

AUSTALIAN GOLD SENSITIVE SUN PROTECTION SPF 50- avobenzone, 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.

Australian Gold Little Joey Sensitive Sun Protection SPF 50

INACTIVE INGREDIENTS

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Camellia Sinensis (Green Tea) Leaf Extract, Carbomer, Ethylhexylglycerin, Glycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Olea Europaea (Olive) Fruit Oil, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Tetrasodium Glutamate Diacetate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

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. Keep away from face to avoid breathing it.

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.

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.

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

Active Ingredients

Avobenzone 3.0%

Octocrylene 5.0%

Octisalate 5.0%

Homosalate 10%

Directions

- apply liberally 15 minutes before sun exposure and rub into skin
- 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 value 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

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)

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0333
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.28 mg in 1 mL

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	97.6 mg in 1 mL
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	48.8 mg in 1 mL
OCTOCRYLENE (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	48.8 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
SUNFLOWER OIL (UNII: 3W1JG795Y)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
COCOA BUTTER (UNII: 512OYT1CRR)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TEA TREE OIL (UNII: VIF565UC2G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (Off White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0333-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	06/19/2020	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0333) , manufacture(58443-0333) , label(58443-0333) , analysis(58443-0333)

Revised: 5/2020

Prime Enterprises Inc.