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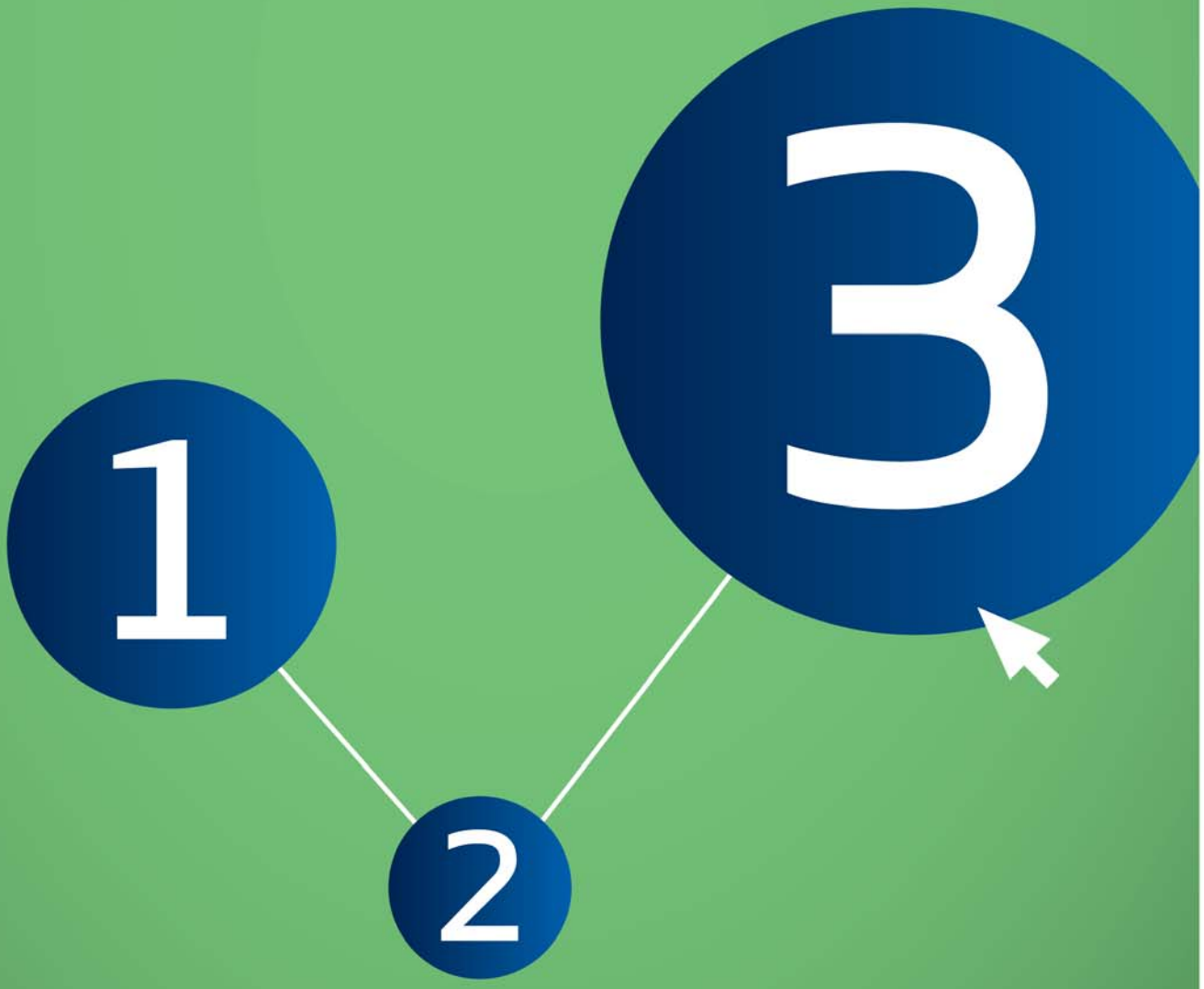
MANUAL

REACH-IT Industry User Manual

Part 16 - How to create and submit a C&L notification using the REACH-IT online tool



Version	Changes
2.0	Document in new layout. Minor text revisions. Links updated.
1.1	Document updated to reflect the changes introduced by the 2nd ATP to the CLP Regulation. Changes have been made in the "Environmental hazards" section. Changes have been made also in Tables 11, 12, and 14.
1.0	First version

Part 16 - How to create and submit a C&L notification using the REACH-IT online tool

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1. Introduction

The Industry User Manual (IUM) serves as the reference manual for all REACH-IT functionalities, which are, and will be, available to the industry. As more functionalities become available, additional or updated parts of this IUM will be released and made available via the ECHA website. This IUM is meant for any industry user who needs to use REACH-IT to submit or view data.

Prior to using this 'Part 16 - How to create and submit a C&L notification using the REACH-IT online tool

', it is strongly recommended that the user reads Part 1 – Getting started with REACH-IT, where the following topics are discussed in more detail:

- Structure of this IUM.
- Conventions used, in terms of icons, text, buttons, links.
- Background information on REACH-IT and its link to the IUCLID 5 website and application.
- Definitions of parties, users, message box, contacts, legal entity object.

The purpose of this industry user manual (IUM) part 16 is to assist in **the preparation of a Classification and Labelling (C&L) notification dossier under the CLP Regulation (EC) No 1272/2008 directly in REACH-IT**. More particularly it outlines the information to be filled-in in order to prepare a complete C&L notification dossier according to Article 40 (1) of the CLP Regulation.

Each subsequent part of this IUM will provide you step-by-step instructions to perform the required tasks of CLP submission of data.

2. General concept of C&L notification

There are three options to prepare and submit a C&L notification:

- Enter the information required for the C&L notification directly online in the REACH-IT system following a step-by-step procedure until the final validation and submission at the end of the procedure.
- Prepare a bulk C&L notification using the bulk excel tool. For example if you want to submit several C&L notifications in one go.
- Prepare the information required for the C&L notification as an IUCLID 5 dossier and submit this dossier via REACH-IT.

The following step-by step instructions deal only with option 1. If you wish to proceed via option 2 or 3 you should refer to the respective manuals available on the ECHA website at: http://echa.europa.eu/clp/inventory_notification/notification_how_en.asp.

For more details on your duties regarding C&L notification under the CLP Regulation, you can consult the CLP FAQ available at: http://echa.europa.eu/web/guest/support/faqs/clp-frequently-asked-questions

3. What to prepare before starting the online C&L?

Before you start your online C&L notification, make sure that you have the following **minimum information** available.

You can use the following tables as a check-list before starting an online C&L.

3.1 Substance identity and composition

In order to help you identify your substance correctly we recommend that before preparing and submitting your C&L notification dossier you familiarise yourself with the Guidance for identification and naming of substances under REACH available at http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf

Table 1: Checklist: minimum information needed on the substance for a mono-constituent

√ / X	Minimum Information
	Degree of purity of the substance.
	IUPAC name of the main constituent.
	Typical concentration of the main constituent.
	For the main constituent: o EC number; or o CAS number; or o Molecular formula + Molecular weight range + Structural formula.
	IUPAC name of each impurity or additive.
	Concentration range of each impurity or additive.

Table 2: Checklist: minimum information needed on the substance for a multi-constituent

√ / X	Minimum Information
	Degree of purity of the substance.
	IUPAC name or EC number or CAS number of the multi-constituent substance.

	IUPAC name of each main constituent.
	Concentration range of each main constituent.
	For each main constituent (at least 2 main constituents): o EC number; or o CAS number; or o Molecular formula + Molecular weight range + Structural formula.
	IUPAC name of each impurity or additive.
	Concentration range of each impurity or additive.

Table 3: Checklist: minimum information needed on the substance for a UVCB substance

√ / X	Minimum Information
	Degree of purity of the substance.
	Chemical name of the UVCB substance.
	Description of the UVCB substance or the process to produce the UVCB.
	At least one constituent of the UVCB.
	IUPAC name of each constituent.
	Concentration range of each constituent.
	IUPAC name of each additive.
	Concentration range of each additive.

3.2 Classification and Labelling

Before starting the online C&L, we recommend you to check if your substance is already harmonised in Annex VI to CLP. Check Table 3.1 of Annex VI at: http://echa.europa.eu/legislation/classification_legislation_en.asp

Before starting the online C&L, in case your substance is not listed in Annex VI to CLP, you need to gather all available and relevant information on all the hazardous properties of your substance.

Note that this is necessary also for the hazards not covered by the harmonised classification.

Table 4: Checklist: minimum information needed on the classification and labelling (if the substance fulfils the criteria for classification as hazardous)

√ / X	Minimum Information
	If a harmonised C&L exists: Index number from table 3.1 of Annex VI to CLP.
	For each hazard class or differentiation: "Hazard category" and "Hazard statement"; or a "Reason for no classification".
	For the STOT-Single exposure and STOT-Repeated exposure hazard class: "Hazard category" and "Hazard statement" and "Affected organs" (if the affected organ was not known specify it in this field also); or a "Reason for no classification".
	If a "Specific concentration limit" is specified: a "Concentration range" (at least one of the range fields) and at least one associated "Hazard category".
	A "Signal word".
	At least one "Hazard statement" used in the labelling of the substance.
	If applicable, "Supplemental hazard statement".
	If applicable, "Hazard pictogram".

3.3 Scientific justifications

Table 5: Checklist: minimum scientific justifications needed

√ / X	Minimum Information
	Scientific justification to set an M-factor under the strict conditions of Article 10 of the CLP Regulation.
	Scientific justification to set specific concentration limit(s) (SCL) under the strict conditions of Article 10 of the CLP Regulation.

	Scientific justification to explain that a hazard is only caused by (a) specific route(s) of exposure.
	In the case you do not agree with the classification and labelling (excluding the harmonised ones in Part 3 of Annex VI) already present in the C&L inventory, you have to provide a reason for this specific hazard class or differentiation (cf. CLP Article 16). The reason can include for example: o Indication that an impurity/additive has an impact on the C&L (Figure 27 and Figure 28); or/and o Indication of the substance form/state (Figure 15); or/and o Justification that you have relevant data/information supporting the classification of the substance (Figure 66).

It is recommended that the scientific justifications are .PDF documents.

For the scientific justification, you should use the relevant parts of the Chemical Safety Report format according to Annex I to REACH. There is no need for a justification if the value is in line with the one given in Table 3.1 of Annex VI to the CLP Regulation ("the harmonised list").

3.4 In case of submission as a group of Manufacturers/Importers

Table 6: Checklist: in case the submission is on behalf of a group

√ / X	Minimum Information
	The group is already created in REACH-IT (not compulsory: you can create it when making your online C&L notification).
	The members of the group are clearly identified (VAT, DUNS or REACH-IT UUID) and they all agree to the C&L of the substance.
	The submitting entity must be able to document that it has been mandated to act on behalf and in the name of the Manufacturers and Importers that are part of the group and that the Manufacturers and Importers acknowledge that they remain solely and fully responsible to fulfil all their obligations associated with the notification.

3.5 Contact information

Table 7: Checklist: contact information

√ / X	Minimum Information
	First and last name of the contact person.

	Phone number of the contact person.
	E-mail address of the contact person (it can be a functional mailbox).
	Complete address of the contact person.

3.6 Information needed in case of update

Table 8: Checklist: contact information

√ / X	Minimum Information
	The reference number (notification number) already assigned to your substance.
	The EC or list number already assigned to your substance.

You can retrieve this information by searching in REACH-IT under:

<Classification And Labelling > View My Submitted C&L>

4. Strengths and limitations of the online C&L

4.1 What REACH-IT does and does not do!

The online C&L module in REACH-IT is one of the submission tools made available to Manufacturers and Importers in order to notify the C&L of their substance(s) under the CLP Regulation.

It aims to ease the encoding of the information by using for example the <I agree> button.

The Classification and Labelling of a substance and encoding it in REACH-IT remains the responsibility of the notifier. ECHA or Member State competent authorities will not review, assess or take any responsibility of the C&L that is displayed in the online module.

4.2 What you can do!

In the online C&L notification module you can:

- Create and update a C&L notification for a substance with one composition and one C&L.
- Update a C&L notification previously submitted in bulk, online or via IUCLID 5.
- Respect a C&L already harmonised and classify other hazard classes or differentiations not (yet) harmonised (including the setting of SCLs and M-Factors, as appropriate).

- Agree with a C&L already notified or registered by another company.

4.3 What you cannot do!

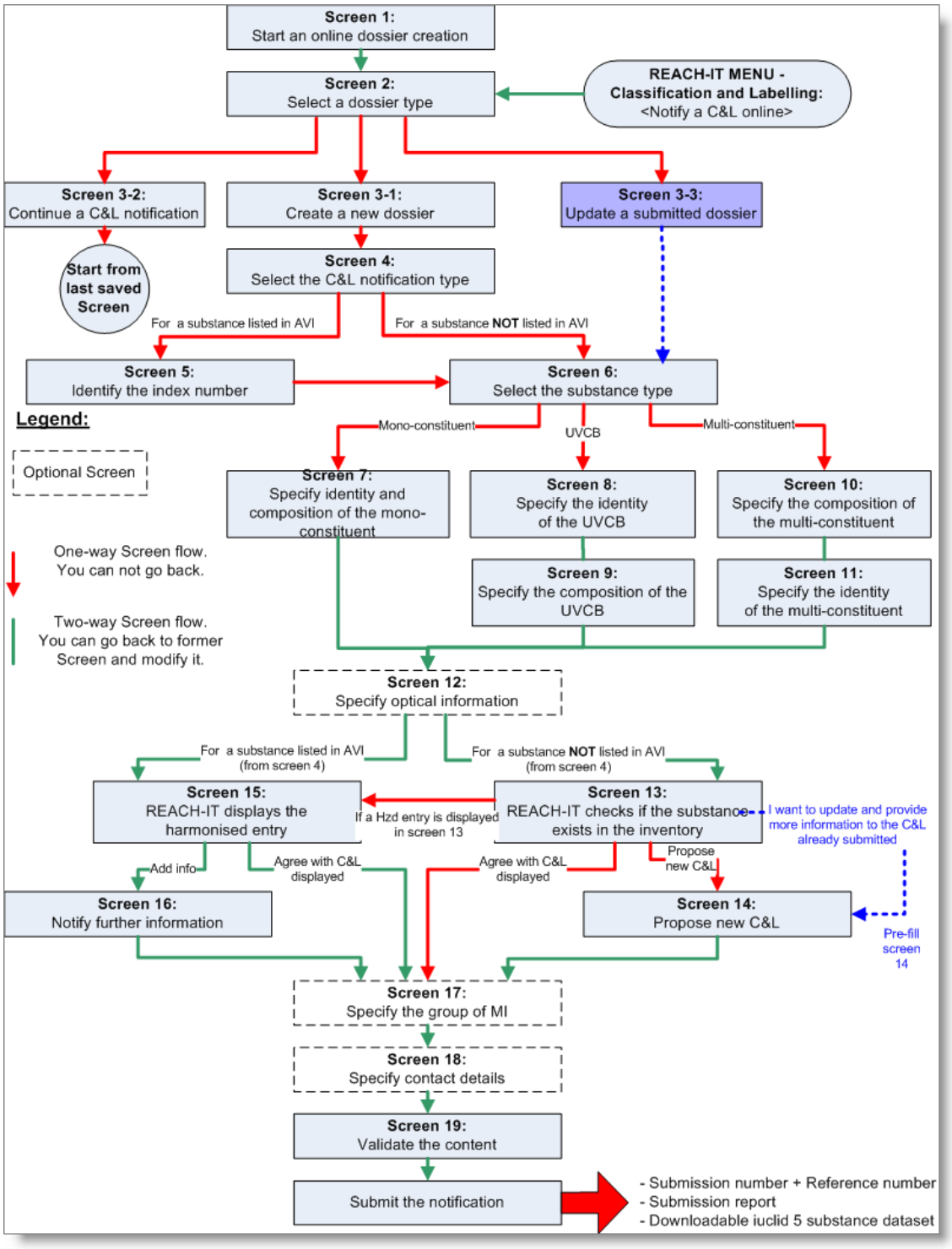
In the online C&L notification module you cannot:

- Create or update a C&L notification for a substance having more than one composition and/or more than one C&L. To do so, you shall submit a C&L notification prepared in IUCLID 5.
- Update the C&L section from a registration dossier. To do so, you shall submit a registration dossier update.
- Update the C&L section from a NONS dossier notified above 1 tonne (notification under Directive 67/548EEC). To do so, you shall submit a registration dossier update.
- Claim confidentiality on the IUPAC name of your substance. To do so, you shall submit a C&L notification prepared in IUCLID 5.
- Update a C&L if you are a member of a group of Manufacturers/Importers (group of MI). Only the company that has submitted the C&L notification can update the notification.

5. Screen-flow overview

Figure 1 provides an overview of the online dossier creation process for C&L notifications.

Figure 1: Screen-flow diagram



The following Table 9 provides you direct links to the chapter describing the different screens:

Table 9: Link between the screen-flow and the chapters of this manual

Screen number	Related chapter in this manual
Screen 1	6.1 Starting an online dossier

Screen 2	6.1 Starting an online dossier
Screen 3-1	6.2.1 Create a new dossier
Screen 3-2	6.2.2 Continue with an existing dossier
Screen 3-3	6.2.3 Update a dossier already successfully submitted
Screen 4	6.3 Select the C&L notification type
Screen 5	6.3.2 C&L notification for a substance ALREADY listed in Annex VI
Screen 6	6.4 Select the substance type
Screen 7	6.5.1 Specify the substance identity and composition for a mono-constituent substance
Screen 8	6.5.3.1 Substance identity of a UVCB
Screen 9	6.5.3.2 Composition of a UVCB
Screen 10	6.5.2.1 Main constituents
Screen 11	6.5.2.3 Identity of the multi-constituent substance
Screen 12	6.6 Specify the optical activity
Screen 13	6.7.1 Is there any C&L for the same substance already in the inventory?
Screen 14	6.7.4 Propose a new C&L
Screen 15	6.7.2 Your substance is already harmonised in Annex VI to CLP
Screen 16	6.7.2.1 Notify further information to a substance already harmonised
Screen 17	6.8 Specify if the submission is made on behalf of a group of MI
Screen 18	6.9 Specify your contact details
Screen 19	6.10 Validate the content of your C&L notification
Submit	6.11 Submit the notification

Within the online dossier creation process you have the possibility to save (button Save) the creation of your online dossier at any stage and to continue it later if needed (see chapter 6.2.2 for more details).

On top of that an automatic saving of your online dossier is performed by REACH-IT every time you move from one screen to another.

If you hover with your mouse pointer over the ? symbol you find more details on the requested information.

At the end of the C&L notification online dossier creation wizard, after submission of your dossier, you receive:

- A submission number.
- A reference number (notification number) only if your submission is successful.
- A submission report.
- A IUCLID 5 substance dataset containing all the information you have specified in the online module. This IUCLID 5 substance dataset can be then imported in your IUCLID 5 database and used for example as a basis to later encode your registration dossier.

