# MINERAL SUNSCREEN 20PERCENT ZINC OXIDE- zinc oxide cream ESTHETICS BY MINDY LLC

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## Active Ingredients:

Zinc Oxide 20%

# **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 broken or damaged 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.

## Warnings:

Keep out of reach of children

### **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 a.m. - 2 p.m. Wear long-sleeved shirts, pants, hats and sunglasses.

# **Inactive Ingredients:**

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate,

### Other Information:

Protect this product from excessive heat and direct sun

#### DRUG FACTS

ACTIVE INGREDIENTS: Zinc Oxide 20%

PURPOSE: Sunscreen

#### HSES:

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 40 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:

- $\bullet$  Limit time in the sun, especially from 10 am-2 pm
- · Wear long-sleeved shirts, pants, hats, and sunglasses

#### INACTIVE INGREDIENTS:

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethicone, Disodium EDTA, Glycerin, Hydrogren Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

### OTHER INFORMATION:

Protect this product from excessive heat and direct sun

### MANUFACTURED FOR:

Esthetics by Mindy Leesburg, VA 20175





## **MINERAL SUNSCREEN 20PERCENT ZINC OXIDE**

zinc oxide cream

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:85987-205

Route of Administration TOPICAL

### **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	200 mg in 1 g

Inactive	

Ingredient Name	Strengt
ingredient Name	Juen

CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
WATER (UNII: 059QF0KO0R)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TRIETHANOLAMINE (UNII: 903K93S3TK)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
GLYCERIN (UNII: PDC6A3C0OX)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
DIMETHICONE (UNII: 92RU3N3Y10)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CYCLOPENTASILOXANE (UNII: 0THT5PCIOR)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	

F	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:85987- 205-04	113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/17/2024		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M020	10/17/2024		

# Labeler - ESTHETICS BY MINDY LLC (058916535)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Fragrance Manufacturing Inc.		793406000	manufacture(85987-205)		

# **Establishment**

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis (85987-205)

Revised: 8/2025 ESTHETICS BY MINDY LLC