

LIP PROTECTING- titanium dioxide, zinc oxide stick
JOHANNA'S SKIN CARE

LIP PROTECTING

Anti-Aging

REEF SAFE SUNSCREEN

BROAD SPECTRUM SPF 45

WATER RESISTANT (80 MINUTES)

Net Wt. 14 oz / 4.5 g



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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, and 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 **MANUFACTURED FOR:** Johanna's Skin Care | San Diego, CA 92122 | www.johannaskincare.com | 619.962.2167 NDC 385531212451

LIP PROTECTING			
titanium dioxide, zinc oxide stick			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85531-212
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
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Inactive Ingredients

Ingredient Name	Strength
HEXYLDECANOL (UNII: 151Z7P1317)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G)	
CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
PEG-8 (UNII: B697894SGQ)	
ALUMINA (UNII: LMI26O6933)	
CITRIC ACID (UNII: 2968PHW8QP)	
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
SOYBEAN LECITHIN (UNII: 1DI56QDM62)	
ALUMINUM STEARATE (UNII: U6XF9NP8HM)	
PARASORBIC ACID (UNII: DCN48OUK3T)	
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)	
DIPROPYLENE GLYCOL CAPRATE/CAPRYLATE DIESTER (UNII: R6G12EY23X)	
HEXYLDECYL LAURATE (UNII: 0V595C1P6M)	
CI 77491 (UNII: 1K09F3G675)	
CI 77499 (UNII: XM0M87F357)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CERESIN (UNII: Q1LS2UJO3A)	
CI 77492 (UNII: EX438O2MRT)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	KIWI, LIME	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85531-212-45	4.5 g in 1 CYLINDER; Type 0: Not a Combination Product	05/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	05/13/2021	

Labeler - JOHANNA'S SKIN CARE (075462759)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85531-212)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85531-212)