

**BLACK GIRL SUNSCREEN SPF 50 BROAD SPECTRUM- avobenzone, homosalate, octisalate 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.*

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**Black Girl Sunscreen Kids Moisturizing Sunscreen Lotion for Face and Body 50 Broad Spectrum SPF 50**

***Active Ingredients***

Avobenzone 3%

Homosalate 15%

Octisalate 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, 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, Butyrospermum Parkii (Shea) Butter, Carbomer, Chamomilla Recutita (Matricaria) Flower Extract, Daucus Carota Sativa (Carrot) Seed Oil, Disodium EDTA, Ethylhexylglycerin, Helianthus Annuus (Sunflower) Seed Oil, Hydroxypropyl Methylcellulose, Lecithin, Persea Gratissima (Avocado) Oil, Phenoxyethanol, Propylene Glycol, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hydroxide, Sorbitan Oleate, Tocopheryl Acetate, Water

## Other Information

- protect this product from excessive heat and direct sun

## Black Girl Sunscreen Kids Moisturizing Sunscreen Lotion for Face and Body 50 Broad Spectrum SPF 50

**BLACK GIRL SUNSCREEN**  
Bye bye umbrella

**BLACK GIRL SUNSCREEN**

**kids**

**MOISTURIZING SUNSCREEN LOTION FOR FACE AND BODY**

**50**

**BROAD SPECTRUM SPF 50**  
Water Resistant (80 minutes)

**No Parabens, Fragrance**  
**Oxybenzone & Octinoxate**

**WHITE RESIDUE FREE**  
3 FL OZ. (89mL)

**Drug Facts**

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Octisalate 5%	

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**Other information:**

- protect this product from excessive heat and direct sun

Manufactured for:  
**Black Girl Sunscreen, Inc.**  
P.O. Box 8260  
Van Nuys, CA 91409  
www.blackgirlsunscreen.com

**Made in USA**  
From US and imported ingredients

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# BLACK GIRL SUNSCREEN SPF 50 BROAD SPECTRUM

avobenzone, homosalate, octisalate lotion

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0294
Route of Administration	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.16 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	145.8 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.6 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARROT SEED OIL (UNII: 595AO13F11)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
WATER (UNII: 059QF0K00R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SUNFLOWER SEED (UNII: R9N3379M4Z)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
JOJOBA OIL (UNII: 724GKU717M)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CARBOMER 980 (UNII: 4Q93RCW27E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SHEA BUTTER (UNII: K49155WL9Y)	
CHAMOMILE (UNII: FGL3685T2X)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	

## Product Characteristics

Color	white (White to off white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0294-3	89 mL in 1 TUBE; Type 0: Not a Combination Product	04/29/2019	

  

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/29/2019	

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

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

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(58443-0294) , analysis(58443-0294) , pack(58443-0294) , label(58443-0294)

Revised: 1/2020

Prime Enterprises Inc.