TINTED REPLENISHING DAILY PROTECTION- zinc oxide cream SKINPLICITY STUDIO LLC

DRUG FACTS

ACTIVE INGREDIENT: PURPOSE:
Zinc Oxide 16% 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
- · 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 am 2 pm
 - · Wear long-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS:

Capric/Caprylic Triglyceride, Ceramide 3, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Hydrogen Dimethicone, Iron Oxide, PEG-10 Dimethicone, Polyhydroxystearic Acid, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun
- May stain some fabrics.

MANUFACTURED FOR:

SKINplicity Studio San Jose, CA 95124 www.skinplicitystudio.com

Reef-Safe • Cruelty-Free





by Michelle Nguyen, RN

TINTED REPLENISHING DAILY PROTECTION

Broad Spectrum SPF 40



Non-Comedogenic

Net Wt. 1.75 oz / 50 g

TINTED REPLENISHING DAILY PROTECTION

zinc oxide cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:85611-208

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	Ingredient Name	Basis of Strength	Strength
ı	ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	160 mg in 1 g

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Inactive	писч	

Ingredient Name	Strength

CYCLOHEXASILOXANE (UNII: XHK3U310BA)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
CERAMIDE 3 (UNII: 4370DF050B)	
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)	
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)	
CI 77491 (UNII: 1K09F3G675)	
CI 77499 (UNII: XM0M87F357)	
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)	
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CI 77492 (UNII: EX438O2MRT)	
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)	
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)	

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:85611- 208-50	50 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/14/2023	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	07/14/2023	

Labeler - SKINPLICITY STUDIO LLC (835518452)

Establishment				
Name	Address	ID/FEI	Business Operations	
Fragrance Manufacturing INC		793406000	manufacture(85611-208)	

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85611-208)

Revised: 6/2025 SKINPLICITY STUDIO LLC