



SLOVENSKI STANDARD

SIST EN 28317:1996

01-avgust-1996

Embalaža, varna za otroke - Zahteve in preskusni postopki za embalažo, ki jo je mogoče večkrat zapreti (ISO 8317:1989)

Child-resistant packaging - Requirements and testing procedure for reclosable packages (ISO 8317:1989)

Kindersichere Verpackung - Anforderungen und Prüfverfahren für wiederverschließbare Verpackungen (ISO 8317:1989)

Emballages a l'épreuve des enfants - Exigences et méthodes d'essai pour emballages refermables (ISO 8317:1989)

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ICS:

55.020	Pakiranje in distribucija blaga na splošno	Packaging and distribution of goods in general
97.190	Otroška oprema	Equipment for children

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EUROPEAN STANDARD

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English version

**Child-resistant packaging - Requirements and
testing procedures for reclosable packages
(ISO 8317:1989)**

Emballages à l'épreuve des enfants - Exigences
et méthodes d'essai pour emballages refermables
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This European Standard was approved by CEN on 1992-10-30. 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 Central Secretariat or to any CEN member.

The European Standards exist 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

In 1991, ISO 8317:1989 "Child-resistant packaging - Requirements and testing procedures for reclosable packages" was submitted to the CEN Primary Questionnaire procedure.

Following the positive result of the CEN/CS Proposal ISO 8317:1989 was submitted to the Formal Vote.

The result of the Formal Vote was positive.

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 May 1993, and conflicting national standards shall be withdrawn at the latest by May 1993.

According to the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom. (standards.iteh.ai)

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The text of the International Standard ISO 8317:1989 was approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

**ISO
8317**

First edition
1989-07-01

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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Reference number
ISO 8317 : 1989 (E)

ISO 8317 : 1989 (E)**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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 8317 was prepared by Technical Committee ISO/TC 122, *Packaging*.

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Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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

0 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 drugs and medicines, 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 to 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 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-resistant packaging as against other fac-

tors, 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-resistant 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 must be administered by some responsible authority in each country adopting the International Standard, as all must have confidence in the manner in which testing is carried out and 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 Guide 25, *General requirements for the technical competence of testing laboratories*, which provide useful guidance on these topics.

ISO 8317 : 1989 (E)

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.

NOTES

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.

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.

1 Scope and field of application

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.

Means of performing the test on a series of similar packages are given in annex A and guidance for persons carrying out the tests is given in annexes B and C.

2 Definitions

For the purposes of this International Standard, the following definitions apply.

2.1 child-resistant package: A package which is difficult for young children under the age of five to open (or gain access to the contents), but which is not difficult for adults to use properly in accordance with the requirements of this International Standard.

2.2 reclosable package: Any package which, after it has 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 substitute product: An inert substitute resembling the product it replaces.

NOTE — Solid substitute products for child-resistant packages should normally consist of powder, granules or units of any similar shape and size varying from 5 to 30 mm in any dimension, preferably of a neutral colour, and not harmful in any way. Liquid substitute product should always be uncoloured water.

3 General**3.1 Compliance with this International Standard**

A child-resistant package tested in accordance with the requirements of this International Standard is shown to be capable, when correctly made and used, of providing a satisfactory degree of resistance to opening by children while maintaining accessibility to its contents by adults; in other words, the test is designed for type approval. Manufacturers and fillers of such packages will be required to initiate and operate such procedures as are necessary to control production and use, and to ensure that all packages meet the required quality standards.

3.2 Packages for testing

Sufficient packages shall be supplied to enable a representative sample to be selected for testing by the supervisor and to provide a reserve for reference purposes. In every test, a new package shall be provided for each member of the test group.

Before child testing is carried out on reclosable child-resistant packages, both manufacturers and fillers shall satisfy themselves that the life expectancy of the child-resistant package will exceed the maximum expected number of openings and closings which are likely to occur in practice without unacceptable impairment of the child-resistant property.

3.3 Test panels

Testing is carried out with two classes of people:

- a) a test with young children between 42 and 51 months of age, inclusive;
- b) a test with adults between 18 and 65 years of age, inclusive.

4 Requirements**4.1 General safety requirements**

A child-resistant package, in addition to satisfying the requirements for child resistance specified in 4.2, shall meet the requirements for packaging, such as being appropriate for the contents, providing mechanical protection and functioning properly for the life of the package.

