INTERNATIONAL STANDARD

ISO 8317

First edition
1989-07-01

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 : 1989 (E)

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 8317 was prepared by Technical Committee ISO/TC 122, *Packaging*.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Printed in Switzerland

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

0 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 drugs and medicines, 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 to 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 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-resistant 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-resistant 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 must be administered by some responsible authority in each country adopting the International Standard, as all must have confidence in the manner in which testing is carried out and 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 Guide 25, *General requirements for the technical competence of testing 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.

NOTES

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.

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.

1 Scope and field of application

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.

Means of performing the test on a series of similar packages are given in annex A and guidance for persons carrying out the tests is given in annexes B and C.

2 Definitions

For the purposes of this International Standard, the following definitions apply.

2.1 child-resistant package: A package which is difficult for young children under the age of five to open (or gain access to the contents), but which is not difficult for adults to use properly in accordance with the requirements of this International Standard.

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

2.3 substitute product: An inert substitute resembling the product it replaces.

NOTE — Solid substitute products for child-resistant packages should normally consist of powder, granules or units of any similar shape and size varying from 5 to 30 mm in any dimension, preferably of a neutral colour, and not harmful in any way. Liquid substitute product should always be 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 such packages will be required to initiate and operate such procedures as are necessary to control production and use, and to ensure that all packages meet the required quality standards.

3.2 Packages for testing

Sufficient packages shall be supplied 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.

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

3.3 Test panels

Testing is carried out with two classes of people:

a) a test with young children between 42 and 51 months of age, inclusive;

b) a test with adults between 18 and 65 years of age, inclusive.

4 Requirements

4.1 General safety requirements

A child-resistant package, in addition to satisfying the requirements for child resistance specified in 4.2, 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.

4.2 Performance requirements

4.2.1 Requirements concerning children

When the packaging is tested in accordance with 5.3, the following requirements shall be met:

a) at least 85 % of the children in the test panel shall be unable to open the package within 5 min without a demonstration, and

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

4.2.2 Requirements concerning adults

When the packaging is tested in accordance with 5.4, at least 90 % of the adults shall be able to open and reclose the package properly within 5 min and without a demonstration.

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.

Guidance for persons carrying out the tests is given in annexes B and C.

5.2 Preliminary checking and preparation

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

Packages which incorporate a 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 child test.

No hazardous product shall be used to fill any package submitted for test. A suitable substitute product shall be used for adult tests; a suitable substitute product shall also be used for child tests except in cases where this would conflict with national requirements. When a substitute product is used, packages up to a volume of 1 litre shall be filled to their nominal size capacity (i.e. as sold); packages greater than 1 litre volume shall be filled with 1 kg of solid or 1 litre of liquid substitute product as appropriate.

5.3 Child test

5.3.1 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. As far as possible they shall represent the social, ethnic and cultural origins of the country as a whole. They shall all be healthy with no evident physical or mental handicap associated with 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 1 week between the tests.

5.3.2 Location

The children shall perform the test in any place with which they are familiar, e.g. in their usual school or kindergarten, but they shall be removed from the general school population and separated from extraneous distractions. Several venues should be selected from different demographic areas. The test series need not necessarily be completed at one venue at one time.

5.3.3 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 5.3.1 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.

NOTE — If required by the regulatory body, an official observer may be present, but the requirements laid down in clause B.1 still apply.

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(s) 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.

5.3.4 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.

5.4 Adult test (18 to 65 years inclusive)

5.4.1 Composition of test group

Enough normal adults to ensure 100 valid participants shall be available. All should be able to understand the operating

instructions used on the package concerned in the test. 70 % of the adults shall be female. 80 of the adults shall be between 18 and 60 years of age inclusive and 20 shall be between 61 and 65 years of age inclusive. In other words, one adult between 61 and 65 years of age inclusive shall be tested for every 4 adults between 18 and 60 years of age inclusive.

5.4.2 Procedure

Adult tests may be carried out on all 100 adults or by a sequential procedure. If the latter is used, the number of adults tested will depend on the results obtained (see 6.2.2). When testing sequentially, the age and sex constraints specified in 5.4.1 shall be adhered to.

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. A period of 5 min shall be allowed for the person to read the instructions, open the package and reclose it properly.

5.4.3 Expression of results (see also 6.2)

It shall be recorded whether or not the adult succeeds in opening and properly reclosing the package in the period of 5 min allowed.

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

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

a) fill in a square immediately to the right of the previous result on figure 1a) if the test child failed to open the package (or gain access to the contents) in the first 5 min, and on figure 1b) 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);

b) fill in a square immediately above the previous result on figures 1a) and 1b) if the test child succeeded in opening the package (or gaining access to the contents) in the first 5 min, or only on figure 1b) 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".

