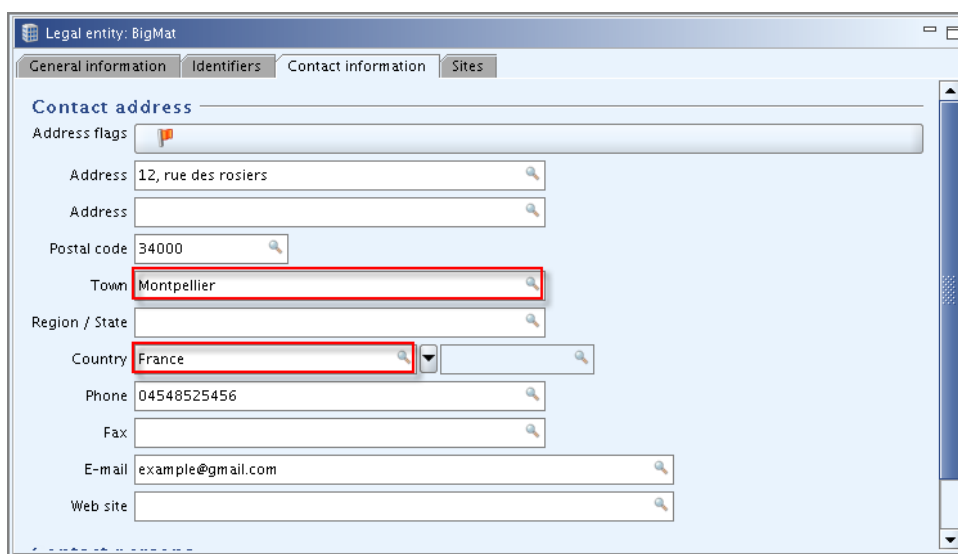
#### 4.1.8. Section 1.8 - Recipients

This IUCLID 5 section only needs to be provided 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 to link an existing Legal entity or to create a new one), and filling the information in the Legal entity tab "Contact information" (press the arrow button to go to the Legal entity information) (Figure 22). The minimum information to provide in the tab "Contact information" is the "Town" and the "Country" (Figure 23).

**Figure 23: The town and country entry fields for a PPORD recipient**

Legal entity: BigMat

General information Identifiers Contact information Sites

Contact address

Address flags 

Address 12, rue des rosiers

Address

Postal code 34000

Town Montpellier

Region / State

Country France

Phone 04548525456

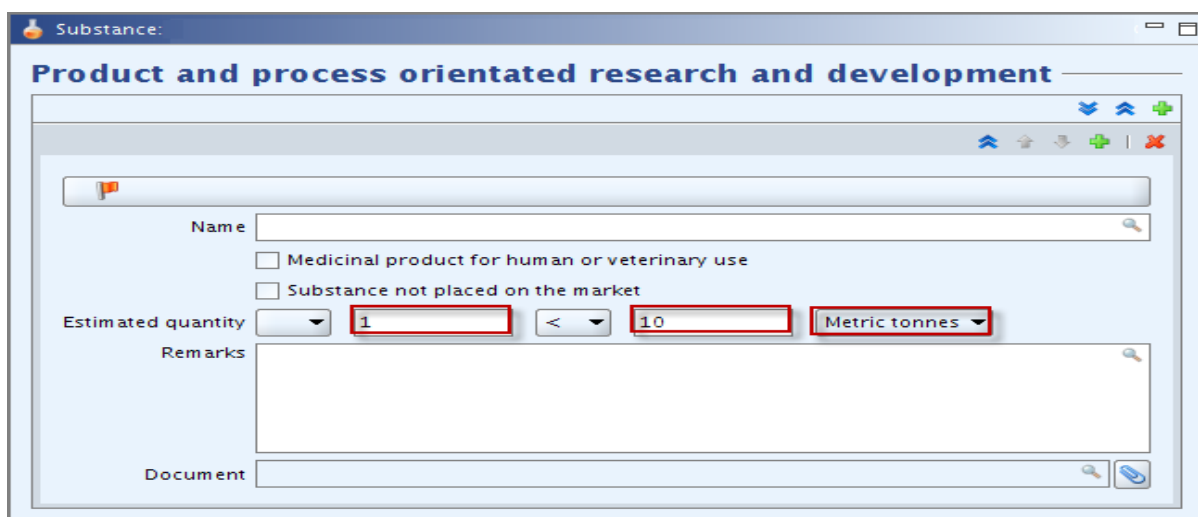
Fax

E-mail example@gmail.com

Web site


#### 4.1.9. Section 1.9 - Product and process orientated research and development

This IUCLID 5 section only needs to be provided 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**

Substance:

Product and process orientated research and development



Name

Medicinal product for human or veterinary use

Substance not placed on the market


Estimated quantity 1 < 10 Metric tonnes

Remarks

Document

#### 4.2. Section 2 – Classification & Labelling and PBT assessment

There are two sections for entering information related to classification and labelling (C&L) in IUCLID 5; section 2.1 "GHS" and section 2.2 "DSD – DPD". In addition, the section 2.3 "PBT assessment" will allow you to store the outcome of the PBT assessment performed under the REACH Regulation.


 **GHS** is the abbreviation for the United Nations Globally Harmonised System. 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).

The CLP Regulation is replacing DSD and DPD in a stepwise approach. Further information on CLP is available on our website at <http://echa.europa.eu/web/guest/regulations/clp>.

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 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) is optional from that date.

 It is not possible to submit a separate CLP notification if you have already submitted a registration dossier.

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

Completeness check rules are applicable to CLP and DSD (IUCLID 5 sections 2.1 and 2.2, respectively).

Here below are listed some principles to follow for completing both IUCLID 5 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). This is 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).

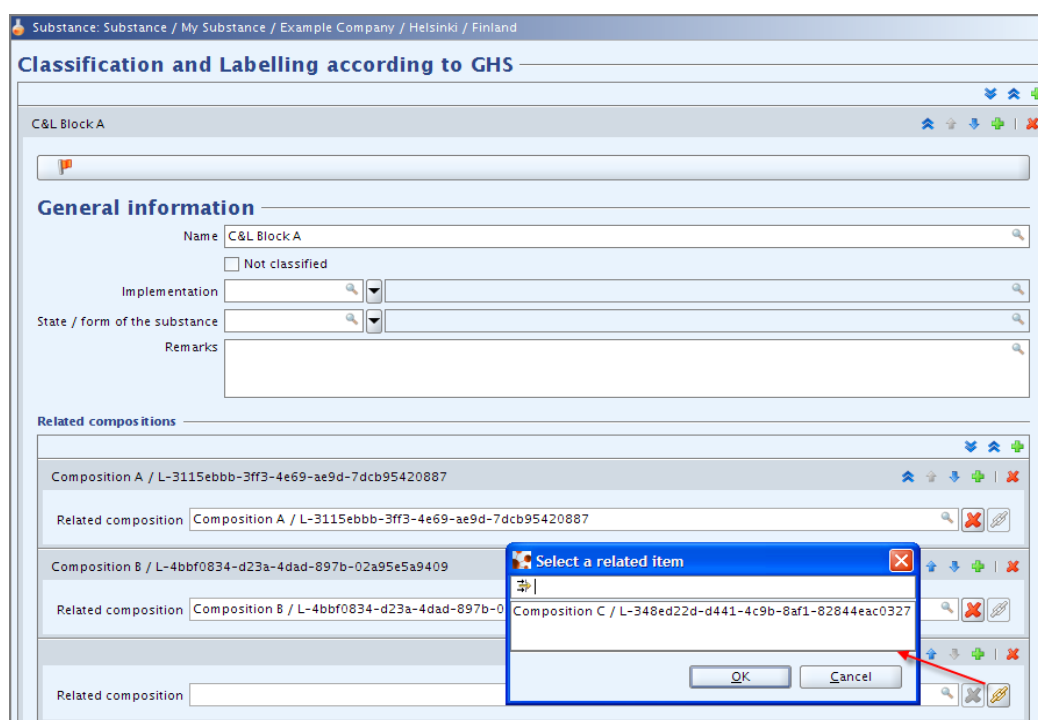
In IUCLID 5 the fields "Reason for no classification" are pre-filled indicating "data lacking" by default. Where applicable, you should change this default setting to another appropriate reason for no classification, such as "Inconclusive" or "conclusive but not sufficient for classification", or if the criteria for classification were met, you should specify a "Hazard category" and a "Hazard statement".

If multiple repeatable blocks are created in IUCLID 5 sections 2.1 and 2.2 then all of these blocks must be complete.

If you have several compositions (several blocks in IUCLID 5 section 1.2) and several Classification and Labelling blocks in section 2.1, then you should link each C&L block to its related composition(s) by using the field "Related composition" (Figure 25).

Several compositions can be linked to the same C&L block. In case of multiple compositions and multiple C&L blocks, each composition block must be linked to at least one C&L block (Figure 25).

**Figure 25: Linking compositions to the C&L**



#### 4.2.1. C&L 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:

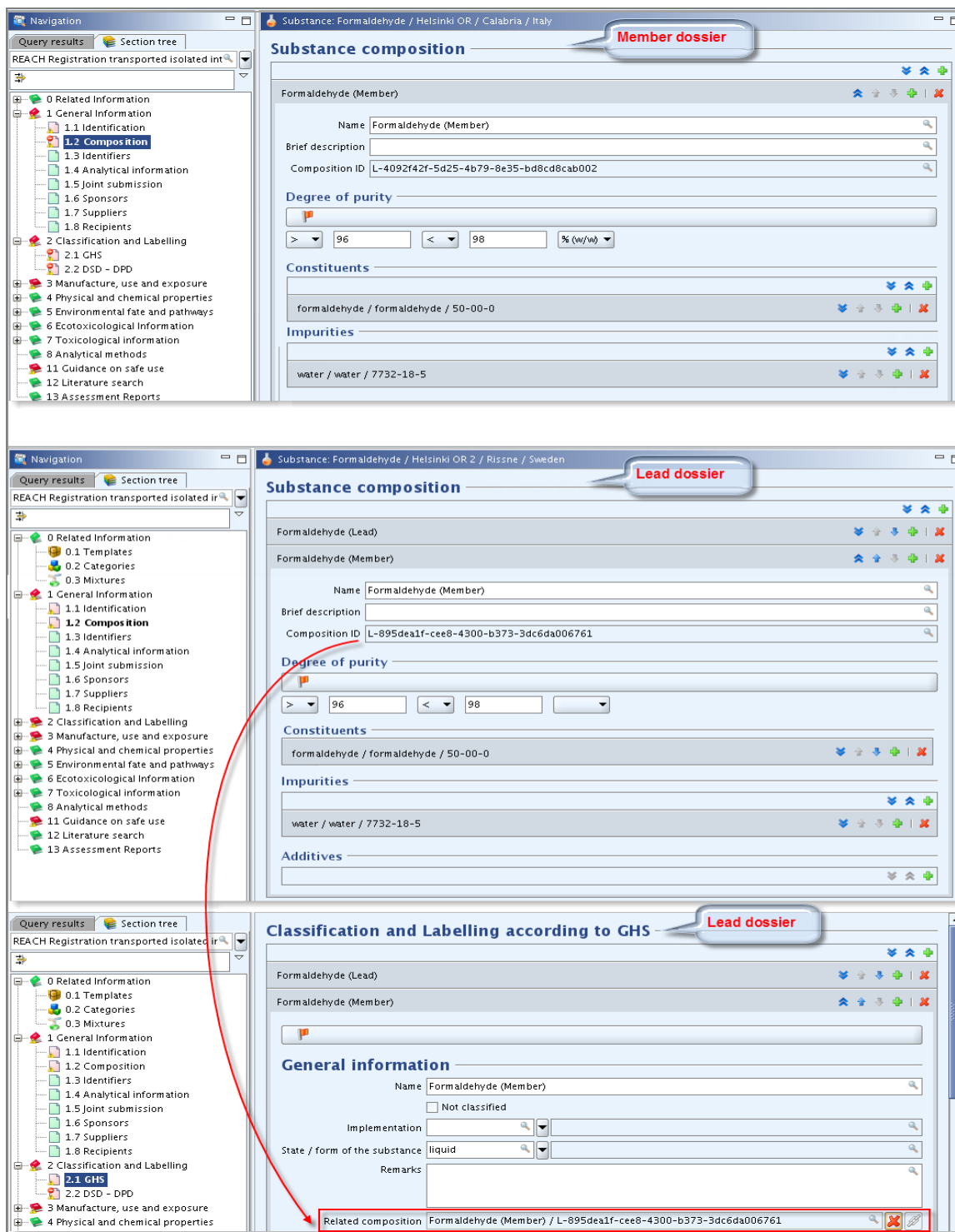
1) The member has the same C&L as the lead. In this case, the member should not provide any information in sections 2.1 and 2.2 of its IUCLID 5 dossier.

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 5 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 5 section 1.2 but should leave the IUCLID 5 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 to the appropriate C&L block through the field "Related composition" 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 26).

**Figure 26: Linking the composition and C&L of a Member (not opting out) and Lead of a joint submission**








### 4.2.2. 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 5 to specify the C&L information requested under Article 40(1- c, d, e and f) of the CLP Regulation.

