

**SUN BUM SPF 50 PREMIUM MOISTURIZING SUNSCREEN- avobenzone, homosalate, octisalate, octocrylene lotion**

**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 SPF 50 Premium Moisturizing Sunscreen**

***Drug Facts***

***Active Ingredients***

Avobenzone 3.00%, Homosalate 10.00%

Octisalate 5.00%, Octocrylene 10.00%

***Purpose***

Sunscreen

***Uses***

- Helps prevent sunburn.
- higher SPF gives more sunburn protection.
- 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 am - 2 pm.
- Wear long-sleeve shirts, pants, hats, and sunglasses.
- Children under 6 months: Ask a doctor.

***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, Caprylyl Methicone, Ethylhexyl Stearate, Trideceth-6, Glyceryl Stearate, PEG-100 Stearate, Fragrance, Sodium Polyacrylate, Behenyl Alcohol, Dimethyl Capramide, Ethylhexylglycerin, Trimethylsiloxysilicate, Xanthan Gum, Polyaminopropyl Biguanide, Tocopheryl Acetate, BHT, Disodium EDTA, Methylisothiazolinone.

***Questions or Comments?***

Call +1 (877) 978-6286

***Package Labeling:***

Premium Moisturizing Sunscreen Lotion



50

Broad Spectrum SPF 50  
UVA / UVB Protection With Parsol® 1789  
Water Resistant (80 Minutes)

Gluten Free and Vegan  
Antioxidant Enriched (Vitamin E)  
Dermatologist Tested

3 FL OZ / 88 mL e

Sun Bum® sunscreens are carefully formulated to protect those of us who live and love in the sun.

Trust The Bum®

- Paraben Free
- Vegan
- Oxybenzone Free
- Oil / PABA Free
- Cruelty Free
- Non-Comedogenic
- Hypoallergenic
- Gluten Free
- Retinyl Palmitate Free

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**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69039-220
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL

<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
<b>OCTISALATE</b> (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68 WGF6 WM) (OCTOCRYLENE - UNII:5A68 WGF6 WM)	OCTOCRYLENE	100 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>VINYLPYRROLIDONE/HEXADECENE COPOLYMER</b> (UNII: KFR5QEN0N9)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED)</b> (UNII: T9296U138P)	
<b>CAPRYLYL TRISILOXANE</b> (UNII: Q95M2P1KJL)	
<b>ETHYLHEXYL STEARATE</b> (UNII: EG3PA2K3K5)	
<b>TRIDECETH-6</b> (UNII: 3T5PCR2H0C)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
<b>DIMETHYL CAPRAMIDE</b> (UNII: O29Y6X2JEZ)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-220-01	1 in 1 BOX	08/26/2017	
1		88 mL in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/26/2017	

**Labeler** - Sun Bum, LLC (028642574)