

**BLACK GIRL SUNSCREEN SPF 45- avobenzone, homosalate, octisalate, octocrylene gel**  
**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.*

-----

**Black Girl Sunscreen Broad Spectrum SPF 45 Ultra Sheer Sunscreen Gel**

**Active Ingredients**

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 10%

**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**

**Do not use** on damaged or broken skin

**When using this product**

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

**Stop use and ask a doctor**

**Stop use and ask a doctor** if rash occurs

**Keep out of reach of children.**

**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-sleeved shirts, pants, hats and sunglasses

children under 6 months: Ask a doctor.

Diisopropyl Adipate, Diisopropyl Sebacate, Cetyl Ethylhexanoate, Neopentyl Glycol Diethylhexanoate, Silica Silylate, VP/Hexadecene Copolymer, Silica, Butyrospermum Parkii (Shea) Butter, Squalane, Tocopheryl Acetate, Cocos Nucifera (Coconut) Oil, Aloe Barbadensis Leaf Extract

## **Other information**

Protect this product from excessive heat and direct sun

**PRINCIPAL DISPLAY LABEL - 1.7oz Black Girl Sunscreen Broad Spectrum SPF 45 Ultra Sheer Sunscreen Gel**



## BLACK GIRL SUNSCREEN SPF 45

avobenzone, homosalate, octisalate, octocrylene gel

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:58443-0629

|                         |         |
|-------------------------|---------|
| Route of Administration | TOPICAL |
|-------------------------|---------|

Active Ingredient/Active Moiety

| Ingredient Name                                                       | Basis of Strength | Strength        |
|-----------------------------------------------------------------------|-------------------|-----------------|
| <b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE       | 95 mg in 1 mL   |
| <b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)   | OCTISALATE        | 47.5 mg in 1 mL |
| <b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)   | AVOBENZONE        | 28.5 mg in 1 mL |
| <b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)   | HOMOSALATE        | 95 mg in 1 mL   |

Inactive Ingredients

| Ingredient Name                                                 | Strength |
|-----------------------------------------------------------------|----------|
| <b>CETYL ETHYLHEXANOATE</b> (UNII: 134647WMX4)                  |          |
| <b>NEOPENTYL GLYCOL DIETHYLHEXANOATE</b> (UNII: U68ZV6W62C)     |          |
| <b>VINYLPYRROLIDONE/HEXADECENE COPOLYMER</b> (UNII: KFR5QEN0N9) |          |
| <b>COCONUT OIL</b> (UNII: Q9L0O73W7L)                           |          |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                           |          |
| <b>DIISOPROPYL ADIPATE</b> (UNII: P7E6YFV72X)                   |          |
| <b>DIISOPROPYL SEBACATE</b> (UNII: J8T3X564IH)                  |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                       |          |
| <b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)              |          |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                        |          |
| <b>SQUALANE</b> (UNII: GW89575KF9)                              |          |

Product Characteristics

|          |                       |              |  |
|----------|-----------------------|--------------|--|
| Color    | yellow (Light Yellow) | Score        |  |
| Shape    |                       | Size         |  |
| Flavor   |                       | Imprint Code |  |
| Contains |                       |              |  |

Packaging

| # | Item Code        | Package Description                                | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------------------------------|----------------------|--------------------|
| 1 | NDC:58443-0629-3 | 50 mL in 1 TUBE; Type 0: Not a Combination Product | 08/04/2023           |                    |

Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|------------------------------------------|----------------------|--------------------|
| OTC monograph final | M020                                     | 08/04/2023           |                    |

Labeler - Prime Enterprises, Inc. (101946028)

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

## Establishment

| Name                    | Address | ID/FEI    | Business Operations                                                                   |
|-------------------------|---------|-----------|---------------------------------------------------------------------------------------|
| Prime Enterprises, Inc. |         | 101946028 | manufacture(58443-0629) , label(58443-0629) , analysis(58443-0629) , pack(58443-0629) |

Revised: 8/2023

Prime Enterprises, Inc.