PROTECTING CHILDREN WITH LIFESAVING PACKAGING

An evaluation of current and future child-resistant packaging trends in the pharmaceutical industry

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Abstract

Unintentional child poisoning remains a considerable risk in the home. In the United States (US), over 300 children under the age of 20 are treated in the emergency department every day, and two die as a result of poisoning.[1] In the European Union (EU), poisoning is the fifth leading cause of unintentional death for children and adolescents, with 3,000 young children aged 0 to 14 dying of acute poisoning every year.[2] One of the most commonly cited causes of poisoning is medicinal drugs, sparking increased efforts to improve parental education in 'child-proofing' homes and understanding mechanisms of child-resistant packaging, which has led to a decrease in the number of poisoning cases. A 2019 report shows that between 2010 and 2016, visits to emergency rooms (ERs) for children under 6 years old in the US who had been exposed to medicines decreased by 32%, and the number of calls to poison control centers decreased by 20%.[3] Despite this downward trend, the risk of poisoning still exists. Patients and stakeholders are calling on pharmaceutical companies to recognize the importance of child-resistant closures (CRCs) in medical packaging. Since its introduction, child-resistant packaging has developed and matured into an accepted and effective product in the United Kingdom (UK), EU, US, Canada, and Australia, and is rapidly gaining acceptance in the Asia Pacific (APAC) region.[4] An important feature of child-resistant packaging is the ability of older patients to access medication, while ensuring children cannot open it. While most packaging solutions must meet child-resistant senior-friendly (CRSF) certification protocols, concern remains around the impact of CRCs on elderly patient compliance. This paper discusses these trends, and reviews current research and viewpoints of the industry in child-resistant packaging innovation.

Introduction

Poisoning is a relatively widespread medical emergency across the globe, with children at highest risk of accidental intoxications that could prove fatal.[5] In 2012, nearly 6,000 children aged 0 through 4 were hospitalized and another 55,000 were treated and released from United States (US) emergency rooms (ERs) for medication poisoning.[6] Hospitalization due to poisoning is therefore not only a danger to children's health, possibly causing long-term organ damage, but treatment and monitoring is extremely costly. In fact, these poisonings resulted in $154 million in medical spending and $14 million in parent work losses.[6] Most cases of unintentional child poisoning occur within the home, where often young children exploring their surroundings have gained access to harmful substances that are improperly stored. Cleaning chemicals, fuels, alcohol, and tobacco are commonly cited causes of poisoning, but medication is most often the cause. Although parents/carers have the prime responsibility for ensuring harmful products are stored out of reach of children, manufacturers are being increasingly called upon to make the packaging of their products as difficult for children to open as possible, while maintaining usability by adults – particularly seniors.

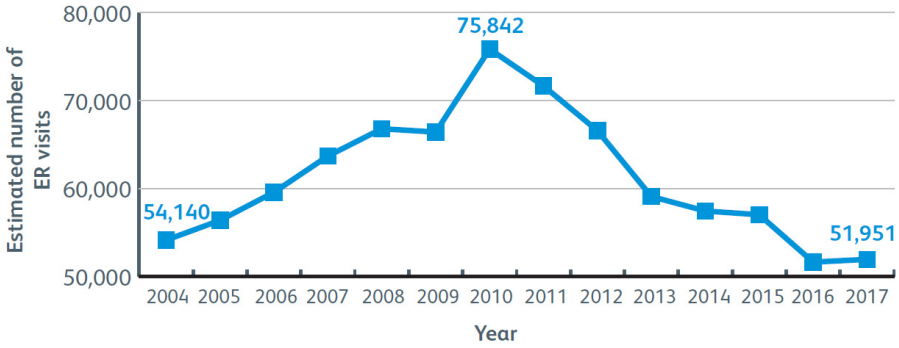

Figure 1: Estimated number of emergency room (ER) visits in the United States for accidental medicine poisoning in children under the age of 6 years.[3]

