

**FLORIDA GLOW SPF 50- avobenzene, homosalate, octisalate,  
octocrylene lotion  
Prime Enterprises, Inc.**

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**Florida Glow Face + Body SPF 50 Sunscreen Lotion**

***Active ingredients***

Avobenzene 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.

**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 sleeve shirts, pants, hats, & sunglasses

- children under 6 months: Ask a doctor

### ***Inactive ingredients***

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Ethylhexylglycerin, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polyethylene, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

### ***Other information***

- protect this product from heat and direct sun
- may stain or damage some fabrics or surfaces

### ***Questions or comments?***

Call 1(800) 931-9254

**Florida Glow SPF 50 Face + Body Sunscreen Lotion**



SPF  
**50**

**FACE + BODY  
SUNSCREEN LOTION**

BROAD SPECTRUM SPF 50  
WATER RESISTANT  
(80 MINUTES)

**COCOA BUTTER + ALOE**

Hydrating Formula  
Fragrance Free

Net Wt. 8fl. oz (237 mL)

## Drug Facts

### Active Ingredients

Homosalate	10%
Octisalate	5%
Octocrylene	5%
Avobenzone	3%



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## FLORIDA GLOW SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0641
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	101 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50.5 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	50.5 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30.3 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>WATER</b> (UNII: 059QF0KO0R)	

## Product Characteristics

<b>Color</b>	white (White)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0641-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/23/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/23/2021	

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

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

### **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Prime Enterprises, Inc.		101946028	manufacture(58443-0641) , label(58443-0641) , analysis(58443-0641) , pack(58443-0641)

Revised: 11/2023

Prime Enterprises, Inc.