

AUSTRALIAN GOLD BROAD SPECTRUM SPF 50 SUNSCREEN- octisalate, avobenzone, octocrylene, homosalate 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 Broad Spectrum SPF 50 Sun Screen

Active Ingredients

Avobenzone 3%

Homosalate 10%

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 or irritation develops and lasts.

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
- **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 10am-2pm
- wear long sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive Ingredients

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

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 Broad Spectrum SPF 50

Australian Gold

SPF 50 Spray Gel with Bronzer

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

Drug Facts

Active Ingredients	Purpose
Avobenzone 3%	} Sunscreen
Homosalate 10%	
Octisalate 5%	
Octocrylene 5%	

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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 • **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-sleeve shirts, pants, hats and sunglasses • children under 6 months: Ask a doctor

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

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www.AustralianGold.com



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725006-001





**Australian
Gold®**

**INSTANT
BRONZER**

NON-GREASY
ANTIOXIDANT RICH
QUICK DRY FORMULA

50

SPRAY GEL SUNSCREEN

WATER RESISTANT (80 MINUTES)

BROAD SPECTRUM SPF 50

8 FL OZ (237 mL)

AUSTRALIAN GOLD BROAD SPECTRUM SPF 50 SUNSCREEN

octisalate, avobenzene, octocrylene, homosalate spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0611
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	49.6 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.7 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.6 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	99.1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARAMEL (UNII: T9D99G2B1R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TEA TREE OIL (UNII: VIF565UC2G)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

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:58443-0611-4	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	10/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/26/2017	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0611) , manufacture(58443-0611) , label(58443-0611) , analysis(58443-0611)

Revised: 3/2023

Prime Enterprises Inc.