# MDSOLARSCIENCES SPF 50 MINERAL- titanium dioxide and zinc oxide cream MD Solar Sciences

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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#### MDSOLARSCIENCES™ SPF 50 Mineral Crème

#### **Drug Facts**

Active ingredients	Purpose
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 Extract, Vaccinium Macrocarpon (Cranberry) Fruit Extract, Punica Granatum Extract

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

**MD**Solar**Sciences** TM

50

MINERAL CRÈME

BROAD SPECTRUM SPF 50 UVA-UVB SUNSCREEN

<sup>+</sup>R

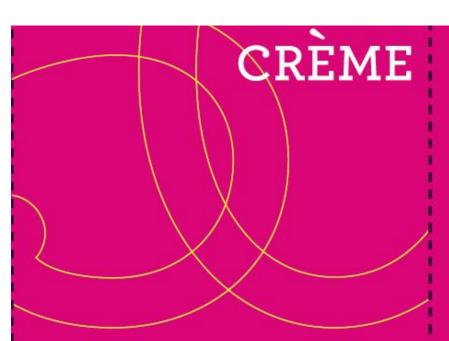
enhanced with **ProVention-R**™
Antioxidant Complex

*Developed & Approved by Dermatologists* 

water resistant (80 minutes) / non-comedogenic suited for all skin types including acne & rosacea formulated without fragrance

Net Wt. 48 g - 1.7 Oz.





NO Oxybenzone, Octinoxate, Aminobenzoic Acid (PABA), or PARABENS.

- Hypoallergenic
- Non-comedogenic
- · Not tested on animals
- Gluten free

# BROAD SPECTRUM SPF 50 UVA-UVB SUNSCREEN



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Protecting yourself from the sun is not always on your mind, however, it is always 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 UV protective ingredients coupled with our proprietary ProVention-R<sup>TM</sup> antioxidant compounds.

# SUN PROTECTION MEASURES:

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- Limit time in the sun, especially from 10AM - 2PM
- Wear long-sleeved shirts, pants, hats & sunglasses

Learn more about us at:

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





Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49358-546
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) (TITANIUM DIO XIDE - UNII:15FIX9 V2JP)	TITANIUM DIO XIDE	15 mg in 1 g	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	170 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
Dimethicone (UNII: 92RU3N3Y1O)		
Medium-Chain Triglycerides (UNII: C9H2L21V7U)		
Glyceryl Isostearate (UNII: HYE7O27HAO)		
Silicon Dioxide (UNII: ETJ7Z6XBU4)		
Butyloctyl Salicylate (UNII: 2EH13UN8D3)		
Polysilicone-15 (UNII: F8 DRP5BB29)		
PEG/PPG-18/18 Dimethicone (UNII: 9H0 AO7T794)		
Triethoxycaprylylsilane (UNII: LDC331P08E)		
Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)		
Green Tea Leaf (UNII: W2ZU1RY8B0)		
Cranberry (UNII: 0MVO31Q3QS)		
Punica Granatum Root Bark (UNII: CLV24I3T1D)		

F	Packaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1	NDC:49358-546-01	1 in 1 CARTON		
1		48 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part352	0 2/0 1/20 13	

# Labeler - MD Solar Sciences (013647301)

Revised: 1/2013 MD Solar Sciences