

208- zinc oxide cream
PETER L. KOPELSON, M.D.,

DRUG FACTS

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-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.

MANUFACTURED FOR:

The Kopelson Clinic
 414 N. Camden Drive
 Ste. 640
 Beverly Hills, California 90210
 310-271-7400



KOPELSON CLINIC

TKC
MINERAL SPF 40
Tinted

Antioxidants C & E
Broad Spectrum SPF 40

NET WT. 1.75 OZ / 50 G

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

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zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85443-208(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
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CI 77491 (UNII: 1K09F3G675)
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)
CERAMIDE 3 (UNII: 4370DF050B)
CI 77499 (UNII: XM0M87F357)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
DIMETHICONE (UNII: 92RU3N3Y1O)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
CI 77492 (UNII: EX438O2MRT)
CYCLOHEXASILOXANE (UNII: XHK3U310BA)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85443-208-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/09/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/09/2022	

Labeler - PETER L. KOPELSON, M.D., (170705078)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85443-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85443-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85443-208)