Despite a reduction in child poisoning cases since 2010 in the US (Figure 1), accidents still occur. While it is impossible to completely 'child proof' a product, there is an upward trend in the number of adults taking over-the-counter (OTC) and prescription medications, so pharmaceutical and healthcare industries are realizing the need to optimize the safety of child-resistant packaging. The global pharmaceutical packaging market was valued at approximately $71 billion in 2018, and is projected to grow at a CAGR of nearly 6% during 2019-2029.[7] This market growth has been influenced by an upward trend in contract manufacturing and an increasing focus on child-resistant packaging, both contributing considerably to the future pharmaceutical packaging landscape. Other trends influencing the market include patient compliance – which continues to be a top priority for packaging solutions – as well as regulatory standards, both of which are important considerations in designing and manufacturing child-resistant packaging. According to the World Health Organization (WHO): "Packaging must not only increase compliance through its design, but must also protect the patient and indicate the integrity of the product."[8]

There are numerous mechanisms for child-resistant closures (CRC) on medical packaging – primarily categorized into re-closable (bottles) or non-re-closable (blister packs), which include:

Re-closable

- Push & turn caps
- Squeeze & turn caps

Non-re-closable

- Peel & push

Although the overall aim of each type of packaging is to protect children from ingesting the contents, the strategies can vary. For example, the aim of most bottle CRCs is to stop the child opening the packaging altogether, but if the feature becomes disabled or the cap is left off accidentally, the CRC becomes invalid. Other designs focus on limiting the dose a child is exposed to if the container is opened, for example with liquid flow limiters that only allow one dose to be dispensed. Dose guards provide more of a secondary barrier for blister packs, where the user must peel away a backing layer to then push the oral dose through the packaging (Figure 2c), and offer both ease of patient use and child resistance.

In some countries, pharmaceutical and healthcare companies are required by law to produce packaging that is child-resistant, while maintaining accessibility for the consumer/patient. Protocols for child-resistant packaging were established in the US in 1966 and in 1970, the Poison Prevention Packaging Act (PPPA) was passed and placed under the jurisdiction of the Food and Drug Administration (FDA). This Act was transferred in 1973 to the Consumer Product Safety Commission (CPSC), which is responsible for drugs and household substances.[9] Additionally, the International Organization for Standardization (ISO) has published an internationally agreed standard test procedure for re-closable child-resistant packaging[10] and in Europe, several norms have been introduced that complement the ISO standard.

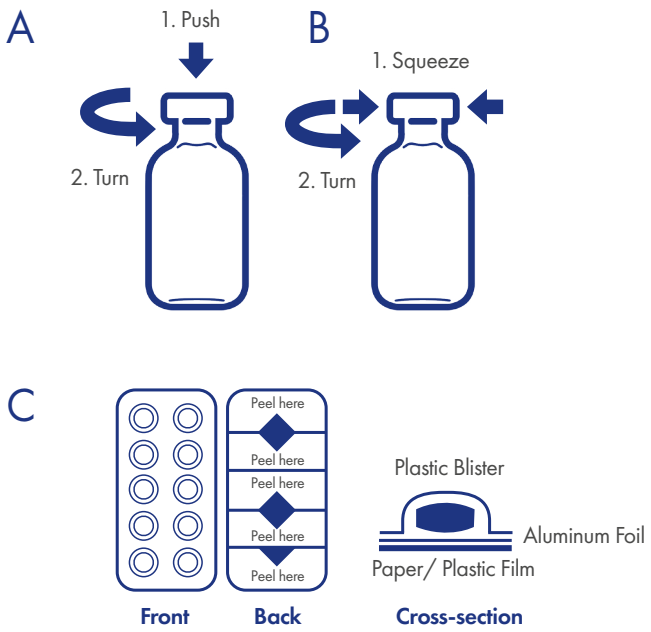

Figure 2: Different types of child-resistant packaging (a) re-closable push & turn (b) re-closable squeeze & turn, and (c) non re-closable peel & push, where back paper/plastic film is peeled back before tablet is pushed through aluminum foil.

For packaging to be classed as child-resistant, it must meet one of the following standards:

- **ISO 8317:2015:** International standard covering re-closable packaging for any contents.[10]
- **BS EN 14375:2018:** European standard covering non re-closable packaging for medicines.[11]
- **16 CFR 1700.20:** American regulation covering re-closable and non-re-closable packaging applicable to both medicines and non-medicines.[12] Initially only mandatorily required for products sold in the US, it has more recently been adopted by other countries as a standard.