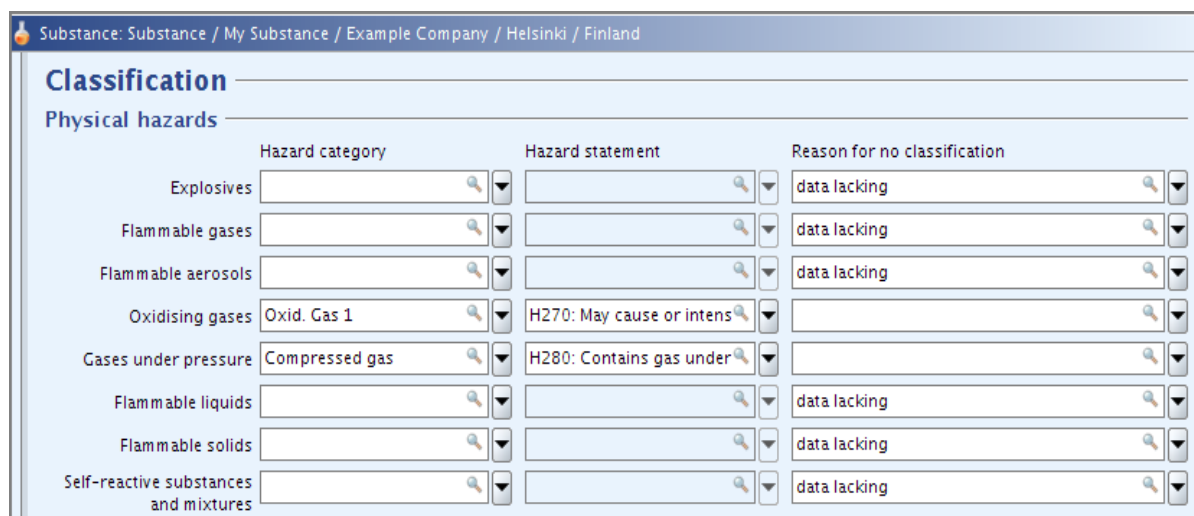
 More detailed information concerning C&L can be found in the Data Submission Manual 12 "How to Prepare and Submit a Classification and Labelling Notification Using IUCLID" available on the ECHA website at:  
<http://echa.europa.eu/web/guest/support/dossier-submission-tools>.

 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 criteria:  
<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp>.

#### 4.2.2.1. 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 27). Note, that the "Reason for no classification" is pre-set to "Data lacking" by default.

Figure 27: Entry fields for classification



	Hazard category	Hazard statement	Reason for no classification
Explosives			data lacking
Flammable gases			data lacking
Flammable aerosols			data lacking
Oxidising gases	Oxid. Gas 1	H270: May cause or intens	
Gases under pressure	Compressed gas	H280: Contains gas under	
Flammable liquids			data lacking
Flammable solids			data lacking
Self-reactive substances and mixtures			data lacking

- ❗ 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 available in section 2.1 do not exist in the CLP Regulation and shall therefore not be selected in your registration dossier. These categories/statements are listed in Data Submission Manual 12 at: <http://echa.europa.eu/web/guest/support/dossier-submission-tools>.

#### 4.2.2.2. Block "Physical hazards"

For all hazard classes indicated in the block "Physical hazards", either the two first fields "Hazard category" and the field "Hazard statement" should be filled in, or the field "Reason for no classification" should be filled in (Figure 28).

Figure 28: Physical hazards

	Hazard category	Hazard statement	Reason for no classification
Explosives			data lacking
Flammable gases			data lacking
Flammable aerosols			data lacking
Oxidising gases			data lacking
Gases under pressure			data lacking
Flammable liquids	Flam. Liquid 1	H226: Flammable liquid and vapor	
Flammable solids			data lacking
Self-reactive substances and mixtures			data lacking
Pyrophoric liquids			data lacking
Pyrophoric solids			data lacking
Self-heating substances and mixtures			data lacking
Substances and mixtures which in contact with water emit flammable gases			data lacking
Oxidising liquids	Oxid. Liquid 2	H271: May cause fire or explosion	
Oxidising solids			data lacking
Organic peroxides			data lacking
Corrosive to metals			data lacking

#### 4.2.2.3. 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 29).

**Figure 29: Health hazards**

The screenshot displays a web-based form for hazard classification. It is organized into several sections:

- Health hazards:** A table with columns for 'Hazard statement' and 'Reason for no classification'. The 'Reason for no classification' dropdowns for 'Acute toxicity - oral', 'Acute toxicity - dermal', 'Acute toxicity - inhalation', 'Skin corrosion/irritation', 'Serious eye damage/eye irritation', 'Respiratory sensitisation', 'Skin sensitisation', and 'Aspiration hazard' are all set to 'data lacking'. A red box highlights these dropdowns.
- Reproductive toxicity:** Includes fields for 'Reproductive toxicity', 'Specific effect', 'Route of exposure', and 'Effects on or via lactation'. The 'Reason for no classification' dropdown for 'Reproductive toxicity' is set to 'data lacking'.
- Germ cell mutagenicity:** Includes 'Hazard statement', 'Reason for no classification', and 'Route of exposure'. The 'Reason for no classification' dropdown is set to 'data lacking'.
- Carcinogenicity:** Includes 'Hazard statement', 'Reason for no classification', and 'Route of exposure'. The 'Reason for no classification' dropdown is set to 'data lacking'.

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 TCC stage. For these and other hazard classes/differentiations, you are also advised to indicate the "Route of exposure", where available.

-  In keeping with the rules imposed under the CLP regulation (GHS), the field "Affected organs" is compulsory to pass the completeness check if the substance has been classified STOT-single or STOT-repeated.
-  If the affected organ is unknown, indicate "unknown" in the free text field "Affected organs".

**Figure 30: Affected organs**

The image shows two sections of a data entry form. The top section is titled "Specific target organ toxicity - single" and contains fields for "Specific target organ toxicity - single", "Hazard statement" (H371: May cause damage to...), "Reason for no classification", "Affected organs" (kidneys), and "Route of exposure" (Oral). The bottom section is titled "Specific target organ toxicity - repeated" and contains fields for "Specific target organ toxicity - repeated", "Hazard statement" (H373: May cause damage to...), "Reason for no classification", "Affected organs" (liver), and "Route of exposure" (Oral). Red boxes highlight the "Affected organs" and "Route of exposure" fields in both sections.

#### 4.2.2.4. Block "Specific concentration limits"

In case specific concentration limit(s) apply to some of your classification(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 indicate the relevant "Hazard categories" (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 TCC stage.

**Figure 31: Specific concentration limits**

The image shows a form titled "Specific concentration limits". It has a "Concentration range (%)" field with a dropdown set to ">" and a text input containing "10". Below this is a section titled "Hazard categories" which contains a sub-section "Expl. Div. 1.1" with a text input field containing "Expl. Div. 1.1". Red boxes highlight the "Concentration range (%)" field and the "Expl. Div. 1.1" field.

#### 4.2.2.5. 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**

The screenshot shows a form titled "Environmental hazards" with three rows of classification options. Each row has three columns: "Hazard category", "Hazard statement", and "Reason for no classification".

- Row 1:** "Hazardous to the aquatic environment (acute/short-term)". "Hazard category" is "Aquatic Acute 2", "Hazard statement" is "H401: Toxic to aquatic life.", and "Reason for no classification" is empty.
- Row 2:** "Hazardous to the aquatic environment (long-term)". "Hazard category" and "Hazard statement" are empty, and "Reason for no classification" is "data lacking".
- Row 3:** "Hazardous to the ozone layer". "Hazard category" and "Hazard statement" are empty, and "Reason for no classification" is "data lacking".

Below the rows, there are two input fields: "M-Factor acute" with the value "1" and "M-Factor chronic" with the value "10".

- 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/web/guest/support/dossier-submission-tools>.

#### 4.2.2.6. 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".

- In the case where there is no appropriate hazard statement(s) for your substance in the "Hazard statements" drop-down list, you may instead provide a "CLP supplemental hazard statement" under "Additional labelling requirements".

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

Figure 33: Labelling for IUCLID 5 section 2.1

The screenshot displays the 'Labelling' section of the IUCLID 5 interface. It is organized into several sections, each with a title bar and a list of items with management icons (up, down, left, right, add, delete).  
1. **Signal word**: A dropdown menu with 'Danger' selected.  
2. **Hazard pictogram**: A list containing 'GHS01: exploding bomb'. Below the list, a 'Hazard Pictogram' field shows the exploding bomb symbol, and a 'Code' field contains 'GHS01: exploding bomb'.  
3. **Hazard statements**: A list containing 'H200: Unstable explosives.'. Below the list, a 'Hazard statement' field contains 'H200: Unstable explosives.', and an 'Additional text' field is empty.  
4. **Precautionary statements**: A list with one empty entry.  
5. **Additional labelling requirements**: A list containing 'CLP supplemental hazard statement'. Below the list, a 'CLP supplemental hazard statement' field is empty, and an 'Additional text' field is empty.

### 4.2.3. Section 2.2 - DSD - DPD

#### 4.2.3.1. 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 information must be provided for all the endpoints and at least one "Classification" field must be filled in (Figure 34). Note that the "Reason for no classification" is pre-set to "Data lacking" by default.

**Figure 34: "Annex 1" status - Classification entry fields**

Endpoint	Classification	Reason for no classification
Explosiveness		data lacking
Oxidising properties		data lacking
Flammability	F; R11 Highly flammable; Highly flammable	
Thermal stability		data lacking
Acute toxicity		data lacking
Acute toxicity - irreversible damage after single exposure		data lacking
Repeated dose toxicity		data lacking
Irritation / Corrosion		data lacking
Sensitisation		data lacking
Carcinogenicity		data lacking
Mutagenicity - Genetic Toxicity		data lacking
Toxicity to reproduction - fertility		data lacking
Toxicity to reproduction - development		data lacking
Toxicity to reproduction - breastfed babies		data lacking
Environment		data lacking

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**

Endpoint	Classification	Reason for no classification
Explosiveness		data lacking
Oxidising properties		data lacking
Flammability	F; R11 Highly flammable; Highly flammable	
Thermal stability		data lacking
Acute toxicity		data lacking
Acute toxicity - irreversible damage after single exposure		data lacking
Repeated dose toxicity		data lacking
Irritation / Corrosion		data lacking
Sensitisation		data lacking
Carcinogenicity		data lacking
Mutagenicity - Genetic Toxicity		data lacking
Toxicity to reproduction - fertility		data lacking
Toxicity to reproduction - development		data lacking
Toxicity to reproduction - breastfed babies		data lacking
Environment		data lacking

#### 4.2.3.2. 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 (Figure 36).


Figure 36: Risk phrases

The screenshot shows the 'Labelling' section of the IUCLID 5 interface. It includes three main fields: 'Indication of danger' with 'T - toxic', 'Risk phrases' with 'R25 - toxic if swallowed', and 'Safety phrases' with 'S36/37 - wear suitable protective clothing and gloves'. The 'Risk phrases' field is highlighted with a red border. Each field has a set of control icons (up/down arrows, plus, minus, and delete) on the right side.

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

#### 4.2.4. Section 2.3 – PBT assessment

Section 2.3 on the PBT assessment is a new section that has been introduced in IUCLID 5.4. It consists of an endpoint summary, and endpoint study records. Although the new fields related to the PBT assessment are not currently subject to TCC, registrants of tonnages above 10 tonnes are encouraged to complete them already now in the best possible manner with information from the CSR. This way you may avoid updating your dossier at a later stage.

 If you are required to provide a CSR, then in order for your dossier to be accepted for processing, i.e. pass the Business Rules check, at least an endpoint summary has to be created (by right clicking on the section number) and a choice has to be made in the drop-down list "PBT assessment: overall result". If "PBT assessment does not apply" is selected, a justification should be provided in the free text field. PBT assessment is currently not subject to TCC.

The above rule applies also to member registrants who are required a CSR and for whom the lead is not providing it on their behalf.

### 4.3. Section 3 - Manufacture, use and exposure

This chapter contains information on how to provide data in IUCLID 5 on the technological processes used, estimated quantities, site(s), information on mixtures, life cycle description, uses advised against and exposure. Each topic will be presented in a separate chapter.

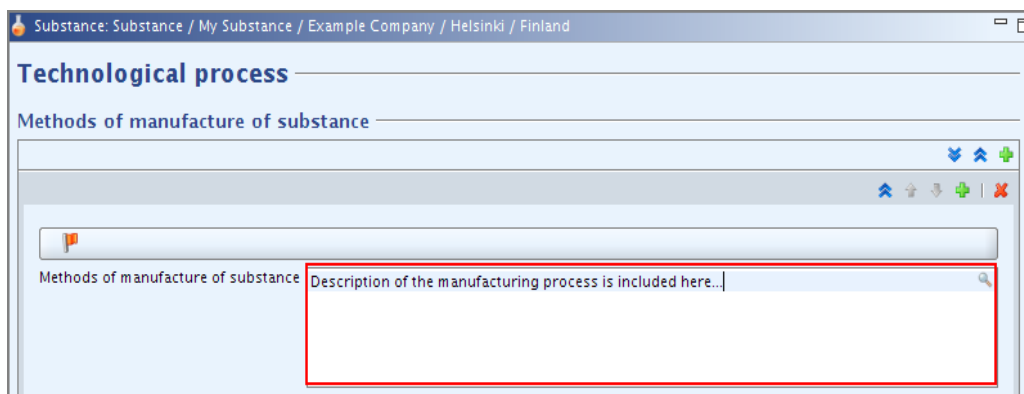
#### 4.3.1. Section 3.1 - Technological process

Following the requirement of section 3.2 of Annex VI of REACH, when a standard tonnage



band is registered and the "Role in supply chain" is (also) "Manufacturer" in section 1.1, then a brief description of the manufacturing process must be provided in the field "Methods of manufacture of substance" (Figure 37). If several blocks are created in this section, all of them have to be completed.

