



## Child Resistant Packaging: A Prime Concern for Packaging of Medicinal Products

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### ABSTRACT

Before a medicinal product for human use is placed on the market, it generally has to have undergone extensive studies, including preclinical tests and clinical trials, to ensure that it is safe, of high quality and effective for use in the target population. According to the World Health Organization, the third-leading cause of unintentional death in children through age 14 is acute poisoning. WHO estimates that 3,000 children in that age group die each year, and that 90% of those poisonings take place in the home. According to the World Health Organization (WHO), medicinal drugs are the leading cause of non-fatal poisoning in children in middle-income and high-income countries. Child-resistant (CR) packaging is used to minimize the risk of children accessing or ingesting medication and is one of the best-documented successes in preventing the unintentional poisoning of children. So, manufacturers & companies are utilizing the techniques of child resistant packaging for medicinal products as per the established norms & standards of the country.

**Keywords:** Child-resistant, WHO, poisoning, packaging.

### INTRODUCTION

The Poison Prevention Packaging Act (PPPA) defines special packaging as "Packaging that is designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly."<sup>1</sup>

Human performance tests were developed to measure child resistant and adult use effectiveness. Children aged 42 to 51 months were chosen as the test subjects. The test method was developed to try to mimic the situation found at home. The test involves giving packages to pairs of children. The children were given five minutes to try to open the package. If they did not open that package within that time period, the children were given a single visual demonstration and then given another 5 minutes to attempt to open the package. The package was considered to be child resistant if not more than 20 percent of 200 children tested could open the package. The packages also had to be opened and properly closed by adults. Adults aged 18 to 45 were chosen as the test subjects. The adults had a 5 minute time period to open and properly close the package. If 90 percent of 100 adults tested could open and close the child-resistant package, it passed.<sup>2</sup> Only those medicines containing aspirin, paracetamol, and more than 24mg of elemental iron must legally be placed on the market in packaging which has been shown to be child resistant. Child resistant packaging is a useful deterrent in preventing accidental poisoning of young children. However, it is intended to be a last line of defense with safe and appropriate storage of medicines being the primary preventative measure in harm reduction. A child resistant package is a package which is difficult for young children

to open (or gain access to the contents) but which is not difficult for adults to use properly.<sup>3</sup> Before any medicine is authorised for use in adults, the product must have undergone extensive testing including pre-clinical tests and clinical trials to ensure that it is safe, of high quality and effective. The same may not be true for medicines used to treat children.<sup>4</sup> Child resistant packaging reduces child mortality from the unintentional ingestion of oral prescription drugs. Some of the deaths resulting from the ingestion of an unspecified drug may have involved drugs not covered by the child resistant packaging requirements.<sup>5</sup>

### Factors affecting child resistance<sup>6</sup>

Child resistance is a factor of the packaging system and containers and closures must be tested together. Should aspects of the packaging system change it may be necessary to vary the marketing authorization and include additional evidence that the new packaging system has been shown to comply with the relevant international standard.

Factors which may affect the child resistant properties of a container-closure system include (but are not restricted to):

- Change in foil material
- Change in blister material
- Change in adhesive
- Different orientation of blister pockets
- Different wadding materials in closures
- Inclusion of a liquid medicine in a container-closure system previously used for solid dosage forms.



**Available standards<sup>6</sup>**

- International standards exist for both reclosable and non-reclosable packaging and marketing authorization holders are required to demonstrate compliance with these standards as part of their marketing authorization or variation application.
- Reclosable packaging consists of container-closure systems which when the closure is removed permit access to more than one dosage unit and which can be reassembled to form a child resistant pack. These containers should be tested to demonstrate compliance with BS EN ISO 8317.
- Non-reclosable containers are container-closure systems which when opened cannot be reassembled to form a child resistant package. Blister packs will fall into this category. Such non-reclosable packs must be tested to demonstrate compliance with BS EN 14375.
- The British Standards Institute which is responsible for the development and oversight of standards for child resistant packaging have produced a consumers' guide to child resistant packaging and the standards which are available.

