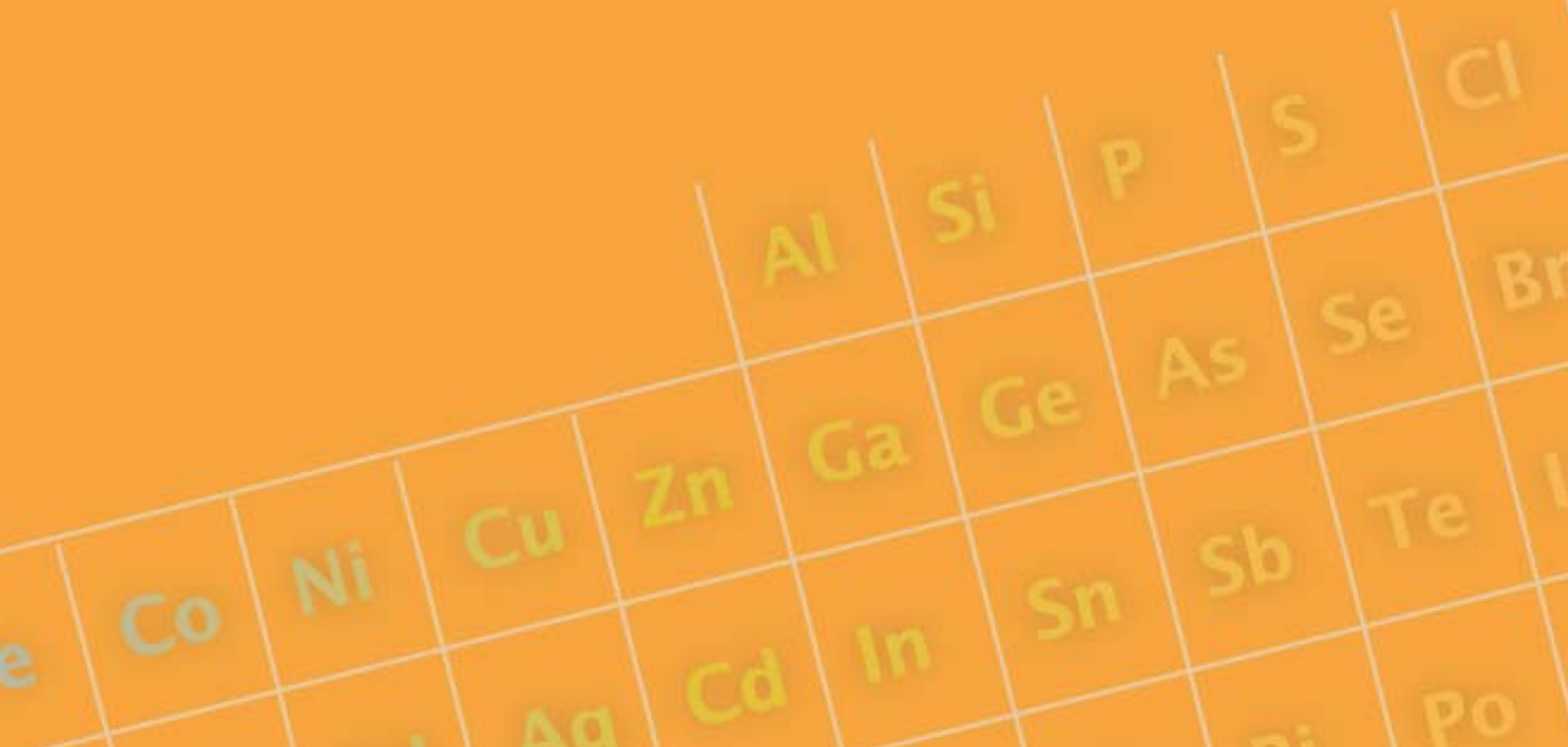
Practical guide 7:

How to notify substances in the Classification and Labelling Inventory



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Practical guide 7:
How to Notify Substances to the Classification & Labelling Inventory

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NOTIFICATION

Highlights

- **Importers and manufacturers must notify hazardous substances if they are placing them on the market, on their own or in mixtures and irrespective of the tonnage.**

- **Importers and manufacturers must notify substances subject to registration under the REACH Regulation if they are placing them on the market.**

- **Existing registrations of substances placed on the market may need to be updated with the CLP classification and labelling.**

- **From 1 December 2010, notification should be made within one month of placing a substance on the market.**

- **The first notification deadline is 3 January 2011.**

- **Notification is free of charge**

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1. INTRODUCTION

1.1. What is this document about?

This document contains information which helps you to find out whether you have to notify your substances to the Classification and Labelling Inventory, which has been set up at the European Chemicals Agency (ECHA). It will also explain how to prepare for and submit a notification in accordance with Regulation (EC) No 1272/2008 (CLP Regulation). Nevertheless, it is assumed that you are already familiar with the key concepts and terms of classification and labelling because these are not explained in this document.

