

**TINTED MINERAL LIP SUNSCREEN- titanium dioxide, zinc oxide stick**  
**ORAIOS BEAUTY LLC**

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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

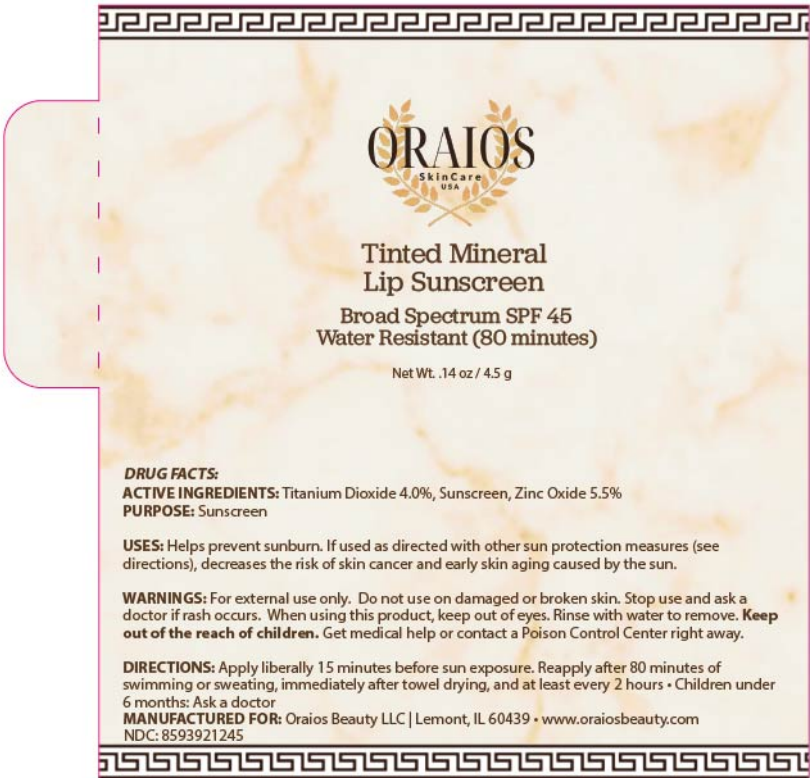
**Directions:**

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, Asorbic Acid, Ascorbyl Palmitate, C12-15Alkyl Benzoate, Cetearyl Isononanoate, Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone, Citric Acid, Dipropylene Glycol Dicaprylate-Caprate, Ethylhexyl Palmitate, Flavor, Helianthus annuus (Sunflower) Seed Wax, Hexyldecanol, Hexyldecyl Laurate, Iron Oxide, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxystearic

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



# TINTED MINERAL LIP SUNSCREEN

titanium dioxide, zinc oxide stick

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85939-212
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	55 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	40 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
CI 77499 (UNII: XM0M87F357)	
PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)	
DIPROPYLENE GLYCOL CAPRATE/CAPRYLATE DIESTER (UNII: R6G12EY23X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
ALUMINA (UNII: LMI26O6933)	
HEXYLDECANOL (UNII: 151Z7P1317)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CI 77492 (UNII: EX438O2MRT)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
CERESIN (UNII: Q1LS2UJO3A)	
PEG-8 (UNII: B697894SGQ)	
CI 77491 (UNII: 1K09F3G675)	
CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G)	
CITRIC ACID (UNII: 2968PHW8QP)	
HEXYLDECYL LAURATE (UNII: 0V595C1P6M)	
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IU00)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	LIME, KIWI	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85939-212-45	1 in 1 CARTON	02/04/2022	
1		4.5 g in 1 CYLINDER; Type 0: Not a Combination Product		

Marketing Information			
Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M020	02/04/2022	

**Labeler -** ORAIOS BEAUTY LLC (126239175)

**Establishment**

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85939-212)

**Establishment**

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85939-212)