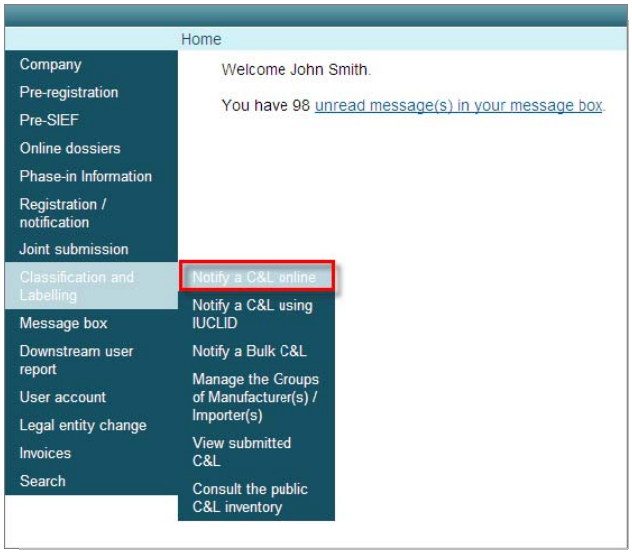
In case of online notification made by a group of MI: a submission report is generated to the company who submits the notification, not to the members of the group of the C&L notification. The company submitting on behalf of the group of MI shall provide this submission report and the reference number to the members of the group of MI outside REACH-IT.

6. Step by step instructions

6.1 Starting an online dossier

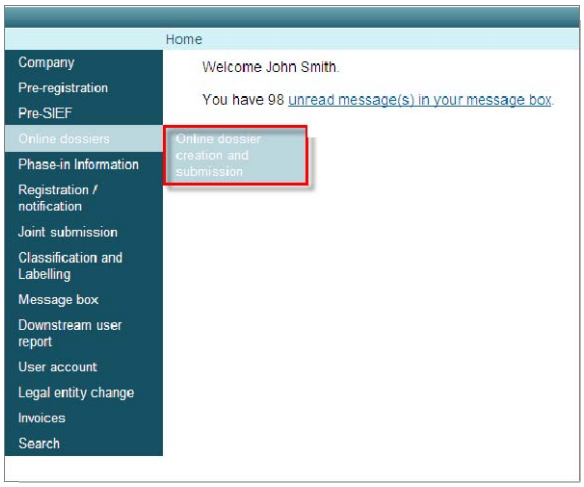
To start the online dossier creation, go to the menu option <Classification and Labelling> menu on the left-hand side of the REACH-IT screen, and click on the sub-menu <Notify a C&L> (Figure 2).

Figure 2: Start an online dossier creation from the <C&L> menu



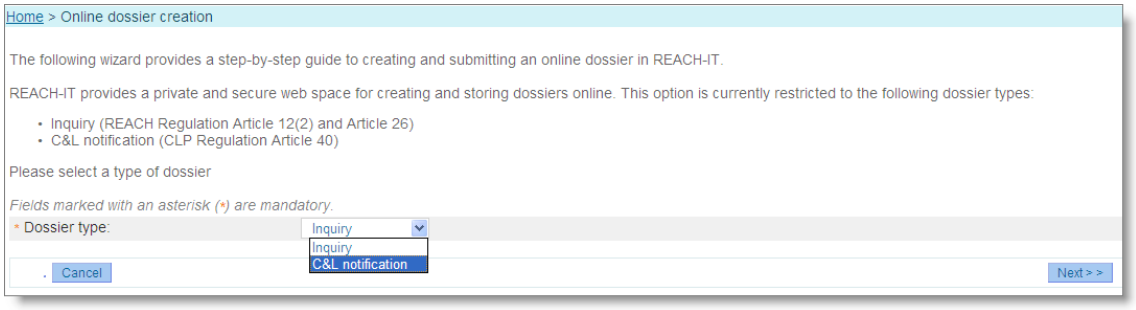
Alternatively, you can also go to the menu option <Online Dossiers> on the left-hand side of the REACH-IT screen, and click on the sub-menu <Online dossier creation and submission> (Figure 3).

Figure 3: Start an online dossier creation from the <Online Dossier> menu



The dossier selection page opens (Figure 4). Select the dossier type by clicking and select the option <C&L notification> from the pull drop down list that appears.

Figure 4: Dossier type

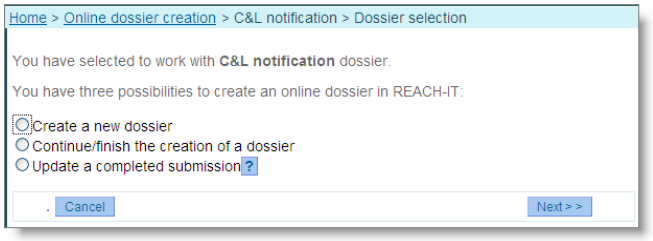


Click on the button Next > > to proceed.

6.2 Select whether to create a new online dossier or not

Select whether to create a new C&L notification dossier, or to continue with an existing C&L notification dossier you have not yet submitted, or to update a C&L notification you have already successfully submitted (Figure 5).

Figure 5: Select to create a new dossier or not



6.2.1 Create a new dossier

Please note that REACH-IT automatically saves your dossier as you create it. This means that you do not need to manually save it at intervals.

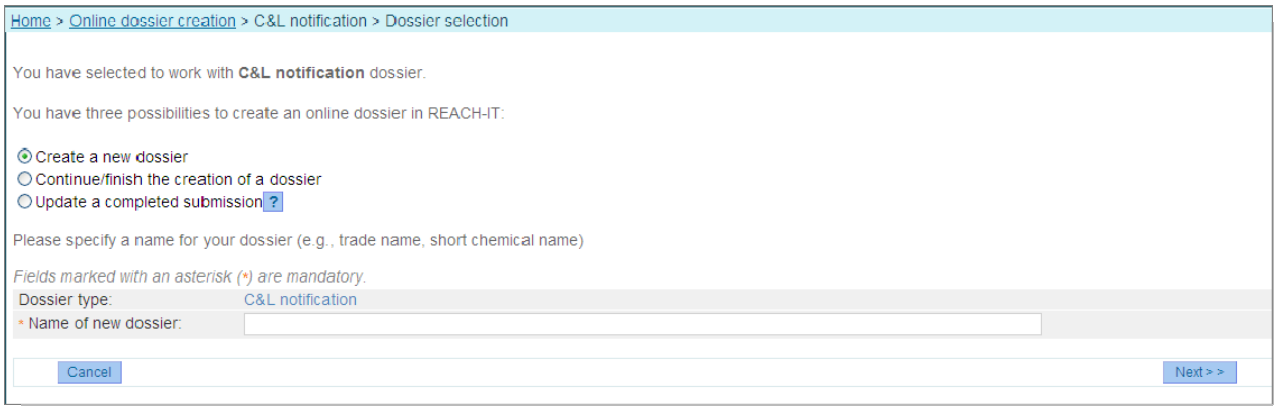
Select the option <Create a new dossier>. Specify a name for the online C&L notification dossier in the text field, this can be anything but it is recommended to use something related

to the substance you intend to notify e.g. trade name (Figure 6).

Click on the button Next > > to proceed.

REACH-IT checks that the name given for the new online C&L notification dossier has not already been used for another notification dossier you have created.

Figure 6: Name a new dossier

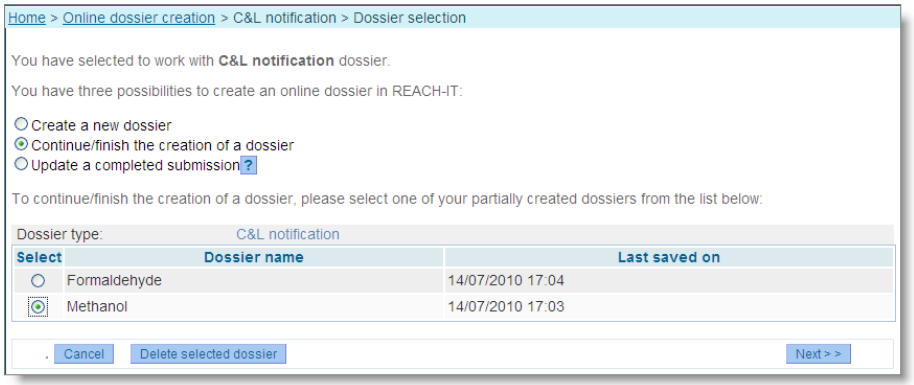


6.2.2 Continue with an existing dossier

You can continue an existing online C&L notification dossier which has not been submitted by selecting <Continue/finish the creation of a dossier> and then select the relevant dossier by clicking the radio button beside it (Figure 7).

Click on the button Next > > to proceed.

Figure 7: Continue/finish the creation of a dossier



Once you have submitted the C&L notification dossier created online it is no longer visible under <Continue/finish the creation of a dossier>.

On this screen you can also delete a C&L notification dossier that you have not yet submitted: select the relevant dossier by clicking the radio button beside it and click on the <Delete selected dossier> button (Figure 8).

You will be asked to confirm the deletion (Figure 9).

Figure 8: Delete a non-finish dossier

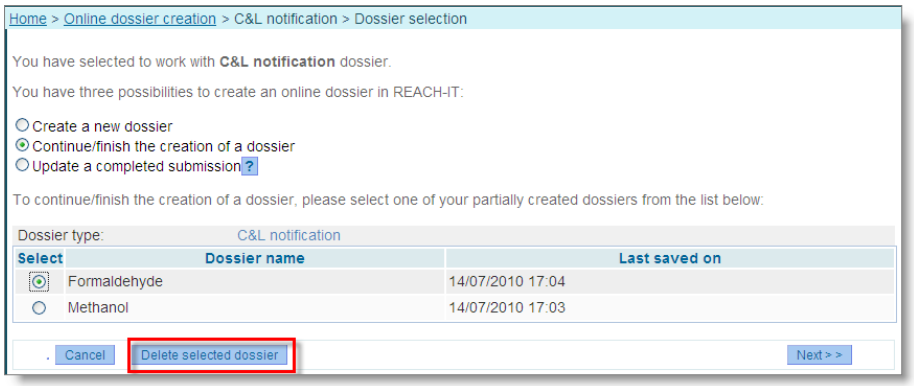
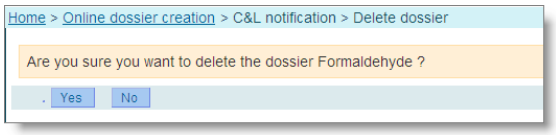


Figure 9: Confirm a dossier deletion



The deletion of the dossier is definitive.

6.2.3 Update a dossier already successfully submitted

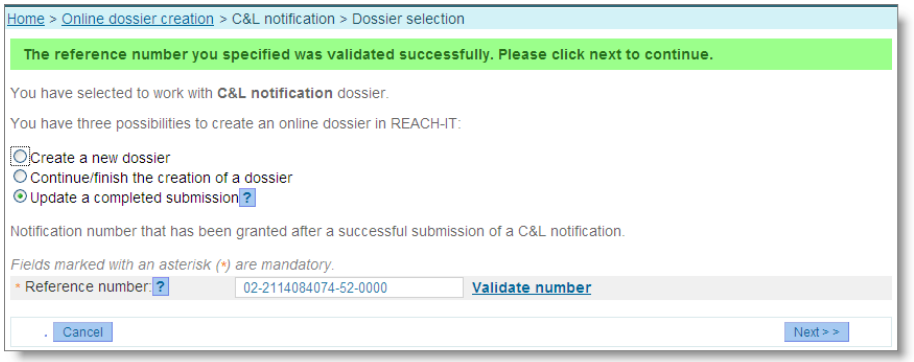
You can update a C&L notification dossier that has been already successfully submitted (i.e. a reference number has been assigned to the C&L notification) by selecting <Update a completed submission> (Figure 5).

Enter the exact reference number of the C&L notification you want to update: the reference number has the following format 02-XXXXXXXXXX-CC-XXXX.

Click on <Validate number>, and then on the button Next > > to proceed (Figure 10).

Only the company who owns the C&L notification (i.e. the one who has submitted the notification) is able to make an update for it.

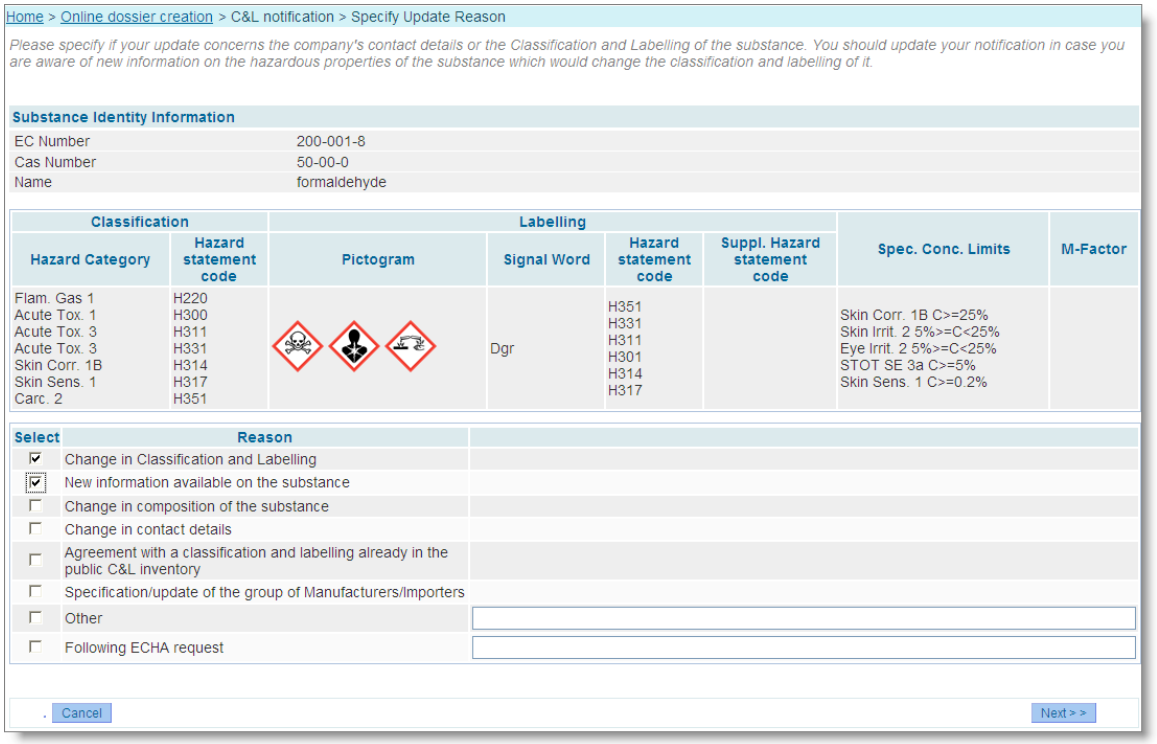
Figure 10: Reference number validated



A new screen <Specify Update Reason> opens (Figure 11) where you see the identifiers related to your substance (EC number, CAS number, substance name) as well as the Classification and Labelling previously submitted.

Select one or several reasons for update by ticking the relevant box(es).

Figure 11: Specify update reason



Click on the button Next > > to proceed. The <Substance type> selection page opens (Figure 15). After you have confirmed the substance type (by clicking on the Next > > button), all subsequent screens (substance identity, substance composition, C&L) will be automatically filled in with the information extracted from your former C&L notification. You can then update / add / delete information in your C&L notification.

The following types of C&L notification can be updated online:

- Online C&L notification.
- Individual C&L notification previously submitted in bulk.
- IUCLID 5 C&L notification with one composition and one C&L only.

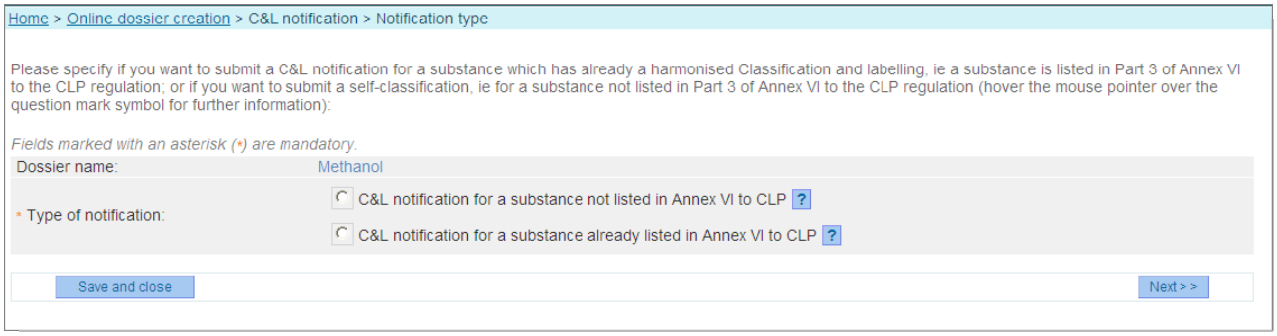
Classification and Labelling submitted as part of a registration dossier cannot be updated online. To do so, you have to update your registration dossier.

You can add information to the substance identity of the substance notified, but you shall not change already existing information (e.g. replace an EC number by another EC number).

6.3 Select the C&L notification type

After deciding that you want to create a new C&L notification dossier (Figure 6), the Notification type page opens (Figure 12).

Figure 12: C&L notification type



Select the C&L notification type among:

- C&L notification for a substance NOT listed in Annex VI to CLP (<C&L notification for a substance NOT listed in Annex VI to CLP>); or
- C&L notification for a substance ALREADY listed in Annex VI to CLP (<C&L notification for a substance already listed in Annex VI to CLP>).

Click on the button Next > > to proceed.

As soon as you have selected a C&L notification type and clicked on the Next > > button, the C&L notification type cannot be changed at a later stage.

Nevertheless, if you selected the first option, and if your substance is in fact listed in Annex VI to the CLP Regulation, the harmonised C&L will be displayed anyway to you at a later stage (Figure 44).

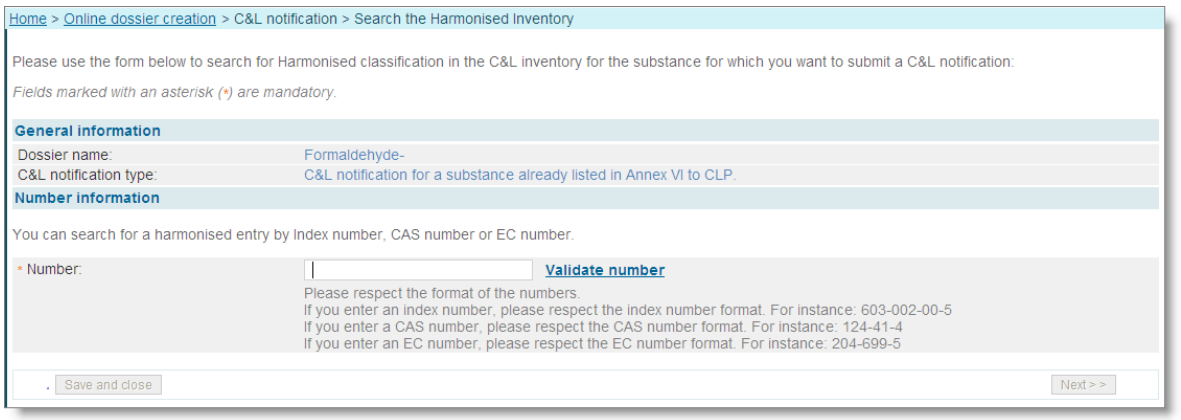
6.3.1 C&L notification for a substance NOT listed in Annex VI to CLP

If you select <C&L notification for a substance NOT listed in Annex VI to CLP> (Figure 12), the Substance type selection page opens (Figure 15).

6.3.2 C&L notification for a substance ALREADY listed in Annex VI

If you select <C&L notification for a substance already listed in Annex VI to CLP> (Figure 12), the Search the Harmonised Inventory page opens (Figure 13).

