AUSTRALIAN GOLD BROAD SPECTRUM 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 Sport Continuous 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-sleeved shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive ingredients

Aloe Barbadensis Leaf Extract, Fragrance, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Menthol, Polyester-8, 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
- May stain some fabrics or surfaces

Questions or comments?

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

Australian Gold Extreme Sport SPF 50



AUSTRALIAN GOLD BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0168
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	10 g in 100 g		
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	5 g in 100 g		

Inactive Ingredients	
Ingredient Name	Strength
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)	
ALCOHOL (UNII: 3K9958V90M)	
VINYL ACETATE (UNII: L9 MK238 N77)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	
ISOBORNYL ACRYLATE (UNII: IX0 PRH184P)	
WATER (UNII: 059QF0KO0R)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
KAKADU PLUM (UNII: 0 ZQ 1D2FDLI)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
TEA TREE OIL (UNII: VIF565UC2G)	
MENTHOL (UNII: L7T10 EIP3A)	
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296U138P)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics				
Color	yellow (very light Yellow to yellow clear)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

l	Pac	kaging			
l	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NI	OC:13630-0168-4	170 g in 1 CAN; Type 0: Not a Combination Product	11/07/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	11/07/2019		

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0168), analysis(13630-0168)

Establishment			
Name	Address	ID/FEI	Business Operations

Prime Packaging, Inc.	805987059	label(13630-0168), pack(13630-0168)

Revised: 9/2020 Prime Packaging, Inc.