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Tampons — Menstrual



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- Australian Chamber of Commerce and Industry
- Australian Food and Grocery Council
- Australian Society for Microbiology
- Department of Health (Australian Government)
- Family Planning Association NSW
- Medical Technology Association of Australia
- National Retail Association Australia
- Royal Australian and New Zealand College of Obstetricians and Gynaecologists
- Royal College of Pathologists of Australasia
- Therapeutic Goods Administration
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Tampons — Menstrual

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Preface

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee CS-065, Tampons, to supersede AS 2869—2008.

The objective of this document is to provide requirements for the manufacture of tampons in order to minimize known health hazards associated with the use of tampons, and so they are of appropriate quality and performance when supplied to consumers.

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

The major changes in this edition are as follows:

- (a) Harmonization of the absorbency ranges with the EDANA (European) Code of Practice for Tampon Labeling.
- (b) An increased absorbency range of greater than 15 g up to and including 18 g has been added.
- (c) Primary absorbency labelling markings have been amended to include an appropriate descriptor to denote the range of absorbency.
- (d) Optional secondary absorbency labelling markings have been added which include the use of the appropriate number of droplets and/or approximate absorbency.
- (e) Details to be included in the information leaflet have been listed.
- (f) Microbial content has been updated to provide for use of either an Australian or international pharmacopoeial test methods for determining aerobic microbial count.
- (g) The ether soluble substances test has been deleted as this test did not reflect any absorbency performance attribute and offered no additional value for safety.

The terms “normative” and “informative” are used in Standards to define the application of the appendices 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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Introduction

The name Toxic Shock Syndrome (TSS) was first applied to a condition characterized by toxæmia associated with *Staphylococcus aureus* (*S. 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 in the 1980s 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 needs to be taken during the manufacture of the tampon and in the design of the package so 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.

The initial request for a standard for tampons followed the confirmation, in 1981, of several cases of TSS in Australia which were associated with the use of tampons by menstruating women.

Although the incidence of TSS in Australia is low, and investigations have shown that unopened tampons have not been contaminated by *S. aureus*, the development of a standard was considered desirable so as to maintain the high level of quality and safety. In addition, there were other aspects which related to the health and comfort of tampon users that could 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 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 were intended to provide tampon users with information that would allow them 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 was provided.

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

The 2008 edition was undertaken following a request from industry and from the then 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 were also adjusted so that the absorbency of tampons would not change significantly as a result of changes to the test methodology.

This 2022 revision was undertaken following a request from industry to harmonize the absorbency ranges with the EDANA (European) Code of Practice for Tampon Labeling. This has meant adding an increased absorbency range for tampons available in Australia and updating other information as outlined in the preface.

The risk of TSS and infection is greatest when the tampon is left *in situ* for a prolonged time, and this is most likely to occur if the absorbency of the tampon is higher than necessary to maintain hygiene for a few hours. This 2022 revision introduces changes to labelling and to information that needs to be provided to tampon users to increase awareness of the connection between prolonged use, absorbency and TSS infection. This is particularly important now that Australian women will have an opportunity to use tampons that are more absorbent than previously available.

It is noted that since 1 July 2018 tampons no longer need to be entered on the Australian Register of Therapeutic Goods before being supplied in Australia. As a result, a Therapeutic Goods Order sets out the standard that applies to tampons supplied in Australia.

NOTES

Australian Standard®

Tampons — Menstrual

1 Scope

This document specifies requirements for menstrual tampons, including permissible materials, design requirements, specific absorptive capacity, withdrawal cord pull strength and water repellency, hygiene requirements, marking and packaging. The document also provides sample information to be included in an accompanying information leaflet.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document.

NOTE Documents referenced for informative purposes are listed in the Bibliography.

AS 2193, *Calibration and classification of force-measuring systems*

AS 2252.2, *Controlled environments, Part 2: Biological safety cabinets Class II—Design*

AS 2252.6, *Controlled environments, Part 6: Clean workstations—Design, installation and use*

ISO 14644-7, *Cleanrooms and associated controlled environments — Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)*

EN 12469, *Biotechnology — Performance for microbiological safety cabinets*

ASTM D 3492, *Standard Specification for Rubber Contraceptives (Male Condoms)*

NWSP 350.1.R1 (15), *Menstrual Tampons Absorbency — Syngina Method*

British Pharmacopoeia Appendix XVI B. *Microbiological examination of non-sterile products: 1. Test for specified microorganisms*

British Pharmacopoeia Appendix XVI B. *Microbiological examination of non-sterile products: 2. Microbial enumeration tests*

European Pharmacopoeia Ph. Eur. Method 2.6.12, *Microbiological examination of non-sterile products: Microbial enumeration tests*

United States Pharmacopeia <61> *Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests*

3 Terms and definitions

For the purpose of this document, the following terms and definitions apply.

