AUSTRALIAN GOLD BOAD SPECTRUM SPF 30- avobenzone, homosalate, octisalate, octocrylene and oxybenzone 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

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 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.

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

Directions

- apply 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 area
- 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

Blue 1 (CI 42090), Diethylhexyl 2,6-Naphthalate, Fragrance (Parfum), Glycerin, Polyester-8, Red 40 (CI 16035), SD Alcohol 40-B (Alcohol Denat.), VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Water (Aqua), Yellow 5 (CI 19140)

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 - 177 mL Bottle Label

EXOTIC BLEND

#1 Fragrance

30

Continuous Spray Sunscreen

with instant

BRONZER

BROAD SPECTRUM SPF 30

WATER RESISTANT (80 MINUTES)

Australian

Gold

6 FL OZ (177 mL)

AUSTRALIAN GOLD BOAD SPECTRUM SPF 30

avobenzone, homosalate, octisalate, octocrylene and oxybenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0071
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.1 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	62.7 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	41.8 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	22.9 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	16.7 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:58443-0071-4	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/06/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

OTC monograph final	part352	11/06/2013	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0071) , pack(58443-0071) , manufacture(58443-0071) , analysis(58443-0071)

Revised: 1/2020 Prime Enterprises, Inc.