**ASTM (American Society for Testing and Materials) Classifications<sup>7</sup>**

Type I: Reclosable Packaging - Continuous Thread Closure

Type II: Reclosable Packaging -Lug Finish Closure

Type III: Reclosable Packagin - Snap Closure

Type IV: Unit Non Reclosable Packaging - Flexible (Strip/Pouch)

Type V: Unit Non Reclosable – rigid

Type VI: Unit Reclosable Packages

Type VII: Aerosol Packages

Type VIII: Non Reclosable Packages - Semi Rigid (Blister)

Type IX: Dispensers (Not Intended To Be Removed)

Type X: Box Or Tray Package

Type XI: Reclosable Packaging - Flexible

Type XII: Dispenser (may be removed)

Type XIII: Reclosable Packaging Semi Rigid (Blister)

The ASTM classifications are extracted, with permission, from D3475-09, Standard Classification of Child Resistant Packages.

**Child-Resistant Products<sup>5</sup>**

The PPPA allows the Commission to set rules requiring child-resistant packaging for specific types of products customarily used in or around the household if it determines:

- That those products present a risk of serious injury or serious illness to children under five who are able to open the packages of the products and drink, eat, or handle the contents;
- That technology exists or can be developed to produce child-resistant packaging for such products, that the packaging can be used with modern mass production and assembly techniques.

To date, the Commission has issued rules that require child-resistant packaging for the following types of products:

## 1) Chemical and cosmetic products:

a) The following products that contain 10% or more by weight of petroleum distillates: furniture polish, and kindling and illuminating products such as lighter fluid and lamp oil;

b) Paint solvents that contain 10% or more by weight of benzene, toluene, xylene, or petroleum distillates;

c) Dry products such as granules, flakes or powders that contain 10% or more by weight of sodium or potassium hydroxide, and all other products containing 2% or more of these chemicals;

d) Liquid products containing 4% or more by weight of methyl alcohol;

e) Liquid products containing 10% or more by weight of turpentine;

f) Products containing 10% or more by weight of sulfuric acid;

g) Liquid products containing 10% of more by weight of ethylene glycol;

h) Liquid home permanent wave neutralizers that contain more that 600 mg of sodium bromate or more than 50 mg of potassium bromated;

i) Liquid glue removers containing more than 500 mg of acetonitrile;

j) Liquid products containing more than 5% methacrylic acid on a weight to volume basis;

k) Products containing more than 50 mg of elemental fluoride in a concentration that is more than 0.5% on a weight-to-volume basis for liquids and a weight-to-weight basis for solid products.

2) Mouthwash products containing 3 grams or more of ethanol. Please note that mouthwashes that are drugs and that have 3 grams or more ethanol also require child-resistant packaging.

## 3) Drugs and dietary supplements:

a) The following products for human use that are intended to be taken orally: aspirin; prescription and controlled drugs; products containing more than 1 gram of acetaminophen, products containing 1 gram or more of ibuprofen; products containing more than the equivalent

of 66 mg of diphenhydramine base; and products containing more than 0.045 mg of loperamide;

b) Liquid products containing more than 5% methyl salicylate;

c) Products containing 250 mg. or more of elemental iron in a concentration of 0.025% or more on a weight-to-volume basis for liquids and 0.05% on a weight-to-weight basis for non-liquids;

d) Products containing more than 5 mg of lidocaine or 0.5 mg of dibucaine;

e) Products for human use containing 250 mg or more of naproxen, or more than 50 mg of ketoprofen;

f) Products containing fluoride and mouthwash containing ethanol;

g) Products for human use containing more than 14 mg minoxidil.

In terms of packaging, these tips urge users to “Store medicine, cleaners, paints/varnishes, and pesticides in their original packaging in locked cabinets or containers” and “Purchase and keep all medicines in containers with safety caps”.<sup>8</sup>

#### Method of testing CR (Child-resistant) package

For a package to be child-resistant, a total of 80% of the children tested according to the procedure summarized below must not open the package during a full 10 minutes of testing. To make sure that adults are able to use a child-resistant package properly, 90% of adults tested have up to five minutes, and then another minute in a second test, to open and close the package so that it is child-resistant again.<sup>2</sup>

#### Test of child resistant package

Before starting a test, you should review the test protocol carefully to make sure that you comply with all of the testing requirements. If you choose not to test a package yourself, we recommend that you find a qualified child-testing laboratory in the United States to perform the test. A list of test firms known to the staff is available from the Office of Compliance. The test uses at least one, and up to four, test panels of 50 children between the ages of 42 and 51 months to test child-resistant packages. Each panel is divided into 3 groups – 30 children 42 to 44 months old, 40 children 45 to 48 months old and 30 children 49 to 51 months old. Approximately ½ of the children in each group must be boys. The test procedure allows a 10% variation in the number of boys and girls in each group. Each child in the test panel must have no illness, injury, or disability that would interfere with the child's ability to test the package. No child may test more than two packages. If a child tests two packages, the packages cannot have the same design. This keeps the child from learning how to open the package. Two children at a time participate in the test in a well-lit room that is familiar to them and is free from distractions. The tester gives each child an empty child-resistant