You may find this document especially useful if your company manufactures and places substances on the market in EU[1] countries, or imports substances or mixtures from non-EU countries into the EU.

This document is important for you if your company carries out one or more of the following activities *and* places the involved substances or mixtures (preparation) on the market:

- Manufactures substances (including isolated intermediates) subject to registration in accordance with the REACH Regulation[2];
- Imports substances (e.g. dye stuffs) subject to registration in accordance with the REACH Regulation;
- Manufactures or imports substances which are classified as hazardous, irrespective of the quantity involved;
- Imports mixtures containing hazardous substances, irrespective of the quantity involved;
- Imports articles containing substances which are subject to registration under REACH Article 7.

This document is available and downloadable on the ECHA website in 22 official EU languages. The following chapters do not only provide you with basic information for notification, but also with links to the most important guidance documents and tools to complete your notification.

[1] The EU Member States are Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. Once the EFTA States that are signatories to the EEA Agreement (these are currently Iceland, Liechtenstein and Norway) have incorporated the CLP Regulation into their national legislation, references in this document to 'the EU' and 'the Member States' should be read to include the corresponding countries.

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

1.2. What is the CLP Regulation?

The CLP Regulation is the new EU legislation on Classification, Labelling and Packaging of substances and mixtures. It integrates the classification criteria of the United Nations Globally Harmonised System (GHS) into EU law. The CLP Regulation will gradually replace the Dangerous Substances Directive[3] (DSD) and the Dangerous Preparations Directive[4] (DPD).

The CLP Regulation stipulates that all substances must be classified and labelled according to the CLP criteria from 1 December 2010 onwards[5] and that all mixtures must be classified and labelled according to the CLP criteria from 1 June 2015. Further guidance on the CLP Regulation is available in the

Introductory Guidance on the CLP Regulation

and more detailed information on classification and labelling in the

Guidance on the Application of the CLP Criteria.

Both of these and the CLP Regulation, as well as other practical and explanatory documents, are available on the ECHA website under

http://echa.europa.eu/clp_en.asp,

see also the links at the end of this document.

With the entry into force of the CLP Regulation, Title XI of the REACH Regulation has been repealed. The harmonised classifications contained in Annex I to DSD have been transferred to Table 3.2 of Annex VI to the CLP Regulation and are legally binding.

1.3. What is notification under the CLP Regulation?

Articles 39 to 42 of the CLP Regulation deal with notification to the Classification and Labelling Inventory.

In general, notification under the CLP Regulation means that manufacturers and importers submit certain classification and labelling information of substances they are placing on the market to the Classification & Labelling Inventory held by ECHA (see Chapter 3 for practical details). The Inventory is a new database which did not exist under the previous legislation of classification and labelling (DSD and DPD).

Notification under the CLP Regulation applies to all hazardous substances of all tonnages and also to all non-hazardous substances subject to registration under REACH whenever they are placed on the market in the EU.

Notification under the CLP Regulation is due by certain time lines; see chapter 2.4 of this document.

[3] Council Directive 67/548/EEC the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous substances.
[4] Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.
[5] The classification of substances according to the DSD should still be included in the Safety Data Sheets until 1 June 2015.

1.4. What is the Classification & Labelling Inventory?

Information submitted in notifications will be collected in a database called the Classification & Labelling Inventory. The database will also contain information from REACH registration dossiers and on substances having a harmonised classification and labelling, i.e. the substances listed in Part 3 of Annex VI to the CLP Regulation. In particular, each entry will include information on whether

- It has a harmonised classification and labelling;
- It is based on a joint submission between registrants of the same substance under the REACH Regulation;
- It differs from another entry for the same substance;
- It was agreed by different notifiers.

A first public version of the Classification & Labelling Inventory will be made available on ECHA's website in late 2010. It will be a central source of information on the classification and labelling of substances for all users of chemicals.

The public version of the database will include substance identifiers referred to in Article 119(1) of the REACH Regulation, the classification, labelling elements and any relevant specific concentration limit (SCL) or multiplying factor (M-factor) for each substance. The identity of the notifier will not be made publicly available.

