

# SaferConcepts

## Child-Resistant Packaging

Stephen Karabatsos

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## FOREWARD

The purpose of this testing is to assess the efficacy of Safer Concepts' Patented Child-Resistant Packaging based on the specific criteria recommended by Kidsafe and Standards Australia for the sole purpose of meeting and or exceeding Kidsafe and Standards Australia requirements for Child-resistant packaging prior to implementing Patented design within marketplace.

For the testing of the Patented Child-resistant packaging, it will be noted that although Standards Australia criteria required a child panel of children aged 42 to 51 months, the children in the child panel were aged 24 to 66 months. This age group is at an even higher end of age range at which it is deemed that child poisoning is most common. This was undertaken to ensure a greater challenge to the packaging with children most likely to have dexterity to succeed.

Extensive discussions that were undertaken between designers and prototype manufacturers during the design and development stage of the proposed child-resistant packaging to ensure exacting tolerances, design and specifications were adhered to to provide a suitable working prototype to the respective panel of children. It must also be noted that the prototype, although to exacting standards, is of an inferior grade, strength and quality to the final product anticipated for market applications.

As referenced in Standard Australia, it should be noted that 'child-resistant' is not synonymous with 'child-proof'. The aim of Safer Concepts' Child-resistant packaging is to delay access in the protection of children against accidental poisoning and burns. It is also necessary to highlight that other precautions should be taken by parents, legislators, educators and marketeers to ensure that dangerous products such as pharmaceuticals and matches are kept beyond the reach of children.

It was understood prior to testing that the Standard required that the panel of children be given the specified packages to open and that the criteria for complying with the Standard was expressed in terms of the minimum number of children who will successfully open the package.

## **SECTION 1 SCOPE AND GENERAL REQUIREMENTS**

### **1.1 SCOPE**

The testing undertaken is specific to the Standard which specifies requirements for reclosable (containers with closures) and non-reclosable packages, designated as being resistant to opening by children. It is intended to be particularly applicable to the packaging of chemicals, e.g. poisons, including medicines and toxic substances, where child-resistant packaging is required.

### **1.2 REFERENCED DOCUMENT**

The document below is referred to in this report.  
Standards Australia- Australian Standard Child-resistant packages.

### **1.3 DEFINITIONS**

For the purpose of this report, the definitions below apply.

#### **1.3.1 Blister**

A package in which one or more dosage units are enclosed between a pre-formed tray with individual pockets and a lidding material which may be flat or shaped. The dosage units can only be extracted singly. The material of the tray is usually different from that of the lid.

#### **1.3.2 Placebo**

An inert substitute for the product it is to simulate.

#### **1.3.3 Reclosable package (system)**

A form of container with closure which, once opened, can be reclosed to its original form.

### **1.4 MATERIALS**

The materials used in the fabrication of the components of the Patented Child-resistant packaging were non-toxic and retained the properties that ensure the child-resistant characteristics of the child-resistant package.

### **1.5 FREEDOM FROM DEFECTS**

The components of the package were manufactured in accordance with nominated tolerances and were free from defects which may have significantly affected the safety and performance of the package.

## 1.6 MARKING

It must be noted that the container and closure of the reclosable packages were identifiable by means of written instructions for testing purposes. Final identification marks will be incorporated into tooling during manufacturing process to encapsulate Standards Australia criteria for markings.

## 1.7 PACKING

The Patented Child-resistant packaging does not bear any resemblance to any item manufactured as a toy. Design considerations were taken into account inclusive of shape and colour, to avoid features that may attract the attention of children.

The package -

- (a) Is of design which does not require sight, unusual strength or unusual dexterity to obtain access to the contents and to re-engage the feature;
- (b) Retains its child-resistant properties for the expected life of the product; and
- (c) Is sufficiently strong to withstand the usual risks of transport, handling and storage.

**NOTE:** Safer Concepts has made note that the final product will be made of either a Polypropylene or ABS material that provides greater strength, durability and ease of operation. It is claimed that the package design can be manufactured to withstand varying cycles of operation to retain its child-resistant properties for the expected life of the product.

