

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-sleeved shirts, pants, hats, & sunglasses.
 - Children under 6 months: Ask a doctor

Inactive Ingredients

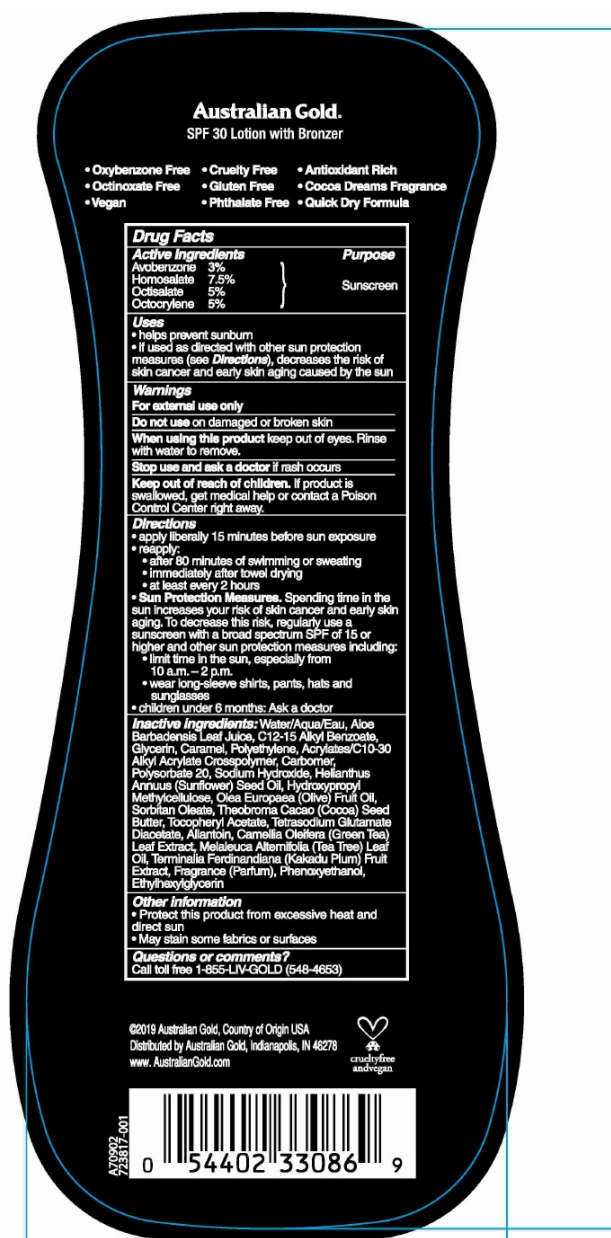
Other information

- 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 30 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0270
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	51.05 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.63 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	51.05 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	76.575 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TEA TREE OIL (UNII: VIF565UC2G)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CARAMEL (UNII: T9D99G2B1R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
CARBOMER 980 (UNII: 4Q93RCW27E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
WATER (UNII: 059QF0KO0R)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
COCOA BUTTER (UNII: 512OYT1CRR)	
ALLANTOIN (UNII: 344S277G0Z)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

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:58443-0270-4	237 mL in 1 TUBE; Type 0: Not a Combination Product	10/31/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/31/2019	

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

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0270) , manufacture(58443-0270) , label(58443-0270) , analysis(58443-0270)

Revised: 1/2021

Prime Enterprises Inc.