

**GLOW STICK- titanium dioxide, zinc oxide stick**  
**Skin Apeel, Inc.**

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**Active Ingredients:**

Titanium Dioxide 4%

Zinc Oxide 5.5%

**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 skin aging caused by the sun.

**Warnings:**

For external use only. Do not use on broken or damaged 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.

**Warnings:**

Keep out of reach of children

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

**Inactive Ingredients:**

Alumina, Aluminum Hydroxide, Aluminum Stearate, Ascorbic Acid, Ascorbyl Palmitate, C12-15 Alkyl Benzoate, Cetearyl Isononanoate, Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone, Citric Acid, Ethylene Brassylate, Ethylhexyl Palmitate, Helianthus Annuus (Sunflower) Wax, Hexyldecanol, Hexyldecyl Laurate, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxystearic Acid, Propylene Glycol

Dicaprylate/Dicaprate, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Oil

Other Information:

- Protect this product from excessive heat and direct sun

**DRUG FACTS (continued)**

**INACTIVE INGREDIENTS:** Alumina, Aluminum Hydroxide, Aluminum Stearate, Ascorbic Acid, Ascorbyl Palmitate, C12-15 Alkyl Benzoate, Cetearyl Isononanoate, Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone, Citric Acid, Ethylene Brassylate, Ethylhexyl Palmitate, Helianthus Annuus (Sunflower) Wax, Hexyldecanol, Hexyldecyl Laurate, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxystearic Acid, Propylene Glycol Dicaprylate/Dicaprate, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Oil

**Other Information:** • Protect this product from excessive heat and direct sun

**DRUG FACTS**

Active Ingredients	Purpose
Titanium Dioxide 4.0%	Sunscreen
Zinc Oxide 5.5%	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 • **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

GLOW STICK			
titanium dioxide, zinc oxide stick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83628-219
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	40 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	55 mg in 1 g
Inactive Ingredients			
Ingredient Name			Strength
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)			
CITRIC ACID (UNII: 2968PHW8QP)			
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV)			
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)			
ETHYLHEXYL PALMITATE (UNII: 2865993309)			
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)			
ALUMINUM STEARATE (UNII: U6XF9NP8HM)			
CETEARYL ISONONANOATE (UNII: P5O01U99NI)			

<b>CETYL DIMETHYLBUTYL ETHER</b> (UNII: 7LAB1GXC9G)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>ETHYLENE BRASSYLATE</b> (UNII: 9A87HC7ROD)	
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>HEXYLDECYL LAURATE</b> (UNII: 0V595C1P6M)	
<b>CERESIN</b> (UNII: Q1LS2UJO3A)	
<b>PEG-8</b> (UNII: B697894SGQ)	
<b>ALUMINA</b> (UNII: LMI26O6933)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>HEXYLDECANOL</b> (UNII: 151Z7P1317)	
<b>POLYHYDROXYSTEARIC ACID (2300 MW)</b> (UNII: YXH47AOU0F)	
<b>ALUMINUM HYDROXIDE</b> (UNII: 5QB0T2IUN0)	
<b>PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE</b> (UNII: O4446S9CRA)	
<b>ZINGIBER OFFICINALE (GINGER) ROOT OIL</b> (UNII: SAS9Z1SVUK)	
<b>ASCORBYL PALMITATE</b> (UNII: QN83US2B0N)	
<b>PEG/PPG-15/15 DIMETHICONE</b> (UNII: 184IZ28A2G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83628-219-30	30 g in 1 CYLINDER; Type 0: Not a Combination Product	07/28/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/28/2025	

Labeler - Skin Apeel, Inc. (840716328)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(83628-219)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(83628-219)