ECHA
EUROPEAN CHEMICALS AGENCY

Classification, Labelling and Packaging (CLP) Regulation Handbook

May 2023

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LEGAL NOTICE

This document aims to assist national helpdesks and users with their obligations under the CLP Regulation. However, users are reminded that the text of the CLP Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regards to the use that may be made of the information contained in this document.

Version	Changes	Date
Version 0	First edition	May 2022
Version 1	Addition of two sections: 3.2 Mixture classification and 7- New hazard classes Updated links to the Q&A due to the new tool used. Other minor editorial changes.	May 2023

If you have questions or comments in relation to this document, please send them by using the information request form. The information request form can be accessed via the Contact ECHA page at: http://echa.europa.eu/contact

1. Introduction

The purpose of the Classification, Labelling and Packaging Regulation ((EC) No 1272/2008, known as CLP) is to ensure a high level of protection of human health and the environment, as well as the free movement of substances, mixtures and articles. It is based on the United Nations' Globally Harmonised System (GHS).

Link: Understanding CLP - ECHA (europa.eu)

Legislation : CLP Legislation - ECHA (europa.eu)

2. Scope

CLP requires manufacturers, importers and downstream users of substances or mixtures to classify, label and package their hazardous chemicals appropriately before placing them on the market.

This Regulation sets detailed criteria for the labelling elements: pictograms, signal words and standard statements for hazard, prevention, response, storage, and disposal, for every hazard class, category and differentiation. It also sets general packaging requirements to ensure the safe supply of hazardous substances and mixtures.

The following processes are also part of CLP: requesting of alternative chemical names in mixtures; harmonised classification and labelling; C&L Inventory; submission of information relating to emergency health response.

3. Classification

Classification of a substance or mixture by the manufacturer, importer or downstream user is a core principle in the CLP Regulation. It involves identifying all relevant available information related to the hazards of a substance or mixture and comparing the data with the criteria laid down in CLP.

Classification is the result of the assessment of whether a substance or mixture displays physical, health and/or environmental hazards. These hazards must then be properly communicated in the supply chain with appropriate labelling when the product is placed on the market, regardless of the volume of the substance or mixture.

For the hazards of highest concern (mainly carcinogenicity, mutagenicity, reproductive toxicity (CMR) and respiratory sensitisers) and for other hazard classes on a case-by-case basis, classification and labelling should be harmonised throughout the EU to ensure an adequate risk management. This is done through the harmonised classification and labelling (CLH) process.

Harmonised classifications are listed in Annex VI. They must be applied by all manufacturers, importers and downstream users of such substances and of mixtures containing them.

A CLH can be proposed for both substances without a current entry in Annex VI to CLP, and for those with an existing harmonised classification. In the second case, they need to be changed either due to availability of new information, new scientific or technical developments, changes in the classification criteria or based on the re-evaluation of existing data.

A Member State competent authority (MSCA), or a manufacturer, importer and downstream user of a substance can submit a CLH proposal to ECHA in the following three situations:

- Where a substance is CMR or a respiratory sensitiser.
- When it is justified that a classification for a substance at EU level is needed for other hazard classes.
- To add one or more new hazard classes to an existing entry (under the conditions above).

Only MSCAs may propose:

- A revision of an existing harmonised entry, for any substance that is under the scope of the CLP Regulation. However, industry can prepare a proposal and submit it to a MSCA for their consideration.
- When a substance is an active substance in biocidal or plant protection products.

Links: Classification of substances and mixtures - ECHA (europa.eu)

Introductory Guidance on the CLP Regulation (PDF document)

ECHA Guidance on the application of CLP criteria (PDF document)

Harmonised classification and labelling (CLH)

Guidance on the preparation of dossiers for harmonised classification and labelling (PDF document)

Guidance for identification and naming of substances under REACH and CLP (PDF document)

3.1. C&L Inventory

This database contains classification and labelling information on registered substances and substances notified by manufacturers and importers. It also includes the list of harmonised classifications and the names of those substances translated in all EU languages.