Figure 13: Search the Harmonised Inventory



In order to quickly identify the substance you notify, enter one of the numbers specified in **Table 3.1 of Annex VI to the CLP Regulation.**

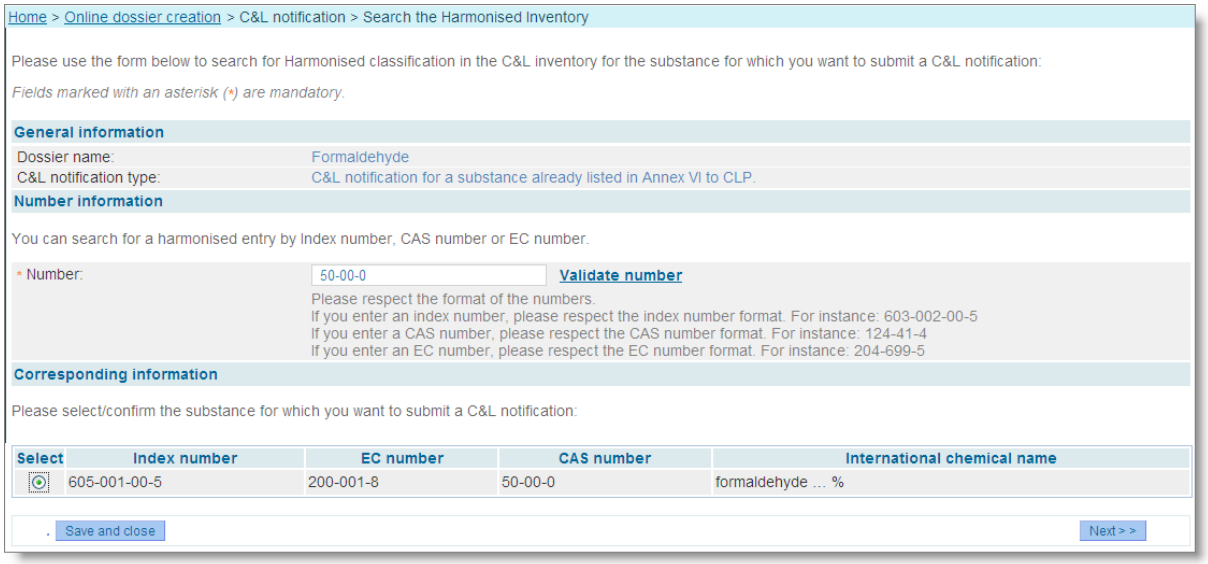
Click on <Validate number>. REACH-IT searches in the Harmonised Inventory (Table 3.1 of Annex VI to CLP) if the number specified exists, and displays the results (Figure 14).

You can indicate:

- The Index number of the substance you want to notify. For instance: 603-002-00-5.
- The CAS number of the substance you want to notify. For instance: 124-41-4.
- The EC number of the substance you want to notify. For instance: 204-699-5.

Wild card search is not possible on this page. You shall enter the complete number. Please respect the format of the number.

Figure 14: Select a harmonised C&L



Select the substance for which you want to submit a C&L notification and click on the button Next > > to proceed.

The subsequent screens in the online module are automatically filled-in with the information extracted from Annex VI to CLP:

- The International Chemical Identification.
- The EC number of the substance if any.
- The CAS number of the substance if any.
- The harmonised Classification and Labelling.

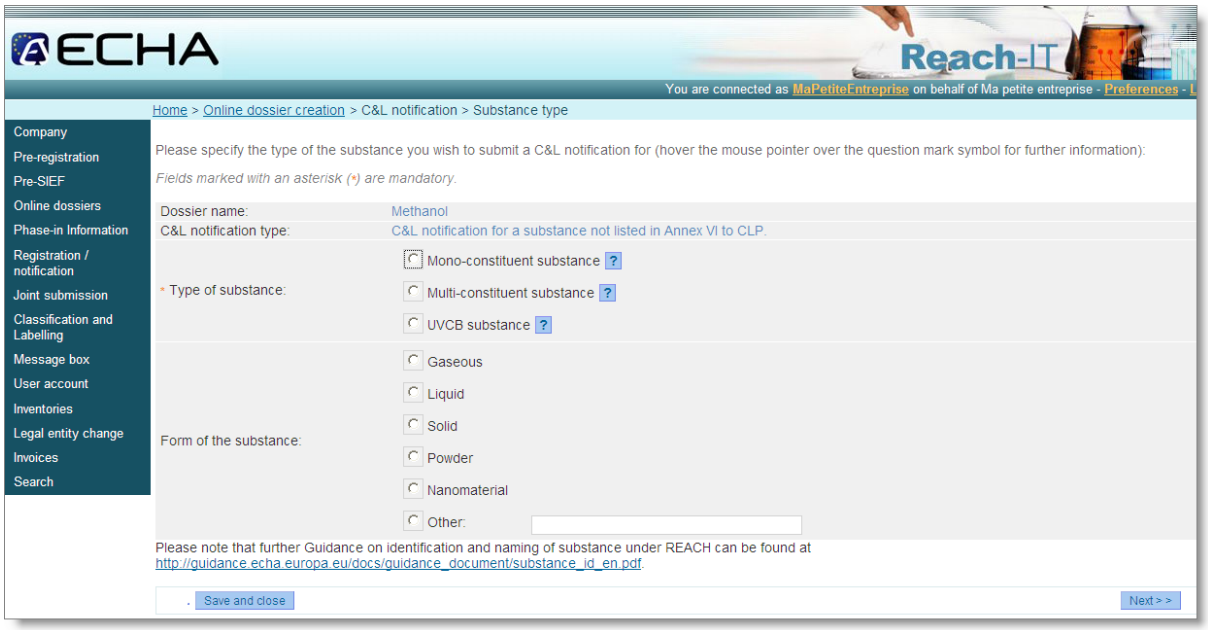
6.4 Select the substance type

On the Substance type selection page (Figure 15), select the appropriate substance type. If you hover the mouse pointer over the ? symbol you find further information on each type of substance. We also recommend you to read the Guidance for identification and naming of substances under REACH available at: http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach

Indicate also the state/physical form of the substance by selecting the appropriate term from the pick-list. This information may be useful in justifying the classification for a substance.

Click on the button Next > > to proceed.

Figure 15: Substance type



Altering your substance type is prohibited as soon as you have selected a substance type and subsequently clicked on the Next > > button.

6.5 Substance identity and composition

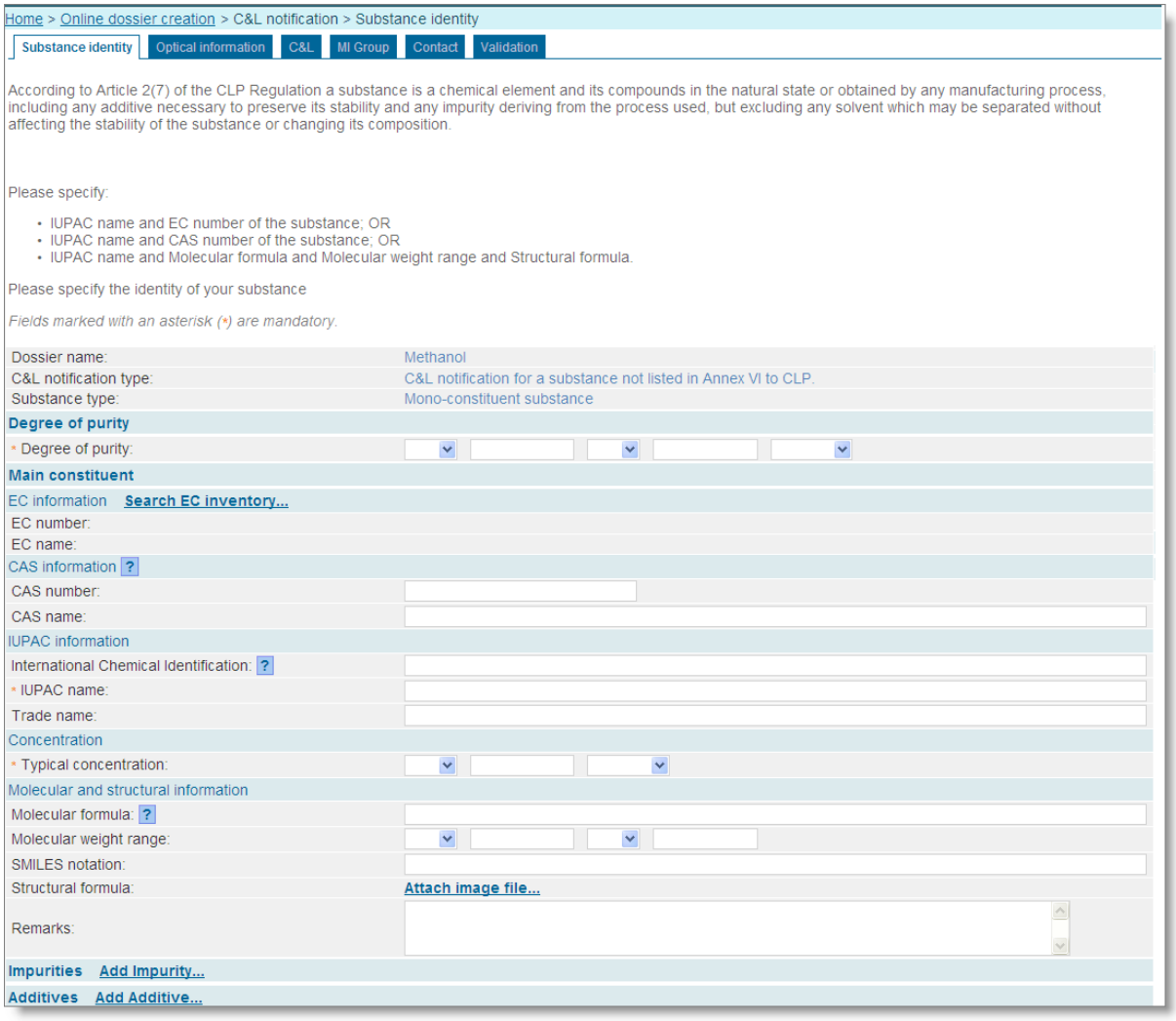
There are some differences in the creation of the substance identity and composition information between mono-constituent substances, multi-constituent substances and UVCB substances and therefore each substance type is described separately.

If you want to submit a C&L notification for a polymer, select <UVCB substance> as a substance type.

6.5.1 Specify the substance identity and composition for a mono-constituent substance

Select <Mono-constituent substance> and click on the button Next > > to proceed; the Substance identity page opens (Figure 16).

Figure 16: Substance identity for a mono-constituent substance



6.5.1.1 Identity and main constituent

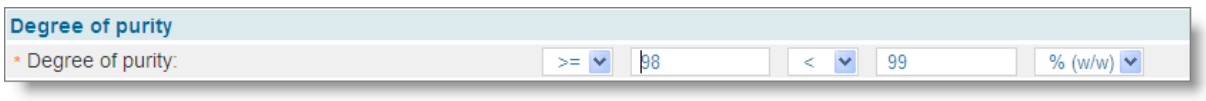
For a mono-constituent substance please complete as many fields as possible but at least the minimum information as outlined in Table 1 of this Manual.

The fields marked by * are mandatory and you must provide the appropriate information to proceed to the next step. Please take note of the following advices related to each field.

a) Degree of purity (mandatory field)

Your substance is a well-defined mono-constituent substance therefore you must have a defined purity range (Figure 17). In these fields specify a minimum value and a maximum value ensuring you use the appropriate prefix (>=, <=, < or >). We recommend that you avoid the use of the <ca.> prefix as this would not be considered appropriate for a substance with a defined composition. Remember to select the correct unit for purity as if left blank you are not able to proceed.

Figure 17: Degree of purity



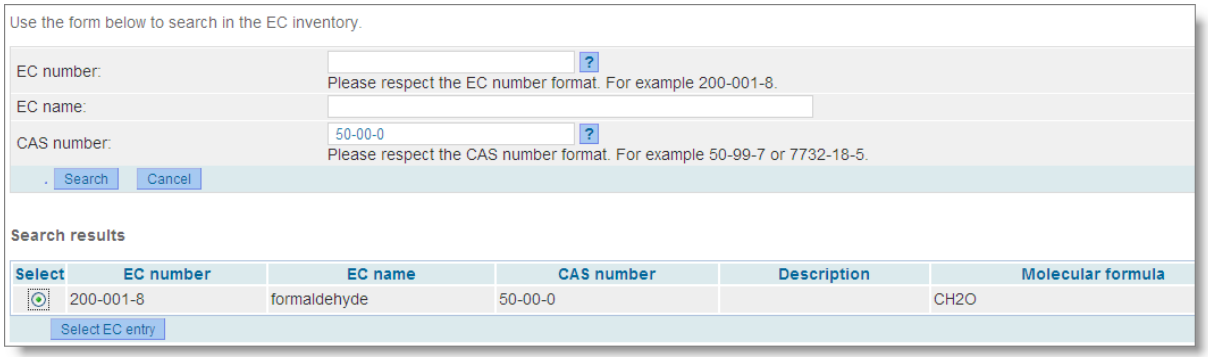
b) EC inventory

We recommend you always search the EC inventory for your substance by clicking <Search EC inventory… > (Figure 18).

Figure 18: EC inventory

Please search by any of the criteria, EC number, EC name or CAS number. From the list provided select the correct identity for your substance (Figure 19) and click on the <Select EC entry> button.

Figure 19: EC inventory search



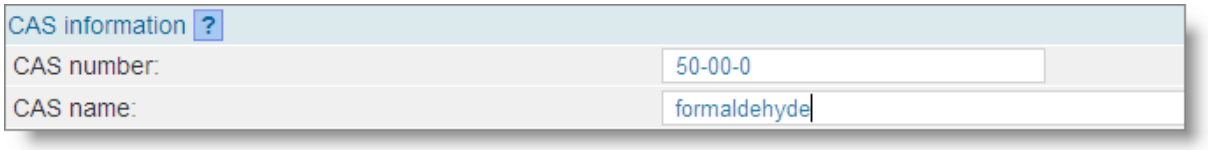
If you have assigned the wrong identity for your substance (e.g. wrong EC number), you can delete it using the red cross  and select a new one if needed.

The EC number is pre-filled automatically by REACH-IT if you have selected from Figure 12 <C&L notification for a substance already listed in Annex VI to CLP>, and if this information is available in Table 3.1 of Annex VI to CLP.

c) CAS information

If available for your substance, please provide in this field the CAS number in the correct format. If a CAS number is provided we encourage you to also provide the CAS name as found in the CAS registry (Figure 20).

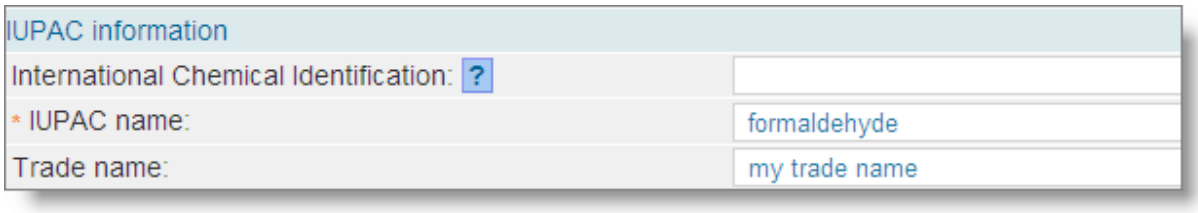
Figure 20: CAS information



d) IUPAC name (mandatory field) and other substance name

Please provide in this field the IUPAC name for your substance (Figure 21). The IUPAC name provided should follow the current IUPAC nomenclature rules. As this is a mandatory field failure to specify an IUPAC name will prevent you from proceeding to the next step.

Figure 21: IUPAC information and other names



You can also specify the trade name of your substance.

International Chemical Identification is pre-filled automatically by REACH-IT if you have selected from Figure 12 <C&L notification for a substance already listed in Annex VI to CLP>.

e) Typical concentration (mandatory field)

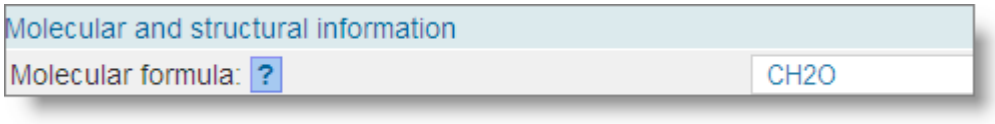
This is the typical concentration of your substance, a single value that is often the average of 5 consecutive production batches. Remember to select the correct unit as if left blank you are not able to proceed (Figure 22).

Figure 22: Typical concentration

f) Molecular formula

Please provide the molecular formula for your substance (Figure 23). The preferred system for writing the molecular formula is the Hill system. In addition, if different from the Hill formula, you should also provide the CAS formula in the same field. The formula should be separated by a double forward slash "//". As this is a mandatory field in case your substance is not identified by a CAS or an EC number, failure to specify a molecular formula will prevent you from proceeding to the next step.

Figure 23: Molecular formula



g) Molecular weight range

Please provide in this field the molecular weight or molecular weight range for your substance (Figure 24). In the common case where your substance has a single defined molecular weight, please provide this value in the first field without using any prefixes. As this is a mandatory field in case your substance is not identified by a CAS or an EC number, failure to specify a molecular formula will prevent you from proceeding to the next tab.

Figure 24: Molecular weight range

h) SMILES notation

Please provide in this field the SMILES notation for your substance (Figure 16).

i) Structural formula

Please attach a structural formula for your substance (Figure 16). Click on the link <Attach image file…> to add your file. The following types are allowed:

- jpg/jpeg
- tiff
- mol
- pdf
- txt
- doc
- rtf

As this is a mandatory field in case your substance is not identified by a CAS or an EC number, failure to attach a structural formula will prevent you from proceeding to the next tab.

j) Remarks

Please use this field to provide any comments related to your substance that may assist us in assessing your dossier (Figure 16).

