Australian Standard®

CHILD-RESISTANT PACKAGING

This Australian standard was prepared by Committee PK/26, Child Resistant Packaging of Therapeutic Goods. It was approved on behalf of the Council of the Standards Association of Australia on 21 September 1982 and published on 8 November 1982.

The following interests were represented on the Committee responsible for the preparation of this standard:

Agricultural and Veterinary Chemicals Association of Australia

Australian Institute of Packaging

Confederation of Australian Industry

Department of Consumer Affairs, N.S.W.(Product Safety Committee)

Department of Health (National Biological Standards Laboratory)

Education Department of New South Wales

Health Commission of New South Wales

Health Commission of Victoria

Health Services Department, Tasmania

National Council of Chemical and Pharmaceutical Industries

Packaging Council of Australia

Pharmaceutical Society of Australia

Public Health Department, Western Australia

Royal Alexandra Hospital for Children, Sydney

Royal Children's Hospital, Melbourne

The Proprietary Association of Australia

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PREFACE

This edition of this standard was prepared by the Association's Committee on Child Resistant Packaging of Therapeutic Goods, under the direction of the Association's Packaging Standards Board and at the request of the Australian Department of Health, to supersede AS 1928—1976.

Among the principal changes in this edition, the scope has been altered to make the standard a specification of requirements for child-resistant packaging, with consequent change in the title, as the former edition dealt only with methods of test. The standard now also includes sequential procedures for testing of reclosable packages using panels of adults and children, designed to allow conclusions to be reached with the fewest possible volunteers while retaining the probabilities associated with the use of full panels.

The constitution of panels of children and adults and procedure to be followed when testing the child-resistant packages as well as the evaluation of a series of similar reclosable packages is described in Appendices B, C, D and E. Appendix F describes a test for integrity of seal for non-reclosable packages.

For discussion on principles of sequential sampling, reference may be required to the following standards:

AS 1199 Sampling Procedures and Tables for Inspection by Attributes

AS 1399 Guide to AS 1199, Sampling Procedures and Tables for Inspection by Attributes.

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for
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FOREWORD

In developing the second edition of this standard, the committee considered similar work proceeding in the British Standards Institution, the International Organization for Standardization, the Canadian Government Specification Board and the American Society for Testing and Materials. The committee took special note of the consequences which would flow from departure from the parameters of current British Canadian and American standards, including for example the age specifications and allowable percentages of failure in the child and adult panels. Thus although each parameter was carefully examined, a conservative approach was taken to any proposed deviations which may have made overseas work invalid in Australia.

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 45 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 will obviously need help, as with many other aspects of daily living.

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.

Child-resistant packaging should not bear any resemblance to any item manufactured as a toy. Except for printing, packaging in bright primary colours, which might attract the attention of children should be avoided. The package should—

(a) be of a design which does not require sight, unusual strength or unusual dexterity to obtain access to the contents and, if appropriate, to replace the closure, if appropriate;

(b) retain its child resistant properties for the expected life of the product; and

(c) be sufficiently strong to withstand the usual risks of transport, handling and storage.

Sight may well be needed to read the instructions in the first instance, but it should be possible for a partially sighted or blind person to be told how to open the package and then to succeed in the task.

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 marketers to ensure that hazardous substances are kept out of reach of children.

SECTION 1. SCOPE AND GENERAL REQUIREMENTS

1.1 SCOPE. This standard specifies requirements for packages, both reclosable (containers with closures) and non-reclosable (strip and blister packages), designated as being resistant to opening by children. It is intended to be particularly applicable to the packaging of poisons, including medicinal poisons, where child-resistant packaging is required.

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 that will successfully open the packages and the maximum number of adults that 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.

1.2 DEFINITIONS. For the purpose of this standard, the following definitions apply:

1.2.1 Placebo—an inert substitute for the product it is to simulate.

1.2.2 Reclosable package—a form of container with closure, which, once opened, can be reclosed to its original form.

1.2.3 Non-reclosable package—a package in which a dosage unit such as a pill, capsule or tablet is individually protected until the time of release, e.g. from a strip or blister package.

1.2.4 Strip package—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.

1.2.5 Blister package—a package in which one or more dosage units are enclosed between a pre-formed tray with individual pockets and a ridding 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 MATERIALS. The components of the package shall be compatible with the substance they are intended to contain.

1.4 FREEDOM FROM DEFECTS. The package shall be manufactured in accordance with good engineering practice and shall be free from defects which may significantly affect performance of the substance or package.

1.5 MARKING. Both container and closure of a reclosable package shall be identifiable.

NOTE. Manufacturers who place the number of this Australian standard on child-resistant packaging or literature related thereto should ensure that the packaging is manufactured to comply with this standard.