# AUSTRALIAN GOLD BOTANICAL SUNSCREEN BROAD SPECTRUM SPF 30 NATURAL-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.

-----

#### **Botanical Sunscreen Broad Spectrum SPF 30 Natural**

#### **Active Ingredients**

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

#### 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 presssure.** Do not puncture or incinerate. Store at temperatures below 120°C (48°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 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**

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

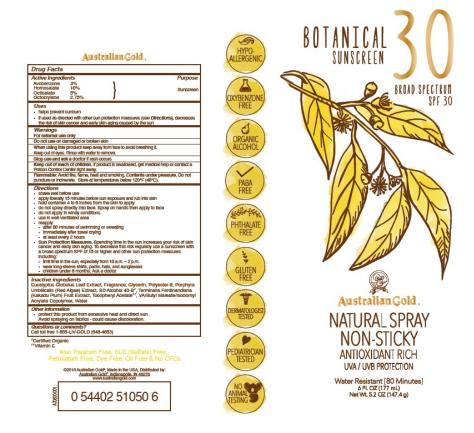
#### Other Information

- 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)

#### **Botanical Sunscreen Broad Spectrum SPF 30 Natural**



## AUSTRALIAN GOLD BOTANICAL SUNSCREEN BROAD SPECTRUM SPF 30 NATURAL

avobenzone, homosalate, octisalate, octocrylene spray

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0110	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	26.04 mg in 1 mL		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	86.8 mg in 1 mL		
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	43.4 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	23.87 mg in 1 mL		

Inactive Ingredients			
Ingredient Name	Strength		
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)			
ALCOHOL (UNII: 3K9958V90M)			
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296U138P)			
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)			
KAKADU PLUM (UNII: 0 ZQ 1D2FDLI)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
WATER (UNII: 059QF0KO0R)			
EUCALYPTUS GLOBULUS LEAF (UNII: S546 YLW6E6)			
GLYCERIN (UNII: PDC6A3C0OX)			

Product Characteristics			
Color	yello w	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

ı	Packaging			
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 NDC:13630-0110-4	177 mL in 1 CAN; Type 0: Not a Combination Product	07/15/2016	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	07/15/2016		

## Labeler - Prime Packaging Inc. (805987059)

## Registrant - Prime Packaging Inc. (805987059)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0110), analysis(13630-0110)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	pack(13630-0110), label(13630-0110)

Revised: 1/2020 Prime Packaging Inc.