

Specification for

Packagings resistant to opening by children

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Packaging and Freight Containers Standards Committee (PKM/-) to Technical Committee PKM/587 upon which the following bodies were represented:

Aluminium Federation
Association of the British Pharmaceutical Industry
British Association for Chemical Specialities
British Paper and Board Industry Federation
British Plastics Federation
Child Accident Prevention Trust
Consumer Standards Advisory Committee of BSI
Department of Health and Social Security
Department of Trade and Industry
Flexible Packaging Association
Glass Manufacturers Federation
Guild of Hospital Pharmacists
Health and Safety Executive
Loughborough University of Technology
Metal Packaging Manufacturers' Association
National Pharmaceutical Association
Pira (the Research Association for the Paper and Board, Printing and Packaging Industries)
Packaging and Industrial Films Association
Pharmaceutical Services Negotiating Committee
Pharmaceutical Society of Great Britain
Proprietary Association of Great Britain
Royal College of Nursing and National Council for Nurses of the UK
Royal Society for the Prevention of Accidents
Soap and Detergent Industry Association

This British Standard, having been prepared under the direction of the Packaging and Freight Container*) Standards Committee, was published under the authority of the Board of BSI and comes into effect on 30 September 1985

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Foreword

This British Standard has been prepared at the request of the Department of Trade and Industry under the direction of the Packaging and Freight Containers Standards Committee.

BS 6652 extends the scope of BS 5321:1975 to cover products other than pharmaceutical products and incorporate a sequential test procedure as the preferred method. BS 5321:1975 will however remain in force for some time after publication of this British Standard and will be withdrawn only when implementation of BS 6652 for pharmaceutical products has been agreed by the Department of Health and Social Security.

This standard deals with only one facet of the problems of preventing accidental ingestion by young children of hazardous products. Child-resistant packagings are intended only as a last line of defence when other precautions have failed. The common sense rule that all hazardous products should be kept out of reach of children should still be applied.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 12, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This British Standard specifies requirements and test procedures¹⁾ for a type test for packagings designated as resistant to opening by children. The standard describes the appropriate test procedures using child and adult test subjects in Appendix A and Appendix B, respectively.

NOTE 1 An optional tout using elderly adults is described in Appendix E, but compliance with the test is not a requirement of this standard and it is included for information and guidance only.

The standard applies to both reclosable packagings and non-reclosable packagings of the "single-use" type. Non-reclosable packagings for pharmaceutical products are excluded.

NOTE 2 The title of the publication referred to in this standard is given on the inside back cover.

2 Definitions

For the purposes of this British Standard the following definitions apply.

2.1

child-resistant packaging

packaging designed and constructed to be difficult for young children to open within a reasonable time and that is not difficult for adults to use properly

2.2

reclosable packaging

packaging that having 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

non-reclosable packaging

any packaging that having once been opened is not capable of being reclosed

2.4

single-use packaging

a non-reclosable packaging that contains only sufficient product for one application

2.5

sequential test

a test procedure in which individual results are plotted on control charts as they are obtained and the test stopped as soon as the plot exceeds the prescribed limits

2.6

series

a range of packagings that differ only in size and/or shape and in which the materials of construction are similar in performance characteristics and the design principle of the closure system is the same throughout

3 General

3.1 Compliance with this standard

Child-resistant packaging shall be tested by means of the child and adult tests detailed in Appendix A and Appendix B, respectively, for compliance with the performance requirements specified in 4.1.1 or 4.2.1 and 4.1.2 or 4.2.2, respectively, to show a satisfactory degree of resistance to opening by children while maintaining accessibility to its contents by adults. The tests are designed for type approval and are not intended for quality control testing.

NOTE 1 Before testing by children is carried out on reclosable child-resistant packaging, both manufacturers and potential users should satisfy themselves that the life expectancy of the child-resistant packaging will exceed the maximum expected number of openings and closings that are likely to occur in practice without unacceptable impairment of the child-resistant property.

NOTE 2 BS 6652 is concerned solely with the child-resistant characteristics of the packaging and it is the users' responsibility to establish compatibility with the contents and protective characteristics and to provide adequate instructions for opening, safe handling, etc.

NOTE 3 It is essential that the supplier (manufacturer) carries out routine quality control testing to ensure that the manufacturing specification is maintained throughout production.