**Figure 37: Entry field Methods of manufacture of substance**





#### 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) that is subject to registration, per calendar year of the registration (Annex VI of REACH, section 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 IUCLID 5 section 3.2 "Estimated quantities".

It will be checked that as a minimum the fields "Year" and "Total tonnage" (manufactured and/or imported) are completed ( Figure 38). In rare cases where the tonnage fields could not be filled in, explanatory text must be provided in the field "Remarks".

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

 The fields under "Total tonnage" should include the information on 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 chapters 2.2.6 "Calculation of the volume to be registered" and 5.2.3.1 "How to report the tonnage" found in the "Guidance on registration" available at:  
<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach>.

**Figure 38: Estimated quantities and year**

**Estimated quantities**

2009

Year

**Total tonnage (tonnes/year)**

Manufactured

Imported

Tonnage directly exported

**Details on tonnages (tonnes/year)**

Tonnage for own use

Tonnage used as intermediate under strictly controlled conditions (transported)

Tonnage used as intermediate under strictly controlled conditions (on-site)

Tonnage used for research purposes

Tonnage imported in articles

Tonnage in produced articles

Remarks

2010

2011

In addition to these rules, it is also recommended to fill in the fields under "Details on tonnages".



#### 4.3.2.1. Special considerations for intermediate registrants

Please note that uses of intermediates for which strictly controlled conditions in the meaning of REACH Articles 17 and 18 cannot be demonstrated, should be reported as any other use in a full registrations (REACH Article 10) in both IUCLID sections 3.2 (Estimated quantities) and 3.5 (Life Cycle description) and should also be accounted for in the exposure assessment and risk characterisation in the Chemical Safety Report. Hence, the fields "Tonnage used as intermediate under strictly controlled conditions (transported)" and "Tonnage used as intermediate strictly controlled conditions (on-site)" in IUCLID section 3.2 should only be filled with the tonnage of the intermediate used under the conditions as set out in Articles 17 and 18.

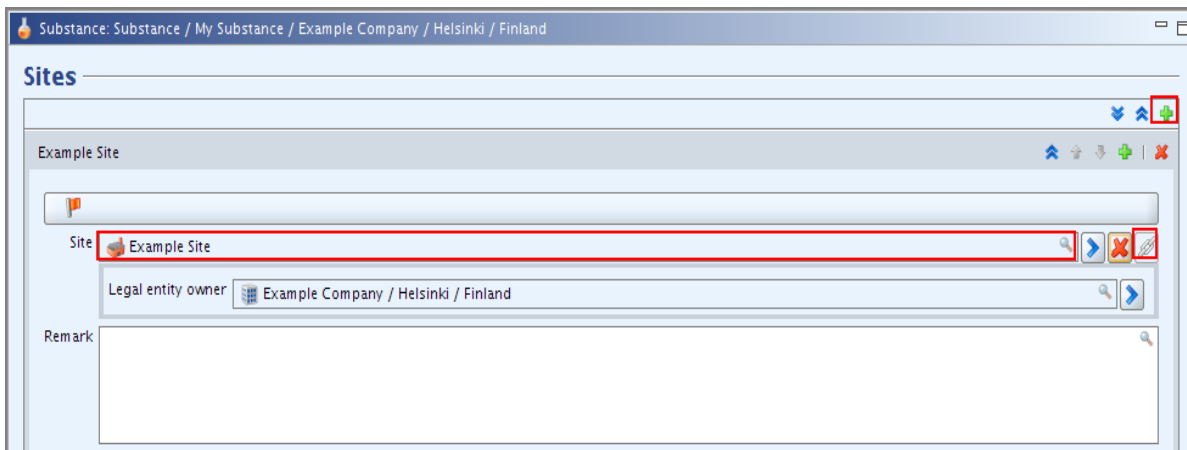
Registrants who wish to report both uses requiring a full registration (Article 10) and uses of intermediates under Articles 17 and 18, are advised to submit a combination dossier. Only in this case they are expected to report a tonnage for use as intermediate in IUCLID section 3.2 and, additionally, are allowed to exclude the intermediate tonnage under strictly controlled conditions from the exposure assessment. The tonnages reported for each use in IUCLID section 3.5 should be consistent with the estimated quantities in IUCLID section 3.2 and should not exceed the tonnages in the dossier header (tonnage bands) for both the tonnage requiring a full registration (Article 10) and the isolated intermediate tonnage.

### 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.

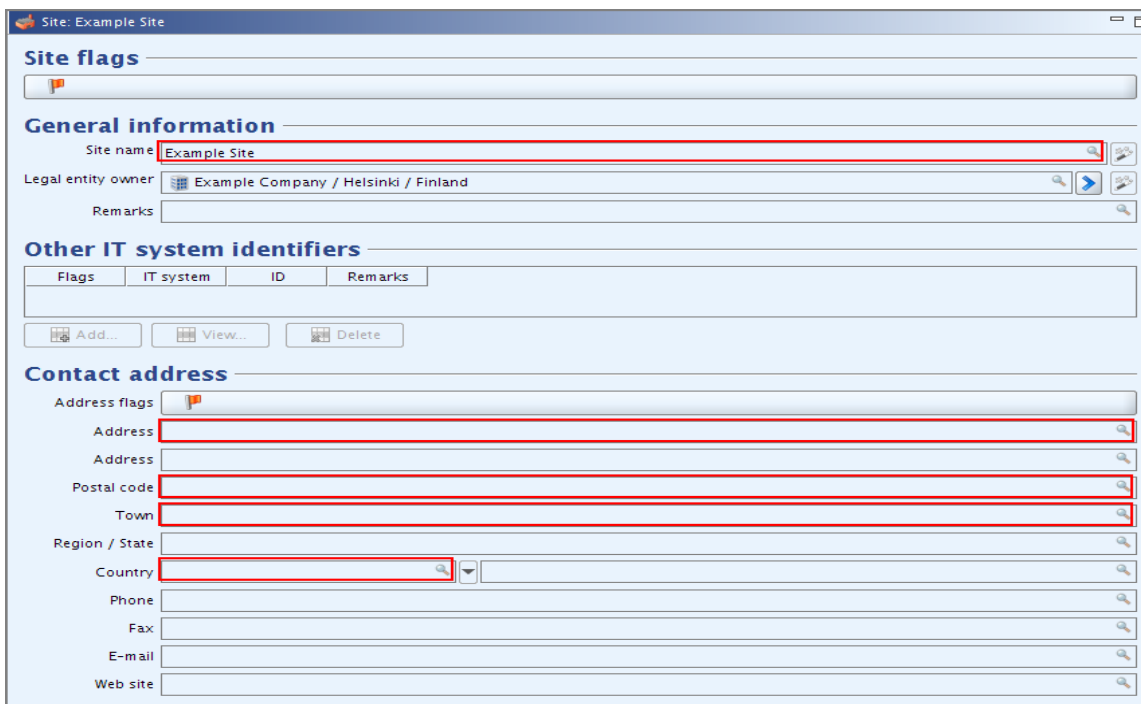
To provide a site, a new block should be created in section 3.3 by clicking on the green cross button  (Figure 39). Every created site block must have a site linked to it. To do so one should click on the chain button  (Figure 39).

**Figure 39: Site entry field**



Each created site block must be complete, i.e. contain a linked site with a complete contact address. The following fields in the Contact address must be filled in: "Site name", "Address", "Postal code", "Town" and "Country" (Figure 40).

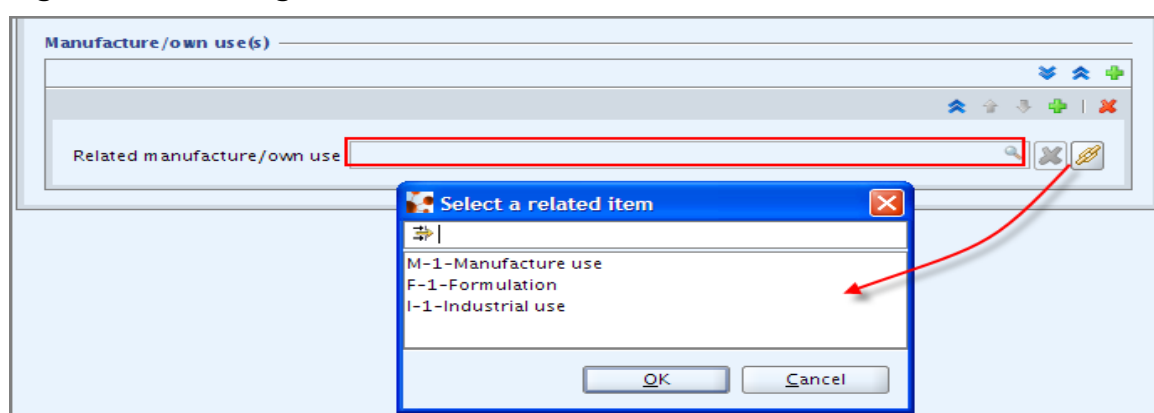
**Figure 40: Contact address**




In addition, for all registration dossiers, if "Sites" is provided, then each site must be linked under "Manufacture/own use(s)" in section 3.3 to at least one use identified in section 3.5. Only uses reported in the tables "Manufacture", "Formulation" and "Uses at industrial sites" can be related to a site (Figure 41).

If you indicated in IUCLID 5 section 1.1 that your "Role in the supply chain" is (also) "Manufacturer", then you must provide at least one site related to the manufacture of the substance in section 3.3. To indicate a site as manufacture site, you must create a link from "Manufacture/own use(s)" to at least one reported manufacture in the table "Manufacture" of section 3.5. Links to the table "Manufacture" are identified with the letter "M" (Figure 41).

**Figure 41: Linking the uses**



**!** If the box "Manufacturer" is ticked in IUCLID 5 section 1.1 "Identification", then at least one manufacture site must be provided by linking to a manufacture use in section 3.5 (Figure 41).

**!** Special note for PPORD dossiers: if the "Role in the supply chain" in section 1.1 contains "Manufacturer", then at least one site must be provided in section 3.3. Every site block must have a site linked to it. To do so one should click on the chain button  (Figure 39). For each site the fields "Address", "Postal code", "Town" and "Country" must be filled in (Figure 40). The block "Manufacture/own use(s)" is not subject to TCC in case of a PPORD dossier.

For substances/dossiers migrated from an older version of IUCLID 5 (version 5.3 or older), the migrated values in the heading of the block "Manufacture/own use(s)" ("Production site", "Production/Use site" and "Use site") are also valid. Please note, that in case these migrated values are edited, they automatically get removed from your IUCLID 5.4 dataset and new uses need to be linked to that block according to the instructions above (Figure 41).

Note that in IUCLID 5, sites are connected to legal entities. If you change the legal entity in section 1.1 "Identification" of the substance dataset, any site(s) linked in section 3.3 that belonged to that legal entity will be removed from the substance dataset. After changing the legal entity in section 1.1, you need to go to section 3.3 and manually link the appropriate sites of the new legal entity.

#### 4.3.4. Section 3.4 - Information on mixtures

The information in section 3.4 is recommended to be filled in if the substance is used in the preparation of mixtures. Section 3.4 will not be checked for completeness.

#### 4.3.5. Section 3.5 - Life Cycle description

This chapter provides information on the identified uses 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). In IUCLID 5 this translates to that in section 3.5 "Life Cycle description" at least one use must be described in any of the five following tables of this section: "Manufacture", "Formulation", "Uses at industrial sites", "Uses by professional workers", and/or "Consumer uses". Each use described must be complete. The minimum requirements for completeness for the respective tables vary as detailed below, and in Figure 42:

- For a complete row in the table "**Manufacture**" at least the fields "Manufacture name" and "Process Category" must be filled in. If your "Role in the supply chain" in section 1.1 is "Manufacturer", at least one of your uses must be described here;

- For a complete row in the table "**Formulation**" at least the fields "Identified Use name", "Process Category" and "Technical function of the substance during formulation" must be filled in. In case that the "Technical function..." field could not be completed, a description of the function of the substance must be provided in the field "Remarks" of that row;


- For a complete row in the table "**Uses at industrial sites**" at least the fields "Identified Use name", "Process Category" and "Technical function of the substance" must be filled in. In addition, the fields "Environmental release category" and "Subsequent service life relevant for that use?" should be provided, but if unavailable, the field "Sector of end use" must be filled in. In case that the "Technical function..." field could not be completed, a description of the function of the substance must be provided in the field "Remarks" of that row;

- For a complete row in the table "**Uses by professional workers**" at least the fields "Identified Use name", "Process Category" and "Technical function of the substance" must be filled in. In addition, the fields "Environmental release category" and "Subsequent service life relevant for that use?" should be provided, but if unavailable, the field "Sector of end use" must be filled in. In case that the "Technical function..." field could not be completed, a description of the function of the substance must be provided in the field "Remarks" of that row;

- For a complete row in the table "**Consumer Uses**" at least the fields "Identified Use name" and "Technical function of the substance" must be filled in. In case that the "Technical function..." field could not be completed, a description of the function of the substance must be provided in the field "Remarks" of that row.



