

**MINERAL BROAD SPECTRUM SPF 50 SUNSCREEN UVA-UVB SUNCREEN- titanium dioxide and zinc oxide cream**

**MDSolarSciences**

*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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**Mineral Crème**

**Broad Spectrum SPF 50 Sunscreen UVA-UVB Sunscreen**

***Drug Facts***

<b><i>Active Ingredients</i></b>	<b><i>Purpose</i></b>
Titanium Dioxide 1.5%	Sunscreen
Zinc Oxide 17%	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

**Stop use and ask a doctor** if rash occurs

**When using this product** keep out of eyes. Rinse with water to remove

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

**Shake well. Rub in well.**

- 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 Broad Spectrum SPF of 15 or higher and other sun protection measures including:
  - Limit time in the sun, especially from 10a.m. – 2p.m.
  - Wear long-sleeved shirts, pants, hats and sunglasses

**Other Information**

- Protect the product in this container from excessive heat and direct sunlight
- May stain some fabrics
- You may report serious adverse reactions to: Report Reaction, LLC. PO Box 22, Plainsboro, NJ 08536-0222

**Inactive ingredients**

Dimethicone, Dimethicone Crosspolymer, Caprylic/Capric Triglyceride, Glyceryl Isostearate, Polyhydroxystearic Acid, Silica, Butyloctyl Salicylate, Polysilicone-15, Dimethicone/Vinyl Dimethicone Crosspolymer, Iron Oxides, PEG/PPG-18/18 Dimethicone, Triethoxycaprylylsilane, Tetrahexyldecyl Ascorbate, Camellia Sinensis (GreenTea) Extract, Vaccinium Macrocarpon (Cranberry) Fruit Extract, Punica Granatum (Pomegranate) Extract

**PRINCIPAL DISPLAY PANEL - 48 g Tube Carton**

**MDSolarSciences™**

**50**

**MINERAL  
CRÈME**

**BROAD SPECTRUM  
SPF 50  
UVA-UVB SUNSCREEN**

**+R  
enhanced with  
ProVention-R™**

**developed & approved  
by Dermatologists**

**Water resistant (80 minutes)  
Non-comedogenic – won't clog pores**

sun care

**Net Wt. 48 g - 1.7 Oz**



MDSolarSciences™



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Net Wt. 48 g - 1.7 Oz.

Problem skin?  
No problem

Lightweight "barely there"  
formula goes on  
silky smooth and blends  
quickly, leaving a  
matte finish.

Maximum SPF protection  
that is non irritating  
even for most sensitive  
skin types including acne  
and rosacea prone.

Naturally derived and  
safer mineral UVA-UVB  
protection helps reduce  
the risk of photo aging  
and skin cancer.  
Enhanced with  
ProVention-R™  
antioxidants including  
Vitamin C, green tea,  
cranberry fruits and  
pomegranate extracts.

Zinc Oxide and Titanium  
Dioxide gently yet  
effectively shield you  
from the harmful  
rays of the sun.

MDSolarSciences™  
mineral sunscreens are  
derived from natural  
minerals and do not  
contain Oxybenzone,  
Octinoxate, Aminobenzoic  
Acid (PABA), Parabens  
or fragrance.

- ✓ For all skin types including acne/ rosacea prone and sensitive
- ✓ Oil-free
- ✓ Hypoallergenic
- ✓ Gentle enough for kids 6 months and older

Protecting yourself  
from the sun is not  
always on your mind,  
however,  
it is on ours...

We are dedicated to  
providing safer and  
more efficacious  
products for your skin.  
Our Scientific Advisory  
Council governs our  
formulations, ensuring  
state of the art broad  
spectrum protection to  
help prevent skin  
cancer and repair the  
visible signs of sun  
induced aging.  
Experience the benefits  
of our doctor-selected  
ProVention-R™  
Ingredient Library.

We take pride in our  
ongoing commitment to  
quality and safety for you  
and the environment.

- ✓ Not tested on animals
- ✓ Gluten free
- ✓ Eco-cert naturally derived mineral sunscreen
- ✓ Carton made with sustainable wind energy



Learn more about us at:  
[www.mdsolarsciences.com](http://www.mdsolarsciences.com)

**Drug Facts**

**Active Ingredients** ..... **Purpose**  
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Zinc Oxide 17% ..... Sunscreen

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Distributed by:

MDSolarSciences Corp.  
40 Richards Avenue, 3rd Fl, Norwalk, CT 06854  
1-877-301-5355 MADE IN U.S.A.

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# MINERAL BROAD SPECTRUM SPF 50 SUNSCREEN UVA-UVB SUNCREEN

titanium dioxide and zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:49358-554
<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	2.7 g in 35 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	1.3 g in 35 g

## Inactive Ingredients

Ingredient Name	Strength
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>DIMETHICONE/DIENE DIMETHICONE CROSSPOLYMER</b> (UNII: RSA9I5610K)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>GLYCERYL ISOSTEARATE</b> (UNII: HYE7O27HAO)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>Silicon Dioxide</b> (UNII: ETJ7Z6XBU4)	
<b>BUTYLOCTYL SALICYLATE</b> (UNII: 2EH13UN8D3)	
<b>POLYSILICONE-15</b> (UNII: F8DRP5BB29)	
<b>DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE)</b> (UNII: 9E4CO0W6C5)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>PEG/PPG-18/18 DIMETHICONE</b> (UNII: 9H0AO7T794)	
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>CRANBERRY</b> (UNII: 0MVO31Q3QS)	
<b>POMEGRANATE JUICE</b> (UNII: 99S671U9KB)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49358-554-01	1 in 1 CARTON	01/01/2016	
1		48 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	01/01/2016	

**Labeler** - MDSolarSciences (013647301)

Revised: 9/2018

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