INTERNATIONAL STANDARD

ISO 8317

Second edition
2003-04-15

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

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

Reference number
ISO 8317:2003(E)

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Published in Switzerland

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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.

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.

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.

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.

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 comforming 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

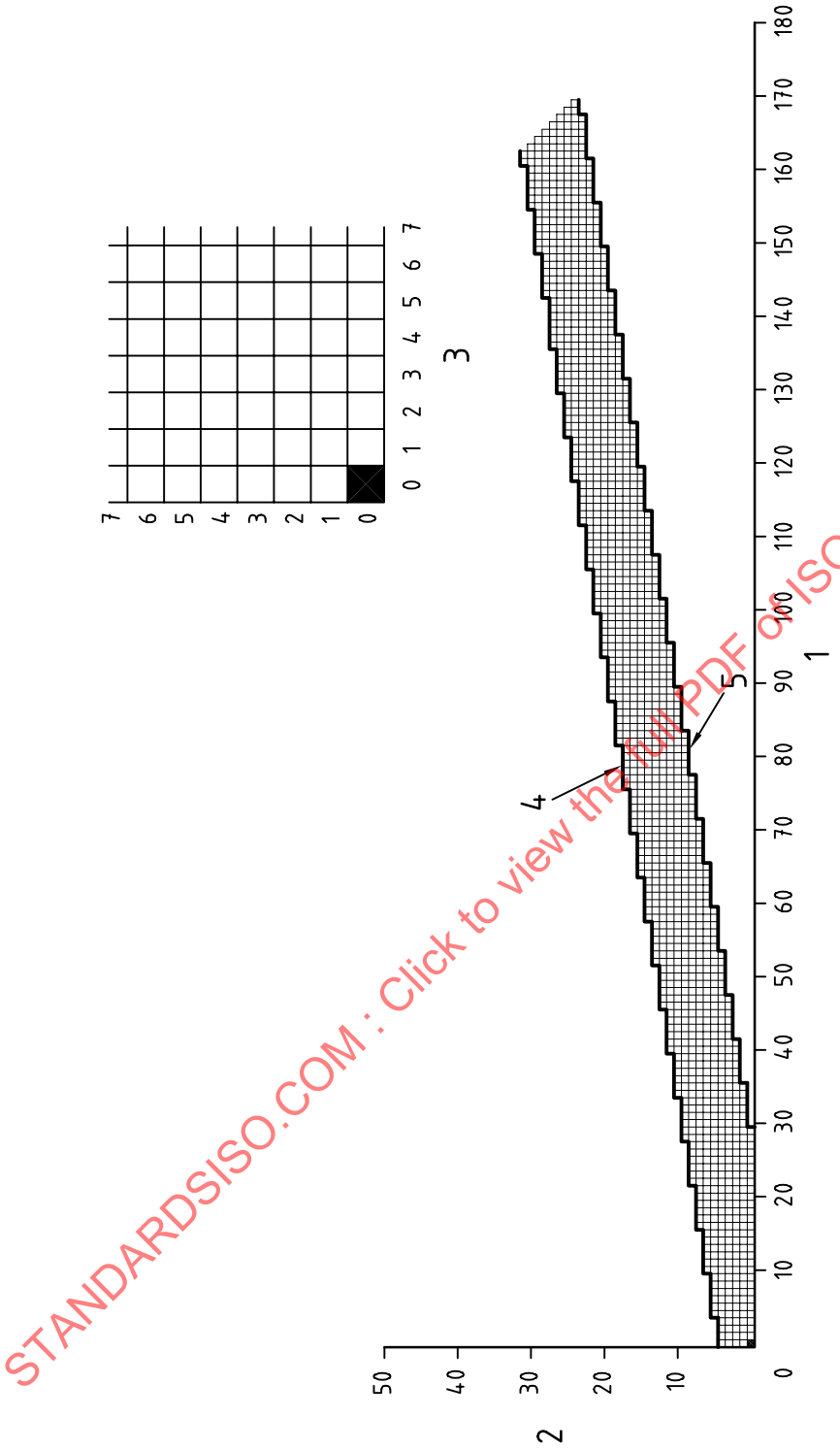
b) at least 80 % of the 200 children in the test panel shall be unable to open the package within another 5 min after a demonstration has been given to those children unable to open the package in the first 5 min.

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.