At least one use must be described in any of the five following tables of section 3.5: "Manufacture", "Formulation", "Uses at industrial sites", "Uses by professional workers", and/or "Consumer uses".

 If the box "Manufacturer" is ticked in section 1.1 "Identification", then at least one Manufacture use must be provided in section 3.5 (Figure 42).

**Figure 42: Information on identified uses**

Manufacture										
Flags	Manufacture num...	Manufacture name	Tonnage ...	Number of...	Environmental ...	Process Category	Exposure scen...	Use coverage ...	Remarks	

Formulation													
Flags	Identified Use num...	Identified Use name	Brief descr...	Tonnage ...	Number ...	Env...	Process Category	Product	Technical function ...	Substanc...	Exposure ... a	Use coverag...	Remarks


Uses at industrial sites															
Flags	Identified Use num...	Identified Use name	Brief descr...	Tonnage ...	Number ...	Environmental Release...	Process Category	Produc...	Sector of end use	Technical function ...	Substance...	Subsequent service life...	Link...	Exposure ... Use...	Remarks

Uses by professional workers														
Flags	Identified Use num...	Identified Use name	Brief descr...	Tonnage ...	Environmental Release...	Process Category	Product Cat...	Sector of end use	Technical function ...	Substance s...	Subsequent service life ...	Link to the ...	Exposure ... Use coverage ...	Remarks


  

Consumer Uses												
Flags	Identified Use num...	Identified Use name	Tonnage of ...	Environmen...	Product Cat...	Technical function of the substance	Substance suppl...	Subsequent...	Link to the ...	Exposure scenario...	Use coverage in CSR...	Remarks

 In the specific case that the box "Downstream user" is ticked in section 1.1 "Identification", then at least one of your uses must be described in the table "Article service life" and identified as minimum by its "Service life name" (Figure 43).

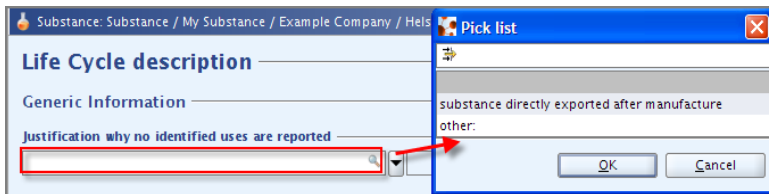
**Figure 43: "Article service life"**

Article service life														
Flags	Service life num...	Service life name	Tonnage ...	Article used by	Article category ...	Further descriptio...	Exposure ...	Environmental ...	Process Category	Typical concentration	Technical function ...	Exposure scenario ...	Use coverage ...	Remarks

-  When completing this section, please note the following:
- If "other:" is selected in any of the section 3.5 drop-down lists then the adjacent free text field must be filled in.
  - If there are no uses identified, a selection must be made in the drop-down list "Justification why no identified uses are reported" (Figure 44). Please note, that this option is not applicable in case you indicated in IUCLID 5 section 1.1 that your "Role in the supply chain" is (also) "Manufacturer" or "Downstream user".
  - 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 "Consumer Uses" then both rows have to be complete according to the rules described above).

- The field "Subsequent service life relevant for that use?" is filled in by default with a "yes". Therefore, you should change this value appropriately.

**Figure 44: Justification why no identified uses are reported**



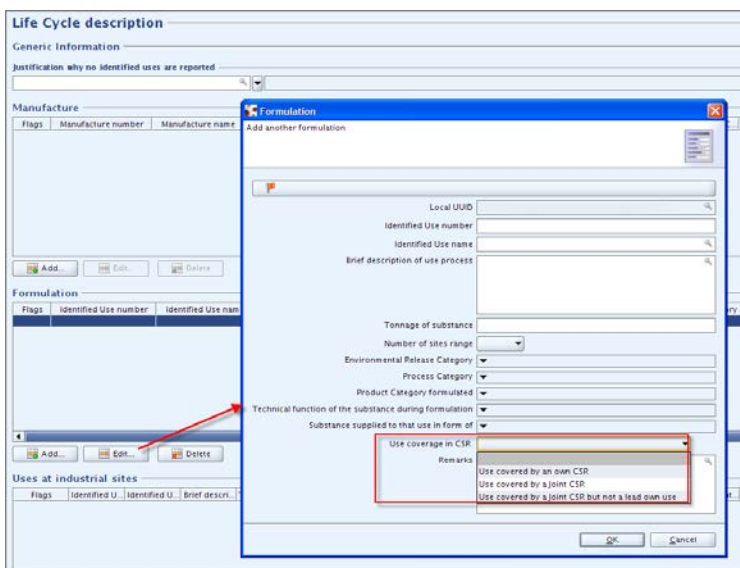
For further instructions on how to report uses for individual registrants, please see Annex 5 of the present document.

#### 4.3.5.2. Reporting uses for joint submission

REACH allows the joint submission of Chemical Safety Reports, which poses challenges for the transparent reporting of uses in the technical dossier. In particular, IUCLID 5.3 provided limited functionality to discriminate between the uses of the lead registrant and the member uses reported by the lead registrant, because of their inclusion in the joint Chemical Safety Report.

IUCLID 5.4 alleviates this deficiency, by adding the field "Use coverage in CSR" in Life Cycle description in section 3.5 (Figure 45). The appropriate use of this field allows correct reporting of all uses and, although it is currently outside the scope of the TCC, it is highly recommended that all registrants use this field correctly. This is particularly important for lead registrants reporting the use of intermediates registered under REACH Articles 17 and 18, but at the same time providing a joint Chemical Safety Report to cover members that report other uses (requiring a full registration under Article 10).

**Figure 45: Section 3.5 of IUCLID 5.4, with focus on the "Use coverage in CSR" that is available in all six life cycle description tables**





- ! For further instructions on how to report uses for lead or member registrants, please see Annex 5 of the present document.

#### 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 5 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" of corresponding row.

#### 4.3.7. Section 3.7 - Exposure scenarios, exposure and risk assessment

During the migration to IUCLID version 5.4, the information previously stored in section 3.7 "Waste from production and use" has been transferred to a html file and saved as an attachment to the substance dataset (Figure 46).

**Figure 46: Waste from production and use (migrated information)**



The information on waste management should now be included either in the Chemical Safety Report that is attached to IUCLID 5 section 13 or, if a CSR is not required, as a report in section 13 (Figure 63).

##### 4.3.7.1. Sections 3.7.1 and 3.7.2

In IUCLID 5.4 new sections have been introduced under section 3 to capture in a structured way the information on Exposure scenarios and local assessment.

Although these sections ("Exposure scenarios and local assessment" and "Environmental assessment for aggregated sources") are currently not checked for completeness, the registrants are encouraged to fill them in already providing as much information as possible. This way you may avoid updating your dossier at a later stage.

##### 4.3.7.2. Sections 3.7.3 – Generic exposure potential

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 in section 3.7.3.

The information provided in section 3.7.3 is currently not checked for completeness.

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

### 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 5 Section 4 "Physical and chemical properties"
- IUCLID 5 Section 5 "Environmental fate and pathways"
- IUCLID 5 Section 6 "Ecotoxicological information"
- IUCLID 5 Section 7 "Toxicological information"
- IUCLID 5 Section 8 "Analytical methods"

The particular studies that are required in a dossier are dependent on the type of registration and on the tonnage band of the dossier (Annex 1). Once you have determined which studies need to be provided in the dossier, the content of each study must be filled in. 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 information requirement corresponding to the tonnage band and type of dossier, at least one (robust) study summary should be provided. Such studies should be marked with the purpose flag "Key study".

Instead of this key study, the information requirement can also be satisfied via a testing proposal or via an adaptation listed in REACH Annexes VII to XI.

For each (robust) study summary, the same fields have to be provided 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.

### 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 5.

- 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 a 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 an endpoint study record, and a justification must be entered in the appropriate field. In this case, no further information should be included in the same endpoint study record.
- Testing proposal: If, for the information requirements in Annexes IX and X, a testing proposal is submitted instead of a study result then, as a minimum, information about the guideline/method and the time schedule must be provided in the designated fields of the endpoint study record. You are also recommended to provide information in the endpoint study record about the test type, test material, test animals and the administration route.
- Weight of evidence and Key study: 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 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. section 8.6.1 of Annex VIII of REACH requires a short term repeated dose toxicity which could be provided 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 in IUCLID 5 could be used to meet more than one REACH data requirement (e.g. see IUCLID 5 section 7.3.1 "skin irritation/corrosion" in Annex 1 of this manual). Therefore one IUCLID 5 section could correspond to two or three REACH Annex numbers and one REACH Annex number could correspond to two or three IUCLID 5 sections.
- If one IUCLID 5 section corresponds to two or three REACH Annex numbers then one endpoint study record in this IUCLID 5 section could be enough to cover the two or three REACH requirements.




For dossiers above 10 tonnes: at least 2 endpoint study records must be provided in IUCLID 5 section 7.6.1.


- If one REACH Annex number corresponds to two or three IUCLID 5 sections then one endpoint study record in one of these IUCLID 5 sections is enough to cover this REACH requirement.

 For dossiers above 10 tonnes: for the specific case of the endpoint acute toxicity three IUCLID 5 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").

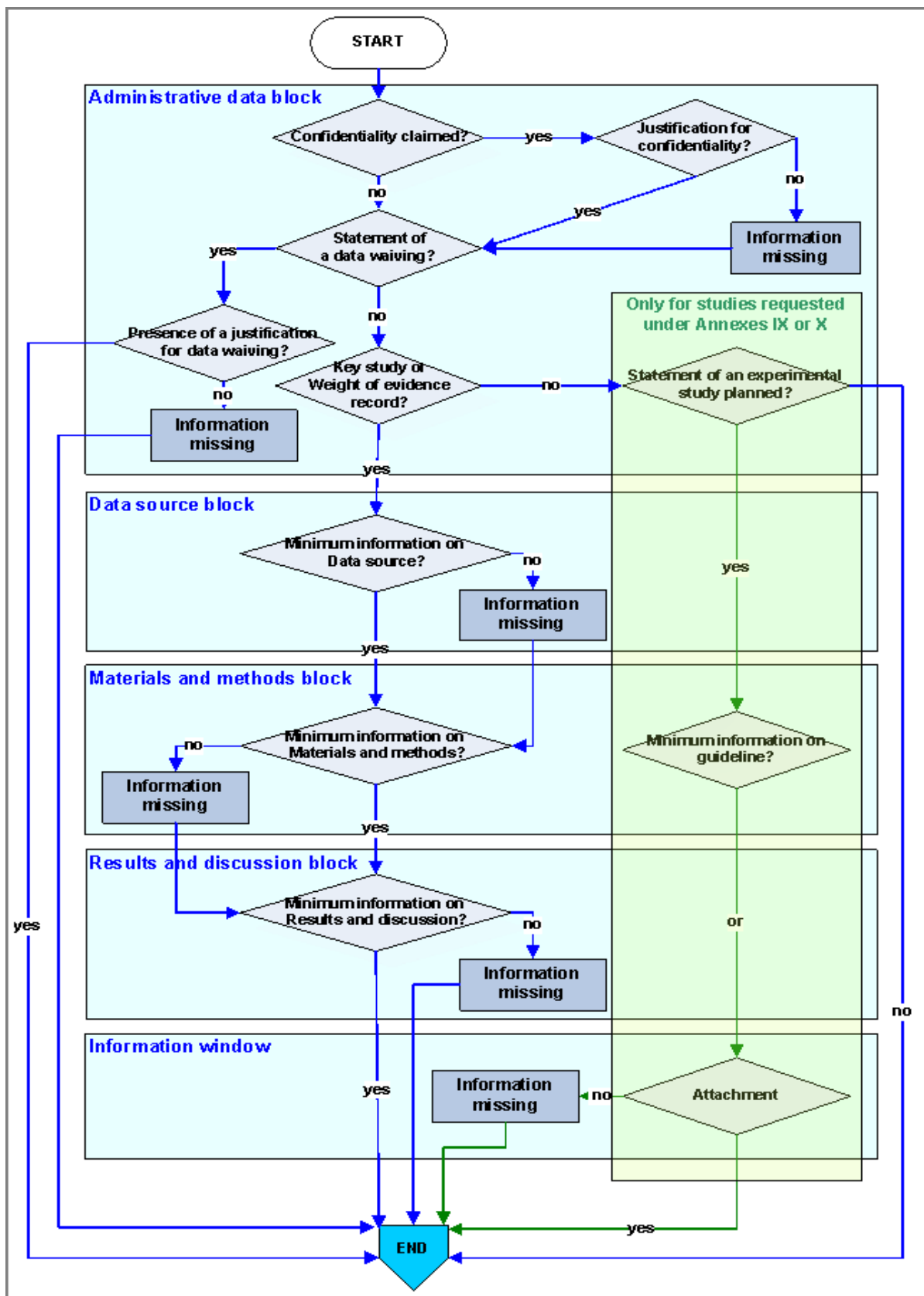
In cases where more than one study is provided for one endpoint then it is recommendable to create an endpoint summary to summarise and highlight the main points of your endpoint study records. These endpoint summaries can be created by making a right click on the specific IUCLID 5 endpoint (endpoint summaries are indicated with a blue symbol ). However, 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 plug-in can only be accomplished if the appropriate endpoint summaries are provided.

