ECHA
EUROPEAN CHEMICALS AGENCY

Dissemination and confidentiality claims of Safety Data Sheet information in IUCLID 5.4

Questions and Answers

This document explains in detail which Safety Data Sheet information will be disseminated and how the data can be claimed confidential in IUCLID 5.4.

Questions and Answers **Dissemination and confidentiality claims of Safety Data Sheet information in IUCLID 5.4**

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1. What is safety data sheet information?

According to Article 119(2)(d) of the REACH Regulation, ECHA has to make the information which is contained in the safety data sheet, and which is not already disseminated under other articles of REACH[1] available over the internet, unless the registrant successfully claims confidentiality. Since a copy of the safety data sheet document as such is not part of the data submitted to ECHA, it has been determined which information has to be listed in both the safety data sheet (as set out in Annex II of REACH) and the registration dossier (as set out in Article 10 and Annexes I and VI of REACH). Information meeting both criteria that is not already disseminated for other reasons (in accordance with Article 119 of REACH) is considered to be "safety data sheet information".

It includes:

- registration number;
- registrant name;
- life cycle description and uses advised against information;
- exposure scenario elements;
- result of the PBT (Persistent, Bioaccumulative and Toxic chemicals) and vPvB (very Persistent and very Bioaccumulative) assessment;
- indication of whether a chemical safety assessment (CSA) was performed.

In the questions that follow, it will be explained in detail which data is concerned and how the data can be claimed confidential in IUCLID 5.4.

2. Will my safety data sheet information be disseminated?

Safety data sheet information will be disseminated from all registration dossiers, whether the substance requires a safety data sheet or not, unless claimed confidential. It should be stressed that confidentiality needs to be claimed separately for each item, using the confidentiality flags in the IUCLID dossier.

In dossiers for substances which do not require a safety data sheet, it is deemed that the registrant 'volunteers' the safety data sheet information for publication if the information is not claimed confidential.

The information will be disseminated on the ECHA website in the section on Registered Substances, at http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances.

[1] Several pieces of information which is available in the safety data sheet is already disseminated under other articles of REACH, such as the substance name (Article 119(1)(a) and (b)), the trade name (Article 119(2)(e)), the classification and labelling (Article 119(1)(c)), the results of physicochemical studies and studies of fate, ecotoxicology and toxicology (Article 119(1)(d) and (e)), the derived no-effect level and the predicted no-effect concentration (Article 119(1)(f)), the guidance on safe use (Article 119(1)(g)), and the identity of hazardous impurities (Article 119(2)(a)).

3. Where in the IUCLID dossier can I find the safety data sheet information? How can I claim this information confidential?

Safety data sheet information is found throughout the IUCLID dossier. You will find below, IUCLID section by IUCLID section, an overview of the safety data sheet information to be disseminated on the ECHA website as well as instructions on how to claim confidentiality for it. More detailed explanations will be provided in the updated Data Submission Manuals 15 and 16, that will be published together with the new version of REACH-IT in July.

Section 1 of the IUCLID dossier: the registrant name

Which fields will be disseminated?

For manufacturers and importers, the registrant name will be disseminated unless it is claimed confidential. Only Representatives (ORs) do not necessarily supply the substance and they have the possibility to indicate in section 1.7 of the IUCLID dossier who the actual suppliers (importers) are. The identity of the ORs will be disseminated unless it is claimed confidential, or unless suppliers are listed in section 1.7 whose identity is not claimed confidential. Note that if the OR chooses to have the supplier's name disseminated instead of their own, the OR has to obtain and attach in section 1.7 the agreement by the supplier for the dissemination of their company name (Figure 1).

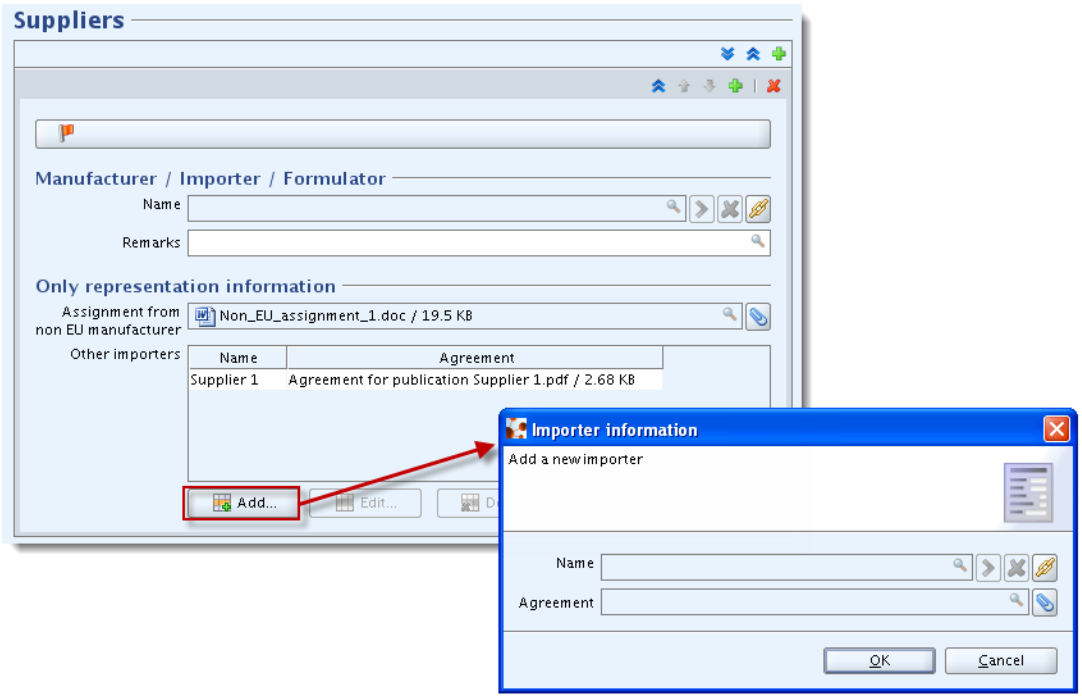
In all cases, the fields that will be disseminated unless validly claimed confidential are the legal entity name, the full address and phone number. Table 1 provides an overview of the data to be disseminated.

The name of the Third Party Representative (TPR), if provided, will not be disseminated.

Table 1: Overview of legal entity dissemination.