package, and asks the children to try to open it. Each child has five minutes to try to do this. If a child opens the package, he or she is not tested further and that child's test is counted as a failure of the package to be child-resistant. The tester shows any child who does not open the package in the first five minutes how to do so, and also tells any child who has not tried to use his or her teeth to try to open the package that it is all right to do so. The child then has five more minutes to try to open the package. Any child who succeeds in opening it in the second five minutes is also counted as a failure of the package. For a package to pass, at least 85% of the children tested must be unable to open it before they receive the demonstration of how it works, and 80% after the demonstration. For the first 50-child test panel, if 5 or fewer children open the package, the package passes. If 15 or more children open it, the package fails. In either case, no further testing is necessary. If 6 through 14 children in the first panel open the package, test a second 50-child panel. Depending on the results of that test, the package may pass, fail, or require more testing. Testing stops after a fourth panel of children, if the test has gone that far.<sup>5</sup>

#### How do you test adults?

The test uses a panel of 100 senior adults divided into 3 groups – 25 adults 50 to 54 years old, 25 adults 55 to 59 years old, and 50 adults 60 to 70 years old. Seventy percent of the participants, age 50 to 59 and 60 to 70, must be females. The test uses senior adults because they are the group most likely to have trouble using child-resistant packaging. Thus, if senior adults are able to open and properly close a package, younger adults should have little difficulty. Each adult tested must have no obvious overt mental or physical disability. The adults are tested one at a time. Each adult is given a package with the printed instructions that are on the package or that will accompany the package when it is sold to consumers. Each adult has up to 5 minutes to open and, if it is reclosable, to properly close the package. Each adult who is successful has one minute to open and properly close the same package again. This ensures that the package will be easy to open during continued use after the adults have first learned how to open it. Adults who are not able to open the child-resistant package in the first five-minute test are screened to see if they can open and close two regular packages that are not child-resistant in one minute. If they cannot, their results are not counted in the child-resistant package test because they have difficulty in using all packages, not just child-resistant ones. For a package to pass the adult test, 90% of the adults tested must be able to open and properly close the package during both the 5-minute and one minute tests. The regulation also contains a test for aerosol products and metal cans that use younger adults aged 18 to 45, instead of senior adults.<sup>5</sup>

- Reclosable child resistant packaging solutions obtain their child resistance by either asking the user to undertake two opposing actions simultaneously, thus



creating a barrier of dexterity. Examples are push down & turn - the classic Klik Lok or KidLoK, squeeze & turn, or procedures for lining up the arrows and then opening; this is a barrier of cognizance as well as dexterity. Non-reclosable products usually contain a barrier of cognizance, in other words fold at 45degrees and thus reveal a hidden tear start. Or peel back and push a two stage opening procedure.<sup>9</sup>

**Table 1:** Countries with standards and legislation for pharmaceutical CR packaging<sup>10</sup>

Countries	Year
United States of America	1970
United Kingdom,	1975
Germany, DIN 55559	1979
Canada	1979
Italy (Regulation only, no Std)	1984
Australia	1985
Netherlands, following DIN	1985
UK, BS 8404	2003

#### Standards for Reclosables and Non-Reclosables<sup>10,11</sup>

Standard for Reclosables: BS EN 28317:1993 (due for revision 2004)

- The International Organization for Standardization Standard ISO 8317:1989 entitled *Child-resistant packaging – Requirements and testing procedures for reclosable packages*
- The British Standards Institution Standard BS EN 28317:1993 entitled *Child-resistant packaging – Requirements and testing procedures for reclosable package*
- The Canadian Standards Association Standard CSA Z76.1-99 entitled *Reclosable Child-Resistant Packages*;
- The United States Code of Federal Regulations, Title 16, Section 1700.15, entitled Poison prevention standard and Section 1700.20, entitled Testing procedure for special packaging, as in effect at the date of this Order
- The Australian Standard AS 1928-2007 entitled *Child-resistant packaging- Requirements and testing procedures for reclosable packages (ISO 8317:2003, MOD)*.

