



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

**Public Summary**

|                                |   |                                   |
|--------------------------------|---|-----------------------------------|
| <b>Summary for ARTG Entry:</b> | 101595  | COD LIVER OIL 500mg capsule bulk. |
| <b>ARTG entry for</b>          | Medicine Listed (Export Only)                 |                                   |
| <b>Sponsor</b>                 | Sphere Healthcare Pty Ltd                     |                                   |
| <b>Postal Address</b>          | PO Box 566, MOOREBANK, NSW, 1875<br>Australia |                                   |
| <b>ARTG Start Date</b>         | 25/05/2004                                    |                                   |
| <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.

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 . COD LIVER OIL 500mg capsule bulk.**

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 25/05/2004 |
|---------------------|-------------------------|-----------------------|------------|

**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**

Nutritional supplement.

**Warnings**

No Warnings included on Record

**Additional Product information**

**Container information**

| Type           | Material     | Life Time    | Temperature  | Closure      | Conditions   |
|----------------|--------------|--------------|--------------|--------------|--------------|
| Bulk Container | Not recorded | Not recorded | Not recorded | Not recorded | Not recorded |

**Pack Size/Poison information**

| Pack Size    | Poison Schedule                            |
|--------------|--|
| Not Required | Not scheduled. Not considered by committee |

**Components**

**1 . SOFT CAPSULE**

|                                |   |
|--------------------------------|---|
| <b>Dosage Form</b>             | Capsule, soft   |
| <b>Route of Administration</b> | Oral  |
| <b>Visual Identification</b>   | Clear yellow liquid in an oval shaped soft gelatin capsule. |

**Active Ingredients**

|                      |               |
|----------------------|---------------|
| <b>Cod-liver oil</b> | <b>500 mg</b> |
|----------------------|---------------|

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|                            |        |
|----------------------------|--------|
| Equivalent: retinol        | 300 IU |
| Equivalent: colecalciferol | 30 IU  |

**Other Ingredients (Excipients)**

**Gelatin**  
**glycerol**  
**purified water**

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