The package shall be deemed to have failed the test as soon as the trail of filled squares passes above limit line 2 on figure 1a) or figure 1b) or to have passed the test as soon as the trail passes below limit line 1 on both figure 1a) and figure 1b); if neither occurs, the results shall be assessed in accordance with the requirements laid down in 4.2.1.

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 4.2.1.

6.2 Adult test

6.2.1 Success/failure

The result of the test is a failure if the packaging cannot be opened and properly reclosed within 5 min.

6.2.2 Sequential method

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

a) fill in a square immediately to the right of the previous result if the test adult succeeded in opening the package and reclosing it properly in the time allowed, i.e. the result is a success (see 6.2.1);

b) fill in a square immediately above the previous result if the test adult failed to open the package and reclose it properly in the time allowed, i.e. the result is a failure (see 6.2.1).

NOTE — The chart shown in figure 2 is appropriate for plotting the results obtained in the adult test.

The package shall be deemed to have failed the test as soon as the trail of filled squares passes above limit line 2 or to have passed the test as soon as the trail passes below limit line 1; if neither occurs, the results shall be assessed in accordance with the requirements laid down in 4.2.2.

6.2.3 Full test

If a sequential procedure is not used and the full number of adults is tested, the results shall be assessed in accordance with the requirements laid down in 4.2.2.

7 Test report

7.1 General

The supervisor shall record at least the following information:

