

**AUSTRALIAN GOLD SPF 6 BRONZER OXYBENZONE- avobenzone,
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 Instant Bronzer Spray Gel Sunscreen Broad Spectrum SPF 4

Active Ingredients

Avobenzone 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 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

Water, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Glycerin, Butylphthalimide, Caramel, Phenoxyethanol, Fragrance, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Isopropylphthalimide, Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Trimethylsiloxysilicate, Sodium Hydroxide, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Olea Europaea (Olive) Fruit Oil, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Ethylhexylglycerin, Propylene Glycol, Sorbitan Oleate, 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

Questions or Comments?

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

Australian Gold Instant Bronzer Spray Gel Sunscreen Broad Spectrum SPF 4



**Australian
Gold.**

**INSTANT
BRONZER**

4

NON-GREASY
CRUELTY FREE
OXYBENZONE FREE

SPRAY GEL SUNSCREEN

WATER RESISTANT (80 MINUTES)

BROAD SPECTRUM SPF 4

8 FL OZ (237 mL)

Australian Gold.

SPF 4 Spray Gel with Bronzer

- Oxybenzone Free
- Cruelty Free
- Antioxidant Rich
- Octinoxate Free
- Gluten Free
- Cocoa Dreams Fragrance
- Vegan
- Phthalate Free
- Quick Dry Formula

Drug Facts

Active Ingredients	Purpose
Avobenzone 1% Octocrylene 1%	} Sunscreen

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Inactive ingredients: Water/Aqua/Eau, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Glycerin, Butylphthalimide, Caramel, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Isopropylphthalimide, Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Trimethylsiloxysilicate, Sodium Hydroxide, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Olea Europaea (Olive) Fruit Oil, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Propylene Glycol, Polysorbate 20, Sorbitan Oleate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Fragrance (Parfum), Phenoxyethanol, Ethylhexylglycerin

Other information

• Protect this product from excessive heat and direct sun • May stain some fabrics or surfaces

Questions or comments?

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www.AustralianGold.com



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723831-001



AUSTRALIAN GOLD SPF 6 BRONZER OXYBENZONE

avobenzone, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13630-0236
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	9.71 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	9.71 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
TEA TREE OIL (UNII: VIF565UC2G)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)	
CAMEL (UNII: T9D99G2B1R)	
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	

Product Characteristics

Color	brown (Caramel)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13630-0236-4	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/18/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	03/18/2022	

Labeler - Prime Packaging, Inc. (805987059)

Registrant - Prime Packaging, Inc. (805987059)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(13630-0236) , analysis(13630-0236)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Packaging, Inc.		805987059	label(13630-0236) , pack(13630-0236)

Revised: 4/2022

Prime Packaging, Inc.