# SUN BUM MINERAL SUNSCREEN SPF 50- titanium dioxide, zinc oxide liquid 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 Mineral Sunscreen SPRAY SPF 50

# **Drug Facts**

## Active ingredients

Titanium dioxide 3.4%, Zinc oxide 16%

## **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.
- use only as directed. Interntional misuse by delibarately concentrating and inhaling the contents can be harmful or fatal.
- do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F.

# 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.
- hold container 4 to 6 inches from the skin to apply
- spray liberally and spread evenly by hand 15 minutes before sun exposure
- do not spray directly into face. spray on hands then apply to face
- do not apply in windy conditions
- use in well-ventilated area
- Reapply: after 80 minutes of swimming or sweating immediately after towel drying
   at least every 2 hours •children under 6 months: 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

water, butyloctyl salicylate, helianthus annuus (sunflower) seed oil, dicaprylyl carbonate, propanediol, isocetyl stearoyl stearate, methyl dihydroabietate, cetearyl alcohol, polyester-8, sodium stearoyl glutamate, coco-glucoside, aloe barbadensis leaf juice, musa sapientum (banana) fruit extract, tocopherol, glycerin, cellulose gum, bentonite, microcrystalline cellulose, caprylyl glycol, silica, polyhydroxystearic acid, citric acid, alumina, bisabolol, sodium gluconate, caprylhydroxamic acid

## Questions?

1-877-978-6286

# Package Labeling:

Trust The Bum'

Gluten Free Oxybenzone Free Vegan Retinyl Palmitate Free Hypoallergenic Paraben Free

### **Drug Facts**

Active ingredients Titanium dioxide 3,4%, Zinc oxide 16%

Purpose

 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

#### For external use only

Do not use on damaged or broken skin

#### When using this product

- when using this product
  keep out of eyes. Rinse with water to remove.
  use only as directed, Intentional misuse by deliberately
  concentrating and inhaling the contents can be harmful or fatal.
  do not puncture or incinerate, Contents under pressure, Do not store at temperatures above 120°F.

#### 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.

shake well before use - hold container 4 to 6 inches from the skin to apply - spray liberally and spread evenly by hand 15 minutes before sun exposure - do not spray directly into face, Spray on hands then apply to face - do not apply in windy conditions - use in well-ventilated area - Reapply: - after 80 minutes of swimming or sweating - immediately after the well diving at best traver. diately 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 water, butyloctyl salicylate, helianthus annuus (sunflower) seed oil, dicaprylyl carbonate, propanediol, isocetyl stearoyl stearate, methyl dihydroabietate, cetearyl alcohol, fragrance, polyester-8, sodium stearoyl glutamate, coco-glucoside, aloe barbadensis leaf juice, musa sapientum (banana) fruit extract, tocopherol, glycerin, cellulose gum, bentonite, microcrystalline cellulose, caprylyl glycol, silica, polyhydroxystearic acid, citric acid, alumina, bisabolol, sodium gluconate, caprylhy-

Questions? 1-877-978-6286



Mfg. for and Dist, by Sun Bum, LLC. PO Box 320598 Cocoa Beach, FL, 32932 USA. @ 2018 Sun Burn, LLC. Product of USA, R444102, 20 M5655



0087

Shake It Up



# Mineral

Continuous Sunscreen Spray Broad Spectrum SPF 50 Water Resistant (80 Minutes) **Dermatologist Tested** 



Net Wt. 6 OZ / 170 g

### **SUN BUM MINERAL SUNSCREEN SPF 50**

titanium dioxide, zinc oxide liquid

#### **Product Information**

**Product Type Item Code (Source)** HUMAN OTC DRUG NDC:69039-630

**Route of Administration** TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	34 mg in 1 g	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	160 mg in 1 g	

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)	
PROPANEDIOL (UNII: 5965N8W85T)	
ISOCETYL STEAROYL STEARATE (UNII: IJV4LS383R)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024)	
COCO GLUCOSIDE (UNII: ICS790225B)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BANANA (UNII: 4AJZ4765R9)	
TOCOPHEROL (UNII: R0ZB2556P8)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)	
BENTONITE (UNII: A3N5ZCN45C)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
LEVOMENOL (UNII: 24WE03BX2T)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-630- 01	170 g in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2021	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part352	02/22/2021		

# Labeler - Sun Bum LLC (028642574)

Revised: 2/2022 Sun Bum LLC