# NO-AD BROAD SPECTRUM SPORT SPF 30- avobenzone, homosalate, octisalate, octocrylene 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.

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### NO-AD Sport Broad Spectrum SPF 50 Sport Sunscreen Lotion

#### **Active Ingredients**

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 5%

#### **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
- children under 6 months of age: ask a doctor
- **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 value 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-sleeved shirts, pants, hats, and sunglasses
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- at least every 2 hours

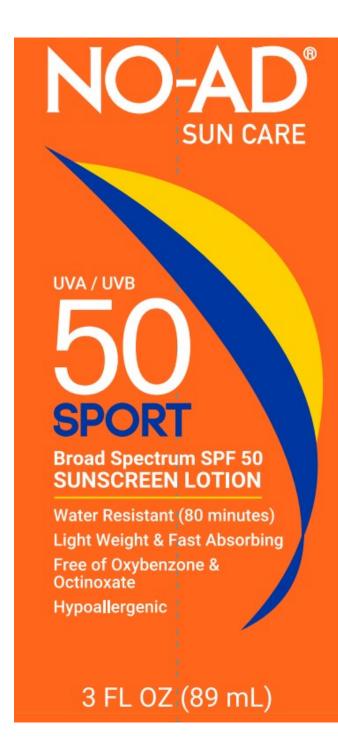
#### Other information

- protect this product from excessive heat and direct sun
- may stain some fabrics/materials or surfaces

## Inactive ingredients

Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Carbomer, Disodium EDTA, Ethylhexylglycerin, Fragrance, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polyester-8, Polyethylene, Polysilicone-15, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

**NO-AD Sport Broad Spectrum SPF 30 Sunscreen Lotion** 



**Drug Facts** 

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Distributed by: Oleander Brands International LLC Skillman, NJ 08558

NA607-DM-1

#### NO-AD BROAD SPECTRUM SPORT SPF 30

avobenzone, homosalate, octisalate, octocrylene lotion

#### **Product Information** HUMAN OTC DRUG **Product Type Item Code (Source)** NDC:58443-0607 **TOPICAL Route of Administration**

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	28.89 g in 1 mL	
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.15 g in 1 mL	

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	48.15 g in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII: V06SV4M95S)	HOMOSALATE	96.3 g in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
POLYESTER-8 (1400 MW, CYANODIPHENYLPROPENOYL CAPPED) (UNII: T9296U138P)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
COCOA BUTTER (UNII: 5120YT1CRR)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
<b>CARBOMER 980</b> (UNII: 4Q93RCW27E)	
POLYSILICONE-15 (UNII: F8DRP5BB29)	

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- 0607-3	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2021	

Marketing Information			
Marketing Application Number or Monog Category Citation		Marketing Start Date	Marketing End Date
OTC monograph final	M020	10/01/2021	

# **Labeler -** Prime Enterprises Inc. (101946028)

# Registrant - Prime Enterprises Inc. (101946028)

Establishment			
Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0607), manufacture(58443-0607), label(58443-0607), analysis (58443-0607)

Revised: 1/2023 Prime Enterprises Inc.