

**SUN BUM MINERAL SUNSCREEN ROLL ON SPF 50- titanium 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.*

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**Sun Bum Mineral Sunscreen Roll On Lotion 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.

**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 • apply liberally and spread by hand 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***

water, butyloctyl salicylate, dicaprylyl carbonate, isononyl isononanoate, propanediol, isocetyl stearoyl stearate, methyl dihydroabietate, cetearyl alcohol, aloe barbadensis leaf juice, musa sapientum (banana) fruit extract, bisabolol, bentonite, cellulose gum, C18-21 alkane, caprylyl glycol, citric acid, coco-glucoside, glycerin, microcrystalline cellulose, polyhydroxystearic acid, sodium gluconate, sodium stearoyl glutamate, tocopherol, polyester-8, silica, alumina, caprylhydroxamic acid

### ***Questions?***

1-877-978-6286

### ***Package Labeling:***



50

Mineral Sunscreen Roll-On Lotion  
Broad Spectrum SPF 50  
Water Resistant (80 Minutes)

3 FL OZ / 88 mL

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Mfg. for and Dist. by Sun Bum, LLC, PO Box 320598 Cocoa Beach, FL, 32932 USA. © 2021 Sun Bum, LLC. Product of USA. R444101.



**SUN BUM MINERAL SUNSCREEN ROLL ON SPF 50**

titanium dioxide, zinc oxide lotion

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69039-641
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>DICAPRYLYL CARBONATE</b> (UNII: 609A3V1SUA)	
<b>ISONONYL ISONONANOATE</b> (UNII: 54V5BS6GCX)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>ISOCETYL STEAROYL STEARATE</b> (UNII: IJV4LS383R)	
<b>METHYL DIHYDROABIETATE</b> (UNII: 7666FJ0J9F)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>BANANA</b> (UNII: 4AJZ4765R9)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
<b>BENTONITE</b> (UNII: A3N5ZCN45C)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>C18-C21 ALKANE</b> (UNII: 33822S0M40)	
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	
<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)	
<b>TOCOPHEROL</b> (UNII: ROZB2556P8)	
<b>POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED)</b> (UNII: T9296U138P)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-641-01	88 mL in 1 TUBE; Type 0: Not a Combination Product	01/01/2022	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/01/2022	

