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

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.

United Spirit of America Broad Spectrum SPF 50 Sunscreen

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 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

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 2 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 broad spectrum SPF 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-sleeve shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Allantoin, Aluminum Hydroxide, C12-15 Alkyl Benzoate, Camellia Oleifera (Green Tea) Leaf Extract, Caprylyl Glycol, Ceteareth-20, Cetyl Alcohol, Dibutyl Adipate, Glycerin, Hexyl Laurate, Magnesium Aluminum Silicate, Methylcellulose, Octyldodecyl Citrate Crosspolymer, Phenoxyethanol, Polyglyceryl-3 Distearate, Stearic Acid, Stearyl Alcohol, Triethoxycaprylylsilane, VP/Eicosene Copolymer, Water, Xanthan Gum

Other Information

- protect this product from excessive heat and direct sun

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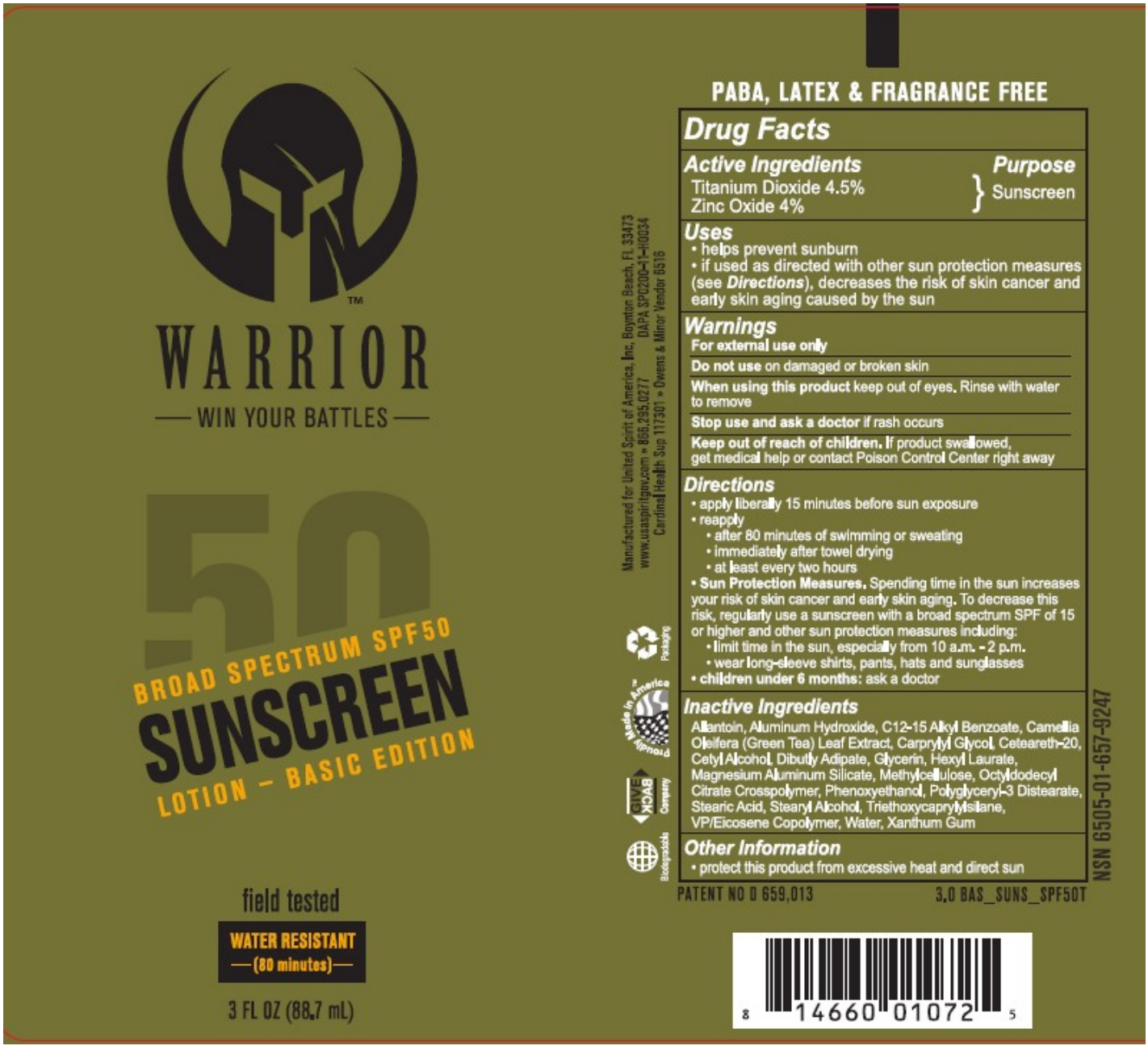

UNITED SPIRIT OF AMERICA BROAD SPECTRUM SPF 50 SUNSCREEN

titanium dioxide, zinc oxide lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58443-0240
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	44.6 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	39.6 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
STEARIC ACID (UNII: 4ELV7Z65AP)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIBUTYL ADIPATE (UNII: F4K100DXP3)	
METHYLCELLULOSE (15 CPS) (UNII: NPU9M2E6L8)	
OCTYLDODECYL CITRATE CROSSPOLYMER (UNII: X323T6QO4M)	
POLYGLYCERYL-3 DISTEARATE (UNII: ZI1LK470XV)	
ALLANTOIN (UNII: 344S277G0Z)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
HEXYL LAURATE (UNII: 4CG9F9W01Q)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
GLYCERIN (UNII: PDC6A3C0OX)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0240-3	88.7 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/16/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	08/11/2016	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0240) , manufacture(58443-0240) , label(58443-0240) , analysis(58443-0240)

Revised: 8/2021 Prime Enterprises Inc.