

**AUSTRALIAN GOLD BROAD SPECTRUM SPF 30 SHEER SUNSCREEN- avobenzone, homosalate, 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.

Australian Gold Broad Spectrum SPF 30 Sheer Sunscreen

Active Ingredients

Avobenzone 3%

Homosalate 7.5%

Octisalate 5%

Octocrylene 2.75%

Oxybenzone 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

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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Butylphthalimide, Camellia Sinensis (Green Tea) Leaf

Extract, Cetyl Alcohol, Disodium EDTA, Fragrance (Parfum), Glycerin, Glycyrrhiza Glabra (Licorice) Root Extract, Isopropylphthalimide, Methylisothiazolinone, Phenoxyethanol, Phenyl Trimethicone, Polyethylene, Polysilicone-15, Potassium Cetyl Phosphate, Potassium Hydroxide, Propylene Glycol, Silica, Stearyl Alcohol, Styrene/Acrylates Copolymer, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Tocopheryl Acetate, 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)

Australian Gold Broad Spectrum SPF 30 Sheer Sunscreen

Australian Gold

Drug Facts

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Inactive ingredients Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Crosspolymer, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Butylphthalimide, Camellia Sinensis (Green Tea) Leaf Extract, Cetyl Alcohol, Disodium EDTA, Fragrance (Parfum), Glycerin, Glycyrrhiza Glabra (Licorice) Root Extract, Isopropylphthalimide, Methylisothiazolinone, Phenoxyethanol, Phenyl Trimethicone, Polyethylene, Polysilicone-15, Potassium Cetyl Phosphate, Potassium Hydroxide, Propylene Glycol, Silica, Stearyl Alcohol, Styrene/Acrylates Copolymer, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Tocopheryl Acetate, Water (Aqua)

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AUSTRALIAN GOLD BROAD SPECTRUM SPF 30 SHEER SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	20.4 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.6 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	76.5 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	51 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	28.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
STYRENE/ACRYLAMIDE COPOLYMER (MW 500000) (UNII: 5Z4DPO246A)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSILICONE-15 (UNII: F8DRP5BB29)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
LICORICE (UNII: 61ZBX54883)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0203-4	177 mL in 1 TUBE; Type 0: Not a Combination Product	03/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part352	03/01/2014	
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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(58443-0203) , manufacture(58443-0203) , label(58443-0203) , analysis(58443-0203)

Revised: 1/2020

Prime Enterprises Inc.