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

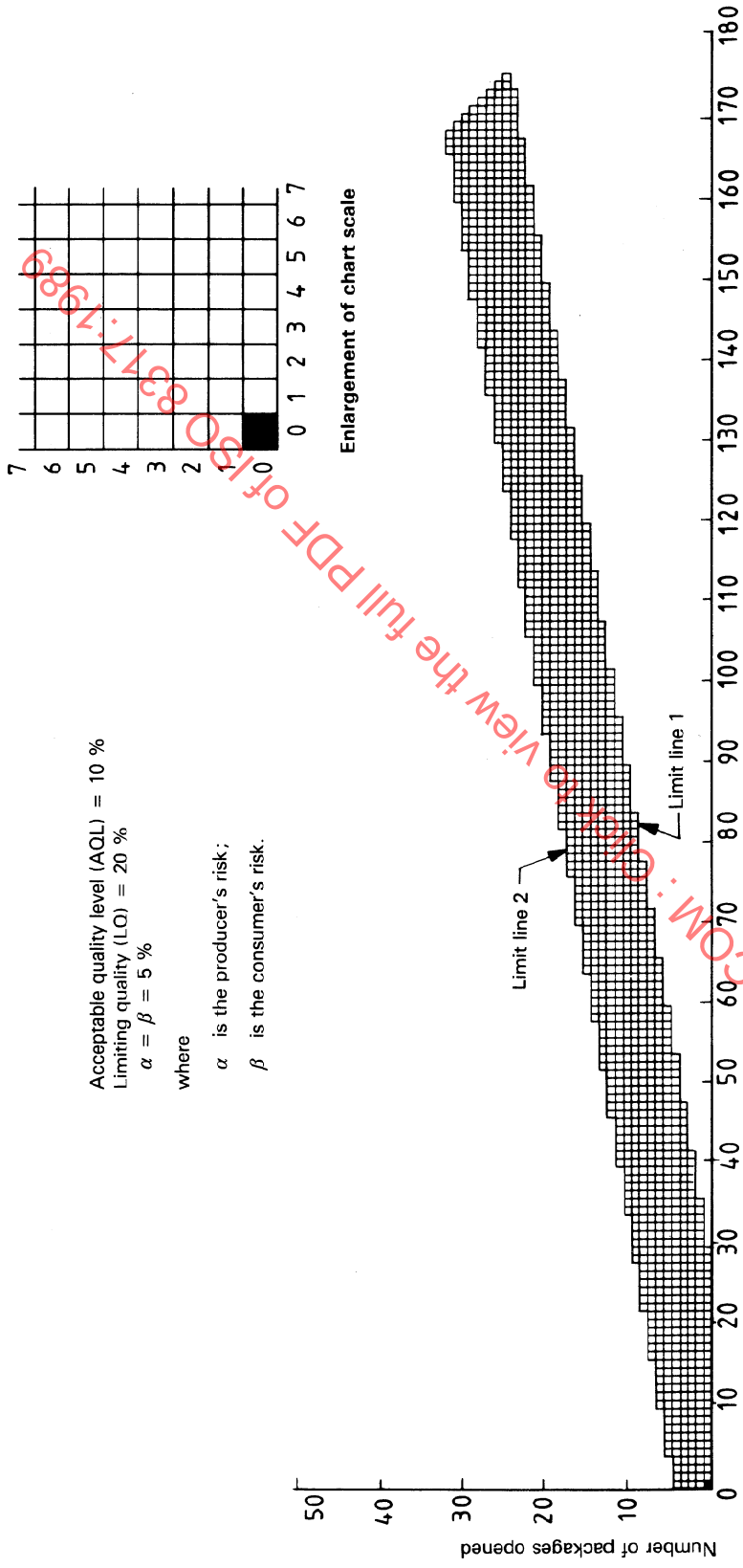
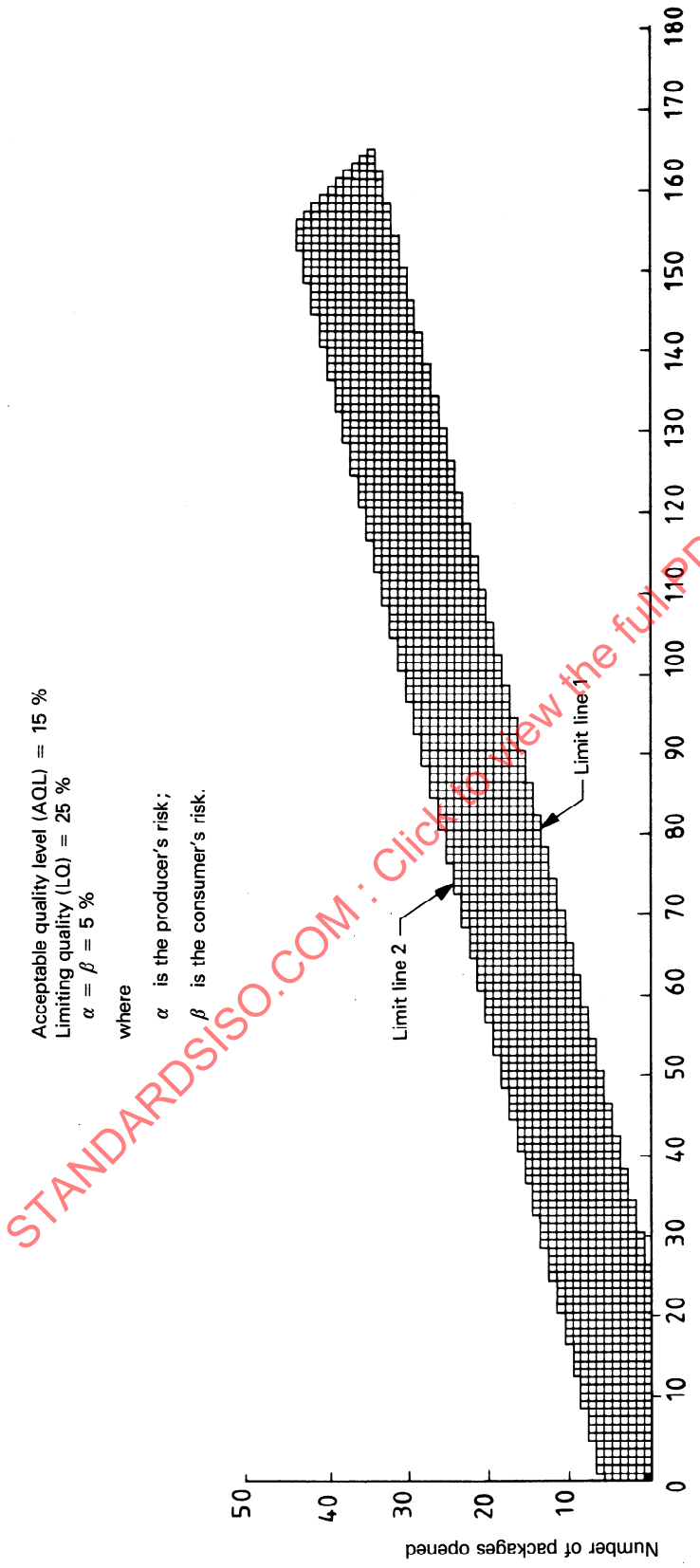
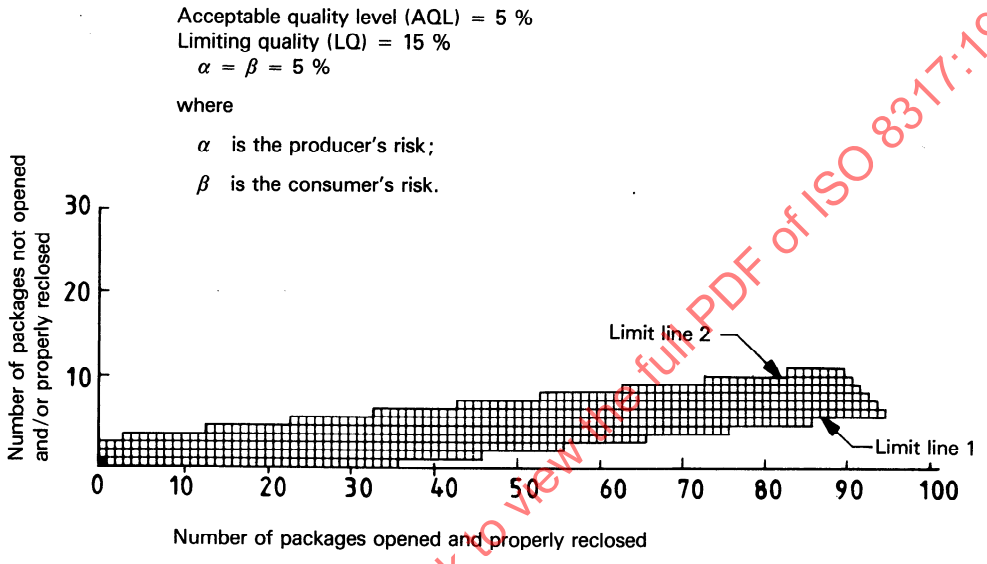


