

UNITED SPIRIT OF AMERICA BROAD SPECTRUM SPF 30 SUNSCREEN- avobenzene, homosalate, octisalate, octocrylene, oxybenzone 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 30 Sunscreen

Active Ingredients

Avobenzene 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 America Broad Spectrum SPF 30 Sunscreen

SUNSCREEN

★★★★★

UNITED[®] SPIRIT OF AMERICA

BROAD SPECTRUM SPF 30

Water Resistant (80 Minutes)

3 FL OZ (85ml)

HIGH-TECH HYGIENE SOLUTIONS

Drug Facts

Active Ingredients
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Octocrylene (2.75%), Oxybenzone (2.0%) } **Purpose**
Sunscreen

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Other Information • Protect product from excessive heat and direct sun

Patent No D 659,013

BAS_SUNS

GIVE
KID
Company

Biodegradable

Packaging

Proudly Made in America
Distributed by
United Spirit of America, LLC
Boynton Beach, FL 33473
www.usa-spirit.com
www.militries.com
1 (866) 295-0277
GSA CONTRACT NUMBER
GS-07F-0227X SIN 852-1

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:58 443-0 189
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	19.2 mg in 1 mL
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - 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)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
SORBITOL (UNII: 506T60A25R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
WATER (UNII: 059QF0KO0R)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
COCOA BUTTER (UNII: 512OYT1CRR)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	

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 final	part352	08/04/2010	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		10 19 46 0 2 8	pack(58 443-0 18 9) , manufacture(58 443-0 18 9) , label(58 443-0 18 9)

Revised: 1/2020

Prime Enterprises Inc.