FAIR AND SQUARE SPORT SUNSCREEN SPF 50- avobenzone, homosalate, octisalate, octocrylene, and 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.

Active ingredients

Avobenzone 1.5%, Homosalate 15%, Octisalate 5%, Octocrylene 1.25%, and Oxybenzone 6%

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 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 & early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher & 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

Inactive Ingredients

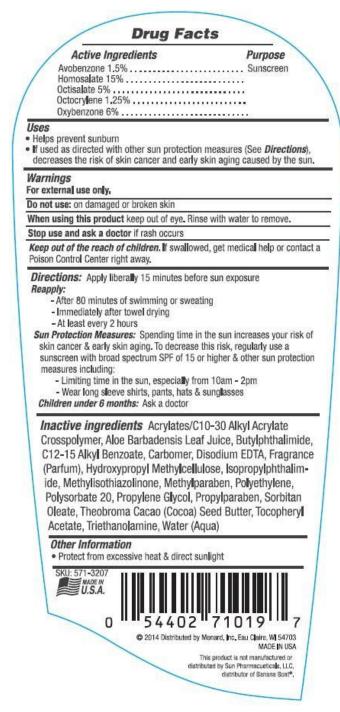
Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, Butylphthalimide, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Fragrance (Parfum), Hydroxypropyl Methylcellulose,

Isopropylphthalimide, Methylisothiazolinone, Methylparaben, Polyethylene, Polysorbate 20, Propylene Glycol, Propylparaben, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Triethanolamine, Water (Aqua)

Other information

protect from excesive heat & direct sunlight

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label





FAIR

&

SQUARE

SPORT

SUNSCREEN

Lotion With

Endurance Formula

50

Broad Spectrum

SPF 50

UVA/UVB Protection

Water Resistant (80 minutes)

Oil-Free, Non-Greasy Formula

Compare to Banana Boat

8 FL OZ (237mL)

FAIR AND SQUARE SPORT SUNSCREEN SPF 50

avobenzone, homosalate, octisalate, octocrylene, and oxybenzone lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0152
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	15 mg in 1 mL		
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	150 mg in 1 mL		
OCTISALATE (UNII: 4X49 Y0596 W) (OCTISALATE - UNII:4X49 Y0596 W)	OCTISALATE	50 mg in 1 mL		
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	12.5 mg in 1 mL		
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	60 mg in 1 mL		

Inactive Ingredients				
Ingredient Name	Strength			
C10-30 CHOLESTEROL/LANOSTEROL ESTERS (UNII: 137SL7IL0Y)				
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				
N-BUTYLPHTHALIMIDE (UNII: 5TH1DKT35E)				
ISOPROPYLPHTHALIMIDE (UNII: 1J1MM83329)				
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)				
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)				
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
METHYLISOTHIAZOLINONE (UNII: 229 D0 E1QFA)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)				
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)				

POLYSORBATE 20 (UNII: 7T1F30V5YH)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		
PEG-6 SORBITAN OLEATE (UNII: 5807V09UCI)		
COCOA BUTTER (UNII: 5120 YT1CRR)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		
TROLAMINE (UNII: 9O3K93S3TK)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Pa	ckaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1 N	NDC:58443-0152-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/12/2014	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	0 3/12/20 14		

Labeler - Prime Enterprises, Inc. (101946028)

Registrant - Prime Enterprises, Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises, Inc.		101946028	label(58443-0152), pack(58443-0152), manufacture(58443-0152), analysis(58443-0152)

Revised: 1/2020 Prime Enterprises, Inc.