

**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 Tinted Face Medium Broad Spectrum SPF 50

Active Ingredients

Titanium Dioxide 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

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

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 Tinted Face 50

Australian Gold.



BOTANICAL 50 TINTED FACE

BB CREAM FOR MEDIUM TO TAN SKIN TONES

LIGHTWEIGHT • MATTE FINISH
HYPOALLERGENIC

WATER RESISTANT (80 MINUTES)
BROAD SPECTRUM SPF 50

3 FL OZ (88 mL)

Australian Gold.

Drug Facts	
Active Ingredients	Purpose
Titanium Dioxide 4% Zinc Oxide 4%	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	
Alumina, Butyrospermum Parkii (Shea) Butter, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclopentasiloxane, Dimethicone Crosspolymer, Disodium EDTA, Distearidimonium Hectorite, Eucalyptus Globulus Leaf Extract, Glycerin, Hexyl Laurate, Iron Oxides, Panthenol, PEG-10 Dimethicone, Phenoxyethanol, Polyglyceryl-4 Isostearate, Polymethylsilsesquioxane, Porphyra Umbilicalis Extract, Silica, Squalane, Stearic Acid, Tocopheryl Acetate*, Triethoxycaprylylsilane, Water	
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, Phthalate Free, PABA Free, Sulfate Free, Petrolatum Free, BPA Free & No Artificial Dyes

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Distributed by: Australian Gold, Indianapolis, IN 46278
www.AustralianGold.com

70886
10005-001



AUSTRALIAN GOLD BROAD SPECTRUM SPF 50 SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0552
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	42.4 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	42.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
PANTHENOL (UNII: WW9CM0O67Z)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
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)	

Product Characteristics

Color	brown (Dark Nude)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0552-3	88 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(58443-0552) , manufacture(58443-0552) , label(58443-0552) , analysis(58443-0552)

Revised: 4/2022

Prime Enterprises Inc.