

## MINERAL SPF 40 MOISTURIZER- zinc oxide and titanium dioxide lotion

### Mineral Fusion brands

*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 SPF 40 Moisturizer

#### *Drug Facts*

<i>Active Ingredients</i>	<i>Purpose</i>
Titanium Dioxide 7.5%	Sunscreen
Zinc Oxide 5.0%	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
- **When using this product** keep out of eyes. Rinse with water to remove.
- **Stop use and ask a doctor** if rash occurs
- **Keep out of reach of children.** If product is swallowed, get medical help or contact a Poison Control Center right away.

#### Directions

- Apply liberally to clean skin 15 minutes before sun exposure
- **Reapply:**
  - after 40 minutes of swimming or sweating
  - immediately after towel drying
  - at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
  - limit time in the sun, especially from 10 a.m. – 2 p.m.
  - wear long-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

#### Inactive Ingredients

Mineral Water (Aqua), Aloe Barbadensis (Aloe Vera) Leaf Juice<sup>1</sup> Caprylic/Capric Triglyceride, Ethylhexyl Palmitate, Glyceryl Stearate, Cetyl Dimethicone, Vegetable Glycerin, Hexyl Laurate, Polyglyceryl-4 Isostearate, Cetyl Alcohol, Myristyl Myristate, Simmondsia Chinensis (Jojoba) Seed Oil<sup>1</sup> Butyrospermum Parkii (Shea) Butter<sup>1</sup>, Panthenol, Malachite Extract, Smithsonite Extract,

Rhodochrosite Extract, Hematite Extract, Palmitoyl Pentapeptide-3, Cucumis Sativus (Cucumber) Fruit Extract<sup>1</sup>, Tocopherol Acetate, Allantoin, Soy Lecithin, Camellia Sinensis (Green Tea) Leaf Extract<sup>1</sup>, Sodium PCA, Hyaluronic Acid, Chamomilla Recutita (Matricaria) Flower Extract<sup>1</sup>, Rosmarinus Officinalis (Rosemary) Leaf Oil, Calendula Officinalis Flower Extract<sup>1</sup>, Cedrus Atlantica (Cedarwood) Bark Oil, Ginkgo Biloba Leaf Extract<sup>1</sup>, Alaria Esculenta (Sea Kelp) Extract, Pelargonium Graveolens (Geranium) Flower Oil, Magnesium Aluminum Silicate, Benzyl Alcohol, Ethylhexylglycerin, Phenoxyethanol, Natural Fragrance.

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<sup>1</sup> Certified Organic

## **Questions**

Call 1-800-428-1668

Mon-Fri 8 a.m. – 5 p.m. PST

Dist. by Mineral Fusion

Petaluma, CA 94954 USA

## **PRINCIPAL DISPLAY PANEL - 96 g Tube Carton**

Mineral SPF 40

Moisturizer

Nourishing Hydration

with Shea Butter

Broad Spectrum

MINERAL  
FUSION<sup>®</sup>

Making

Beauty

Healthy<sup>®</sup>

Net Wt 3.4 oz e 96 g

Nourishing shea butter delivers rich moisture for a softer, glowing complexion in a daily moisturizer that boasts broad spectrum sun defense and elasticity-promoting peptides for a more youthful appearance.

Perfect for all skin types.

Making Beauty Healthy\*

VEGAN  
CRUELTY FREE  
GLUTEN FREE  
PARABEN FREE  
HYPO-ALLERGENIC

mineralfusion.com



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## Mineral SPF 40 Moisturizer

*Hydratant Minéral FPS 40*

Nourishing Hydration  
with Shea Butter  
Broad Spectrum

MINERAL  
FUSION®



Making  
Beauty  
Healthy\*

Net Wt 3.4 oz e 96 g

Made in USA with domestic  
and imported materials.  
Dist. by Mineral Fusion  
Petaltuma, CA 94954 USA



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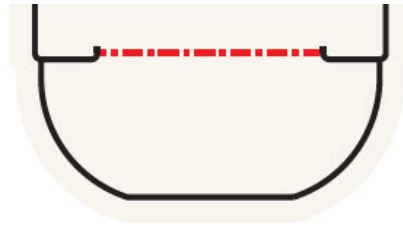
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## MINERAL SPF 40 MOISTURIZER

zinc oxide and titanium dioxide lotion

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55789-3109
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	5 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	7.5 g in 100 mL

### Inactive Ingredients

Ingredient Name	Strength
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL DIMETHICONE 25 (UNII: U4AS1BW4ZB)	
GLYCERIN (UNII: PDC6A3C0OX)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SHEA BUTTER (UNII: K49155WL9Y)	
PANTHENOL (UNII: WV9CM0O67Z)	
MAGNESIUM ASPARTATE (UNII: R17X820ROL)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	
JOJOBA OIL (UNII: 724GKU717M)	
TOCOPHEROL (UNII: R0ZB2556P8)	
COPPER GLUCONATE (UNII: RV823G6G67)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
PALMITOYL PENTAPEPTIDE-4 (UNII: KK181SM5JG)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALLANTOIN (UNII: 344S277G0Z)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55789-3109-2	1 in 1 CARTON	09/17/2019	
1		60 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 NOT FINAL	part352	12/10/2012	

**Labeler** - Mineral Fusion brands (831770032)

Revised: 9/2019

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