2. IDENTIFICATION OF ROLES AND OBLIGATIONS

2.1. Do I have to submit a notification to the Inventory?

If you are one of the suppliers listed in the box in chapter 1.1. of this document, then you have to notify the classification and labelling of your substances to the Inventory. Companies that manufacture substances or formulate mixtures outside the EU are not required to notify to the Classification & Labelling Inventory at the European Chemicals Agency (ECHA). Non-EU manufacturers and formulators who intend to import substances and mixtures into the EU should provide the relevant information (e.g. an IUCLID data set) to their EU importers who must submit the notification.

If non-EU manufacturers or formulators, for confidentiality reasons, do not want to disclose the composition of their substances or mixtures to their EU importers, they may appoint one of the importers to notify also on behalf of the other importers (see chapter 4.2. on notification as a group). In this case only the selected importer would receive any confidential information needed for the purposes of the C&L notification. Such an importer could also be an Only Representative (OR) who has already been appointed by the non-EU manufacturer or formulator for the purposes of registration under REACH: the OR can be made an importer by supplying him with a sample of the respective substances or mixtures so that he becomes responsible for the import.

2.2. Which substances do I have to notify to the Inventory?

In general, the obligation to notify to the Classification & Labelling Inventory includes **all hazardous substances** within the scope of the CLP Regulation, either on their own or contained in a hazardous mixture above specified concentration limits, see attachment 1 to this document, and which are imported or manufactured and **placed on the market** within the EU. Also non-classified **substances subject to registration under the REACH Regulation**, i.e. a substance manufactured or imported in volumes at or above 1 tonne per year, must be notified (see also chapter 1.6). This includes substances on their own, substances contained in mixtures and those substances contained in imported articles where Article 7 of the REACH Regulation provides for registration. Note that you must notify a substance even if its classification and labelling is (completely) harmonised and it is listed in Part 3 of Annex VI to the CLP Regulation.

However, the obligation to notify does not apply to a number of **substances and mixtures in the finished state** and intended for the final user or for uses for which there is specific legislation in place, e.g. radioactive materials, medicinal products, cosmetic products and food and feeding stuffs. For more details, please see Article 1 “Purpose and scope” of the CLP Regulation.

Substances notified under Directive 67/548/EEC (NONS) are deemed to be registered under the REACH Regulation. For NONS manufactured or imported in a volume of more than or equal to 1 tonne per year, the respective dossiers will have to be updated with the CLP classifications without undue delay, and a separate notification is therefore not required. For NONS manufactured or imported in a volume of less than 1 tonne per year, a separate notification to the Inventory will have to be made if the substance is classified as hazardous. However, in cases

where a supplier has already claimed a registration number for such NONS, the dossiers of the low-tonnage NONS will have to be updated without undue delay, while a separate notification is not required.

Substances and mixtures for scientific research and development (R&D) are exempted from the CLP Regulation only if they are used under controlled conditions in accordance with Community workplace and environmental legislation and when they are not placed on the market. In situations where this is not the case, they would fall under the CLP Regulation irrespective of the tonnage, and they should be notified if they meet the criteria for classification as hazardous on the basis of the available information.

The classification and labelling of **active substances contained in plant protection products[6] (PPPs) and biocidal products[7] (BPs)** is normally harmonised for all hazard classes and appears both in Tables 3.1 and 3.2 of Annex VI to the CLP Regulation. Notification to the Inventory must always be done for active substances when they are placed on the market.

Alloys are considered special preparations (CLP terminology: mixtures) under the REACH and CLP Regulations. The components of alloys need to be notified to the Inventory in case they are hazardous and contained in the alloy above specified concentration limits, see attachment 1 to this document.

Polymers must be notified to the Inventory if they are classified as hazardous and if they are imported or manufactured and placed on the market, on the basis of CLP Article 39(b) and 40. By contrast, **monomers** contained in such polymers are not considered as being placed on the market, and their notification is not necessary.

According to the CLP Regulation, importers of **articles** do not need to notify the classification and labelling of a substance contained in an article, unless the substance needs to be registered in accordance with Article 7 of the REACH Regulation.

2.3. Should I agree with others on the classification and labelling who notify the same substance?

Prospective notifiers and registrants shall make every effort to find a common classification and labelling for the same substance to be included in the Inventory. The notifiers may also form a group of manufacturers and/or importers as described in chapter 4.2. and notify their classification and labelling to ECHA as a joint entry.

