

AUSTRALIAN GOLD BOTANICALS SUNSCREEN 70 MINERALS- 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 Sunscreen 70 Mineral Lotion

Active Ingredients

Titanium Dioxide 4.4%

Zinc Oxide 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 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

Alumina, Butyrospermum Parkii (Shea) Butter, C13-15 Alkane, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclopentasiloxane, Dimethicone Crosspolymer, Disodium EDTA, Disterdimonium Hectorite, Eucalyptus Globulus (Eucalyptus) Leaf Extract, Fragrance (Parfum), Glycerin, Hexyl Laurate, Isododecane, Isohexadecane, Panthenol, PEG-10 Dimethicone, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Porphyra Umbilicalis Extract, Silica, Squalane, Stearic Acid, Tocopheryl Acetate, Water/Aqua/Eau

Other information

- Protect this product from excessive heat and direct sun
- May stain some fabrics or surfaces

Questions or comments?

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

Botanical Sunscreen 70 Broad Spectrum SPF 70 Mineral Lotion

Australian Gold.

Australian Gold.



BOTANICAL 70

100% MINERAL SUNSCREEN
HYPOALLERGENIC • ANTIOXIDANT RICH
LONG LASTING PROTECTION
WATER RESISTANT (80 MINUTES)
BROAD SPECTRUM SPF 70

5 FL OZ (147 mL)

Drug Facts	
Active Ingredients	Purpose
Titanium Dioxide 4.4% Zinc Oxide 5%	Sunscreen
Uses	
<ul style="list-style-type: none"> 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	
<ul style="list-style-type: none"> apply liberally 15 minutes before sun exposure reapply <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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	
Water, Cyclopentasiloxane, Isohexadecane, Isododecane, Glycerin, Cetyl PEG/PPG-10/1 Dimethicone, Disterdimonium Hectorite, C13-15 Alkane, PEG-10 Dimethicone, Polymethylsilsesquioxane, Silica, Hexyl Laurate, Polyglyceryl-4 Isostearate, Dimethicone Crosspolymer, Stearic Acid, Fragrance, Alumina, Phenoxyethanol, Caprylyl Glycol, Butyrospermum Parkii (Shea) Butter, Panthenol, Squalane, Tocopheryl Acetate*, Disodium EDTA, Eucalyptus Globulus (Eucalyptus) Leaf Extract, Porphyra Umbilicalis Extract	
Other information	
<ul style="list-style-type: none"> Protect this product from excessive heat and direct sun May stain some fabrics or surfaces 	
Questions or comments?	
Call toll free 1-855-LIV-GOLD (548-4653)	

*Vitamin E



No Added Parabens, Alcohol Free, Dye Free, Oil Free, PABA Free, Sulfate Free, Petrolatum Free & BPA Free

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www.AustralianGold.com



AUSTRALIAN GOLD BOTANICALS SUNSCREEN 70 MINERALS

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0624
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	43.82 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	49.8 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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ALUMINUM OXIDE (UNII: LMI26O6933)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)
C13-15 ALKANE (UNII: 114P5I43UJ)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
ISOHEXADECANE (UNII: 918X1OUF1E)
ISODODECANE (UNII: A8289P68Y2)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
WATER (UNII: 059QF0KO0R)
SHEA BUTTER (UNII: K49155WL9Y)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
PANTHENOL (UNII: WW9CM0O67Z)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
SQUALANE (UNII: GW89575KF9)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
STEARIC ACID (UNII: 4ELV7Z65AP)
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLV6E6)
EDETATE DISODIUM (UNII: 7FLD91C86K)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
GLYCERIN (UNII: PDC6A3C0OX)
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0624-4	147 mL in 1 TUBE; Type 0: Not a Combination Product	07/17/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	07/17/2023	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0624) , manufacture(58443-0624) , label(58443-0624) , analysis(58443-0624)

Revised: 7/2023

Prime Enterprises Inc.