

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.

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, especially from 10 a.m. - 2 p.m.
- wear long-sleeved 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

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50 Broad Spectrum SPF 50**



Bye bye umbrella®

Drug Facts

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



BLACK GIRL SUNSCREEN®

kids

MOISTURIZING SUNSCREEN LOTION FOR FACE AND BODY

50

BROAD SPECTRUM SPF 50

Water Resistant (80 minutes)

Paraben & Fragrance Free

NO WHITE RESIDUE

6 FL OZ. (178mL)

BLACK GIRL SUNSCREEN SPF 50 BROAD SPECTRUM

avobenzone, homosalate, octisalate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0625
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	28.77 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	143.85 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	47.95 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: 059QF0KO0R)	
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)	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)	
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:58443-0625-4	178 mL in 1 TUBE; Type 0: Not a Combination Product	04/22/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	04/22/2019	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(58443-0625) , analysis(58443-0625) , pack(58443-0625) , label(58443-0625)

Revised: 7/2023

Prime Enterprises Inc.