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BABIES' DUMMIES

STANDARDS ASSOCIATION OF AUSTRALIA
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THE FOLLOWING SCIENTIFIC, INDUSTRIAL, CONSUMER AND GOVERNMENTAL organizations and departments were officially represented on the committee entrusted with the preparation of this standard:

Australian Consumers Association

Australian British Trade Association

Confederation of Australian Industry

Department of Business and Consumer Affairs

Department of Consumer Affairs, N.S.W.

Department of Health

Department of Preventative Dentistry—University of Sydney

Health Commission of New South Wales

National Safety Council of Western Australia Incorporated

Nursing Mothers Association

Pharmacy Guild of Australia

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AUSTRALIAN STANDARD

BABIES' DUMMIES

AS 2432—1981

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PREFACE

This standard was prepared by the Association's Committee on Babies' Dummies in response to a request by the Health Commission of New South Wales, which resulted from public concern about the safety aspects of materials, construction and performance of babies' dummies.

The standard has been based on the following documents:

BS 5239 Babies' Dummies

US Federal Register
Title 16 Commercial Practices
Chapter II, Consumer Product Safety Commission

Canadian Hazardous Product (Pacifier) Regulations

AS 1647 Children's Toys (Safety Requirements)
Part 2—Constructional Requirements
Part 3—Toxicological Requirements

This standard makes reference to the following standards:

AS 1152 Test Sieves

AS 2070 Plastics Materials for Food Contact Use
Part 1—Polyethylene
Part 2—Polyvinyl Chloride (PVC) Compounds
Part 3—Styrene Plastics Materials
Part 4—Acrylonitrile Plastics Materials
Part 5—Polypropylene

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard for BABIES' DUMMIES

FOREWORD

This standard aims to establish, through manufacturing requirements, a desirable level of inherent safety in babies' dummies (also known as pacifiers, or soothers) and to highlight, by way of labelling requirements, the consumer's responsibilities in the proper use and hygienic care of the product.

It will be noted from Clause 4 that the materials for construction have been limited to plastics and rubber compounds only. This has become necessary because the vast majority of dummies are made from only these compounds. It is appreciated that other materials may possibly be used to a greater degree at some later date, and it is the intention of the Association to review the standard when such a condition arises.

It will also be noted from Clause 4.2 that the concentration of heavy metal elements, which are used as colourants in the plastics materials, has been limited. The test procedure specified for evaluating the level of the heavy metal elements is intended to simulate the leaching out of the heavy metal elements from the plastics materials by the action of gastric acids on the assumption that the plastics material had been swallowed. It may be argued that such a test procedure is inappropriate because the purpose of the standard is to obviate the possibility of the dummy or any component of the dummy being ingested. As such, it could appear that the test procedure should more appropriately relate to a saliva extraction test since leaching, if any, would normally occur only in the baby's mouth. However, it was believed that the baby's environment should be as free from possible harmful elements as is practicable. Accordingly, Clause 4.2 specifies an acid-extraction test because the simulated gastric acid solution would provide an additional factor of safety since acid is a stronger leaching medium than saliva.

With regard to the design and construction requirements specified in Clause 5, it will be noted that the shield dimensions not only need to comply with the template test (i.e. the shield must *not* pass through the template opening) but the shield must also have a minimum width dimension (viz 35 mm). It has become necessary to specify the minimum width dimension because the template test alone is considered insufficient to ensure that the shield dimension would be of a size that would minimize the chances of the baby taking the whole of the dummy into its mouth.

Further, it was argued that the template test was deficient because it specified only a two-dimensional requirement, whereas a three-dimensional requirement was needed. That is, it was argued that since there was no effective thickness requirements, the actual thickness of a dummy was very small thereby allowing a baby to easily take the whole dummy into its mouth by inserting it into the mouth edge first. Although the ring would increase the effective thickness of the dummy to some degree, some members of the committee believed that this was insufficient because the standard allows rings which offer no resistance (i.e. the ring merely flops over under its own weight) to edge-on entry of the dummy into a baby's mouth. These members argued that the ring should be so designed that it would spring back to its upright position when the ring was depressed and then released. Such an arrangement, together with possibly increasing the stiffness of the teat portion, would reduce the chance of the whole dummy being taken into the baby's mouth. On the other hand other members of the committee argued that such a requirement would be undesirable because it could increase the chances of the dummy becoming wedged in the baby's mouth, if the baby happened to force the whole of the dummy into its mouth and the ring and/or the teat sprang back to their upright position in the baby's mouth. Consequently, since there was no evidence to support the need for an effective thickness, this question was left in abeyance.

Although it is believed that dummies complying with the standard will reduce the risk to babies using such a product, it is nevertheless stressed that the standard *cannot* eliminate all possible risks and parental control is of paramount importance. In this regard attention is particularly drawn to the warning notice which states that the dummy should be used with supervision. Further, the warning notice states that the dummy should *not* be tied around the baby's neck as this presents a strangulation hazard. Another reason why a string should *not* be attached to the dummy is that the string could cut-off blood circulation to the baby's finger or hand if the string becomes wrapped around the finger or wrist of the baby. Finally, it is most essential that parents carefully follow the recommended use and hygienic care instructions included on the packing, to ensure that the dummy is properly cleaned and sterilized.

