SUN BUM TINTED SUNSCREEN FACE UVA/UVB BROAD SPECTRUM SPF 30titanium dioxide, 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 Tinted Sunscreen Face Lotion UVA/UVB Broad Spectrum SPF 30

Drug Facts

Active ingredient

Titanium dioxide 5.3%

Zinc oxide 2.4%

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 40 minutes of swimming or sweating, immediately after towel drying
- at least every 2 hours.
- children under 6 months of age: ask a doctor.
- **Sun Protections Measures-** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regurlarly 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

cyclopentasiloxane, isopropyl myristate, polyamide-5, stearalkonium hectorite, dimethicone crosspolymer, polysilicone-11, oryza sativa (rice) bran extract, rosemarinus officinalis (rosemary) leaf extract, helianthus annus (sunflower) extract, tocopherol, mica, iron oxides, propylene carbonate, synthetic wax, hydrogen dimethicone, isopropyl titanium triisostearate, aluminum hydroxide, silica silylate, octyldodecyl oleate

Questions?

1-877-978-6286

Package Labeling:



SUN BUM TINTED SUNSCREEN FACE UVA/UVB BROAD SPECTRUM SPF 30

titanium dioxide, zinc oxide lotion

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-621	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	53 mg in 1 mL		
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	24 mg in 1 mL		

Inactive Ingredients		
Ingredient Name	Strength	
CYCLOMETHICONE 5 (UNII: 0THT5PCIOR)		
ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)		
STEARALKONIUM HECTORITE (UNII: OLX698AH5P)		
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)		
RICE BRAN (UNII: R60QEP13IC)		
ROSEMARY (UNII: IJ67X351P9)		
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)		
TOCOPHEROL (UNII: R0ZB2556P8)		
MICA (UNII: V8A1AW0880)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
PROPYLENE CARBONATE (UNII: 8D08K3S51E)		
ISOPROPYL TITANIUM TRIISOSTEARATE (UNII: 949E3KBJ1I)		
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)		
OCTYLDODECYL OLEATE (UNII: MCA43PK7MH)		

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:69039-621- 01	1 in 1 BOX	02/22/2021				
1		50 mL in 1 TUBE; Type 0: Not a Combination Product					

Marketing Information					
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
part352	02/22/2021				
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date			

Labeler - Sun Bum LLC (028642574)

Revised: 2/2022 Sun Bum LLC