AUSTRALIAN GOLD SPF 50- avobenzone, homosalate, octisalate, octocrylene spray Prime Packaging Inc.

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.

Australian Gold SPF 50 Continuous Sunscreen Spray

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 5%

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 aging caused by the sun

Warnings

For external use only.

Do not use on damaged or broken skin.

When using this product keep away from face to avoid breathing it . 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 or contact a Poison Control Center right away.

Flammable: Avoid fire, flame, heat, and smoking. **Contents under pressure.** Do not puncture or incinerate. Do no store at temperatures above 120°F (50°C).

Directions

- shake well before use
- applyliberally 15 minutes before sun exposure and rub into skin
- hold container 4 to 6 inches from the skin to apply

- apply liberally 15 minutues before sun exposure
- do not spray directly into face. Spray on hands then apply to face
- do not apply in windy conditions
- use in a well-ventilated area
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours
- **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 of 15 or higher and other sun protection measures including:
- limit time in the sun, especially from 10 a.m. 2 p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive Ingredients

SD Alcohol 40-B, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Fragrance, Polyester-8, Helianthus Annuus (Sunflower) Seed Oil, Tocopheryl Acetate, Aloe Barbadensis Leaf Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil

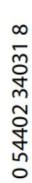
Other Information

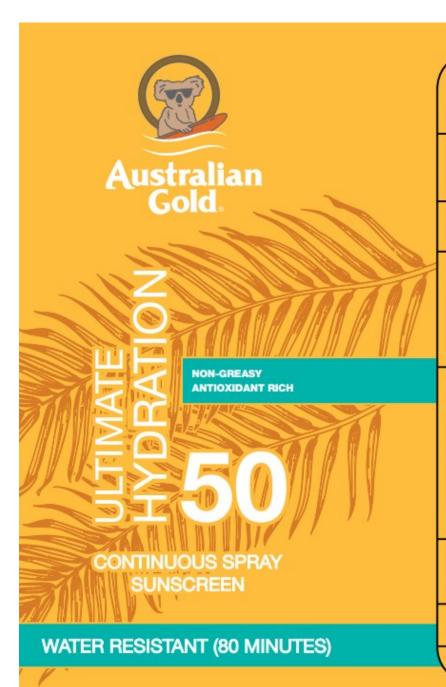
- Protect this product from excessive heat and direct sun
- May stain some fabrics or surfaces

Question or comments?

Call toll free 1-855-LIV-GOLD (548-4653)

Australian Gold SPF 50 Continuous Sunscreen Spray





BROAD SPECTRUM SPF 50

Net Wt. 6 oz (170 g)

Australian Gold

SPF 50 Continuous Spray

· Cocoa Dreams Fragrance • Gluten Free • Phthalate Free Quick Dry Formula

Drug Facts

Active Ingredients
Avobenzone 39 Purpose Homosalate 10% Sunscreen Octocrylene

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Inactive Ingredients
SD Alcohol 40-B, VA/Butyl Maleate/Isobornyl Acrylate
Copolymer, Fragrance, Polyester-8, Helianthus
Annuus (Sunflower) Seed Oil, Tocopheryl Acetate,
Aloe Barbadensis Leaf Extract, Melaleuca Alternifolia

Other information

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Questions or comments?

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AUSTRALIAN GOLD SPF 50

avobenzone, homosalate, octisalate, octocrylene spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:13630-0269 **Route of Administration TOPICAL**

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	25.08 g in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	83.6 g in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	41.8 g in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	41.8 g in 1 mL	

Inactive Ingredients				
Ingredient Name	Strength			
TEA TREE OIL (UNII: VIF565UC2G)				
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
ALCOHOL (UNII: 3K9958V90M)				
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)				
SUNFLOWER OIL (UNII: 3W1JG795YI)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				

Product Characteristics			
Color	yellow (Light Yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630- 0269-4	203 mL in 1 CAN; Type 0: Not a Combination Product	11/18/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	11/18/2019	

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment			
Address	ID/FEI	Business Operations	
	101946028	manufacture(13630-0269), analysis(13630-0269)	
	Address	,	

Establishment				
Name	Address	ID/FEI	Business Operations	
Prime Packaging Inc.		805987059	pack(13630-0269) , label(13630-0269)	

Revised: 2/2023 Prime Packaging Inc.