Role in Supply Chain	Legal Entity (LE) Flag in 1.1	Supplier(s) present in 1.7	Suppliers all flagged as confidential in 1.7	What will be disseminated
Manufacturer, Importer	No	NA	NA	Manufacturer / Importer LE Name, full address, phone number (taken from the REACH-IT account)
Manufacturer, Importer		NA	NA	[Confidential]
Only representative	No	No	NA	OR LE Name, full address, phone number (taken from the REACH-IT account)
Only representative	No	Yes		OR LE Name, full address, phone number (taken from the REACH-IT account)
Only representative	No	Yes	No	Non-confidential Supplier(s) LE Name(s), full address(es), phone number(s) (taken from IUCLID 5.4 section 1.7)
Only representative		NA	NA	[Confidential]

Figure 1: Only Representatives can indicate the actual suppliers in the table 'Other importers' in IUCLID section 1.7. The suppliers' name will only be considered as valid for dissemination if a letter of agreement is provided in this table.



How will the information be disseminated?

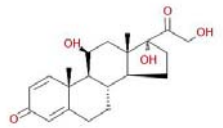
A list of registrants and their contact details will be made available on the ECHA website (Figure 2).

Figure 2: Example of safety data sheet information disseminated

Substance identification

Substance example

EC Number	200-123-4
EC Name	Substance example
CAS Number	12-34-5
Molecular formula	C21H28O5
IUPAC Name	11,17,21-trihydroxypregna-1,4-diene-3,20-dione



Type of substance

Composition	mono constituent substance
Origin	organic 12

Trade names

Substance

Total Tonnage Band

100 – 1 000 tonnes per year

Registrants

A company	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Be Chemicals	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Example Corp	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Finchem	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Zetec Chemicals Inc	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
[Confidential]		

Registration Numbers

01-211457123-45-0000	01-211457123-45-0001	01-211457123-45-0002
01-211457123-45-0003	01-211457123-45-0004	01-211457123-45-0007
01-211457123-45-xxxx	[Confidential]	

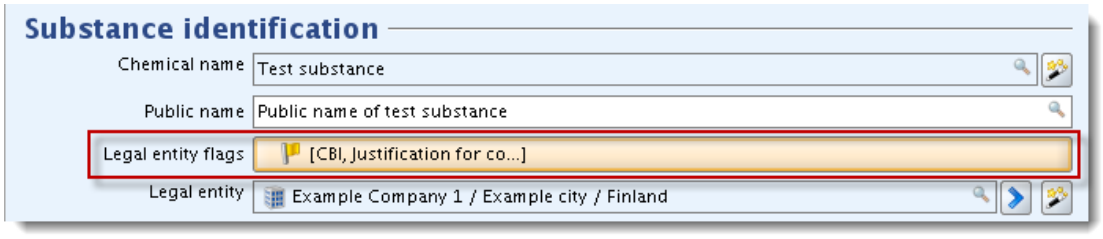
Contact Persons Responsible for SDS

A company	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Be Chemicals	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Example Corp	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Finchem	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
Zetec Chemicals Inc	123 Mannerheimintie, 00123 Helsinki, Finland	040 9736 1237
[Confidential]		

How can I claim the information confidential?

The registrant name can be claimed confidential using the confidentiality flag in section 1.1 on the Legal entity (Figure 3). This is regardless of whether a TPR is appointed or not.

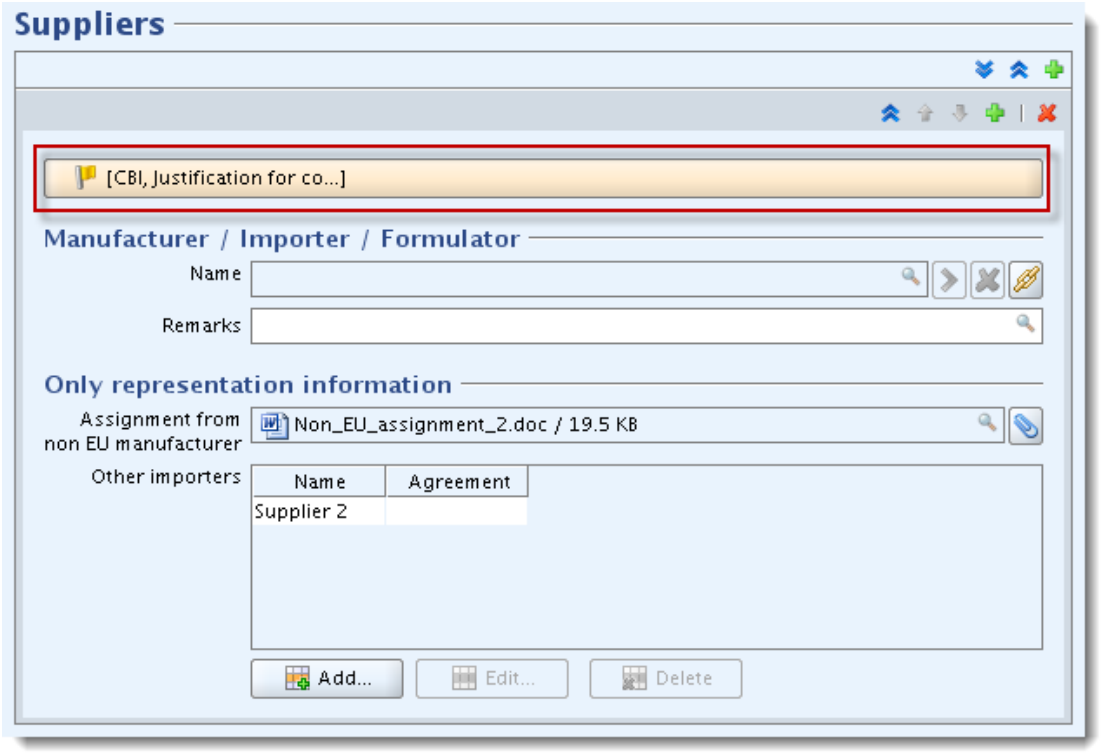
Figure 3: Confidentiality of the registrant name can be claimed in section 1.1, in the field 'Legal entity flags'



Only Representatives should also claim confidentiality using this flag. In this case, no information on the OR or their suppliers will be disseminated (see Table 1 above). ORs have to ensure that they indicate in section 1.1 (tick-box) that their role in the supply chain is Only Representative.

If an OR chooses to list the actual suppliers in section 1.7, those whose names should not be disseminated can be claimed confidential using the confidentiality flags in section 1.7 (Figure 4).

Figure 4: The OR can claim confidentiality on their suppliers' names in section 1.7.



Section 1 of the IUCLID dossier: the registration number

Which fields will be disseminated?

The registration number will be disseminated in full (13 digits) unless claimed confidential. If the registrant name has been claimed confidential but the registration number has not, the last four digits of the registration number will be masked to protect the unique identification of the registrant.

Table 2. Overview of registration number dissemination.