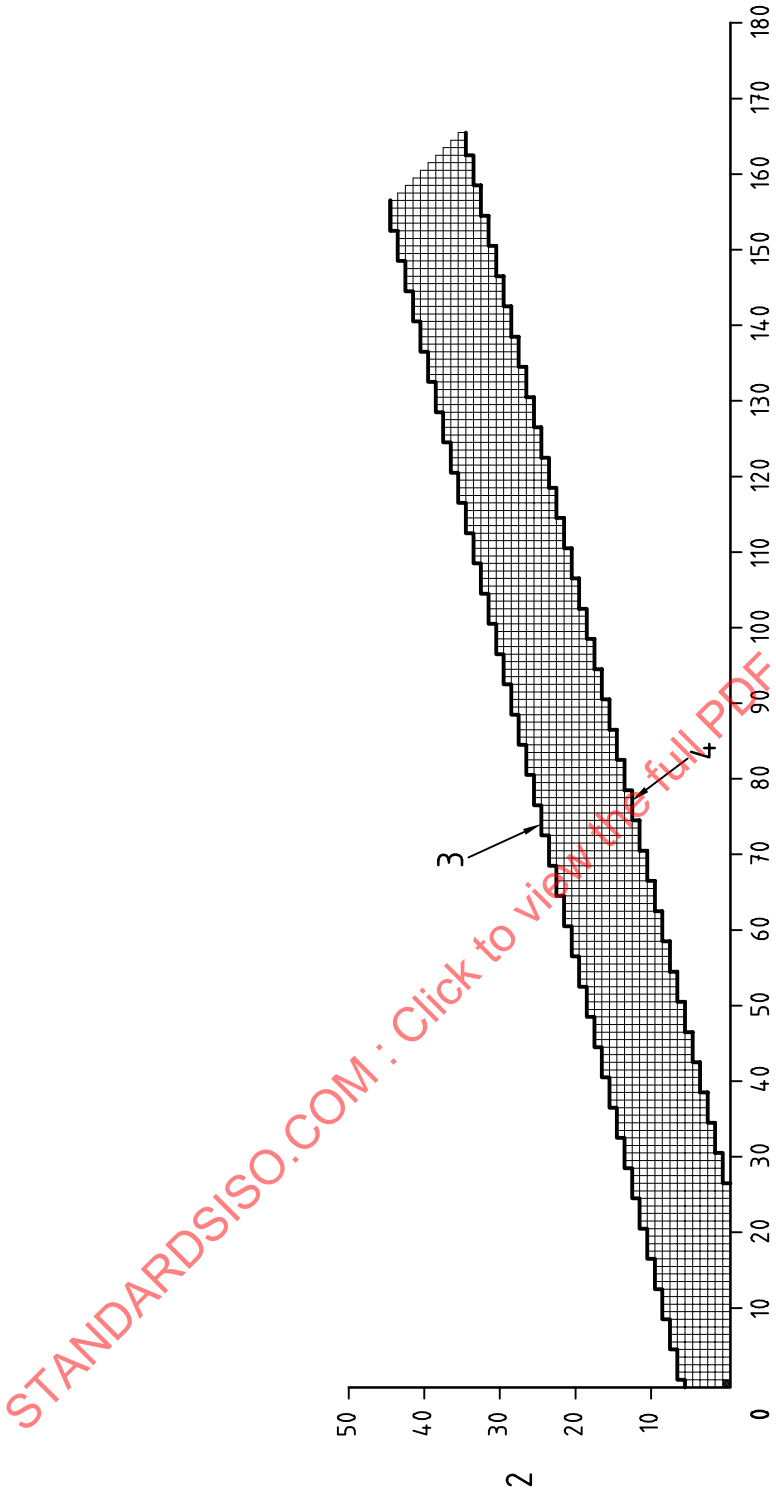


Key

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

5 Test procedures

5.1 Test supervision

All procedures shall be carried out under the supervision of (an) impartial and appropriately qualified person(s). For the child test, the supervisor(s) shall also be skilled in handling children.

5.2 Sample packages

Sufficient packages shall be supplied conforming to the container and closure drawings and specifications 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.

5.3 Preliminary checking and preparation

Before packages are tested, each package shall be opened and properly reclosed.

Packages which incorporate an exterior tamper-evident seal in addition to being child-resistant shall have the seal broken; they shall be opened and checked by the test supervisor(s) as specified in the previous paragraph, prior to the tests.

No hazardous product shall be used to fill any package submitted for test. A suitable substitute product shall be used for both the adult and child tests. When a substitute product is used, packages up to a volume of 1 l shall be filled to their nominal size capacity (i.e. as sold); packages greater than 1 l volume shall be filled with 1 kg of solid or 1 l of liquid substitute product as appropriate. The rationale for limiting the amount of substitute product to 1 kg of solid or 1 l of liquid is that such contents provide adequate weight to the container without causing it to become too heavy for the test panel child to be able to lift or manipulate it during the test period.

