Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024

I, Gaelene Pyke, as delegate of the Minister for Health and Aged Care, make the following determination.

Dated 6 June 2024

Gaelene Pyke
Acting Assistant Secretary
Complementary and Over-the-Counter Medicines Branch
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024*.

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 July 2024.	1 July 2024

Note: This table relates only to the provisions of this instrument as originally made.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 *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

Therapeutic Goods (Excluded Goods) Determination 2018

1 Section 4 (definition of *AS/NZS 2604:1998*)

Repeal the definition.

2 Section 4 (definition of *AS/NZS 2604:2012*)

Repeal the definition.

3 Section 4

Insert:

AS/NZS 2604:2021 means the document Australian/New Zealand Standard AS/NZS 2604:2021, *Sunscreen products - Evaluation and classification*, published jointly by, or on behalf of, Standards Australia and Standards New Zealand, as in force or existing on 1 July 2024.

secondary sunscreen product has the same meaning as in AS/NZS 2604:2021.

4 Section 7 (heading)

Repeal the heading, substitute:

7 Application, saving and transitional provisions

5 Section 7

Before "Item 16", insert "(1)".

6 At the end of section 7

Add:

(2) Items 14 and 15 of the table in Schedule 1 and items 5 and 9 of the table in Schedule 2, as in force immediately before the commencement of the *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024*, continue to apply to goods covered by those items only where:

(a) the goods were excluded goods under those items on 30 June 2024; and

(b) paragraph (b) in column 2 of each of those items, as in force immediately before the commencement of the *Therapeutic Goods (Excluded Goods) Amendment (Sunscreen) Determination 2024*, applies to the goods; and

(c) the goods are imported, manufactured or supplied before 1 July 2029.

7 Schedule 1 (table item 14)

Repeal the item, substitute:

14	products containing sunscreen that are intended for application to the lips, and that: (a) do not contain any substance included in Schedule 2, 3, 4 or 8 to the Poisons Standard; and (b) are a secondary sunscreen product; and

(c) have any protection factor or equivalent category description stated on the product's label in accordance with clause 5 of AS/NZS 2604:2021; and
(d) if the product's label states a protection factor—have a label that meets the requirements of clauses 6.1 and 6.3 of AS/NZS 2604:2021; and
(e) meet the performance requirements for a broad-spectrum product set out in clause 5.3 and Table 1 in clause 4.2 of AS/NZS 2604:2021

8 Schedule 1 (table item 15)

Repeal the item, substitute:

15	tinted bases and foundations, such as liquids, pastes or powders, that contain sunscreen, and that: (a) do not contain any substance included in Schedule 2, 3, 4 or 8 to the Poisons Standard; and (b) are a secondary sunscreen product; and (c) have any protection factor or equivalent category description stated on the product's label in accordance with clause 5 of AS/NZS 2604:2021; and (d) if the product's label states a protection factor—have a label that meets the requirements of clauses 6.1 and 6.3 of AS/NZS 2604:2021; and (e) meet the performance requirements for a broad-spectrum product set out in clause 5.3 and Table 1 in clause 4.2 of AS/NZS 2604:2021	

9 Schedule 2 (table item 5)

Repeal the item, substitute:

5	moisturising skin care products containing sunscreen that are intended for dermal application (including anti-wrinkle, anti-ageing and skin whitening products), and that: (a) do not contain any substance included in Schedule 2, 3, 4 or 8 to the Poisons Standard; and (b) are a secondary sunscreen product; and (c) have any protection factor or equivalent category description stated on the product's label in accordance with clause 5 of AS/NZS 2604:2021; and (d) if the product's label states a protection factor—have a label that meets the requirements of clauses 6.1 and 6.3 of AS/NZS 2604:2021; and (e) meet the performance requirements for a	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 300 mL or 300 g; and (e) does not have any therapeutic claims made in relation to it (including claims about skin cancer), other than those in relation to premature ageing in connection with sun exposure

	broad-spectrum product set out in clause 5.3 and Table 1 in clause 4.2 of AS/NZS 2604:2021	

10 Schedule 2 (table item 10)

Repeal the item, substitute:

10	sunbathing skin care products that contain sunscreen (such as oils, creams, gels, tanning products without sun, and after-sun care products), and that: (a) have a sun protection factor of at least 4 and not more than 15; and (b) do not contain any substance included in Schedule 2, 3, 4 or 8 to the Poisons Standard; and (c) are a secondary sunscreen product; and (d) have any protection factor or equivalent category description stated on the product's label in accordance with clause 5 of AS/NZS 2604:2021; and (e) if the product's label states a protection factor—have a label that meets the requirements of clauses 6.1 and 6.3 of AS/NZS 2604:2021; and (f) meet the performance requirements for a broad-spectrum product set out in clause 5.3 and Table 1 in clause 4.2 of AS/NZS 2604:2021	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 300 mL or 300 g; and (e) does not have any therapeutic claims made in relation to it (including claims about skin cancer), other than those in relation to premature ageing in connection with sun exposure