# MINERAL SUNSCREEN BROAD SPECTRUM SPF 40 SUNSCREEN UVA-UVB SUNSCREEN- titanium dioxide and zinc oxide stick 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 Sunscreen Stick Broad Spectrum SPF 40 Sunscreen UVA-UVB Sunscreen

### **Drug Facts**

Active Ingredients	Purpose
Titanium Dioxide 8.1%	Sunscreen
Zinc Oxide 6.6%	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**

- 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.

 You may report serious adverse reactions to Report Reaction, LLC. PO BOX 22, Plainsboro, NJ 08536-0222

## **Inactive Ingredients**

Polyethylene, Dimethicone, Butyrospermum Parkii (Shea) Butter, Petrolatum, Butyloctyl Salicylate, C12-15 Alkyl Benzoate, Undecylcrylene Dimethicone, Neopentyl Glycol Diheptanoate, Acrylates/Ethylhexyl Acrylate/Dimethicone Methacrylate Copolymer, Behenyl Olivate, Aluminum Hydroxide, Stearic Acid, Glyceryl Isostearate, Beeswax, Polyhydroxystearic Acid, Cetyl PEG/PPG-10/1 Dimethicone, BHT, Benzylidene Dimethoxydimethylindanone, Tetrahexyldecyl Ascorbate

Distributed by:

MDSolarSciences Corp.

40 Richards Avenue, 3rd Fl., Norwalk, CT 06854

### PRINCIPAL DISPLAY PANEL - 17 g Tube Carton

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

40

MINERAL

SUNSCREEN STICK BROAD SPECTRUM

**SPF 40** 

**UVA-UVB SUNSCREEN** 

<sup>+</sup>R

enhanced with **ProVention-R**TM

developed & approved by Dermatologists

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

sun care

Net Wt. 17 g - 0.6 Oz.



MDSolarSciences\*\*

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# Drug Facts (cont.)

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Polyethylene, Di-methicone, Butyrospermum Parkii (Shea) Butter, Petrolatum, Butyloctyl Salicylate, C12-15 Alkyl Benzoate. Undecylcrylene Dimethicone, Neopentyl Glycol Diheptanoate. Acrylates/Ethylhexyl Acrylate/Dimethicone Methacrylate Copoly-mer, Behenyl Olivate, Aluminum Hydroxide, Stearic Acid, Glyceryl Isostearate, Beeswax, Polyhydroxystearic Acid, Cetyl PEG/PPG-10/1 Dimethicone, BHT Benzylidene Dimethoxydimethylindanone. Tetrahexyldecyl Ascorbate



Distributed by: MDSolarSciences Corp. 0 Richards Avenue, 3rd FL Norwalk, CT 06854 1-877-301-5355 MADE IN U.S.A.

MDSolarSciences\*\*



BROAD SPECTRUM UVA-UVB SUNSCREEN

+R enhanced with ProVention-R™

bevorage & begoleveb by Dermatologiete

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

sun care

Net Wt. 17 q - 0.6 Oz.

#### COMPLEMENT YOUR ACTIVE LIFESTYLE

Convenient and portable, this lightweight and easy-to-apply stick is for people on the move. Grab and go.

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

- For all skin types
- **Dil-Free**
- Gentle enough for kids 6 months and older
- Not tested on enimele
- Gluten free

Learn more about us at: www.mdsolareclences.com

# 2271001

**FPO** 

# MINERAL SUNSCREEN BROAD SPECTRUM SPF 40 SUNSCREEN UVA-UVB SUNSCREEN

titanium dioxide and zinc oxide stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49358-553
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	0.96 g in 12 g	
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	0.792 g in 12 g	

Inactive Ingredients		
Ingredient Name	Strength	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)		
Dimethicone (UNII: 92RU3N3Y1O)		
SHEA BUTTER (UNII: K49 155WL9 Y)		
PETROLATUM (UNII: 4T6H12BN9U)		
BUTYLOCTYL OLEATE (UNII: 2830 Y2FNR6)		
SALICYLIC ACID (UNII: O414PZ4LPZ)		
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)		
NEOPENTYL GLYCOL DIHEPTANO ATE (UNII: 5LKW3C543X)		
BEHENYL OLIVATE (UNII: NGS1GGK4GW)		
ALUMINUM HYDRO XIDE (UNII: 5QB0T2IUN0)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)		
YELLOW WAX (UNII: 2ZA36H0S2V)		
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)		
CETYL PEG/PPG-10/1 DIMETHICO NE (HLB 2) (UNII: V2W71V8T0X)		
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)		
BENZYLIDENE DIMETHO XYDIMETHYLINDANO NE (UNII: 75HIF3C97L)		
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)		

	Packaging			
:	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
	NDC:49358-553-01	1 in 1 CARTON	02/01/2016	
	1	17 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	0 2/0 1/20 16	

# Labeler - MDSolarSciences (013647301)

Revised: 10/2018 MDSolarSciences