



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	318246	Qsilica Ceramosides + Antioxidant Pro Collagen One-A-Day Capsules
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Planet Health Pty Ltd	
<b>Postal Address</b>	42 Bowral Street, BOWRAL, NSW, 2576 Australia	
<b>ARTG Start Date</b>	3/06/2019	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Qsilica Ceramosides + Antioxidant Pro Collagen One-A-Day Capsules**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	3/06/2019
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation
- Maintain/support collagen health
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support nail health/strength/thickness
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- Maintain/support bone mass/density/integrity
- Help maintain/support bone mineralisation
- Helps maintain/supports healthy joint cartilage growth/development/production
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy ligaments
- Maintain/support tendon health
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support skin health

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Maintain/support skin integrity/structure

Maintain/support wound healing

**Indication Requirements**

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.

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).

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

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

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

No Warnings included on Record

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>calcium ascorbate dihydrate</b>	<b>49.67 mg</b>
Equivalent: ascorbic acid	45 mg
<b>colloidal anhydrous silica</b>	<b>130 mg</b>
Equivalent: silicon	60 mg
<b>Malpighia glabra fruit Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Malpighia glabra (Dry)	500 mg
<b>Triticum aestivum</b>	<b>30 mg</b>

**Other Ingredients (Excipients)**

**Acacia**

**disodium edetate**

**gellan gum**

**hypromellose**

**maltodextrin**

**Oryza sativa**

**potable water**

**potassium acetate**

**Sunflower Oil**

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