3.1

batch

quantity of tampons which, as far as practicable, consists of material or items of a single type, grade, class, quality, absorptive capacity and composition, and which has been manufactured under essentially the same conditions in a specified period of time

3.2

contamination

<1> presence of deleterious physical, chemical and/or biological materials not intended to be present in the finished product

<2> undesirable transfer of organisms from one person, material or environment to another

3.4

manufacturer

person or organization that is responsible for the design, production, packaging and labelling of the tampon before it is supplied under their name, or who organizes another person or organization to carry out some or all of these operations on their behalf

3.5

menstrual tampon

tampon

product made of permissible materials that is inserted into the vagina and used to absorb menstrual discharge

Note 1 to entry: See [Clause 4.1](#) for information on permissible materials.

3.6

packaging

<unit pack> pack enclosing a single tampon and applicator, where provided

<primary pack> pack containing one or more unit packs

<supply pack> pack that is supplied to the consumer

Note 1 to entry: It may be the primary pack, or contain one or more primary packs.

<transport pack> pack intended for transportation of one or more supply packs

3.7

sponsor

person or organization that —

- (a) arranges the exportation of tampons from Australia;
- (b) imports, or arranges the importation of, tampons into Australia; or
- (c) in Australia, manufactures tampons, or arranges for another person to manufacture tampons, for supply in Australia or elsewhere

3.8

syngina

synthetic vagina

4 Materials

4.1 Permissible materials

Tampons should be manufactured from cellulosic materials (such as cotton and viscose rayon), or synthetic textile polymers, either singly or in combination, provided that adequate testing does not demonstrate a hazard.

Super absorbent polymers, such as polyester foam and carboxymethylcellulose (CMC), shall not be included in tampons.

NOTE Although *in vitro* studies have indicated that polyester foam and not CMC may have been responsible for enhancing the production of TSST-1 toxin under certain test conditions, high absorbency materials have been implicated in some epidemiological studies. Concern has also been expressed about acrylate modified rayons. Where such materials are used, evidence is required that no demonstrable hazard exists.

4.2 Freedom from toxic and irritant effect

Tampons should be designed and manufactured to be safe. Tampons shall not contain ingredients or components likely to cause a cumulative or immediate toxic or irritant reaction when used as directed.

NOTE For design checks and test methods, refer to the ISO 10993 series on biological evaluation of medical devices.

4.3 Freedom from impurities

When visually inspected, no foreign matter shall be evident.

5 Design requirements

5.1 Length of withdrawal cord

The length of the withdrawal cord hanging free from the tampon shall be not less than 80 mm.

5.2 Applicator

The applicator, where provided, should be smooth and designed to minimize risk of trauma.

6 Performance requirements

6.1 Absorptive capacity

Each batch of tampons shall be classified into one of the absorbency ranges given in [Table 1](#).

When tested in accordance with [Appendix A](#), the classified absorbency range for a batch of tampons shall be the range into which at least 90 % of the estimated population of that batch fall.

The procedure for sampling shall be as follows:

- (a) Determine the process capability.
- (b) Based on the process capability, determine a sample size that estimates the proportion of tampons with absorbencies within the defined limits of 90 % confidence and 5 % error. In cases where the determined process capability approximates 1, resulting in an excessively small required sample size (below 10), a minimum sample size of 10 tampons shall be adopted.
- (c) Use the sample size calculated in Item (b) to test the hypothesis that at least 90 % of the tampons from this sample have absorbencies within the specified limits with 90 % confidence.

NOTE An example of how to determine the process capability and sample size is given in [Appendix E](#).

6.2 Additions to test report

In addition to the test report requirements in [Appendix A](#), the test report shall also contain the following information:

- (a) The highest and lowest absorptive capacity results in grams of water per tampon.
- (b) The absorbency range, as given in [Table 1](#), into which 90 % of the estimated population fall.

6.3 Invalid test

When tested in accordance with [Appendix A](#), a test shall be considered invalid when —

- (a) a hydrostatic pressure of 180 ± 10 mm is not maintained; and
- (b) a tampon expands longitudinally forcing the top of the condom open.

A new condom shall be inserted in the syngina in every such case and the determination is repeated.

6.4 Pull strength of withdrawal cord and its attachment point

When tested in accordance with the method in [Appendix B](#), the pull strength of the withdrawal cord and its attachment point shall be such that the mean force required to break or detach the cord is not less than 28 N. No withdrawal cord shall have a pull strength less than 22.4 N.

6.5 Water repellency of withdrawal cord

The withdrawal cord shall be water repellent.