4.2 Performance requirements**4.2.1 Requirements concerning children**

When the packaging is tested in accordance with 5.3, the following requirements shall be met:

a) at least 85 % of the children in the test panel shall be unable to open the package within 5 min without a demonstration, and

b) at least 80 % of the children in the test panel shall be unable to open the package within 5 min without a demonstration and within another 5 min after a demonstration has been given to those children unable to open the package in the first 5 min.

4.2.2 Requirements concerning adults

When the packaging is tested in accordance with 5.4, at least 90 % of the adults shall be able to open and reclose the package properly within 5 min and without a demonstration.

5 Test procedures

5.1 Test supervision

All procedures shall be carried out under the supervision of (an) impartial and appropriately qualified person(s). For the child test, the supervisor(s) shall also be skilled in handling children.

Guidance for persons carrying out the tests is given in annexes B and C.

5.2 Preliminary checking and preparation

Before packages are tested, each package should be opened and properly reclosed.

Packages which incorporate a tamper-evident seal in addition to being child-resistant shall have the seal broken; they shall be opened and checked by the test supervisor(s) as specified in the previous paragraph prior to the child test.

No hazardous product shall be used to fill any package submitted for test. A suitable substitute product shall be used for adult tests; a suitable substitute product shall also be used for child tests except in cases where this would conflict with national requirements. When a substitute product is used, packages up to a volume of 1 litre shall be filled to their nominal size capacity (i.e. as sold); packages greater than 1 litre volume shall be filled with 1 kg of solid or 1 litre of liquid substitute product as appropriate.

5.3 Child test

5.3.1 Composition of test group

Enough children to ensure 200 valid participants between the ages of 42 and 51 months inclusive, with an even distribution of age and sex, shall be available. As far as possible they shall represent the social, ethnic and cultural origins of the country as a whole. They shall all be healthy with no evident physical or mental handicap associated with manual dexterity. They shall not have taken part in more than one previous test and, in that test, a packaging of a different type with opening arrangements based on a different principle shall have been involved. If a child is used on more than one test panel, it is desirable that there should be at least 1 week between the tests.

5.3.2 Location

The children shall perform the test in any place with which they are familiar, e.g. in their usual school or kindergarten, but they shall be removed from the general school population and separated from extraneous distractions. Several venues should be selected from different demographic areas. The test series need not necessarily be completed at one venue at one time.

5.3.3 Procedure

The test may be carried out on all 200 children or by a sequential procedure. If the latter is used, the number of children tested will depend on the results obtained (see 6.1.2). When testing sequentially, the age and sex constraints specified in 5.3.1 shall be adhered to.

The children shall be tested in pairs, each pair being monitored by one supervisor. If desired, a number of pairs (up to five) may be tested in the same room at the same time, provided that arrangements are such that they cannot distract other pairs. They may adopt any attitude or position they find convenient. Should a child wander off during the test, action by the supervisor(s) shall be limited to leading the child back to its place and requesting that he or she continue the test, without any additional instruction being given concerning the opening of the package; this fact shall be included in the report.

NOTE — If required by the regulatory body, an official observer may be present, but the requirements laid down in clause B.1 still apply.

Each child shall be given a package with the request that it be opened by whatever means the child wishes to use; in order to achieve this, 5 min shall be allowed. No attempt shall be made to stop a child using its teeth or any other method of opening the package. However, no tools or implements should be accessible which might be used by the child, except where such tools or devices are specifically supplied as part of the design of the child-resistant package; where this is so, the children shall have unobtrusive access to that tool, but it shall not be drawn to their attention until and unless it is used in the demonstration.

If a child succeeds in opening the package within 5 min that child shall remain in the test area until the end of the period. Any child failing to open the packaging in 5 min shall then watch a package being opened and reclosed by the supervisor(s) in full view, without emphasis being placed on the actions of opening and without any verbal instruction. The child shall then have a further 5 min to open the package.

5.3.4 Expression of results (see also 6.1)

After each period of 5 min, it shall be recorded whether a child fails to open the package; if the child succeeds, it shall be recorded whether this was before or after a demonstration. It shall also be recorded whether teeth (or any other means) were used to open the package.

5.4 Adult test (18 to 65 years inclusive)

5.4.1 Composition of test group

Enough normal adults to ensure 100 valid participants shall be available. All should be able to understand the operating