Australian Standard™

Child-resistant packages

Standards Australia

This Australian Standard was prepared by Committee HE-001, Medical, Diagnostic and Surgical Products. It was approved on behalf of the Council of Standards Australia on 15 December 2000 and published on 31 January 2001.

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Australian Chemical Specialties Manufacturers Association

Australian Institute of Packaging

Australian Self Medication Industry

Commonwealth Department of Health and Aged Care

Consumers Federation of Australia

Consumers Health Forum of Australia

Department of Human Services, Vic.

Health Department, W.A.

National Injury Prevention Advisory Council Standards WorkingGroup

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PREFACE

This Standard was prepared by the Standards Australia Subcommittee HE-001-08, Packaging Systems and Devices—Child-resistant—Chemicals, under the responsibility of Committee HE-001, Medical, Diagnostic and Surgical Products, as a revision of AS 1928—1982, *Child-resistant packaging*.

The objective of this Standard is to set particular requirements for packages, containing chemicals, that will be resistant to opening by children.

This Standard differs from the 1982 edition in the following respects:

(a) The adult panel has been extended to include a broader age range.

(b) The range of closures of packaging systems in Appendix D has been varied.

(c) The sequential test strategy has been modified for both children and adults testing panels.

(d) Consideration has been given to other forms of non-reclosable packages (see Section 3 and Appendix E).

In the preparation of this Standard, account was taken of the *Code of Federal Regulations, Subchapter E—Poison Prevention Packaging Act of 1970 Regulations*, BS EN 862:1997, *Packaging—Child-resistant packaging—Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products*, and ISO 8317:1989, *Child-resistant packaging—Requirements and testing procedures for reclosable packages*. The Standard differs from ISO 8317:1989 in the following aspects:

(a) A distinction in the categories of reclosable and non-access packages has been made.

(b) Requirements for non-reclosable packages are specified.

(c) Appendix D reflects the local experience with extrapolating results from type testing to evaluation of similar reclosable packages.

In a future edition of the Standard, consideration may be given in Appendix B to an instruction that children may use their teeth to open packages if new evidence is forthcoming.

The terms ‘normative’ and ‘informative’ have been used in this Standard to define the application of the appendix to which they apply. A ‘normative’ appendix is an integral part of a Standard, whereas an ‘informative’ appendix is only for information and guidance.

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FOREWORD

The purpose of this Standard is to assess the resistance of packaging, designated as being child-resistant, to opening by children. However, the Committee recognizes that adults, particularly aged persons, represent a significant proportion of the consuming public. It therefore recommends that bodies approving packaging as child-resistant for legal purposes should take into account the possible inability of some old or disabled people to open certain types of packaging which comply with this Standard.

For the testing of reclosable packages, it will be noted that the children in the child panel are aged 42 to 51 months. This is at the high end of the age range at which child poisoning is most common, so as to challenge the packaging with children most likely to have the dexterity to succeed. Similarly the adult age range of 18 to 65 years is not intended to be representative of the population as a whole, but of the adults who can read the instructions and would be expected to be able to implement them with a high probability of success. Older or non-English-speaking people are more likely to need help.

It is recommended that discussion take place between designers, manufacturers, testing and regulatory authorities during the design and development stage of proposed child-resistant packaging.

The Committee had no data on the effect of transparency of the package and has not specified this aspect in the present revision. It recommends that this matter, together with the questions of physical standards for both reclosable and non-reclosable packages and the ability of old or disabled people to open the package should be considered at a future revision when more data may be available and valid tests may have been developed.

It should be noted that 'child-resistant' is not synonymous with 'child-proof'. Child-resistant packaging provides only one safeguard—delay in access—in the protection of children against accidental poisoning. Other precautions should also be taken by parents, legislators, educators and marketeers to ensure that hazardous substances are kept out of reach of children.

For reclosable packages, the Standard requires that panels of children and adults be given the packages to open and the criteria for complying with the Standard are expressed in terms of the minimum number of children in the children's panel who will successfully open the packages and the maximum number of adults who may fail to open the packages.

For non-reclosable packages, the Standard requires an examination of the materials of construction and the carrying out of tests for seal strength and seal integrity. Compliance is expressed in terms of the material requirements and maximum permissible leakage.

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SECTION 1 SCOPE AND GENERAL REQUIREMENTS

1.1 SCOPE

This Standard specifies requirements for reclosable (containers with closures) and non-reclosable packages, designated as being resistant to opening by children. It is intended to be particularly applicable to the packaging of chemicals, e.g. poisons, including medicines and toxic substances, where child-resistant packaging is required.

NOTE: Packaging systems for chemicals, not intended for access by humans, are dealt with in another Standard.

1.2 REFERENCED DOCUMENT

The document below is referred to in this Standard.

ICH Guidelines for Good Clinical Practice.

1.3 DEFINITIONS

For the purpose of this Standard, the definitions below apply.

1.3.1 Blister

A package in which one or more dosage units are enclosed between a pre-formed tray with individual pockets and a lidding material which may be flat or shaped. The dosage units can only be extracted singly. The material of the tray is usually different from that of the lid.

1.3.2 Non-reclosable package

A package in which a unit of use is individually protected until the time of release, e.g. from a strip, blister, pouch or sachet.

1.3.3 Placebo

An inert substitute for the product it is to simulate.

1.3.4 Reclosable package (system)

A form of container with closure which, once opened, can be reclosed to its original form.

1.3.5 Strip

A package in which one or more dosage units are enclosed individually in a continuous strip made by bonding two layers of material together so that the dosage units are separated and protected and can only be extracted singly. Each layer may be of the same or different material.