

Australian Standard[®]

**Child-resistant packaging—
Requirements and testing procedures
for non-reclosable packages for non-
pharmaceutical products
(EN 862:2005, MOD)**

STANDARDS
Australia



This Australian Standard® was prepared by Committee HE-016, Child-Resistant Packaging. It was approved on behalf of the Council of Standards Australia on 10 September 2009. This Standard was published on 24 September 2009.

The following are represented on Committee HE-016:

- ACCORD Australasia
 - Australian Chamber of Commerce and Industry
 - Australian Institute of Packaging
 - Australian Paint Manufacturers' Federation
 - Australian Self Medication Industry
 - Commonwealth Department of Health and Ageing
 - Consumers' Federation of Australia
 - Department of Health and Human Services, Tas.
 - Department of Health, SA
 - Department of Human Services, Vic.
 - Griffith University
 - Packaging Council of Australia
 - Pharmaceutical Society of Australia
 - Queensland Injury Surveillance Unit
 - The Children's Hospital at Westmead
-

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PREFACE

This Standard was prepared by the Standards Australia Committee HE-016, Child-Resistant Packaging. Preparation of this Standard was commenced following requests from several state health departments that a Standard be prepared for non-reclosable, child-resistant packaging for non-pharmaceutical products such as dishwasher tablets and other household goods.

This Standard has been adopted with national modifications and has been reproduced from EN 862:2005, *Packaging—Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products*. EN 862:2005 has been varied as indicated to take account of Australian conditions.

Variations to EN 862:2005 for application in Australia are set out in Appendix ZZ.

As this Standard is reproduced from a European Standard, the following applies:

- (a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.
- (b) In the source text ‘this European Standard’ should read ‘this Australian Standard’.
- (c) A full point should be substituted for a comma when referring to a decimal marker.

References to international Standards should be replaced by references, where appropriate, to the following Australian Standards:

<i>Reference to European/International Standard</i>	<i>Australian Standard</i>
EN	AS
14375 Child-resistant non-reclosable packaging for pharmaceutical products—Requirements and testing	514 Child-resistant non-reclosable packaging for pharmaceutical products (in preparation)
EN/ISO	AS/NZS ISO
9001 Quality management systems—Requirements	9001 Quality management systems—Requirements
EN ISO/IEC	AS ISO/IEC
17025 General requirements for the competence of testing and calibration laboratories	17025 General requirements for the competence of testing and calibration laboratories

Only references that have been adopted as Australian Standards have been listed.

AUSTRALIAN FOREWORD

The purpose of this Standard is to provide a method for assessing the resistance of non-reclosable packaging that is intended to contain non-pharmaceutical products, to opening by children. It provides an objective basis for defining such packaging as 'child-resistant'.

This Standard applies to non-reclosable packages that immediately enclose a unit quantity of a substance that is intended to be used in its entirety upon opening the package. A product may have an external packaging that contains multiple, individually-packaged unit quantities within the external packaging. This Standard sets out criteria for testing the package that immediately contains the unit quantity, not the external packaging.

Child resistance criteria for packages that enclose larger quantities for use on more than one occasion, normally considered to be reclosable, are set out in AS 1928—2007, *Child-resistant packaging—Requirements and testing procedures for reclosable packages*. Products requiring reclosable child-resistant packaging should be packaged in accordance with AS 1928—2007.

It should be noted that the term 'child-resistant' is not synonymous with 'child-proof'. Child-resistant packaging is only the last in a series of protective measures, and does not release parents or guardians from their duty to keep hazardous products out of the reach of children. Child-resistant packages provide only the safeguard of delay in access in the protection of children against accidental poisoning. Other precautions need to be taken by parents, legislators, educators and marketers to ensure the safety of children when these products are kept.

The Committee recognizes that, while some forms of packaging, such as blister cards and sachets limit access to their contents, such packagings cannot be assumed to be child-resistant.

The Committee also notes that some forms of non-reclosable packages such as blister cards that contain confectionery, toys or food, are deliberately designed to attract the attention of children. Similarities in appearance between such products and hazardous products packaged in a similar way can have the unintended consequence of encouraging children to access these hazardous products. The use of, or presentation of, child-resistant packaging such that it resembles or contains confectionery, toys or food items is discouraged.

In preparing this Standard, the Committee considered various international and regional standards that apply to child-resistant packaging and agreed that alignment with EN 862:2005 was the preferred option for non-reclosable child-resistant packages for non-pharmaceutical products.

The age range for children in the child panel is 42 to 51 months. This is at the high end of the age range at which child poisoning is most common, so as to challenge the packaging with children most likely to have the ability to understand the instructions given in the test and the dexterity to succeed in opening the package. It is internationally recognized that this age range provides the best compromise between the at-risk age group and the practicalities of administering the test.

