



Figure 1: Medicine is the most common cause of poisoning in young children

Images: ivm

Personal Protection

Both children and the elderly require specialised blister packaging and the difficulty can be getting the balance right – but a versatile new label concept is gaining ground

Rolf Abelmann at ivm – childsafe and Reinhard Kuge at Faubel

In the pharmaceutical industry, blister packaging has become the most widespread solution for packaging drugs. It provides effective protection to unit doses, such as tablets or pills, extends shelf-life, and offers a degree of tamper resistance at the same time. If blister packaging is child-resistant, young children are prevented from accessing the packaged product, or certainly cannot do so easily. Designing blister packaging that complies with the European product standard EN 14375 for pharmaceutical products, or with US 16 CFR 1700.20 in the US is a technical challenge for which many factors have to be considered. Thanks to the Child-Resistant and Senior-Friendly (CRSF) Blister Label, it is now possible for the first time to simplify this process – to achieve child safety in pharmaceutical packaging while complementing it with various possible applications.

Young Children's Health

Young children begin to explore their environment at a very early age. They tend to do so by using all of their senses and putting almost everything they find in their mouths, and pills can be so easily confused with sweets. This is why young children under four are the most prone to accidental poisoning, with over 80 per cent of cases affecting this age group. In Germany alone there are some 100,000 cases of child poisoning per year, more than 50 per cent of which are caused by drugs.

Child-resistant packaging can remedy this by preventing young children from accessing the contents of drug packs, should they manage to lay their hands on them despite precautions. Blisters are a suitable type of drug packaging as they comply with

EN 14375 or US 16 CFR 1700.20 stipulating the use of non-reclosable child-resistant packaging for pharmaceutical products. It has been achieved by combining adequate packaging materials with an ingenious opening mechanism.

Although in Europe push-through packaging is still used with multi-layer laminated films – hence reinforced to meet these requirements – more sophisticated systems are currently gaining momentum in the US. Besides requiring more strength from the user, they feature various barrier levels involving cognitive and motor skills, such as peel/push blister packaging.

Legal Requirements

With its Poison Prevention Packaging Act, the US was, historically speaking,

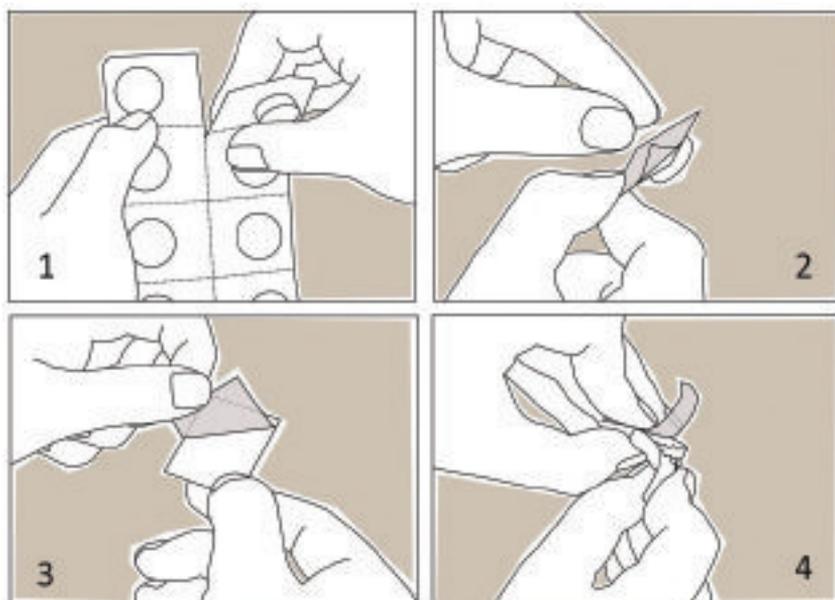


Figure 2: How to open peel/push blister packs

the first country to enforce the use of child-resistant packaging for prescription medicine and for a number of over-the-counter drugs in the 1970s. Today, there are similar regulations and standards in use in Germany and the rest of the world (including relevant sections of the German Medicine Act, the UK Medicines (Child Safety) Regulations, EN 14375 and ISO 8317). After 'passing the tests', the conformity of the packaging with current regulations will be evidenced by certificates.

Child-resistant packaging for drugs is ruled by an ever-increasing array of national regulations. The need for worldwide harmonisation, as well as growing awareness of child safety in medicines, are likely to boost the use of child-resistant packaging and make higher demands on child safety in the future.

