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

*Emballages à l'épreuve des enfants — Exigences et méthodes d'essai
pour emballages refermables*

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 8317 was prepared by Technical Committee ISO/TC 122, *Packaging*, Subcommittee SC 3, *Performance requirements and tests for means of packaging, packages and unit loads (as required by ISO/TC 122)*.

This second edition cancels and replaces the first edition (ISO 8317:1989), which has been technically revised.

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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?

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- 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. (standards.iteh.ai)

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. <https://standards.iteh.ai/catalog/standards/sist/79db361a-54ee-46f4-8f6c-25af0519d0de/iso-8317-2003>

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.

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.

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2 Terms and definitions (standards.iteh.ai)

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

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2.1 container <https://standards.iteh.ai/catalog/standards/sist/79db361a-54ee-46f4-8f6c-25af0519d0de/iso-8317-2003>

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.

3 General

3.1 Compliance with this International Standard

A child-resistant package tested in accordance with the requirements of this International Standard is shown to be capable, when correctly made and used, of providing a satisfactory degree of resistance to opening by children while maintaining accessibility to its contents by adults; in other words, the test is designed for type approval. Manufacturers and fillers of child-resistant packaging shall be required to identify the attributes of the packaging which confer resistance to opening by children of less than 52 months old and to devise and institute tests as part of an implemented and documented quality control procedure to ensure that all packages meet these child-resistance criteria. The type of testing required may be specific to the design of the child-resistant package, but the test parameters of various classifications of the Coleman Research Corporation (CRC) can be found in the American Society for Testing and Materials (ASTM) Standards Annual Volume 15.09 [1], which can be used as a basis for developing an appropriate protocol.

The data compiled from mechanical test methods can be used to prove compliance of a package falling within a “series of similar packaging”.

3.2 Packages for testing

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 correct closings which are likely to occur in practice without resulting in unacceptable impairment of the child-resistant property.

3.3 Test panels

Testing is carried out with two panels of people:

- a) a test with young children of between 42 months and 51 months old, inclusive;
- b) a test with adults of between 50 years and 70 years old, inclusive.

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4 Requirements

4.1 Test requirements

Whilst only new packages shall be submitted for testing, the following instructions for the evaluation of a series of similar packaging submitted at one time shall be applied; however the manufacturer and/or filler shall provide a rationale for the series which discloses the degree of commonality.

If a series of closures differs only in diameter, where the largest diameter exceeds the smallest by 1,5 times, then the largest and smallest diameter closures and one intermediate closure size shall be tested.

If the container of the packaging differs only in capacity and the closures are identical, tests shall be carried out only on the largest and smallest container sizes.

If the container of the packaging differs only in capacity and the closures differ only in diameter but are similar in all essential characteristics, the largest and smallest diameters of closure fitted to the largest and smallest container shall be tested, i.e. normally four container/closure combinations subject to the 1,5 times diameter rule above.

The container and closure system tested shall be representative of those in normal use and shall include any wad or liner, if this is an integral part of the closure system.

If all pass the test, containers and closures of intermediate sizes in the same series shall be regarded as conforming to this International Standard.

If several container shapes are involved, but all other characteristics are the same and the closures are identical or differ only in diameter, a selection from the range shall be made to test each body shape and to ensure that the minimum requirement of at least four container/closure combinations are tested.

If all pass the test, containers and closures of other sizes in the same series shall be regarded as complying with this International Standard.

If, after a range of packages has been tested and approved, sizes of packages outside the dimensions of the accepted range are to be added, they shall be tested to extend the range specified.

All other variations shall be treated as a separate series and tested accordingly. Minor changes of container or closure can be accommodated by the development and provision of mechanical test data showing compliance.

4.2 Safety requirements

A child-resistant package, in addition to satisfying the requirements for child resistance specified in 4.3, shall meet the requirements for packaging, such as being appropriate for the contents, providing mechanical protection and functioning properly for the life of the package.