3.2 Supervisory committee

Testing for compliance with this standard is under the control of the supervisory committee which is administered by Certification and Assessment Services, British Standards Institution, Linford Wood, Milton Keynes, MK14 6LE and which is composed of independent experts.

Applications for testing shall be made to the secretariat of the supervisory committee through Certification and Assessment Services, British Standards Institution at the above address.

The supervisory committee shall approve the issue of certificates of compliance on completion of satisfactory testing.

¹⁾ Advice on the application of this British Standard may be obtained from the secretariat of the supervisory committee through Certification and Assessment Services, British Standards Institution, Linford Wood, Milton Keynes, MK14 6LE.

3.3 Packaging specification

A full manufacturing specification for each type of packaging, including appropriate drawings, shall be submitted with necessary samples to the supervisory committee with each application for test, and packagings submitted for test shall comply with that specification. Only packagings that are approved by the supervisory committee as being in compliance with the manufacturing specification shall be tested.

3.4 Evaluation of a series (see 2.6) of similar packagings

3.4.1 *General.* Whilst all new packagings shall be submitted for certification, the following instructions for the evaluation of a series of similar packagings submitted at one time shall be applied. Where a series includes a packaging with a brimful capacity of 275 mL, packagings less than 275 mL shall be evaluated in accordance with 3.4.2 and packagings equal to or greater than 275 mL shall be evaluated in accordance with 3.4.3.

3.4.2 *Packagings with a brimful capacity of less than 275 mL.*

3.4.2.1 When the body of the packaging differs only in capacity and the closures are identical, tests shall be carried out only on the largest and smallest sizes. If both packagings pass the test, then packagings of intermediate capacity in the same series shall be regarded as complying with the standard.

3.4.2.2 When the body of the packaging differs only in capacity and the closures are different only in dimensions but similar in all essential characteristics, then the largest and smallest diameter of closure fitted to the largest and smallest packaging shall be tested, i.e. normally four body/closure combinations.

If all pass the test, then packagings and closures of intermediate sizes in the same series shall be regarded as complying with the standard.

3.4.2.3 When several body shapes are involved, but all other characteristics are the same and the closures are identical or differ only in diameter, then 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 3.4.2.2 shall be tested.

If all pass the test, then packagings and closures of other sizes in the same series shall be regarded as complying with the standard.

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

3.4.2.5 Subsequent to a range of packagings having been tested and approved, if additional sizes are outside the dimensions of the accepted range, they shall be tested to extend the range as in 3.4.2.1 to 3.4.2.3.

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

3.4.3 *Packagings with a brimful capacity equal to or greater than 275 mL.*

3.4.3.1 When the body of the packaging 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 packagings pass the test, then all other packagings in the series shall be regarded as complying with the standard.

3.4.3.2 When the body of the packaging differs only in capacity and shape and the closures differ only in dimensions but are similar in all essential characteristics, then 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 packagings pass the test, then all other packagings in the series shall be regarded as complying with the standard.

3.4.3.3 Subsequent to a range of packagings having been tested and approved, if additional sizes are outside the dimensions of the accepted range, they shall be tested to extend the range as in 3.4.3.1 and 3.4.3.2.

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

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

4 Performance requirements

4.1 Reclosable packagings

4.1.1 *Child test.* When carrying out the test in accordance with the procedure given in Appendix A:

- a) at least 85 % of the test panel of children shall be unable to open the packagings prior to the demonstration;
- b) at least 80 % of the same children shall still be unable to open the packagings after the demonstration.

4.1.2 *Adult test.* When carrying out the test in accordance with the procedure given in Appendix B, at least 90 % of the panel of adults shall be able to open and properly reclose the packagings by following written instructions but without having received a demonstration.

4.2 Non-reclosable packagings

4.2.1 *Child test.* When carrying out the test in accordance with the procedure given in Appendix A, at least 80 % of the test panel of children shall be unable to open the packagings in the time allowed.

4.2.2 *Adult test.* When carrying out the test in accordance with the procedure given in Appendix B, at least 90 % of the panel of adults shall be able to open the packagings by following the written instructions.

5 Test supervision

5.1 The procedure for testing by children and by adults described in Appendix A and Appendix B respectively shall be conducted under the supervision of an impartial and appropriately qualified person approved by the supervisory committee. Instructions to persons supervising tests with children and adults are given in Appendix C and Appendix D, respectively.

