

AUSTRALIAN GOLD BROAD SPECTRUM SPF 4 SUNSCREEN- 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.

Australian Gold Broad Spectrum SPF 4 Sunscreen

Active Ingredients

Avobenzone 1%

Octocrylene 0.85%

Oxybenzone 0.5%

Purpose

Sunscreen

Uses

- helps prevent sunburn

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

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, 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)

Australian Gold Broad Spectrum SPF 4 Sunscreen



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AUSTRALIAN GOLD BROAD SPECTRUM SPF 4 SUNSCREEN

avobenzone, octocrylene, and oxybenzone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0220
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	9.74 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	8.28 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	4.87 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TEA TREE OIL (UNII: VIF565UC2G)	
COCOA BUTTER (UNII: 512OYT1CRR)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALLANTOIN (UNII: 344S277G0Z)	
WATER (UNII: 059QF0K00R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
N-BUTYLPHthalimide (UNII: 5TH1DKT35E)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYSILICONE-15 (UNII: F8DRP5BB29)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
ISOPROPYLPHthalimide (UNII: 1J1MM83329)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0220-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/11/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/07/2015	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0220) , manufacture(58443-0220) , label(58443-0220) , analysis(58443-0220)

Revised: 1/2020

Prime Enterprises Inc.