Registration Number Flag (Dossier Header and / or 1.3)	Legal Entity Flag in 1.1	What will be Disseminated
No	No	01-0000012345-67-0089
No		01-0000012345-67-xxxx
	NA	[Confidential]

How will the information be disseminated?

A list of registration numbers will be made available as shown in Table 1 above. The registration numbers will not be linked to the registrants' names.

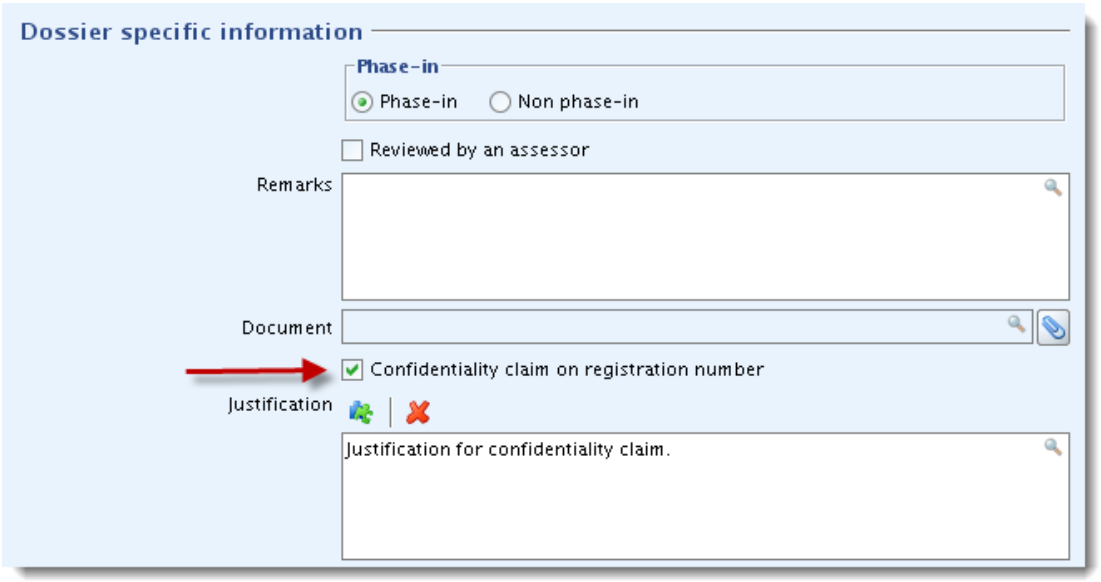
How can I claim the information confidential?

There are two ways to claim the registration number confidential:

- in the dossier header when creating the registration dossier;
- in section 1.3 of IUCLID.

A new confidentiality flag (tick-box) has been introduced in the dossier header in IUCLID 5.4 to indicate a confidentiality claim on the registration number (Figure 5). This can be used when the dossier is an initial submission and does not yet have an existing registration number. Note that this flag needs to be re-introduced every time the dossier is recreated if the confidentiality claim is to remain in place.

Figure 5: Confidentiality claims on the registration number can be indicated in two places. For initial submissions, or update submissions which do not yet have a registration number, confidentiality on the registration is more conveniently indicated during dossier creation, in the dossier header.

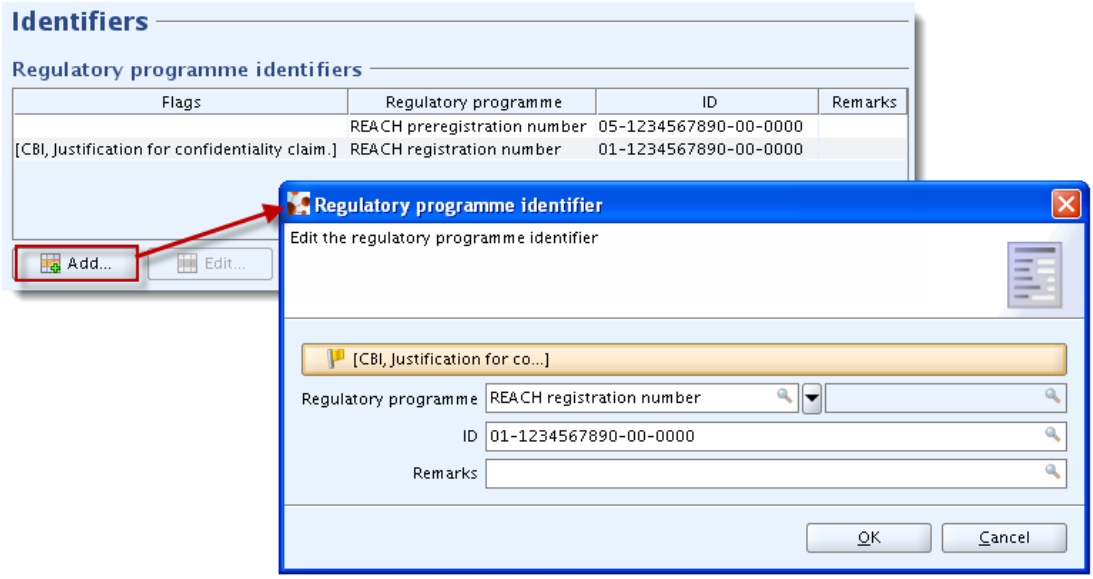


Alternatively, the confidentiality flag in section 1.3 on the regulatory identifiers can be used for the row corresponding to the registration number.

To avoid forgetting to re-introduce the confidentiality flag in the dossier header during dossier creation, it is recommended to introduce the flag in section 1.3 for future dossier updates.

Note that a confidentiality flag in section 1.3 is only considered as a claim on the registration number if it is placed on the same row as a reference number of the regulatory programme type ‘REACH registration number’ (Figure 6).

Figure 6: For update submissions of existing registrations, confidentiality claims on the registration number are preferably indicated in section 1.3, next to the registration number.



Section 2 of the IUCLID dossier: the PBT/vPvB assessment

Which fields will be disseminated?

In IUCLID 5.4, a new section 2.3 has been introduced to capture the results of the PBT and vPvB assessment. The section consists of an endpoint summary and endpoint study records. The information on the PBT/vPvB assessment results will be disseminated, unless it is claimed confidential. This includes data from the endpoint study records and the endpoint summary. The reference substance attached to an endpoint study record in this section and the remark for the assessed substance will not be disseminated. Further information on the exact fields to be disseminated will become available in the *Data Submission Manual 15* (http://echa.europa.eu/web/guest/support/dossier-submission-tools). This manual will be updated for IUCLID 5.4 and the updated version will be published at the same time as the release of the new version of REACH-IT.

