Australian Government
Department of Health
Therapeutic Goods Administration

Guidance on the regulation of tampons in Australia

Version 3.0, April 2019

TGA Health Safety Regulation

The purpose of this guidance is to help sponsors understand how the TGA interprets regulations, and thus indicate how a sponsor can comply.

This is a guide only, and sponsors are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia. If necessary, seek professional advice as it is the responsibility of each sponsor to understand and comply with these requirements.

This document will evolve over time and updates and clarifications will be included as required. Feedback on the guidance is always welcome.

Contents

Introduction

Tampons are therapeutic products that are exempt from inclusion on the Australian Register of Therapeutic Goods (ARTG).

Tampons are required to comply with *Therapeutic Goods (Standards for Tampons) (TGO 103) Order 2019* before they can be supplied in Australia. This order states that the Australian Standard "*AS 2869:2008 Tampons – Menstrual*" is currently the applicable standard for menstrual tampons in Australia.

AS 2869:2008 aims to ensure that tampons are manufactured in a manner that will minimise recognised risks to health associated with the use of these products. The standard covers a range of factors including, but not limited to:

- Packaging
- Labelling
- Performance requirements
- Specific absorptive capacity
- Microbial content
- Withdrawal cord pull strength
- Water repellence

You can obtain a copy of *AS 2869:2008 Tampons – Menstrual* from SAI Global.

If you have a problem with a tampon, please tell us about it using the Report a medical device adverse event (medical device user) form.

Note

Tampons must meet *AS 2869:2008 Tampons – Menstrual.*

It is an offence to import and/or supply the therapeutic goods in Australia that do not conform with a standard applicable to the goods (refer sections 14 and 14A of the *Therapeutic Goods Act 1989)*.

Related guidance and legislation

Tampons must also adhere to the requirements as set out in the:

- *Therapeutic Goods Act 1989*
- *Therapeutic Goods Regulations 1990*
- Therapeutic Goods (Standards for Tampons) (TGO 103) Order 2019
- Therapeutic Goods Advertising Code 2015
- Therapeutic Goods (Single Therapeutic Goods) Order No.1 of 1991

Regulatory requirements

Your product **must** meet the requirements under *AS 2869:2008 Tampons – Menstrual*. Each section below gives a brief outline of the regulatory requirements stated in the Standard.

Components

The following is an extract from *AS 2869:2008 Tampons – Menstrual*:

5 MATERIALS

5.1 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. Polyester foam shall not be used. Carboxymethylcellulose (CMC) shall not be added to tampons.

> **NOTE:** Although in-vitro studies have indicated that polyester foam and not CMC may be responsible for enhancing the production of TSST-1 toxin under certain test conditions, high absorbency per se has been implicated in some epidemiological studies. It was therefore decided to prohibit the use of polyester foam, and to prohibit the addition of CMC to tampons. This requirement is in recognition of the fact that, although naturally occurring low background levels may be present, CMC is not added to tampons as there are consumer concerns about this substance. Concern has also been expressed about acrylate modified rayons. Where such materials are used, evidence is required that no demonstratable hazard exists.

5.2 Freedom from toxic and irritant effect

Tampons shall not contain ingredients in sufficient concentration to cause a toxic or irritant reaction when used as directed.

> **NOTE:** A suitable method is given in AS ISO 10993.10

5.3 Freedom from impurities

No foreign matter shall be evident when the material is visually inspected.

Design requirements

Withdrawal cord

Your product must contain a withdrawal cord. When the cord is hanging free from the tampon the length of the cord should be no less than 80mm long. The withdrawal cord must also meet minimum standards for water repellence and pull strength of the cord at its attachment point as set out in *AS 2869:2008 Tampons – Menstrual*.

Applicators

If your product includes an applicator the product should be smooth and designed so as to minimise trauma to the end consumer.

Packaging

There are four main elements to the packaging of tampons:

- Unit Pack
- Primary Pack
- Supply Pack
- Transport Pack

Unit Pack

Each individual tampon (and applicator, where provided) must be enclosed in a closed unit pack capable of maintaining the quality of the product until it is opened by the consumer. Unit packs should then be contained within a Primary Pack.

Primary Pack

A Primary Pack contains one or more Unit Packs and is designed to protect the Unit Packs during normal transport and storage. Primary Packs must be marked with the following information:

- The batch or lot number which must be identified with the words “Batch No.” or “Lot No.” or by words and/or symbols that have the same meaning.
- Labelling identifying the absorbency range of the product as follows:

Absorbency range	Label
Less than 6g	As tampons with an absorbency of less than 6g are not widely available, no label is given
6 - 9g	Approximately 8g of absorbency Suitable for light flow
Greater than 9 - 12g	Approximately 11g absorbency Suitable for medium flow
Greater than 12 - 15g	Approximately 14g absorbency Suitable for heavy flow

- The following warning in words with a height not less than one millimetre:

> 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.

Note

While you are required to label your primary pack with the wording shown in the table above, this does not preclude you from using other words to identify the absorbency of your product as a part of your brand. Words such as “mini”, “regular” and “super” may also be used.

You must use the specific label for the tampons contained within the Primary Pack on the front of your packaging. If you choose to display a table or labelling showing the absorbency of other tampons in your product range, this information should be on the back of the Primary Pack along with information again identifying the absorbency of the tampons contained within the Primary Pack.

