REPLENISHING MINERAL SUNSCREEN- zinc oxide cream
Skin Philosophy by Kelly

DRUG FACTS

ACTIVE INGREDIENT:
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 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:
　· 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)

3 85330 20850 1

CRUELTY FREE
NON-COMEDOGENIC
REEF SAFE

sun
PHILOSOPHY

TINTED
**Replenishing
Mineral Sunscreen**

SPF
40

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

SKIN
PHILOSOPHY

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(NDC:58892-208)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	160 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength

CI 77491 (UNII: 1K09F3G675)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
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)	
CI 77492 (UNII: EX438O2MRT)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
CERAMIDE 3 (UNII: 4370DF050B)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

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	Business Operations
Custom Analytics LLC		144949372	analysis(85330-208)

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85330-208)

Revised: 12/2025

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