## **SECTION 2 REQUIREMENTS FOR RECLOSABLE PACKAGES**

### **2.1 DESIGN IN RELATION TO WADS OR LINERS**

It must be noted that the Patented Child-resistant packaging is designed to encompass blister packs consistent with pharmaceutical and complementary medicines. It is designed to be a stand-alone product to accommodate blister packs and matches or as a complimentary product to encompass the abovementioned products and their current packaging.

### **2.2 PERFORMANCE TESTS FOR RESISTANCE TO OPENING**

#### **2.2.1 Test requirements**

Each test was conducted using only one combination of closure and container. Reclosable packages were subjected to opening tests by panel of children, constituted in accordance with Appendix A of the Australian Standard for Child-resistant packages.

#### **2.2.2 Acceptance Criteria**

##### **2.2.2.1 Testing by panel of children**

The criteria was in accordance with the Reduced Panel-Sequential Testing, Appendix B4, that requires a minimum of forty (40) children be tested. The package complied with the criteria required by Standards Australia as appropriate, according to the number of children who gained access to the placebo(s)-following as appropriate.

- (i) Before demonstration; and
- (ii) After demonstration.

## **SECTION 3 RECORDING OF RESULTS**

### **3.1 SAMPLE DEFICIENCIES**

At the time of testing there were no known deficiencies with product samples that would have adversely affected its operation during testing.

### **3.2 TESTING**

Testing was undertaken by Associate Lecturer Stephen Karabatsos from Latrobe University.

### **3.3 TEST COMPLETION DATES**

Testing commenced on Wednesday 2<sup>nd</sup> October and was completed on Friday 4<sup>th</sup> October.

### **3.4 INSTITUTIONS DETAILS**

The following educational institutions assisted in the testing process.

- i. Erasmus School- 40 Lisson Grove, Hawthorn, Victoria.
- ii. Peninsula Childcare Centre-1141-1143 Frankston-Dandenong Rd, Carrum Downs, Victoria.

### **3.5 MANUFACTURING DETAILS**

RPM SOLUTIONS S.A.

Ph: 08 8340 8344

### **3.6 TEST PERSONNEL**

The following person(s) were present as either test personnel or observers during the course of testing:

- i. Mr Stephen Karabatsos
- ii. Mr Raja Lingham
- iii. Mr Ralph Mason
- iv. Mr Nick Katsis
- v. Ms Suzanne El-Katateny
- vi. Mrs Helen Nichol
- vii. Mrs Gwen Morrish

### **3.7 PRODUCT DESCRIPTION**

The samples of product tested were of a rectangular box design encompassing an inner and outer section with the following dimensions:

- i. 70mm x 55mm
- ii. 127mm x 58mm
- iii. 105mm x 89mm

## **CONCLUSION**

After extensive testing which encompassed fifty (50) children, it was evident that Safer Concepts' Child-resistant packaging was comprehensively beyond the dexterity and strength of kindergarten and early primary-aged children. The test validated claims made by Safer Concepts in relation to the efficacy of their product.

The most obvious observation made during testing was the onset of boredom at an early stage after initial contact with the stated product. The inability to open the stated product discouraged children from continued operation of item. The products was subsequently used as building blocks by children aged 2-3.

Furthermore, the product was successful with children aged beyond Standards Australia requirements. The results offered, visibly illustrate the effectiveness of the product even though the samples were of inferior quality to final product.

Subsequently, I find it categorically difficult to disprove Safer Concepts' claims in relation to their product as a result of the 100% success rate that was evident to all those present during testing. Further clarification in relation to the extent of Safer Concepts' product can be sought by contacting me direct on 0439853393. I would be more than happy to discuss all particulars in relation to all facets of the testing process.

Stephen Karabatsos  
BA (Hons),  
Grad Dips Lib & Info Studies, Educ, Comp.Ed,  
M of I.T. in Educ. (AALIA)

# **APPENDIX A**

## **CONSTITUTION OF TEST PANELS**

(Normative)

### **A1 SCOPE**

This Appendix sets out requirements for the constitution of child and adult test panels.