This will be facilitated in the online submission by using the Inventory as background information: while notifying a substance online, you may consider the classification and labelling appropriate which is already in the database, i.e. which has already been provided by another notifier. In this case you can just tick the box “I agree” and the classification and labelling fields of your dossier are automatically filled in. If your substance has an EU harmonised classification and labelling for any hazard classes, you must classify and label your substance for those hazard classes and differentiations as specified in Part III of Annex VI to the CLP Regulation.

[6] The substances concerned by Council Directive 91/414/EEC.
[7] The substances concerned by Directive 98/8/EC of the European Parliament and of the Council.

2.4. When should I notify a substance?

As a general rule, you must notify the classification and labelling of a substance within one month of placing it on the market on or after 1 December 2010. For importers, the one month delay is counted from the day when a substance, on its own or contained in a mixture, is physically introduced in the customs territory of the Community.

The first working day in 2011 is 3 January. This means that the first notification deadline is 3 January, namely for all substances placed on the market on 1, 2 and 3 December 2010.

ECHA recommends that notifications are submitted from now on and well before 24 December 2010.

2.5. Should I submit a notification for substances that are subject to registration under the REACH Regulation?

You do not need to submit a separate notification for a substance that you have placed on the market if you have already registered it under REACH ***and*** if the registration dossier contains the classification and labelling according to the CLP Regulation (section 2.1 of IUCLID 5). This is because the registration dossier then contains already, the information that is required for substances to be notified to the Classification & Labelling Inventory.

The obligation to classify and label substances according to the new CLP criteria applies from 1 December 2010. This means that in cases where you submit a registration after 1 December 2010, you must **always** include the CLP classification and labelling.

In cases where you have already registered your substance earlier than 1 December 2010 and the registration dossier does not contain the classification and labelling according to the CLP Regulation, but only those according to the Dangerous Substances Directive, you must update your registration dossier by including the classification and labelling according to the CLP Regulation. This has to be done without undue delay, i.e. as soon as possible and practical, after 1 December 2010. However, it is advisable that you include the classification and labelling in accordance with the CLP Regulation in the first submission of your registration dossier because this saves the time and effort to update it later on.

If your substance is a phase-in substance to be registered in 2013 or 2018 only, but it is placed on the market earlier, you must submit a notification for this substance to the Classification & Labelling Inventory within one month of placing it on the market. If you are placing it on the market on 1, 2 or 3 December 2010, you must submit a notification for this substance to the Classification & Labelling Inventory by 3 January 2011. If you place a phase-in substance on the market after 1 December 2010, a notification must be submitted within one month of placing it on the market. Substances subject to registration under REACH and placed on the market must be notified even if they are not classified as hazardous.

The obligation to notify substances subject to registration under REACH also applies to those members of substance information exchange forums (SIEFs) who will

register their substances in 2013 or 2018 only. Provided that the lead registrant has already submitted his registration, it is possible for the other SIEF members to agree to the classification & labelling provided by the lead registrant by ticking the box “I agree”. The classification and labelling fields are then automatically filled in for the respective notification. However, this can only be done where the SIEF members have created their notification in REACH-IT. SIEF members may also decide to notify as a group of manufacturers and importers the agreed classification & labelling of a substance (see chapter 4.2.).

2.6. When should I update my notification?

Whenever you become aware of new and reliable information which changes the classification and labelling of your substance, you must update the information provided in your notification. If you have provided the information required for notification in a registration dossier, you must update the respective registration dossier.

The requirement to update classification and labelling information of substances does not apply when **harmonised hazard classes and differentiations** are already listed in Table 3.1 in Annex VI to the CLP Regulation at the time of your notification.

In cases where a substance classification is harmonised after you have notified it to the Inventory, you should update your notification at the latest when that harmonised classification becomes legally applicable.

Also your contact details should be up-to-date.

3. NOTIFICATION IN PRACTICE

3.1. What information should I provide in the notification?

For each substance, the notification must include the information requested in Article 40 of the CLP Regulation:

- **Name** and **contact details** of the notifier;
- **Identity** of the substance, including name and other identifiers, information related to molecular and structural formula, composition and nature and amount of additives (see chapter 4.3. of this document and also specifications in sections 2.1. to 2.3.4. of Annex VI to the REACH Regulation);
- **Classification** of the substance according to the CLP criteria;
- In case the substance is classified in some but not all hazard classes or differentiations, an **indication of** whether this is due to lack of data, inconclusive data, or data which is conclusive for non-classification;
- **Specific concentration limits and M-factors**, including a justification for setting them; and
- **Label elements**, including hazard pictograms, signal words, hazard statements and any supplemental hazard statements.

