

AUSTRALIAN GOLD SPF 15 C/S SUNSCREEN WITH BRONZER- avobenzone, octisalate, and octocrylene 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.

Australian Gold SPF 15 C/S Sunscreen with Bronzer

Active Ingredients

Avobenzone 2%

Octisalate 5%

Octocrylene 1.85%

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. Keep away from face to avoid breathing it. Contents under pressure - do not puncture or incinerate. Do not store at temperatures above 120°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 a 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

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

Other Information

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

Question or comments ?

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

Australian Gold SPF 15 C/S Sunscreen with Bronzer



AUSTRALIAN GOLD SPF 15 C/S SUNSCREEN WITH BRONZER

avobenzone, octisalate, and octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0101
---------------------	----------------	---------------------------	----------------

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	16.2 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	40.5 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	15 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
ALCOHOL (UNII: 3K9958V90M)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	
WATER (UNII: 059QF0K00R)	
POLYESTER-8 (1400 MW, CYANO DIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0101-4	240 mL in 1 CAN; Type 0: Not a Combination Product	02/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	02/01/2016	

Labeler - Prime Packaging Inc. (805987059)**Registrant** - Prime Packaging Inc. (805987059)**Establishment**

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0101) , analysis(13630-0101)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	pack(13630-0101) , label(13630-0101)

Revised: 1/2020

Prime Packaging Inc.