

**AUSTRALIAN GOLD SPF 30- avobenzone, homosalate, octisalate, octocrylene lotion**  
**Prime Enterprises, 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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**Active ingredients**

Avobenzone 3 %

Homosalate 7.5 %

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 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.

**Directions**

- apply liberally 15 minutes before sun exposure
- 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 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**

Water, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Glycerin, Polyethylene, Phenoxyethanol, Fragrance, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Carbomer, Sodium Hydroxide, Disodium EDTA, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Hydroxypropyl Methylcellulose, Ethylhexylglycerin, Allantoin, Camellia Oleifera (Green Tea) Leaf Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Sodium Chloride

### **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)

### **PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label**



**Australian  
Gold®**

**ULTIMATE  
HYDRATION**

**NON-GREASY  
QUICK DRY  
ANTIOXIDANT RICH**

**30**

**LOTION SUNSCREEN**

**WATER RESISTANT (80 MINUTES)**

**BROAD SPECTRUM SPF 30**

**8 FL OZ (237 mL)**

# Australian Gold.

SPF 30 Lotion

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

## Drug Facts

Active Ingredients	Purpose
Avobenzone 3%	} Sunscreen
Homosalate 7.5%	
Octisalate 5%	
Octocrylene 5%	

## 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 out of eyes. Rinse with water to remove.

**Stop use and ask a doctor** if rash occurs or irritation develops and lasts.

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

## Directions

- apply liberally 15 minutes before sun exposure
- reapply:
  - after 80 minutes of swimming or sweating
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**Inactive ingredients:** Water, Aloe Barbadosensis Leaf Juice, C12-15 Alkyl Benzoate, Glycerin, Polyethylene, Phenoxyethanol, Fragrance, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Carbomer, Sodium Hydroxide, Disodium EDTA, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Hydroxypropyl Methylcellulose, Ethylhexylglycerin, Allantoin, Camellia Oleifera (Green Tea) Leaf Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Sodium Chloride

## Other information

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Distributed by Australian Gold, Indianapolis, IN 46278  
www.AustralianGold.com



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725021-002



**AUSTRALIAN GOLD SPF 30**

avobenzone, homosalate, octisalate, octocrylene lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0609
<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	30.09 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	75.23 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50.15 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50.15 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER COPOLYMER TYPE A</b> (UNII: 71DD5V995L)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CARBOMER HOMOPOLYMER TYPE C</b> (UNII: 4Q93RCW27E)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MELALEUCA ALTERNIFOLIA LEAF</b> (UNII: G43C57162K)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	

## Product Characteristics

<b>Color</b>	white	<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:58443-0609-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/23/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	11/23/2020	

**Labeler** - Prime Enterprises, Inc. (101946028)

**Registrant** - Prime Enterprises, Inc. (101946028)

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0609) , pack(58443-0609) , manufacture(58443-0609) , analysis(58443-0609)

Revised: 3/2023

Prime Enterprises, Inc.