

**PREMIUM MOISTURIZING SUNSCREEN BROAD SPECTRUM SPF 15-
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 15 Premium Moisturizing Sunscreen Lotion

Active ingredients

Avobenzone 2%, Homosalate 5%,

Octisalate 2%, 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

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, styrene/acrylates copolymer, VP/hexadecene copolymer, polyester-8, dimethicone, 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 15

Water Resistant (80 Minutes)

Gluten Free and Vegan

Antioxidant Enriched (Vitamin E)

Dermatologist Tested

6 FL OZ / 177 mL



Sun Bum® / 6 Oz / SPF 15 Lotion (Tube)

File Name: SB_OG_6Oz_SPF 15 Lotion_R1V1_444104

USA

Production Revision: R444104

Round: 01 | Version: 01

Color Callouts:

- Pantone 7601 C
- Pantone 72322 C
- CMYK / 4 Color
- White

Proper UPC?	Stretched Logo?
Yes <input checked="" type="checkbox"/> N/A <input type="checkbox"/>	Yes <input type="checkbox"/> N/A <input type="checkbox"/>
No <input type="checkbox"/>	No <input checked="" type="checkbox"/>

CCL TUBE	Tube Size: 2" (D) x 5-11/16" (H)	Created: 3/23/17 PG	GENERAL NOTES <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.
	Drawing No: 2X5-11-16-DP-SunBum	Revisions: N/A	
	Shoulder Margin: 0"		
	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

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Premium Moisturizing Sunscreen Lotion
Broad Spectrum SPF 15
Water Resistant (80 Minutes)

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Antioxidant Enriched (Vitamin E)
Dermatologist Tested

6 FL OZ / 177 mL

Trust The Bum®

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

Drug Facts

Active ingredients	Purpose
Avobenzone 2%, Homosalate 5%, Octisalate 2%, 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

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Stop use and ask a doctor if rash occurs

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Directions

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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, styrene/acrylates copolymer, VP/hexadecene copolymer, polyester-8, dimethicone, caprylyl methicone, ethylhexyl stearate, triacetin-6, glyceryl stearate, PEG-100 stearate, fragrance, sodium polyacrylate, behenyl alcohol, dimethyl capramide, ethylhexylglycerin, trimethylsilyloxy silicate, xanthan gum, polyaminopropyl biguanide, tocoferyl acetate, BHT, disodium EDTA, methylisothiazolinone

Questions? 1-877-978-6286

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

Open End

5 11/16" Tube Sleeve Length

Shoulder

PREMIUM MOISTURIZING SUNSCREEN BROAD SPECTRUM SPF 15

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44717-072
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	2 g in 100 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	5 g in 100 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
DIMETHICONE 100 (UNII: RO266O364U)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
DOCOSANOL (UNII: 9G1OE216XY)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYAMINOPROPYL BIGUANIDE (UNII: DT9D8Z79ET)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44717-072-01	177 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