AUSTRALIAN GOLD SPF 50- 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.

Australian Gold SPF 50 Continuous Sunscreen 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. Do no store at temperatures above 120°F (50°C).

Directions

- shake well before use
- applyliberally 15 minutes before sun exposure and rub into skin
- hold container 4 to 6 inches from the skin to apply

- apply liberally 15 minutues before sun exposure
- 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

SD Alcohol 40-B, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Fragrance, Polyester-8, Helianthus Annuus (Sunflower) Seed Oil, Tocopheryl Acetate, Water, Glycerin, Aloe Barbadensis Leaf Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract

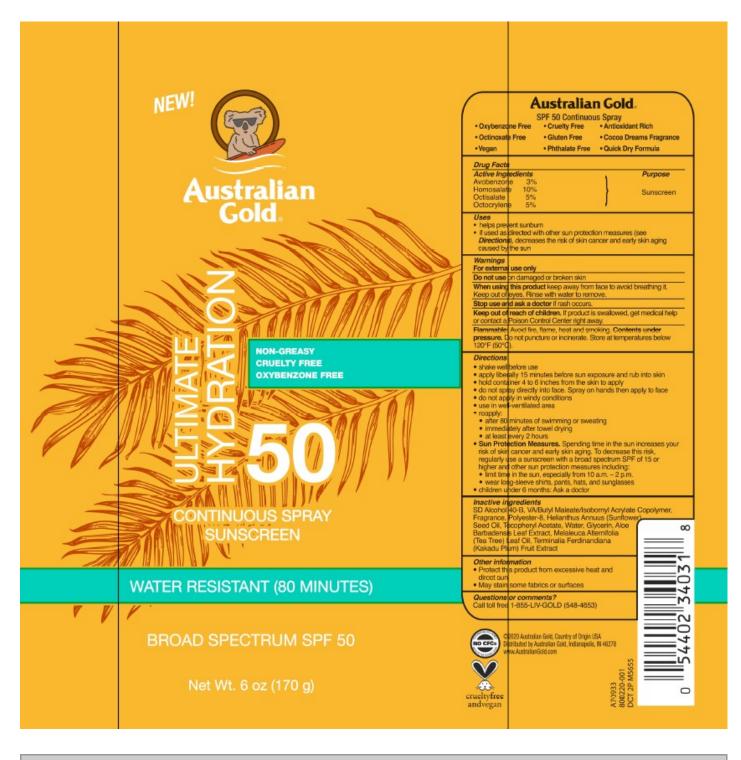
Other Information

- protect this product from excessive heat and direct sun
- may stain some fabrics or surfaces

Question or comments?

Call toll free 1-855-LIV-GOLD (548-4653)

Australian Gold SPF 50 Continuous Sunscreen Spray



AUSTRALIAN GOLD SPF 50

avobenzone, homosalate, octisalate, octocrylene spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0180
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	25.89 mg in 1 mL		

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	86.3 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	43.15 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	43.15 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
TEA TREE OIL (UNII: VIF565UC2G)			
GLYCERIN (UNII: PDC6A3C0OX)			
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
ALCOHOL (UNII: 3K9958V90M)			
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)			
WATER (UNII: 059QF0KO0R)			
SUNFLOWER OIL (UNII: 3W1JG795YI)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
KAKADU PLUM (UNII: 0ZQ1D2FDLI)			

Product Characteristics			
Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:13630- 0180-4	197 mL in 1 CAN; Type 0: Not a Combination Product	10/12/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	10/12/2020		

Labeler - Prime Packaging Inc. (805987059)

Registrant - Prime Packaging Inc. (805987059)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(13630-0180), analysis(13630-0180)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging Inc.		805987059	pack(13630-0180), label(13630-0180)

Revised: 8/2021 Prime Packaging Inc.