# Health Hazards Classification and Labeling

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**Abstract**

The European Union CLP Regulation (EC No 1272/2008) brings the UN Globally Harmonized System of Classification and Labelling of Chemicals (UN-GHS) into force in the European Union. The structure of the CLP hazard classification and the rules for labelling hazardous substances and mixtures are described. The structure and uses of Safety Data Sheets (emergencies/safe use scenarios) are described.

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## European Chemicals Legislation

Several regulations of the European Union (EU) aim to ensure a high level of protection of human health from the risks that can be posed by chemicals on the EU market.

Due to the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation (EC No 1907/2006, European Parliament and Council 2006), industry is responsible for assessing and managing the risks and to gather all relevant substance information for registration at the European Chemicals Agency (ECHA). The *REACH Regulation* (see chapter "▶ Reach (and CLP). Its Role in Regulatory Toxicology") also incorporates updated requirements for the Safety Data Sheet, an important document informing professionals on safe use of a substance or mixture ("product").

Classification and labelling of hazardous substances and mixtures is important in communicating the potential hazards and providing the basis to describe and plan for safe use. Furthermore, classification supports the poisoning risk assessment if persons have been exposed in an unsafe way. To harmonize hazard classification criteria and communication elements worldwide, the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (UN-GHS) was developed. The *CLP Regulation* on Classification, Labelling and Packaging of substances and mixtures (EC No 1272/2008, European Parliament and Council 2008) implements UN-GHS (UNCED 1992) in the EU. The CLP Regulation has entered into force on 20 January 2009 and has replaced the existing rules on classification, labelling, and packaging of substances since 1 December 2010 and will replace those for mixtures from 1 June 2015.

## Health Hazard Classification and Labelling

The framework of the CLP health hazard classification (CLP, Annex I, Part 3) is mainly based on health hazard classes, describing the quality of action of the hazard in focus (e.g., "acute toxicity," "specific target organ toxicity"). The quantity measure (strength or potency) of a hazard quality is described using numeric hazard categories, where higher category numbers (1 to a maximum of 4,) indicate lower toxicity. For some classes, category 1 is subdivided into 1A, 1B, and 1C. An overview of CLP health hazard classes and categories is presented in Table 1.

Each hazard category is linked to four groups of specific hazard communication elements: *signal words*, *hazard pictograms*, *hazard statements*, and *precautionary statements*.

The signal word "Danger" is associated with categories of higher hazard and "Warning" with those of lower hazard.

Four health hazard pictograms are used in the hazard communication (see Fig. 1). Carried over from the preceding legislation (with some graphical amendments) are the "skull and crossbones" pictogram and the "corrosion" pictogram. The "health hazard" pictogram and "exclamation mark" pictogram have no preceding equivalent.

**Table 1** CLP health hazard classes

| CLP Annex I chapter | CLP health hazard class | Differentiation |
|---|---|---|
| 3.1 | Acute toxicity | Oral, dermal, inhalation |
| 3.2 | Skin corrosion/ irritation | |
| 3.3 | Serious eye damage/eye irritation | |
| 3.4 | Respiratory or skin sensitization | Respiratory, skin |
| 3.5 | Germ cell mutagenicity | |
| 3.6 | Carcinogenicity | |
| 3.7 | Reproductive toxicity | Sexual function and fertility, development of the offspring |
| 3.8 | Specific target organ toxicity – single exposure | |
| 3.9 | Specific target organ toxicity – repeated exposure | |
| 3.10 | Aspiration hazard | |

