



SLOVENSKI STANDARD

SIST EN 862:2002

01-januar-2002

BUXca Yý U
SIST EN 862:1998

Embalaža - Embalaža, varna za otroke - Zahteve in preskusni postopki za embalažo, ki se ne zapira ponovno in ni za farmacevtske proizvode

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

Verpackung - Kindergesicherte Verpackung - Anforderungen und Prüfverfahren für nichtwiederverschließbare Verpackungen für nichtpharmazeutische Produkte

Emballages - Emballage a l'épreuve des enfants - Exigences et méthodes d'essai pour emballages non refermables pour les produits non pharmaceutiques

Ta slovenski standard je istoveten z: EN 862:2001

ICS:

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

SIST EN 862:2002 en

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 862:2002

<https://standards.iteh.ai/catalog/standards/sist/ba9df93-7ac9-45d5-b324-b6e2d7e1b154/sist-en-862-2002>

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 862

July 2001

ICS 55.020

Supersedes EN 862:1997

English version

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

Emballages - Emballage à l'épreuve des enfants - Exigences et méthodes d'essai pour emballages non refermables pour les produits non pharmaceutiques

Verpackung - Kindergesicherte Verpackung - Anforderungen und Prüfverfahren für nichtwiederverschließbare Verpackungen für nichtpharmazeutische Produkte

This European Standard was approved by CEN on 9 May 2001.

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 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 Management Centre has the same status as the official versions.

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



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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Contents

	page
Introduction	4
1 Scope	6
2 Normative references	6
3 Terms and definitions.....	6
4 General.....	7
4.1 Compliance with the European Standard.....	7
4.2 Packages for testing.....	7
5 Requirements	7
5.1 General safety requirements	7
5.2 Design requirements	7
5.3 Acceptance requirements	7
5.4 Child test.....	8
5.5 Adult test (optional)	9
6 Assessment of results.....	9
6.1 Child test.....	9
6.2 Sequential method.....	9
6.3 Adult test (optional)	10
6.4 Overall result	10
7 Test report	10
7.1 General.....	10
7.2 Child test.....	11
7.3 Adult test (optional)	11
7.4 Additional (option) information to be recorded	11
7.5 Overall test result.....	11
Annex A (normative) Tables for sequential test procedure	12
Annex B (normative) Charts for a sequential test procedure	20
Annex C (informative) Non-closable child-resistant packaging — Advice on providing opening instructions.....	24
Annex D (informative) Guidance for persons supervising tests with children	25
Annex E (informative) Notes for guidance in adult testing	26
Bibliography	27

iTech STANDARD PREVIEW
(standards.iteh.ai)

SIST EN 862:2002

<https://standards.iteh.ai/catalog/standards/sist/ba9dfe93-7ac9-45d5-b324->

[66e2d7e1415d/sist-en-862-2002](https://standards.iteh.ai/catalog/standards/sist/ba9dfe93-7ac9-45d5-b324-66e2d7e1415d/sist-en-862-2002)

Foreword

This European Standard has been prepared 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 January 2002, and conflicting national standards shall be withdrawn at the latest by January 2002.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association

This European Standard supersedes EN 862:1997.

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

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN 862:2002](https://standards.iteh.ai/catalog/standards/sist/ba9df93-7ac9-45d5-b324-b6e2d7e1b154/sist-en-862-2002)

<https://standards.iteh.ai/catalog/standards/sist/ba9df93-7ac9-45d5-b324-b6e2d7e1b154/sist-en-862-2002>

Introduction

The use of potentially hazardous agents in certain products is necessary to achieve effectiveness. Consequently, steps are 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 at protecting the child by educating the parents 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 could 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 acts as a last defence if other barriers separating children and hazardous products have failed.

This standard is designed to meet the requirements of the Directive 67/548/EEC as amended for the fourteenth time by Council Directive 91/410/EEC and complement the EN 28317 relating to child-resistant reclosable packages. 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 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. The development of European Standards incorporating mechanical test methods based on current European or national standards is appropriate to avoid unnecessary child panel testing and is essential in developing physical package attributes usable by manufacturers.

Because of the increasing use of child-resistant packaging, it is desirable to achieve European agreement on testing procedures in order to avoid confusion and misunderstanding in an area of great importance to the safety of young children. A European 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 should be administered by some responsible authority in each country adopting the European Standard, which should 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 ?
- how is it ensured that an identical package format is not tested more than once by different laboratories other than for enforcement ?

Attention is drawn to the need to have adequate accreditation bodies. Evidence of conformity with this standard may be certified only by laboratories which conform with European Standards Series EN 45000.

This European 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 in 2 years and revised if necessary in the light of experience.

NOTE 1 This European 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 The on-going development of non-reclosable packaging offers a significant area for innovation in packaging. The styles of non-reclosable packages can be wide-ranging in design.

