

GHS - the new system for the classification and labeling of chemicals in the EU

Introduction of the Globally Harmonized System (GHS) for Classification and Labeling of Chemicals and their mixtures in the European Union

NEW GHS REGULATION

On January 20, 2009 the regulation (EC) no. 1272/2008, called the GHS or CLP Regulation, entered into force.

It regulates the classification, labeling and packaging of substances and mixtures (CLP: Regulation on Classification, Labeling and Packaging of substances and mixtures) and as of 2015 will completely replace the European Dangerous Substances Directive 67/548/EEC as well as the Dangerous Preparations Directive 1999/45/EC.

The CLP Regulation is based on the recommendation of the UN, the so-called 'Globally Harmonized System' (UNGHS, or "purple book"), that can be traced back to the sustainability conference in Rio de Janeiro in 1992 (Agenda 21, Chapter 19).

Implementation deadlines		
Label	Old labeling	New labeling
Substances	Permitted until 1.12.2010. (Stocks: + 2 years)	Permitted as of 20.1.2009 mandatory as of 1.12.2010
Mixtures	Permitted until 1.6.2015. (Stocks: + 2 years)	Permitted as of 20.1.2009 mandatory as of 1.6.2015
Safety data sheet	Old classification	New classification
Substances	Mandatory until 1.6.2015	Permitted as of 20.1.2009 mandatory as of 1.12.2010
Mixtures	Mandatory until 1.6.2015	Permitted as of 20.1.2009 mandatory as of 1.6.2015

WHAT WILL CHANGE?

Labeling must take place in accordance with the CLP as of December 1, 2010 for substances and as of June 1, 2015 for mixtures, however this labeling is already allowed as of now.

Regardless of which labeling law is selected within the transition periods, only one form of labeling is allowed on the label - either in accordance with the old law or the new one. The old classification in accordance with directives 67/548/EEC and 1999/45/EC must still be provided in the safety data sheet until June 1, 2015.

The long transition period for the labeling systems (2009 - 2015) is intended to ensure that all of the relevant parties - public authorities, companies and stakeholders - are able to concentrate their resources on the new obligations in a timely manner.

The new European CLP Regulation is based on the previous system of classification and labeling as it represents a compromise between the established systems in North America and the EU.

The most noticeable feature is the change in the labeling symbols: instead of the hazard symbols with black printing on orange-yellow rectangles that have been used to date, now nine hazard pictograms with black symbols on a white background with red-rimmed rhombuses are used to provide warnings (Annex V, CLP Regulation). While most of the nine hazard pictograms correspond to the well-known hazard symbols, the pictograms GHS 04, GHS 07 and GHS 08 are completely new. The St. Andrew's cross (Xn/Xi) that has been used to date no longer exists.

GHS01 Exploding bombs 	GHS02 Flame 	GHS03 Flame over circle
GHS04 Gas cylinder 	GHS05 Corrosion 	GHS06 Skull and crossbones
GHS07 Exclamation mark 	GHS08 Health hazard 	GHS09 Environment

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The previous "nomenclature for hazards" (e.g. toxic, harmful to health), that were assigned to the hazard symbols have now been replaced by the two "signal words" ›Danger‹ or ›Warning‹. R and S sentences have been replaced by H and P statements (hazard and precautionary statements).

CONSEQUENCES FOR SUBSTANCES

Instead of being assigned to one of 15 ›hazardous properties‹ (also called hazard categories) as in the past, substances are now categorized into ›hazard classes‹ and ›hazard categories‹ (Annex I, Part 2-4 of the CLP Regulation). With the new regulation there are now 16 classes for physical dangers, 10 for health hazards and two classes for environmental dangers that apply in the EU. While the danger classes indicate the type of danger, the danger categories are used for indicating levels within the classes.

Physical dangers

Examples for new PC danger classes are ›gases under pressure‹, ›self-reactive substances‹ and ›self-heating substances‹. In the case of explosive characteristics that were previously determined using the intrinsic properties of the substance (thermal and mechanical sensitivity), the classification scheme that was originally developed for the transportation of dangerous goods - which is also based on the testing of packaged substances - has now been adopted.

Health hazards

Instead of the nine old hazardous properties, in accordance with the CLP regulation the health hazards are subdivided into 10 hazard classes: for the ›acute toxicity‹, ›skin or respiratory tract sensitization‹, ›reproductive toxicity‹ and ›specific target organ toxicity - single exposure‹ hazard classes, various routes of exposure or modes of action are differentiated (e.g. acute / chronic).

A further significant change is that substances which are acutely toxic are now labeled with a skull and crossbones if the LD50 (the dosage of a substance that proves fatal for 50% of the laboratory animals when consumed) lies between 200 - 300 mg/kg (oral) or 400 - 1000 mg/kg (dermal), and are still labeled with the St. Andrew's cross (Xn) in accordance with previous EU criteria. The classification of gases is also changing due to the GHS criteria.

Environmental hazards

The CLP Regulation intends the ›hazardous to aquatic environment‹ class to be used mainly for environmental dangers, which are divided into acute and chronic hazards to the aquatic environment. Furthermore, the CLP Regulation contains a second danger class, ›hazardous to the ozone layer‹, which does not however have its own pictogram.

CONSEQUENCES FOR MIXTURES

The rules have changed for the classification of mixtures (previously preparations) in particular: there is a greater freedom of evaluation than before. An expert evaluation is granted more freedom to deviate from the standard criteria. In addition, as a ›supplier‹ (previously: ›distributor‹), it will become possible for a company to determine specific concentration limits for many hazard classes itself. The European Commission plans to have guidelines created for this.

In particular, the classification of mixtures with regard to the level of irritation they can cause has been tightened. The concentration limits used to classify mixtures have been lowered by a factor of 3-5 such that now the "exclamation mark" or "corrosion" hazard pictograms will be attached to considerably more mixtures.

LISTS OF SUBSTANCES FOR CLASSIFICATION AND LABELING

The regulations for the ›classification and labeling inventory‹ have been moved from the Chemical Regulation 1907/2006 (Reach, Art. 112 - 116) to the CLP Regulation (Art. 39 - 42). Annex I of the Dangerous Substances Directive 67/548/EEC has been deleted and transferred to the CLP Regulation (Attachment VI, Part 3, Table 3.2) - including a translation into the new system (Table 3.1).

Furthermore, as a rule only those substances and inhalation allergens which are carcinogenic, mutagenic and teratogenic will have a legally binding classification and labeling. The classification of all additional chemicals available on the market should be carried out by December 1, 2010 by the respective ›supplier‹ itself, and the European Chemicals Agency (ECHA) should be notified. All classifications will then be published on the internet.

HOW DO WE PREPARE OURSELVES FOR THE NEW SYSTEM?

This flyer is a good first step. A guide to the GHS provides further insight: in the fall of 2007 the German Federal Environmental Agency (at the time still using the draft CLP as a basis) published the GHS, which is intended to provide the manufacturers and formulators with a basic understanding of the new regulation (see below for web link).

For further information consult the website of your local Competent Authority, for example in the UK, the HSE - <http://www.hse.gov.uk/ghs/eureg.htm>