

**AUSTRALIAN GOLD SPF 70- 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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**Australian Gold SPF 70 Plant Based Lotion Sunscreen**

***Active Ingredients***

Avobenzone 3%

Homosalate 15%

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 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, & sunglasses.
- Children under 6 months: Ask a doctor

### ***Inactive Ingredients***

Aloe Barbadensis Leaf Juice, Water, Cocos Nucifera (Coconut) Oil, Glycerin, Styrene/Acrylates Copolymer, VP/Acrylates/Lauryl Methacrylate Copolymer, Phenoxyethanol, Tapioca Starch, Acrylic Acid/VP Crosspolymer, Fragrance (Parfum), Sodium Hydroxide, Caprylyl Glycol, Polyacrylate-13, Ethylhexylglycerin, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Polyisobutene, Polymethylsilsesquioxane, Polysorbate 20

### ***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)

### ***Australian Gold Plant Based Lotion Sunscreen SPF 70***



WATER RESISTANT (80 MINUTES)  
BROAD SPECTRUM SPF 70  
6 FL OZ (177 mL)

Use the natural and effective power of plants to support healthy skin. Made with Aloe Vera and Coconut Oil, this lotion is packed with nutrients your skin will love. Broad Spectrum coverage offers protection from aging UVA rays and burning UVB rays so you can be free to celebrate life outside.



This container was made with over 50% recycled materials, which creates unique imperfections.

Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 5%	Sunscreen
<b>Uses</b>	
• helps prevent sunburn • if used as directed with other sun protection measures (see <b>Directions</b> ), decreases the risk of skin cancer and early skin aging caused by the sun	
<b>Warnings</b>	
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.	
<b>Directions</b>	
• apply liberally 15 minutes before sun exposure	
• reapply:	
• after 80 minutes of swimming or sweating	
• immediately after towel drying	
• at least every 2 hours	
• <b>Sun Protection Measures.</b> 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	
<b>Inactive Ingredients</b>	
Aloe Barbadensis Leaf Juice, Water/Aqua/Eau, Cocos Nucifera (Coconut) Oil, Glycerin, Styrene/Acrylates Copolymer, VP/Acrylates/Lauryl Methacrylate Copolymer, Phenoxyethanol, Tapioca Starch, Acrylic Acid/VP Crosspolymer, Fragrance (Parfum), Sodium Hydroxide, Caprylyl Glycol, Polyacrylate-13, Ethylhexylglycerin, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Polyisobutene, Polymethylsilsesquioxane, Polysorbate 20	
<b>Other information</b>	
• Protect this product from excessive heat and direct sun	
• May stain some fabrics or surfaces	
<b>Questions or comments?</b> Call 1-855-LIV-GOLD (548-4653)	

\* Vitamin E  
^ Hawaii compliant – no Oxybenzone or Octinoxate

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www.AustralianGold.com



## AUSTRALIAN GOLD SPF 70

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0374
<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	29.4 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	49 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	147 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCONUT OIL (UNII: Q9L0O73W7L)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYISOBUTYLENE (85000 MW) (UNII: 7X53O5S2ZY)	
STYRENE/ACRYLAMIDE COPOLYMER (500000 MW) (UNII: 5Z4DPO246A)	
STARCH, TAPIOCA (UNII: 24SC3U704I)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWW)	

## Product Characteristics

Color	white (Off-White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0374-4	177 mL in 1 TUBE; Type 0: Not a Combination Product	12/11/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/11/2020	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	pack(58443-0374) , manufacture(58443-0374) , label(58443-0374) , analysis(58443-0374)

