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 120ºC (48ºC).

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

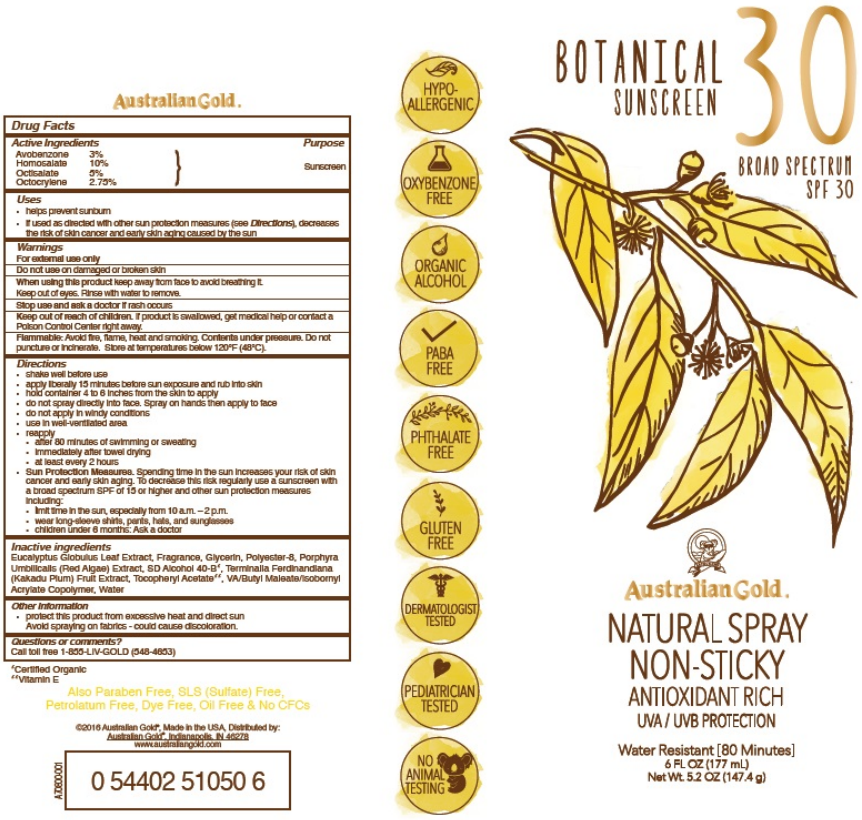
Other Information

- 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



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avobenzone, homosalate, octisalate, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13630-0199
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.44 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	84.8 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	42.4 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	23.32 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, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	

PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0199-4	177 mL in 1 CAN; Type 0: Not a Combination Product	03/17/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/17/2020	

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0199) , analysis(13630-0199)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	pack(13630-0199) , label(13630-0199)

Revised: 11/2021 Prime Packaging Inc.