The Committee noted that the adult test set out in EN 862:2005 is optional but its inclusion in the testing program is encouraged. Where the adult test is to be conducted, it should be carried out before the child test in order to minimize the exposure of children to unnecessary testing.

The age range for adults is 50 to 70 years, to reflect the age group that may have difficulties in opening child-resistant packages. While this group is not intended to represent the population as a whole, it covers adults who can read the instructions and would be expected to implement them with a high likelihood of success.

It is recognized that aged persons or those with disabilities may have problems in opening some packages that comply with this Standard. Designers of such packaging should consider this when designing the package and preparing instructions for opening the packaging.

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INTRODUCTION

Child-resistant packaging is used to create a physical barrier between a child and a potentially hazardous product. Various types of packaging are recognized as being child-resistant, based on performance testing against standards for specific product categories and packaging types.

Since this type of packaging was introduced, the incidence of accidental ingestion of potentially hazardous products by children under 5 years old has fallen. The degree to which this is due to the use of child-resistant packaging as opposed to other factors, such as greater public awareness of the hazards, is not easily assessed, but there is little doubt that this packaging has made a positive contribution to the reduction.

The use of child-resistant packaging needs to be confined to those products that are potentially hazardous, or for which any legislation makes its use mandatory, since, if used in other circumstances, there could be confusion over the degree of hazard posed by the product.

In any case, proper labelling and information by the manufacturer is important for the safe use of the product in the home.

Child-resistant packaging acts as the last line of defence if other barriers separating the child and hazardous product have failed. However, it has to be recognized that it is unrealistic to expect that any functional packaging can be totally impossible for a child of 42 to 51 months inclusive to open and that child-resistant packaging cannot be a substitute for other safety precautions.

There has been an increasing use of child-resistant packaging, therefore it is desirable to achieve agreement on testing procedures in order to avoid confusion and misunderstanding in an area of great importance to the safety of young children.

This standard aims to reduce the number of children "exposed to training" during panel testing. Since the introduction of performance testing much has been learned about the use of children for testing child-resistant packaging and attention has been focused on how the number of children involved may be reduced. Future development of standards based on mechanical test methods is required to avoid unnecessary child panel testing and is essential in developing physical package attributes useable by manufacturers.

Child-resistant packaging is only the last in a series of protective measures, and does not release parents or guardians from their duty to keep potentially dangerous products out of the reach of children.

The on-going development of non-reclosable packaging offers a significant area for innovation in packaging. The styles of non-reclosable packages can be wide-ranging in design.

Mechanical test methods may be used to generate test data for comparison and demonstration that the notified packaging is as safe as the original reference one. Mechanical tests are test methods generating data by destructive or non destructive tests of a specific reference package having shown child-resistant properties. Consequently, the development of mechanical test methods by manufacturers allied to current EN or national standards should be pursued as a means of reducing the reliance on child panel testing.

AUSTRALIAN STANDARD

Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products (EN 862:2005, MOD)

1 Scope

This European Standard specifies performance requirements and methods of test for non-reclosable packaging that has been designated child-resistant and which is intended to contain non-pharmaceutical products. This standard is intended for type approval only (2.5) and is not intended for quality assurance purposes.

This European Standard applies to non-reclosable packages of the single-use type consisting of one or more individual units.

Non-reclosable packages for pharmaceutical products are excluded from the scope of this standard. These are the subject of a separate standard, EN 14375 *Child-resistant non-reclosable packaging for pharmaceutical products - Requirements and testing*.

2 Terms and definitions

For the purposes of this European standard, the following terms and definitions apply.

2.1

child-resistant package

package which is difficult for young children to open (or gain access to the contents), but which it is possible for adults to use properly

2.2

non-reclosable child-resistant package

child-resistant package or part of a child-resistant package which, when all or part of the contents have been removed, cannot be properly closed again

2.3

substitute product

inert substitute resembling the product it replaces, i.e. powder, tablets or liquids (uncoloured water), etc.

2.4

unit

discrete quantity of any product to be removed from its immediate packaging in its entirety

2.5

type approval

procedure to certify as child-resistant a specific type of non-reclosable package, formed from a specified set of materials, which has met the requirements of this standard

2.6

single use package

package of one or several units which are not only individually protected but also individually packed for single use

3 Requirements

3.1 General requirements

A non-reclosable child-resistant package, when tested in accordance with the requirements of this standard, shall be capable of providing a satisfactory degree of resistance to opening by children (3.2.1). Accessibility to its contents by adults can be checked according to the optional adult test (3.2.2).