

**EMME DIANE PURE PROTECTION TINTED ANTIOXIDANT SUNSCREEN- zinc oxide cream**  
**Emme Diane, Inc.**

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**Drug Facts:**

**Active Ingredients:**

Zinc Oxide 16%

**Purpose:**

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
- Use a water resistant product if swimming or sweating.
- Reapply 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:**

Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane,

Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer

**Other Information:**

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

**Principal Display Panel - 50 g Bottle Label**

**EMME DIANE**

**PURE  
PROTECTION  
TINTED ANTIOXIDANT  
SUNSCREEN**

SPF 40 BROAD SPECTRUM

NET WT. 1.75 OZ (50 G)

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Distributed by Emme Diane, Inc.  
Scottsdale, AZ - www.emmediane.com



NET WT. 1.75 OZ (50G)



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zinc oxide cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81377-208
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	160 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>CERAMIDE NP</b> (UNII: 4370DF050B)	
<b>Cyclomethicone 6</b> (UNII: XHK3U310BA)	
<b>Cyclomethicone 5</b> (UNII: 0THT5PCI0R)	
<b>Dimethicone 20</b> (UNII: H8YMB5QY0D)	
<b>Dimethicone Crosspolymer (450000 MPA.S AT 12% in Cyclopentasiloxane)</b> (UNII: UF7620L1W6)	
<b>Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle)</b> (UNII: 9E4CO0W6C5)	
<b>Dimethiconol (2000 CST)</b> (UNII: T74O12AN6Y)	
<b>Brown Iron Oxide</b> (UNII: 1N032N7MFO)	
<b>Hydrogen Dimethicone (20 CST)</b> (UNII: 12Z59IF64N)	
<b>PEG-10 Dimethicone (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER</b> (UNII: 9NH1UDD2RR)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:81377-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/01/2022	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M020	09/01/2022	

**Labeler** - Emme Diane, Inc. (116110568)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Custom Analytics LLC		144949372	ANALYSIS(81377-208)

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<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(81377-208) , PACK(81377-208)

Revised: 1/2025

Emme Diane, Inc.