

AUSTRALIAN GOLD INSTANT BRONZER 30 SUNSCREEN- avobenzone, 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.

Australian Gold Instant Bronzer 30 Lotion Sunscreen

Active Ingredients

Avobenzone 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 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

- 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 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, & sunglasses
- Children under 6 months: Ask a doctor

Inactive Ingredients

Water, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Glycerin, Caramel, Polyethylene, Phenoxyethanol, Fragrance, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Carbomer, Polysorbate 20, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Hydroxypropyl Methylcellulose, Ethylhexylglycerin, Allantoin, Camellia Oleifera (Green Tea) Leaf Extract, 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 30 Lotion Sunscreen



**Australian
Gold®**

**INSTANT
BRONZER**

NON-GREASY
CRUELTY FREE
OXYBENZONE FREE

30

LOTION SUNSCREEN

WATER RESISTANT (80 MINUTES)

BROAD SPECTRUM SPF 30

8 FL OZ (237 mL)

Australian Gold.

SPF 30 Lotion with Bronzer

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

Drug Facts

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Distributed by Australian Gold, Indianapolis, IN 46276

www.AustralianGold.com



AZ0902
75625-001



AUSTRALIAN GOLD INSTANT BRONZER 30 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0604
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.19 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.65 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	48.65 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	72.98 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
ALLANTOIN (UNII: 344S277G0Z)	
TEA TREE OIL (UNII: VIF565UC2G)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAMELLIA OLEIFERA LEAF (UNII: 5077ELOC60)	
CARAMEL (UNII: T9D99G2B1R)	
CARBOMER 980 (UNII: 4Q93RCW27E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
WATER (UNII: 059QF0KO0R)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCOA BUTTER (UNII: 512OYT1CRR)	

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:58443-0604-4	237 mL in 1 TUBE; Type 0: Not a Combination Product	10/17/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/17/2019	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0604) , manufacture(58443-0604) , label(58443-0604) , analysis(58443-0604)

Revised: 1/2023

Prime Enterprises Inc.