Consequently, the development of mechanical test methods by manufacturers allied to current EN or national standards should be pursued as a means of reducing the reliance on child panel testing.

NOTE 3 A fundamental change to the test period philosophy is applied because

- there is a significant difference in the performance required from a non-reclosable packaging and ;
- there is the difficulty in keeping the children motivated during a test period of 5 minutes.

NOTE 4 Mechanical test methods may be used to generate test data for comparison and demonstration that the notified packaging is as safe as the original reference one. Mechanical tests are test methods generating data by destructive or non destructive tests of a specific reference package having shown child-resistant properties.

A standard is in preparation to complement this EN 862.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN 862:2002](https://standards.iteh.ai/catalog/standards/sist/ba9dfe93-7ac9-45d5-b324-b6e2d7e1b154/sist-en-862-2002)

<https://standards.iteh.ai/catalog/standards/sist/ba9dfe93-7ac9-45d5-b324-b6e2d7e1b154/sist-en-862-2002>

EN 862:2001 (E)**1 Scope**

This European Standard specifies the requirements and test methods for non-reclosable child-resistant packages designated as resistant to opening by children.

The standard applies to non-reclosable packages of the 'single-use' type of one or several individual units.

Non-reclosable packages for pharmaceutical products are excluded.

Acceptance criteria are given for the package when tested by specific methods. These methods do not only provide a measure of the effectiveness of the package but also cover the accessibility to the contents by adults.

This European Standard is intended for type approval only (see **4.1**) and is not intended for quality assurance purposes.

NOTE The term 'non-reclosable child-resistant package' covers not only packages where the seal is provided by a system to prevent access by young children, designed for that purpose (for example, a package comprising separate compartments and including a supporting medium, pre-formed or not, which contains the product, along with a film material which constitutes the closure) but also those packages where there is no specific method of opening (for example, completely sealed sachets, etc.).

2 Normative references

This European 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 European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

Not applicable.

3 Terms and definitions

<https://standards.iteh.ai/catalog/standards/sist/ba9dfe93-7ac9-45d5-b324-b6e2d7e1b154/sist-en-862-2002>
SIST EN 862:2002

For the purposes of this Standard, the following terms and definitions 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 in accordance with the requirements of this European Standard

3.2**non-reclosable child-resistant package**

child-resistant package or part of a child-resistant package from which the entire content has to be removed at once and which cannot be properly closed again once opened, in a child-resistant form

3.3**substitute product**

inert substitute resembling the product it replaces i.e. powder, tablets or liquids (uncoloured water) etc.

3.4**single use package**

package of one or several unit doses which are not only individually protected but are also individually packaged

NOTE A blister is an example of a single-use package of the single-use type of one or several individual units.

3.5**unit dose**

discrete quantity of any product to be removed from its immediate packaging in its entirety

4 General

4.1 Compliance with the European Standard

A child-resistant package tested in accordance with the requirements of this European Standard is shown to be capable, when correctly made and used, of providing a satisfactory degree of resistance to opening by children (see 6.3).

Accessibility to its contents by adults can be checked according to the optional adult test (see 5.5).

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 them to ensure that all packages meet the required quality standards.

NOTE 1 Contrary to reclosable packages where an adult test is needed for safety considerations as it is of major importance to know if the package is correctly reclosed after use, such safety consideration is unnecessary for non-reclosable packages and the adult test can be optional for commercial assessment only.

NOTE 2 Any adult test should be carried out before subjecting the package to child testing, in order to reduce exposing children to unnecessary testing.

4.2 Packages for testing

Sufficient packages shall be produced by the proposed manufacturing process 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. Dangerous products shall not be used to fill the package to be tested. An appropriate substitute product with a salty or bitter taste shall be used.

NOTE Packages for child panel test should be unprinted.

5 Requirements

<https://standards.iteh.ai/catalog/standards/sist/ba9dfe93-7ac9-45d5-b324-b6e2d7e1b154/sist-en-862-2002>

5.1 General safety requirements

A child-resistant package, in addition to satisfying the requirements for child resistance specified in 5.2, shall meet the requirements for packaging, such as being appropriate for the contents providing mechanical protection and functioning properly for the life of the content and its packaging.

5.2 Design requirements

5.2.1 The child-resistant packaging shall comply with the technical specification needed for the packaging of a given product, and it shall conform with the quality requirements of the assembled package.

5.2.2 The conditions described in 5.2.1 shall be complied with throughout the foreseeable shelf life of the content and its packaging.

5.2.3 The design and method of opening used for the child-resistant package shall not cause adults difficulty when opening the package.

For this reason, those parts of the packaging used to carry information shall clearly state and/or illustrate the method used for opening the package (see Annex C *Advice on providing opening instructions*).

