



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

The Locals

for approval to supply

The Locals Sandfly & Mozzie Spray

ARTG Identifier AUST L 180204
ARTG Start date 18/02/2011
Product type: Listed Medicine

Manufacturer Details	Address	Manufacturing Steps
AMS Laboratories Pty Limited	8 Rachael Close SILVERWATER, NSW, 2128 Australia	Testing microbial
Australian Laboratory Services Pty Ltd	Units 1 & 16 & 17 & 18 / 8 Leighton Place ASQUITH, NSW, 2077 Australia	Testing chemical and physical
Delta Laboratories Pty Ltd	8 Warringah Close SOMERSBY, NSW, 2250 Australia	Manufacture of dosage form Packaging and labelling Release for supply Secondary packaging Testing chemical and physical

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 Office of Complementary Medicines, Therapeutic Goods Administration, upon request.
- The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.
- All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.
- The sponsor shall not supply the listed medicine after the expiry date of the goods.
- 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 Head, Office of Complementary Medicines, Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products covered by this Entry

1. The Locals Sandfly & Mozzie Spray

Product Specific Conditions

No specific conditions have been recorded against this entry.

Product Standard Indications

No standard indications have been recorded against this entry.

Product Specific Indications

- To help relieve the itching of insect bites.

Warnings

- Contains ethanol. (or words to that effect). (ETHAN)
- Contains phenoxyethanol (or words to that effect). (PHOETH)
- If symptoms persist consult your healthcare practitioner (or words to that effect). (S)

Dosage Form

Spray

Route of Administration

- Topical

Visual Identification

Not recorded

Additional Product information**Product Formulation(s)****Active Ingredients**

	Quantity	Units
Eucalyptus Oil	7.15	mg/g
Lavender Oil	7.15	mg/g

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