

AUSTALIAN GOLD BROAD SPECTRUM SPF 50 SUNSCREEN- 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 Broad Spectrum SPF 50

INACTIVE INGREDIENTS

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

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. Keep away from face to avoid breathing it.

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.

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.

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

Active Ingredients

Titanium Oxide 4%

Zinc Oxide 4%

Directions

- apply liberally 15 minutes before sun exposure and rub into skin
- 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 a broad spectrum SPF value of 15 or higher and other sun protection measures including:
- limit time in the sun, especially from 10am-2pm
- wear long sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Other Information

Protect this product from excessive heat and direct sun

Questions or Comments?

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

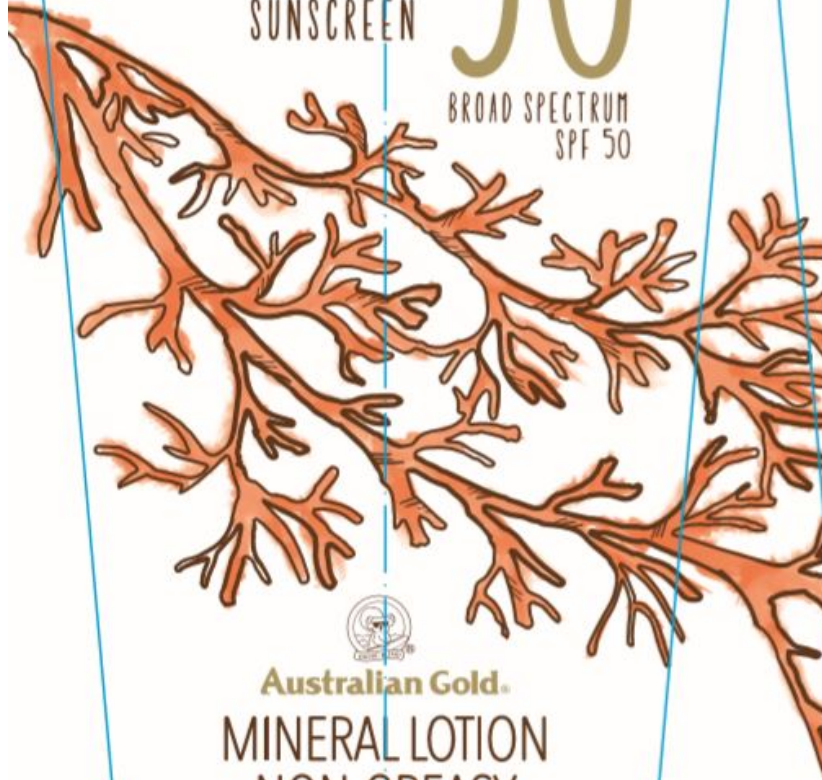
Australian Gold Botanical Sunscreen Broad Spectrum SPF 50

Australian Gold.

**BOTANICAL
SUNSCREEN**

50

**BROAD SPECTRUM
SPF 50**



Australian Gold.

MINERAL LOTION

NON-GREASY

ANTIOXIDANT RICH

UVA / UVB PROTECTION

Water Resistant [80 Minutes]

5 FL OZ (147 mL)

Drug Facts

Active Ingredients	Purpose
Titanium Dioxide 4% Zinc Oxide 4%	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 a 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, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclopentasiloxane, Dimethicone Crosspolymer, Disodium EDTA, Distearidimonium Hectorite, Eucalyptus Globulus Leaf Extract, Fragrance, Glycerin, Hexyl Laurate, Parthenol, PEG-10 Dimethicone, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Porphyra Umbilicalis (Red Algae) Extract, Silica, Squalane, Stearic Acid, 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)

*Vitamin E



Also Non-Nano, SLS (Sulfate) Free, Petrolatum Free, Alcohol Free, Dye Free, Oil Free & BPA Free

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www.AustralianGold.com



AUSTALIAN GOLD BROAD SPECTRUM SPF 50 SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0319
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	42.8 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	42.8 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PANTHENOL (UNII: WV9CM0067Z)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
ALUMINUM OXIDE (UNII: LM26O6933)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SQUALANE (UNII: GW89575KF9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYMETHYLSILSESQUIOXANE (4.5 MICRONS) (UNII: 59Z907ZB69)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
SHEA BUTTER (UNII: K49155WL9Y)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	

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:58443-0319-4	147 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/15/2017	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0319) , manufacture(58443-0319) , label(58443-0319) , analysis(58443-0319)

Revised: 5/2020

Prime Enterprises Inc.