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.

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-sleeve 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, Tocopheryl Acetate, Trimethoxybenzylidene Pentanedione, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Water/Aqua/Eau

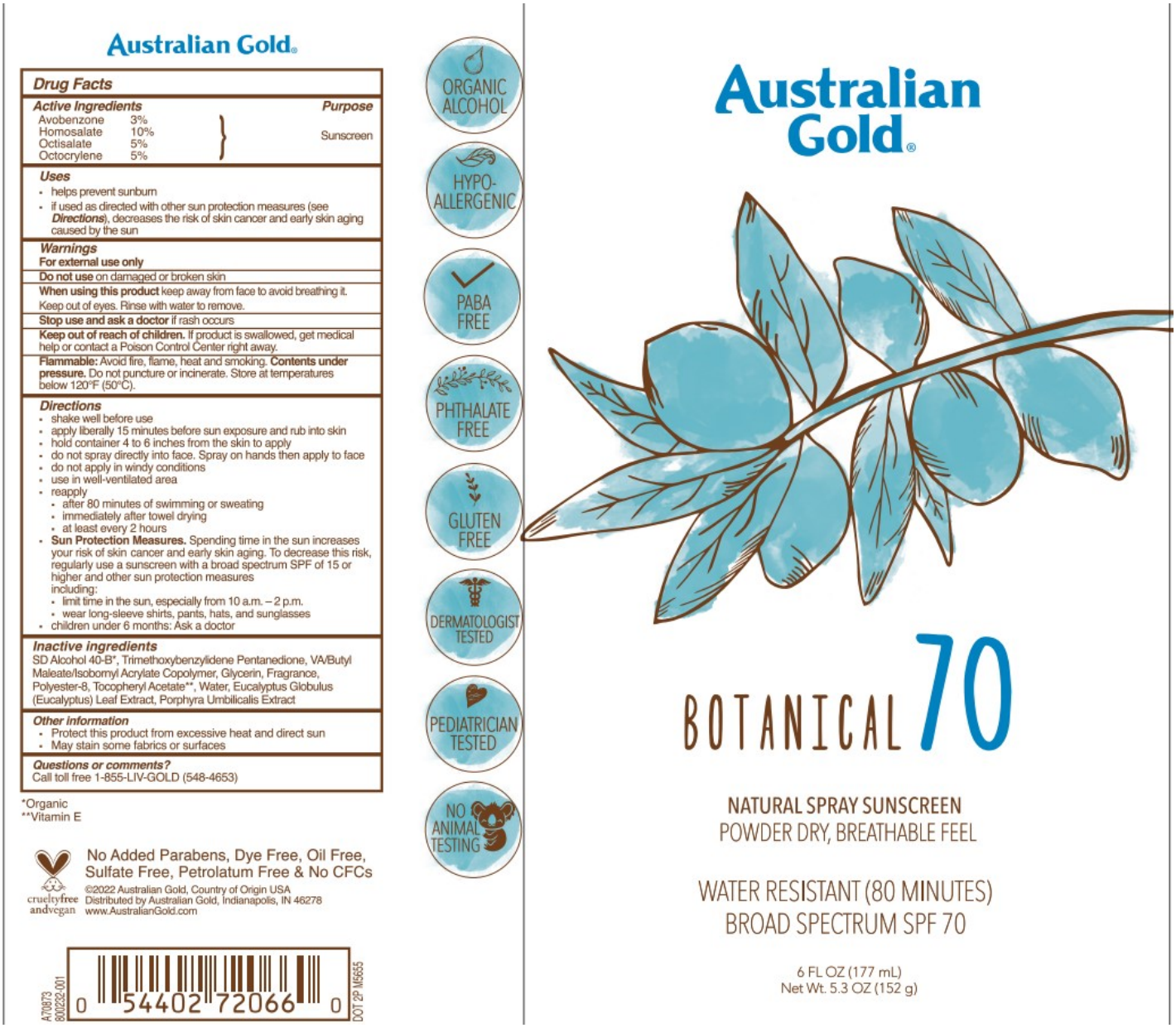
Other information

- 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 BOTANICAL BROAD SPECTRUM SPF 70

avobenzone, homosalate, octisalate, octocrylene spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13630-0275
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.71 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	85.7 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	42.85 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	42.85 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	
PORPHYRA UMBILICALIS (UNII: 14AN0J70WO)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIMETHOXYBENZYLIDENE PENTANEDIONE (UNII: 322V0ACF25)	
ISOBORNYL ACRYLATE (UNII: IX0PRH184P)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALCOHOL (UNII: 3K9958V90M)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
VINYL ACETATE (UNII: L9MK238N77)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	

Product Characteristics

Color	yellow	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0275-4	177 mL in 1 CAN; Type 0: Not a Combination Product	12/05/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/05/2022	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0275) , analysis(13630-0275)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0275) , pack(13630-0275)