

**SUN BUM MINERAL SUNSCREEN BROAD SPECTRUM SPF 50- 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 Lotion Broad Spectrum SPF 50**

***Drug Facts***

***Active ingredient***

Zinc oxide 20%

***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 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 Protections 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***

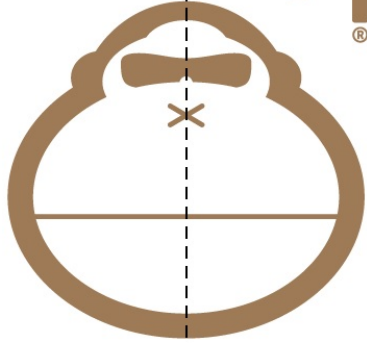
water, cocos nucifera (coconut) oil, butyloctyl salicylate, diheptyl succinate, methyl dihydroabietate, butyrospermum parkii (shea butter), capryloyl glycerin/sebacic acid copolymer, sodium stearoyl glutamate, cetearyl alcohol, arachidyl alcohol, coco glucoside, tocopherol, theobroma cacao (cocoa) seed butter, cetyl alcohol, behenyl alcohol, bisabolol, arachidyl glucoside, microcrystalline cellulose, cellulose gum, sodium hyaluronate, sodium gluconate, phenoxyethanol, citric acid, ethylhexylglycerin, polyhydroxystearic acid

### ***Questions?***

1-877-978-6286

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

# SUN BUM



## 50

Mineral Sunscreen Lotion  
Broad Spectrum SPF 50  
With Zinc Oxide  
Water Resistant (80 Minutes)  
Fragrance Free for Sensitive Skin  
Hypoallergenic  
Vegan

3 FL OZ / 88 mL

### Drug Facts

Active ingredient	Purpose
Zinc oxide 20%	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 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, cocos nucifera (coconut) oil, butyloctyl salicylate, diheptyl succinate, methyl dihydroabietate, butyrospermum parkii (shea) butter, capryloyl glycerin/sebacic acid copolymer, sodium stearoyl glutamate, cetearyl alcohol, arachidyl alcohol, coco-glucoside, tocopherol, theobroma cacao (cocoa) seed butter, cetyl alcohol, behenyl alcohol, bisabolol, arachidyl glucoside, microcrystalline cellulose, cellulose gum, sodium hyaluronate, sodium gluconate, phenoxyethanol, citric acid, ethylhexylglycerin, polyhydroxystearic acid

**Questions?** 1-877-978-6286

Mfg. for and Dist. by Sun Bum, LLC, PO Box 320598 Cocoa Beach, FL, 32932 USA, © 2019 Sun Bum, LLC, Product of USA, R444102.



SunBum.com



Package Labeling:69039-623-02

Quiet zone. All copy must be 1/16" below the eye-mark.



50

Mineral Sunscreen Lotion  
Broad Spectrum SPF 50  
With Zinc Oxide  
Water Resistant (80 Minutes)  
Fragrance Free for Sensitive Skin  
Hypoallergenic  
Vegan

1 FL OZ / 30 mL

**Drug Facts**

Active Ingredients	Purpose
Zinc oxide 20%	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 product is swallowed, get medical help or contact a Poison Control Center right away.

**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: ask a doctor
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: • limit time in sun, especially from 10am-2pm • wear long-sleeved shirts, pants, hats and sunglasses

**Other Information** protect this product from excessive heat and direct sun.

**Inactive Ingredients** water, cocos nucifera (coconut) oil, butyloctyl salicylate, diheptyl succinate, methyl dihydroabietate, butyrospermum parkii (shea) butter, capryloyl glycerin/sebacic acid copolymer, sodium stearyl glutamate, cetearyl alcohol, arachidyl alcohol, coco-glucoside, tocopherol, theobroma cacao (cocoa) seed butter, cetyl alcohol, behenyl alcohol, bisabolol, arachidyl glucoside, microcrystalline cellulose, cellulose gum, sodium hyaluronate, sodium gluconate, phenoxyethanol, citric acid, ethylhexylglycerin, polyhydroxystearic acid

**Questions?** 1-877-978-6286

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1/4"

NO COPY IN THIS AREA, BACKGROUND PANEL ONLY

# SUN BUM MINERAL SUNSCREEN BROAD SPECTRUM SPF 50

zinc oxide lotion

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69039-623
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	200 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>DIHEPTYL SUCCINATE</b> (UNII: 057N7SS26Y)	
<b>METHYL DIHYDROABIETATE</b> (UNII: 7666FJ0J9F)	
<b>SHEA BUTTER</b> (UNII: K49155WL9Y)	
<b>CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S)</b> (UNII: N7YC58165T)	
<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>ARACHIDYL ALCOHOL</b> (UNII: 1QR1QRA9BU)	
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
<b>LEVOMENOL</b> (UNII: 24WE03BX2T)	
<b>ARACHIDYL GLUCOSIDE</b> (UNII: 6JVVW35JOOJ)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH)	
<b>SODIUM GLUCONATE</b> (UNII: R6Q3791S76)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69039-623-01	88 mL in 1 TUBE; Type 0: Not a Combination Product	02/22/2021	
2	NDC:69039-623-	30 mL in 1 TUBE; Type 0: Not a Combination	02/22/2021	

**Marketing Information**

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

**Labeler** - Sun Bum LLC (028642574)

Revised: 2/2022

Sun Bum LLC