Functional Reliability

Packaging designed to prevent access to drugs by small children must be tested for reliability. Sophisticated opening mechanisms or the use of certain materials are no guarantee that young children will not be able to open the pack if they try hard enough. Time and again, supposedly child-resistant packaging fails in practice because young children manage to open it relatively quickly. How effective a type of child-resistant packaging truly is depends on a number of factors.

Safety Requirements

The tests required to establish how safe blister packaging is for young children are described in the EN 14375 standard, as well as in the procedure set forth by US 16 CFR 1700.20 for non-reclosable packages containing pharmaceutical products. The suitability of packaging for senior adults is also investigated.

In two test periods of five minutes each, about 200 children aged between 42 and 51 months are asked to open blister packs filled with placebos. Before the second trial, opening is demonstrated to them without any further explanation. Within the first five-minute time period, the percentage of children able to extract more than eight unit doses from the pack must not exceed 15 per cent. (For testing according to US 16 CFR 1700.20, the number of units to open can be adjusted to the toxicity and the dose of the individual packaged product, and may therefore be lower). In line with the standards, no more than 20 per cent of children should be able to open the packs within 10 minutes. In tests involving senior citizens, at least 90 out of 100 participants between 50 and 70 years of age

should be able to extract a unit dose from a blister card in less than one minute. To be certified, the packaging concerned must have passed both tests, the one involving young children and the one for senior adults. Testing and certification is carried out by institutes whose accreditation must comply with 45011 to be acknowledged by market participants and institutions.

Innovative Safety Concept

The CRSF label has been developed to take into account the principle of child resistance and senior friendliness in packaging, as well as the safety issue. Thanks to its special safety features, the label can enhance a finished pharmaceutical blister card with no child protection. So far unique, this concept has a wide range of applications. In addition, it can accommodate detailed client and product information which, normally, would not fit on an ordinary blister card. By enhancing blister packaging with a CRSF label, one obtains a child-resistant packaging that fulfills the safety requirements set forth by various standards. It contains six barrier levels that make it difficult for young children to open blister cards, whereas senior adults can access their medication without effort, and can be affixed to either side of a blister card like a label. Not only does this solution meet high



Figure 3: Toddler trying to open a blister pack



Figure 4: Child-resistant and senior-friendly: multiple barriers for enhanced child protection and effective senior adult use

expectations in terms of safety, but it is also very cost-effective. Blister packaging protected by this label has already been certified according to EN 14375 and US 16 CFR 1700.20.

The Six-Barrier Principle

To design packaging that is safer for children, it is important to integrate obstacles which can only be overcome with difficulty by children but easily by senior adults (aged between 50 and 70). To solve this dilemma, the opening of a child-resistant and senior-friendly solution relies on the following user abilities: strength, fine motor skills, logical thinking, experience, patience and intuition. A CRSF label is made up of three layers:

- A layer covering the entire blister card, which needs to be peeled off first (peelable layer)
- An additional peelable layer covering each unit dose, which only comes off if a 'motion trick' is applied
- A push-through layer, which can only be pressed through by applying force along marked break points

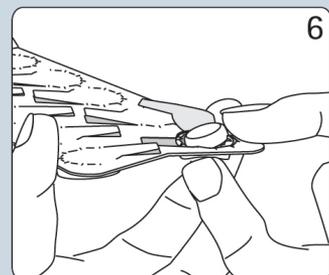
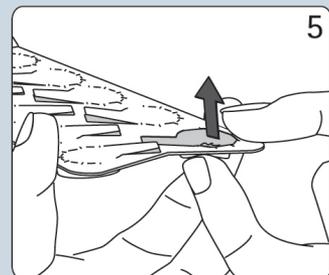
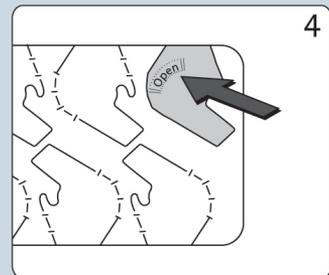
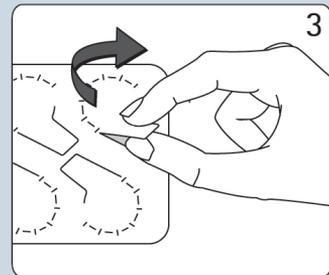
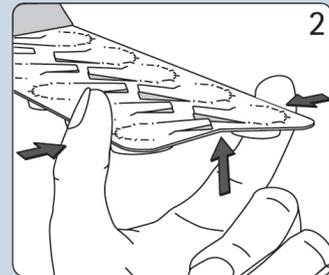
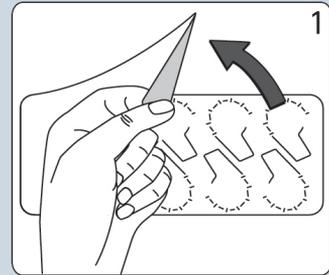
These three layers are designed to form six safety barrier levels: three mechanical and three logical ones.

