Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-11102004-LI-000007-1

Previously granted under Licence number: 1291

This licence is subject to the requirements of the *Therapeutic Goods Act1989,* and its Regulations.

Section 40(4) of the *Therapeutic Goods Act 1989* and Regulation 19, 20, 21 and 22 of the Therapeutic Goods Regulations 1990 impose various statutory conditions on all licences to manufacture therapeutic goods.

In addition to that, the specific conditions mentioned in Part 2 of this licence have been imposed under Section 40(1) or 40(2) of the *Therapeutic Goods Act 1989.*

Originally Granted: **29 July 1992**

Date Revised: **18 December 2014**

Signed: .....

Jenny Hantzinikolas, Delegate of the Secretary

This Licence is valid only if the security provisions (blue and grey curved dotted lines across the bottom half of each page) are visible.
This Licence is the property of the Therapeutic Goods Administration and must be returned or destroyed upon demand.
This Licence remains valid until otherwise suspended or revoked by the Therapeutic Goods Administration.
The status of an Australian Licence may be viewed at https://www.ebs.tga.gov.au/

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-11102004-LI-000007-1

Previously granted under Licence number: 1291

Granted to:

Ross Cosmetics Aust Pty Ltd

ACN: 004 249 530

Manufacturing Site Address:

14-22 Carrick Drive

TULLAMARINE VIC 3043

The manufacturer above is hereby authorised under Section 38 of the *Therapeutic Goods Act 1989* to carry out the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Sterility	Dosage Form	Product Category	Manufacturing Step
Medicine manufacture	Non Sterile	Liquids	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Semi Solids	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Sunscreen manufacture	Non Sterile	Topical Sunscreen Forms	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine manufacture	Non Sterile	Semi Solids	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing

Signed: .....

Jenny Hantzinikolas, Delegate of the Secretary

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TGA Health Safety Regulation

Australian Government

Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 2:

Schedule of Conditions

Licence Number:

MI-11102004-LI-000007-1

Previously issued under Licence number: 1291

Issued to:

Ross Cosmetics Aust Pty Ltd

ACN: 004 249 530

Manufacturing Site Address:

14-22 Carrick Drive

TULLAMARINE VIC 3043

In addition to the statutory conditions that have been imposed on all licences to manufacture therapeutic goods under Section 40(4) of the *Therapeutic Goods Act 1989* and Regulations 19, 20 and 21 of the Therapeutic Goods Regulations 1990, the conditions specified below have been imposed on this licence under Section/s 40(1) and/or 40(2) of the *Therapeutic Goods Act 1989*:

This licence authorises only the manufacture of medicines in liquid and semi-solid form and sunscreens in solid form.

This licence does not authorise the manufacture of preparations containing penicillins, cephalosporins, hormones, steroids, antineoplastic medicines s or medicines to which Schedule 4 or 8 of the Poisons Standard applies.

Persons currently nominated under Section 37(1)(e) of the Act as having control:

Production: Peter Rachwalski

Quality Control: Stelios Liberatos

Originally imposed: **29 July 1992** Date Revised: **18 December 2014**

Signed: .....

Jenny Hantzinikolas, Delegate of the Secretary

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