

SHIELD MINERAL SUNSCREEN NON 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, 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.

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
Non-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 NON TINTED			
zinc oxide cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85417-226(NDC:58892-226)
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

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85417-226-50	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(85417-226)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85417-226)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85417-226)