INTERNATIONAL STANDARD

ISO 8317

Third edition
2015-11-01

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 8317:2015(E)

International Organization for Standardization

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is 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 third edition cancels and replaces the second edition (ISO 8317:2003), which has been technically revised. It also incorporates the Corrigenda, ISO 8317:2003/Corr 1:2005.

In addition to a number of editorial revisions, the following technical revisions have been made with respect to the previous edition:

— introduction revised to remove historical discussion;

— definitions added for mechanical testing, mechanical test data, liner, essential characteristics, and minor modifications (2.6 to 2.10)

— former Clauses 3 and 4 consolidated into new Clause 3 and subsequent clauses renumbered;

— requirements in previous edition 3.1, 3.2 and 4.2 not part of the testing, have been relocated and are now informative. These are now included in the Introduction;

— introduction need to consider essential characteristics for a series of similar packaging (3.1.1);

— clarified instructions for evaluation of a series of similar packaging submitted at one time by separation under component type (3.1.2.2, 3.1.2.3, 3.1.2.4);

— added new subclause on additions to a series and minor modifications (3.1.2.5);

— reference made to ISO 13127 (Introduction and 3.1.2.5);

— charts for sequential testing updated to correct errors (Figures 1 and 2);

— need to disable all (or any) incorporated tamper evident features before testing added (4.3);

— use of torque meter added for sample preparation of packages with torque dependent closures (4.3);

— deleted the limit (35 %) for the percentage of child tests administered by an individual tester (4.4.3);

— deleted the limit for number (30) of adults obtained from and tested at any one site, and number (35) of adult tests administered by an individual tester (4.5.2).

Introduction

A significant number of suspected cases of ingestion by children of products used about the home are 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 are not known to have caused injury. However, whether ingestion (actual or suspected) causes injuries or not, such incidents can have traumatic effects on both the child and the 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. 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. 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. The packaging functions as a last defence if other barriers separating children and hazardous products have failed. Hence, the overall responsibility rests with the parents or other responsible adults.

For the assessment of minor modifications to packages previously tested according to ISO 8317, ISO 13127[1] describes appropriate methodology that may be used.

Attention is drawn to the need to have adequate supervisory and accreditation bodies, please see ISO/IEC 17025,[2] which provides useful guidance on these topics.

In addition to child resistant reclosable packages meeting the requirements of this International Standard, attention is drawn to the need for the relevant parties in the supply chain to ensure that

a) appropriate quality systems are in place to ensure that the child resistant packaging are correctly manufactured and remain in compliance with this International Standard,

b) the life expectancy of the child resistant packaging exceeds 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 or function, and

c) the package meets the requirements of packaging, such as being appropriate for, and compatible with, the contents, providing mechanical protection and functioning properly for the life of the package in the intended geographical regions and climatic conditions.

NOTE Certain products can affect the physical or mechanical properties of a packaging system which can lead to a loss of the child resistant function over time. In such a case, the packaging might not remain in compliance with this International Standard. Compatibility between the packaging and the contents needs to be assessed using appropriate methodology.

ISO/TC 122/SC 3 do not see the changes made in this edition invalidating the classification of packages certified as child resistant under the previous edition of this International Standard since the adult and child panel tests remain unchanged.

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

1 Scope

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

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

This International Standard is applicable to reclosable packages for any product intended to be exposed or removed from the packaging in normal use.

This International Standard is intended for type approval only 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 packaging
package consisting of a container and appropriate closure which is difficult for young children under the age of 52 months to open (or gain access to the contents), but which is not difficult for adults to use properly

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 1 to entry: 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.

Note 2 to entry: Liquid substitute product is always uncoloured water.

2.6
mechanical testing
documented and reproducible test methods intended to measure the resistance of the relevant features of a child resistant packaging system

2.7
mechanical test data
data generated by mechanical testing

Note 1 to entry: These data can be used for the verification of equivalency of a child resistant packaging system to the type-approved package.

2.8
liner
medium used to form a seal between a closure and a container

2.9
essential characteristics
those elements, properties or attributes of the container/closure system that are critical for maintaining the child resistant functionality

Note 1 to entry: See 3.1.1 for examples of essential characteristics.

2.10
minor modifications
changes that potentially have no significant effect on child resistant functionality

3 Requirements

3.1 Test requirements

3.1.1 General

Only new packages shall be submitted for testing.

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.

Packages may be tested individually or as part of a series of similar packaging submitted at the same time.

When testing a series of similar packaging, the requirements in 3.1.2 shall be applied.