6.5.1.2 Impurities and Additives

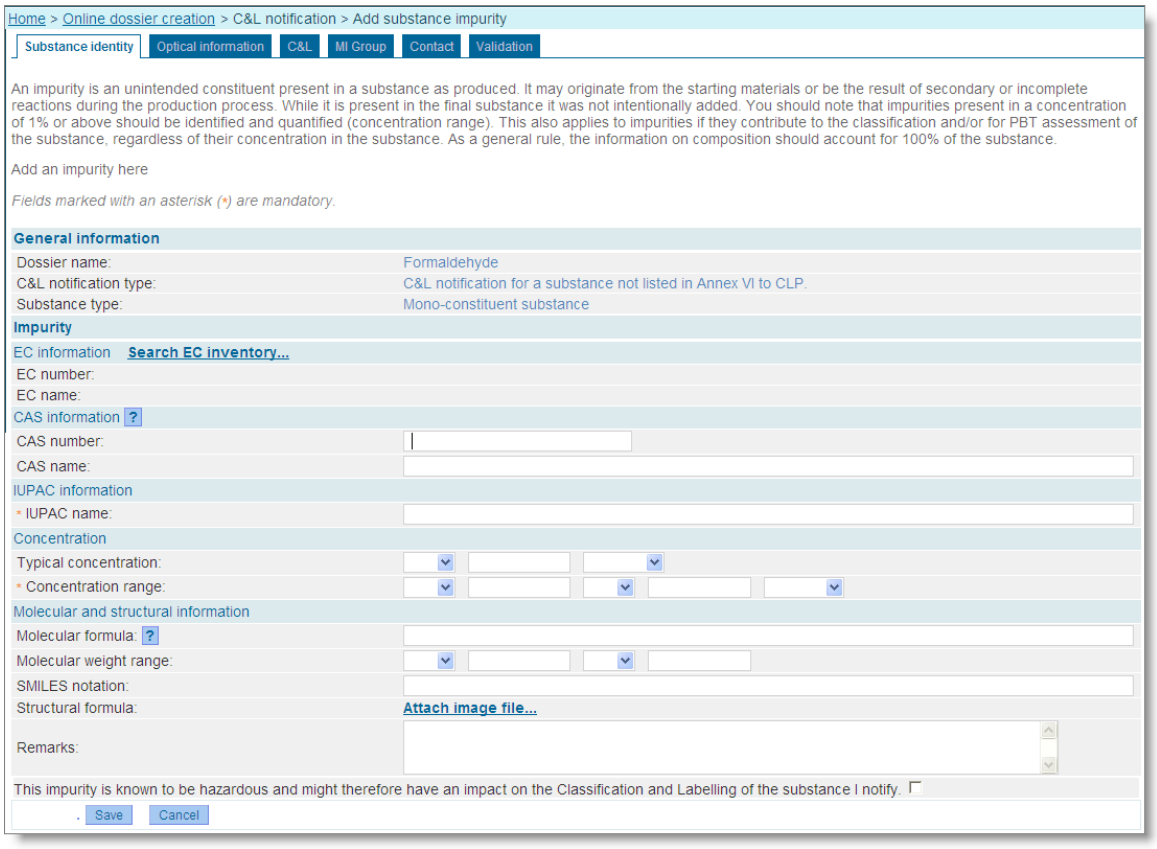
Click on the link <Add Impurity...> or <Add Additive…> in order to add information on impurities and/or additives (Figure 25). Please complete the fields using the same approach as used for the main constituent(s) described above. Note that the <IUPAC name> and <Concentration range> are mandatory fields and must be completed before being able to proceed further. Click on the button Save after providing the relevant information.

You can specify the function of the additive in the remarks field.

Figure 25: Add Impurity and add Additive

Click on the button Next > > to proceed. By clicking on the <Add Impurity…> link information about the impurities can be added as shown in Figure 26.

Figure 26: Add impurity

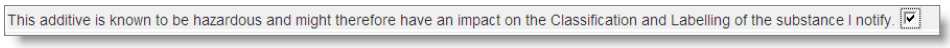


Complete as many fields as possible using the same approach as used for the main constituent(s) described above. The fields marked by * are mandatory and you must provide the appropriate information to proceed. Please take note of the advice related to each field given above.

Indicate for each impurity or additive if it has an impact on the classification of the substance by ticking the related box (Figure 27 and Figure 28).

Figure 27: Indicate if an impurity is relevant for the C&L of the substance

Figure 28: Indicate if an additive is relevant for the C&L of the substance



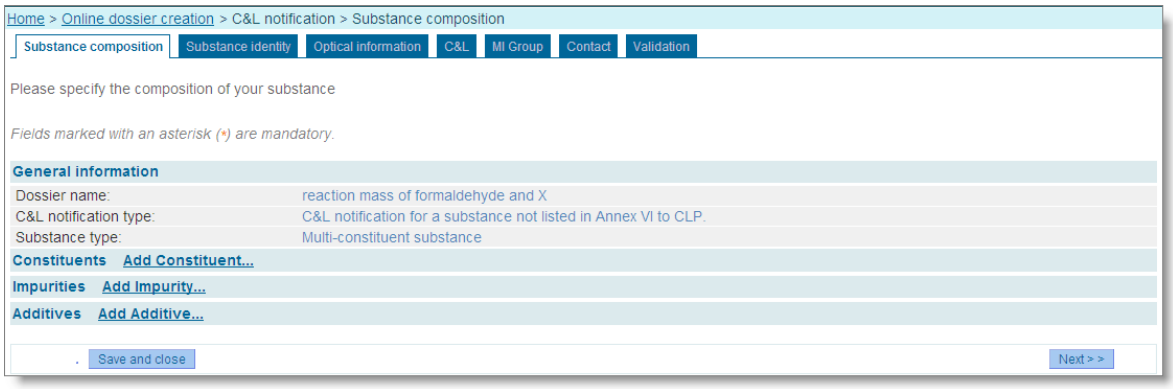
Click on the button Next > > to proceed.

Go to section on optical information of this manual (Chapter 6.6).

6.5.2 Specify the substance identity and composition for a multi-constituent substance

If you select <multi-constituent substance> as substance type, the <Substance composition> page for multi-constituent substance opens first (Figure 29).

Figure 29: Substance composition of a multi-constituent substance

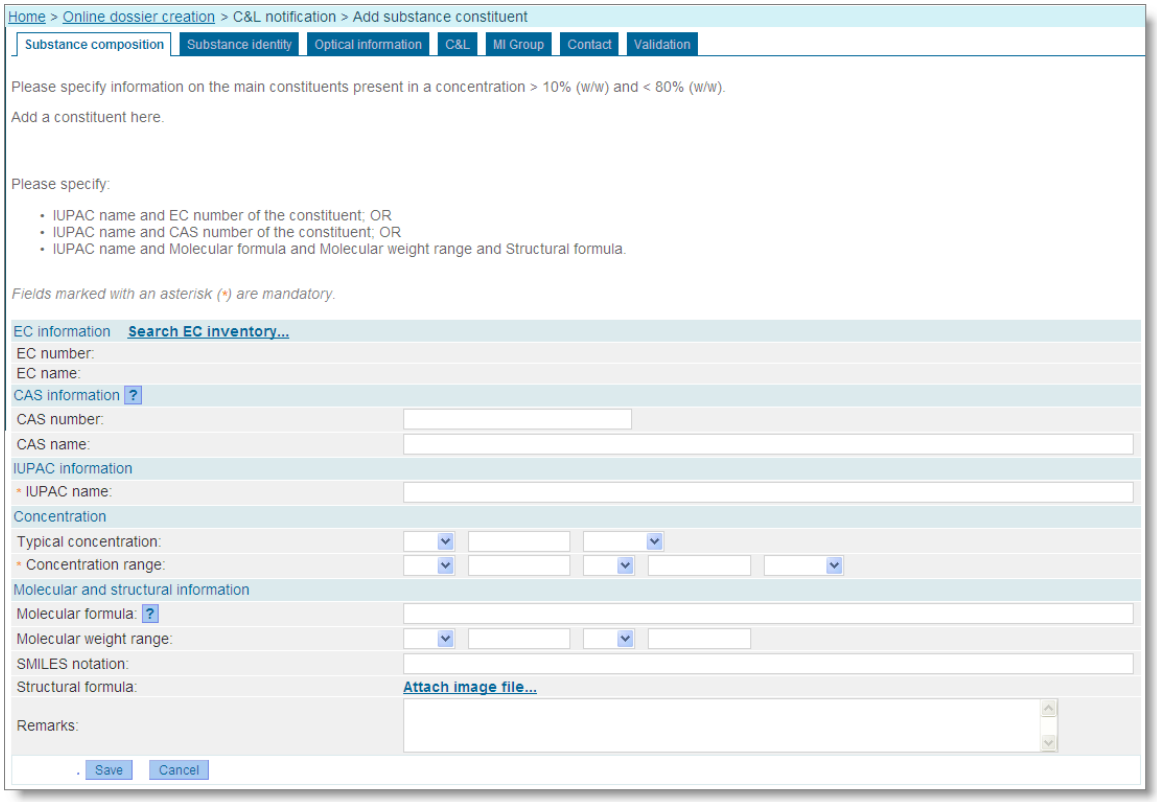


For a multi-constituent substance you need to specify at least two and not more than ten main constituents.

6.5.2.1 Main constituents

Click on the link <Add constituent…> and a new page opens (Figure 30).

Figure 30: Adding main constituents



For each main constituent, please complete as many fields as possible.

The fields marked by * are mandatory and you must provide the appropriate information to proceed to the next step. Please take note of the following advices related to each field.

k) Typical concentration

This is the typical concentration (Figure 22) of your main constituent. Remember to select the correct unit as if left blank you are not able to proceed.

l) Concentration range (mandatory field)

Your substance is a well-defined multi-constituent substance therefore you must have a defined concentration range for each constituent. In these fields specify a minimum value and a maximum value ensuring you use the appropriate prefix (>=, <=, < or >). We recommend that you avoid the use of the <ca.> prefix as this would not be considered appropriate for a substance with a defined composition. Remember to select the correct unit as if is left blank you are not able to proceed.

Figure 31: Concentration range

m) EC inventory

We recommend you to always search the EC inventory for your main constituent by clicking <Search EC inventory… > link (Figure 18). Please search by any of the criteria, namely EC number, EC name or CAS number. Select the correct identity for your constituent (Figure 19) and click on the <Select EC entry> button.

n) CAS information

If available for your main constituent, please provide in this field the CAS number in the correct format. If a CAS number is provided we encourage you to also provide the CA index name as found in the CAS registry (Figure 20).

o) IUPAC name (mandatory field)

Please provide in this field the IUPAC name for your main constituent (Figure 21). The IUPAC name provided should follow the current IUPAC nomenclature rules. As this is a mandatory field failure to specify an IUPAC name will prevent you from proceeding to the next step.

p) Molecular formula

Please provide the molecular formula of your main constituent (Figure 23). The preferred system for writing the molecular formula is the Hill system. In addition, if different from the Hill formula, you should also provide the CAS formula in the same field. The formula should be separated by a double forward slash "//".As this is a mandatory field in case your constituent is not identified by a CAS or an EC number, failure to specify a molecular formula will prevent you from proceeding to the next step.

q) Molecular weight range

Please provide in this field the molecular weight or molecular weight range for your main constituent (Figure 24). In the common case where your substance has a single defined molecular weight, please provide this value in the first field (see highlighted below) without

using any prefixes. As this is a mandatory field in case your constituent is not identified by a CAS or an EC number, failure to specify a molecular formula will prevent you from proceeding to the next step.

r) SMILES notation

Please provide in this field the SMILES notation for your main constituent.

s) Structural formula (mandatory field)

Please attach a structural formula for your main constituent. Click <Attach file…> to add your file. The following types are allowed:

- jpg/jpeg
- tiff
- mol
- pdf
- txt
- doc
- rtf

As this is a mandatory field in case your constituent is not identified by a CAS or an EC number, failure to specify a structural formula will prevent you from proceeding to the next step.

t) Remarks

Please use this field to provide any comments related to your main constituent that may assist us in assessing your dossier.

When you have completed first main constituent click Save and add the second main constituent.

6.5.2.2 Impurities and Additives

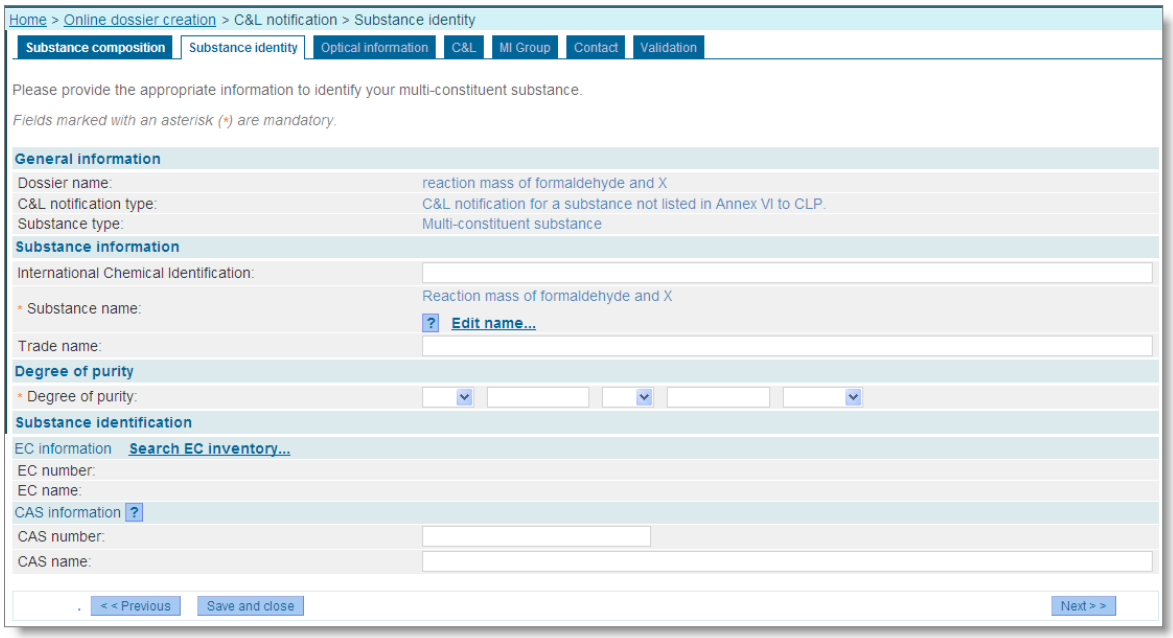
When you have added all main constituents you can continue to impurities by clicking on the link <Add Impurity...> or to additives by clicking on <Add Additive…> (Figure 25).

You can specify the function of the additive in the remark field.

6.5.2.3 Identity of the multi-constituent substance

When you have completed the <Substance composition> click Next > >. The substance identity page opens. REACH-IT automatically names multi-constituent substances as <Reaction mass of [names of the main constituents]> (Figure 32). These main constituents are those specified in the substance composition.

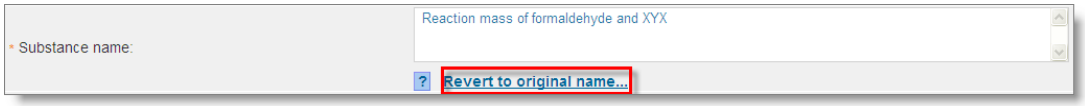
Figure 32: Naming of multi-constituent substance



If you do not agree with the automatically assigned name, you may change it by clicking on the link <Edit name> (Figure 32). Click on the button Save and close when you are done.

If you want to revert back to the original name suggested by REACH-IT, click on the link <Revert to original name…> (Figure 33).

Figure 33: Edit name of a multi-constituent substance



u) Degree of purity (mandatory field)

Next specify the degree of purity of your multi-constituent substance (Figure 17). In these fields specify a minimum value and a maximum value ensuring you use the appropriate prefix (>=, <=, < or >).

We recommend that you avoid the use of the <ca.> prefix as this would not be considered appropriate for a substance with a defined composition. Remember to select the correct unit as if left blank you are not able to proceed.

This field is a mandatory field and must be completed in order to proceed.

v) EC inventory

We recommend you always search the EC inventory for your substance by clicking on the link <Search EC inventory… > link (Figure 18). Please search by any of the criteria, namely EC number, EC name or CAS number.

w) CAS information

If available for your substance, please provide in this field the CAS number in the correct

format (Figure 20). If a CAS number is provided, we encourage you to also provide the CAS name as found in the CAS registry.

Complete as many fields as possible using the same approach as used for the main constituents described above. The fields marked by * are mandatory and you must provide the appropriate information to proceed. Please take note of the advice related to each field given above.

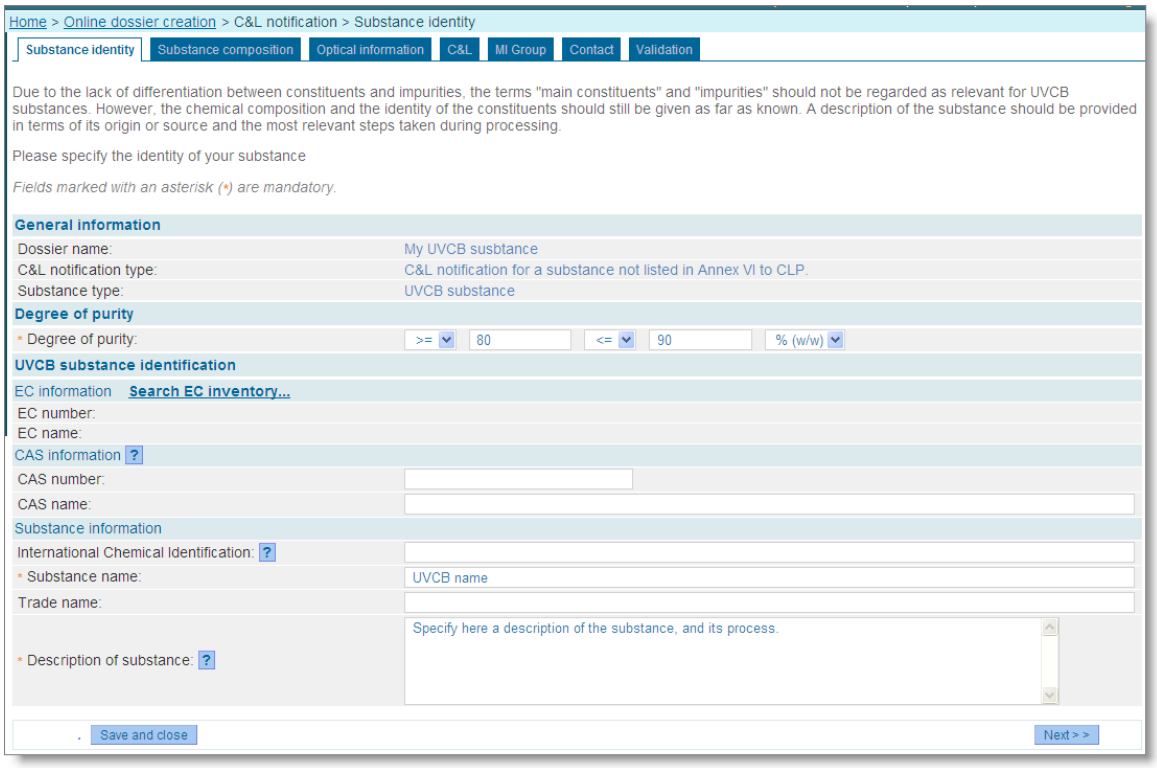
Click on the button Next > > to proceed.

Go to section on optical information of this manual (Chapter 6.6).

6.5.3 Specify the substance identity and composition for a UVCB substance

If you select <UVCB substance> as substance type, the <Substance identity> page for UVCB substance opens first (Figure 34).

Figure 34: Substance composition of a UVCB substance



6.5.3.1 Substance identity of a UVCB

The fields marked by * are mandatory and you must provide the appropriate information to proceed. Please take note of the following advice related to each field.

x) Degree of purity (mandatory field)

In these fields specify (Figure 17), where possible, a minimum value and a maximum value ensuring you use the appropriate prefix (>=, <=, < or >). As your substance is a UVCB substance a purity of, for example, ca. 100 % w/w may be appropriate. Remember to select the correct unit as if left blank you are not able to proceed. As this field is a mandatory field failure to specify a degree of purity will prevent you from proceeding to the next step.

y) EC inventory

We recommend you always search the EC inventory for your substance by clicking <Search EC inventory… > link (Figure 18). Please search by any of the criteria, EC number, EC name or CAS number (Figure 18 and Figure 19). Hover the mouse pointer over the ? symbol for further information. From the list provided select the correct identity for your substance.

z) CAS information

If available for your substance, please provide in this field the CAS number in the correct format. If a CAS number is provided we encourage you to also provide the CAS name as found in the CAS registry (Figure 20). Hover the mouse pointer over the ? symbol for further information.

aa) Substance name (mandatory field)

Please provide in this field the name for your substance. The name provided should follow the naming rules for UVCB substances as described in the Guidance for identification and naming of substances under REACH available at: http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

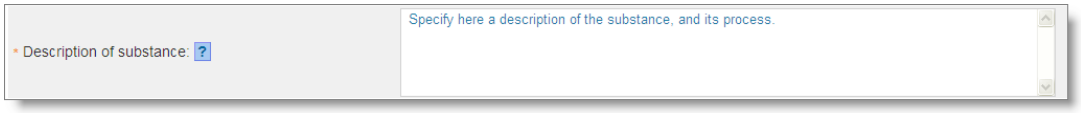
As this is a mandatory field failure to specify a substance name will prevent you from proceeding to the next step.

