AUSTRALIAN GOLD HELLO KITTY BROAD SPECTRUM 50- avobenzone, homoslate, octisalate, octocrylene and oxybenzone aerosol, spray Prime Packaging, 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

Avobenzone 3 %, Homosalate 10 %, Octisalate 5 %, Octocrylene 2.75 % and Oxybenzone 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 broken or damaged skin

When using this product keep out of eyes. Rinse with water to remove. Keep away from face to avoid breathing it. Contents under pressure - do not puncture or incinirate. Do not store at temperatures above 120 ⁰F

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.

Flammable: Do not use near heat, flame or while smoking

Directions

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- hold container 4 to 6 inches from the skin to apply
- do not spray directly into face. Spray on hands then apply to face
- do not apply in windy conditions
- use in well-ventilated areas
- reapply:
 - o 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

Inactive Ingredients

Artemisia Princeps (Yomogi) Extract, Buddleja Davidii (Butterfly Bush) Extract, C12-15 Alkyl Benzoate, Diethylhexyl 2,6-Naphthalate, Diisopropyl Adipate, Fragrance (Parfum), Octyldodecyl Citrate Crosspolymer, Phenethyl Benzoate, Polyester-8, Propylene Glycol, SD Alcohol 40-B (Alcohol Denat.), Tocopheryl Acetate, Tridecyl Neopentanoate, VA/Butyl Maleate/Isobornyl Acrylate Copolymer

Other information

- protect this product from excessive heat and direct sun
- avoid spraying on fabrics could cause discoloration

Questions or Comments?

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

PRINCIPAL DISPLAY PANEL - 150 mL Can Label



Australian G old®

HELLO

KITTY

Wet/Dry Skin Formula

Body Mist Sunscreen

Paradise Pineapple

50

BROAD SPECTRUM SPF 50

Water Resistant (80 minutes)

5 FL OZ (150mL)

AUSTRALIAN GOLD HELLO KITTY BROAD SPECTRUM 50

avobenzone, homoslate, octisalate ,octocrylene and oxybenzone aerosol, spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0087	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	26.7 mg in 1 mL		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	89 mg in 1 mL		
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	44.5 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	24.5 mg in 1 mL		
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	35.6 mg in 1 mL		

Inactive Ingredients	
Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: 10 DQJ7YGXM)	
DIISOPROPYL ADIPATE (UNII: P7E6 YFV72X)	
TRIO CTYLDO DECYL CITRATE (UNII: 35X8CT063R)	
PHENETHYL BENZOATE (UNII: 0 C 1439 29 GK)	
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296U138P)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIDECYL NEO PENTANO ATE (UNII: 3Z8 H1DA7J5)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ARTEMISIA PRINCEPS LEAF (UNII: SY077EW02G)	
BUDDLEJA DAVIDII LEAF (UNII: X380815D32)	
ISOBORNYL ACRYLATE (UNII: IX0 PRH18 4P)	

Product Characteristics			
Color	yello w	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

l	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:13630-0087-4	150 mL in 1 CAN; Type 0: Not a Combination Product	12/25/2013	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	12/25/2013		

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0087), analysis(13630-0087)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0087), pack(13630-0087)

Revised: 1/2020 Prime Packaging, Inc.