Pharmaceutical companies must have certification for child resistance for the full packaging solution – both the container and the closure. While many pharmaceutical containers are produced with CRCs, it cannot be assumed that one pack combination will pass testing because another previously has. If a container and closure have been certified as child-resistant, even if only the container is changed or slightly modified, the entire packaging must be re-certified. The time and cost associated with certification is significant, so drug manufacturers can streamline the process by partnering with packaging manufacturers that can not only supply innovative, high quality packaging, but also provide the required certification (ISO 8317:2015 in the UK and Europe, and 16 CFR 1700.20 in the US).

The FDA released guidance in 2019 to assist applicants, manufacturers, packagers, and distributors that choose to include child-resistant packaging statements in their drug product labelling, but which does not establish legally enforceable responsibility.[13]

International efforts to address childhood poisoning

A 2012 report from the European Child Safety Alliance, developed as part of the Tools to Address Childhood Trauma, Injury and Children's Safety (TACTICS) project, provides overviews of the safety levels that 31 countries provided to their youngest and most vulnerable citizens through national policy, addressing unintentional injury in nine unintentional injury areas, including poisoning.[2] There are large differences in rates of injury between countries and within countries. Injury has a steeper social class gradient than any other cause of childhood death or long-term disability. The level of poisoning prevention for children was assessed based on the country's adoption, implementation and enforcement of evidence-based national level policies relating to poisoning prevention including, but not limited to, national laws requiring child-resistant packaging of medications.

Countries were assessed based on these good practice measures and given a score out of a possible 5 stars, with 5 stars being the highest score. Figure 3 shows the outcome of this analysis, where it was found that although 21 countries have one or more educational strategies in place, only 12 countries report having well-enforced laws requiring child-resistant packaging of both medications and household cleaners (Austria, England, Germany, Hungary, Iceland, Israel, Italy, Poland, Scotland, Spain, Sweden and Wales). Three countries (Belgium, Bulgaria and Romania) report laws that are not fully implemented or enforced and Greece reports no national law for either.

Drivers of CRC packaging

Large pharmaceutical companies are now driving awareness and innovation in child-resistant packaging, and designs are becoming more advanced every year. For example, squeeze & turn and push & turn caps continue to be the most widely used CRCs in the industry, with updated designs including caps that integrate measuring beakers to control dosage, or packaging with 'press-to-engage' resealable sliders that are difficult for under-fives but easy for adults of all ages. There are several important considerations, however, regarding advancing packaging designs for child resistance:

- **Cost** – Failure to comply with requirements for child-resistant packaging could result in court fines or company payouts in case of child injury or death. For example, Dr. Reddy's Laboratories – a large multinational pharmaceutical company – faced a $5 million penalty for failing to comply with the PPPA and the Consumer Product Safety Act (CPSA) in 2017.[14] Pharmaceutical companies also risk brand damage in the event of child injury or death as a result of unintentional poisoning, and expensive lawsuits.
- **Sustainability** – Increasing environmental awareness across the global pharmaceutical industry has drawn attention to the need for more sustainable pharmaceutical packaging solutions. Manufacturers now face the challenge of adhering to regulations and patient safety requirements while ensuring products are as environmentally friendly as possible. Aligning this with the additional components required for innovative child-resistant packaging requires smart (and cost-effective) manufacturing processes.