7 Hygiene requirements

7.1 Manufacturing requirements

Tampons shall be manufactured in a hygienic environment.

NOTE For guidance on microbiological methods for determining the presence of microorganism populations on products, refer to ISO 11737-1.

7.2 Microbial content

When tested in accordance with [Appendix C](#) or the following pharmacopeial test methods, the total aerobic microbial count in each tampon (and applicator where this is provided) shall not exceed 1.0×10^3 CFU per gram:

- (a) British Pharmacopoeia Appendix XVI B.
- (b) European Pharmacopoeia Ph. Eur. Method 2.6.12.
- (c) United States Pharmacopeia <61>.

NOTE 1 The pharmacopeial test methods should be validated for use on tampons.

NOTE 2 Identification of, and testing for, other pathogenic organisms may also be appropriate. Reference to relevant test methods may include British Pharmacopoeia Appendix XVI B, European Pharmacopoeia Ph. Eur. Method 2.6.13 and United States Pharmacopeia <61>.

8 Packaging

The following requirements and recommendations apply to the packaging of tampons:

- (a) Each tampon (and applicator where this is provided) shall be packed in a closed unit pack (i.e. individually wrapped) capable of maintaining product quality until opened by the consumer.
- (b) The unit packs should be packed in a primary pack which is sufficiently robust to protect the tampons against damage during normal transport and normal storage. The primary pack should be designed, overwrapped or sealed, so that tampering can be easily detected.
- (c) The primary pack shall contain an information leaflet in accordance with [Clause 10](#).

9 Marking

9.1 Primary packs

Primary packs shall be permanently and legibly marked with the following information:

- (a) The batch number of the tampons which may be immediately preceded by the words “Batch No.”, “Lot No.” or by words or symbols having a similar meaning.
- (b) The primary marking given in [Table 1](#) appropriate to the absorbency range of the tampons, e.g. “regular, suitable for medium flow”, where the absorbency range of the tampons is greater than 9 g and less than or equal to 12 g.

NOTE [Table 2](#) provides additional marking options.

- (c) The following warning in letters having a height of not less than 1.0 mm, preceded by the word “important” or “caution” or “warning” in capitals. For example:

IMPORTANT: Tampon use has been associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and keep the enclosed information.

9.2 Supply packs

Supply packs, as received by the consumer, shall be permanently and legibly marked with the following information, visible at the time of purchase:

- (a) Description of the contents, including the number, and the primary marking given in [Table 1](#) appropriate to the absorbency range of the tampons, e.g. “10 tampons. Regular. Suitable for medium flow”, where the absorbency range of the tampons is greater than 9 g and less than or equal to 12 g.
- (b) A list of the constituents of the body of the tampon.
- (c) The following warning in letters having a height of not less than 1.0 mm, preceded by the word “important” or “caution” or “warning” in capitals. For example:

IMPORTANT: Tampon use has been associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and keep the enclosed information.

The information required in Items (a), (b) and (c) may be given on the primary pack only and not repeated on the supply pack, provided it is visible on the primary pack at the time of purchase.

Table 1 — Absorbency labelling

Absorbency range	Primary marking
Less than 6 g	—
Equal to or greater than 6 g up to and including 9 g	Mini Suitable for light flow
Greater than 9 g up to and including 12 g	Regular Suitable for medium flow
Greater than 12 g up to and including 15 g	Super Suitable for heavy flow
Greater than 15g up to and including 18g	Super Plus Suitable for very heavy flow

NOTE 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.

Table 2 — Absorbency labelling options

Absorbency range	Optional secondary marking
Less than 6 g	—
Equal to or greater than 6 g up to and including 9 g	Approximately 8 g absorbency and/or a graphic representation of 2 droplets
Greater than 9 g up to and including 12 g	Approximately 11 g absorbency and/or a graphic representation of 3 droplets
Greater than 12 g up to and including 15 g	Approximately 14 g absorbency and/or a graphic representation of 4 droplets
Greater than 15g up to and including 18 g	Approximately 17 g absorbency and/or a graphic representation of 5 droplets

NOTE 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.

9.3 Manufacturer's details

The name or trade mark of the manufacturer or sponsor shall be permanently and legibly marked on the supply pack or on the leaflet in the primary pack (see [Clause 10](#)) contained therein.

9.4 Transport pack

The transport pack, as received by the retailer, shall be marked so that the date code or the batch numbers of the enclosed primary packs is identifiable.

10 Information leaflet

A leaflet containing the following information shall be enclosed in each primary pack:

- (a) Detailed instructions for use including:
 - (i) Hygiene and care in insertion.
 - (ii) Duration of use.
 - (iii) Using lowest absorbency required.

NOTE 1 See [Appendix D](#) for examples of suggested wording for instructions.