Standard for Non Reclosables: BS 8404:2001, EN 14375:2003

#### Reclosable and Non Reclosable Packs for Pharmaceutical Products<sup>10</sup>

In Europe more than 80% of all Solids are packed in Non Reclosable Packages (Blisters)

The main Reasons are following as:

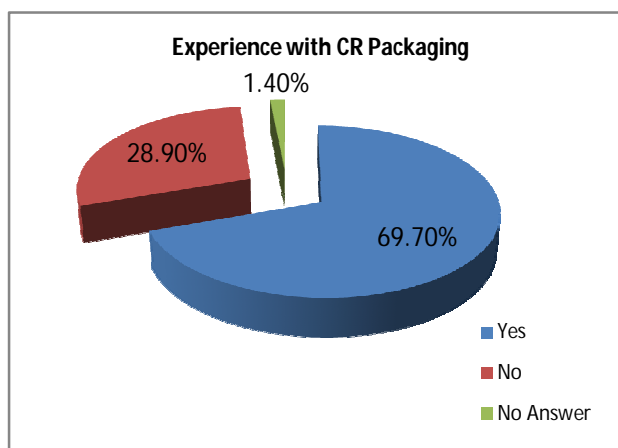
- High level of protection of each individual unit
- longer shelf life
- Patient Compliance
- Hygiene
- Only one dose available at a time

#### Extrapolation of test results

Extrapolation of test results refers to situations where the results from testing one combination of container and closure are taken to apply to a combination of container and closure of the same design but of different size, shape and/or neck diameter, in order to establish compliance with a Standard by analogy. Many of the nominated Standards permit extrapolation of test results over a range of similar packages [e.g. over a range of closure (neck diameter) or container sizes] provided all other characteristics of the package remain the same. For example, if a series of containers differ only in capacity and the closures are identical, the International Standards Organization Standard ISO 8317:2003 requires testing only on the largest and smallest container sizes. Extrapolation of results from one package to another in a series to the extent permitted by the nominated Standard chosen for test is acceptable.<sup>12</sup>

#### Experience with CR Packaging<sup>10</sup>

Do you, yourself have trouble opening child-resistant packages?



Source: "Packaging" USA, June 1990<sup>10</sup>

**Figure 1:** Experience with CR Packaging

Almost 70% have trouble opening child-resistant packages.

Difficulty in opening:

- Young Parent - 51.5%
- Middle aged parent - 68.0%
- Working older Couple - 78.3%
- Retired older Couple - 82.2%



**CHILD RESISTANT PACKAGING IN COUNTRIES****Australia**

'Child-resistant packaging' means packaging that:<sup>13</sup>

- a. complies with the requirements of the Australian Standard AS1928-2007 entitled Child resistant packages as specified or amended from time to time;
- b. is reclosable and complies with the requirements of at least one of the above mentioned standards for reclosable packages as specified or amended from time to time;
- c. is approved as child-resistant by any order made under section 10(3) of the Commonwealth Therapeutic Goods Act 1989; or
- d. is in the form of blister or strip packaging in which a unit of use is individually protected until the time of release and that complies with Section 3 (Requirements for nonreclosable packages) of Australian Standard AS 1928-2001 Child-resistant packages.

The performance standards for reclosable packages are based on compliance with the type testing requirements of any one of five nominated national or international Standards mentioned above. Inclusion of the range of national or international Standards is intended to facilitate the use of packaging originating overseas, and to minimise the need for involvement of children in testing. Although there are minor differences between Standards from different organisations, the key parameters of the child panel tests (ages of children and pass/fail criteria) and adult panel tests (ages and pass/fail criteria) are consistent. Therefore compliance with any one of these Standards is considered to provide equal assurance that a package, when type tested according to the Standards, meets an acceptable level of child-resistance and ease of use for adults. There is no order of precedence for the Standards nominated - all are accepted with equal standing and if compliance with an overseas Standard is established, testing in accordance with the nominated Australian Standard is not required. The age group tested in the child panel tests of the nominated Standards is specified as 42 to 51 months of age. Although this age group is at the high end of the age range at which child poisoning is most common, it is deliberately chosen in the Standards in order to challenge the packaging with children most likely to have the dexterity to succeed. While packaging that complies with the requirements of any of the Standards can be expected to be difficult for children of other ages to open, the ability of children outside the given age range to open the package is not tested and thus cannot be assumed. It should be noted also that 'child-resistant' is not synonymous with 'child-proof' and that compliance of a package with any of the nominated Standards does not mean that all children included in the test group were unable to open the package or gain access to the contents.<sup>12</sup>

