

NON-TINTED SPORTS STICK- titanium dioxide, zinc oxide stick HELTON SKIN & LASER INSTITUTE

DRUG FACTS (continued)

INACTIVE INGREDIENTS: Alumina, Aluminum Hydroxide, Aluminum Stearate, Ascorbic Acid, Ascorbyl Palmitate, C12-15 Alkyl Benzoate, Cetearyl Isononanoate, Cetyl PEG/PPG-15/15 Butyl Ether Dimethicone, Citric Acid, Ethylene Brassylate, Ethylhexyl Palmitate, Helianthus Annuus (Sunflower) Wax, Hexyldecanol, Hexyldecyl Laurate, Lecithin, Ozokerite, PEG-8, Polyglyceryl-3 Diisostearate, Polyhydroxystearic Acid, Propylene Glycol Dicaprylate/Dicaprate, Stearic Acid, Tocopherol, Tocopheryl Acetate, Zingiber Officinale (Ginger) Root Oil

OTHER INFORMATION: - Protect this product from excessive heat and direct sun

MANUFACTURED FOR:
Helton Skin & Laser Institute
Newport Beach, CA 92660



*Non-Tinted
Sports Stick*

SPF 45
Broad Spectrum
Water Resistant (80 minutes)

Sunscreen
Net Wt. 1 oz. / 30g

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 - **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

NON-TINTED SPORTS STICK

titanium dioxide, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85679-219(NDC:58892-219)
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
CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXXG9G)	
CITRIC ACID (UNII: 2968PHW8QP)	
HEXYLDECYL LAURATE (UNII: 0V595C1P6M)	
CERESIN (UNII: Q1LS2UJ03A)	
PEG-8 (UNII: B697894SGQ)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G)
CETEARYL ISONONANOATE (UNII: P5O01U99NI)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
ALUMINA (UNII: LMI26O6933)
HEXYLDECANOL (UNII: 151Z7P1317)
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV)
ALUMINUM STEARATE (UNII: U6XF9NP8HM)
ASCORBIC ACID (UNII: PQ6CK8PD0R)
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85679-219-30	30 g in 1 CYLINDER; Type 0: Not a Combination Product	02/22/2024	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/22/2024	

Labeler - HELTON SKIN & LASER INSTITUTE (043023268)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85679-219)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85679-219)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85679-219)