



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	58564	SUNNYGREEN HEALTH SQUALENE 500mg capsule bottle
ARTG entry for	Medicine Listed (Export Only)	
Sponsor	Sunnygreen Pty Ltd	
Postal Address	5/20 Booran Drive, WOODRIDGE, QLD, 4114 Australia	
ARTG Start Date	13/01/1997	
Product Category	Medicine	
Status	Active	
Approval Area	Export only Medicines	

Conditions

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 February 1992, 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 February 1992, other than condition No. 11.

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.

A copy of a signed and dated certificate of analysis, which is not more than six months old, for the first batch of goods manufactured is to be provided to the Head, Listing Treaties & Export Section, Chemical & Non Prescription Drug Branch within six months of the date of supply of the goods.

Products

1 . SUNNYGREEN HEALTH SQUALENE 500mg capsule bottle

Product Type	Single Medicine Product	Effective Date	3/07/2002
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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

Squalene is the main constituent of the oil obtained from the livers of deep sea sharks. Aids, assists or helps in the maintenance of general well-being.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	3 Years	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
60 capsules	Not scheduled. Not considered by committee
100 capsules	Not scheduled. Not considered by committee
120 capsules	Not scheduled. Not considered by committee
200 capsules	Not scheduled. Not considered by committee
240 capsules	Not scheduled. Not considered by committee

Components

1 . capsules

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Dosage Form Capsule, soft
Route of Administration Oral
Visual Identification One piece softgel capsule, oval shaped, natural colour.

Active Ingredients

squalene 500 mg

Other Ingredients (Excipients)

Gelatin
glycerol
purified water

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