SUN BUM MINERAL SUNSCREEN BROAD SPECTRUM 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 Broad Spectrum SPF 50

Drug Facts

Active ingredient

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. 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 room temperature 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 to6 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 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

water, butyloctyl salicylat, helianthus annus (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:



SUN BUM MINERAL SUNSCREEN BROAD SPECTRUM SPF 50

titanium dioxide, zinc oxide liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69039-624
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	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)	
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)	
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:69039-624- 01	170 g in 1 BOTTLE; Type 0: Not a Combination Product	02/22/2021	

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)

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