3.2. How can I prepare for the notification?

Before submitting your notification to ECHA, you must classify and label your substance according to the CLP criteria. The following preparatory steps for classification and labelling should be completed:

1. **Make an inventory** of the substances and mixtures that you are manufacturing in the EU and that you are importing from non-EU countries;

2. **Clarify** whether any of these substances are exempted from the CLP Regulation (see Article 1 of the CLP Regulation);

3. **Check** whether any of your substances are subject to registration under the REACH Regulation;

4. **Collect** all available information on substances identity, including the IUPAC name, EINECS number, CAS number or other identity codes and clarify the qualitative and quantitative composition of your substances;

5. **Name the substances** in line with the guidance for identification and naming of substances under the REACH Regulation;

6. **Check** whether the substances are listed in Part 3 of Annex VI to the CLP Regulation, see http://echa.europa.eu/legislation/classification_legislation_en.asp, i.e. whether the classification and labelling of the substance is harmonised. If there is a harmonised classification and labelling for a substance this must be used, and you may not self-classify the substance for those hazard classes or differentiations. Based on adequate and reliable information you should self-

classify those hazard classes and differentiations which are not covered by the harmonised classification and labelling;

7. **Gather** all available and reliable **information** on the hazardous properties of any substance where the classification and labelling of your substance is not harmonised;

8. **Classify** your substance by comparing the available information with the classification criteria[8];

9. In cases where you want to specify a multiplying factor (M-factor) or set a specific concentration limit (SCL) according to Article 10 of the CLP Regulation, **provide a justification** using the relevant parts of sections 1, 2, and 3 of Annex I to the REACH Regulation;

10. **Determine** whether a mixture which contains a hazardous substance must be classified under the CLP Regulation due to the presence of that substance;

11. **Decide** if you want to establish **or join a group of manufacturers and/or importers** with other prospective notifiers and registrants of the same substance and eventually submit a joint classification and labelling for the substance;

12. **Create your REACH-IT account** (if not done already).

3.3. How do I create a notification?

You can use one of the following tools to prepare your classification and labelling notification:

A. IUCLID 5. You can specify all the requested information in IUCLID 5, and create a classification and labelling notification dossier in IUCLID.

- IUCLID 5 allows you to include more than one composition for the same substance (e.g. due to different impurity profiles) and link each composition to a specific classification and labelling. Note that each notifier can submit only one notification per substance and this is the only tool where you can submit several compositions for one substance.
- This option could be practical for you if you have used IUCLID 5 before.
- This option could also be practical for you, if you intend to submit a registration under the REACH Regulation (e.g. for the registration deadlines in 2013 or 2018)

B. BULK. You can create a bulk XML file containing more than one classification and labelling notification.

The bulk XML file can be created either using the excel tool provided by ECHA or by using the XML schema (this option may be preferred for users with an IT background).

[8] See Annex I to the CLP Regulation and the *Guidance on the application on the classification criteria* for further information.

- The bulk XML file allows you to submit notification information for several or a large number of substances defined by their EC or CAS number in a single file.
- **Note.** *XML bulk submission can be used only when each substance is identified either by CAS or EC number and identified by one composition only. In addition, no M-factor or SCL can be specified.*

C. **ONLINE.** You can manually enter the required information in REACH-IT *(not yet available)*

- If you need to notify only a few substances and you are not currently using IUCLID 5, an online notification via REACH-IT could be your preferred option.

Up-to-date information on the REACH-IT online notification functionality and the XML tool is available in the CLP section of the ECHA website at:

http://echa.europa.eu/clp_en.asp

You can already start to prepare your files for:

- IUCLID notification: by collecting required information and inserting the information in IUCLID 5;
- XML classification and labelling notification: by compiling the required information;
- Online classification and labelling notification: by compiling the required information.

3.4. How to submit a notification?

Classification and labelling notifications must be submitted electronically via the REACH-IT portal on the ECHA website. **Please note that you need to create your company account in REACH-IT[9] before you start to notify your substances.**

You will find the notification application access point in the REACH-IT section of the website.

When you enter REACH-IT, go to the classification and labelling section of the main menu (on the left-hand side of the REACH-IT screen), you will be guided through dedicated pages where **you can choose from the three following possibilities** to submit your classification and labelling notification:

1. Submit a classification and labelling notification dossier created in **IUCLID 5:** prepare a notification dossier in your local IUCLID 5 installation and upload it directly in REACH-IT;

2. Submit a **bulk** notification: upload in REACH-IT an XML bulk file (format to be available on the ECHA website);

[9] See the link at the end of this document for further information.