Figure 35: Substance name field

bb) Description of substance (mandatory field)

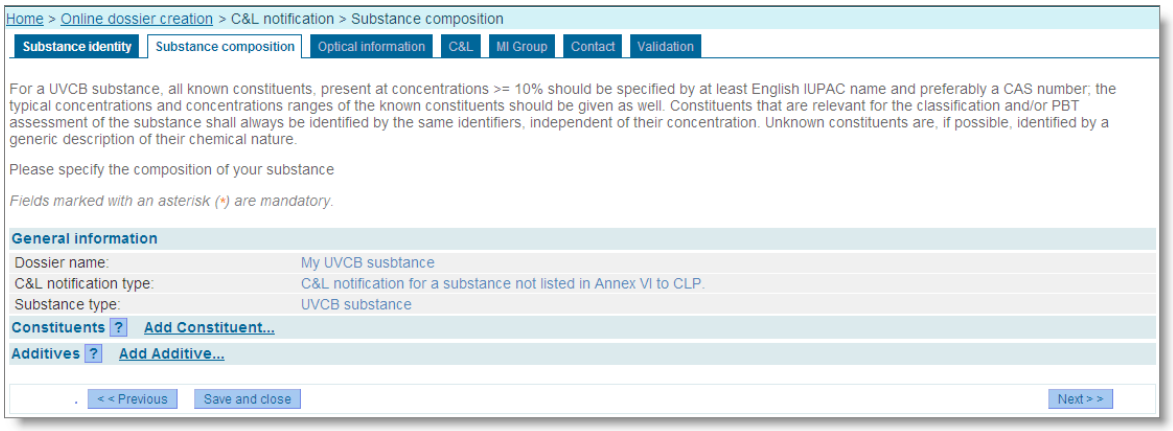
For UVCB substances a description of the substance should be provided in terms of source (starting materials or name of the species and family) and process (type of chemical reaction or refinement step and other identifiers) (Figure 36). Hover the mouse over the ? symbol for more information. As this is a mandatory field failure to specify a description will prevent you from proceeding to the next step.

Figure 36: Description field



Click on the button Next > > to proceed. The substance composition page opens (Figure 37).

Figure 37: Substance composition of UVCB substance



6.5.3.2 Composition of a UVCB

Due to the lack of differentiation between constituents and impurities, the terms "main constituents" and "impurities" should not be regarded as relevant for UVCB substances. However, the chemical composition and the identity of the constituents should still be given as far as known.

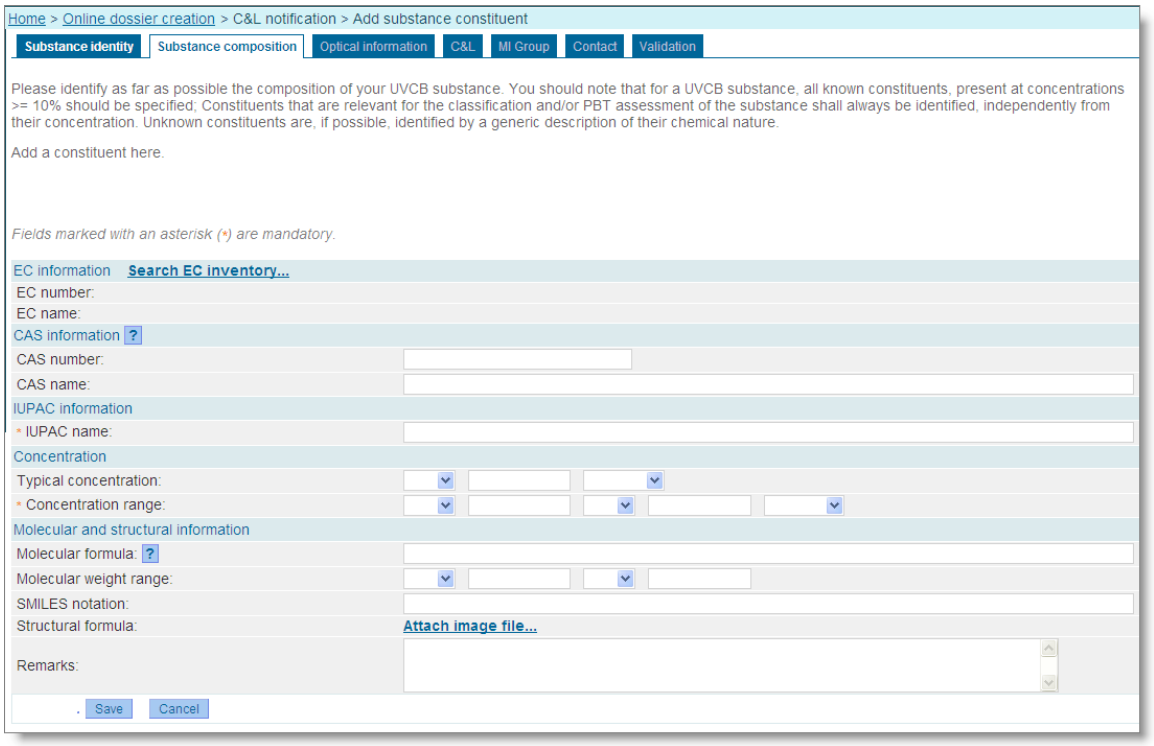
Click <Add constituent…> to add your constituents. A new page opens (Figure 38).

You must always add at least one constituent. In the case you cannot identify or quantify any constituents please state the substance name of your UVCB (as specified in the substance composition page) in the IUPAC name field and state the purity range for the UVCB (as specified in the substance composition page) in the concentration range field.

Click <Add additives…> to add your additives. A new page opens.

You can specify the function of the additive in the remark field.

Figure 38: Add constituents of a UVCB substance



Please complete as many fields as possible.

The fields marked by * are mandatory and you must provide the appropriate information to proceed.

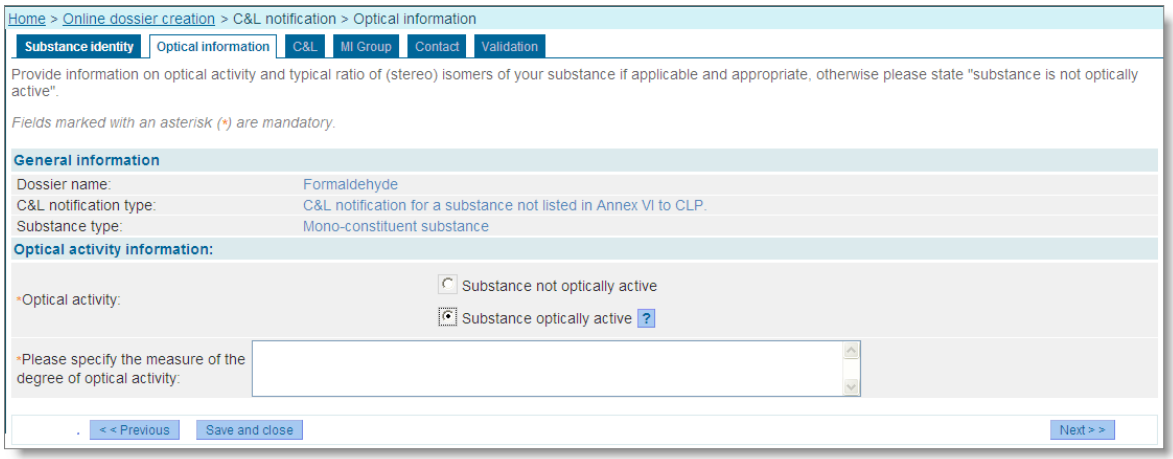
Click on the button Next > > to proceed.

6.6 Specify the optical activity

After having specified the substance identity and the substance composition of your substance, you can provide information on optical activity and typical ratio of (stereo) isomers of your substance if applicable and appropriate (Figure 39).

Click on the button Next > > to proceed.

Figure 39: Optical activity



If you have indicated your substance as optically active you should also specify the value for the specific rotation (in degrees) indicating also the temperature of measurement (in °C) and the wavelength of the incident light source (in nanometres). The direction of rotation should also be specified as either + or -. If a sample solution is used the concentration and solvent name should also be provided.

Typically specific rotation is specified as follows:

[α] tλ°

Where:
[α] = specific rotation

t = temperature in °C

λ= wavelength of incident light; for sodium D lamp (598 nm) this is indicated simply by D

6.7 Specify the Classification and Labelling

Use the C&L section to specify the information requested under Article 40(1- c, d, e and f) of the CLP Regulation, or to agree with a C&L already harmonised, registered and/or notified (included in the C&L inventory).

6.7.1 Is there any C&L for the same substance already in the inventory?

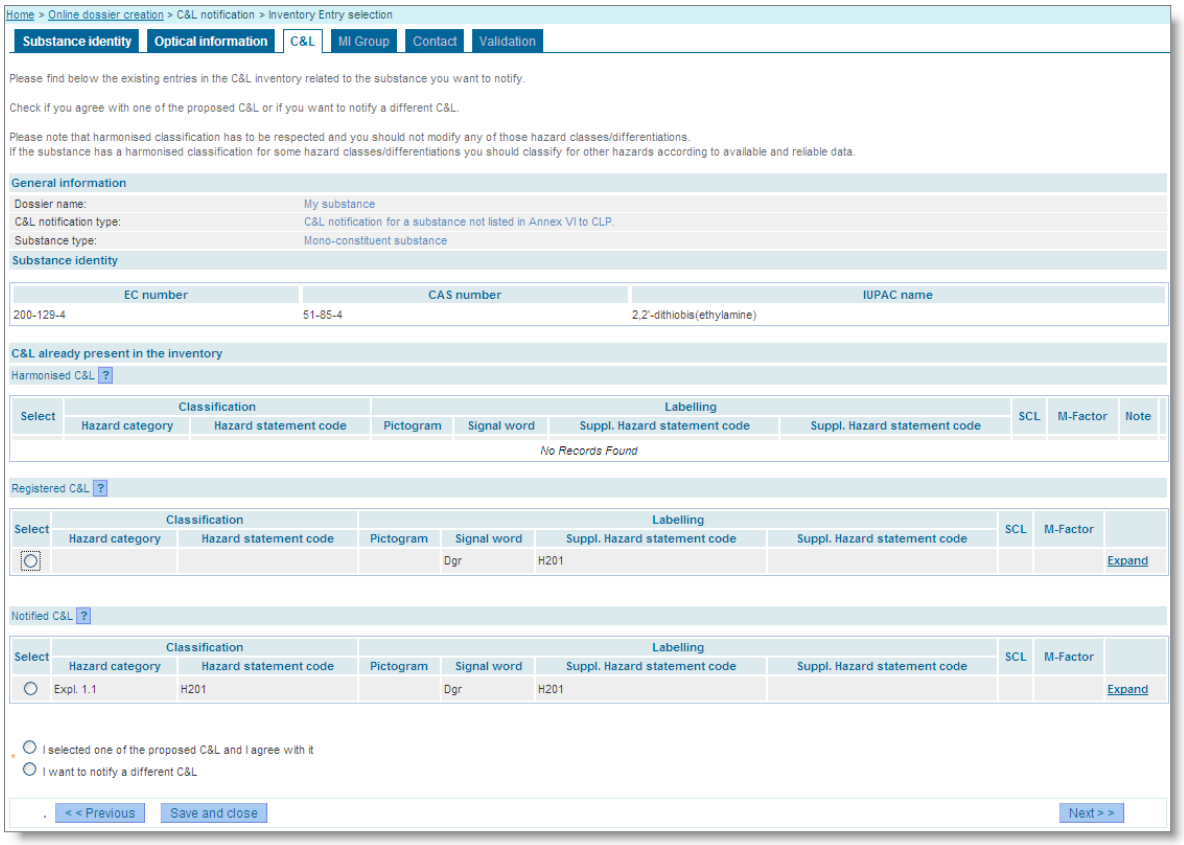
Based on the substance identity you have specified in the previous screens, REACH-IT searches automatically in the C&L inventory if:

- The substance has already a harmonised C&L in Annex VI to CLP.
- The substance has already been registered under the REACH Regulation including a C&L according to CLP Regulation.
- The substance has already been notified under the CLP Regulation.

REACH-IT will display in 3 different tables the results of the search (Figure 40).

In case the substance you notify is already harmonised, then only the harmonised table is displayed (Figure 44).

Figure 40: C&L for the same substance in the inventory



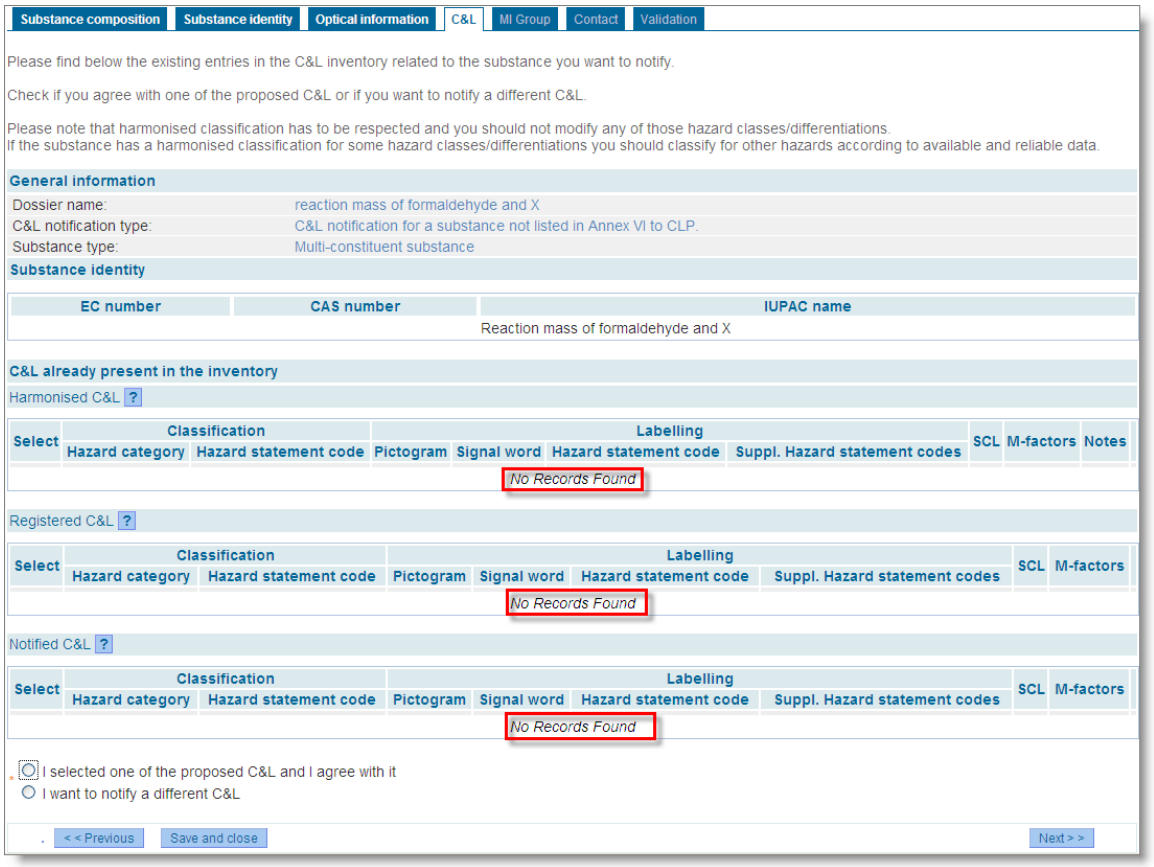
Only the C&L information is displayed on this page. The identity of the previous notifier(s) or registrant(s) is never displayed.

For performance issue, only the latest 500 notified C&L are displayed on the screen.

There might be a delay between the moment a C&L is submitted by a notifier/registrant, and the moment this C&L is displayed in this table.

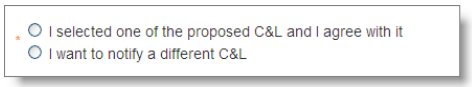
In case the substance you notify is not yet in the inventory (not yet notified, nor registered, nor harmonised), the message <No Records Found> is displayed in the table(s) (Figure 41).

Figure 41: No C&L for the same substance in the inventory



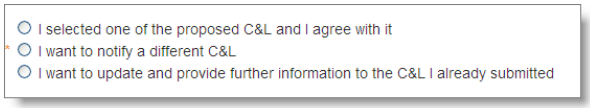
You have the possibility to select whether you agree with a C&L already present in the C&L inventory, or to propose a new or different C&L than the one already in the inventory, or to update a C&L notification you have already successfully submitted (Figure 42).

Figure 42: Select to agree with a C&L or propose a new one



The third option <Update my previously submitted C&L> is available only if you have selected (cf. chapter 6.2.3) that you want to update a previously successfully submitted C&L notification (Figure 43).

Figure 43: Select to update your C&L notification



If you notify a substance already listed in Part 3 of Annex VI to CLP, i.e. there is a harmonised C&L for the substance, the use of a harmonised classification and labelling of a substance is mandatory.

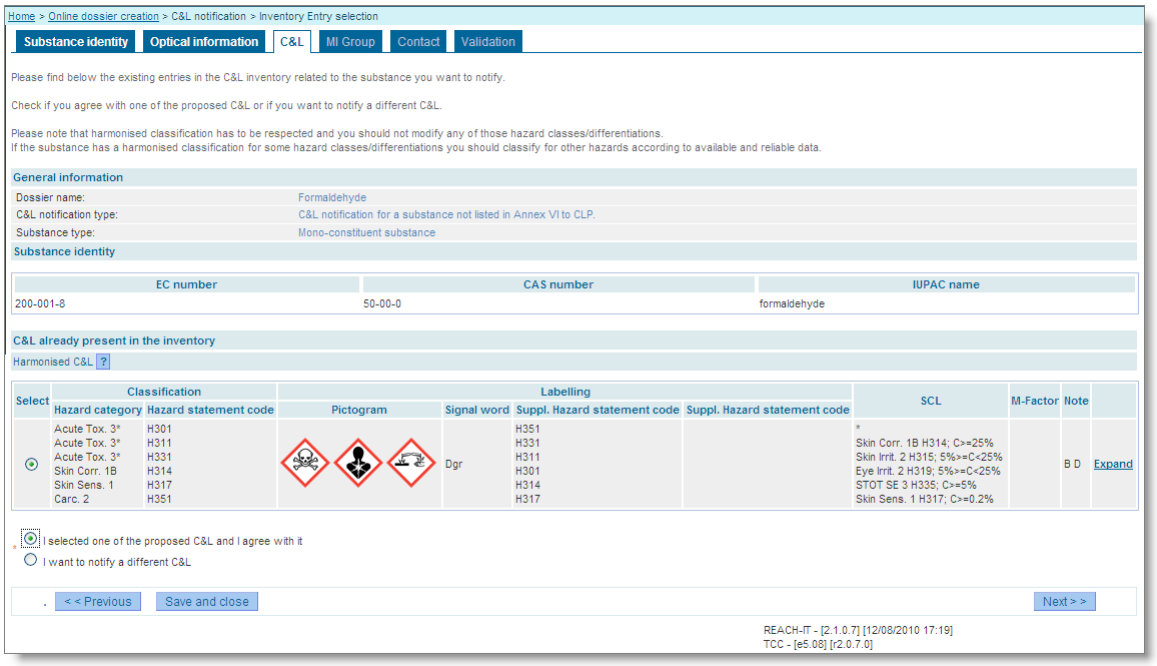
Therefore REACH-IT displays only the harmonised C&L (Figure 44).

