

# **AUSTRALIAN GOLD BOTANICAL TINTED FACE MINERAL SUNSCREEN BROAD SPECTRUM SPF 50- 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 Tinted Face Mineral Sunscreen 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 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

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

### ***Questions or Comments?***

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

**Australian Gold Botanical Tinted Face Mineral Sunscreen Broad Spectrum SPF 50**

Australian Gold®

**BOTANICAL SUNSCREEN TINTED FACE 50**  
**BROAD SPECTRUM SPF 50**



**Australian Gold®**  
**MINERAL LOTION**  
**NON-GREASY**  
**ANTIOXIDANT RICH**  
**UVA / UVB PROTECTION**  
**Water Resistant [80 Minutes]**  
**3 FL OZ (89 mL)**

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Titanium Dioxide 4%	Sunscreen
Zinc Oxide 4%	
<b>Uses</b>	
<ul style="list-style-type: none"> <li>helps prevent sunburn</li> <li>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</li> </ul>	
<b>Warnings</b>	
<b>For external use only</b>	
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.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>apply liberally 15 minutes before sun exposure</li> <li>reapply <ul style="list-style-type: none"> <li>after 80 minutes of swimming or sweating</li> <li>immediately after towel drying</li> <li>at least every 2 hours</li> </ul> </li> <li><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: <ul style="list-style-type: none"> <li>limit time in the sun, especially from 10 a.m. – 2 p.m.</li> <li>wear long-sleeve shirts, pants, hats, and sunglasses</li> <li>children under 6 months: Ask a doctor</li> </ul> </li> </ul>	
<b>Inactive ingredients</b>	
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 (Red Algae) Extract, Silica, Squalane, Stearic Acid, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Tocopheryl Acetate*, Triethoxycaprylylsilane, Water (aqua)	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Protect this product from excessive heat and direct sun</li> </ul>	
<b>Questions or comments?</b>	
Call toll free 1-855-LIV-GOLD (548-4653)	

\*Vitamin E



Also Non-Nano, SLS (Sulfate) Free, Petrolatum Free, Paraben Free, Alcohol Free, Oil Free, BPA Free & No Artificial Dyes  
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**AUSTRALIAN GOLD BOTANICAL TINTED FACE MINERAL SUNSCREEN BROAD SPECTRUM SPF 50**

titanium dioxide, zinc oxide lotion

Product Information			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0568
<b>Route of Administration</b>	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	41.4 mg	in 1 mL

**TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 41.4 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>KAKADU PLUM</b> (UNII: 0ZQ1D2FDLI)	
<b>SQUALANE</b> (UNII: GW89575KF9)	
<b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)	
<b>PORPHYRA UMBILICALIS</b> (UNII: 14AN0J70WO)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2)</b> (UNII: V2W71V8TOX)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE)</b> (UNII: UF7620L1W6)	
<b>DISTEARDIMONIUM HECTORITE</b> (UNII: X687XDK09L)	
<b>EUCALYPTUS GLOBULUS LEAF</b> (UNII: S546YLVW6E6)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)	
<b>PANTHENOL</b> (UNII: WW9CM0067Z)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>PEG-10 DIMETHICONE (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYGLYCERYL-4 ISOSTEARATE</b> (UNII: 820DPX33S7)	

### 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:58443-0568-3	89 mL in 1 TUBE; 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	M020	01/27/2021	
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**Labeler** - Prime Enterprises Inc. (101946028)

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

**Establishment**

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0568) , manufacture(58443-0568) , label(58443-0568) , analysis(58443-0568)

Revised: 9/2022

Prime Enterprises Inc.