

**SUN BUM FACE 50 PREMIUM SUNSCREEN SPF 50- avobenzene, homosalte, 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 Face 50 Premium Sunscreen Lotion SPF 50

Active ingredients Purpose

Avobenzene 3 %, Homosalate 10%

Octisalate 5.%, 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
- 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 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-sleeve 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, tocopherol acetate, BHT, glyceryl stearate, PEG-100 stearate, ethylhexyl stearate, behenyl alcohol, caprylyl

methicone, trimethylsiloxysilicate, dimethyl capramide, sodium polyacrylate, xanthan gum, trideceth-6, disodium EDTA, ethylhexylglycerin, polyaminopropyl biguanide, methylisothiazolinone

Sun Bum

Face 50

Premium Sunscreen Face Lotion

Broad Spectrum SPF 50

Water Resistant (80 Minutes)

Lightweight

Breakout Free

Fragrance Free, Oxbenzone Free

Dermatologist Tested

Gluten Free

Vegan

3 FL OZ / 88 mL



Sun Bum®/ Face 50 Lotion / 3 Oz

USA

Color Callouts:

- Pantone®/2322 C
- White

File Name: SB_OG_Face50_3oz_Lotion_R1V1_444103

Production Revision: R444103

Round: 01 | Version: 01

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

119.32 mm
125.00 mm

Printing Area 115.00 mm
Uncoated Area 8.00 mm

2.00 mm

Trust The Bum®

- Moisturizing
- Hypoallergenic
- Paraben Free
- Phthalate Free
- Octinoxate Free
- Retinyl Palmate Free

Drug Facts

Active Ingredients	Purpose
Avobenzone 3%, Homosalate 10%	Sunscreen
Octisalate 5%, Octocrylene 10%	

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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Questions? 1-877-978-8286

Mfg. for and Dist. by Sun Bum, LLC, PO Box 320598 Cocoa Beach, FL 32932 USA. © 2016 Sun Bum, LLC. Made in the USA with globally sourced components. R444103.

Face 50

Premium Sunscreen Face Lotion
Broad Spectrum SPF 50
Water Resistant (80 Minutes)
Lightweight • Breakout Free
Fragrance Free, Oxybenzone Free
Dermatologist Tested
Gluten Free
Vegan

3 FL OZ / 88 mL

SUN BUM FACE 50 PREMIUM SUNSCREEN SPF 50

avobenzone, homosalte, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44717-080
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	10 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
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ETHYLHEXYL STEARATE (UNII: EG3PA2K3K5)	
DOCOSANOL (UNII: 9G10E216XY)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
DIMETHYL CAPRAMIDE (UNII: O29Y6X2JEZ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
TRIDECETH-6 (UNII: 3T5PCR2H0C)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
POLYAMINOPROPYL BIGUANIDE (UNII: DT9D8Z79ET)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44717-080-01	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