

# The opening act

Leading flexible packaging material supplier **Constantia Flexibles** offers insights into the current child-resistant/senior-friendly regulations, and asks how packaging can strike a balance between safety and accessibility.

**I**n recent years, increasing numbers of medicines have been protected with child-resistant (CR) packaging. These measures often conflict with packaging that is simple for seniors to open. Consequently, seniors sometimes need other people to empty the tablets from the blister pack into a bowl, as they cannot open the packaging themselves.

Rising life expectancy means the present generation of over-60-year-olds will be the biggest population group in the next 30 years. Purchase behaviour will change because these keen shoppers like easy-to-use products – particularly when it comes to medicines.

A medicine must be placed in child-resistant packaging if accidental consumption by children is harmful to health. The standard DIN 14375 applies within the EU for non-reclosable tablet blister packs for child-resistance and for senior-friendliness (SF).

## Put to the test

The child-resistance trial uses a test group of 200 children aged 42–51 months. Packaging is considered child-resistant if:

- at least 85% of children are unable to gain access to more than eight dose units within five minutes, without having first seen a demonstration of how to open the packaging
- at least 80% of children are unable to gain access to more than eight dose units within ten minutes, following a demonstration of how to open the packaging.

If a maximum of eight dose units were opened, this is termed child-resistance stage F8. A maximum of one opening is termed F1. The targeted level of child-resistance is based on the dosage and toxicity of the medicine.

The senior-friendliness test is performed in a group of 100 participants aged between 50 and 70 years. The test is considered failed if 90% of participants do not gain access to at least one tablet within one minute without a demonstration.

US standards – such as CPSC (CFR) title 16 part 1700 – are slightly different from the EU standard. British Standard BS 8404 is similar to the old DIN 55559, which is now incorporated into EU DIN 14375.

Pharmacists are responsible for testing whether a blister pack is child-resistant. Apart from the packaging – blister lidding foil and blister foil – the product and the blister and cavity size also play a big role. Only the complete blister pack can receive the child-resistance certificate.

## A look at CR/SF blister packs

In Europe, push-through is often used as a lidding foil in combination with a coloured base foil, a two-layer laminate foil. The situation in North America is quite different, where

Constantia Flexibles' CR blister lidding foil requires the removal of a top layer before the aluminium can be pushed through.



peel-push, peel-off and bend-and-tear systems, cross-perforated blister lidding foils and three-layer laminates are used. A tablet cavity is torn off and then either the blister lidding foil is completely pulled open or part of the laminate is pulled off and the tablet pressed through the aluminium layer of the foil.

Constantia Flexibles' CR blister lidding foil F1 is a three-layer laminate with a top layer that can be peeled after being moistened. The aluminium foil can then be pushed through. The laminate can be produced in different ways to determine when peelability begins.

Other types of packaging that fall under the banner of child-resistance/senior-friendliness include stick packs, which are normally provided with a tearing notch. To simplify opening, there are various opening aids on the market.

With laser perforation, the outer PET layer is lasered away linearly, which creates a predetermined breaking point allowing the stick to be opened cleanly. With the Constantia Tobepal opening feature, the PET is weakened punctually in order to simplify opening. Both opening mechanisms are also available in a CR/SF design, when the patient must fold the stick first, before he/she can tear it open.

Given the complexity of the issue and its apparent contradictions, it is not easy to find a solution that also fits the product. As requirements continue to increase in the future, pharmacists, packers and foil converters will have to search for new solutions together. ■

## Further information

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