

AUSTRALIAN GOLD BROAD SPECTRUM SPF 50- avobenzone, homosalate, octisalate, octocrylene, 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 10 %, Octisalate 5 %, Octocrylene 2.75 %, 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 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 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 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

Acacia Senegal Flower/Stem Extract, Blue 1 (CI 42090), Camellia Sinensis (Green Tea) Leaf Extract, Coffea Arabica (Kona Coffee) Seed Extract, Diethylhexyl 2,6-Naphthalate, Fragrance (Parfum), Glycerin, Polyester-8, Propylene Glycol, Red 40 (CI 16035), SD Alcohol 40-B (Alcohol Denat.), Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Tocopheryl Aceate, 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

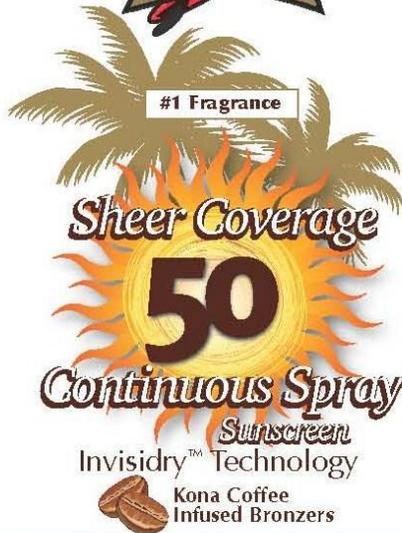
Questions or Comments?

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

PRINCIPAL DISPLAY PANEL - 177 mL Can Label



#1 Fragrance



BROAD SPECTRUM SPF 50

WATER RESISTANT
(80 MINUTES)

**Australian
Gold.**

177 mL / 6 Fl. Oz

**Australian
Gold.**

Drug Facts

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Australian Gold LLC, Indianapolis, IN 46228
BDRUS Rue de la Croixee 10A, BE-7170, Morsay, Belgium
www.austliangold.com

AZ766-2001

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EXOTIC BLEND

#1 Fragrance

Sheer Coverage

50

Continuous Spray

Sunscreen

Invisidry Technology

Kona Coffee

Infused Bronzers

BROAD SPECTRUM SPF 50

WATER RESISANT

(80 MINUTES)

Australian Gold

177 mL / 6 Fl. Oz

AUSTRALIAN GOLD BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene, oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0027
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.8 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	86 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	43 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	23.7 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0 Y) (OXYBENZONE - UNII:95OOS7VE0 Y)	OXYBENZONE	34.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0K00R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ACACIA SENEGAL FLOWER (UNII: 72P931MTC2)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ARABICA COFFEE BEAN (UNII: 3SW678MX72)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:13630-0027-4	177 mL in 1 CAN; Type 0: Not a Combination Product	06/14/2012	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part352		06/14/2012	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0027) , analysis(13630-0027)

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Prime Packaging, Inc.		805987059	label(13630-0027) , pack(13630-0027)

Revised: 1/2020

Prime Packaging, Inc.