



**Australian Government**

**Department of Health and Ageing**  
Therapeutic Goods Administration

# Therapeutic Goods (Excluded Goods) Order

## Extract

No. 1 of 1998

No. 2 of 1998

No. 1 of 1997 (draft)

**TGA** Health Safety  
Regulation



## About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

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**Extract from**

*Therapeutic Goods (Excluded Goods) Order No.1 of 1998, Therapeutic Goods (Excluded Goods) Order No.2 of 1998, & Therapeutic Goods (Excluded Goods) Order No.1 of 1997*

**Definition**

- (2) In this order:  
“scientifically validated” means that significant clinically validated studies as specified for registrable devices have been undertaken, however the principle only needs to be validated once for all devices of the kind rather than for each device applying for entry on the ARTG.

**Goods that are not therapeutic goods**

- (3) For the purposes of the *Therapeutic Goods Act 1989*, the following goods, being goods intended for use in humans, are declared not to be therapeutic goods:
- (a) hair bleaches, hair dyes, hair colorants or hair-perming preparations;
  - (b) household and personal aids, or furniture and utensils, for the disabled;
  - (c) menstrual pads or similar hygiene devices, other than tampons;
  - (d) incontinence pads, mattress overlays or mattress protectors;
  - (e) dental bleaches or dental whiteners;
  - (f) preparations that are applied topically to the nails to harden, or to deter biting of, the nails;
  - (g) compressed nitrogen for use as a power source for therapeutic devices;
  - (h) disinfectant and sterilant gases;
  - (i) equipment, or substances, for use in the purification or treatment of drinking water;
  - (j) sanitation, environmental control or environmental detoxification equipment, other than:
  - (k) non implantable devices, equipment or apparel intended for use in; improving comfort, enhancing relaxation, exercising or improving physiological fitness, modifying anatomical physique, improving appearance, muscle or skin tone, easing minor aches and pains, fatigue or tiredness (due to normal ageing or day to day activities), or stimulating circulation (via exercise or the application of heat or massage);
  - (l) goods for the measurement of alcohol level either in body fluids or exhaled air;
  - (m) goods related to colostomy and ileostomy that are adhesive removers or non-medicated skin cleansers;
  - (n) goods for retail sale to the ultimate consumer for retention, cushioning or repairing of dentures;
  - (o) fresh viable:
    - (i) human tissue, other than blood; or
    - (ii) human organs; or
    - (iii) parts of human organs; or
    - (iv) human bone marrow;intended for direct donor-to-host transplantation;
  - (p) non invasive locators of, or stimulators for, 'acupoints' or 'energy meridians';
  - (q) devices that emit, measure or absorb, or claim to emit, measure or absorb, vibrations, waves or particles or energy for which health benefit claims are made, the principals of which have not been scientifically validated.

**Goods that are not therapeutic goods when used, advertised, or presented for supply in a particular way**

- (4) For the purposes of the *Therapeutic Goods Act 1989*, the goods specified in column 2 in an item in the Schedule, being goods that:
- (a) are intended for use in humans, and
  - (b) are used or labelled in the way specified in column 3;
- are declared not to be therapeutic goods when used, advertised, or presented for supply in the way specified.

**Revocation**

(5) Therapeutic Goods (Excluded Goods) Order No.1 of 1992 dated 1 July 1992 is revoked.

<b>Col. 1 Item</b>	<b>Column 2 Goods</b>	<b>Column 3 Specified use, advertisement, or presentation for supply</b>
1	Deodorant preparations	Use for dermal application or with therapeutic devices
2	Oral hygiene preparations or devices (including dentifrices, mouth washes, breath fresheners, brushes and flosses) that are not included in a Schedule to the Poisons Standard	If, benefits claimed to result from the use of the goods are restricted to those consequential on improvements to oral hygiene or the use of fluoride for the prevention of tooth decay
3	Unmedicated dental chewing gums	If benefits claimed to result from the use of the goods are restricted to those consequential on improvements to oral hygiene
4	Creams, lotions or similar products for dermal application, other than: (a) preparations intended for extemporaneous dispensing for therapeutic use; or (b) products intended to provide a barrier against infection	If the goods are used solely for, or are represented to be for use solely for, emollients, moisturisers, cleansers, or protectants against water or irritant agents
5	Soap and detergent, other than medicated soap and medicated detergent	Use for skin cleansing or hair cleansing
6	Non-sterile protective or safety apparel or equipment	Use in the home or for occupational or recreational use
7	Non-sterile apparel (including fitted support or insulating garments)	Use as an aid to physical comfort or relief of discomfort in persons with a disease, ailment, disability or injury
8	Non-prescription spectacles	Use solely for magnification of image or sun protection
9	Jewellery and objects or adornments with reputed remedial or therapeutic powers,	Use by wearing or keeping the jewellery, object or adornment on or near the body or the clothes of a person
10	Preparations containing a suncreening substance, if the primary purpose of the preparations is neither protection of the skin from injury from solar radiation nor another therapeutic purpose	If the labelling of goods does not include: (a) a statement of a claimed sun protection factor; or (b) a description of a claimed sun protection category; or (c) a reference to another therapeutic use in respect of the goods;

**APPENDIX 7.**

<b>Col. 1 Item</b>	<b>Column 2 Goods</b>	<b>Column 3 Specified use, advertisement, or presentation for supply</b>
10A	<p>Preparations defined in the Australian/New Zealand Standard for Sunscreen Products as secondary sunscreen preparations which are:</p> <p>(a) preparations for the application to the lips which are tinted and unmedicated; or</p> <p>(b) tinted facial makeup (other than moisturisers);</p> <p>and which are not for any other therapeutic purpose.</p>	<p>If the specified use, advertisement or presentation for supply of the goods makes no claims in relation to sun protection or, if any such claims are made they relate only to a sun protection factor or equivalent category description (or both) in the Australian/New Zealand Standard AS/NZS 2604-1997; and do not include a reference to another therapeutic use in respect of the goods.</p>
11	Depilatory preparations	Use for dermal application
12	Spa waters or natural mineral waters	If no therapeutic claims are made

**Therapeutic Goods (Excluded Goods) Order No 1 of 1997**  
**SUBSECTION 7 (1) ORDER**

Item	Goods	Specified Use or Labelling
1	Sanitisers, detergents, laundry soaps and other cleaning preparations, the primary purpose of which is household and commercial cleaning.	Labelled so that: (a) benefits claimed are limited to: (i) an improvement in hygiene; or (ii) the removal or reduction of non-specific micro-organisms to a sanitary level; or (iii) antibacterial action; or (iv) bacteriostatic action; and (b) no claims are made that the product is: (i) a disinfectant; or (ii) a sterilant; or (iii) bactericidal, sporicidal, tuberculocidal or virucidal; or (iv) fungicidal unless the claims are limited to the use of the product in the food and beverage industries, or in the destruction of mould.
2	Deodorisers	Labelled so that the benefits claimed are limited to deodorising air and no claims are made that the goods are: (a) bactericidal, fungicidal, sporicidal, tuberculocidal or virucidal; or (b) that the product is a disinfectant for inanimate surfaces.
3	Cleaning wipes claiming an antibacterial action	Labelled so that: (a) the benefits claimed are limited to the killing or reduction of non specific micro-organisms within the wipe; and (b) no claims are made relating to the disinfection of inanimate surfaces coming into contact with the wipe.

## **Therapeutic Goods Administration**

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