AS 1928—2007

Australian Standard®

# Child-resistant packaging—Requirements and testing procedures for reclosable packages (ISO 8317:2003, 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 11 September 2007.
This Standard was published on 31 October 2007.

---

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 Tasmania
- Department of Health, South Australia
- Department of Health Western Australia
- Department of Human Services (Victoria)
- Griffith University
- Queensland Injury Surveillance Unit
- Packaging Council of Australia
- Pharmaceutical Society of Australia
- Royal Children's Hospital, Melbourne
- The Children's Hospital at Westmead

---

This Standard was issued in draft form for comment as DR 07128.

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.

---

## Keeping Standards up-to-date

Australian Standards® are living documents that reflect progress in science, technology and systems. To maintain their currency, all Standards are periodically reviewed, and new editions are published. Between editions, amendments may be issued.

Standards may also be withdrawn. It is important that readers assure themselves they are using a current Standard, which should include any amendments that may have been published since the Standard was published.

Detailed information about Australian Standards, drafts, amendments and new projects can be found by visiting www.standards.org.au

Standards Australia welcomes suggestions for improvements, and encourages readers to notify us immediately of any apparent inaccuracies or ambiguities. Contact us via email at mail@standards.org.au, or write to Standards Australia, GPO Box 476, Sydney, NSW 2001.

---

Australian Standard®

# Child-resistant packaging—Requirements and testing procedures for reclosable packages (ISO 8317:2003, MOD)

Originated as AS 1928—1976.
Previous edition 2001.
Fourth edition 2007.



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

ISBN 0 7337 8448 8

# PREFACE

This Standard was prepared by Standards Australia Committee HE-016, Child-Resistant Packaging, to supersede (in part) AS 1928—2001, *Child-resistant packages*. This Standard has been adopted with national modifications and has been reproduced from ISO 8317:2003, *Child-resistant packaging—Requirements and testing procedures for reclosable packages* and its Technical Corrigendum 1 (2005), which is added after the source text. Text affected by the Corrigendum is indicated by a marginal bar.

Unlike AS 1928—2001, this edition does not include requirements for non-reclosable packaging. Until such time as a Standard giving requirements and testing procedures for non-reclosable packages is adopted in Australia, those aspects of AS 1928—2001 relating to non-reclosable packages remain in force.

Variations to ISO 8317:2003 and ISO 8317:2003/Cor.1:2005 for application in Australia are set out in Appendix ZZ and acceptance criteria are specified in Appendix ZA.

The objective of this revision is to align with the current ISO Standard for reclosable child-resistant packaging.

As this Standard is reproduced from an International Standard, the following apply:

(a) *Terminology* The words 'this Australian Standard' should replace the words 'this International Standard' wherever they appear.

(b) *Decimal comma* The decimal point should replace the decimal comma wherever it appears.

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

| *Reference to International Standard* | | *Australian Standard* | |
|---|---|---|---|
| ISO/IEC | | | |
| Guide 23 | Methods of indicating conformity with standards for third-party certification systems | HB 18.23 | Guidelines for third-party certification and accreditation<br>Guide 23—Methods of indicating conformity with standards for third-party certification systems |
| | | 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.

# CONTENTS

*Page*

## AUSTRALIAN FOREWORD

The purpose of this Standard is to provide a method of assessing the resistance of reclosable packaging to opening by children, and an objective basis for referring to packaging as 'child-resistant.'

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 kept.

The Committee recognizes that other forms of packaging, such as restrictive flow inserts, aerosols, and metered-dose sprays, limit access to their contents, but such packagings are not considered child-resistant.

In preparing this edition of the Standard, the Committee considered the various international and regional standards that apply to child-resistant packaging and agreed that alignment with ISO 8317 was preferred for reclosable child-resistant packages. Australian variations to the International Standard are largely based upon the practicalities of testing in the Australian situation, with a smaller population and limited testing capabilities. A detailed comparison of ISO 8317 and AS 1928—2001 was made, resulting in the following significant Australian modifications being made to ISO 8317:

(a) The allowance in AS 1928—2001 for sequential tests for both children and adults has been retained.