**United Kingdom**

It can be fairly said that the 1970s saw the greater part of the United Kingdom (UKs) consumer legislation being enacted. Amongst this plethora of regulation were the 1975 Medicines (Child Safety) regulations. Initially these regulations were applicable only to children's Aspirin and Paracetamol. Although subsequently increased to include adult versions of these drugs, Aspirin and Paracetamol remained the only products where child resistant packaging is legally required. The regulations were drafted by a committee of physicians, pharmacists and pharmaceutical manufacturers but sad to say not one packaging designer or engineer. And it is probably for this reason that the anomaly of blister and strip packs first came into being and has continued to this day. Keep in mind blister and strip packs were fairly rare in the United Kingdom back in the early 1970s. However the regulations initially said, and I quote, "Blister packs should be constructed from materials with a view to making them child resistant."

Over the intervening years between the mid 70s and late 90s this rather woolly specification grew into the dictum, again quoting, "Blister packs may be considered to be inherently child resistant". In 1995 the United Kingdom Government, in response to EU directive 92/27EEC concerning patient information, launched what it termed the Patient Pack Initiative.<sup>14</sup>

In the United Kingdom the standards for CR packaging have been BS 5321 (1975), BS 6652 (1985), BS EN 28317 (1989) and subsequently ISO 8317, this was revised in 2000.<sup>15</sup>

**United States**

The Consumer Product Safety Act 1970 allows for the appointment of a five- person commission which administers and makes regulations for CRP on toxic substances in accordance with the Poison Prevention Packaging Act 1970. Substances are deemed to require on the basis of assessed hazard with regard to the availability of the substance and the feasibility of imposing Child Resistant Packaging (CRP). The overriding criterion is that the material be a 'household substance'. The United States control prefers the term 'special packaging' rather than CRP. Special packaging is defined as:

"packaging that is designed or constructed to be significantly difficult for children under five years of age to open or to obtain a toxic or harmful amount of the substance contained therein within a reasonable time, but not difficult for normal adults to use properly. It does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time."

Container sizes that require CRP for a listed toxic substance are not indicated in the United States Controls.<sup>16</sup>

In early summer 1995 the Child-Safe Packaging Group tested a series of blister packs then and now widely used in the United Kingdom. The protocol was the then current US standard. Using sequential testing a sample of forty children was employed. The results were disturbing but predictable.

- 92.5% of the sample of forty children accessed at least three tablets from the blister pack prior to demonstration.
- 45% accessed all fifteen tablets, again prior to demonstration.
- 90%, after ten minutes testing, had accessed all fifteen tablets.
- Only one child had accessed less than three tablets.

These results were worrying in view of the fact that three adult paracetamol tablets could be fatal to a child.<sup>17</sup>

**EN 28317:1992** Child resistant packaging- Requirements and testing procedure for reclosable packages.

**EN 862:2001** Packaging- Child resistant packaging- Requirements and testing procedure for non- reclosable package for non pharmaceutical products.

**EN 28317:1992:ac1993** child resistant packaging- Requirements and testing procedure for reclosable packages.

#### **New Zealand**

In New Zealand, child safety caps are required to meet the current New Zealand Standard (NZS 5825:1991). The majority of caps are mainly of the "palm-n-turn" variety. Recently on the market, there are the "3rd generation caps" available which allow an increased level of protection whilst providing easier access for adults.<sup>18</sup>

#### **India**

The Indian standard IS 14233 (1995) "Packaging Pharmaceutical Products- child resistant, temper proof, packaging for solid dosage forms- code of practice" is similar to BS 7236 & describe blisters & strip packs. Test of the package is not carried out with children but is a mechanical test.<sup>19</sup>

#### **Japan**

In Japan there is no regulation/standard as to CR/SF. It is up to the pharma company whether and how to pack the pharmaceuticals with protection for children.<sup>19</sup>

#### **Canada**

Here the Canadian standard CSA 276 C: Drugs I is effective. According to this standard a package is child-resistant when compliant with CSA 276 (1992 last edition concerning non-reclosable packages), reclosable packages (1995), UK Standard BS 5321 and PPPA.<sup>19</sup>

#### **Child resistant packaging: USA vs Europe**

Child-resistant packaging in the USA is a result of the Poison Prevention Act (PPA) passed by the US Congress in

1970. Congress gave the Consumer Products Safety Commission (CPSC) the responsibility and authority to administer and enforce the statutes. The purpose of the law is to decrease the opportunity for children to gain access to substances, resulting in accidental poisoning. The PPA, a mandatory statute, includes all potentially harmful products to children that may be ingested, including drugs and nutritional supplements with an iron content of 30mg or more. The European standard only mandates those packages that contain drugs containing paracetamol, aspirin and medicines containing 24mg of iron. In addition, the PPA extends to all states or localities in the USA and is the one standard applied for all applicable products. In Europe there are efforts to develop a unified standard that can be adopted by all the countries in Europe.

