

**AUSTALIAN GOLD SPF 6 SUNSCREEN LOW PROTECTION- n/a 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 Spray Oil Sunscreen SPF 6 LOW PROTECTION

Active Ingredients

Avobenzone 1%

Octocrylene 0.85%

Oxybenzone 0.5%

Purpose

Sunscreen

Uses

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

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
- children under 6 months: Ask a doctor

INACTIVE INGREDIENTS

Acetylated Lanolin Alcohol, Aloe Barbadensis Leaf Extract, BHT, Caprylic/Capric Triglyceride, Cetyl Acetate, Daucus Carota Sativa (Carrot) Seed Oil, Diethylhexyl Syringylidenemalonate, Fragrance, Glycine Soja (Soybean) Oil, Helianthus Annuus

(Sunflower) Seed Oil, Isopropyl Lanolate, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Olea Europaea (Olive) Fruit Oil, Terminalia Ferdinandiana (Kakadu Plum) Seed Oil, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, VP/Hexadecene Copolymer

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 Spray Oil Sunscreen Hydrating formula SPF 6 LOW PROTECTION

Drug Facts

| Active Ingredients | Purpose |
|--------------------|-----------|
| Avobenzone 1% | Sunscreen |
| Octocrylene 0.85% | |
| Oxybenzone 0.5% | |

Uses

- helps prevent sunburn

Warnings

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

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.

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www.AustralianGold.com

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AUSTALIAN GOLD SPF 6 SUNSCREEN LOW PROTECTION

n/a spray

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58443-0318 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 7.65 mg in 1 mL |
| OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y) | OXYBENZONE | 4.5 mg in 1 mL |
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 9 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| TEA TREE OIL (UNII: VIF565UC2G) | |
| ACETYLATED LANOLIN ALCOHOLS (UNII: SNN716810P) | |
| VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| LANOLIN ACID (UNII: D1CZ545P7Z) | |
| SOYBEAN OIL (UNII: 241ATL177A) | |
| LIMONENE, (+)- (UNII: GFD7C86Q1W) | |
| FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK) | |
| SUNFLOWER OIL (UNII: 3W1JG795YI) | |
| OLIVE OIL (UNII: 6UYK2W1W1E) | |
| KAKADU PLUM (UNII: 0ZQ1D2FDLI) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CETYL ACETATE (UNII: 4Q43814HXS) | |
| CARROT SEED OIL (UNII: 595AO13F11) | |
| COCOA BUTTER (UNII: 512OYT1CRR) | |
| CITRAL (UNII: T7EU0O9VPP) | |
| LINALOOL, (+/-)- (UNII: D81QY6I88E) | |
| COUMARIN (UNII: A4VZ22K1WT) | |
| DIETHYLHEXYL SYRINGYLIDENEMALONATE (UNII: 3V5U97P248) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|--|
| Color | yellow | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:58443-0318-4 | 237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 01/30/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
|--------------------|--|----------------------|--------------------|

| | | | |
|---------------------|---------|------------|--|
| OTC monograph final | part352 | 01/30/2017 | |
|---------------------|---------|------------|--|

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|---|
| Prime Enterprises Inc. | | 101946028 | pack(58443-0318) , manufacture(58443-0318) , label(58443-0318) , analysis(58443-0318) |

Revised: 9/2022

Prime Enterprises Inc.