In specifying a series of similar packaging, the following essential characteristics shall be taken into consideration.

NOTE The following list of attributes does not claim to be exhaustive.

CR system

— push down and turn;

— squeeze and turn, etc.

Container

— critical dimensions;

— material: glass, metal, different polymers, etc.;

— shape: round, square, rectangular, oval, etc.;

— handling: handle position, handle design, etc.;

— thread: form, position;

— neck: position, orientation, design, etc.;

— rigidity.

Closure

— critical dimensions;

— material: metal, different polymers, etc.;

— shape: round, square, rectangular, oval, etc.;

— handling: external gripping feature;

— thread: form, position;

— sealing feature: wad-liner, plug, etc.

3.1.2 Evaluation of a series of similar packaging

3.1.2.1 Rationale

The rationale for a series of similar packaging, which discloses the degree of commonality, shall be recorded.

3.1.2.2 Closures

If a series of closures differ only in diameter, but are similar in all essential characteristics, where the largest diameter is smaller than or equal to 1,5 times the smallest diameter, then the largest and smallest size shall be tested.

If a series of closures differ only in diameter, but are similar in all essential characteristics, where the largest diameter is greater than 1,5 times the smallest diameter, then the largest, smallest and one intermediate size shall be tested.

EXAMPLE If the smallest diameter closure is 20 mm and the largest is no greater than 30 mm, test the smallest and the largest sizes. If the smallest diameter closure is 20 mm and the largest is greater than 30 mm, test the smallest, the largest and one intermediate size.

3.1.2.3 Containers

If the containers of the packaging differ only in capacity and the closures are identical, tests shall be performed only on the largest and smallest container sizes.

3.1.2.4 Containers and closures

If the containers of the packaging differ 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, this means normally four container/closure combinations subject to the 1,5 times diameter rule given in 3.1.2.2.

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 at least four container/closure combinations are tested.

If all the packages specified in 3.1.2.2, 3.1.2.3 and 3.1.2.4 pass the test, containers and closures of intermediate sizes in the same series shall be regarded as conforming to this International Standard.

3.1.2.5 Additions and modifications

If, after a range of packaging has been tested and approved, sizes of containers and closures outside the dimensions of the accepted range are to be added, the packages shall be tested as specified in 3.1.2.2, 3.1.2.3 and 3.1.2.4 to extend the range specified.

Minor modifications of container or closure can be evaluated by the development and provision of mechanical test data showing compliance.

NOTE Test methods for mechanical testing of reclosable child resistant packaging are specified in ISO 13127.[1]

Other modifications, which are outside the range of a series of similar packaging, shall be treated as a separate series and tested accordingly.

3.2 Test panels

Testing shall be performed with two panels of people

a) a test with young children aged between 42 and 51 months old, inclusive,

b) a test with adults aged between 50 and 70 years old, inclusive.

3.3 Performance requirements

3.3.1 Requirements concerning children

3.3.1.1 Using a test panel of 200 children

When the package is tested in accordance with 4.4.4, 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;

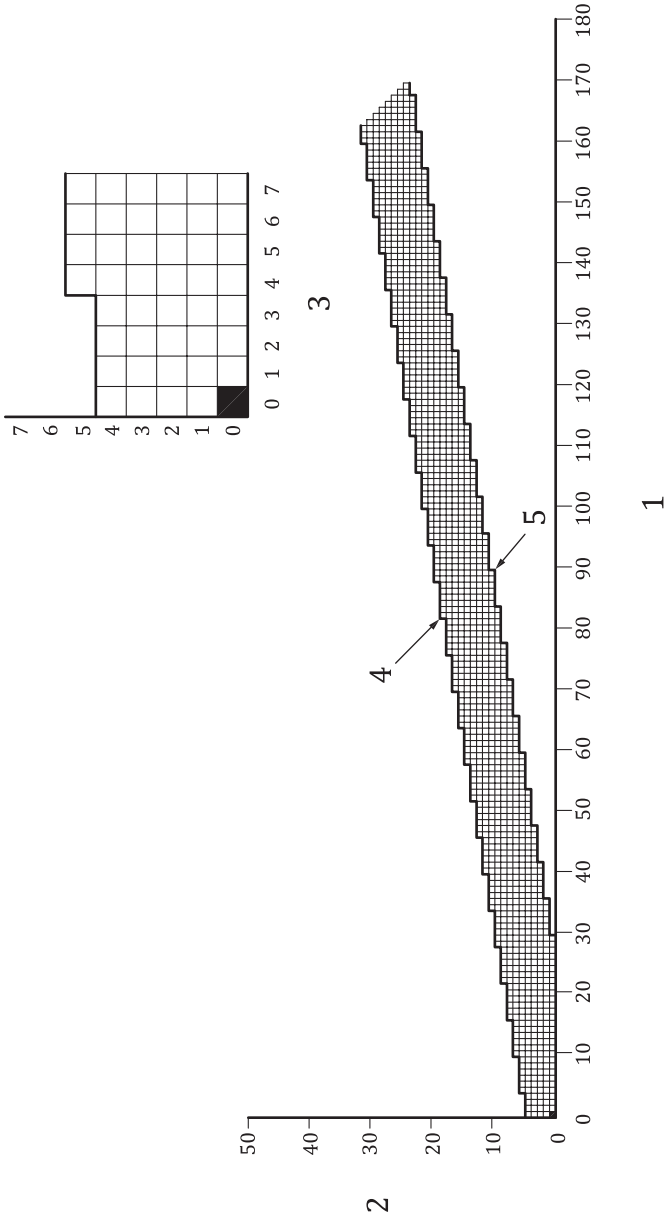
b) at least 80 % of the 200 children in the test panel shall be unable to open the package within another 5 min after a demonstration has been given to those children unable to open the package in the first 5 min.