SPECIFICATION

1 SCOPE. This standard specifies safety requirements relating to the materials, design, construction and performance, together with recommendations for the use and hygienic care of babies' dummies, all of which are important for the health and well-being of a baby.

NOTE: Babies' dummies are also known as pacifiers or soothers.

2 APPLICATION. This standard applies to all babies' dummies except those intended for use by premature babies, or for therapuetic application or the like, whereby the usage is under medical supervision or direction.

NOTE: Because of certain physical properties which are requirements of this standard, e.g. the size of the shield, dummies complying with this standard may not be suitable for use by small premature babies or babies that are being treated for cleft palate or other malformation. Consequently, a dummy that is intended for such an application is exempted from the requirements of this standard.

Nevertheless, it is strongly recommended that the standard be used as a reference and that even a dummy that is exempted should comply with the pertinent requirements, e.g. Clauses 4 and 6, of the standard.

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

3.1 Dummy means an article used to pacify a baby, which article includes a teat which the baby sucks but from which the baby does not obtain fluid.

3.2 Ring means a structure positioned adjacent to or on the shield to facilitate handling of the dummy.

NOTE: The ring may be integral with the shield or plug or it may be a separate component that is suitably attached to the shield or plug.

3.3 Shield means a structure positioned at the rear of the teat to reduce the likelihood of the dummy being drawn into the baby's mouth.

3.4 Plug means a structure inserted into the rear of the teat to fixedly attach the teat to the shield.

3.5 Plastics material means a material based on synthetic polymers or modified natural polymers which during manufacture may be formed to shape by flow aided in many cases by heat and pressure, but which material cannot be substantially deformed by a weak force and does not rapidly return approximately to its initial dimensions and shape, after release of the force.

3.6 Rubber material means a polymeric material which rapidly returns approximately to its initial dimensions and shape after being substantially deformed by a weak force which is subsequently released.

3.7 Projected plan area of a shield means the maximum area obtained by projecting all points on the periphery of a shield onto a flat plane wherein all the projections are at right-angles to the flat plane (see Fig. 1).

NOTE: When determining the boundary of the projected plan area, no force is to be applied to the shield to alter its projected plan area. For example, if a dummy has a shield which is contoured to conform with the child's mouth, when determining the boundary of the projected plan area, the shield is not to be flattened, in order to obtain a larger projected plan area.

3.8 Width of a shield means the minimum distance between two parallel straight lines, wherein each straight line contacts one or more extreme points on the projected plan area of a shield, but does not pass through the projected plan area (see Fig. 1).

4 MATERIAL REQUIREMENTS.

4.1 General. A dummy shall be made from plastics and/or rubber materials each of which shall not contain any leachable constituent—

(a) in such concentration, which is known to be harmful to health;
(b) which is known to cause mucosal irritation; and
(c) which would flavour any part of the dummy.

NOTE: The use of materials other than plastics and/or rubber, as defined in Clauses 3.5 and 3.6 is NOT permitted in dummies (see comments in the Foreword).

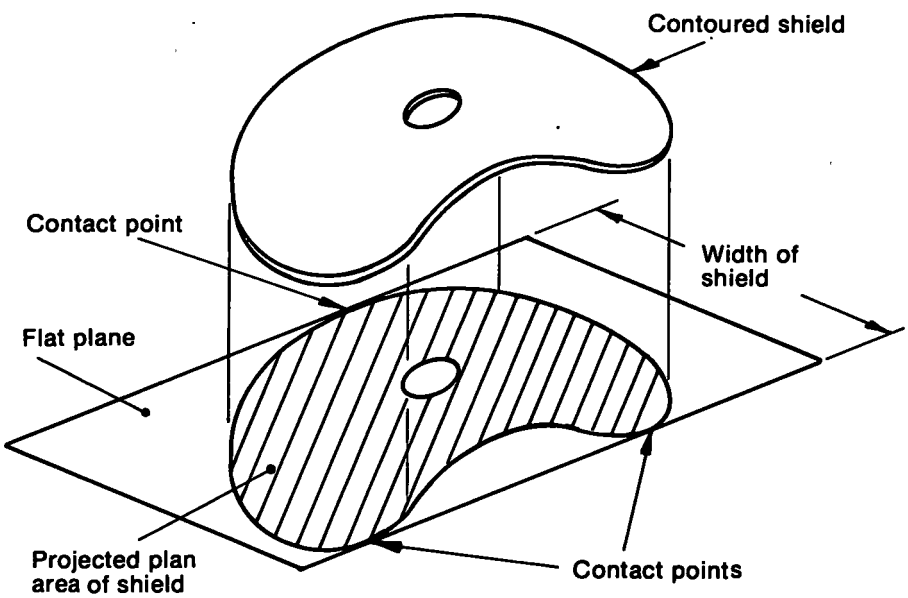

Fig. 1. PROJECTED PLAN AREA AND WIDTH OF A SHIELD