AS 2869:2022

Australian STANDARD®

STANDARDS Australia

Tampons — Menstrual

AS 2869:2022

This Australian Standard ® was prepared by CS-065, Tampons. It was approved on behalf of the Council of Standards Australia on 22 April 2022.

This Standard was published on 6 May 2022.

The following are represented on Committee CS-065:

Accord Australasia
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
University of New South Wales

This Standard was issued in draft form for comment as DR AS 2869:2022

Keeping Standards up-to-date

Ensure you have the latest versions of our publications and keep up-to-date about Amendments, Rulings, Withdrawals, and new projects by visiting:
www.standards.org.au

ISBN 978 1 76113 722 8

Tampons — Menstrual

Originated in Australia as AS 2869—1986.
Jointly revised and redesignated as AS/NZS 2869:1995.
Third edition 1998.
Revised and redesignated AS 2869—2008.
Fifth edition AS 2869:2022.

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 d

(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.

Contents

Preface ii
Introduction iv
1 Scope 1
2 Normative references 1
3 Terms and definitions 1
4 Materials 2
4.1 Permissible materials 2
4.2 Freedom from toxic and irritant effect 3
4.3 Freedom from impurities 3
5 Design requirements 3
5.1 Length of withdrawal cord 3
5.2 Applicator 3
6 Performance requirements 3
6.1 [illegible] 3
6.2 [illegible] 3
6.3 Invalid test 4
6.4 Pull strength of withdrawal cord and its attachment point 4
6.5 Water repellency of withdrawal cord 4
7 Hygiene requirements 4
7.1 Manufacturing requirements 4
7.2 Microbial content 4
8 Packaging 5
9 Marking 5
9.1 Primary packs 5
9.2 Supply packs 5
9.3 Manufacturer's details 6
9.4 Transport pack 6
10 Information leaflet 6
Appendix A (normative) **Method for measuring absorptive capacity** 8
Appendix B (normative) **Method for testing the strength of the withdrawal cord and its attachment to the tampon** 17
Appendix C (normative) **Method for determining total aerobic microbial count** 23
Appendix D (informative) **Sample information on TSS for inclusion in information leaflet** 27
Appendix E (informative) **Sample size calculation** 30
Bibliography 33

Introduction

The name Toxic Shock Syndrome (TSS) was first applied to a condition characterized by toxaemia 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 toxaemia 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 [illegible]

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.