AUSTRALIAN GOLD INSTANT BRONZER BROAD SPECTRUM SPF 15avobenzone, 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 INSTANT BRONZER 15 CONTINUOUS SPRAY SUNSCREEN

Active Ingredients

Avobenzone 2%

Octisalate 5%

Octocrylene 2%

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 into 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

SD Alcohol 40-B [Alohol Denat.], Water/Aqua/Eau, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Fragrance, Polyester-8, Helianthus Annuus (Sunflower) Seed Oil, Tocopheryl Acetate, Yellow 5 (CI 19140), Glycerin, Aloe Barbadensis Leaf Extract, Red 40 (CI 16035), Melaleuca Alternifolia (Tea Tree) Leaf Oil, Blue 1 (CI 42090)

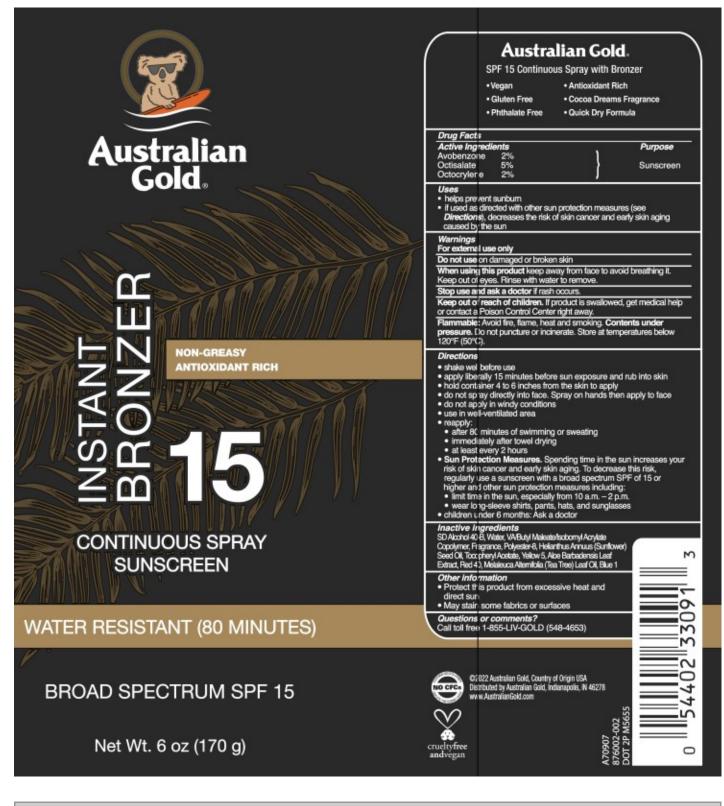
Other information

- 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)

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AUSTRALIAN GOLD INSTANT BRONZER BROAD SPECTRUM SPF 15

avobenzone, octisalate, octocrylene spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0255
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	16.42 g in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	41.03 g in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	16.42 g in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
SUNFLOWER OIL (UNII: 3W1JG795YI)			
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
ISOBORNYL ACRYLATE (UNII: IXOPRH184P)			
ALCOHOL (UNII: 3K9958V90M)			
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)			
VINYL ACETATE (UNII: L9MK238N77)			
DIBUTYL MALEATE (UNII: 4X371TMK9K)			
TEA TREE OIL (UNII: VIF565UC2G)			

Product Characteristics				
Color	brown (Dark Amber)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630- 0255-4	207 mL in 1 CAN; Type 0: Not a Combination Product	11/13/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	11/13/2019	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0255), analysis(13630-0255)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0255), pack(13630-0255)

Revised: 11/2022 Prime Packaging, Inc.