UNITED SPIRIT SUNSCREEN BROAD SPECTRUM SPF 50- titanium dioxide, zinc oxide lotion
Prime Enterprises

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Warrior SPF 50 No Trace Tinted Mineral Sunscreen Lotion

Active Ingredients

Titanium Dioxide 4.5%

Zinc Oxide 4%

Purpose

Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions), decreases 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.

When using this product

keep out of eyes. Rinse with water to remove

Stop use and ask a doctor

if rash occurs

Keep out of reach of children

If product is 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

•at least every two hours
- 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 of 15 or higher and other sun protection measures including: •limit time in the sun, especially from 10 am to 2 pm •wear long-sleeve shirts, pants, hats and sunglasses
- children under 6 months: ask a doctor

Inactive Ingredients

Acrylic Acid/VP Crosspolymer, Allantoin, Aluminum Hydroxide, C12-15 Alkyl Benzoate, C13-15 Alkane, Camellia Oleifera (Green Tea) Leaf Extract, Caprylyl Glycol, Ceteareth-20, Cetyl Alcohol, Ethyl Ferulate, Glycerin, Iron Oxides, Isododecane, Isohexadecane, Phenoxyethanol, Polyglyceryl-3 Distearate, Sodium Hydroxide, Stearic Acid, Stearyl Alcohol, Triethoxycaprylylsilane, VP/Acrylates/Lauryl Methacrylate Copolymer, Water

Other Information

protect this product from excessive heat and direct sun

Warrior No Trace Tinted Mineral Sunscreen Broad Spectrum SPF 50 Lotion

UNITED SPIRIT SUNSCREEN BROAD SPECTRUM SPF 50

titanium dioxide, zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0628
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	44.145 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	39.24 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ACRYLIC ACID (UNII: J94PBK7X8S)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
ISODODECANE (UNII: A8289P68Y2)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
N-VINYLPYRROLIDINONE (UNII: 76H9G81541)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
LAURYL METHACRYLATE (UNII: B6L83074BZ)	
ETHYL FERULATE (UNII: 5B8915UELW)	
ALLANTOIN (UNII: 344S277G0Z)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
C13-15 ALKANE (UNII: 114P5I43UJ)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	

Product Characteristics

Color	brown (Light Brown)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0628-3	88.7 mL in 1 TUBE; Type 0: Not a Combination Product	08/03/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	08/03/2023	

Labeler - Prime Enterprises (101946028)

Registrant - Prime Enterprises (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises		101946028	manufacture(58443-0628) , label(58443-0628) , analysis(58443-0628) , pack(58443-0628)

Revised: 8/2023 Prime Enterprises