SLOVENSKI STANDARD
oSIST prEN ISO 28862:2022

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Embalaža - Embalaža, varna za otroke - Zahteve in preskusni postopki za embalažo, ki je ni mogoče večkrat zapreti in ni za farmacevtske proizvode (ISO 28862:2018)

Packaging - Child-resistant packaging - Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products (ISO 28862:2018)

Verpackung - Kindergesicherte Verpackung - Anforderungen und Prüfverfahren für nichtwiederverschließbare Verpackungen für nichtpharmazeutische Produkte (ISO 28862:2018)

Emballages - Emballage à l'épreuve des enfants - Exigences et méthodes d'essai pour emballages non refermables pour les produits non pharmaceutiques (ISO 28862:2018)

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97.190	Otroška oprema	Equipment for children

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INTERNATIONAL STANDARD

ISO 28862

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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

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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.

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 (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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This document was prepared by the European Committee for Standardization (CEN) (as EN 862) and was adopted, under a special "fast-track procedure", 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)*.

There are no changes to the content of the EN 862 document apart from the addition of Clause 2, Normative references.

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 document 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 standards should be pursued as a means of reducing the reliance on child panel testing.

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

1 Scope

This document 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 document is intended for type approval only (see 2.5) and is not intended for quality assurance purposes.

This document 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 document. These are the subject of a separate standard, ISO 14375, *Child-resistant non-reclosable packaging for pharmaceutical products — Requirements and testing.*

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
child-resistant package
package which is difficult for young children to open (or gain access to the contents), but which is possible for adults to use properly

3.2
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

3.3
substitute product
inert substitute resembling the product it replaces

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

3.4
unit
discrete quantity of any product to be removed from its immediate packaging in its entirety

3.5
type approval
procedure to certify as child-resistant a specific type of non-reclosable package, formed from a specified set of materials

3.6
single use package
package of one or several units which are not only individually protected but also individually packed for single use

4 Requirements

4.1 General requirements

A non-reclosable child-resistant package, when tested in accordance with the requirements of this document, shall be capable of providing a satisfactory degree of resistance to opening by children (4.2.1). Accessibility to its contents by adults can be checked according to the optional adult test (4.2.2).

A non-reclosable child-resistant package, in addition to conforming to the performance requirements specified in this document (4.2), 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 document.

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

4.2 Performance requirements

4.2.1 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 5.3.2 and evaluated in accordance with 5.4.1, the packaging shall be child-resistant.

4.2.2 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 5.3.3 and evaluated in accordance with 5.4.2, 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.

5 Testing

5.1 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 document if at least 90 % of the adults are able to access at least 1 unit in 1 min.

5.2 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.

5.3 Procedure

5.3.1 General

The test procedure is carried out in two stages:

a) child test (5.3.2);

b) adult test (5.3.3).

5.3.2 Child test

5.3.2.1 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.

5.3.2.2 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.