

SUN BUM SIGNATURE CLEAR SPF 50- octisalate, octocrylene, zinc oxide 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 Signature Lotion Clear SPF 50

Drug Facts

Active ingredients

Octisalate 5%, Octocrylene 10%. Zinc oxide 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

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 right away.

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 10a.m. - 2.p.m.
- wear long-sleeve shirts, pants, hats, and sunglasses.

Other information

- protect this product from excessive heat and direct sun. Keep outer carton for complete labeling information

Inactive ingredients

water, C12-15 alkyl benzoate, triethylpentanediol/ adipic acid copolymer, butyrospermum parkii (shee) butter, glycerin, polyster-8, arachidyl alcohol, panthenol, aloe barbadensis leaf juice, tocopheryl acetate, sodium hyaluronate, ascorbyl palmitate, beeswax, behenylalcohol, arachidyl glucoside, sorbitan oleate, sorbitol, lecithin, xanthan gum, oleic acid, glyceryl caprylate, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, triethoxycaprylate, disodium EDTA, phenoxyethanol, caprylyl glycol, ethylhexylglycerin

Questions?

1(877)978-6286

Package Labeling:44ml



Drug Facts

Active Ingredients Octinoxate 9%, Octocrylene 10%, Zinc oxide 10%.....Sunscreen **Purpose**

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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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 may also age. 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-sleeve shirts, pants, hats, and sunglasses.

Other Information • protect this product from excessive heat and direct sun. Keep outer carton for complete labeling information

Inactive Ingredients
water, C12-15 alkyl benzoate, trimethylpentanediol/adipic acid copolymer, butyrospermum parkii (shea) butter, glycerin, polyester-8, arachidyl alcohol, panthenol, aloe barbadensis leaf juice, tocopheryl acetate, sodium hyaluronate, acetyl palmitate, beeswax, behenyl alcohol, arachidyl glucoside, sorbitan oleate, sorbitol, lecithin, xanthan gum, oleic acid, glyceryl caprylate, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, triethoxycaprylylsilane, disodium EDTA, phenoxethanol, caprylyl glycol, ethylhexylglycerin.

Questions?
1 (877) 978-6286

Manufactured for and Dist. by
Sun Bum, LLC, PO Box 220908
Cocoa Beach, FL, 32932 USA.
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Product of USA.
R644105.



Signature Lotion
Clear

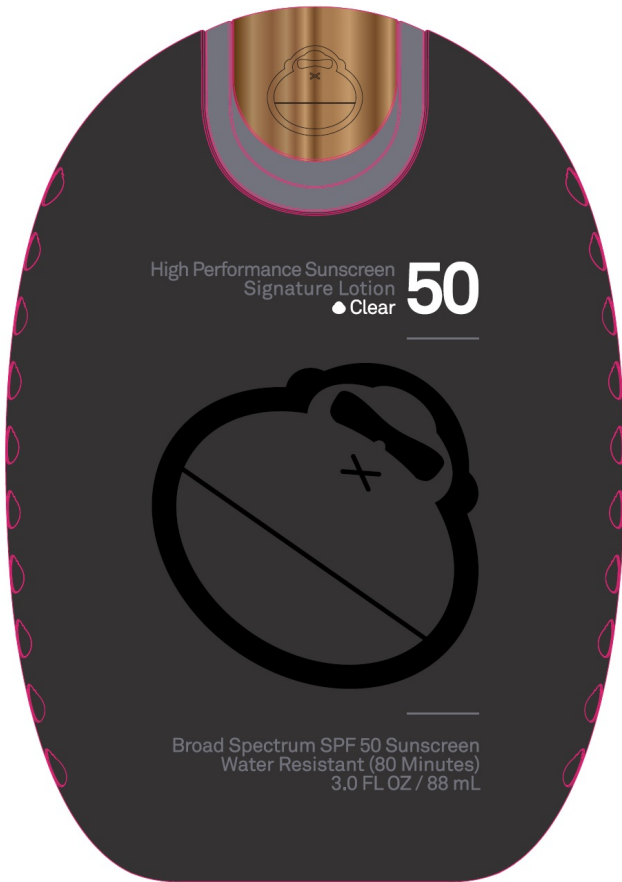
High Performance Sunscreen
Broad Spectrum SPF 50 Sunscreen
Water Resistant (80 Minutes) **50**
1.5 FL OZ / 44 mL

Sun Bum™
TrustTheBum.com



Package Labeling:88ml

Front



Back



High Performance Sunscreen
Signature Lotion
• Clear **50**



Broad Spectrum SPF 50 Sunscreen
Water Resistant (80 Minutes)
3.0 FL OZ / 88 mL

Sun BumTM

Sun Bum Signature[®] sunscreens are carefully formulated to help protect those of us who live and play hard in the sun.

Trust The Bum[®]

● **Active Ingredients** *Purpose*
Octisalate 5%, Octocrylene 10%,
Zinc oxide 10%.....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.

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SUN BUM SIGNATURE CLEAR SPF 50

octisalate, octocrylene, zinc oxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-617
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GLYCERIN (UNII: PDC6A3C0OX)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
PANTHENOL (UNII: WW9CM0067Z)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
DOCOSANOL (UNII: 9G1OE216XY)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35J00J)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
SORBITOL (UNII: 506T60A25R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
OLEIC ACID (UNII: 2UMI9U37CP)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-617-01	44 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2020	
2	NDC:69039-617-02	88 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/11/2020	

Labeler - Sun Bum LLC (028642574)