3.3.1.2 Using the sequential test procedure

If less than the full test panel is used in accordance with 5.1.2, the result shall be obtained from completing Figure 1 and Figure 2.

3.3.2 Requirements concerning adults

When the package is tested in accordance with 4.5.3, 90 % of the eligible adults shall be able to open and properly reclose the packaging.

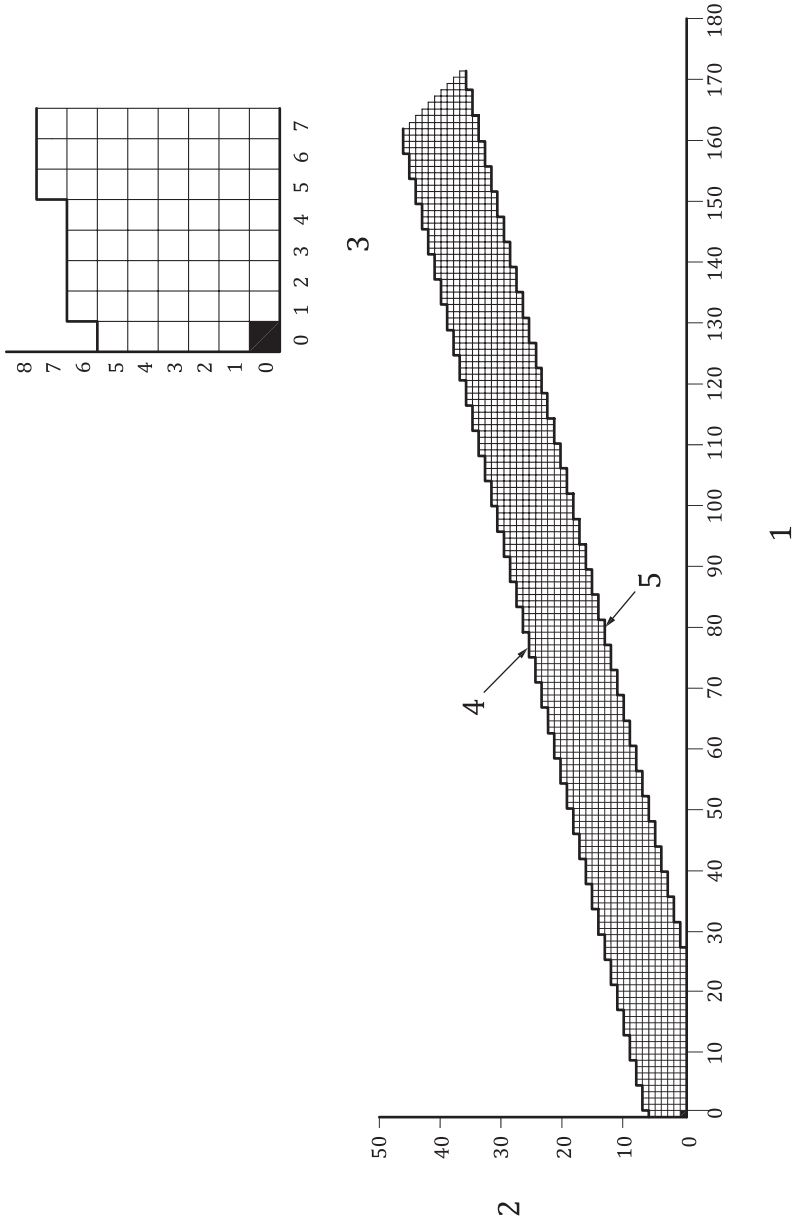


Key

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

NOTE Acceptable quality limit (AQL) = 10 %; 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	4	limit line 2
2	number of packages opened	5	limit line 1
3	enlargement of chart scale		

NOTE Acceptable quality limit (AQL) = 15 %; limiting quality (LQ): 25 %; $\alpha = \beta = 5$ %, where α is the producer's risk; β is the consumer's risk.

