

EMME DIANE TINTED MINERAL SUNSCREEN- titanium dioxide, zinc oxide cream
Emme Diane, Inc

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.

Drug Facts:

Active Ingredients:

Titanium Dioxide 8%

Zinc Oxide 3.8%

Purpose:

Sunscreen

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 the 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 this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- Limit time in the sun, especially from 10:00 am - 2:00 pm
- Wear long-sleeved shirts, pants, hats, and sunglasses

Inactive Ingredients:

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxide (CI 77491), Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

Other Information:

- Protect this product from excessive heat and direct sun
- May stain some fabrics
- PA +++

Manufactured by Emme Diane™

Scottsdale, AZ - www.emmediane.com

Principal Display Panel - 53 g Bottle Label

EMME DIANE

**TINTED
MINERAL
SUNSCREEN**

**BROAD SPECTRUM SPF 40
WATER RESISTANT
(80 MINUTES)**

NET WT. 1.8 OZ (53 G)

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81377-203
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	80 mg in 1 g
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	38 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Aluminum Hydroxide (UNII: 5QB0T2IUN0)	
Cyclomethicone 6 (UNII: XHK3U310BA)	

Cyclomethicone 5 (UNII: 0THT5PCI0R)	
Dimethicone 20 (UNII: H8YMB5QY0D)	
Dimethicone Crosspolymer (450000 MPA.S AT 12% in Cyclopentasiloxane) (UNII: UF7620L1W6)	
Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle) (UNII: 9E4CO0W6C5)	
Dimethiconol (2000 CST) (UNII: T74O12AN6Y)	
Brown Iron Oxide (UNII: 1N032N7MFO)	
Lauryl PEG/PPG-18/18 Methicone (UNII: ZJ5S27D9NX)	
Hydrogen Dimethicone (20 CST) (UNII: 12Z59IF64N)	
PEG-10 Dimethicone (600 CST) (UNII: 8PR7V1SVM0)	
Tetrahexyldecyl Ascorbate (UNII: 9LBV3F07AZ)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81377-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	01/22/2022	

Labeler - Emme Diane, Inc (116110568)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(81377-203)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(81377-203) , PACK(81377-203)

Revised: 1/2023

Emme Diane, Inc