

SHUNLY ZN20 TINTED LIGHT MOISTURIZER- zinc oxide cream
Shunly Skin Care LLC

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 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
- Reapply:
 - After 40 minutes of swimming or sweating
 - Immediately after towel drying
 - 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:

Bismuth Oxychloride, 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, Iron Oxides, Hydrogen Dimethicone, Mica, 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.

FREE FROM: Chemical Sunscreens, Oils, PABA, Parabens, Fragrances

Manufactured for: **Shunly Skin Care LLC**

Meridian, ID 83646

www.shunlyskincare.com

Principal Display Panel - 60 g Bottle Label

shunly®

A BOTTLE
FULL OF SKINCARE

Zn20+ Tinted

**SPF40 Light
Moisturizer**

Broad Spectrum UV Defense

FUSION FORMULA® with
Zinc Oxide 20% / C / E

Water Resistant (40 mins)

NET.WT. 2.1 oz | 60 g

DRUG FACTS (cont)

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3 SkinCareACTS™ Protection

shunly
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Broad Spectrum UV Defense

FUSION FORMULA® with
Zinc Oxide 20% / C / E

Water Resistant (40 mins)

NET WT. 2.1 oz | 60 g

This unique formulation offers Broad Spectrum UVA-I / UVA-II / UVB while providing sheer and elegant super photo protective performance for the face that truly feels like silk on your skin. Apply evenly on skin before sun exposure and reapply if active, sweaty, or after swimming.

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zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81381-204
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
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	

CAPRYLYL GLYCOL (UNII: 00YIU5438U)
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 5) (UNII: 035JKJ76MT)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
DIMETHICONE 100 (UNII: RO266O364U)
DIMETHICONE CROSSPOLYMER (45000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)
EDETATE DISODIUM (UNII: 7FLD91C86K)
GLYCERIN (UNII: PDC6A3C0OX)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)
MICA (UNII: V8A1AW0880)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)
PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
POLYSORBATE 20 (UNII: 7T1F30V5YH)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TROLAMINE (UNII: 9O3K93S3TK)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81381-204-60	60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/01/2022	

Labeler - Shunly Skin Care LLC (040374013)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(81381-204)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(81381-204) , PACK(81381-204)

Revised: 1/2024

Shunly Skin Care LLC