# AUSTRALIAN GOLD EXTREME SPORT SPF 30- 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.

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### Australian Gold Extreme Sport SPF 30

# **Active Ingredients**

Avobenzone 3%

Homosalate 7.5%

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 so 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 to apply
- 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 30



# **AUSTRALIAN GOLD EXTREME SPORT SPF 30**

avobenzone, homosalate, octisalate, octocrylene spray

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0169		
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	7.5 g in 100 g			
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	5 g in 100 g			
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	5 g in 100 g			

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
KAKADU PLUM (UNII: 0 ZQ 1D2FDLI)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALCOHOL (UNII: 3K9958V90M)	
VINYL ACETATE (UNII: L9 MK238 N77)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	
ISOBORNYL ACRYLATE (UNII: IX0 PRH184P)	
POLYESTER-8 (1400 MW, CYANO DIPHENYLPRO PENO YL CAPPED) (UNII: T9296U138P)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TEA TREE OIL (UNII: VIF565UC2G)	
MENTHOL (UNII: L7T10 EIP3A)	

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

ı	Packaging						
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>			
ı	1 NDC:13630-0169-4	170 g in 1 CAN; Type 0: Not a Combination Product	11/05/2019				

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part352	11/05/2019				

# Labeler - Prime Packaging, Inc. (805987059)

# Registrant - Prime Packaging, Inc. (805987059)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0169), analysis(13630-0169)

Establishment			
Name	Address	ID/FEI	Business Operations

Prime Packaging, Inc.	805987059	label(13630-0169), pack(13630-0169)	

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