

AUSTRALIAN GOLD BOTANICAL MINERAL SUNSCREEN BROAD SPECTRUM SPF 30- titanium dioxide, zinc oxide 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 Botanical Mineral Sunscreen Broad Spectrum SPF 30

Active Ingredients

Titanium Dioxide 3%

Zinc Oxide 3%

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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Alumina, Butyrospermum Parkii (Shea) Butter, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclopentasiloxane, Dimethicone Crosspolymer, Disodium EDTA, Distearidimonium Hectorite, Eucalyptus Globulus Leaf Extract, Fragrance, Glycerin, Hexyl Laurate, Panthenol, PEG-10 Dimethicone, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Porphyra Umbilicalis Extract, Silica, Squalane, Stearic Acid, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Tocopheryl Acetate, Water

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 Botanical Mineral Sunscreen Broad Spectrum SPF 30



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*Vitamin E

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AUSTRALIAN GOLD BOTANICAL MINERAL SUNSCREEN BROAD SPECTRUM SPF 30

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0572
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	31.5 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	31.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
SQUALANE (UNII: GW89575KF9)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
SHEA BUTTER (UNII: K49155WL9Y)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLV6E6)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
PANTHENOL (UNII: WW9CM0067Z)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	

Product Characteristics

Color	white (White to Off White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0572-3	29 mL in 1 TUBE; Type 0: Not a Combination Product	12/09/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/09/2017	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0572) , manufacture(58443-0572) , label(58443-0572) , analysis(58443-0572)

Revised: 9/2022

Prime Enterprises Inc.