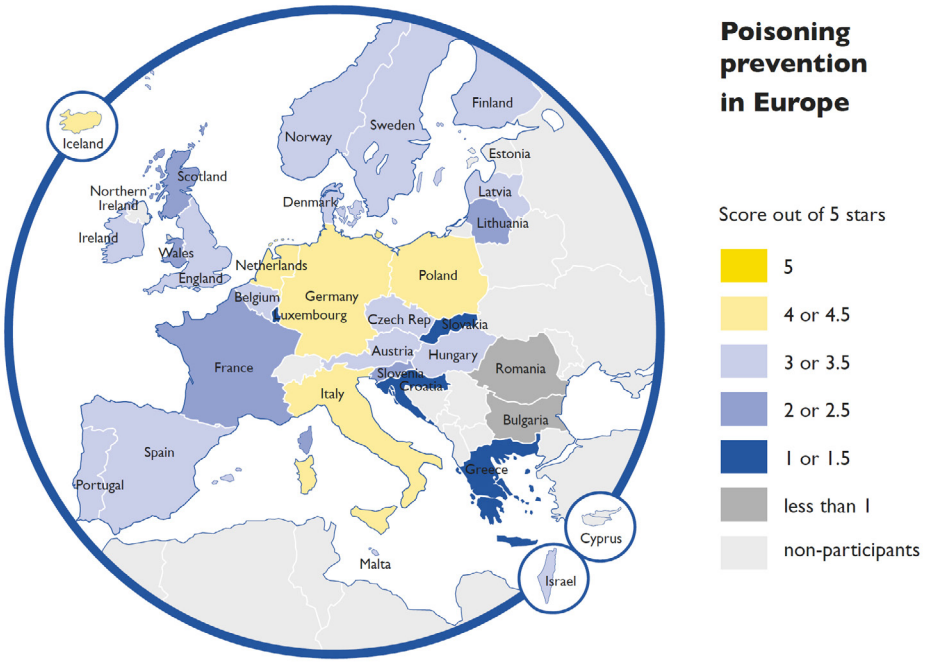

Figure 3: Map depicting the poisoning prevention scores of 31 countries in Europe, from 0–5 stars, with 5 being the highest score, based on criteria determined by the 2012 Child Safety Report Card.[2]

Industry expert perspective

Dr Rolf Abelmann, Managing Director, IVM Childsafe GmbH

Here at the Packaging Market Research Institute (IVM) in Germany, we've witnessed the impact of child-resistant packaging (Child-resistant packaging) in reducing the number of children who have died from poisoning in countries where comprehensive regulations have been introduced. Children are curious by nature and unaware of the danger of these products and substances. They use their sense of touch and taste to discover the world around them—and as such we have a duty to protect them, morally and legally.

Child-resistant packaging is an affordable and relatively simple means to restrict access to substances that are hazardous to small children. Available in both re-closable and non-reclosable designs, child-resistant packaging was developed to create hurdles that are difficult for children to overcome, but also are easy enough for senior citizens to solve and operate. The most well-known reclosable packaging is the screw-on cap, which can be opened only by pushing down and turning simultaneously. The most frequently used non-reclosable design is blister packaging that contains individually wrapped pills or tablets.

Whatever the choice of child-resistant packaging, organizations must review its safety function to ensure that it works correctly. International standards for child-resistant packaging—such as ISO 8317 (2015), ISO 14375 (2018) or US16 CFR § 1700.20—describe requirements and test procedures to ensure the packaging is child-resistant and meets the necessary legal requirements.

For example, the packaging will undergo a panel test with small children (from 42 to 51 months old) and seniors (aged 50 to 70 years) to ensure that small children cannot open the packaging while presenting limited problems for the adults.

This standardized certification procedure offers clarity about the packaging's quality and product safety at that time. Additionally, a certificate issued by an ISO 17065 accredited organization is able to provide legal protection to manufacturers, market participants, consumers and officials.

We estimate the use of child-resistant packaging will continue to increase for the foreseeable future, as international standards become more stringent. But beyond the legal requirements, child-resistant packaging makes a profound impact on pharmaceutical companies' larger goal to improve the health of people. If there is danger to the health of small children, child-resistant packaging must be used and tested to establish that it works satisfactorily. As the last barrier between the child and the packaged content, child-resistant packaging has an important part to play in solving the problem of unintentional child poisoning.

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Senior-friendly focus

An increasingly ageing population, combined with the growing trend of home care (partly intensified by the COVID-19 pandemic), is refining the focus of child-resistant packaging to the accessibility needs of senior patients. The need for more user-friendly child-resistant packaging was recognized by the Consumer Product Safety Commission (CPSC) in the early 1990s in the US, leading to the current protocol that employs 100 adults between the ages of 50 and 70 who do not have "obvious or overt physical or mental disabilities."[15] These adults must be able to open the package twice within allotted test periods, and at least 80% of children should be unable to open during specified test periods. Although the current protocols go some way to ensure older patients can access their medication, they have also been criticized for their lack of acknowledgement of vulnerable and disabled patients,[16] who are more likely to struggle with adhering to treatment regimes in the first place.

If such patients are not acknowledged in testing protocols, and child-resistant packaging remains too difficult for them to open, it could result in these patients leaving the closures off their medication and increasing the risk of child poisoning. There is therefore an opportunity for pharmaceutical packaging manufacturers and pharmaceutical companies to lead the industry in truly child-resistant senior-friendly (CRSF) packaging for medicines.