Supply Pack

The Supply Pack is the form that the entire product takes when procured by the consumer. This may be the Primary Pack, but may also be the over-wrapping or sealing over the Primary Pack. The Supply Pack must be permanently and legibly marked with the following so it is visible at the time of purchase or procurement, or the Supply Pack must allow this information to be visible on the Primary Pack:

- Description of the contents, including the number of Unit Packs and the absorbency range label as outlined above.
- A list of the components that form the body of the tampon
- The following warning in words with a height not less than one millimetre:

> 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.

Transport Pack

The Transport Pack is the form a retailer or supplier will receive the product in. The Transport Pack must be marked with a date code or the same batch numbers as those on the enclosed Primary Packs.

Note

Transport Packs are only required when sending your product to retailers or suppliers. If you are selling your product directly to consumers, you are not required to adhere to the Transport Pack requirements.

Manufacturer’s details

The Manufacturer or Supplier of the tampons must be able to be identified through their name or trademark, which should be permanently and legibly included on the Supply Pack or on the Information Leaflet enclosed in the Primary Pack.

Information leaflet

An information leaflet containing the following information must be included with each Primary Pack:

- Detailed instructions for use including warnings emphasising the need for hygiene and care during insertion.
- Information about Toxic Shock Syndrome (an example of the information you might include is contained in *AS 2869:2008 Tampons – Menstrual*).
- Notification that tampons are not supplied sterile and that while tampons contain small amounts of bacteria normally present in the air, they have not been shown to carry the bacteria that cause Toxic Shock Syndrome (TSS).

AS 2869:2008 Tampons – Menstrual contains an example of wording that can be used in the information leaflet. Generally the leaflet should be written in plain English and a simple style that will be easy for younger women, and women for whom English is a second language, to understand. Other factors you might like to consider in the preparation of your information leaflet:

Factor to consider	Description
Content	• Avoid using medical terms, or explain them if you must use them. • The information must appear in English. • You may elect to include the information in another language, but the translation of the information is your responsibility and will not be assessed or reviewed by us.
Font	• Use a font style that is easy to read, avoiding fonts that look like handwriting. • Use lower case as much as possible, keeping upper case for headings and warnings only. • Choose the colour of your fonts and graphics carefully, and aim to maximise readability.
Graphic Aids	• As some people using your product may have limited language and literacy skills, support your information with graphics where possible. • Graphic representations should be simply line drawings or photos. • Limit graphic representations to the most important information. • Make sure graphics appear next to the text that describes what they are representing.

Other labelling requirements

In addition to the above requirements, you must also include the following on the Supply Pack or on the Primary Pack (but visible through the Supply Pack):

- The name of your product
- The name and address of the manufacturer or the sponsor
- The quantity of tampons within the pack.

Kits containing tampons

If you are producing a kit that contains tampons bundled with other consumables, your product may meet the definition of a therapeutic kit.

Tampons that are included in a kit must meet *AS 2869:2008 Tampons – Menstrual*, and be included on the ARTG before the kit can be supplied to consumers. This means that the tampons contained in the kit must be supplied in a way that satisfies the packaging requirements as outlined above, there must be an information leaflet included in the Primary Pack, and the Supply Pack must be sufficient to preserve the tampons from any damage that may be caused by other products in the kit.

Note

Therapeutic kits must have their own, separate, listing on the ARTG.

If you intend to supply a therapeutic kit you will need to submit an application for listing of "Other Therapeutic Good – Listed other" through TGA's Business Services.

Test reports

The requirements for test reports for tampons are comprehensively outlined in *AS 2869:2008 Tampons – Menstrual*. These reports and their associated certificates must be signed and dated by the analyst, be less than 2 years old, and be from an acceptable test laboratory.

Laboratories undertaking testing to establish compliance with the requirements must have certification in the form of:

- NATA/NATA MRA partner or equivalent accreditation; or
- certification from a recognised authority to ISO 13485 - Medical Devices - Quality Management Systems; or
- certification from a recognised authority to ISO Guide 17025:2005 - General Requirements for the Competence of Testing and Calibration Laboratories and ISO 17025 1:2006 - Technical Corrigendum 1.

Absorptive capacity

Your test report will need to reference Appendix A of *AS 2869:2008 Tampons – Menstrual* and contain the following information:

- The number of tampons tested
- The highest and lowest absorptive capacity results in grams of water per tampon.
- The absorbency range, into which 90% of the estimated population falls.

Withdrawal cord strength

Your test report will need to reference Appendix B of *AS 2869:2008 Tampons – Menstrual* and contain the following information:

- For the dry state, the results of 10 individual tests and the mean force of those 10 tests.
- For the wet state, the results of 10 individual tests and the mean force of those 10 tests.

Withdrawal cord water repellence

Your test report will need to reference Appendix C of *AS 2869:2008 Tampons – Menstrual*, and state whether any of the samples sank completely beneath the water surface.

Total aerobic microbial count

Your test report will need to reference Appendix D of *AS 2869:2008 Tampons – Menstrual* and state the total aerobic microbial count per gram of each tampon and each applicator (if they are included with your product).

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Branch, TGA	August 2017
V2.0	Updated to reflect the exemption of tampons from the regulatory requirement to include them on the ARTG	Medical Devices Branch, TGA	August 2018
V3.0	Therapeutic Goods order for Tampons renewed	Medical Devices Branch, TGA	April 2019

Therapeutic Goods Administration

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Reference/Publication #