



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**Aero Healthcare**

for approval to supply

**AeroAid Antiseptic Cream**

**ARTG Identifier** AUST L 281191  
**ARTG Start Date** 10/10/2016  
**Product Type** Listed Medicine

Manufacturer Details	Address	Manufacturing Steps
Australian Laboratory Services Pty Ltd	Unit 10 2-8 South Street RYDALMERE , NSW , 2116 Australia	Testing chemical and physical
C Lim Consulting Pty Ltd	2302/ 30 Glen Street MILSONS POINT , NSW , 2061 Australia	Release for supply
Delta Laboratories Pty Ltd	8 Warringah Close SOMERSBY , NSW , 2250 Australia	Packaging and labelling Manufacture of dosage form Testing chemical and physical Release for supply
Eurofins ams Laboratories Pty Ltd	8 Rachael Close SILVERWATER , NSW , 2128 Australia	Testing microbial
G S Packaging Pty Ltd T/A Arrowpak	14-15 Cassola Place PENRITH , NSW , 27 50 Australia	Packaging and labelling

### ARTG Standard Conditions

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

- The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.
- The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.
- Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

### Products Covered by This Entry

**1. AeroAid Antiseptic Cream**

### Product Specific Conditions

No specific conditions have been recorded against this entry.

**Product Permitted Indications**

- Soothe/relieve mild skin burn/sunburns
- Antiseptic for minor cuts and abrasions
- Enhance/improve healing of minor skin wound/cuts/scratches/abrasions
- Decrease/reduce/relieve symptoms of insect bite/sting

**Product Indication Requirements**

- Product presentation must not imply or refer to serious infections.
- Product presentation must only refer to 'mild' burns.
- Label statement: If symptoms persist, talk to your health professional.
- If product is indicated for skin burn, Label statement: Immediate treatment of burns should be application of cold water for ten minutes (or words to that effect).
- If product is indicated for skin burn, Label statement: Only to be used for minor burns after initial first aid treatment, medical advice should be sought for serious burns.

**Product Standard Indications**

No standard indications have been recorded against this entry.

**Product Specific Indications**

No specific indications have been recorded against this entry.

**Warnings**

- Contains phenoxyethanol (or words to that effect). ( PHOETH )
- Contains hydroxybenzoates (or words to this effect) if the medicines contains more than one hydroxybenzoate source OR Contains (insert the approved name of hydroxybenzoate used)(or words to this effect) if product contains one hydroxybenzoate source. ( TOTBNZ )
- If symptoms persist consult your healthcare practitioner (or words to that effect). ( S )

**Dosage Form**

- Cream

**Route of Administration**

- Topical

**Visual Identification**

Not recorded

**Additional Product information**

**Product Formulation(s)**

**Active Ingredients**

	Quantity	Units
Melaleuca Oil	47.5	mg/g

Therapeutic Goods Administration  
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