Please note that to pass business rules in REACH-IT with IUCLID 5.4 dossiers, it will be mandatory to include the endpoint summary for the PBT/vPvB assessment for registrants submitting a chemical safety report (CSR). At the same time, it is strongly recommended to provide the relevant endpoint study records for the PBT/vPvB assessment, to support the overall outcome reported in the endpoint summary.

If the dossier includes a PBT/vPvB assessment for more than one substance (e.g. for the substance itself and a degradation product), all the relevant endpoint study records will be disseminated, except for the ones claimed confidential.

How will the information be disseminated?

The PBT/vPvB assessment will be disseminated in the same way as all the other endpoint study records and endpoint summaries in the dossier. When members of a joint submission include a PBT/vPvB assessment in their dossier, there will be multiple PBT assessments available in the disseminated dossier. The PBT/vPvB assessments provided by members will be indicated as “Member PBT/vPvB assessment”.

How can I claim the information confidential?

The result of the PBT and vPvB assessment in section 2.3 of IUCLID 5.4 can be claimed confidential using the flags at the top of each endpoint study record and the flag at the top of the endpoint summary (Figures 7 and 8).

Figure 7: Confidentiality claims on the overall result of the PBT assessment are indicated at the top of the section 2.3 endpoint summary.

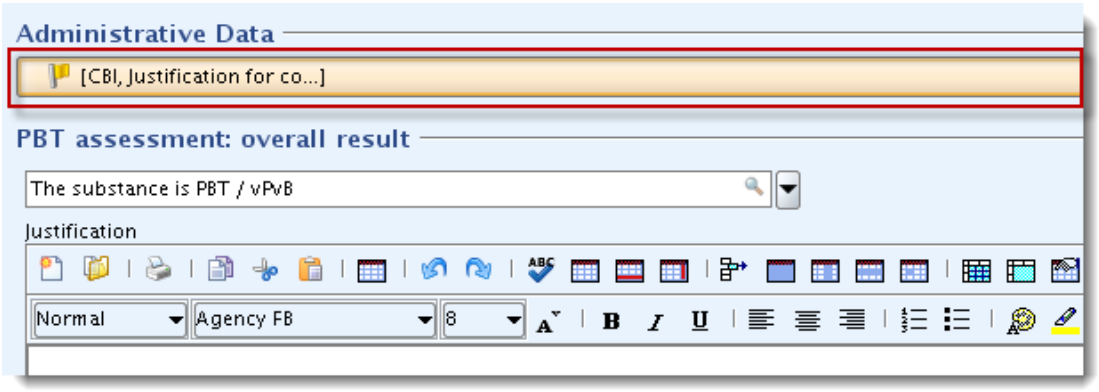
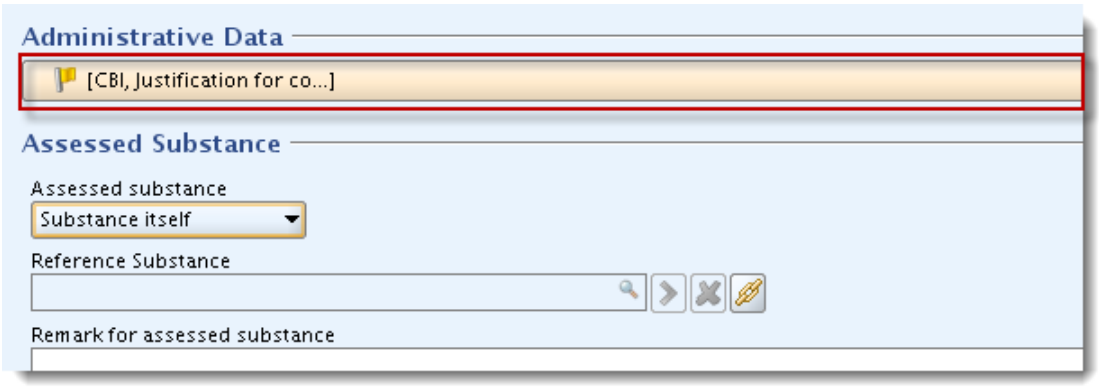


Figure 8: Confidentiality claims on the endpoint study records of the PBT assessment are indicated at the top of each section 2.3 endpoint study record.



Section 3 of the IUCLID dossier: Life Cycle description (formerly Uses) and Uses advised against

Which fields will be disseminated?

The section containing the Identified uses (section 3.5) in IUCLID 5.4 has been renamed Life Cycle description and has been restructured and expanded. The uses entered in the tables in section 3.5 and the uses advised against entered in section 3.6 are currently disseminated, unless claimed confidential. The same information will be disseminated with IUCLID 5.4. The new tables in these sections (for example Formulation) will be disseminated in a similar way.

How will the information be disseminated?

The Life Cycle description and the Uses advised against will continue to be disseminated the

same way as they are at the moment: the uses provided by the lead and the members in a joint submission are listed one after the other; exact duplicates will continue to be removed.

How can I claim the information confidential?

Each entered use can be claimed confidential separately using the confidentiality flag in the first column of the table for the row containing the use (Figures 9 and 10).

Figure 9: Uses are claimed confidential by placing a confidentiality flag on the corresponding rows in the tables of section 3.5. The flag is inserted in the edit window of each use.

