



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989

Therapeutic Goods (Excluded Goods) Order

No. 1 of 2005

TG1/2005

I, DAVID GRAHAM, National Manager of the Therapeutic Goods Administration and a delegate of the Secretary of the Department of Health and Ageing for the purposes of section 7 of the *Therapeutic Goods Act 1989*, make the following Order under subsection 7(1) of that Act.

Dated 31 October 2005

.....
Dr David Graham
Delegate of the Secretary of the
Department of Health and Ageing

Citation

1. This Order may be cited as the Therapeutic Goods (Excluded Goods) Order No. 1 of 2005.

Commencement

This Order commences on the day it is published in the Commonwealth of Australia Gazette.
[Note: See *Therapeutic Goods Act 1989*, s 7(3)]

Goods that are not therapeutic goods

2. For the purpose 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 people with disabilities;
- (c) menstrual pads 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 gases when supplied for use as a power source for medical devices;

- (h) piped medical gas systems installed to comply with **AS 2896-1998/Amdt No. 1-1999 : Medical gas systems - Installation and testing of non-flammable medical gas pipeline systems**;
- (i) disinfectant and sterilant gases;
- (j) equipment for use in the purification or treatment of drinking water;
- (k) sanitation, environmental control or environmental detoxification equipment;
- (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 and used in accordance with applicable laws and standards.

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

3. For the purposes of the *Therapeutic Goods Act 1989*, the goods specified in column 2 in an item in the following Table, being goods that:

(a) are intended for use in humans, and

(b) are used, advertised, or presented for supply 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.

TABLE

Col 1 Item	Col 2 Goods	Col 3 Specified use, advertisement, or presentation for supply
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) other than those: (a) included in a Schedule to the Poisons Standard; or (b) required to be included in the Australian Register of Therapeutic Goods	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 for 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 as, or are represented to be for use solely as, 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 solely as an aid to physical comfort or relief of discomfort
8	Non-prescription spectacles	Use solely for magnification of image or sun protection
9	Preparations containing a sunscreening substance, if the primary purpose of the preparations is neither protection of the skin from injury from solar radiation nor another therapeutic purpose	If representations about the goods do 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
10	Preparations defined in the Australian/New Zealand Standard for Sunscreen Products as secondary sunscreen preparations which are: (a) preparations for applications to the lips which are tinted and unmedicated; or (b) tinted facial make-up (other than moisturisers); and which are not for any other therapeutic purpose	If the specified use, advertisement or presentation for supply of the goods makes no claim 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
11	Depilatory preparations	Use for dermal application
12	Spa waters or natural mineral waters	If no claims are made for therapeutic use
13	Substances for use in the purification or treatment of drinking water	If no claims are made for therapeutic use
14	Packs or kits containing medical devices for the prevention of blood borne and sexually transmissible diseases	Supply of the packs or kits: - is a part of a Government endorsed health promotion program; and - has been authorised by that Government as part of that program; and where each individual therapeutic good within the packs or kits is already included on the Australian Register of Therapeutic Goods

Revocation

4. Therapeutic Goods (Excluded Goods) Order No. 1 of 2004 dated 31 August 2004 is revoked on and from the date of gazettal of this Order.