

**AUSTRALIAN GOLD BROAD SPECTRUM SPF 30- avobenzene, 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 Broad Spectrum SPF 50**

**Active ingredients**

Avobenzene 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 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, Cocos Nucifera (Coconut) Oil, Glycerin, Tapioca Starch, VP/Acrylates/Lauryl Methacrylate Copolymer, Phenoxyethanol, Acrylic Acid/VP Crosspolymer, Fragrance, 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)

## PRINCIPAL DISPLAY PANEL



**Australian Gold®**

PLANT BASED

50

LOTION SUNSCREEN

aloe & coconut

WATER RESISTANT (80 MINUTES)  
BROAD SPECTRUM SPF 50

1 FL OZ (30 mL)

HYPO-ALLERGENIC

DERMATOLOGIST TESTED

VEGAN

NO ADDED PARABENS

GLUTEN FREE

SULFATE FREE

REEF FRIENDLY

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

Drug Facts	Purpose
<b>Active Ingredients</b> Avobenzone 3%, Homosalate 10%, 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> <i>For external use only</i> 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, 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 BROAD SPECTRUM SPF 30

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0505
<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	28.86 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	96.2 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.1 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	48.1 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>N-VINYLPYRROLIDINONE</b> (UNII: 76H9G81541)	
<b>STARCH, TAPIOCA</b> (UNII: 24SC3U704I)	
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	
<b>POLYISOBUTYLENE (1000 MW)</b> (UNII: 5XB3A63Y52)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>POLYACRYLAMIDE (1300000 MW)</b> (UNII: SC5Y4X78TG)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>TETRASODIUM GLUTAMATE DIACETATE</b> (UNII: 5EHL50I4MY)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>LAURYL METHACRYLATE</b> (UNII: B6L83074BZ)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	

### Product Characteristics

<b>Color</b>	white (Off 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:58443-0505-3	29 mL in 1 TUBE; Type 0: Not a Combination Product	06/08/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/08/2021	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0505) , pack(58443-0505) , manufacture(58443-0505) , analysis(58443-0505)

Revised: 1/2022

Prime Enterprises, Inc.