3. Submit a classification and labelling notification **online** (available in the second quarter of 2010) by entering the required information substance by substance directly into the REACH-IT system.

A notifier can submit only one notification per substance. However, each notification can contain more than one composition for the same substance (e.g. due to different impurity profiles) and each composition can be linked to a specific classification and labelling. This function is available in the IUCLID 5 submission only.

Practical tips for notification and choosing a submission tool

- **Do not wait** until the last minute to submit your classification and labelling notification to ECHA.
- We recommend you to **start submitting** your classification and labelling notifications to ECHA as soon as the notification tools are available on the ECHA website.
- If you need to notify a few substances only and you are currently not using IUCLID 5, the **online notification via REACH-IT** could be your preferred option.
- **Bulk notification** using the XML option may be more practical for companies who will notify many chemical substances since it allows the submission of classification and labelling notifications for several substances in a single file.
- Use IUCLID 5 when you need to submit **several compositions for one substance** and specify classification and labelling for each composition.

4. KEY INFORMATION

4.1. Placing on the market

Placing a substance or mixture on the market under the CLP Regulation means to make it physically available to third parties, whether in return for payment or free of charge. Also, importing from non-EU countries into the EU customs territory is considered as placing on the market. Placing on the market would include the situation where a substance or mixture is sent from a company or research institute to a laboratory with a different legal entity.

In relation to notification, placing on the market is a pre-condition: A substance which is referred to in Article 39 of the CLP Regulation should be notified only in cases where it is placed on the market. Nevertheless, notification is not needed if the information required under the CLP Regulation Article 40 has already been provided as part of a previous registration or notification by the same notifier.

As to the date when notification is due, this depends on the date when the substance is actively placed on the market. When a substance is placed on the market on or after 1 December 2010, it must be notified to the Classification & Labelling Inventory within 1 month of placing it on the market, e.g. the notification deadline is 3 January 2011, applying to substances placed on the market on 1, 2 or 3 December 2010. If a substance is placed on the market before 1 December 2010, e.g. on 10 October 2010, and placing on the market is done again on 17 January 2011, then notification will be due on 17 February 2011.

Substances that are in stock on 1 December 2010 are not considered to be placed on the market on that day, and they will not have to be notified by 3 January 2011. They will only have to be notified, within 1 month, if they are (*again*) placed on the market by their manufacturer or importer later on. A **distributor** who takes substances off the shelves where they have been stored for a while, in order to sell them to others, will **not have to notify,** as this obligation is **only** on **manufacturers** and **importers**.

4.2. Group of manufacturers or importers

The classification and labelling notification of a substance can be made by a group of manufacturers or importers. A group of manufacturers or importers can, for instance, be:

- a corporate company with different legal entities;
- several companies that have no specific links between each other;
- several companies from one specific industry sector; or
- a substance information exchange forum (SIEF)

In cases where a notification is done by a group, only one classification and labelling notification will be submitted on behalf of all group members. To this end, the group

members should agree on the classification and labelling of the respective substance[10].

If the classification and labelling notification is submitted on behalf of a group, this shall be indicated in REACH-IT. For more details you should consult the Industry User Manual "IUM part 15: Manage your group of manufacturers or importers".

The members of a group are recommended to document fully their agreement, and the basis on which classification decisions have been made. On request, they have to make available to ECHA, to the competent authorities and to the relevant enforcement authorities of the Member States all the information used for the purposes of classification and labelling under the CLP Regulation.

When a group of manufacturers and/or importers cooperate in this way, each member shall remain fully responsible for the classification, labelling and packaging of substances and mixtures he places on the market, and for meeting any other requirements of the CLP Regulation.

4.3. Substance identification essentials

You have to identify your substance as specified in sections 2.1 to 2.3.4 of Annex VI to the REACH Regulation. The substance definitions in the CLP and REACH Regulations are identical although less information is required for the classification and labelling notification compared to the registration. The substance definition also corresponds to the definition of a substance in the 7th Amendment to the Dangerous Substances Directive[11]. The definition goes beyond a pure chemical compound defined by a single molecule. **It is recommended that all prospective notifiers consult the**

Guidance for identification and naming of substances under REACH

see the links to related material in chapter 5 of this document.