If the closure system used on the package to be tested is torque dependant, then the packs shall be assembled by the test supervisor by hand and left for 72 h at room temperature prior to conducting tests. This is to allow materials (e.g. closure/liner/wad) to take "a set". Application torque should be recorded in the test report. Once the packagings have been prepared for testing they should be handled carefully.

5.4 Child test

5.4.1 Guidance for persons supervising tests

5.4.1.1 Surroundings and personnel

The surroundings and personnel should be familiar and friendly.

5.4.1.2 Presence of parents

Children perform differently when the package is 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 by excluding them from the test area.

5.4.1.3 Presence of official observer

If required by the regulatory body, an official observer may be present but the requirements of 5.4.1.1 still apply.

5.4.1.4 Social circumstances of the children

There is a highly significant correlation between the success rate in opening packagings and the social class of children. Children should be selected to represent as closely as possible the different social, ethnic and cultural origins of the population of the country, not just of the immediate district in which the test is conducted. If this is not possible, any clear-cut deviation from this method of selection should be noted.

5.4.1.5 Avoidance of extraneous distractions

During the test, children should be removed from the general student body in the test location and protected from extraneous distractions.

5.4.1.6 Seating the children

The children should be seated in pairs at tables or desks arranged in a familiar manner, or they may sit on the floor if they wish.

5.4.2 Composition of test group

Enough children to ensure 200 valid participants between the ages of 42 months and 51 months inclusive, with an even distribution of age and sex, shall be available. They shall all be healthy with no evident physical handicap which may affect manual dexterity. They shall not have taken part in more than one previous test and, in that test, a packaging of a different type with opening arrangements based on a different principle shall have been involved. If a child is used on more than one test panel, it is desirable that there should be at least one week between the tests.

It is preferable for only one test to be carried out in one testing session, because there may be a statistically significant difference in the results between the first and second packaging tried.

5.4.3 Test location

The children shall perform the test in any place with which they are familiar or relaxed, for example, in their usual school or nursery, but they shall be removed from the general school population and separated from extraneous distractions. A minimum of three sites shall be used, selected from different demographic areas. No individual tester shall administer the test to more than 35 % of the children tested.

5.4.4 Procedure

The test may be carried out on all 200 children or by a sequential procedure. If the latter is used, the number of children tested will depend on the results obtained (see 6.1.2). When testing sequentially, the age and sex constraints specified in 5.4.2 shall be adhered to.

The children shall be tested in pairs, each pair being monitored by one supervisor. If desired, a number of pairs (up to five) may be tested in the same room at the same time, provided that arrangements are such that they cannot distract other pairs. They may adopt any attitude or position they find convenient. Should a child wander off during the test, action by the supervisor(s) shall be limited to leading the child back to its place and requesting that he or she continue the test, without any additional instruction being given concerning the opening of the package; this fact shall be included in the report.

Each child shall be given a package with the request that it be opened by whatever means the child wishes to use; in order to achieve this, 5 min shall be allowed. No attempt shall be made to stop a child using its teeth or any other method of opening the package. However, no tools or implements should be accessible which might be used by the child, except where such tools or devices are specifically supplied 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 until and unless it is used in the demonstration.

If a child succeeds in opening the package within 5 min, that child shall remain in the test area until the end of the period. Any child failing to open the packaging in 5 min shall then watch a package being opened and

reclosed by the supervisor in full view, without emphasis being placed on the actions of opening and without any verbal instruction. The child shall then have a further 5 min to open the package.

5.4.5 Expression of results (see also 6.1)

After each period of 5 min, it shall be recorded whether a child fails to open the package; if the child succeeds, it shall be recorded whether this was before or after a demonstration. It shall also be recorded whether teeth (or any other means) were used to open the package.

5.5 Adult test (50 years to 70 years old inclusive)

5.5.1 General

Unlike child testing, there is no need for the adults to be tested at any particular place or time.

5.5.2 Composition of test group

Enough adults shall be in the test group to ensure that 100 valid participants shall be available to conduct the test after screening, which is done by obtaining a negative answer to the following question:

"Are you professionally concerned with the design, manufacture or use of child-resistant packaging?"

In order to elicit this information and, at the same time, to ascertain that the individual is literate, it is possible to present the question on a typed (printed) form and give it to the person to read. Persons with obvious physical handicaps which may affect manual dexterity should not be approached and those unable to understand the instructions should be discounted.

The purpose of the test shall be explained in reasonable detail, but no demonstration shall be given.

The 100 valid participants shall be randomly selected between the ages of 50 and 70 according to the criteria given in Table 1. Not more than 30 of the adults tested shall be obtained from or tested at any one site. No individual tester shall administer the test to more than 35 adults.

