

NO-AD BROAD SPECTRUM 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.

NO-AD Broad Spectrum SPF 30 Sunscreen Lotion

Active Ingredients

Avobenzone 3%

Homosalate 7.5%

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, Polyethylene, Polysorbate 20, Propylene Glycol, Sodium Hydroxide, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Water

NO-AD Broad Spectrum SPF 30 Sunscreen Lotion

NO-AD[®]

SUN CARE

UVA / UVB

30

Broad Spectrum SPF 30 SUNSCREEN LOTION

Water Resistant (80 minutes)
Light Weight & Fast Absorbing
Free of Oxybenzone &
Octinoxate

3 FL OZ (89 mL)

Drug Facts

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



www.no-ad.com

Distributed by: Oleander Brands International LLC
Skillman, NJ 08558

NA605-DM-1

NO-AD BROAD SPECTRUM SPF 30

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0601
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.19 g in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.6 g in 1 mL

OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	48.6 g in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	72.9 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
COCOA BUTTER (UNII: 512OYT1CRR)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
.ALPHA.-TOCOPHEROL 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)	
CARBOMER 980 (UNII: 4Q93RCW27E)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0601-3	89 mL in 1 TUBE; Type 0: Not a Combination Product	09/09/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	09/09/2021	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0601) , manufacture(58443-0601) , label(58443-0601) , analysis(58443-0601)

Revised: 11/2022

Prime Enterprises Inc.