

**AUSTRALIAN GOLD BOTANICAL BROAD SPECTRUM SPF 70- avobenzone, 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.*

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**Botanical Sunscreen 70 Natural Spray**

***Active Ingredients***

Avobenzone 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 and 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***

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

### ***Other information***

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

### ***Questions or comments?***

Call toll free 1-885-LIV-GOLD (548-4653)

**Botanical Sunscreen 70 Broad Spectrum SPF 70 Natural Spray**

Australian Gold.

Drug Facts	
<b>Active ingredients</b>	<b>Purpose</b>
Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 5%	Sunscreen
<b>Uses</b>	
<ul style="list-style-type: none"> <li>Helps prevent sunburn</li> <li>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.</li> </ul>	
<b>Warnings</b>	
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.	
<b>Precautions:</b> Avoid fire, flame, heat and smoking. Contents under pressure. Do not puncture or incinerate. Store at temperatures below 120°F (50°C).	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>shake well before use</li> <li>apply liberally 15 minutes before sun exposure and rub into skin</li> <li>hold container 4 to 6 inches from the skin to apply</li> <li>do not spray directly into face. Spray on hands then apply to face</li> <li>do not apply in windy conditions</li> <li>use in well-ventilated area</li> <li>reapply               <ul style="list-style-type: none"> <li>after 80 minutes of swimming or sweating</li> <li>immediately after towel drying</li> <li>at least every 2 hours</li> </ul> </li> <li><b>Sun Protection Measures:</b> 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:               <ul style="list-style-type: none"> <li>limit time in the sun, especially from 10 a.m.–3 p.m.</li> <li>wear long-sleeve shirts, pants, hats, and sunglasses.</li> <li>children under 6 months: Ask a doctor</li> </ul> </li> </ul>	
<b>Inactive ingredients</b>	
SD-Alcohol-40-5*, Trimethylbenzylidene Polyanedone, VA/Butyl Methacrylate Copolymer (Acrylate Copolymer, Glycerin, Fragrance (Parfum), Water/Aqua/Eau, Polybutyl-6-Tercepthenyl Acetate**, Eucalyptus Globulus (Eucalyptus) Leaf Extract, Potolphy Umbellifera Extract, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>Protect this product from excessive heat and direct sun</li> <li>May stain some fabrics or surfaces</li> </ul>	
<b>Questions or comments?</b>	
Call toll free 1-855-11-AU-GOLD (548-4663)	

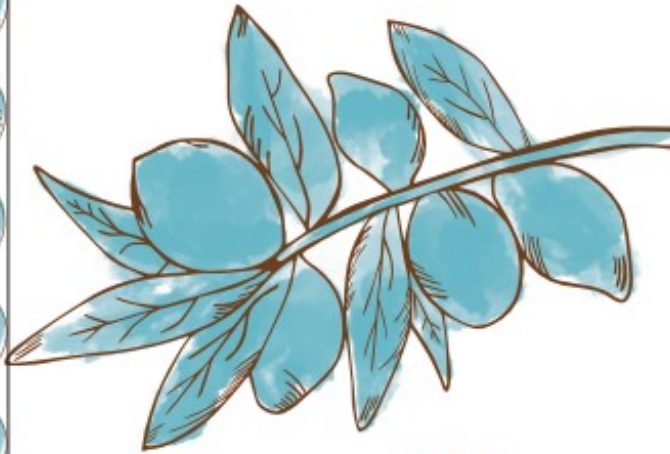
\*Organic  
\*\*Vitamin E

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- PEDIATRICIAN TESTED
- NO ANIMAL TESTING

Australian Gold.



BOTANICAL 70

NATURAL SPRAY SUNSCREEN  
POWDER DRY, BREATHABLE FEEL

WATER RESISTANT (80 MINUTES)  
BROAD SPECTRUM SPF 70

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

## AUSTRALIAN GOLD BOTANICAL BROAD SPECTRUM SPF 70

avobenzone, homosalate, octisalate, octocrylene spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13630-0140
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	86.1 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.83 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	43.05 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	43.05 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>EUCALYPTUS GLOBULUS LEAF</b> (UNII: S546YLW6E6)	

<b>PORPHYRA UMBILICALIS</b> (UNII: 14AN0J70WO)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>TRIMETHOXYBENZYLIDENE PENTANEDIONE</b> (UNII: 322V0ACF25)	
<b>ISOBORNYL ACRYLATE</b> (UNII: IX0PRH184P)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>KAKADU PLUM</b> (UNII: 0ZQ1D2FDLI)	
<b>POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED)</b> (UNII: T9296U138P)	
<b>VINYL ACETATE</b> (UNII: L9MK238N77)	
<b>DIBUTYL MALEATE</b> (UNII: 4X371TMK9K)	

### Product Characteristics

<b>Color</b>	yellow	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0140-4	177 mL in 1 CAN; Type 0: Not a Combination Product	10/02/2018	02/28/2025

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/02/2018	02/28/2025

**Labeler** - Prime Packaging, Inc. (805987059)

**Registrant** - Prime Packaging, Inc. (805987059)

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0140) , analysis(13630-0140)

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0140) , pack(13630-0140)