The approach described above results in the following practical scheme (Figure 47).

Figure 47: 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 TCC. However, for all endpoint study records not indicated as data waivers, all the other fields under "Data source", "Materials and methods" and "Results and discussions" 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", please refer to section 5.2.4 "Information requirements on intrinsic properties" found in the "Guidance on registration" available at:  
<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach>.

If handbook data are used in an endpoint study record and 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 is made in the "Data waiving" drop-down list and a justification is written in the "Justification for data waiving" free text field), it is recommended to arrange it in such a way that it appears as the first record of the respective endpoint 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 drop-down list "Data waiving" then the only further field that should be filled-in in the endpoint study record is the field "Justification for data waiving" (Figure 48).

**Figure 48: Drop-down list and the justification field for data waiving**

The screenshot shows a software interface with a tabbed menu at the top: 'Administrative Data', 'Data source', and 'Materials and methods'. Under 'Administrative Data', there are sub-tabs: 'all fields', 'Results and discussions', 'Overall remarks, attachments', and 'Applicant's summary and conclusion'. The 'Administrative Data' section contains several fields: 'Purpose flag', 'Data waiving', 'Justification for data waiving', 'Study result type', 'Reliability', and 'Rationale for reliability incl. deficiencies'. A 'Pick list' dialog box is open over the 'Data waiving' field, displaying a list of options: 'study technically not feasible', 'study scientifically unjustified', 'exposure considerations', and 'other justification'. The 'Data waiving' field and the 'Pick list' dialog are highlighted with red boxes.

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

The approach to be followed in this case is:

- Purpose flag: empty
- Data waiving: a selection must be made in the drop-down list. ("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
- No other fields should be filled in in the endpoint study record.

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

This last introductory paragraph states that "When, for certain endpoints, information is not provided for other reasons than those mentioned in column 2 of this Annex [VII, VIII, IX or X] 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
- Study result type: empty
- Reliability score: empty
- No other fields should be filled in in the endpoint study record.

## **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.

In this case, an endpoint study record should be created for each of the existing data/study and the record(s) should be completed as follow:

- Purpose flag: "key study" or "weight of evidence"
- 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 discussions" must be filled in as described for study results (chapter 4.4.5).

### 2. Weight of evidence

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

- At least two 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 records flagged as "weight of evidence" and a rationale for using this evidence instead of standard testing.

Each data/study which is part of the weight of evidence should be summarised in separate endpoint study record and should be completed as follow:

- Purpose flag: "weight of evidence"
- 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 discussions" must be filled in as described for study results (chapter 4.4.5).

The following 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 by the Technical Completeness Check are unknown or irrelevant.

- Purpose flag: "supporting 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 discussions" should be filled in as much as possible as described for study results (chapter 4.4.5).



For some endpoints/tonnage bands, a certain type of study is expected (e.g. two-generation, long-term, in-vivo...). These specific endpoints are listed at the end of section 4.4.5.3 of this manual). If you intend to omit this type of study using a

weight of evidence approach, you should provide a "Data waiving" endpoint study record with a justification for not submitting this specific study. In addition, all information supporting this data waiving should be submitted in separate endpoint study record(s) flagged as "Weight of evidence" or as "Supporting study".

### 3. QSAR

A QSAR can be used on its own in case but should preferably be used as part of a "weight of evidence" approach. In any case a QSAR results may be used only when they fulfil the conditions listed in REACH Annex XI, 1.3.

The approach to be followed in this case is:

- Purpose flag: "key study" or "weight of evidence"
- Data waiving: empty
- Justification for data waiving: empty
- Study result type: "(Q)SAR"
- Reliability: a reliability score must be selected.
- Other fields in the blocks "Data source", "Materials and methods" and "Results and discussions" must be filled in as described for study results (chapter 4.4.5).
- Additional information: It is also recommended to attach the (Q)SAR model reporting format (QMRF) and the (Q)SAR prediction reporting format (QPRF) to this endpoint study record. Please see "QSARs and grouping of chemicals (Chapter R.6 – Section R.6.1.9 and R.6.1.10)" at <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>.

### 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.

The approach to be followed in this case is:

- Purpose flag: "key study" or "weight of evidence"
- Data waiving: empty
- Justification for data waiving: empty
- Study result type: "experimental study"
- Reliability: a reliability score must be selected.
- Other fields in the blocks "Data source", "Materials and methods" and "Results and discussions" must be filled in as described for study results (chapter 4.4.5).

### 5. Grouping and read-across

If a substance is part of a category then a IUCLID 5 category should be created and included in the dossier. Inherit templates can be used to store the data common to the category.

Endpoint study records in an inherit template linked to a category or directly to the registered substance will be checked for completeness.

Endpoint study records in category member substances will not be checked for



completeness.

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

- Purpose flag: "key study" or "weight of evidence"
- 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: a reliability score must be selected.
- Other fields in the blocks "Data source", "Materials and methods" and "Results and discussions" must be filled in as described for study results (chapter 4.4.5).
- Additional information: It is also recommended to attach the completed "Reporting Format for the analogue approach" or the "Reporting Format for a chemical category" to this endpoint study record or in IUCLID 5 section 13. Please see "QSARs and grouping of chemicals (Chapter R.6 – Section R.6.1.6)" at <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>.

#### **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
- No other fields should be filled in in the endpoint study record.

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

Testing may be omitted based on exposure for REACH Annex VIII (only for sections 8.6 and 8.7) and for REACH Annexes IX and X only if the conditions listed in Annex XI(3) are fulfilled. The approach to be followed in this case is:

- 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
- No other fields should be filled in in the endpoint study record. However the justification and documentation for this 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 49).

**Figure 49: Drop-down list for study result type**

The screenshot shows the 'Administrative Data' section of a software interface. A dropdown menu for 'Study result type' is open, displaying a list of options. The option 'experimental study planned' is highlighted with a red box. Other options include 'experimental result', 'estimated by calculation', 'read-across based on grouping of substances (category approach)', 'read-across from supporting substance (structural analogue or surrogate)', '(Q)SAR', and 'other: no data'. The 'Study result type' field in the background is also highlighted with a red box, and a red arrow points from it to the dropdown menu.

In this case, information must be provided about the time schedule in the field "Study period" (Figure 50).

**Figure 50: Indicated time schedule for a testing proposal**

The screenshot shows the 'Endpoint study record: Long-term toxicity to fish.001' form. The 'Administrative Data' section is visible. The 'Study result type' field is set to 'experimental study planned' and the 'Study period' field is set to '6 months after ECHA's final decision'. Both fields are highlighted with red boxes. The 'Study period' field is also highlighted with a red box.

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" or as an attachment under "Attached background material" (Figure 51).

**Figure 51: Guideline and method used**

The figure shows two screenshots of a software interface. The top screenshot is titled "Endpoint study record: Long-term toxicity to fish.001" and shows the "Materials and methods" section. It includes a "Life stage / endpoint studied" field, a "Test guideline" table with one entry "OECD Guideline 210 (Fish, Early-Life Stage Toxicity Test)", a "Principles of method if other than guideline" field, and a "GLP compliance" field. The bottom screenshot is titled "Overall remarks, attachments" and shows a rich text editor for "Remarks on results including tables and figures", an "Attached background material" table with one entry "Attachment.jpg / 205.4 KB (image/jpeg)", and an "Attached full study report" table.

**Materials and methods**

Life stage / endpoint studied

Test guideline

Qualifier	Guideline	Deviations
	OECD Guideline 210 (Fish, Early-Life Stage Toxicity Test)	

Principles of method if other than guideline

GLP compliance

**Overall remarks, attachments**

Remarks on results including tables and figures

Attached background material

Attached document	Remarks
Attachment.jpg / 205.4 KB (image/jpeg)	

Attached full study report

Attached full study report
----------------------------

#### 4.4.5. Study results

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

##### 4.4.5.1. Block Administrative data

A selection must be made in the drop-down 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-specific, i.e. is based on all records flagged that way for a unique regulatory endpoint.
- 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**

The screenshot shows a web-based form for an endpoint study record. The title bar reads "Endpoint study record: Short-term toxicity to fish.001". The form is divided into two main sections: "Administrative Data" and "Materials and methods".

**Administrative Data section:**

- Purpose flag:** A dropdown menu is set to "key study". To its right are three checkboxes: "robust study summary", "used for classification", and "used for MSDS", all of which are unchecked.
- Data waiving:** A text input field.
- Justification for data waiving:** A larger text input field.
- Study result type:** A dropdown menu is set to "experimental result". To its right is a "Study period" text input field.
- Reliability:** A dropdown menu is set to "1 (reliable w/out restriction)".
- Rationale for reliability:** A larger text input field.

**Materials and methods section:**

- Test guideline:** A table with three columns: "Qualifier", "Guideline", and "Deviations". The table is currently empty.

At the bottom of the form, there are several action buttons: "Add...", "Edit...", "Delete", "Move up", and "Move down".

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 made in the drop-down list "Purpose flag" will not be checked for completeness.

For instance if you submit twenty endpoint study records for an endpoint, and 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 5 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 then this section would not fail the completeness check.

In addition, a selection must be made in the pick-list "Study result type" (experimental result, estimated by calculation, read across, QSAR) and in the pick-list "Reliability" (1, 2, 3, 4 or other) (Figure 52). If "other" is selected in any of the drop-down lists then the adjacent field must be filled in.

- ! It is also recommended to make a selection in the pick-lists "Study result type" and "Reliability" for all endpoint study records with a selection made in the "Purpose flag", even for "Supporting study" and for IUCLID 5 sections not required

in REACH Annexes VII to X.

The next chapters provide instructions for completing the blocks "Data source", "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 this reference table as much as possible. Many combinations are considered as a complete reference, but as a minimum the following fields are required:

- The "Year" or the "Report date" must always be provided.
- If the data is from a literature source, the field "Bibliographic source" must be provided.
- If the data is from a testing laboratory, the field "Testing laboratory" must be completed. The full address of the testing laboratory has to be provided including city and country. In addition, either "Report no.", "Company study no" or "Title" has to be provided.
- If the data is from a company, either the field "Report no." or the field "Company study no." must be filled in. In addition, information should be provided in the fields "Author", "Owner company" and/or "Title" (Figure 53).

**Figure 53: Entry fields for reference of the data source**

Reference type	Author	Year	Title	Bibliographic s...	Testing laborat...	Report no.	Owner company	Company stud...	Report date
	Jones, M.	1985	The effects of Chemical X on		Testing Lab	012345-67	Tester		1985-11-21

**!** Note that the CSR plug-in 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 the relevant records. If no individuals are cited as authors, enter the name of the company or organisation or "Anon. " as appropriate.

In addition, a value must be selected in the field "Data access" (Figure 54). If you select "other" then the adjacent field must be filled in.

**Figure 54: Entry field for Data access**

Endpoint study record: Density.001

Detail level: Administrative Data | Data source | Materials and methods

all fields | Results and discussion | Overall remarks, attachments | Applicant's summary and conclusion

**Data source**

Reference

Reference type	Author	Year	Title	Bibliographic s...	Testing laborat...	Report no.	Owner company	Company stud...	Report date
	Jones, M.	1985	The effects of Chemical X on ...		Testing Lab	012345-67	Tester		1985-11-21

Add... Edit... Delete Move up Move down Select Insert

Data access

data submitter is data owner

Data protection claimed

Cross-reference to same study

#### 4.4.5.3. Block "Materials and methods"

##### Guideline

A check will be carried out to ascertain 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", since there might be cases where a specific method will have to be developed for a substance (Figure 55). If you add several rows to the "Test guideline" table then you must select guideline for each of these rows. If "other guideline" is selected in the field "Guideline" then the adjacent field must be filled in.

**Figure 55: Entry fields for other guidelines**

Endpoint study record: Long-term toxicity to fish.001

Detail level: Administrative Data | Data source | Materials and methods

all fields | Results and discussions | Overall remarks, attachments | Applicant's summary and conclusion

**Materials and methods**

Life stage / endpoint studied

Test guideline

Qualifier	Guideline	Deviations
	OECD Guideline 210 (Fish, Early-Life Stage Toxicity Test)	

Add... Edit... Delete Move up Move down

Principles of method if other than guideline OR

GLP compliance

##### GLP

For the endpoint study records that are indicated as "experimental result", "read-across based on grouping of substances (category approach)" or "read-across from supporting substance (structural analogue or surrogate)" in 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. This is done by selecting one of the following options: "yes (incl. certificate)", "yes", "no" or "no data" from the drop-down list "GLP compliance"

Figure 56).

**Figure 56: Entry fields for GLP compliance**

The screenshot shows a software interface for an endpoint study record. The main section is titled 'Materials and methods'. Below this, there are sections for 'Test guideline' (with a table for Qualifier, Guideline, and Deviations), 'Principles of method if other than guideline', and 'GLP compliance'. The 'GLP compliance' dropdown menu is open, showing the following options: 'yes', 'yes (incl. certificate)', 'yes', 'no', and 'no data'. The 'yes' option is currently selected. Below the dropdown, there is a text field with a search icon and a label 'Test material identity'.

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 5 block "Data source" must be filled in (Figure 53).

