Therapeutic Goods (Excluded Goods) Determination 2018

I, Adjunct Professor John Skerritt, as delegate of the Minister for Health, make the following determination.

Dated 26 September 2018

(Signed by)

ADJUNCT PROFESSOR JOHN SKERRITT
Deputy Secretary
Health Products Regulation Group
Department of Health

1 Name

This instrument is the *Therapeutic Goods (Excluded Goods) Determination 2018*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	1 October 2018	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 7AA of the Act.

4 Definitions

Note: A number of expressions used in this instrument are defined in the Act including:

(a) advertise;

(b) label;

(c) medical device;

(d) Register;

(e) supply; and

(f) therapeutic use.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

AS 2896–2011 means the document, *Australian Standard: Medical gas systems – Installation and testing of non-flammable medical gas pipeline systems (AS 2896–2011)*, prepared by Committee HE-017 (Medical Gas Systems), approved on behalf of the Council of Standards Australia on 13 January 2011, and published by SAI Global Limited under licence from

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Standards Australia on 8 May 2011, as in force or existing immediately before the commencement of this instrument.

AS/NZS 2604:1998 means the document, *Australian/New Zealand Standard: Sunscreen products – Evaluation and classification (AS/NZS 2604:1998)*, prepared by the Joint Technical Committee CS/42 (Sunscreen Agents), approved on behalf of the Council of Standards Australia on 31 July 1998 and the Council of Standards New Zealand on 24 August 1998, and published jointly by Standards Australia and Standards New Zealand on 5 October 1998, as in force or existing immediately before the commencement of this instrument.

AS/NSZ 2604:2012 means the document, *Australian/New Zealand Standard: Sunscreen products – Evaluation and classification (AS/NZS 2604:2012)*, prepared by the Joint Technical Committee CS-042 (Sunscreen Agents), approved on behalf of the Council of Standards Australia on 9 May 2012 and the Council of Standards New Zealand on 9 May 2012, and published by SAI Global Limited under licence from Standards Australia on 30 May 2012, as in force or existing immediately before the commencement of this instrument.

Note: Section 2B of the *Acts Interpretation Act 1901* defines Standards Australia.

Poisons Standard means the legislative instrument made under section 52D of the Act, as in force immediately before the commencement of this instrument.

5 Excluded goods

For subsection 7AA(1) of the Act, the goods specified in Schedule 1 are excluded goods for the purposes of the Act.

6 Excluded goods when used, advertised or presented for supply in a particular way

For subsection 7AA(2) of the Act, the goods specified in Schedule 2, when used, advertised, or presented for supply in a way specified in that Schedule are excluded goods for the purposes of the Act.

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Schedule 1 Specified goods

(section 5)

Specified goods	
Column 1	**Column 2**
Item	**Specified goods**
1	adhesive removers and non-medicated skin cleansers relating to colostomy and ileostomy
2	antiperspirant preparations that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only
3	dental bleaches and dental whiteners
4	devices for measuring alcohol content in body fluids or exhaled air
5	disinfectant and sterilant gases
6	drinking water purification and treatment equipment
7	ear candles
8	hair bleaches, hair dyes, hair-colorants and hair-perming preparations
9	household and personal aids, or furniture and utensils, for people with disabilities
10	incontinence pads, mattress overlays and mattress protectors
11	menstrual pads other than tampons and menstrual cups
12	sanitation, environmental control and environmental detoxification equipment
13	topical preparations applied to the nails to harden, or deter the biting of, nails
14	products intended for application to the lips, that contain sunscreen, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, in relation to which one of the following two paragraphs applies: (a) for a product imported into, or manufactured in, Australia before 1 August 2018, both: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:1998 or AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or (b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and (iii) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012; and (iv) the product must meet the performance requirements for a ***broad-spectrum product*** set out in clause 6.3 of AS/NZS 2604: 2012 and Table 1 in clause 5.2 of AS/NZS 2604: 2012

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15	tinted bases and foundations, such as liquids, pastes or powders, that contain sunscreen, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, in relation to which one of the following two paragraphs applies: (a) for a product imported into, or manufactured in, Australia before 1 August 2018, both: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:1998 or AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or (b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and (iii) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012; and (iv) the product must meet the performance requirements for a ***broad-spectrum product*** set out in clause 6.3 of AS/NZS 2604: 2012 and Table 1 in clause 5.2 of AS/NZS 2604: 2012

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Schedule 2 Specified goods used, advertised or presented for supply in a particular way

(section 6)

Specified goods		
Column 1	**Column 2**	**Column 3**
Item	**Specified goods**	**When used, advertised or presented for supply in a particular way**
1	anti-acne skin care products, including spot treatments, cleansers, face scrubs and masks, that do not contain any substance included in Schedules 2, 3, 4 or 8 to Poisons Standard	when advertised or presented for supply as controlling or preventing acne only through cleansing, moisturising, exfoliating or drying the skin
2	antibacterial skin care products that do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard	when advertised or presented for supply as being active against bacteria and not advertised or presented for supply as being: (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 venepuncture or delivery of an injection

