

**AUSTRALIAN 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

Active Ingredients

Titanium Oxide 4%

Zinc Oxide 4%

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 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

INACTIVE INGREDIENTS

Cyclopentasiloxane, Water, Glycerin, Silica, Cetyl PEG/PPG-10/1 Dimethicone, Distearidimonium 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

Other Information

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

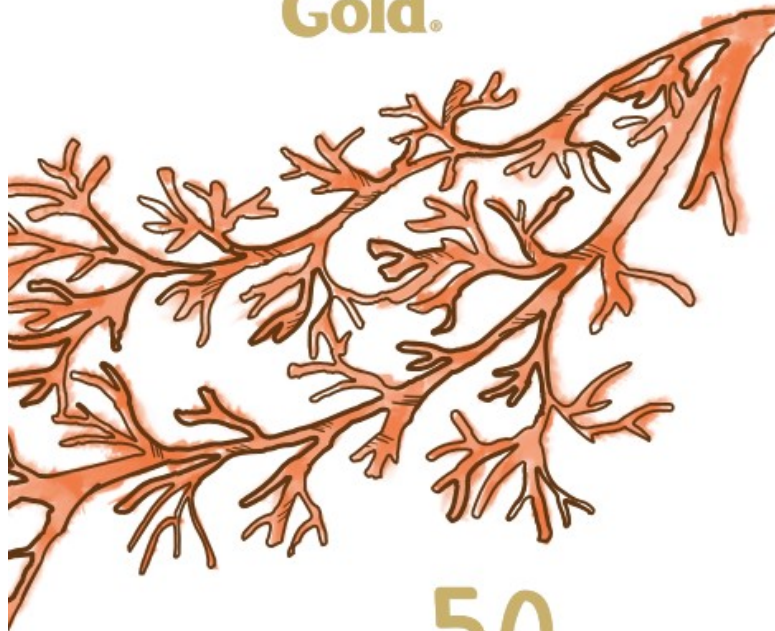
Questions or Comments?

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

Australian Gold Botanical Sunscreen Broad Spectrum SPF 50

Australian Gold.

Australian Gold.



BOTANICAL 50

100% MINERAL SUNSCREEN
ANTI-AGING • ANTIOXIDANT RICH

LONG LASTING PROTECTION

WATER RESISTANT (80 MINUTES)
BROAD SPECTRUM SPF 50

5 FL OZ (147 mL)

Drug Facts

Active Ingredients	Titanium Dioxide 4% Zinc Oxide 4%	Purpose Sunscreen
Uses	<ul style="list-style-type: none"> helps prevent sunburn • if used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun 	
Warnings	<p>For external use only</p> <ul style="list-style-type: none"> 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	Cyclopentasiloxane, Water/Aqua/Eau, Glycerin, Silica, Cetyl PEG/PPG-10/1 Dimethicone, Distearidimonium Hectorite, Polymethylsilsesquioxane, PEG-10 Dimethicone, Hexyl Laurate, Polyglyceryl-4 Isostearate, Dimethicone Crosspolymer, Fragrance (Parfum), 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	
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 (548-1653)	

*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

870803
300275-004



AUSTRALIAN GOLD BROAD SPECTRUM SPF 50 SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0551
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	41.2 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	41.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
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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: 059QF0KO0R)
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLVW6E6)
SHEA BUTTER (UNII: K49155WL9Y)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
HEXYL LAURATE (UNII: 4CG9F9W01Q)
PANTHENOL (UNII: WW9CM0O67Z)
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
ALUMINUM OXIDE (UNII: LMI26O6933)

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:58443-0551-4	147 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/04/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/04/2022	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)**Establishment**

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0551) , manufacture(58443-0551) , label(58443-0551) , analysis(58443-0551)

Revised: 4/2022

Prime Enterprises Inc.