Links: C&L Inventory - ECHA (europa.eu)

Who has to submit and what can be submitted in a notification?

Submitting and updating your notification

Classification of substances and mixtures

Fact sheet on the public inventory

3.2. Mixture classification

Importers and formulators of mixtures within the EU are responsible for the classification, labelling and packaging of the mixture they place on the market. They need to be aware of the hazards of the mixtures imported or formulated and they need to communicate them in their supply chain. Distributors of mixtures also have obligations under CLP: to make sure that the label and the packaging is in accordance with CLP.

Links: Mixture classification - ECHA (europa.eu)

Introductory Guidance on the CLP Regulation

ECHA Guidance on the application of CLP criteria (PDF document)

4. Labelling and Packaging

Manufacturers, importers, downstream users and distributors, as well as producers and importers of certain specific articles, must communicate the identified hazards down the supply chain, including to consumers, with the means of a CLP-compliant label.

Links: Labelling and packaging - ECHA (europa.eu)

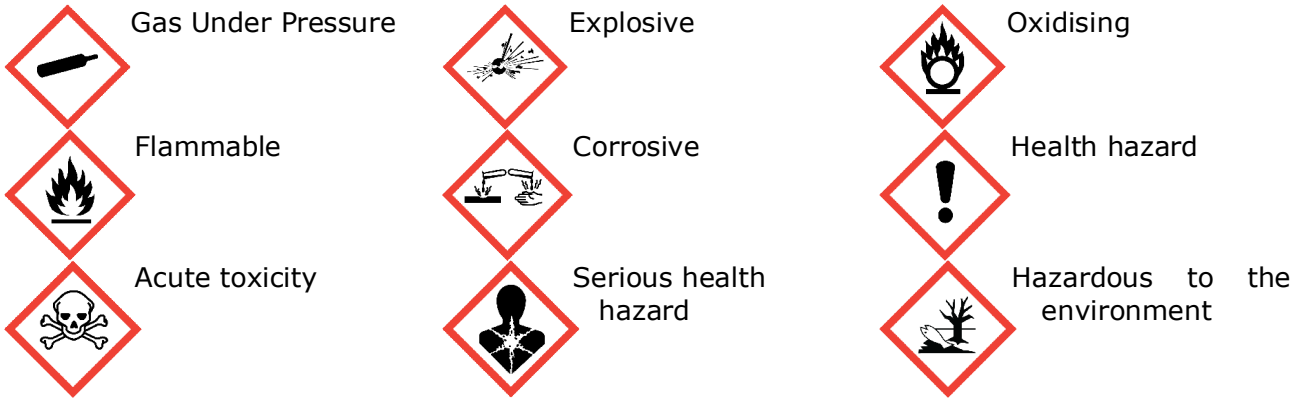
Specific labelling and packaging situations

https://echa.europa.eu/documents/10162/2324906/clp_labelling_en.pdf/

Languages required for labels and safety data sheets

4.1. CLP Pictograms

A hazard pictogram is in the shape of a square set at a point image that includes a warning symbol with a red border. It intends to provide information about the damage a particular substance or mixture can cause to human health or the environment.



Links: CLP Pictograms - ECHA (europa.eu)

CLP quiz - ECHA (europa.eu)

What does the label contain - ECHA (europa.eu)

4.2. Alternative chemical name in mixtures

Manufacturers, importers and downstream users based in the EU who are concerned about disclosing the exact composition of a mixture, on the label or in the safety data sheet, can request the **use of an alternative chemical name** for a substance in the mixture. This way they can protect the confidential nature of their business, and in particular, their intellectual property rights.

