

AUSTRALIAN GOLD SPF 30- avobenzene, homosalate, octisalate, octocrylene lotion
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.

Active ingredients

Avobenzene 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 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

- apply liberally 15 minutes before sun exposure
- 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 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, C12-15 Alkyl Benzoate, Glycerin, Polyethylene, Phenoxyethanol, Fragrance, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Carbomer, Sodium Hydroxide, Disodium EDTA, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Olea Europaea (Olive) Fruit Oil, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Ethylhexylglycerin, Allantoin, Aloe Barbadensis Leaf Juice, Camellia Oleifera (Green Tea) Leaf Extract, 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)

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label

Label:781104 Date:1/12/2021



press web direction

Australian Gold

SPF 30 Lotion

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

Drug Facts

Active Ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 7.5%	
Octisalate 5%	
Octocrylene 5%	

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Water/Aqua/Eau, C12-15 Alkyl Benzoate, Glycerin, Polyethylene, Phenylethanol, Fragrance (Parfum), Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Carbomer, Sodium Hydroxide, Disodium EDTA, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Olea Europaea (Olive) Fruit Oil, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Ethylhexylglycerin, Alantoin, Aloe Barbadensis Leaf Juice, Camellia Oleifera (Green Tea) Leaf Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Terminalia Pedunculata (Kakade Plum) Fruit Extract

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 www.AustralianGold.com



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723611-001



AUSTRALIAN GOLD SPF 30

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0409
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.87 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	77.175 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	51.45 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	51.45 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
ALLANTOIN (UNII: 344S277G0Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
COCOA BUTTER (UNII: 512OYT1CRR)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0409-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/13/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/13/2021	

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0409) , pack(58443-0409) , manufacture(58443-0409) , analysis(58443-0409)

Revised: 8/2021

Prime Enterprises, Inc.