



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 TODDLER SPF15+ ULTRA LOTION

ARTG Identifier AUST C 58307
ARTG Start date 10/12/1996
Product type Sponsor cancelled at SIMELOAD Medicine
Export Names JOHNSON'S BABY BROADSPECTRUM SUNSCREEN SPF15+
SUNDOWN BROADSPECTRUM SUNSCREEN TODDLER SPF 15+,

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

ARTG Standard Conditions

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

- Except where the sponsor has been contracted by an overseas party to manufacture the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods and, upon the request of the Head, Office of Medicines Authorisation, Therapeutic Goods Administration, shall produce such evidence to the Director.,
- 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.,
- The therapeutic goods grouped in this registration/listing as export only goods under the following names are included in the Australian Register of Therapeutic Goods and may not be supplied in Australia. Export Name(s) to be added:,
- 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, other than condition No. 8 and condition No. 9.,
- 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, other than condition No. 11.

Products Covered by This Entry

1. SUNDOWN* BROAD SPECTRUM SUNSCREEN TODDLER SPF15+ ULTRA LOTION

Product Specific Conditions

- JOHNSON'S BABY BROADSPECTRUM SUNSCREEN SPF15+, SUNDOWN BROADSPECTRUM SUNSCREEN TODDLER SPF 15+.

Product Standard Indications

- A broad spectrum sunscreensing preparation of SPF30+. May reduce the risk of some skin cancers.

Product Specific Indications

No specific indications have been recorded against this entry.

Warnings

No warnings have been recorded against this entry.

Dosage Form

Lotion

Route of Administration

- Topical

Visual Identification

White to off-white lotion

Additional Product information

WHITE OPAQUE PLASTIC BOTTLE WITH BLUE FLIP TOP CAP

Product Formulation(s)**Active Ingredients**

	Quantity	Units
Oxybenzone	40	mg/mL
Octyl salicylate	20	mg/mL
Octyl methoxycinnamate	100	mg/mL
Butyl methoxydibenzoylmethane	12.5	mg/mL

Therapeutic Goods Administration
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