# AUSTRALIAN GOLD BOTANICAL 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.

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#### Australian Gold Botanical SPF 50 Continuous 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 or smoking. Contents under pressure. Do not puncture or incinerate. Store at temperatures below 120°F (50°C).

#### **Directions**

- shake well before use
- apply liberally 15 minutes before sun exposure and rub into skin

- hold container 4 to 6 inches from the skin to apply
- do not spray directly onto 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-sleeved shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

#### Inactive ingredients

SD Alcohol 40-B, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Glycerin, Fragrance, Water, Polyester-8, Tocopheryl Acetate, Eucalyptus Globulus (Eucalyptus) Leaf Extract, Porphyra Umbilicalis Extract, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract

#### Other information

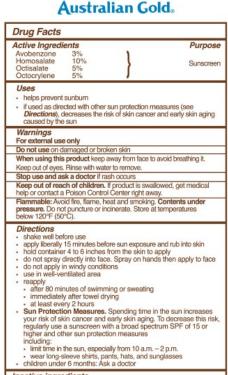
- Protect this product from excessive heat and direct sun
- May stain some fabrics or surfaces

#### Questions or comments?

Call toll free 1-855-LIV-GOLD (584-4653)

#### **Australian Gold Botanical SPF 50**

#### Australian Gold.



Inactive ingredients
SD Alcohol 40-B\*, VA/Butyl Maleate/Isobornyl Acrylate
Copolymer, Glycerin, Fragrance, Polyester-8, Tocopheryl
Acetate\*\*, Water, Eucalybus Globulus (Eucalyptus) Leaf
Extract, Porphyra Umbilicalis Extract

#### Other information

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

Questions or comments? Call toll free 1-855-LIV-GOLD (548-4653)

\*Organic \*\*Vitamin E



No Added Parabens, Dye Free, Oil Free, Sulfate Free, Petrolatum Free & No CFCs

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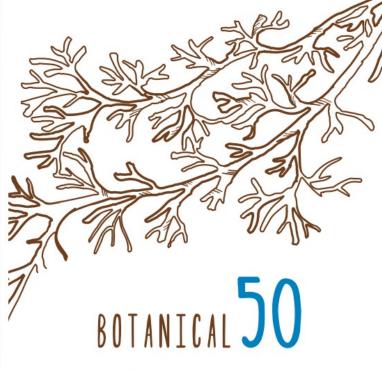








# **Australian** Gold.



**NATURAL SPRAY SUNSCREEN** POWDER DRY, BREATHABLE FEEL

WATER RESISTANT (80 MINUTES) BROAD SPECTRUM SPF 50

> 6 FL OZ (177 mL) Net Wt. 5.3 OZ (152 g)

## **AUSTRALIAN GOLD BOTANICAL SPF 50**

avobenzone, homosalate, octisalate, octocrylene spray

#### **Product Information Product Type HUMAN OTC DRUG** Item Code (Source) NDC:13630-0267 **Route of Administration TOPICAL**

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.2 g in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	84 g in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	42 g in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	42 g in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)		
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)		
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)		
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)		
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
ALCOHOL (UNII: 3K9958V90M)		
VINYL ACETATE (UNII: L9MK238N77)		
DIBUTYL MALEATE (UNII: 4X371TMK9K)		
ISOBORNYL ACRYLATE (UNII: IX0PRH184P)		

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

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
		NDC:13630- 0267-4	177 mL in 1 CAN; Type 0: Not a Combination Product	10/18/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/18/2016	

# Labeler - Prime Packaging, Inc. (805987059)

# Registrant - Prime Packaging, Inc. (805987059)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	analysis(13630-0267), manufacture(13630-0267)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0267) , pack(13630-0267)

Revised: 12/2022 Prime Packaging, Inc.