If required by the supervisory committee, the presence of an official observer designated by them shall be allowed at all times.

5.2 The results expressed as in A.3 for children and B.3 for adults and recorded as in clause 7 shall be submitted to, and evaluated by, the supervisory committee.

6 Selection of personnel for test panels

6.1 Numbers of personnel

To carry out the test, sufficient children and adults to ensure 200 valid child test results and 100 valid adult test results shall be selected.

6.2 Children

The 200 children shall be between the ages of 42 months and 51 months inclusive, with an even distribution of age and sex. They shall be healthy, with no obvious physical or mental handicap influencing their proficiency. They shall not have taken part in more than one previous test and in that test a packaging of a different type, whose opening arrangements are based on a different principle, shall have been tested. As far as possible they shall represent the social, ethnic and cultural origins of the country as a whole, see C.3.

The even-age distribution shall be obtained by having 20 ± 2 children whose nearest age is 42 months, 20 ± 2 children whose nearest age is 43 months, and so on up to and including 20 ± 2 children whose nearest age is 51 months.

The even-sex distribution shall be obtained by having no more than a 10 % preponderance of either sex in each age group.

6.3 Adults

The 100 adults, of whom 70 shall be female, shall be between 18 years and 60 years inclusive and have no obvious physical or mental handicap likely to affect the results of the test, and all shall be able to read the language used in or on the packagings concerned in the test.

NOTE An optional test using elderly adults is described in Appendix E, but compliance with the test is not a requirement of this standard and it is included for information and guidance only.

7 Records and results

7.1 General

The supervisor shall record the following information for all tests:

- 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/supplier of the packagings tested;
- d) the name(s) of the person(s) supervising the test;
- e) the specification number, drawing numbers and a complete description of the packaging tested;
- f) a direct quotation of the exact instructions, etc. given to adults and children during the test;
- g) a copy of the manufacturer's/supplier's instructions on opening and reclosing the packaging given to the adults during the test;
- h) the names, addresses and ages of all the children and adults participating in the tests;
- i) certification of the written consent of parents/guardians of the children to participate in the tests, and a declaration that they have taken part in not more than one previous test of a child-resistant packaging and that of a different type, and also that they have no history of accidental poisonings;
- j) a description of the physical form of the substitute product used in the test.

7.2 Child test

For a child test, in addition to the information required by 7.1, the supervisor shall record the following information:

- a) the number of children, together with their age and sex, who successfully opened the packaging:
 - 1) before a demonstration;
 - 2) after a demonstration;
- b) the means used by the children who were successful in opening the packaging;

c) the number of children who failed to open the packaging;

d) if the full test has been used, the percentage number of children who failed to open the packaging.

7.3 Adult test (and elderly adult test, if carried out)

For an adult test (and elderly adult test, if carried out), in addition to the information required by 7.1, the supervisor shall record the following information:

a) the number, age and sex of the adults who successfully opened and, if applicable, properly reclosed the packaging;

b) the number, age and sex of the adults who failed to open and, if applicable, properly reclose the packaging;

c) the number, age and sex of the adults who opened but, if applicable, could not properly reclose the packaging;

d) if the full test has been used, the percentage number of adults who successfully opened and, if applicable, properly reclosed the packaging.

7.4 Additional information

In addition to the information required by 7.1 and either 7.2 or 7.3 (as appropriate), the supervisor(s) shall record any other information or occurrences which may affect the assessment of the results.

Appendix A Child test

A.1 Packagings for testing

A.1.1 General

Sufficient packagings^{2^} shall be supplied to enable samples to be submitted for testing and to provide a reserve for reference purposes.

A.1.2 Preliminary opening and closing of reclosable packagings

Each of the packagings to be tested shall be opened and properly reclosed by the person supervising the test.

Packagings which incorporate a tamper-evident seal in addition to being child-resistant shall have the seal broken and be opened and properly reclosed by the test supervisor prior to being tested.

A.1.3 Substitute products

No hazardous product shall be used to fill either reclosable or non-reclosable packagings. The packagings shall contain a substitute product resembling the appearance of the product it replaces, i.e. powder, tablets (uncoated placebo), liquid, etc. Where liquid is used this shall be uncoloured water. The packagings shall be filled to nominal size capacity (i.e. as sold) up to 1 L capacity for both liquid and solid products. Above this volume they shall be filled with 1 kg of solid or 1 L of liquid substitute product.

