

**Australian Government** 

## **Department of Health**

## Therapeutic Goods Administration

## **Public Summary**

Summary for ARTG Entry:	384232	Collagen Beauty
	001202	
ARTG entry for	Medicine Listed	
Sponsor	Nutra Organics	Pty Ltd
Postal Address	2/2 Kite Crescer Australia	nt, South Murwillumbah, NSW, 2484
ARTG Start Date	18/02/2022	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	S
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 . Collagen Be	eauty		
Product Type	Single Medicine Product	Effective Date	18/02/2022
Permitted Indication	ons		
Antioxidant/Reduce	free radicals formed in the body		
Maintain/support ha	air health		
Maintain/support na	ail health/strength/thickness		
Maintain/support he	ealthy gastrointestinal function		
Maintain/support sk	in health		
Helps enhance/imp	rove/promote/increase skin hydration		
Maintain/support sk	in hydration		
Maintain/support sk	-		
Maintain/support sk			
Maintain/support sk	in repair/healing/regeneration		
Indication Require	ements		
No Indication Requi	irements included on Record		
Standard Indicatio	ons		
No Standard Indicat	tions included on Record		
Specific Indication	IS		
No Specific Indication	ons included on Record		
Warnings			
Vitamins and minera	als can only be of assistance if dietary intak	e is inadequate OR Vitamin and/or m	ineral supplements should not replace a balanced diet.
Additional Product	t information		
Pack Size/Poison i	information		
Pack Size		Poison Schedule	
Components			
1. Formulation 1	1		
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Dosage Form	Tablet, film coated			
Route of Administration	Oral			
Visual Identification				
Active Ingredients				
hydrolysed collagen		833.33 mg		
Malpighia glabra fruit Extr	act dry concentrate standardised	55.56 mg		
Equivalent: Malpighia glat	ora (Dry)	1.389 g		
Matricaria chamomilla flow	wer Extract dry concentrate	100 mg		
Equivalent: Matricaria cha	momilla (Dry)	2 g		
Psidium guajava leaf Extra	act dry concentrate	16.67 mg		
Equivalent: Psidium guaja	ıva (Dry)	166.7 mg		
Other Ingredients (Excipie	ents)			
beet red				
calcium carbonate				
calcium hydrogen phosphate dihydrate				
Carnauba Wax				
colloidal anhydrous silica				
croscarmellose sodium				
hypromellose				
macrogol 400				
magnesium hydroxide				
magnesium stearate				
maltodextrin				

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