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 productkeep 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, Disteardimonium 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, Wate

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

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: WV9CM0O67Z)	
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)