

Overview of Key Obligations Under Regulation (EC) No. 1272/2008 on the Classification, Labelling and Packaging of Substances and Mixtures (CLP)

Summary

This document examines the key aspects of the CLP Regulation; the obligation to classify, label and package substances and mixtures; and the obligation to notify certain information to the European Chemicals Agency (ECHA). The scope of these obligations and the key dates relating to their implementation are summarised below:

CLP Obligation	Scope	Key Dates
Obligation to classify, label and package substances (Article 4)	Substances placed on to the European Market (Article 4.1) Substances that are subject to registration or notification under REACH (Article 4.2)	The obligation to classify substances in line with CLP applies from 1 December 2010 (Article 62)
Obligation to notify the Agency (Article 40)	Substances that are subject to registration under REACH and are placed on the market on or after 1 December 2010 (Article 39(a)) Substances classified as hazardous and which are placed on the market either on their own or in mixtures above specified concentration limits, which result in the classification of the mixture as hazardous (Article 39(b))	Substances placed on the market on or after 1 December 2010* must be notified within 1 month after being placed on the market (Article 40) This means that the first notification deadline will be 3 January 2011
Obligation to classify, label and package mixtures (Article 4)	Mixtures placed on European Market (Article 4.1)	The obligation to classify mixtures in line with CLP applies from 1 June 2015 (Article 62)



* It is recommended that manufacturers and importers of substances placed on the market before 1 December 2010, complete C&L notifications well before that legal deadline.



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1. Introduction

Regulation (EC) No 1272/2008 (CLP) entered into force on 20 January 2009. CLP introduces the UN Globally Harmonised System (GHS) into the legislative framework of the European Union.

The CLP Regulation is directly-acting in all EU Member States, requiring no national transposition. Its provisions will be phased in over a period of years until 1 June 2015 when the Regulation will be fully in force. This is intended to help suppliers and users of chemicals change from the current EU classification and labelling system to the new GHS-based system.

CLP is concerned with the classification, labelling and packaging of chemical substances and mixtures. According to CLP, it is the task of industry to establish the hazards of substances and mixtures before they are placed on the market, and to classify them in line with the identified hazards. In case a substance or a mixture is hazardous, it has to be labelled so that workers and consumers know about its effects before they handle it.

The European Community currently has two pieces of active legislation in the area of classification, labelling and packaging; the Dangerous Substances Directive 67/548/EEC (DSD) and the Dangerous Preparations Directive 1999/45/EC (DPD).

The CLP Regulation will run in parallel with this existing legislation until 1 June 2015. CLP will eventually repeal both these Directives (although they are not fully repealed until 1 June 2015).

CLP does not apply to the following: radioactive substances and mixtures within the scope of Directive 96/29/Euratom; substances and mixtures which are subject to customs supervision; non-isolated intermediates; or substances and mixtures used for scientific research and development, which are not placed on the market.

CLP does not apply to substances and mixtures in the following forms (in the finished state, intended for the final user): medicinal products as defined in Directive 2001/83/EC; veterinary medicinal products as defined in Directive 2001/82/EC; cosmetic products as defined in Directive 76/768/EEC; medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC; and food or feeding stuffs as defined by Regulation (EC) No 178/2002.



2. CLP and REACH

The classification of substances plays a key role in Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Substance classifications must be included in REACH registration dossiers. In addition, classification triggers certain provisions such as the performance of exposure assessments and risk characterisation as part of the Chemical Safety Assessment. The obligation to provide Safety Data Sheets is also related to classification. Classification of a substance as mutagenic, carcinogenic or toxic to reproduction may also lead to restrictions and the need to apply for authorisations.

Furthermore, if the classification of a substance or mixture changes as a result of implementing CLP, it will be necessary to update Safety Data Sheets. It may also be necessary to prepare new Safety Data Sheets for substances or mixtures which were not classified as hazardous under DSD or DPD. Registration deadlines may also change as a result of a reclassification under CLP.

As REACH and CLP are closely interlinked, it is recommended to coordinate the implementation of CLP together with processes related to obligations under REACH.



3. Obligation to Classify Substances and Mixtures

General Obligation to classify substances and mixtures

The obligation to classify substances and mixtures is based on two pieces of legislation, the CLP Regulation itself and the REACH Regulation.

Article 4.1 CLP requires manufacturers, importers and downstream users to classify substances or mixtures in accordance with CLP before placing them on the market. *This obligation is independent of the tonnage to be placed on the market.*

According to Article 4.2 manufacturers and importers should also classify substances which are not placed on the market if they are subject to registration or notification in line with Articles 6, 9, 17 or 18 of REACH. This includes the classification of monomers, on-site isolated intermediates, transported intermediates as well as substances used for product and process-orientated research and development (PPORD).

