

## **Child-resistant packaging - Requirements and testing procedures for reclosable packages**

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testing procedures for reclosable packages

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 8317:2004 sisaldab Euroopa standardi EN ISO 8317:2004 + AC:2005 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 23.11.2004 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 8317:2004 consists of the English text of the European standard EN ISO 8317:2004 + AC:2005.</p> <p>This document is endorsed on 23.11.2004 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p><b>Käsitlusala:</b></p> <p>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.</p>	<p><b>Scope:</b></p> <p>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.</p>
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ICS 55.020

Võtmesõnad:

English version

Child-resistant packaging - Requirements and testing  
procedures for reclosable packages (ISO 8317:2003)

Emballages à l'épreuve des enfants - Exigences et  
méthodes d'essai pour emballages refermables (ISO  
8317:2003)

Kindersichere Verpackung - Anforderungen und  
Prüfverfahren für wiederverschließbare Verpackungen (ISO  
8317:2003)

This European Standard was approved by CEN on 15 July 2004.

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## Foreword

The text of ISO 8317:2003 has been prepared by Technical Committee ISO/TC 122 "Packaging" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 8317:2004 by Technical Committee CEN/TC 261 "Packaging", the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2005, and conflicting national standards shall be withdrawn at the latest by March 2005.

This document supersedes EN 28317:1992.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

## Endorsement notice

The text of ISO 8317:2003 has been approved by CEN as EN ISO 8317:2004 without any modifications.

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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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## 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 8317 was prepared by Technical Committee 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 second edition cancels and replaces the first edition (ISO 8317:1989), which has been technically revised.



## 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 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 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 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. 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 that 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-restraint 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-restraint 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 has to be administered by some responsible authority in each country adopting the International Standard, as all have to have confidence in the manner in which testing is carried. 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 17025:1999, *General requirements for the competence of testing and calibration 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.

NOTE 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.

NOTE 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.

The rationale for the proposed amendments to ISO 8317:1989 is as follows.

The publication and adoption of ISO 8317:1989 has resulted in a wider use of reclosable child-resistant packaging, which has enforced a growing awareness that the elderly and physically handicapped have difficulty in opening this style of packaging.

This, on occasion, can result in the child-resistant closure not being properly reapplied. The US Consumer Product Safety Commission (CPSC) has also recognized this concern and, in 1996, introduced amendments to their adult test protocol.

ISO/TC 122/SC 3/WG 3, when reviewing ISO 8317:1989, considered that certain aspects of the changes made by the CPSC to its protocol were worthy of incorporation into ISO 8317:1989, principally to adopt the older age range of adults forming the test panel and the method of the test.

ISO/TC 122/SC 3/WG 3 do not see these changes invalidating the classification of packages certified as child-resistant under the previous International Standard for the child panel test, but, as the main purpose of the adult test was to prove that adults could resecure the closure properly, the revised adult test protocol will require repeating to reaffirm full child-resistant status of the package.

During the review, the opportunity was taken to incorporate Annexes A, B and C, together with the amendment, into the main body of the document.

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

## 1 Scope

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.

## 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 package

package consisting of a container and appropriate closure which is difficult for young children under the age of fifty-two months to open (or gain access to the contents), but which is not difficult for adults to use properly when tested and approved in accordance with the requirements of this International Standard

### 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** 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. Liquid substitute product is always uncoloured water.