

FLORIDA BABE SPORT MINERAL SUNSCREEN STICK TINTED- titanium dioxide, zinc oxide stick

Tichy Anesthesia PA

DRUG FACTS (continued)

INACTIVE INGREDIENTS: Alumina, Aluminum Hydroxide, Aluminum Stearate, Ascorbic Acid, Ascorbyl Palmitate, Ci2-I5 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, Iron Oxide, 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 • May stain some fabrics

Manufactured For:
The Skin Spot Laser & Skincare Club
Cape Coral, FL 33991





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

FLORIDA BABE SPORT MINERAL SUNSCREEN STICK TINTED

titanium dioxide, zinc oxide stick

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85337-220(NDC:58892-220)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	40 mg in 1 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	55 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALUMINA (UNII: LMI26O6933)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CETEARYL ISONONANOATE (UNII: P5O01U99NI)	
CETYL DIMETHYLBUTYL ETHER (UNII: 7LAB1GXG9G)	
STEARIC ACID (UNII: 4ELV7Z 65AP)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ZINGIBER OFFICINALE (GINGER) ROOT OIL (UNII: SAS9Z1SVUK)	
HELIANTHUS ANNUUS (SUNFLOWER) SEED WAX (UNII: 42DG15CHXV)	

HEXYLDECANOL (UNII: 151Z7P1317)
HEXYLDECYL LAURATE (UNII: 0V595C1P6M)
CI 77492 (UNII: EX438O2MRT)
CI 77499 (UNII: XM0M87F357)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)
CERESIN (UNII: Q1LS2UJO3A)
PEG-8 (UNII: B697894SGQ)
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)
CI 77491 (UNII: 1K09F3G675)
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)
PROPYLENE GLYCOL DICAPRYLATE/DICAPRATE (UNII: O4446S9CRA)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ)
CITRIC ACID (UNII: 2968PHW8QP)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
ALUMINUM STEARATE (UNII: U6XF9NP8HM)
ASCORBYL PALMITATE (UNII: QN83US2B0N)
PEG/PPG-15/15 DIMETHICONE (UNII: 184IZ28A2G)
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85337-220-30	30 g in 1 CYLINDER; Type 0: Not a Combination Product	06/26/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/26/2023	

Labeler - Tichy Anesthesia PA (041678845)

Establishment

Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85337-220)

Establishment

Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing Inc.		793406000	manufacture(85337-220)

Establishment

Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85337-220)

