

AUSTRALIAN GOLD INSTANT BRONZER 15 SUNSCREEN- avobenzone, 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 15 Lotion Sunscreen

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 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

Water/Aqua/Eau, Aloe Barbadensis Leaf Juice, Glycerin, Butylphthalimide, Caramel, Polyethylene, Isopropylphthalimide, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Sodium Hydroxide, Carbomer, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Olea Europaea (Olive) Fruit Oil, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Allantoin, Camellia Oleifera (Green Tea) Leaf Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Fragrance(Parfum), Phenoxyethanol, Ethylhexylglycerin

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 15 Lotion Sunscreen

NEW!



Australian Gold®

INSTANT BRONZER

NON-GREASY
CRUELTY FREE
OXYBENZONE FREE

15

LOTION SUNSCREEN

WATER RESISTANT (80 MINUTES)

BROAD SPECTRUM SPF 15

8 FL OZ (237 mL)

Australian Gold.
SPF 15 Lotion with Bronzer

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

Drug Facts

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Octocrylene 2%	

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www.AustralianGold.com



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723815-001



AUSTRALIAN GOLD INSTANT BRONZER 15 SUNSCREEN

avobenzone, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0280
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20.36 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	50.9 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	20.36 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
N-BUTYLPHthalimide (UNII: 5TH1DKT35E)	
ISOPROPYLPHthalimide (UNII: 1J1MM83329)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
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)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
CARAMEL (UNII: T9D99G2B1R)	
CARBOMER 980 (UNII: 4Q93RCW27E)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
WATER (UNII: 059QF0K00R)	
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:58443-0280-4	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	
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Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0280) , manufacture(58443-0280) , label(58443-0280) , analysis(58443-0280)

Revised: 1/2021

Prime Enterprises Inc.