

**AUSTRALIAN GOLD BROAD SPECTRUM SPF30- titanium dioxide and 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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**Active ingredients**

Titanium Dioxide 3 % and Zinc Oxide 4 %

**Purpose**

Sunscreen

**Uses**

- helps prevent sunburn
- if used as directed with other sun protection measure (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. – 2 p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

**Inactive Ingredients**

Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aluminum Hydroxide, Artemisia Princeps (Yomogi) Extract, Buddleja Davidii (Butterfly Bush) Extract, C12-15 Alkyl Benzoate, Cetareth-20, Cetyl Alcohol, Citric Acid, Dibutyl Adipate, Dimethicone, Fragrance (Parfum), Glycerin, Hexyl Laurate, Magnesium Aluminum Silicate, Methylisothiazolinone, PEG-12 Dimethicone, Phenoxyethanol,

Polyglyceryl-3 Distearate, Propylene Glycol, Sodium Hydroxide, Stearic Acid, Stearyl Alcohol, Triethoxycaprylylsilane, Water (Aqua), Xanthan Gum

### Other information

- protect this product from excessive heat and direct sun

Questions or Comments?

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

### PRINCIPAL DISPLAY PANEL - 150 mL Bottle Label

**Australian Gold.**  
**HELLO KITTY**  
**Mineral Sunscreen Lotion**  
**Summer Berry**

**30**  
BROAD SPECTRUM SPF 30

Water Resistant (80 minutes)  
5 FL OZ (150 mL)

**HELLO KITTY**  
by Sanrio  
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Made in the USA. Distributed by:  
Australian Gold LLC  
Indianapolis, IN 46276  
www.austalgold.com

**HELLO KITTY**  
Australian Gold.  
**Drug Facts**  
Active Ingredients: Titanium Dioxide 3%, 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.  
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: Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aluminum Hydroxide, Artemisia Princeps (Yomogi) Extract, Buddleja Davidii (Butterfly Bush) Extract, C12-15 Alkyl Benzene, Ceteareth-20, Cetyl Alcohol, Citric Acid, Dibutyl Adipate, Dimethicone, Fragrance (Parfum), Glycerin, Hexyl Laurate, Magnesium Aluminum Silicate, Methylisothiazolinone, PEG-12 Dimethicone, Phenoxyethanol, Polyglyceryl-3 Distearate, Propylene Glycol, Sodium Hydroxide, Stearic Acid, Stearyl Alcohol, Triethoxycaprylylsilane, Water (Aqua), Xanthan Gum.  
Other information: protect this product from excessive heat and direct sun.  
Questions or comments? Call toll free 1-855-LIV-GOLD (548-4653)

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DENVILLE, USA LLC  
DORAL, FL 33172  
www.denvillergold.com  
MADE IN USA

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Australian Gold

HELLO

KITTY

Mineral

Sunscreen Lotion

Summer Berry

30

BROAD SPECTRUM SPF 30

Water Resistant (80 minutes)

5 FL OZ (150 mL)

## AUSTRALIAN GOLD BROAD SPECTRUM SPF30

tanium dioxide and zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0081
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	29.8 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	39.7 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PEG-12 DIMETHICONE/PPG-20 CROSSPOLYMER (UNII: 965K72OQXO)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BUDDLEJA DAVIDII LEAF (UNII: X380815D32)	
ARTEMISIA PRINCEPS LEAF (UNII: SY077EW02G)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
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<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:58443-0081-4	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/12/2013	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/12/2013	

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

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

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0081) , pack(58443-0081) , manufacture(58443-0081) , analysis(58443-0081)

Revised: 1/2020

Prime Enterprises, Inc.