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

4 Test procedures

4.1 Test supervision

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

4.2 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.

4.3 Preliminary checking and preparation

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

Packages which incorporate a tamper-evident feature shall have the tamper-evident feature disabled. No hazardous product shall be used to fill any packaging 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.

NOTE 1 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 packages shall be assembled by the test supervisor by hand. The packages shall then be closed using a torque meter up to a specified torque, 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 packages have been prepared for testing they should be handled carefully.

NOTE 2 The application torque to be recorded is that torque used to assemble the packages to be conditioned for 72 h to take set, prior to conducting the tests. It is not necessarily the application torque that might be applied on a packaging line, nor does it imply that packages closed at this torque are child resistant. The same application torque will be required for preparation of samples where mechanical testing according to ISO 13127 is used to assess continued conformity. If not recorded in the test report, the application torque information will need to be readily accessible.

4.4 Child test

4.4.1 Guidance for persons supervising tests

4.4.1.1 Surroundings and personnel

The surroundings and personnel should be familiar and friendly.

4.4.1.2 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.

4.4.1.3 Presence of official observer

If required by the regulatory body, an official observer may be present but the requirements of 4.4.1.1 still apply.

4.4.1.4 Social circumstances of the children

There is a highly significant correlation between the success rate in opening packages 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 documented.

4.4.1.5 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.

4.4.1.6 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.

4.4.2 Composition of test group

Enough children to ensure 200 valid participants between the ages of 42 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 might affect manual dexterity. They shall not have taken part in more than one previous test and, in that test, a package 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 performed in one testing session, because there might be a statistically significant difference in the results between the first and second package tried.

4.4.3 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 should 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.

4.4.4 Procedure

The test may be performed 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 5.1.2). When testing sequentially, the age and sex constraints specified in 4.4.2 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 package 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.

4.4.5 Expression of results (see also 5.1)

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.

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

4.5.1 General

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

4.5.2 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 permitted 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 in accordance with the criteria specified in Table 1.

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**

4.5.3 Procedure

The adult test panel shall consist of 100 panellists. Those panellists failing the screening test shall be 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.

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 package.

If, in the 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.

4.5.4 Expression of results (see also 5.2)

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 4.5.3 and 3.3.2.

5 Assessment of results

5.1 Child test

5.1.1 Success/failure

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

5.1.2 Sequential method

5.1.2.1 Recording test results on a graph

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

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 5.1.1);

— 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 5.1.1).

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

5.1.2.2 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 specified in 3.3.1.

5.1.3 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 3.3.1.

5.2 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 screening test given in 4.5.3.

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.

5.3 Overall test result

Only packages which satisfy both the child and the adult test criteria as specified in 3.3.1 and 3.3.2 shall be deemed to conform to this International Standard.

6 Test report

6.1 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.

6.2 Child test

At least the following information shall be recorded:

a) the location of the test;

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

c) the number of children, together with their age and sex, who successfully opened the package

   1) before a demonstration,

   2) after a demonstration,

   3) the means used by the children who were successful in opening the package;

d) if the full child test has been carried out, the percentage number of children who failed to open the package.

6.3 Adult test

At least the following information shall be recorded:

a) the number, age and sex of the adults involved;

b) the number, age and sex of adults who successfully opened and reclosed the package properly;

c) the number who opened but could not reclose the package properly;

d) the number who failed to open the package.

6.4 Additional (optional) information to be recorded

Any other information deemed to be useful in assessing the interpretation of the result shall be recorded.

EXAMPLE The time required for adults and children to open the package and, where appropriate, to reclose it properly, the method used by children to gain access, etc. shall be recorded.

6.5 Overall test result

It shall be recorded whether the overall result of the test was a pass or a failure.

Bibliography

[1] ISO 13127, *Packaging — Child resistant packaging — Mechanical test methods for reclosable child resistant packaging systems*

[2] ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

ICS 55.020

Price based on 13 pages