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 Lotion

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



BROAD SPECTRUM SPF 30

8 FL OZ (237 mL)

Australian Gold.

SPF 30 Lotion Sport Ultra Chill

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

- · Quick Dry Formula · Cruelty Free · Coastal Breeze Fragrance

- Octinoxate Free
- Vegan
- · Phthalate Free

Drug Facts

Active Ingredients Avobenzone 3% 7.5% Homosalate Octisalate

Purpose Sunscreen

Octocrylene

helps prevent sunburn

5%

· 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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When using this product keep out of eyes. Rinse with water to remove.

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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 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 Juloe, C12-15 Alkyl Benzoate, Glycerin, Aluminum Starch Octenylsuccinate, Polyethylene, Phenoxyethanol, Acrylates/C10-30 Alkyl Acrylate Crosspólymer, Polysórbate 20, Sodium Hydroxide, Carbomer, Fragrance, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Hydroxypropyl Methylcelulosa, Ethylhexylglycerin, Allantoin, Menthol, Camellia Oleifera (Green Tea) Leaf Extract, Sodium Chloride, Cetyl Phosphate, Melaleuca Alternifolia (Tea Tree) Leaf Oil

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)

62022 Australian Gold, Country of Origin USA Distributed by Australian Gold, Indianapolis, IN 46278





AUSTRALIAN GOLD SPF 30 SPORT ULTRA CHILL

octisalate, avobenzone, homosalate, octocrylene lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:58443-0602

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) | AVOBENZ ONE | 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) | |
| 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 | | |

| Packaging | | | | |
|-----------|----------------------|---|-------------------------|-----------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:58443- 0602-4 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/14/2019 | |

| Marketing Information | | | | |
|-------------------------|---|-------------------------|-----------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph not final | part352 | 10/14/2019 | | |
| | | | | |

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

| Establishment | | | |
|------------------------|---------|-----------|--|
| Name | Address | ID/FEI | Business Operations |
| Prime Enterprises Inc. | | 101946028 | pack(58443-0602) , manufacture(58443-0602) , label(58443-0602) , analysis (58443-0602) |

Revised: 12/2022 Prime Enterprises Inc.