



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Therapeutic Goods Act 1989

Therapeutic Goods (Excluded Goods) Order No. 1 of 2008

TG1/2008

I, ROHAN HAMMETT, the delegate of the Secretary of the Department of Health and Ageing for the purposes of section 7 of the *Therapeutic Goods Act 1989* (the Act), make the following Order under subsection 7(1) of the Act.

30th

May 2008

A handwritten signature in black ink, appearing to read 'Rohan Hammett'.

Dr Rohan Hammett
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 2008.

Commencement

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

Revocation

3. Therapeutic Goods (Excluded Goods) Order No. 1 of 2005 published in the Commonwealth of Australia *Gazette*, No GN 44, dated 9 November 2005 is revoked on and from the date of gazettal of this Order.

Goods that are not therapeutic goods

4. For the purpose of the *Therapeutic Goods Act 1989* and subject to section 5 of this Order, 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

5. 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.

TABLE

Col 1 Item	Column 2 Goods	Column 3 Specified use, advertisement, or presentation for supply
1	Deodorant preparations	Use for dermal application or with therapeutic devices
2	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
3	Soap and detergent, other than medicated soap and medicated detergent	Use for skin cleansing or hair cleansing
4	Non-sterile protective or safety apparel or equipment	Use in the home or for occupational or recreational use
5	Non-sterile apparel (including fitted support or insulating garments)	Use solely as an aid to physical comfort or relief of discomfort
6	Non-prescription spectacles	Use solely for magnification of image or sun protection
7	Preparations containing a sun screening 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: <ul style="list-style-type: none">a. a statement of a claimed sun protection factor, orb. a description of a claimed sun protection category; orc. a reference to another therapeutic use in respect of the goods
8	Depilatory preparations	Use for dermal application
9	Spa waters or natural mineral waters	If no claims are made for therapeutic

		use
10	Substances for use in the purification or treatment of drinking water	If no claims are made for therapeutic use
11	Packs or kits containing medical devices for the prevention of blood borne and sexually transmissible diseases	<p>Supply of the packs or kits:</p> <ul style="list-style-type: none"> • is a part of a Government endorsed health promotion program; and • has been authorised by that Government as part of that program; and <p>where each individual therapeutic good within the packs or kits is already included on the Australian Register of Therapeutic Goods</p>

Goods that are not therapeutic goods, with allowable limited therapeutic use when advertised, represented or presented for supply in a particular way

6. 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 cosmetics under the *Industrial Chemicals Notification and Assessment Act 1989* (the ICNA Act) and comply with the Cosmetics Standards 2007 made under subsection 81(1) of the ICNA Act, and
- (b) (i) does not contain ingredients included in Schedules 2, 3, 4 or 8 to the Poisons Standard; or
- (ii) are not promoted, represented, presented or labeled for therapeutic use, except for those therapeutic use specified in column 3 of Table 2

are declared not to be therapeutic goods.

Table 2

Col 1 Item	Column 2 Goods	Column 3 Allowable therapeutic use
1	Tinted bases or foundation (liquids, pastes or powders) with sunscreen	
2	Products intended for application to the lips with sunscreen	
3	Moisturising products with sunscreen for dermal application, including anti-wrinkle, anti-ageing and skin whitening	
4	Sunbathing products (eg oils, creams or gels, including products for	Representations in connection with the product about pre-mature ageing linked to sun-exposure

	tanning without sun and after sun care products) with a sun protection factor of at least 4 and not more than 15	
		If:
5	Antibacterial skin products	<ul style="list-style-type: none"> a. presented as being active only against bacteria; and b. not presented as being: <ul style="list-style-type: none"> (a) active against viruses, fungi or other microbial organisms (other than bacteria); or (b) for use in connection with disease, disorders or medical conditions; or (c) active against a named bacterium that is known to be associated with a disease, disorder or medical condition; or (d) for use in connection with piercing of the skin or mucous membrane, for cosmetic or any other purpose; or (e) for use in connection with any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids; or (f) for use before physical contact with a person who is accessing medical or health services, or who is undergoing any medical or health care procedure; or (g) for use in connection with a procedure involving venipuncture or delivery of an injection
6	Anti-acne skin care products (including spot treatments, cleansers, face scrubs and masks)	If presented as controlling or preventing acne only through cleansing, moisturizing, exfoliating or drying the skin
7	Oral hygiene products for care of the teeth and the mouth (e.g. dentrifrices, mouth washes and breath fresheners)	<p>If:</p> <ul style="list-style-type: none"> a. any benefits claimed to result from use are directly related to improvements to oral hygiene, including for the prevention of tooth decay or the use of fluoride for

		<p>the prevention of tooth decay; and</p> <p>b. other benefits in relation to diseases or ailments, e.g. gum or other oral disease or periodontal condition are not claimed to result from use</p>
8	Anti-dandruff hair care products	If presented as controlling or preventing dandruff only through cleansing, moisturizing, exfoliating or drying the scalp