AUSTRALIAN GOLD BROAD SPECTRUM SPF 50- 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, Aluminum Hydroxide, Artemisia Princeps (Yomogi) Extract, Buddleja Davidii (Butterfly Bush) Extract, C12-15 Alkyl Benzoate, Ceteareth-20, Cetyl Alcohol, Dibutly Adipate, Dimethicone, Fragrance (Parfum), Glycerin, Hexyl Laurate, Magnesium Aluminum Silicate, Methylcellulose, Methylisothiazolinone, PEG-12 Dimethicone, Phenoxyethanol,

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

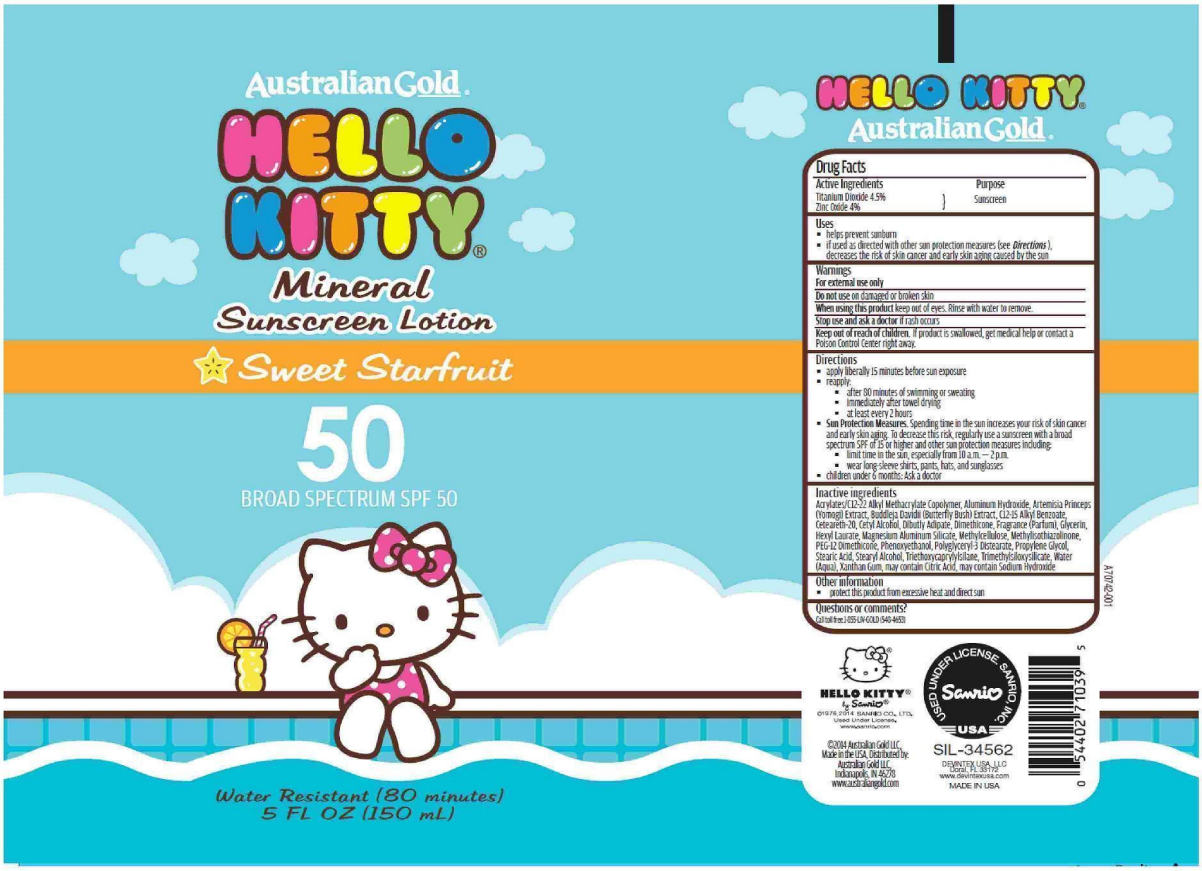
Other information

- protect this product from excesive heat and direct sun

Questions or Comments?

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

PRINCIPAL DISPLAY PANEL - 150 mL Bottle Label



Australian G old

HELLO

KITTY

Mineral

Sunscreen Lotion

Sweet Starfruit

50

BROAD SPECTRUM SPF 50

Water Resistant (80 minutes)

5 FL OZ (150 mL)

AUSTRALIAN GOLD BROAD SPECTRUM SPF 50

titanium dioxide and zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0136
Route of Administration	TOPICAL		

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

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
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)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
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)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
ARTEMISIA PRINCEPS WHOLE (UNII: 2849G48V9J)	
BUDDLEJA DAVIDII WHOLE (UNII: 8JZ8B2V1OV)	

XANTHAN GUM (UNII: TTV12P4NEE)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0136-4	150 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/18/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/18/2014	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0136) , pack(58443-0136) , manufacture(58443-0136) , analysis(58443-0136)

Revised: 1/2020 Prime Enterprises, Inc.