



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	331240	ODOURLESS NATURAL FISH OIL 1000
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Phytologic Holdings Pty Limited	
<b>Postal Address</b>	16-20 Baker Street, Banksmeadow, NSW, 2019 Australia	
<b>ARTG Start Date</b>	16/03/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

### Products

#### 1 . ODOURLESS NATURAL FISH OIL 1000

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	7/06/2023
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### Permitted Indications

- Helps maintain/support healthy eye development in children up to 12 years of age
- Maintain/support eye health
- Maintain/support healthy growth and development in children
- Maintain/support general health and wellbeing
- Anti-inflammatory/relieve inflammation
- Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- Maintain/support joint health
- Decrease/reduce/relieve mild joint inflammation/swelling
- Maintain/support joint mobility/flexibility
- Decrease/reduce/relieve mild joint stiffness
- Helps in the maintenance of healthy blood lipids/blood fats
- Helps maintain/support healthy cholesterol
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Maintain/support cognitive function/mental function
- Maintain/support brain health
- Maintain/support nervous system health
- Maintain/support brain/central nervous system development in children up to 12 years of age
- Maintain/support nervous system function
- Support healthy emotional/mood balance

### Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Product presentation must only refer to mild joint symptoms.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.



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Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.  
Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range  
Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.  
Product presentation must not imply or refer to neurological conditions or developmental delays.  
Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.  
Product presentation must not imply or refer to serious cardiovascular conditions.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Contains fish OR Contains fish products.  
If symptoms persist consult your healthcare practitioner (or words to that effect).

**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, soft

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>natural fish oil</b>	<b>1 g</b>
Equivalent: docosahexaenoic acid	120 mg
Equivalent: eicosapentaenoic acid	180 mg
Equivalent: omega-3 marine triglycerides	300 mg

**Other Ingredients (Excipients)**

**d-alpha-tocopherol**

**Gelatin**

**glycerol**

**Lemon Oil**

**purified water**

**Soya Oil**

**vanillin**

Public Summary

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