Classification of Substances

From 1 December 2010 substances within the aforementioned scope must be classified using the provisions of CLP. Until 1 June 2015, a classification under DSD must also be provided (alongside any CLP classification). Prior to 1 December 2010, substances must be classified, labelled and packaged in accordance with DSD.

According to Article 61, substances may be classified, labelled and packaged in accordance with CLP before the 1 December 2010 deadline. If this is done, the provisions on labelling and packaging in DSD will not apply.



It is recommended that manufacturers, importers and downstream users of substances begin to classify, label and package in line with CLP as soon as possible, rather than waiting for the 1 December 2010 deadline.

Hazard classification is the process of assigning a substance to a particular hazard class. This involves an evaluation of the available information on the hazardous properties of substances against the specific classification criteria set out in Annex I to CLP. There are two types of classification under CLP, harmonised classification and self-classification:

Harmonised classification

Harmonised classification means the decision on classification for a particular hazard of a substance is taken at Community level. Some 8000 substances have a harmonised classification under CLP. These have been translated from the substances with harmonised classification under DSD. A harmonized classification must be applied by default by the suppliers of respective substances.

Harmonised classifications for those substances currently listed in Annex I to DSD have been translated into the new CLP classifications; these can be found in Table 3.1 of Annex VI to CLP. The classifications based on the DSD criteria can be found in Table 3.2 of Annex VI. These tables will be amended by Regulation (EC) No 790/2009 from 1 December 2010. Regulation (EC) No 790/2009 will update classifications for substances already subject to harmonised classification and install new harmonised classifications; the amendments will also delete entries for certain substances.

Proposals for new harmonised classifications may be submitted either by Member State Competent Authorities or by manufacturers, importers, or downstream users themselves (Article 37).

Self-classification

Self-classification is where the decision on classification is taken by the manufacturer, importer or downstream user. Self-classification may only be applied in the absence of a harmonized classification, or where a harmonized classification is only available for selected hazards.

Manufacturers, importers and downstream users are obliged to perform any additional testing necessary to make a full assessment of the physical hazards, unless adequate and reliable information is already available (Article 8.2). Information produced towards compliance with REACH, or which is obtained through information sharing within a Substance Information Exchange Forum (SIEF) may be used to establish a classification under CLP.

With regards to Health and Environmental Hazards; manufacturers, importers and downstream users are not obliged to carry out further testing (Article 8.1). It will be sufficient to state that a classification has not been made due to a lack of data. In the absence of data, there is also the possibility to use Annex VII of CLP to translate existing classifications under DSD in to CLP compliant classifications.



Classification of Mixtures

From 1 June 2015 mixtures within the aforementioned scope must be classified using the provisions of CLP. Prior to 1 June 2015, mixtures must be classified in accordance with DPD. However, under Article 61, mixtures may be classified, labelled and packaged in line with CLP before 1 June 2015. If this is done, the provisions on labelling and packaging in DPD will not apply.

For mixtures, a classification under DSD must still be provided (alongside any CLP classification) up until 1 June 2015.



The 1 June 2015 deadline is also relatively close, when one considers the vast amount of work involved in the reclassification of mixtures; therefore it is recommended that manufacturers, importers and downstream users of mixtures begin to classify, label and package in line with CLP as soon as possible, rather than waiting for the 1 June 2015 deadline.

The classification of mixtures under CLP is essentially the same as that for substances. As a general rule, available data on the mixture as a whole should primarily be used to determine the classification (Article 6).

With regards to the classification of the health or environmental hazards of mixtures; if no information on the mixture itself is available, CLP provides a number of “bridging principles” which can be employed in order to establish the classification of a mixture based on its component substances.

4. Obligation to Notify the European Chemicals Agency

For substances which are placed on the market before and still, or again, on 1 December 2010, the deadline for notification to the inventory is one month after this date, i.e. 1 January 2011. However, as 1 January is a Saturday and 2 January falls on a Sunday, the notification deadline is in practice the 3 January 2011. The same applies for substances that are placed on the market on 1 December 2010 for the first time.

However, according to Article 40.3, substances placed on the market before 1 December 2010 may be notified in accordance with CLP before that date.



The notification process involves a significant amount of effort, especially for large numbers of substances; therefore it is recommended that manufacturers and importers placing substances on the market before 1 December 2010 take advantage of the opportunity to notify the Agency as soon as possible.

Under CLP manufacturers and importers of substances and mixtures will have to notify certain information to the Agency if the substance is:

- Subject to registration under REACH and placed on the market (Article 39(a)).
- Classified as hazardous and is placed on the market either on its own or as part of a mixture above concentration limits specified in CLP (or Directive 1999/45/EC, where relevant) which result in the classification of the mixture as hazardous (Article 39(b)).