**!** 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 "Identity of test material same as for substance defined in section 1 (if not read-across)". 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" (by inserting the identifier and the 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**

The screenshot shows the 'Test materials' form. At the top, there is a dropdown menu labeled 'Identity of test material same as for substance defined in section 1 (if not read-across)' with 'yes' selected. Below this is a table titled 'Test material identity' with columns 'Identifier' and 'Identity'. The 'EC number' is '200-200-2'. Below the table are buttons for 'Add...', 'Edit...', 'Delete', 'Move up', and 'Move down'. There is also a 'Test material form' field and a 'Details on test material' section with a search icon and a blue expand/collapse arrow.

- To select "No" in the field "Identity of test material same as for substance defined in section 1 (if not read-across)". In this case either the table "Test material identity" (by inserting the identifier and the identity) or the field "Details on test material" must be filled in (Figure 58).

**Figure 58: Entry fields for test material with "no"**

The screenshot shows the 'Test materials' form with 'no' selected in the identity dropdown. The 'Test material identity' table is highlighted with a red box, showing 'Identifier' and 'Identity' columns. The 'EC number' is '200-200-2'. The 'Details on test material' section is also highlighted with a red box and contains a search icon and a blue expand/collapse arrow.

- In rare cases where a selection in the field "Identity of test material same as for substance defined in section 1 (if not read-across)" would not be relevant then this field should be left 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**

The screenshot shows the 'Test materials' form with the identity dropdown menu blank. The 'Test material identity' table is highlighted with a red box, showing 'Identifier' and 'Identity' columns. The 'EC number' is '200-200-2'. The 'Details on test material' section is also highlighted with a red box and contains a search icon and a blue expand/collapse arrow.



In addition to these general rules for the 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 in any of the drop-down lists 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 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. CO<sub>2</sub>, 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 cannot be completed, explanatory text must be provided under the field "Any other information on results incl. tables". 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. Take care not to confuse the free text fields with the field named "Overall remarks, attachments".

However, it should be kept in mind, that information should primarily be reported in the specific fields of IUCLID 5 for reporting a result and that the 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.

If you add several lines to the table under "Results and discussion" then all of them must be complete.

### 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 one endpoint summary in section 6 "Ecotoxicological information" and another one in section 7 "Toxicological information". Endpoint summaries are created by right clicking on the corresponding sections in the IUCLID 5 section tree. The information provided in these two endpoint summaries will be checked for completeness for all dossiers above 10 tonnes (except for intermediates and PPORD).

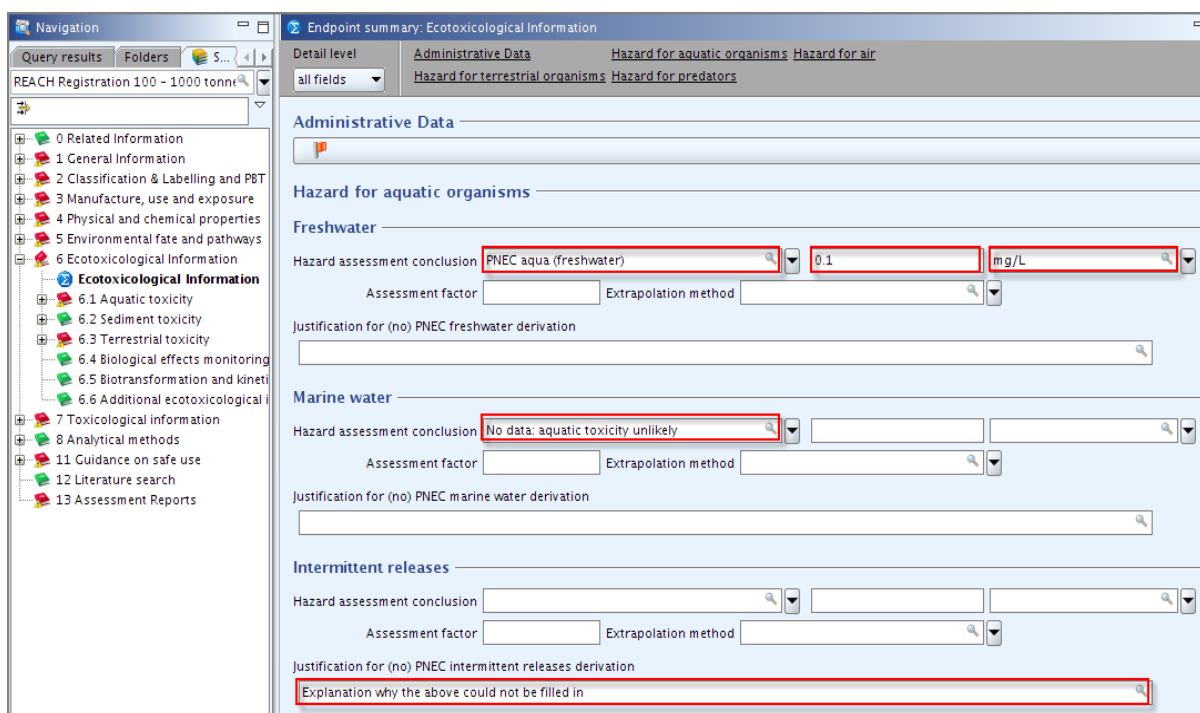
#### 4.4.6.1. PNECs

In the endpoint summary of section 6 "Ecotoxicological information", for each hazard, a selection must be made in the drop-down list "Hazard assessment conclusion". Either a PNEC must be selected and a numerical value and a unit must be provided, or a reason why no PNEC is available must be chosen from that drop-down list.

In the rare case that the above could not be filled in, an explanation must be provided in the field "Justification for (no) PNEC derivation" (Figure 60).

Although TCC does not apply on the new "Hazard for air" section, we recommend you to fill in the related fields if you have these data available.

**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.

For each hazard, a selection must be made in the drop-down list "Hazard assessment

conclusion". Either a DNEL, DMEL or "Other toxicological threshold" must be provided with a numerical value and a unit, or the appropriate reason why no threshold is available must be chosen from that drop-down list.

In case a DN(M)EL was not derived, then a justification must be provided in the field "Justification and comments" or "Discussion"(Figure 61).

Although TCC does not apply on the new "Hazard for the eyes" sections, we recommend you to fill in the related fields if you have these data available.

**Figure 61: Entry fields for DN(M)EL**

#### 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 of section 11:

- "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, 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"
- "Disposal considerations" (since 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) this information should also be provided in the "Disposal considerations" field).



However, specific rules exist for certain dossier types:

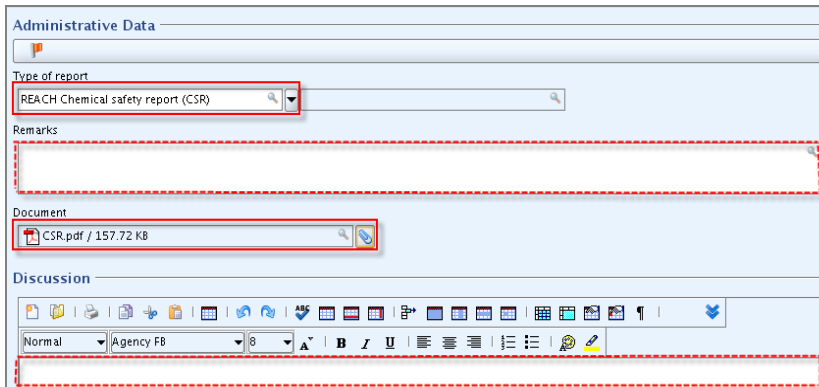
- For joint submissions, the guidance on safe use can be provided jointly or separately (Article 11(1) (paragraph 4)):
  - If the guidance of safe use is provided separately (the lead of the joint submission does not provide the guidance on safe use on behalf of the members), then the member dossiers must contain section 11 "Guidance on safe use".
  - If the guidance on safe use is provided jointly (the lead is providing guidance on safe use on behalf of the members), then the member registrant must tick the corresponding tickbox on the Dossier header indicating that this information is provided by the lead (Figure 65).
- For intermediate dossiers, the rules mentioned above for 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 the section 11, either in the field "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 5 dossier) cannot be provided by lead on behalf of members. Therefore this information needs to be submitted always separately in each intermediate dossier participating as a member of a joint submission.

#### 4.6. Section 13 - Assessment reports

Article 14 requires a chemical safety assessment to be carried out for the substances manufactured or imported at more than 10 tonnes per year. Therefore, at least in one of the assessment reports provided for dossiers above 10 tonnes, the following information is required:


- In the field "Type of report", "REACH Chemical safety report (CSR)" must be selected.
- The CSR must be attached in the field "Document". Alternatively, information on why a CSR was not attached, must be provided in the field "Remarks" or in the field "Discussion", e.g. a justification for not submitting a CSR based on Article 14(2) (Figure 62).

**Figure 62: Entry fields to attach the Chemical safety report (CSR)**



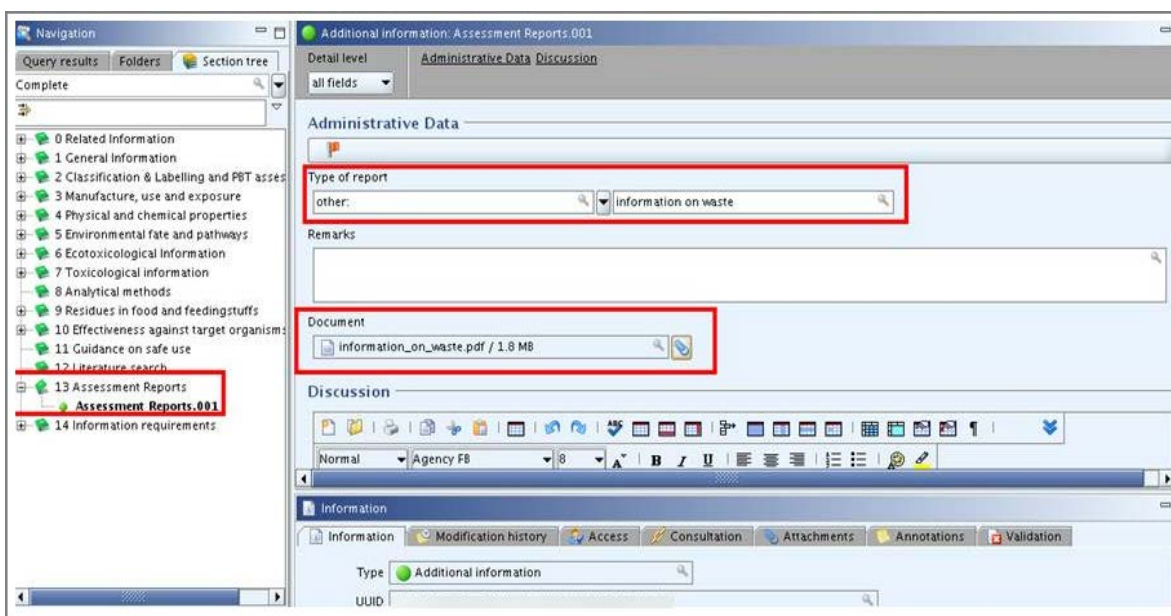
There is a specific rule for member dossiers. For joint submissions the CSR can be provided jointly or separately (Article 11(1), paragraph 4).

- If the lead of the joint submission indicates that the CSR is provided separately then the member dossiers must contain a CSR.
- If the CSR is provided jointly, then the member registrant must tick the corresponding tickbox on the Dossier header indicating that this information is provided by the lead (Figure 65).

 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/web/guest/support/dossier-submission-tools>.


The information on waste management should be included either in the Chemical Safety Report that is attached to section 13 or, if a CSR is not required, as a report in section 13 (Figure 63).


**Figure 63: Report on waste from production and use**




## 4.7. Dossier header

During the IUCLID 5 dossier creation procedure you are requested to enter additional administrative information concerning your dossier (step 6 of the "Dossier creation wizard"). This information will be included in what is called the "IUCLID 5 Dossier header".

 To create a dossier in IUCLID 5, you should start from the IUCLID 5 substance dataset, select the template corresponding to your submission, e.g. REACH Registration 100 - 1000 tonnes, and follow the dossier creation wizard guide. Read carefully the instructions in small print at each step. Then export the dossier and save it on your own computer, 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. whether it is a new registration or an 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" available at:  
<http://echa.europa.eu/web/guest/support/dossier-submission-tools>.

### Joint submission related information

The tickbox "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") (Figure 64).

**Figure 64: Joint submission (lead registrant)**

The screenshot shows the 'Dossier creation wizard' window. The title bar reads 'Dossier creation wizard'. The main text says 'Enter additional administrative information concerning your dossier' and 'Dossier template: REACH Registration 100 - 1000 tonnes'. The 'Type of submission' section has a red box around the checked 'Joint submission' option. Under 'Information provided by the lead on behalf of the member(s)', three checkboxes are present: 'Chemical safety report', 'Guidance on safe use', and 'Review by an assessor', all of which are unchecked. The 'Tonnage band(s) of the lead registrant' section includes a dropdown menu for 'Tonnage band' set to 'Between 10 to 100 tonnes/year', and two empty dropdown menus for 'On-site isolated intermediates tonnage band (REACH Article 17)' and 'Transported isolated intermediates tonnage band (REACH Article 18)'. At the bottom, a progress bar shows 9 steps, with step 7 highlighted. Navigation buttons for '< Back', 'Next >', 'Finish', and 'Cancel' are visible.

