

Dossier: What is a child-resistant packaging, when should it be used and how is it tested?

What is a child-resistant closure or package?

Child-resistant packagings can be divided into two categories, as also stipulated in the European CLP regulation 1272/2008, namely reclosable and non-reclosable child-resistant packaging. Those are subject to requirements and test methods which are imposed in standards by the European Committee for Standardisation (CEN) and the International Organization for Standardization (ISO).



The child-proof fastenings can be classified also according to their types:

- The closure is incomprehensible for children, because two movements are needed at the same time (example: push-turn caps)
- The closure is unreachable for children, for example because too large for children's hand.
- The closure has to be opened with a force too large for the children.



When does a packaging have to be fitted with a child-resistant fastenings?

CLP Regulation 1272/2008 specifies special rules for packaging of substances and mixtures supplied to the general public. In certain cases those packagings have to be foreseen, in function of their classification of child-resistant fastenings, whatever their capacity. A packaging containing a substance or mixture classified for acute toxicity, categories 1 to 3, STOT — single exposure category 1, STOT — repeated exposure category 1, or skin corrosion category 1 shall be fitted with a child-resistant fastenings.

This is also the case when the substance or mixture presents an aspiration hazard and is classified according to sections 3.10.2 and 3.10.3 of Annex I and labelled according to section 3.10.4.1 of Annex I, with the exception of substances and mixtures placed on the market in the form of aerosols or in a container fitted with a sealed spray attachment.

When a substance or mixture has methanol or dichloromethane present in a concentration equal to or greater than the maximum individual concentrations specified, which are supplied to the general public, the packagings of whatever capacity shall be fitted with child-resistant fastenings.

Requirements for child-resistant packaging.

As reported in the CLP regulation, child-resistant fastenings must meet specific standards, depending on their type (reclosable or non-reclosable). Different standards are available to the industry. On basis of these standards, packers and/or fillers can get their child-resistant packaging tested before they are made available to the public.

- **ISO 8317** – This is the international standard for **reclosable child-resistant packaging**. This standard is applicable for pharmaceutical, technical or chemical products. For the certification of a child-resistant packaging these packaging's have to pass two test procedures. First a test with 200 children, age between 42 to 51 months. The children have to try to open the packaging, which is filled with a harmless product (e.g. water). The goal is that they will not succeed. This test is split into two parts and in totality lasts 10 minutes. Regarding the children test a sequential test is allowed. For the second test procedure there are 100 adults needed, age between 50 and 70 years. They should be able to open and reclose the packaging problem-free. A packaging is considered as child-safe when less than 10% of the children succeeded in opening the package within the first 5 minutes test and when less than 20% of the children succeeded in opening the package during the whole duration of 10 minutes. For the adults, there is at least 90% of adults expected to open and close the package correctly.
- **EN 862** – is a European standard for **non-reclosable child-resistant packaging for non-pharmaceutical products**. There are different types of non-reclosable child-resistant packaging such as the packages whose contents is used in one application (one dose, one unit), sealed bags, flow packs and packaging that are made of single-use merged packs. (e.g. blister pack). As in the ISO standard 8317 it is also necessary to prove that a certain percentage of children, age between 42 and 51 months cannot open the packaging. Testing with adults between 50 and 70 years is optional.
- **EN 14375** – is a European standard for **non-reclosable child-resistant packaging for pharmaceutical products**. This standard is applicable for blister packs and for stick packs (these are elongated, tubular bags that are sealed at both ends and longitudinally) or granular pouches/pockets. As in the ISO standard 8317 it is also necessary to prove that a certain percentage of children, age between 42 and 51 months cannot open the packaging and that a certain percentage of adults between 50 and 70 years can open the packaging properly.
- **ISO 13127** – this international standard defines **mechanical test methods for reclosable child-resistant packaging**. This standard does not replace the ISO 8317 standard, but is an extension of it. This test method allows the lab in first instance to compare mechanically minor changes on an original tested packaging (with children and adults = panel test), to compare if they can still be considered as equivalent. There is a tolerance of 5% allowed on the measurement results. If it appears that the opening force is lower, tests must be repeated with children. If the opening force is higher, tests must be repeated with the adults.



This standard allows a reduction of the complete panel testing procedures, which reduces the cost and this with the only purpose of having more child-resistant packaging on the market.

The American continent has its own protocol on child-resistant packaging's.

- **US 16 CFR & 1700.20** is the protocol that should be followed when you want to put child-resistant packagings on the US market. The test procedure with children is slightly larger in comparison with the ISO 8317 but remains the same for the adults test.

Only laboratories which are conform to the norm EN ISO/IEC 17025 shall be competent to verify if there is any compliance with the above standards. The Belgian packaging Institute is accredited by BELAC, accreditation number 282-TEST, according to the latest standard and is therefore a reliable partner for the execution and delivery of test certificates according to all the above mentioned standards.

Currently, more and more verifications are done by the Government on packaging that are made available to the public to see if on the one hand, all the products requiring a child-resistant packaging, this according to the CLP regulation, are provide under this condition. On the other hand, that packaging equipped with child-resistant fastenings and/or mentioning child resistant have the necessary test certificates. It is important to note that the entire packaging-combination bottle/closure – should be tested. It is not enough to have a closure with a child-safe mechanism on a vial in order to have the guarantee that it is a child-resistant packaging.

By the selection of a combination to be tested, different materials, neck orientations and screw threads are taken into consideration. These factors can affect the child-resistant features. With a family composition (same packaging in different volumes), where essential characteristics are identical in terms of material, form, thread and closure, the smallest and the largest volume will undergo the full panel test. All between volumes are than part of the same range.

A packaging can be brought on the market as child safe once the combination container-closure have passed a full panel test and the positive results are described in a report with its certificate.



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