Table 1 — Composition of the adult test group

Age range (years)	Male	Female	Total
50 to 54	8 or 7	17 or 18	25
55 to 59	7 or 8	18 or 17	25
60 to 70	15	35	50
Total	**30**	**70**	**100**

5.5.3 Procedure

The adult test panel consists of 100 panellists. Those panellists failing the screening test are discounted and their place taken by new panellists.

Each adult shall be given a package together with any accessories and written instructions on how to open and reclose it properly that will be printed in or on the package when supplied to a consumer.

No demonstration of how to open or reclose the package shall be given. Acting independently, a period of 5 min shall be allowed for the test participants to familiarize themselves with the package to be tested by reading the opening and closing instructions and attempting to open and reclose it properly.

If, in this period of 5 min, a panellist is unable to open the package being tested he or she will be given a screening test. This screening test shall consist of asking the panellist to open and reclose two conventional non-child-resistant closures in 1 min each, these being:

a) a 28 mm diameter continuous screw thread closure applied at 1,1 Nm torque onto a 25 ml to 50 ml cylindrical plastic container;

b) a 28 mm diameter “snap-on” closure applied to a 25 ml to 50 ml round plastic container.

Panellists unable to open or reclose both of these packages in the 1 min screening test are to be discounted from the adult panel results.

Panellists who are able to open both these packages are counted as a failure in the overall result.

Those panellists who successfully open the test package within the 5 min period shall be given a new identical package with a request to open and reclose this one as quickly as possible. A 1 min test period shall be allowed for the panellists to open and properly reclose the packaging.

5.5.4 Expression of results (see also 6.2)

Record whether or not the adult succeeds in opening and properly reclosing the package in the 1 min test periods, including the screening test if carried out, see 5.5.3 and 4.3.2.

6 Assessment of results

6.1 Child test

6.1.1 Success/failure

The result of the test is a failure if the child succeeds in opening the package (or gaining access to the contents).

6.1.2 Sequential method

6.1.2.1 Recording test results on a graph

As each result is obtained, it shall be plotted on the appropriate chart by filling in a square as follows:

— fill in a square immediately to the right of the previous result on Figure 1 if the test child failed to open the package (or gain access to the contents) in the first 5 min, and on Figure 2 if the test child failed to open the package (or gain access to the contents) in the second 5 min, i.e. the result is a success (see 6.1.1);

— fill in a square immediately above the previous result on Figures 1 and 2 if the test child succeeded in opening the package (or gaining access to the contents) in the first 5 min, or only on Figure 2 if the test child succeeded in opening the package (or gaining access to the contents) in the second 5 min, i.e. the result is a failure (see 6.1.1).

A separate chart shall be prepared for results obtained before and after a demonstration.

NOTE In the case of the first result to be plotted, the blanked out square is regarded as the “previous result”.

6.1.2.2 Determination of the results

The package shall be deemed to have:

— passed the test as soon as the trail of filled squares passes below limit line 1 on both Figure 1 and Figure 2;

— failed the test as soon as the trail of filled squares passes above limit line 2 on either Figure 1 or Figure 2;

— if neither occurs, the results shall be assessed in accordance with the requirements laid down in 4.3.1.

6.1.3 Full test

If a sequential procedure is not used and the full number of children is tested, the results shall be assessed in accordance with the requirements laid down in 4.3.1.

6.2 Adult test

The result of the test is a success if 90 % or more of the eligible adults are able to open the package in the first 5 min test period and open and properly reclose it in the 1 min test period. An eligible adult is one who has not been discounted by the procedure given in 5.5.3.

The result of an individual adult test is a failure if the eligible candidate opened the package in the first 5 min test but failed to open and properly reclose the package in the 1 min test period.

6.3 Overall test result

Only packaging which satisfies both the child and the adult test criteria as specified in clause 4.3.1.1 and 4.3.2 shall be deemed to conform to this International Standard.

7 Test report

7.1 General

At least the following information shall be recorded by the supervisor:

a) the name of the agency carrying out the test;

b) the date(s) on which the test was carried out;

c) the name and address of the manufacturer and/or filler/packer of the package tested;

d) the name(s) of the person(s) supervising the test;

e) the specification number, drawing numbers and a complete description of the package tested;

f) a direct quotation of the exact instructions, etc. given to the adults and the children during the test;

g) a copy of the manufacturer's instructions on opening and reclosing the package given to the adults during the test;

h) a description of the substitute product used in the test.

7.2 Child test

At least the following information shall be recorded:

a) the location of the test;

b) the number, name, age and sex of the children involved;