

**AUSTRALIAN GOLD BROAD SPECTRUM SPF 50- 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.*

-----  
**Australian Gold Broad Spectrum SPF 50 Sunscreen Lotion**

**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 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**

Water, Aloe Barbadensis Leaf Juice, Glycerin, Polyethylene, Phenoxyethanol, Fragrance, Polysorbate 20, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, 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)

**Australian Gold Broad Spectrum SPF 50 Sunscreen Lotion - 237 mL**

## Australian Gold.

SPF 50 Lotion

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

### Drug Facts

Active Ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 10%	
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

**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:** Water, Aloe Barbadensis Leaf Juice, Glycerin, Polyethylene, Phenoxyethanol, Fragrance, Polysorbate 20, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, 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)



ULTIMATE  
HYDRATION

NON-GREASY  
CRUELTY FREE  
OXYBENZONE FREE

50

LOTION SUNSCREEN

WATER RESISTANT (80 MINUTES)

BROAD SPECTRUM SPF 50

8 FL OZ (237 mL)

©2022 Australian Gold, Country of Origin USA  
Distributed by Australian Gold, Indianapolis, IN 46278  
www.AustralianGold.com



A70917  
725640-001



## AUSTRALIAN GOLD BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0605
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.55 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	98.5 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.25 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	49.25 mg in 1 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>CARBOMER INTERPOLYMER TYPE A (55000 CPS)</b> (UNII: 59TL3WG5CO)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>CAMELLIA OLEIFERA LEAF</b> (UNII: 5077ELOC60)	
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<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	Marketing End
---	-----------	---------------------	-----------------	---------------

#	Item Code	Package Description	Date	Date
1	NDC:58443-0605-4	237 mL in 1 TUBE; Type 0: Not a Combination Product	12/19/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/19/2020	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0605) , pack(58443-0605) , manufacture(58443-0605) , analysis(58443-0605)

Revised: 1/2023

Prime Enterprises, Inc.