

SHUNLY NATURAL COVER SPF50- titanium dioxide, zinc oxide cream

Shunly Skin Care

ACTIVE INGREDIENTS:

Titanium Dioxide 10%

Zinc Oxide 3%

PURPOSE:

Sunscreen

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

INACTIVE INGREDIENTS:

Bismuth Oxychloride, Capric/Caprylic Triglyceride, Caprylhydroxamic Acid, Caprylyl Glycol, Cetareth-20, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Disodium EDTA, Ethylhexyl Hydroxystearate Benzoate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Melissa Officinalis (Balm Mint) Extract, Mica, Microcrystalline Wax, Octyldodecyl Neopentanoate, PEG-30 Dipolyhydroxystearate, Sodium Chloride, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Tocopherol, 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 83642

www.shunlyskincare.com

Keep out of the reach of children.

Principal Display Panel - 53 g Bottle Label

shunly®

A BOTTLE
FULL OF SKINCARE

Natural Cover

SPF50

Broad Spectrum UV Defense

Satin Finish With Hydrate & Antioxidants

**FUSION FORMULA® with
Physical Filters / C / E**

Water Resistant (40 minutes)

NET. WT. 1.8 oz | 53 g

DRUG FACTS (cont)

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3 SkinCareACTS™ Protection

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Satin Finish With Hydrate & Antioxidants

FUSION FORMULA® with
Physical Filters / C / E

Water Resistant (40 minutes)

NET. WT. 1.8 oz | 53 g

Mineral Broad Spectrum UV rays while providing antioxidants help defend the skin against free radicals. The sheer satin finish offers an elegant photo-protective performance to shield the skin from UV rays.

DRUG FACTS

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titanium dioxide, zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81381-258(NDC:58892-258)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	100 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	30 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)
CAPRYLYL GLYCOL (UNII: 00YIU5438U)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)
CYCLOMETHICONE 6 (UNII: XHK3U310BA)
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)
DIMETHICONE (UNII: 92RU3N3Y1O)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
ETHYLHEXYL HYDROXYSTEARATE BENZOATE (UNII: 3W8F25684B)
GLYCERIN (UNII: PDC6A3C0OX)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
FERROSFERRIC OXIDE (UNII: XM0M87F357)
ISODODECANE (UNII: A8289P68Y2)
ISOHEXADECANE (UNII: 918X1OUF1E)
MELISSA OFFICINALIS WHOLE (UNII: YF70189L0N)
MICA (UNII: V8A1AW0880)
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)
OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T)
PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW) (UNII: 9713Q0S7FO)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
TOCOPHEROL (UNII: R0ZB2556P8)
TROLAMINE (UNII: 9O3K93S3TK)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
WATER (UNII: 059QF0K00R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81381-258-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/14/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/14/2023	

Labeler - Shunly Skin Care (040374013)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(81381-258)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	manufacture(81381-258) , pack(81381-258)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(81381-258)

Revised: 12/2025

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