

**AUSTRALIAN GOLD 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 Ultimate Hydration Lotion Sunscreen SPF 30**

**Active Ingredients**

Avobenzene 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 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, 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, Hydroxypropyl Methylcellulose, Olea Europaea (Olive) Fruit Oil, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Ethylhexylglycerin, Allantoin, Aloe Barbadensis Leaf Juice, Camellia Oleifera (Green Tea) Leaf Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract

## **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 Ultimate Hydration Lotion Sunscreen SPF 30***

**NEW!**



**Australian Gold**

**ULTIMATE HYDRATION**

**30**

**LOTION SUNSCREEN**

**NON-GREASY  
CRUELTY FREE  
OXYBENZONE FREE**


**WATER RESISTANT (80 MINUTES)**

**BROAD SPECTRUM SPF 30**

3.4 FL OZ (100 mL)

Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
Avobenzone 3%	} Sunscreen
Homosalate 7.5%	
Octisalate 5%	
Octocrylene 5%	
<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> Water/Aqua/Eau, C12-15 Alkyl Benzoate, Glycerin, Polyethylene, Phenoxethanol, Fragrance (Parfum), Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Carbomer, Sodium Hydroxide, Disodium EDTA, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Olea Europaea (Olive) Fruit Oil, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Ethylhexylglycerin, Allantoin, Aloe Barbadosis Leaf Juice, Camellia Oleifera (Green Tea) Leaf Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract	
<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 toll free 1-855-LIV-GOLD (548-4653)	

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www.AustralianGold.com



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## AUSTRALIAN GOLD SPF 30

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0382
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	51.45 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.87 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	77.175 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	51.45 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>KAKADU PLUM</b> (UNII: 0ZQ1D2FDLI)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>ALLANTOIN</b> (UNII: 344S277G0Z)	
<b>CAMELLIA OLEIFERA LEAF</b> (UNII: 5077EL0C60)	

## 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:58443-0382-3	100 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	part352	11/23/2020	

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

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

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(58443-0382) , label(58443-0382) , analysis(58443-0382) , pack(58443-0382)

Revised: 1/2021

Prime Enterprises, Inc.