

AUSTRALIAN GOLD SPF 30 SUNSCREEN- avobenzone, homosalate, octisalate, 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 Ultimate Hydration 30 Spray Gel Sunscreen

Active Ingredients

Avobenzone 3%

Homosalate 7.5%

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
- **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 10 a.m. – 2 p.m. • wear long-sleeve shirts, pants, hats, and sunglasses • children under 6 months: Ask a doctor

Inactive ingredients

Water/Aqua/Eau, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Glycerin, Phenoxyethanol, Fragrance, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Dimethicone, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Trimethylsiloxysilicate, Sodium Hydroxide, Disodium EDTA, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Tocopheryl Acetate, Hydroxypropyl Methylcellulose, Ethylhexylglycerin, 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 ULTIMATE HYDRATION 30 SPRAY GEL SUNSCREEN

NEW!



Australian
Gold®

ULTIMATE
HYDRATION

NON-GREASY
CRUELTY FREE
OXYBENZONE FREE

30

SPRAY GEL SUNSCREEN

WATER RESISTANT (80 MINUTES)

BROAD SPECTRUM SPF 30

8 FL OZ (237 mL)

Australian Gold.

SPF 30 Spray Gel

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

Drug Facts

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www.AustralianGold.com



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AUSTRALIAN GOLD SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0614
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.25 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	73.13 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.75 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	48.75 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TEA TREE OIL (UNII: VIF565UC2G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
.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)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0614-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	12/14/2019	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0614) , manufacture(58443-0614) , label(58443-0614) , analysis(58443-0614)

Revised: 3/2023

Prime Enterprises Inc.