

Child-resistant Packaging

The European Union (EU) is adapting its system for the classification of chemical substances and mixtures to the Globally Harmonised System (GHS) of the United Nations (UN).

This international system mandates uniform labeling of chemicals on the basis of their risk characteristics and the use of child-resistant packaging. What then needs to be kept in mind due to the recent changes? If hazardous substances and mixtures pose a health risk for infants in case of misuse, they may only be placed on the market in child-resistant packaging. The packaging needs to comply with standards ISO 8317 or EN 862 for child-resistant packaging. Market participants prove compliance with the standards by means of the appropriate certificates.



I CLP Regulation

Through child-resistant packaging infants can be protected against access to dangerous substances and mixtures. In this way they are protected against serious accidents, which represent the greatest threat to their life and health. Such dangers lurk daily for children. There are not only trendy colorful washing and cleaning products, which are reminiscent of juices or energy drinks, but also paints and varnishes. All of which attract attention through their bright colours. All of these substances and mixtures need to be identified according to their toxicity and placed in child-resistant packaging. Similar guidelines can be found in the EC Directives 67/548/EEC (Dangerous Substances Directive) and 1999/45/EC (Dangerous Preparations Directive). Both form the basis of the currently valid classification and labeling system. On the 1st June 2015 it is set that they are to be withdrawn. Then, the European Parliament's and the Council's regulation of 16 December 2008 (EC) No 1272/2008 on

classification, labeling and packaging of substances and mixtures will come into force. This regulation, also known as CLP regulation (Regulation of Classification, Labelling and Packaging of Substances and Mixtures) it is intended to ensure a higher level of protection for human health and the environment as well as the free movement of chemical substances, mixtures and certain specific articles while enhancing competitiveness and innovation. It will therefore replace directives 67/548/EEC (Dangerous Substances Directive) and 1999/45/EC (Dangerous Preparations Directive) and change Regulation (EC) No 1907/200.

I Globally Harmonised System

In 1992, the United Nations Conference on Environment and Development (UNCED) already had the goal to make of the level of protection for human health and the environment more consistent, transparent and comparable.

However, the Globally Harmonised System of Classification and Labeling of Chemicals (GHS), was first presented by the UN Commission in 2003 and has been appearing in an updated version every two years ever since.

With the adoption of the CLP Regulation, the EU has joined this new system. The regulation is directly valid in all EU Member States and came into force on the 20th of January 2009. Since then, the classification, labeling and packaging of substances and preparations can be executed, without exceptions, in compliance with the provisions of the CLP or GHS Regulations. The provisions of the Dangerous Substances Directive and the Dangerous Preparations Directive are no longer in force with regards to substances. However for mixtures the classification, labeling and packaging is still applicable in line with the Directive 199/45/EC until 01 June 2015.

I Definitions of substances and mixtures?

The following definitions for substances and mixtures apply:

Substance: "chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and impurities due to the process used, but excluding any solvent which can be removed without affecting the stability and changing its composition.

Mixture: "mixtures or solvent composed of two or more substances. The term "mixture" as defined in this regulation shall have the same meaning as the term "preparation", which previously used in Community legislation."

I What applies under the CLP Regulation for child-resistant packaging?

Hazardous substances and mixtures, which children come into contact with in everyday life, such as cleaning and washing products, may contain many different ingredients such as acids, alkalis, chlorine compounds and/or surfactants. Direct contact with these often provokes irritating or even corrosive injuries. Ingestion may cause nausea, vomiting or diarrhea and in the worst case can cause lung damage and suffocation. The CLP Regulation which came into force 20 January 2009 mandates the use of child-resistant packaging in these instances. According to the CLP, dangerous substances and mixtures which give rise to different health hazards need to be placed in child-resistant packaging and are to be fitted with child-resistant fastenings.



Please see below the following extracts:

- packaging containing a substance or mixture that is supplied to the general public and classified for acute toxicity, specific target organ toxic or corrosive to the skin, are to be equipped with child-resistant closures, regardless of capacity.
- packaging that contains a substance or mixture which is supplied to the general public and represents an aspiration hazard is to be equipped with child-resistant closures, regardless of capacity.
- Contains a substance or mixture of at least one of the following substances in a concentration that is at least as high as that specified for the substance in the individual concentration limits, and is supplied to the general public, the packaging of whatever capacity shall be equipped with child-resistant closures. The CLP regulation also mandates hazard communication for specific labeling elements,

No.	CAS-No.	Substance	EC-Nr.	Concentration Limit
1	67-56-1	Methanol	200-659-6	≥ 3 %
2	75-09-2	Dichloromethane	200-838-9	≥ 1 %

such as hazard pictograms. These have diamond-shaped back with a red border, a white background and black symbols on the physical, health and environmental hazards.

Examples of which can be seen in the table below.

	Fatal poisoning	Even small amounts of lead to serious or even fatal poisoning
	Serious health risk, possibly leading to death in children	Risk of pregnancy, carcinogenic and / or similarly serious health risks.
	Corrosive	Destruction of skin or eyes
	Health hazard (less severe)	Skin irritation or sensitisation with subsequent triggering of an allergy.
	Easily flammable	Health hazard due to easy flammability near heat or flame.

Continued

Child-resistant packaging: Continued



Which standards and regulations are valid under the CLP regulation?

To classify as a child-resistant package, the package must meet the standards required by the CLP standards and guidelines, for reclosable and non-reclosable packaging

- For reclosable packaging, child-resistant closures have to comply with the current edition of EN ISO 8317. Requirements and testing procedures for reclosable packages of the European Committee for Standardisation (CEN) and the International Standards Organisation (ISO) are the same.
- For non-reclosable packaging child-resistant closures have to comply with the current edition of EN 862. This is the standard for the requirements and

testing procedures for non-reclosable packages for non-pharmaceutical products as per the European Committee for Standardisation (CEN).

What do the cited standards and regulations say? How is legal certainty ensured in the event of an accident? How can the proper functioning of the packaging be ensured, for example, that it can only be opened by pressing and turning simultaneously? Furthermore, how is it ensured that small children cannot open it, yet easy opening for seniors remains?

Only an examination in compliance with the CLP Regulation, as specified in the standards, ensures legal certainty and protection in the event of an accident. The EN ISO 8317 (2004) is an international standard with requirements and test methods for reclosable packaging. The EN 862, was issued in 2006, for non-reclosable packaging.

Standards EN ISO 8317 and EN 862 are internationally accepted test methods. They describe test methods by which a group of up to 200 toddlers aged 42-51 months receive up to 10 minutes to open the packaging to be tested. In addition, participants from a group of 100 seniors in an age group from 50 to 70 years have to be able to open the packaging with ease, within in one minute, and to seal/close it properly again if necessary. Testing and certification is carried out by accredited institutions who comply with EN 45011 for certification authorities (e.g. www.ivm-childsafe.com).

How can an accurate overall solution be achieved?

It must be ensured that a child-resistant packaging has the required compliance with the standards. Therefore for precise solutions to be achieved all the important factors must come together.

For the development and selection of packaging solutions, companies need a competent partner, an accredited institution compliant with EN 45011 (www.ivm-childsafe.com). This ensures that existing requirements are met and the goal of child resistant packaging is reached without complications. Only in this way, the result will be a harmonious overall picture with an appropriate protection for the companies bearing the responsibility to ensure child-resistance of their packaging solutions.



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