



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	80756	SEAZEST SEA CUCUMBER 500mg ORAL TABLET EFFERVESCENT tube
<b>ARTG entry for</b>	Medicine Listed (Export Only)	
<b>Sponsor</b>	Reef Organics Pty Ltd	
<b>Postal Address</b>	PO Box 712N, NORTH CAIRNS, QLD, 4870 Australia	
<b>ARTG Start Date</b>	29/10/2001	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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.

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.

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.

### Products

#### 1 . SEAZEST SEA CUCUMBER 500mg ORAL TABLET EFFERVESCENT tube

<b>Product Type</b>	Composite Pack	<b>Effective Date</b>	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

For the relief of the pain and swelling associated with arthritis and rheumatism

#### Warnings

No Warnings included on Record

#### Additional Product information

#### Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Tube	Not recorded	3 Years	Store below 30 degrees Celsius	Not recorded	Store in a Dry Place Protect from Light

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
export	Not scheduled. Not considered by committee

#### Components





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Public Summary