

**SUNSCREEN- avobenzonone, homosalate, octisalate, octocrylene lotion**  
**American Sales Company**

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**Care One 769.000/769AA**  
**Ultra Sunscreen Lotion SPF 30**

**Active Ingredients**

Avobenzonone 3%

Homosalate 10%

Octisalate 5%

Octocrylene 10%

**Purpose**

Sunscreen

**Uses**

- helps prevent sunburn
- if used as directed with other sun protections 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 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
  - children under 6 months of age: Ask a doctor

### **Other Information**

- Protect the product in this container from excessive heat and direct sun

### **Inactive ingredients**

water, ethylhexyl palmitate, sorbitol, polyamide-8, benzyl alcohol, tocopherol, caprylic/capric triglyceride, triethanolamine, fragrance, acrylates/C10-30 alkyl acrylate crosspolymer, chlorphenesin, sodium ascorbyl phosphate, oleth-3, disodium EDTA

### **ADVERSE REACTION**

Distributed by Foodhold USA, LLC

Landover, MD 20785

1-877-849-9949

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Quality guaranteed your your money back.

### **May stain or damage some fabrics or surfaces.**

\*This product is not manufactured or distributed by Bayer, distributor of Coppertone Ultra Guard Sunscreen Lotion Broad Spectrum SPF 30.

\*\*Oxybenzone & Octinoxate free

### **principal display panel**

Care One

Compare to Coppertone Ultra Guard Sunscreen Lotion SPF 30\*

Sunscreen

Lotion

SPF 30 UVA/UVB Protection

BROAD SPECTRUM SPF 30

- Water resistant (80 minutes)
- Enriched with moisturizers
- Hypoallergenic

REEF FRIENDLY\*\*

8 FL OZ (236 mL)

**Drug Facts**

Active ingredients	Purpose
Avobenzone 3%	Sunscreen
Homosalate 10%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 10%	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
- apply to all skin exposed to the sun
- 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 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
  - children under 6 months of age: Ask a doctor

**Other information**

- protect the product in this container from excessive heat and direct sun

**Inactive ingredients**  
water, ethylhexyl palmitate, sorbitol, polyamide-8, benzyl alcohol, tocopherol, caprylic/capric triglyceride, triethoxycaprylylsilane, fragrance, acrylates/C10-30 alkyl acrylate crosspolymer, chlorophanesin, sodium ascorbyl phosphate, dext-3, disodium EDTA

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LAWDOR, MD 20776  
1-877-848-8848  
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Locally manufactured or your country best.

May stain or damage some fabrics or surfaces  
\*This product is not manufactured or distributed by Bayer, distributor of Coppertone® Ultra Guard Sunscreen Lotion Broad Spectrum SPF 30  
\*\*Oxybenzone & Octinoxate free

**CAREone**<sup>®</sup>

Compare to Coppertone®  
Sunscreen Lotion  
Ultra Guard SPF 30\*

# SUNSCREEN

## Lotion

**Broad Spectrum SPF 30**

- Water resistant (80 min)
- Enriched with moisturizers
- Hypoallergenic

**REEF FRIENDLY**

8 FL OZ (236 mL)

## SUNSCREEN

avobenzone, homosalate, octisalate, octocrylene lotion

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:41520-769

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	50 mg in 1 mL
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	100 mg in 1 mL
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ETHYLHEXYL PALMITATE</b> (UNII: 2865993309)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>POLYAMIDE-8 (4500 MW)</b> (UNII: 77723GV81A)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>CHLORPHENESIN</b> (UNII: I670DAL4SZ)	
<b>SODIUM ASCORBYL PHOSPHATE</b> (UNII: 836SJG51DR)	
<b>OLETH-3</b> (UNII: BQZ26235UC)	
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-769-34	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/12/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	01/12/2016	

**Labeler** - American Sales Company (809183973)

**Registrant** - Nice-Pak Products, LLC (119091520)

### Establishment

Name	Address	ID/FEI	Business Operations
Nice-Pak Products, LLC		119091514	manufacture(41520-769)