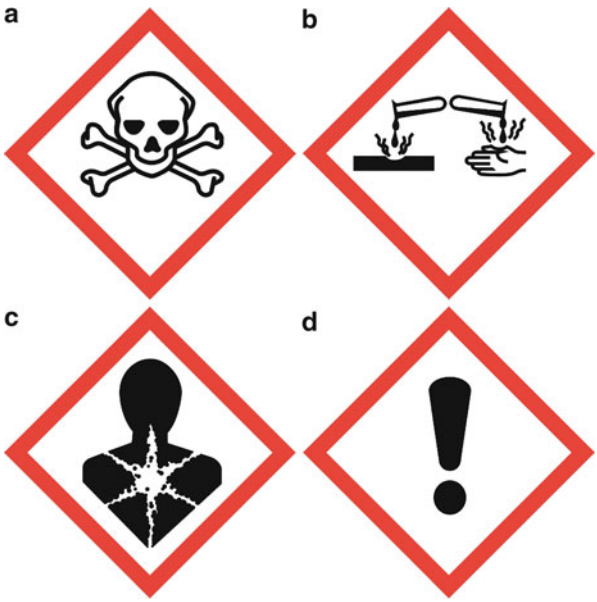


**Fig. 1** Pictograms for health hazards according to the CLP Regulation (EC) No 1272/2008. (**a**) skull and crossbones, (**b**) corrosion, (**c**) health hazard, (**d**) exclamation mark (From UNECE 2012, with permission)

An overview of the fixed connection of health hazard classes and categories with signal words and hazard pictograms is presented in Fig. 2.

Hazard (H)-statements are used to describe the character of the hazard often in combination with the route of exposure (see Table 2 for some examples). Precautionary (P)-statements advise about the correct handling of chemical substances and mixtures. A complete list of hazard and precautionary statements (with translations in all EU languages) is included, respectively, as Annex III and Annex IV to the CLP Regulation.

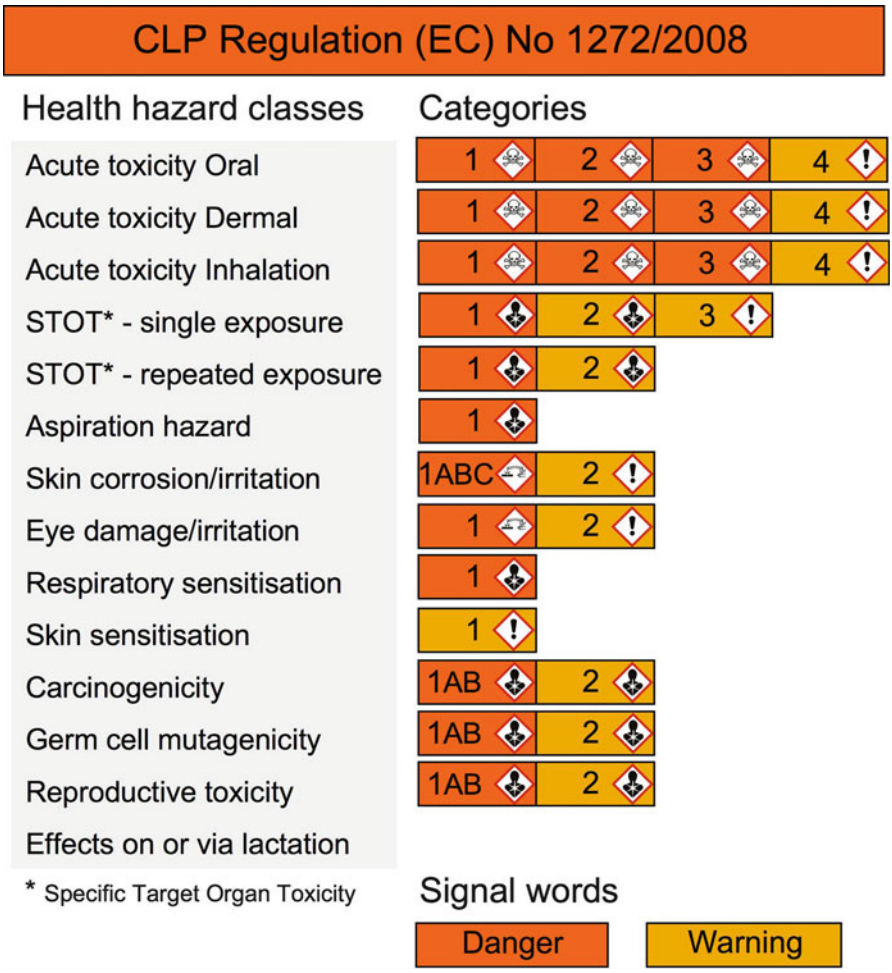


**Fig. 2** Health hazard classification of substances and mixtures according to the CLP Regulation (EC) No 1272/2008 with corresponding signal words and hazard pictograms (Adapted from Clinical Toxicology (2010) 48, 28–33)

Classification and labelling information on substances is made available online in the Classification & Labelling Inventory (maintained by ECHA). This database includes all substances with a harmonized (and legally binding) hazard classification as listed in Annex VI of the CLP Regulation and substances registered under REACH for which the manufacturer or importer is responsible for correct classification and labelling.

