



Australian Government

Department of Health and Aged Care  
Therapeutic Goods Administration

<b>Record Summary</b>	412755	PhytoLove Ahiflower Oil
<b>Sponsor</b>	Phytolove Pty Ltd	
<b>Therapeutic Type</b>	Medicine	
<b>Product Category</b>	Listed	
<b>ARTG Start Date</b>	6/07/2023	
<b>Postal Address</b>	701 Left Bank Road, Mullumbimby Creek, NSW, 2482 Australia	
<b>Billing Address</b>	701 Left Bank Road, Mullumbimby Creek, NSW, 2482 Australia	
<b>Product Type</b>	Medicine - - Listed	
<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.

**Manufacturers**

Name	Address	Manufacturing steps
Australian Laboratory Services Pty Ltd	Unit 10 2-8 South Street RYDALMERE , NSW , 2116 Australia	Testing chemical and physical
Chem-Chrom Laboratories and Services	Unit 15 / 10-12 Montore Road Minto , NSW , 2566 Australia	Testing chemical and physical
Ferngrove Pharmaceuticals Australia Pty Ltd	5 Ferngrove Place SOUTH GRANVILLE , NSW , 2142 Australia	Manufacture of dosage form Packaging and labelling Release for supply Secondary packaging Testing chemical and physical
Naturalab Pty Ltd	Level 2 / 111 Stephans Road BOTANY , NSW , 2019 Australia	Testing chemical and physical
Silliker Australia Pty Ltd	Unit C2 / 391 Park Road Regents Park Estate REGENTS PARK , NSW , 2143 Australia	Testing microbial
Southern Cross Analytical Research Laboratory	Level 3 T Block and N Block Military Road Southern Cross University LISMORE , NSW , 2480 Australia	Testing chemical and physical
Symbio Laboratories PTY LTD	2 Sirius Road Lane Cove West , NSW , 2066 Australia	Testing microbial

**Products**

1 . PhytoLove Ahiflower Oil

Product Type Single Medicine Product

Status

Current

Effective Date

6/07/2023

### Permitted Indications

Maintain/support general health and wellbeing  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Aid/assist/helps synthesis of (insert vitamin) in the body

### Indication Requirements

Label statement: Vitamins can only be of assistance if the dietary vitamin intake is inadequate OR Vitamin supplements should not replace a balanced diet.  
If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).  
Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

NTAKEN3 Not to be taken by children under 3 years old (or words to that effect).

### Specific Conditions

No Specific Conditions included on Record

### Components

#### 1 . Formulation 1

Dosage Form Capsule, soft  
Route of Administration Oral  
Maximum Daily Dose 3

#### Formulations

Active Ingredients	Category	Quantity	Units
refined Buglossoides arvensis seed oil	AHS	772	mg
Equivalent			
stearidonic acid		162.12	mg

Excipient Ingredients	Category	Quantity	Units
glycerol	AAN		
purified water	AAN		
Vegan gel	PI	280	mg

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