

SUN BUM SPF 15 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 15 Premium Moisturizing Sunscreen

Drug Facts

Active Ingredients

Avobenzone 2.00%, Homosalate 5.00%

Octisalate 2.00%, Octocrylene 10.00%

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 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, Styrene/Acrylates Copolymer, Dimethicone, VP/Hexadecene Copolymer, 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:



SUN BUM SPF 15 PREMIUM MOISTURIZING SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-212
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	20 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	50 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	20 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6VM) (OCTOCRYLENE - UNII:5A68WGF6VM)	OCTOCRYLENE	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL 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)	
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-212-01	1 in 1 BOX	08/24/2017	
1		237 mL in 1 BOTTLE; 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	08/24/2017	

Labeler - Sun Bum, LLC (028642574)