

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

Other Information

- protect this product from excessive heat and direct sun

Black Girl Sunscreen SPF 30 Sunscreen Lotion for Face and Body



Bye bye umbrella®

Drug Facts

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Manufactured for:
 Black Girl Sunscreen, Inc.
 P.O. Box 8260
 Van Nuys, CA 91409
 www.blackgirlsunscreens.com
Made in USA
 From US and imported ingredients

BLACK GIRL SUNSCREEN®

MOISTURIZING SUNSCREEN LOTION FOR FACE AND BODY

30

BROAD SPECTRUM SPF 30
 INFUSED WITH JOJOBA AND AVOCADO
 Water Resistant (80 minutes)
 Oxybenzone and Octinoxate Free
 ULTRA SHEER
 NO WHITE RESIDUE
 FRAGRANCE FREE
 3 FL OZ. (89mL)

BLACK GIRL SUNSCREEN SUNSCREEN SPF 30 BROAD SPECTRUM

avobenzone, homosalate, octisalate, and octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0636
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.4 mg in 1 mL

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

Inactive Ingredients

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

Product Characteristics

Color	white (Off white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0636-3	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(58443-0636) , analysis(58443-0636) , pack(58443-0636) , label(58443-0636)

Revised: 8/2023

Prime Enterprises Inc.