

**AUSTRALIAN GOLD INSTANT BRONZER BROAD SPECTRUM SPF 4 SUNSCREEN-  
avobenzone, 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 Broad Spectrum SPF 4 Sunscreen**

**INACTIVE INGREDIENTS**

Water, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Glycerin, Butylphthalimide, Caramel, Phenoxyethanol, Fragrance, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Isopropylphthalimide, Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Trimethoxysiloxysilicate, 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

**Warnings**

**Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

**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.

**Purpose**

Sunscreen

**Uses**

- helps prevent sunburn

**Active Ingredients**

Avobenzone 1%

Octocrylene 1%

**Directions**

- shake well before use
- apply liberally 15 minutes before sun exposure and rub into skin
- hold container 4 to 6 inches from 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
- 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 SPF 4 BROAD SPECTRUM Sunscreen**

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**INSTANT  
BRONZER**

**NON-GREASY  
QUICK DRY  
ANTIOXIDANT RICH**

**4**

**SPRAY GEL SUNSCREEN**

**WATER RESISTANT (80 MINUTES)**

**BROAD SPECTRUM SPF 4**

**8 FL OZ (237 mL)**

# Australian Gold®

## SPF 4 Spray Gel with Bronzer

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

### Drug Facts

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www.AustralianGold.com



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## AUSTRALIAN GOLD INSTANT BRONZER BROAD SPECTRUM SPF 4 SUNSCREEN

avobenzone, octocrylene spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0633
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	10 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	10 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>SUNFLOWER SEED</b> (UNII: R9N3379M4Z)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>TETRASODIUM GLUTAMATE DIACETATE</b> (UNII: 5EHL50I4MY)	
<b>TEA TREE OIL</b> (UNII: VIF565UC2G)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	

<b>CARBOMER INTERPOLYMER TYPE A (55000 CPS)</b> (UNII: 59TL3WG5CO)
<b>CARAMEL</b> (UNII: T9D99G2B1R)
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>N-BUTYLPHthalimide</b> (UNII: 5TH1DKT35E)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>ISOPROPYLPHthalimide</b> (UNII: 1J1MM83329)
<b>TRIMETHYLSILOXYSILICATE (M/Q 1.0-1.2)</b> (UNII: 78GX033D7I)
<b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L)

### 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:58443-0633-4	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/04/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	08/04/2023	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0633) , manufacture(58443-0633) , label(58443-0633) , analysis(58443-0633)