

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.

Sun Bum SPF 50 Premium Moisturizing Sunscreen

Drug Facts

Active Ingredients

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

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 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-sleeved shirts, pants, hats, and sunglasses.
- Children under 6 months: Ask a doctor.

Other Information

protect this product from excessive heat and directed 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, trimethylsioxysilicate, xanthan gum, polyaminopropyl biguanide, tocopheryl acetate, BHT, disodium EDTA, methylisothiazolinone

Questions?

Call 1-877-978-6286

Package Labeling:

Premium Moisturizing Sunscreen Lotion



50

**Broad Spectrum SPF 50
Water Resistant (80 Minutes)**

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

1 Gal / 3.78 L

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

Trust The Bum®

- Paraben Free
- Vegan
- Oxybenzone Free
- Gluten Free
- Hypoallergenic
- Retinyl Palmitate Free

Drug Facts

Active ingredients	Purpose
Avobenzone 3%, Homosalate 10%, Octisalate 5%, Octocrylene 10%	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 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-sleeved 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? call 1-877-978-6286

Manufactured for and Distributed by Sun Bum, LLC, Cocoa Beach, FL, 32932 USA. © 2018 Sun Bum, LLC. Product of USA. R444100.



SUN BUM SPF 50 PREMIUM MOISTURIZING SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-232
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 g in 1 L
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 g in 1 L
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 g in 1 L
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 g in 1 L

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENYL CAPPED) (UNII: T9296U138P)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
DOCOSANOL (UNII: 9G1OE216XY)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
XANTHAN GUM (UNII: TTV12P4NEE)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-232-01	3.78 L in 1 BOTTLE; Type 0: Not a Combination Product	08/28/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	08/28/2012	

Labeler - Sun Bum LLC (028642574)