

**CLOVE HILL TINTED MINERAL SUNSCREEN SPF 40- titanium dioxide, zinc oxide cream**  
**Clove Hill LLC**

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**DRUG FACTS**

**ACTIVE INGREDIENTS:**

Titanium Dioxide 8%

Zinc Oxide 3.8%

**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 80 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 10:00 a.m.-2:00 p.m.
- Wear long-sleeved shirts, pants, hats, and sunglasses

**INACTIVE INGREDIENTS:**

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Iron Oxide (CI77491), Lauryl PEG/PPG-18/18-Hydrogen Dimethicone, 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+++

**Principal Display Panel -53 g Bottle Label**

**CLOVE HILL**

**come home to clear skin**

tinted

mineral sunscreen

spf 40 broad spectrum

water resistant (80 mins)

net wt. 1.8 oz / 53 g

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Manufactured For: Clove Hill, Wheat Ridge CO 80033

CLOVE HILL  
come home to clear skin



tinted  
mineral sunscreen

spf 40 broad spectrum  
water resistant (80 mins)  
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## CLOVE HILL TINTED MINERAL SUNSCREEN SPF 40

titanium dioxide, zinc oxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82746-203
<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	80 mg in 1 g
<b>Zinc Oxide</b> (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	38 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Aluminum Hydroxide</b> (UNII: 5QB0T2IUN0)	
<b>Cyclomethicone 6</b> (UNII: XHK3U310BA)	
<b>Cyclomethicone 5</b> (UNII: 0THT5PC10R)	

<b>Dimethicone 20</b> (UNII: H8YMB5QY0D)	
<b>Dimethicone Crosspolymer (450000 MPA.S AT 12% in Cyclopentasiloxane)</b> (UNII: UF7620L1W6)	
<b>Dimethicone/Vinyl Dimethicone Crosspolymer (Soft Particle)</b> (UNII: 9E4CO0W6C5)	
<b>Dimethiconol (2000 CST)</b> (UNII: T74O12AN6Y)	
<b>Brown Iron Oxide</b> (UNII: 1N032N7MFO)	
<b>Lauryl PEG/PPG-18/18 Methicone</b> (UNII: ZJ5S27D9NX)	
<b>Hydrogen Dimethicone (20 CST)</b> (UNII: 12Z59IF64N)	
<b>PEG-10 Dimethicone (600 CST)</b> (UNII: 8PR7V1SVM0)	
<b>Tetrahexyldecyl Ascorbate</b> (UNII: 9LBV3F07AZ)	
<b>.Alpha.-Tocopherol Acetate</b> (UNII: 9E8X80D2L0)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82746-203-50	53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/04/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	10/18/2022	

**Labeler** - Clove Hill LLC (071183319)

### Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	ANALYSIS(82746-203)

### Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc. (FMI)		793406000	MANUFACTURE(82746-203) , PACK(82746-203)

Revised: 10/2023

Clove Hill LLC