In the USA, protocol testing methods were developed primarily to address cap-and-vial closures as this was the preferred packaging format in the 1970s with unit dose formats being virtually non-existent. Today, there is a significant bias towards unit dose formats such a blister and strip packaging. During the protocol development era, it has been estimated that blister use and unit of use packaging formats represented less than 20 per cent of US drug packaging. This compares to over 80 per cent blister usage in Europe during the same time frame. Only in later years have blisters become more common in the US with Rx and OTC products. As a result, there is intense lobbying to get the CPSC to update the protocol to consider the existence of blisters as the highest compliance package that is currently being used. Several different types of unit dose formats are capable of passing the CPSC protocol yet pharmaceutical companies, laboratories and contract packagers always consider unit-of-use packaging as their primary choice, because this format offers significant benefits to drug manufacturers and consumers alike. Unit-of-use formats can be relied upon to:

- provide tamper evidence
- increase shelf life
- facilitate distribution
- increase brand awareness
- facilitate compliance with pharmaceutical regimens
- prevent counterfeiting and diversion
- protect each dosage unit from the time it is manufactured until the time it is ingested.

These are attributes that have been appreciated in Europe for decades. For consumers, unit dose formats:

- reduce the likelihood of medication errors
- enhance portability
- ensure product protection
- offer superior child-resistance



Generally speaking, CPSC regulations require that the following drug products be dispensed by the manufacturer in primary packaging deemed child-resistant:

- Anything that requires a doctor's prescription (unless it has been specifically exempted from CR requirements)
- Certain OTC products including those that contain specific amounts of aspirin, acetaminophen, ibuprofen, iron, fluoride and several other listed substances
- Any solid oral dosage product approved for OTC sale by FDA after 29 January 2002 which contains an active ingredient that had previously been available by prescription only
- Investigational substances being used in clinical trials dispensed on an out-patient basis, and containing a substance that could be expected to cause serious injury or illness to a small child.

US and European testing methodologies are not very different but there are substantial differences in the additional requirements and criteria that US drugs must meet to be labelled Child-resistant, including determination that if ingested by a child, the drug toxicity level would cause harm or injury. This is not a consideration in determining the type of package used in Europe. A final point is that CPSC does not require manufacturers to test their packages. Instead, the Commission monitors data such as emergency-room admissions and calls to poison control centres in an effort to identify packaging that could be dangerous. When CPSC identifies such packaging, which is extremely rare, the Commission has the ability to penalise the manufacturer and recall any product contained in those packages.<sup>20,21</sup>

### Child Resistant Closures



**Figure 2:** Child resistant closures

Child resistant closures help to significantly reduce the chances of a child accessing a drug or chemical. They are legally required on some medication and chemicals, and can be purchased from pharmacies for use on other

products. Child resistant closures are not "child proof" They are designed to increase the time it takes for a younger child to access the medication or chemical. They are "packaging that is designed or constructed to be significantly difficult for most children under five years of age to open or obtain a toxic amount of the substance within a reasonable time. It is not child proof packaging".<sup>22</sup>

### Types of Child Resistant Closures

Child resistant closures include both re-closeable and non re-closeable packaging. Non re-closeable closures are packages like aluminium foil (strip packaging) or opaque/clear laminated plastic (blister packaging) generally contain a single tablet (such as a medicine or dishwasher tablet).

Re-closeable packaging involves a container fitted with a re-closeable top, or a child safety cap such as the "Palm-n-Turn" or "Clic-Loc" variety (such as methylated spirits or dishwasher powders).<sup>22</sup>

### General Prevention Advice for Child resistant closure

- Child resistant closures need to be used correctly to be able to limit the chances of a poisoning. Turn it until you hear a click, and make sure you can't just pull it off.
- Always replace the child resistant closure correctly after each and every use. Never leave a lid off to make it easier to use the product; this also makes it easier for a child to be poisoned.
- Products with child resistant closures still need to be stored in a secure location.

### List of Chemicals Requiring Child Resistant Closures

The following list is based on the 1998 Code of Practice for Child Resistant Packaging and Toxic substance, produced by the Ministry of Health.