Select with a radio-button the harmonised C&L you want to continue with, and then select the <I selected one of the proposed C&L and I agree with it> button

(Figure 44).

If you do not select this option an error message is displayed (Figure 87).

Figure 44: Continue with the harmonised C&L



Click on the button Next > > to proceed.

6.7.2 Your substance is already harmonised in Annex VI to CLP

If the substance you notify is already harmonised at the EU level and is included in Annex VI to the CLP Regulation, the harmonised Classification and Labelling page opens (Figure 45).

This page is automatically pre-filled with all the information from Table 3.1 of Annex VI to CLP Regulation.

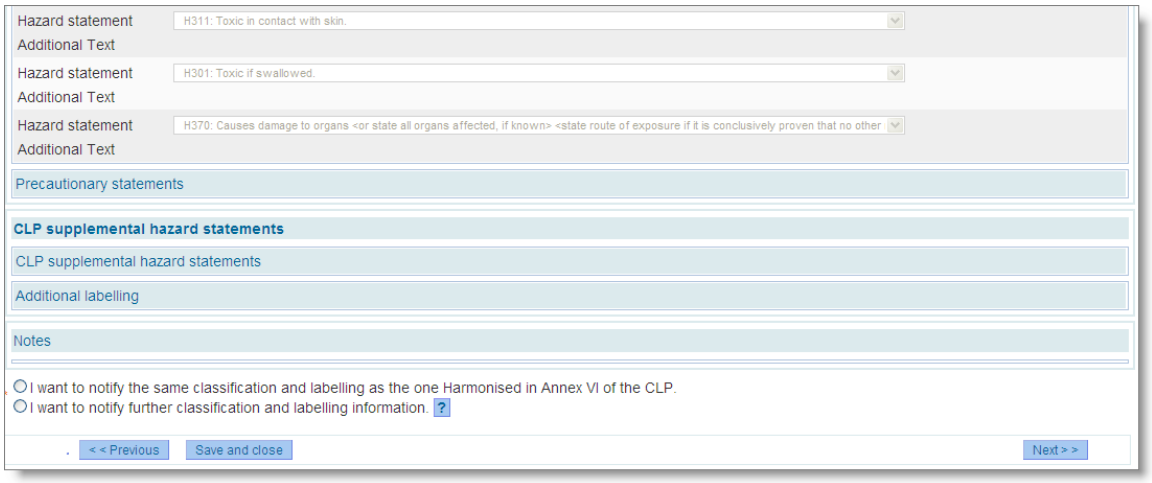
If the substance you notify is already harmonised in Annex VI to the CLP Regulation, you have to use that classification and labelling for the hazards concerned.

The legally binding harmonised C&L at the EU level are contained in Annex VI to the CLP Regulation, as amended, and all published in the Official Journal of the European Union.

It is the responsibility of the user to make sure that the information displayed by REACH-IT is correct.

If you do not want to add any information to a harmonised C&L (e.g. information for hazard classes/differentiations not yet harmonised, or refining minimum classification as set in section 1.2 of Annex VI to CLP), select the <I want to notify the same classification and labelling as the one Harmonised in Annex VI of the CLP> button, and click on the button Next > > to proceed.

Figure 45: Harmonised C&L



6.7.2.1 Notify further information to a substance already harmonised

Nevertheless you may self-classify based on available data a substance listed in Part 3 of Annex VI to CLP for those hazards not covered by the harmonised classification.

It should be noted also, that if you have access to information for a substance subject to a minimum classification (section 1.2 of Annex VI to the CLP Regulation) that leads to classification in a more severe category, then the more severe category must be applied.

Furthermore, an M-factor based on available data shall be set for a substance classified as hazardous to the aquatic environment, category acute 1 or category chronic 1, if not given in Part 3 of Annex VI to CLP. To do so, select <I want to notify further classification and labelling information> (Figure 45), and click on the button Next > > to proceed. The C&L page changes in "edit" mode where you can notify further information related to the classification and labelling of your substance (see chapter 6.7.4.2 and 6.7.4.3 for more information on how to specify information on C&L).

Harmonised classification has to be respected and you should not modify any of those hazard classes/differentiations. If the substance has a harmonised classification for some hazard classes/differentiations you should classify for other hazards according to available and reliable data.

Please consult Annex VI to CLP available on ECHA website at:
http://echa.europa.eu/clp/inventory_notification/notification_how_en.asp

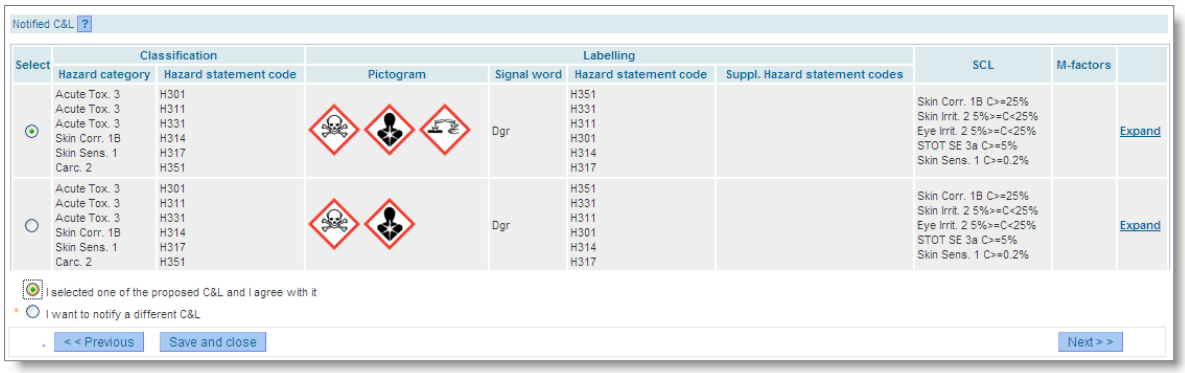
6.7.3 Agree with a C&L previously notified/registered

To agree with a C&L already notified or registered in the inventory, you first need to select with a radio-button the C&L you want to agree with, and then select the <I agree> button (Figure 46).

Click on the button Next > > to proceed.

If you forget to select a C&L, and click on Next > >, an error message is displayed (Figure 86).

Figure 46: Agree with C&L already in the inventory



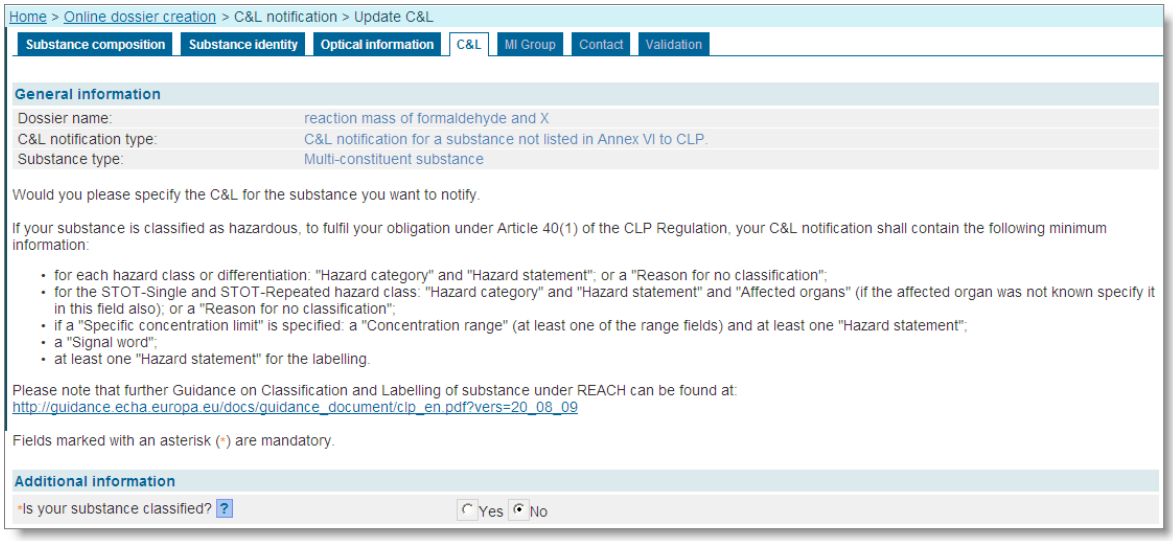
When you agree with a C&L already notified or registered, you do not need to provide more information.

The C&L including the <reasons for no classification> is automatically pre-filled in your dossier.

6.7.4 Propose a new C&L

If you select <I want to notify a different C&L> the C&L page opens (Figure 47).

Figure 47: C&L page



6.7.4.1 Is the substance hazardous?

Figure 48: Select if the substance is hazardous

If you submit a C&L notification for a substance that does not meet the criteria for classification under CLP you should tick the box "Not classified" and then you do not need to specify anything else (Figure 48).

It is highly recommended to consult Annex I to the CLP Regulation for the classification criteria and for more detailed instructions on the application of the Classification and Labelling rules the related Introductory guidance on the CLP

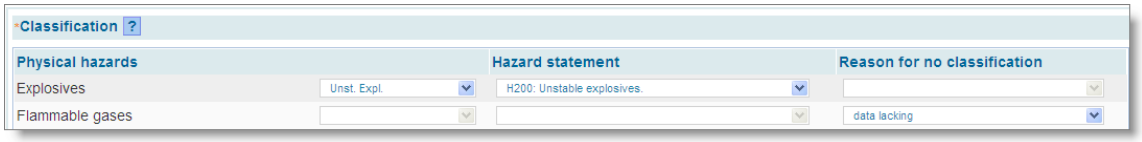
Regulation. (http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp)

6.7.4.2 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 49).

Indeed in case a substance is classified in some but not all hazard classes you have to indicate the "Reason for no classification" for the other hazard classes or differentiations.

Figure 49: Entry fields for classification



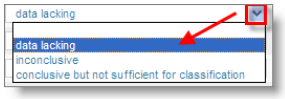
The field "Reason for no classification" is pre-filled indicating "data lacking" by default. You can:

- Update the "Reason for no classification" by selecting the appropriate reason for that hazard class/differentiation from the pick-list (Figure 50);

OR

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

Figure 50: Pick-list with reasons 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.

There are certain classification waivers in CLP:

- If a substance is classified for skin corrosion cat. 1, it does not need to be classified for serious eye damage (but not vice versa).
- If a substance is classified for certain physical hazards, it does not need to

be classified for certain others.

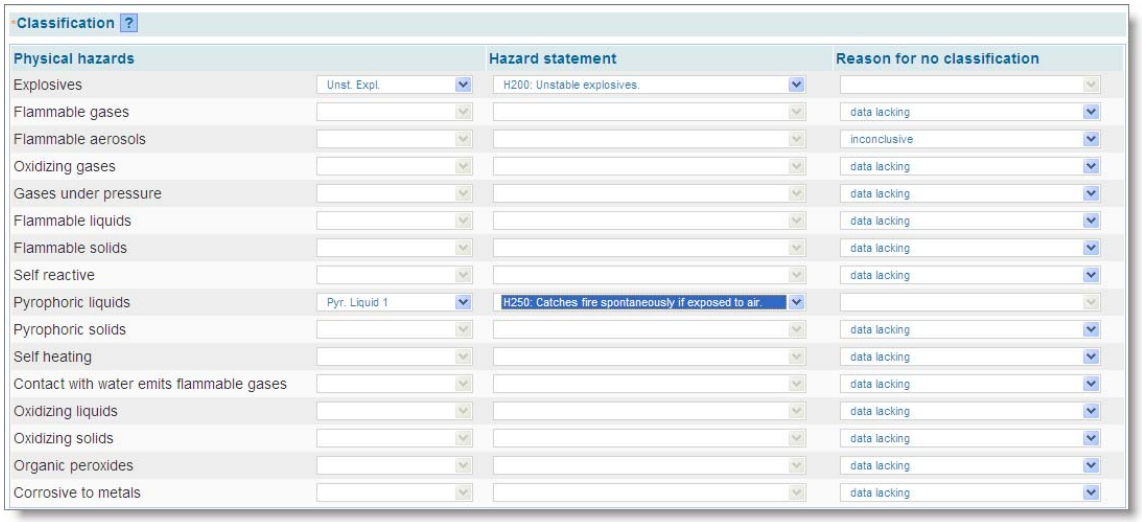
- If a substance has a particular physical state, e.g. it is a gas, it does not need to be classified for hazards requiring another physical state, e.g. as an oxidising solid or as corrosive to metals.

In case of such classification waivers you should select "conclusive, but not sufficient for classification" as a reason for no classification.

cc) Classification - Physical hazards (mandatory)

For all hazards indicated in the block "Physical hazards", either the two first fields (i.e. the field "Hazard category" (e.g. Expl. Div. 1.1) and the field "Hazard statement" (e.g. explosive; mass explosion hazard)) shall be filled in, or the field "Reason for no classification" shall be filled in (Figure 51).

Figure 51: Specify hazard category and hazard statement for the Physical hazards



The following hazard category and hazard statement do not exist in the CLP Regulation and shall not be used in your C&L notification (Table 10):

Table 10: Physical hazard category and hazard statement not in CLP

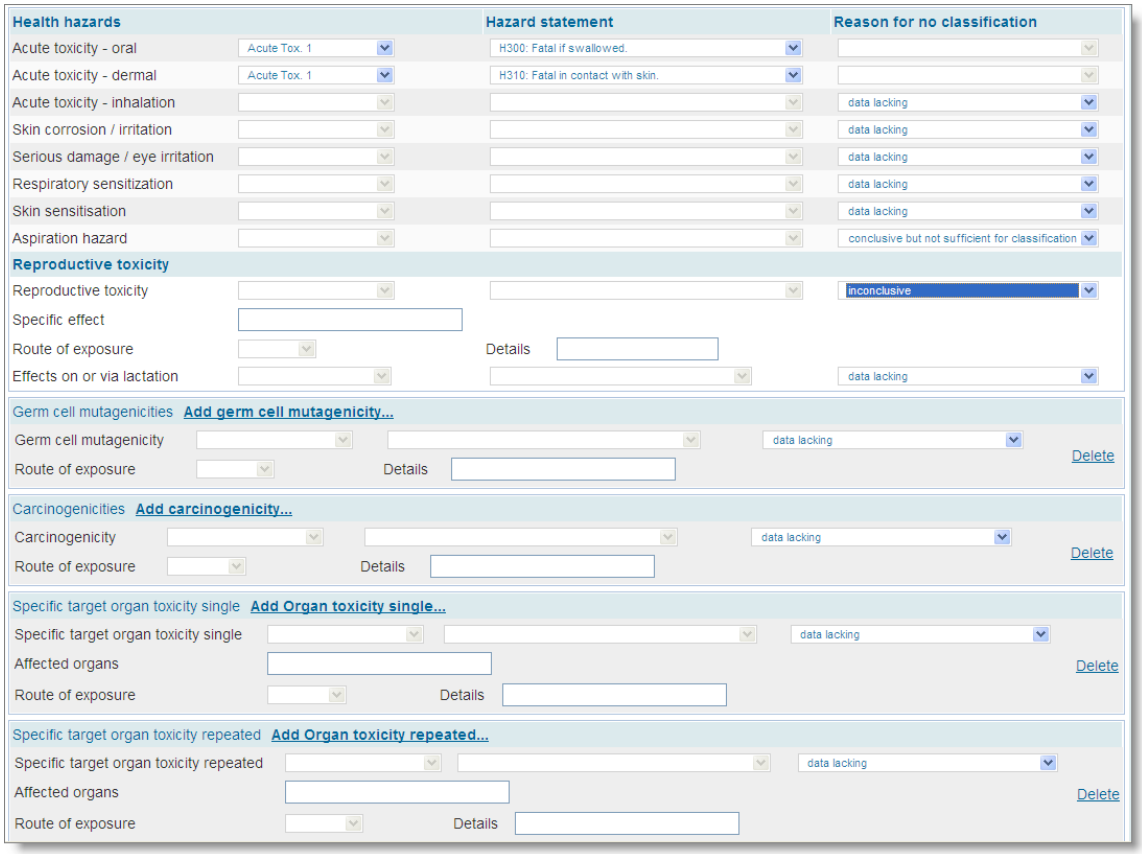
Classification hazard class	Hazard category	Hazard statement
Flammable liquids	Flammable liquid 4	H227: Combustible liquid

dd) Classification - Health hazards (mandatory)

For all hazard classes indicated in the block "Health 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 52).

For the following hazard class: "Specific target organ toxicity – single" and "Specific target organ toxicity – repeated" either the 3 fields "Hazard category" and "Hazard statement" and "Affected organs" should be filled in, or the field "Reason for no classification" should be filled in (Figure 55).

Figure 52: Specify hazard category and hazard statement for the Health hazards

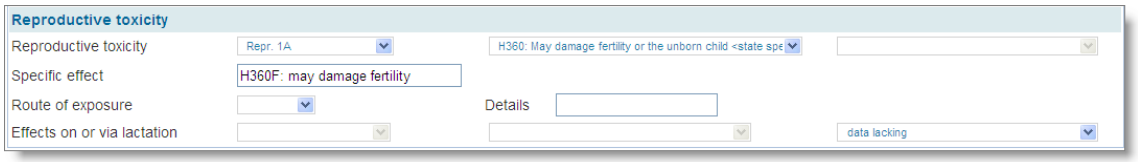


In case you have conclusive data which enables you to specify the nature of reproductive toxicity effects (i.e. damage to fertility and/or the unborn child), you should indicate that in the field "Specific effect" by including the appropriate additional hazard statement code(s) in that field. (Figure 53) The following additional codes are specified in Annex VI, 1.1.2.1.2: to the CLP Regulation:

- H360F - May damage fertility.
- H360D - May damage the unborn child.
- H361f - Suspected of damaging fertility.
- H361d - Suspected of damaging the unborn child.
- H360FD - May damage fertility. May damage the unborn child.
- H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.
- H360Fd - May damage fertility. Suspected of damaging the unborn child.
- H360Df - May damage the unborn child. Suspected of damaging fertility.

For more instructions on the selection of these codes, please consult the Guidance on the application of the CLP criteria at:
http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp

Figure 53: Specify the nature of reproductive toxicity effects

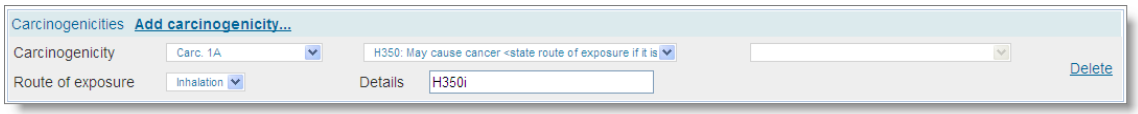


The route of exposure for reproductive toxicity should only be specified if it is conclusively proven that no other routes of exposure cause the hazard. Supporting evidence should be attached (Figure 66) unless it is already specified in Annex VI to the CLP Regulation.

