AUSTRALIAN GOLD BROAD SPECTRUM 30- avobenzone, homoslate, octisalate ,octocrylene and oxybenzone 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 7.5 %, Octisalate 5 %, Octocrylene 2.75 % and Oxybenzone 2 %

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 ^{0}F

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:
  - 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 excesive 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 Gold

HELLO

KITTY

Wet/Dry Skin Formula

Body Mist Sunscreen

Krazy Kiwi

30

BROAD SPECTRUM SPF 30

Water Resistant (80 minutes)

5 FL OZ (150mL)

AUSTRALIAN GOLD BROAD SPECTRUM 30
avobenzone, homoslate, octisalate ,octocrylene and oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13630-0071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	26.6 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	66.5 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	44.4 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	24.4 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	17.7 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
DIISOPROPYL ADIPATE (UNII: P7E6YFV72X)	
PHENETHYL BENZOATE (UNII: 0C143929GK)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIDECYL NEOPENTANOATE (UNII: 3Z8H1DA7J5)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ARTEMISIA PRINCEPS LEAF (UNII: SY077EW02G)	
BUDDLEJA DAVIDII LEAF (UNII: X380815D32)	
TRIOCTYLDODECYL CITRATE (UNII: 35X8CT063R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0071-3	150 mL in 1 CAN; Type 0: Not a Combination Product	12/19/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	12/19/2013	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0071) , analysis(13630-0071)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0071) , pack(13630-0071)

Revised: 1/2020 Prime Packaging, Inc.