

**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.*

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**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 not store at temperatures above 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

- apply liberally 15 minutes 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**



**Australian Gold**

ULTIMATE  
HYDRATION

NON-GREASY  
ANTIOXIDANT RICH

50

CONTINUOUS SPRAY  
SUNSCREEN

WATER RESISTANT (80 MINUTES)

BROAD SPECTRUM SPF 50

Net Wt. 6 oz (170 g)

**Australian Gold**

SPF 50 Continuous Spray

- Antioxidant Rich
- Gluten Free
- Cocoa Dreams Fragrance
- Vegan
- Phthalate Free
- Quick Dry Formula

**Drug Facts**

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www.AustralianGold.com



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andvegan

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876009-001  
DOT 2 P M5655

**AUSTRALIAN GOLD SPF 50**

avobenzone, homosalate, octisalate, octocrylene spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13630-0269
<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	25.08 g in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	83.6 g in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	41.8 g in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	41.8 g in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED)</b> (UNII: T9296U138P)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	

## Product Characteristics

<b>Color</b>	yellow (Light Yellow)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item 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

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0269) , analysis(13630-0269)

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

Revised: 2/2023

Prime Packaging Inc.