SLOVENSKI STANDARD
kSIST FprEN 862:2016

01-februar-2016

Embalaža - Embalaža, varna za otroke - Zahteve in preskusni postopki za embalažo, ki je ni mogoče večkrat zapreti 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 à l'épreuve des enfants - Exigences et méthodes d'essai pour emballages non refermables pour les produits non pharmaceutiques

Ta slovenski standard je istoveten z: **FprEN 862**

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

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
FprEN 862

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ICS 55.020; 97.190

Will supersede EN 862:2005

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 draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 261.

If this draft becomes a European Standard, 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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European foreword

This document (FprEN 862:2015) has been prepared by Technical Committee CEN/TC 261 “Packaging”, the secretariat of which is held by AFNOR.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede EN 862:2005.

The document has been revised from edition EN 862:2005 to correct Clause 4.4.1.3.1.

Introduction

Child-resistant packaging is used to create a physical barrier between a child and a potentially hazardous product. Various types of packaging are recognized as being child-resistant, based on performance testing against standards for specific product categories and packaging types.

Since this type of packaging was introduced, the incidence of accidental ingestion of potentially hazardous products by children under 5 years old has fallen. The degree to which this is due to the use of child-resistant packaging as opposed to other factors, such as greater public awareness of the hazards, is not easily assessed, but there is little doubt that this packaging has made a positive contribution to the reduction.

The use of child-resistant packaging needs to be confined to those products that are potentially hazardous, or for which any legislation makes its use mandatory, since, if used in other circumstances, there could be confusion over the degree of hazard posed by the product.

In any case, proper labelling and information by the manufacturer is important for the safe use of the product in the home.

Child-resistant packaging acts as the last line of defence if other barriers separating the child and hazardous product have failed. However, it has to 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.

There has been an increasing use of child-resistant packaging, therefore it is desirable to achieve agreement on testing procedures in order to avoid confusion and misunderstanding in an area of great importance to the safety of young children.

This European Standard aims to reduce the number of children “exposed to training” during panel testing. Since the introduction of performance testing, 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. Future development of standards based on mechanical test methods is required to avoid unnecessary child panel testing and is essential in developing physical package attributes useable by manufacturers.

Child-resistant packaging is only the last in a series of protective measures, and does not release parents or guardians from their duty to keep potentially dangerous products out of the reach of children.

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.

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. 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.

1 Scope

This European Standard specifies performance requirements and methods of test for non-reclosable packaging that has been designated child-resistant and which is intended to contain non-pharmaceutical products. This European standard is intended for type approval only (2.5) and is not intended for quality assurance purposes.

This European Standard applies to non-reclosable packages of the single-use type consisting of one or more individual units.

Non-reclosable packages for pharmaceutical products are excluded from the scope of this European standard. These are the subject of a separate standard, EN 14375, *Child-resistant non-reclosable packaging for pharmaceutical products - Requirements and testing.*

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
child-resistant package
package which is difficult for young children to open (or gain access to the contents), but which it is possible for adults to use properly

2.2
non-reclosable child-resistant package
child-resistant package or part of a child-resistant package which, when all or part of the contents have been removed, cannot be properly closed again

2.3
substitute product
inert substitute resembling the product it replaces

EXAMPLE Powder, tablets or liquids (uncoloured water), etc.

2.4
unit
discrete quantity of any product to be removed from its immediate packaging in its entirety

2.5
type approval
procedure to certify as child-resistant a specific type of non-reclosable package, formed from a specified set of materials, which has met the requirements of this European standard

2.6
single use package
package of one or several units which are not only individually protected but also individually packed for single use

3 Requirements

3.1 General requirements

A non-reclosable child-resistant package, when tested in accordance with the requirements of this European Standard, shall be capable of providing a satisfactory degree of resistance to opening by children (3.2.1). Accessibility to its contents by adults can be checked according to the optional adult test (3.2.2).

A non-reclosable child-resistant package, in addition to conforming to the performance requirements specified in this European Standard (3.2), shall be appropriate for the contents, provide mechanical protection and function properly for the life of the content and packaging.

Manufacturers, component manufacturers, fillers and packers of such packages shall initiate and operate procedures to control the quality of packaging materials so that type approved packaging is in accordance with the requirements of this European Standard.

NOTE EN ISO 9001 specifies requirements for quality management systems where organizations need to demonstrate their capability of supplying conforming products to customers.

3.2 Performance requirements

3.2.1 Child test

An individual child test shall be considered a failure in relation to a single use package if within 10 min, or 5 min when no demonstration has been given, the child gains access to one or more units from the packaging provided.

When tested in accordance with 4.3.2 and evaluated in accordance with 4.4.1, the packaging shall be child-resistant.

3.2.2 Adult test

This test is optional unless a tool is supplied to open the container at the point of sale.

When tested in accordance with 4.3.3 and evaluated in accordance with 4.4.2, at least 90 % of the adults shall be able to access at least 1 unit within the 1 min test period, without a demonstration.

