BLACK GIRL SUNSCREEN SPF 50- octocrylene, octisalate, homosalate, avobenzone gel Prime Enterprises

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 Make it Pop SPF 50 Sun Gloss for Lips

Active ingredients

Octocrylene 9%

Octisalate 5%

Homosalate 4.5%

Avobenzone 3%

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 swalloed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure
- use a water resistant sunscreen if swimming or sweating
- reapply 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 am to 2 pm • wear long-sleeved shirts, pants, hats, and sunglasses
- children under 6 months: ask a doctor

Inactive ingredients

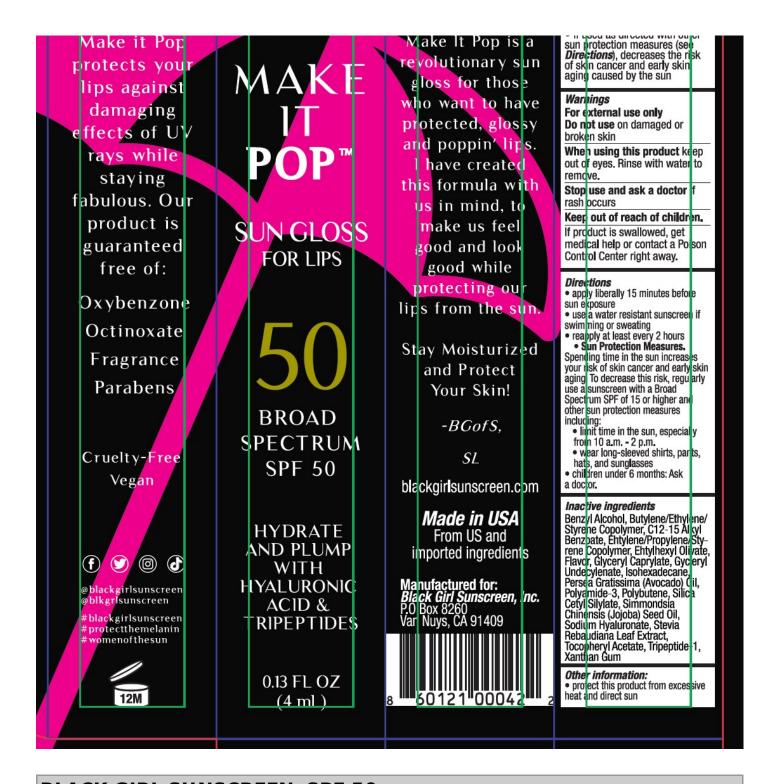
Benzyl Alcohol, Butylene/Ethylene/Styrene Copolymer, C12-15 Alkyl Benzoate, Ethylene/Propylene/Styrene Copolymer, Ethylhexyl Olivate, Flavor, Glyceryl Caprylate, Glyceryl Undecylenate, Isohexadecane, Persea Gratissima (Avocado) Oil, Polyamide-3, Polybutene, Silica Cetyl Silylate, Simmondsia Chinensis (Jojoba) Seed Oil, Sodium Hyaluronate, Stevia Rebaudiana Leaf Extract, Tocopheryl Acetate, Tripeptide-1, Xanthan Gum

Other Information

protect this product from excessive heat and direct sun

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BLACK GIRL SUNSCREEN SPF 50

octocrylene, octisalate, homosalate, avobenzone gel

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:58443-0632 Route of Administration TOPICAL Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	44.5 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZ ONE	26.7 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	40.05 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	80.1 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)			
POLYAMIDE-3 (20000 MW) (UNII: PLF06VZ9SQ)			
POLYBUTENE (1400 MW) (UNII: 1NA5AO9GH7)			
STEVIA LEAF (UNII: 6TC6NN0876)			
1-BUTENE (UNII: LY001N554L)			
ETHYLENE (UNII: 91GW059KN7)			
STYRENE (UNII: 44LJ2U959V)			
GLYCERYL CAPRYLATE (UNII: TM2TZ D4G4A)			
GLYCERYL 1-UNDECYLENATE (UNII: B68LJT9544)			
ISOHEXADECANE (UNII: 918X1OUF1E)			
AVOCADO OIL (UNII: 6VNO72PFC1)			
HYALURONATE SODIUM (UNII: YSE9PPT4TH)			
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
XANTHAN GUM (UNII: TTV12P4NEE)			
JOJOBA OIL (UNII: 724GKU717M)			
BENZYL ALCOHOL (UNII: LKG8494WBH)			
PROPYLENE (UNII: AUG1H506LY)			
PREZATIDE (UNII: 39TG2H631E)			

Product Characteristics			
Color	yellow (Hint of Yellow to Light Yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:58443- 0632-2	4 mL in 1 BOTTLE, WTH APPLICATOR; 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	

Registrant - Prime Enterprises (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises		101946028	analysis(58443-0632), label(58443-0632), manufacture(58443-0632), pack(58443-0632)

Revised: 8/2023 Prime Enterprises