The pharmaceutical industry must undoubtedly incorporate innovative development plans, for drug products and packaging, to keep pace with clinical demands in healthcare. Packaging is crucial in supporting the move to a more patient-centered, rather than product-centered treatment approach, with patient needs driving innovation.[17] A strong relationship between drug manufacturers and packaging suppliers, as well as with healthcare providers and patients, will help facilitate this approach, for example by overcoming the currently perceived trade-off between child resistance and senior-friendly packaging.

Government initiatives

To address the concern that the increase in use of OTC and prescription medication in adults is putting children more at risk of unintentional poisoning, the Centers for Disease Control and Prevention (CDC) launched the PROTECT initiative (Prevention of Overdoses and Treatment Errors in Children Taskforce).[18] This initiative aims to bring together public health agencies, private sector companies, professional organizations, consumer/patient advocates, and academic experts to develop strategies to keep children safe from unintentional medication overdoses. PROTECT addresses the key factors that could improve the safety of medicines in the home, including safer use, safer storage, and safer packaging.

PROTECT participants have assessed the efficacy of specific innovative packaging designs and encourage the adoption of such packaging.

An example of where the efficacy of enhanced safety packaging has been demonstrated is in a multi-site randomized trial led by the CDC in collaboration with Georgia Poison Control Center, Atlanta. The study demonstrated that flow restrictors could limit the amount of liquid medicine that a young child can access even when the CRC is not fully secured, therefore complementing the safety provided by current child-resistant packaging.[29]

Figure 4: Transition of lenticular distractor as vial is moved. Reproduced from reference 21 in accordance with the Creative Commons Attribution License http://creativecommons.org/licenses/by/4.0/.

Review of recent research

As a result of these drivers of innovation, the volume of research into improving child-resistant packaging for medications, as well as modernizing the testing criteria for CRSF packaging, has increased significantly. Some important findings include:

Novel approaches to child resistance

The following three studies demonstrate the variety of approaches being taken to improve the effectiveness of child-resistant packaging:

1. **Multi-step mechanisms:** Researchers designed and validated the performance of a novel child-resistant packaging system for oral solid dosage forms, with a unique stepwise mechanism that showed considerable effectiveness in preventing children from opening the package.[20] The features include (i) re-closable packaging that involves a box container installed "click lock" on either side of the system, (ii) an outer packaging box of 8 cm width, which is too large for the palm width of children under 5 years of age, making it difficult to open, and (iii) a unique irritating sounding buzzer that either motivates the child to cease their attempt or alerts an adult to the attempt. Only 6% of children succeeded in opening the packaging, while 94% of children failed to open it within 5 minutes. On the other hand, 96% of adults succeeded within 5 minutes, indicating that the mechanism does not significantly hinder patient access to medication.
2. **Visual distractors:** As well as new designs for manual CRC mechanisms, research is also being carried out to investigate other elements of packaging that could prevent or restrict child access. For example, visual distractors have been shown to effectively delay young children (24-41 months) from opening medicines, in which time adults could be more likely to notice and prevent ingestion. In this study, the visual distracter consisted of a lenticular graphic characterized by a stereoscopic, 3D perspective that yielded the illusion of movement and depth, changing colors from yellow to red when the vial was moved (Figure 4).[21] While it was recognized that visual distractors could potentially attract children to a container they might have otherwise ignored, the approach and consideration of targeting children's early stage processing (i.e. perception) rather than relying on late stages of information processing is an area that could be explored further.
3. **'Smart' packaging:** As packaging technology becomes more advanced, smart containers could become more commonplace in the market. Preliminary results from a recent study indicate that smart pill bottles can be used to reliably detect children trying to open pill bottles and, by emitting an aural alarm, reduce risk of child-poisoning events.[22] In this study, a prototype bottle could sense an adult opening the container with 98.16% sensitivity, and a child with 96.67% sensitivity.

Updating testing criteria

The following two studies indicate how some elements of child-resistant packaging testing criteria are being called into question, and whether these should be updated to reflect a wider demographic:

1. **A global divide:** Some researchers have raised the question over whether different geographical regions should be covered by the same global testing criteria for child-resistant packaging. For example, there is currently no regulation mandating the use of child-resistant packaging in Japan, but the consistently high levels of reported child drug accidents in the country have led to considerations over whether packaging that meets US requirements is suitable for Japanese children. Researchers investigated pediatric characteristics such as literacy ability and finger function in Japanese subjects and examined the usefulness of child-resistant packaging technologies used in the US when given to children in Japan.[23] Results suggested that the differences in the language, culture, and preschool education between Japan and the US have a significant influence on pediatric characteristics.