### **A2 GENERAL**

Test panel shall consist of children or adults who are free from obvious visual, mental or physical infirmities which could affect the outcome of the test.

Children perform differently when the packages are presented to them in the presence of their parents. Involvement of parents introduces a bias, as children tend to perform in accordance with implicit or explicit parental expectations. It is important, therefore, to avoid parental influence where possible.

children should be selected so as to be, as far as reasonably possible, representative of children in the population as a whole. They should therefore not be all from the same kindergarten or all from a select group. It is preferable that they be drawn from several districts.

adults should be, as far as possible, representative of the population as a whole and of the age range 18 years to 65 years. They shall all be healthy with no evident physical or mental handicap associated with manual dexterity.

### **A3 CHILDREN**

#### **A 3.1 General**

Children shall not have taken part in more than one previous test, and then only on a package of a different type having an opening arrangement based on a different principle. The panel shall consist of an even distribution of age and sex. As far as practicable, the children shall represent the social, ethnic and cultural origins of Australia as a whole.

#### **A3.2 Complete Panel**

The panel shall consist of 200 children between the ages of 42 months and 51 months, inclusive.

#### **A3.3 Reduced Panel**

The criteria was in accordance with Item (b) as appropriate.

- (b) *Reduced panel- Sequential test* A minimum of 36 adults shall be tested. Packages shall comply with (or fail) the criteria shown in Columns 3 and 5 of Tables 2.3 according to the number of children, shown in Column 1, who gained access to the placebo(s) and who re-engaged the child-resistant feature following the instructions supplied.

## **APPENDIX B PROCEDURES FOR TESTING BY CHILDREN (Normative)**

### **B1 SCOPE**

This Appendix sets out the procedure to be followed when the testing of child-resistant packaging is to be carried out by panels of children.

### **B2 GENERAL**

Children shall perform the tests in any area with which they are familiar, e.g. in their customary school or kindergarten and in any attitude or position they find convenient, but removed from general student body in the test location and protected from extraneous distractions. Assistance shall be limited to leading children back to their positions should the children wander off from their places during the test period.

The test panels need not necessarily complete the test in any one place, at any one time. However, children should be seated in two's up to five pairs of children being taken into a familiar room within the test location with the person(s) supervising the test.

**WARNING: ETHICAL ASPECTS ARISING FROM THE TESTING OF CHILD-RESISTANT PACKAGES WITH CHILDREN SHOULD BE TAKEN INTO ACCOUNT, AND PARENTAL APPROVAL/IDEMNITY BY THE PERSON OR ORGANISATION CONDUCTING THE TESTS IS RECOMMENDED. FOR GUIDANCE, REFERENCE SHOULD BE MADE TO ICH GUIDELINES FOR GOOD CLINICAL PRACTICE.**

### **B3 CONDUCT OF TEST**

#### **B3.1 Preparation of samples for test**

Sufficient packages shall be supplied to enable a representative sample to be selected for testing by the supervisor, and to provide a reserve for reference purposes. In every test, a new package shall be provided for each member of the test group.

Before child testing is carried out on reclosable child-resistant packages, both manufacturers and fillers shall satisfy themselves that the life expectancy of the child-resistant package will exceed the maximum expected number of openings and closings which are likely to occur in practice without unacceptable impairment of the child-resistant property.

The test supervisor shall ensure that prior to testing at least ten unit placebos, or an appropriate volume of solid or liquid placebo not exceeding 100g, has been placed into each of the prepared packages and shall ensure that they are effectively closed in the manner specified by the manufacturer or supplier. Where the closure is applied by a turning action, the closure shall be turned sufficiently to engage the child-resistant feature.

Before packages are tested, each package should be opened and properly closed. Packages, which incorporate a tamper-evident feature in addition to being child-resistant, shall have the feature disabled; they shall be opened and checked by the test supervisor as specified above prior to the child test.. Any deficiencies in the packages shall be recorded and reported.

