AUSTRALIAN GOLD SPF 30 SPORT ULTRA CHILL- octisalate, avobenzone, homosalate, 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 SPF 30 Sport Ultra Chill

Purpose

Sunscreen

Active Ingredients

Avobenzone 3%

Homosalate 7.5%

Octisalate 5%

Octocrylene 5%

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 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

INACTIVE INGREDIENTS

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

Other Information

- Protect this product from excesive heat and direct sun
- May stain some fabrics or surfaces

Questions or Comments?

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

Australian Gold SPF 30 Lotion Sport Ultra Chill

Australian Gold

SPF 30 Lotion Sport Ultra Chill

Australian Gold's Extreme Sport line is designed for active lifestyles. The sweat activated cooling and odor fighting properties keep skin feeling fresh and fuel your performance so you can celebrate life outside!

- Quick Dry Formula
 Cruelty Free
 Coastal Breeze Fragrance
- Oxybenzone Free
- Gluten Free Antioxidant Rich
- Octinoxate Free
- Vegan
- Phthalate Free

Drug Facts

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

Purpose Sunscreen

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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

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Stop use and ask a doctor if rash occurs

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- 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 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, Aluminum Starch Octenylsuccinate, Polyethylene, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Polysorbate 20, Sodium Hydroxide, Carbomer, Fragrance (Parlum), Cetyl Phosphate, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Menthol, Olea Europaea (Olive) Fruit Methyliceniusse, Mehinor, Olea Europaea (Cirve) From Oil, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Allantoin, Camellia Oleifera (Green Tea) Leaf Extract, Terminalia Ferdinandiana (Kakadu Plum) Fruit Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Phenoxyethanol, Ethylhexylglycerin

Other information

- Protect this product from excessive heat and direct sun
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Questions or comments? Call toll free 1-855-LIV-GOLD (548-4653)

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AUSTRALIAN GOLD SPF 30 SPORT ULTRA CHILL

octisalate, avobenzone, homosalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0501
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	74.48 mg in 1 mL	
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	49.65 mg in 1 mL	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.79 mg in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.65 mg in 1 mL	

Inactive Ingredients	
Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
CETYL PHOSPHATE (UNII: VT07D6X67O)	
ALUMINUM STARCH OCTENYLSUCCINATE (UNII: 19PJ006294)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAKADU PLUM (UNII: 0ZQ1D2FDLI)	
MENTHOL (UNII: L7T10EIP3A)	
TEA TREE OIL (UNII: VIF565UC2G)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
COCOA BUTTER (UNII: 5120YT1CRR)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
ALLANTOIN (UNII: 344S277G0Z)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	

Contains

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443- 0501-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/03/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	07/03/2019	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0501) , manufacture(58443-0501) , label(58443-0501) , analysis (58443-0501)

Revised: 1/2022 Prime Enterprises Inc.