



heinlein
PLASTIK-TECHNIK



WHITE PAPER

CHILD-RESISTANT CLOSURES (CRC)



OVERVIEW

CHILD-RESISTANT & SENIOR-FRIENDLY CLOSURES

Child-resistant closures are currently the most important tool for preventing cases of poisoning among children of pre-school age. They are the last line of defence against accidental swallowing of potentially hazardous substances, especially medicines and household chemicals.

Nevertheless, they do not relieve supervising adults of their duty of care. Only closures certified as child-resistant (e.g. according to DIN EN ISO 8317 within the EU) are guaranteed to fulfil the performance requirements. The certification test includes a further procedure to check that the closure is also "senior-friendly". This ensures that containers can be easily opened and properly closed again with relatively little effort.

CRC BY HEINLEIN: KEEPING OUR CHILDREN AS SAFE AS POSSIBLE

Heinlein has been developing child-resistant closures since the early seventies. These can be provided with or without tamper-evident features such as "closing without axial force" or "clearly audible clicking sound in opening direction".

Heinlein CRCs are among the safest closures currently available on the market. They are certified according to the latest standards (e.g. DIN EN ISO 8317) and have achieved outstanding results and clearly exceeded the requirements in all certification tests, even achieving success rates of 100% among some groups of subjects. Furthermore, Heinlein CRCs can be easily processed and assembled on all common systems



INTRODUCTION

Around 100,000 accidental poisonings are reported each year in Germany alone. Over two thirds of these accidents involve children of pre-school age. And around half are caused by children swallowing medicines they have got their hands on. Similarly, access to household chemicals – especially detergents and cleaning products – represents another major cause of poisoning. In view of the large number of accidents, the associated deaths and the risk of permanent harm to children, (preventive) measures are essential. One particularly important measure is the use of child-resistant (CR) closures on containers in which medicines or chemicals are stored.

HISTORICAL BACKGROUND

In the USA, the topic of child-resistant packaging and closures first entered public discourse on a broad scale in the 1960s. This was prompted by the increasing number of accidental poisonings due to swallowing medicines and household chemicals, especially among children of pre-school age. In response to this, so-called “poison control centres” were set up in the United States, where relevant information about such household accidents was collected, logged and analysed.



The first Heinlein CRCs:
Models from the 70s

Based on the collected data – and due to growing public awareness of the potential risk – efforts to protect children in this area were stepped up, first in the USA and then in Europe. These efforts focused in particular on the opening and reclosing of containers used for storing potentially hazardous substances.

Even in these early days, Heinlein was a pioneer in the sector. The company patented its first CRC solution as far back as the early 1970s. Heinlein has been producing child-resistant and senior-friendly closures with push-and-turn technology since 1985. Tamper-evident closures were added to the range of solutions in 2000.

In the mid-nineties, there was a greater need to adapt the existing child-safe products to the requirements and capabilities of older people too (i.e. “senior-friendly design”). The new closures should be more user-friendly for everyone. In other words, elderly people (not just children) should also be able to open them easily and reclose them securely.



CHILD-RESISTANT CLOSURES: WHAT DOES THEIR QUALITY DEPEND ON?

Important: Child-resistant closures generally offer a high level of protection and, in the vast majority of cases, prevent children of preschool-age from being able to open containers filled with dangerous substances. However, they should only be seen as an important additional measure, i.e. as a last line of defence against opening. They cannot prevent accidents with hazardous substances from happening altogether. This is because, if the containers were made even safer for children, for example, they would become too difficult to open for certain other groups of users, especially elderly or weaker people. This would not be congruent with the goal of making packaging for pharmaceutical or chemical products as easy to open and reclose as possible while also fulfilling the safety requirements.

The quality of child-resistant closures therefore depends on combining the following three functions and parameters in the most effective way:

- **Senior-friendly child-safety function**
- **User-friendly functional principle**
- **Minimum cost and time required for production and integration**

Child safety is naturally at the top of the hierarchy of these three functions. However, in order to develop and manufacture a competitive product, the other parameters must also be taken into account in equal measure.

WHAT DOES HEINLEIN PLASTIK-TECHNIK OFFER?

Thanks to our decades of experience in the development and production of child-resistant closures, we have been able to combine these three factors in an increasingly optimum way in our solutions over time.

The result: CRC products that offer maximum child safety while also being easy to use.