The approach to identify a substance depends on the substance type. Substances can be divided into two main groups:

A. **'Well defined substances'**: Substances with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification information required by section 2 of Annex VI to the REACH Regulation. 'Well defined substances' are sub-divided as follows:
    a) ***Mono-constituent substances,*** i.e., as a general rule, substances in which one constituent is present at a concentration of at least 80% (w/w); the remaining 20% are regarded as impurities / additives.
    b) ***Multi-constituent substances,*** i.e., as a general rule, substances consisting of several main constituents present at concentrations ≥10% and <80 % (w/w). All constituents present <10% are regarded as impurities.
    c) ***Substances defined by more than the chemical composition***, i.e. substances defined as mono- or multi-constituent substances but require additional parameters in order to identify the substance

[10] In this context substances can be considered to be the same if the main constituents are the same and the substance has the same EC number or CAS number or IUPAC name. See further information in the *Guidance for identification and naming of substances under REACH*.
[11] Directive 92/32/EEC amending Directive 67/548/EEC.

unequivocally. Such parameters may include, but are not limited to, crystalline structure, shape, hardness etc.

B. **'UVCB substances'**: Substances of Unknown or Variable composition, Complex reaction products or Biological materials. These substances cannot be sufficiently identified based on their composition alone. Further identifiers, depending on the type of UVCB substance, are required such as source or production process.

All notified substances should contain sufficient information to enable each substance to be properly identified. Sections 2.1 to 2.3.4 of Annex VI to the REACH Regulation specify the information that must be provided to meet the criteria for proper identification of a substance for notification to the Classification & Labelling Inventory. In general, the identifiers should be unambiguous and consistent in all cases. For example, the IUPAC name should reflect the structural and molecular formula. All constituents should be identified by IUPAC name and CAS identifiers and include a structural formula. In terms of quantitative information, a concentration range (minimum and maximum) should be, as far as possible, provided for all constituents. The composition information should account for 100% of the substance.

5. FURTHER INFORMATION

The ECHA website is an easy way to access information.

The ECHA website provides a single point of access to information on the CLP and REACH Regulation containing:

- General information about the CLP Regulation and links to CLP guidance documents in the classification section;
- General information about the REACH Regulation in the 'About REACH' section;
- User manuals (IUCLID 5 and REACH-IT); and
- Submission manuals for notification (IUCLID-5, online, bulk, and management of groups of manufacturers/importers).

If you have questions on notification:

- The CLP / REACH helpdesk in your country provides advice on your roles, responsibilities and about available guidance and should be your first point of contact. The contact information of the national helpdesks can be found on the ECHA website;
- The ECHA Helpdesk will assist you with technical questions related to REACH-IT, IUCLID, registration under REACH and notification to the Classification and Labelling Inventory. You can submit your questions by filling in an information request form on the ECHA website; and
- Your industry association can be a good source of information for sector-specific questions.

Links to related material

CLP Section on the ECHA website

- http://echa.europa.eu/clp_en.asp

Classification & Labelling Inventory (available in late 2010):

- ECHA Dissemination website ECHA CHEM: http://echa.europa.eu/chem_data_en.asp

Guidance:

- **Introductory Guidance on the CLP Regulation**
  http://guidance.echa.europa.eu/docs/guidance_document/clp_introductory_en.pdf

- **Guidance on the Application of the CLP Criteria**
  http://guidance.echa.europa.eu/docs/guidance_document/clp_en.pdf

- **Questions and Answers on CLP**
  http://echa.europa.eu/doc/classification/questions_and_answers_clp_20090526.pdf

- **CLP Frequently Asked Questions**
  http://echa.europa.eu/clp/clp_help/clp_faq_en.asp?fuseaction=home.faq

- **Guidance for substance identification and naming of substances under REACH**

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

IT-tools and manuals:

- **IUCLID 5**
http://echa.europa.eu/iuclid

- **REACH-IT**
http://echa.europa.eu/reachit

- **REACH-IT supporting documents**
http://echa.europa.eu/reachit/supp_docs_en.asp

Manuals for notification

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

- **Data Submission Manual part 12:** How to prepare and submit a C&L notification using IUCLID?

- **Data Submission Manual part 13:** How to prepare and submit a bulk C&L notification (bulk xml file)?