5.3 Acceptance requirements

5.3.1 Child test

The following requirements shall be met when all 200 children are used to test the package in accordance with 5.4 :

- at least 85 % of the children in the test panel shall be unable to open the package within 3 min without a demonstration ;

EN 862:2001 (E)

- at least 80 % of the children in the test panel shall be unable to open the package within 6 min (3 min without a demonstration and 3 min after a demonstration).

5.3.2 Adult test

When the packaging is tested in accordance with **5.5** at least 90 % of the adults shall be able to open the package properly within 5 min without a demonstration.

5.4 Child test**5.4.1 Composition of child 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 and design shall have been used. If a child is used for more than one test, it is preferable that there should be at least 4 weeks between tests.

5.4.2 Test location

The children shall perform the test in any place with which they are familiar or relaxed, for example, in their usual school or nursery, but they shall be removed from the general school population and separated from extraneous distractions. Several locations may be selected from different demographic areas. The test series need not necessarily be completed at one location at one time.

5.4.3 Test 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 **5.4.1** shall be adhered to.

Pairs of children shall be involved in the test, each pair being monitored by one supervisor. If desired, a number of pairs (up to five) may undertake tests 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 that 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.

If a child leaves the test place during the test period (3 min or 6 min) or refuses to participate in the test despite encouragement the result shall not be taken into account but the event recorded.

Each child shall be given a package with the request that it be opened by whatever means the child wishes to use ; 3 min shall be allocated for this purpose. No attempt shall be made to prevent 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 supplied with the package ; where this is so, the children shall have access to that tool, but it shall not be drawn to their attention other than by being used in the demonstration.

Children failing to open the package in the first 3 min shall then watch a single demonstration by the test supervisor of the package being opened, with no emphasis being placed on the actions of opening and with no verbal instructions.

The children then have a further 3 min to open the package.

When tools are needed to open the package but these are not supplied with it, there shall be no demonstration ; the test is therefore limited to the first part where they are given a maximum of 3 min and no demonstration.

NOTE 1 If required by the regulatory body, an official observer can be present, but the requirements laid down in annex **D.1** still apply.

5.4.3.1 Recording of results

After each period of 3 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. Additional information could be recorded for the use of the manufacturers of the packaging, if requested.

5.5 Adult test (optional)

5.5.1 Composition of adult test group

Enough normal adults to ensure 100 valid participants shall be available. All shall be able to understand the opening instructions used on the package concerned in the test. 70 % of the adults shall be female. 80 of the adults shall be between 18 and 60 years of age inclusive and 20 shall be between 61 and 65 years of age inclusive. In other words, one adult between 61 and 65 of age inclusive shall be tested for every 4 adults between 18 and 60 years of age inclusive.

They shall all be healthy with no evident physical or mental handicap associated with manual dexterity.

5.5.2 Test procedure

Adult tests may be carried out on all 100 adults or by a sequential procedure. If the latter is used, the number of adults tested will depend on the results obtained (see **6.2.2**). When testing sequentially, the age and sex constraints specified in **5.5.1** shall be adhered to.

Each adult shall be given a package together with any accessories and written instructions on how to open it properly that will be printed in or on the package when supplied to a consumer. No demonstration of how to open the package shall be given. A period of 5 min shall be allowed for the person to read the instructions and open the package.

iteh STANDARD PREVIEW
(standards.iteh.ai)

6 Assessment of results

[SIST EN 862:2002](#)

6.1 Child test

<https://standards.iteh.ai/catalog/standards/sist/ba9dfe93-7ac9-45d5-b324-b6e2d7e1b154/sist-en-862-2002>

6.1.1 Success/failure

The result of the test is a failure if the child succeeds in opening the package or gaining access to the contents.

6.1.2 Sequential method

As each result is obtained, it is plotted on either table A.1 or A.2 as given in annex A or on the chart in figure B.1 or B.2 given in annex B. The chart shall be used as follows :

- a) fill in a square immediately to the right of the previous result on figure B.1 if the child failed to open the package (or gain access to the contents) in the first 3 min, and on figure B.2 if the child failed to open the package (or gain access to the contents) in the second 3 min, i.e. the result is a success (see **6.1.1**) ;
- b) fill in a square immediately above the previous result in figures B.1 and B.2 if the child succeeded in opening the package (or in accessing to the contents) in the first 3 min. Enter only on figure B.2, if the child succeeded in opening the package (or in accessing the contents) in the second 3 min, when the result is a failure (see **6.1.1**).

The results for all children who succeeded in opening the package in the first phase shall also be recorded as a failure of the package as in Figure **B.2**.

NOTE 1 In the case of the first result to be plotted, the blanked out square is regarded as the "previous result".

NOTE 2 The package is deemed to have failed the test as soon as a trail or filled squares passes into the rejection zone, or to have passed the test as soon as the trails pass into the acceptance zone.