

**AUSTALIAN GOLD BROAD SPECTRUM SPF 30 SUNSCREEN- octisalate, avobenzone, octocrylene, homosalate 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 Broad Spectrum SPF 30 Sun Screen**

**INACTIVE INGREDIENTS**

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Caramel, Dimethicone, Ethylhexylglycerin, Fragrance, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Olea Europaea (Olive) Fruit Oil, Phenoxyethanol, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Tetrasodium Glutamate Diacetate, Tocopheryl Acetate, Trimethylsiloxysilicate, Water

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

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.

**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.

**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

**Active Ingredients**

Avobenzone 3.0%

Octocrylene 5.0%

Octisalate 5.0%

Homosalate 7.5%

***Directions***

- 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 on to 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 value of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10am-2pm
  - wear long sleeve shirts, pants, hats, and sunglasses
  - children under 6 months: Ask a doctor

***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 Broad Spectrum SPF 30**



## AUSTALIAN GOLD BROAD SPECTRUM SPF 30 SUNSCREEN

octisalate, avobenzene, octocrylene, homosalate spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0312
<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	48.5 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.1 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.5 mg in 1 mL

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	72.75 mg in 1 mL
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### Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
GLYCERIN (UNII: PDC6A3C0OX)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARAMEL (UNII: T9D99G2B1R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW) (UNII: JZ1374NL9E)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
TEA TREE OIL (UNII: VIF565UC2G)	

### Product Characteristics

Color	brown (Caramel)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0312-4	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/30/2019	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/30/2019	

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

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		10 1946 028	pack(58443-0312) , manufacture(58443-0312) , label(58443-0312) , analysis(58443-0312)

Revised: 5/2020

Prime Enterprises Inc.