

**BLACK GIRL SUNSCREEN SUNSCREEN SPF 30 BROAD SPECTRUM- avobenzone, homosalate, octisalate, and 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.*

-----  
**Black Girl Sunscreen Broad Spectrum SPF 30 Ultra Sheer Lotion**

***Active Ingredients***

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 2.75%

***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, specially from 10 a.m. - 2 p.m.
- wear long-sleeve shirts, pants, hats & sunglasses.
- children under 6 months: Ask a doctor.

### ***Inactive ingredients***

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aloe Barbadensis Leaf Juice, Butylphthalimide, Carbomer, Daucus Carota Sativa (Carrot) Seed Oil, Disodium EDTA, Ethylhexylglycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Lecithin, Persea Gratissima (Avocado) Oil, Phenoxyethanol, Propylene Glycol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water, Olus Oil

### ***Other Information***

- protect this product from excessive heat and direct sun

## **Black Girl Sunscreen Little Mermaid SPF 30 Sunscreen Lotion for Face and Body**



Be Empowered by  
the Beauty of Your Skin

**Drug Facts**

Active ingredients	Purpose
Avobenzone 3% Homosalate 10% Octisalate 5% Octocrylene 2.75%	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-sleeved shirts, pants, hats, and sunglasses  
 • children under 6 months: Ask a doctor.

**Inactive ingredients**  
 Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Acrylates/C12-22 Alkyl Methacrylate Copolymer, Aloe Barbadensis Leaf Juice, Butylphthalimide, Carbomer, Daucus Carota Sativa (Carrot) Seed Oil, Disodium EDTA, Ethylhexylglycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Isopropylphthalimide, Lecithin, Persea Gratissima (Avocado) Oil, Phenoxethanol, Propylene Glycol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water, Olus Oil

**Other information:**  
 • protect this product from excessive heat and direct sun



Manufactured for:  
**Black Girl Sunscreen, LLC**  
 P.O.Box 8260 • Van Nuys, CA 91409  
 www.blackgirlsunscreen.com  
**Made in USA**  
 From US and imported ingredients  
 ©Disney



BLACK GIRL  
SUNSCREEN®

Disney  
THE  
LITTLE  
MERMAID



30

BROAD SPECTRUM SPF 30  
Water Resistant for 80 Min.

3 FL OZ. | MOISTURIZING  
(89mL) | SUNSCREEN  
LOTION

**BLACK GIRL SUNSCREEN SUNSCREEN SPF 30 BROAD SPECTRUM**

avobenzone, homosalate, octisalate, and octocrylene lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0638
<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	29.4 mg in 1 mL

<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	98 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	26.95 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED)</b> (UNII: 71DD5V995L)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>AVOCADO OIL</b> (UNII: 6VNO72PFC1)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>CARROT SEED OIL</b> (UNII: 595AO13F11)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ISOPROPYLPHTHALIMIDE</b> (UNII: 1J1MM83329)	
<b>SUNFLOWER SEED</b> (UNII: R9N3379M4Z)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>N-BUTYLPHTHALIMIDE</b> (UNII: 5TH1DKT35E)	
<b>CARBOMER HOMOPOLYMER TYPE C</b> (UNII: 4Q93RCW27E)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

## Product Characteristics

<b>Color</b>	white (Off 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:58443-0638-3	89 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(58443-0638) , analysis(58443-0638) , pack(58443-0638) , label(58443-0638)

Revised: 8/2023

Prime Enterprises Inc.