As part of notification, the following information must be sent to ECHA (Article 40):

- Identity of notifier (as specified in section 1 of Annex VI to REACH).
- Identity of the substance, including name and other identifiers, information related to molecular and structural formula, composition, nature and amount of additives (as specified in section 2.1 to 2.3.4 of Annex VI to REACH).
- Classification of the substance according to the CLP criteria. Where the substance has been classified in some but not all CLP hazard classes or differentiations, an indication of whether this is due to lack of data, inconclusive data, or data which are conclusive although insufficient for classification.
- Specific concentration limits or M-factors, where relevant, including a justification for setting them.

- Label elements, including hazard pictograms, signal words, hazard statements and any supplemental hazard statements.

If you have already provided the information to be notified to the Agency in form of a registration under REACH, it will not be necessary to submit an additional notification to the Agency (CLP Article 40.1).

If you manufacture or import substances in quantities less than 1000 tonnes per year and it is not a phase-in substance that is classified as CMR category 1 or 2 according to DSD in quantities at or above one tonne per year, or as R50/53 at or above 100 tonnes per year, you may not have registered your substance under REACH by 1 December 2010 and will therefore have to notify it by 3 January 2011, provided you place them on the market on 1 December 2010.

Preparation and Submission of Classification and Labelling Notifications

Notifications in accordance with Article 40 must be submitted electronically via the REACH-IT portal on the ECHA website. You must first sign-up in REACH-IT and create an account to be able to submit your notification. The following tools are available for dossier preparation:

- **IUCLID 5** - You can specify all the requested information in IUCLID 5, and create a 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.
- **BULK** - You can create a bulk XML file containing more than one C&L notification. The bulk XML file can be created using the EXCEL tool provided by ECHA. 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.

XML bulk submission can only be used 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 set, if it is not already specified in Annex VI to the CLP Regulation for the substance to be notified.

- **ONLINE** - REACH-IT now allows manufacturers and importers to create and submit classification and labelling notifications online directly via REACH-IT. This tool was added to REACH-IT on the 31st May 2010. If you only need to notify a few substances and you are not currently using IUCLID 5, an online notification via REACH-IT could be your preferred option.

Having prepared your notification dossier file, you can submit it to ECHA directly via REACH-IT.

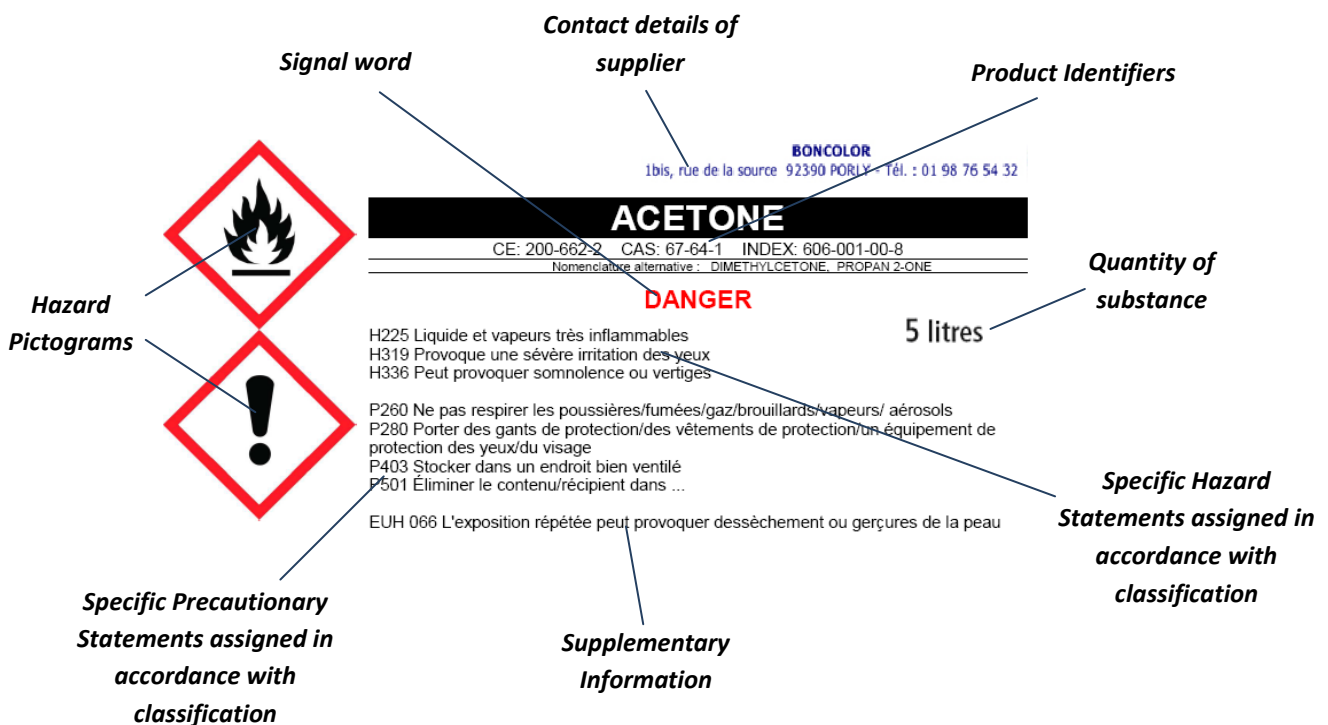
5. Hazard Communication in the form of product labelling