In case you have conclusive data which enables you to explicitly specify the hazard of carcinogenicity via inhalation (or it is specified in Annex VI to the CLP Regulation) you should include the corresponding additional hazard statement code (H350i) in the free text field under "Route of exposure" (Figure 54).

The route of exposure for carcinogenicity should only be specified if it is conclusively proven that no other route of exposure causes the hazard. Supporting evidence should be attached (Figure 66) unless it is already specified in Annex VI to the CLP Regulation.

Figure 54: Specify the hazard of carcinogenicity via inhalation

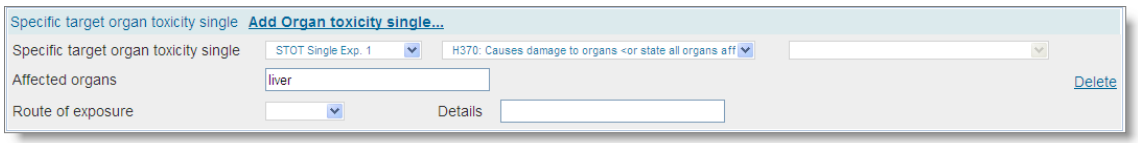


For the STOT-Single and STOT-Repeated hazard classes you have to indicate in the field "Affected organs" the primary target organs. It is recommended to include no more than three primary target organs for practical reasons and because the classification is for specific target organ toxicity. If more target organs are affected it is recommended that the overall systemic damage should be reflected by the phrase "damage to organs" (Figure 55).

If the affected organ is unknown indicate it in the field "Affected organs".

The route of exposure should only be specified if it is conclusively proven that no other route of exposure causes the hazard. Supporting evidence should be attached (Figure 66) unless it is already specified in Annex VI to the CLP Regulation.

Figure 55: Specify the affected organ



The following hazard category and hazard statement do not exist in the CLP Regulation and shall not be used in your C&L notification (Table 11) :

Table 11: Health hazard category and hazard statement not in CLP

Classification hazard class	Hazard category	Hazard statement
Acute toxicity - oral	Acute Toxicity 5	H303
Acute toxicity - dermal	Acute Toxicity 5	H313
Acute toxicity - inhalation	Acute Toxicity 5	H333
Skin corrosion/irritation	Skin Mild Irritation 3	H316
Serious eye damage / eye irritation	Eye irritation 2A Eye irritation 2B	H320
Aspiration Hazard	Asp toxicity 2	H305

ee) Classification – Specific concentration limits (if relevant)

Harmonised classification has to be applied: if your substance has (a) harmonised specific concentration limit(s), you shall specify it in this section (Figure 56).

If you propose to set specific concentration limit(s) under the strict condition of Article 10 of the CLP Regulation, you have to provide a scientific justification accordingly. Please refer to the description of chapter 6.7.4.4 of this manual for more information.

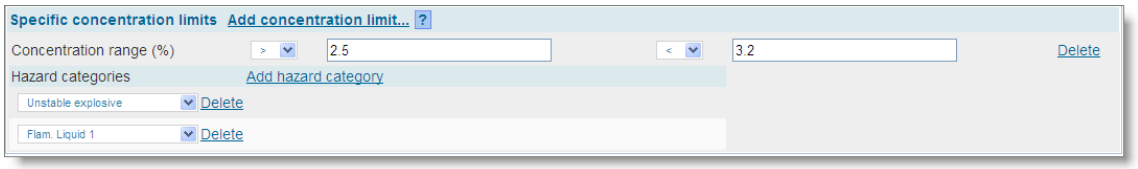
For each specific concentration limit (SCL), you should specify:

- A concentration range (at least one of the two range fields).
- At least one hazard statement related to the SCL.

You can specify more than one specific concentration limit by clicking <Add specific concentration limit>.

You can specify more than one hazard category per specific concentration limit by clicking <Add hazard category>.

Figure 56: Specific concentration limit



The following hazard categories do not exist in the CLP Regulation and shall not be used in your C&L notification to specify the specific concentration limit (Table 12):

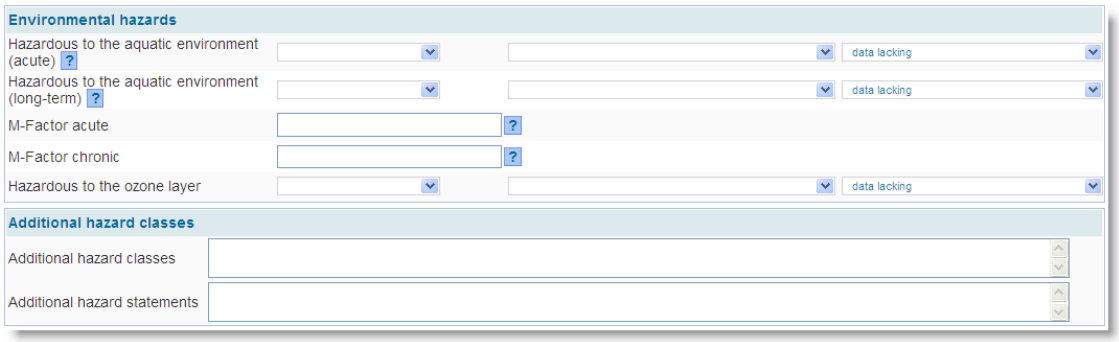
Table 12: Hazard category not in CLP

Classification	Hazard category
Specific concentration limit	Flammable liquid 4
	Acute Toxicity 5
	Skin Mild Irritation 3
	Eye irritation 2A
	Eye irritation 2B
	Asp toxicity 2

ff) Classification - Environmental hazards (mandatory)

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 57).

Figure 57: Specify hazard category and hazard statement for the Environmental hazards



The following hazard categories and hazard statements do not exist in the CLP Regulation and shall not be used in your C&L notification (Table 13):

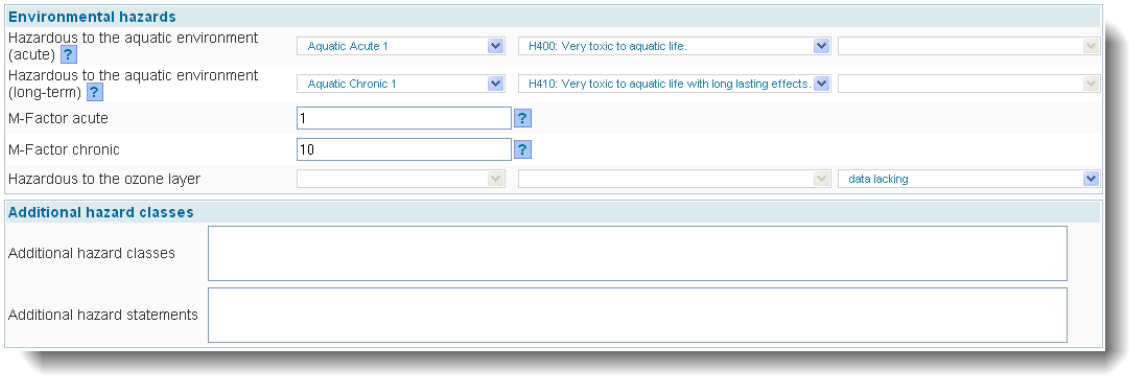
Table 13: Environmental hazard category and hazard statement not in CLP

Classification hazard class	Hazard category	Hazard statement
Hazardous to the aquatic environment	Aquatic acute 2 Aquatic acute 3	H401 H402

If a substance meets the criteria for classification 'Hazardous to the aquatic environment' as both, category aquatic acute 1 AND aquatic chronic 1:

- Select from the pick-list for "Environmental hazards/Hazardous to the aquatic environment (acute)", the category "Aquatic acute 1" and the Hazard statement "H400".
- Select from the pick-list for "Environmental hazards/Hazardous to the aquatic environment (long-term)", the category "Aquatic Chronic 1" and the Hazard statement "H410". (Figure 58).

Figure 58: Specify hazard category and hazard statement for the hazards to aquatic environment



When a substance is classified as "Aquatic Acute 1" and/or "Aquatic Chronic 1", multiplying factor(s) (M-Factor) has/have to be assigned as described in Article 10 of the CLP regulation. Where appropriate, M-Factors shall be set for acute and long-term hazards separately. This means that there can be two different M-Factors for one substance in case the classification for long-term hazards has been derived by chronic toxicity data (Figure 59).

Figure 59: Specify M-Factor

If you propose to set such M-Factor(s) you have to provide a scientific justification. Please refer to the description in chapter 6.7.4.4 for further guidance.

6.7.4.3 Labelling

gg) Signal word (mandatory)

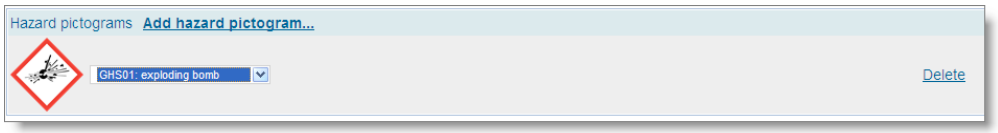
"Danger", "Warning" or "No signal word" should be selected in the field "Signal word" (Figure 60).

Figure 60: Specify a signal word

hh) Hazard pictograms (if relevant)

If applicable, you can select a hazard pictogram from the pick-list (Figure 61).

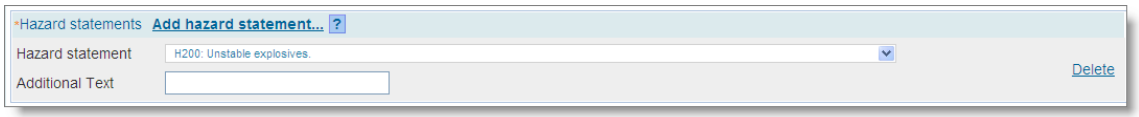
Figure 61: Specify a hazard pictogram



ii) Hazard statements used in the labelling (mandatory)

You should select at least one hazard statement from the pick-list and type in the free text fields where applicable (Figure 62).

Figure 62: Specify labelling hazard statement



If no hazard statement applies to your substance, then you can select "No hazard statement" from the pick-list. This statement is located at the real end of the pick-list.

You can specify more than one hazard statement for the labelling by clicking <Add hazard statement>.

The following hazard statements and combination of hazard statements do not exist in the CLP Regulation and shall not be used in your C&L notification in the labelling part (Table 14):

Table 14: Hazard statement not in CLP

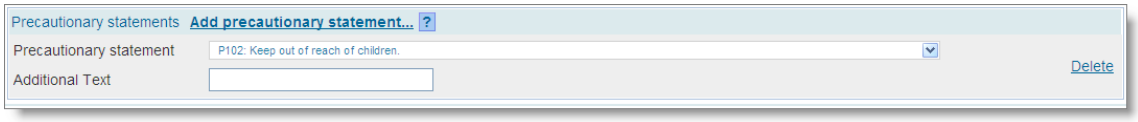
Hazard statement (in Labelling section):
H227: Combustible liquid
H303: May be harmful if swallowed

H305:	May be harmful if swallowed and enters airways
H313:	May be harmful in contact with skin
H316:	Causes mild skin irritation
H320:	Causes eye irritation
H401:	Toxic to aquatic life
H402:	Harmful to aquatic life
H303+H313: May be harmful if swallowed or in contact with skin	
H303+H333: May be harmful if swallowed or if inhaled	
H313+H333: May be harmful in contact with skin or if inhaled	
H303+H313+H333: May be harmful if swallowed, in contact with skin or if inhaled	
H315+H320: Causes skin and eye irritation	

jj) Precautionary statements

This information is not requested under the CLP Regulation, nevertheless you can select precautionary statement(s) from the pick-list (Figure 63).

Figure 63: Specify a precautionary statement



You can specify more than one precautionary statement for the labelling by clicking <Add precautionary statement>.

It is recommended to not apply more than 10 precautionary statements on a labelling.

kk) CLP supplemental hazard statement (if relevant)

If applicable, you can select a supplemental hazard statement from the pick-list (Figure 64).

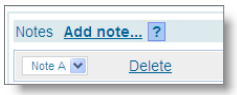
Figure 64: Specify a supplemental hazard statement

You can specify more than one supplemental hazard statement for the labelling by clicking <Add supplemental hazard statement>.

ll) Notes

This information is not requested under the CLP Regulation; nevertheless you can select note(s) from the pick-list (Figure 65).

Figure 65: Specify a note

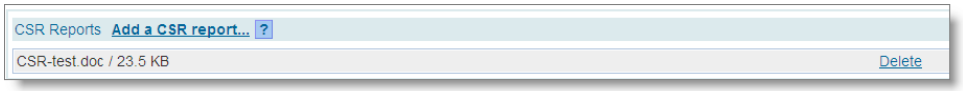


6.7.4.4 Scientific justification

Use this section to attach the scientific justification requested under Article 40(1-e).

If you want to set specific concentration limit(s) (SCL) or an M-factor under the strict conditions of Article 10 of the CLP Regulation, you have to attach a scientific justification for it (Figure 67).

Figure 66: Attach a scientific justification



You should use the relevant parts of the Chemical Safety Report (CSR) format according to Annex I to REACH. There is no need for a justification if the value is given in Table 3.1 of Annex VI to the CLP Regulation ("the harmonised list").

Further, this section should be used to declare that a hazard is only caused by (a) specific route(s) of exposure (unless specified in the harmonised list (Annex VI to CLP) or to submit the reasons for classification and labelling deviating from existing entries in the C&L inventory (Article 16(1) of the CLP Regulation).

Use this section to attach if needed the justification requested under Article 16(1).

It should be noted indeed that in the case you do not agree with the classification and labelling (excluding the harmonised ones in Part 3 of Annex VI) already present in the C&L inventory, you have to provide a reason for this specific hazard class or differentiation. The reason can include for example an:

- Indication that an impurity/additive has an impact on the C&L (Figure 27 and Figure 28); or/and
- Indication of the substance form/state (Figure 15); or/and

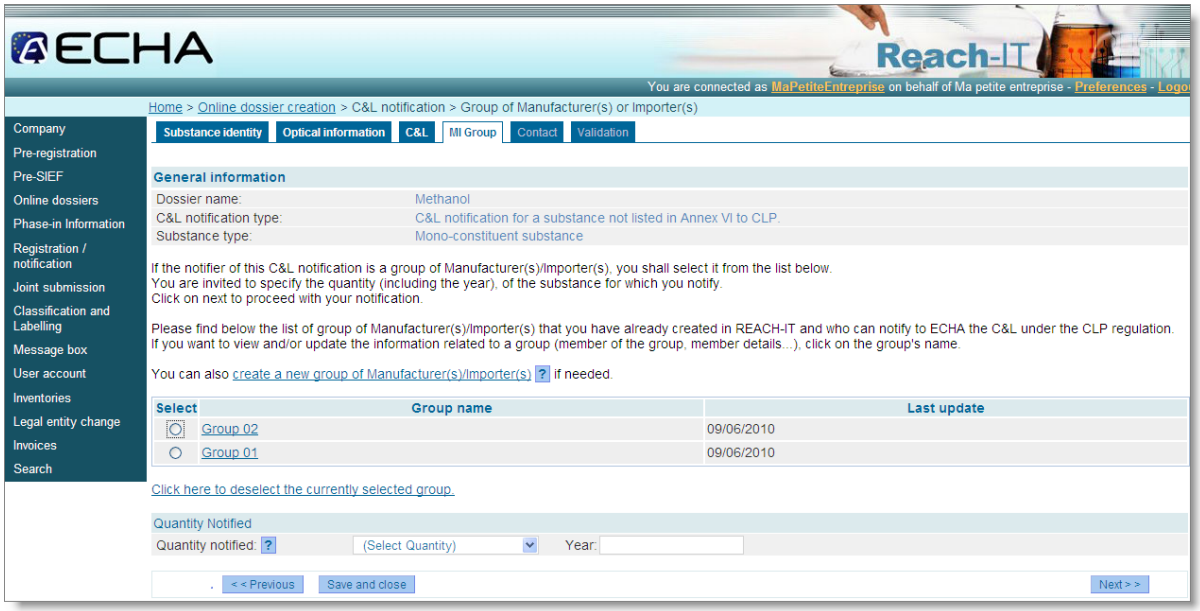
- Indication that you have relevant data/information supporting your classification of the substance (Figure 66).

You can attach up to 5 different documents.

6.8 Specify if the submission is made on behalf of a group of MI

On this screen, you are asked to specify if you submit the C&L notification on your own or on behalf of a group of Manufacturers and/or Importers (group of MI) (Figure 67).

Figure 67: Specify if the submission is on behalf of a group



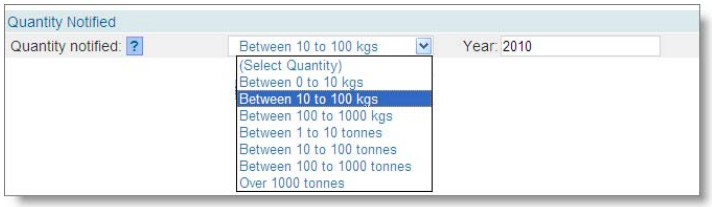
On this screen, you can:

- Select a group of MI and assign it to your submission.
- Continue without selecting a group of MI, by clicking <next>.
- Create a new group.

For more details on the functionalities related to managing of groups offered in this screen, please consult DSM part 15 available on ECHA website.

You may also indicate the volume range of the substance notified and the year (Figure 68).

Figure 68: Indicate volume range



In the case the substance you notify is subject to registration in accordance with the REACH Regulation, please indicate in this field the volume range produced or imported.

In the case the substance you notify is a hazardous substance placed on the market either on its own or in a mixture, please indicate in this field the volume range of the substance marketed.

This information is not mandatory and will, if provided, not be inserted in the submission report, nor published on ECHA website but used for internal statistics only.

Please be aware that if you decide to provide this information both fields, quantity and year, need to be filled.

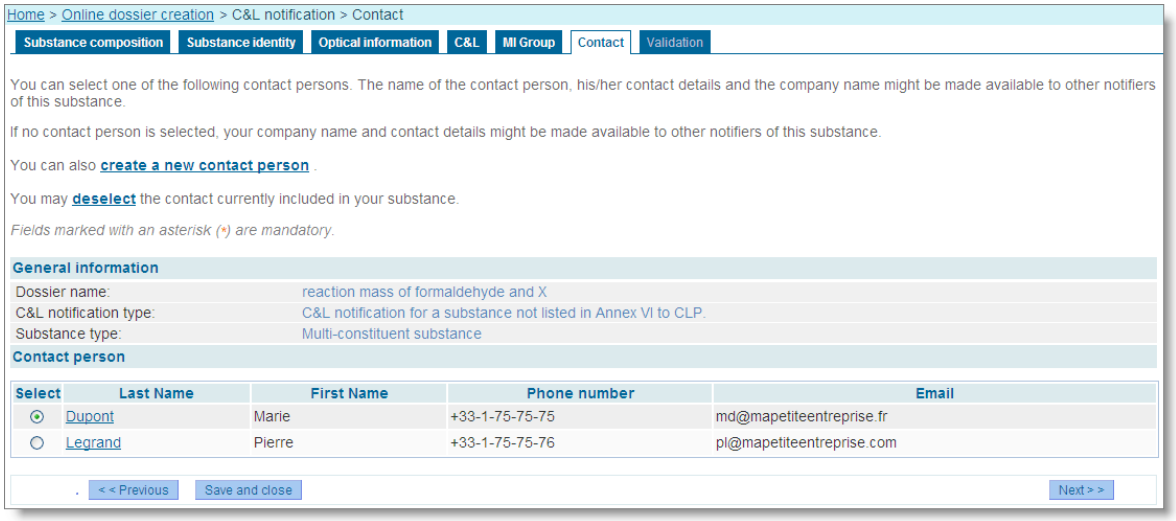
Click on the button Next > > to proceed.