- Alkaline salts -dishwasher powders
- Alkaline salts -dishwasher liquids
- Cineole
- Clove oil
- Eucalyptus oil preparations containing greater than 50%
- Eugenol
- Hydrocarbons when packaged as kerosene, lamp oil, mineral turps, thinner, reducers, white petroleum spirits or dry cleaning fluids
- Hydrochloric acid
- Melaleuca oil (tea tree oil)
- Methylated Spirits
- Methyl salicylate preparations containing greater than 50%

- Oil of turpentine
- Potassium hydroxide
- Sodium hydroxide

#### List of Medicines Requiring Child Resistant Closures

Under Pharmac it is a requirement under the Pharmacy Contractors Section 51 Advice Notice that child safety caps must be placed on the so called dirty dozen:

- Paracetamol
- Salicylates/NSAIDs
- Anticonvulsants
- Thyroxine
- Antidepressants
- Narcotics
- Beta-2-agonists
- Benzodiazepines
- Theophylline
- Iron salts
- Digoxin
- Phenothiazines

#### Accidental Poisoning in Children

Vitamins and minerals can be dangerous to small children, although we often think of vitamins as non-toxic substances. Iron is especially harmful to small children. Between June 1992 and January 1993, five toddlers died after eating iron supplements according to the national Centers for Disease Control and Prevention's Morbidity and Mortality Weekly Report of Feb. 19, 1993. Iron is available without a prescription and it is often found in children's, prenatal, and adult vitamins. The amount of iron contained in children's and adult vitamins can be enough to kill a child when taken in excessive amounts. In 1997 the FDA implemented new rules that require unit-dose packaging for iron-containing products with 30 milligrams or more of iron per dosage unit. For a small child, as little as 600 milligrams of iron can be fatal. Children have died after swallowing such everyday substances as charcoal lighter fluid, paint thinner and remover, antifreeze, turpentine, and pesticides. All of these products must be stored out of the reach of small children. Special shelves and cabinets can be installed to make these items inaccessible. If you keep these items in a garden shed be sure that childproof latches are in place to keep curious children from gaining entrance into them. Be careful never to place rodent or insect baits where small children can get to them. Teach children that pesticides are poisons- something they should not touch. Mr. Yuk stickers can be obtained from your local poison control center for placement on dangerous substances.<sup>23</sup>

#### Accidental Poisoning Case

Harrison is the youngest of five children in an Australian family. One day, Lisa, his mother, changed her usual morning routine. Instead of going directly to the kitchen, checking that the cupboard doors were locked and preparing breakfast, she put on a video for Harrison's older sister. In that brief period, 18-month-old Harrison opened a cupboard, removed the cap from a container of dishwasher detergent and swallowed the powder. Lisa heard his cry and ran to the kitchen to find him vomiting blood. An ambulance rushed Harrison to hospital where doctors were unsure if he would survive. The container Harrison had managed to open had a cap that looked like a child resistant closure. To secure this closure, the cap had to click twice. Instructions to this effect, though, were not displayed on the packaging and Lisa mistakenly thought the container was securely closed when she felt the first click.

Harrison survived, but his injuries changed his life and the lives of his family. Lisa publicized his case, which was then actively taken up by the media. Harrison's story, and the details of other small children who had sustained similar injuries, became first local and then national news. While Australian laws stipulated that all dishwasher gels and liquids with a pH value greater than 11.5 be supplied in containers with child-resistant closures, with specific warnings as to the caustic nature of the contents, powders were exempt from this regulation. The powder swallowed by Harrison was extremely alkaline – with a pH of 13.4. The manufacturer of the dishwasher detergent was contacted. Faced with the evidence, the company placed warning labels on all its containers informing consumers of the "double-click mechanism" to engage the child-resistant closure. The company then redesigned the container itself, incorporating a device to limit the flow of powder and changing the closure to a "single-click" mechanism. Unfortunately, this was only one product of many on the supermarket shelves, leaving other manufacturers' products unchanged.

Government agencies and nongovernmental organizations lobbied for a change to the law, which was eventually amended. Dishwasher powder must now be distributed in child-resistant containers with specific warning labels if the pH exceeds 11.5. Furthermore, detergents with a pH greater than 12.5 have been removed from the domestic market. In addition, the performance standard for the child-resistant closure is also under review. The aim is to ensure that if a closure *appears* to be child-resistant, then it must function as such. There cannot be different stages of functionality, such as the "single-click" and "double-click" stages that Lisa's container incorporated.<sup>24</sup>

#### What to do if a poisoning occurs?<sup>23</sup>

In case of accidental poisoning, try your best to remain calm. Obtaining a complete and reliable history is the first step in evaluating the potential problems. Keep the number of your local poison control center by the phone.





