

SIGNATURE SPF 50 CLEAR FACE- homosalate, octocrylene, octisalate, titanium dioxide, zinc oxide stick
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.

Signature SPF 50 Clear Face Stick

Drug Facts

Active ingredients

Homosalate 10%, Octocrylene 10%, Octisalate 5%, Titanium Dioxide 4.23%, Zinc Oxide 7%

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 immediately.

Directions

- 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 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. Keep this outer card for complete labeling information.

Inactive ingredients

octyl palmitate, ozokerite, paraffin, beeswax, butyloctyl salicylate, stearyl alcohol, cetareth-20, dimethicone, adipic acid/diglycol crosspolymer, tocopheryl acetate, VP/hexadecene copolymer, triethoxycaprylylsilane

Questions?

1 (877) 978-6286

Package Labeling:



Drug Facts

Active ingredients Purpose
Homosalate 10%, Octocrylene 10%, Octisalate 5%, Titanium Dioxide 4.23%, Zinc Oxide 7%.....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 • 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. Keep this outer card for complete labeling information.

Inactive ingredients octyl palmitate, ozokerite, paraffin, beeswax, butyloctyl salicylate, stearyl alcohol, ceteareth-20, dimethicone, adipic acid/diglycol crosspolymer, tocopheryl acetate, VP/hexadecene copolymer, triethoxycaprylylsilane

Questions? 1 (877) 976-6286



Signature Face Stick

Clear



High Performance Sunscreen

Water Resistant (80 Minutes)
Broad Spectrum SPF 30
13 G / 0.45 OZ NET

30

Mfg. for and Dist. by Sun Bum, LLC, PO Box 320598
Cocoa Beach, FL 32932
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Front

Back



SIGNATURE SPF 50 CLEAR FACE

homosalate, octocrylene, octisalate, titanium dioxide, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-610
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	42.3 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	70 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYL PALMITATE (UNII: 2865993309)	

CERESIN (UNII: Q1LS2UJO3A)
PARAFFIN (UNII: I9O0E3H2ZE)
YELLOW WAX (UNII: 2ZA36H0S2V)
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
DIMETHICONE (UNII: 92RU3N3Y1O)
ADIPIC ACID/DIGLYCOL CROSSPOLYMER (20000 MPA.S) (UNII: R9TPS68K19)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
VINYLPYRROLIDONE/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-610-01	1 in 1 BOX	01/01/2020	
1		13 g in 1 CARTRIDGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2020	

Labeler - Sun Bum LLC (028642574)