### **B3.2 Test Panel**

The test shall be carried out, either using the complete panel of children (as described in Clause 2.3.2.1 (a)) or as a sequential test using the reduced panel (as described in Clause 2.3.2.1(b)).

### **B3.3 Procedure**

One consumer package, prepared in accordance with Paragraph b3.1, shall be given to each child with the request that it be opened. No additional instructions shall be given concerning the opening of the package. No attempt shall be made to stop a child using teeth, or any other means to open the package. However, no tools or implements should be accessible which could be used by a child to gain access, except where specifically supplied or recommended as part of the design of the child-resistant package. Where this is so, the children shall have unobtrusive access to that tool, but it shall not be drawn to their attention unless it is used in the demonstration.

Where a child succeeds in opening the package, that child is dismissed from the area. Where a child is unable to open the package in 5 min, the package shall be opened and reclosed once by the supervisor in full sight, without undue exaggeration of the mechanical actions required, and without oral instruction. This child shall then be given a further 5 min in which to open the package.

**NOTE:** It is recommended that, at the end of the test period, the tester should say, 'Thank you for helping'. If any of the children used their teeth, the tester should say, 'I know you used your teeth today, but you should not put things like this in your mouth again'. In addition, the tester should say, 'Never play with or touch packages like this. This kind of package might have something in it that would make you sick.'

### **B3.4 Recording of results**

The test results shall include the following information:

Any deficiencies in the preparation of samples for the test panels.

The name and location of the person or organisation responsible for conducting the test.

The dates the test was conducted and completed.

The name and location of the manufacturer or supplier (or both) of the child-resistant package tested.

The names of the test personnel and names of affiliation of any observers present in the area during the test.

A complete description of the components of the package, including component dimensions which fully identify the child-resistant package tested.

A direct quotation of all instructions given to children at the time of the test.

Any instructions on opening and closing of the package given to the test supervisor by the manufacturer or supplier.

The sequential number, name, age in months and sex of each who participated in the test.

The number and percentage of children able to open the container-

(i) before receiving demonstration;

(ii) after receiving demonstration.

The means used by the children who were successful in opening the package-

(iii) without having received a demonstration;

(iv) after having received a demonstration.

Any further observations which may assist in the interpretation of the test.

#### **B4 REPORT**

The report shall include the following information;

Whether a complete panel or reduced panel was used.

A record of the test results (see Paragraph B3.4).

Any deficiencies in the preparation of samples for the test panels.

A conclusion as to compliance or failure of the package.

A reference to this test method, i.e. AS 1928, Appendix B.





*Peninsula Childcare Centre*  
1141/1143 Frankston-Dandenong Road  
Carrum Downs Vic 3802  
Phone: 8787 7000  
Fax: 8787 7077  
E-mail:peninsulchildcare@ozemail.com.au



# Peninsula Childcare Centre

Tuesday 08<sup>th</sup> October, 2005

Mr Stephen Karabatsos

Dear Sir/Madam,

This letter confirms the attendance of Associate Lecturer Stephen Karabatsos and his colleagues at Peninsula Childcare Centre, situated at 1141-1143 Frankston-Dandenong Rd, Carrum Downs, Victoria, on Friday 04<sup>th</sup> October.

During this visit, Mr Karabatsos and his colleagues conducted controlled trials of the 'Safer Concepts' Patented Child-Resistant Packaging with children between the ages of 2-4 years. The trials were of approximately 1.5 hours in duration.

Of the 31 children offered the child resistant packaging, none were able to remove the packaging, and a 100% success rate was observed by Centre staff in attendance during the trials.

The trials were conducted in a controlled environment, under the careful supervision of both Mr Karabatsos, and his colleagues, and independent observers present, including the Centre Director, Ms Suzanne El-Katateny.

It was a pleasure to be a part of the trial and we wish Mr Karabatsos and his colleagues every success in this endeavour.

For further information on this visit or the trials, please do not hesitate to contact myself directly on (03) 87 87 7000.

Yours Sincerely,

Suzanne El Katateny  
Director

*Just Quality Care, No Surprises*