If you are unable to locate this number, call your local emergency number (911 in most areas) or the operator and they will get you the Poison Control Center. Be prepared to provide the following information when you reach a member of the Poison Control Center:

- The child's age and approximate weight.
- Important medical information about the child, for example any existing health problems or conditions.
- The substance involved, was it ingested (swallowed), inhaled, splashed into the eyes, or absorbed through the skin?
- How much of the potential poison was involved? When unsure of the exact amount, err on the side of over-estimating. For example, if you are unsure how many pills remained in the bottle assume that the child ingested the full number that were prescribed.
- Any treatment that has already been given
- Is the child awake, lethargic, or drowsy and are they exhibiting any other symptoms?
- Your exact location and how far you are from the nearest hospital
- Save all original containers or bottles as they contain a list of ingredients included in the medication or product in question.

Some general guidelines for safety regarding accidental poisoning.<sup>23</sup>

- Never refer to medicine as "candy".
- Do not leave alcohol within a child's reach
- Read labels explicitly before administering medications (especially in the middle of the night).
- Always replace the safety caps as soon as you pour any medicine or use a household substance that can cause injury.
- Keep the telephone number of your local poison control center by the phone.
- Teach children never to eat or drink anything that is offered to them by a stranger.
- Keep a bottle of syrup of ipecac in the home but only give it after first consulting with your doctor or the poison control center.
- Never place non-edible products in food containers.
- Before applying pesticides remove children and their toys as well as pets from the area and keep them away until the pesticide has dried or as long as is recommended on the label. Be alert for repeat poisonings. Statistics show that children who swallow a poison are likely to attempt it again within a year.

## RESULTS

The Netherlands has legislation on child resistant packaging for household chemicals, since the Dutch Government made child resistant packages obligatory for household chemicals (1986) and human medicines (1990), the number of hospitalizations and treatments at a hospital accident and emergency department following an accidental intoxication of children has decreased about 33%. Similar results have been achieved in UK.

International evidence has identified that CRCs have been effective in reducing childhood poisonings. In particular, research has shown that CRCs prevent 40% to 80% of childhood poisonings. International evidence has identified that child safety caps have been effective in reducing childhood poisonings. Amending the Medicines Regulations (1984) is the preferred option for increasing the coverage of medicines with child safety packaging.

The Poison Prevention Packaging Act (PPPA) was introduced in the United States in 1970 to reduce accidental childhood poisoning. The law requires for all toxic, corrosive, or irritant substances to be packaged so that it is difficult for children under 5 years old to open these. Under this legislation CRCs were introduced for aspirin during the 1970s in the United States. Since 1970, there has been an extension in the number of substances with safety packaging to include prescription medicines, non-prescription and household products. This has resulted in a significant mortality rate reduction of 45% from levels projected without child-resistant packaging requirements. In 1997, the Federal Register, FDA in the United States introduced unit-dose packaging for iron-containing products with 30 milligrams or more of iron per dosage unit. FDA believed that the unit-dose packaging would increase the time and effort required to open the unit-dose and hence limit the number of tablets a child could swallow. In Britain since 1 January 1976 all aspirin and paracetamol dispensed for children had to be dispensed in Child Resistant Containers (CRCs). This was followed later (April 1976) by a voluntary agreement to dispense aspirin and paracetamol for adults in Child Resistant Containers (CRCs). This action resulted from 2nd March 1981 in all members of the pharmaceutical profession agreeing that all prescribed medicines would be dispensed in CRCs unless requested in an ordinary container.

Child resistant packaging includes both non-recloseable and recloseable packaging. Non-recloseable packaging generally contains a single tablet in either aluminium foil (strip packaging) or opaque/clear laminated plastic (blister packaging). Recloseable packaging involves a container fitted with a recloseable top, or a child safety cap such as the Palm-n-Turn or Clic-Loc variety.

## CONCLUSION

Child-resistant packaging reduces child mortality from the unintentional ingestion of oral prescription drugs. If the child resistant packaging will be used in an effective



manner, then definitely, we can save many lives of children. So, each & every manufacturer & company should consider necessity of child resistant packaging of medicinal products.

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