UV DEFENSE MINERAL SUNSCREEN TINTED- titanium dioxide, zinc oxide cream CCLEAR SOLUTIONS ACNE & SKIN CARE CLINIC

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:

Alumina, Cyclohexasiloxane,
Cyclopentasiloxane, Dimethicone,
Dimethicone Crosspolymer,
Dimethicone/Vinyl Dimethicone
Crosspolymer, Dimethicono,
Iron Oxide
(CI 77491), Lauryl PEG/PPG-18/18
Methicone, Hydrogen Dimethicone,
PEG-10 Dimethicone, Tetrahexyldecyl
Ascorbate, Tocopheryl Acetate

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun
- · May stain some fabrics
- · PA +++

MANUFACTURED FOR:

Clear Solutions Acne & Skin Care Clinic Latham, NY 12110 www.clearsolutionsacne.com





UV DEFENSE

MINERAL SUNSCREEN Tinted

Broad Spectrum SPF 40 Water Resistant (80 Minutes)

Acne Safe
Net Wt. 1.8 oz / 53 q

DRUG FACTS

ACTIVE INGREDIENTS:

PURPOSE:

Titanium Dioxide 8% Zinc Oxide 3.8% 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 80 minutes of swimming or sweating
 - · Immediately after towel drying
 - · At least every 2 hours
- · Children under 6 months: Ask a doctor

UV DEFENSE MINERAL SUNSCREEN TINTED

titanium dioxide, zinc oxide cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85495-203	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	38 mg in 1 g	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	80 mg in 1 g	

Inactive Ingredients

Ingredient Name	Strength
CI 77499 (UNII: XM0M87F357)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
CI 77492 (UNII: EX43802MRT)	
CI 77491 (UNII: 1K09F3G675)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
CYCLOPENTASILOXANE (UNII: OTHT5PCIOR)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALUMINA (UNII: LMI26O6933)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85495- 203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/20/2025	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	03/20/2025	

Labeler - CCLEAR SOLUTIONS ACNE & SKIN CARE CLINIC (090274216)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85495-203)

Establishment					
Name	Address	ID/FEI	Business Operations		
Custom Analytics LLC		144949372	analysis (85495-203)		

Revised: 5/2025 CCLEAR SOLUTIONS ACNE & SKIN CARE CLINIC