Packagings tested with water shall be regarded as suitable for both liquid and solid products if they pass the test. Packagings tested with a solid substitute product and which pass the test shall be regarded as suitable for solid products only. A further test with water shall be necessary if such a packaging is subsequently to be used for liquid products.

A.2 Test procedure

Carry out the test preferably by a sequential procedure or, alternatively, using all 200 children. When the former is used the number of children carrying out the test will depend on the results obtained (see clause A.3). When testing sequentially, maintain the even distribution by age and sex.

The children shall carry out the test in pairs in a location that is familiar to them, e.g. in their customary nursery school or kindergarten. Give each child of the pair a packaging simultaneously and request that it be opened. Do not attempt to stop a child using its teeth or other means of opening the packaging. Only such tools or devices as are specifically supplied as part of the design of the packaging shall be accessible to the child and the child shall have unobtrusive access to that tool, but it shall not be drawn to the child's attention until and unless it is used in the demonstration.

NOTE No other tools should be accessible which might be used by the child.

Allow each child 5 min to open the packaging. For those children unable to open the packaging in this time, give, where applicable, a single visual demonstration of the correct method of opening the packaging, but without a verbal explanation. Then allow a second 5 min for those children to open the packaging.

The test series need not be completed in one place at one time.

Further instructions on the surroundings and on the method of conducting the test are given in Appendix C.

A.3 Expression and assessment of results

A.3.1 General

Where a packaging requires more than one testing session plot the results of each session in chronological order.

A.3.2 Sequential method (preferred method)

As each result is obtained, plot it 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 child failed to open the packaging in the time allowed;
- b) fill in a square immediately above the previous result if the child succeeded in opening the packaging in the time allowed.

Prepare a separate trail of filled squares for results obtained before and after a demonstration. For reclosable packagings the chart shown in Figure 1 is appropriate for plotting the results before a demonstration and the chart shown in Figure 2 for plotting the results after a demonstration.

^{2^}> This is currently 506, to cover both child and adult teats and a reserve for reference purposes.

The chart shown in Figure 3 is appropriate for tests on non-reclosable packagings.

If more than one child carries out a test on one occasion, it shall be decided in advance in what order the individuals' results shall be plotted, e.g. alphabetical order of surname.

The packaging is regarded as having passed the test as soon as the trail of filled squares passes below limit line 1 or as having failed the test as soon as the trail passes above limit line 2.

The test shall be stopped as soon as either limit 1 or limit 2 is exceeded. If this does not occur, the results shall be assessed according to the postulates given in 4.1.1 a), 4.1.1 b) or 4.2.1.

A.3.3 *Full child test*

If the sequential procedure is not used and the full number of children carry out the tests, the results shall be assessed according to the postulates given in 4.1.1 a), 4.1.1 b) or 4.2.1.

Appendix B Adult test

B.1 Packagings for testing

B.1.1 *General*

Sufficient packagings³⁾, shall be supplied to enable samples to be submitted for testing and to provide a reserve for reference purposes.

B.1.2 *Preliminary opening and closing of reclosable packagings*

Each of the packagings to be tested shall be opened and properly reclosed by the person supervising the test.

Packagings which incorporate a tamper-evident seal in addition to being child-resistant shall have the seal broken and be opened and properly reclosed by the test supervisor prior to being tested.

B.1.3 *Substitute products*

No hazardous product shall be used to fill either reclosable or non-reclosable packagings. The packagings shall contain a substitute product resembling the appearance of the product it replaces, i.e. powder, tablets (uncoated placebo), liquid, etc. Where liquid is used this shall be uncoloured water. The packagings shall be filled to nominal size capacity (i.e. as sold) up to 1 L capacity for both liquid and solid products. Above this volume they shall be filled with 1 kg of solid or 1 L of liquid substitute product.

Packagings tested with water shall be regarded as suitable for both liquid and solid products if they pass the test. Packagings tested with a solid substitute product and which pass the test shall be regarded as suitable for solid products only. A further test with water shall be necessary if such a packaging is subsequently to be used for liquid products.

B.2 Test procedure

Carry out the test preferably by a sequential procedure or, alternatively, using all 100 adults. When the former is used the number of adults carrying out the test will depend on the results obtained (see clause B.3).

