## BLACK GIRL SUNSCREEN SPF45- avobenzone, homosalate, octisalate, octocrylene gel 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 Make it Matte Broad Spectrum SPF 45

### **Active Ingredients**

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 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, and sunglasses

children under 6 months: Ask a doctor.

## Inactive ingredients

Aloe Barbadensis Leaf Extract, Butyrospermum Parkii (Shea) Butter, Cocos Nucifera (Coconut) Oil, Dimethicone Crosspolymer-3, Isododecane, Silica, Squalane, Tocopheryl Acetate

#### Other information:

protect this product from excessive heat and direct sun

Black Girl Sunscreen Make It Matte Broad Spectrum SPF 45



#### **BLACK GIRL SUNSCREEN SPF45**

avobenzone, homosalate, octisalate, octocrylene gel

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:58443-0398 Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	79 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	39.5 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	23.7 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	39.5 mg in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
SHEA BUTTER (UNII: K49155WL9Y)			
ISODODECANE (UNII: A8289P68Y2)			
SQUALANE (UNII: GW89575KF9)			
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
COCONUT OIL (UNII: Q9L0O73W7L)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			

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

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:58443- 0398-3	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/19/2021		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/19/2021	

## Labeler - Prime Enterprises, Inc. (101946028)

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

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	manufacture(58443-0398) , pack(58443-0398) , label(58443-0398) , analysis (58443-0398)

Revised: 2/2021 Prime Enterprises, Inc.