AUSTRALIAN GOLD HELLO KITTY BROAD SPECTRUM SPF 45- 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.

Active ingredients

Titanium Dioxide 4.5 %, and 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. – 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, Artemisia Princeps (Yomogi) Extract, Buddleja Davidii (Butterfly Bush) Extract, C12-15 Alkyl Benzoate, Ceteareth-20, Cetyl Alcohol, Dibutly Adipate, Dimethicone, Glycerin, Hexyl Laurate, Magnesium Aluminum Silicate, Methylcellulose,

Methylisothiazolinone, PEG-12 Dimethicone, Phenoxyethanol, Polyglyceryl-3 Distearate, Propylene Glycol, Stearyl Alcohol, Trimethylsiloxysilicate, Water (Aqua), Xanthan Gum, may contain Citric Acid, may contain Sodium Hydroxide

Other information

- protect this product from excesive heat and direct sun

Questions or Comments?

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

PRINCIPAL DISPLAY PANEL - 88 mL Bottle Label

Australian G old

HELLO

KITTY

Mineral Faces

Sunscreen Lotion

Fragrance-Free

45

BROAD SPECTRUM SPF 45

Water Resistant (80 minutes)

3 FL OZ (88 mL)

AUSTRALIAN GOLD HELLO KITTY BROAD SPECTRUM SPF 45

titanium dioxide and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0083
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	45.45 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	40.4 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ALUMINUM HYDRIDE (UNII: KZJ3T010RQ)	
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)	
CETEARETH-22 (UNII: 28VZG1E234)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIMETHYLSILOXYSILICATE (M/Q 0.8-1.0) (UNII: 25LXE464L2)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLCELLULOSE (100 CPS) (UNII: 4GFU244C4J)	
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	

SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ARTEMISIA PRINCEPS LEAF OIL (UNII: F9S1101A2V)	
BUDDLEJA DAVIDII LEAF (UNII: X380815D32)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0083-3	88 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/23/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/23/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0083) , pack(58443-0083) , manufacture(58443-0083) , analysis(58443-0083)

Revised: 1/2020 Prime Enterprises, Inc.