The adults shall carry out the test individually. The location of testing is not important. Give the adults only such printed instructions on how to open and, where applicable, properly reclose the packaging as will appear in or on the packaging as it is supplied to the public. Give each adult one packaging and ask the adult to open it and, if it is reclosable, to reclose it and repeat the opening and reclosing procedure.

NOTE The second opening and reclosing procedure should be easily and rapidly accomplished (e.g. within 30 s).

Allow 5 min to read the instructions and complete the required opening and, where applicable, reclosing procedures. Do not give a demonstration to the adults.

Further instructions on the surroundings and on the method of conducting the test are given in Appendix D.

B.3 Expression and assessment of results

B.3.1 *General*

Where a packaging requires more than one testing session plot the results of each session in chronological order.

B.3.2 *Sequential method (preferred method)*

As each result is obtained, plot it on the appropriate chart (see Figure 4) by filling in a square as follows:

- a) fill in a square immediately to the right of the previous result if the adult succeeded in opening and, if applicable, properly reclosing the packaging in the time allowed;
- b) fill in a square immediately above the previous result if the adult failed to open and, if applicable, properly reclose the packaging in the time allowed.

If more than one adult carries out a test on one occasion, it shall be decided in advance in what order the individuals' results shall be plotted, e.g. alphabetical order of surname.

³⁾ This is currently 506, to cover both child and adult tests and a reserve for reference purposes.

