

**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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**Australian Gold Plant Based Lotion Sunscreen SPF 30**

**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 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**

Aloe Barbadensis Leaf Juice, Water/Aqua/Eau, Cocos Nucifera (Coconut) Oil, Glycerin, Tapioca Starch, VP/Acrylates/Lauryl Methacrylate Copolymer, Phenoxyethanol, 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 1-855-LIV-GOLD (548-4653)

### **Australian Gold Plant Based Lotion Sunscreen SPF 30**



**Australian Gold**

PLANT-BASED

**30**

LOTION SUNSCREEN

*aloe & coconut*

WATER RESISTANT (80 MINUTES)  
BROAD SPECTRUM SPF 30

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 7.5%, Octisalate 5%, Octocrylene 5%	Sunscreen
<b>Uses</b>	
• helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i> ), 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.	
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• after 80 minutes of swimming or sweating	
• immediately after towel drying	
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• 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, Tapioca Starch, VP/Acrylates/Lauryl Methacrylate Copolymer, Phenoxyethanol, 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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Distributed by Australian Gold, Indianapolis, IN 46278  
www.AustralianGold.com



## AUSTRALIAN GOLD SPF 30

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0375
<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	29.67 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	74.18 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	49.45 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.45 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
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<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)
<b>FRAGRANCE LAVENDER &amp; CHIA F-153480</b> (UNII: SXS9CO2TZK)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>STARCH, TAPIOCA</b> (UNII: 24SC3U704I)
<b>POLYISOBUTYLENE (85000 MW)</b> (UNII: 7X53O5S2ZY)
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>TETRASODIUM GLUTAMATE DIACETATE</b> (UNII: 5EHL50I4MY)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>POLYACRYLAMIDE (1500 MW)</b> (UNII: 5D6TC4BRWW)

### Product Characteristics

<b>Color</b>	white (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:58443-0375-4	177 mL in 1 TUBE; Type 0: Not a Combination Product	12/10/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/10/2020	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(58443-0375) , label(58443-0375) , analysis(58443-0375) , pack(58443-0375)