(b) The ISO criteria for a maximum number of persons to be tested at any one site has been removed.

(c) The ISO requirements for packages to be prepared by the test supervisor 72 h prior to their being tested have been removed.

(d) The smaller package size given in AS 1928—2001 (100 g versus 1 kg in ISO 8317) has been retained.

(e) The requirement of AS 1928—2001 that the package not resemble a toy or other item that could attract the attention of children has been retained.

(f) Requirements for the evaluation of a series of similar packages are now normative and are specified in the body of ISO 8317. Such evaluation was an informative appendix (Appendix D) in the 2000 edition of AS 1928.

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 has been raised from 18 to 65 years, to 50 to 70 years, to better reflect the age group that may experience 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. Older people may be perceived to be more likely to need help in opening such packages.

# INTRODUCTION

A significant number of suspected cases of ingestion by children of products used about the home is reported to the medical profession each year. Most are not serious and those that are associated with more serious side effects involve products known to be hazardous, e.g. certain medicinal products, liquid fuels and solvents, strongly acid or alkaline preparations and some garden products. Most commonly used household detergents, cleaning agents and maintenance and care products do not appear on the list of products which have caused injury. However, whether ingestion (actual or suspected) causes injuries or not, such incidents can have traumatic effects on both the child and its parents.

The use of potentially hazardous agents in certain products is necessary to achieve effectiveness; consequently, steps have to be taken to limit the occurrence of accidents. One approach has been to try to increase general awareness of hazards associated with various products; this approach has been used, but public education aimed to protect the child by educating the parent and other adults about correct storage practices, etc. has never been completely effective. Nevertheless, proper labelling and information by the manufacturer is important for the safe use of products in the home.

Another approach has been the use of child-resistant packaging to put a physical barrier between the child and the hazardous product. Such packaging should only be used for products as mentioned above since, if used in other circumstances, it could lead to confusion among consumers. It has to be recognized that it is unrealistic to expect that any functional packaging can be totally impossible for a child to open and that this type of packaging cannot be a substitute for normal safety precautions. The packaging functions as a last defence if other barriers separating children and hazardous products have failed.

Historically, the United States of America was the first country to introduce a standard method of testing based on the inability of 200 children of a specific age and sex distribution to open the package and the ability of 100 adults of a particular age and sex distribution to open and, where applicable, reclose the package properly. Since then, a number of other countries have introduced standard test methods based on similar principles. There are now around the world various types of packagings, which are recognized as child-resistant, based on a test of the nature described. There is evidence that, since these test methods were introduced, the incidence of ingestion by children of hazardous products has fallen. The degree to which this is due to the use of child-restraint packaging as against other factors, such as greater public awareness, is not easily assessed, but there is little doubt that child-resistant packaging has made a positive contribution.

Over the last decade, 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. So far, it has not been possible to achieve an objective set of tests and criteria which would render the use of children in subjective testing unnecessary, but work should be directed towards achieving this aim as a matter of some urgency.

Because of the increasing use of child-restraint packaging, it is desirable to achieve international agreement on testing procedures in order to avoid confusion and misunderstanding in an area of great importance to the safety of young children. An International Standard should also serve to reduce the number of children exposed to “training” during panel testing. However, it should not be supposed that the provision of a standard method for assessing child resistance is all that is needed either nationally or internationally. The test has to be administered by some responsible authority in each country adopting the International Standard, as all have to have confidence in the manner in which testing is carried. Thus common procedures should be adopted by all administering authorities covering such questions as:

— How is it decided that a child-resistant packaging is needed?

— How is the test to be authorized and carried out?

— How and by whom will the results be evaluated and recorded?

— What minimum qualifications are required of supervisors who carry out the procedure?

