

**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 Tinted Face 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

Do not use on damaged or broken skin

When using this product

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor

Stop use and ask a doctor if rash occurs

Keep out of reach of children.

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, 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

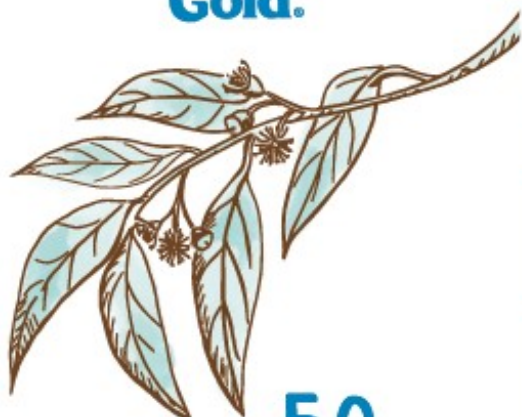
- Protect this product from excessive heat and direct sun
- May stain some fabrics or surfaces

Questions or Comments?

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

Australian Gold Botanical Tinted Face Broad Spectrum SPF 50

Australian Gold.



BOTANICAL 50 TINTED FACE

BB CREAM FOR FAIR TO LIGHT SKIN TONES

LIGHTWEIGHT • MATTE FINISH
ANTI-AGING

WATER RESISTANT (80 MINUTES)
BROAD SPECTRUM SPF 50

3 FL. OZ. (88 mL)

Australian Gold.

Drug Facts	
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 of 15 or higher and other sun protection measures including: • limit time in the sun, especially from 10 a.m. to 4 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses • children under 6 months: Ask a doctor	
Inactive Ingredients Cyclopentasiloxane, Water, Aqua, Calcium, Zinc, Silica, Cetyl PEG/PPG-10/1 Dimethicone, Dimethiconium Hectorite, Polymethylsiloxane, PEG-10 Dimethicone, Hood Lecithin, Polyglyceryl-4 Isostearate, Trimethylsilyl Dimethicone, Hexadecyl Fatty Acid, Escalopin Diethylester, Ethylhexyl Stearate, Propylene Unibutylate, Dimethicone Crosspolymer, Stearic Acid, Caprylyl Glycol, Tocopherol Acetate, Butylacrylate, Pentaerythritol Diacrylate, Panthenol, Glycerin, Disodium EDTA, Triethoxycaprylylsilane, Aluminum, Phenoxyethanol, Iron Oxides (CI 77491, CI 77492, CI 77499)	
Other information • Protect this product from excessive heat and direct sun • May stain some fabrics or surfaces	
Questions or comments? Call 1-800-4-AUGOLD (1-800-468-6603)	



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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www.augold.com



AUSTALIAN GOLD BROAD SPECTRUM SPF 50 SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0315
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	42.8 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
POLYMETHYLSILSESQUIOXANE (11 MICRONS) (UNII: Z570VEV8XK)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII:	

UF7620L1W6)	
PANTHENOL (UNII: WW9CM0067Z)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SQUALANE (UNII: GW89575KF9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
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: S546YLW6E6)	
SHEA BUTTER (UNII: K49155WL9Y)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0315-3	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/27/2021	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0315) , manufacture(58443-0315) , label(58443-0315) , analysis(58443-0315)

