



Australian Government
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* BROAD SPECTRUM SUNSCREEN SPF 15 CREAM,
FORMULA SCR/15
SUNDOWN* BROAD SPECTRUM SUNSCREEN SPF 15 CREAM,
FORMULA SCR/15 PLUS
SUNDOWN* BROAD SPECTRUM SUNSCREEN SPF 15 CREAM,
FORMULA SCR/15**

ARTG Identifier AUST L 63437
ARTG Start date 27/02/1998
Product type Listed Medicine

Manufacturer Details	Address	Manufacturing Steps
Johnson & Johnson Pacific Pty Ltd	45 Jones Street ULTIMO, NSW, 2007 Australia	Manufacture of dosage form, Packaging and labelling, Release for supply, Secondary packaging, Testing microbial, Testing chemical and physical

ARTG Standard Conditions

The above Medicine Listed has been entered on the Register subject to the following conditions:

- A copy of a signed and dated certificate of analysis, which is not more than six months old, for the first batch of goods manufactured is to be provided to the Head, Listing Treaties & Export Section, Chemical & Non Prescription Drug Branch within six months of the date of supply of the goods.,
- 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 July 1995.,
- 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 July 1995.

Products Covered by This Entry

1. SUNDOWN* BROAD SPECTRUM SUNSCREEN SPF 15 CREAM, FORMULA SCR/15

Product Specific Conditions

- Changes as per ELF Application dated 23 March 98 for the Grouping of this good.

Product Standard Indications

- Sunscreen SPF15

Product Specific Indications

- Sundown* gives broad spectrum from UVA and UVB rays and if used regularly may help prevent premature ageing of the skin and skin cancer caused by the sun. Water resistant for 2 hours.

Warnings

No warnings have been recorded against this entry.

Dosage Form

Cream

Route of Administration

- Topical
- Topical
- Topical

Visual Identification

Off white to pale yellow cream

Additional Product information

White plastic tube with plastic flip-top cap

Product Formulation(s)

Component: COMPONENT ONE

Active Ingredients

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

2. SUNDOWN* BROAD SPECTRUM SUNSCREEN SPF 15 CREAM, FORMULA SCR/15 PLUS**Product Specific Conditions**

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Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653
Email: info@tga.gov.au

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