

Australian Standard[®]

Tampons—Menstrual



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The following are represented on Committee CS-065:

- Australian Chamber of Commerce and Industry
 - Australian Food and Grocery Council
 - Australian Retailers Association
 - Australian Society for Microbiology
 - Commonwealth Department of Health and Ageing
 - Consumers' Federation of Australia
 - Medical Technology Association of Australia
 - Royal Australian and New Zealand College of Obstetricians & Gynaecologists
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Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

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Tampons—Menstrual

Originated in Australia as AS 2869—1986.
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PREFACE

This Standard was prepared by the Australian members of Joint Standards Australia/Standards New Zealand Committee CS-065, Tampons to supersede AS/NZS 2869:1998. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

This Standard is intended as a manufacturing specification which is achievable by a manufacturer which adheres to an appropriate quality management system.

The initial request for a Standard for tampons followed the confirmation, in 1981, of several cases of Toxic Shock Syndrome (TSS) in Australia which were associated with the use of tampons by menstruating women.

Although the incidence of TSS in Australia and New Zealand is low, and investigations have shown that unopened tampons have not been contaminated by *Staphylococcus aureus* (the microorganism associated with TSS), the Committee believed the development of a Standard was highly desirable so that this position did not deteriorate. In addition, the Committee agreed that there were other aspects which also related to the health and comfort of users that should be dealt with in such a Standard.

The first edition (1986) therefore concerned itself with these aspects by specifying materials, performance tests for absorptive capacity, the strength of the withdrawal cord, a microbial count to detect possible contamination during manufacture, instructions for hygienic use, and information about TSS and its warning symptoms, which was based on the recommendations of the National Health and Medical Research Council.

The 1995 edition of the Standard was undertaken to provide legislative interests with a revision suitable for reference in legislation, with particular regard to the need of objective labelling. It introduced a table of absorbency ranges and descriptors for different tampon types, giving phrases to be used for product labelling by manufacturers. These phrases are intended to provide the tampon user with information that will allow her to select products with equivalent absorbency, irrespective of the brand.

As tampons with an absorbency of less than 6 g are not widely available in Australia, no absorbency range limits or range label is provided.

The 1998 edition was undertaken at the request of the Commonwealth Government to improve readability of the information leaflet provided with the product.

This revision was undertaken following a request from Industry and from the Australian Government Department of Health and Ageing (Therapeutic Goods Administration) to harmonize the absorbency test method with that used by manufacturers in the European Union and the United States of America. The absorbency ranges to be used for labelling purposes have also been adjusted so as to ensure that the absorbency of tampons will not change significantly as a result of changes to the test methodology.

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 name Toxic Shock Syndrome (TSS) was first applied to a condition characterized by toxæmia associated with *Staphylococcus aureus*. In 1980, cases resembling TSS were reported in the United States of America; almost all were in menstruating women and an association with tampon use was found. However, the exact connection between *S. aureus*, menstruation and tampons is not fully understood. TSS is a toxæmia mainly caused by the toxin, TSST-1, produced by some strains of *S. aureus*.

Cases of TSS have also been confirmed in non-menstruating women, in men and in children where it has been associated with local infections caused by *S. aureus*. There is no record of anyone contracting TSS from someone who has already had the disease.

Extensive investigations in Australia and New Zealand have revealed no evidence of contamination of unopened tampons by *S. aureus*, but evidence suggests that tampon use in association with staphylococcal infection is important in the disease.

Intensive investigation was carried out by the US Centers for Disease Control and Prevention (CDC), Atlanta, Georgia. Studies indicated that the organism *S. aureus* was found in the vagina of 98% of women suffering from TSS who had cultures taken before receiving antibiotics. *S. aureus* is found in the vagina of about 10% of healthy women.

Although it is acknowledged that the vagina can be colonized with staphylococci, every precaution should be taken during the manufacture of the tampon and in the design of the package to ensure that contamination of the tampon does not occur.

It is also important that women using tampons be aware of the need for special care with personal hygiene during menstruation and with the way in which they handle the tampon, and also that they recognize the symptoms of TSS, should it occur.

STANDARDS AUSTRALIA

Australian Standard Tampons—Menstrual

1 SCOPE

This Standard specifies requirements for menstrual tampons, including the specific absorptive capacity, microbial content, withdrawal cord pull strength and water repellency, marking and packaging. Information to be included in an accompanying leaflet is described.

2 OBJECTIVE

The objective of this Standard is to ensure that tampons are manufactured to requirements that will minimize known hazards to health associated with the use of tampons, and are of appropriate quality and performance when supplied to consumers.

3 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS

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| 1386 | Cleanrooms and clean workstations (series) |
| 1766 | Food microbiology |
| 1766.2.2 | Method 2.2: Examination for specific organisms—Colony count of yeasts and moulds |
| 1766.5 | Method 5: Preparation of culture media, diluents and reagents |
| 2001 | Methods of test for textiles |
| 2001.3.4 | Method 3.4: Chemical tests—Determination of solvent extractable matter |
| 2193 | Calibration and classification of force-measuring systems |
| 2252 | Biological safety cabinets |
| 2252.2 | Part 2: Laminar flow biological safety cabinets (Class II) for personnel, environment and product protection |
| 2490 | Sampling procedures and charts for inspection by variables for percent nonconforming |
| 2766 | Petri dishes—Plastic—For single use |
| 5013 | Food microbiology |
| 5013.1 | Examination for specific organisms—Standard plate count |

AS ISO

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| 10993 | Biological evaluation of medical devices |
| 10993.10 | Part 10: Tests for irritation and delayed-type hypersensitivity |

AS/NZS

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| 2243 | Safety in laboratories |
| 2243.1 | Part 1: Planning and operational aspects |
| 2243.2 | Part 2: Chemical aspects |
| 2243.3 | Part 3: Microbiological aspects and containment facilities |

ISO

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| 4074 | Natural latex rubber condoms—Requirements and test methods |
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