

AUSTRALIAN GOLD BROAD SPECTRUM SPF 4- avobenzene, octocrylene oil Prime Enterprises, 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 Spray Oil Sunscreen Broad Spectrum SPF 4

Active ingredients

Avobenzene 1 %

Octocrylene 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 help prevent sunburn, not skin cancer or early skin aging

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.

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
- 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

Helianthus Annuus (Sunflower) Seed Oil, Acetylated Lanolin Alcohol, Fragrance, Isopropyl Lanolate, VP/Hexadecene Copolymer, Cetyl Acetate, Aleurites Moluccana Seed Oil, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Fruit Oil, BHT, Tocopheryl Acetate, Diethylhexyl Syringylidene-Malonate, Aloe Barbadensis Leaf Extract, Caprylic/Capric Triglyceride, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Daucus Carota Sativa (Carrot) Seed Oil

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)

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label



**Australian
Gold®**

**HYDRATING
SPRAY OIL**

**CARROT OIL
CRUELTY FREE
OXYBENZONE FREE**

4

SPRAY OIL SUNSCREEN

WATER RESISTANT (80 MINUTES)

BROAD SPECTRUM SPF 4

8 FL OZ (237 mL)

Australian Gold.

SPF 4 Spray Oil

- Vitamin E
- Tea Tree Oil

- Carrot Oil
- Gluten Free

- Antioxidant Rich
- Cocoa Dreams Fragrance

Drug Facts

Active Ingredients	Purpose
Avobenzone 1% Octocrylene 1%	} Sunscreen

Uses

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Distributed by Australian Gold, Indianapolis, IN 46278
www.AustralianGold.com

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725004-001



AUSTRALIAN GOLD BROAD SPECTRUM SPF 4

avobenzone, octocrylene oil

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0610
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	9 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
KUKUI NUT OIL (UNII: TP11QR7B8R)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ACETATE (UNII: 4Q43814HXS)	
ACETYLATED LANOLIN ALCOHOLS (UNII: SNN716810P)	
CARROT SEED OIL (UNII: 595AO13F11)	
DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ISOPROPYL LINOLEATE (UNII: 4MW1E9AT4H)	
TEA TREE OIL (UNII: VIF565UC2G)	
COCONUT OIL (UNII: Q9L0073W7L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRICAPRIN (UNII: O1PB8EU98M)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0610-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/22/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/22/2020	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0610) , pack(58443-0610) , manufacture(58443-0610) , analysis(58443-0610)

Revised: 3/2023

Prime Enterprises, Inc.