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Child-resistant non-reclosable packaging for pharmaceutical products - Requirements and testing (ISO 14375:2018)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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English Version

Child-resistant non-reclosable packaging for pharmaceutical products - Requirements and testing (ISO 14375:2018)

Emballages non refermables à l'épreuve des enfants
pour produits pharmaceutiques - Exigences et essais
(ISO 14375:2018)

Kindergesicherte, nichtwiederverschließbare
Verpackungen für pharmazeutische Produkte -
Anforderungen und Prüfung (ISO 14375:2018)

This European Standard was approved by CEN on 17 March 2023.

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EN ISO 14375:2023 (E)

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European foreword

The text of ISO 14375:2018 has been prepared by Technical Committee ISO/TC 122 "Packaging" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 14375:2023 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of an identical text or by endorsement, at the latest by September 2023, and conflicting national standards shall be withdrawn at the latest by September 2023.

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Endorsement notice

The text of ISO 14375:2018 has been approved by CEN as EN ISO 14375:2023 without any modification.

INTERNATIONAL STANDARD

ISO 14375

First edition
2018-07

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

*Emballages à l'épreuve des enfants, non refermables pour produits
pharmaceutiques — Exigences et essais*



Reference number
ISO 14375:2018(E)

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ISO 14375:2018(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.

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).

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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 14375) 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 14375 document.

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 document 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.

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

1 Scope

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

2 Normative references

There are no normative references in this document.

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