## GLOW SHIELD SPF- zinc oxide cream ACNE SOLUTIONS NYC INC

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## Active Ingredient:

Zinc Oxide 20%

### **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.

#### **Directions:**

• Apply liberally 15 minutes before sun exposure • Reapply: • After 40 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:**

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG-10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Hydrogen Dimethicone, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

#### Other Information:

Protect this product from excessive heat and direct sun.

### Warnings:

Keep out of the reach of children.



GLOW SHIELD SPF

MINERAL ACNE-SAFE SUNSCREEN

NON-TINTED

Broad Spectrum SPF 40 Water Resistant (40 minutes)



Net Wt. 4 oz. / 113 g

#### **DRUG FACTS**

ACTIVE INGREDIENT: PURPOSE: Zinc Oxide 20% 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
- · Reapply:
  - · After 40 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 I5 or higher and other sun protection measures includir
  - Limit time in the sun, especially from 10 am 2 pm
  - · Wear long-sleeved shirts, pants, hats, and sunglasses

#### **INACTIVE INGREDIENTS:**

C12-15 Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG IO/I
Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone
Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium ED
Glycerin, Hydrogren Dimethicone, Microcrystalline Wax, PEG-IO Dimethicone, PEG-IO
Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 2
Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate,
Triethanolamine, Triethoxycaprylylsilane, Water

#### OTHER INFORMATION:

· Protect this product from excessive heat and direct sun

MANUFACTURED FOR: AcneClinicNYC 2579 E 17th St Ste 21 Brooklyn, NY 11235

acneclinicnyc.com



## **GLOW SHIELD SPF**

zinc oxide cream

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:85291-205

Route of Administration TOPICAL

	Active Ingredient/Active Moiety				
	Ingredient Name	<b>Basis of Strength</b>	Strength		
- 1					

ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) ZINC OXIDE 200 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
TRIETHANOLAMINE (UNII: 903K93S3TK)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	
WATER (UNII: 059QF0KO0R)	
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
DIMETHICONE (UNII: 92RU3N3Y10)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:85291- 205-04	113 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/09/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/09/2024	

## Labeler - ACNE SOLUTIONS NYC INC (109970809)

Establishment					
Name	Address	ID/FEI	<b>Business Operations</b>		
Fragrance Manufacturing Inc.		793406000	manufacture(85291-205)		

Establishment					
Name	Address	ID/FEI	Business Operations		
Custom Analytics LLC		144949372	analys is (85291-205)		

Revised: 3/2025 ACNE SOLUTIONS NYC INC