6.9 Specify your contact details

Here you can specify a contact person whose name and contact details might be made available to other notifiers of the same substance, or to competent Authorities (Figure 69).

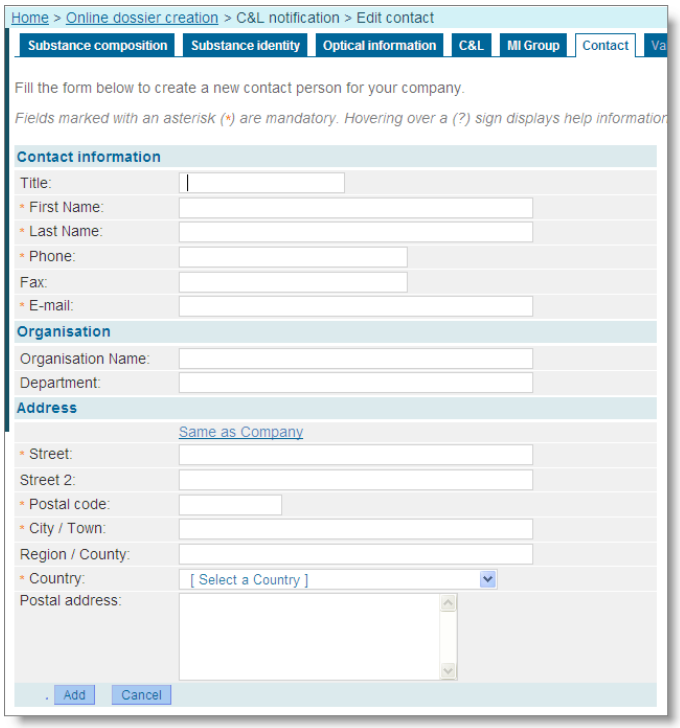
If you do not specify any contact person, the contact information provided during company sign-up might be made available to other notifiers of the same substance, or to competent Authorities.

Figure 69: Specify a contact



If there is no contact person in the list and you want to have a specific contact point click on <create a new contact person>. Complete the mandatory fields (*) (Figure 70) and click <Add>.

Figure 70: Add a new contact



Select the relevant contact person by clicking the radio button next to it.

If you have selected a contact person which you do not want to use click <deselect>.

Click on the button Next > > to proceed.

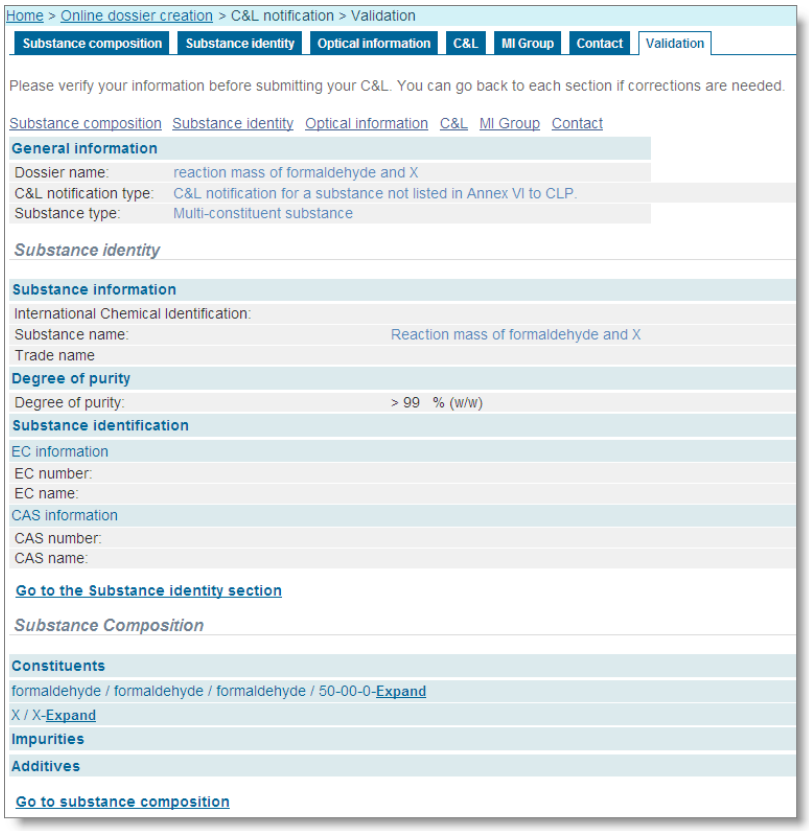
- It is possible to have only one contact person.
- The contact person provided at this stage will be added to the company list of contact persons.
- If a contact person with the same first name, last name and email address already exists, the information will be overwritten.

6.10 Validate the content of your C&L notification

The <Validation> page opens (Figure 71) to allow you to verify the data you have entered during the C&L notification dossier creation.

- Once the C&L notification dossier has been submitted it is no longer possible to make any amendments to it.

Figure 71: Validation of C&L notification dossier



You should carefully review the information presented. If it is correct click on the button Submit. If you wish to amend any of the information, then click on the relevant <Go to…> link which will take you to the appropriate section where you can amend the relevant information or you can go directly to the relevant tabs on the top of the page by clicking on it.

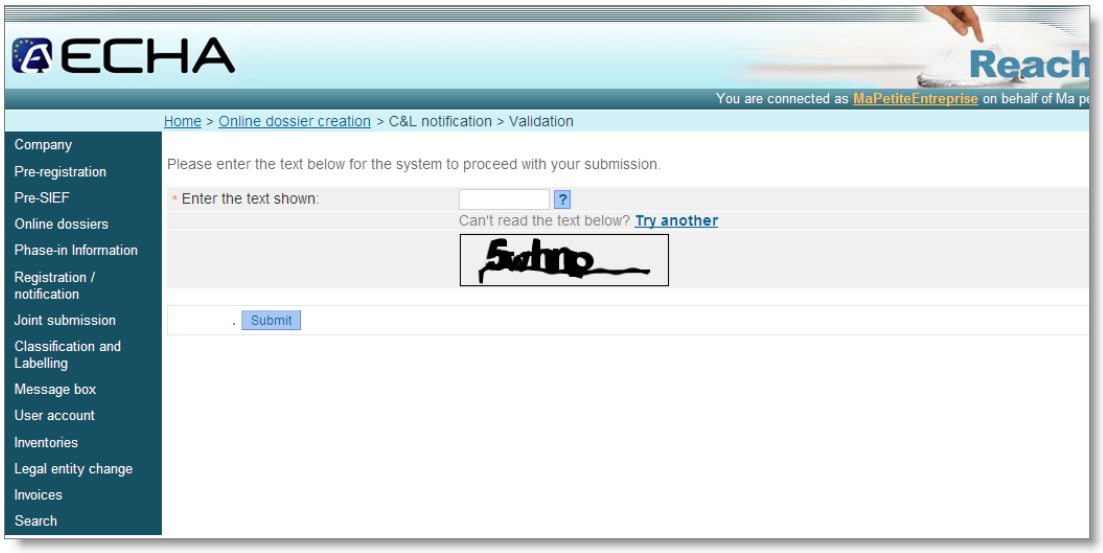
When you have amended the appropriate section always click on the <Validation> tab at the top of the screen which will take you back to the validation page.

Once you have made your amendments click on the button Submit.

6.11 Submit

Enter the CAPTCHA text and click on the button Submit (Figure 72).

Figure 72: Verification

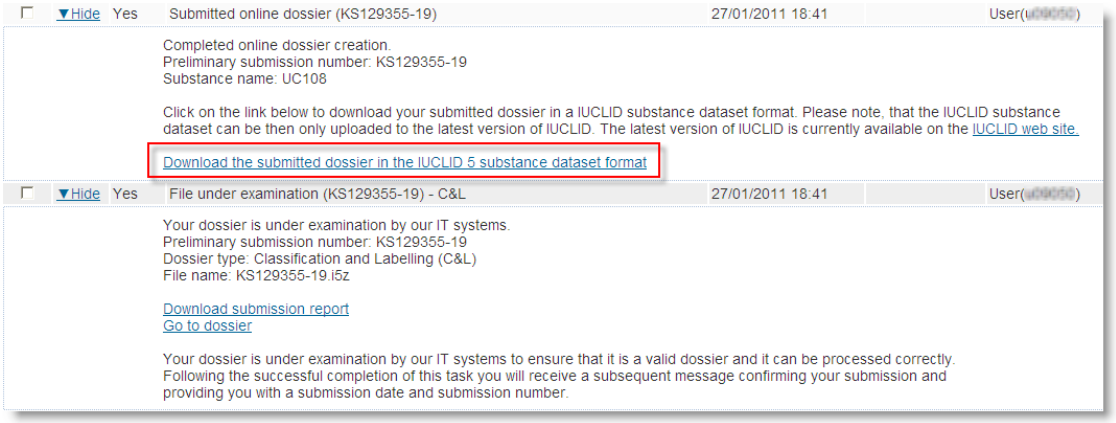


You will get a confirmation that your C&L notification dossier submission was successful and you are provided with a (preliminary) submission number. You will also receive a confirmation message, containing the submission report, in your REACH-IT Message box (Figure 73).

You will also receive an IUCLID 5 substance dataset of the online dossier you have just created and submitted. This IUCLID 5 substance dataset can be then imported in your IUCLID 5 database and be used as a base to encode your future registration dossier, as appropriate.

Please refer to the IUCLID 5 website (http://iuclid.eu/) for more instructions on how to import a substance dataset in an IUCLID 5 database.

Figure 73: Successful messages



6.12 Receive your notification number

If your notification is complete and passes the Business Rules check, you will receive a second message (Figure 74) containing your notification number (Reference number), and an updated submission report (Figure 75), in your REACH-IT message box.

Figure 74: Internal message with notification number

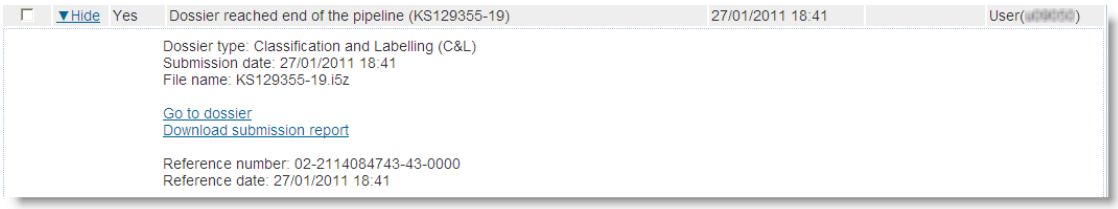
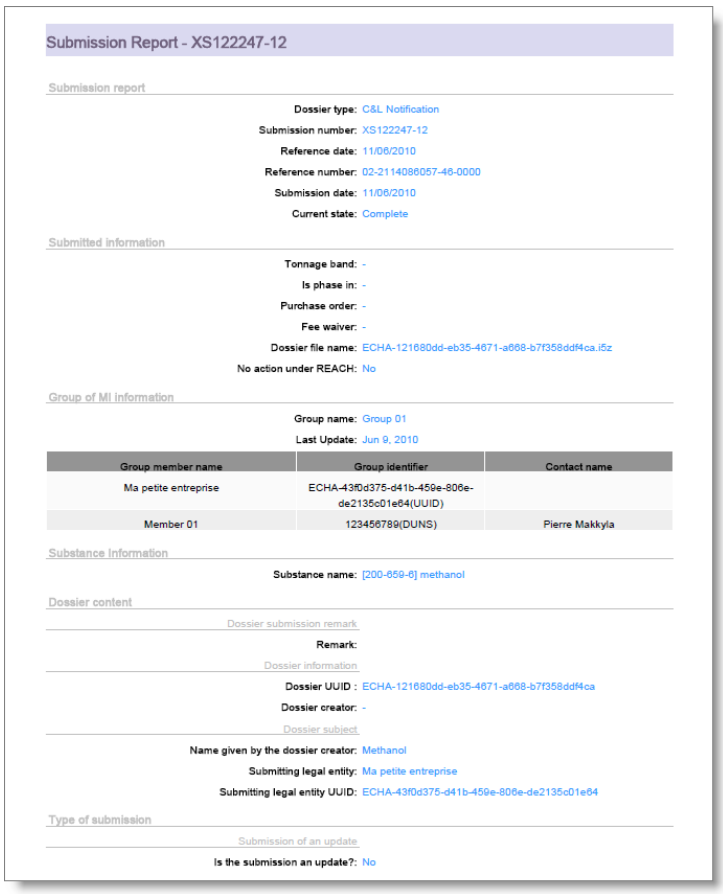


Figure 75: Submission report



Submission Report - XS122247-12

Submission report

Dossier type: C&L Notification
Submission number: XS122247-12
Reference date: 11/06/2010
Reference number: 02-2114086057-46-0000
Submission date: 11/06/2010
Current state: Complete

Submitted information

Tonnage band: -
Is phase in: -
Purchase order: -
Fee waiver: -
Dossier file name: ECHA-121680dd-eb35-4671-a668-b7f358ddf4ca.i5z
No action under REACH: No

Group of MI information

Group name: Group 01
Last Update: Jun 9, 2010

Group member name	Group identifier	Contact name
Ma petite entreprise	ECHA-43f0d375-d41b-459e-806e-de2135c01e64(UUID)	
Member 01	123456789(DUNS)	Pierre Makkyla

Substance Information

Substance name: [200-659-6] methanol

Dossier content

Dossier submission remark

Remark:

Dossier information

Dossier UUID : ECHA-121680dd-eb35-4671-a668-b7f358ddf4ca
Dossier creator: -

Dossier subject

Name given by the dossier creator: Methanol
Submitting legal entity: Ma petite entreprise
Submitting legal entity UUID: ECHA-43f0d375-d41b-459e-806e-de2135c01e64

Type of submission

Submission of an update

Is the submission an update?: No

If the C&L notification has been submitted as a group of MI, then this information is available in the submission report.

The members of a group of MI will not receive a submission report and they should contact the original notifier to receive a copy of the submission number and the reference number. The enforcement authorities of the Member States will have access to REACH-IT to confirm whether a manufacturer or importer member of a group of MI has notified according to CLP Regulation.

7. Common warning and error messages

7.1 Definitions

Error message: means that the user can not go to a further step in the wizard until he has solved the mentioned issue (e.g. mandatory field not filled in, wrong CAS number format…)

Error messages always appear on a red background.

Warning message: invites the user to pay attention to what he has just filled in (e.g. No impurity has been specified…). A warning message does not block the user to go to the next step. By clicking a second time on the next button, the warning message will disappear and the user will be able to proceed further.

Warning messages always appear on a yellow/orange background.

7.2 Common warning messages

Figure 76: Warning message in case no impurity has been specified for a mono-constituent

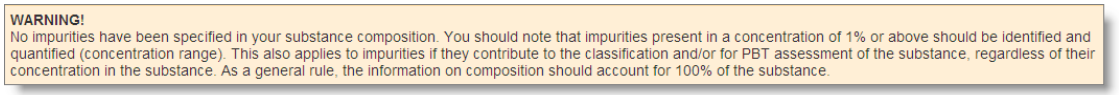


Figure 77: Warning message in case CAS information is incomplete

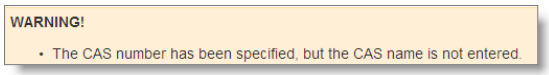
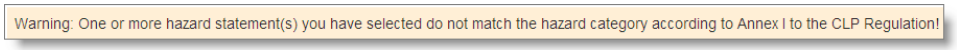


Figure 78: Warning message in case hazard category selected do not match the hazard statement



7.3 Common error messages

Figure 79: Error message if a mandatory field is not filled in

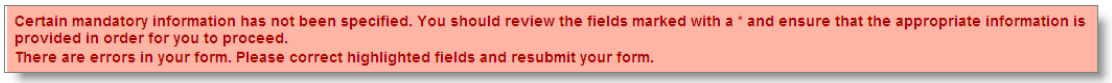


Figure 80: Error message in case of incorrect range specification

Figure 81: Error message in case of incorrect value specification

Figure 82: Error message in case of wrong CAS number format

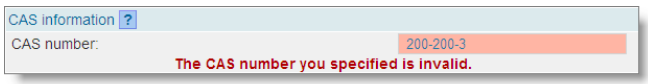


Figure 83: Error message if a reference number does not belong to your company

Figure 84: Error message if the dossier name specified already exists

Figure 85: Error message if the hazard category or statement does not exist in the CLP

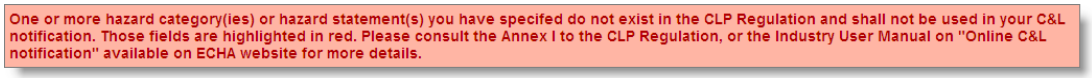


Figure 86: Error message if you forget to select the C&L you agree with

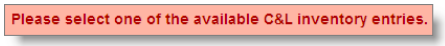


Figure 87: Error message if you do not respect the harmonised C&L

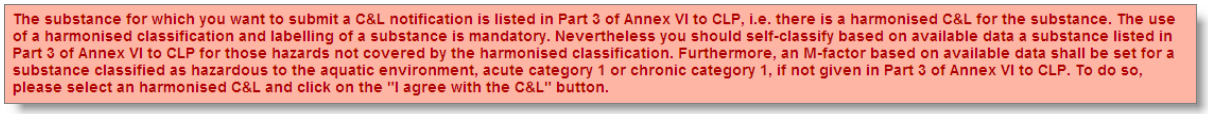
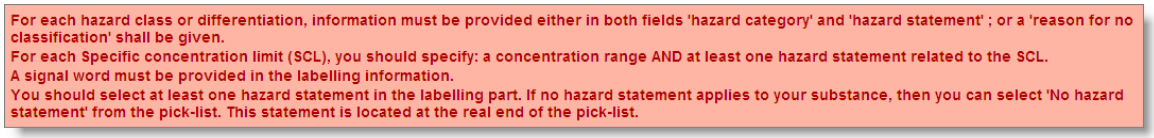


Figure 88: Error message if missing information in the C&L section



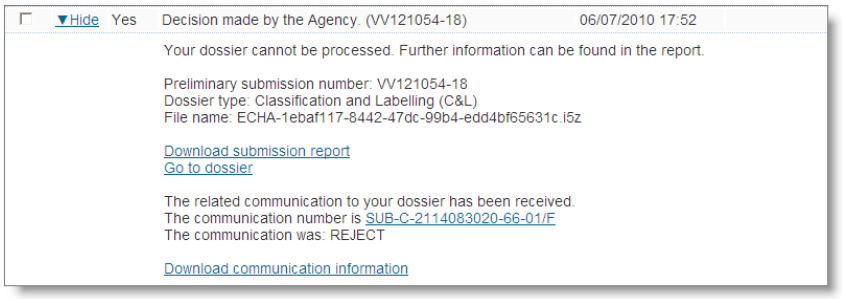
7.4 Dossier submission failure

A submission failure is always communicated via an internal message in your REACH-IT Message box.

Click on the link <Show> and the message details is displayed (Figure 89), e.g. the dossier violates a business rule, or the file format is invalid. An explanation for the dossier failure is given in the message. The information provided in the message is only a summary.

For more details, you can <Download submission report> (in PDF format) or you can <Go to dossier> to consult the complete dossier information.

Figure 89: Internal message with dossier submission failure details



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