

MINERAL KIDCREME SPF 50- 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.

Mineral KidCrème® SPF 50 **Mineral Broad Spectrum Sunscreen SPF 50 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 22, Plainsboro, NJ 08536-0222

Inactive Ingredients

Dimethicone, Caprylic/Capric Triglyceride, Dimethicone Crosspolymer, Dimethicone/ Vinyl Dimethicone Crosspolymer, Butyloctyl Salicylate, Glyceryl Isostearate, Polysilicone-15, Punica Granatum Extract (Pomegranate), Vaccinium Macrocarpon (Cranberry) Fruit Extract, Ubiquinone (CoQ10), Camellia Sinensis Leaf Extract (Green Tea), Tetrahexyldecyl Ascorbate (Vitamin C), Tocopheryl Acetate (Vitamin E), Squalane, Polyhydroxystearic Acid, Silica, PEG/PPG-18/18 Dimethicone, Triethoxycaprylylsilane, Iron Oxides (CI 77491, CI 77492, CI 77499).

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

PRINCIPAL DISPLAY PANEL - 100 ML Tube Carton

MDSOLARSCIENCES®

PROTECT & NOURISH

MINERAL
KIDCRÈME®

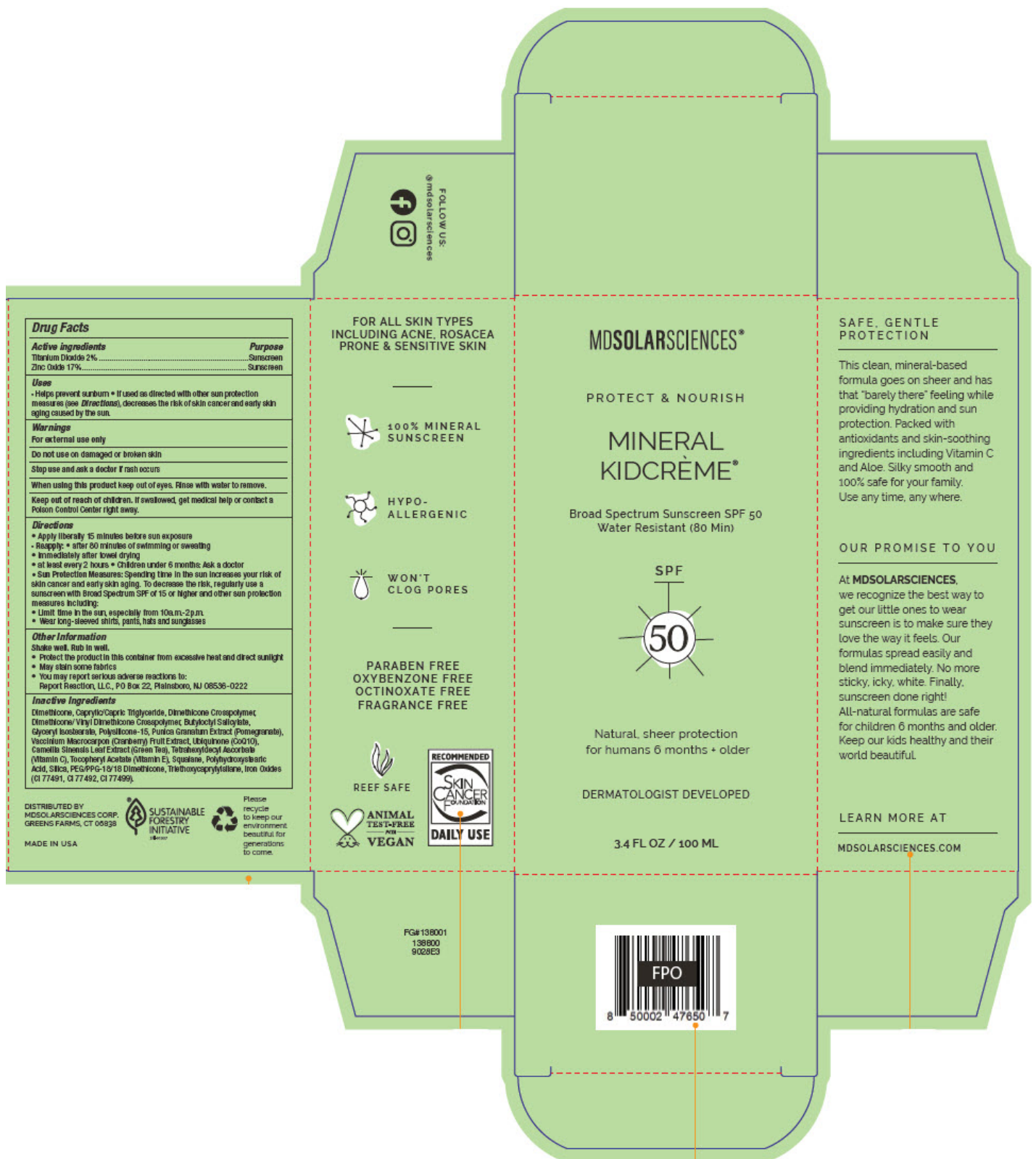
Broad Spectrum Sunscreen SPF 50
Water Resistant (80 Min)

SPF
50

Natural, sheer protection
for humans 6 months + older

DERMATOLOGIST DEVELOPED

3.4 FL OZ / 100 ML



MINERAL KIDCREME SPF 50

titanium dioxide and zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49358-584
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	20 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	170 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE/DIENE DIMETHICONE CROSSPOLYMER (UNII: RSA9I561OK)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)	
GLYCERYL ISOSTEARATE (UNII: HYE7O27HAO)	
POLYSILICONE-15 (UNII: F8DRP5BB29)	
POMEGRANATE JUICE (UNII: 99S671U9KB)	
CRANBERRY (UNII: 0MVO31Q3QS)	
UBIDECARENONE (UNII: EJ27X76M46)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SQUALANE (UNII: GW89575KF9)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
May contain	FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
May contain	FERRIC OXIDE RED (UNII: 1K09F3G675)	
May contain	FERROSFERRIC OXIDE (UNII: XM0M87F357)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49358-584-01	1 in 1 CARTON	07/01/2023	
1		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
OTC monograph final	part352	07/01/2023	

Labeler - MDSolarSciences (013647301)

Establishment

Name	Address	ID/FEI	Business Operations
Englewood Lab, Inc.		172198223	MANUFACTURE(49358-584)

Revised: 9/2023

MDSolarSciences