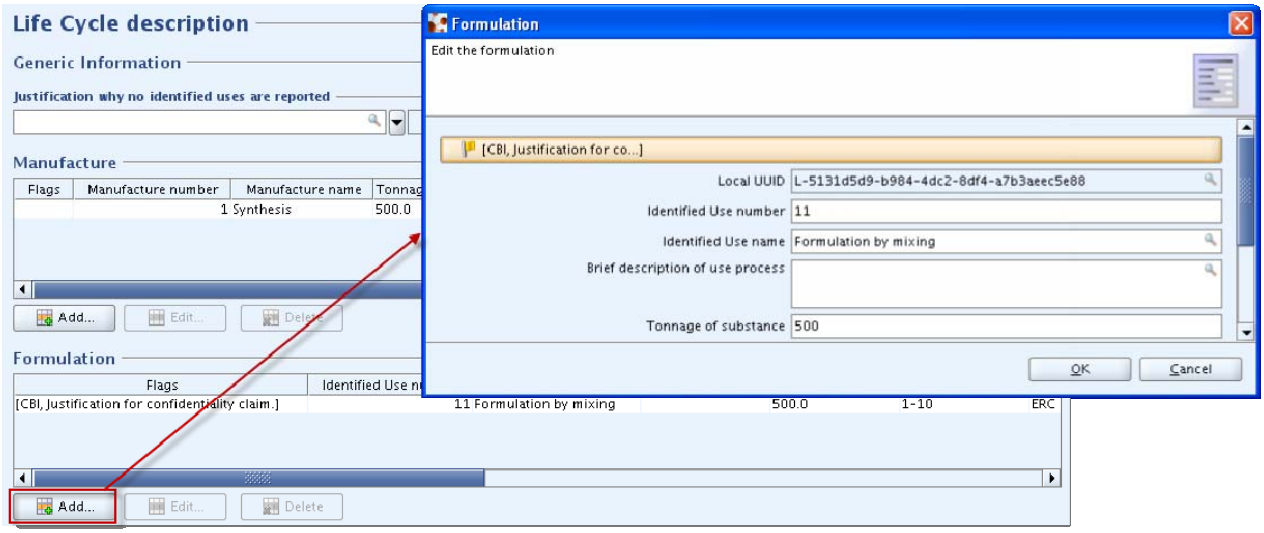
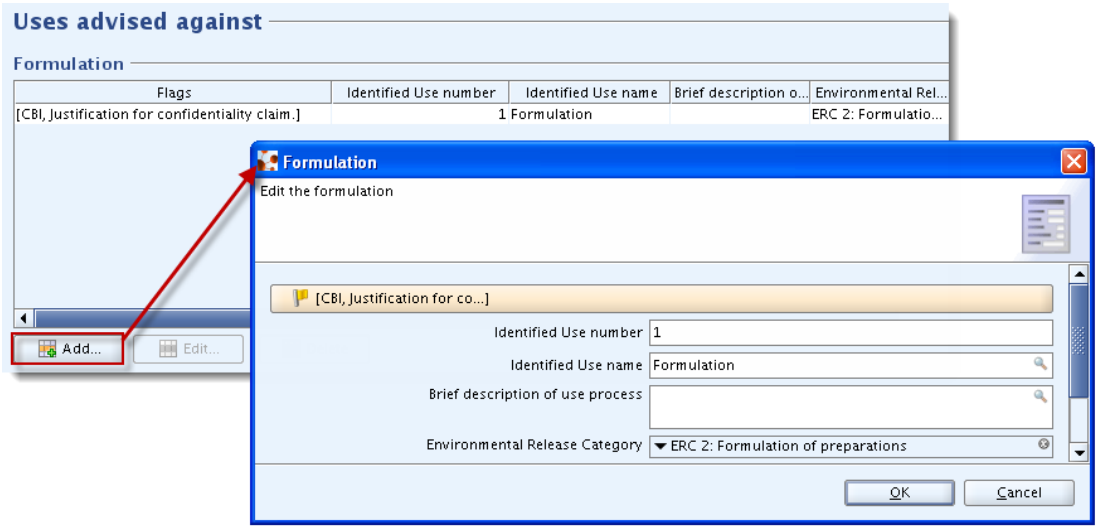


Figure 10: Uses advised against are claimed confidential by placing a confidentiality flag on the corresponding rows in the tables of section 3.6. The flag is inserted in the edit window of each use advised against.



Section 3 of the IUCLID dossier: Exposure Scenarios, exposure and risk assessment

Which fields will be disseminated?

In IUCLID 5.4, a new endpoint has been introduced in section 3 to capture the information on exposure scenarios and local assessment in a structured way. Certain elements of the information entered in the new section 3.7.1 is information contained in the safety data sheet. This section is expected to become mandatory only after the second registration deadline in 2013 and will subsequently be disseminated, unless it is claimed confidential. Registrants are encouraged to complete this section comprehensively, since IUCLID 5.4 is providing the opportunity to store this information in a structured and harmonised format in one single database; thus facilitating queries, exchange of information among globally acting companies and efficient processing of the information in general. For the moment, there is no need to flag this section confidential and a further announcement on the specific fields to be disseminated will be published well in advance. This will allow registrants to decide whether a confidentiality claim is indeed needed and to ensure that the justification for the confidentiality claim(s) is sufficiently precise to describe the particular concern.

Section 3.7.3 on Generic exposure potential will be disseminated in full, unless it is claimed confidential. The fields in section 3.7.3 were previously part of section 3.5 on the uses, and the information will automatically be migrated to the new section when the IUCLID installation is upgraded to IUCLID 5.4.

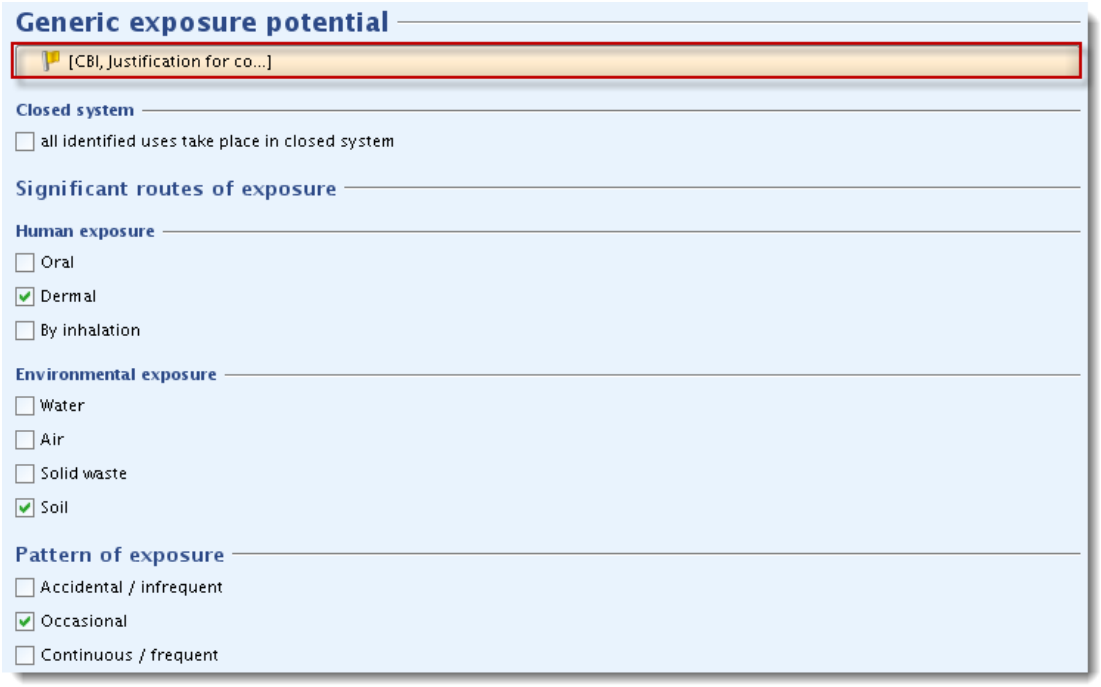
How will the information be disseminated?

