



Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Aero Healthcare

for approval to supply

AeroAid First Aid Spray

ARTG Identifier AUST L 200806
ARTG Start Date 8/09/2012
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
Delta Laboratories Pty Ltd	8 Warringah Close SOMERSBY , NSW , 2250 Australia	Testing chemical and physical Manufacture of dosage form Release for supply Packaging and labelling
Delta Laboratories Pty Ltd	9 Chivers Road Somersby , NSW , 22 50 Australia	Testing chemical and physical Secondary packaging Manufacture of dosage form
Eurofins ams Laboratories Pty Ltd	8 Rachael Close SILVERWATER , NSW , 2128 Australia	Testing microbial

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 First Aid Spray

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

- 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 presentation must not imply or refer to serious infections.
- Product presentation must only refer to 'mild' 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 ethanol or contains alcohol. (ETHAN)
- If symptoms persist consult your healthcare practitioner (or words to that effect). (S)
- 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)

Dosage Form

- Spray

Route of Administration

- Topical

Visual Identification

Not recorded

Additional Product information

Product Formulation(s)

Active Ingredients

	Quantity	Units
Melaleuca Oil	50	mg/g

Therapeutic Goods Administration
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