Figure 1a) — Chart of a sequential child test procedure (before demonstration) for child-resistant reclosable packages



NOTE — For an enlargement of the chart scale, see figure 1a).

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



NOTE — For an enlargement of the chart scale, see figure 1a).

Figure 2 — Chart of a sequential adult test procedure for child-resistant reclosable packages

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

c) the name and address of the manufacturer and/or supplier 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 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;

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

1) before a demonstration,

2) after a demonstration, and

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

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

7.3 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;

e) if the full test has been carried out, the percentage number of adults who successfully opened and properly reclosed the package.

7.4 Additional (optional) information to be recorded

Any other information deemed to be useful in assessing the interpretation of the result, such as the time required for adults and children to open the package and, where appropriate, to reclose it properly.

7.5 Overall test result

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

Annex A

Evaluation of a series of similar packages

(This annex does not form an integral part of the standard.)

A.1 General

While all new packages shall be submitted for testing, the following instructions for the evaluation of a series of similar packages submitted at one time shall be applied.

If a series includes a package with a brimful capacity of 275 ml, packages less than 275 ml shall be evaluated in accordance with clause A.2 and packages equal to or greater than 275 ml shall be evaluated in accordance with clause A.3.

If a series includes closures with a diameter of less than 20 mm or greater than 50 mm, the largest and smallest diameter closures and one intermediate size shall be tested.

A.2 Packages with a brimful capacity of less than 275 ml

A.2.1 If the body of the package differs only in capacity and the closures are identical, tests shall be carried out only on the largest and smallest sizes.

If both packages pass the test, packages of intermediate capacity in the same series shall be regarded as complying with this International Standard.

A.2.2 If the body of the package differs only in capacity and the closures differ only in dimensions but are similar in all essential characteristics, the largest and smallest diameters of closure fitted to the largest and smallest packages shall be tested, i.e. normally four body/closure combinations.

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

A.2.3 If several body 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 every body shape and to ensure that the minimum requirement of at least four body/closure combinations as in A.2.2 shall be tested.

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

A.2.4 If, after a range of packages has been tested and approved, sizes of packages outside the dimensions of the accepted range are added, they shall be tested to extend the range as specified in A.2.1 to A.2.3.

NOTE — Additional sizes may be added without further testing provided that such additional sizes fall within the size limits of the range tested.

A.2.5 All other variations shall be treated as separate series and tested accordingly.

A.3 Packages with a brimful capacity equal to or greater than 275 ml

A.3.1 If the body of the package differs only in capacity and shape and the closures are identical, tests shall be carried out only on the largest and smallest sizes.

If both packages pass the test, all other packages in the series shall be regarded as complying with this International Standard.

A.3.2 If the body of the package differs only in capacity and shape and the closures differ only in dimensions but are similar in all essential characteristics, the largest diameter closure fitted to the largest size body and the smallest diameter closure fitted to the smallest size body shall be tested.

If both packages pass the test, all other packages in the series shall be regarded as complying with this International Standard.

A.3.3 If, after a range of packages has been tested and approved, sizes of packages outside the dimensions of the accepted range are added, they shall be tested to extend the range as specified in A.3.1 and A.3.2.

NOTE — Additional sizes may be added without further testing provided that such additional sizes fall within the size limits of the range tested.

A.3.4 All other variations shall be treated as separate series and tested accordingly.

A.4 Closure system common to more than one type (series) of body

If a closure system from a previously approved series is used with a packaging body which has not been tested, further testing shall not be required if the following criteria are satisfied:

a) the neck finish of the untested packaging is identical with that of the approved packaging (this shall be verified by examination of dimensional drawings, specifications and samples);

b) the closure and body sizes are within the previously approved range;

c) the closure and liner are identical with those of the previously approved series.