

**AUSTRALIAN GOLD SPF 15- 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 Instant Bronzer Spray Gel Sunscreen SPF 15**

**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, Aloe Barbadensis leaf Juice, Glycerin, Butylphthalimide, Caramel, Phenoxyethanol, Isopropylphthalimide, Fragrance, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, polysorbate 20, Trimethylsiloxysilicate, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Hydroxypropyl Methylcellulose, Ethylhexylglycerin, Sodium Hydroxide, propylene Glycol, 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 Gold Instant Bronzer Spray Gel Sunscreen SPF15**



**Australian  
Gold®**

**INSTANT  
BRONZER**

**NON-GREASY  
CRUELTY FREE  
OXYBENZONE FREE**

**15**

**SPRAY GEL SUNSCREEN**

**WATER RESISTANT (80 MINUTES)**

**BROAD SPECTRUM SPF 15**

**3.4 FL OZ (100mL)**

### Drug Facts

Active Ingredients	Purpose
Avobenzone 2%	Sunscreen
Octisalate 5%	
Octocrylene 2%	

### Uses

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### Warnings

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### 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

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Distributed by Australian Gold, Indianapolis, IN 46278  
[www.AustralianGold.com](http://www.AustralianGold.com)



A70406  
725019-001



avobenzone, octisalate, octocrylene spray

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0588
<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	19.4 g in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.5 g in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	19.4 g in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ISOPROPYLPHthalIMIDE</b> (UNII: 1J1MM83329)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>TETRASODIUM GLUTAMATE DIACETATE</b> (UNII: 5EHL50I4MY)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>N-BUTYLPHthalIMIDE</b> (UNII: 5TH1DKT35E)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0)</b> (UNII: 25LXE464L2)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>CARAMEL</b> (UNII: T9D99G2B1R)	
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	

## Product Characteristics

<b>Color</b>	brown (Caramel)	<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:58443-0588-3	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	01/22/2021	

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	01/22/2021	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(58443-0588) , label(58443-0588) , analysis(58443-0588) , pack(58443-0588)

Revised: 11/2022

Prime Enterprises, Inc.