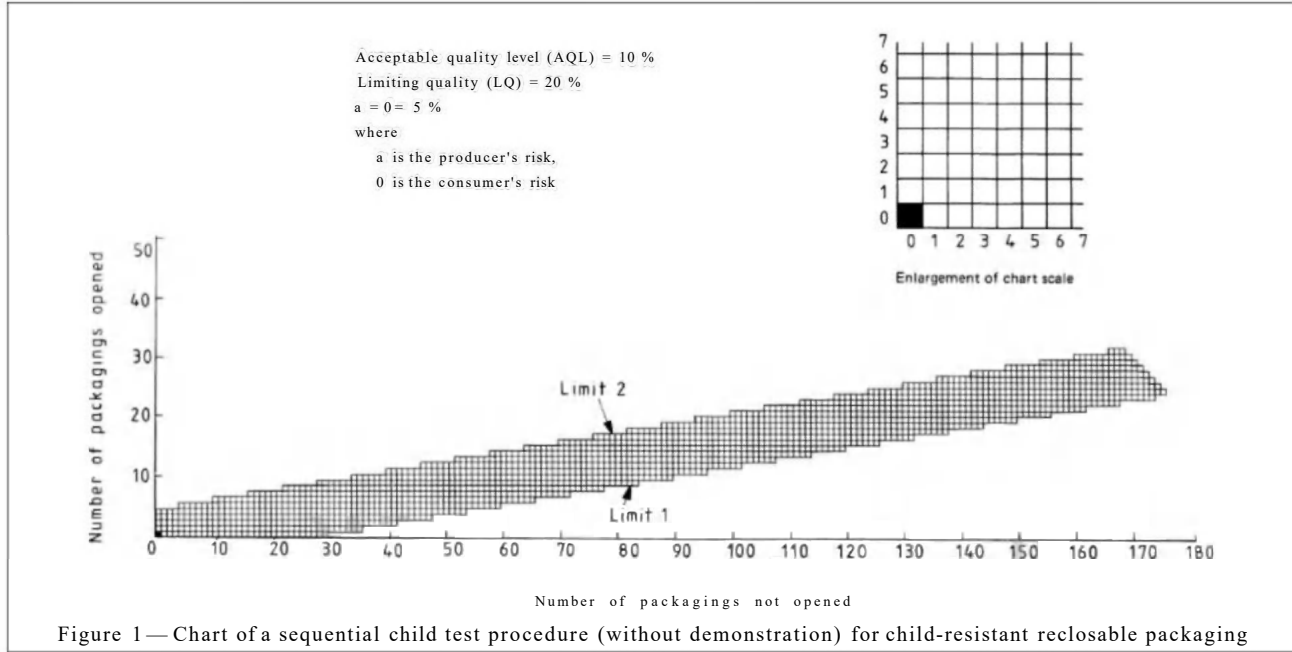
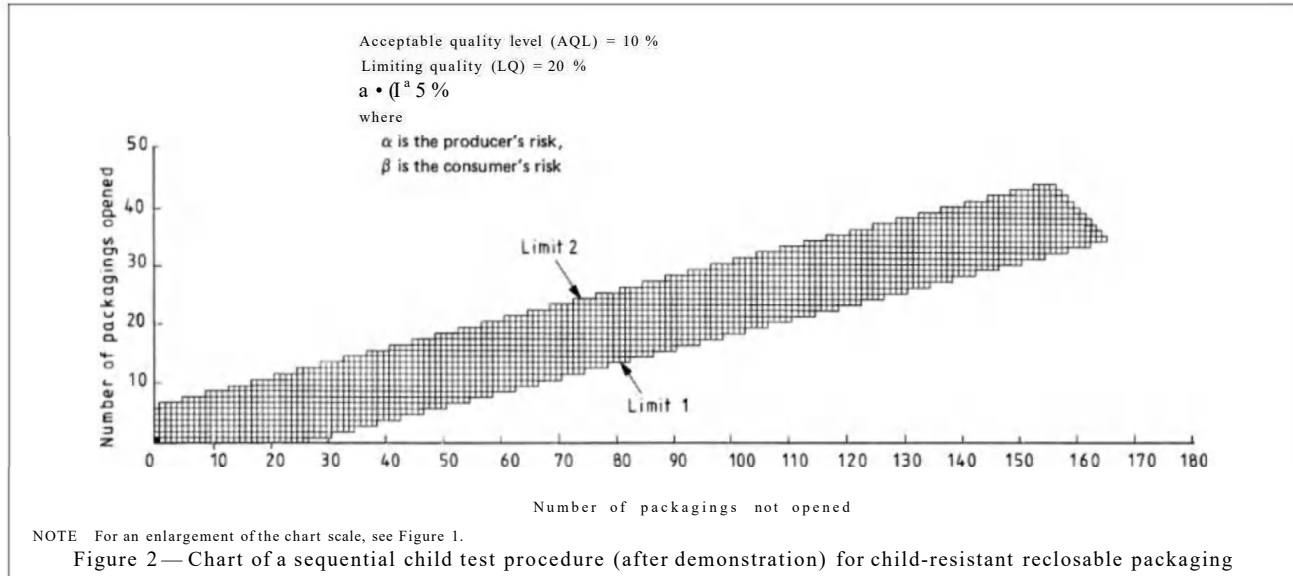
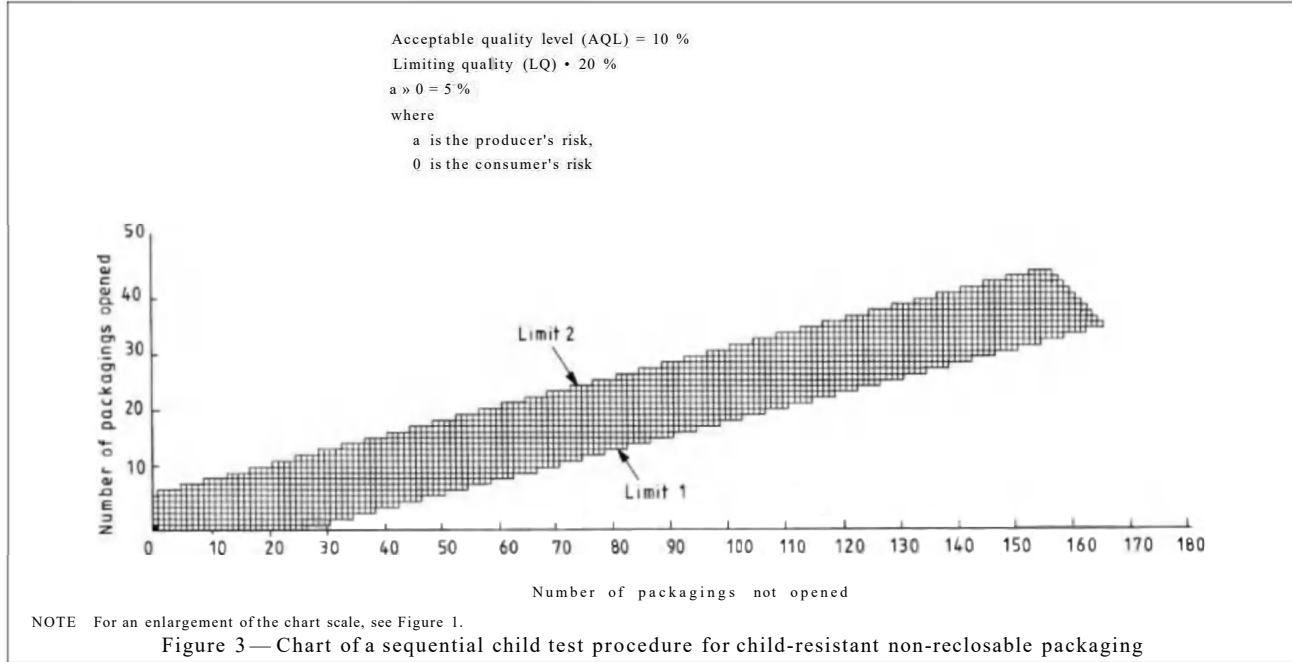
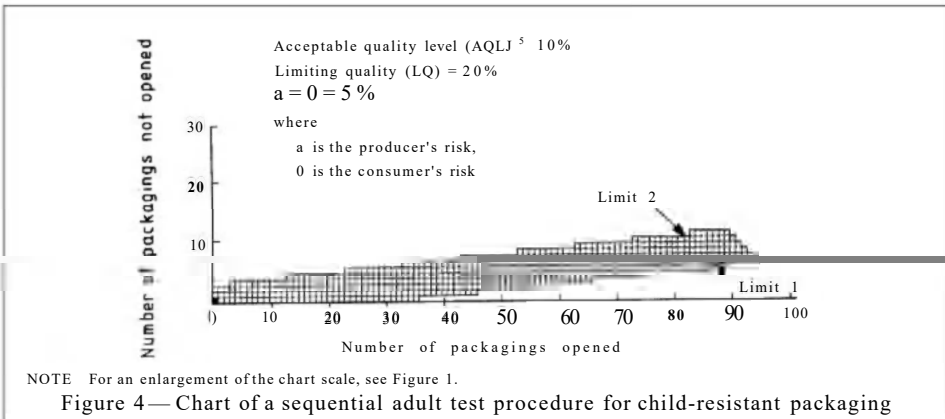


