



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

| | | |
|--------------------------------|---|-----------------|
| Summary for ARTG Entry: | 115089 | Squalene 1000mg |
| ARTG entry for | Medicine Listed (Export Only) | |
| Sponsor | Aulong Development Pty Ltd | |
| Postal Address | 7/2 Belmore Street, BURWOOD, NSW, 2134 Australia | |
| ARTG Start Date | 10/12/2004 | |
| Product Category | Medicine | |
| Status | Active | |
| Approval Area | Export only Medicines | |

Conditions

Except where the sponsor has been contracted by an overseas party to manufacturer 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 Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

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, 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 July 1995, other than condition No.11

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

Products

1 . Squalene 1000mg

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 10/12/2004 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Assists in the maintenance of healthy skin and hair. Functions as a strong antioxidant.

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

| | |
|------------------|------------------------|
| Pack Size | Poison Schedule |
|------------------|------------------------|

Components

1 . Medicine Component

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

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squalene

1 g

Other Ingredients (Excipients)

d-alpha-tocopherol

Gelatin

glycerol

purified water

Soya Oil

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