

**UNITED SPIRIT OF AMERICA BROAD SPECTRUM SPF 30 SUNSCREEN-
avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion
Prime Enterprises Inc.**

United Spirit of America Broad Spectrum SPF 30 Sunscreen

Active Ingredients

Avobenzone 2.0%

Homosalate 7.5%

Octisalate 5.0%

Octocrylene 2.75%

Oxybenzone 2.0%

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

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 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
- **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 a.m. - 2 p.m., wear long-sleeve shirts, pants, hats and sunglasses
- **Children under 6 months:** ask a doctor

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Allantoin, Aloe Barbadensis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Carrageenan, Citric Acid, Diethylhexyl 2,6-Naphthalate, Disodium EDTA, Fragrance, Glyceryl Stearate, Isopropylphthalimide, Methylisothiazolinone, Methylparaben, Polyester-8, Polyethylene, Propylparaben, Sorbitol, Stearic Acid, Stearyl Alcohol, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl

Acetate, Triethanolamine, Water

Other Information

Protect this product from excessive heat and direct sun

United Spirit of American Broad Spectrum SPF 30 Sunscreen



WARRIOR
— WIN YOUR BATTLES —

BROAD SPECTRUM SPF30
SUNSCREEN
LOTION — BASIC EDITION

field tested

WATER RESISTANT
— (80 minutes) —

3 FL OZ (88.7 mL)

Manufactured for United Spirit of America, Inc., Boynton Beach, FL 33473
www.unitedspiritofamerica.com • 888-295-0277
DAPA SP0200-11-10034
Cardinal Health Sup 117301 • Owens & Minor Vendor 6516

 Recycle
 Made in America
 NCAAB
 Biodegradable

Drug Facts

Active Ingredients	Purpose
Avobenzone 2% Homosalate 7.5% Octisalate 5% Octocrylene 2.75% Oxybenzone 2%	Sunscreen

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PATENT NO D 659,013

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UNITED SPIRIT OF AMERICA BROAD SPECTRUM SPF 30 SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene, oxybenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0189
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZ ONE - UNII:95OOS7VE0Y)	OXYBENZONE	19.2 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZ ONE - UNII:G63QQF2NOX)	AVOBENZONE	19.2 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	72 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	26.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLPHthalIDE (UNII: 822Q956KGM)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALLANTOIN (UNII: 344S277G0Z)	
DIETHYLHEXYL 2,6-NAPHTHALATE (UNII: I0DQJ7YGXM)	
(C10-C30)ALKYL METHACRYLATE ESTER (UNII: XH2FQZ38D8)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
ISOPROPYLPHthalIMIDE (UNII: 1J1MM83329)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0KO0R)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
TROLAMINE (UNII: 9O3K93S3TK)	
COCOA BUTTER (UNII: 512OYT1CRR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0189-3	85 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/04/2010	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0189) , manufacture(58443-0189) , label(58443-0189)

Revised: 5/2024

Prime Enterprises Inc.