

Packaging — Child-resistant packaging — Requirements and testing procedures for non-reclosable packages for pharmaceutical products

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Committees responsible for this British Standards

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- Association of the British Pharmaceutical Industry
- British Association for Chemical Specialities
- British Glass Manufacturers Confederation
- British Plastics Federation
- Child Accident Prevention Trust
- Consumer Policy Committee of BSI
- Department of Health — Medicines Control Agency
- Department of Trade and Industry — Consumer Safety Unit
- Flexible Packaging Association
- ICE — Ergonomics
- National Pharmaceutical Association
- Proprietary Association of Great Britain
- Royal Pharmaceutical Society of Great Britain

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Foreword

This British Standard has been prepared by Technical Subcommittee PKW/5/27, Child-resistant packaging. It is based on the draft of a proposed European Standard being prepared by CEN/TC 261, Packaging, by which it may eventually be replaced.

Product testing. Users of this British Standard are advised to consider the desirability of third-party testing of product conformity with this British Standard. Appropriate conformity attestation arrangements are described in the EN 45000 series of standards. Users seeking assistance in identifying appropriate conformity assessment bodies or schemes may ask BSI to forward their enquiries to the relevant association.

Annex A and annex C are informative. Annex B is normative.

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

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 16, an inside back cover and a back cover.

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Introduction

Child-resistant packaging is used to create a physical barrier between a child and a potentially hazardous product. Various types of packaging are recognized as being child-resistant, based on performance testing against standards for specific product categories and packaging types.

Since this type of packaging was introduced, the incidence of accidental ingestion of potentially hazardous products by children under 5 years old has fallen. The degree to which this is due to the use of child-resistant packaging as opposed to other factors, such as greater public awareness of the hazards, is not easily assessed, but there is little doubt that this packaging has made a positive contribution to the reduction.

The use of child-resistant packaging needs to be confined to those products that are potentially hazardous, or for which any legislation makes its use mandatory, since, if used in other circumstances, there could be confusion over the degree of hazard posed by the product.

In any case, proper labelling and information by the manufacturer is important for the safe use of the product in the home.

Child-resistant packaging acts as the last line of defence if other barriers separating the child and hazardous product have failed. However, it has to 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.

There has been an increasing use of child-resistant packaging, therefore it is desirable to achieve agreement on testing procedures in order to avoid confusion and misunderstanding in an area of great importance to the safety of young children.

This British Standard aims to reduce the number of children “exposed to training” during panel testing. Since the introduction of performance testing 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. Future development of standards based on mechanical test methods is required to avoid unnecessary child panel testing and is essential in developing physical package attributes useable by manufacturers.

Child-resistant packaging is only the last in a series of protective measures, and does not release parents or guardians from their duty to keep medicinal products out of the reach of children.

1 Scope

This standard specifies performance requirements and methods of test for non-reclosable packaging for pharmaceutical products that have been designated child-resistant. This standard is intended for type approval only (see 3.5) and is not intended for quality assurance purposes.

2 Normative references

This standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this standard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies (including amendments).

BS EN 862, *Packaging — Child-resistant packaging — Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products.*

3 Terms and definitions

For the purposes of this standard, the terms and definitions given in BS EN 862, some of which are repeated below for convenience, and the following apply.

3.1

child-resistant package

package which is difficult for young children to open (or gain access to the contents), but which is not difficult for adults to use properly

NOTE Requirements for the levels of accessibility to children and adults are contained within this standard and in BS EN 862.

3.2

non-reclosable child-resistant package

child-resistant package or part of a child-resistant package which, when all or part of the contents have been removed, cannot be properly closed again

3.3

substitute product

inert substitute resembling the product it replaces, i.e. powder, tablets or liquids (uncoloured water) [BS EN 862]

NOTE This is sometimes referred to as a placebo product.

3.4

unit dose

discrete quantity of any product to be removed from its immediate packaging in its entirety [BS EN 862]

3.5

type approval

procedure to certify as child-resistant a specific type of non-reclosable package, formed from a specified set of materials, which has met the requirements of this standard

4 Requirements

4.1 General requirements

A non-reclosable child-resistant package, when tested in accordance with the requirements of this standard, shall be capable of providing a satisfactory degree of resistance to opening by children (see 4.2.1) and a satisfactory level of accessibility to its contents by adults (see 4.2.2).

A non-reclosable child-resistant package, in addition to conforming to the performance requirements specified in this standard (see 4.2), shall be appropriate for the contents, provide mechanical protection and function properly for the life of the content and packaging.

Manufacturers, fillers and packers of such packages shall initiate and operate procedures to control the quality of packaging materials so that they are in accordance with the requirements of this standard.

NOTE BS EN ISO 9001:2000 specifies requirements for quality management systems where organizations need to demonstrate their capability of supplying conforming products to customers.

4.2 Performance requirements

4.2.1 Child test

When tested in accordance with 5.3.2 and evaluated in accordance with 5.4.1, the packaging shall be child-resistant.

4.2.2 Adult test

When tested in accordance with 5.3.3, at least 90 % of the adults shall be able to access at least 1 unit dose, henceforth referred to as "unit", within the 1 min test period, without a demonstration.

5 Testing

5.1 Principle

Type approval for non-reclosable child-resistant packaging is obtained by a sequential test method for children and a full panel test for adults. A test group of up to 200 children aged 42 to 51 months is divided into pairs. Each child is given a number of non-reclosable packages to be opened by whatever means they wish to use. If a child fails to gain access within 5 min, the method of opening is demonstrated by the supervisor and the child is given a further 5 min to open the package. The results are recorded sequentially, as obtained. The package is deemed child-resistant if the trail of results on the test charts passes into the acceptance zone or if at least 80 % of the children are unable to access more than 8 units within 10 min and at least 85 % of the children are unable to access more than 8 units within the first 5 min. The package's accessibility by a test group of 100 adults is also assessed. Each adult is given a non-reclosable package, any associated opening tools and written instructions, and is allowed 5 min to familiarize themselves with the packaging. The number of adults opening the package within a subsequent 1 min test period is recorded. The package is deemed to conform to the requirements of this standard if at least 90 % of the adults are able to access at least 1 unit in 1 min.