

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

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-Caprato, 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(NDC:58892-212)
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)	
TOCOPHEROL (UNII: R0ZB2556P8)	
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)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
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: 5QB0T2IUN0)	

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

Labeler - ORAIOS BEAUTY LLC (126239175)

Establishment

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

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85939-212)

Revised: 12/2025

ORAIOS BEAUTY LLC