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 in dossier creation step 1 ("Member of a joint submission – general case" or "Member of a joint submission – intermediates" as appropriate).

As a member of a joint submission you have to indicate if information is provided by the lead on your behalf ("Chemical safety report", "Guidance on safe use", "Reviewed by an assessor"). The corresponding tickboxes must be ticked as appropriate at step 6 of the Dossier creation wizard and will be checked for completeness (Figure 65).

**Figure 65: Joint submission (member registrant)**

The screenshot shows the 'Dossier creation wizard' window. The title bar reads 'Dossier creation wizard'. The main text says 'Enter additional administrative information concerning your dossier' and 'Dossier template: REACH Registration member of a joint submission – general case'. The 'Type of submission' section is empty. Under 'Information provided by the lead on behalf of the member(s)', three checkboxes are present: 'Chemical safety report', 'Guidance on safe use', and 'Review by an assessor', all of which are unchecked. The 'Tonnage band(s) of the member registrant' section includes a dropdown menu for 'Tonnage band' set to 'Between 10 to 100 tonnes/year', and two empty dropdown menus for 'On-site isolated intermediates tonnage band (REACH Article 17)' and 'Transported isolated intermediates tonnage band (REACH Article 18)'. At the bottom, a progress bar shows 9 steps, with step 7 highlighted. Navigation buttons for '< Back', 'Next >', 'Finish', and 'Cancel' are visible.

## Tonnage band(s)

In the field "Tonnage band(s)..." you 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.

## Specific submissions

In case your submission is an update, then the "Specific submissions" part of the "Dossier header" should be completed. "The submission is an update" tickbox needs to be ticked and the submission number of the previous submission has to be indicated in the corresponding field.

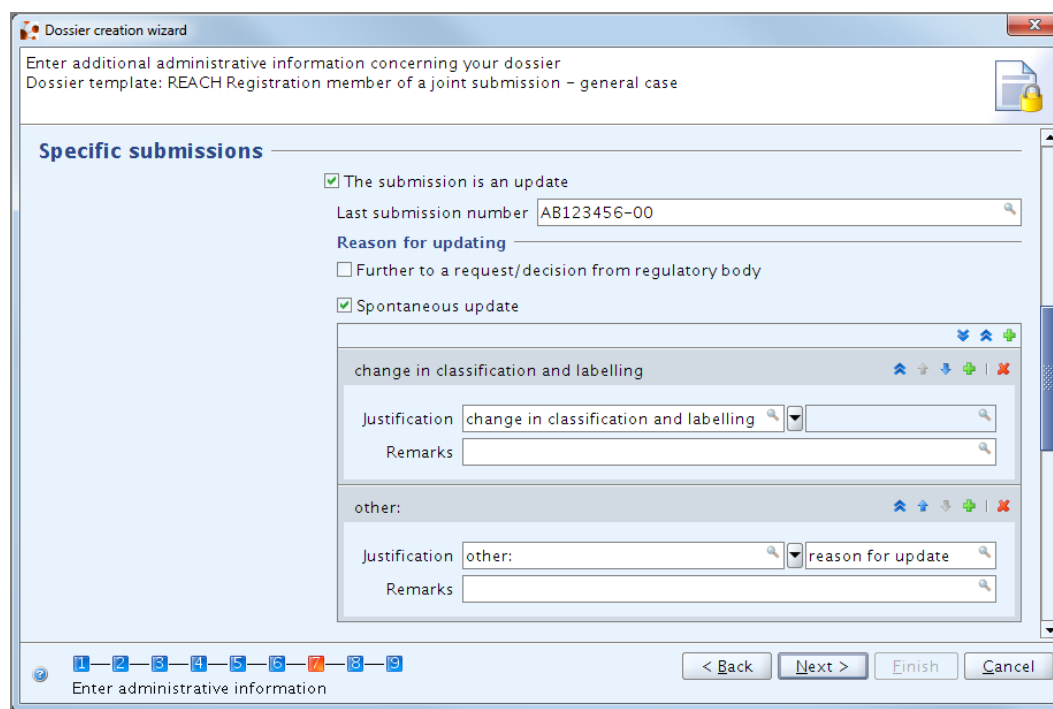
- In case of a **requested update** the tick-box "Further to a request/decision from regulatory body" shall be ticked and the communication/decision number of the document requesting this further information needs to be indicated in the field "Number" (Figure 66).
- In case of a **spontaneous update** the tick-box "Spontaneous update" shall be ticked and an update reason must be chosen from the drop-down list "Justification". If "other:" is chosen then an explanation must be written in the free text field next to it (Figure 67). Please note that Article 22 of REACH foresees that registrants keep their registration dossiers up to date and spontaneously submit new information to ECHA.

Figure 66: Requested update

The screenshot shows the 'Dossier creation wizard' window. The title bar reads 'Dossier creation wizard'. The main content area is titled 'Enter additional administrative information concerning your dossier' and 'Dossier template: REACH Registration member of a joint submission - general case'. The 'Type of submission' section is expanded to show 'Information provided by the lead on behalf of the member(s)' with three unchecked checkboxes: 'Chemical safety report', 'Guidance on safe use', and 'Review by an assessor'. Below this is the 'Tonnage band(s) of the member registrant' section with three dropdown menus: 'Tonnage band' (set to 'Between 10 to 100 tonnes/year'), 'On-site isolated intermediates tonnage band (REACH Article 17)', and 'Transported isolated intermediates tonnage band (REACH Article 18)'. The 'Specific submissions' section has the 'The submission is an update' checkbox checked. The 'Last submission number' field contains 'AB123456-00'. Under 'Reason for updating', the 'Further to a request/decision from regulatory body' checkbox is checked, and a sub-window is open showing a 'Number' field with 'SUB-C-1234567890-00-01/F' and an empty 'Remarks' field. The 'Spontaneous update' checkbox is unchecked. At the bottom, there is a progress bar with 10 steps, and navigation buttons for '< Back', 'Next >', 'Finish', and 'Cancel'.



**Figure 67: Spontaneous update**



### Dossier specific information

Indicate the Phase-in status of your substance by selecting the radio button "Phase-in" or "Non phase-in" (Figure 68).

As a general rule for the "Dossier header", when one of the tickboxes under "Dossier specific information" ("Reviewed by an assessor", "Confidentiality claim on tonnage band", etc.) is selected, then the associated free text fields below the tickbox must be filled in. If a tickbox is ticked, and its associated free text field is empty, this is considered as a TCC failure. In the same manner, if free text is written in any of these fields but the associated tickbox is not ticked, this is also considered a TCC failure.

The tickbox "Reviewed by an assessor" is not compulsory, but if the dossier, or parts of it, have been reviewed by an assessor (in accordance to Article 10 (a) (viii)), it must be indicated here.

The tickbox "**Confidentiality claim on registration number**" has been introduced in the dossier header in IUCLID 5.4 to indicate a confidentiality claim on the registration number. This can be used when the dossier is an initial submission and does not yet have a registration number or an update submission which does not yet have a registration number. This flag needs to be re-introduced every time the dossier is resubmitted if the confidentiality claim is to remain in place (for your convenience we recommend you to include a confidentiality flag also in IUCLID 5 section 1.3, if you wish to keep the registration number confidential in future submissions).

"**Confidentiality claim on registration number**" and "**Confidentiality claim on tonnage band**" and its "Justification" fields only need to be filled in case you want to claim the relevant data 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/web/guest/support/dossier-submission-tools>). Leaving the two tickboxes un-ticked and the free text empty does not lead to a TCC failure.

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

The tickbox "**Fee waiving 1-10 tonnes, complete dossier**" only needs to be filled-in in case you 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. In this case no fee is levied for such registration but it is imperative that the registrant claims the fee waiver when creating the dossier in IUCLID 5 (applicable for both initial and update registrations). If you tick this specific tickbox it is not compulsory to fill its "Justification" field below. Leaving the tickbox un-ticked does not lead to a TCC failure.

**Figure 68: Dossier specific information**

Dossier creation wizard

Enter additional administrative information concerning your dossier  
Dossier template: REACH Registration member of a joint submission - general case

**Dossier specific information**

Phase-in  
 Phase-in  Non phase-in

Reviewed by an assessor

Remarks

Document

Confidentiality claim on registration number  
 Confidentiality claim on tonnage band  
 Data sharing issues  
 Fee waiving 1-10 tonnes, complete dossier

**Compulsory information for isolated intermediates under REACH Article 17 and 18**

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

1 2 3 4 5 6 7 8 9  
Enter administrative information

< Back Next > Finish Cancel

### Compulsory information for isolated intermediates

The tickboxes under "Compulsory information for isolated intermediates under REACH Article 17 and 18" 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 (Figure 68).

## 5. Technical Completeness Check (TCC)

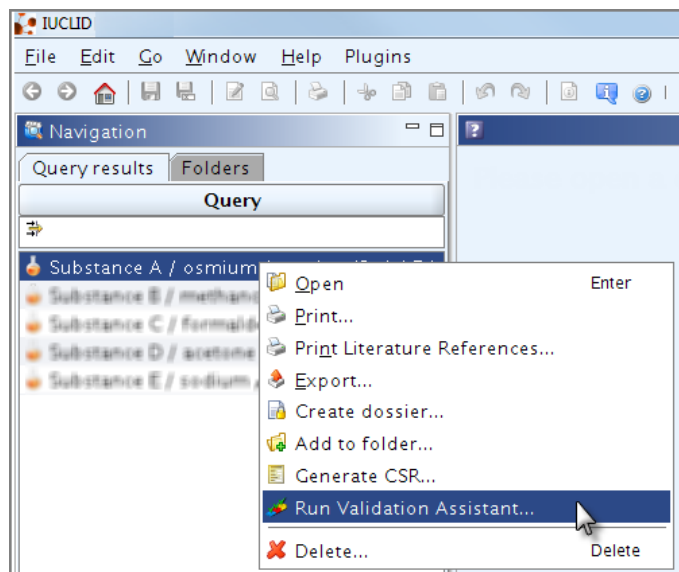
### 5.1. The Validation Assistant plug-in

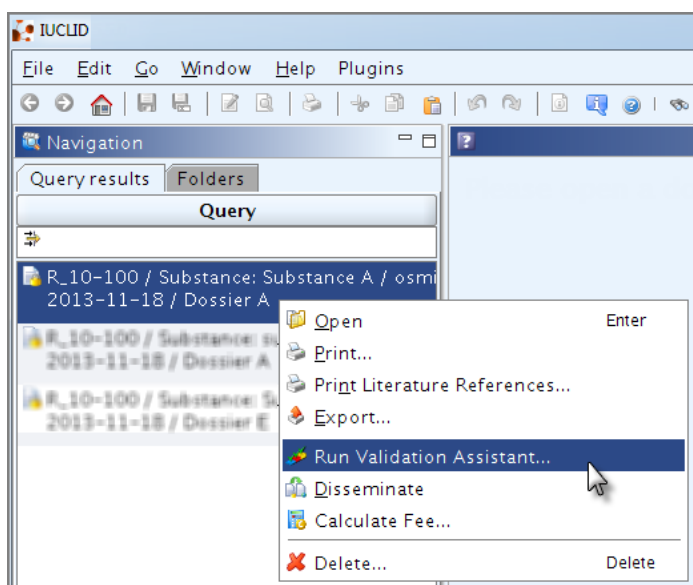
As mentioned in chapter 1 of this manual, IT software has been developed in order to offer you the possibility to check the completeness of your registration/notification before you submit it to ECHA via REACH-IT. This IT software is available as an IUCLID 5 plug-in, called **Validation Assistant** (previously known as TCC plug-in). The latest version of it can be downloaded via your IUCLID 5 website account at: <http://iuclid.echa.europa.eu>.




The plug-in can be used to simulate TCC for substance datasets and dossiers of the type registration and PPORD. It also performs a reduced business rules check on all supported dossier templates.

We strongly advise you to use the Validation Assistant plug-in in two steps: first to check your substance dataset 🧪 (before the dossier is created) to be able to correct any failures reported at this level in an interactive way, and then to check the final dossier 📄 (when the Dossier header has been added). For instructions on how to run the Validation Assistant plug-in, please see the screenshots below (Figure 69 and Figure 70).

**Figure 69: Running the Validation Assistant plug-in on the substance dataset**



**Figure 70: Running the Validation Assistant plug-in on the final dossier**

-  Before you submit your dossier to ECHA, please check your submission by using the Validation Assistant plug-in first on the substance dataset and then on the final dossier. Using the plug-in in both steps is vital for you to avoid any unnecessary failures and potential rejection if the submission is for a requested update.
-  If you are uncertain about how to enter the required information in the correct format in your IUCLID 5 dossier or how to run the Validation Assistant plug-in, please contact the ECHA Helpdesk at <http://echa.europa.eu/web/guest/contact>. ECHA will then provide you with specific advice on how to proceed.
-  In addition, the plug-in hosts the Dossier Quality Assistant for substance datasets and dossiers of the type registration and inquiry, the results of which are shown in a separate screen and have no impact on the outcome of the completeness check. However, you are encouraged to analyse the results obtained from the Dossier Quality Assistant and revise your dossier. This will help you identify shortcomings and increase the quality of registrations.

