

NO-AD BROAD SPECTRUM SPF 85- 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 85 Sunscreen Lotion

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 10%

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 Kids Broad Spectrum SPF 50 Sunscreen Lotion

NO-AD[®]

SUN CARE

UVA / UVB

85

**Broad Spectrum SPF 85
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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Acrylates/C10-30 Alkyl Acrylate
Crosspolymer, Aloe Barbaderensis Leaf
Juice, C12-15 Alkyl Benzoate, Carbomer,
Disodium EDTA, Ethylhexylglycerin,
Fragrance, Hydroxypropyl
Methylcellulose, Phenoxyethanol,
Polyethylene, Polysorbate 20, Propylene
Glycol, Sodium Hydroxide, Sorbitan
Oleate, Styrene/Acrylates Copolymer,
Theobroma Cacao (Cocoa) Seed Butter,
Tocopheryl Acetate, Water

www.no-ad.com

Distributed by: Oleander Brands International LLC
Skillman, NJ 08558



NA608-DM-1

NO-AD BROAD SPECTRUM SPF 85

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58443-0600 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 29.49 g in 1 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 49.15 g in 1 mL |

| | | |
|---|-------------|----------------|
| OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM) | OCTOCRYLENE | 98.3 g in 1 mL |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 98.3 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:58443-0600-3 | 89 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/17/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | M020 | 10/17/2021 | |

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|---|
| Prime Enterprises Inc. | | 101946028 | pack(58443-0600) , manufacture(58443-0600) , label(58443-0600) , analysis(58443-0600) |

Revised: 11/2022

Prime Enterprises Inc.