For mixtures, data indicating their (toxic) hazard profile are only rarely available. If there are no data on a mixture to be classified, then procedures listed in Annex I of the CLP Regulation can be used to calculate or evaluate its hazard

**Table 2** Hazard statements for acute toxicity (selected examples for oral and dermal exposure)

| Category of acute toxicity | Route | Hazard statement code | Hazard statement |
|---|---|---|---|
| 1 | Oral | H300 | Fatal if swallowed |
| 2 | Oral | H300 | Fatal if swallowed |
| 3 | Oral | H301 | Toxic if swallowed |
| 4 | Oral | H302 | Harmful of swallowed |
| 1 | Dermal | H310 | Fatal in contact with skin |
| 2 | Dermal | H310 | Fatal in contact with skin |
| 3 | Dermal | H311 | Toxic in contact with skin |
| 4 | Dermal | H312 | Harmful in contact with skin |

**Table 3** Structure of Safety Data Sheet according to REACH

| Section number | Content |
|---|---|
| 1 | Company name and address and emergency telephone number |
| 2 | Description of the hazards of the substance or mixture and the appropriate warning information associated with those hazards |
| 3 | Composition/information on ingredients. Listing all ingredients classified as hazardous (above specified concentration thresholds) and their concentration (either exact or ranges) |
| 4 | First aid measures by relevant routes of exposure |
| 11 | A description of the various toxicological (health) effects and the available data used to identify those effects, including where appropriate information on toxicokinetics, metabolism, and distribution |

(*these bridging principles are described in chapter* "► *Bridging. The Regulation of Toxic Mixtures*" *of this monograph*). The most important tools are calculation methods that allow deduction of the mixture classification from classification of its ingredients.

## Safety Data Sheet

For a more detailed risk assessment, especially in emergency situations and for development of scenarios for safe use of hazardous substances and mixtures at the workplace, the communication elements on the label are not sufficient. Additional information is provided in the *Safety Data Sheet* (SDS). The SDS has a fixed structure with 16 sections. The content of the sections with important use for toxicology are listed in Table 3.

The toxicological information in section 11 shall apply to the substance or mixture as placed on the market. If available, the relevant toxicological properties of the hazardous substances in a mixture shall also be provided. For every relevant health hazard class (for mixtures for every "relevant effect" until from 1 June 2015, the new hazard classification applies), toxicological information should be included, and if available, human data should be provided.

For substances, section 11 of the SDS will include (a summary consistent with) the toxicological information which is supplied for the registration of the substance according to the REACH Regulation.

For some substances, a Chemical Safety Report (CSR) is compiled for the REACH registration which includes *exposure scenarios* giving a.o. information on how the mixture will be used by professional users or consumers (e.g., duration and frequency) and risk management measures to reduce or avoid direct and indirect exposure. These exposure scenarios will be made available as an Annex to the SDS.

## Poisons Centers Perspective

Consumers are informed about the hazards and safe use of a product by communication elements on the product label, professional users have access to additional information on the SDS, but in case of incidents (unsafe exposures), the SDS is only a starting point and more detailed information is necessary for medical management in many cases.

When exposure cases are treated in the medical system, most often in a hospital, *poisons centers* can be consulted for toxicological support. Poisons centers often have to deal with unusual exposures, e.g., intake of large doses, untypical exposure pathways (intravenous application, ingestion), or special patient groups (e.g., pregnant, child, immunosuppressed patients, or patients with reduced mental capacity).

Although the improved toxicological information on the SDS will be helpful, an important shortcoming of the SDS for poisons centers practice is that only substances that are classified as hazardous have to be mentioned and only above specified threshold concentrations. Furthermore, as guidelines on the notification of the concentration of ingredients are not available in practice, wide concentration ranges are often used. To perform a risk assessment in individual poisoning cases, poisons centers need and have access to a detailed product composition of all hazardous products.

Notification of product information for poisons centers is described in chapter "► Notification of Cosmetic Products and Dangerous Mixtures in Regulatory Toxicology."

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