

SIGNATURE SPF 50 TINTED FACE- titanium dioxide 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 Tinted Face Stick

Drug Facts

Active ingredients

Titanium dioxide 20.8%

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

Inactive ingredients

aluminum hydroxide, butyloctyl salicylate, C12-15 alkyl benzoate, caprylyl methicone, copernicia cerifera (carnauba) wax, dimethicone, hydrogenated polydecane, iron oxides (CI 77491 CI 77492, CI 77499), isostearic acid, kaolin, methyl methacrylate crosspolymer, microcrystalline wax, phytosteryl/behynyl/octyldodecyl lauroyl glutamate, polyethylene, tocopheryl acetate

Questions?

1 (877) 978-6286

Package Labeling:



Front

Back



SIGNATURE SPF 50 TINTED FACE

titanium dioxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-609
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	208 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

DIMETHICONE (UNII: 92RU3N3Y1O)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
KAOLIN (UNII: 24H4NWX5CO)	
METHYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: EG97988M5Q)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-609-01	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)