Suppliers of hazardous substances are required to communicate these hazards via two means:

- The Safety Data Sheet
- Product labeling

The requirements of the SDS are outlined in the REACH regulation (as amended by CLP). The main provision for hazard communication set up under CLP is the product label. Substance and mixtures classified as hazardous must be labeled as such (Article 17).

CLP introduces hazard pictograms (Article 19) that are different from the existing danger symbols used under the Dangerous Substances Directive. Risk and safety phrases are replaced with Hazard (Article 21) and Precautionary statements (Article 22) respectively. The label must also include a signal word in accordance with the classification of the hazardous substance or mixture (Article 20). The signal word indicates whether a hazard is generally more severe or less severe. For more severe hazards, the signal word 'danger' is to be used; for less severe hazards, the signal word 'warning' should be applied. An example of a product label designed in accordance with CLP is pictured below.



Serving the Industry

6. Fees payable to the European Chemicals Agency

Commission Regulation (EU) No 440/2010 on the fees payable to the European Chemicals Agency pursuant to CLP was published in the Official Journal of the European Union 21 May 2010.

Fees are required for:

- A request for a harmonized classification and labelling (Article 37)
- Requests for confidentiality under Article 24.

In accordance with Article 24, the manufacturer, importer or downstream user of a substance in a mixture may submit a request to the Agency to use an alternative chemical name which refers to that substance in a mixture either by means of a name that identifies the most important functional chemical groups or by means of an alternative designation, where the substance meets the criteria set out in Part 1 of Annex I and where he can demonstrate that disclosure on the label or in the safety data sheet of the chemical identity of that substance puts the confidential nature of his business, in particular his intellectual property rights, at risk.

SMEs benefit from reduced fees up to 90% depending size. The fees are summarized in the table below:

Request		Standard fee	Reduced fees for SMEs		
			Medium-sized Enterprises	Small Enterprises	Micro Enterprises
Request for use of an alternative chemical name [Article 24(1)]	Substance in up to five mixtures	4 000 €	2 800 €	1 600 €	400 €
	Fee per 10 additional mixtures	500 €	350 €	200 €	100 €
Request for a harmonized classification and labeling [Article 37(3)]		12 000 €	8 400 €	4 800 €	1 200 €

No ECHA fees are required for notifications to the C&L inventory in accordance with Article 40.

7. Penalties for non-compliance

CLP requires that Member States introduce penalties for non-compliance and that those penalties must be effective, proportionate and dissuasive (Article 47).

8. Key Considerations for the Implementation of CLP

Identify which products will require reclassification and/or notification

- Develop a detailed inventory of your products (you may already have done this for the purposes of REACH) as a means of assessing which of your products will require reclassification and/or notification.
- Consider the REACH registration deadlines for your substances and the likely amount of information that may be available to you on these substances.
- Do not assume that only those products currently classified as hazardous will require reclassification.
- **Consider products manufactured or imported below the 1 tonne threshold.**

In-house tasks resulting from obligations under CLP

Significant costs and resources are likely to be involved in reclassifying and labelling substances and mixtures:

- Decide who will carry out the reclassification, and what resources may be needed to do this. Consider whether you have sufficient appropriate technical and regulatory staff.
- Train staff in the new requirements.
- If your company uses software tools for classification labeling and packaging, you may need to invest in upgrading these to make sure they fully cover the new requirements. Similarly, any Safety Data Sheet authoring software will need to be updated.
- Awareness of the new labels will be low amongst customers in the early days, and you may have to spend some time educating your sales force and customers on the changes.



- Consider knock-on effects; if any of your products change classification, you may need to change your packaging.

When to start

CLP imposes deadlines for reclassification, of 1 Dec 2010 for substances and 1 June 2015 for mixtures. However, you should not wait until the last minute to make these changes, start now.

If you are a downstream user (formulator) with respect to any substances you will also need to decide whether to wait until the component ingredients in your mixture have been reclassified by your supplier. You may wish to start contacting your suppliers to find out what their plans are, and whether they anticipate any changes in the classification of their products under CLP.

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