Links: Alternative chemical name in mixtures - ECHA (europa.eu)

How to request an alternative chemical name in mixtures

How to request for a review of a decision on the use of an alternative chemical name

5. Testing in CLP

For classification and labelling purposes, manufacturers, importers and downstream users of a substance or mixture are required to gather and assess any existing available information related to the hazardous properties of a substance or mixture.

If no data are available, physico-chemical, ecotoxicological and toxicological tests should be performed, complying with the requirements under the REACH Regulation, the OECD principles of good laboratory practice (GLP) and any internationally recognised methods validated according to international procedures to ensure that the data are of high quality and reliable.

Tests on animals are allowed only where no other alternatives, which provide adequate reliability and quality of data, are possible. If animal tests are performed, they must comply with the requirements for the protection of laboratory animals (Directive 2010/63/EU).

Links: The role of testing in CLP - ECHA (europa.eu)

Alternatives to animal testing under REACH - ECHA (europa.eu)

Testing methods and alternatives

6. Emergency response (Poison Centres)

According to Article 45 of the CLP Regulation, companies placing hazardous mixtures on the EU market are obliged to provide information about certain hazardous mixtures to the national appointed bodies. The national bodies make this information available to poison centres so that they can give advice to the citizens or medical personnel in the event of an emergency. Annex VIII to the CLP Regulation, adopted in March 2017, defines the harmonised requirements for the 'poison centre notifications' (PCN), applicable as of 1 January 2021.

Please also refer to the Poison centre notifications Handbook for further support.

Links: Poison Centres

Steps for industry

Tools

Support

7. New hazard classes

The European Commission published the Delegated Regulation 2023/707 amending the CLP Regulation, which sets out new hazard classes and criteria for the classification, labelling and packaging of substances and mixtures.

It applies to all chemical substances and mixtures placed on the EU market. It also applies to active substances in biocidal products and plant protection products, which are normally prioritised for harmonised classification in the EU.

The new hazard classes are:

- ED HH in Category 1 and Category 2 (Endocrine disruption for human health)
- ED ENV in Category 1 and Category 2 (Endocrine disruption for the environment)
- PBT (persistent, bioaccumulative, toxic), vPvB (very persistent, very bioaccumulative)
- PMT (persistent, mobile, toxic), vPvM (very persistent, very mobile)

The entry into force was 20 April, establishing the following compliances dates:

- 1 May 2025 for substances, with a transitional period until 1 November 2026. During this period, substance already placed on the market do not need to be classified according to the new hazard classes.
- 1 May 2026 for mixtures, with a transitional period until 1 May 2028. During this period, mixtures already placed on the market do not need to be classified according to the new hazard classes.

Links: New hazard classes 2023 - ECHA (europa.eu)

What new elements does the Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 add to the CLP Regulation?

What are the obligations for companies following the entry into force of the Commission Delegated Regulation (EU) 2023/707 of 19 December 2022?

Delegated Regulation 2023/707 amending CLP Regulation (EC) No 1272/2008

8. Legislation

The CLP legal text is regularly amended by the Adaptations to Technical Progress (ATP). They are included in the consolidated version of the legal text. Along with the dedicated webpage of ECHA, another source of information is the European Commission. They host a web page about chemical legislation covering CLP. That section includes the different ATPs and other related legislation.

Links: CLP Legislation - ECHA (europa.eu)

Chemicals legislation (europa.eu)

9. Q&As

In this Section you will find all the Q&As sections on CLP available on the ECHA website:

Link: All CLP Q&As

- Understanding CLP
- Scope and exemptions under CLP
- Classification
- Labelling
- Hazard communication with means other than labelling
- Industry roles under CLP
- Public Classification and Labelling Inventory
- Technical questions and answers on C and L notifications

Submitting a C&L notification

C&L notification updates

Reference numbers for C&L notification

Group of manufacturers-importers in REACH-IT

Bulk C&L migration

- Request for use of an alternative chemical name
- Poison Centres
- Notification-Classification and Labelling Inventory
- Annex VI to CLP