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

Emballages à l'épreuve des enfants — Exigences et méthodes d'essai pour emballages refermables

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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/Cor 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;

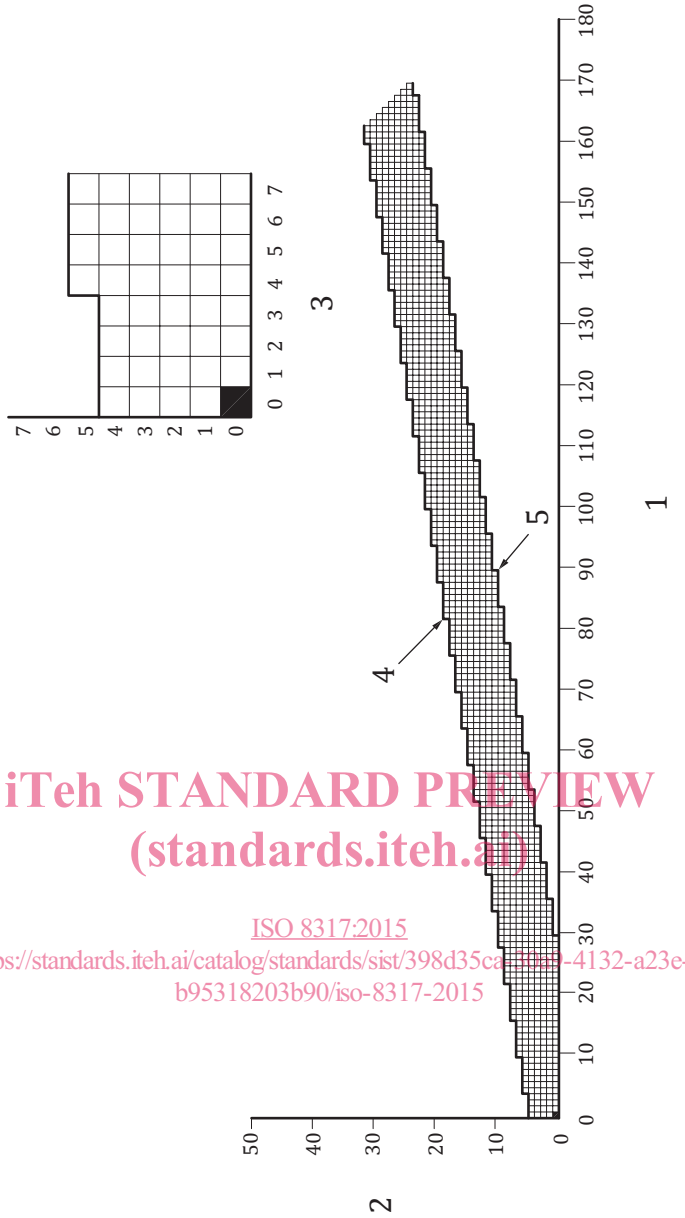
b) at least 80 % of the 200 children in the test panel shall be unable to open the package within another 5 min after a demonstration has been given to those children unable to open the package in the first 5 min.

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