

## **SHUNLY NATURAL COVER SPF50- titanium dioxide, zinc oxide cream**

### **Shunly Skin Care**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **DRUG FACTS**

#### **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](http://www.shunlyskincare.com)**

### **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

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

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.

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## SHUNLY NATURAL COVER SPF50

titanium dioxide, zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81381-258
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP) (Titanium Dioxide - UNII:15FIX9V2JP)	Titanium Dioxide	100 mg in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	30 mg in 1 g

### Inactive Ingredients

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

<b>CAPRYLHYDROXAMIC ACID</b> (UNII: UPY805K99W)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)
<b>CYCLOMETHICONE 6</b> (UNII: XHK3U310BA)
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>ETHYLHEXYL HYDROXYSTEARATE BENZOATE</b> (UNII: 3W8F25684B)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)
<b>ISODODECANE</b> (UNII: A8289P68Y2)
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)
<b>MELISSA OFFICINALIS WHOLE</b> (UNII: YF70189L0N)
<b>MICA</b> (UNII: V8A1AW0880)
<b>MICROCRYSTALLINE WAX</b> (UNII: XOF597Q3KY)
<b>OCTYLDODECYL NEOPENTANOATE</b> (UNII: X8725R883T)
<b>PEG-30 DIPOLYHYDROXYSTEARATE (4000 MW)</b> (UNII: 9713Q0S7FO)
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)
<b>TETRAHEXYLDECYL ASCORBATE</b> (UNII: 9LBV3F07AZ)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>WATER</b> (UNII: 059QF0KO0R)

### 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 not final	part352	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)

Revised: 8/2023

Shunly Skin Care