## SUN BUM FACE 50 SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene cream SUN BUM, LLC

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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#### Sun Bum Face 50 Sunscreen Lotion

#### **Drug Facts**

#### **Active Ingredients**

Avobenzone 3 %, Homosalate 10%

Octisalate 5.%, Octocrylene 10%

#### 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 swallowed, get medical help or contact a Poison Control Center immediately.

#### 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.
- children under 6 months of age: ask a doctor.
- **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, and sunglasses.

#### **Other Information**

• protect this product from excessive heat and direct sun.

#### **Inactive Ingredients**

water, butyloctyl salicylate, hydrated silica, VP/hexadecene copolymer, styrene/acrylates copolymer, dimethicone, polyester-8, tocopherol acetate, BHT, glyceryl stearate, PEG-100 stearate, ethylhexyl stearate, behenyl alcohol, caprylyl methicone, trimethylsiloxysilicate, dimethyl capramide, sodium polyacrylate, xanthan gum, trideceth-

6, disodium EDTA, ethylhexylglycerin, polyaminopropyl biguanide, methylisothiazolinone

#### **Questions or Comments?**

call +1 (877) 978-6286

#### Package Labeling:

No lacquer area. All copy must be below the eye mark.

#### Trust The Bum®

Drug Facts	
Active ingredients wobenzone 3%, Homosala	Purpose
Octisalate 5%, Octocrylene 1	10% Sunscreen
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Varnings For external use only	
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uestions? call 1-877-978	
Exclusively Manufacture Sun Bum, LLC, Cocoa © 2017 Sun Bum, LLC,	ed for and Distributed by Beach, FL, 32932 USA

# **Face 50** UVA / UVB Broad Spectrum SPF 50 Water Resistant (80 Minutes) Lightweight • Oil Free Fragrance Free, Break-Out Free Dermatologist Tested Gluten Free Vegan

3 FL OZ / 88 mL

**Premium Sunscreen Face Lotion** 

### **SUN BUM FACE 50 SUNSCREEN**

avobenzone, homosalate, octisalate, octocrylene cream

Product Information						
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-250			
Route of Administration	TOPICAL					
Active Ingredient/Active Moiety						
Active migredient/Active Molecy						

Ingredient Name AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	Basis of Strengt AVOBENZ ONE HOMOSALATE OCTISALATE	h Strength 30 mg in 1 mL 100 mg in 1 ml
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) DCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	HOMOSALATE	3
DCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)		100 mg in 1 m
	OCTISALATE	100 mg m 1 m
CTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)		50 mg in 1 mL
	) OCTOCRYLENE	100 mg in 1 m
nactive Ingredients		
Ingredient Name		Strength
NATER (UNII: 059QF0KO0R)		
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)		
HYDRATED SILICA (UNII: Y6O7T4G8P9)		
/INYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)		
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)		
PEG-100 STEARATE (UNII: YD01N1999R)		
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)		
DOCOSANOL (UNII: 9G10E216XY)		
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)		
DIMETHYL CAPRAMIDE (UNII: 029Y6X2JEZ)		
KANTHAN GUM (UNII: TTV12P4NEE)		
TRIDECETH-6 (UNII: 3T5PCR2H0C)		
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)		
Packaging		
м	larketing Start M	larketing End
# Item Code Package Description	Date	Date
NDC:69039-250- 88.7 mL in 1 TUBE; Type 0: Not a Combination 10/0 Product 10/0	05/2017	
Marketing Information		

OTC monograph not part352 10/05/2017	Marketing	Application Number or Monograph	Marketing Start	Marketing End
	Category	Citation	Date	Date
	OTC monograph not final	part352	10/05/2017	

## Labeler - SUN BUM, LLC (028642574)