

Department of Health and Ageing Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Johnson & Johnson Pacific Pty Ltd

for approval to supply

SUNDOWN Broadspectrum Maximum Protection SunscreenSPF15+ Ultra Cream (Formula Number SCR/15 Plus)

ARTG Identifier AUST C 10177

ARTG Start date 14/06/1991

Product type Sponsor cancelled at SIMELOAD Medicine

Manufacturer Details	Address	Manufacturing Steps
Johnson & Johnson Pacific Pty Ltd	45 Jones Street ULTIMO, NSW, 2007 Australia	Release for supply

ARTG Standard Conditions

The above Medicine Sponsor cancelled at SIMELOAD has been entered on the Register subject to the following conditions:

- Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions
 Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act
 1989" effective 1 February 1992.,
- Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 February 1992.,
- Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 15 February 1991.,
- Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 15 February 1991.

Products Covered by This Entry

1. SUNDOWN Broadspectrum Maximum Protection SunscreenSPF15+ Ultra Cream (Formula Number SCR/15 Plus)

Product Specific Conditions

- A certificate of analysis, less than six months old, is to be provided to the Therapeutic Goods Administration prior to these goods being exported or supplied for human use.,
- · Changes as described in the letter of the 7 June 1995 from M L Blair

Product Standard Indications

No standard indications have been recorded against this entry.

Product Specific Indications

 Broadspectrum maximum protection SPF15+ sunscreen cream. Gives broadspectrum protection from the full ultraviolet range of A, B and C rays. May help to prevent premature ageing of the skin and skin cancer caused by the sun. Water resistant for 2 hours in water.

Warnings

No warnings have been recorded against this entry.

Dosage Form

Cream

Route of Administration

Topical

Visual Identification

Off-white to pale yellow cream

Additional Product information

Product Formulation(s)

Active Ingredients

		Quantity	Units
Butyl methoxydibenzoylmethane	1	13	mg/mL
Octyl methoxycinnamate	1	100	mg/mL
Octyl salicylate	3	30	mg/mL

Therapeutic Goods Administration PO Box 100, Woden ACT 2606 Australia

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