Figure 1— Chart of a sequential child test procedure (without demonstration) for child-resistant reclosable packaging







The packaging is regarded as having passed the test as soon as the trail of filled squares passes below limit line 1 or as having failed the test as soon as the trail passes above limit line 2.

The test shall be stopped as soon as either limit line 1 or limit line 2 is exceeded. If this does not occur, the results shall be assessed according to the postulates given in 4.1.2 or 4.2.2.

B.3.3 Full adult test

If the sequential procedure is not used and the full number of adults carry out the tests, the results shall be assessed according to the postulates given in 4.1.2 or 4.2.2.

Appendix C Instructions to persons supervising tests with children

C.1 Surroundings and personnel

Surroundings and personnel should be familiar and friendly. Personnel not familiar to the children should visit the test location (nursery school, kindergarten, etc) beforehand in order to obtain the confidence of the children.

C.2 Presence of parents

Children perform differently when the packagings are 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 parents from the test.

C.3 Social circumstances of the children

There is a highly significant correlation between the success rate in opening packagings and the social class of children. Those from poorer homes perform better than those in private nurseries and kindergartens.

Children should be selected to represent as closely as possible the different social, ethnic and cultural origins of the population of the country as a whole 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.

C.4 History of previous poisoning

Since a history of previous accidental ingestion may be associated with greater efficiency in opening packagings, any child who has been involved in such an incident should be excluded from the test panel.

C.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.

C.6 Standardization of numbers of children tested in one room on a single occasion

Children should be taken in pairs into a familiar room within the test location with the person(s) supervising the test.

C.7 Seating the children

Children should be seated in pairs at tables or desks arranged in a familiar manner and may sit on the floor if desired. They may adopt any attitude or position they find convenient.

C.8 Uniformity of assistance

Assistance should be limited to leading children who wander off back to their places.

C.9 Frequency of testing

It is preferable for only one test to be conducted at one testing session because there is a statistically significant difference in the results between the first and second packaging tried. Children perform less well in the first test. If a child is used in more than one test panel, it is desirable that there should be at least a week between the tests.

