PREMIUM MOISTURIZING SUNSCREEN BROAD SPECTRUM SPF 70avobenzone, homosalate, octisalate, octocrylene lotion Wasatch Product Development, 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 Lotion

Active ingredients

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Stop use and ask a doctor if rash occurs

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

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 your time in the sun, especially from 10a.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, ethylhexylglycerin, tetrasodium glutamate diacetate

Sun Bum

70

Premium Moisturizing Sunscreen Lotion

Broad Spectrum SPF 70

Water Resistant (80 Minutes)

Gluten Free and Vegan

Antioxidant Enriched (Vitamin E)

Dermatologist Tested

6 FL OZ / 177 mL



Sun Bum³/6 Oz/SPF70 Lotion (Tube) File Name: SB_OG_6 Oz_SPF70 Lotion_R1V1_444103 Production Revision: R444103 Round: 01 | Version: 01 Color Callouts: Proper UPC? Stretched Logo? Yes ⋈ N/A | Yes ⋈

No 🗙

No 🗍

	Tube Size: 2" (D) x 5-11/16" (H)		GENERAL NOTES	
7	Drawing No: 2X5-11-16-DP-SunBum	Created: 3/23/17 PG	Measurements are in inches.	
CCLTUBE	Shoulder Margin: 0"	Revisions: N/A	All copy must be 1/16" below the eye-mark.	
	Open End Margin: 1/4"		Please include a PDF, list of colors, and convert text to outlines when submitting	
	Eye-mark Size: 1/8" x 1/4"		artwork.	
	Scale: 100%			
	Die Line Type: Direct Print			
	700005			

1/32" bleed (left side) for overlap, and 1/8" bleed (bottom) for printing over the White



avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:44717-070

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 mL		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 mL		
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
DIMETHICONE 100 (UNII: RO266O364U)	
PEG-100 STEARATE (UNII: YD01N1999R)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
GLYCYRRHIZINATE DIPOTASSIUM (UNII: CA2Y0FE3FX)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	

ı	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:44717-070- 01	177 mL in 1 TUBE; Type 0: Not a Combination Product	02/01/2023		
П						

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M020	02/01/2023		

Labeler - Wasatch Product Development, LLC (962452533)

Revised: 2/2023 Wasatch Product Development, LLC