

MORNING REPLENISH- zinc oxide cream
KATHY JONES AESTHETICS LLC

DRUG FACTS (cont)

- 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 10am-2pm
 - Wear long-sleeved shirts, pants, hats, and sunglasses
- INACTIVE INGREDIENTS:
 Capric/Caprylic Trigly- ceride, Ceramide 3, Cyclohexasiloxane, Cyclo- pentasiloxane, Dimethicone, Dimethicone Cross- polymer, Dimethicone/Vinyl Dimethicone Cross- polymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide (CI 77491), PEG-10 Dimethicone, Poly- hydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Methi- cone Silsesquioxane Crosspolymer
- OTHER INFORMATION:
 • Protect this product from excessive heat and direct sun.
 • May stain some fabrics.



Morning Replenish

SPF 40 Broad Spectrum
 With Ceramides, Zinc Oxide
 & Antioxidants C & E

Distributed By Kathy Jones Aesthetics
 3215 Madison Rd., Cincinnati, OH 45209
 513-279-2220

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Net Wt. 1.75 oz | 50 g

MORNING REPLENISH

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85714-208(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 77499 (UNII: XM0M87F357)
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)
CI 77491 (UNII: 1K09F3G675)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)
CI 77492 (UNII: EX438O2MRT)
CERAMIDE 3 (UNII: 4370DF050B)
DIMETHICONE (UNII: 92RU3N3Y1O)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
CYCLOHEXASILOXANE (UNII: XHK3U310BA)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85714-208-50	50 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/26/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/26/2017	

Labeler - KATHY JONES AESTHETHICS LLC (039052958)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85714-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85714-208)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85714-208)