

AUSTRALIAN GOLD HELLO KITTY MINERAL FACES 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 Hello Kitty Mineral Faces Sunscreen

Active Ingredients

Titanium Dioxide 4.5%

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.

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

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, Dibutyl Adipate, Dimethicone, 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 excessive heat and direct sun

Questions or Comments?

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

Australian Gold Hello Kitty Mineral Faces Sunscreen

Australian Gold.
HELLO KITTY
Mineral Faces
Sunscreen Lotion

Fragrance-Free

45
BROAD SPECTRUM SPF 45

Water Resistant (80 minutes)
3 FL OZ (88 mL)

Drug Facts

Active Ingredients	Purpose
Titanium Dioxide 4.5 % Zinc Oxide 4%	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, Dibutyl Adipate, Dimethicone, Glycerin, Hexyl Laurate, Magnesium Aluminum Silicate, Methylcellulose, Methylisothiazolinone, PEG-12 Dimethicone, Phenoxethanol, 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 excessive heat and direct sun

Questions or comments?
Call toll free 1-855-LIV-GOLD (548-4653)

HELLO KITTY
by **Sanrio**
©1976,2014 SANRIO CO., LTD.
Used Under License:
www.sanrio.com

©2013 Australian Gold LLC,
Made in the USA, Distributed by:
Australian Gold LLC,
Indianapolis, IN 46270
www.australiangold.com

USED UNDER LICENSE, SANRIO INC.
Sanrio
USA
SIL-34562
DEVINTEX USA, LLC
Doral, FL 33172
www.devinTEXusa.com
MADE IN USA

0 54402 70093 8

AUSTRALIAN GOLD HELLO KITTY MINERAL FACES SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0219
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	41.6 mg in 1 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	46.8 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLYGLYCERYL-3 DISTEARATE (UNII: Z11LK470XV)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CETEARETH-22 (UNII: 28VZG1E234)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
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)	
WATER (UNII: 059QF0KO0R)	
PEG-12 DIMETHICONE (300 CST) (UNII: ZEL54N6W95)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
BUDDLEJA DAVIDII LEAF (UNII: X380815D32)	
ARTEMISIA PRINCEPS LEAF OIL (UNII: F9S1101A2V)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0219-3	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	pack(58443-0219) , manufacture(58443-0219) , label(58443-0219) , analysis(58443-0219)

Revised: 1/2020

Prime Enterprises Inc.