

Child-resistant non-reclosable packaging for medicinal products - Requirements and testing

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medicinal products - Requirements and testing

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 14375:2004 sisaldab Euroopa standardi EN 14375:2003 + AC:2006 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 20.02.2004 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 14375:2004 consists of the English text of the European standard EN 14375:2003 + AC:2006.</p> <p>This document is endorsed on 20.02.2004 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala:</p> <p>This European Standard specifies performance requirements and methods of test for non-reclosable packaging that have been designated child-resistant. This standard is intended for type approval only (see 3.5) and is not intended for quality assurance purposes</p>	<p>Scope:</p> <p>This European Standard specifies performance requirements and methods of test for non-reclosable packaging that have been designated child-resistant. This standard is intended for type approval only (see 3.5) and is not intended for quality assurance purposes</p>
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ICS 11.120.01, 55.020, 97.190

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ICS 11.120.01; 55.020; 97.190

English version

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

Emballage à l'épreuve des enfants, non refermables pour produits pharmaceutiques - Exigences et essais

Kindergesicherte, nichtwiederverschließbare Verpackungen für pharmazeutische Produkte - Anforderungen und Prüfungen

This European Standard was approved by CEN on 1 September 2003.

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.

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Foreword

This document (EN 14375:2003) 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 May 2004, and conflicting national standards shall be withdrawn at the latest by May 2004.

Annexes A and C are informative.

Annex B is normative.

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, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

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 child-resistant 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 child-resistant 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 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.

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.

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.

This standard aims to minimize 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 can be reduced. Future development of standards based on mechanical test methods is needed 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 medicinal products out of the reach of children.

1 Scope

This European Standard specifies performance requirements and methods of test for non-reclosable packaging that have been designated child-resistant. This standard is intended for type approval only (see 3.5) and is not intended for quality assurance purposes.

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).

EN 862:2001 *Packaging - Child-resistant packaging - Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products.*

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN 862:2001 and the following apply.

3.1

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

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, i.e. powder, tablets or liquids (uncoloured water), etc.

NOTE This is sometimes referred to as a placebo product.

3.4

unit dose

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, which has met the requirements of this standard

4 Requirements

4.1 General requirements

A non-reclosable child-resistant package, when tested in accordance with the requirements of this standard, shall be capable of providing a satisfactory degree of resistance to opening by children (see 4.2.1) and a satisfactory level of accessibility to its contents by adults (see 4.2.2).