SUN BUM SPF 70 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 70 Premium Moisturizing Sunscreen

Drug Facts

Active ingredients

Avobenzone 3%, Homosalate 15%, Octisalate 5%, Octocrylene 10%

Purpose

Sunscreen

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

- shake well before use
- 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 value 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-sleeved shirts, pants, hats and sunglasses

Other information

protect this product from excessive heat and direct sun

Inactive ingredients

water, cetyl palmitate, 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, phenoxyethanol, dimethyl capramide, sodium polyacrylate, trimethylsiloxysilicate, xanthan gum, BHT, dipotassium glycyrrhizate, tocopheryl acetate, ethylhexyl glycerin, tetrasodium glutamate diacetate

Questions?

1-877-978-6286

Package Labeling:

Sun Bum®/ Project Header
USA

Color Callouts:
Pantone® 2322 C
White
Pantone® 601 C

SUN BUM SPF 70 PREMIUM MOISTURIZING SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69039-611
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	150 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
WATER (UNII: 059QF0KO0R)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

PEG-100 STEARATE (UNII: YD01N1999R)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-611-01	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	03/01/2020	

Labeler - Sun Bum LLC (028642574)

Revised: 2/2022 Sun Bum LLC