

AUSTRALIAN GOLD INSTANT BRONZER SPF 4 SUNSCREEN- avobenzone, octocrylene spray
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 Instant Bronzer 4 Spray Gel Sunscreen

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 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

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?

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

AUSTRALIAN GOLD INSTANT BRONZER 4 SPRAY GEL SUNSCREEN

Australian Gold.

SPF 4 Spray Gel with Bronzer

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

Drug Facts

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**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 INSTANT BRONZER SPF 4 SUNSCREEN

avobenzone, octocrylene spray

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0617
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)			AVOBENZONE	9.9 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)			OCTOCRYLENE	9.9 mg in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)				
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
TRIMETHYLSILOXYSILICATE (M/Q 1.0-1.2) (UNII: 78GX033D7I)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
GLYCERIN (UNII: PDC6A3C0OX)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
CAMEL (UNII: T9D99G2B1R)				
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)				
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)				
WATER (UNII: 059QF0KO0R)				
SUNFLOWER OIL (UNII: 3W1JG795YI)				
TEA TREE OIL (UNII: VIF565UC2G)				
OLIVE OIL (UNII: 6UYK2W1W1E)				
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)				
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:58443-0617-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/16/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/16/2019	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0617) , manufacture(58443-0617) , label(58443-0617) , analysis(58443-0617)

Revised: 3/2023

Prime Enterprises Inc.