

AUSTRALIAN GOLD BROAD SPECTRUM SPF 8- avobenzone, octocrylene, and oxybenzone 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.

Active ingredients

Avobenzone 1 %, Octocrylene 2.75%, Oxybenzone 1 %

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

Skin Cancer /Skin Aging Alert:

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, **not** skin cancer or early skin aging.

For external use only

Do not use on broken or damaged skin

When using this product keep out of eyes. Rinse with water to remove. Keep away from face to avoid breathing it. Contents under pressure - do not puncture or incinerate. Do not store at temperatures above 120 °F

Stop use and ask a doctor if rash occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Flammable: Do not use near heat, flame or while smoking

Directions

- spray liberally and spread evenly by hand 15 minutes before sun exposure
- hold container 4 to 6 inches from the skin to apply
- do not spray directly into face. Spray on hands and apply to face
- do not apply in windy conditions
- use in well-ventilated areas
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- children under 6 months: Ask a doctor

Inactive Ingredients

Blue 1 (CI 42090), C12-15 Alkyl Benzoate, Diethylhexyl 2,6-Naphthalate, Fragrance (Parfum), Polyester-8, Red 40 (CI 16035), SD Alcohol 40-B, VA/Butyl Maleate/Isobornyl Acrylate Copolymer, Yellow 5 (CI 19140), Water (Aqua)

Other information

- Protect this product from excessive heat and direct sun
- avoid spraying on fabrics - could cause discoloration

Questions or Comments?

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

PRINCIPAL DISPLAY PANEL - 177 mL Can Label

Australian Gold

EXOTIC BLEND

#1 Fragrance

8
Continuous Spray
Sunscreen
with instant
BRONZER

BROAD SPECTRUM SPF 8

WATER RESISTANT
(80 MINUTES)

Australian Gold

177 mL / 6 Fl. Oz.

Drug Facts	
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Odo crylene 2.75%	
Oxy benzene 1%	
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Australian Gold LLC, Indianapolis, IN
www.austalgold.com

NO CPSC
RETESTING

24H
A70593-001

0 54402 26094 4

Exotic Blend

1 Fragrance

8

Continuous Spray Sunscreen

with instant BRONZER

BROAD SPECTRUM SPF 8

WATER RESISTANT(80 MINUTES)

Australian Gold

177 mL / 6 Fl. Oz

AUSTRALIAN GOLD BROAD SPECTRUM SPF 8

avobenzone, octocrylene, and oxybenzone spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0065
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	8.2 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	22.5 mg in 1 mL
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	8.2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
WATER (UNII: 059QF0KO0R)	
DIBUTYL MALEATE (UNII: 4X371TMK9K)	

Product Characteristics

Color	brown	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0065-4	177 mL in 1 CAN; Type 0: Not a Combination Product	04/25/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/25/2012	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0065) , analysis(13630-0065)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0065) , pack(13630-0065)

Revised: 1/2020

Prime Packaging, Inc.