4.3 Performance requirements

4.3.1 Requirements concerning children

4.3.1.1 Using a test panel of 200 children

When the packaging is tested in accordance with 5.4.3, the following requirements shall be met:

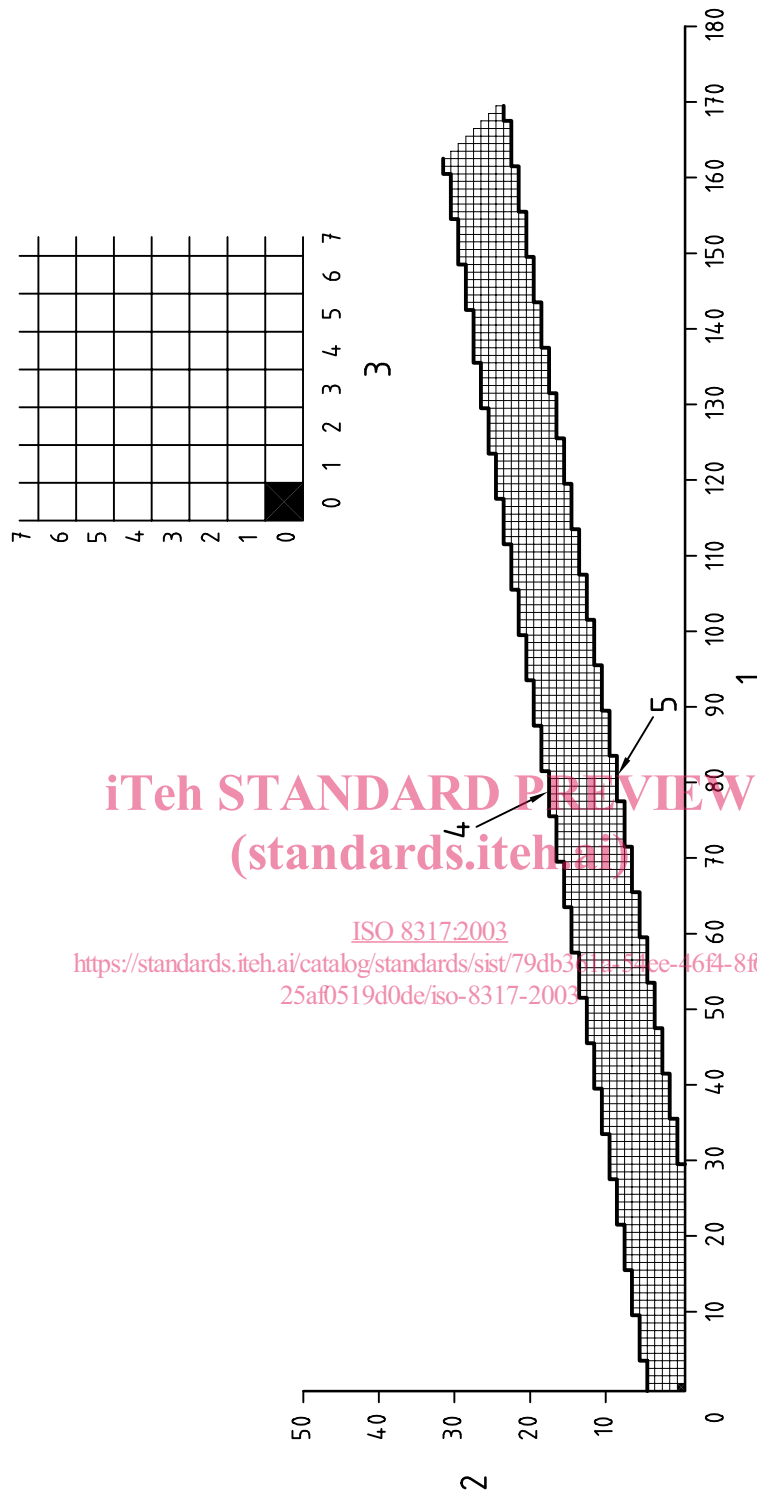
- a) at least 85 % of the 200 children in the test panel shall be unable to open the package within the first 5 min without a demonstration, and
- b) at least 80 % of the 200 children in the test panel shall be unable to open the package within another 5 min after a demonstration has been given to those children unable to open the package in the first 5 min.

4.3.1.2 Using the sequential test method

If less than the full test panel is used in accordance with 6.1.2, the result is obtained from completing Figure 1 and Figure 2.

4.3.2 Requirements concerning adults

When the packaging is tested in accordance with 5.5.2, 90 % of the eligible adults shall be able to open and properly reclose the packaging.

