#### MINERAL CREME SPF 50 MINERAL CREME SPF 50 BROAD SPECTRUM UVA-UVB SUNSCREEN WATER RESISTANT (80 MIN)- 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 SPF 50 Mineral Crème SPF 50 Broad Spectrum UVA-UVB Sunscreen Water Resistant (80 min)

## **Drug Facts**

Active ingredients	Purpose
Titanium Dioxide 2%	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

- 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**

## Shake well. Rub in well.

- 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 611, Pompton Plains, NJ 07444

## **Inactive Ingredients**

Dimethicone, Caprylic/Capric Triglyceride, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Butyloctyl Salicylate, Glyceryl Isostearate, Polysilicone-15, Tetrahexyldecyl Ascorbate (Vitamin C), Camellia Sinensis Leaf Extract (Green Tea), Punica Granatum Extract (Pomegranate), Vaccinium Macrocarpon (Cranberry) Fruit Extract, Silica, Polyhydroxystearic Acid, May Contain: (CI 77891, CI 77492, CI 77491, CI 77499)

## DISTRIBUTED BY MDSOLARSCIENCES CORP. GREENS FARMS, CT 06838

## **PRINCIPAL DISPLAY PANEL - 100 ML Tube Carton**

MDSOLARSCIENCES<sup>®</sup>

MINERAL CRÈME

Broad Spectrum SPF 50 Water Resistant (80 Min) 100% Mineral Sunscreen

**SPF 50** 

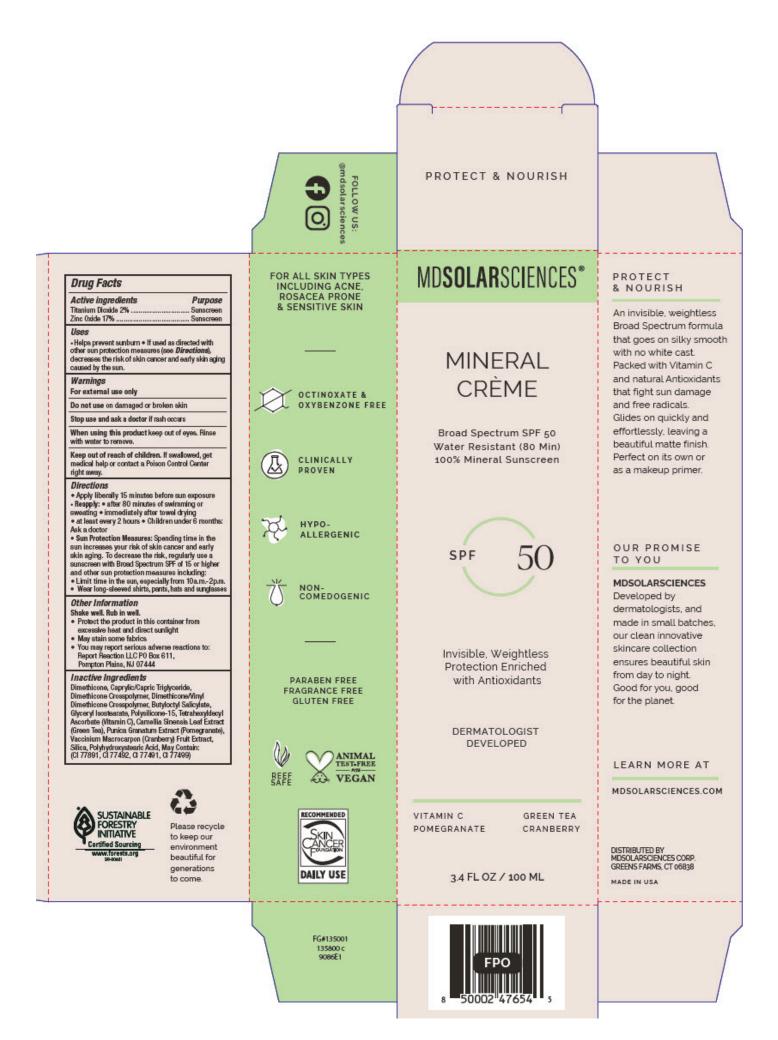
Invisible, Weightless Protection Enriched with Antioxidants

DERMATOLOGIST DEVELOPED

VITAMIN C POMEGRANATE

GREEN TEA CRANBERRY

3.4 FL OZ / 100 ML



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titanium dioxide and zinc oxide cream

<b>Product Information</b>						
Product Type	HUMAN OTC DRUG	ltem Code	Item Code (Source) NDC		C:49358-570	
Route of Administration	TOPICAL					
Active Ingredient/Act	ive Moietv					
	Ingredient Name Basis of Strength				h Strength	
		(9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP) Titanium Dioxide			20 mg in 1 mL	
Zinc Oxide (UNII: SOI2LOH54	• • •	•	Zinc Oxide		170 mg in 1 m	
					-	
Inactive Ingredients						
	Ingredient Na	me			Strengt	
Dimethicone (UNII: 92RU3N3)	Y10)					
MEDIUM-CHAIN TRIGLYCER	<b>DES</b> (UNII: C9H2L21V7U)					
DIMETHICONE/DIENE DIMET						
DIMETHICONE/VINYL DIMET		SOFT PARTICLE	•) (UNII: 9E4CO0W6C5	5)		
BUTYLOCTYL SALICYLATE (						
GLYCERYL ISOSTEARATE (U						
POLYSILICONE-15 (UNII: F8D						
GREEN TEA LEAF (UNII: W2Z)						
POMEGRANATE JUICE (UNII:						
CRANBERRY (UNII: 0MVO31Q						
SILICON DIOXIDE (UNII: ETJ7	207804)					
Other Ingredients						
Ingredient Kind	Ing	Ingredient Name		C	Quantity	
May contain		ERRIC OXIDE YELLOW (UNII: EX43802MRT)				
May contain	FERRIC OXIDE RED (UNII: 1K09F3G675)					
May contain	FERROSOFERRIC OXIDE (U	JNII: XM0M87F35	7)			
Packaging						
			rketing Start	Market		

#	item Code	Раскаде резсприон	Date	Date			
1	NDC:49358-570- 01	1 in 1 CARTON	07/01/2023				
1		50 mL in 1 TUBE; Type 0: Not a Combination Product					
2	NDC:49358-570- 02	1 in 1 CARTON	07/01/2023				
2		100 mL in 1 TUBE; Type 0: Not a Combination Product					
Marketing Information							
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
-	rc monograph Nal	part352	07/01/2023				

# Labeler - MDSolarSciences (013647301)

Revised: 9/2023

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