

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	384693	Qsilica Skin, Hair & Nails ONE-A-DAY Multi-Nutrient Tablets	
ARTG entry for	Medicine Listed		
Sponsor	Planet Health Pt	y Ltd	
Postal Address	42 Bowral Street, BOWRAL, NSW, 2576 Australia		
ARTG Start Date	25/02/2022		
Product Category	Medicine		
Status	Active		
Approval Area	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

Product Type	Single Medicine Product	Effective Date	25/02/2022	
Permitted Indicati	J.			
	e free radicals formed in the body			
	ease free radical damage to body cells			
Maintain/support c	č			
Maintain/support of	•			
	eneral health and wellbeing			
Maintain/support h				
	ail brittleness/splitting/chipping in females			
	ail health/strength/thickness			
	promote/increase nail health/strength/thickne	ss in females		
	onnective tissue health			
	nnective tissue production/formation			
Maintain/support b				
	one mass/density/integrity			
Help maintain/supp	port bone mineralisation			
Helps maintain/sup	ports healthy joint cartilage growth/developm	nent/production		
Maintain/support h	ealthy ligaments			
Maintain/support te	endon health			
Helps prevent dieta	ary (state vitamin/mineral/nutrient) deficiency			
Maintain/support sl	kin health			
Maintain/support sl	kin integrity/structure			
Maintain/support sl	kin regeneration			
Maintain/support w	round healing			
Indication Require	ements			

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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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 bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. 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

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This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

Additional Product information

				-
Pack	Size/F	Poison	info	ormation

Pack Size		Poison Schedule		
Components				
1 . Formulation 1				
Dosage Form	Tablet, film coated			
Route of Administration	Oral			
Visual Identification				
Active Ingredients				
Biotin			2.5 mg	
colloidal anhydrous silica			450 mg	
Equivalent: silicon			210.38 mg	
selenomethionine			250 microgram	
Equivalent: selenium			100 microgram	
zinc citrate dihydrate			75.3 mg	
Equivalent: zinc			24.17 mg	
Other Ingredients (Excipier	nts)			
calcium carbonate				
calcium hydrogen phospha	ate dihydrate			
Carnauba Wax				
chlorophyllin-copper comp	lex			
croscarmellose sodium				
crospovidone				C
hypromellose iron oxide yellow				
magnesium stearate				
microcrystalline cellulose				
povidone				
tapioca starch				
triethyl citrate				

Public Summa

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