The third important parameter for our customers is cost. This is because, despite the high demand, child-resistant products can only establish themselves in the market if they are sold at competitive prices.

Heinlein offers its customers solutions that, despite their exceptional safety characteristics, can be produced at relatively low cost in terms of materials and processing.

At the same time, the universally applied, modular design principle removes the need for further machining or assembly and thereby avoids additional costs. Because the CR closures can be easily integrated with all types of closures offered by Heinlein (both with and without tamper-evident features) and the associated components, Heinlein customers do not need to adapt their existing manufacturing or assembly processes at any stage. This removes or minimises the need for retooling or having to purchase expensive new equipment when switching to CR closures.



CURRENT CLOSURE METHODS IN THE AREA OF CHILD-RESISTANT AND SENIOR-FRIENDLY PACKAGING

On packaging for household chemicals, one-piece push-turn closures are often used, which respond to a combination of pressure and twisting.

In the CR sector, Heinlein has particular expertise in push-turn closures, which are opened with downward pressure followed by a twisting motion. These closures, which are mainly used in the pharmaceutical industry on glass and plastic containers, consist of two parts. They are extremely robust and can be supplied with or without tamper-evident features. This means that the customer can choose to have the CR closures customised with additional functions such as “closing without axial force” or “clicking sound in opening direction”.

The latter function serves as an audible early warning system to alert nearby adults.

The child safety offered by Heinlein push-turn closures is based on a catch mechanism. Due to the special shape and geometry, the two parts of the closure can only engage if firm, downward pressure is applied at the same time as twisting it in the opening direction.

Significantly less pressure then needs to be applied when reclosing the cap, as the grooves on the opposite side are vertically flanked, making it much easier to twist the closure in that direction.



Vertical pressure with following rotary motion



CERTIFICATIONS

Manufacturers can only guarantee that a closure is child-resistant by having it certified according to a recognised standard by an institute accredited for this purpose (ivm Institut Verpackungs- und Marktforschung GmbH, Braunschweig). This certification is the only way for customers and end users to be sure that the desired safety function is fully compliant with the relevant safety standards.

Within the EU, all child-resistant and senior-friendly push-turn closures must comply with the standard DIN EN ISO 8317 ("Child-resistant packaging — Requirements and testing procedures for reclosable packages"). This standard is used in the field of pharmaceuticals, as well as for chemical products.

Products sold on the American market must be certified according to "US 16 CFR §1700.20". The requirements of both standards for the packaging solutions to be tested are largely similar. Nevertheless, there are a few noteworthy differences, such as the mandatory "bite test" in the US version.

To obtain long-term ISO 8317 certification for a certain product, it must be tested every two years. Manufacturers must then undergo full recertification ten years after the initial certification.

Important to know: Compliance with the child safety requirements can only be demonstrated by showing proof of certification according to DIN EN ISO 8317 or "US 16 CFR §1700.20". Icons on the closures, for example, offer no guarantee that they have actually been tested or that they meet the requirements.



TEST METHOD

The requirements for passing a certification test for DIN EN ISO 8317 are comprehensive and complex. This calls for adequate preparation.

For the child safety test, the group of subjects consists of at least 100 participants aged between 3.5 and 4.25 years. The children are given the smallest and the largest version of a product model. In addition, the test has to be carried out in an environment that is familiar to the children, such as kindergarten.

THE TEST PROCEDURE

The test takes place over two periods of five minutes each. During the first phase, the children are asked repeatedly to open the containers. Phase two takes place after the children have been shown how to open the bottle. The test procedure is then documented thoroughly, i.e. including any nonconformities.

RESULT

The certification is awarded if at least 85 of the 100 test subjects were not able to open the container in phase one and at least 80 in phase two.

REQUIREMENTS AND TEST METHOD FOR SENIOR-FRIENDLY PRODUCTS

Tests to determine whether a product is senior-friendly are carried out with at least 200 subjects between the ages of fifty and seventy. The test is usually considered to have been passed if 90% (i.e. at least 180 subjects) were able to open the CR closure and properly close it again within sixty seconds.

Important: Products with Heinlein child-resistant closures have met all the requirements of DIN EN ISO 8317 and US 16 CFR §1700.20 in every certification test carried out to date. The test requirements and the necessary 80, 85 or 90% success rate were not only met in each case but far exceeded, with 100% closure safety achieved in some groups of subjects.



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