

SHIELD MINERAL SUNSCREEN TINTED- zinc oxide cream  
SMOOTHE 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 10 am - 2 pm.
- Wear long-sleeved shirts, pants, hats, and sunglasses.

**INACTIVE INGREDIENTS:**  
Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer

**OTHER INFORMATION:**

- Protect this product from excessive heat and direct sun.
- May stain some fabrics.

**FREE** of chemical sunscreen filters, dyes, fragrances, and preservatives.

**MANUFACTURED FOR:**

Smoothe LLC | Raleigh, NC 27604  
www.smootheraleigh.com

SHIELD  
MINERAL SUNSCREEN

SPF 40

BROAD SPECTRUM  
SUN PROTECTION  
FOR DAILY USE

Reef Friendly • Cruelty Free  
Non-Comedogenic  
Tinted



Net Wt. 1.75oz / 50g

DRUG FACTS

**ACTIVE INGREDIENT:** Zinc Oxide 16%  
**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.  
• Use a water resistant product if swimming or sweating.  
• Reapply at least every 2 hours.  
• Children under 6 months: Ask a doctor.



SHIELD MINERAL SUNSCREEN TINTED			
zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85417-208(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

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85417-208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/14/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	04/14/2023	

**Labeler -** SMOOTHE LLC (085215094)

## Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85417-208)

## Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85417-208)

## Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85417-208)