# REPLENISHING MINERAL SUNSCREEN- zinc oxide cream Skin Philosophy by Kelly

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### DRUG FACTS

ACTIVE INGREDIENT:

PURPOSE:

Zinc Oxide 16%

Sunscreen

#### USES:

Helps prevent sunburn. If used as directed with other sun protection measures (see directions), decreases the risk of skin cancer and early 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 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:
  - $\cdot$  Limit time in the sun, especially from 10 am- 2 pm
  - · Wear long sleeve shirts and 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.

MANUFACTURED FOR:

Skin Philosophy by Kelly | Livermore, CA 94550 skinphilosophybykelly.com · 916.813.SKIN(7546)



CRUELTY FREE NON-COMEDOGENIC REEF SAFE



TINTED

### Replenishing Mineral Sunscreen



spf 40 broad spectrum with ceramides, zinc oxide & antioxidants C & E



net wt. 1.75 oz | 50 g

### REPLENISHING MINERAL SUNSCREEN

zinc oxide cream

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:85330-208

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	160 mg in 1 g

### **Inactive Ingredients**

Ingred	lient N	lame

Strength

CI 77491 (UNII: 1K09F3G675)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
CI 77499 (UNII: XM0M87F357)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
CI 77492 (UNII: EX43802MRT)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
<b>CERAMIDE 3</b> (UNII: 4370DF050B)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:85330- 208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/10/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/10/2023	

## **Labeler -** Skin Philosophy by Kelly (040889756)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Fragrance Manufacturing Inc.		793406000	manufacture(85330-208)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
Custom Analytics LLC		144949372	analysis (85330-208)

Revised: 5/2025 Skin Philosophy by Kelly