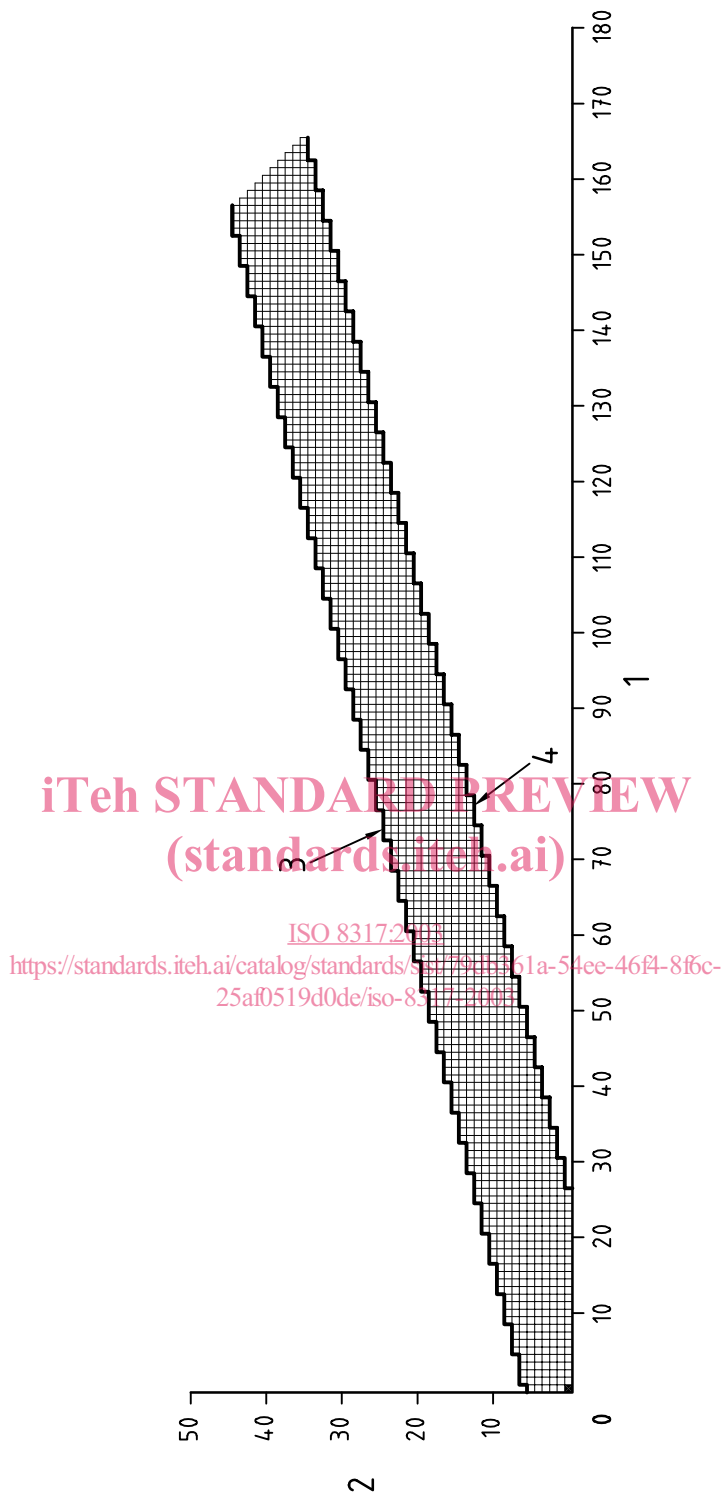


Key

- | | | | |
|---|-------------------------------|---|--------------|
| 1 | number of packages not opened | 4 | limit line 2 |
| 2 | number of packages opened | 5 | limit line 1 |
| 3 | enlargement of chart scale | | |

Acceptable quality limit (AQL) = 5 %; limiting quality (LQ): 20 %; $\alpha = \beta = 5 \%$, where α is the producer's risk; β is the consumer's risk.

Figure 1 — Chart of a sequential child test procedure (before demonstration) for child-resistant reclosable packages



Key

- | | | | |
|---|-------------------------------|---|--------------|
| 1 | number of packages not opened | 3 | limit line 2 |
| 2 | number of packages opened | 4 | limit line 1 |

Acceptable quality limit (AQL) = 5 %; limiting quality (LQ): 20 %; $\alpha = \beta = 5 \%$, where α is the producer's risk; β is the consumer's risk.

NOTE For an enlargement of the chart scale, see Figure 1.

Figure 2 — Chart of a sequential child test procedure (after demonstration) for child-resistant packages