All fields from section 3.7.3 will be disseminated. Note that for joint submissions the tick-box selections will be merged.

How can I claim the information confidential?

The information in section 3.7.3 of IUCLID 5.4 can be claimed confidential using the flag at the top of the section (Figure 11).

Figure 11: Information on the generic exposure potential can be claimed confidential by placing a flag at the top of section 3.7.3



Section 13 of the IUCLID dossier: Chemical Safety Assessment was performed

Which fields will be disseminated?

An indication of whether a CSA was performed will be disseminated, unless claimed confidential. This will be shown by publishing whether an assessment report of the type 'REACH Chemical safety report (CSR)' was included in the dossier, and the existence or absence of an attachment.

Note that the CSR itself will not be disseminated. Information on other types of assessment reports potentially included in the dossier will not be disseminated either.

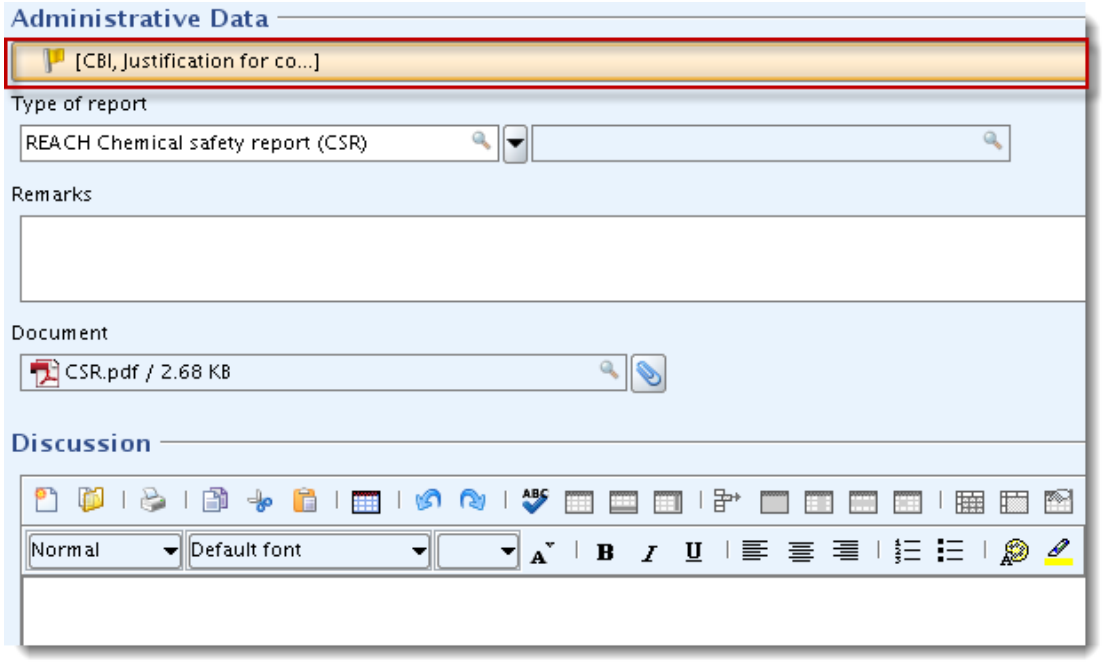
How will the information be disseminated?

Section 13 will be disseminated in the same way as all other endpoint study records in the dossier. Endpoint study records will be added one after the other; exact duplicates will be removed.

How can I claim the information confidential?

The information on whether a CSA was performed can be claimed confidential using the flag at the top of the endpoint study record (Figure 12).

Figure 12: Confidentiality on whether a chemical safety assessment has been carried out can be claimed by placing a flag at the top of each endpoint study record of the type 'REACH Chemical safety report (CSR)'.

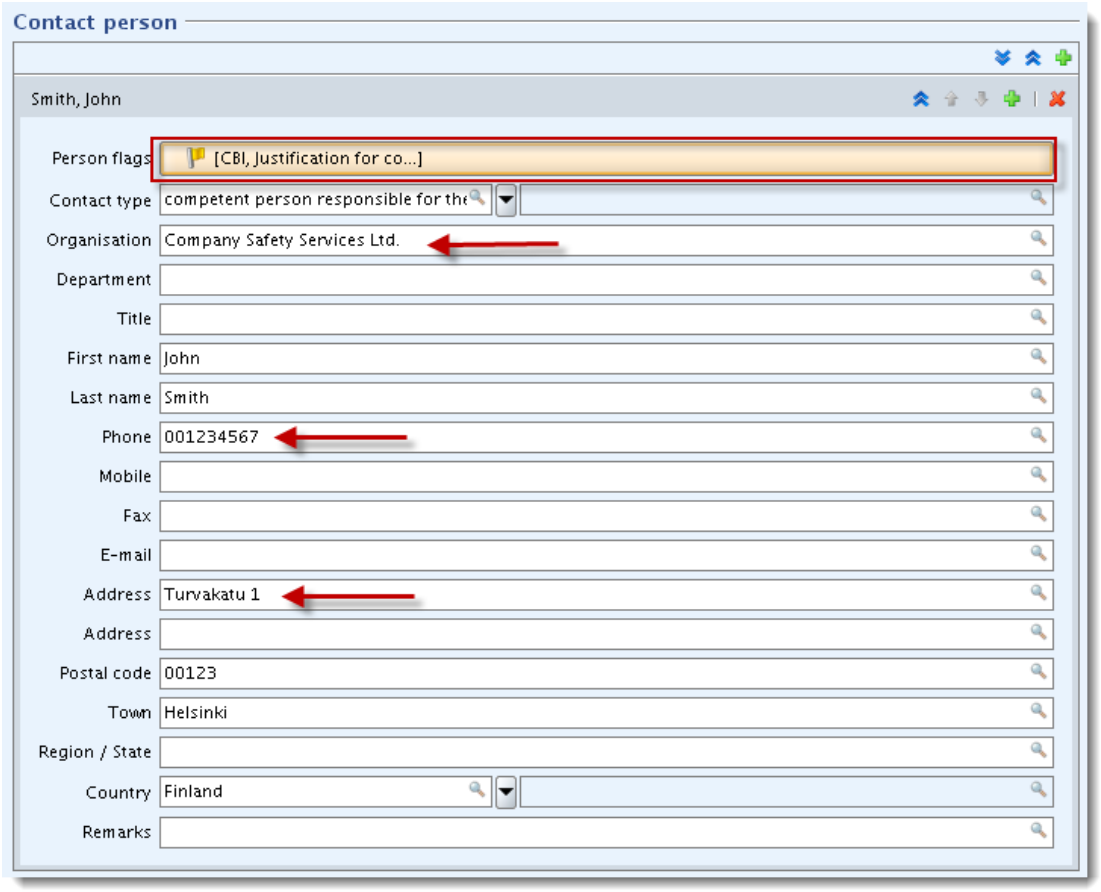


Additional fields in IUCLID 5.4: competent person responsible for the safety data sheet

In section 1.1 of IUCLID 5.4, a new type of contact person is introduced: competent person responsible for the safety data sheet. Information on this type of contact person will be disseminated unless claimed confidential, using the corresponding flag in section 1.1 (Figure 13). Contact persons that are not identified as a competent person responsible for the safety data sheet are not disseminated. Confidentiality claims on this information – which is not as such SDS information – are not charged and their justification is not assessed.

