

AUSTRALIAN GOLD BROAD SPECTRUM SPF 15- avobenzone, octisalate, octocrylene, and oxybenzone 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.

Active ingredients

Avobenzone 2 %, Octisalate 5 %, Octocrylene 1.85 %, and Oxybenzone 0.5 %

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

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Caramel, Carbomer, Coffea Arabica (Kona Coffee) Seed Extract, Disodium EDTA, Fragrance (Parfum),

Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Methylisothiazolinone, Olea Europaea (Olive) Fruit Oil, Phenoxyethanol, Polyethylene, Polysilicone-15, Polysorbate 20, Propylene Glycol, Sorbitan Oleate, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Triethanolamine, Water (Aqua)

Other information

- protect this product from excessive heat and direct sun

Questions or Comments?

Call toll free 1-855-LIV-GOLD (548-4653)

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label

Australian Gold[®]

SPF 15 LOTION WITH KONA COFFEE INFUSED BRONZERS

Enjoy an immediate sun-kissed glow and important sunscreen protection while native Australian extracts hydrate and soften skin.

Drug Facts

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Australian Gold LLC, Indianapolis, IN 46278
www.australiangold.com

A70663-002



WITH KONA COFFEE
INFUSED BRONZERS



#1 Fragrance



with instant
BRONZER

BROAD SPECTRUM SPF 15

WATER RESISTANT (80 MINUTES)

Australian Gold[®]

237 mL / 8 Fl. Oz

WITH KONA COFFEE
INFUSED BRONZERS
EXOTIC BLEND
#1 Fragrance

15

Lotion

Sunscreen

with instant

BRONZER

BROAD SPECTRUM SPF 15

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Australian

Gold®

237 mL / 8 FL. Oz

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0038
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	19.6 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	49 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	18.13 in 1 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	4.9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
N-BUTYLPHthalimide (UNII: 5TH1DKT35E)	
ISOPROPYLPHthalimide (UNII: 1J1MM83329)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARAMEL (UNII: T9D99G2B1R)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TEA TREE OIL (UNII: VIF565UC2G)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
COCOA BUTTER (UNII: 512OYT1CRR)	
OLIVE OIL (UNII: 6UYK2W1W1E)	

OLETH-10 (UNII: JD797EF70J)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TROLAMINE (UNII: 9O3K93S3TK)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
POLYSILICONE-15 (UNII: F8DRP5BB29)
WATER (UNII: 059QF0K00R)
GLYCERIN (UNII: PDC6A3C0OX)
ARABICA COFFEE BEAN (UNII: 3SW678MX72)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
KAKADU PLUM (UNII: 0ZQ1D2FDLI)

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0038-4	237 mL in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product	10/22/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	10/22/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0038) , pack(58443-0038) , manufacture(58443-0038) , analysis(58443-0038)