

SUN BUM SPF 70 PREMIUM MOISTURIZING SUNSCREEN- avobenzone, homosalate, octinoxate, 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.

Sun Bum SPF 70 Premium Moisturizing Sunscreen

Drug Facts

Active Ingredients

Avobenzone 3.00%, Homosalate 10.00%, Octinoxate 5.00%

Octisalate 5.00%, Octocrylene 10.00%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.
- higher SPF gives more suburn 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, Beeswax, Hydrated Silica, Acrylates / C12-22 Alkyl Methacrylate Copolymer Caprylyl Methicone, Styrene/Acrylates Copolymer, Cetyl Dimethicone, Glyceryl Stearate, PEG-100 Stearate, Polyester-8, Trideceth-6, Dimethicone, Ethylhexyl Stearate, Fragrance, Dimethyl Capramide, Sodium Polyacrylate, Ethylhexylglycerin, Trimethylsiloxysilicate, Xanthan Gum, BHT, Dipotassium Glycyrrhizate, Polyaminopropyl Biguanide, Tocopheryl Acetate, Disodium EDTA, Methylisothiazolinone.

Questions or Comments?

Call +1 (877) 978-6286

Package Labeling:

Premium Moisturizing Sunscreen Lotion



70

Broad Spectrum SPF 70
UVA / UVB Protection With Parsol® 1789
Water Resistant (80 Minutes)

Paraben Free and Hypoallergenic
Antioxidant Enriched (Vitamin E)
Dermatologist Tested

6 FL OZ / 177 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
- Oxybenzone Free
- Retinyl Palmitate Free
- Oil/PABA Free
- Non-Comedogenic
- Propylene Glycol Free
- Cruelty Free
- Hypoallergenic
- Dermatologist Tested

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avobenzone, homosalate, octinoxate, octisalate, octocrylene lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-222
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL	
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	50 mg in 1 mL	

OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
WATER (UNII: 059QF0K00R)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-222-01	1 in 1 BOX	08/26/2017	
1		177 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)

Revised: 12/2018

Sun Bum, LLC