

**PREMIUM MOISTURIZING SUNSCREEN BROAD SPECTRUM SPF 30-
avobenzone, 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 30 Premium Moisturizing Sunscreen Lotion

Active Ingredients Purpose

Avobenzone 3% Sunscreen

Homosalate 5% Sunscreen

Octisalate 3% Sunscreen

Octocrylene 10% 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

Protect this product from excessive heat and direct sun

Inactive ingredients

water, butyloctyl salicylate, hydrated silica, VP/hexadecene 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

Sun Bum

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Premium Moisturizing Sunscreen Lotion

Broad Spectrum SPF 30

Water Resistant (80 Minutes)

Gluten Free and Vegan

Antioxidant Enriched (Vitamin E)

Dermatologist Tested

6 FL OZ / 177 mL



Sun Bum® / 6 Oz / SPF 30 Lotion (Tube)

File Name: SB_OG_6Oz_SPF30 Lotion_R1V1_444103

USA

Production Revision: R444103

Color Callouts:

- Pantone 7601 C
- Pantone 72322 C
- White

Round: 01 | Version: 01

Proper UPC?

- Yes N/A
 No

Stretched Logo?

- Yes N/A
 No

CCL TUBE	Tube Size: 2" (D) x 5-11/16" (H)	GENERAL NOTES	
	Drawing No: 2X5-11-16-DP-SunBum	Created: 3/23/17 PG	<ul style="list-style-type: none"> Measurements are in inches. All copy must be 1/16" below the eye-mark. Please include a PDF, list of colors, and convert text to outlines when submitting artwork.
	Shoulder Margin: 0"	Revisions: N/A	
	Open End Margin: 1/4"		
	Eye-mark Size: 1/8" x 1/4"		
	Scale: 100%		
Die Line Type: Direct Print			

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

1/4" NO PRINT AREA

Quiet zone. All copy must be 1/16" below the eye-mark.

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Premium Moisturizing Sunscreen Lotion
Broad Spectrum SPF 30
Water Resistant (80 Minutes)

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

6 FL OZ / 177 mL

1/4" NO COPY IN THIS AREA, BACKGROUND PANEL ONLY

Trust The Bum®

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

Drug Facts

Active ingredients	Purpose
Avobenzone 3%, Homosalate 5%, Octisalate 3%, Octocrylene 10%	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 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 30 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, 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, trimethylsilyloxyacetate, xanthan gum, polyaminopropyl biguanide, tocopheryl acetate, BHT, disodium EDTA, methylisothiazolinone

Questions? 1-877-978-6286

Mfg. for and Dist. by Sun Bum, LLC, PO Box 320598 Cocoa Beach, FL 32932 USA. © 2019 Sun Bum, LLC. Made in the USA with globally sourced components. R444103.

Open End

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5 11/16" Tube Sleeve Length

↓

Shoulder

PREMIUM MOISTURIZING SUNSCREEN BROAD SPECTRUM SPF 30

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44717-068
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	5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 g in 100 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PEG-100 STEARATE (UNII: YD01N1999R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
POLYAMINOPROPYL BIGUANIDE (UNII: DT9D8Z79ET)	
DOCOSANOL (UNII: 9G1OE216XY)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44717-068-01	177 mL in 1 TUBE; Type 0: Not a Combination Product	02/01/2023	
2	NDC:44717-068-02	88 mL in 1 TUBE; Type 0: Not a Combination Product	02/01/2023	

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