

# **COLLAGEN GLOW CREME SPF 50- avobenzone, octisalate, octocrylene cream NAKED SUNDAYS PTY LTD**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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## **NAKED SUNDAYS COLLAGEN GLOW CREME SPF 50**

### **ACTIVE INGREDIENTS**

Avobenzone 3%  
Octisalate 5%  
Octocrylene 10%

### **Purpose**

Sunscreen

### **USES**

- Helps prevent sunburn.
- If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early skin ageing caused by the sun.

### **WARNINGS**

For external use only.

- Do not use on damaged or broken skin.
- When using this product: keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor if: rash occurs.
- Keep out of reach of children: If product is swallowed, get medical help.

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

### **DIRECTIONS**

- Apply generously 15 minutes before sun exposure.
- Reapply after 80 minutes of swimming or sweating.
- Reapply immediately after towel drying.
- Reapply at least every 2 hours.
- Children under 3 years of age: Ask a doctor.

### **SUN PROTECTION MEASURES**

Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- Limit time in the sun, especially from 10.00AM - 2.00PM
- Wear long-sleeved shirts, pants, hats, and sunglasses

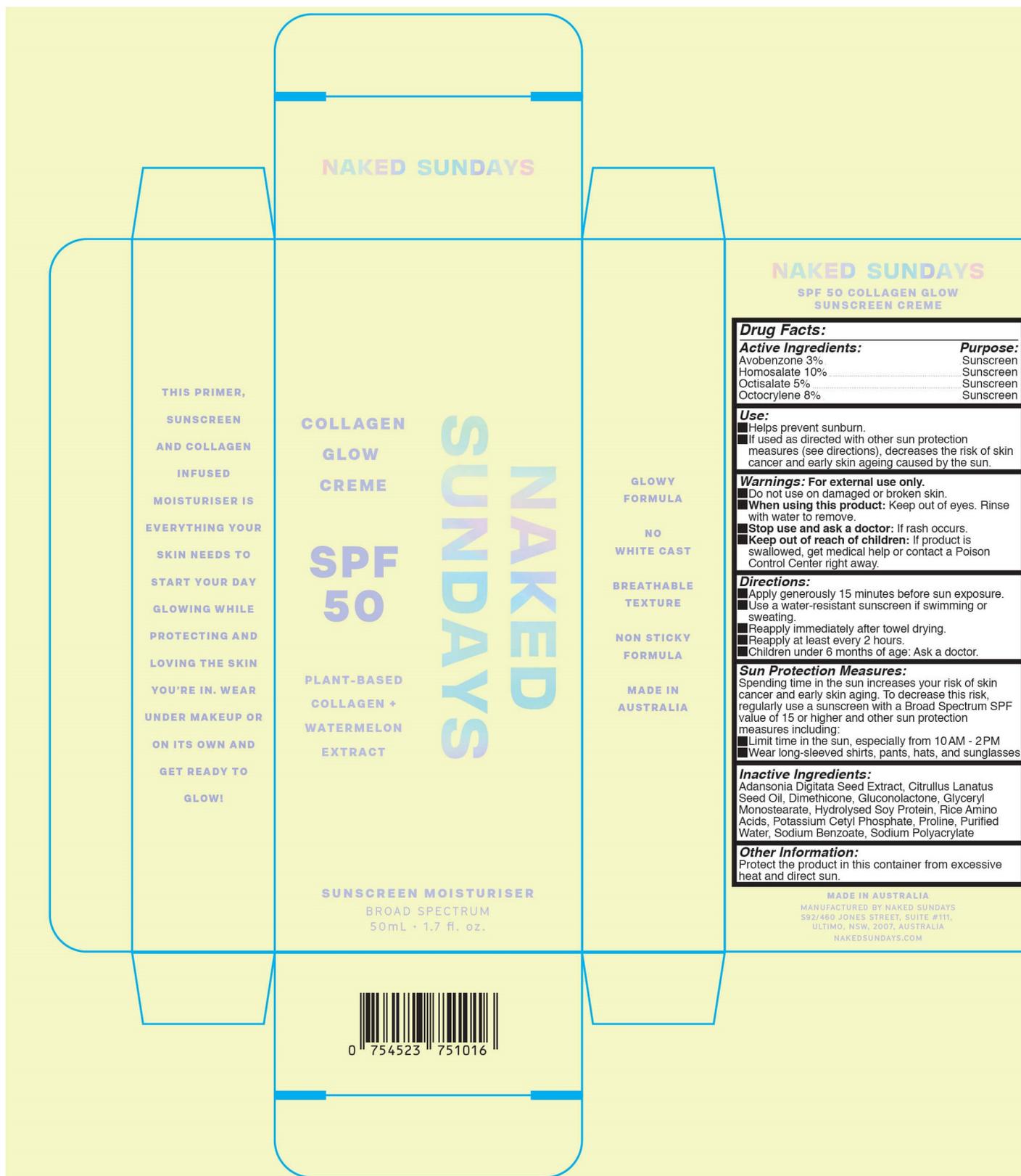
### **INACTIVE INGREDIENTS**

Dimethicone 350, Ethylhexylglycerin, Glyceryl monostearate, Hydrolysed adansonia digitata leaf extract, Enzacamene, Hydrolysed rice protein, Hydrolysed soy protein, Phenoxyethanol, Potassium cetyl phosphate, Proline, Water (Aqua), Sodium benzoate, Sodium polyacrylate, Citrullus lanatus fruit extract (Watermelon).

### **OTHER INFORMATION**

Protect the product in this container from excessive heat and direct sun.

**label**



## COLLAGEN GLOW CREME SPF 50

avobenzone, octisalate, octocrylene cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81104-101(NDC:30807-1006)
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>DIMETHICONE 350</b> (UNII: 2Y53S6ATLU)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>ADANSONIA DIGITATA LEAF</b> (UNII: G75S8RQS56)	
<b>ENZACAMENE</b> (UNII: 8I3XWY40L9)	
<b>ORYZA SATIVA WHOLE</b> (UNII: 84IVV0906Z)	
<b>HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW)</b> (UNII: 1394NXB9L6)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>PROLINE</b> (UNII: 9DLQ4CIU6V)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)	
<b>WATERMELON</b> (UNII: 231473QB6R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81104-101-11	50 mL in 1 TUBE; Type 0: Not a Combination Product	11/19/2020	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/19/2020	

**Labeler** - NAKED SUNDAYS PTY LTD (746918845)