To minimize the exposure of children to unnecessary testing, the adult test should be carried out before the child test.

4 Testing

4.1 Principle

Type approval for non-reclosable child-resistant packaging is obtained by a sequential test method for children. A test group of up to 200 children aged 42 to 51 months is divided into pairs. Each child is given a number of non-reclosable packages to be opened by whatever means they wish to use. If a child fails to gain access within 5 min, the method of opening is demonstrated by the supervisor and the child is given a further 5 min to open the package. The results are recorded sequentially, as obtained. The package is deemed child-resistant if the trail of results on the test charts passes into the acceptance zone or if at least 80 % of the children are unable to access one or more units within 10 min and at least 85 % of the children are unable to access one or more units within the first 5 min. The package's accessibility may also be assessed by an optional full panel test for adults using a test group of 100 adults. Each adult is given a non-reclosable package, any associated opening tools and written instructions, and is allowed 5 min to familiarise themselves with the packaging. The number of adults opening the package within a 1 min test period is recorded. The package is deemed to comply with the

requirements of this European Standard if at least 90 % of the adults are able to access at least 1 unit in 1 min.

4.2 Samples and sample preparation

Sufficient packages shall be produced by the proposed manufacturing process to enable a representative sample to be selected by the supervisor for testing and to provide a reserve for reference purposes. Dangerous products shall not be used to fill the package to be tested; an appropriate substitute product shall be used. The material and design of the test samples shall conform to the technical specification and they shall be representative of an average batch of original packages.

Packages for the child panel test shall be unprinted.

In every test, a new package shall be provided for each member of the test group.

Each sample package shall be checked for integrity before the test is conducted. The packages shall be presented to the children without the outer retail packaging, giving them access to the individual units.

4.3 Procedure

4.3.1 General

The test procedure is carried out in two stages:

a) child test (4.3.2);

b) adult test (4.3.3).

4.3.2 Child test

4.3.2.1 Composition of child test group

The test group shall comprise no more than 200 children aged 42 to 51 months, inclusive, with approximately equal numbers of girls and boys. As far as possible, there shall be an even distribution of ages and sexes within the panel. The children shall be selected at random and shall have no apparent physical or mental disability that might affect 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, there shall be at least 4 weeks between tests. Parental or guardian consent shall be obtained before the child is used as a part of the test group. Any children having been involved in a reported poisoning accident shall be excluded from the test.

Children should be selected to represent, as closely as is reasonably possible, the different social, ethnic and cultural origins of the population as a whole, and not just of the immediate district in which the test is carried out.

4.3.2.2 Test procedure

Testing shall be carried out in the presence of a test supervisor. The child test shall take place in an environment familiar to the children.

Test personnel should visit the test location beforehand and become known by the children in order to gain their confidence. Only the supervisors should be present, parents being excluded from the test.

The test shall be carried out by a sequential procedure (4.4.1.1 to 4.4.1.3). The number of children tested will therefore depend on the results obtained, however, the age and sex constraints specified in 4.3.2.1 shall be adhered to.

Pairs of children shall be involved in the test, each pair being monitored by one supervisor. Should a child wander off during the test, action by the supervisor 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 (Clause 5).

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 and should not be restrained. During the test, children should be removed as far as possible from extraneous distractions. If other means of observation are used, the supervisor may stand at a distance from the children.

Each child shall be given sufficient packages (see 4.2) with the request that they be opened by whatever means the child wishes to use; 10 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 shall be accessible which might be used by the child, other than those supplied by the manufacturer/filler or packer at point of sale.

Children failing to open or gain access to a minimum of 1 unit in the first 5 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. These children then have a further 5 min to open the package or gain access to its contents.

When tools are needed to open the package, but these are not supplied by the manufacturer, there shall be no demonstration. The test is therefore limited to the first 5 min test period.

If a child leaves the test area during the test period (5 min or 10 min) or refuses to participate in the test despite encouragement, the result shall not be taken into account but the event recorded.

At the conclusion of the each test, the children should be warned not to play with, or attempt to open, these types of packages.

Annex A provides a summary of the requirements and guidance to be followed by test supervisors. If required by the regulatory body, an official observer will be present, but the guidance laid down in Annex A still applies.

4.3.3 Adult test

4.3.3.1 Composition of adult test group

The test group shall comprise 100 participants. These shall be selected using a screening procedure in which potential participants shall be asked the following question.

“Are you professionally concerned with the design, manufacture or use of child-resistant packaging?”

Only those participants responding with a negative answer shall be selected.

In order to elicit this information and, at the same time, to ascertain whether the individual is literate, this question shall be presented on a typed or printed form and given to the person to read.

Persons with obvious physical disabilities that might affect manual dexterity shall not be approached and those unable to understand the written opening instructions shall not be tested.

The purpose of the test shall be explained but no demonstration shall be given.

The 100 participants shall be randomly selected between the ages of 50 and 70 in accordance with the requirements given in Table 1. Not more than 30 of the adults tested shall be obtained from or tested at any one site. No individual supervisor shall administer the test to more than 35 adults.