

AUSTRALIAN GOLD BOTANICAL SPF 50- avobenzene, homosalate, octisalate, 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 Botanical SPF 50 Continuous spray

Active Ingredients

Avobenzene 3%

Homosalate 10%

Octisalate 5%

Octocrylene 5%

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 away from face to avoid breathing it. 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: Avoid fire, flame, heat or smoking. Contents under pressure. Do not puncture or incinerate. Store at temperatures below 120°F (50°C).

Directions

- shake well before use
- apply liberally 15 minutes before sun exposure and rub into skin

- hold container 4 to 6 inches from the skin to apply
- do not spray directly onto 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-sleeved shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

Inactive ingredients

SD Alcohol 40-B, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Glycerin, Fragrance, Water, Polyester-8, Tocopheryl Acetate, Eucalyptus Globulus (Eucalyptus) Leaf Extract, Porphyra Umbilicalis Extract, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract

Other information

- Protect this product from excessive heat and direct sun
- May stain some fabrics or surfaces

Questions or comments?

Call toll free 1-855-LIV-GOLD (584-4653)

Australian Gold Botanical SPF 50

Australian Gold.

Drug Facts	
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Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 5%	Sunscreen
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Questions or comments?	
Call toll free 1-855-LIV-GOLD (548-4653)	

*Organic
**Vitamin E



No Added Parabens, Dye Free, Oil Free, Sulfate Free, Petrolatum Free & No CFCs

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www.AustralianGold.com



- ORGANIC ALCOHOL
- HYPO-ALLERGENIC
- PABA FREE
- PHTHALATE FREE
- GLUTEN FREE
- DERMATOLOGIST TESTED
- PEDIATRICIAN TESTED
- NO ANIMAL TESTING

Australian Gold®



BOTANICAL 50

NATURAL SPRAY SUNSCREEN
POWDER DRY, BREATHABLE FEEL

WATER RESISTANT (80 MINUTES)
BROAD SPECTRUM SPF 50

6 FL OZ (177 mL)
Net Wt. 5.3 OZ (152 g)

AUSTRALIAN GOLD BOTANICAL SPF 50

avobenzone, homosalate, octisalate, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0267
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.2 g in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	84 g in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	42 g in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	42 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALCOHOL (UNII: 3K9958V90M)	
VINYL ACETATE (UNII: L9MK238N77)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	
ISOBORNYL ACRYLATE (UNII: IX0PRH184P)	

Product Characteristics

Color	yellow (Pale Yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0267-4	177 mL in 1 CAN; Type 0: Not a Combination Product	10/18/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/18/2016	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	analysis(13630-0267) , manufacture(13630-0267)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0267) , pack(13630-0267)