Note that the competent person disseminated is the legal rather than the natural person. The fields disseminated are the organisation name, the full address fields and phone number.

Figure 13: Information on the 'competent person responsible for the safety data sheet' can be protected from publication by placing a flag in the field 'Person flags'.



4. Will I be charged for a confidentiality claim on safety data sheet information?

Confidentiality claims on safety data sheet information will only be charged if the substance requires a safety data sheet.

The fee for confidentiality claims on safety data sheet information is detailed in Annex IV of the Fee regulation. The fee will be charged only once per registration, regardless of the number of confidentiality claims on some or all of the specific items of SDS information. If the fee has been charged once, subsequently placed confidentiality claims on safety data sheet information will not be charged anymore. However, a specific justification for each of the types of information claimed confidential will still be required.

It should be noted that confidentiality claims on the PBT assessment (section 2.3), on exposure scenarios and local assessment (section 3.7.1), and on whether a CSA was performed (section 13) will be invoiced if the substance requires a safety data sheet **and** the registrant submits a CSR. As an example, if in a joint submission the lead registrant provides the CSR on behalf of the members, only the lead will be invoiced for the before mentioned specific sections (i.e. provided that in the member dossier it is indicated that the CSR is submitted by the lead on behalf of the member). If a member individually submits the CSR, they will be charged for all potential SDS confidentiality claims (including sections 2.3, 3.7.1 and 13) as described above.

If the substance does not require a safety data sheet, it is deemed that the confidentiality claim indicates that the registrant does not volunteer the publication of the information, and no fee will be charged for keeping this information confidential.

Registrants can verify whether they will be charged for a confidentiality claim on safety data sheet information using the Fee Calculation plug-in in IUCLID. The plug-in will be updated for IUCLID 5.4 and the updated version will become available at the same time as the release of the new version of REACH-IT.

5. How do I indicate whether the substance requires a safety data sheet?

You do not need to indicate whether the substance requires a safety data sheet. REACH-IT will determine this, and consequently whether a confidentiality claim will be invoiced or not (see above). For determining whether the substance requires a safety data sheet, REACH-IT will verify in the registration dossier if the conditions set out in Article 31 of REACH are met:

- the substance is classified as hazardous according to the CLP Regulation[2]; and/or
- the substance is PBT or vPvB; and/or
- the substance is listed on the candidate list;
- and it concerns a full registration or a registration for a transported isolated intermediate.

6. Do I need to justify my confidentiality claim and will it be assessed?

Although invoiced only once, each item falling under Article 119(2)(d) must be separately claimed in the dossier and the reason for confidentiality justified separately. Confidentiality claims that fall under the criteria of being chargeable[3] will be assessed. In such cases, the justification for each confidentiality claim needs to include: (1) a declaration that the information is not in the public domain or general knowledge in the industry, (2) a demonstration of a commercial interest worthy of protection for non-disclosure of the information, and (3) a demonstration that disclosure of the information would cause potential harm to the commercial interest of the registrant or a third party.

In IUCLID 5.4, the maximum length of the justification field has been increased to 35 000 characters. In addition, a template for justifying a confidentiality claim can be directly inserted in the justification field by selecting ‘Show free text templates’ (Figures 14 and 15). For dossier updates, justifications previously attached to the dossier in pdf format can be maintained.

[2] For members of a joint submission, the classification of the substance is verified from the lead registration dossier, unless the member has opted-out and provided this information themselves.
[3] Also claims on safety data sheet information which are added at a later time and for which no fee is charged because the fee was already invoiced during a previous submission, will be assessed.

Figure 14: In IUCLID 5.4, a free text template can be inserted into the 'Justification' field of a confidentiality claim using the green-and-blue icon.

