

**AUSTRALIAN GOLD SPF 15 SUNSCREEN- avobenzone, octisalate, octocrylene spray**  
**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 15 Spray Gel Sunscreen**

***Active Ingredients***

Avobenzone 2%

Octisalate 5%

Octocrylene 2%

***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 away from face to avoid breathing it. 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***

- shake well before use • apply liberally 15 minutes before sun exposure and rub into skin • hold container 4 to 6 inches from the skin to apply • do not spray directly into face. Spray on hands then apply to face • 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/Aqua/Eau, Aloe Barbadensis Leaf Juice, Glycerin, Butylphthalimide, Phenoxyethanol, Isopropylphthalimide, Fragrance (Parfum), Acrylates/C12-22 Alkyl Methacrylate Copolymer, Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Trimethylsiloxysilicate, Disodium EDTA, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Tocopheryl Acetate, Hydroxypropyl Methylcellulose, Ethylhexylglycerin, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, 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 GLD ULTIMATE HYDRATION 15 SPRAY GEL SUNSCREEN**



**Australian  
Gold.**

**ULTIMATE  
HYDRATION**

**NON-GREASY  
ANTIOXIDANT RICH  
QUICK DRY FORMULA**

**15**

**SPRAY GEL SUNSCREEN**

**WATER RESISTANT (80 MINUTES)**

**BROAD SPECTRUM SPF 15**

**8 FL OZ (237 mL)**

# Australian Gold.

SPF 15 Spray Gel

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

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
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Octocrylene 2%	
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<b>Warnings</b>	
• <b>For external use only</b> • <b>Do not use</b> on damaged or broken skin • <b>When using this product</b> keep away from face to avoid breathing it. Keep out of eyes. Rinse with water to remove. • <b>Stop use and ask a doctor</b> if rash occurs • <b>Keep out of reach of children</b> . If product is swallowed, get medical help or contact a Poison Control Center right away.	
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<b>Inactive Ingredients:</b> Water, Aloe Barbadensis Leaf Juice, Glycerin, Butylphthalimide, Phenoxyethanol, Isopropylphthalimide, Fragrance, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Trimethylsiloxysilicate, Disodium EDTA, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Tocopheryl Acetate, Hydroxypropyl Methylcellulose, Ethylhexylglycerin, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Sodium Chloride	
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<b>Questions or comments?</b>	
Call toll free 1-855-LIV-GOLD (548-4653)	

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[www.AustralianGold.com](http://www.AustralianGold.com)



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725012-001



## AUSTRALIAN GOLD SPF 15 SUNSCREEN

avobenzone, octisalate, octocrylene spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0613
<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	19.4 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	19.4 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>N-BUTYLPHTHALIMIDE</b> (UNII: 5TH1DKT35E)	
<b>ISOPROPYLPHTHALIMIDE</b> (UNII: 1J1MM83329)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>TRIMETHYLSILOXYSILICATE (M/Q 1.0-1.2)</b> (UNII: 78GX033D7I)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<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 Date	Marketing End Date
1	NDC:58443-0613-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/11/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/11/2019	

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

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

## Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0613) , manufacture(58443-0613) , label(58443-0613) , analysis(58443-0613)

Revised: 3/2023

Prime Enterprises Inc.