— How is it ensured that no child takes part in more than two tests, and then only on packagings that are significantly different?

Attention is drawn to the need to have adequate supervisory and accreditation bodies, and reference should be made to ISO/IEC Guide 23, *Methods of indicating conformity with standards for third-party certification systems,* and ISO/IEC 17025:1999, *General requirements for the competence of testing and calibration laboratories,* which provide useful guidance on these topics.

This International Standard has been prepared to specify requirements and testing procedures for child-resistant packaging intended for potentially harmful products; it has been written as the best consensus which can be achieved at present and should be reviewed more frequently than other International Standards and revised in the light of experience.

NOTE 1 This International Standard refers only to accessibility to the contents of the package. Attention is drawn to the need, when designing a child-resistant package, to give consideration to possible dangers linked to the risk of spillage, which can happen unexpectedly when opening or trying to open the package.

NOTE 2 Studies are at present being carried out to determine whether it is feasible to develop an International Standard for non-reclosable packages and other International Standards may be published in future detailing mechanical methods which may be suitable for regulatory and quality assurance purposes.

The rationale for the proposed amendments to ISO 8317:1989 is as follows.

The publication and adoption of ISO 8317:1989 has resulted in a wider use of reclosable child-resistant packaging, which has enforced a growing awareness that the elderly and physically handicapped have difficulty in opening this style of packaging.

This, on occasion, can result in the child-resistant closure not being properly reapplied. The US Consumer Product Safety Commission (CPSC) has also recognized this concern and, in 1996, introduced amendments to their adult test protocol.

ISO/TC 122/SC 3/WG 3, when reviewing ISO 8317:1989, considered that certain aspects of the changes made by the CPSC to its protocol were worthy of incorporation into ISO 8317:1989, principally to adopt the older age range of adults forming the test panel and the method of the test.

ISO/TC 122/SC 3/WG 3 do not see these changes invalidating the classification of packages certified as child-resistant under the previous International Standard for the child panel test, but, as the main purpose of the adult test was to prove that adults could resecure the closure properly, the revised adult test protocol will require repeating to reaffirm full child-resistant status of the package.

During the review, the opportunity was taken to incorporate Annexes A, B and C, together with the amendment, into the main body of the document.

AUSTRALIAN STANDARD

# Child-resistant packaging — Requirements and testing procedures for reclosable packages

## 1 Scope

This International Standard specifies the requirements and test methods for reclosable packages designated as resistant to opening by children.

Acceptance criteria are given for the package when tested by specified methods. These methods not only provide a measure of the effectiveness of the package in restricting access by children, but also cover the accessibility to the contents by adults.

Reclosable packages for any product intended to be exposed or removed from the packaging in normal use are covered by the procedures.

This International Standard is intended for type approval only (see 3.1) and is not intended for quality assurance purposes.

## 2 Terms and definitions

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

**2.1**
**container**
vessel of glass, metal, plastic or a combination of materials designed to provide appropriate packaging for a product and having a neck finish suitable for the proper attachment of a closure

**2.2**
**closure**
cap or securing device of metal, plastic or a combination of materials designed to fit an appropriate container providing a secure seal against environmental challenges

**2.3**
**child-resistant package**
package consisting of a container and appropriate closure which is difficult for young children under the age of fifty-two months to open (or gain access to the contents), but which is not difficult for adults to use properly when tested and approved in accordance with the requirements of this International Standard

**2.4**
**reclosable package**
package which, after it has been initially opened, is capable of being reclosed with a similar degree of security and is capable of being used a sufficient number of times to dispense the total contents without loss of security

**2.5**
**substitute product**
inert substitute resembling the product it replaces

NOTE Solid substitute products for child-resistant packages normally consist of powder, granules or units of any similar shape and size, varying from 5 mm to 30 mm in any dimension, preferably of a neutral colour, and not harmful in any way. Liquid substitute product is always uncoloured water.