

Australian Standard[®]

**Child-resistant packaging—
Requirements and testing procedures
for non-reclosable packages for
pharmaceutical products
(EN 14375:2003, MOD)**



This Australian Standard® was prepared by Committee HE-016, Child-Resistant Packaging. It was approved on behalf of the Council of Standards Australia on 4 June 2010. This Standard was published on 28 June 2010.

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
 - Consumers' Federation of Australia
 - Department of Health and Human Services, Tas.
 - Department of Health, SA
 - Department of Health, Vic.
 - Griffith University
 - Pharmaceutical Society of Australia
 - Queensland Injury Surveillance Unit
 - The Children's Hospital at Westmead
 - Therapeutic Goods Administration
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This Standard was issued in draft form for comment as DR AS 5014.

Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

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First published as AS 5014—2010.

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Published by Standards Australia GPO Box 476, Sydney, NSW 2001, Australia

ISBN 978 0 7337 9625 8

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 pharmaceutical products.

This Standard has been adopted with national modifications and has been reproduced from EN 14375:2003, *Child-resistant non-reclosable packaging for pharmaceutical products—Requirements and testing* and its Corrigendum 1 (2006), which is incorporated in the source text.

Variations to EN 14375:2003 and EN 14375:2003/Cor.1:2006 for application in Australia are set out in Appendix ZZ. A rationale for the variations is given in the Australian Foreword.

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 862	AS 5808
Packaging—Child-resistant packaging— Requirements and testing procedures for non-reclosable packages for non- pharmaceutical products	Child-resistant packaging— Requirements and testing procedures for non-reclosable packages for non- pharmaceutical products
EN/ISO 9001	AS/NZS ISO 9001
Quality management systems— Requirements	Quality management systems— Requirements
EN ISO/IEC 17025	AS ISO/IEC 17025
General requirements for the competence of testing and calibration laboratories	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 of assessing the resistance to opening by children of non-reclosable packaging that is intended to contain pharmaceutical products. It provides an objective test for defining such packaging as ‘child-resistant’.

This Standard applies to non-reclosable packages that immediately enclose one or more unit doses of a pharmaceutical substance, each of which is individually sealed and can only be extracted individually. A product may have an external packaging that contains these multiple, individually-packaged unit doses, which may be joined (e.g. blister and strip packaging) or separate (e.g. sachets). This Standard sets out a test method for testing the packaging that immediately encloses the unit doses, not the external packaging.

Child resistance criteria for packages that enclose multiple dosage units intended for consumption on more than one occasion, where the dosage units are not individually sealed (normally considered to be reclosable packages) 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 where these products are available.

The Committee recognizes that some forms of non-reclosable packaging, such as blister packs limit access to their contents, but such packagings cannot necessarily be assumed to be child-resistant.

The Committee also notes that some forms of non-reclosable packages such as blister cards that contain confectionary, 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, a child-resistant package such that it resembles packages that contain confectionery, toys or food items, is discouraged.

In preparing this edition of the Standard, the Committee considered various international and regional standards that apply to child-resistant packaging and agreed that alignment with EN 14375:2003 was the preferred option for non-reclosable child-resistant packages for pharmaceutical products. Australian variations to the European Standard are largely based upon the practicalities of testing in the Australian situation, with a smaller population and limited testing capabilities. A detailed study of EN 14375:2003 was made, resulting in the following significant Australian modifications being made to EN 14375:

- (a) The test methods given in EN 14375 have been adopted. The performance criteria of 8 unit doses specified in EN 14375 has been retained as a point at which testing is stopped and the package is deemed to have failed the child resistance test. Reporting requirements have been modified to provide for possible future development of graduated classifications in which the desired outcome is set to be less than 8 unit doses.
- (b) The EN requirements for a maximum number of adults to be tested at any one site or by any one supervisor have been removed.

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 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 packages that comply with the 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 child-resistant 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 child-resistant 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 should 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.

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.

This standard aims to minimize 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 can be reduced. Future development of standards based on mechanical test methods is needed 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 medicinal products out of the reach of children.

Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for pharmaceutical products (EN 14375:2003, MOD)

1 Scope

This European Standard specifies performance requirements and methods of test for non-reclosable packaging that have been designated child-resistant. This standard is intended for type approval only (see 3.5) and is not intended for quality assurance purposes.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN 862:2001 and the following apply.

3.1

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

3.2

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

3.3

substitute product

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

NOTE This is sometimes referred to as a placebo product.

3.4

unit dose

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

3.5

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

4 Requirements

4.1 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 (see 4.2.1) and a satisfactory level of accessibility to its contents by adults (see 4.2.2).