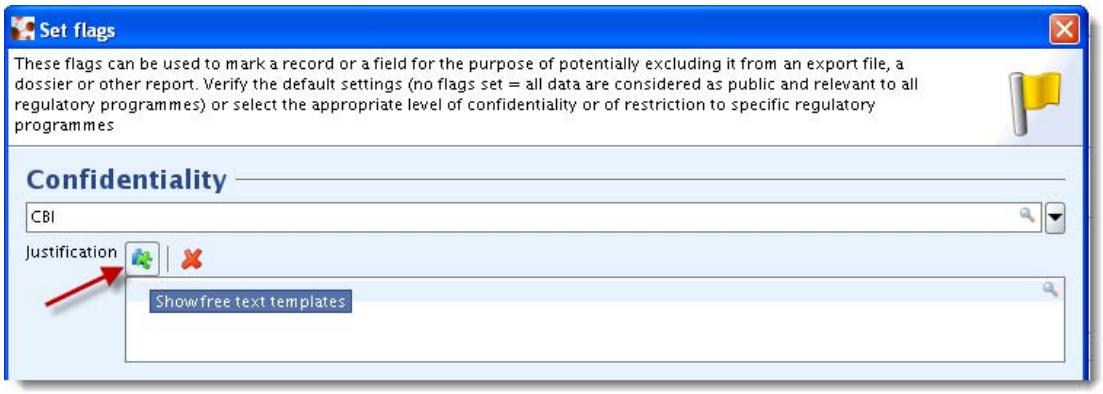
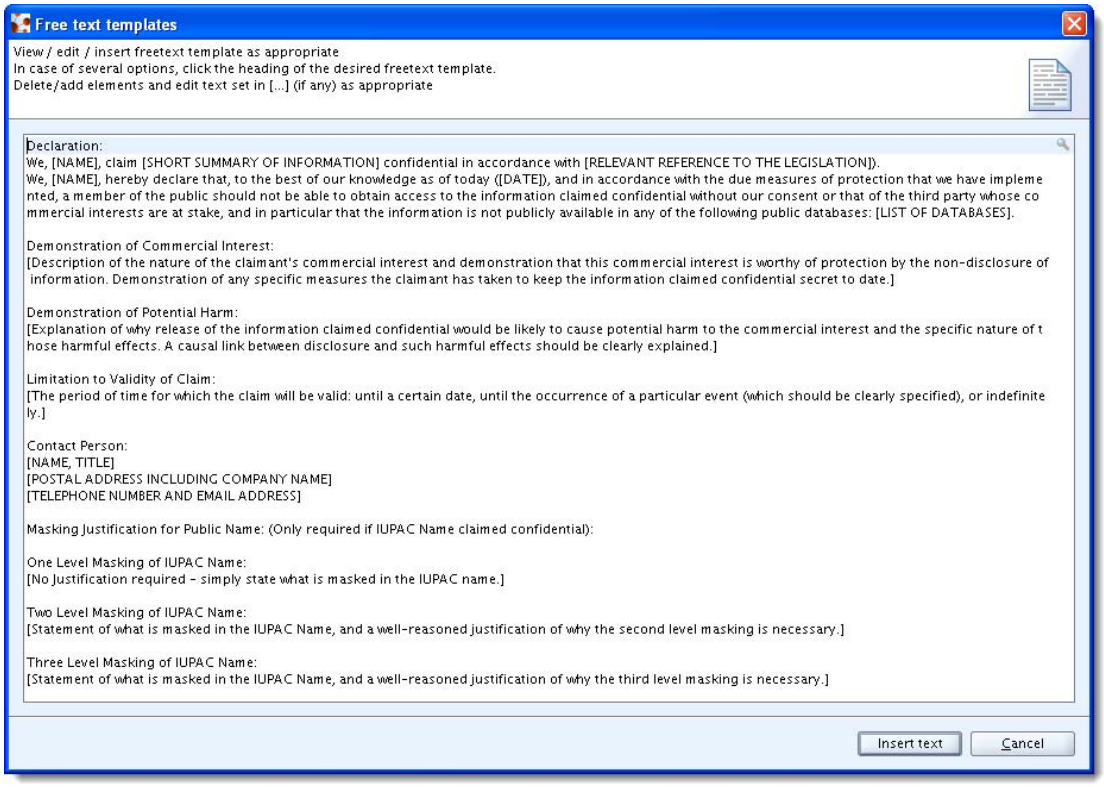


Figure 15: The free text template contains the main headings for preparing a proper justification for a confidentiality claim.



Further information on how to prepare justifications for confidentiality requests is available in *Data Submission Manual 16* published on the Data Submission Manuals section on the ECHA website at http://echa.europa.eu/web/guest/support/dossier-submission-tools. This manual will be updated for IUCLID 5.4 and the updated version will become available at the same time as the release of the new version of REACH-IT.

7. When will the changes related to the dissemination of safety data sheet information take place?

IUCLID 5.4 was released in 5 June 2012. Subsequently to the IUCLID 5.4 release, REACH-IT will be updated in order to be able to process dossiers prepared in the new IUCLID format and to invoice new confidentiality claims on safety data sheet information. The new version of REACH-IT is planned to be released in July 2012. The dissemination process will also be updated for IUCLID 5.4 and the new safety data sheet information. It is foreseen that safety data sheet information from dossiers submitted in IUCLID 5.4 will become available on the ECHA website starting from October 2012.

8. My dossier is already disseminated. How am I affected?

For the dossiers which have already been submitted, ECHA will invite the registrants at the time that IUCLID 5.4 is made available to review their dossiers – in particular to determine their need for additional confidentiality claims, or justifications – and prepare an update where needed. Registrants will be invited to resubmit those dossiers after the new version of REACH-IT is released. The resubmission deadline will be set to October 31, 2012. After the closure of the resubmission window, the database of registration dossiers will be re-disseminated in batches and any safety data sheet information that has not been claimed confidential will be made publicly available.

9. My dossier is a NONS. How am I affected?

Notifiers that have claimed their registration number are receiving specific advice via a message in REACH-IT, regarding potential updates of the SDS information.

10. Should I consider updating my dossier?

With the extension of the safety data sheet information in the IUCLID 5.4 which is about to be released, there may be several reasons for updating a registration dossier. You should update your dossier if any of the following applies:

- you have a concern about the dissemination of your legal entity name, registration number, information on your uses or uses advised against, the generic exposure potential or whether a CSA was performed. Flag the information confidential and provide justifications as explained above.

- you are an OR and have listed your suppliers in section 1.7 of your dossier. If you do not have the suppliers' permission to publish their legal entity name, then flag those suppliers as confidential. If you do have written permission from the supplier to publish their legal entity name, please attach it in section 1.7.

11. Which tools and manuals are available for dissemination and confidentiality claims of safety data sheet information?

The manuals on how to create, verify and submit IUCLID 5.4 dossiers using REACH-IT (i.e. Data Submission Manuals and REACH-IT Industry User Manuals) will be updated and published together with the new REACH-IT release.

Relevant manuals concerning the dissemination of safety data sheet information include:

- 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

These manuals are published in the Data Submission Manuals section on the ECHA website at http://echa.europa.eu/web/guest/support/dossier-submission-tools. The manuals will be updated for IUCLID 5.4 and the updated versions will become available at the same time as the release of the new version of REACH-IT.

ECHA has also developed a series of IUCLID plug-ins to help registrants preparing their dossiers. These plug-ins are available free of charge on the IUCLID website at iuclid.eu. Plug-ins currently available for IUCLID 5.3 will be updated for IUCLID 5.4 and will be made available at the same time as the release of the new version of REACH-IT. Relevant plug-ins concerning the dissemination of safety data sheet information are:

- the Dissemination IUCLID plug-in, which simulates which information from the registration will be made available on the ECHA website.
- the Fee Calculation IUCLID plug-in, which 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.

12. Are there any other changes in dissemination with IUCLID 5.4?

Aside from these major changes in IUCLID 5.4 which affect dissemination, there are a number of minor changes to IUCLID 5.4 and to the dissemination rules, which will be explained and detailed in the Dissemination manual (DSM 15 and its technical annexes mentioned above), and implemented in the IUCLID dissemination plug-in.

An indicative list is given below:

- a more visible confidentiality flag on the IUPAC name of the substance being registered (in section 1.1);
- an extended section on DNEL (derived no-effect level) and PNEC (predicted no-effect concentration);
- an indication of which confidentiality flags were introduced by the registrant (the justification for claiming confidentiality will not be disseminated);
- CAS numbers provided for registered substances and test material substances will be disseminated, unless the substance IUPAC name has been claimed confidential.

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