

**NO-AD BROAD SPECTRUM SPF 50 KIDS- 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 Broad Spectrum SPF 50 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, Chamomilla Recutita (Matricaria) Flower Extract, Disodium EDTA, Ethylhexylglycerin, Fragrance, Hydroxypropyl Methylcellulose, Lonicera Caprifolium (Honeysuckle) Flower Extract, 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<sup>®</sup>

## SUN CARE

UVA / UVB

# 50

## KIDS



**Broad Spectrum SPF 50  
SUNSCREEN LOTION**

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

3 FL OZ (89 mL)

### Drug Facts

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Octisalate 5%, Octocrylene 5%.....Sunscreen

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Crosspolymer, Aloe Barbadensis Leaf Juice, C12-15 Alkyl Benzoate, Carbomer, Chamomilla Recutita (Matricaria) Flower Extract, Disodium EDTA, Ethylhexylglycerin, Fragrance, Hydroxypropyl Methylcellulose, Lonicera Caprifolium (Honeysuckle) Flower Extract, 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

NA606-DM-1

## NO-AD BROAD SPECTRUM SPF 50 KIDS

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0599
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.19 g in 1 mL
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	48.65 g in 1 mL

<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	48.65 g in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	97.3 g in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>COCOA BUTTER</b> (UNII: 512OYT1CRR)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>HIGH DENSITY POLYETHYLENE</b> (UNII: UG00KM4WR7)	
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>CARBOMER 980</b> (UNII: 4Q93RCW27E)	
<b>LONICERA CAPRIFOLIUM FLOWER</b> (UNII: 5N1WD9784U)	
<b>MATRICARIA CHAMOMILLA WHOLE</b> (UNII: G0R4UBI2ZZ)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0599-3	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/30/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	09/30/2021	

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

**Registrant** - Prime Enterprises Inc. (101946028)**Establishment**

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0599) , manufacture(58443-0599) , label(58443-0599) , analysis(58443-0599)

Revised: 11/2022

Prime Enterprises Inc.