- **Industry User Manual part 16:** How to do an online submission to the C&L Inventory *(will be published shortly)*

- **Industry User Manual part 15:** Manage your group of manufacturers or importers

- **Industry User Manual part 6:** section 3.1.2.5 is related to submission of I5 C&L notification

CLP Helpdesks:

- **National Helpdesks:**
First points of contact for companies from the European Economic Area (EEA).
http://echa.europa.eu/help/nationalhelp_contact_en.asp

- **ECHA Helpdesk:**
Provides support e.g. on IUCLID 5, REACH-IT and specific submissions of data via the REACH-IT portal. Non-EEA companies may turn to ECHA if they seek advice on the implementation of REACH or CLP Regulations in the EEA.
http://echa.europa.eu/help/echahelp_en.asp

EU legislation:

- **CLP Regulation (EC) No 1272/2008**
http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF

- **REACH Regulation (EC) No 1907/2006**
http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:EN:PDF

Attachment 1

Concentration limits for notification to the Inventory

1. Health and environmental hazards

The concentration limits referred to in CLP Article 39(b) are either the ones applicable under the Dangerous Preparations Directive 1999/45/EC (DPD) or under the CLP Regulation. If they are taken from DPD, these are either the specific concentration limits set under the Dangerous Substances Directive 67/548/EEC (DSD) or the generic concentration limits as referred to in Part B of Annex II to DPD for human health hazards and in Part B of Annex III to DPD for environmental hazards.

The applicable concentration limits under CLP are listed in the table below.

Hazard class/category/differentiation of the ingredient substance	**Applicable concentration limit for the purpose of notification under CLP Art. 39(b)** ***both weight percentage and volume percentage if not specified otherwise***
Acute toxicity, cat. 1-3	0.1%
Acute toxicity, cat. 4	1%
Skin corrosion, cat. 1A, 1B or 1C (additive)	1% unless a lower SCL has been set (see section 3.2.3.3.1 of Annex I)
Skin corrosion, cat. 1A, 1B or 1C (non-additive)	1% or lower where relevant (see section 3.2.3.3.6 of Annex I)
Skin irritation, cat. 2 (additive)	1% unless a lower SCL has been set (see section 3.2.3.3.1 of Annex I)
Skin irritation, cat. 2 (non-additive)	3% or lower where relevant (see section 3.2.3.3.6)
Serious eye damage, cat. 1 (additive)	1% unless a lower SCL has been set (see section 3.3.3.3.1 of Annex I)
Serious eye damage, cat. 1 (non-additive)	3% or lower where relevant (see section 3.3.3.3.6 of Annex I)
Eye irritation, cat. 2 (additive)	1% unless a lower SCL has been set (see section 3.3.3.3.1 of Annex I)
Eye irritation, cat. 2 (non-additive)	3% or lower where relevant (see section 3.3.3.3.6 of Annex I)
Respiratory sensitisation, cat. 1	1% w/w (solid/liquid) 0.2% v/v (gas)

Skin sensitisation, cat. 1	1% unless a lower SCL has been set
Germ cell mutagenicity, cat. 1A or 1B	0.1%
Germ cell mutagenicity, cat. 2	1%
Carcinogenicity, cat. 1A or 1B	0.1% unless a lower SCL has been set
Carcinogenicity, cat. 2	1% unless a lower SCL has been set
Reproductive toxicity, cat. 1A or 1B	0.3%
Reproductive toxicity, cat. 2	3%
Effects on or via lactation	0.3%
STOT-SE, cat. 1	1% unless a lower SCL has been set
STOT-SE, cat. 2	10%
STOT-RE, cat. 1	1% unless a lower SCL has been set
STOT-RE, cat. 2	10%
Aspiration toxicity, cat. 1	Not applicable; mixture must be tested in order to confirm its classification based on the presence of a particular substances that is classified for that hazard.
Aquatic acute, cat. 1	0.1% unless 0.1/M is lower
Aquatic chronic 1	0.1% unless 0.1/M is lower
Aquatic chronic 2-4	1%
Hazardous to the ozone layer	0.1%

It should be noted that a particular concentration limit may not necessarily trigger the classification of the mixture where the substance is contained. The classification of the mixture itself will depend on the applicable rules to determine the classification of the mixture as set out in Parts 3-5 of Annex I to CLP, see e.g. Table 3.3.3 of Annex I to CLP for serious eye damage / eye irritation.

2. Physical hazards

Notification to the Inventory must also be done for substances classified for a particular physical hazard and contained in a mixture whenever the mixture is placed on the market and needs to be classified for a physical hazard due to the presence of *that* substance. It should be noted that the physical hazard class to which the mixture belongs could be different from that of the substance(s) causing the hazard. Expert judgment should be sought in case of doubt.

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