   Additionally, the standard for child-resistant packaging testing in the US specifies that at least 90% of adults older than 50 years must be able to open the packaging within 5 minutes. However, in Japan, people are considered elderly at an age equal to or greater than 65 years, so it is considered inappropriate to set a target age of over 50 years as a criterion for judging whether packaging can be easily opened by elderly people. Therefore, when introducing child-resistant packaging technologies in Japan, it is suggested that a specialized opening test is required for elderly people aged 65 years or higher and for handicapped people.

2. **Improving understanding:** As mentioned previously in this paper, the criteria for ensuring adults can open child-resistant packaging stipulates that participants in testing must be able-bodied. Therefore, the existing test protocols for evaluation and validation of this type of package do not consider users with special needs, such as wheelchair users and people with limited range of hand movements, who are the most affected by the process of opening. Some studies have focused on better understanding the restricted movements of elderly or disabled users using devices such as movement restriction gloves, creating awareness in the hope of influencing these test protocols, as well as informing ergonomic packaging design.[24]

Conclusion

Over the last fifty years, there has been a gradual development in awareness of unintentional child poisoning risk and, following the introduction of child-resistant packaging requirements, the incidence of poisoning events has decreased steadily over the last decade. This decrease is thought to be attributed in part to increasing awareness campaigns and educational efforts, through initiatives such as the CDC PROTECT Initiative, the Up and Away Campaign, and Safe Kids Worldwide's medicine safety program.

However, poisonings and, sadly, fatalities, still occur across the globe as a result of children gaining access to both OTC and prescription medication. The risk to children depends heavily on the environment around them, and with more and more adults receiving prescriptions for medication such as sleeping aids, strong painkillers, and antidepressants, childhood exposure increases.

Certain drugs have become more problematic for child safety than others in recent years. Over the past two decades, the prescribing of opioids has increased dramatically in North America, and a 2018 study found that between 1999 and 2016, deaths from opioids increased among children and adolescents.[26]

The need for safe, compliant child-resistant packaging has therefore received increasing attention. There is still room to improve the safety of pharmaceutical packaging that also maintains compliance with patients, particularly seniors. Child-resistant packaging that is truly senior-friendly is undergoing innovation every year, and this development will be accelerated by strong relationships between drug manufacturers and packaging suppliers. By partnering with packaging manufacturers that can offer certified, advanced solutions for CRSF packaging, pharmaceutical companies can guarantee their products meet relevant regulatory requirements.

For more information about global cannabidiol regulations, download our white paper: "Navigating the Cannabidiol Regulatory Landscape."

For more information about Ensiemo, please visit https://www.sgd-pharma.com/ensiemo

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About SGD Pharma

Founded in 1896 in France, SGD Pharma is a global producer of molded and tubular glass for pharmaceutical primary packaging, operating worldwide with five factories and a network of more than 90 partners and distributors. The company has a long-term investment plan to regularly leverage its manufacturing facilities and develop workforce capabilities to remain at the cutting edge of technology. SGD Pharma commits to achieving consistent standards in all its facilities. In 2020, all plants are certified according to ISO 15378 standards, are pharma Good Manufacturing Practice (GMP) compliant and are equipped with ISO 8 clean rooms. With a global footprint and a strong sales force, SGD Pharma is recognized worldwide as a key player that customers can rely on to support new product development, day-to-day delivery, and quality and regulatory support. SGD Pharma benefits from over a century of expertise and a best-in-class manufacturing footprint, cementing its leading position in pharma, biopharma, veterinary, alternative medicine, and beauty and care markets. For more information, please visit www.sgd-pharma.com

About IVM Childsafe

As a packaging and market research institute, IVM has been working towards better standards of child safety since 1975. Today, IVM is one of the few accredited institutes in Europe according to ISO 17025 as a testing laboratory for child resistant packaging. Furthermore, it is the only accredited certification body for child resistant packaging in Europe in accordance with ISO 17065. IVM is recognized for its high standards by both consumers and governing bodies from within the industry, as an institute that can issue certificates in conjunction to the testing conducted.

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