

**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.*

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**Australian Gold Botanical Sunscreen Tinted Face 50 (non-Kakadu)**

***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, 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 (non-Kakadu)**

# Australian Gold.



## BOTANICAL 50 TINTED FACE

BB CREAM FOR FAIR TO LIGHT SKIN TONES

LIGHTWEIGHT • MATTE FINISH  
HYPOALLERGENIC

WATER RESISTANT (80 MINUTES)  
BROAD SPECTRUM SPF 50

3 FL OZ (88 mL)

### Australian Gold.

Drug Facts	
<b>Active Ingredients</b> Titanium Dioxide 4% Zinc Oxide 4%	<b>Purpose</b> Sunscreen
<b>Uses</b> • helps prevent sunburn • if used as directed with other sun protection measures (see <b>Directions</b> ), decreases the risk of skin cancer and early skin aging caused by the sun	
<b>Warnings</b> <b>For external use only</b> <b>Do not use</b> on damaged or broken skin <b>When using this product</b> keep out of eyes. Rinse with water to remove. <b>Stop use and ask a doctor</b> if rash occurs <b>Keep out of reach of children.</b> If product is swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b> • apply liberally 15 minutes before sun exposure • reapply • after 80 minutes of swimming or sweating • immediately after towel drying • at least every 2 hours • <b>Sun Protection Measures.</b> 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	
<b>Inactive ingredients</b> Alumina, Butyrospermum Parkii (Shea) Butter, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclopentasiloxane, Dimethicone Crosspolymer, Disodium EDTA, Distearidimonium Hectonite, 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	
<b>Other information</b> • Protect this product from excessive heat and direct sun • May stain some fabrics or surfaces	
<b>Questions or comments?</b> 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

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## AUSTALIAN GOLD BROAD SPECTRUM SPF 50 SUNSCREEN

titanium dioxide, zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0562
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	41 mg in 1 mL
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	41 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>POLYMETHYLSILSESQUIOXANE (11 MICRONS)</b> (UNII: Z570VEV8XK)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2)</b> (UNII: V2W71V8T0X)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE)</b> (UNII: UF7620L1W6)	
<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>PORPHYRA UMBILICALIS</b> (UNII: 14AN0J70WO)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>EUCALYPTUS GLOBULUS LEAF</b> (UNII: S546YLVW6E6)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	

## Product Characteristics

<b>Color</b>	brown (Nude)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0562-3	88 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/20/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	07/20/2022	

**Labeler** - Prime Enterprises Inc. (101946028)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0562) , manufacture(58443-0562) , label(58443-0562) , analysis(58443-0562)

Revised: 8/2022

Prime Enterprises Inc.