

CALMING PROTECTION SPF40- zinc oxide cream
FRESH FACED SKIN CARE LLC

DRUG FACTS (cont)

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, 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
- May stain some fabrics

Manufactured for:
 Fresh Faced Skin Care
 New Castle, DE 19720
 www.freshfacedskincare.com



fresh faced

CALMING PROTECTION SPF 40

SENSITIVE SKIN
 NON-COMEDOGENIC
 CHEMICAL SUNSCREEN FREE
 REEF FRIENDLY

BROAD SPECTRUM SPF 40
 WATER RESISTANT (40 MINS)



4 OZ | 115 G

DRUG FACTS

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

CALMING PROTECTION SPF40

zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85630-205(NDC:58892-205)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
TRIETHANOLAMINE (UNII: 9O3K93S3TK)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)
GLYCERIN (UNII: PDC6A3C0OX)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
DIMETHICONE (UNII: 92RU3N3Y1O)
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)
CYCLOHEXASILOXANE (UNII: XHK3U310BA)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
WATER (UNII: 059QF0KO0R)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85630-205-04	113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/29/2020	

Labeler - FRESH FACED SKIN CARE LLC (059577134)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85630-205)

Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

Fragrance Manufacturing INC		793406000	manufacture(85630-205)
-----------------------------	--	-----------	------------------------

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85630-205)

Revised: 12/2025

FRESH FACED SKIN CARE LLC