

ILLUMINATING MINERAL BEAUTY BALM WITH SPF 9- titanium dioxide cream Mineral Fusion Natural Brands LLC

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.

Illuminating Mineral Beauty Balm with SPF 9

Drug Facts

Active Ingredient

Titanium Dioxide 7.4%

Purpose

Sunscreen

Uses

- Helps prevent sunburn.

Warnings

Skin Cancer/Skin Aging Alert

Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early aging.

- **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 15 minutes before sun exposure.

- Use a water resistant sunscreen if swimming or sweating.
- Reapply at least every 2 hours.
- Children under 6 months: Ask a doctor.

Inactive Ingredients

Water (Aqua), Caprylic/Capric Triglyceride, Jojoba Esters, Mica, Vegetable Glycerin, Sorbitan Sesquioleate, Cetearyl Oliviate, Sorbitan Oliviate, Potassium Cetyl Phosphate, Dimethicone, Hydroxyethylcellulose, Citric Acid, Punica Granatum (Pomegranate) Extract, Tetrahexyldecyl Ascorbate (Vitamin C), Mineral-Peptide Blend (Magnesium Aspartate, Zinc Gluconate, Copper Gluconate, and Palmitoyl Tripeptide-5), Camellia Sinensis (White Tea) Leaf Extract, Aloe Barbadensis Leaf Juice, Glycyrrhiza Glabra (Licorice) Extract, Lavandula Angustifolia (Lavender) Extract, Rosa Canina (Rose) Flower Extract, Olea Europaea (Olive) Leaf Extract, Potassium Sorbate, Sodium Dehydroacetate, Sodium Benzoate, Iron Oxides (CI 77491, CI 77492, CI 77499).

Other Information

Protect this product from excessive heat and direct sun.

Questions or Comments?

Call toll free 1-800-428-1668 Mon-Fri 8 AM-5 PM MST

PRINCIPAL DISPLAY PANEL - 60 ml Tube Label

MINERAL FUSION[®]
minerals on a mission[®]

illuminating
mineral beauty balm
broad spectrum SPF 9

LUMINOUS FINISH
Ultra-sheer for all skin tones

ALL-IN-ONE
BB

Makeup + moisturizer
+ age-defying treatment

Hypo-allergenic, Fragrance free

2.0 fl oz / 60 mL e

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GLUTEN FREE • PARABEN FREE
 100% VEGAN



Mineral Fusion Natural Brands™
 600 W Bayaud Ave., Denver, CO 80223
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www.mineralfusion.com



ILLUMINATING MINERAL BEAUTY BALM WITH SPF 9

titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55789-2401
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	74 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
JOJOBA OIL (UNII: 724GKU717M)	
MICA (UNII: V8A1AW0880)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HYDROXYETHYL CELLULOSE (100 MPA.S AT 2%) (UNII: R33S7TK2EP)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PUNICA GRANATUM ROOT BARK (UNII: CLV24I3T1D)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
MAGNESIUM ASPARTATE (UNII: R17X820ROL)	
COPPER GLUCONATE (UNII: RV823G6G67)	
PALMITOYL TRIPEPTIDE-5 (UNII: 2A3916MQHO)	
CAMELLIA SINENSIS FLOWER (UNII: 9I2BJY2J17)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
LAVANDULA ANGUSTIFOLIA SUBSP. ANGUSTIFOLIA FLOWERING TOP (UNII: 9YT4B71U8P)	
ROSA CANINA FRUIT (UNII: 3TNW8D08V3)	
OLEA EUROPAEA LEAF (UNII: MJ95C3OH47)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ZINC GLUCONATE (UNII: U6WSN5SQ1Z)	

Product Characteristics

Color	BROWN	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55789-2401-1	1 in 1 CARTON	04/01/2013	
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	04/01/2013	

Labeler - Mineral Fusion Natural Brands LLC (831770032)

Establishment

Name	Address	ID/FEI	Business Operations
Columbia Cosmetics		068267863	MANUFACTURE(55789-2401)

Revised: 9/2019

Mineral Fusion Natural Brands LLC