# FLAWLESS BRIGHTENING SUNSCREEN- titanium dioxide, zinc oxide cream Flawless Skin Care LLC

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## **Active Ingredients:**

Titanium Dioxide 8% Zinc Oxide 3.8%

## **Purpose:**

Sunscreen

### Uses:

Helps prevents 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.

## Warnings:

Keep out of the reach of children

## **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 am-2 pm •Wear long-sleeved shirts, pants, hats, and sunglasses

## **Inactive Ingredients:**

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, 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.
- Cleanse thoroughly at nighttime.
- PA +++

### 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, Cyclopentasilox ane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethicone, 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
- Cleanse thoroughly at nighttime
- PA+++

Exclusively Made for Abby Skin Clinic 2345 Willow Pass Rd Concord, Ca 94520 www.abbyskinmedspa.com



# FLAWLESS BRIGHTENING SUNSCREEN

SPF 40 Broad Spectrum Water Resistant (80 Minutes) Oil Free Facial Mineral Sunscreen Paraben Free Reef Friendly

Net Wt 3 oz / 85 g

#### **DRUG FACTS**

ACTIVE INGREDIENTS:
Titanium Dioxide 8%
Zinc Oxide 3.8%
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



## FLAWLESS BRIGHTENING SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81535-201	
Route of Administration	TOPICAL			

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

# **Inactive Ingredients**

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

l	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:81535- 201-85	85 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	05/18/2021	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/18/2021	

# **Labeler -** Flawless Skin Care LLC (031934930)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Fragrance Manufacturing Inc.		793406000	manufacture(81535-201)	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Custom Analytics LLC		144949372	analysis(81535-201)	

Revised: 3/2025 Flawless Skin Care LLC