## 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
<b>4</b>	<b>Physical and chemical properties</b>												
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

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
4.10	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
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
<b>5</b>	<b>Environmental fate and pathways</b>												
5.1.2	Hydrolysis	8	9.2.2.1		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
5.2.1	Biodegradation in water: screening tests	7	9.2.1.1	At least one complete endpoint study record must contain in the field "Test type" either "Ready biodegradability" or "other" (with the adjacent field filled in).	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 5 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
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

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
<b>6</b>	<b>Ecotoxicological Information</b>												
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	For >1000T, the "Test duration type" should be	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
				"long-term toxicity".									
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.	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)	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
6.3.3	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 micro-organisms	9	9.4.2		o	o	o	r	r	o	o	o	o
6.3.5	Toxicity to birds	10	9.6.1	For R>1000T, the "Test type" should be "reproduction"	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
				toxicity" or "other" (with the adjacent field filled in).									
<b>7</b>	<b>Toxicological information</b>												
7.2.1	Acute toxicity: oral	7	8.5.1		o	r	r	r	r	o	o	r	o
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-	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

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	8.1.1 (in vivo skin irritation)	vitro with a possible new guideline that covers corrosion and irritation).  For >10T, 1 in-vivo endpoint study record must be provided.	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-vitro or 1 in vivo endpoint study record must be provided.  For >10T: 1 in-vivo endpoint study record must be provided.	o	r	r	r	r	o	o	r	o
		8	8.2.1 (in vivo)		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.	o	o	r	r	r	o	o	o	o
		9	8.6.2 (sub-chronic)		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
		8	8.4.3 (in vitro gene mutation in mammalian cells)	(e.g. if there is a positive result in 8.4.1 or in 8.4.2, then 8.4.3 does not need to be provided).	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. For >100T, 1 two-generation study must be provided.	o	o	r	r	r	o	o	o	o
		9	8.7.3 (two-generation)		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 20°C 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 "Water 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 under the table "Test result".
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 (with unit).
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 field "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 selection must be made in the field "Transformation products". If "yes" is selected then the field "Identity of the degradation products" must be filled in.
5.3.1	The field "Type" and "Value" under "Bioaccumulation factor" must be filled in.
5.4.1	Either the table "Adsorption coefficient" or the table "Other adsorption coefficients" or the field "Details on results (HPLC method)" or the field "Adsorption and desorption constants" must be filled in. For each entry in the table "Adsorption coefficient" and in the table "Other adsorption coefficients", a selection must be made in the field "Type" and a "Value" must be given. In addition, if "Kd" is selected then the field "% Org. carbon" 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 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" (blank 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.
7.6.1	At least the fields "Species/strain", "Metabolic activation", "Genotoxicity" and "Cytotoxicity" must be filled in.



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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 – Dissemination of information and Confidentiality claims

Article 119 of the REACH Regulation stipulates that the European Chemicals Agency (ECHA) shall publish certain information it holds on registered substances (whether on their own, in mixtures or in articles) free of charge over the internet. This dissemination of information, to provide online access to the public, is released via the Registered substances page on the ECHA website.

- ! The registered substances page can be accessed via the ECHA website, by selecting "Information on Chemicals" in the top menu, and clicking "Registered Substances" or via: <http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>.

However, in certain cases information can be withheld, if the registrant submitting the information also indicates the appropriate flag(s) in the IUCLID 5 dossier together with a justification as to why publishing the information would be potentially harmful to the commercial interests of the registrant or any other party concerned. Requests for information not to be disseminated are often also referred to as "confidentiality claims". Such justifications will be assessed by ECHA in accordance with Article 119(2), and where the justification is accepted as valid by ECHA, the information concerned will not be published.

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.

- ! The following relevant manuals, concerning the dissemination of information from a registration dossier, are available at: <http://echa.europa.eu/web/guest/support/dossier-submission-tools/>.

- Data Submission Manual 15 "How to determine what will be published on the ECHA website from the registration dossier",
- The technical annexes to Data Submission Manual 15, detailing with screenshots of the entire registration dossier which information will be disseminated,
- Data Submission Manual 16 "How to write justifications for confidentiality requests".

- ! Relevant IUCLID 5 plug-ins, concerning the dissemination of information from a registration dossier, are available at: [iuclid.echa.europa.eu](http://iuclid.echa.europa.eu).
  - The Dissemination IUCLID 5 plug-in simulates which information from the registration will be made available on the ECHA website.
  - The Fee Calculation IUCLID 5 plug-in allows registrants to verify whether they will be charged for a confidentiality claim on safety data sheet information and calculates all fees associated to a registration.

- ! You are able to simulate the fee associated to your submission by using the Fee Calculation plug-in. However, registrants should wait for ECHA to issue an invoice before making their payment.

### 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" available at:

<http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/nons>.

## 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 updates
- Other updates

Please see the detailed description and the requirements set to these update types below.


### Tonnage band updates

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 TCC requirements outlined in this document must be met, without any possibility to make derogations due to the substance being previously notified under Directive 67/548/EEC.

 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 requirements 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 5. Therefore, if you are updating a SNIF file migrated to IUCLID 5 then you should be aware that ECHA could consider the endpoint requirement 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 must include as a minimum the following information:

#### **A) New and updated information submitted**

The new and updated information submitted as a consequence of the update has to meet all of the TCC requirements described in the present manual, with no special exceptions due to the status as a previously notified substance, e.g. if you are updating your dossier to include the classification and labelling according to the CLP Regulation, IUCLID 5 section 2.1 has to be complete.

 The new and updated information submitted has to meet all of the TCC requirements, i.e. the updated IUCLID 5 section has to be complete.

For any new study and for the studies requested by a Competent Authority 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 updates under Article 22, e.g. new identified use, the relevant sections of your IUCLID 5 dossier should be updated, e.g. section 3.5 "Life cycle description".

#### **B) Section 1 - General Information**

**Section 1.1 "Identification" and 1.2 "Composition"**. These sections have to be complete to meet all of the TCC 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.

**Section 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 (that you received when claiming your registration number via REACH-IT) have to be included here.

**Section 1.7 "Suppliers"**. If you are acting as Only Representative you are advised to attach here the documentation regarding your appointment as the Only Representative.

#### **C) Section 2 - Classification and Labelling and PBT assessment**

**Section 2.1 "GHS"**. 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 5 dossier. If you have previously submitted a dossier without section 2.1, you should provide this information in a registration update without undue delay.

**Section 2.3 "PBT assessment"** has been introduced together with IUCLID 5.4. It consists of an endpoint summary and endpoint study records. If the updated notification is above 10 tonnes per year then you need to create an endpoint summary in section 2.3 "PBT assessment" (by right clicking on the section number) and make sure that a choice has been made in the drop-down list "PBT assessment: overall result". If "PBT assessment does not apply" is selected, a justification should be provided in the free text field (Figure 71).

**Figure 71: Justification for not submitting a PBT assessment (only if relevant)**

Endpoint summary: PBT assessment

Detail level: Administrative Data PBT assessment: overall result

all fields

Administrative Data

PBT assessment: overall result

PBT assessment does not apply

Justification

A PBT assessment is not submitted because it is a previously notified substance which did not reach the next tonnage threshold and which does not fall within the scope of Articles 22(1)(d), 22(1)(e) and 22(1)(f) of the REACH Regulation.

#### D) Section 3 - Manufacture, use and exposure

In case you indicated in IUCLID 5 section 1.1 that your "Role in the supply chain" is (also) "Manufacturer" then the following subsection has to be complete:

**Section 3.3 "Sites"**. If the tickbox "Manufacturer" is ticked in IUCLID 5 section 1.1 "Identification", then at least one manufacture site must be provided by linking to a manufacture use in **section 3.5**

To indicate a site as a manufacture site, you must create a link from "Manufacture/own use(s)" to at least one reported manufacture in the table "Manufacture" of section 3.5. Links to the table "Manufacture" are identified with the letter "M" (Figure 41). Please read the paragraph 4.3.3 "Section 3 – Sites" of this manual for instructions on how to complete that section.

Also, if the tickbox "Manufacturer" is ticked in section 1.1 "Identification", then at least one Manufacture use must be provided in **section 3.5** (Figure 42).

#### E) Section 13 - Chemical Safety Report

When the update does not involve a change in tonnage band, the notifier does not normally need to submit a CSR. However, if 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, a CSR has to be provided.

- ! The "Guidance on Registration" provides further details on the necessity to submit a CSR. It is available on the ECHA website at: <http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach>.

Therefore, if you do not need to submit a CSR, you should select "REACH Chemical safety report (CSR)" from the drop-down list "Type of report" in section 13 and write the justification for not providing the CSR either in the field "Remarks" or in the field "Discussion". Please use the relevant justification from the following examples:

- a) "A CSR is not submitted because it is a previously notified substance which did not reach the next tonnage threshold and which does not fall within the scope of Articles 22(1)(d), 22(1)(e) and 22(1)(f) of the REACH Regulation."

- b) "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 if relevant)**

The screenshot shows a web form titled "Administrative Data". Under the "Type of report" section, a dropdown menu is set to "REACH Chemical safety report (CSR)". Below this, the "Remarks" field contains the text: "A CSR is not submitted because it is a previously notified substance which did not reach the next tonnage threshold and which does not fall within the scope of Articles 22(1)(d), 22(1)(e) and 22(1)(f) of the REACH Regulation."

### F) Dossier header - Derogation statement

The following derogation statement in your Dossier header has to be written in the "Dossier submission remark" field (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 the derogation statement**

The screenshot shows the "Dossier creation wizard" interface. It prompts the user to "Enter additional administrative information concerning your dossier" for a "Dossier template: REACH Registration 100 - 1000 tonnes". The "Name (given by user)" field contains "Registration update ...". The "Dossier submission remark" field contains the text: "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."

## Annex 5 – Instructions on reporting uses in IUCLID 5.4 for lead, member and individual registrants

IUCLID 5.4 allows the following four possible choices for "Use coverage in CSR":

**Figure 74: Possible choices for "Use coverage in CSR"**

Option number	Option
1	use covered by an own CSR
2	use covered by a joint CSR
3	use covered by a joint CSR but not a lead own use
4	- (= this use is not covered in a CSR)

Following tables show how the different types of use (uses of intermediates registered according to REACH Articles 17 and 18 and uses that require full registration according to REACH Article 10) should be reported in the different types of registrations (lead, member, individual, 1-10 ton/y and > 10 ton/y) as far as the correct choice of "Use coverage in CSR" is concerned.

**Figure 75: Use coverage in the case of lead registrants**

Case		Uses requiring a full registration under REACH (Article 10)		Uses that can appear in an intermediate registration under REACH (Article 17 & 18)	
		Own use	Use by members in JS	Own use	Use by members in JS
L <sub>A</sub>	lead (intermediate), provides joint CSR	n/a	3 <sup>a</sup>	4	n/a
L <sub>B</sub>	lead (intermediate) does not provide joint CSR	n/a	n/a	4	n/a
L <sub>C</sub>	lead (full, > 10 ton/y), provides joint CSR	2	3 <sup>a</sup>	4	n/a
L <sub>D</sub>	lead (full, > 10 ton/y), does not provide joint CSR	1	n/a	4	n/a
L <sub>E</sub>	lead (full, 1-10 ton/y) provides joint CSR	4	3 <sup>a</sup>	4	n/a
L <sub>F</sub>	lead (full, 1-10 ton/y) does not provide joint CSR	4	n/a	4	n/a

<sup>a</sup> the lead registrant should not report a member use if this use is covered in part B of the partial CSR submitted by the member registrant



**Figure 76: Use coverage in the case of member registrants**

Case		Uses requiring a full registration under REACH (Article 10)		Uses that can appear in an intermediate registration under REACH (Article 17 & 18)	
		Own use	Use by members in JS	Own use	Use by members in JS
<b>M<sub>A</sub></b>	member (intermediate)	n/a	n/a	4	n/a
<b>M<sub>B</sub></b>	member (full, > 10 ton/y), JS with joint CSR	2 (or 1) <sup>a</sup>	n/a	4	n/a
<b>M<sub>C</sub></b>	member (full, > 10 ton/y) JS without joint CSR	1	n/a	4	n/a
<b>M<sub>D</sub></b>	member (full, 1-10 ton/y), JS with joint CSR	4	n/a	4	n/a
<b>M<sub>E</sub></b>	member (full, 1-10 ton/y) JS without joint CSR	4	n/a	4	n/a
<b>M<sub>F</sub></b>	lead (full, 1-10 ton/y) does not provide joint CSR	4	n/a	4	n/a

<sup>a</sup> can be 1 only for the uses of member registrants not covered in part B of the joint CSR. These uses should be covered in part B of the partial CSR provided by the member registrant.

**Figure 77: Use coverage in the case of individual registrants**

Case		Uses requiring a full registration under REACH (Article 10)		Uses that can appear in an intermediate registration under REACH (Article 17 & 18)	
		Own use	Use by members in JS	Own use	Use by members in JS
<b>I<sub>A</sub></b>	intermediate	n/a	n/a	4	n/a
<b>I<sub>B</sub></b>	full, > 10 ton/y	1	n/a	4	n/a
<b>I<sub>C</sub></b>	full, 1-10 ton/y	4	n/a	4	n/a

EUROPEAN CHEMICALS AGENCY  
ANNANKATU 18, P.O. BOX 400,  
FI-00121 HELSINKI, FINLAND  
ECHA.EUROPA.EU