Appendix D Instructions to persons supervising tests with adults

D.1 General

Unlike child testing there is no need for the adults to carry out the tests at any particular place or time.

D.2 Screening

Each adult should be screened before carrying out the test and should give negative answers to the following questions:

- a) In the last six months have you taken part in any test related to child-resistant packaging?
- b) Are you professionally concerned with the design, manufacture or use of child-resistant packaging?

NOTE In order to establish that the individual is literate, it is possible to provide the questions on a typed (printed) form and give this to the person to read. Persons with obvious physical handicaps likely to affect their performance should not be approached.

D.3 Purposes of the test

The purpose of the test should be explained in reasonable detail and, with elderly adults, a demonstration of the opening procedure with verbal guidance should be given before starting the test.

Appendix E Elderly adult test

E.1 Performance criteria

At least 85 % of the test panel should be able to open and, if appropriate, properly reclose the packagings after having been given a demonstration.

E.2 Selection of personnel for test panel

Select 100 elderly adults, of whom 70 are female, between 60 years and 75 years of age inclusive and who have no obvious physical or mental handicap likely to affect the results of the test.

E.3 Packagings for testing

Sufficient packagings should be supplied to enable samples to be selected for testing and to provide a reserve for reference purposes.

E.4 Procedure

Carry out the test preferably by a sequential procedure or, alternatively using all 100 adults.

When the former is used the number of elderly adults carrying out the test will depend on the results obtained (see E.5.1).

The elderly adults should carry out the tests individually. The location of the tests is not important. Give the elderly adults a demonstration, including verbal guidance, of how to open and, if appropriate, properly reclose the packaging and then ask them to attempt the test. Allow the elderly adults 5 min to open and, if appropriate, properly reclose the packaging.

E.5 Expression and assessment of results

E.5.1 *Sequential method (preferred method)*

As each result is obtained, plot it on the appropriate chart (see Figure 5) by filling in a square as follows:

- a) fill in a square immediately to the right of the previous result if the adult succeeded in opening and, if appropriate, properly reclosing the packaging in the time allowed;
- b) fill in a square immediately above the previous result if the adult failed to open and, if appropriate, properly reclose the packaging in the time allowed.

The packaging is regarded as having passed the test as soon as the trail of filled squares passes below limit line 1 or as having failed the test as soon as the trail passes above limit line 2.

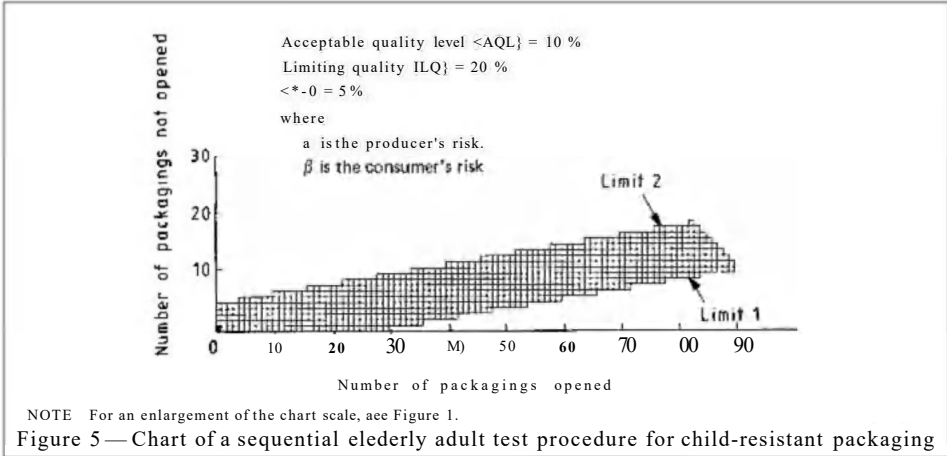
Stop the test as soon as either limit 1 or limit 2 is exceeded. If this does not occur, assess the results according to the postulate given in E.1.

E.5.2 *Full elderly adult test*

If the sequential procedure is not used and the full number of elderly adults carry out the test, assess the results according to the postulate given in E.1.

E.6 Records and results

When an elderly adult test is carried out, report records and results as detailed in 7.1, 7.3 and 7.4.



Publication referred to

BS 5321, *Reclosable pharmaceutical containers resistant to opening by children**.

⁴⁾ Referred to in the foreword only.

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