

Specification for

Packagings resistant to opening by children

UDC 615.014.87:621.798.26-78-053.2

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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 Containers Standards Committee, was published under the authority of the Board of BSI and comes into effect on 30 September 1985

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The following BSI references relate to the work on this standard:
Committee reference PKM/587
Draft for comment 84/40128 DC

ISBN 0 580 14636 7

Amendments issued since publication

Amd. No.	Date of issue	Comments

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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 BS 5321:1975 will however remain in force for some time after publication of this British Standard and will be withdrawn only when implementation of BS 6652 for pharmaceutical products has been agreed by the Department of Health and Social Security.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 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.

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.