

BLACK GIRL SUNSCREEN SPF 50 BROAD SPECTRUM- homosalate, octocrylene, octisalate, zinc oxide 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 Mineral Combo Sunscreen Lotion for Face & Body 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

Acrylic Acid/VP Crosspolymer, Aloe Barbadensis Leaf Juice, Butyrospermum Parkii (Shea) Butter, Caprylhydroxamic Acid, Caprylic/Capric Triglyceride, Daucus Carota Sativa (Carrot) Seed Oil, Ethyl Ferulate, Glycerin, Glyceryl Caprylate, Glyceryl Undecylenate, Helianthus Annuus (Sunflower) Seed Oil, Lavandula Angustifolia (Lavender) Oil, Olus Oil, Persea Gratissima (Avocado) Oil, Pongamia Pinnata Seed Extract, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hydroxide, Tetrasodium Glutamate Diacetate , Tocopheryl Acetate, Triethoxycaprylylsilane, VP/Acrylates/Lauryl Methacrylate Copolymer, Water

Other Information

- protect this product from excessive heat and direct sun

Black Girl Sunscreen Mineral Combo Sunscreen Lotion for Face & Body Broad Spectrum SPF 50



Drug Facts

Active ingredients	Purpose
Homosalate 10% Octisalate 5% Octocrylene 5% Zinc Oxide 5%	} Sunscreen

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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

MAKE IT HYBRID

Mineral Combo

SUNSCREEN LOTION FOR FACE & BODY

50

BROAD SPECTRUM SPF 50

Fragrance Free

WATER RESISTANT (80 minutes)

3 FL OZ. (89mL)

BLACK GIRL SUNSCREEN SPF 50 BROAD SPECTRUM

homosalate, octocrylene, octisalate, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0509
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	50 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	50 mg in 1 mL

HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
CORN OIL (UNII: 8470G57WFM)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
ETHYL FERULATE (UNII: 5B8915UELW)	
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)	
MILLETTIA PINNATA SEED (UNII: C2BRV53B1V)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
CARROT SEED OIL (UNII: 595AO13F11)	
WATER (UNII: 059QF0KO0R)	
SUNFLOWER SEED (UNII: R9N3379M4Z)	
JOJOBA OIL (UNII: 724GKU717M)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SHEA BUTTER (UNII: K49155WL9Y)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	

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:58443-0509-3	89 mL in 1 TUBE; Type 0: Not a Combination Product	11/24/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/24/2021	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc		101946028	manufacture(58443-0509) , analysis(58443-0509) , pack(58443-0509) , label(58443-0509)

Revised: 1/2022

Prime Enterprises Inc.