

**AUSTRALIAN GOLD BROAD SPECTRUM SPF 50- 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.*

-----

**Australian Gold Plant Based Lotion Sunscreen Broad Spectrum SPF 50**

**Active ingredients**

Avobenzene 3 %, Homosalate 10 %, 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 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**

Aloe Barbadensis Leaf Juice, Water, Cocos Nucifera (Coconut) Oil, Glycerin, Tapioca Starch, VP/Acrylates/Lauryl Methacrylate Copolymer, Phenoxyethanol, Acrylic Acid/VP Crosspolymer, Fragrance, Sodium Hydroxide, Caprylyl Glycol, Polyacrylate-13, Ethylhexylglycerin, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Polyisobutene, Polymethylsilsesquioxane, Polysorbate 20

## **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**



**Australian Gold**

PLANT-BASED

50

LOTION SUNSCREEN

*aloe & coconut*

WATER RESISTANT (80 MINUTES)  
BROAD SPECTRUM SPF 50

6 FL OZ (177 mL)

Use the natural and effective power of plants to support healthy skin. Made with Aloe Vera and Coconut Oil, this lotion is packed with nutrients your skin will love. Broad Spectrum coverage offers protection from aging UVA rays and burning UVB rays so you can be free to celebrate life outside.



This container was made with over 50% recycled materials, which creates unique imperfections.

| Drug Facts  |                |
|---|----------------|
| <b>Active Ingredients</b>   | <b>Purpose</b> |
| Avobenzone 3%, Homosalate 10%,<br>Octisalate 5%, Octocrylene 5%   | Sunscreen      |
| <b>Uses</b>   |                |
| • helps prevent sunburn • if used as directed with other sun protection measures (see <b>Directions</b> ), decreases the risk of skin cancer and early skin aging caused by the sun   |                |
| <b>Warnings</b>   |                |
| 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.   |                |
| <b>Directions</b>   |                |
| • apply liberally 15 minutes before sun exposure  |                |
| • reapply:  |                |
| • after 80 minutes of swimming or sweating  |                |
| • immediately after towel drying  |                |
| • at least every 2 hours  |                |
| • <b>Sun Protection Measures.</b> 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   |                |
| <b>Inactive ingredients</b>   |                |
| Aloe Barbadensis Leaf Juice, Water/Aqua/Eau, Cocos Nucifera (Coconut) Oil, Glycerin, Tapioca Starch, VP/Acrylates/Lauryl Methacrylate Copolymer, Phenoxyethanol, Acrylic Acid/VP Crosspolymer, Fragrance (Parfum), Sodium Hydroxide, Caprylyl Glycol, Polyacrylate-13, Ethylhexylglycerin, Tocopheryl Acetate, Tetrasodium Glutamate Diacetate, Polyisobutene, Polymethylsilsesquioxane, Polysorbate 20 |                |
| <b>Other information</b>  |                |
| • Protect this product from excessive heat and direct sun   |                |
| • May stain some fabrics or surfaces  |                |
| <b>Questions or comments?</b>   |                |
| Call 1-855-LN-GOLD (548-4653)   |                |

\* Vitamin E

\* Hawaii compliant – no Oxybenzone or Octinoxate

©2020 Australian Gold, Country of Origin USA  
Distributed by Australian Gold, Indianapolis, IN 46278  
www.AustralianGold.com

170940  
100330-001



## AUSTRALIAN GOLD BROAD SPECTRUM SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

|                                |                |                           |                |
|--------------------------------|----------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:58443-0459 |
| <b>Route of Administration</b> | TOPICAL        |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength | Strength         |
|---|-------------------|------------------|
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE        | 29.07 mg in 1 mL |
| <b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE        | 96.9 mg in 1 mL  |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE        | 48.45 mg in 1 mL |
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 48.5 mg in 1 mL  |

## Inactive Ingredients

| Ingredient Name   | Strength |
|---|----------|
| <b>N-VINYLPYRROLIDINONE</b> (UNII: 76H9G81541)  |          |
| <b>STARCH, TAPIOCA</b> (UNII: 24SC3U704I)   |          |
| <b>POLYMETHYLSILSESQUIOXANE (4.5 MICRONS)</b> (UNII: 59Z907ZB69)                        |          |
| <b>POLYISOBUTYLENE (1000 MW)</b> (UNII: 5XB3A63Y52)                                     |          |
| <b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)  |          |
| <b>POLYACRYLAMIDE (1300000 MW)</b> (UNII: SC5Y4X78TG)                                   |          |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)  |          |
| <b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)   |          |
| <b>TETRASODIUM GLUTAMATE DIACETATE</b> (UNII: 5EHL50I4MY)                               |          |
| <b>WATER</b> (UNII: 059QF0KO0R)   |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)  |          |
| <b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L) |          |
| <b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)  |          |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)   |          |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)  |          |
| <b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)                                    |          |
| <b>LAURYL METHACRYLATE</b> (UNII: B6L83074BZ)   |          |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)  |          |

## Product Characteristics

|                 |       |                     |  |
|-----------------|-------|---------------------|--|
| <b>Color</b>    | white | <b>Score</b>        |  |
| <b>Shape</b>    |       | <b>Size</b>         |  |
| <b>Flavor</b>   |       | <b>Imprint Code</b> |  |
| <b>Contains</b> |       |                     |  |

## Packaging

| # | Item Code        | Package Description                                 | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:58443-0459-4 | 177 mL in 1 TUBE; Type 0: Not a Combination Product | 11/23/2020           |                    |

## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352                                  | 11/23/2020           |                    |

**Labeler** - Prime Enterprises, Inc. (101946028)

**Registrant** - Prime Enterprises, Inc. (101946028)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|------|---------|--------|---------------------|
|------|---------|--------|---------------------|

|                         |           |   |
|-------------------------|-----------|---|
| Prime Enterprises, Inc. | 101946028 | label(58443-0459) , pack(58443-0459) , manufacture(58443-0459) , analysis(58443-0459) |
|-------------------------|-----------|---|

Revised: 12/2021

Prime Enterprises, Inc.