

AUSTRALIAN GOLD BROAD SPECTRUM SPF 8- avobenzone, 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 0.5 %, Octocrylene 2 %, and Oxybenzone 1.5 %

Purpose

Sunscreen

Uses

- helps prevent sunburn

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 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
- Children under 6 months: Ask a doctor

Inactive Ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, BHT (Butylated Hydroxytoluene), Butylphthalimide, Cetyl Alcohol, Disodium EDTA, Fragrance (Parfum), Glycyrrhiza Glabra (Licorice) Root Extract, Isopropylphthalimide, Methylisothiazolinone, Methylparaben, Phenyl Trimethicone, Polyethylene, Polysilicone-15, Potassium Cetyl Phosphate, Potassium Hydroxide, Propylene Glycol, Propylparaben, Silica, Stearyl Alcohol, Styrene/Acrylates Copolymer, 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 - 177 mL Tube Label



EXOTIC BLEND®

#1 Fragrance

Sheer Coverage

8

Lotion
Sunscreen

InvisiDry™ Technology
Clean and Hydrating

BROAD SPECTRUM SPF 8

WATER RESISTANT
(80 MINUTES)

**Australian
Gold**®

177 mL / 6 Fl. Oz

**Australian
Gold**®

Drug Facts

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Octocrylene 2%	
Oxybenzone 1.5%	

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8

Lotion Sunscreen

InvisiDry Technology

Clean and Hydrating

Broad Spectrum SPF 8

WATER RESISTANT

(80 MINUTES)

Australian

Gold

177 mL / 6 Fl. Oz

AUSTRALIAN GOLD BROAD SPECTRUM SPF 8

avobenzone, octocrylene, and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0029
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	4.9 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	19.4 mg in 1 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	14.6 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
3-BUTYLPHthalide (UNII: 822Q956KGM)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLPARABEN (UNII: A218C7HI9T)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSILICONE-15 (UNII: F8DRP5BB29)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	

GLYCYRRHIZA GLABRA LEAF (UNII: GH32M797Y9)

PROPYLPARABEN (UNII: Z8IX2SC1OH)

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

STEARYL ALCOHOL (UNII: 2KR89I4HIY)

STYRENE (UNII: 44LJ2U959V)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0029-4	177 mL in 1 TUBE; Type 0: Not a Combination Product	11/18/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/18/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0029) , pack(58443-0029) , manufacture(58443-0029) , analysis(58443-0029)

Revised: 1/2020

Prime Enterprises, Inc.