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3	anti-dandruff hair care products	when advertised or presented for supply as controlling or preventing dandruff only through cleansing, moisturising, exfoliating or drying the scalp
4	compressed gases	when used as a power source for medical devices
5	moisturising skin care products, that contain sunscreen, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, for dermal application, including anti-wrinkle, anti-ageing and skin whitening products, in relation to which one of the following two paragraphs applies: (a) for a product imported into, or manufactured in, Australia before 1 August 2018, both: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:1998 or AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or (b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:2012; and (ii) the product meets the performance requirements for a ***broad-spectrum product*** set out in clause	when the product: (a) is not advertised or presented for supply as having a sun protection factor of more than 15; and (b) is not advertised or presented for supply as being water-resistant; and (c) if the product is not stable for at least 36 months – includes an expiry date on its label; and (d) has a pack size not larger than 300mL or 300g; and (e) except in the manner provided below, does not have any therapeutic claims made in relation to it, including claims about skin cancer; and therapeutic claims made in relation to the product are limited to those in relation to premature ageing in connection with sun exposure, and are only made if the product meets the performance requirements for ***broad-spectrum product*** set out in: (a) clause 7.2 of AS/NZS 2604:1998; or (b) both clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012

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	6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012; and (iii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and (iv) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012	
6	oral hygiene products for the care of the teeth and the mouth, including dentifrices, mouth washes and breath fresheners, that do not contain any substance included in Schedules 2, 3, 4 or 8 to Poisons Standard	when advertised or presented for supply, the following two paragraphs apply: (a) the only benefits claimed to result from the use of the product is consequential on improvements to oral hygiene, including for the prevention of tooth decay or the use of fluoride for the prevention of tooth decay; and (b) benefits in relation to such other diseases or aliments, such as gum or other oral disease or periodontal condition, are not claimed to result from use of the product
7	packs and kits containing medical devices for the prevention of blood borne and sexually transmissible diseases where each individual therapeutic good contained within the packs or kits is already included on the Register	when advertised or presented for supply as a part of a Government endorsed health promotion program, having been expressly authorised by that Government as part of that program
8	piped medical gas systems	when installed and used in compliance with AS 2896–2011
9	preparations containing a sunscreening substance, if the primary purpose of the preparation is neither protection from solar radiation nor another therapeutic purpose	when the preparation is not advertised or presented for supply with: (a) a statement of claimed sun protection factor; or (b) a description of a claimed sun protection factor; or (c) a reference to another therapeutic

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		use in respect of the preparation
10	sunbathing skin care products, such as oils, creams, gels, tanning products without sun and after-sun care products, that contain sunscreen with a sun protection factor of at least 4 and not more than 15, and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard, in relation to which one of the following two paragraphs applies: (a) for a product imported into, or manufactured in, Australia before 1 August 2018, both: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:1998 or AS/NZS 2604:2012; and (ii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 6.2 and 6.3 of AS/NZS 2604: 1998 or clauses 5 and 6 of AS/NSZ 2604:2012; or (b) for a product imported into, or manufactured in, Australia on or after 1 August 2018, all of the following: (i) the product is a secondary sunscreen product within the definition of ***secondary sunscreen product*** in AS/NZS 2604:2012; and (ii) the product meets the performance requirements for a ***broad-spectrum product*** set out in clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012; and	when the product: (a) is not advertised or presented for supply as having a sun protection factor of more than 15; and (b) is not advertised or presented for supply as being water-resistant; and (c) if the product is not stable for at least 36 months – includes an expiry date on its label; (d) has a pack size not larger than 300mL or 300g; and (e) except in the manner provided below, does not have any therapeutic claims made in relation to it, including claims about skin cancer; and therapeutic claims made in relation to the product are limited to those in relation to premature ageing in connection with sun exposure, and are only made if the product meets the performance requirements for ***broad-spectrum product*** set out in: (a) clause 7.2 of AS/NZS 2604:1998; or (b) both clause 6.3 of AS/NZS 2604:2012 and Table 1 in clause 5.2 of AS/NZS 2604:2012

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	(iii) any protection factor or equivalent category description stated on the product's label is in accordance with clauses 5 and 6 of AS/NSZ 2604:2012; and (iv) if the product's label states a protection factor, the label meets the requirements of clauses 7.1 and 7.3 of AS/NZS 2604: 2012	
11	therapeutic goods for retaining, cushioning or repairing dentures	when advertised or presented for supply to the ultimate consumer

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislation under the *Legislation Act 2003*. See http://www.legislation.gov.au

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