

Child-resistant packaging - Requirements and testing
procedures for reclosable packages (ISO 8317:2015)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 8317:2015 sisaldab Euroopa standardi EN ISO 8317:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 8317:2015 consists of the English text of the European standard EN ISO 8317:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 02.12.2015.	Date of Availability of the European standard is 02.12.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 55.020

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:

Aru 10, 10317 Tallinn, Eesti; koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Aru 10, 10317 Tallinn, Estonia; homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

English Version

Child-resistant packaging - Requirements and testing
procedures for reclosable packages (ISO 8317:2015)

Emballages à l'épreuve des enfants - Exigences et
méthodes d'essai pour emballages refermables (ISO
8317:2015)

Kindergesicherte Verpackungen - Anforderungen und
Prüfverfahren für wiederverschließbare Verpackungen
(ISO 8317:2015)

This European Standard was approved by CEN on 17 October 2015.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

This document (EN ISO 8317:2015) has been prepared by Technical Committee ISO/TC 122 "Packaging" in collaboration with 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 June 2016, and conflicting national standards shall be withdrawn at the latest by June 2016.

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

This document supersedes EN ISO 8317:2004.

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

Endorsement notice

The text of ISO 8317:2015 has been approved by CEN as EN ISO 8317:2015 without any modification.

Contents

	Page
Foreword	iv
Introduction	vi
1 Scope	1
2 Terms and definitions	1
3 Requirements	2
3.1 Test requirements.....	2
3.1.1 General.....	2
3.1.2 Evaluation of a series of similar packaging.....	3
3.2 Test panels.....	4
3.3 Performance requirements.....	4
3.3.1 Requirements concerning children.....	4
3.3.2 Requirements concerning adults.....	4
4 Test procedures	6
4.1 Test supervision.....	6
4.2 Sample packages.....	7
4.3 Preliminary checking and preparation.....	7
4.4 Child test.....	7
4.4.1 Guidance for persons supervising tests.....	7
4.4.2 Composition of test group.....	8
4.4.3 Test location.....	8
4.4.4 Procedure.....	8
4.4.5 Expression of results (see also 5.1).....	9
4.5 Adult test (50 years to 70 years old inclusive).....	9
4.5.1 General.....	9
4.5.2 Composition of test group.....	9
4.5.3 Procedure.....	9
4.5.4 Expression of results (see also 5.2).....	10
5 Assessment of results	10
5.1 Child test.....	10
5.1.1 Success/failure.....	10
5.1.2 Sequential method.....	10
5.1.3 Full test.....	11
5.2 Adult test.....	11
5.3 Overall test result.....	11
6 Test report	11
6.1 General.....	11
6.2 Child test.....	11
6.3 Adult test.....	12
6.4 Additional (optional) information to be recorded.....	12
6.5 Overall test result.....	12
Bibliography	13

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.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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/Corr 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](#)).

This document is a preview generated by EVS

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.