



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	97806	SQUALENE 1000mg
ARTG entry for	Medicine Listed (Export Only)	
Sponsor	Kelbra Holdings Pty Ltd	
Postal Address	27 McCauley Street, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	28/10/2003	
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 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	28/10/2003 1:00:57 PM
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

Aids, assists or helps in the maintenance or improvement of general well-being.

Specific Indications

Anti-oxidant; helps in the maintenance or improvement of healthy skin and hair; helps body perform in peak condition; helps provide stamina and endurance.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	3 Years	Store below 30 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
60 capsules	Not scheduled. Not considered by committee
various	Not scheduled. Not considered by committee

Components

1 . Medicine Component

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	clear yellow liquid in an oblong shaped soft transparent capsule

Active Ingredients



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squalene

1 g

Other Ingredients (Excipients)

Gelatin

glycerol

purified water

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