Mechanical barriers made up of three layers tend to reduce the likelihood of young children accessing the contents of the blister card by using skill, effort or scratching off the lidding foil. But overcoming logical obstacles – deciphering pictograms, understanding the mechanism and, as a result, finding out the way to proceed through experience and intuition – is very difficult for children aged between 42 and 51 months. Opening by trying is complicated by the fact that children do not have the patience and the ability needed to concentrate for long periods of time. The six-barrier principle is, however, no challenge to the cognitive or motor skills of senior adults. Opening packs of this kind quickly becomes second nature. The materials used to produce child-proof labels are saliva-, bite- and tear-proof; the adhesives used are certified food safe.

The CRSF label can be affixed to blister packs with different contents. It is available in many standard packaging sizes and it can be adapted to the particular nature of the cavities. Such a state-of-the-art, child-resistant and senior-friendly solution can be realised in cooperation with the drug manufacturer and

Figure 5: How to open a blister pack protected by a CRSF label

1. First barrier level: a labelling layer which can be custom-designed is pulled up
2. Second barrier level: to open the peelable seal of a single unit dose, you need to understand the corresponding pictogram. If you press the blister pack from both sides, it will bend in the middle, raising the opening grips of the cavities
3. Third barrier level: once the opening grip is up, it can only be fully removed by pulling it straight up, thus requiring more effort. Fourth barrier level: as explained by the pictogram, applying the 'motion trick', a slight twist to the right helps to open the peelable seal
4. Fifth barrier level: once the peelable seal has come off, the push-through layer becomes visible. Simply pressing it through is virtually impossible, even with considerable force
5. Sixth barrier level: a text and a pictogram explain how to open the push-through layer easily by pressing along marked break points. By pressing out the tablet, it is relatively easy to break through this barrier layer, but only in the 'open here' area
6. The lidding aluminum foil can only be broken now to remove the tablet from its cavity



tailored to meet the level of efficiency and cost-effectiveness required in the production process.

A Common Path for Protecting Children

In pharmaceutical packaging, the proportion of child-resistant packaging is expected to increase worldwide. This is spurred by harmonised regulations which are being more effectively enforced. As a result, companies feel the need to address the resulting challenges at the right time. The key question that forward-looking businesses are asking themselves is: 'What actions and changes are needed to promote child-resistant packaging?' In many cases, it has become obvious that the widespread use of child-resistant packaging requires considerably less effort and expense than originally expected.

Often, the appropriate measures merely involve catering for the ongoing replacement of materials, such as foils or packaging components, once

at the beginning. The CRSF label is a versatile element of the system. Until the packaging is finally certified, this process is a particular challenge to the cooperation and communication

between the partners involved, such as pharmaceutical companies, packaging manufacturers, service providers and testing institutes, but our children's health is well worth the effort.

About the authors



Rolf Abelmann has been Managing Director of ivm – childsafe since 2006, after joining as Head of Testing in 2003. He was born in 1976 and schooled in the city of Braunschweig, Germany. Between 1996 and 2000, Rolf studied business at the University of Göttingen before securing a management position with ALDI from 2001 to 2003. He also completed a doctorate with the University of Göttingen in 2005. Email: info@ivm-childsafe.de



Reinhard Kuge is Corporate Managing Partner of Faubel & Co. Nachfolger GmbH. He joined the company in 1982. Reinhard passed his training as a printer at Mohn-Druck, a graphic arts company of Bertelsmann publishing group, and was educated at the Akademie für Führungskräfte der Wirtschaft in Bad Harzburg as Management Assistant in 1980. He has many years of printing experience across product development and production for the pharmaceutical industry. Email: info@faubel.de



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Faubel & Co. Nachfolger GmbH
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